EUROPEAN
COMMISSION

Brussels, 26.11.2020
C(2020) 8153 final

COMMISSION DECISION

of 26.11.2020

relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union (the Treaty) and Article 53 of the EEA Agreement

(AT.39686-CEPHALON)

(Text with EEA relevance)

(Only the English text is authentic)

TABLE OF CONTENTS

COMMISSION DECISION

of 26.11.2020

relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union (the Treaty) and Article 53 of the EEA Agreement

(AT.39686-CEPHALON)

(Text with EEA relevance)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,[1]

Having regard to the Agreement on the European Economic Area,[2]

Having regard to Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty,[3] and in particular Article 7 and Article 23(2) thereof,

Having regard to Commission Decision of 28 April 2011 to initiate proceedings in this case,

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission pursuant to Article 27(1) of Regulation (EC) No 1/2003 and Article 12 of Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the Treaty,[4]

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Having regard to the final report of the hearing officer in this case,

Whereas:

---

1 OJ C 115, 9/5/2008, p. 47.

2 OJ L 1, 3.1.1994, p. 3; "EEA Agreement".

3 OJ L 1, 4.1.2003, p.1. With effect from 1 December 2009, Articles 81 and 82 of the EC Treaty have become Articles 101 and 102, respectively, of the TFEU on the Functioning of the European Union ("TFEU"). The two sets of provisions are, in substance, identical. For the purposes of this Decision, references to Articles 101 and 102 of the TFEU should be understood as references to Articles 81 and 82, respectively, of the EC Treaty when where appropriate. The TFEU also introduced certain changes in terminology, such as the replacement of "Community" by "Union" and "common market" by "internal market". Where the meaning remains unchanged, the terminology of the TFEU will be used throughout this Decision.

4 OJ L 123, 27.4.2004, p. 18.

1. INTRODUCTION

(1) This Decision concerns a patent dispute settlement agreement between Cephalon, the originator producer of the medicine modafinil, a medicine used to treat sleeping disorders, and Teva, a producer of generic modafinil. When the agreement was concluded in 2005, Cephalon's primary patent protecting modafinil had expired and Teva had already launched its generic modafinil in one Member State, was preparing entry in other Member States and was convinced that it would not be blocked by the remaining secondary patents of Cephalon. In the agreement, in exchange for receiving a significant transfer of value from Cephalon, Teva committed not to enter the market with its generic modafinil and not to challenge Cephalon's secondary patents.

(2) The transfer of value provided for in the agreement was made, next to some cash payments, mainly through a number of commercial transactions that were beneficial to Teva and had no other plausible explanation than to serve as inducement of Teva to stay out of the market. In particular, Cephalon purchased a licence to certain intellectual property rights held by Teva, granted Teva access to certain unrelated clinical data allowing Teva to gain time in obtaining regulatory approvals for its Parkinson's disease medicine Azilect and transferred to Teva a an amount of approximately EUR 5.5 million as an alleged payment for avoided litigation costs. Furthermore, for the period of five years, Cephalon appointed Teva as its exclusive distributor of modafinil in the United Kingdom and it committed for a period of five years to buy from Teva the modafinil active pharmaceutical ingredient. The agreement also allowed Teva to sell generic modafinil under a royalty bearing licence from Cephalon as from 2012.

(3) This Decision establishes that the patent dispute settlement agreement between Cephalon and Teva, which included the commercial transactions and cash payments as value transfer, constitutes an infringement of Article 101 TFEU and Article 53 of the EEA Agreement.

(4) The Decision is structured as follows. Chapter 2 provides an overview of Cephalon's and Teva's business activities, the medicine concerned and the pharmaceutical sector more generally. Chapter 3 summarises the procedure in this case. Chapter 4 contains a comprehensive description of the relevant facts, in particular, the content and context of the Settlement Agreement and the facts preceding and following its conclusion. Chapters 5 to 10 set out the Commission's legal assessment of the Settlement Agreement under Article 101 TFEU, both as a restriction of competition by object (Chapters 5 and 6) and as a restriction of competition by effect (Chapters 7 and 8) that affect trade between Member States (Chapter 9) and that are not exempted pursuant to Article 101(3) TFEU (Chapter 10). Chapter 11 describes the corresponding assessment under Article 53 of the EEA Agreement. Chapters 13 to 15 set out the duration of the infringement, the addressees of this Decision and explain the amount of the fine.

2. THE UNDERTAKINGS AND THE MEDICINE INVOLVED, THE PHARMACEUTICAL SECTOR AND ITS REGULATORY FRAMEWORK

2.1. Undertakings subject to the present proceedings

(5) This Decision is addressed jointly to Cephalon, Inc., United States ("Cephalon") and Teva Pharmaceutical Industries Ltd., Israel ("Teva"), hereinafter also referred to as

"the Parties". Teva acquired Cephalon in 2011[5] and they are since part of the same undertaking.

(6) Cephalon is a United States-based biopharmaceutical company supplying both originator and generic pharmaceuticals worldwide. Cephalon's principal activities encompass the discovery, development and bringing to the market of medications with a particular focus on central nervous system disorders, including sleeping disorders, pain, oncology, inflammatory disease and regenerative medicine.

(7) In 2010[6], Cephalon had worldwide net sales of approximately USD 2.76 billion (approximately EUR 2.09 billion), out of which over USD 658 million (approximately EUR 498 million) were generated in the EEA.[7] The EEA sales of modafinil products went approximately from EUR 29,216,000 in 2005 up to EUR 46,455,000 in 2010.[8]

(8) Teva is a worldwide pharmaceutical company which is active in the development, production and marketing of generic drugs as well as innovative and specialty pharmaceuticals, active pharmaceutical ingredients and over-the-counter products. Headquartered in Israel, Teva ranks among the 15 top pharmaceutical companies in the world, based on the sales of prescription medicines. It is the world´s largest generic pharmaceutical company.

(9) In 2019, Teva had net revenues of USD 16.9 billion (approximately EUR 15.08 billion).[9]

2.2. The product concerned

(10) This Decision concerns medicines containing the active pharmaceutical ingredient ("API") modafinil. Modafinil[10] is a long-acting wake-promoting agent used for the treatment of certain sleep disorders. Modafinil-containing medicines can help patients who suffer from mild to moderate excessive daytime sleepiness ("EDS"). Daytime sleepiness (or hypersomnia) is a condition in which a person has trouble staying awake during the day.[11] EDS is a symptom of narcolepsy with or without cataplexy,[12] disturbed night-time sleeping patterns (due to work-shift or obstructive sleep apnoea) or unknown causes (in which case it is called idiopathic hypersomnia) (see also Sections 8.1.1.1 - 8.1.1.3).

(11) Modafinil was discovered by Laboratoire L. Lafon ("Lafon"), a French pharmaceutical company, in 1976. Lafon first registered its modafinil product under the brand name Modiodal on 24 June 1992 in France and later in other countries

---

5 Commission Decision of 13 October 2011 in Case M.6258-*Teva/Cephalon*.

6 The last financial year before Teva acquired Cephalon, see Section 4.8.2.4.

7 ID 2206.

8 ID 1771-117. Data submitted by Cephalon.

9 ID 3908.

10 A synthetic acetamide derivative also known as 2-(benzhydrylsulfinyl) acetamide (or 2-[(diphenylmethyl)sulfinyl]acetamide).

11 American Academy of Sleep Medicine, 'The international classification of sleep disorders: diagnostic & coding manual' (2nd ed, 2005) *Westchester, IL: American Academy of Sleep Medicine*.

12 ID 2824.

under brand names Provigil, Vigil or Modasomil.[13] It was mainly sold in the form of tablets of 100 mg.[14]

(12) In 1993, Cephalon obtained exclusive rights to modafinil from Lafon and ultimately, in 2001, acquired the entire company.[15] In 1997, Cephalon started selling modafinil under the Provigil brand in the United Kingdom. By 2005, it was selling modafinil product in Austria, Belgium, Czechia, Denmark, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Slovakia, Spain and Sweden.[16]

(13) In the EEA,[17] Cephalon's different national compound patents for the modafinil API expired at the latest in 2003[18], while data protection in relation to that active ingredient expired at the latest in 2005.[19]

(14) Provigil was the most important product in Cephalon's portfolio in terms of sales. In the years immediately preceding the Settlement Agreement, it made up more than 40% of all Cephalon's worldwide sales.[20] Also in the EEA, Provigil was Cephalon's most prominent product. In the United Kingdom, for instance, Provigil accounted for 73% of the annual turnover of the Cephalon's subsidiary in the UK, Cephalon (UK) Limited ("Cephalon UK") in 2004,[21] and was forecast to make 56% of its turnover in 2006 on the assumption that there were no generic competitors in the market.[22] Cephalon planned sales in at least 24 Contracting Parties to the EEA Agreement until 2016.[23]

(15) Cephalon also worked on a second-generation product (named Nuvigil) based on the modafinil API which it planned to place on the market to replace Provigil from 2006 onwards, first in the United States and subsequently in the EEA. The settlement agreements with generic challengers were also intended to provide more time to

---

13 ID 2539, p. 8, ID 2559. MODIODAL is the trade name for Cephalon's modafinil product in France, Spain, Denmark, The Netherlands, Greece, Iceland, Norway, Portugal, Sweden and Turkey. It is PROVIGIL in the United States, United Kingdom, Ireland, Italy, Belgium and Luxembourg, VIGIL in Germany and Hungary and MODASOMIL in Austria and Switzerland.

14 ID 1314. Some countries approved a product licence for a tablet of 200 mg, which was also sold in those markets (United Kingdom in 2002, Ireland in 2003, Spain in 2006 or Germany in 2011), see also ID 247, p. 2-3, ID 2571 and ID 2581.

15 Following the acquisition by Cephalon, Lafon was renamed to Cephalon France SAS.

16 ID 1314.

17 The United Kingdom withdrew from the European Union as of 1 February 2020. During the transition period until 31 December 2020 (unless extended), Union law - with certain limited exceptions which are irrelevant for this Decision - continues to be applicable to and in the United Kingdom. Therefore, any reference to Member States in Union law shall be understood as including the United Kingdom. Every reference to EU or EEA Member States in this Decision includes the United Kingdom.

18 Includes the patent term extensions granted under Supplementary Protection Certificate; in France, the SPC expired in 2005, see Section 4.1.2.1.

19 This was the view expressed by Cephalon and its distribution partner in the United Kingdom […] at the time of the generic entry of Teva in the United Kingdom. Other facts appear to indicate that the data protection would expire even earlier (see Recital (173), in particular footnote 307). For the purpose of this Decision, this difference is not material. In the United States, Provigil's market exclusivity (including additional exclusive rights for treating rare disorders) expired in December 2005.

20 ID 2200, p. 12.

21 ID 1627, p. 14.

22 ID 285, p. 115.

23 Cephalon expanded the use of Provigil geographically in the EEA by means of licence and distribution agreements with other pharmaceutical companies, including [*company names and respective countries*]. ID 210, p. 4-13. See also ID 210, p. 14-15 (situation until July 2002) and ID 210, p. 20-22 (situation until May 2005).

Cephalon to switch patients from Provigil to Nuvigil. However, ultimately Cephalon did not launch Nuvigil in the EEA (see in more detail Sections 4.2.3.2 and 4.8.1.4).

2.3. Main features of the pharmaceutical sector

(16) The pharmaceutical sector has a great variety of stakeholders, significant involvement of public authorities and a high degree of regulation. The following sections briefly explain the structure of the supply and demand sides on the markets for prescription medicines (Section 2.3.1), the price sensitivity of prescription medicines (Section 2.3.2) and their general life cycle (Section 2.3.3).

2.3.1. Supply and demand side

(17) On the supply side, originator companies are active in research and development (including approval procedures), manufacturing, marketing and supply of innovative medicines (originator medicinal product). Their products are usually protected by patents for a certain period laid down by law, allowing companies some degree of market exclusivity.

(18) Generic companies produce and supply medicines that have the same qualitative and quantitative composition of APIs and the same pharmaceutical form as the originator (or "reference") medicinal product and have been shown to be bioequivalent with it. Therefore, generic medicines can be used to treat the same medical indications.

(19) The entry of generic products to the market often imposes strong competitive constraints on originator products, as generic medicines are typically sold at significantly lower prices and their entry quickly leads, *"to a very appreciable fall in the sale price of medicines containing an active ingredient that are henceforth sold not only by the manufacturer of the originator medicine, but also by manufacturers of generic medicines"*.[24] Generic entry normally leads to a shift of volumes from the originator to the generic competitor, unless, for example, the originator company decreases the price of the originator product in line with generic prices or manages to move the market to a second generation product for which no generics exist yet.[25]

(20) Therefore, as the Court of Justice concluded in case *Generics (UK) and Others* that "the medicines sector is particularly sensitive to a delay in the market entry of the generic version of an originator medicine" since such "delay leads to the maintenance on the market of the medicine concerned of a monopoly price, which is very appreciably higher than the price at which generic versions of that medicine would be sold following their market entry and which has considerable financial consequences, if not for the final consumer, at least for social security authorities"[26].

(21) On the demand side, the pharmaceutical sector is unusual in that, for prescription medicines, the ultimate consumer (the patient) is not the decision maker nor the main payer for the product. It is the doctor who prescribes a specific medicine and the national health (insurance) schemes that mostly cover/and or reimburse the price of the medicine. Pharmacists also play a role on the demand side, especially regarding the choice between originator and generic products.

---

[24] Judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 69.

[25] Commission Staff Working Document, Pharmaceutical Sector Inquiry, the Final Report (8 July 2009) ("Final report on the Pharmaceutical Sector Inquiry"), p. 98 and subsequent. See also Section 4.2.3.

[26] Case C-307/18, *Generics (UK) and Others*, paragraph 70, see also Sections 6.5; 8.3-8.5.

2.3.2. Price sensitivity

(22) Another peculiarity of the pharmaceutical sector in the EEA is that prices are, in many Member States, often the result of a regulated decision-making process, involving negotiations between the authorities representing buyers and the sellers (pharmaceutical companies). Where prices are not regulated and pharmaceutical companies can set prices unilaterally, that is in countries with so-called "free pricing", prices are typically still constrained to some extent by the agreed/fixed reimbursement levels. As a result of coverage and/or reimbursement schemes, patients do not bear (most of) the cost of the medicine and doctors and pharmacists, as decision-makers on the demand side, are typically not very price-sensitive.

(23) However, various mechanisms to control prescription medicine budgets exist that try to correct this and increase demand elasticity. For example, in instances where the patient contributes to a significant part of the payment of a medicine (the so-called "co-payment"), demand elasticity will be increased.

2.3.3. Life cycle of medicines

(24) The life cycle of an originator medicine can be broken down in three distinct phases: (i) R&D phase up to market launch; (ii) the period between market launch and loss of exclusivity on the molecule, upon expiry of any compound patents and supplementary protection certificates ("SPCs"), and data exclusivity; and (iii) the period after the loss of exclusivity, when generic products can enter the market.

(25) During the first phase, companies identify and develop potential new medicines, patent new compounds and active substances and take them through intensive pre-clinical and clinical trials to confirm their safety and efficacy in order to obtain marketing authorisations ("MA"). Companies also develop the industrial production processes and generally seek to protect these with additional patents. The time between filing an application for the first compound patent and the launch of the product typically takes several years and varies significantly.

(26) During the second phase, originator companies market the new medicines they have developed. Medicines sold on prescription cannot be advertised to the general public in the EEA. Nonetheless, originator companies can engage in tightly regulated marketing activities towards the medical practitioners. The purpose of these activities is to promote their products, raise awareness among the medical community and differentiate them from those of their competitors. Originator companies often carry out clinical trials, even after they have obtained MA for their products, with a view to demonstrating the relative efficacy and limited side effects of their products. Such studies may also be conducted with a view to obtaining approval for additional indications for their products. They might also consider refinement of their products or the launch of second generation products.

(27) During the third phase, following the originator's loss of exclusivity on the molecule due to the expiry of the compound patent and marketing and data exclusivity, generic manufacturers can enter the market with their own products based on the same molecule. As the Court of Justice put it, there is *"the opening of a market of a medecine containing an active ingredient that has recently entered the public domain to the manufacturers of generic medicines"*. This entry by generic manufacturers is subject to regulatory constraints. First, *"no medicine may be placed on the market of a Member State unless an MA has been issued by the competent authorities of that Member State or an authorisation has been granted"*. Second, *"full account must be*

taken of the intellectual property rights and, in particular, the patents held by the manufacturers of originator medicines relating to one or more processes of manufacturing an active ingredient that is in the public domain, rights which enjoy a high level of protection in the internal market".[27] Although after expiry of the compound patent certain features of (the production of) originator products are often still protected by secondary patents, generic competitors will usually try to find non-infringing ways to launch their product as early as possible after the compound patent expires. Such "inventing around" an originator's remaining secondary patents often leads to patentable inventions by generic manufacturers.

(28) Generic manufacturers may also challenge the validity of the originators' patents in court proceedings or take the risk of being subject to infringement proceedings upon entering the market. Notably, as the Court of Justice stated in the *Generics (UK) and Others* case *"uncertainty as to the validity of patents covering medicines is a fundamental characteristic of the pharmaceutical sector"*[28]. The Court further emphasised that *"a patent does not guarantee protection against actions seeking to contest its validity"* and that, in particular, a patent on the manufacturing process of an active ingredient that is in the public domain cannot be regarded as such as *"insurmountable barrier"* for entry. In this context, the Court also considered that *"the presumption of validity of a patent for an originator medicine does not amount to a presumption that a generic version of that medicine properly placed on the market is illegal"*[29].

(29) When in the third phase generic entry occurs, price tends to drop significantly (sometimes up to 80%-90%) and volume shifts to the generic product(s) (see also Recital (19)).[30] This leads to the elimination of the high margin that the originator enjoyed during the period before generic entry (the second phase). Regulatory systems usually include measures that are specifically designed to stimulate competition between the originator product and generic products. These measures include, for instance, mandatory substitution of the originator for the generic by pharmacies or incentives for pharmacies to dispense the generic product instead of the originator product. Some Member States provide for statutory price cuts on the price of the originator product when a generic enters the market.

2.4. Regulatory framework in the pharmaceutical sector

(30) The dense regulatory framework of the pharmaceutical sector in the EEA is set by law and regulation applicable at national and EU/EEA level. It aims at removing obstacles to the free movement of medicinal products while ensuring a high level of health protection that guarantees the quality, safety and efficacy of medicinal products and stimulates innovation. At the EEA level, the main sets of legislation relevant for the purposes of this Decision are: patent law and rules on marketing authorisation as well as rules concerning the price and reimbursement of medicinal products. Member States are solely competent to regulate the prices and reimbursement levels of medicines sold in their territory, although such rules must abide by certain transparency, equality and accountability standards.

---

27 Case C-307/18, *Generics (UK) and Others*, paragraphs 40-41.
28 Case C-307/18, *Generics (UK) and Others*, paragraph 51.
29 Case C-307/18, *Generics (UK) and Others*, paragraph 48-51.
30 Final report on the Pharmaceutical Sector Inquiry, p. 98 and subsequent.

2.4.1. The patent system

2.4.1.1. Overview

(31) In the pharmaceutical sector, patents play an important role. A patent confers on its holder the exclusive right to prevent unauthorised use of the invention by any third party[31]. Patents covering new API are usually referred to as "primary", "basic" or "compound" patents. Subsequent patents covering, for example, new production processes for active ingredients or new formulations are usually referred to as "secondary" patents. For secondary patents such as process patents, the protection conferred by a European patent extends to products directly obtained by the process that is the subject-matter of the patent.

(32) The term of protection granted by a patent is 20 years from the date of filing the patent application.[32] In the pharmaceutical sector, in order to compensate for the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to actually place the medicinal product on the market, the SPC was created at the EU level[33] in order to maintain the incentives to research and develop innovative medicines. The SPC extends the term of the basic patent protecting a medicinal product which has been subject to an MA before being placed on the market, for a maximum of five years in the territory of the designated Member State(s).

2.4.1.2. The objective of stimulating innovation

(33) Patent protection aims at stimulating innovation. Patent laws reward the inventor by granting a period of exclusive use of the invention while, in return, ensuring public disclosure of the invention (the patent specification). Patent protection is time-limited. By granting a period of exclusive use to the inventor, patent laws enable inventors to be rewarded for the invention, while providing incentives for the inventor to continue to innovate and develop further innovative products benefitting from patent protection. At the same time, the inventor is encouraged to bring the innovation to the market as quickly as possible. Commercial exploitation includes the placing on the market of products based on the invention and/or the granting of licences to third parties, usually in return for royalties.

2.4.1.3. Obtaining patents in the EEA

(34) In the EEA, patents can be obtained by making an application to the patent office in the member state concerned or, if the protection is sought for several countries, through a single application for a European patent to the European Patent Office ("EPO") pursuant to the European Patent Convention ("EPC")[34]. A European patent gives its holder the same rights as would the national patent confer in each of the

---

31 A patent is therefore an intellectual property right. See Article 28(1) of the WTO Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS").

32 See Article 63 of the European Patent Convention.

33 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, p. 1.

34 The EPC is an international treaty binding all Contracting Parties to the EEA Agreement as well as some other European countries (for example, Switzerland, Serbia), which establishes a common system of law for the grant of patents.

contracting parties of the EPC, for which patent protection is sought (that is to say it results in a bundle of national patents)[35].

(35) A patent will be granted if the invention is new, involves an inventive step and is susceptible of industrial application. In accordance with Article 69 of the EPC the extent of the protection conferred by a European patent shall be determined by the claims, which describe the features of the invention.[36]

(36) In the pharmaceutical industry, inventions relate for example, to new active ingredients, to new formulations of existing active ingredients or to new ways of producing or delivering active ingredients. All of these are, in principle, patentable.

2.4.1.4. Invalidity and infringement of patents

(37) Once the patent has been granted, third parties can challenge the validity of a patent in opposition proceedings for a short period of time (before the EPO in case of a European patent, or, if provided under national law, before national authorities for national patents).

(38) Third parties may also launch patent revocation proceedings before national courts regarding the national patent or the relevant national part of a European patent. Even in case of a European patent, the outcome of the national proceedings would thus be limited to the respective jurisdiction and not have effects in other designated countries of the European patent.

(39) An infringement of a European patent is also dealt with under national law.[37] In the event of an actual or threatened infringement of a patent, the patent holder may apply to a national court seeking the remedies provided for under national law. Generally speaking, these include a declaration of infringement, and/or an injunction (interim or permanent) prohibiting the sale of the infringing product, and/or damages. If the interim injunction is granted, the court will order that the infringer (such as a generic company) stops marketing its product until the main proceeding has been decided. However, interim measures in no way prejudge the merits of an infringement action brought by patent holder.

(40) In the pharmaceutical sector, when a generic company launches, or is about to launch, a generic product on a market whilst the patent holder still holds a number of secondary patents, the patent holder may react by initiating an action before the national court for infringement of one or more of those secondary patents against the generic company concerned as well as possibly against other companies involved in the production and marketing of the product. Such a generic product launch is called "at risk".[38] When being challenged in court, the generic company is not necessarily actually infringing the patent holder's patents and this does not indicate any

---

35 See Article 64(1) of the EPC.

36 See Article 69(1) of the EPC. A protocol on the interpretation of Article 69 attaches to the EPC and forms an integral part of it.

37 See Article 64(3) of the EPC.

38 In the EU, there are no limits to the number of patents which originators can obtain to protect the same compound. In the Pharmaceutical Sector Inquiry, the Commission found that besides the 'primary', 'basic' or compound patent, originators apply for many other 'secondary patents' to protect their blockbuster medicines such as patents for different manufacturing processes and for different formulations. Often, originators apply for secondary patents after the medicine has been on the market for some time, and the compound patent is about to expire.

likelihood of infringement. The patent holder often has only insufficient knowledge about the exact API production process used by the generic company, and therefore has difficulty to know when it launches litigation whether the generic company is really infringing its patent(s). The outcome of court proceedings is therefore generally difficult to predict and uncertain.

(41) Under national law, a party defending itself against allegations of patent infringement may, and often does, counterclaim that the patent is invalid (see also Recital (39)).[39]

2.4.2. Marketing authorisation

2.4.2.1. Introduction

(42) In the EEA,[40] medicinal products may only be placed on the market after they have obtained MA. This applies to all medicinal products, regardless whether they are new medicines or generic versions of existing medicines. The main objective of the MA rules is to ensure a high level of health protection and the free movement of medicines in the EU, by ensuring that only medicines that satisfy requirements of quality, efficacy and safety can be put on the market.[41]

2.4.2.2. Procedure: application, grant and data exclusivity

(43) MA procedures are fully harmonized in the EEA.[42] There are three different routes to obtaining an MA: central authorisation, mutual recognition and the decentralised procedure.[43]

(44) The centralised procedure results in an MA that is valid for the entire EEA. It is granted by the European Commission following a scientific evaluation by the European Medicines Agency ("EMA"). The scope of the centralised procedure has been extended over the years and now also applies to some generic products.

(45) The mutual recognition procedure ("MRP") must be used when a product is already authorised in at least one Member State on a national basis and the MA holder wishes to obtain an MA in at least one other Member State. The Member State that has already authorised the product (known as the Reference Member State ("RMS")) submits an evaluation of the product to other Member State/s (known as Concerned

---

39 This occurs in the United Kingdom and other jurisdictions. In other Member States, such as in Germany, there are bifurcated proceedings for validity and for infringement of the patent.

40 Norway, Iceland and Liechtenstein which together with the EU form the EEA have agreed to adopt, through the EEA agreement, the *acquis communautaire* on medicinal products. They are therefore parties to the EU MA procedures, with the only exception that legally binding acts adopted by the EU (for example, Commission Decisions) do not directly confer rights and obligations but first have to be transposed into legally binding acts in the respective countries. The MA's granted by Norway, Iceland and Liechtenstein are eligible for the mutual recognition procedures in the EU in same way as MA's granted in the EU.

41 As most medicines, even after they have received MA still present risks, such as side effects, for each medicine, the benefits must outweigh the risks. This risk-benefit balance must continue in favour of the benefits if the medicine is to remain on the market, see, for example, Section 4.8.2.1.

42 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67 and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.

43 See www.ema.europa.eu.

Member States ("CMS")) that are asked to mutually recognise the MA of the RMS. The CMS will then issue an MA permitting the marketing of the product in their territory.

(46) The decentralised procedure is used in cases where a medicinal product has not been granted MA at the time of the application. In this case, the RMS will prepare the draft assessment report on the medicinal product and will act as central point for the CMS and the applicant. The other CMS will grant MA in accordance with the approved assessment report, the summary of the product characteristics, package leaflet and labelling as approved. At the end of the procedure, each Member State will issue an MA permitting the marketing of the product in their territory.[44]

(47) The applicant for an MA must submit, among others, detailed results of pharmaceutical (physio-chemical, biological or microbiological) tests, pre-clinical (toxicological and pharmacological) tests and clinical trials.[45] Once an innovator medicine (the "reference product") has been authorised for a number of years on the basis of a full dossier that includes the results of these tests and trials, generic companies can apply for MA for a 'generic' version of the reference product through an abbreviated procedure.[46]

(48) Under the abbreviated procedure, the generic company applying for an MA is not required to provide the results of pre-clinical tests and clinical trials. Instead, the competent authority can rely on the results of the tests and trials in the full dossier supporting the MA application for the reference product. The generic company has to demonstrate that the generic is 'essentially similar' to the reference product by providing the results of bioavailability studies.

(49) However, an originator company enjoys a data exclusivity period during which its pre-clinical and clinical trials data may not be referenced in the regulatory filings of a generic company. Before November 2005, the period of data exclusivity varied between Member States, and was either 6 years or 10 years. After November 2005, for MA applications made in a centralised procedure, the period of data exclusivity is eight years, while marketing protection[47] is a further two years.[48]

---

44 The decentralised procedure was introduced by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136, 30.04.2004, p. 34, which entered into force on 30 October 2005.

45 See Article 8(3) of Directive 2001/83/EC.

46 Under Article 10(2) (a) and (b) of Directive 2001/83/EC, a 'reference product' is a medicine which has received MA, in the EU, or in a Member State on the basis of a full dossier, as provided for in Article 8 of Directive 2001/83/EC. A 'generic' medicine is a medicine which has (i) the same qualitative and quantitative composition, in terms of active ingredients (API) as the reference product, (ii) the same pharmaceutical form as the reference product and (iii) which has shown to be bioequivalent with the reference product (see Article 10(1) of Directive 2001/83/EC). For this purpose, different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an API are considered to be the same API, unless they differ significantly with regard to safety and/or efficacy. The grant of MA to a medicine (whether innovator or generic) must be followed by the placing on the market of the authorised medicine within 3 years, otherwise the MA will cease to be valid (see Article 24(4) of Directive 2001/83/EC).

47 A period during which the generic cannot be placed on the market even though it has already received MA.

48 Article 14(11) of Regulation (EC) No 726/2004.

2.4.2.3. Relationship between MA, patent protection and entry

(50) In the EEA, the rules on patents and on data exclusivity provide different and parallel sources of protection for innovative medicines, which may overlap.[49] In many cases, however, the data exclusivity period expires before the expiry of the relevant patents (including SPCs).[50] In such situations, competent authorities are not prevented from granting an MA to generic medicines just because the reference product is protected by a patent (whether a primary or secondary patent).

(51) MA decisions are taken on the basis only of scientific criteria regarding the quality, safety and efficacy of the medicinal product. Factors such as the fact that the reference product is covered by a patent cannot be invoked by competent authorities in order to refuse, suspend or withdraw a MA to a generic medicine.[51] Once a generic medicine has obtained an MA it can be launched onto the market[52], provided other national legal requirements relating to price approval and reimbursement status have been satisfied and without waiting for the originator's relevant patents to expire. It is in these cases that one generally speaks of launch 'at risk' as the generic may still be prevented from entering the market or its products may subsequently have to be withdrawn pursuant to a court order/injunction in patent litigation proceedings initiated by the originator.[53]

2.4.2.4. Changes in MA

(52) If, after a medicinal product has been placed on the market, information about the use of the medicine (such as adverse reactions) submitted to the authorities reveals that the medicine is more harmful than previously known, it may lead the competent authorities to issue recommendations for the use of the medicine, or to restrict its marketing. In some cases, a so-called EU-referral procedure is used to deal with concerns over the safety of a medicine or a class of medicines.[54] In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines and to provide a recommendation. For most referrals, the European Commission will then issue a Decision to all Member States reflecting the measures to take following the EMA's recommendation.

---

49 See Final report on the Pharmaceutical Sector Inquiry, point 324.

50 While innovator medicines benefit from a single period of data exclusivity, there may be several patents protecting the same compound, some of which (particularly 'secondary' patents for new manufacturing processes, new formulations and the like) may have been applied for several years after the innovator medicine was first launched onto the market and often close to the expiry of the data exclusivity and the compound patent.

51 See Article 81 of Regulation No 726/2004 and Articles 10(1) and 126 of Directive 2001/83/EC. See also, Final report on the Pharmaceutical Sector Inquiry, point 336. By contrast, in the United States, under the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417, known as the 'Hatch-Waxman' Act) the Food and Drug Administration ("FDA") cannot grant MA to a generic under an Abbreviated New Drug Application ("ANDA") if there are patent(s) in force protecting the innovator product, which are listed in the so-called 'Orange Book' and the patent(s) may be infringed. A generic company submitting an ANDA in that situation must certify to the FDA that the relevant patent(s) are invalid, unenforceable or will not be infringed by the manufacture/marketing of the generic medicine. This is called a 'paragraph (iv) certification'.

52 See also Recital (50) for MA submitted after November 2005.

53 In the EU, applying for a generic MA through an abbreviated procedure is not considered to be contrary to patent rights, see Article 10(6) of Directive 2001/83/EC.

54 See Articles 31 and 107 of Directive 2001/83/EC.

2.4.3. Pricing, reimbursement and substitution

(53) In many Member States, a medicinal product can only be marketed after a decision on the price and reimbursement status has been taken. The pricing decision determines the commercial terms of access to the market in a particular country. This requirement aims to ensure (i) that patients have access to the necessary medicines and originator companies have adequate incentives to continue innovating and (ii) that health budgets remain under control in order to ensure sustainability of the health system. In order to preserve incentives for further innovation, Member States typically accord high price levels for innovative medicines.

(54) Even in Member States in which pricing is not regulated, indirect price controls exist through reimbursement decisions. If no reimbursement is offered for an expensive product for which a cheaper alternative is available (such as a generic version), or a very significant co-payment contribution by the patient is required, a significant share of patients may refrain from using such a medicine.

(55) Pricing and reimbursement decisions must be taken within the timeframe set by Council Directive 89/105/EEC (the "Transparency Directive").[55] The setting of price and reimbursement levels of medicines are generally regulated at Member State level, with each Member State following its own policy.

(56) In several Member States, notably Germany, companies are in principle free to set the initial price of new medicines. In other Member States, the initial price of new medicines is the subject of negotiation with or without approval by the public authorities.

(57) Reimbursement levels for patients are set by the public authorities, whether at 100% of the price level or at a lower percentage. Even in Member States which leave the pricing of new medicines free, the reimbursement level of a medicine, if lower than 100%, tend to exert a moderating influence on how companies price their medicines, as patients may not be willing to buy a certain medicine if they have to make a significant co-payment. A number of Member States compare the price requested by the producer to the prices of the same medicine in a selection of other Member States (so-called "reference pricing"). As prices set in one Member State can thus become a reference point for subsequent price determinations in other Member States, traditionally the United Kingdom and Germany have been targeted by originator companies as "early launch" countries because they allow the originator companies to freely set the price of a new medicine.

(58) Once pricing and reimbursement conditions are established, there is limited knowledge and experience of competition and actual substitution patterns between the product in question and other products. Pricing processes therefore typically do not tend to take the competitive landscape into account. Once generic competition for an active ingredient becomes possible, public authorities will tend to put more emphasis on budget control and broad access for patients to the medicine concerned. This is done by for example, requiring physicians to prescribe medicines by their international-non-proprietary-name (INN), namely by the active ingredient instead of the brand name, imposing prescription quotas for generic medicines or by

[55] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ L 40, 11.2.1989, p. 8.

encouraging or obliging pharmacists to substitute a generic medicine with the same active ingredient(s) for another, usually a brand medicine.

3. PROCEDURE IN THIS CASE

(59) The Commission commenced this ex-officio investigation with unannounced inspections under Article 20(4) of Regulation (EC) No 1/2003, carried out at the premises of Cephalon […]* and Teva , […] between 9 and 11 December 2009.

(60) On 28 April 2011, the Commission initiated formal proceedings against Cephalon and Teva within the meaning of Article 11(6) of Regulation (EC) No 1/2003 and Article 2(1) of the Regulation (EC) No 773/2004. No third parties are involved in the case.

(61) In the course of the investigation, the Commission sent several requests for information pursuant to Article 18(1) of Regulation (EC) No 1/2003 (the "Article 18 Request") to Cephalon and Teva as well as to third parties. On 29 July 2015, a Decision pursuant to Article 18(3) of Regulation (EC) No 1/2003 requesting the production of documents was sent to Teva to which the company replied in full on 27 August 2015.

(62) On 17 July 2017, the Commission addressed a statement of objections (the "SO") to the Parties and provided the Parties with access to the main part of the Commission's investigation file. Access was provided, on one hand, by means of DVDs delivered on 14 August 2017 and a data room procedure that took place between 12 and 16 October 2017, and, on the other hand, by means of a confidentiality ring arrangement agreed between the Parties and [*company name*], in a 'Disclosure and Access Agreement' dated 22 February 2014.

(63) On 21 December 2017, Teva asked that the deadline for responding to the SO be extended to 26 January 2018. The Directorate General for Competition granted the extension sought. On 26 January 2018 the Parties submitted their written reply to the SO (the "SO Reply")[56] and they exercised their right to be heard orally by participating at the Oral Hearing on 13 March 2018.

(64) On 1 July 2019 the Commission sent to the Parties a Letter of Facts (the "LoF") informing them about three categories of evidence relevant to support the preliminary conclusions in the SO: (i) evidence on the file that was not expressly relied on in the SO; (ii) evidence that was submitted by the Parties together with their written SO Reply; and (iii) an additional piece of evidence that came to the Commission's attention after the adoption of the SO. On 26 July 2019, the Parties submitted their Response to the LoF.[57]

(65) On 8 April 2020, the Commission sent to the Parties a second LoF informing them about further additional evidence supporting the preliminary conclusions in the SO. All this evidence had been submitted by the Parties with their SO Reply. In addition,

---

[56] ID 3694-26.

* *Parts of this text have been edited to ensure that confidential information is not disclosed. Those parts are replaced by a non-confidential summary in square brackets or are shown as […].*

[57] ID 3763.

the Commission informed the Parties of corrections of two clerical errors in the SO. The Parties submitted their response to the second LoF on 6 May 2020.[58]

(66) On 8 June 2020, the Commission addressed a supplementary statement of objections (the "SSO") to the Parties. The SSO complemented and clarified the SO and in particular, (i) it complemented and clarified the Commission's reasoning underlying the preliminary conclusion reached in the SO that the Parties' conduct constitutes a restriction of competition by object under Article 101(1) TFEU (and of Article 53 of the EEA Agreement, where relevant), also in light of the recent case-law of the Union Courts, and (ii) it revised and complemented the indications provided in the SO concerning the calculation of the fine that could be imposed on Teva.

(67) In the cover letter of 8 June 2020, accompanying the SSO, the Commission noted that since the adoption of the SO, only documents that had already been shared with the Parties or that had been provided by the Parties themselves were added as accessible documents to the Commission's file. In this regard, the Commission provided to the Parties an index of documents, which have become part of the Commission's file in this investigation since the adoption of the SO, allowing the Parties to verify that the file did not contain any accessible documents to which access needed to be granted in order for the Parties to exercise their rights of defence. The Parties did not make a request for additional access to the Commission's file following receipt of the SSO.

(68) On 6 July 2020 the Parties submitted a written reply to the SSO (the "SSO Reply")[59] and exercised their right to be heard orally by participating at an Oral Hearing held on 22 July 2020.

4. FACTS

(69) In this Chapter, the Commission describes in detail the facts relevant for assessing the Settlement Agreement by which the Parties settled their litigation and agreed on a package of diverse commercial transactions in exchange for Teva agreeing not to enter modafinil markets and not to challenge Cephalon's patents. In particular, the Chapter sets out the facts preceding the Settlement Agreement (Sections 4.1-4.4), the facts relating to its negotiation (Section 4.5), the content and the context of the concluded Settlement Agreement and the commercial transactions concluded as part thereof (Sections 4.6-4.7) and, finally, relevant facts that occurred after the conclusion of the Settlement Agreement (Section 4.8).

(70) As regards the facts preceding the Settlement Agreement, the Commission first describes Cephalon's modafinil marketing authorisations, Cephalon's patent situation with regard to modafinil and its envisaged second-generation medicine (armodafinil), as well as the distribution system Cephalon set up in the EEA (Section 4.1). Second, the Commission describes Cephalon's concerns about generic entry given the expected loss of exclusivity of its best-selling product modafinil and shows the strategy Cephalon had devised against the generic entry (Section 4.2). Third, the Commission describes the relevant facts concerning Teva's preparations to launch its own generic modafinil product and the actual launch in the United Kingdom (Section 4.3). Fourth, the Commission describes the events that directly

[58] ID 3790.
[59] ID 3851.

preceded the Settlement Agreement, namely the legal action taken by Cephalon against Teva in the United Kingdom in reaction to Teva's entry, the first verifications run by Cephalon showing that Teva's samples did not infringe Cephalon's patents and, lastly, the initial approach by Teva to Cephalon to discuss about a potential settlement (Section 4.4).

4.1. Cephalon's modafinil marketing authorisations, relevant patents and distribution of modafinil medicinal products in the EEA

4.1.1. Cephalon's MA for modafinil in the EEA

(71) MAs for modafinil were obtained in various European countries.[60] This section focuses on the situation in those EU Member States where Cephalon generated the vast majority of its EEA modafinil sales.[61] The relevance of those countries in terms of Cephalon's sales is also why the assessment of the Settlement Agreement as a restriction of competition by effect in Chapter 8 focuses on these countries.

(72) As mentioned in Chapter 2, modafinil (Modiodal, 100 mg tablets) received the first marketing authorisation in the EEA in France in 1992. The MA holder was Lafon and the approved therapeutic indications were narcolepsy (with or without cataplexy[62]) and idiopathic hypersomnia.[63] Subsequent changes to the MA described in further detail how these indications should be established.[64] By way of example, the change of 24 February 1999 provides that the diagnosis of typical narcolepsy with cataplexy should be clinical.[65] On 3 June 2004 residual daytime sleepiness associated with obstructive sleep apnoea was added to the indications[66] and a Decision of the European Commission of 27 January 2011 restricted the indications for modafinil-containing medicines[67] to only the treatment of excessive sleepiness associated with "narcolepsy with or without cataplexy".[68]

(73) In Spain, modafinil (Modiodal, 100 mg tablets) was first approved in September 1997 with an indication "narcolepsy with or without cataplexy".[69] In the Netherlands, modafinil (Modiodal, 100 mg tablets) was first approved on 13 November 1997 for treatment of narcolepsy.[70] The MA holder was Laboratoires L. LAFON.

---

60 See also ID 247, p. 2.

61 Modafinil value sales have been unevenly distributed across the EEA. Modafinil sales in France, Germany, the Netherlands, Spain, Sweden and the United Kingdom accounted for more than 85% of the value sales in the EEA in the period of 2002-2014; see Section 8.1.1.4.

62 Cataplexy is a sudden and transient episode of muscle weakness accompanied by full conscious awareness. It is the cardinal symptom of narcolepsy with cataplexy affecting roughly 70% of people who have narcolepsy.

63 ID 2558, ID 2559.

64 ID 2560, ID 2561, ID 2562, ID 2563.

65 ID 2563.

66 ID 2564.

67 Commission Decision of 27 January 2011, C(2011)578/F1, concerning, in the Framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations for the medicinal products for human use which contain the active substance "modafinil" ("Commission Decision C(2011)578 concerning MA for modafinil").

68 ID 2565, See also Section 4.8.2.1.

69 ID 2586, see also ID 2584.

70 ID 2566, ID 2569.

(74) In the United Kingdom, modafinil (Provigil, 100 mg tablets) was first approved on 14 October 1997 for treatment of narcolepsy.[71] The MA holder was Cephalon UK. On 3 December 2002 and on 1 April 2004 additional indications of "*obstructive sleep apnoea/hypopnoea syndrome*" and "*treatment of excessive sleepiness associated with chronic pathological conditions and moderate to severe shift work sleep disorder*" were added.[72] On 9 July 2007, the wording was clarified so that it read: "*PROVIGIL is indicated for the symptomatic relief of excessive sleepiness associated with narcolepsy, obstructive sleep apnoea/hypopnoea syndrome (OSAHS) and Moderate to severe chronic shift work sleep disorder (SWSD).*"[73] The indications remained unchanged until the Decision of the European Commission of 27 January 2011.[74]

(75) In Germany, modafinil (Modiodal, 100 mg tablets) was first approved on 18 February 1998 with an indication "treatment of narcolepsy with and without cataplexy". The MA holder was Laboratoire L. LAFON.[75] The product name was subsequently changed to Vigil and the indication was amended on 20 June 2003 so as to include the moderate to severe chronic sleep apnoea syndrome with excessive daytime sleepiness despite adequate CPAP (continuous positive airway pressure) therapy.[76] The indication was amended again on 15 June 2005 so as to include moderate to severe shift work disorder characterized by excessive sleepiness in patients with night shift (to be prescribed if other measures of sleep treatment have failed).[77] On 18 March 2011, the German health authority restricted the indications in line with the Commission Decision C(2011)578 concerning MA for modafinil.[78]

(76) In Sweden, modafinil (Modiodal, 100 mg tablets) was first authorised on 5 October 2001, with the indication "*Narcolepsy with or without cataplexy. Idiopathic hypersomnia*."[79] The MA was held by Laboratoire L LAFON and on 16 February 2004 transferred to Cephalon France.[80] On 1 April 2011, the Swedish health authority restricted the therapeutic indications for modafinil in accordance with the Commission Decision C(2011)578 concerning MA for modafinil.[81]

4.1.2. Cephalon's patents on modafinil

4.1.2.1. Cephalon's modafinil patent rights

(77) Cephalon's main patents in the EEA related to modafinil are shown in Table 1. They include notably the (primary) modafinil compound patent, as well as some secondary patents: two Particle Size Patents and a patent on formulations comprising modafinil. These patents are described in more detail in the following subsections.

---

71 ID 2571, ID 2575.
72 ID 2571, ID 2573, ID 2572.
73 ID 2571, ID 2574.
74 See Section 4.8.2.1.
75 ID 2578, ID 2577.
76 ID 2578, ID 2583.
77 ID 2578, ID 2583, ID 2579.
78 ID 2578, ID 2583, ID 2582, ID 2580. See also Section 4.8.2.1.
79 ID 2598, ID 2597.
80 ID 2598, ID 2595.
81 ID 2598. See also ID 2594.

Table 1: Cephalon's main modafinil patents in the EEA

Number	Name	Date of publication	Protection period	Territory of protection
FR2385693[82] (primary compound patent)	Derives D'acetamide Utiles Notamment En Therapeutique	27.10.1978	27.02.1978-27.02.2005[83]	FR[84]
EP0731698[85] (secondary Particle Size Patent)	Modafinil Having Defined Particle Size	12.01.2000	04.10.1995-04.10.2015	AT – BE – DE – DK – ES – FR – GB – GR – IE – IT – LI – LU – NL – PT – SE[86]
EP0966962[87] (secondary Particle Size Patent)	Modafinil Having Defined Particle Size	21.02.2001	04.10.1995-04.10.2015	AT – BE – DE – DK – ES – FR – GB – GR – IE – IT – LI – LU – NL – PT – SE[88]
EP1397127[89] (other secondary patent)	Solid Pharmaceutical Formulations Comprising Modafinil	21.03.2007	24.05.2002-24.05.2022	AT – BE – CY – DE – DK – ES – FI – FR – GB – GR – IE – IT – LI – LU – NL – PT – SE[90]

Source: European Patent Office

4.1.2.1.1. Modafinil compound patent

(78) Racemate (that is two-isomer) modafinil compound (also known as 2-(benzhydrylsulfinyl) acetamide) has been first described as a stimulant for the central nervous system in French Patent No. FR2385693[91] and in US Pat. No. 4,177,290,[92] both held by Lafon. Lafon applied for the patent first in the United Kingdom on

82 ID 2881. See also Section 4.1.2.1.1.

83 See also the Section 4.1.2.1.1.

84 Other national patents were granted in Belgium, Denmark, Germany, Italy, Ireland, the Netherlands, Spain and the United Kingdom (see Section 4.1.2.1.1).

85 ID 2894. See also Section 4.1.2.1.2.

86 National counterparts of this patent were granted also in other European countries including Bulgaria, Czechia, Finland, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, Iceland and Norway. See ID 2895. See also Section 4.1.2.1.2. Cephalon also filed a patent application in Estonia which was however abandoned on 4 December 2000. See ID 3267, ID 3268 and ID 325, p. 1.

87 ID 2897. See also Section 4.1.2.1.2.

88 National counterparts of this patent were granted also in other European countries including Bulgaria, Czechia, Finland, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, Iceland and Norway. ID 2896. See also Section 4.1.3.1.2. Cephalon also filed a patent application in Estonia which was however abandoned on 4 December 2000. See ID 3267, ID 3268 and ID 325, p. 1.

89 ID 2900. See also Section 4.1.2.1.3.

90 The rights resulting from this patent also covered Latvia, Lithuania, Romania and Slovenia (as the so-called extension states of the European Patent Convention, namely the countries where the relevant patent rights were applied on the basis of their extension agreements with the European Patent Organisation until they became full EPO member states). Cephalon however did not pay the relevant patent fees for those countries. See ID 3269. A national counterpart of this patent was granted in Norway, see ID 2901.

91 ID 2881.

92 ID 2893.

31 March 1977 (Application No. 13579/77, later the UK patent 1584462),[93] but the completed specification was filed only one year later, on 31 March 1978. Therefore, the French Patent (FR2385693), applied for on 27 February 1978, was the first complete patent application (with reference to the United Kingdom application). The United Kingdom patent expired on 30 March 1998. An SPC was granted on 5 August 1998 which expired on 30 March 2003.[94] In France, an SPC was granted on 6 November 1992 which expired in 2005.[95]

(79) In March 1978, Lafon applied for patent protection in Belgium, Denmark, Germany, Ireland, Italy, the Netherlands and Spain.[96] In these countries, the patents expired in 1998, following which a protection by SPCs lasted for the maximum of another five years until 2003 (with exception of Italy where the SPC application was rejected).[97]

(80) In the United States, the modafinil compound patent expired in 2001.[98]

(81) Accordingly, at the time of the conclusion of the Settlement Agreement on 8 December 2005, Cephalon's primary/compound patents on modafinil had expired.

4.1.2.1.2. Particle Size Patents (secondary patents)

(82) In the EEA, Cephalon held at the time of the Settlement Agreement two patents for modafinil with defined particle size. Applications for both patents were filed on 4 October 1995 with the EPO. On 12 January 2000, the grant of the patent EP 0731698 ("EP '698 Patent") was published,[99] and on 21 February 2001, the grant of the patent EP 0966962 ("EP '962 Patent");[100] the EP '698 Patent and EP '962 Patent are hereinafter referred to collectively as the "Particle Size Patents").

(83) The Particle Size Patents were both named "Modafinil having defined particle size" and were granted amongst others for the following countries: Austria, Belgium, Denmark, Germany, Greece, France, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom.

(84) Until the date of the Settlement Agreement, national counterparts of the Particle Size Patents were also granted in Bulgaria (patent BG62952, published on 29 December 2000[101]), Czechia (patent CZ291700, published on 10 March 2003[102]), Iceland (patent IS1987, published on 15 February 2005[103]), Latvia (patent LV11852, published on 20 March 1998[104]), Lithuania (patent LT4303, published on 25 March 1998[105]), Norway (patent NO318818, published on 9 May 2005[106]), Poland

93 ID 2884. See also ID 2883.
94 ID 2890.
95 ID 2936.
96 ID 2882.
97 For example, ID 2887-2891.
98 ID 267, p. 2.
99 ID 2894.
100 ID 2897.
101 ID 3308.
102 ID 2939.
103 ID 3272.
104 ID 3275, ID 3307.
105 ID 3274, ID 3283.
106 ID 2942.

(patent PL181523, published on 31 August 2001[107]), Romania (patent RO118928, published on 30 January 2004[108]), Slovakia (patent SK283632, published on 4 November 2003[109]) and Slovenia (SI9520106, published on 28 February 1998[110]). In Finland and Hungary, the national counterparts of the Particle Size Patents were published after 2005 (Finland: patent FI121454, on 30 November 2010,[111] Hungary: patent HU226411, on 28 November 2008[112]). These national patents covered the scope of both European Particle Size Patents (similarly to the US '516 Patent, see Recital (88)).

(85) The EP '698 Patent has nine claims of which claim 1 is independent (namely all other claims are dependent on it).[113] Claim 1 is defined as follows: "*A pharmaceutical composition comprising a substantially homogeneous mixture of modafinil particles wherein at least about 95% of the cumulative total of modafinil particles in said composition have a diameter of less than about 200 micrometers and said composition contains between about 50 milligrams and about 700 milligrams of said modafinil*."

(86) The EP '962 Patent has seventeen claims of which claims 1, 7, 11 and 16 are independent (all other claims are dependent on them).[114] Moreover, the invention according to the patent is defined in claim 1.[115] Claim 1 is defined as follows: "*The use of modafinil for the manufacture of a pharmaceutical composition comprising modafinil particles having a median particle size of about 2 to about 60 micrometres for use in altering somnolent state of a mammal involving administering about 50 to 700 milligrams of said modafinil particles to said mammal*".[116]

(87) In the United States, Cephalon filed on 6 October 1994 a patent application which issued on 8 April 1997 as US patent No. 5,618,845 ("US '845 Patent"), entitled "Acetamide derivative having defined particle size" with six claims. On 1 April 1999, Cephalon filed a new patent application seeking a reissue of the US '845 Patent. The United States Patent and Trademark Office ("PTO") issued US Reissue Patent No. 37,516 ("US '516 Patent" or "US Particle Size Patent"),[117] under the same title as the US '845 Patent, on 15 January 2002. The US '516 Patent had 26 claims. It expired on 6 October 2014.[118] The US '516 patent was the counterpart

---

107 ID 2941.

108 ID 3309.

109 ID 2940.

110 ID 3276. Additional claims to this patent were granted on 31 December 2003.

111 ID 3270.

112 ID 3271.

113 See also the description of the Particle Size Patents as made by Cephalon, ID 206, p. 11. In another document, Cephalon's lawyers indicated that the claim 1 of the EP '698 Patent is the "main claim" for establishing the protective scope of the patent, ID 2144/74, p. 4-5.

114 See also the description of the Particle Size Patents as made by Cephalon, ID 206, p. 11.

115 See the findings of the Stockholm District Court of 5 October 2010 in the litigation between Cephalon France SAS and […], ID 1738, p. 2. Cephalon's lawyers indicated that the claim 1 of the EP '962 Patent is the "main claim" for establishing the protective scope of the patent, ID 2144-74, p. 4-5. See also ID 2089-53, p. 3.

116 Claim 7 of the EP '962 Patent follows the same structure but instead of defining the median particle size applies the mean particle size, claim 11 applies the mode particle size and claim 16 is in essence based on claim 1 of the EP '698 Patent.

117 ID 2902.

118 See https://patents.google.com/patent/USRE37516E1/en.

of the European Particle Size Patents, incorporating in one document all their claims.[119]

(88) According to the Parties, the Particle Size Patents covered the products Provigil (also sold under the brand names Modiodal, Vigil or Modasomil) and Nuvigil.[120]

4.1.2.1.3. Other (secondary) modafinil patents

(89) In addition to the Particle Size Patents,[121] Cephalon owned worldwide (including in the EEA and in the United States) other modafinil-related patents.

(90) In particular, three patents "under which a claim of patent infringement could reasonably be asserted"[122] were published at Cephalon's request in the United States' publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (known also as the "Orange Book")[123] as patents protecting Provigil between 2005 and 2011[124.] These patents also had their counterparts in the EEA.

(91) In addition to the US '516 Patent described in Recital (88), in 2005 the Orange Book listed for Provigil the patent US 4,927,855 ("US '855 Patent"; this patent was listed in the Orange Book until 2008). In 2008, a patent US 7,297,346 ("US '346 Patent") was added for Provigil in the Orange Book and was still listed in 2016.[125] Since the US '855 Patent relates to armodafinil, the follow-on product of modafinil, it is, along with the corresponding European patent EP 0233106, described in more detail in the following Section 4.1.2.2.

(92) The US '346 Patent "Pharmaceutical formulations of modafinil" encompasses the formulations (solidfinal dose either in tablet or capsule form) of both modafinil and

---

119 See, for example, ID 206, p. 11 where Cephalon lists collectively the US '516 Patent and the Particle Size Patents as the patents that "*cover the approved products by claiming pharmaceutical formulations having particle sizes of modafinil of less than about 200 microns".*

120 Nuvigil is Cephalon's second-generation wakefulness product based on API armodafinil (following modafinil-based medicines). For more details, see Section 4.2.3. ID 135, Annex Q12. Concerning the different brand names, see footnote 13.

121 For the sake of completeness, Cephalon held yet a third European patent regarding modafinil having defined particles, EP 1 088 549. However, this patent was granted only on 9 July 2008 and did not play a role in the modafinil dispute with the generic companies, nor in the Settlement Agreement negotiations. The (only) independent claim 1 of this patent covered "*A process for the preparation of the pharmaceutical composition comprising incorporating an effective amount of modafinil particles wherein at least about 95% of the cumulative total of said modafinil patients in said composition have a diameter of less than 200 mum and wherein the median particle size is about 10 to 60 mum about into said composition and forming the same into a tablet, capsule, powder or pill.*" Also, this patent did not correspond to any of the patents listed in the United States Orange Book as protecting modafinil until 2011 (and later). See Recital (xxx).

122 According to the United States jurisprudence "(*T)he FDA publishes a list of all patents covering a drug under which a claim of patent infringement could reasonably be asserted in the 'Approved Drug Products with Therapeutic Equivalence Evaluations' publication, also known as the Orange Book*." See ID 2465, p. 4, footnote 3.

123 The Orange Book identifies drug products approved on the basis of safety and effectiveness by the United States FDA under the Federal Food, Drug, and Cosmetic Act. In addition, the Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products (generic drugs). Finally, the Orange Book lists patents that are purported to protect each drug. Patent listings are provided by the drug application owner.

124 The period 2005-2011 delineates, according to the conclusions of the Commission, the duration of the infringement assessed in this Decision. See Section 14.

125 See in particular ID 2872-2877 and ID 2879 for the entries for modafinil in the Orange Book in 2005-2011.

armodafinil.[126] Its European counterpart is patent EP 1397127 "Solid pharmaceutical formulations comprising modafinil" ("EP '127 Patent").[127] Cephalon filed the patent application with the EPO on 23 May 2002 and the patent was published on 21 March 2007. The EP '127 Patent covers Austria, Belgium, Cyprus, Denmark, Finland, France, Germany Greece, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom. It also includes Latvia, Lithuania, Romania and Slovenia (as the so-called extension states[128]). In Norway, a corollary national patent NO328805 was published on 18 May 2010 (and ceased on 31 May 2016).[129] No such patent existed in Czechia Republic, Poland and Slovakia. The EP '127 Patent is set to expire on 23 May 2022. The EP '127 Patent protects novel tablet compositions of modafinil according to claim 1. In particular, the active ingredient modafinil is admixed with various excipients (inactive substances) to formulate a solid dose of modafinil.[130] Claims 1-8 of the patent cover pharmaceutical formulations of modafinil, and claims 9-10 pharmaceutical formulations of armodafinil (or "levorotatory isomer of modafinil") whereby the ratio between the active substance and the excipients remains the same.

(93) In addition to the above-mentioned main modafinil-related patents held by Cephalon (as summarized in Recital (78), Table 1), in the United States, Cephalon filed on 7 August 2003 a patent application relating to polymorphic (crystalline) forms of modafinil (patent application Nº 10/635,445, "Modafinil polymorphic forms" – "US '445 Patent Application"). The application was based on discovery by Lafon scientists, made already in 1995, of three crystalline forms of modafinil (see Recital (293)). The respective patent issued on 31 January 2006 as No. 6,992,219 ("US '219 Patent").[131] As shown in Section 4.7.1.5, this patent and the course of the proceedings resulting of its grant, is an important element of the context in which Cephalon purchased the licence to Teva's Intellectual Property Rights (see also Sections 4.7.1 and 4.6.3.2).

(94) In sum, at the time of the Settlement Agreement Cephalon held in the EEA also the following (secondary) patents related to modafinil:

Table 2: Cephalon's other modafinil patents in the EEA in 2005

Number	**Name**	**Date of publication**	**Protection period**	**Territory of protection**
EP0462004[132]	New Use Of Modafinil	06.09.2005	12.06.1991-12.06.2011	AT – BE – DE – DK – FR – GB – IT – LI – LU – NL – SE

126 ID 2903.
127 ID 2900.
128 See footnote 90.
129 ID 2901.
130 The composition of a tablet according to claim 1 (the only independent claim) is defined by weight amounts (given in percentages of the total weight) of modafinil and excipients used to formulate the tablet (for example, a tablet should comprise 30% to 50% by its weight of modafinil).
131 ID 2933.
132 ID 3277, p. 3-4.

HU215590[133] (national counterpart of EP0462004)	Process For Producing Pharmaceutical Composition Comprising Modafinil Which Is Applicable For Treatment Of Degenerative Diseases Of Central Nervous System	04.12.1998	13.06.1991-13.06.2011	HU
EP0547952[134]	Use Of Modafinil For The Manufacture Of An Anti-Ischemic Medicament	06.09.2005	11.12.1992-11.12.2012	AT – BE – DE – DK – FR – GB – IT – LI – LU – NL – SE
HU216193[135] (national counterpart of EP0547952)	Process for the preparation of pharmaceutical compositions containing modafinil and having protective action against the repercussions of ischaemia	31.03.1999	11.12.1992-11.12.2012	HU
EP0705099[136]	Use of modafinil for the treatment of sleep apnoea and ventilation problems of central origin	24.10.2001	22.06.1993-22.06.2013	AT – BE – DE – DK – ES – FR – GB – GR – IE – IT – LI – LU – NL – PT – SE
HU216731[137] (national counterpart of EP0705099)	Use of modafinil for preparing pharmaceutical compositions for the treatment of sleep apnoea and ventilation problems of central origin	05.07.1999	14.06.1994-14.06.2014	HU
EP1251842[138]	Use of modafinil for the manufacture of a medicament for correcting vigilance disorders related to myopathies	27.08.2003	29.01.2001-29.01.2021	AT – BE – CY – DE – DK – ES – FI – FR – GB – GR – IE – IT – LI – LU – NL – PT – SE

4.1.2.1.4. Conclusion: Cephalon's modafinil patent rights in the EEA in 2005

(95) The information presented in Recitals (83)-(95) shows that at the time of the concluding the Settlement Agreement, Cephalon held a number of secondary patents related to modafinil in a number of countries (see Table 3). As explained in Section 4.1.2.1.1., at the time of the conclusion of the Settlement Agreement, the primary patent protection for modafinil had expired.

133 ID 3278.
134 ID 3277, p. 1-2.
135 ID 3279.
136 ID 3277, p. 5-6.
137 ID 3280.
138 ID 3281.

Table 3: Countries with Cephalon's modafinil patents in 2005

Country	**Particle Size Patents**		**Other modafinil patent**	
EU	**Number**	**Date of publication**	**Number**	**Date of publication**
Austria	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Belgium	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Bulgaria	BG62952	29.12.2000	–	n/a
Czechia	CZ291700	10.3.2003	–	n/a
Cyprus	–	n/a	EP1251842	27.8.2003
Denmark	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Finland	– [139]	n/a	EP1251842	27.8.2003
France	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Germany	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Greece	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0705099	27.8.2003 24.10.2001
Hungary	– [140]	n/a	HU215590 HU216193	28.01.1999 28.05.1999

139 Patent FI121454 was granted only on 30.11.2010 in Finland.

140 Patent HU226411 was granted only on 28.11.2008 in Hungary.

			HU216731[141]	05.07.1999
Ireland	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0705099	27.8.2003 24.10.2001
Italy	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Latvia	LV11852	20.3.1998	–	n/a
Lithuania	LT4303	25.3.1998	–	n/a
Luxembourg	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Netherlands	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Poland	PL181523	31.08.2001	–	n/a
Portugal	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0705099	27.8.2003 24.10.2001
Romania	RO118928	30.01.2004	–	n/a
Slovakia	SK283632	04.11.2003	–	n/a
Slovenia	SI9520106	28.02.1998	–	n/a
Spain	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0705099	27.8.2003 24.10.2001
Sweden	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
United Kingdom	EP0731698	08.03.2000	EP1251842	27.8.2003

[141] These three Hungarian patents were also issued as EP06462004 (12.06.1991), EP0547952 (11.12.1992) and EP0705099 (22.06.1993) for a number of Contracting Parties to the EEA Agreement (not for Estonia or Malta).

	EP0966962	21.03.2001	EP0462004 EP0547952 EP0705099	06.09.2005 06.09.2005 24.10.2001
EFTA				
Iceland	IS1987	15.02.2005	–	n/a
Liechtenstein	EP0731698 EP0966962	08.03.2000 21.03.2001	EP1251842 EP0462004 EP0547952 EP0705099	27.8.2003 06.09.2005 06.09.2005 24.10.2001
Norway	NO318818	09.05.2005	–	n/a

4.1.2.2. Cephalon's armodafinil patent rights

(96) Armodafinil (or also "R-modafinil")[142] is the active pharmaceutical ingredient in Nuvigil, Cephalon's second-generation wakefulness product. Armodafinil has pharmacological properties similar to those of modafinil, which contrary to armodafinil includes a mixture of R- and S-modafinil.[143] In documents dating from after the Settlement Agreement, both Teva[144] and Cephalon[145] considered that armodafinil was protected by the Particle Size Patents. Beyond that, armodafinil, not being a precise chemical equivalent of modafinil, has enjoyed protection from specific patents related to this compound. Cephalon started filing armodafinil patent applications both in the EEA and the United States well before the conclusion of the Settlement Agreement.[146]

---

142 The Parties have used the terms "armodafinil" and "r-modafinil" in their internal documents. The Commission uses the term "armodafinil", but will leave the term as used by the Parties in the quotes of the Parties' documents.

143 See *Highlights of Prescribing Information*, NUVIGIL® (armodafinil) tablets, for oral use, C-IV, p.4, available at: https://www.nuvigil.com/globalassets/nuvigil-consumer/prescribinginformation.pdf.
Modafinil is a compound comprised of two enantiomers, the S-enantiomer and the R-enantiomer. Armodafinil is only comprised of the R-enantiomer of Modafinil, while the S-enantiomer of Modafinil is not used. Both, Modafinil and Armodafinil share similar pharmacological properties, while Armodafinil is believed to be more potent, see: https://www.modafinil.com/armodafinil-vs-modafinil/.

144 ID 132, p. 1 "Armodafinil-New Litigation" of 3December 2009 concerning Teva's patent litigation in the United States on armodafinil: "*Cephalon has alleged infringement of 3 patents, covering particle size, crystalline form and formulations. We already have a license to 2 of those patents (formulation and particle size) as part of our modafinil settlement, so as to those patents, Cephalon is only looking to prevent us from selling our product prior to the license date which is currently April 6, 2012 but can be accelerated under certain conditions.*"

145 ID 189, p. 74 "Patent Protection on Nuvigil" of 29 May 2008 listing "*Fine particles patent*" with the expiry in 2015 in Europe ID 221, p. 44-47 of 12-13 June 2008: "*I mentioned CP 138* [Particle Size Patents] *in the list of patents covering the product NUVIGIL as it must be known when evaluating the patent protection.* […] *Both Provigil (Modafinil) and Nuvigil (Armodafinil) current formulations are covered by this patent.*" In a meeting of 15 May 2006, it was still to be "*Check*[ed] *with legal if Nuvigil in Europe would be protected by particle size patent.*" ID 282, p. 4. See also ID 212, p. 160 of 24 October 2006 indicating "*per our interpretation of the claim*".

146 For internal Cephalon overviews of United States and foreign patents for Provigil and Nuvigil, see ID 212, p. 160-161; ID 212, p. 162-164; and ID 212, p. 168-169.

(97) The patent EP 0233106 protected armodafinil compound until its expiration on 19 January 2007.[147] Cephalon filed an application for this patent on 19 January 1987 and the patent was published on 31 May 1989 under the name "(–)– Benzhydrylsulfinylacetamide, process for its preparation and its use in therapy."[148] In the EEA, the patent covered amongst others the following countries: Austria, Belgium, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Spain, Sweden, the United Kingdom and Liechtenstein. National counterparts of this patent existed in Denmark (DK165594) and Ireland (IE59832).[149]

(98) The equivalent 'US '855 Patent "Levorotatory isomer of benzhydrylsulfinyl derivatives", filed on 28 January 1986 and issued on 22 May 1990, provided for protection until 22 October 2010.[150]

(99) On 18 December 2003, Cephalon applied, both before the EPO and in the United States, for a patent on particular compositions of matter of the Form I polymorph of armodafinil, as well as pharmaceutical formulations and methods of manufacturing. The EP application Nº 1572635 "*Method for the production of crystalline forms and crystalline forms of optical enantiomers of modafinil*" issued as patent EP1572635 on 12 April 2017 ("EP '635 Patent").[151] The protection period runs until 18 December 2023. The geographical scope of the EP '635 Patent covers Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom. In Poland (PL377196)[152] and on Iceland (IS7947),[153] separate national procedures were launched at the same date as at the European Patent Office, and a national patent NO335724 was granted in Norway on 2 February 2015.[154]

(100) Based on the EP '635 Patent application, Cephalon filed five further divisional applications, namely patent applications that divide the initial application in different parts and each claim a separate invention, on 18 December 2003. Of these, two were granted European patents – EP 2343275 named "crystalline form of the optical enantiomers of modafinil", published on 1 March 2013,[155] and EP 2679578 named "preparation method and crystalline form of optical enantiomers of modafinil", published on 9 March 2016.[156] The geographical scope of the aforementioned patents is the same as the one of the EP '635 Patent including the Norwegian patent (NO335724) and the separate patent applications in Poland (PL377196) and on Iceland (IS7947). The protection period of both patents is also until 18 December 2023.[157, 158]

---

147 ID 2906. See also ID 196, p. 10.

148 In chemical nomenclature, the prefix "(–)-" stands for "levorotatory".

149 ID 2899.

150 ID 2909. The PTO granted patent term extension between 2006 and 2010 based on the time lapsed between the filing for the patent and the FDA authorisation to market armodafinil in the United States.

151 ID 3282.

152 ID 2930.

153 ID 3273, ID 325, p. 7.

154 ID 2928.

155 ID 2937 and ID 2908.

156 ID 2938 and ID 2911.

157 ID 2450.

(101) Conversely, the United States application corresponding to the EP '635 Patent issued as patent US 7,132,570 ("US '570 Patent) on 7 November 2006.[159] The US '570 Patent will expire on 18 December 2023, or, if paediatric exclusivity is granted, on 18 June 2024. Upon its grant, Cephalon viewed the patent as primary protection for armodafinil. In a press release, Cephalon's President of Research and Development stated that the polymorphic Form I claimed in the US '570 Patent "*is present in the formulation that we expect to bring to market, and is very likely to be present in any other formulation of armodafinil that may be developed*." Therefore, "(*W*)*e believe this patent will provide strong protection for Nuvigil*."[160] The Vice-President and General Counsel of Cephalon added: "*Our Provigil patent litigation settlements of the past year, and the associated licenses to certain intellectual property, do not grant any rights to this important patent. This new protection provides us with the confidence to continue to develop this market and expand our wakefulness franchise*."[161] [162]

4.1.3. Distribution of Provigil in the EEA

(102) In the United Kingdom and Ireland, Cephalon assigned […] as the exclusive distributor of Provigil between January 2001 and […]. The Provigil distribution by […] was part of a broader collaboration between Cephalon and […] on the basis of the Collaboration Agreement of 27 November 2000 ("Collaboration Agreement").[163] In essence, Cephalon UK was responsible for marketing, advertising and promoting various products of both parties, whilst […] was responsible for their distribution.[164] The provision by Cephalon of marketing, advertising and promotion services concerning these products (including in particular Provigil) was set out in the Managed Services Agreement of 27 November 2000,[165] whilst the provision by […]

---

158 Cephalon filed further armodafinil related patent applications in the EEA, before the conclusion of the Settlement Agreement, for example, for the patent EP 1663963 to process for enantioselective synthesis of single enantiomers of modafinil by asymmetric oxidation (patent application of 17 September 2004), patent EP 1797021 to methods for the separation of modafinil (patent application of 13 September 2005), and the patent application Nr. 10001997.5 of 1 February 2005 to compositions comprising a polymorphic form of armodafinil which was withdrawn on 3 July 2015.

159 ID 2912.

160 ID 2422.

161 *Ibid*. Cephalon's Vice-President refers to the Modafinil Settlements (see, for example, Sections 4.5, 4.6, and 4.8.1.3) and to the authorised generic entry licences for the generic companies.

162 Between December 2009 and August 2010 Cephalon filed patent infringement lawsuits against seven companies – Teva, Actavis, Mylan, Watson, Sandoz, Lupin and Apotex – based upon the applications filed by these firms with the FDA seeking approval to market a generic form of Nuvigil. The lawsuits claimed infringement of US '570 Patent, US '346 Patent and US '516 Patent. On 30 April 2012, Cephalon/Teva settled the patent dispute with Mylan (ID 2425). On 30 March 2013, the United States court particularly upheld the validity of the US '570 Patent and, because the defendants have admitted that their generic armodafinil products would infringe claims 6 and 9 of the said patent, the court enjoined the FDA from approving defendants' products, and enjoined the defendants from commercially manufacturing, using, offering for sale or selling their product prior to the expiration of the US '570 Patent (ID 2418). The judgment was appealed, however in June and July 2014 Cephalon/Teva settled the litigation with Sandoz, Lupin, Apotex and Actavis (ID 2424; in November 2012, Watson acquired Actavis and adopted its name for its worldwide operations).

163 ID 249, p. 30 and subsequent.

164 ID 1436, p. 13. See also ID 1627, p. 6 (paragraph 16), and , for example, Article 2 of the Collaboration Agreement, Article 1 of the […] Distribution Agreement, and Article 2 and Schedule 1 of the Managed Services Agreement.

165 ID 249, p. 1 and subsequent.

of the distribution services was laid down in the Distribution Agreement between Cephalon UK and […] of 27 November 2000[166] ("[…]Distribution Agreement").

(103) The services provided by […] pursuant to the […] Distribution Agreement were, in particular, warehousing, taking orders and distributing Provigil. They did not include marketing and promotion activities. […] gross margin from the distribution amounted to approximately […%].[167] […] […].[168]

(104) In the event that the […].[169] The initial term of the Collaboration Agreement and the […] Distribution Agreement was […].[170]

(105) […] offered Cephalon's Provigil either as 30 x 100 mg tablet packs or 30 x 200 mg tablet packs. In 2004, […].[171] The NHS list price (the end consumer price) of the 30 x 100 mg tablet pack of Provigil was GBP 60. [*Distributor*] sold the product at the […][172] to pharmacies and hospitals. In 2005, 95% of Provigil United Kingdom sales were made at retail pharmacy level with the remaining 5% in hospitals.[173]

(106) The general performance of the collaboration, in particular with regard to Provigil, the "*key growth driver in the collaboration*"[174], was not as originally expected. […].[175] The development in 2001-2004 showed increasing shortfalls in sales of Provigil.[176] […].[177] […][178] […].[179]

(107) Cephalon later recognized the main reasons why the collaboration was not a success (and should therefore be terminated).[180] First, Provigil sales had not performed as originally envisaged, and second, there was rarely agreement between the Parties on what level of investment was warranted by the products covered by the collaboration.[181] In addition, Cephalon had grown significantly in the five years since

---

166 ID 250, p. 1 and subsequent.

167 ID 1318, p. 7. In its response to Article 18 Request of 9 November 2010 Cephalon states that the Collaboration Agreement "*provides that [...] would purchase the 30x100 mg presentation at a price of GBP45.00 per pack. At that time, the NHS List Price was GBP 60.00 per pack. […] would have sold the product to wholesalers at the* […] Cephalon however mistakenly calculates a gross margin of approximately […] because it divides the gross profit of […] by the price of the goods sold (that is […]). The gross margin is however calculated by dividing the gross profit by the revenue (that is […] in the case at hand) which gives the result of approximately […].

168 See also ID 1627, p. 11, paragraph 40.

169 Article 12.5 of the Collaboration Agreement and Schedule 7 (Special Payments) Part III (Provigil Sales Shortfall) of the Collaboration Agreement.

170 See Article 14.1 in conjunction with Article 1.1 (Definitions and Interpretation) of the Collaboration Agreement, and Article 2.2 in conjunction with Article 1.1 (Interpretation) of the […] Distribution Agreement.

171 According to Witness Statement of […], ID 1627, p. 4 (paragraph 7), the total market value of Provigil in the United Kingdom in 2004 was GBP 4.5 million, and GBP 5.4 million including sales of 200 mg tablets.

172 ID 1627, p. 8 (paragraph 24). See also ID 1318, p. 7.

173 ID 285, p. 112.

174 ID 2543, p.1.

175 ID 2521, p. 6. See also ID 2537, p. 2.

176 ID 2543, p. 1.

177 *Ibid*. See also SO Reply, p. 38, and Annexes 12 and 13 to the SO Reply, ID 3694-4 and ID 3694-05.

178 ID 2537, p. 4.

179 See Recital (105)

180 ID 2542, p. 2.

181 *Ibid.*

the start of the collaboration, and the collaboration was not as important to it as it was at the beginning.[182]

(108) Cephalon relied on other distributors for modafinil products in a number of the EEA countries, such as [*company name*] in Italy, [*company name*] in Belgium, Denmark, Finland, Luxemburg, The Netherlands and Sweden, [*company name*] in Spain and [*company name*] in certain Eastern European and Balkan countries.[183] Cephalon informed the Commission that the responsibilities of the other distributors were broader than those of […] pursuant to the […] Distribution Agreement (and also than those of Teva under the distribution agreement entered into in the context of the Settlement Agreement). In particular, these other distributors "*have responsibility for marketing and promotion, and are often required to commit to purchasing minimum volumes of product per year. The distributor's gross margin in such distribution agreements is, accordingly, higher*."[184] For example, the distribution margin for [*company name*] was […] during the first five years of the distribution and […] thereafter of [*company name*] net sales.[185] The distribution margin for [*company name*] was […] of [*company name*] net sales.[186]

4.2. Cephalon's concerns about generic entry

(109) This Section explains the outstanding commercial importance of modafinil for Cephalon (Section 4.2.1), how Cephalon expected to lose exclusivity of its best-selling product modafinil (Section 4.2.2)) and the strategy it had devised against the entry of generic modafinil suppliers (Section 4.2.3).

4.2.1. Provigil is a key product for Cephalon's business

(110) Between 2001 and 2010, Provigil was the best-selling product in Cephalon's portfolio world-wide, and at least between 2004 and 2006 in the EEA. The vast majority of worldwide sales of Provigil (and identical modafinil products marketed under different brand names, see Recital (11)), consistently over 90%, occurred in the US market, with 4% (in 2009) to 7% (in 2005) in the EEA.[187]

---

182 *Ibid*. There were at least two instances where the Parties were not able to agree on investment into Provigil within the collaboration framework. One instance was in mid- 2003 (see ID 2542, p. 2). Another one happened between April and May 2004 when […]. See the letter Re: Cephalon Inc […] Collaboration Agreement Restructuring Proposal, of 10 May 2004, ID 2543. See also ID 3694-5.

183 ID 247, p. 2-3. International Supply and Distribution Agreement between Cephalon UK and […]of 24 June 1998 ("[*company name*] Distribution Agreement"), ID 269, p. 2-29; International Supply and Distribution Agreement between […] and […] ("[*company name*] Distribution Agreement"), ID 269, p. 51-101.

184 ID 1318, p. 7. See also Article 2.1 of [*company name*] Distribution Agreement (ID 269, p. 2-29), and Article 2.1 of [*company name*] Distribution Agreement (ID 269, p. 51-101). According to the latter, [*company name*] took responsibility also for the packaging of the product.

185 Article 1.9 in conjunction with Schedule A (Product Purchase Price) of [*company name*] Distribution Agreement, ID 269, p. 4 and 27.

186 Article 4.2(a) of [*company name*] Distribution Agreement, ID 269, p. 63-64.

187 For example, in the years 2004 and 2005, the United States sales accounted for 92-93% of the worldwide sales. ID 2201, p. 33, ID 2202, p. 52. In 2010, at the peak of Cephalon's sales of Provigil, approximately 94% of the sales were recorded in the United States and 4-5% in the EEA. Calculated on the basis of the figures provided by the Parties, the weighted average of the sales in the EEA between 2005-2012 was 4,48% of the total sales. ID 2206, p. 46.

(111) The worldwide net sales of USD 25 million in the launch year (1999)[188] in the United States increased to approximately USD 207 million in 2002 and USD 291 million in 2003,[189] that is in the year when Cephalon started facing the threat of generic competition in the United States. In the following year, Cephalon recorded worldwide sales of Provigil in the amount of approximately USD 440 million (increase of 51%),[190] and in 2005, that is in the year of the Settlement Agreement, sales of approximately USD 513 million (thus a lower increase of 17%).[191] The sales increased again by 43% in 2006 to over USD 734 million[192].

(112) Cephalon's Provigil worldwide sales surpassed the 1 billion USD mark in 2009, making it a blockbuster drug.[193] The figure climbed up to almost USD 1.125 billion in 2010.[194] A major decline of Provigil worldwide sales occurred in 2011 as the result of launches of generic modafinil products by competitors, as well as the launch by Cephalon of its own second-generation modafinil drug Nuvigil. Worldwide sales of Provigil further fell from USD 350 million in 2011 to USD 91 million in 2013.[195]

(113) Within Cephalon's overall commercial activity, Provigil was the key product. It made up more than 40% of Cephalon's overall worldwide sales in 2003 and approximately 42-43% in 2004 and 2005, namely in the years immediately preceding the Settlement Agreement.[196]

(114) With regard to the situation in the EEA, in 2006-2010, Cephalon's modafinil sales totalled approximately EUR 183 million.[197] In the EEA, Provigil (and other brands of the same medicine) was Cephalon's most prominent product. For example, in the United Kingdom, Provigil accounted for 73% of Cephalon UK's annual turnover in 2004,[198] and was forecast to make 56% of its turnover in 2006 on the assumption that there were no generic competitors in the market (in the case of generic entry, the forecast would change to about 33% in 2006).[199]

(115) Cephalon was very much conscious that modafinil was very important to its business. In its Annual Reports of 2003 and 2004, Cephalon stated: "*Our future success is highly dependent on obtaining and maintaining patent protection for our products and technology. With respect to Provigil, we have filed a patent infringement suit against four generic competitors. Depending on the results of this litigation, we could face generic competition as early as December 2005… The loss of patent protection on any of our existing products, whether by third-party challenge, invalidation or circumvention or by patent expiration, would materially impact our results of operations*."[200]

---

188 ID 2200, p. 4.
189 ID 2200, p. 12.
190 ID 2201, p. 37.
191 ID 2202, p. 56.
192 See footnote 643.
193 ID 2206, p. 53.
194 Ibid.
195 ID 2234, p. 68. In this context, it should be recalled that in October 2011, Cephalon was wholly acquired by Teva. See Section 4.8.2.4.
196 ID 2200, p. 29; ID 2202, p. 56.
197 ID 1771-117.
198 ID 1627, p. 14.
199 ID 285, p. 115.
200 ID 2200, p. 12.

4.2.2. Cephalon anticipated the loss of exclusivity

(116) This and the following Section describe the challenge of Cephalon's modafinil medicine by producers of generic modafinil, the assessment by Cephalon as well as by the expert community of the prospect of success of that challenge and the development by Cephalon of a strategic response to the perceived threat from generic manufacturers.

(117) These Sections describe, in particular, the situation in the United States which was further advanced than the situation in the EEA, and provides a useful contextual framework for the subsequent developments in the EEA. The events in the United States and in the EEA were integral parts of a single generic challenge to Cephalon's modafinil medicine, notably in the case of Teva (resulting eventually in a single worldwide solution being adopted in the Settlement Agreement, see Section 4.6). Given that over 90% of Cephalon's modafinil sales were made in the United States, representing over 40% of its worldwide revenues (Recitals (111) and (114)), the situation in the United States also illustrates the stakes for Cephalon's business in the worldwide generic challenge and, accordingly, clarifies the basic economic rationale behind the Settlement Agreement. Finally, the Particle Size Patents, which Cephalon held against the generic companies both in the United States and across the EEA,[201] provided for the same scope of protection, and hence were equally vulnerable against a patent challenge. This was reflected in the Parties' assessment of the possibility of generic penetration in both regions.[202] Details on the threat of generic entry in the EEA by Teva are set out Section 4.3.

(118) Since 1994 (United States) and 1995 (EEA), Cephalon had started preparing for the expiration of its modafinil compound patents by means of filing the Particle Size Patents, to maintain its market exclusivity for modafinil through 2014/2015 (see Section 4.1.3.1.2). However, these patents, as they were secondary and not compound patents, offered weaker protection from generic competition than the compound patent. An expert consultant warned Cephalon in 2002 that "*all generic drug companies know… the* [US Particle Size Patent[203]] *may be easily circumvented*."[204]

(119) Cephalon itself stated in its Annual Report for 2003 about its patent position concerning Provigil: "We own U.S. and foreign patent rights that expire between 2014 and 2015 covering pharmaceutical compositions and uses of modafinil, and, more specifically, covering certain particle sizes of modafinil contained in the pharmaceutical composition. Ultimately, these particle- size patents might be found

---

201 See Section 4.1.2.1.

202 The Parties' considerations concerning the exact timing and urgency of the generic challenge in the context of the regulatory environment (which is different in the United States and in the EEA) may differ. Nevertheless, the main circumstances – namely the fact that after the expiry of the modafinil compound patent (see Recitals (79) and (80)) and of the market or data protection in both jurisdictions (see footnote 19 and Recital (173)) the only remaining barriers to generic entry were the Particle Size Patents, that the only way how to keep the generics off the market (besides voluntary withdrawal of the generics) was finding of infringement of those patents, the Parties' expectations about the outcome of the patent infringement litigations and its economic impact on the business and, finally, the Parties' actions based on those expectations – apply in the same manner both in the United States and in the EEA.

203 Which was the counterpart of the European Particle Size Patents, see Recital (88).

204 ID 2215, paragraph 35.

invalid if challenged by a third party, or a potential competitor could develop a competing product or product formulation that avoids infringement of these patents."[205]

(120) In an internal presentation of December 2005, Cephalon evaluated the strength of its Particle Size patent: "*Inability to Design Around: 50%;* [Probability of successful] *Defending: 50%*."[206] With regard specifically to the European Particle Size Patents, Cephalon UK's Director of Legal Services indicated on 17 October 2005: "*It should be noted that we have certain issues concerning the definitions the patents which indicate number (rather than volume weight) based values for the particle size measurements – this may create difficulties in terms of obviousness and insufficiency*."[207]

(121) In the United States, four generic competitors – Teva Pharmaceuticals USA, Inc. ("Teva US", subsidiary of Teva), Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), Mylan Pharmaceuticals Inc. ("Mylan") and Barr Laboratories, Inc. ("Barr") – submitted on 24 December 2002 applications for generic MAs to the FDA.[208] The aim was to starting marketing generic modafinil products in 2006.[209] In accordance with United States law, the companies certified that, in their opinion and to the best of their knowledge, the US '516 Patent is invalid, unenforceable, or will not be infringed by the manufacture or marketing of their generic version of Provigil.

(122) On 28 March 2003, Cephalon filed a patent infringement suit against the generic challengers in the United States. However, Cephalon was uncertain about the success of these law suits, stating in internal documents: "*On March 28, 2003, we filed a patent infringement lawsuit in US District Court in New Jersey against Teva Pharmaceuticals USA, Inc., Mylan Pharmaceuticals, Inc., Ranbaxy Pharmaceuticals, Inc. and Barr Laboratories, Inc. … The lawsuit claims infringement of our US patent No. RE37516. While we intend to vigorously defend the validity of this patent and prevent infringement, these efforts will be both expensive and time consuming and, ultimately, may not be successful.*"[210] In the same vein, Cephalon later expressed doubts about the outcome of the litigation in the United Kingdom that started in July 2005 and concerned the question of validity and infringement of the European Particle Size Patents (that is the same patent claims as defined in the US '516 Patent), guessing its chance of success at 50% (see Recital (186)).

---

205 ID 2200, p. 4. See also ID 267, p. 2.

206 ID 1595, p. 25.

207 ID 2144-55, p. 2.

208 ANDA pursuant to the Hatch-Waxman Act. Under the Hatch-Waxman rules, a company can seek approval from the FDA to market a generic drug before the expiration of a patent relating to the brand name drug upon which the generic is based. To this end, the generic applicant submits with the FDA the ANDA. The first company to submit an ANDA has the exclusive right to market the generic drug for 180 days, if its drug is approved.

209 The Hatch-Waxman rules require that the holder of the patent which would arguably hinder the generic entry (in this case Cephalon) must be notified of the ANDA. If the patent holder files an infringement suit against the generic applicant within 45 days of the ANDA notification, FDA approval to market the generic drug is automatically postponed for 30 months, unless, before that time, the patent expires or is judged to be invalid or not infringed.

210 ID 2200, p. 20.

(123) The generic defendants, including Teva, asserted in their pleadings to the United States court of December 2004 that Cephalon had made material misrepresentations and omissions to the PTO when prosecuting the US '516 (Particle Size) Patent, including that the named inventors did not invent the modafinil composition covered by this patent.[211] The same facts and defences as cited by the generic defendants in this patent litigation were later, in 2006, presented to a United States court by another generic company, Apotex, in patent litigation against Cephalon. Apotex won the litigation and the US '516 Patent was declared invalid and unenforceable on 7 November 2011.[212]

(124) Cephalon itself considered that, as a general matter, the outcome of such litigation was uncertain. Cephalon's Vice-President and General Counsel said later (in 2006), when asked why Cephalon anticipated the possibility of Provigil's decline in 2006: "*When you litigate, you can win or you can lose. […] I'm – all I'm saying is the company was regarding litigation as an uncertain process, and it was prudent to think about various alternatives.*"[213] Accordingly, despite the legal action, Cephalon prepared for an entry of generic modafinil product in June-July 2006 (which means following the expected judgment in the United States concerning the infringement and validity of the US Particle Size Patent). Internal presentation "*Cephalon Commercial Business… Strategies and Priorities*" of 7 June 2005, states: "*The next 18 months present an unprecedented set of commercial challenges. Loss of exclusivity: losing exclusivity on two products accounting for ~90% of revenue.*"[214] The presentation further specifies: "*Expected Loss of PROVIGIL Exclusivity (Week 26-June 26)* (2006)".[215]

(125) In its Transition Plan of October 2005, Cephalon anticipated as a base case scenario the generic modafinil entry in July 2006. It assumed that the United States Provigil sales of USD 531 million in 2005 would fall to USD 361 million in 2006, then to only USD 70 million in 2007 and USD 43 million in 2008.[216] Cephalon's expectation of the generic modafinil entry in the United States in June-July 2006 appears also in other documents.[217]

(126) In November 2005, Cephalon issued earnings guidance to the investment community that explicitly assumed that Provigil was "*going away*" because of generic entry in 2006. One of the "*key assumptions*" in Cephalon's 2006 guidance, according to the

---

211 ID 2465, p. 5-6.

212 See Section 4.8.2.5. Court declaration of patent's unenforceability on grounds of inequitable conduct is specific to the United States law and cannot be made in the patent litigations in the EEA.

213 ID 3694-3, p. 44.

214 ID 194, p. 59. The two products where Cephalon anticipates loss of exclusivity are Provigil and Actiq (Cephalon's opiate-based painkiller).

215 *Ibid*, p. 71.

216 The transition plan envisaged the transition from Provigil, to a follow-on product Nuvigil (based on a second-generation API armodafinil). Therefore, the United States sales forecast for 2006-2008 also foresees, besides sales of Provigil, the sales of Nuvigil and a new modafinil-based medicine Sparlon that was aimed at treating Attention Deficit Hyperactivity Disorder (ADHD) in children but was never launched as it did not secure FDA approval. See http://www.pharmatimes.com/news/cephalon_drops_sparlon_after_fda_says_no_996067, ID 194, p. 19. For more details to the planned switch to Nuvigil see Section 4.2.3

217 ID 194, p. 23; ID 194, p. 60 and 67.

company's Chief Financial Officer, was that "*generic versions of modafinil enter the market midyear*."[218]

(127) Cephalon's expectations were in line with the assessment by market analysts who projected generic entry in 2006. A September 2005 report from American Technology Research noted that "*current* [Wall] *Street expectations are for generic competition to Provigil in the mid-2006 time frame*." An October 2005 report from Lazard Capital Markets forecasted: "*Our projections assume that there will be shared generic exclusivity for Provigil and that final (FDA) approval will be awarded… (i.e. in mid-2006). At this point, generic(s) will launch at risk*."[219]

(128) In 2005, Cephalon's Vice-President responsible for generic strategy projected that, if generic versions of modafinil entered the market in 2006, they would be priced 75-90% below the price of branded Provigil and would cut Cephalon's revenues by at least USD 400 million within one year, amounting to almost 75% of Provigil annual sales. Cephalon's CEO stated that such losses would have been devastating for the company.[220]

4.2.3. Cephalon's strategy against generic modafinil

(129) Cephalon's strategy to counter the threat of generic modafinil entry was centred on the United States market, but was a worldwide strategy that aimed to safeguard also Cephalon's market position in the EEA. The following Sections set out the principal elements of this global strategy. In 2005, Cephalon pursued a similar strategy both in the United States and in the EEA, despite certain differences resulting mainly from different regulatory environments.

4.2.3.1. Cephalon's strategy worldwide and in the United States

(130) A handwritten note of Cephalon Europe´s Legal Director summarised ex post Cephalon's initial strategy to defend its exclusive market position against generic modafinil entry succinctly as follows: "*If a generic applies for* [MA] *in US, if you sue for patent infringement, you can stop FDA from issuing a license for 30 months. Ceph. sues generics. At same time, Ceph starts looking at Nuvigil. Alternative to launch Nuvigil = settle with generic competitors.*"[221] The sequence of steps undertaken by Cephalon between the end of 2003 and the end of 2005, as described in Recitals (132) - (142), shows how the company pursued this strategy.

(131) Cephalon clearly expected generic modafinil entry in the United States in early 2006. Also in the EEA, the risk of a possibly unfavourable judgment on the infringement and validity of Cephalon's Particle Size Patents was anticipated for as early as March/April 2006 (see Recital (186)).

(132) Accordingly, Cephalon devised a plan which included phasing out of Provigil and replacing it by a second-generation product Nuvigil that benefitted from a much longer patent protection.[222] In addition, Cephalon planned the launch of yet another

---

218 ID 2215, paragraph 48.

219 ID 2215, paragraph 51. Expectations of the immediate generic entry included also EEA markets. See in particular the analysis of Cephalon's distribution partner in the United Kingdom and Ireland […] of June-July 2005 in Section 4.3.2.

220 ID 2215, paragraph 39.

221 ID 187, p. 129. As to the identity of author, see ID 186, p. 6.

222 In October 2004, Cephalon was considering launch of its own authorised generic modafinil product to counter the challenge by the generic companies: "*Sometimes decisions are made quickly and in this*

modafinil-based medicine Attenace/Sparlon[223] for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

(133) The API in Nuvigil is armodafinil (see Recital (97)). At the time of conclusion of the Settlement Agreement, the only way of manufacturing armodafinil was to separate it from modafinil. Between 2.4 and 2.5 kg of modafinil were required to produce 1 kg of armodafinil API. Cephalon developed armodafinil for the same indications as modafinil (that is to say narcolepsy, obstructive sleep apnoea / hypopnea syndrome and shift-work sleep disorder).[224] Armodafinil has approximately twice as strong (longer-lasting) therapeutic effect as modafinil, so it can be administered only once daily, contrary to a twice-daily intake of Provigil.[225] This would reduce the side effects of the medicine (including, for example, possible serious skin reactions).[226] Cephalon intended to use these elements in order to present a "(*W*)*ell-supported differentiation story from modafinil*",[227] which means to present Nuvigil as "*the 'new' / advanced standard of care for patients.*"[228] Armodafinil is sold, like modafinil, in the form of tablets, and the approved strengths are 50 mg, 150 mg, 200 mg and 250 mg.[229]

(134) In late 2003, Cephalon commenced Phase III clinical trials with Nuvigil and Sparlon in the United States.[230] From the beginning of 2004, Cephalon started setting up its supply chain for armodafinil. In April 2004, Cephalon told […], one of its potential armodafinil manufacturers (see in Recital (363)), that Cephalon expected to have only nine months following marketing approval for armodafinil to switch from modafinil to armodafinil before the generic competitors would be on the market. "*As Cephalon had an aggressive switch plan and they expected to convert most of their Modafinil sales to Armodafinil before generic competition i.e. within the time-span of*

---

case we must focus on time to market for a 100mg and a 200mg ODT [European Commission: orally disintegrated tablet] *formulation of modafinil as a* ***branded generic*** *to be launched prior to entry of any generic formulation of modafinil.*" (Bold in original.) ID 206, p. 1. On the other hand, a document of 11 November 2005 implies that the authorised generic route has been re-assessed by that time: "*Operations: … No branded generic being considered.*" (A handwritten note adds to the end of the text: "*early*"). ID 194, p. 22.

223 The initial working name Attenace was during the preparation phase changed to Sparlon. Alternatively, Cephalon sometimes used the name modafinil ADHD.

224 ID 196, p. 10. For detailed description of modafinil indications see Section 8.1.1.3.1.

225 As acknowledged by a court in the United States see ID 2435, p. 10 (paragraph 6) and p. 37 (paragraph 95). See also ID 206, p. 24.

226 See also Comments on Cephalon's United States Modafinil Development Plants of July 2003, ID 206, p. 24: "*Assumptions are that there will be a longer half-life* [of armodafinil over modafinil], *reduction in side effects, maybe longer onset of action?, maybe different enzyme inducing properties*?"

227 ID 194, p. 63. See also *ibid*, p. 14.

228 *Ibid*, p. 10.

229 The 50 mg, 150 mg and 250 mg strengths were approved in the initial armodafinil licence granted by the FDA on 15 June 2007. In addition, the strengths of 100 mg and 200 mg were approved on 26 March 2009, of which the 100 mg doses were later discontinued. See FDA, Center for Drug Evaluation and Research: Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), 36th Edition, 2016.

230 ID 2200, p. 3. For an overview of the Nuvigil regulatory history and time line from 2002 until launch in June 2009, see ID 212, p. 156-159.

9 months - 1 year post NDA[231] *approval early-medio 2006, demand for Armodafinil would be very high almost instantaneous.*"[232]

(135) On 21 December 2004, Cephalon filed a New Drug Application ("NDA") with the United States FDA for Sparlon, and on 31 March 2005 the NDA for Nuvigil. Cephalon expected a decision from the agency as early as the first quarter of 2006.[233] According to its Annual Report for 2004, Cephalon planned the launch of Nuvigil and Sparlon in the United States in 2006-2007.[234] The Global Manufacturing & Logistics Meeting of 9 July 2003 already concluded that "[R-modafinil] *is needed before the first generic reaches the market which could be as early as July 2006.*"[235]

(136) Cephalon's transition plan of October/November 2005 defines as the "Objective: Successfully introduce NUVIGIL, a new, long active wake promoting agent, as the successor to PROVIGIL and a means to retain Cephalon's franchise value."[236] On the Commission's file, there are several versions of Cephalon's transition plan from Provigil to Nuvigil drafted between June and November 2005 and setting out, amongst others, the timing links between the phasing out of Provigil, planned launch of Nuvigil and the launch of generic modafinil.[237]

(137) In 2005, Cephalon had significantly reduced its expenses for Provigil, in particular in marketing and promotional activities. One of its strategic documents reads: "*Provigil Decline… minimal 'Provigil messaging*', *No sample distribution, Work down existing samples in office… Market preparation for Nuvigil*."[238] Cephalon's CEO later acknowledged: "[W]*e expected not to have* [Provigil] *in our portfolio*." As a result, "[we] *haven't spent any money* [in the] *second half of '05 on Provigil*."[239] Accordingly, the amounts of modafinil API for manufacturing of Provigil were scheduled to go down in favour of those necessary for manufacturing of armodafinil, the API in Nuvigil. In a draft forecast for modafinil volumes needed to manufacture armodafinil (Nuvigil) in 2006, Cephalon's director for Tactical Supply Management remarked: "*Note… a high side* [forecast] *at USD 262 million* [2006 sales of Nuvigil]*… This scenario is based on the assumption that we would stop selling Provigil near the end of the year. This would force Provigil use to go to zero at the time of launch in Feb.*"[240]

(138) At the same time, Cephalon's timeline for the launch of Nuvigil became more precise. In several versions of its strategies for transition from Provigil to Nuvigil, Cephalon envisaged the launch of Nuvigil in mid-February ("early launch") or mid-

---

231 An NDA is an application for approval to bring an innovative medicine to the market in the United States filed with the FDA according to the United States law ('Hatch-Waxman' Act).

232 ID 2325, p. 4.

233 ID 2153, p. 14-15.

234 See, for example, ID 2201, p. 5. Nuvigil was granted the approval in the United States by the FDA on 19 June 2007. Sparlon was never approved, see Recital (419). Following the conclusion of the Modafinil Settlements, the introduction of Nuvigil was delayed until 2009, see in particular Section 4.8.1.4.

235 ID 260, p. 4.

236 ID 194, p. 18.

237 See ID 194, p. 19; ID 194, p. 23; ID 194, p. 52; ID 194, p. 60 and 67.

238 *Ibid*.

239 ID 2215, paragraph 49.

240 ID 1587, p. 2.

April 2006 ("expected launch"),[241] "*~ 2.5 months prior to availability of generic modafinil*".[242]

(139) However, Cephalon saw a significant number of risks and uncertainties with regard to the launch of Nuvigil. According to its analysis, the "*NUVIGIL Critical Success Factors*" were, in particular, (i) a well-supported differentiation story from modafinil available at launch and (ii) time and ability to initiate Nuvigil introduction. Cephalon believed that "*Opportunity to recapture value created by Provigil is limited*"[243] or "*questionable*".[244] Significantly more published data existed on Provigil than on Nuvigil, although the Nuvigil label, as filed with the FDA for approval, claimed that Nuvigil was likely to be on par with Provigil. This complicated Nuvigil's differentiation from Provigil and a successful management of public relations, and, in particular to show its "*Superiority versus PROVIGIL and 'reason to believe'*".[245] Cephalon acknowledged that carrying out additional studies was necessary to support those claims critical to Nuvigil's success.[246]

(140) Also, Cephalon believed that the "*Fast-tracked, forced switch strategy is risky and highly time dependent*".[247] From the timing point of view, Cephalon's final assessment was that the discontinuation strategy was "*doable… However – Not an Advised Course of Action given Nuvigil launch timing.*"[248] Cephalon cited, for example, the following main risk factors high up-front cost, massive field-force effort and required time before launch of generics, uncertainty that in the near-term Nuvigil could survive the fast-following availability of generic modafinil, limited expectations for business net gain (or even net loss), and a widespread potential for significant backlash from key physicians and patients for its reputation.[249]

(141) Cephalon therefore pursued an alternative strategy to protect its wakefulness business and concluded settlement agreements containing non-compete and non-challenge provisions with all potential generic competitors in the United States. These settlements extended Provigil's exclusive position in the market by six years (see Section 4.8.1.1).[250] This led to a reinvigoration of the Provigil programme, and the launch of Nuvigil was delayed until 2009. These developments are described in detail in Sections 4.8.1.3 and 4.8.1.4.

4.2.3.2. Cephalon's plans with Nuvigil for the EEA

(142) This Section describes Cephalon's envisaged strategy to introduce Nuvigil in the national markets in the EEA. Although no armodafinil product was eventually launched in the EEA, the evidence shows that Cephalon considered this option ex ante, that is to say at the time of the Settlement Agreement, and although the

---

241 ID 194, p. 19 and 20. ID 194, p. 23 and 52. ID 194, p. 60 and 67.
242 ID 194, p. 67 and 70.
243 ID 194, p. 63.
244 *Ibid*, p. 61.
245 *Ibid*, p. 64. See also ID 194, p. 24.
246 ID 194, p. 64.
247 *Ibid*, p. 61.
248 *Ibid*, p. 72.
249 *Ibid*.
250 From 8 December 2005 until 1 February 2006 Cephalon settled modafinil litigations with Teva, Ranbaxy, Mylan and Barr (see Section 4.8.1.3).

regulatory situation in the EEA was not beneficial for the launch, Cephalon kept this option open as long as until at least 2009.

(143) A possible launch of Nuvigil in the EEA was discussed already in July 2003. Whilst questions were raised as to dosages, how to establish advantages over Provigil without comparative studies etc., Cephalon concluded that Germany, Austria and Switzerland had a "(*S*)*trong interest in the development of Armodafinil as part of the future oriented life cycle management (LCM) programme for Modafinil. Overall objective of the programme should be: creating optimal conditions for constant growth of the usage of Modafinil / Armodafinil in terms of volume… and at the same time minimization of price erosion over the time or – if achievable – on maximization of premium price opportunities for Modafinil / Armodafinil in the markets… Commercial EU product strategy for Armodafinil and Modafinil in terms of branding, launch / withdrawal (e.g. timepoint, all European countries vs. selected countries), pricing, etc. has to be developed on a country by country base*."[251]

(144) In April 2003, Cephalon filed a clinical trial application in the EEA to conduct Phase 1 Studies on Nuvigil.[252] In July 2008, Cephalon's European brand team identified the following "*Key points*:

I. Regulatory and legal status: Patent protection for modafinil and R-modafinil in Europe, protection with particle size: status?

II. …

III. Clinical testing:

→ Comparison between modafinil and R-modafinil efficacy and safety – Status, timing?

→ European needs:

- *Studies with modafinil or Armodafinil versus placebo or competitor?*
- *Status for each country?*"[253]

(145) The crucial issue for Cephalon's plan to launch Nuvigil in the EEA was the level of protection that the new product would obtain. From the perspective of the patent protection, Cephalon applied in 1987 and was granted the armodafinil compound patent EP 0233106 set to expire on 19 January 2007 covering France, Germany, the Netherlands, Spain, Sweden, United Kingdom, Austria, Belgium, Denmark, Greece, Ireland, Italy, Liechtenstein and Luxembourg, including via national patents (see Recital (98)). Cephalon was exploring in 2004 the possibility to apply for a Supplementary Protection Certificate concerning the compound patent.[254] In 2003, Cephalon filed the EP '635 Patent Application claiming the crystalline Form 1 of armodafinil (the counterpart of the US '570 Patent which, in Cephalon's opinion provided for a strong protection; see Recital (102)). In addition, further patent applications covering armodafinil formulations and manufacturing process were pursued in the EEA and other European countries.[255] However, on

---

251 ID 206, p. 24-25.
252 ID 212, p. 156 and 157.
253 ID 1596, p. 1.
254 ID 196, p. 19, ID 196, p. 10.
255 See Section 4.1.2.2.

4 September 2006, Cephalon's European patent attorney warned that the armodafinil compound patent would expire soon, that there would be no possibility for an SPC and that there were process patents pending for Nuvigil which could be bypassed.[256]

(146) Cephalon also assessed the possibility to gain the data protection and marketing exclusivity related to an MA for Nuvigil. It was however sceptical that Nuvigil could be granted an MA as a new substance because according to the newly published Directive 2004/27/EC, a successful differentiation between modafinil and armodafinil would be difficult. Therefore, Cephalon did not believe that Nuvigil would be granted the 10-year data exclusivity: "*For Europe, we believe that we will have to generate clinical data comparing R-modafinil with the racemic mixture… However, a longer duration of action of R-modafinil compared to the racemic mixture may be difficult to demonstrate therapeutically.*[257] In the (European) New Products Planning Meeting of 7-8 July 2005, a full overview of actions concerning Nuvigil in the EEA was agreed, in particular:

"*Nuvigil patent:*

Establish whether the small particle patent for modafinil have an transferability to armodafinil.

Establish how strong the process patents for armodafinil are likely to be.

Establish the applicability of directive 27 (ie re data exclusivity) would be for Nuvigil. If not currently satisfied:

- *What would it take to be granted (eg superiority of safety, efficacy etc) – include timings and*
- *What is the likelihood of demonstrating the above?*

Nuvigil clinical/regulatory:

Prepare proposal as to what would be required to obtain a marketing authorisation in Europe for Nuvigil including additional data and resources.

If it is agreed that we will not be pursuing a launch of Nuvigil in Europe – prepare a position statement as to why Europe is taking a different path to US."[258]

(147) Another paper drafted at the above-mentioned meeting repeated in particular "*Very little/no differentiation vs Provigil*", but found, at the same time, that "*Currently no ongoing European regulatory position on Nuvigil*" and asked "*What extra would be required for an EU registration and filing*", in terms of data and personnel.[259] In a document "*Regional Products Project Teams Modafinil*" originating from approximately the same time, Cephalon states:

"Strategic Objective(s):

Protect Modafinil brand. Anticipate Modafinil Generic introduction and brand erosion.

---

256 ID 189, p. 63: "*Il existe aussi plusieurs autres brevets déposés aux USA et en Europe, mais il's'agit de brevets de procédés donc contournables*."

257 ID 1610, p. 4.

258 ID 206, p. 14.

259 ID 289, p. 14-15.

Proposed Actions for the Teams:

(1) Consider R.Modafinil for new indications.

(2) ...

(3) Prepare R.Modafinil introduction…"

Possible Expected Outcome:

(4) Extended Modafinil life cycle and optimize sales.

(5) Assure continuation of the brand on the market.

(6) Keep sales momentum and be prepared for a possible switch strategy."[260]

(148) While Cephalon continued to pursue the option of switching from Provigil to Nuvigil after the conclusion of the Settlement Agreement, this switching strategy then also took into account Teva's entry on the modafinil market under the conditions set out in the Settlement Agreement (see Sections 4.6.4 and 4.7.6) as it is apparent from Cephalon's internal presentation of 29 May 2008 "*Patent protection on Nuvigil*" when the conclusion is made for "*Timeframe for Europe*" and the expiration dates of patents protecting armodafinil ("*Oct. 15-Fine Particles Patent, Dec. 23-Crystalline form 1 Patent, Sep. 24-Process patent*") are juxtaposed versus the date "*Apr. 12-Agreement with Teva*" (that is the entry of Teva's generic modafinil under royalty-bearing licence). In the 2008 objectives for the European regulatory affairs department, Nuvigil is the first listed molecule and tasks include "*Q1-Develop Regulatory Positioning*."[261]

(149) The discussion in Cephalon Europe about the pros and cons of launching Nuvigil were still present in March 2009, when Cephalon Europe's Vice-President for Regulatory Affairs repeated the cautious position towards a possible data protection for armodafinil: "*Based on* [analysis of decision-making of the EMA] *and input we have received from a UK law firm we really suspect that in filing armodafinil in Europe in new indications in absence of proven difference with modafinil we may only get one year data protection as for new indication and not the 10 years period.*"[262] However, the President of Cephalon Europe maintained: "*If Armodafinil is showing positive results in a new indication then it seems worth to pursue this and be a little more 'creative'.*"[263] Similarly, when Cephalon's patent attorney asked in May 2009 whether Cephalon should defend before EPO its patent application for crystalline Form 1 of armodafinil – which was challenged by a third party – in light of the fact that obtaining the data protection for Nuvigil was "*very uncertain*", Cephalon Europe's President replied: "*We all know that the* [regulatory] *environment is not really favourable. However I suggest that we defend such patent as much as possible…*"[264] In an internal document of 11 December 2009, Cephalon still foresaw the final approval in the EEA and the launch date of armodafinil product for 2013. Cephalon expected a market share for armodafinil product of 20% between 2017 and

260 ID 206, p. 20.
261 ID 196, p. 34-36.
262 ID 189, p. 54.
263 *Ibid.*
264 ID 189, p. 49-50.

2023 (the expected last year of exclusivity).[265] Ultimately, however, no armodafinil product has been launched in the EEA by Cephalon.

(150) In sum, based on the evidence set out in this Section, it follows that Cephalon was considering a switch to Nuvigil in the EEA to counter the threat of generic modafinil entry and to protect its profitability.

4.3. Teva prepares to launch its generic modafinil in Europe and proceeds to launch it in the United Kingdom

(151) The Section describes Teva's conviction not to be blocked by Cephalon's patents (Section 4.3.1) and its actions to launch its generic modafinil in Europe (Section 4.3.2). The Section also sets out the facts showing that Cephalon's modafinil distributor […] had anticipated generic entry and that, shortly after the entry by Teva, Cephalon and […] terminated their distribution agreement (Section 4.3.3).

4.3.1. Teva believed that Cephalon's Particle Size Patents do not block its modafinil product

(152) Teva started developing a generic version of modafinil in 2000.[266] At the latest by the end of 2002 / beginning of 2003, Teva was confident that it had developed a generic modafinil product that could enter the markets after expiry of the compound modafinil patent regardless of Cephalon's Particle Size Patents. Teva sourced modafinil API from its own subsidiary specialised in API manufacturing (TAPI).

(153) Teva declared that the US '516 Patent (the counterpart of the European Particle Size Patents) was both invalid and not infringed by its modafinil product in the application for the United States generic MA of December 2002.[267] Teva's UK patent counsel expressed a similar view after its launch of modafinil in the United Kingdom, when Cephalon threatened Teva with a patent lawsuit, in his summary for Teva's CEO: "*[…] We also felt that we have quite a strong position on the validity and non-infringement of the patent. I still think we have a very strong patent position…*"[268]

(154) In December 2004, during the United States modafinil patent litigation with Cephalon, Teva submitted pleadings to a United States court asserting that Cephalon procured its US '516 patent by inequitable conduct, that is to say with intention to deceive the PTO examiner (see Recital (124)). The Settlement Agreement put an end to such argumentation between the Parties. However, the United States court assessing in 2011 in substance the same arguments brought against Cephalon by Apotex, another generic competitor, fully confirmed this view and rendered Cephalon's US '516 modafinil patent unenforceable.[269]

---

265 ID 192, p. 11-12.

266 ID 979, p. 94.

267 See Recital (122).

268 ID 979, p. 46. Cephalon Inc.'s Vice-President and Chief Patent Counsel noted in an e-mail of 3 October 2006 (ID 221, p. 5) that Cephalon's third Particle Size Patent, which was only granted after the Settlement Agreement, would "*provide significantly more protection for modafinil in Europe*".

269 See also Section 4.8.2.5

(155) Teva considered in particular that Cephalon's Particle Size Patents were invalid for obviousness. Teva internally expressed the view that "*the obviousness attack on the patents is a very strong one*".[270]

(156) In a letter to Cephalon of 5 July 2005, Teva maintained that Cephalon's European Particle Size Patents are "*plainly invalid*".[271] Teva then went on explaining that "*it was (and for many years had been) standard pharmaceutical formulation knowledge that reducing the particle size of a solid drug would ordinarily increase the dissolution rate and dose uniformity. Indeed, anyone involved in pharmaceutical formulation would have known many years before the priority date of the patents that an increase in the dissolution rate for a given amount of drug could ordinarily be achieved by decreasing the particle size of the drug... There is no patent remaining on modafinil as such. The basic patent expired a considerable time ago. There is no justification for the patents in question or for disrupting our client's continuing activities in respect of modafinil. Accordingly, in the event that proceedings are commenced in respect of our client's product, an immediate application will be made to revoke the patents.*"[272] It is noteworthy that the same obviousness reasoning was later applied by both the United States and the United Kingdom courts declaring Cephalon's Particle Size Patents invalid.[273]

(157) With regard to the non-infringement position, Teva's scientist stated already in April 2003: "*Concerning the* [particle size distribution] *Teva has succeeded in showing bioequivalence* [with Cephalon's modafinil] *by formulating a material which is outside the scope of the Cephalon patent*."[274] In the same vein, a presentation "modafinil" of Teva's API division of the second quarter 2005 addressed to potential customers offered a product which "*is Anhydrous crystal form the same as the Innovator. We can offer customized* [particle size distribution]."[275]

(158) When, following the launch at risk in the United Kingdom, Cephalon took Teva to court over the purported modafinil patents infringement in July 2005,[276] and Teva senior management and lawyers were discussing the defence strategy, Teva's CEO remarked with reference to the arguments prepared for the injunction hearing: "*I am surprised that our defence is based just on non-validity arguments. I was expecting strong non infringement arguments as well*."[277] In response, Teva's top patent lawyer explained that Teva had invalidity arguments against both Cephalon's European Particle Size Patents EP '698 and EP '962 and that it had non-infringement arguments against the EP '698 Patent which depended on the way the claims were construed. The strong invalidity arguments should therefore be used for the injunctions hearing (where straightforward arguments are needed) but "[O]*ur non-infringement position will of course be raised in the main action.*"[278]

---

270 ID 120, p. 4.

271 ID 214, p. 1. Similarly, Teva's letter of 24 June 2015 (including also non-infringement position), ID 273, p. 19-21.

272 ID 214, p. 1-2.

273 See Sections 4.8.2.2 and 4.8.2.5.

274 ID 979, p. 92. This analysis confirms the view of Teva's patent lawyer taken in the same conversation. *Ibid*, p. 93.

275 ID 1848, p. 3.

276 See Section 4.4.

277 E-mail of 8 July 2005, ID 338, p. 3.

278 E-mail of 8 July 2005, ID 338, p. 2.

(159) Teva's conviction of the non-infringing nature of its modafinil manufacturing process was reinvigorated by the testing on its modafinil samples in the initial phase of the patent court proceedings in the United Kingdom. The tests were performed by a laboratory in the United States chosen by Cephalon and showed that Teva's modafinil indeed did not infringe Cephalon's Particle Size Patents.[279]

(160) The Parties explain in the SO Reply that in the United States summary judgment motions of August 2005, Teva filed only on ground of non-infringement, while in its initial counterclaims, Teva had also raised patent invalidity claims (paragraph 38). According to the Parties, this omission is significant: if Teva were convinced it had a strong invalidity case, it would have included the claim in summary judgment motion (two other generics did). In addition, according to the Parties, other market participants (for example, […]) also considered the outcome of their patent litigation, and in particular the success of a patent invalidity claim, uncertain.

(161) As for the Teva's choice regarding the United States summary judgment motions, the Commission notes that various litigation strategies are based on the particular character of the proceedings and can be driven by multiple reasons (for example, cost efficiency). Without contemporaneous explanation, litigation choices provide little (if any) additional insight. It should be recalled that, for example, in the United Kingdom Teva was advised by its external patent lawyer to pursue the invalidity claims because they are "more straightforward" which is important for this type of proceedings, while nonetheless pursuing both invalidity and non-infringement claims in the main proceedings (see Section 4.4).

(162) As to the documents specifically relied on by the Parties ([…]),[280] the Commission notes that the assessment under this Decision does not depend on which grounds, whether invalidity or non-infringement or both, Teva could have defeated Cephalon in the litigation. Evidence shows that Teva was convinced that it had both strong invalidity and non-infringement claims against Cephalon. In addition, *ex post* Cephalon's patents were found invalid in both the United States and the United Kingdom (see Sections 4.8.2.2 and 4.8.2.5).

4.3.2. Teva applies for MAs in several European countries and launches modafinil in the United Kingdom

(163) Teva applied for MA for its generic modafinil medicine in France on 29 March 2003 and in the United Kingdom[281] on 31 March 2003. Teva UK received the MA for a generic modafinil medicine in the United Kingdom on 6 June 2005 and, on the same day, Teva offered its product to two big pharmacy chains in the United Kingdom ([…]).[282]

(164) The offer was for 30 x 100 mg tablet packs at a price of approximately GBP 30.[283] This amounted to a 50% reduction of the list price […] offered for Provigil by […] on behalf of Cephalon UK.[284] Teva's product was launched on 14 June 2005.[285]

---

279 For more details see Section 4.4.2.

280 ID 3656, ID 3657 and ID 3650.

281 In the United Kingdom, Teva applied for MA through another company, Tenlec Pharma Limited that acted on behalf of Teva as special agent and transferred the MA to Teva after it was issued.

282 ID 212, p. 1-2, ID 2539, p. 10.

283 ID 2539, p. 10 and 12; ID 1627, p. 9 (paragraph 26); ID 1627, p. 35 (paragraph 2); ID 212, p. 1; ID 212, p. 2 (reporting on a contact made by Alliance to […]).

(165) On 7 July 2005, Teva filed applications for MA in fourteen other countries in the EEA as summarized in [Table 4]. All applications for the MAs, except the applications in the United Kingdom and France, were filed based on the mutual recognition procedure with the United Kingdom.[286]

Table 4: MA filing dates

Country concerned	**Date of filing**	**Date of grant**
France	29/03/2003	21/11/2006
United Kingdom	31/03/2003	06/06/2005
Austria	07/07/2005	31/01/2008
Belgium	07/07/2005	29/01/2007
Czechia	07/07/2005	21/06/2006
Denmark	07/07/2005	05/07/2007
Germany	07/07/2005	12/092006
Spain	07/07/2005	24/03/2008
Ireland	07/07/2005	08/09/2006
Italy	07/07/2005	NA[287]
The Netherlands	07/07/2005	03/11/2009

284 ID 1627, p. 10, paragraph 29. See also […]. In a phone call with Cephalon's employee one week later, a sales manager at [*pharmacy chain*] estimated that the "open market" price for finished generic modafinil product would be in the region of about GBP 50 (but could not confirm this) and the offer to [*pharmacy chain*] was made due to its big buying power (ID 190, p. 3). In view of the different contemporaneous documents from Teva (see previous footnote), […] and Cephalon, the Commission considers that the suggested launch price of GBP 59.99 as indicated in Teva's response to the Article 18 Request of 22 July 2013, question 4, ID 1844, p. 3, and in the contemporaneous launch notes (ID 1841) was not put in practice by Teva when actually approaching the customers.

285 ID 333, p. 288-289.

286 These applications were filed based on the mutual recognition procedure with the United Kingdom as the reference Member State. Regarding the mutual recognition procedure, see Section 2.4.2.2. Teva could have relied on the mutual recognition procedure to facilitate issuance of MAs in all other Contracting Parties to the EEA Agreement as well. With respect to Bulgaria and Romania the mutual recognition procedure became available on 1 January 2007 as the date of their accession to the EU (Article 52 of the Act concerning the Conditions of Accession of the Republic of Bulgaria and Romania and the Adjustments to the Treaties on which the European Union is Founded (OJ L 157, 21.6.2005, p. 203).

287 The application in Italy was withdrawn in 2011, namely after the date of the Settlement Agreement. In addition, Teva requested withdrawals of already granted marketing authorisations in several countries (such as in Belgium, Czechia, Denmark, Spain). However, all these requests were made only after the date of the Settlement Agreement. As to the Norway, Teva informed the European Commission that it did not know the date of the MA grant but it requested the withdrawal on 10 October 2007 (ID 1844, p. 5-6).

Poland	07/07/2005	14/12/2006
Norway	07/07/2005	Not known
Portugal	07/07/2005	22/09/2006
Slovakia	07/07/2005	27/09/2006
Sweden	07/07/2005	05/06/2008[288]

Source: ID 1844, p. 5-6.

(166) Teva's European business accounted for USD 1.53 billion (approximately EUR 1.2 billion) in sales amounting to 29% of its worldwide sales. The European market was Teva's second largest generics market (after the United States). Prior to 2005, Teva had experienced a rapid growth and expected that its robust pipeline of product applications and approvals would generate significant growth in the following years. Teva was a leading generics manufacturer in several EEA countries (such as in the United Kingdom, the Netherlands and Italy) and one of the largest generic manufacturers in others (for example, in Hungary). Teva also had operations in Germany (through Teva Pharmaceuticals Germany GmbH), Belgium, Lithuania and Czechia.[289] In 2004, Teva established subsidiaries in Spain, Sweden, Portugal and the Slovak Republic, which started their commercial activities in 2005. In 2005, Teva realized significantly higher European sales of generic products (resulting from new product launches) as well as an increase in net sales in every Contracting Party to the EEA Agreement in which Teva operated. Following the acquisition of IVAX Corporation (completed on 26 January 2006), Teva significantly boosted its presence and reach in, *inter alia*, Western Europe (for example, in France, the United Kingdom, and Ireland) and Central and Eastern European countries, such as Czechia and Poland.[290]

(167) Modafinil was one of Teva's "Platinum Products. These are the potentially large selling products or products in which [Teva] ha[s] competitive advantage (patent, exclusivity, […]) for a short or long term. We must have them in Europe (at least in few markets) in order to grow substantially our business."[291] The specific reasons as to why modafinil has platinum status are "T[eva] API, niche and first to market".[292]

---

288 According to Teva, during the mutual recognition procedure several member states raised objections with respect to acceptability of the initial indications which may possibly account for different timeline of approvals in different countries. As regards the specific regulatory situation in Portugal (see footnote 865), the Commission's file does not include indications of Cephalon seeking to challenge Teva's marketing authorisation on patent grounds.

289 Even in the countries which were referenced as smaller operations for Teva (such as Czechia), it was the Settlement Agreement that was understood as the reason preventing launch of Teva's generic modafinil product rather than the inadequacy of Teva's operations (for example, ID 460, p. 2). Teva's operations in Germany in 2005 were sufficient enough to support "*significant sales increases*" of Copaxone, Teva's leading product and its first major innovative drug (Germany was termed as the largest multiple-sclerosis market in the EEA) (ID 2275, p. 25).

290 ID 2275, p. 13, 18, 19, 38, 39 and 40. The Commission notes that the fact that Teva intended to acquire IVAX Corporation had been known already at the time of the Settlement Agreement (ID 351, p. 240).

291 ID 2089-120, p. 3. Document distributed to participants at EPRM meeting on 25-26 August 5-, 2004.

292 ID 2089-125, p. 3. Document of 26 August 2005.

To be included as a platinum product, the source of the material must be "TAPI exclusive or semi exclusive and others".[293]

(168) In an e-mail of 22 November 2005, Teva estimated the market value for modafinil products in the United Kingdom at roughly EUR 8 million and assessed the market as "*rapidly growing*". It also expected to be the only generic in the market.[294] During the three weeks in June/July 2005 when Teva UK sold its modafinil product in the United Kingdom, it achieved sales of approximately GBP 300,000.[295] In the United Kingdom at the time of the launch of generic modafinil by Teva (2005), 93% of the prescriptions for Provigil were filled in its International Non-Proprietary Name (INN), namely modafinil, rather than under the brand name Provigil.[296] Under these circumstances, once a generic medicine becomes available, it can capture a large market share very quickly; given that pharmacists have an interest to dispense the cheapest product (see Section 2.1). Teva anticipated gaining at least 80% market share in the United Kingdom.[297]

4.3.3. Generic entry was anticipated in particular by Cephalon's modafinil distributor […]

(169) Further to the facts set out in Sections 4.2.2 – 4.2.3 showing that generic manufacturers, experts in the field and Cephalon itself considered it largely uncertain whether secondary modafinil patents provided sufficient protection against generic entry, this Section shows, with a particular focus on the EEA, that […], Cephalon's modafinil distributor, also anticipated generic entry.

(170) […] did not believe that the Particle Size Patents could protect Provigil from a generic challenge.[298] It expressed the opinion that […][299] […][300].

(171) According to […], the […][301]."[302] Therefore, […] working assumption for the United Kingdom market was that […][303].

---

293 ID 2089-120, p. 3.

294 ID 979, p. 41-42. Neither Teva, nor Cephalon / […] were at the time of Teva's entry in the United Kingdom modafinil market aware of any other generic competitor that would prepare for entering EEA markets with modafinil products. Cephalon replied to the Article 18 Request of 27 May 2011, question 8, ID 1436, p. 12: "*Cephalon did not have any information in 2005 that indicated that any specific generic manufacturer other than Teva would enter the UK or other EEA markets with modafinil products. Nor did Cephalon have any expectation that any specific generic manufacturer would do so.*". Teva replied to the Article 18 Request of 27 May 2011, question 2, ID 1428, p. 5: "*Teva expected limited competition in the EEA markets, but was not aware at the time whether other generic manufacturers were planning to launch modafinil products in the UK or other EEA markets. Teva was aware, however, of IMS data showing that* […] *had launched a modafinil product in the Czech Republic, Poland and Slovakia."* According to the Commission however, IQVIA data do not show the presence of […]in Czechia, Poland or Slovakia. See also ID 2529, p. 1; ID 2539, p. 8.

295 ID 979, p. 42.

296 ID 1841, p.3.

297 ID 1841, p. 2 (see also p. 3 concerning the percentage rate of the generic prescribing). See in this context also similar views given by the managing director of Cephalon UK, ID 1627, p. 11 (paragraph 37).

298 See, for example, ID 2540.

299 ID 2539, p. 4. In the same document on p. 6, […].

300 ID 2540, p. 1.

301 Under then applicable rules, a pharmaceutical product enjoyed marketing exclusivity of up to 10 years following the grant of the first MA in Europe, see Section 2.4.2.2.

302 ID 2539, p. 4. In the document […], ID 2540, p. 1, […].

303 *Ibid*, p. 6.

(172) Initially, […],[304] […][305] However, at the Collaboration Executive Committee Meeting of 28 April 2005, Cephalon surprisingly suggested – and later confirmed – that in its view the data exclusivity for Provigil had expired. That was because Cephalon acquired modafinil rights from Lafon – and later the whole of Lafon[306] - and Lafon first registered modafinil as "Modiodal" already in January 1995 in France. Hence, 1995 was the first date of registration in the EEA, which overrode the data protection afforded by the United Kingdom National licence, and thus data exclusivity would have expired in January 2005.[307]

(173) According to […], […].[308] […].[309] Specifically, […] anticipated that […][310].

(174) At the Collaboration Executive Committee Meeting of 24 August 2005, [*Distributor's*]' view was […][311] Just before that, […] had reduced prospective Provigil sales by […] for the final quarter 2005 based on a reduction of sales from major customers in July 2005 following the entry of Teva's generic product.[312]

(175) In the light of the imminent threat of generic entry,[313] taken together with the broader view that the Collaboration was not in the best interest of the Parties,[314] Cephalon and […] agreed on the termination of the Collaboration Agreement. […][315] […][316] The Collaboration Agreement was terminated by a […][317] ("Termination Agreement") […].[318] […][319].

4.4. Cephalon initiates legal action against Teva and Teva's settlement proposal

(176) The launch of Teva's generic modafinil in the United Kingdom immediately triggered Cephalon's legal action against Teva.

(177) First, Cephalon was foremost concerned with the effect on Provigil sales upon the generic entry. In a marketing plan for Provigil for 2006, drafted before the Settlement Agreement, Cephalon admitted that "*Generic modafinil (challenge of) our patents in*

---

304 ID 2539, p. 8.

305 Ibid. p. 6. See also ID 2540, p. 1.

306 See Recital (12)

307 ID 2539, p. 7-8. This […]. In fact, Modiodal was first approved in France already on 24 June 1992, see Section 4.1.1. See also Cephalon's internal document ID 247, p. 2 (of 28 October 2005), which says that the product with the trade name Modiodal was approved for Lafon in France in 1992 and launched in 1994, or similarly the witness statement of Cephalon's Executive Vice-President for Technical Operations, to the United Kingdom High Court of Justice in the proceedings between Cephalon and Teva, ID 1627, p. 41 (paragraph 9), indicating that modafinil was launched in France in September 1994.

308 See ID 2539, pp. 6-7.

309 ID 2540, p. 1.

310 *Ibid*.

311 ID 200, p. 3, paragraph 4.10.

312 ID 2529, p. 1.

313 In its response to the Article 18 Request ("Article 18 request of 20 July 2010"), […] (ID 2521, p. 7). ID 287, p. 27.

314 See Section 4.1.3.

315 ID 2541.

316 ID 2532, p. 2. See the unsigned version of Parties' Letter of Intent (to end the Collaboration) of 20 December 2005, ID 1203. See also ID 2542, p. 2.

317 […], ID 187, p. 164 and subsequent.

318 Article 1.1 of the Termination Agreement.

319 Article 3.1 of the Termination Agreement.

the UK… will have drastic effects on the sales of Provigil if their challenge is successful…"[320]

(178) According to the testimony of Cephalon's UK managing director […]made during the UK patent court proceedings, the price difference offered by Teva "*would inevitably result in immediate and irrecoverable price erosion for Provigil, in order for Cephalon UK via* […] *to continue to compete versus the generics. This would then be followed… in predicted significant long-term market share erosion. In addition,… if there were* (other generic competitors waiting) *to enter the market* [before the court trial] *to compete with Cephalon UK /* […] *and Teva, then the price spiral would occur even faster*."[321] "*Given that Provigil is Cephalon UK's flagship product, a serious loss of sales would have a significant and substantial impact on the general business activities and expenditure of Cephalon UK.*"[322]

(179) The managing director concluded: "In summary, generic entry into the modafinil market would have a significant impact directly and/or indirectly on both Cephalon UK and Cephalon, Inc. Immediate and largely irreversible price erosion is inevitable (real pressure in this regard has already been felt…), followed by significant and irreversible long-term market share erosion. Looking to the Citalopram market, also a young market,[323] branded market share erosion from 100% to 14% took place within three years. At the relevant time, Citalopram was prescribed generically at a significantly lower level than modafinil presently is. The effects of generic entry may well therefore, by analogy, be both faster and more detrimental."[324]

(180) Second, generic entry raised an additional risk to Cephalon. In case Provigil sales fell short of the volumes provided for under the Collaboration Agreement with […], Cephalon would be obliged to pay to its distributor.[325] Cephalon calculated in October 2005 that the fall in its Provigil sales in 2006-2010 due to the generic competition could result in a "fine" of about USD 40 million.[326]

4.4.1. Cephalon takes Teva to court in the United Kingdom

(181) When Cephalon learned on 14 June 2005 that Teva UK had approached the […] pharmacy chains,[327] its legal representatives sent to Teva UK on 17 June 2005 a warning letter. In the letter, Cephalon's external lawyers stated, inter alia, that in order to obtain a licence (MA) for modafinil as a generic substitute for Provigil, an applicant is required to demonstrate that its product is "*essentially similar*" to Provigil. They further maintained that in order to achieve essential similarity with Provigil, it was necessary to use modafinil particles falling within the size range claimed in Cephalon's patents. In the light of this, Cephalon's lawyers required that Teva UK either provided Cephalon with a full explanation that its generic modafinil product did not fall into the scope of Particle Size Patents (together with a

320 ID 285, p. 113.
321 ID 1627, p. 10 (paragraph 29 and 30).
322 ID 1627, p. 14 (paragraph 46). See also the conclusion in ibid., p.16 (paragraph 56).
323 Cephalon UK's managing director draw the detailed comparison with the entry of generic Citalopram into the branded Cipramil market to illustrate the "drastic" effect of generic entry. See ID 1627, p. 10-11.
324 ID 1627, p. 16 (paragraph 56).
325 See Section 4.1.3.
326 ID 287, p. 27. See also ID 1627, p. 12-13 (paragraph 41).
327 ID 1627, p. 9, paragraph 26; ID 1627, p. 35, paragraph 2.

description of the product, samples of the product and bulk starting material for Cephalon's inspection) or with undertakings that it would not make, supply, dispose of, offer and use its generic modafinil product.[328]

(182) On 24 June 2005, the lawyers for Teva UK refuted Cephalon's "*unsubstantiated assertion*" that to achieve essential similarity with Cephalon's product it is necessary to use modafinil particles in a way infringing Cephalon's Particle Size Patents. They clarified: "*In any event, we have advised our clients that their product does not fall within the scope of your clients' two European patents and/or the claims of the two European patents are invalid*."[329] Teva UK's lawyers confirmed that they had asked their clients to provide samples of formulated product and API for Cephalon carrying out tests on possible patent infringement. Enclosed to the letter was for Cephalon's consideration a copy of Product Specifications for Teva UK's product.[330] On 4 July 2005, Teva UK provided Cephalon with samples of its modafinil API and finished product (tablets) as indicated in the letter of 24 June.[331]

(183) Between 28 June and 5 July 2005, the Parties exchanged more letters in which neither of them yielded its position. They also discussed how to proceed with testing on Teva's samples.[332] On 6 July 2005, Cephalon and Cephalon UK filed a patent infringement lawsuit against Teva UK with the High Court of London and applied for an interim injunction to prevent Teva from selling the product in the United Kingdom.[333] Teva UK replied with a counterclaim for revocation.[334]

(184) Just prior to the hearing on the request for interim injunctions scheduled for 11 July 2005, Teva agreed to stop selling generic modafinil products in the United Kingdom. In exchange, Cephalon and Cephalon UK agreed to grant Teva a cross-undertaking for damages and Cephalon agreed to provide a bond of GBP 2.1 million (approximately EUR 3.07 million[335]) as a security in the event that Teva succeeded at trial and was entitled to claim damages for foregone profit.[336]

(185) Cephalon expected that the trial would start in March 2006 at the earliest and the judgment would be served within 3 to 4 weeks, still before the decision in the litigation in the United States (see Recital (123)). Cephalon was of the view that "*Teva may be intentionally seeking a UK judgement prior to US*".[337] Cephalon had doubts about a successful outcome of the litigation. In an e-mail conversation

---

328 ID 273, p. 16-18. An identical letter was sent to Tenlec Pharma Limited, a company that represented Teva UK in the United Kingdom proceedings to obtain the MA (ID 273, p. 13-15). At this stage, Cephalon did not know that Tenlec Pharma acted on behalf of Teva UK.

329 ID 273, p. 19.

330 ID 273, pp. 19-21.

331 ID 214, p. 1; ID 1627, p. 36, paragraph 4.

332 ID 273, p. 22-23; ID 273, p. 24; ID 273, p. 25; ID 214, pp. 1-2.

333 See, for example, ID 273, p. 29.

334 The relevant litigation in the United Kingdom bears the High Court's reference number HC 05C 01802. See ID 2841-69, ID 978, ID 2089-22 and ID 1184.

335 Based on the average GBP-EUR exchange rate in 2006.

336 ID 273, p. 29. Cephalon's external lawyers indicated that "*Although our clients are prepared in principle to provide a bond for up to £2 million, we do not accept that this sum is an accurate estimate of your potential loss before trial, particularly given that your client would have sold at around half our client's price*." ID 190, pp. 6-7.

337 ID 2531, p. 2. See Recital (190) with regard to the risk posed by the UK trial for the outcome of the US litigation for Cephalon, bearing in mind that the market in the US accounted for more than 90% of Cephalon's modafinil sales (see for example, ID 2202, p. 56 and ID 2206, p. 53).

between Cephalon's UK senior management, the Senior Tax Director indicated on 21 October 2005: "*From what I heard and learned in the Q3 conference call, there is a 50% chance of a successful outcome* [of the UK Teva litigation] *which we may not know until Q1 2006.*"[338]

4.4.2. First tests on Teva's samples show non-infringement of Cephalon's patents

(186) Cephalon sent the modafinil samples obtained on 4 July 2005 from Teva[339] to SSCI, a United States-based laboratory that had already earlier analysed Teva's modafinil in the United States proceedings. The results of the analysis on the United Kingdom samples were transmitted to Teva on 10 October 2005.[340] They showed the United Kingdom modafinil samples falling outside the scope of Cephalon's Particle Size Patents (including the European '962 Patent). This was different from the tests results in the United States proceedings where the samples were shown to infringe Cephalon's patents. Cephalon's explanations for that ranged from the assumption that Teva's process was subject to high variation, the assertion that Teva's method of collecting the samples was flawed, to the admission that Teva's manufacturing process had changed and that particle size distribution had changed along.[341]

(187) Cephalon contested the test results and demanded that new tests be conducted with new samples taken at Teva's manufacturing site in Israel, in accordance with Cephalon's sampling protocol and in presence of its experts. Teva agreed.[342] Three samples were scheduled to be collected at Teva's Israel plant on 28-30 November 2005, following a sampling protocol devised by Cephalon's appointed expert from SSCI. Shortly before the sampling, a Teva executive noted: "*Should the results of psd (particle size distribution) test turn out to be non-infringing we intend to move to the Court to lift the injunctions and re-enter market a.s.a.p.*"[343]

(188) While Cephalon's expert was in Teva's plant in Israel collecting new samples for testing, the Parties reached agreement in principle to settle all modafinil patent litigation. Cephalon's expert thereupon suspended his work. Accordingly, no further tests were performed.[344]

4.4.3. Teva proposes to Cephalon to settle their patent dispute

(189) On 8 July 2005, on the second day after Cephalon initiated the court proceedings in the United Kingdom, the President and CEO of Teva Pharmaceutical Europe wrote an e-mail to Teva's (internal) patent counsel: "*Teva's top priority is to settle with Cephalon and to add to the table also the Sulphone patent*[345] *that we have. In my*

---

338 ID 2144-57, p. 1.

339 See Recital (183).

340 ID 187, p. 133.

341 *Ibid*. See also e-mail by Teva Patent Department of 22 November 2005: "(*The*) *results indicated non-infringement, but were inconsistent with those of the samples provided in the US litigation*." ID 979, p. 42.

342 ID 979, p. 41-42.

343 *Ibid*.

344 ID 1844, p. 8.

345 Sulphone patent means in particular Teva's United States patent applications covering method for preparing highly pure modafinil, crystalline forms of modafinil and methods of preparing the crystalline forms, to which Cephalon purchased a licence from Teva according to Article 2.2 of the Settlement Agreement. See Recital (284) for the US '120 Patent and Recital (287) concerning its European counterpart EP '547.

opinion the combination of the two patents may lock any realistic option to anyone else to get into the market. I strongly believe that a settlement is optimal for both companies. I wonder what is the best way to approach them, whether through the lawyers or directly through Teva UK, but I have no doubt that now is the high time for any settlement…"[346]

(190) In subsequent communication, he added: "[Cephalon has] a triple risk: the compensation they may have to pay us, the impact on the US trial and the impact of France which is their main market. On the other hand they have some opportunities by combining their patent with our requested patent."[347]

(191) The next day, Teva's patent counsel contacted Teva´s external patent lawyer in London that Teva "*will ask you to initiate discussions with Cephalon.* [CEO of Teva Pharmaceutical Europe] *thinks that they have good reasons to settle…* [348]. On 11 July 2005, Teva's external lawyer reported back to Teva: "*Have now spoken to* [the partner at Cephalon's external law firm] *I outlined to him the proposed terms i.e. T to distribute C product with revenue split 50/50 plus licence under prospective T patent.*"[349]

(192) No further communication on a possible settlement is documented until late November 2005. It seems that Cephalon focused on testing samples of Teva's product with a view to establishing whether it infringes Cephalon's patents or not.

4.5. Negotiation of the Settlement Agreement

4.5.1. Cephalon and Teva negotiate the Settlement Agreement

(193) After the initial contacts in July 2005, the actual negotiations of the Settlement Agreement started in late November 2005. The communication during these negotiations, as described in this Section, show that, next to settling their ongoing litigation, the idea to transfer sufficient value to Teva was a key consideration for the Parties and that in the course of the negotiations different options regarding the nature and content of potential side deals were considered before agreeing on the final package of transactions contained in Article 2 of the Settlement Agreement.

(194) On 23 November 2005 (which is at the time when the visit of Cephalon's testing experts at Teva in Israel to collect the modafinil samples was being prepared), Teva's chief negotiator wrote to other Teva executives about the value that, in his view, Teva should try to get from Cephalon: *"We should think about the value we could get with a comprehensive settlement if possible. Do we have planned activities outside of the UK and the US?"*[350] Teva's patent lawyer replied: *"I understand that you'll be visiting us next week. If you have the time, let me know if you are available for a quick meeting to briefly discuss the option of a potential comprehensive agreement. I think someone from TAPI [Teva's business unit manufacturing modafinil API] should be included as we are in a three-fronts situation."*[351]

---

346 ID 95, p. 46.
347 ID 95, p. 43-44.
348 ID 120, p. 3.
349 ID 338, p. 1. Under the "*prospective T patent*" is meant the "Sulphone" patent (see footnote 360).
350 ID 979, p. 41.
351 ID 979, p. 40- 41.

(195) On 28 November 2005, Cephalon's chief negotiator addressed Teva's chief negotiator and, inter alia, summarised his understanding of what Teva may be interested in obtaining from Cephalon:

"*As you know, we are seeking to better define the terms under which we would be interested in settling the ongoing litigations in the US and UK.*

I have had some discussions internally to outline the terms that we talked about on Friday [which is most probably on 25 November 2005]*, and am providing this note solely for purposes of our settlement discussions.*

Our intention is to move this forward expeditiously, though I expect that you appreciate that we must touch base with several groups in the company to flush out the details. We understand that you also may be interested in one or more of the following: (i) access to the CEP-1347 data in connection with your product application, (ii) engagement to manufacture api for one or more of our cancer therapeutic compounds in development, and (iii) possible cross license of our respective patents covering polymorphs contained in modafinil as a means of avoiding an interference proceeding.

With this broad framework, we will get back to you with a more detailed proposal very shortly.

It also would help me to better understand your sense of urgency related to the 1347 data. Please let me know if you have a date certain in mind by which we would need to reach agreement on this aspect."[352]

(196) Later that day, after Teva's negotiator asked for the access to the CEP-1347 Data[353] in the same week, Cephalon's negotiator replied: *"I am willing to provide access under the [Confidentiality agreement] for purposes of facilitating final [agreement] on settlement…"*[354]

(197) Cephalon started discussing internally which transactions it could offer to Teva days before the above e-mail. With regard to a potential commitment to purchase Teva's API, Cephalon's attorney and one of the main negotiators asked his colleagues:

"*Subject: Settlement Discussions: I have urgent need to discuss potential oportunities with each of you that may be relevant to the settlement of the Provigil Patent litigation. Please provide me ASAP with your availability for a brief discussion today or tomorrow… before our next scheduled discussion in this matter with one of the defendants on Monday, November 21*."[355]

(198) The reply by Cephalon's Vice-President for Worldwide Facilities and Corporate Engineering identified several such "*potential opportunities*" that could be offered to Teva in the areas of tablet manufacturing, active pharmaceutical ingredients

---

352 ID 1616, p. 1-2.

353 For explanation of the CEP-1347 Data, see Section 4.6.3.3.

354 ID 2166-81, p. 4-5

355 ID 2144-49, p. 2. The addressees included the Chief Financial Officer and Head of Business Development of Cephalon Europe, Cephalon Inc.'s Vice-President for Commercial Operations, and Cephalon Inc.'s Vice-President for Worldwide Facilities and Corporate Engineering.

(including Treanda[356]) and the finished product, and concluded that "*We are open to new contract manufacturers.*"[357]

(199) Cephalon's attorney, who had requested the information, reacted:

"(We) *need to consider what might be a fit for Teva. Spoke to* [Cephalon's Vice-President for Global Manufacturing] *about Treanda and CEP-701, but these have very small volumes.*

[…] *confirmed that Modafinil manufacturing for conversion to R-modafinil could be a possibility for Teva as well. He also thought there could be some volumes around Vivitrex and other sterile products.*

What about Trisenox final product manufacturing volumes? Any other prospects you can think of?

If you could provide me ASAP with any other leads and the potential annual value of the opportunities that would be great, as our next call is tomorrow."[358]

(200) On 3 December 2005, Cephalon's and Teva´s chief negotiators discussed the grant by Cephalon of the CEP-1347 Data to Teva, Cephalon's licence to Teva's intellectual property rights and the modafinil API supply arrangement. Teva's negotiator starts by expressing his concerns about Cephalon's delay to transfer to Teva the CEP-1347 data:

" […] *– I'm being told that to the extent that we want to be able to use the data by Wednesday[359] we really need to start working a summary for the FDA. My folks were disappointed that they didn't get it on Friday as was previously discussed and are now saying that Monday early is really the latest for them to get it and are pushing for tomorrow…*"

Cephalon negotiator's reply:

"*Yes, possible to send tomorrow with* [confidentiality agreement] *and firm* [agreement] *in principle with docs to be signed Tuesday. Let's talk tomorrow, but I cannot say we can move on terms, and I think we should forget about api other than agmt to continue discussions.*"

To which Teva's negotiator responded:

"*Ok timing on data sounds good – but I'd appreciate your checking with your* [operations] *guys on the API – understand that we have some dedicated capacity issues there and soft language where we agree to agree is not giving them much. And* [Teva's modafinil patent rights] *is in some respects tied to our API. Financially I don't think the 50 percent mark-up on API supply is that significant and is fairly common. And as you mentioned you have needs there.*

On the other issues we should be ok but I'm still getting confirmation on what to do re Europe. Maybe we limit to UK only?"

Cephalon's response:

---

356 Cephalon's cancer medicine.

357 ID 2144-49, p. 1-2.

358 ID 2144-49, p. 1.

359 The deadline for Teva to present the clinical data to the FDA in order to obtain marketing approval.

"*Ok, I will talk further with* [technical operations]. *What is your cost per kilo in rough numbers?*

In light of the relatively [limited] *European market, and the prevalence of parallel imports I see the EU as a corollary to UK, and settlement there also consistent with the* [worldwide non-exclusive] *license grant.*"

Later that day, Cephalon's negotiator specified in more detail:

"*On api, I can agree to include modafinil supply of 7 tons. We will accept cost plus 30 percent, with a max price per kilo on a sliding scale of 650, 550, 500 for the first four* [years] *of the supply agmt…. We will go forward with the earlier discussed royalty structure if you accept this refinement of your proposal on api*."

Teva's response:

"*I just received word from my API group – we would be pleased to supply API on the* [prices proposed by Cephalon] *with a 10MT commitment. When do you think we will be receiving a draft Settlement Agreement*?"[360]

(201) The exchange between Cephalon's and Teva's negotiators of 3 December included also this Teva's pricing proposal:

"*I had a brief discussion with our API head. Would you agree to put into the Section on API a commitment to buy the yearly requirements of 14MT*[361] *- 20 MT at cost plus 50 percent?*

...

The IP piece is tied somewhat to the API piece so accommodation there would help and should get us where we need to be other than perhaps some structure issues (still working with finance)."

To which Cephalon retorted:

"*Not sure what you mean by the ip piece, but if that refers to the royalty structure we believe we have offered an appropriate set of terms*."[362]

(202) Teva's assertive stance on the API supply transaction somewhat disgruntled Cephalon's negotiators. When Teva returned to Cephalon setting out the pricing structure assuming a commitment by Cephalon to purchase 10,000 kg (10 MT) of modafinil API[363] Cephalon's negotiator internally observed:

"*Unbelievable! He is still negotiating! (This will be interesting, because we have not yet had a discussion as to the terms of the actual Provigil generic license,*[364] *other than date certain, and the license terms are covered by Section 3 of the Settlement Agreement*)."[365]

---

360 ID 2166-78, p. 2.

361 Metric ton.

362 ID 1621, p. 1.

363 Which was then indeed included in the Settlement Agreement.

364 Licence allowing Teva to enter modafinil markets three years before the expiration of Cephalon patents (Article 3.1 of the Settlement Agreement).

365 ID 2144-30, p. 1.

(203) When during the discussions Teva's negotiator came back with a proposal of 14-20 MT at cost plus 50 % margin (see above), Cephalon's chief negotiator internally remarked: "*These guys don't know when to quit.*"[366]

(204) In the last days before the Parties agreed on the terms of the Settlement Agreement, one member of Teva´s negotiating team briefed Teva´s chief negotiator on his discussion with Teva´s CEO:

"*I have discussed the results of yesterday´s meeting with* [Teva Pharmaceuticals Europe's CEO]. *He did not accept the proposal of paying them 50% of our profits in the UK… and an 2007 entrance into the French market*."

The chief negotiator replied:

"*Ok thanks… for following up with* [Teva Pharmaceuticals Europe's CEO]*… The below was really done without much discussion and we could just as easily propose payment to Teva of the 2.1MM bond, immediate UK entry no royalty, and 2007 in France. In the end there are several moving parts here, each representing a different value proposition, and we will lose leverage in my opinion if we don´t work in a comprehensive manner to resolve…*"[367] [368]

(205) On 3 December 2005, five days before the signing of the Settlement Agreement, Teva´s chief negotiator reported to Teva´s team the outcome of the negotiations:

"*Cephalon has agreed to the below subject to Teva approval…*

1. Settlement of the US generic litigation by Tuesday. Dismissal of the litigation with an entry date by us with our product on the earlier of (i) favourable court decision in any of the other generic cases (ii) generic entry or (iii) 2011…

2. Licence of our IP to Cephalon on a worldwide basis in exchange for 30MM on signature (projected for Tuesday), and a 3 percent royalty on their worldwide sales of modafinil, armodafinil (their next generation product) and their ADHD modafinil product Sparlon which they say is expected to be approved in 06. Royalty expires in 2011.

Currently they say they have 600MM in sales of modafinil and they are forecasting about 200MM for Sparlon starting in 06. So we´re looking at a yearly royalty of about 20-25MM in addition to the 30MM upfront.

Also 3MM payment to Teva on approval of Sparlon.

They want to cap our royalties over the term at 125MM. Not crazy about this but maybe we also have a minimum royalty of the same amount. Need to think about the implications.

3. They will release the data we need for rasagiline on Monday and we can use it for our FDA meeting on Wednesday. They will send it to us on Monday so we can prepare for the FDA meeting. We pay them 1MM for the data.

---

366 ID 2144-15.

367 Initially, Cephalon designed the 2.1 million amount as a bond related to interim injunction during the United Kingdom patent litigation. The money should have been paid to Teva as damages in the case that Cephalon lost the litigation (see Section 4.4). The Settlement Agreement converted the amount into a payment for avoided United Kingdom litigation costs (Article 2.5.(i) of the Settlement Agreement).

368 ID 979, p. 36.

4. Will agree to negotiate supply agreement for up to 20MT of their API needs for modafinil and armodafinil on commercially reasonable terms.

5. They would also like to settle the UK litigation for a payment to Teva of 4MM (release of the bond we have in place today) and entry by Teva with its product on the earlier of (i) a favourable court decision in any other generic case (ii) generic entry or (iii) 2011. Also they would be prepared to have Teva starting in 06 distribute their product on commercially reasonable terms for "physical distribution". Probably looking at single digits of net sales for the service and we would not book sales.

Also a 5MM upfront payment for a similar distribution arrangement for France."[369]

(206) Teva's General Patent Counsel replied to this: "*Great job. Sounds like a good deal to me.*"[370] The same reaction came for Teva's General Counsel and Corporate Secretary in response to the internal announcement of the transaction: ""*Further to our discussion in the morning – great job done by the leading legal people*!"[371] Senior Assistant of Teva's General Patent Counsel reacted in a surprised way: "*Cephalon has more patents out there. I would be happy if the agreement would cover those too (= in case we launch, they don't sue us)… Also (this is more out of curiosity), it sounds like they are paying a huge sum for our IP (30MM plus royalties?!) Am I missing something here? Or could we have got more?*"[372]

(207) The agreement with Cephalon announced internally in the above e-mail[373] was confirmed two days later in an almost identical e-mail by Teva's negotiator of 5 December 2005.[374]

(208) On Cephalon's side, its Chief Patent Counsel informed Cephalon Europe's president, managing director and the top patent attorneys on 5 December 2005: "*To the extent you are not already aware, you should know that we are in active settlement discussions with Teva for the US litigation and which will include settlement of the UK litigation…*"[375] The president of Cephalon Europe replied to this e-mail: "*I was aware... Teva is one piece of the equation and if we can settle that this (is) great…*"[376]

(209) On 8 December 2005, Cephalon signed the Settlement Agreement with Teva and Teva USA.[377]

4.5.2. Discussion of the contemplated Settlement Agreement at Cephalon's Board of Directors during the negotiation

(210) Cephalon's Board of Directors discussed the settlements with potential modafinil entrants ("Modafinil Settlements") negotiated by Cephalon on 1 December 2005.[378]

---

369 ID 979, p. 38-39. This deal was confirmed two days later in Teva chief negotiator's almost identical e-mail of 5 December 2005.

370 ID 979, p. 37-38.

371 ID 979, p. 54.

372 *Ibid*, p. 37.

373 See Recital (206).

374 ID 979, p. 55.

375 ID 1020, p. 2.

376 ID 1020, p. 1.

377 ID 176.

The Directors discussed, in particular, the risks of antitrust infringements, since outright payments to the generic producers were seen as risky, whereas offering to the generics business transactions at arm's length was believed to be permissible. The meeting document stated:

"*– Increasing number of generic patent infringement lawsuit settlements driven by desire for certainty.*

– [United States Federal Trade Commission ("US FTC")] *indicated its displeasure with certain of these settlements (e.g. those involving payments to generic firms), but several US Courts of Appeals have sided with proprietary firms and upheld these arrangements. US Supreme Court has not yet decided whether to review 11th Circuit case involving Schering-Plough.*

– Although outright payments to generic firms will be viewed as suspect, it is permissible to structure terms at arms' length related to other business interests between the companies (e.g. manufacturing licensure, other disputes)."[379]

(211) The document goes on informing on the "*Current status of negotiations:*

TEVA
– Contemplated settlement of both US and UK litigation.

– Same as Barr and Ranbaxy on entry dates (contingent right on third party entry; 3 years ahead of exclusivity expiry).[380]

– Right to access to CEP-1347 clinical and safety data for reference in connection with its own product under FDA review.

– Cross-License or assignment of polymorph patents held by both parties to avoid pending interference proceeding, with de minimus royalty to be paid by Cephalon to Teva on all racemic modafinil products (PROVIGIL and SPARLON).

– Possibly non-exclusive API manufacturing rights/requirements contract for modafinil in the United States, and/or expanded manufacturing for cancer therapeutic injectables."[381]

(212) On 4 December 2005, the Special Committee of Cephalon's Board of Directors convened to discuss approval of the Settlement Agreement. According to the Minutes of the Meeting:

"*The purpose of the meeting was to review the proposed settlement terms with Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (together "Teva") regarding the pending patent infringement disputes in the United States and the United Kingdom related to PROVIGIL® (modafinil) tablets* [C-IV]. *The proposed settlement with Teva, along with the possible settlement with the other generic filers, was first discussed with and approved by the Board of Directors of the Company at its meeting of December 1, 2005.* [Cephalon's Chairman and CEO] *began the meeting by describing*

---

378 Apart for Teva, Cephalon also entered into three other settlements, namely the settlement agreement with Ranbaxy of 22 December 2005, the settlement agreement with Mylan of 9 January 2006, and the settlement agreement with Barr of 1 February 2006 (see Section 4.8.1.3; see Recital (474)).

379 ID 2144-48, p. 2.

380 The part of this document describing the status of negotiations with […]. The part on negotiations with […] contains the same conditions. ID 2144-48, p. 3.

381 ID 144-48, p. 2.

the current status of negotiations with Teva. He then reviewed for the other committee members the terms and conditions contained in Section 2 of the draft Settlement Agreement… Specifically, [Cephalon's Chairman and CEO] *discussed the license granted by Teva to its modafinil intellectual property, the license granted by Cephalon to use its CEP-1347 data, the modafinil API supply agreement, the UK distribution agreement and the settlement of the pending UK action, among other things.*

Thereafter, [Cephalon's Chairman and CEO] *reviewed the specific terms related to Teva's right to sell a generic modafinil product prior to the expiration of the PROVIGIL patent, including the proposed dates of possible entry for Teva and the royalty on net profits that would be paid to Cephalon upon Teva's early entry…*

Following further discussion, and upon motion duly made and seconded, the Committee then unanimously approved the Settlement Agreement on the terms and conditions described to the Committee, and authorized management to finalize negotiations with Teva…".[382]

4.6. Main elements of the concluded Settlement Agreement and its implementing agreements

(213) This Section describes the main elements of the Settlement Agreement and the various implementing agreements that were envisaged therein or concluded thereafter by the Parties. First, the Section provides an overview of the Settlement Agreement (Section 4.6.1) and highlights certain elements included in its preamble revealing the context of the Settlement Agreement (Section 4.6.2). Second, the Section sets out in detail the rights and obligations established through the Settlement Agreement for the Parties, relating to the 'non-compete' and 'non-challenge commitments', the conclusion of a package of various commercial transactions and the granting of a non-exclusive licence to Teva to enter the modafinil market in the future under a set of conditions (Sections 4.6.3 - 4.6.4). Finally, the Section describes the Implementing Agreements concluded between the Parties as a follow-on from the Settlement Agreement (Section 4.6.6). Additional facts and details specifically relating to the package of commercial transactions agreed between the Parties in exchange for Teva committing not to compete and not to challenge are then described in a separate Section (4.7).

4.6.1. Main elements of the Settlement Agreement

(214) The Settlement Agreement[383] was concluded between Cephalon and Teva[384] on 8 December 2005.[385] The Parties entered the Agreement also for their Affiliates.[386] The Agreement became effective as of 4 December 2005 ("Effective Date").

(215) Cephalon and Teva agreed in particular on the following (Articles 2, 3 and 4 of the Settlement Agreement[387]):

---

382 ID 2144-5, p. 1.

383 ID 176.

384 The contracting parties on the side of Teva were Teva Pharmaceutical Industries, and Teva Pharmaceuticals USA, Inc.

385 See the Preamble of the Settlement Agreement, ID 176, p. 1.

386 The term "*Affiliate*" pursuant to Article 1.2 of the Settlement Agreement includes any corporation, partnership, joint venture or firm which controls, is controlled by or under common control with a specified person or entity.

(a) Commitments with respect to manufacturing, marketing and sale of modafinil products:

– Teva committed not to enter with its generic modafinil product the markets in the United States, United Kingdom or any other country where Cephalon held modafinil patent rights, nor to assist any entity in doing so, including providing such entity with modafinil API provided that Teva knew or had reason to know that this entity prepared to make or sell generic modafinil product in the aforementioned countries ("Non-compete commitment", Article 2.1 of the Settlement Agreement; see in more detail under Section 4.6.3.1.1).

– Cephalon and Teva committed not to challenge each other's modafinil patent rights on a worldwide basis ("Non-challenge commitment", Articles 2.1, 2.2 (a), 2.5 (a), 3.8 and 8.12 (b) of the Settlement Agreement; see in more detail under Section 4.6.3.1.2).

– The Parties committed to discontinue immediately their pending modafinil litigations in the United States and in the United Kingdom. The Parties also undertook to execute for this purpose all necessary documents under certain time limits.[388] (Article 4 of the Settlement Agreement; see in more detail under Section 4.6.5).

– Cephalon agreed to grant to Teva a non-exclusive right under the Listed Patents[389] to manufacture, use, market and sell its generic modafinil product in the United States and other markets, including provision of modafinil API for finished drugs, which has modafinil as an active ingredient, as from 2012 (Article 3.1 of the Settlement Agreement; see in more detail under Section 4.6.4).[390]

(b) Cephalon's payments to Teva:

– Cephalon paid to Teva GBP 2.1 million, purportedly in recognition of the costs of litigation avoided in the United Kingdom through the Settlement Agreement (Article 2.5 (b) of the Settlement Agreement; see in more detail under 4.6.3.5).

– Cephalon paid to Teva EUR 2.5 million, purportedly in recognition of the costs of litigation avoided in "*European and other markets*" outside of the United States or the United Kingdom through the Settlement Agreement (Article 2.5 (c) of the Settlement Agreement; see in more detail under 4.6.3.5).

(c) Commercial transactions between Cephalon and Teva:

---

387 The Settlement Agreement refers to its provisions as to Sections. The Commission refers to the provisions of the Settlement Agreement as to Articles, first for the sake of consistency (provisions of all agreements quoted in this Decision are referred to as Articles), as well as in order to prevent misunderstanding (the Decision refers to its chapters as Sections).

388 The Settlement Agreement provided that the respective submissions should be filed with the competent United States court within five business days following the Effective Date of the Settlement Agreement (that is 4 December 2005), and "*as soon as practicable*" in the United Kingdom.

389 Listed Patents are Cephalon's modafinil patents defined in Article 1.12 of the Settlement Agreement as "*the RE '516 Patent, United States Patent No. 4,927,855, and any other patent that may be listed in the FDA Orange Book for PROVIGIL®, and for markets outside of the United States, the foreign counterparts of such patents.*"

390 For exact provision governing the effective date of the licence see Recital (248).

– Cephalon purchased from Teva a licence to its modafinil-related intellectual property rights in exchange for royalty payments totalling to USD 125,000,000 (Article 2.2 of the Settlement Agreement; see in more detail under 4.6.3.2).

– Cephalon granted to Teva a licence to clinical and safety data co-developed by Cephalon in connection with studies for the treatment of Parkinson's disease ("CEP-1347 Data") – which Teva needed for its new innovative product Azilect, not related to modafinil[391] – in exchange for USD 1 million (Article 2.3 of the Settlement Agreement; see in more detail under 4.6.3.3).

– Cephalon and Teva committed to enter into a supply agreement for modafinil API, pursuant to which Teva should supply Cephalon with fixed volumes of modafinil API at fixed prices for five years (Article 2.4 of the Settlement Agreement; see in more detail under 4.6.3.4).

– Cephalon committed to appoint Teva's United Kingdom subsidiary as exclusive distributor of all its modafinil products in the United Kingdom for five years, with 20% distribution margin (Article 2.6 of the Settlement Agreement; see in more detail under 4.2.3.6.). Cephalon also committed to make a one-time payment of EUR 2.5 million to Teva upon Teva's commercial launch of Cephalon's modafinil product (Article 2.6 (a) of the Settlement Agreement).

(216) The Settlement Agreement foresaw that the commercial transactions in Article 2 of the Settlement Agreement (but for the licence to CEP-1347 Data), as well as the non-exclusive right to Teva under Cephalon's Listed Patents (Article 3.1. of the Settlement Agreement), would be implemented by individual follow-up agreements (the "Implementing Agreements"). Article 3.2 of the Settlement Agreement listed four Implementing Agreements:

(1) Licence agreement with respect to the licences granted by Cephalon to Teva to modafinil product as from 2012 according to Article 3 of the Settlement Agreement (Section 4.6.4),

(2) Licence agreement concerning the licence to Teva's Intellectual Property Rights (Section 4.6.3.2),

(3) United Kingdom Exclusive Supply and Distribution Agreement (Section 4.6.6.2),

(4) Modafinil API Supply Agreement (Section 4.6.6.1).

(217) However, Article 3.2 acknowledged that "subject to applicable laws, the terms and conditions contained herein are binding notwithstanding the failure of the parties to enter into the agreements referenced in this Section 3.2."

(218) Of the four envisaged Implementing Agreements, eventually only two were executed, mainly by local subsidiaries of Cephalon and Teva (see in more detail Section 4.6.6)):

(1) Modafinil API Supply Agreement[392] of 7 November 2006 between Cephalon, Inc. and Plantex USA Inc.[393] ("Modafinil API Supply Agreement"),

---

391 See Section 4.7.2.

392 Pursuant to Article 2.4 of the Settlement Agreement.

(2) Supply and Distribution Agreement[394] of 7 August 2006 between Cephalon UK and Teva UK, appointing Teva UK as exclusive distributor of Cephalon's modafinil products in the United Kingdom ("Teva Distribution Agreement").[395]

(219) The licence agreement with respect to licences to be granted by Cephalon to Teva to modafinil product as from 2012[396] and the licence agreement concerning Teva's modafinil Intellectual Property Rights,[397] were never concluded.[398] Nonetheless, Cephalon paid royalties in the amount of USD 125 million as a consideration for the licence to Teva's modafinil Intellectual Property Rights pursuant to Article 2.2 of the Settlement Agreement. It should be noted that the essential components of the above-mentioned commercial transactions (such as the object of purchase/sale, quantities, prices and duration of the transactions) were stipulated in the respective provisions of the Settlement Agreement.

(220) In addition to the Implementing Agreements, the provisions of the Settlement Agreement also stipulated two optional agreements (or, as the case may be, set of agreements):

(1) Pursuant to Article 2.6(b), the Parties undertook "to consider in good faith whether a similar resale and distribution services provider arrangement [as the Teva Distribution Agreement, see Recital (217)(3)] may be feasible in any other countries."

(2) Pursuant to Article 2.7, the Parties agreed "to discuss commercially reasonable terms for expansion of an existing clinical supply and development relationship between Cephalon and [Teva's group company] to include a potential supply agreement for Cephalon requirements for the API contained in the Cephalon cancer drug TREANDA ®."

(221) However, the Parties did not assume any obligation to conclude these optional transactions. Eventually, Cephalon and Teva did not engage in any of them.

(222) The key provisions of the Settlement Agreement that lay down the Parties' commitments are in Article 2 (Obligations of the Parties), Article 3 (Teva Generic Rights) and Article 4 (Dismissal). These binding provisions are introduced by a Preamble. The Preamble and the key binding provisions of the Settlement Agreement are described in the following Subsections.

4.6.2. Preamble

(223) The Parties first recall the circumstances of their patent litigation pending in the United States (referring in particular to Cephalon's ownership of the US '516 Patent, Cephalon's lawsuit against Teva based on this patent, and to Teva's defences that the patent in question was either not infringed, invalid and/or unenforceable). They further recall the pending patent litigation in the United Kingdom (referring, again,

---

393 United States subsidiary of Teva.

394 Pursuant to Article 2.6 of the Settlement Agreement.

395 The Teva Distribution Agreement was accompanied by two technical side agreements – Safety Data Exchange Agreement and Technical Agreement.

396 Article 3.1 of the Settlement Agreement.

397 Article 2.2 of the Settlement Agreement.

398 ID 1436, p. 16; ID 1428, p. 8. Although Teva sent in response to Commission asking for the modafinil Licence Agreement concluded pursuant to Article 3.2 of the Settlement Agreement the Annex 13 with an agreement, it was not the requested licence agreement but Plantex Supply Agreement.

specifically to the European Particle Size Patents "*which are the subject of the UK Action*" brought by Cephalon).

(224) The Preamble continues:

"*WHEREAS, the parties respectively possess other relevant intellectual property rights related to modafinil in the United States, Europe or elsewhere that are or may be the subject of further as yet unfiled disputes between the parties related to matters at issue in the respective litigations in the United States and/or United Kingdom, or with respect to which the parties may have interest in reaching suitable commercial arrangements so as to avoid the necessity of future litigation.*

WHEREAS, to avoid the time and expense of further litigation, and in compromise of the disputed claims set forth above, the parties now desire to resolve their disputes on a worldwide basis, including, but not limited to, with respect to the litigation matters pending in the United States and the United Kingdom, by settlement and to enter into such licensing or other commercial arrangements as shall fairly effect an amicable resolution of such unfiled disputes to avoid the time and expense of future potential litigation.

WHEREAS, Cephalon desires to license from Teva Irael, and Teva Israel is willing to license to Cephalon on the terms and conditions set forth herein, worldwide intellectual property rights owned by Teva that relate to the compound modafinil, including, without limitation, its salts, esters, enantiomers, isomers and polymorphs.

WHEREAS, in addition to the above-described arrangements,

(a) the parties desire to provide for the supply by Teva Israel and the purchase by Cephalon of the active pharmaceutical ingredient ("АРІ") modafinil; and

(b) Teva desires to obtain and Cephalon desires to grant Teva a license to use certain clinical and safety data obtained from studies of CEP-1347 in connection with Teva's regulatory applications to market rasagaline."

4.6.3. Obligations of the Parties (Article 2 of the Settlement Agreement)

(225) This Section sets out the obligations of the Parties under the Settlement Agreement. In particular, the Section, first, describes Teva's commitment not to independently enter and compete with Cephalon with respect to modafinil, as well as the commitment not to challenge Cephalon's modafinil patents (Section 4.6.3.1). Second, Teva committed to the above in exchange for receiving a substantial transfer of value from Cephalon through a package of commercial transactions. The Section then describes those commercial transactions beneficial to Teva and cash payments, through which the transfer of value was made: (i) Purchase of the Licence to Teva's Intellectual Property Rights (4.6.3.2); (ii) Licence to Teva of the right to use CEP-1347 data (Section 4.6.3.3); (iii) Modafinil API Supply Agreement (Section 4.6.3.4); (iv) Payment of avoided litigation costs (Section 4.6.3.5); and (v) Teva Distribution Agreement (Section 4.6.3.6).

4.6.3.1. Teva's non-compete and non-challenge commitments

4.6.3.1.1. Non-compete commitments

(226) Article 2.1 of the Settlement Agreement reads as follows:

"*The parties agree that this Agreement includes a settlement which is a compromise of disputed claims and that acceptance of the consideration herein is not to be construed as an admission by either party as to the underlying merits of the Action*[399]*. However, as an express inducement to Cephalon to enter into this settlement, in consideration of the terms hereof, Teva hereby warrants, represents and agrees that Teva, on behalf of itself and its Affiliates, will not make, use, offer to sell, or sell or actively induce or assist any other entity to make, use, offer to sell, or sell Subject Modafinil Product within the United States, or to import or cause to be imported any Subject Modafinil Product*[400] *into the United States, except as otherwise permitted under, and according to the terms of, the license granted by Cephalon in this Agreement. The parties agree that as used in this Section 2.1, "assist" and "induce" shall include Teva's provision of modafinil API to parties it knows or has reason to know will make, use, offer to sell, sell, import or cause to be imported Subject Modafinil Product in the United States*."

(227) Article 2.5(a) of the Settlement Agreement reads as follows:

"*Settlement of UK Action and Other Potential Disputes; And Associated Teva Warranties*

The parties agree that this Agreement includes a settlement which is a compromise of disputed claims and that acceptance of the consideration herein is not to be construed as an admission by either party as to the underlying merits of the UK Action[401] *or any other dispute. However, as an express inducement to Cephalon to enter into the settlement of the UK Action, and the settlement of potential litigation and disputes in other countries where Cephalon holds modafinil patent rights, Teva Israel, on behalf of itself and its Affiliates, hereby warrants, represents and agrees that Teva will not itself make, use, offer to sell, or sell or actively induce or assist any other entity to make, use, offer to sell, or sell any finished drug which has modafinil as an active ingredient within the United Kingdom or any other country where Cephalon holds modafinil patent rights (other than in the United States market which is addressed in Section 2.1 above) or to import or cause to be imported any finished drug which has modafinil as an active ingredient into the United Kingdom or any other country where Cephalon holds modafinil patent rights (other than the United States market which is addressed in Section 2.1 above), except as otherwise permitted under, and according to the terms of, the license granted by Cephalon in*

---

399 Pursuant Article 1.1 of the Settlement Agreement, *"Action" shall mean Cephalon, Inc. v. Mylan Pharmaceuticals Inc., et al., Civil Action No. 03-CV-1394 (JCL), pending in the United States District Court for the District of New Jersey*." This was the action lodged by Cephalon against four generic challengers in the United States (see Recitals (121) ff.). Footnote added by the Commission.

400 Subject Modafinil Product is defined in Article 1.19 of the Settlement Agreement as "*any finished pharmaceutical product containing modafinil that is manufactured or sold pursuant to (a) NDA 20-717 and all of its current and future supplements, or (b) an ANDA for which the reference listed drug is (i) PROVIGIL®, (ii) any other product that is the subject of NDA 20-717 and all of its current or future supplements, or (iii) any other Cephalon Modafinil Product that is the subject of an NDA or supplemental NDA filed or held by Cephalon for which the RE '516 Patent is listed in the Orange Book.*" ID 176, p. 10. Footnote added by the European Commission.

401 The modafinil litigation between Cephalon and Teva in the United Kingdom. See Section 4.4. This footnote added by the European Commission.

connection with this Agreement.[402] *Subject to Section 3.6 below, the parties agree that as used in this Section 2.5, "assist" and "induce" shall include Teva's provision of modafinil API to parties it knows or has reason to know will make, use, offer to sell, sell, import or cause to be imported any finished drug which has modafinil as an active ingredient into the United Kingdom or any other country where Cephalon holds modafinil patent rights (other than the United States market which is addressed in Section 2.1 above).*"

(228) Article 3.6 stipulates that this Agreement "shall neither operate nor be construed to prohibit any pre-existing relationships of Teva for supply of API, provided, however, that Teva agrees that it shall not prospectively continue any such current (as of the Effective Date hereof[403]) relationships beyond their current term nor prospectively enter into any new such relationships to the extent same would be reasonably likely to operate to cause Teva to breach its obligations under this Agreement, including Sections 2.1 and/or 2.5. In addition, to the extent that Teva is currently selling Teva Generic Modafinil Products[404] as of the Effective Date in any country (other than the United States or the United Kingdom) where Cephalon holds modafinil patent rights, the parties acknowledge that any such commercial sales shall not be deemed to be a breach of the terms of this Agreement, provided that Teva shall use its best efforts to effect an orderly and timely cessation from such market."

4.6.3.1.2. Non-challenge commitments

(229) As explained in Section 4.2.1., Cephalon and Teva committed not to challenge each other's modafinil patent rights on a worldwide basis (Articles 2.1, 2.2 (a), 2.5 (a),3.8 and 8.12 (b) of the Settlement Agreement; see in more detail under Section 4.2.3.1.2.).

(230) Article 8.12 (b) of the Settlement Agreement stipulates that "(N)othing in this Agreement shall operate or be construed as a waiver by Teva of any right to challenge any patent owned by Cephalon other than the Listed Patents."[405]

4.6.3.2. Purchase of the Licence to Teva's Intellectual Property Rights

(231) The purchase by Cephalon from Teva of a licence to Teva's modafinil related Intellectual Property Rights for the maximum sum of USD 125 million (approximately EUR 92.9 million)[406] pursuant to Article 2.2 of the Settlement Agreement ("Licence to Teva's Intellectual Property Rights") is by far the biggest payment from Cephalon to Teva on the basis of the Settlement Agreement.

---

402 The licence granted by Cephalon to Teva according to Article 3.1 of the Settlement Agreement to market the generic modafinil as of 2012. See Section 4.6.4. Footnote added by the European Commission.

403 See Recital (215). Footnote added by the European Commission.

404 Pursuant to Article 1.4, "Teva Generic Modafinil Product" shall mean any Subject Modafinil Product (see footnote 400) marketed and sold by Teva pursuant to the terms of the Settlement Agreement or the same or similar finished pharmaceutical product that contains modafinil as the active ingredient marketed and sold by Teva in a jurisdiction other than the United States. Footnote added by the European Commission.

405 For the definition of the Listed Patents see footnote 389.

406 According to the average exchange rate in 2005 published by the European Central Bank, the amount would be EUR 100.6 million. However, it changes to approximately EUR 92.9 million, if taken into account that the royalties were paid in several quarterly payments in 2006-2009, and the Commission applies to each payment the average exchange rate relevant for the respective year. See Recital (329), Table 5.

(232) The subject-matter of the purchase is defined in Article 2.2 (a) of the Settlement Agreement:

"*Teva Israel hereby grants to Cephalon a non-exclusive, worldwide license to all Intellectual Property Rights solely for the manufacture, development, formulation, use, sale, offer for sale, and importation of finished pharmaceutical products that contain the compound modafinil, including, without limitation, its salts, esters, enantiomers, isomers and polymorphs, including, without limitation, any aspect of such rights which purport to cover or relate to PROVIGIL®, SPARLON® and/or NUVIGIL®. Further, as an express inducement to Teva to enter into this Agreement, in consideration of the terms hereof, Cephalon hereby warrants, represents and agrees that Cephalon, on behalf of itself and its Affiliates, will not challenge or otherwise dispute any issued patents included in the Intellectual Property Rights on a worldwide basis.*"

(233) Teva's Intellectual Property Rights are defined in Article 1.20 of the Settlement Agreement as follows:

"*Intellectual Property Rights" means all patents (including, without limitation, all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, invalidations, supplementary protection certificates and patents of addition) and patent applications (including, without limitation, all provisional applications, continuations, continuations-in-part and divisions), copyrights, data rights, trade secret rights, and know-how owned by Teva on or after the Effective Date that claim or otherwise cover any aspect of the compound modafinil, including, without limitation, its salts, esters, enantiomers, isomers and polymorphs, including without limitation those set forth in Annex 1.20 of this Agreement*."

(234) Annex 1.20 of the Settlement Agreement "Teva Licensed Patents and Patent Applications" lists Teva's worldwide modafinil patent rights as to the Effective Date of the Settlement Agreement. It includes notably:

(a) Two patents:

– United States patent No. 6,849,120 (US '120 Patent);

– South African patent No. 2003/0672;

(b) 19 patent applications of which:

– two in the United States:

- Application No.: 10/947,228, Publication No.: US20050038124A1;
- Application No.: 10/947,227, Publication No.: US20050034652A1;

– one with EPO:

- Application No.: 01961766.1, Publication No.: 1309547;

– Other patent applications around the globe, including Canada, China, Czechia, Croatia, Hungary, Poland, Slovakia, Japan, Mexico etc.[407] [408]

---

[407] Other patent applications included i.a. the patent application PV2003-529 in Czechia, the patent application P0400927 in Hungary, the patent application 6699 in Iceland (abandoned), the patent application P-365613 in Poland and the patent application PV0224-2003S in Slovakia (abandoned).

[408] For the overview the patent rights held by Teva in 2005 see Section 4.7.1.1.

(235) Pursuant to Article 2.2 (b) of the Settlement Agreement, "In consideration of the license set forth in Section 2.2 (a), Cephalon shall make royalty payments to Teva Israel as follows, commencing as of the Effective Date:

(i) *within five (5) business days of the Effective Date: a lump sum royalty payment of $ 15 million U.S. to cover 2005 royalty payments for the Intellectual Property Rights licensed hereunder*;

(ii) upon the achievement of worldwide sales by Cephalon and its Affiliates of Cephalon Modafinil Product[409] *totalling $ 100 million U.S. as determined based upon IMS data, a lump sum payment of an additional $ 7.5 million U.S.;*

(iii) upon the achievement of worldwide sales by Cephalon and its Affiliates of Cephalon Modafinil Product totalling $ 200 million U.S. as determined based upon IMS data, a lump sum payment of an additional $ 7.5 million U.S.;[410]

(iv) on the date of Cephalon's first commercial launch of SPARLON® (or the same modafinil product indicated for the treatment of attention deficit disorder marketed under a different trade name), a lump sum payment in the form of a start up royalty of $ 3 million U.S.; and

(v) from January 1, 2006 and until the earlier of:

(a) the last to expire of any issued patents in the Intellectual Property Rights containing a valid and enforceable claim, (the Intellectual Property Rights will be deemed valid and enforceable unless determined otherwise by a final non-appealable decision of a court of competent jurisdiction); or

(b) until such time as the cumulative sum of all royalties paid by Cephalon under this Section 2.2 (b) (i) through (iv) above & this Section 2.2 (b) (v), as demonstrated by its accounting records maintained in accordance with GAAP, shall have reached a total of $ 125,000,000 U.S. ("Royalty Cap");

(c) Cephalon shall pay to Teva a royalty in the amount of 3% of all worldwide Net Sales[411] of Cephalon Modafinil Product. For the removal of doubt, both this 3% royalty payment and the lump sum payments set forth in Section 2.2 (b) (i) through (iv) shall apply against the Royalty Cap."

(236) Article 2.2(c) of the Agreement then reads as follows:

---

409 Cephalon Modafinil Product is defined in Article 1.3 of the Settlement Agreement as *"all finished pharmaceutical products that contain the compound modafinil, including, without limitation, its salts, esters, enantiomers, isomers and polymorphs, including without limitation, PROVIGIL®, SPARLON® and NUVIGIL®, sold by Cephalon, its Affiliates, distributors and resellers."*. Footnote added by the Commission.

410 With respect to the three lump sum payments listed under (i) -(ii) above, the Commission notes that in their negotiations preceding the Settlement Agreement, the Parties first reached an agreement on the total sum of USD 30 million which was divided only later in the Settlement Agreement. See ID 1436, p. 11-12. Footnote added by the Commission.

411 The detailed definition of "Net Sales" is in Article 1.16 of the Settlement Agreement. Footnote added by the Commission.

"*It is understood and agreed that upon the earlier of (i) the last to expire of any issued patents in the Intellectual Property Rights containing a valid and enforceable claim (the Intellectual Property Rights will be deemed valid and enforceable unless determined otherwise by a final non-appealable decision of a court of competent jurisdiction) or (ii) the date as of which Cephalon royalty payments have reached the Royalty Cap, Cephalon's royalty obligation shall cease and Cephalon shall thereupon have a fully-paid up non-exclusive, worldwide license to all such Intellectual Property Rights owned by Teva.*"

4.6.3.3. Licence to Teva of the Right to Use CEP-1347 Data

(237) According to Article 2.3 of the Settlement Agreement, Cephalon granted to Teva "the right to use certain clinical and safety data co-developed by Cephalon in connection with studies for treatment of Parkinson's disease" ("CEP-1347 Data"), agreed to cooperate promptly in good faith with the reasonable requests of Teva for assistance in identifying and providing further related information, and gave Teva its consent to the use of such data by Teva solely for purposes of supporting Teva's regulatory applications for rasagaline.[412] Teva undertook to pay Cephalon USD 1 million in consideration of the licence.

4.6.3.4. Modafinil API Supply Agreement in the Settlement Agreement

(238) Article 2.4 of the Settlement Agreement foresees the conclusion of an agreement for supplies of modafinil API by Teva to Cephalon in the United States for five years. It is a framework provision that lays down the main elements of the supply arrangement. The Modafinil API Supply Agreement (referred thereafter also as the "Plantex Supply Agreement") was eventually executed on 7 November 2006 (see recitals (258) - (264)).[413]

(239) Article 2.4 of the Settlement Agreement reads:

"*Modafinil API Supply Agreement*

Cephalon and Teva Israel shall enter into a supply agreement, by which Teva Israel shall supply, and Cephalon shall purchase in the United States the following annual volumes of modafinil API per Cephalon specifications at the below prices and upon such other reasonable and customary terms in the industry as the parties shall negotiate in good faith, it being understood that Teva Israel shall use its commercially reasonable efforts to work continuously in good faith to reduce associated costs and increase efficiencies while consistently meeting specifications, and to reflect all such cost reductions and efficiencies through appropriate reductions to the per kilogram price. In addition, the parties agree to cooperate in good faith to work together to help reduce costs.

Teva Israel warrants and represents that the Year 1 price below in this Section 2.4 reflects its current approximate cost to manufacture plus 30%. For purposes of this Section, the parties agree that the initial year of this five year supply commitment shall be calendar year 2007. The parties further agree that they shall undertake to

---

412 Teva needed the licence to CEP-1347 Data in order to obtain the regulatory approvals in the United States, Canada and in Australia for its innovative Parkinson's Disease medicine rasagiline (brand name Azilect) in 2006. For more details, see Section 4.7.2.

413 ID 187, p. 134 *and subsequent.*

work together in good faith promptly following the Effective Date to qualify Teva API material in Cephalon's regulatory filings for modafinil.

Teva Israel agrees to supply and Cephalon agrees to purchase modafinil API per Cephalon specifications at the below minimum quantities as follows:

Contract Year	*Minimum Kg Price*	*Volume*	*Total Payment*
1	*USD 650/kg**	*10,000 kg*	*USD 6.50 million**
2	*USD 600/kg**	*10,000 kg*	*USD 6.00 million**
3	*USD 550/kg**	*10,000 kg*	*USD 5.50 million**
4	*USD 500/kg**	*10,000 kg*	*USD 5.00 million**
5	*USD 500/kg**	*10,000 kg*	*USD 5.00 million**

**=subject to Teva's agreement to use commercially reasonable efforts to work continuously in good faith to reduce costs and create efficiencies while consistently meeting specifications and to reflect all such reductions and efficiencies through appropriate reductions to the associated per kilogram price*."

(240) It results from the above commitments that Cephalon undertook to pay an aggregate amount of at least USD 28 million, for up to 50,000 kg of modafinil API (or 10,000 kg per annum), between 2007 and 2011. For Teva this represented a guaranteed stable revenue stream until 2011.

(241) One earlier draft of the above provision foresaw, in addition, Teva's suggestion for a payment of USD 2 million to Teva "as recognition for the expenses Teva incurred to date in connection with the development and manufacture of the modafinil API and such additional expenses expected for the future to carry out Teva Israel's obligations (to supply modafinil API)". This was rejected by Cephalon and abandoned in the final version of the Agreement.[414]

4.6.3.5. Avoided litigation costs

(242) Article 2.5 (b) of the Settlement Agreement reads as follows:

"*In full and final settlement of the UK Action (to be dismissed in accordance with Section 4.2 below), Cephalon shall, within three (3) business days of the entry of an appropriate order of the English Court dismissing the UK Action with prejudice, release or otherwise pay to Teva Israel the proceeds of the bond issued to Teva Israel by Cephalon in connection with said litigation in the amount of 2.1 million British pounds sterling,*[415] *in recognition of the savings inuring to Cephalon in terms of the avoidance of costs, expenditure of time and resources, disruption and burden associated with prosecuting such litigation in the United Kingdom.*"

(243) Article 2.5 (c) of the Settlement Agreement stipulates:

414 ID 290, p. 18.

415 See Section 4.4. The bond of GBP 2 million plus interest, see ID 153, p. 3. Footnote added by the Commission.

"*On January 2, 2006, Cephalon shall make a one-time payment to Teva Israel of 2.5 million EUROS in recognition of the savings inuring to Cephalon in terms of the avoidance of costs, expenditure of time and resources, disruption and burden associated with prosecuting patent or other litigation in European and other markets outside of the United States or the United Kingdom, wherein Cephalon and Teva have intellectual property rights that are or may in the future be the subject of patent disputes.*"

(244) According to Article 4.2 of the Settlement Agreement, "each Party shall bear its own costs with respect to the Settlement of the UK Action".

4.6.3.6. Distribution of Cephalon's modafinil products in the United Kingdom (Teva Distribution Agreement)

(245) Article 2.6 of the Settlement Agreement foresees the conclusion of a distribution agreement between Cephalon and a subsidiary of Teva to distribute Cephalon's modafinil products in the United Kingdom ("Teva Distribution Agreement"). It is a framework provision that lays down the main elements of the later concluded Teva Distribution Agreement.[416]

(246) Article 2.6 of the Settlement Agreement reads:

"*2.6 – United Kingdom Supply and Distribution Agreement, and Other Potential Distribution Arrangements*

(a) Cephalon shall appoint Teva UK Limited (or shall appoint such other subsidiary designated by Teva Israel) as the exclusive distributor in the United Kingdom for all Cephalon Modafinil Product for a period of five (5) years commencing on or about July 1, 2006 and shall supply such products to Teva at a price equal to 80% of Teva's actual resale price in the United Kingdom, after any deductions, discounts, credits, rebates, returns and allowances. These terms shall be set forth in an exclusive supply and distribution agreement between Cephalon and the appointed distributor and all terms of said agreement shall be negotiated in good faith by the parties and shall comply with all applicable laws and be substantially similar to those customary in the industry. Cephalon shall provide sufficient quantities of Cephalon Modafinil Product to Teva in advance of the commencement date to allow for timely launch by Teva in the United Kingdom.

(i) Upon Teva's commercial launch of Cephalon's modafinil product in the United Kingdom under this distributor agreement, Cephalon shall make a one-time payment of 2.5 million Euros to Teva Israel, in recognition of the cost and expense involved in Teva's preparation for such launch and in recognition of the license to the Intellectual Property Rights.[417]

(ii) In the event that Teva intends to enter the United Kingdom with its own generic modafinil product, as permitted hereunder pursuant to Article 3, the parties shall discuss in good faith any appropriate modifications to the exclusive supply and distribution agreement. If the parties are unable to agree upon such appropriate modifications despite such good faith efforts

---

416 ID 227, p. 1 and subsequent.

417 See the definition of the Intellectual Property Rights in Section 4.6.3.2. Footnote added by the Commission.

within thirty (30) days, the exclusive supply and distribution agreement shall terminate."

(b) The parties will also undertake to consider in good faith whether a similar resale and distribution services provider arrangement as discussed in this Section 2.6 may be feasible in any other countries."

4.6.4. Teva Generic Rights (Article 3 of the Settlement Agreement)

(247) The relevant provisions of Article 3.1 read as follows:

"*3.1 Generic Rights. Cephalon grants to Teva the non-exclusive right under the Listed Patents*[418] *(as applicable) to manufacture, use, market and sell Generic Modafinil Product*[419] *in the United States and other markets (including provision of modafinil API for Subject Modafinil Product or finished drug which has modafinil as an active ingredient) according to the following terms:*

3.1.1 Teva's generic rights under Section 3.1 shall be effective on the Date Certain[420] *in the United States, or with respect to any market outside the United States, the earlier of October 6, 2012 or the date which is three calendar years prior to the expiration of the applicable patents and exclusivities in such markets. Teva shall pay Cephalon a royalty equal to ten percent (10%) of all Net Profits*[421] *of all Teva Generic Modafinil Product sold by Teva and/or its Affiliates in the United States and other markets on or after the effective date of such generic rights until the later of (i) the expiration of all Listed Patents (as applicable) or (ii) the end of any paediatric extension on the Patent in Suit, or with respect to any market outside of the United States, the equivalent later date in such market, subject to any subsequent negotiation concerning an extension of generic rights.*"

(248) Article 3 of the Settlement Agreement foresaw certain situations in which Teva was allowed to launch modafinil prior to the dates agreed in Article 3.1.1:

(a) Article 3.1.2 stipulates that in the event that Cephalon licenses or permits any other entity to sell generic modafinil product prior to the applicable effective date of the licence to Teva, Teva's rights in that market shall become effective at the same time. The royalties paid by Teva will then be 15% of all net profits of all generic modafinil product sold by Teva prior to the effective date of the licence pursuant to Article 3.1.1.

(b) Article 3.1.3 governs various situations in the case that any entity would enter the market with modafinil at risk, that is to say would sell modafinil products

---

418 See footnote 389. Footnote added by the Commission.

419 Generic Modafinil Product means, pursuant to Article 1.11 of the Settlement Agreement, any Subject modafinil Product that is not marketed under the mark Provigil®. For the definition of Subject Modafinil Product see footnote 400. Footnote added by the Commission.

420 Date Certain applies only to the United States licence and not to the licence in other markets. It means, pursuant to Article 1.10 of the Settlement Agreement, the later of: (a) October 6, 2011 (three years prior to the expiration of the US '516 Patent); or (b) in the event that Cephalon obtains a paediatric extension on the aforementioned patent, April 6, 2012 (which is three years prior to the expiration of the paediatric extension, if obtained). Cephalon indeed obtained the paediatric extension, so the Date Certain was 6 April 2012. Memorandum Opinion of 28 January 2015 by the United States District Court for the Eastern District of Pennsylvania, King Drug Company of Florence, Inc., et al., v. Cephalon, Inc., et. al., ID 2163, p. 6. Footnote added by the Commission.

421 As defined in Article 1.15 of the Settlement Agreement. Footnote added by the Commission.

prior to a non-appealable final judgment in any modafinil-related litigation to which such an entity is party.[422] Again, Teva's right to launch modafinil shall become effective at the same time as the entry at risk occurs. The royalties paid by Teva increase to 20% of all net profits on sales of generic modafinil product made by Teva.[423] The scenarios considered in the provision include Cephalon seeking a temporary restraining order or other relief, successfully or unsuccessfully, Cephalon licensing or permitting other entities to offer modafinil products during the proceedings, and Cephalon prevailing or losing in the litigation (Articles 3.1.3.2-3.1.3.7).

(249) Article 3.3 of the Settlement Agreement made clear that "(A)ll sections of Article 3 shall apply mutatis mutantis to territories outside of the United States despite specific reference to the United States, including without limitation the right to enter the market upon entry by another generic set forth in Sections 3.1.2 and 3.1.3."

(250) Article 3.6 of the Settlement Agreement reads:

"*This Agreement shall neither operate nor be construed to prohibit any pre-existing contractual relationships of Teva for supply of API, provided, however, that Teva agrees that it shall not prospectively continue any such current (as of the Effective Date hereof) relationships beyond their current term nor prospectively enter into any new such relationships to the extent same would be reasonably likely to operate to cause Teva to breach its obligations under this Agreement, including Sections 2.1 and/or 2.5. In addition, to the extent that Teva is currently selling Teva Generic Modafinil Products as of the Effective Date in any country (other than the United States or the United Kingdom) where Cephalon holds modafinil patent rights, the parties acknowledge that any such commercial sales shall not be deemed to be a breach of the terms of this Agreement, provided that Teva shall use its best efforts to effect an orderly and timely cessation from such market.*"

(251) Article 3.8 of the Settlement Agreement reads:

"*Notwithstanding the terms of this Section 3, Cephalon covenants that it will not sue Teva for infringement under the Listed Patents, or any other patents owned by Cephalon on or after the Effective Date, for any sales by Teva of a generic version of PROVIGIL (or the same product sold by Cephalon under a different mark in a jurisdiction other than the United States), provided that such sales are not otherwise in breach of this Agreement. Provided, however, in the event that Cephalon changes the mark for the product currently being marketed in the United States as PROVIGIL, the provisions of this Section 3.8 shall continue to apply to any sales by Teva of a generic version of this same product with this new mark.*"

(252) Finally, Article 3 also stipulates other rights and obligations of the Parties' related to Teva Generic Rights (such as Cephalon's buy-back obligations of unsold inventory in case of Teva's entry before the effective date of the licence, Teva's right to prepare for its market entry (such as by starting manufacturing activities) a

---

422 Although Article 3.1.3 of the Settlement Agreement speaks only about entities that would file an ANDA for commercializing modafinil products in the United States, it also applies to territories outside of the United States, pursuant to Article 3.3 (see Recital (250)).

423 Unless Cephalon has during the relevant time licensed or permitted another entity to sell the generic modafinil product in which case the royalty of 15% pursuant to Article 3.1.2 applies.

reasonable period prior to the agreed upon effective date of the licence, Cephalon's obligation to provide reasonable assistance and documentation to Teva).

(253) Teva's licence rights to manufacture, use, market and sell generic modafinil products according to Article 3 of the Settlement Agreement became redundant after Teva acquired Cephalon in October 2011.[424]

4.6.5. Dismissal (Article 4 of the Settlement Agreement)

(254) In Article 4 both Teva and Cephalon undertook to end their modafinil litigation, and to execute for this purpose all necessary documents. The respective submissions should be filed with the competent United States court within five business days following the Effective Date of the Settlement Agreement (that is to say 4 December 2005), and "*as soon as practicable*" in the United Kingdom.

4.6.6. Implementing Agreements

(255) As explained in Section 4.2.1., Cephalon and Teva eventually concluded two out of the four Implementing Agreements provided for in Article 3.2 of the Settlement Agreement, namely the Modafinil API Supply Agreement (concluded on 7 November 2006) and the Teva Distribution Agreement (concluded on 7 August 2006).

(256) The licence agreement with respect to licences to be granted by Cephalon to Teva to modafinil product as from 2012[425] and the licence agreement concerning Teva's modafinil Intellectual Property Rights,[426] were never concluded.[427]

4.6.6.1. Modafinil API Supply Agreement

(257) The Modafinil API Supply Agreement is a commercial contract that implements the terms and conditions laid down in Article 2.4 of the Settlement Agreement and specifies the commercial-technical details of the Modafinil API supply arrangement.

(258) The Preamble of the Modafinil API Supply Agreement refers to the Settlement Agreement:

"*WHEREAS, Cephalon, Teva Pharmaceutical Industries Ltd.. ("Teva") and Teva Pharmaceuticals USA, Inc. ("Teva USA"), are parties to a settlement agreement, effective as of December 4, 2005 ("Settlement Agreement"), pursuant to which, among other things, Cephalon and Teva agreed to enter into an agreement for the supply of the API from Teva to Cephalon;*

WHEREAS, Teva has designated its Affiliate (as defined below), Plantex, as the entity that will enter into the API supply agreement contemplated by the Settlement Agreement…"[428]

---

424 See Section 4.8.2.4. Moreover, after Cephalon merged into Teva, in accordance with Commission Decision in Case M.6258 – *Teva/Cephalon*, Teva granted a third party, […], as part of its merger commitments, that it would not sue […] for infringement of any modafinil patents owned by Teva or Cephalon, when […] manufactures or sells modafinil products in the EEA on or after 6 October 2012. See *ibid*.

425 Article 3.1 of the Settlement Agreement.

426 Article 2.2 of the Settlement Agreement.

427 ID 1436, p. 16; ID 1428, p. 8. Although Teva sent in response to Commission asking for the modafinil Licence Agreement concluded pursuant to Article 3.2 of the Settlement Agreement the Annex 13 with an agreement, it was not the requested licence agreement but Plantex Supply Agreement.

(259) Article II of the Modafinil API Supply Agreement ("*Purchase and Sale*") reads:

"*2.1 Annual Minimums[429]: Purchase Orders; Lead Time. During the Term,[430] in accordance with the terms herein, Cephalon hereby agrees to purchase API from Plantex,· and Plantex agrees to manufacture (either directly or through an Affiliate) and supply Cephalon with API as ordered by Cephalon pursuant to Purchase Orders from time to time. Cephalon will submit to Plantex binding Purchase Orders for delivery of the Annual Minimum during each Calendar Year... Plantex shall accept all Purchase Orders for API in each Calendar Year, up to the aggregate Annual Minimum in each such Calendar Year, subject to variation in the lead time for delivery of the API as set forth in this Section 2.1. Plantex may accept or reject Purchase Orders for deliveries in a Calendar Year if the aggregate Annual Minimum in such Calendar Year has been delivered by Plantex, Cephalon may acquire API from other suppliers without restriction under this Agreement.*

2.3 Use of API. Cephalon and its Affiliates shall use the API only for the manufacture of finished pharmaceutical products. Cephalon and its Affiliates are prohibited from reselling or otherwise transferring all or any portion of the API not used in the manufacture of finished pharmaceutical products to any other person, either directly or indirectly, including through contract manufacturers or other third parties."[431]

(260) Article 3.1 of Section III ("API Quality and Manufacturing Processes; Packaging) reads:

"*3.1 Quality. All API manufactured and sold by Plantex (or its Affiliate) to Cephalon under this Agreement when delivered by Plantex to Cephalon shall meet the API specifications set forth in Schedule A hereto (the "Specifications"), as well as the quality assurance standards established in the Quality Technical Agreement.*"[432]

(261) The pricing for Plantex' product is set out in Article 4.1 of the Modafinil API Supply Agreement:

"*4.1 Purchase Price.[433] Plantex shall invoice Cephalon the Purchase Price for all API delivered as set forth in Schedule D hereto. Plantex hereby warrants and represents that the initial Purchase Price for Calendar Year 2007 set forth on Schedule D reflects the current approximate cost to manufacture the API of Plantex (or its Affiliate), plus thirty percent (30%). Plantex hereby covenants that Plantex will use commercially reasonable efforts to work continuously in good faith to reduce*

---

428 ID 187, p. 134.

429 Pursuant to Article 1.5 of the Plantex Supply Agreement, "*Annual Minimum*" means "*Ten Thousand kilograms (10,000) of API*". Footnote added by the European Commission.

430 The "*Term*" is defined in Article 1.16 of the Plantex Supply Agreement as "*Calendar Years 2007, 2008, 2009, 2010 and 2011, unless earlier terminated pursuant to Article XV.*" "*Calendar Year*" means each of the calendar years commencing January 1 of 2007, 2008, 2009, 2010 and 2011 (Article 1.7 of the Plantex Supply Agreement). ID 187, p. 135. Footnote added by the European Commission.

431 ID 187, p. 137.

432 ID 187, p. 138.

433 Pursuant to Article 1.12 of the Modafinil API Supply Agreement, the "*Purchase Price*" means the per kilogram price set forth on Schedule D for the applicable Calendar Year. Footnote added by the European Commission.

costs and create efficiencies in the manufacture of the API, while consistently meeting the quality and other requirements of this Agreement…"[434]

(262) Schedule D of the Modafinil API Supply Agreement (Purchase Price) stipulates:

"The purchase price of API shall be as follows in each of the applicable Calendar Years, subject to reduction pursuant to Section 4.1 of the Agreement:

Calendar Year	**Purchase Price**
2007	USD 650/kg
2008	USD 600/kg
2009	USD 550/kg
2010	USD 500/kg
2011	USD 500/kg

(263) In accordance with Article 15.1, "*This Agreement shall become effective on the Effective Date and remain in effect during the Term*."[435] The Effective Date of the Modafinil API Supply Agreement was the date of its execution, 7 November 2006.[436]

4.6.6.2. Teva Distribution Agreement

(264) The Teva Distribution Agreement was concluded on 7 August 2006.[437] No further distribution agreements in the EEA, potentially provided for in Article 2.6(b) of the Settlement Agreement, were concluded between the Parties (see also Recital (221) above).

(265) The draft Settlement Agreement dated 6-7 December 2005 (exactly one to two days before the signing of the (final) Settlement Agreement) reveals that the initial wording of Article 2.6(a)(i) did not state any reasons for the one-time payment: "*Cephalon shall… (iv) upon the first commercial launch by Teva in the United Kingdom of Cephalon's modafinil product, make a one-time payment to Teva Israel of $ 4 million EUROS*".[438]) [439] The justifications for the one-time payment according

---

434 *Ibid*.

435 ID 187, p. 150.

436 ID 187, p. 134.

437 The modafinil products covered in the Teva Distribution Agreement are defined in Article 1.1 thereof as *"all finished pharmaceutical products that contain the compound modafinil, including its salts, esters, enantiomers, isomers and polymorphs sold by Cephalon, its Affiliates, distributors and resellers at the Effective Date in the Territory, and such other finished pharmaceutical products that contain the compound modafinil, including its salts, esters, enantiomers, isomers and polymorphs, (such as SPARLON® and NUVIGIL®) as may be sold by Cephalon, its Affiliates, distributors and resellers after the Effective Date which Cephalon decides, in its sole discretion to launch in the Territory."*

438 It is not clear from the wording whether the amount was denominated in United States dollars or in Euros.

439 ID 290, p. 20.

to Article 2.6 (i) of the Settlement Agreement were subsequently added by Cephalon's antitrust counsel.[440]

(266) The Teva Distribution Agreement is a commercial contract that implements the terms and conditions laid down in Article 2.6 of the Settlement Agreement and specifies the commercial-technical details of the distribution arrangement.

(267) Article 2 of the Teva Distribution Agreement ("*Appointment and Term*") stipulated:

"*2.1 This Agreement shall commence on the Effective Date*[441] *and, subject to Clause 12, shall continue for the Term or until terminated by mutual agreement between the Parties.*[442]

2.2 Cephalon hereby appoints Teva UK with effect from the Commencement Date[443] *as its exclusive distributor and reseller of the Products*[444] *in the Territory*[445] *on and subject to the terms and conditions of this Agreement. For the avoidance of doubt Cephalon reserves the right to distribute the Products in all territories outside the Territory. Teva UK shall purchase all its requirements for its commercial needs of Products for distribution and sale in the Territory during the Term exclusively from Cephalon, subject to the terms and conditions of this Agreement.*

2.3 Cephalon will not, during the Term, appoint in the Territory any other distributor or reseller of the Products nor will it directly supply for its own account the Products to distributors, resellers or end users located within the Territory."[446]

(268) Article 3 of the Agreement laid down "*General Undertakings by Teva UK*":

---

440 ID 290, p. 19-20 and p. 50-51. In addition, according to the draft Settlement Agreement of 6-7 December 2005, the provisions concerning Cephalon's obligation to appoint Teva UK as an exclusive distributor in the United Kingdom and the one-time payment formed part of Article 2.5 "*UK Action Settlement and UK Supply and Distribution Agreement*". This broadly drafted Article comprised in one body the settlement of the United Kingdom litigation, Teva's non-compete commitments, and Cephalon's obligations to pay the avoided litigation costs as well as the above-mentioned provisions related to the Teva Distribution Agreement. ID 290, p. 18-20.

441 The "*Effective Date*" of the Teva Distribution Agreement was the date of its execution that is 7 August 2006. ID 227, p. 1. Footnote added by the European Commission.

442 The "*Term*" of the Agreement is defined as "*the period of five (5) years from the Commencement Date*." Article 1.1 of Teva Distribution Agreement, *ibid*, p. 4. Article 12 of the Agreement laid down different options for termination of the Agreement and Parties' obligations following the termination. See also Recital (275). Footnote added by the European Commission.

443 The "*Commencement Date*" meant "*the date when Teva UK commences its activities* [under the Teva Distribution Agreement], *which the Parties agree shall be no later than 1 October 2006, or such earlier date, anticipated to be 1st September 2006, as may be notified…*" Article 1.1 of Teva Distribution Agreement, ID 227, p. 2. Footnote added by the European Commission.

444 "*Product*" or "*Products*" subject to distribution were "*all finished pharmaceutical products that contain the compound modafinil, including its salts, esters, enantiomers, isomers and polymorphs, sold by Cephalon, its Affiliates, distributors and resellers at the Effective Date in the Territory, and such other finished pharmaceutical products that contain the compound modafinil, including its salts, esters, enantiomers, isomers and polymorphs, (such as SPARLON® and NUVIGIL®) as may be sold by Cephalon, its Affiliates, distributors and resellers after the Effective Date which Cephalon decides, in its sole discretion to launch in the Territory, as set out in Schedule 1, as automatically amended from time to time.*" This definition did not include generic modafinil which Cephalon might have decided to market during the Term of the Teva Distribution Agreement. See *ibid*, p. 3. Footnote added by the European Commission.

445 As "*Territory*" the Teva Distribution Agreement defined the United Kingdom. *Ibid*, p. 4. Footnote added by the European Commission.

446 ID 227, p. 4-5.

"3.*1 Except as provided in this Agreement, Teva UK shall not otherwise dispose of the Product within the Territory, and shall not sell the Product within the Territory on behalf of, or in the name of Cephalon, and shall not hold itself out as being the agent of Cephalon.*

3.2 Teva UK shall use its reasonable endeavours to distribute and sell the Products in the Territory in accordance with its obligations under the terms and conditions of this Agreement and industry practice.

…

3.5 Teva UK shall not, during the Term:

(a) actively canvass or solicit orders for the Product outside the Territory; or

(b) open branches for the sale of the Product outside the Territory; or

(c) maintain distribution depots for the Product outside the Territory.

3.6 Teva UK shall not, during the Term, do anything which may prevent the sale, or adversely interfere with the development of sales of the Product in the Territory or which may adversely affect the quality of the Product. However, nothing in this Agreement shall restrict Teva UK's rights to sell any other product, including products for the same therapeutic indication(s) as the Product."

(269) Article 4 of the Agreement laid down "*General Undertakings by Cephalon*":

"*4.1 Cephalon shall, from the Commencement Date for the remainder of the Term, promptly refer to Teva UK (or as Teva UK shall direct) all enquiries it receives for the Product for sale or ultimate delivery within the Territory.*

…

4.3 Cephalon shall, at Cephalon's cost and expense, complete and submit to the relevant Regulatory Authority any such filings as are necessary to update the Product Licence to designate Teva UK (and/or its nominated Affiliate, Norton Healthcare Limited T/A IVAX Pharmaceuticals UK, in the UK) as an authorized storage site and distributor of the Products in the Territory…

4.4 Cephalon shall hold and maintain in its name the Product Licence and all other relevant regulatory approvals, and shall be and remain responsible for all regulatory matters relating to the Product and the Product Licence in the Territory and for all costs relating to the same."

(270) Pursuant to Article 5.2 of the Teva Distribution Agreement, Cephalon was in charge of packaging the product: "On and from the Commencement Date, Teva UK shall purchase from Cephalon for sale in the Territory such amount of Product as shall be agreed from time to time between the Parties in accordance with the forecasting procedure… ready packaged from Cephalon or an Affiliate or designee of Cephalon. Teva UK shall not, and shall procure that its Affiliates do not alter or amend the packaging of any Product so supplied. Cephalon shall determine the Product packaging, artwork and labelling at its sole discretion…."

(271) The purchase price for Teva was set out in Article 7 of the Agreement ("*Pricing and Payment*"). In accordance with Article 7.1, "*Teva UK shall pay to Cephalon the Base Price for Product in accordance with this Clause*." Article 1.1 defined the Base Price as, "*with regard to each dosage strength of the Product, the NHS selling price per unit of Product (excluding transportation and insurance costs and VAT) (the "NHS*

List Price") less twelve and a half percent (12.5%), multiplied by eighty percent (80%), expressed as a formula as follows: (NHS List Price – 12.5%) x 80%."[447] The same provision referred to Schedule 2 of the Teva Distribution Agreement with regard to the anticipated initial Base Price as on the Commencement Date. The Schedule 2, assuming the NHS List Price of GBP 55.80 per 100 mg unit of Provigil and GBP 111.60 per 200 mg unit, set the Anticipated Initial Base Price at GBP 39.06 per 100 mg unit and GBP 78.12 per 200 mg unit.[448]

(272) The following provisions of Article 7 stipulated that "Teva UK has the sole right to establish resale selling prices for the Product to customers in the Territory" (Article 7.3), and that "Teva UK shall be responsible for agreeing the NHS selling price with the Department of Health under the PPRS scheme in respect of the Product price to be applicable from the Commencement Date provided that Teva UK shall not be entitled to agree to any reduction in respect of Product price that shall exceed the maximum percentage reduction stipulated as being required to be implemented pursuant to the PPRS scheme. By way of example if the PPRS regulations require a price reduction of seven percent (7%) generally in respect of Teva UK's prescription product portfolio, the maximum reduction in the price of the Product that Teva UK can apply would be no more than seven percent (7%)".[449]

(273) According to Article 8 of the Agreement ("Marketing, Advertising and Promotion"), "Cephalon shall carry out all marketing, advertising and promotion of the Product in the Territory at its entire discretion."

(274) Article 12.1 ("Termination") of the Teva Distribution Agreement stipulated that "Without prejudice to any right or remedy that either Party may have against the other for breach or non-performance of this Agreement, either Party shall have the right to terminate the Agreement immediately:

(a) on the other party committing a material breach of any of the provisions of the Agreement providing that (where the breach is capable of rectification) the Party in breach has been advised in writing of the breach and has not rectified it within forty-five (45) days of receipt of such advice, or

(b) if an Insolvency Event occurs in relation to the other Party."

(275) Article 12.2 of the said Agreement foresaw an option of terminating the Agreement "(I)n the event that either Teva UK or Cephalon intend to sell in the Territory a generic modafinil product or any other product that competes with the Product, as permitted under this Agreement." In such a situation, the provision stipulated that "the parties should discuss in good faith any appropriate modifications to this Agreement. If the parties are unable to agree upon such appropriate modifications

---

447 The discount of 12.5% of the NHS List Price was the mandatory wholesalers discount granted by wholesalers to pharmacies required by the applicable United Kingdom regulations. See Recital (106).

448 ID 227, p. 25. Schedule 2 also stipulated: "*The above NHS List Price and Initial Base Price have been calculated on the basis that Teva is required to reduce the current NHS List Price (being the price applicable at the Effective Date) by seven percent (7%). If for any reason, Teva is not required to reduce the NHS List Price by seven percent (7%) or elects to reduce the NHS List Price by less than seven percent (7%) by way of modulation, Cephalon shall be entitled to be reimbursed for the difference between the anticipated initial Base Price and the actual Base Price calculated based upon the reduction to the NHS List Price actually agreed under the PPRS Scheme.*"

449 PPRS is the Pharmaceutical Price Regulation Scheme applicable to the brand medicines reimbursed by the NHS.

despite such good faith efforts within thirty (30) days, this Agreement shall terminate."

(276) Pursuant to Article 12.4 of the Teva Distribution Agreement, the Parties could agree in writing not less than three months prior to the end of the agreement's five-year term to enter into discussions for a new supply and distribution agreement for Cephalon's modafinil products.

(277) Finally, Article 17.3 of the Teva Distribution Agreement stated: "Nothing in this Agreement shall prevent or prohibit Teva UK or any Affiliate of Teva UK from exercising its rights under the Modafinil Licence Agreement, as and when they arise."[450]

(278) Along with the Teva Distribution Agreement, Cephalon UK and Teva UK concluded the Safety Data Exchange Agreement[451] (setting out the provisions relating to the reporting and management of adverse events associated with the modafinil products) and the Quality Technical Agreement[452] (describing the quality system requirements and outlining the responsibilities and key contacts to be used by Teva UK and Cephalon to support the distribution activities for the modafinil products and to address quality and compliance related issues).

4.7. Specific facts and context of the package of commercial transactions

(279) This Section describes in further detail the relevant facts concerning the package of specific commercial transactions (side deals) agreed between the Parties in exchange for Teva committing not to compete as regards modafinil and not to challenge Cephalon's relevant patents. These are (i) Cephalon's purchase of a licence to Teva's Intellectual Property Rights (Section 4.7.1), (ii) the grant by Cephalon to Teva of a licence to Cephalon's CEP-1347 clinical data (Section 4.7.2), (iii) the Modafinil API Supply Agreement (Section 4.7.3), (iv) payments for avoided litigation costs (Section 4.7.4), (v) the Teva Distribution Agreement (Section 4.7.5), and (vi) the licence by Cephalon to Teva to allow for generic entry ("Teva Generic Rights", Section 4.7.6). The purpose of the detailed description of individual transactions is to situate them in the precise factual context in which they were concluded and thereby to allow a comprehensive assessment of this package of transactions in Chapters 6 and 8 under Article 101(1) TFEU.

4.7.1. Licence to Teva's Intellectual Property Rights

(280) Pursuant to Article 2.2 of the Settlement Agreement, Teva granted to Cephalon a worldwide non-exclusive licence to all of Teva's modafinil-related intellectual property rights ("Licence to Teva's Intellectual Property Rights"; for the scope of the Licence to Teva's Intellectual Property Rights see Section 4.6.3.2). While Article 3.2 of the Settlement Agreement provided that a separate implementing agreement

---

450 The term "Modafinil Licence Agreement" refers to "*the agreement entered in to or proposed to be entered into between Cephalon, Inc., Teva Pharmaceutical Industries Limited and Teva Pharmaceuticals USA, Inc. on behalf of themselves and their respective Affiliates under which (inter alia) Teva UK is granted certain rights to sell generic modafinil products in the Territory*." (Article 1.1 of the Teva Distribution Agreement, ID 227, p. 3). This Licence Agreement was provided for Article 3.2 of the Settlement Agreement ("Teva Generic Rights", see Section 4.6.4), but was however never concluded. See Recital (221).

451 ID 229.

452 ID 228.

should have been concluded, this eventually did not happen. The Licence to Teva's Intellectual Property Rights concerned patents and patent applications covering claims to certain crystalline forms (or polymorphs) of modafinil and an alternative process for manufacturing highly pure modafinil, as well as other intellectual property rights.[453]

4.7.1.1. Teva's patents on modafinil

(281) Teva started development of its modafinil in 2000 (see Section 4.3) and since 2001 filed for modafinil-related patents around the globe, including in the EEA and in the United States. By 2005, Teva held a number of patent rights to modafinil.

(282) These included, in 2005, notably the United States patent No. 6,849,120 claiming "Oxidation method for preparing highly pure modafinil, crystalline forms of modafinil, and methods of preparing the crystalline forms" ("US '120 Patent"),[454] its counterpart European patent application No. 01961766.1 "Crystalline and pure modafinil, and process of preparing the same"[455] ("EP '766 Patent Application") and a host of divisional patent applications derived from the US '120 Patent and the EP '766 Patent Application. These divisional patent applications, both in the United States and in the EEA, are noteworthy insofar as they defined claims to crystalline (or polymorph) forms of modafinil that initially had been part of the application for the US '120 Patent and of the EP '766 Patent Application but were later separated for independent patent examination procedures, as explained in the following Recitals.

(283) Teva filed for the US '120 Patent on 27 July 2001 (application No. 09/916,885) and the patent issued on 1 February 2005. The claims of the US '120 Patent are limited to processes for preparing highly pure modafinil. Contrary to what the name of the patent indicates, the patent as granted does not contain claims to crystalline forms of modafinil.

(284) The claims to modafinil crystalline forms in the initial patent application were withdrawn from consideration by the PTO on 9 October 2003,[456] and were subsequently included into divisional patent application No. 10/947,227 "Crystalline forms of modafinil" filed on 23 September 2004 ("US '227 Patent Application"). The patent on this application was issued on 26 June 2007 (patent Nº 7,235,691-"US '691 Patent").[457]

(285) The United States patent application No. 10/947,228, which was also filed on 23 September 2004, included another claim concerning "Highly pure modafinil". The patent on this application was granted on 1 November 2011 (patent Nº 8,048,222).[458]

(286) The EP '766 Patent Application was filed with the EPO on 27 July 2001 and published on 14 May 2003. The patent No. EP 1 309 547 ("EP '547 Patent") was granted on 17 January 2007.[459] It is the European counterpart of the US '120 Patent.

---

453 See ID1436, p. 7.
454 ID 2932.
455 ID 2923.
456 ID 2914.
457 ID 2934.
458 ID 2935.
459 ID 2923.

Similarly to the United States, the patent's 10 claims comprise only processes for preparing pure modafinil.[460]

(287) The EP '547 Patent covers, among others, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom. It also includes Latvia, Lithuania and Slovenia (as the so-called extension states[461]). In Poland, a national patent PL206371 was granted on 30 July 2010,[462] in Czechia and Slovakia patent applications were filed also on 27 July 2001 but the proceedings were terminated without grant of patents.[463] The EP '547 Patent (along with the PL206371) is set to expire on 27 July 2021.

(288) Teva pursued the claims to crystalline forms of modafinil before the EPO first in divisional patent application 07000780.2 "*Crystalline and pure modafinil, and process of preparing the same*". The patent No. EP 1 787 980 ("EP '980 Patent") was granted on 30 December 2009, however, it does not comprise the modafinil crystalline claims but only another pure modafinil process claim.[464] Contrary to the United States, in the EEA Teva therefore never obtained a patent to crystalline forms of modafinil.

(289) The EP '980 Patent covers among others Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom. It also includes Slovenia (as the so-called extension state[465]). In Poland, a national patent PL206371 was granted on 30 July 2010,[466] in Czechia and Slovakia patent applications were filed also on 27 July 2001 but the proceedings were terminated without grant of patents.[467] The EP '980 Patent (along with the PL206371) is set to expire on 27 July 2021.

4.7.1.2. Cephalon's explanations for the purchase of the licence

(290) Cephalon argues that it needed the Licence to Teva's Intellectual Property Rights for three reasons:

---

460 The initial claims relating to crystalline forms of modafinil were withdrawn by Teva following the EPO communication of 7 March 2005. The independent claim 1 of the EP '547 Patent is as follows:
"A process for preparing modafinil comprising:
a) oxidizing 2-[(diphenylmethyl)thio] acetamide with H2O2 in a mixture of a mineral acid with an alcohol,
b) precipitating a solid containing modafinil from the mixture, and
c) separating the mixture from the precipitated solid."

461 See footnote 90.

462 ID 2929.

463 ID 2921 and ID 2931.

464 ID 2925. The independent claim 1 is as follows:

"A process for preparing modafinil comprising the steps of: a) oxidizing 2-[(diphenylmethyl)thio]acetamide with H2O2 in a mixture of a mineral acid with a linear, branched or cyclic alcohol, b) precipitating a solid containing modafinil from the mixture, c) separating the mixture from the precipitated solid, and d) isolating modafinil in purity greater than or equal to 99.5% from the precipitated solid by a single crystallization."

465 See footnote 90.

466 ID 2929. See also ID 2924.

467 ID 2921 and ID 2931. See also ID 2924.

(a) Teva's claims to crystalline (polymorph) forms of modafinil were, in Cephalon's words, *"[B]y far the most important to Cephalon"*. Cephalon was concerned that its modafinil may infringe Teva's modafinil patent rights. This would put at risk an essential part of its business including its flagship medicine Provigil and the pipeline products Sparlon and Nuvigil.[468]

(b) Teva's patent to highly pure modafinil was of interest to Cephalon because it recognised that using the technology could bring about manufacturing and cost efficiencies in its planned concurrent production of Provigil, Sparlon and Nuvigil.[469]

(c) Other Intellectual Property Rights relating to modafinil that Teva had at the time or thereafter would acquire allegedly would provide Cephalon with freedom to operate without concerns about potential future disruption of its business.[470]

4.7.1.2.1. Crystalline (polymorph) forms of modafinil

(291) According to the Parties, Teva's claims (which at the time of purchase of the licence were not patented yet, see Section 4.7.1.1) potentially affected Cephalon's freedom to manufacture and market own modafinil products. They came first to Cephalon's attention at the time of their publication in 2002. Cephalon had also submitted a polymorph patent application based on its own research, but not until August 2003, nearly one year after publication of the Teva applications.[471]

(292) Cephalon explains that modafinil is a chemical molecule that can crystallise into more than one distinct crystal structure. In 1995, scientists at Lafon reported the discovery of three different crystalline forms (also called polymorphs) of modafinil (Forms I, II and III). In 1999, Lafon scientists learned that, when employing the process the company used to manufacture commercial modafinil API, modafinil first crystallized predominantly as Form III and then converted predominantly to Form I, the final modafinil form used to manufacture the finished product. Nevertheless, neither Cephalon nor Lafon could confirm that the final API or tablets were purely Form I, namely that residual amounts of Form III or some other polymorph did not remain in the commercial material. Moreover, given the sensitivity of polymorphic formation to subtle changes in conditions of manufacture, Cephalon could not be certain that its commercial manufacture of modafinil API would not produce, transiently and/or permanently, other modafinil polymorphic forms.[472]

(293) Teva's International Application No. PCT/US01/23689 (which originated from the United States patent application No. 09/916,885 disclosed five modafinil polymorphs. In the SO Reply, the Parties explain that Cephalon's scientists considered that polymorphic form II claimed in Teva's application correlated with polymorphic form III claimed in the later Cephalon application.[473] According to the

---

468 See ID 1318, p. 3 and ID 1436, p. 7-8.

469 ID 1436, p. 8-9; SO Reply, paragraph 211.

470 ID 1436, p. 9; ID 2153, p. 10.

471 ID 1318, p. 3. More on Cephalon's patent application to crystalline forms of modafinil see in Section 4.7.1.5.

472 ID 1436, p. 7-8.

473 SO Reply, paragraph 221 ff. See also Expert Report of […] of 24 January 2018, Annex 2 to the SO Reply (" [*Expert report of 24 January 2018*]"), paragraph 47; ID 3694-12, p. 13-14.

Parties, Cephalon faced significant risk that its flagship modafinil products and/or processes would infringe Teva's patent application covering polymorphic form II (Cephalon's form III) of modafinil. In this respect, the Parties argue, supported by Expert Report of […] of 24 January 2018 ("[*Expert report of 24 January 2018*]") that Cephalon faced greater than a 50/50 risk that Teva's Form II modafinil could be detected in Cephalon's commercial API or tablets.[474]

(294) Cephalon was using modafinil API for the manufacture of Provigil and a pipeline product Sparlon. At the time of the licence, the only approved way to manufacture armodafinil API for Nuvigil, the other pipeline product, was also based on modafinil as starting material.[475] "*As a result of its in-license of Teva's modafinil-related intellectual property*," concludes Cephalon, "*Cephalon is free of the risk that Teva could disrupt its supply or sale of modafinil, Cephalon's highest grossing product worldwide.*"[476]

4.7.1.2.2. Highly pure modafinil

(295) According to the Parties, Teva's US '120 Patent presented value for Cephalon (or, as expressed in the [*Expert report of 23 January 2018*], an expert report of 23 January 2018 commissioned by the Parties and relied on by the Parties in their SO Reply, "*a business opportunity and potential value*").[477] Teva's US '120 Patent claims a process for the manufacture of modafinil using a compound Cephalon referred to as CEP-9419. That compound was used as an intermediate in the process that Cephalon had developed for manufacturing armodafinil (for Nuvigil) and hoped to bring on-line for the commercial manufacture of Nuvigil's API (a process known as asymmetric oxidation). The potential to manufacture modafinil and armodafinil API from a common intermediate, particularly in anticipation of the launch of Nuvigil and Sparlon (which would call for increased demand of modafinil supply), offered significant manufacturing efficiencies.[478]

(296) According to the submissions of the Parties', a team of Cephalon's scientists including the Vice President of Worldwide Chemical R&D concluded that employing the Teva process could be a useful way of merging the synthetic pathways for modafinil and armodafinil by utilizing a common intermediate. The principal benefits of doing so were the cost efficiencies.[479]

---

474 SO Reply, paragraphs 204, 209 and 213-214, [*Expert report of 24 January 2018*], ID 3694-12, paragraphs 20, 58. The same conclusions are drawn also in other expert report commissioned by the Parties, the Expert Report of […] of 23 January 2018, Annex 3 to the SO Reply (" [*Expert report of 23 January 2018*]"). The [*Expert report of 23 January 2018*], which is wider in scope than the [*Expert report of 24 January 2018*] (in addition to the infringement risk for Cephalon by Teva's modafinil patent application, it also analyses the usefulnes of Teva's US '120 Patent to manufacture highly pure modafinil for Cephalon and the Plantex Supply Agreement), mostly reflects the findings of the [*Expert report of 24 January 2018*] concerning the infringement risk. See in particular [*Expert report of 23 January 2018*], paragraph 16 and paragraphs 21-25, fn. 25; ID 3694-19, p. 6, 8-11.

475 *Ibid*.

476 *Ibid*.

477 [*Expert report of 23 January 2018*], paragraph 30; ID 3694-19, p. 11.

478 SO Reply, paragraphs 288-289. See also the [*Expert report of 23 January 2018*], paragraphs 30-32, ID 3694-19, p. 11-12, and ID 1436, p. 8-9. See also Response to the LoF, points 40-43 (ID 3763).

479 ID 1726, p. 7. Similarly in ID 1436, p. 9: "*The Teva process provided a possible approach to manufacturing 'highly pure' modafinil from that intermediate*." See also the SO Reply, para 211.

"The flexibility of pursuing this option, if the business case could be made, was a secondary benefit of the Teva IP license."[480]

(297) However, with regard to the above-mentioned findings of Cephalon's scientists, in their reply to the Article 18 Request of 19 August 2013 Cephalon admits that it was unable to substantiate these explanations by reference to the contemporaneous documents: "[t]*o date, Cephalon has not located written studies or analyses relating to this investigation.*"[481]

(298) Moreover, as it is acknowledged in the [*Expert report of 23 January 2018*] relied on by the Parties in their SO Reply, Cephalon never (not even after the Settlement Agreement) used the process described in the Teva's US '120 Patent commercially after having obtained the licence from Teva.[482] […].[483] […].[484] […].[485]

(299) Developing manufacturing process licenced from Teva could have been at best of little economic interest to Cephalon. The Parties argued that Teva's process patent *"offered significant manufacturing efficiencies"*, which resulted from the possibility to have a common intermediate that could be used for manufacturing both modafinil and armodafinil.[486] However, Cephalon did not start working on an industrial application of Teva's technology at least until mid-2007 (which was already after Cephalon was issued a non-approval letter for Sparlon by the FDA in 2006). […][487]. As a result, it appears that it was not possible to have Teva's manufacturing process in place before the launch of Nuvigil which, as explained above, would in turn lead to decreased production of Provigil and would thus not allow for the alleged manufacturing efficiencies to materialise. In this context, the Parties' explanation regarding the usefulness of the licence to Teva's manufacturing process is unfounded.

(300) In addition, after the Settlement Agreement, Cephalon informed the investment community about its plans to launch Nuvigil (armodafinil) in 2010.[488] Nuvigil was eventually launched in June 2009. Cephalon's long-term business strategy was to switch the market from modafinil to armodafinil to protect its modafinil franchise (see Sections 4.2.3 and 4.8.1.4., meaning the launch of armodafinil product would lead in parallel to decline in sales of modafinil product and its eventual phasing-out. The alleged manufacturing efficiencies brought about by Teva's technology would accordingly not materialise.

4.7.1.2.3. Other Intellectual Property Rights

(301) Concerning the "Other Intellectual Property Rights", Cephalon stated:

---

480 ID 1726, p. 7.

481 ID 1726, p.7, where "investigation" refers to the alleged analysis by Cephalon of the benefits of Teva's modafinil process following the publication of Teva's patent application.

482 [*Expert report of 23 January 2018*], paragraph 31; ID 3694-19, paragraph 31. The Parties' expert Dr […] nevertheless notes that "*there was value to licensing the process at the time of entering into the IP Agreement, given the significant synergies that Cephalon recognized could be achieved by using the '120 Patent manufacturing process.*" *Ibid* p. 11-12.

483 […]

484 […]

485 […] IH; ID 3694-8, p. 8.

486 SO Reply, paragraph 289.

487 […] IH, ID 3694-8, p. 26.

488 *Ibid*, p. 25.

"*In addition to the foregoing, the in-license from Teva provided freedom to operate concerning any other intellectual property relating to modafinil Teva had at the time or thereafter acquired. For example, to the extent Teva later applied for patent rights concerning armodafinil (the active ingredient in NUVIGIL®) – which Teva later did – Cephalon was provided the valuable freedom to operate on a worldwide basis.*"[489]

(302) Therefore, the licence to the possible future modafinil patent rights "eliminated the risk that Teva could disrupt Cephalon's current or future supply or sale of modafinil, the active pharmaceutical ingredient in Cephalon's present and planned highest grossing products worldwide."[490]

4.7.1.3. Prior to the Settlement Agreement, Cephalon did not deem Teva's Intellectual Property Rights necessary

(303) An internal presentation by Cephalon's Vice-President of Worldwide Chemical R&D in 2003 discusses Teva's original patent application (that later issued as the US '120 Patent) and all its claims in relation to highly pure modafinil, as well as Teva's claims to crystalline forms. With regard to Teva's modafinil process claims the presentation says:

"*1. Teva Process Claims*

Claims 1-20 are directed to a Process for preparing modafinil… through oxidation of the sulphide-amide…

Conclusion: Teva claims a process which we do not use (we oxidize the sulphide-ester). The 'chloroacetamide route' uses this intermediate[491] *to oxidize to modafinil. We have filed on this. Cephalon's improved process patent application will be filed shortly and is distinct from the above. These Teva claims should have no substantive impact on Cephalon's manufacturing of modafinil as currently practiced."*[492]

With regard to Teva's crystalline claims, the presentation says:

"Patent Application – Not yet issued…

3. Claims to Crystalline Forms…

Teva has pending claims describing 5 crystaline forms of modafinil – 2 polymorphs we have prepared previously, 2 forms which resemble our AcCN solvate, and 1 form which resembles our Form I by powder X-Ray. We have filed our US patent application covering these polymorphs and expect an interference proceeding in the US in 2-3 years. We have predating records of invention of these polymorphs."[493]

---

489 ID 1436, p. 9. The Parties confirmed this view in the SO Reply, paragraph 210; ID 3694-26, p. 58, and [*Expert report of 24 January 2018*], paragraph 24; ID 3694-12, p. 6. The reference to the "freedom to operate" with respect to Nuvigil is understood as to the alleged value of the Intellectual Property Rights with respect to the crystalline forms of modafinil and the highly pure modafinil as armodafinil was produced on the basis of modafinil. See also in this respect ID 1436, p. 7-9.

490 ID 2153, p. 10. Cephalon then names, by way of example, Teva's patent applications concerning armodafinil which, "[h]*ad* [they been] *issued as patents, could have posed additional risk to Cephalon.*" *Ibid*, p. 11. See the SO Reply, paragraph 210.

491 The intermediate "CEP 9419" described by Teva. Relates to claims to a method of manufacturing "highly pure modafinil" by oxidizing 2-[(diphenylmethyl)thio]acetamide (a compound Cephalon internally referred to as "CEP 9419"). See ID 1436.

492 ID 2144-67, p. 1.

493 *Ibid*, p. 3.

The conclusions of the presentation are clear:

"*Conclusions:*

1) The Teva application has not yet issued.

2) Form I is the currently marketed, and only approved Form.

3) Current manufacturing process will not infringe any Teva claims.

4) Unlikely all Teva claims will issue as submitted."[494]

(304) In the presentation, these conclusions are followed by two "*Recommendations*" by Cephalon's patent lawyers. Both are limited to certain laboratory work and none of them either mentions modafinil Form III or advise to approach Teva concerning its patent application.[495]

(305) In late 2004 or early 2005, Cephalon's Vice-President for Global Manufacturing and other executives in charge of manufacturing of modafinil API met with the director of sales of Teva's United States subsidiary Plantex USA, as part of Cephalon's project to build a library of API and dosage form suppliers. This meeting was followed-up by correspondence concerning proposed pricing of modafinil API from Plantex to Cephalon (see also Section 4.7.3.7). Cephalon's Vice-President was however later not able to recall that they would have discussed with Plantex any concerns that Cephalon's modafinil production might infringe on Teva's Intellectual Property Rights.[496]

(306) When, in August 2005 (four months prior to the Settlement Agreement), Cephalon was negotiating with [*a company*] a possible co-promotion deal,[497] Cephalon's patent situation was also discussed. [*A company*] specifically asked whether Cephalon did do a "*freedom to operate search*".[498] In preparing the response, Cephalon's Vice-President and Chief Patent Counsel internally wrote an e-mail to Cephalon's Associate General Counsel: "*We have not done a formal freedom to operate search. As I have explained to JnJ's attorney, we feel confident there are no third party patents out there covering this product since we do, and have been doing for 15 years, extensive watching of US and EP patents for modafinil. We know the patent landscape for modafinil and formulations of modafinil and are not aware of any potential infringement problems.*"[499]

(307) The Parties argue that based on the information available to Cephalon at the time when the Settlement Agreement was concluded, Cephalon faced a significant infringement risk of Teva's patent, if it were issued (which, according to the Parties, was the most likely scenario at the time).[500] However, the [*Expert report of 24 January 2018*] also acknowledges that, at the time of the licence, Cephalon had not detected Form III in its own final API or modafinil product.[501]

---

494 *Ibid*, p. 5.

495 *Ibid*.

496 ID 3694-13, p. 37-38.

497 SO Reply, paragraph 262.

498 ID 3694-7, p. 55. Such search relates to examining whether the company's technology/product does not infringe other patents and patent applications.

499 *Ibid*, p. 55.

500 SO reply, paragraph 244.

501 [*Expert report of 24 January 2018*], paragraph 21 and 67, ID 3694-12.

(308) The [*Expert report of 24 January 2018*] then submits that a "sophisticated litigant – such as Teva – could have detected small amounts of the infringing form through more sensitive detection mechanisms". Although according to the [*Expert report of 24 January 2018*] that risk was evident to Cephalon in December 2005 (and before), neither the report nor the Parties produce any evidence to this end.[502] Consequently, the Parties failed to submit any evidence showing Cephalon's concern (or, for that matter, any internal discussion at all) that any testing could reveal the presence in Cephalon's product of modafinil polymorph that would infringe the claims in Teva's patent application.

(309) The Parties' expert […] expresses the opinion that given what Cephalon knew in 2005, "it was certain that Cephalon form III/Teva Form II… was created during the commercial process Cephalon employed for the manufacture of modafinil API at its own facility in France [Commission: Mitry-Mory], and also a its contract manufacturer's facility in […] [Commission: [*contract manufacturer*]".[503] The [*Expert report of 24 January 2018*] acknowledges that Cephalon's own manufacturing in France predated the Teva polymorph application and therefore likely enjoyed "prior use" rights under French law, insulating it from infringement liability in France.[504] However, according to the [*Expert report of 24 January 2018*] and the Parties, those "prior use" rights would not have extended to protect contract manufacturers outside France that began manufacturing modafinil after Teva had filed its patent application.[505] Given that [*contract manufacturer*] began manufacturing modafinil API in 2004, several years after Teva's application, it would have been, in the opinion of Dr […], at risk of infringement, if Teva's relevant claims issued in Europe.[506]

(310) The [*Expert report of 24 January 2018*] also questions whether Cephalon would be able to rely on its Provigil launch in the United States in 1999 as means to invalidate Teva's polymorph claims under the United States "on sale bar", which is understood to generally invalidate claims to technologies that were commercially on sale more than one year before the filing of the patent application.[507] In this instance, because Teva claimed a priority date of 27 July 2000, Cephalon would need to prove that Form III was contained within Provigil sold in the United States between February 1999 (launch of Provigil in the United States) and July 1999 (one year prior to Teva's priority date).[508] According to Dr […], even subtle changes in the manufacturing process could result in changes in the polymorphic outcome of crystallisation which would have impeded Cephalon from proving that the modafinil product it sold in the United States one year prior to Teva's priority date contained Form III modafinil.[509]

---

502 SO Reply, paragraph 243, [*Expert report of 24 January 2018*], paragraph 21, p. 6. See also [*Expert report of 24 January 2018*], paragraph 67 and subsequent, p. 21-22. In paragraph 69, the Report states as last resort that "*even if sophisticated testing of modafinil did not detect Form III, there could be no assurance that subsequent tests would not*".

503 [*Expert report of 24 January 2018*], ID3694-12, p. 17.

504 [*Expert report of 24 January 2018*], ID3694-12, p. 17-18.

505 SO Reply, paragraphs 229, 243.

506 [*Expert report of 24 January 2018*], ID3694-12, p. 17.

507 [*Expert report of 24 January 2018*], ID3694-12, p. 22.

508 [*Expert report of 24 January 2018*], ID3694-12, p. 22.

509 [*Expert report of 24 January 2018*], ID3694-12, p. 22-23.

(311) In the SO Reply, the Parties drew attention to a number of studies drafted or commissioned by Cephalon between 1995 and 2004 that, in their opinion, made Cephalon aware that it faced an infringement risk resulting from Teva's patent application:[510] Lafon's[511] reports "Polymorphism Study of Modafinil" of 1995[512] and "Analysis Report on the Synthesis of Modafinil" of 1999,[513] a 2003 study by […],[514] and a paper by Professor […] of 2004 "successful Application of the Derived Crystal Packing (DCP) Model in Resolving the Crystal Structure of a Metastable Polymorph of +/ – Modafinil"[515]. According to the Parties, these studies show the existence of polymorphic Form III of modafinil and the likelihood of its presence (however, not the presence itself) during the manufacturing of modafinil API, commercial API and finished products.[516] Dr […] submits that Professor […] study described that polymorphic forms I and III (according to Cephalon's naming) could actually crystalise and grow as "twin crystals", a finding that elevated the risk that residual amounts of Form III could be present in Cephalon's final API or modafinil product, of which Cephalon was well aware.[517] The above findings were according to the [*Expert report of 24 January 2018*] confirmed by studies drafted following the Settlement Agreement, namely a 2006 study by […][518] and a 2008 analysis by the […].[519]

(312) The SO Reply explains, supported by the [*Expert report of 23 January 2018*],[520] why, under the United States patent law, Teva's claims to modafinil polymorphs were likely to have priority over Cephalon's competing claims, either in interference proceedings[521] or in patent infringement litigation initiated potentially by Teva.[522] Since the priority claim of Teva's patent application (27 July 2000) preceded by more than two years the priority date of Cephalon's patent application with overlapping claims (2 August 2002), the burden of proof that it invented first the polymorphic Form III would fall on Cephalon. Accordingly, Cephalon would have had to show that it conceived the invention first and that it exercised reasonable diligence in later putting the invention to practice. The Parties argue that under the relevant United States law, for a discovery prior to 1 January 1996 to establish priority of invention, that discovery must have been made within a country that is signatory to the North American Free Trade Agreement ("NAFTA"). Internal report evidencing that Cephalon discovered polymorphic Form III of modafinil was dated 9 June 1995 in France, thus not fulfilling, according to the Parties, the above condition. Moreover, in the opinion of the Parties, Cephalon faced a significant risk that it would have been deemed to have suppressed or concealed the invention, that is

---

510 SO Reply, p. 64-67; [*Expert report of 24 January 2018*], ID 3694-12, p. 19-23.

511 French company that invented modafinil, acquired by Cephalon in 2001 (see Section 2.2).

512 ID 1494.

513 ID 1496.

514 ID 1771-110.

515 ID 1771-111.

516 SO Reply, paragraphs 237 and subsequent.

517 [*Expert report of 24 January 2018*], paragraph 65, ID 3694-12.

518 ID 1771-116.

519 ID 1771-109.

520 [*Expert report of 23 January 2018*], paragraphs 27-28, ID 3694-19.

521 An interference is an administrative contest between an application and either another application or a patent before the PTO. It serves the purpose of determining priority, that is, which party first invented the commonly claimed invention.

522 SO Reply, p. 62-64.

to say not have exercised reasonable diligence in reducing the invention to practice. The SO Reply submits that Cephalon had discovered Form III in or about 1995 in France, identified it in its manufacturing process in 1999 also in France and took no steps to disclose the invention and pursue the patent until after it had become aware of Teva's application in 2002, that is to say seven years after discovery. From the above, the Parties infer that if patent court proceedings were initiated, Cephalon was at significant risk that Teva would have been granted priority and a patent covering the modafinil form III, while Cephalon would no longer have been entitled to the US '219 patent covering the same polymorph. Therefore, according to the Parties, the SO assertion that "*Cephalon was confident that its application enjoyed prior art advantage to Teva's application" is plainly wrong*."[523]

(313) In reply to the Parties' above arguments, the Commission maintains its conclusion that Cephalon did not perceive an infringement risk allegedly stemming from Teva's Intellectual Property Rights, and especially patent claims to polymorphic forms of modafinil, in particular Form III. The above-mentioned arguments of the Parties and their experts describe possible *ex post* views and interpretations concerning the situation that existed before the conclusion of the Settlement Agreement. The SO Reply and the [*Expert report of 24 January 2018*] admit that their ex post opinions would have been "*possibly*", sometimes "*likely*" shared by Cephalon in its ex ante considerations. The Parties however did not bring forward any contemporaneous evidence that Cephalon, or for that matter Teva, would have concluded that there was any infringement risk for Cephalon prior to, or at the time of the Settlement Agreement. The Parties' assertions thus cannot dispel the contemporaneous evidence quoted by the Commission above, which shows that, prior to and until the time of the Settlement Agreement, Cephalon was of the view that there was no such risk (see Section 4.7.1.3).

4.7.1.4. Teva's view of the value of the Intellectual Property Rights in the context of the Settlement Agreement

(314) As indicated in Recital (190), in an e-mail of 8 July 2005 (two days after the start of the modafinil litigation in the United Kingdom) Teva's CEO mentions for the first time the possibility of a settlement with Cephalon and the role of Teva's patent rights. He seems to imply that both companies' patent rights are complementary and together could exclude other competitors from the market, when combined.

(315) The Patent Department official at Teva involved in the e-mail conversation of 8 July 2005 stressed that "It will be difficult to have the patent granted in Europe in light of the general approach in Europe not to grant patents on pure products" also pointing out "(but we still have an application which is more than nothing for any possible negotiations)"[524]). In an e-mail to Teva's patent counsel of 11 July 2005, Teva's external counsel observes with regard to Teva's possible offer to Cephalon of its modafinil intellectual property rights:

"*I do not know about the value of the Teva's patent to them although I note that it is still an application and again I would be surprised* [if] *the offer of a future licence*

523 See SO Reply, paragraphs 228 and 231.

524 ID 95, p. 44-45.

under it (as and when it grants) would be of sufficient value to bring about a settlement of this application."[525]

4.7.1.5. United States Patent Office grants polymorphs patent to Cephalon and preliminarily rejects Teva's application

(316) Cephalon filed on 7 August 2003 its own patent application relating to polymorphic forms of modafinil, including Form III modafinil (US '445 Patent Application, see Section 4.1.2.1.3). The application was based on discovery by Lafon scientists, made already in 1995, of crystalline Forms I-III of modafinil (see Recital (293)). On 20 September 2005, the PTO issued a Notice of Allowance for Cephalon's US '445 Patent Application.[526] The respective patent issued on 31 January 2006 as patent No. 6,992,219 ("US '219 Patent").[527]

(317) Following the Notice of Allowance leading to the grant of the US '219 Patent, Cephalon's top management (namely the CEO, the Senior Vice-President and General Counsel and the Vice-President and Chief Patent Counsel) contemplated a strategic use of this patent against Teva (as defendant in the pending patent infringement cases).[528]

(318) On the contrary, Teva's claims to crystalline forms of modafinil set out in the US '227 Patent Application "Crystalline forms of modafinil" were rejected in the first Office communication by the PTO of 28 October 2005. In the end, the US '691 Patent issued, but only on 26 June 2007, that is one and half year after the Settlement Agreement and the issue of Cephalon's US '219 patent.[529]

(319) Cephalon was aware of the initial rejection of Teva's US '227 Patent Application. In its reply to the Article 18 Request of 24 June 2013, it however argues:

"[F]*rom an objective standpoint, no party in Cephalon's position could reasonably view the 28 October 2005 office action a signal that Teva's potential blocking patent application would not soon issue. The patent examiner issued a first 'non-final' rejection only. The action does not constitute an ultimate 'rejection' of the polymorph claims in the ordinary sense of the word. As the U.S. P.T.O. explains, 'It is not uncommon for some or all of the claims* [of a patent application] *to be rejected on the first Office action by the examiner; relatively few applications are allowed as filed.' See U.S. P.T.O. 'General Information Concerning Patents' (Nov. 2011). Indeed, Cephalon's own modafinil polymorph application, U.S. Patent App. No. 10/635,455, which had received Notice of Allowance by U.S. P.T.O. in September 2005, had also received a 'non-final' rejection earlier that year.*"[530]

---

525 ID 120, p. 2.

526 ID 2916. See also the Notice of Allowability, ID 2915.

527 ID 2933.

528 ID 2144-24, p. 1-2.

529 ID 2943 and ID 2934. Under Article 2.2 (a) of the Settlement Agreement Cephalon undertook not to challenge any Teva patents included in the Intellectual Property Rights. It is therefore understandable that Cephalon did not dispute either Teva's US '227 Patent Application or later the US '691 Patent itself. Indeed, after the Settlement Agreement Cephalon did not have incentive to challenge Teva's crystalline patent rights. Had it done so, by means of its US '219 Patent ("modafinil polymorphic forms") which was issued one and half year prior to Teva's crystalline patent, the grant of the latter would have been uncertain.

530 ID 1726, p. 8-9.

(320) The Notice of Allowance for issuance of the patent for crystalline forms of modafinil, concerning Teva's US '227 Patent Application, was sent by PTO to Teva's legal representatives on 17 November 2006[531] and the resulting US '691 Patent was issued on 26 June 2007 (Recital (285)).

4.7.1.6. Cephalon bought the Licence to Teva's Intellectual Property Rights without specific negotiations and due diligence

(321) After the start of negotiations between Cephalon and Teva, Cephalon's chief negotiator sent to Teva's chief negotiator on 28 November 2005 the e-mail quoted in Recital (196) that refers to a "*(iii) possible cross license of our respective (modafinil) patents….*"[532]

(322) The evidence on file, including all documents concerning the purchase of the licence that the Commission asked from the Parties,[533] shows that the Parties did not discuss the Licence to Teva's Intellectual Property Rights, its details or its purpose outside the context of the Settlement Agreement.[534] The Parties did not provide any evidence which would show that negotiations covered elements typical for licence agreement such as the monetary value of the patent rights for Cephalon and Teva, the scope of the licence, or took account of the fact that the whole package of the licensed patent rights contains only one relevant patent (Teva's US '120 Patent) and the rest were pending patent applications. The Parties also did not discuss the fact that the US '227 Patent Application (which according to Cephalon's depiction might have potentially restricted its freedom to market own modafinil products, see Recital (291)) has just been rejected by the PTO's first office action, while Cephalon's corresponding US '445 Patent Application was granted a patent (Recital (317)). Notably, Cephalon's US '445 Patent Application was potentially in a position to prevent a patent being issued on Teva's patent application. The Parties (particularly Cephalon) also did not factor in this important circumstance in the negotiations about the royalty price and payment conditions (a large part of the royalties was paid before the grant of the crystalline patent claims in June 2007[535]). In general, the evidence does not show any negotiations about the price of the licence.

(323) Cephalon's Vice-President of Worldwide Chemical R&D […].[536]

(324) Cephalon did not present to the Commission any evidence that it commissioned a legal due diligence of Teva's Intellectual Property Rights prior to their purchase. According to the Parties, Cephalon did not have the ordinary practice to prepare formal due diligence for each transaction involving intellectual property, and rather argued that it conducted "legal analysis" of Teva's patent applications that "occurred at various points in time between about 2002 and about 2005."[537]

---

531 ID 2870.

532 ID 1616, p. 1-2.

533 The Commission repeatedly requested the Parties to submit all documents related to negotiation about the purchase of Teva's licence in the following Article 18 Request, ID 1436, p. 6 and subsequent.

534 See also Section 4.4 for the Parties' positions regarding their intellectual property rights in the context of intellectual property rights litigation launched in July 2005 by Cephalon.

535 See Section 4.7.1.7.

536 […] IH, ID 3694-8, p. 26.

537 Cephalon claimed legal professional privilege to such legal analysis. Following the Commission's Decision of 29 July 2015 pursuant to Article 18(3) of the Regulation 1/2003, requesting Cephalon to

(325) The Commission also asked Cephalon to "provide minutes of Cephalon's management meetings (such as Board of Directors or any other relevant body) in which discussion took place either on the [alleged] due diligence report(s)… or any aspect of the purchase of the license to Teva's intellectual property rights pursuant to the Settlement Agreement (in particular, but not limited to, the value of the license for Cephalon and/or the purchase price for the license)."

(326) After the initial refusal to produce the requested documents based on the alleged U.S. attorney-client privilege[538] and the adoption of the Commission Article 18(3) Decision of 29 July 2015, Cephalon produced to the Commission two documents (Cephalon, Inc.'s Minutes of the Meeting of the Board of Directors of 1 December 2005, and Cephalon, Inc.'s Minutes of the Meeting of the Special Committee of the Board Directors of 4 December 2005[539]). Neither of these documents addressed any specific aspect of the purchase of Teva's licence, with the Minutes of the Meeting of 4 December 2005 merely mentioning in general that the licence (along with other transactions) was "*discussed*". On the other hand, the Minutes of the Meeting of 1 December 2005 clearly state that "(*A*)*lthough outright payments to generic firms* [as part of the settlements] *will be viewed as suspect* [by United States competition authorities and courts], *it is permissible to structure terms at arm's length related to other business interests between the companies (eg, manufacturing, licensure, other disputes).*"[540] In this document, Cephalon explicitly attributed the purchase of the licence to the terms of the Settlement Agreement as opposed to a self-standing transaction with a value of its own. Cephalon did not produce any other supporting documents in response to the Commission's question.

(327) Finally, it is noteworthy that no other companies active in the modafinil business ever showed interest in Teva's Intellectual Property Rights. Teva has never out-licensed the Intellectual Property Rights to other parties, nor did it engage in negotiations with any company other than Cephalon concerning a possible grant of licence to the Intellectual Property Rights.[541] This includes notably the generic contenders […], […] and […] that were ready to launch their modafinil products in early 2006 in the United States.

4.7.1.7. Cephalon's payments of royalties to Teva

(328) Cephalon paid the total of USD 125 million under the Royalty Cap[542] to Teva by a transfer of a lump sum of USD 15 million as a first payment in December 2005 and then in a sequence of quarterly royalty payments until September/November 2009. If

---

produce the relevant, allegedly privileged documents, Cephalon supplied the requested documents on 28 August 2015. However, none of these documents can be qualified as a due diligence report relating to purchase by Cephalon of Teva's Intellectual Property Rights. See Cephalon's reply to Article 18 Request of 27 May 2011, ID 1436, p. 10; reply to Article 18 Request of 19 August 2013, ID 1726, p. 4-5, reply to Article 18 Request of 29 July 2015, ID 2144, SO Reply, paragraph 274.

538 ID 1726, p. 5. The Commission notes that the United States attorney–client privilege does not apply in EU competition proceedings. The minutes of meeting of companies should in principle not be covered by the EU professional legal privilege as those meetings are mainly attended only by company's employees and not by external lawyers (as indeed was the case).

539 ID 2144-5, p. 1 and ID 2144-48.

540 ID 2144-48, p. 2.

541 ID 1840, p. 4.

542 See Section 4.6.3.2.

the payments are grouped by the year's totals, Teva received the following yearly royalties:[543]

Table 5: Yearly royalty payments

Year	Payment (USD)	Payment (EUR)[544]
2005	15,000,000	12,076,500
2006	30,794,515	24,549,387.36
2007	24,747,297	18,085,324.65
2008	27,466,219	18,773,160.69
2009	26,991,969	19,407,225.71
Total	125,000,000	92,891,598.41

Source: ID 1330

4.7.1.8. Costs of development of the Intellectual Property Rights

(329) When calculating Teva's costs related to the development of the Intellectual Property Rights, on the basis of the cost information made available by Teva, the Commission assumed a conservative approach.

(330) First, the scope of research and development expenses related to the intellectual property rights as given by Teva to the Commission is broader, indicating "*research and development expenses for modafinil*". This goes beyond the definition of the Intellectual Property Rights and may also include expenses related to technologies or processes regarding which Teva did not prosecute patent rights. Accordingly, the expenses related specifically to the technologies protected by Teva's modafinil Intellectual Property Rights form only a portion of the total modafinil expenses. Nevertheless, the Commission will take into account the total modafinil R&D costs indicated by Teva.

(331) Second, although royalty payments and the royalty cap were determined in the Settlement Agreement in 2005, the Commission will also take into account Teva's modafinil R&D expenses incurred between 2006 and 2010, as well as all patent prosecution expenses, which were not attributed to a specific year. Total modafinil patent prosecution expenses (namely those paid for having the patent granted) amount to USD 311,669[545] that is EUR 255,942.58.[546]

(332) According to Teva's information, it incurred the following costs related to the development of its modafinil Intellectual Property Rights:

Table 6: Research and development costs related to modafinil for 2000-2010

Year	Total cost (USD)	Total cost (EUR)

543 See ID 1330, p. 3-4 (indicating September 2009 as the month of the last payment), and ID 1316 (indicating 17 November 2009 as the date of the last payment).

544 According to average exchange rate for the relevant year published by the European Central Bank.

545 ID 2154-145. Teva did not specify the timeframe of the expenses.

546 As Cephalon did not indicate which part of these expenses was incurred in which year, the Commission made the conversion to EUR on the average exchange rate between 1 January 2001 to 31 December 2012 as indicated by the European Central Bank (USD 1 = EUR 0,8212). The application for the US '120 Patent was filled in 2011 and the last know Teva's modafinil patent application that was prosecuted (before EPO) was withdrawn in 2012. See Section 4.7.1.1.

2000	182,800	198,502.52
2001	155,800	174,106.50
2002	94,300	100,042.87
2003	94,700	83,885.26
2004	109,800	88,378.02
2005	152,200	122,536.22
2006	37,700	30,054.44
2007	192,200	140,459.76
2008	18,400	12,576.4
2009	108,000	77,652
2010	90,600	68,484.54
Total	1,236,400	1,096,678.53

Source: ID 2154-144

(333) Therefore, the Commission will consider that Teva's total costs related to the development of the Intellectual Property Rights sold to Cephalon by virtue of Article 2.2 of the Settlement Agreement are EUR 1,352,621.11.

4.7.2. Licence to Teva of the Right to Use CEP-1347 Data

(334) Teva needed the licence to CEP-1347 Data in order to obtain the regulatory approvals in the United States, Canada and Australia for its innovative medicine rasagiline (brand name Azilect) in 2006. Teva regarded Azilect as a breakthrough medicine for the treatment of Parkinson's disease.[547] Azilect was approved in the EEA and Israel in 2005.[548]

(335) According to the information obtained from Teva, from the late 1980s through the 1990s, Teva developed and conducted clinical trials for Azilect. By 2005, Teva US was in the process of seeking final approval from the United States FDA to market Azilect. Before granting final approval, however, the FDA raised questions about Azilect's side-effect profile based on the observance of an increased rate of melanoma[549] among patients treated with Azilect. The FDA requested that Teva US conducts further dermatological tests with Azilect patients. A meeting was scheduled between FDA and Teva US for 7 December 2005 to decide whether to approve Azilect following the meeting and, if so, whether Azilect must have a warning label identifying an increased risk of melanoma.[550]

(336) Although Teva conducted the requested tests, those tests were unable to resolve whether the higher incidence of melanoma observed in Azilect patients was caused by the drug or simply reflected the relatively higher prevalence of melanoma in the Parkinson's population generally. Teva learned that Cephalon possessed potentially useful data – the CEP-1347 data – regarding dermatological tests performed on Parkinson's patients. In particular, Teva understood that Cephalon's data might indicate a higher prevalence of melanoma among the Parkinson's disease population, thereby rebutting a causal relationship between Azilect and melanoma, suspected by

547 ID 1330, p. 2.
548 ID 2166-39, p. 84. ID 2166-38, p. 17.
549 The most dangerous type of skin cancer.
550 ID 1330, p. 2 and 4.

the United States FDA, and therefore eliminating the need for the warning label proposed by the FDA.

(337) Teva valued Cephalon's data as "*crucial*" for the regulatory approvals in the United States and Australia. At the same time, Cephalon was the only entity Teva was aware of that conducted dermatological tests on Parkinson's disease patients (in co-operation with [*a company*][551]). Teva knew about no-one else who would have used proactive monitoring of melanoma in the Parkinson's disease population.[552]

(338) Teva also did not contemplate to conduct its own clinical study as such a study could not have been completed before the scheduled decisive meeting on 7 December 2005 with the FDA.[553] In fact, Cephalon's clinical study had taken more than one year and involved about 800 early Parkinson's disease patients.[554] Also, from Teva's ex ante point of view, the outcome of such an own study was uncertain, giving no warranty that FDA would approve Azilect.

(339) Within this context, Teva approached Cephalon about acquiring the CEP-1347data in August 2005 through [*a company*] (that had been Cephalon's partner in developing the data). [*a company*] reported to Teva that Cephalon decided not to approve its request.[555]

(340) Teva referred to its exchanges with [*a company*] regarding the CEP-1347 Data in its internal e-mail of 7 November 2005[556]. In this internal e-mail, Teva mentioned that it seemed that earlier, a number of months before August 2005, Cephalon appeared willing to give the data to Teva:

"*Further to our phone conversation I would like to summarize the mentioned above issue. As you know it is impossible to compare the MM* [melanoma] *data from our clinical development of rasagiline to any other anti PD* [Parkinson's Disease] *in the market as none of them used a proactive monitoring for MM. To the best of our knowledge (published information) the Cephalon-* [*a company*] *drug study had a* [dermatological examination] *at screening and after one year.*

This study included about 800 early PD patients and was stopped after an Interim Analysis because of lack of efficacy. The safety data base includes the [dermatological examination] *data and this may be very helpful for us. In the past we asked several times to receive the data to help us with the FDA. lt seemed a few months ago that Cephalon will be willing to give us the data and* [an employee] *from* [*a company*] *asked us to send a letter explaining what is our need. We sent the letter and received through* [the above-mentioned […] employee] *a negative response.*

Currently these data is crucial not only for the FDA but also for Australia (a [*a company*] *market) as the TGA* [Therapeutic Goods Administration, Australian medicines regulator] *is going to reject our submission because of the MM concern. We prepared an answer to the TGA and are willing to meet with the TGA according*

---

551 [*A company*] was Cephalon's cooperation partner in the CEP-1347 project. […]. ID 2166-41, p. 16. Hence, Teva would have obtained the clinical data for the use in Australia from […]. See ID 2166-40, p. 1.

552 ID 2166-40, p. 1.

553 *Ibid*. See also ID 1330, p. 4.

554 ID 2166-40, p. 1.

555 *Ibid*.

556 *Ibid.*

to [*a company*] *request but we do not have any new data so the Cephalon data is crucial.*

We need any help you can give us to convince [[*a company*]] *to convey at least the number of MM observed, as function of patient years in the active and placebo groups.*"[557]

(341) Teva then came back to Cephalon again in late November 2005 (at the start of the negotiations on the Settlement Agreement, see Section 4.5) and indicated that it sought to obtain the data in advance of an important meeting with the FDA scheduled for 7 December 2005.[558]

(342) Teva explicitly told the Commission:

"*After confirming that the data would likely be useful for Teva's scheduled meeting with the FDA, Cephalon took the apparently firm position that it would not provide any data to Teva for its meeting with the FDA until Teva and Cephalon had fully and finally resolved all pending litigation and other issues relating to modafinil. Teva agreed to commence promptly settlement negotiations with Cephalon with a view of resolving all outstanding issues and obtaining access to the CEP-1347 data.*"[559]

And similarly:

"*Teva approached Cephalon to obtain access to clinical data potentially relevant to the approval of an entirely different drug. Cephalon, however, refused to consider providing that data to a litigation adversary. Teva therefore agreed to participate in negotiations to address all outstanding modafinil-related issues with Cephalon, culminating in the* [Settlement Agreement]".[560]

(343) Teva's above recollection is confirmed by Cephalon's General Counsel: "I do recall probably sometime in November [2005] that [[…], President and CEO of Cephalon] told me that he had gotten a call from a Teva executive and that the executive… was interested in seeing if we would be willing to agree to provide consent for them to access and reference the data that we co-owned with [*a company*]. I was told that Teva's general counsel would be interested in speaking with me about trying to reach an agreement on how that might happen."[561] When Cephalon's General Counsel called Teva back, "(A)s best as I can recall… I'm sure I expressed some view about our general unwillingness to enter into some sort of business transaction with firms with whom we are litigating and, if they wanted to try to structure something with us, we were happy to talk with them, but we would need to discuss how we might resolve our dispute over Provigil as well."[562] Asked whether the deadline that Teva was trying to meet relating to the meeting with the FDA created a sense of urgency concerning the need to come to an agreement with respect to the Provigil patent litigation, he replied: "I have told them… that it was my perspective that we wouldn't be able to to reach an agreement on the data if we were going to continue to litigate with them over the patent… My recommendation would be we are not going to enter

557 ID 2166-40, p. 1.
558 ID 1330, p. 2; ID 2151, p. 14.
559 ID 1330, p. 2.
560 *Ibid*, p. 1-2.
561 ID 3694-2, p. 38.
562 *Ibid*, p. 39.

into a transaction regardless of the magnitude if we are litigating, and that was applicable here."[563]

(344) On the other hand, Cephalon's General Counsel at the time of the Settlement Agreement[564] also acknowledged that obtaining access to the CEP-1347 data was important for Teva's agreement to settle the modafinil litigation. When an FTC attorney asked him about the link between the licence to the CEP-1347 data and Cephalon's proposal to settle the modafinil litigation with entry date three years before the expiration of Cephalon's patents, he replied: "*If you rephrase your question and you didn't include any reference to three years, if you just said would they be willing to settle the patent litigation without regard to anything else that we eventually entered into, then I would say they made it clear that they really wanted access to the data. But I don't mean to suggest that there was ever any overt link between settlement of three-years advancement and data or any of the other things. But it was clear that they were very concerned about the data.*"[565] On the following question whether Teva ever gave any indication to anyone at Cephalon that they would have been willing to settle the patent litigation for three years off the statutory term of the patent without entering into any of the other business arrangements, Cephalon's General Counsel replied: "*I think the answer to that question is no. You know, again, with the modest elaboration… at the very least, it's because they were determined to get rights to the data.*"[566] Statements made by the Parties in their Response to LoF do not alter the Commission's account of the facts (ID 3763, points 7-10).

(345) As a result of the negotiations on the Settlement Agreement, on 4 December 2005 (still before the signing of the Settlement Agreement), Cephalon sent Teva the CEP-1347 Data on the basis of a confidentiality agreement, so that Teva could use the data in the meeting with the FDA on 7 December 2005. On 6 December 2005, Teva's employee responsible for Azilect wrote to the negotiating team, including Teva's CEO:

"[Director of Division of Neuro-Pharmacological Drug Products with the FDA] *told us after reviewing all the documents… He believes that the Cephalon data is very important and may change the FDA request to post approval… The new data is the first and only breakthrough in all this saga… We are here so impressed with the whole process that resulted in this almost impossible achievement of receiving the data before the meeting*!".[567]

(346) The same employee reported on 8 December 2005, one day after the FDA meeting:

"*The outcome of the meeting was very positive… and I have no doubt that the data submitted was very instrumental in reaching this end and I do not think we could*

---

563 *Ibid*, p. 41.

564 At the time of this testimony, on 15 December 2010, […] was no longer Cephalon's General Counsel. The Decision will nevertheless refer to him as to Cephalon's General Counsel, for the sake of simplicity.

565 ID 3694-3, p. 32-33.

566 *Ibid*, p. 31-32.

567 ID 2166-90.

have reached this outcome without the data. I understand that we can use the data also to help us with the same issue in Canada and Australia…".[568]

(347) Following the meeting with the FDA, which Teva attended equipped with Cephalon's CEP-1347 data, Teva United States' CEO reported to the Teva's Board of Directors: "*In the US, we had an excellent meeting two weeks ago with the FDA, and we feel increasingly optimistic that we are moving toward a final approval* [of rasagiline]."[569]

(348) Azilect became available in the United States in 2006 (FDA approval on 16 May 2006).[570] The following table summarizes the main Azilect's sales parameters in the United States since its launch in 2006 until 2014.

Table 7: Azilect sales parameters (in thousands USD)

	2006	**2007**	**2008**	**2009**	**2010**
Net sales	17,260	51,828	58,787	89,423	118,450
COGS[571]	1,742	5,230	5,932	8,224	8,503
Gross profit	15,518	46,598	52,854	81,198	109,947
	2011	**2012**	**2013**	**2014**	**–**
Net sales	151,414	168,481	194,196	230,241	–
COGS	7,502	7,836	9,482	10,748	–
Gross profit	143,911	160,646	184,713	219,493	–

Source: ID 2189

(349) The active pharmaceutical ingredient in Azilect, rasagiline, is protected in the United States in particular by the United States patent 5,453,446. Teva filed the patent application on 7 June 1994 so that the patent term was initially to expire in 2014. However, Teva subsequently filed an application for a patent term restoration with the PTO which was granted and the protection term of the patent was extended until 7 February 2017.

4.7.3. Modafinil API Supply Agreement

(350) The Modafinil API Supply Agreement stipulated that Cephalon would purchase from Teva between 2007 and 2011 at least 50,000 kg of modafinil API.[572] Based on the contracted mark up of 30% over the manufacturing costs, Cephalon paid to Teva the aggregate amount of USD 30,589,177.50 (approximately EUR 21,705,000).

---

568 ID 2166-92, p. 1.
569 ID 2151, p. 13.
570 See also SO, Recital 694.
571 Costs of goods sold. They represent the costs directly attributable to the production of the goods sold by a company.
572 See Section 4.6.3.4.

(351) Cephalon alleges that the goal of the Modafinil API Supply Agreement was to secure modafinil API supplies at a time when its modafinil needs were expected to increase significantly due to expected new products Nuvigil and Sparlon (and the magnitude of the increase was uncertain, adding to the risk and complexity of supply planning).[573] In particular, the projections in 2005 indicated that Cephalon could be faced with a modafinil API shortage, and there was a risk of manufacturing or other (such as labour) problems at Cephalon's single outside supplier ([*contract manufacturer*]) or its own production facilities in France (Mitry-Mory).[574]

(352) In order to assess the rationale and the content of the Modafinil API Supply Agreement, the Commission considers the following: (a) Cephalon's sourcing of modafinil API before the Settlement Agreement (Sections 4.7.3.1 - 4.7.3.3), (b) Cephalon's modafinil API supply capacity and demand estimates for 2006-2008 showing that existing supply capacity was sufficient to meet the API demand for 2006-2008 (Sections 4.7.3.4 - 4.7.3.6), (c) Cephalon's consideration to launch request for proposal for modafinil API in 2005 (Section 4.7.3.7), (d) Cephalon's contacts with Plantex before the Settlement Agreement (Section 4.7.3.8), (e) prices paid to Plantex compared to other supply sources were considerably higher (Section 4.7.3.9), and finally (g) Cephalon's overproduction of modafinil API and need for termination of the [*contract manufacturer's*] supply and closure of the Mitry-Mory facility (Section 4.7.3.10).

4.7.3.1. Cephalon's sourcing of modafinil API

(353) Until 2005, Cephalon covered all its requirements for modafinil API exclusively from its own manufacturing facility in Mitry-Mory, France ("Mitry-Mory"), more precisely from the Mitry-Mory's C-1 plant. In 2005, Cephalon sourced API modafinil internally and from [*contract manufacturer*], its secondary supplier appointed in 2005 in case there were "*supply disruptions from Mitry-Mory*"[575].

(354) In 2005, the total modafinil API supplies to Cephalon were […] kg (32,550 kg from Mitry-Mory's C-1 and […]kg from [*contract manufacturer*]).[576]

(355) As regards the manufacturing costs in Mitry-Mory plant, Cephalon informed the Commission that the costs increased between 2002 and 2005, from EUR 241/kg (2002) to EUR 306/kg (2005).[577] This is in contradiction with Cephalon's internal document of 13 January 2006 where Cephalon indicates that the "*consolidated cost of Orsymonde Modafinil*" is approximately USD 172/kg, which is approximately

---

573 See SO Reply, p. 84.

574 ID 1436, p. 4. See also ID 1723, p. 3, and ID 1726, p. 15.

575 ID 196, p. 5. [*contract manufacturer*] is also mentioned as a second source of modafinil API, available from 2nd quarter 2004, in Cephalon's internal presentation of 16 October 2003, ID 688, p. 13.

576 ID 1432. According to information from [*contract manufacturer*], the supplied quantity in 2005 was […] kg ID 1805, p. 57. The difference may be possibly explained by different accounting. For example, in its information for the Commission, Cephalon indicates no supplies in 2004, however the combined supplies for 2004 and 2005, as indicated to the Commission by [*contract manufacturer*], arrive approximately at […] kg. Or, the combined supplies for 2005-2006, as indicated to the Commission by both Cephalon and [*contract manufacturer*], make together approximately […] kg.

577 ID 1432.

EUR 138/kg. The Commission assumes the latter to be the real costs (as also expressed by the word "*consolidated*").[578]

(356) Cephalon had also plans to expand capacity at Mitry-Mory plant, since the C-1 plant was already about 30 years old, deemed outdated and not providing enough capacity for the growing modafinil business.[579] Cephalon decided to expand Mitry-Mory by a new manufacturing facility C-2: "*In 2002, the sales forecasts in the US market, the steady increase in sales in the European market, as well as the Sparlon project led the group to an investment of EUR 32 million in Mitry-Mory into a construction of a new production facility…*"[580] Cephalon did not plan to immediately replace the C-1 plant by C-2 but rather to increase the overall manufacturing capacity of Mitry-Mory by adding the new C-2 plant to the already existing C-1.[581]

(357) In its 2004 annual report, Cephalon announced the completion of the construction of the new facility in Mitry-Mory and stated: "*This new state-of-the-art facility significantly increases our capacity to manufacture modafinil and other active drug ingredients. The facility also enables us to prepare for production of Nuvigil (armodafinil) and will allow greater control over our entire manufacturing and supply systems.*"[582]

(358) Cephalon planned to start commercial manufacturing in the C-2 facility in the second half of 2006.[583] FDA approved C-2 for modafinil API supplies in August 2006.[584]

(359) The whole Mitry-Mory, including the newly built C-2 plant, was designed to have a total manufacturing capacity of 100,000 kg of modafinil API per year.[585] This was

---

578 While the information giving much higher costs (EUR 241-306) is based on a pure assertion by Cephalon, the lower cost indication supported by Cephalon's contemporary internal document. In addition, the lower price is also much closer to prices paid by Cephalon to [*contract manufacturer*] and prices negotiated with [*potential contract manufacturer*].

579 ID 196, p. 5.

580 ID 1604, p. 3, translation from French. Original text: "*En 2002, les prévisions de ventes sur le March é US, l'augmentation régulière des ventes sur le March é européen, ainsi que le projet Sparlon a amené le groupe à investir 32 millions € sur le site de Mitry-Mory pour la construction d'une nouvelle zone de production,(…)".* See also ID 2201, p. 11.

581 ID 3694-11, p. 34.

582 Cephalon 2004 annual report, ID 2760, p. 16.

583 Cephalon's internal e-mail of 28 November 2005, ID 1583, p. 1 indicates that the C-2 facility should be operational in the 3rd quarter of 2006. See also the presentation for Technical Operations Executive Committee Meeting of 13 January 2006, ID 2010-32, p. 5 and 14 that assumes 1 October 2006 as start of C-2 commercial operations. According to Procès–verbal de la reunion du Comité central d´entreprise de Cephalon France du 18/09/2008, ID 1604, p. 3, the C-2 facility was completed and successfully tested by the FDA in 2005. This is in line with the information given in March 2004 by Cephalon to a [*potential contract manufacturer*] (a potential modafinil API supplier, see Section 4.7.3.3) which indicated that the qualification process of C-2 should have occurred in course of 2004 (installation qualification and operational qualification in July 2004 and validation batches in the 4th quarter 2004). ID 1807, p. 2. Cephalon's e-mail of 28 December 2005, ID 1570, p. 2 mentions the start of manufacturing in C-2 in 2007. This seems to be in contradiction with the above mentioned evidence that supposes C-2 start in the second half of 2006, but would nevertheless have no impact on the Commission´s assessment (see Section 6.6.1).

584 ID 1723, p. 6. The approval by the United States regulatory agency was necessary because the modafinil API manufactured in Mitry-Mory was used for finished medicines sold also in the United States. Cephalon in its reply to the Article 18 Request of 24 June 2013 indicated only the date of C-2's approval for the United States and not for the EEA. The qualification of C-2 for the United States market was decisive for Cephalon because more than 95% of the modafinil product was sold there and hence the appropriate volumes of the modafinil API were required for the United States.

confirmed also later, when, for example, Cephalon's associate director for production planning estimated on 27 February 2006 the potential modafinil supply from Mitry-Mory for 2007 and 2008 at up to 111,000 kg per year (consisting of up to 37,000 kg from the C-1 plant and up to 74,000 from the C-2 plant).[586]

(360) Cephalon selected [*contract manufacturer*] as its secondary modafinil API supplier as a result of a request for proposals in 2003. Since [*contract manufacturer*] did not develop its own modafinil manufacturing process, Cephalon transferred the technology to [*contract manufacturer*] (see Section 4.7.3.2).[587] According to the API supply agreement between Cephalon, […] (" [*contract manufacturer*] Supply Agreement"), [*contract manufacturer*] agreed to maintain annual capacity of up to […] kg/year of the API to be delivered to Cephalon during 2004-2007, though its capacity was substantially higher.[588] The initial term of the [*contract manufacturer*] Supply Agreement was three years, and the Agreement was set to be renewed always by two years, unless either of the parties gave a one-year notice.[589] As for the [*contract manufacturer*] prices, Cephalon paid EUR […] per kg in 2005.[590]

(361) According to Cephalon's long-term planning discussed at the end of 2005, the majority of the modafinil API supplies were to be sourced from the C-2 facility upon its completion, including all modafinil supplies for the final products marketed in the EEA (see Recital (396)).

(362) Furthermore, in view of the planned launch of second-generation armodafinil-based Nuvigil and modafinil ADHD medicine Sparlon (see Section 4.2.3), in the second half of 2004, Cephalon concluded armodafinil supply agreements with three companies: [*armodafinil supplier 1*],[591] [*armodafinil supplier 2*][592] and [*armodafinil supplier 3*].[593] The initial terms of the supply agreements were 2004-

---

585 ID 688, p. 12. See also ID 1807, p. 1.

586 ID 2010-24, p. 1. See also the reported conversation between Cephalon and [*potential contract manufacturer*] in March 2004 where Cephalon mentioned Mitry-Mory's expected annual capacity of 100 tons of modafinil, Section 4.7.3.3.

587 See also ID 1805 p. 5; SO Reply, paragraphs 335-336.

588 Article 3.1 in connection with Schedule C of the [*contract manufacturer*] Supply Agreement (ID 1727).

589 Article 16.1 of the [*contract manufacturer*] Supply Agreement (ID 1727).

590 ID 1432. This seems to be in line with the information on average selling price in 2005 communicated to the Commission by [*contract manufacturer*] as […] […]/kg (approximately EUR […] based on the average reference exchange rate indicated by the European Central Bank). [*contract manufacturer's*] reply to the Article 18 Request of 24 July 2013, Annex 4-Quantities of modafinil sold and prices per kilogram, ID 1805, p. 56-58. See also [*contract manufacturer*] Supply Agreement, Schedule D – Purchase Price, ID 1727, p. 25, where the price is defined on the sliding scale […]/kg as inverse function of the supplied quantity, that is to say that the price was falling with increasing volumes supplied (approximately EUR […] according to the exchange rate published by the European Central Bank).

591 The API Supply Agreement of 24 February 2004 was concluded between Cephalon and , [*armodafinil supplier 1*] but the armodafinil was produced by […]. See ID 1834, p. 10 and subsequent and 1803, p. 1.

592 The API Supply Agreement of 10 August 2004 between Cephalon and [*armodafinil supplier 2*], ID 2336.

593 [*armodafinil supplier 3*], the […], replied to the Article 18 Request that due to passage of time they were not able to identify the API Supply Agreement. [*armodafinil supplier 3*] involvement in the armodafinil manufacturing for Cephalon is however confirmed in Cephalon's internal documents, see, for example, ID 1569, p. 1 or ID 1585, p. 1, as well as documents provided by [*armodafinil supplier 2*] (see, for example, ID 2325, p. 4).

2007.[594] Cephalon would supply the racemate modafinil needed for the production of armodafinil to its armodafinil contract suppliers at no cost (Art. 2.2 of the [*armodafinil supplier 1*] Supply Agreement and Art. 2.2 of the [*armodafinil supplier 2*] Supply Agreement).

4.7.3.2. Technology transfer, qualification and validation of [*contract manufacturer*]

(363) According to the SO Reply, [*contract manufacturer's*] history with Cephalon was short and inconsistent, and its long-term reliability uncertain.[595]

(364) The Parties explain that Cephalon expected that it would take about 18 months to transfer the relevant technology and know-how to [*contract manufacturer*] and receive the necessary regulatory approvals. Cephalon began transferring the relevant technology and know-how to [*contract manufacturer*] in early 2003. However, [*contract manufacturer's*] API was first used commercially by Cephalon in mid-2005, one year behind the plan.[596] The Parties explain that although the FDA approved [*contract manufacturer*] modafinil API for use in Provigil on 14 March 2005, Cephalon did not authorize the use of [*contract manufacturer*] API in its modafinil products until about August-September 2005, after the revalidation was completed.[597] The long period it took to transfer of Cephalon's manufacturing process to [*contract manufacturer*] was costly to Cephalon.[598]

(365) The Commission notes that other evidence on file shows that Cephalon was responsible for the above-mentioned problems with the modafinil technology transfer. Cephalon's Vice-President for Global Manufacturing admitted in a deposition made with the FTC in 2011 that the delay originated on Cephalon's side, in Mitry-Mory (also called Orsymonde). The Vice-President, who joined the company in December 2003 and supervised the team charged with the transfer of technology, wrote in an e-mail of 14 January 2005 to Cephalon's Executive Vice-President for Technical Operations: "*I truly believe that Cephalon has been bordering on being 'unprofessional' in our workings with Orsymonde. This began with the transfer from Orsymonde, their lack of support of control to the tech transfer process and continues today from a* [manufacturing] *and quality perspective. I have never seen contracts and* [quality technical agreements] *take over a year to negotiate!*"[599] The author of this e-mail explained to the FTC on 12 January 2011 that the "unprofessionalism" involved *"the transfer of DSAM and modafinil to the* [*contract manufacturer's*] *site, and that transfer was initiated and managed totally by the Orsymonde manufacturing site and the R&D… they had not provided timely information on the product transfers, on process information to help them with the transfer, and they did not I believe had contracts in place and something called the*

---

[594] See Art. 2.5 of the [*armodafinil supplier 1*] Supply Agreement, ID 1834, p. 13; Article 19.1 of the [*armodafinil supplier 2*] Supply Agreement, ID 2336, p.21.

[595] SO Reply, paragraph 335.

[596] SO Reply, paragraph 336.

[597] The Parties explain that after Cephalon's scientists found an impurity in one of the samples that [*contract manufacturer's*] had supplied for the purpose of applying for the FDA approval, Cephalon initiated a production process improvement program with [*contract manufacturer's*], which led to revalidation of the entire production process; ID 1723, p. 7.

[598] SO Reply, paragraphs 335-336. See also Response to the LoF, points 23-25 (ID 3763).

[599] ID 3694-11, p. 39-40.

quality technical agreement which is from the quality organization. These are things that would normally be done very early on."[600]

(366) Cephalon's Vice-President for Global Manufacturing further specified: "*We have committed volumes* [for supply of modafinil API and DMSAM] *to them* [[*contract manufacturer*]], *given them firm forecasts* [for production] *and not submitted purchase orders*. *Several* [*contract manufacturer's*] *staff have approached me 'off the record' on how to improve the manufacturing and quality relationship. These issues continue to put me in an awkward position with them from a technical perspective. I really believe there is a total lack of leadership with this regard.*"[601] In the next paragraph of the e-mail, he refers to "*the absurd meeting we had yesterday*" [with [*contract manufacturer*]], the "absurdity" being caused by Orsymonde. The e-mail ended: "*It is clear to me that Cephalon does not have depth in the* [Chemistry, Manufacturing and Controls] *development experience*."[602] In sum, according to Cephalon's Vice-President, the technical team in Mitry-Mory "*was not living up to the expectations*" of Cephalon and [*contract manufacturer*], "*they weren't doing a good job, so* [*contract manufacturer*] *was looking for help from the US group… They* [[*contract manufacturer*]] *were looking to get the project moving again. The project had stalled*" as a result of Cephalon's people.[603] It took "*at least a year*" to correct the problems, including removing Mitry-Mory's staff from their positions or terminating their employment.[604]

(367) In November 2005, after the completion of the technology transfer and approval of [*contract manufacturer's*] product by FDA, Cephalon presented [*contract manufacturer*] with an Excellence and Partners in Growth Award congratulating it for its professionalism regarding the technical transfer of modafinil.[605] Cephalon's employees, expressed, at the time of the technology transfer, high esteem for [*contract manufacturer's*] professionalism. On 14 March 2005, the day of FDA approval of [*contract manufacturer's*] modafinil API, Cephalon's Vice-President for Global Manufacturing wrote to its counterparts in [*contract manufacturer*]: "*The entire* [*contract manufacturer*] *team has been a great support to Cephalon and certainly serves as a model for a working partnership*."[606] In this regard, Cephalon's Director of Regulatory Affairs wrote after the FDA approval for [*contract manufacturer's*] modafinil: "*I want to thank everyone involved, especially our* [*contract manufacturer*] *colleagues… who helped to make these quality submissions to the FDA… I can personally attest to the cooperation, communication and professionalism of our* [*contract manufacturer*] *colleagues in working on the DMSAM and modafinil DMFs*."[607] On 19 August 2005, this Vice-President addressed to Cephalon's Executive Vice-President for Worldwide Technical Operations and to Cephalon's head of finance an internal e-mail in preparation of an upcoming visit by [*contract manufacturer*] to Cephalon: "*They* [[*contract manufacturer*]] *are currently approved for modafinil supply and have been a good*

600 ID 3694-11, p. 39-40.
601 *Ibid*, 40-41.
602 *Ibid*, 41.
603 *Ibid*, 40-41.
604 *Ibid*, 40.
605 ID 3694-11, p. 43.
606 ID 3694-13, p. 25.
607 ID 3694-13, p. 25.

partner."[608] At the beginning of January 2006, Cephalon's Vice-President for Global Manufacturing together with its senior director for process development drafted a background memorandum on [*contract manufacturer*] for Cephalon's Chief Financial Officer. The memorandum summarised: "*Our experience with* [*contract manufacturer*] *has been uniformly positive delivering what I consider superb responsiveness to Cephalon's needs and exhibits a flexibility to deal with both the challenges and opportunities of Cephalon's aggressive and opportunistic style.*"[609]

(368) The above evidence, in particular the approval of [*contract manufacturer*] as modafinil API supplier by the FDA (qualification) and Cephalon's internal approval of [*contract manufacturer's*] material (validation), demonstrates that, at the time of the technology transfer, Cephalon considered [*contract manufacturer*] as reliable and professional partner. Technical problems during the technology transfer, causing delay with bringing commercial product onto the market, were caused not by [*contract manufacturer*], as suggested in the SO Reply, but by Cephalon's French subsidiary Mitry-Mory.

(369) The SO Reply also mentions several problems with modafinil production allegedly caused by [*contract manufacturer*]. In one case, [*contract manufacturer*] […].[610] The SO Reply also refers to another manufacturing-related issue concerning [*contract manufacturer's*] […].[611] The Commission notes that the Parties did not support the above allegations by any evidence. In addition, Cephalon's Vice-President for Global Manufacturing acknowledged that Cephalon has never suffered from any shortages in Provigil tablet production attributable to the alleged [*contract manufacturer's*] supply shortages or, that the alleged difficulties with [*contract manufacturer*] did not affect Cephalon's ability to meet demand for Provigil tablets (but purportedly affected Cephalon's inventories).[612] Also, the Vice-President did not indicate whether the problems with [*contract manufacturer*] were in any way significant or out of ordinary.[613]

(370) As a general matter, according to [*contract manufacturer's*] reply to the Commission's Article 18 Request, "During the API Supply Agreement [with [*contract manufacturer*]], the relationship between […] [[*contract manufacturer*]] and Cephalon was good and we are not aware of any problems from both sides." Also, "During all the supply relationship, Cephalon never expressed to us its intention to change or to select an additional modafinil API supplier to its existing ones."[614]

---

608 ID 3694-11, p. 42.

609 ID 3694-11, p. 45.

610 SO Reply, paragraph 336.

611 SO Reply, paragraph 336; ID 1723, p. 7.

612 ID 3694-13, p. 24.

613 *Ibid*, p. 23.

614 ID 1805, p. 7. Contrary to the statements made in the Parties' Response to the LoF (ID 3763, points 27-29), the Commission does not rely on the [*contract manufacturer's*] response to the Article 18 Request of 24 July 2007 to establish Cephalon's demand needs and other supply sources. [*contract manufacturer's*] statements referred to in this Recital confirm, from [*contract manufacturer's*] perspective, the statements made by Cephalon on viability and reliability of [*contract manufacturer*] as a modafinil supplier (see Recitals (366) - (368)).

4.7.3.3. Cephalon's negotiations with [*potential contract manufacturer*]

(371) [*potential contract manufacturer*], a […] company, was between 2002 and 2006 in regular contact with Cephalon concerning contract manufacturing of modafinil API and/or its intermediates for Cephalon.

(372) At the time of the Settlement Agreement, [*potential contract manufacturer*] was already manufacturing for Cephalon […], an API for Cephalon's […].

(373) According to [*potential contract manufacturer*], it submitted offers for contract manufacturing services with regard to modafinil-related products on four occasions, each time upon request by Cephalon.[615] In 2002, it submitted an offer for […], in which [*potential contract manufacturer*] also mentioned its interest in supplying Cephalon with modafinil API: […][616]

(374) [*potential contract manufacturer*] submitted its first formal offer for the manufacture of modafinil API in 2003 (revised early 2004)[617]. The revised offer stated: […]*:*

Annual quantity [kg]	**Price [€/kg]**
[…]	[…]
[…]	[…]
[…]	[…]

[…][*618*]

(375) However, at a meeting of 16 January 2004, Cephalon told [*potential contract manufacturer*] that the modafinil project "is not a very high priority with Cephalon. Their current source, which is manufactured by their French facility, is building additional capacity which will come on line in 2004 and an additional outside source is currently running a validation campaign."[619]At a meeting on 23 March 2004, Cephalon again referred to the modafinil API sources that it was already building, specifying that Mitry-Mory's capacity "is expected to be 100 tons of Modafinil".[620] It clarified that its potential interest in adding [*potential contract manufacturer*] as an additional supply source depended on its plan to launch the second-generation product Nuvigil. This envisaged launch was in turn contingent upon the court ruling in the litigation over the validity of Cephalon's modafinil patent.[621] On 30 August 2005, [*potential contract manufacturer*] repeated to Cephalon the earlier offer (see Recital (375).[622]

---

615 ID 1822, p. 3.

616 ID 1816.

617 ID 1817.

618 ID 1820. The first formal offer of 4 September 2003 proposed a slightly higher prices ([…]) and mentioned that "*Samples of DMSAM and Modafinil have been prepared in excellent yield and quality.*" ID 1817.

619 ID 1821, p. 2.

620 ID 1807, p. 1.

621 *Ibid*, p. 1.

622 ID 1579, p. 1. See also ID 1822, p. 3 and ID 1824. The last formal offer for the manufacture of modafinil API came from [*potential contract manufacturer*] on 24 July 2006, ID 1811. […] (Reply to LoF, ID 3763, point 16 and ID 3694-13, page 35). However, the reasons for termination of the

(376) During the interrogation by the United States FTC in June 2007, Cephalon's Vice-President for Global Manufacturing confirmed: "*We were working towards* [signing a supply agreement with [*potential contract manufacturer*]]. [*potential contract manufacturer*] *had already been part of the early RFP process that was done by France, and they were familiar with the process.*"[623] (See in this regard also Section 4.7.3.7)

4.7.3.4. Cephalon's supply capacity as from 2006

(377) In the forecast of 13 January 2006, Cephalon estimated the capacity of its existing suppliers on 146,400 kg of modafinil production in 2006, assuming FDA´s approval for C-2 manufacturing plant by 1 October 2006:[624]

Table 8: Forecast supply capacity

Plant	**Volume**
C-1	37,000 kg
C-2	29,400 kg
[*contract manufacturer*]	[…]
Total	[…]

Source: ID 2010-32, ID 2010-45 and ID 1805

(378) The above figures concerning the manufacturing capacity of Mitry-Mory were consistent with Cephalon's earlier calculations.[625] As for [*contract manufacturer*], in September 2005, Cephalon estimated that it could provide […] kg of modafinil API, significantly higher than the […] kg capacity reserved to Cephalon under initial agreement (Recital (361)).[626] Already in November 2001, Cephalon internally assumed that [*contract manufacturer*] could produce about […] kg of modafinil API annually: "*I believe that* [*contract manufacturer*] *is currently planning to deliver* […] *kg in each of Q1 and Q2… If they can manufacture at this rate for the entire year, they would be able to deliver about* […] *kg. If we ask them to double their production, they should be able to produce what we need.*"[627]

---

negotiations with [*potential contract manufacturer*] after the Settlement Agreement do not affect the Commission's conclusions regarding the Cephalon's contemplated RFP for modafinil supplies, the prices offered by [*potential contract manufacturer*] during the negotiations or reliability of [*potential contract manufacturer*] as a potential supplier (see Section 6.6.1.4). [*potential contract manufacturer's*] only offer that resulted in actual business with Cephalon was the quotation for the […]. […]. ID 1822, p. 3. See also ID 3694-13, p. 35.

623 ID 3694-13, p. 35.

624 ID 2010-32, p. 5.

625 ID 2010-45, p. 10; ID 1569, p. 1; ID 1567, p. 1; ID 1586, p. 1-2. ID 1583, p. 2. See also Section 4.7.3.1, explaining the forecasted increase of the C-2 plant capacity in 2007 and 2008 of up to 74,000 kg.

626 ID 2010-45, p. 10: "*2006 Volume Discussions – Estimate total requirements is 100 Tons of modafinil for 2006. C-1 can make 35 Tons of modafinil. Estimate* […] *Tons of modafinil from* [*contract manufacturer*]." In the e-mail of 21 November 2005, ID 1569, p. 1, Cephalon attributed to [*contract manufacturer*] modafinil requirements in the amount of […] kg.

627 ID 1569, p. 1.

(379) When, following the peak API requirements estimate of November 2005,[628] Cephalon asked [*contract manufacturer*] whether it had sufficient capacity to supply […] kg of modafinil API in 2006, [*contract manufacturer*] confirmed on 2 December 2005 that it could support these extra requirements. Moreover, [*contract manufacturer*] suggested that it would have a production capacity of up to […] kg of modafinil API in 2007 should Cephalon require this. [*contract manufacturer*] suggested that from 2007 on the target price would be below EUR […].[629] [*contract manufacturer's*] confirmed production capacity of […] tons annually was later included by Cephalon in its capacity planning.[630]

(380) As from 2007 onwards, the supply capacity of Cephalon's existing sources would increase massively:

(a) Mitry-Mory's final capacity was set at approximately 110,000 kg of modafinil API a year, after the start of commercial manufacturing at the C-2 facility in 2006.[631]

(b) On 2 December 2005, [*contract manufacturer*] confirmed to Cephalon (upon Cephalon's request) that it could supply Cephalon with […] kg of modafinil in 2006 and with […] kg of modafinil from 2007. This was in line with Cephalon's internal expectations of November 2005 that [*contract manufacturer*] should be able to produce approximately […] kg of modafinil annually.[632]

(381) Furthermore, Cephalon could have considered supply by [*potential contract manufacturer*]. In 2003, [*potential contract manufacturer*] offered to Cephalon modafinil API supplies in volumes "considerably higher" than […] kg, within one year from the conclusion of a supply contract.[633]

4.7.3.5. Cephalon's API modafinil demand estimates for 2006-2008

(382) Cephalon's estimates for its 2006 modafinil requirements made between June and November 2005 fluctuated, driven by Cephalon's uncertainty whether the generic modafinil would or would not enter the market as soon as in June 2006.[634] The highest requirements estimate was made on 21 November 2005 and envisaged possible maximum modafinil API requirements of up to 148,500 kg[635] (due to plans to expand armodafinil production and to increase Sparlon volumes[636]). This scenario assumed the following product-specific requirements:

---

628 See Section 4.7.3.5.

629 ID 1805, p. 68-69.

630 ID 2010-24, p. 1.

631 As from 2007, C-1's forecast capacity was 37,000 kg annually and C-2's forecast capacity 74,000 kg annually. See Recitals (360), (378).

632 See Section 4.7.3.1. According to [*contract manufacturer*] Supply Agreement of 4 November 2004, [*contract manufacturer's*] minimum annual capacity was […] kg/year of modafinil API.

633 See Section 4.7.3.3. Cephalon refused [*potential contract manufacturer's*] offer with the explanation that it had sufficient modafinil supplies (and that this occurred at the time when Cephalon already was developing its Nuvigil and Sparlon projects).

634 See also Sections 4.2.2, 4.2.3.

635 ID 1569.

636 ID 1585, p. 1.

– Provigil: 11,000 kg (which could go as high as up to 21,000 kg if Cephalon did not face generic competition on Provigil in June 2006)[637];
– Nuvigil: 70,500 kg;
– Sparlon: 57,000 kg.[638]

(383) The largest portion of the 21 November 2005 estimate was attributed to the manufacturing of Nuvigil (70,500 kg).[639] This is because Cephalon considered, in its strategic options developed in 2005, to counter the possible market entry of generic modafinil by early launch of Nuvigil. The conclusion of the Settlement Agreement (and the other settlements negotiated at the same time, see Section 4.8.1.3) would however result in postponement of the Nuvigil launch and a decrease in the respective modafinil requirements overall, and for Nuvigil in particular.

(384) The revised calculations of the end of December 2005 and of the beginning of January 2006 (following the conclusion of the Settlement Agreement) for the year 2006 made this clear:

Table 9: API requirements forecast for 2006

Product	Estimate 28 December 2005	Estimate 13 January 2006
Nuvigil	36,000 kg (high side forecast)[640]	56,000 kg
Provigil	22,000 kg	22,000 kg
Sparlon	57,000 kg	57,000 kg
Total	115,000 kg	135,000 kg

Source: ID 1570 and ID 2010-32

(385) The API requirements for Provigil production rose to 22,000 kg which should ensure sales of Provigil of approximately USD 700 million in 2006[641] provided that there was a full year of production without generic competition[642] (as later confirmed by reality).[643]

(386) In a document drafted by Cephalon's Technical Operations team (in charge of global API supplies) in April 2008, Cephalon noted that: "[I]*n 2005/2006 period, the total requirement for Modafinil was estimated at over 120 MT (depending on marketing*

637 Ibid. See also ID 1569, p. 1

638 ID 1585, p. 1.

639 *Ibid*.

640 As indicated by Cephalon (ID 1570, p. 4). These maximal requirements for modafinil were based on the assumption of the launch of Nuvigil in February 2006 (11-months shipments worth of USD 262 million). Alternative work assumption for Nuvigil-related requirements was a launch in May 2006 which would decrease the requirements by at least 40% (8-months shipments worth of USD 158 million). Ibid., p. 5. Also the requirements needed for manufacturing of Provigil and Sparlon were calculated on the "high side" forecasts). See ibid., p. 3-5.

641 ID 1570, p. 3 and 4. ID 2010-32, p. 6.

642 ID 1570, p. 4.

643 In 2006, in the environment without generic competition, Cephalon achieved total worldwide sales in the amount of USD 734,831,000. See ID 2203, p. 53.

scenarios). This volume was based on the requirements of the following products: Provigil, Sparlon, Nuvigil."[644]

(387) As regards the modafinil API supply estimates for 2007, Cephalon assumed on 28 December 2005 total requirements of 146,400 kg. The break down in product specific requirements is as follows:

– Nuvigil: 45,000 kg;
– Provigil: 26,400 kg;[645]
– Sparlon: 75,000 kg.[646]

(388) Another 2007 estimate dated 27 February 2006 arrived at a lower total demand figure of 121,000 kg (the potential requirements for Provigil went up to 33,000, while requirements of modafinil devoted to Nuvigil fell to 28,000 kg).[647] A forecast of 18 May 2006 indicated even lower total modafinil requirements of 117,000 kg.[648]

(389) As regards the modafinil API requirements for 2008, the forecast of 27 February 2006 estimated total modafinil requirements of 137,000 kg, with the following breakdown:

– Nuvigil: 5,000 kg;
– Provigil: 39,000 kg;
– Sparlon: 93,000 kg.[649]

(390) A presentation of 17 May 2006 by Cephalon's Technical Operations team for the Board of Directors set the total supply needs in 2008 at approximately 160,000 kg:

– Nuvigil: 20,000 kg;
– Provigil: 40,000 kg;
– Sparlon: 100,000 kg.[650]

(391) The above-cited Cephalon's demand and supply forecasts for 2006-2008 (Sections 4.7.3.4 - 4.7.3.5), made at several points in time in 2005 (before concluding the Settlement Agreement) and in 2006, support the finding that Cephalon's existing modafinil supply chain significantly exceeded the expected demand for its modafinil-based, both existing and pipeline products.

644 ID 196, p. 5.
645 The API requirements for the production of Provigil were based on a "*rough estimate*" of annual sales of Provigil of USD 840 million. This "*rough estimate*" assumption was in line with post-Settlement Agreement reality. In 2007, in the environment without generic competition, Cephalon achieved total worldwide sales in the amount of USD 852,047,000. See ID 2203, p. 53.
646 ID 1570, p. 5.
647 ID 2010-24, p. 1.
648 ID 2166-16, p. 1.
649 ID 2010-24, p. 1.
650 ID 709, p. 6.

Table 10 Cephalon's demand and supply estimates (kg/year) for modafinil API in 2006-2008

	Demand	**Available supply**	**Supply sources**
2006	115,000 - 148,500	[*approx demand*]	Mitry-Mory, [*contract manufacturer*]
2007	117,000 – 146,000	[> *demand*]	Mitry-Mory, [*contract manufacturer*]
2008	137,000 – 160,000	[> *demand*]	Mitry-Mory, [*contract manufacturer*]

4.7.3.6. Cephalon's further internal documents show that supply capacity was sufficient

(392) In an internal presentation of 12 October 2005 (and updated on 11 November 2005) including a "*Supply Chain Summary*", Cephalon saw "*No practical constraint on modafinil production volume.*"[651]

(393) In a conversation from 28-29 December 2005, three weeks after the conclusion of the Settlement Agreement, Cephalon's supply manager stated that "*based on the increased input from* [*contract manufacturer*] *and Orsymonde* [that is Mitry-Mory] *we will be able to support the modafinil needs for all 3 products* [that is Provigil, Nuvigil and Sparlon]… *My concern is for the short term (next couple of months) and suggesting that we slow down (stop) R-modafinil production for 2-3 months to build up some Modafinil supply to support any increases to Provigil and Sparlon.*"[652]

(394) This view was confirmed on the same day by another Cephalon manager in charge of modafinil supplies:[653] "*We will be able to support all 3, but the large* [simulated moving bed][654] *will only be able to run to the extent of C2 output in Q1 and Q2. The issue we are having is balance. The current consumption schedule assumes 100 procent consumption of Modafinil… And we will be hand-to-mouth. If anything changes (e.g. Provigil Samples, increase in Sparlon sales, desire to increase Provigil inventory to higher than 2 months), we won't be in a position to do it. Based on current Nuvigil forecast, it just doesn´t make sense to continue to devote this much Modafinil to R-modafinil conversion when we could be jeopardizing sales in Provigil or Sparlon.*"[655]

(395) Even at the peak of Cephalon's estimates for 2006 requirements in November 2005, Cephalon's employees were confident that [*contract manufacturer*] had sufficient

---

651 ID 194, p. 42. The only supply constraint was identified with regard to armodafinil, as opposed to modafinil, and even here the production volume was "*sufficient for most scenarios*." *Ibid.* The potential armodafinil shortage identified by Cephalon is in line with other evidence on file, see, for example, ID 1587, p. 1 and information given to the Commission by one of Cephalon's contracted armodafinil suppliers, […]. ID 2325, p. 4.

652 ID 1570, p. 1. See also the mention of "*short-term supply constraint of modafinil*" on p. 2.

653 See in this regard also ID 1586, p. 1. The e-mail dated 12 September 2005 compares the costs of the additional production in Mitry-Mory with the costs of purchasing the additional demand from [*contract manufacturer*]. ID 2010-45, p. 10. ID 1583, p. 3-4, and ID 1584.

654 Process of manufacturing of r-modafinil for Nuvigil.

655 ID 1570, p. 1. The same explanation for Cephalon's abandoning the armodafinil supply arrangement was identified by [*armodafinil supplier 2*] in its later analysis, see Section 4.8.1.4.

capacity to satisfy, along with Mitry-Mory, their API requirements.[656] On 24 November 2005 (three days after the highest forecast for 2006 API requirements had been made),[657] Cephalon Europe´s (owner of Mitry-Mory plant) Director for Supply Chain asked Cephalon's Vice-President for Worldwide Facilities: "*By the way, […] why do you put all the additional Modafinil at* [*contract manufacturer*], *and why do we not try to make more at Mitry. Would be better for the [costs of goods sold] and related earnings.*"[658] The Vice-President made clear that sourcing the API from [*contract manufacturer*] rather than from own in-house manufacturer was only a "*short term sourcing decision*" because "[T]*he only currently approved modafinil sources are C 1 and* [*contract manufacturer*]*… My goal is to get more modafinil from Orsymonde as soon as C 2 is validated and approved…* [W]*e will then reduce quantities to* [*contract manufacturer*] *in Q3 and Q4… I obviously want to get as much modafinil as possible from Orsymonde and take advantage of the improved economics…*"[659] The question discussed by Cephalon's supply managers was hence not whether Mitry-Mory and [*contract manufacturer*] can produce enough modafinil API for its requirements but only how to distribute the requirements between them.

4.7.3.7. Cephalon considers launching request for proposals for supply of modafinil in 2005

(396) Cephalon's employees in charge of the supply chain discussed prior to the start of the settlement negotiations a potential request for proposals ("RFP", namely asking other potential suppliers to make an offer to Cephalon for a supply arrangement). The primary aim appears to be pushing down the prices for modafinil API.

(397) First, Cephalon contemplated a request for proposals in connection with [*potential contract manufacturer*] offer of 30 August 2005 for a supply arrangement.[660] Cephalon's Vice-President for Global Manufacturing reacted in an e-mail to the Executive Vice-President for Technical Operations: " *[…], FYI. At […] Euro is about […] but I bet we could get them down to less than […]/kg! At […] tons, this could be […] million. If you agree, […] and I will bring this up during our discussions next week and try a squeeze play. If not, then start an RFP in 4Q this year to get another site approved."*[661]

(398) Second, when Cephalon's managers prepared for a meeting with their supplier [*contract manufacturer*] in November 2005, in which the renewal of the [*contract manufacturer*] Supply Agreement should have been discussed, the Vice-President for Global Manufacturing proposed: *"I would tie the RFP into the last item on his* [[*contract manufacturer*] representative's] *agenda, the discussion on the* [renewal] *Modafinil Supply Agreement. Let´s see what they come up with before we inform them. If they come back with a cost reduction, we need to think if the RFP is needed. If they don´t propose one, then, I think we tell them of our intention to start an RFP during mid/late 1Q06. If we go with one, I would want… the new Director of the API group… to meet all our vendors in a short period of time."*[662]

---

656 ID 1569, p. 1.

657 See Section 4.7.3.5.

658 ID 1583, p. 3.

659 *Ibid*, p. 1.

660 See also Section 4.7.3.3.

661 ID 1579, p. 1.

662 ID 1572, p. 1. A similar suggestion linking a potential RFP to the [*contract manufacturer*] Supply Agreement appears in an e-mail by the same Vice-President of 28 July 2007, ID 1573, p. 1.

(399) Eventually, Cephalon did not call for any request for proposals and all new agreements for supplies of modafinil API were concluded directly with the generic companies with which Cephalon settled its modafinil litigations (Teva/Plantex, […], see Sections 4.6.3.4 and 4.8.1.3).

4.7.3.8. Cephalon's contacts with Teva (Plantex) concerning the API modafinil supply prior to negotiations of the Settlement Agreement did not result in a supply agreement

(400) The Commission is aware of contacts between Cephalon and Plantex, a Teva subsidiary, in 2004/2005 in which modafinil API was discussed. According to testimony of Cephalon's Vice-President for Global Manufacturing, Cephalon's representatives met with Plantex in late 2004 / early 2005, as part of Cephalon's project to build a library of API and dosage form suppliers. Plantex was one of the companies that had a meeting with Cephalon during the process of the collection of information on different modafinil vendors. Both companies discussed potential opportunities regarding armodafinil and modafinil. Plantex indicated to Cephalon a price of USD 2,000/kg for modafinil API. When Cephalon asked for a price considering annual supplies of 20,000 kg, Plantex indicated a price of USD 1,000/kg. This price was too high for Cephalon and the talks ended.[663]

(401) On 11 October 2005, senior Plantex' executives visited Cephalon again to inquire about possible supplies of modafinil or armodafinil to Cephalon.[664] In a follow-up phone call between Cephalon's Associated Director for Strategic Supply Management and Plantex' President of 13 October 2005, the Plantex President indicated: "*The other thing he mentioned (unofficial) – there are 2 companies that Cephalon settled with and 1 was with Teva?? They* [Plantex] *could investigate working with us exclusively, of course in the beginning checking with Teva.*" To which Cephalon's Vice-president for Global Manufacturing replied: "*Interesting discussion.*" Cephalon also asked Plantex about prices for modafinil assuming 20,000 kg would be purchased. Plantex' president suggested a price close to USD 1,000/kg. When Plantex later asked if Cephalon was willing to pursue negotiations, Cephalon replied that it was just gathering information.[665] Plantex' President remarked in a note summarizing its conversation on the price offer with Cephalon that "[Cephalon's representative] *was not impressed…*"[666] In view of the ongoing litigation, Teva's patent department instructed Plantex "*do not provide Cephalon with any sample material of Modafinil API or information regarding the process TAPI employs in its manufacture*." [667]

(402) Cephalon's senior managers discussed Plantex' offer on 19 October 2005 (that is approximately one month before Cephalon and Teva started negotiations about the Settlement Agreement).[668] Cephalon's Vice-President for Intellectual Property and Chief Patent Counsel warned the Executive Vice-President for Technical Operations:

"*You should know, if you already don't, that Plantex is a wholly-owned subsidiary of Teva. In fact, Plantex is Teva's supplier of API modafinil for their generic product.*

663 ID 3694-13, p. 38.
664 ID 1571, p. 2.
665 ID 1571, p. 1.
666 ID 529, p. 38.
667 ID 529, p. 35-38.
668 ID 2144-31.

I'm sure they would love to make Armodafinil for us (it will be that much more easier for them to supply Teva with generic armodafinil). We shouldn't have any further contact with them without first consulting our outside litigation attorneys."

To which the Vice-President for Global Manufacturing reacted:

"*They first contacted us early this year looking at general opportunities. We do not have to do any business with them.*"

The Executive Vice-President then concluded:

"*With respect to Plantex, as […] notes, we can walk away from discussions with them.*"[669]

(403) Also an internal Teva document of November 2005 expressed suspicions as to the contact with Cephalon: "*We were suspicious that Cephalon was merely trying to get information from* [Teva] *that it could use against us.*"[670]

4.7.3.9. Prices paid by Cephalon to Teva (Plantex) were considerably higher that those of its other suppliers or its own manufacturing costs

(404) According to Article 2.4 of the Settlement Agreement and the Modafinil API Supply Agreement, Cephalon committed to purchase from Teva/Plantex, throughout the whole period of the supply arrangement, a minimum total volume of 50,000 kg of modafinil API for the aggregate price of USD 28 million. In reality, the final figures went somewhat higher. Cephalon purchased from December 2006 through March 2010 in total 55,449.55 kg modafinil API for the aggregate price of USD 30,589,177.50[671] that is approximately EUR 21,705,094.14.

(405) If the individual payments for the supplied API are grouped by years, Plantex received the following amounts:

Table 11: Cephalon's payments for Modafinil API supplied by Plantex

Year	**Amount (USD)**	**Amount (EUR)[672]**
2006	126,100	100,526
2007	6,585,832.50	4,812,926.39
2008	12,007,740	8,207,290.29
2009	10,509,685	7,556,463.52
2010	1,359,820	1,027,887.94
Total	30,589,177.50	21,705,094.14

Source: ID 1643

669 *Ibid*.
670 ID 979, p. 43-44.
671 ID 1643.
672 The yearly amounts are converted to EUR using the average exchange rate USD – EUR announced by the European Central Bank for each respective year.

(406) Teva's mark-up on sales realised in 2006-2007 to Cephalon was contractually set to costs to manufacture plus 30%.[673] Evidence on file shows that the same mark-up of 30% was also applied for the years 2008-2010 of the Modafinil API Supply Agreement.[674]

(407) The precise prices which Cephalon agreed to pay to Teva/Plantex in Article 2.4 of the Settlement Agreement, compared with the incurred in-house manufacturing costs in the case of Mitry-Mory, the prices paid to [*contract manufacturer*], as well as the price offers by [*contract manufacturer*] and [*potential contract manufacturer*] preceding the Settlement Agreement with Teva show that Cephalon agreed to pay considerably higher prices than offered by its existing or potential suppliers (see Table 12).

673 Article 2.4 of the Settlement Agreement and Article 4.1 of the Plantex Supply Agreement. See Section 4.6.3.4.

674 ID 979, p. 55; ID 2166-38, p. 28. In addition, upon the Commission's question, Teva did not show that the gross margin for 2008-2010 would be different than that for the first year of supplies. ID 2151, p. 12.

Table 12: Price offers and in-house manufacturing costs (EUR/kg)

	2005	2006	2007	2008	2009	2010
[*contract manufacturer*][675]	[…][676]	[…][677]	<[…][678]			
Mitry-Mory[679]	138					
[*potential contract manufacturer*] [680]		[…]				
Plantex (Teva)			549[681]	410	324 - 395[682]	340-378[683]

4.7.3.10. As a result of modafinil API supply agreements, Cephalon suffered from overproduction of modafinil API

(408) In 2008, Cephalon internally concluded that, considering its current worldwide modafinil API stocks and the expected sales of Provigil and Nuvigil, it had sufficient modafinil API for the next three to four years.[684] According to Cephalon's overview made in 2008/2009 of its then (i) modafinil API inventory, (ii) its purchase commitments, the existing inventories would support its requirements for the expected consumption from September 2008 until:

(a) [*contract manufacturer*]'s inventory: 2009,

(b) Mitry-Mory's (both C-1 and C-2) inventory: 2011,

(c) Plantex' inventory: 2012,

---

675 See footnote 590. [*contract manufacturer*] proposed to Cephalon supplies of […] kg of modafinil API in 2006 for […] (approximately EUR […])/kg for the first […]kg, and […] (approximately EUR […]), for the remaining […] kg (ID 1805, p. 68-69). All above rate conversions are made according to the exchange rate statistics of the European Central Bank for the relevant year (average annual exchange rate).

676 This amount in EUR equals […], according to information given by Cephalon in its response to the Article 18 Request of 27 May 2011, Annex Q1, ID 1432.

677 The indicated amounts in EUR equal […] and […], respectively, according to information given by Cephalon in its response to the Article 18 Request of 27 May 2011, Annex Q1, ID 1432.

678 [*contract manufacturer*]´s offer of 2/12/2005 (ID 1805, p. 69).

679 See ID 2144-3, p. 15. The document indicates no precise year to which the price information relates but it was drafted on 13 January 2003, and applied the cost figure as a basis for calculating Cephalon's COGS (cost of goods sold) for 2006. Hence it can be safely assumed that it used up-to-date figures of 2005. The price of USD 172/kg would probably further shrink due to sharply increasing production in Mitry-Mory's C-2 and the resulting economies of scale.

680 [*potential contract manufacturer*]'s offer of 13/01/2004, offer for 1-2 years following the conclusion of the supply agreement, price range refers to the volumes to be contracted, see ID 1820.

681 Plantex supplied to Cephalon 194 kg of modafinil API in 2006 for the price of USD 650. ID 1643.

682 Approximately 10,155 kg for EUR 395/kg, 4,051 kg for EUR 360/kg, and 3,382 kg for EUR 324/kg. *Ibid*.

683 Approximately 1,309 kg for EUR 378, and 6,213 kg for EUR 340.

684 ID 1605, p. 25.

(d) [*company name*][685] inventory: 2016,

(e) [*company name*][686] inventory: 2017.

(409) The above listed estimates for [*contract manufacturer*] and Mitry-Mory assumed that as of 2008, no modafinil API would be manufactured there. The current inventories of the generic manufacturers would be supported throughout the respective periods by the continuous manufacturing as foreseen in their respective Supply Agreements.[687]

(410) A similar calculation of 2010 expected Mitry-Mory to stock-out only in 2012, Plantex in 2014, [*company name*] 2018 and [*company name*] even beyond.[688]

(411) Since 2008, Cephalon has registered in its Annual Reports a considerable reserve for excess purchase commitments for modafinil API not expected to be utilized. Cephalon stated that the reasons for the unused reserve are an improved manufacturing process for Nuvigil and the decision to postpone the launch of Nuvigil in the third quarter of 2009, combined with the existing modafinil supply arrangements with the generics[689]:

"*Under these contracts, we have agreed to purchase minimum amounts of modafinil through 2012, with aggregate future purchase commitments totalling $57.8 million as of December 31, 2008. Based on our current assessment, we have recorded a reserve of $26.0 million for purchase commitments for modafinil raw materials not expected to be utilized.*"[690]

(412) Cephalon explained to the Commission that the reduction in its modafinil demand was due to the unexpected setbacks concerning regulatory refusal of Sparlon and delays with Nuvigil's approval.[691]

(413) At the end of 2009, Cephalon recorded a reserve of USD 9.0 million for modafinil purchase commitments not expected to be utilized. The reduction in the reserve was explained by entering "*into an agreement with one of our modafinil suppliers, paying $13.5 million in exchange for a $23.0 million reduction in our existing purchase*

---

685 Besides the Modafinil API Supply Agreement with Teva, Cephalon concluded at the turn of 2005/2006 modafinil API supply agreements with two other companies, [*company name*] and [*company name*]. Both supply agreements were concluded as parts of the Modafinil Settlements between Cephalon and these modafinil generic challengers between December 2005 and February 2006 in the United States (see Section 4.8.1.3.).

686 [*company name*] was not an API supplier. The API was supplied to [*company name*] by […] API manufacturer [*company name*] and [*company name*] re-sold the API according to its modafinil API supply agreement to Cephalon (see Section 4.8.1.3.).

687 ID 1771-87.

688 ID 1771-88. The chart ends in 2018 with [*company name*] ending inventory of modafinil API still at […] kg.

689 Besides the Modafinil API Supply Agreement with Teva, Cephalon concluded at the turn of 2005/2006 modafinil API supply agreements with two other companies, [*company name*] and [*company name*]. Both supply agreements were concluded as parts of the Modafinil Settlements between Cephalon and these modafinil generic challengers between December 2005 and February 2006 in the United States (see Section 4.8.1.3).

690 ID 2204, p. 80.

691 ID 1726, p. 15-16.

commitments with this supplier."[692] The supplier with whom Cephalon reached this agreement was [*company name*].[693]

(414) The Cephalon's modafinil supply situation in 2008-2009 was well described by a Cephalon's senior supply manager who remarked that by entering into such series of supply agreements, Cephalon created "*a supply chain nightmare*".[694] As shown by the evidence above, Cephalon did not consider to source any API from Mitry-Mory and [*contract manufacturer*] at least from 2008 onwards. Following the modafinil API supply agreements with generic manufacturers, Cephalon terminated its supply relationship with [*contract manufacturer*] and closed the Mitry-Mory business.

(415) When Cephalon informed, on 17 February 2006, its potential armodafinil supplier [*company name*] about the modafinil settlements,[695] it also explained: […][696]

(416) Accordingly, first, Cephalon served a notice of termination to [*contract manufacturer*] on 31 August 2006 and the [*contract manufacturer*] Supply Agreement was terminated with effect of 4 November 2007.[697]

(417) Second, the modafinil production in Mitry-Mory fell substantially between 2006 and 2007.[698] Although the full Mitry-Mory capacity was built to approximately 100,000 kg per year after the start of operation of the C-2 plant at the end of 2006,[699] only 26,000-27,000 kg were manufactured in 2007.[700] Cephalon informed Mitry-Mory that its modafinil requirements for next years were saturated. Accordingly, the demand projection for 2008 and 2009 saw an even more dramatic plunge, forcing the production to mere 1,000-2,000 kg in 2009.[701]

(418) In an internal analysis of April 2008, Cephalon explained this development in particular by the API supply arrangements with the generics ensuing from the modafinil settlements as well as by the termination of the Sparlon project:

"*In early 2006, several agreements were reached with generic competitors that had challenged the Provigil patents. These agreements allowed three generic competitors to supply thirty-five (35) MT Modafinil annually. This also allowed Provigil to remain on the US market.*

Later that year, the FDA determined that the Sparlon product was non-approvable.

With Provigil remaining on the market, the US launch of Nuvigil was postponed…

Also, the SMB contracts supplying Armodafinil were not renewed…[702]

---

692 ID 2205, p. 86.

693 ID 1726, p. 16.

694 ID 2215, paragraph 57, p. 15.

695 See Recital (485) and Section 4.8.1.3.

696 ID 1836, p. 7. In the same vein, [*company name*] CEO reported on 29 September 2006 about his conversation with Cephalon's Vice-President for Global Manufacturing: [Cephalon's Vice-President] […] ID 1836, p. 27.

697 ID 1805, p. 3, 6.

698 ID 1605, p. 24.

699 See Recital (360).

700 ID 1605, p. 24.

701 *Ibid*.

702 This concerns the armodafinil API supply agreements with [*company name*], [*company name*] and [*company name*], see Section 4.7.3.1. Should the Nuvigil launch not have been postponed and the armodafinil API Supply Agreements not terminated, Mitry-Mory would have supplied the armodafinil

Once the generic suppliers are FDA approved (at this time only 1 approved), there will be limited Modafinil requirements from Mitry-Mory."[703]

(419) Cephalon did not find any alternative source of revenue that would compensate Mitry-Mory for the loss of the modafinil business.[704] Cephalon therefore concluded that "[W]ith *the current product portfolio and supply needs, the best alternative is to outsource Cephalon's API needs and sell the Mitry-Mory facility*."[705] This decision was presented in September 2008 to Mitry-Mory's Worker's Council.[706] As the only alternative to Mitry-Mory's sale Cephalon proposed shutting down the plant.[707] Cephalon eventually divested the Mitry-Mory plant to the company Laboratoires Mitry-Mory by way of a Business Transfer Agreement dated 15 April 2011.[708]

4.7.4. Avoided litigation costs

4.7.4.1. In the United Kingdom

(420) Cephalon paid Teva an amount of GBP 2.1 million (approximately EUR 3.07 million)[709] "in recognition of the savings inuring to Cephalon in terms of avoidance of costs, expenditure of time and resources, disruption and burden associated with prosecuting [modafinil-related] litigation in the United Kingdom" (Art. 2.5 (b) of the Settlement Agreement).

(421) The Commission notes that the draft version of the Settlement Agreement of 6-7 December 2005 mentions that Cephalon pays the above-mentioned amount "*also in recognition of Teva's lost revenues*".[710]

(422) Cephalon transferred the amount of GBP 2.1 million by releasing a bond (plus interests) that it had issued in favour of Teva during the modafinil United Kingdom litigation. The bond formed a security for Teva's potential claims for damages incurred as result of it accepting the preliminary injunction not to sell modafinil in the United Kingdom pending the United Kingdom patent court proceedings.[711]

(423) Cephalon consistently projected its own United Kingdom litigation costs up to the High Court trial at GBP 1-1.5 million.[712] One internal calculation "*in the event that the outcome is against us*" adds to the aforementioned figure (set at GBP 1.3 in this particular forecast) Teva's legal costs estimated at GBP 750,000 up to the High Court and further GBP 500,000 for the case of an appeal and damages relating to the loss of sales (no exact figure is mentioned).[713] Up to the end of November 2005, the

---

manufacturers with modafinil API, which was the starting product for armodafinil API. See Recital (363).

703 ID 196, p. 5-6. ID 202, p. 2, contained a similar statement.

704 ID 196, p. 6. See also ID 1605, p. 26-33.

705 ID 196, p. 6.

706 In its SEC Annual Report 2008, ID 2204 p. 80, Cephalon informed: "*We also are initiating a search for a potential acquirer of our manufacturing facility in Mitry-Mory, France where we produce modafinil*."

707 ID 1604, p. 5-6.

708 ID 1726, p. 14.

709 See Sections 4.4., 4.6.3.5.

710 ID 290, p. 48.

711 See Section 4.4.

712 ID 2144-46, ID 189, p. 92, ID 273, p. 30, ID 277, p. 56.

713 ID 277, p. 52.

actual cost of the United Kingdom litigation for Cephalon was USD 576,505 and GBP 2,696.[714]

4.7.4.2. In other markets

(424) Cephalon paid Teva an amount of EUR 2.5 million "in recognition of the savings inuring to Cephalon in terms of avoidance of costs, expenditure of time and resources, disruption and burden associated with prosecuting [modafinil-related] litigation in European and other markets outside of the United States or the United Kingdom, wherein Cephalon and Teva have [modafinil-related] intellectual property rights…" (Art. 2.5 (c) of the Settlement Agreement).

(425) The Parties did not specify any contemporaneous documents supporting the above figure but Cephalon explained in its response to the Commission's Article 18 Request: "*taking into account both that this provision addresses a larger number of countries (including Cephalon's larger national markets, namely France and Germany), and somewhat higher litigation costs in the UK, the figure of €2,5 million (roughly equivalent to £1,7 million at November 2005 exchange rates appears in the circumstances to have approximated likely savings from avoidance of the costs and other burdens associated with potential litigation.*"[715] At the time of the Settlement Agreement there were no pending litigations between Cephalon and Teva other than in the United States and the United Kingdom and therefore, actual costs related to these markets equalled zero.

(426) The Commission, however, notes that the draft version of the Settlement Agreement of 6-7 December 2005, dated only few days before the final agreement was signed on 8 December 2005, indicated that Cephalon would have to pay Teva EUR 1 million in return for the avoided litigation costs in European and other markets outside the United States or the United Kingdom.[716]

4.7.5. Teva Distribution Agreement

(427) Teva UK was appointed as Cephalon's exclusive distributor in the United Kingdom for "*all Cephalon Modafinil Product*" for a period of five years, commencing at the latest on 1 October 2006.[717] Although the Settlement Agreement spoke of distribution of "*all Cephalon Modafinil Product*", Cephalon's only modafinil product approved in the United Kingdom at that time was Provigil, and this did not change during the term of the Teva Distribution Agreement. Teva UK started distributing Provigil in the United Kingdom in September 2006.[718] Cephalon's European Management Team opted for a "*low key trade launch*" of the distribution because of the "*current spotlight on potential antitrust issues in US*".[719]

(428) Cephalon was supplying Teva with Provigil at a price equal to 80% of Teva's actual resale price in the United Kingdom, after any deductions, discounts, credits, rebates,

---

714 ID 274, p. 13.

715 ID 1318, p. 6. See also ID 2153, p. 2.

716 ID 290, p. 19.

717 See Section 4.6.3.6.

718 The commencement date of the distribution was postponed against the date foreseen in the Settlement Agreement because Cephalon's earlier distribution partner […].

719 ID 980, p. 58 of 01/08/2006. The document also indicated "*Whilst Teva US and Cephalon US have been discussing this overall issue and are satisfied that there is no issue with our settlement, they would still prefer a low key trade launch.*"

returns and allowances. In addition, upon Teva's launching Provigil in the United Kingdom, Cephalon paid to Teva a one-time payment of EUR 2.5 million, in recognition of:

(a) Costs and expense involved in Teva's preparation for such launch, and

(b) Licence to the Intellectual Property Rights.[720]

4.7.5.1. Cephalon's reasons for granting the distribution rights to Teva

(429) Teva contacted Cephalon after the start of the United Kingdom litigation in July 2005 with the proposal to settle the litigation in exchange for, inter alia, Teva becoming a distributor of Cephalon's product on a profit sharing basis.[721]

(430) Cephalon's attorney sent on 8 December 2005 (the day of signing) the revised draft Settlement Agreement to the Chief Legal Counsel of Cephalon Europe and another Cephalon Europe's attorney with the comment:

"[The Agreement] *is designed to settle both the US and UK litigation and to settle any as yet unfiled disputes that may arise in Europe or elsewhere (assuming we have patents in those markets).*

However, as I believe […] is aware, the consideration in the UK includes a distribution and supply agreement, which would be effective once the […] arrangements are concluded in the UK in July."[722]

(431) Similarly, the minutes of Cephalon's UK Management Meeting of 30 January 2006 mention: "As part of the settlement with the US, Teva will have distribution rights for Provigil in the UK…"[723]

(432) Cephalon becomes even more explicit in a presentation prepared for a United Kingdom sales review of August 2006 and for a Provigil Marketing Plan of September 2006, indicating the link between the Teva Distribution Agreement and the non-compete arrangement:

"*Market News*

Generic:

Agreement made with major generic houses in US and Europe.

In UK Teva will distribute Provigil and in return will not launch a generic modafinil until 2012."[724]

(433) Cephalon Europe's Regulatory Officer summarised in its explanation of 2008:

"*The situation in the UK is that we have an agreement with Teva that they will not produce a generic but will distribute our product in return for the share of the profits. As a result there are currently no generics of Provigil on the market in the UK…*"[725]

---

720 Under the licence to the Intellectual Property Rights is meant Teva's licence purchased by Cephalon according to Article 2.2 of the Settlement Agreement.

721 See Section 4.4.2.

722 ID 277, p. 57.

723 ID 289, p. 70.

724 ID 224, p. 3; ID 226, p. 7. See also ID 264, p. 15.

725 ID 264, p. 15.

(434) Finally, a handwritten note of the Legal Director of Cephalon Europe of 30 September 2008 indicated: " [*distributor*]: […] when we settled Teva, we terminated the deal with [[*distributor*]] re Provigil. […] We terminated with [*distributor*], so we could give the inputs to TEVA."[726]

4.7.5.2. Teva's revenues from distribution

(435) Teva achieved during the term of the Teva Distribution Agreement the following net revenues, in addition to the one-time payment of EUR 2.5 million (Recital (429)):[727]

Table 13: Net revenues

Year	**Net sales (GBP)**	**Net sales (EUR)**[728]	**Marginal Costs (GBP)**	**Marginal Costs**[729] **(EUR)**
2006	1,330,601	1,951,991.67	1,068,487	1,567,470.43
2007	4,164,962	6,089,590.94	3,112,066	4,550,151.7
2008	6,527,809	8,217,858.75	5,354,220	6,740,427.56
2009	8,443,100	9,483,289.92	7,365,807	8,273,274.42
2010	8,667,156	10,111,970.91	7,303,974	8,521,546.47
2011	7,637,418	8,803,651.73	5,931,421	6,837,148.99
Total:		**44,658,353.92**		**36,490,019.57**

Source: ID 1844

4.7.5.3. Parties' explanations concerning the one-time-payment

4.7.5.3.1. Cephalon's and Teva's claims regarding the need for an upfront payment

(436) The Commission asked Cephalon repeatedly to explain whether an upfront payment for the commercial launch of a distributed product between manufacturing company and distributor is customary and whether Cephalon made this kind of payment to its distributors elsewhere. This question was not limited to the distribution of modafinil products. Cephalon never answered this question.[730]

(437) Instead, Cephalon only emphasized the "*unique circumstances*" and "*particular context*" of the Teva Distribution Agreement:

"*The Commission seeks to compare and/or contrast the terms of the distribution agreement with Teva UK with agreements reached with "distributors elsewhere" (not limited to modafinil)... As explained further below, however, the Teva distribution*

726 ID 187, p. 129.

727 ID 1844, p. 14.

728 The basis for the rate conversions is, for each year separately, the average annual exchange rate GBP-EUR for the relevant year according to the statistics of the European Central Bank.

729 The basis for the rate conversions is, for each year separately, the average annual exchange rate GBP-EUR for the relevant year according to the statistics of the European Central Bank.

730 See ID 1318, p. 6-8; ID 1436, p. 13-14.

agreement arose out of a set of circumstances unique to the UK. Cephalon considers, therefore, that this form of comparative exercise will not assist the Commission. As mentioned in Cephalon's response to Question 7 of the Commission's RFI dated 9 November 2010, Cephalon's distribution arrangements are the result of individual negotiations, and their commercial terms must be assessed in their individual context. For this reason, it is not appropriate to frame particular terms of such agreements as being "customary" or otherwise.

In relation to the specific UK context, as Cephalon has previously informed the Commission, the UK distribution agreement with Teva closely resembles Cephalon's prior distribution agreement concluded with […] in November 2000…[731]

The UK distribution arrangements subsequently concluded between Cephalon and Teva arose out of the specific context of these earlier [*distributor*] *arrangements, which were intended to meet Cephalon's particular needs in relation to the UK market at the relevant time, but in circumstances where* [*distributor*] *had indicated that it was keen to end the collaboration arrangements… It is for this reason that the* [*distributor*] *agreement is the only distribution agreement (relating to modafinil) which is similar to the Teva agreement.*[732]

…

As with the Teva UK agreement… this payment must be assessed in its particular context…"[733]

(438) Cephalon then attributed the payment in large part to the alleged Teva's launch costs.[734]

(439) The Commission also asked Teva whether an upfront payment for commercial launch of a distributed product between manufacturing company and distributor is customary and to indicate whether it had in the past made (as manufacturer to a distributor) or received (as distributor by a manufacturer) such payments (not limited only to modafinil products).

(440) Teva's reply showed only two upfront payments paid from the distributor to the principal (manufacturer) in recognition of the grant of the exclusive distribution right (hence the opposite direction than the upfront payment in Teva Distribution Agreement).[735] A third example provided by Teva of a payment was in reality not an upfront payment because it was made in settlement of obligations ensuing from a preceding distribution agreement.[736]

---

731 The Commission however notes that […]. (ID 250).

732 ID 1436, p.13. Cephalon similarly stated that "[T]*he distribution agreement concluded with Teva UK in August 2006 is very similar to the distribution agreement concluded with […]*…" in its reply to the Article 18 Request of 8 November 2010, question 7, ID 1318, p. 7.

733 ID 1436, p. 14.

734 *Ibid*. See also SO Reply, paragraph 130.

735 Distribution Agreement between [*company name*] and [*company name*] of 17 May 2005 and Distribution Agreement between Teva and [*company name*] of 7 October 2004 as described in ID 1329.

736 Termination and distribution Agreement between Teva and [*company name*] of 21 August 2003 as described in ID 1329.

4.7.5.3.2. Allocation and calculation of the one-time payment

(441) In the Article 18 Request to Cephalon and Teva dated 8 November 2010, the Commission asked the Parties which part of the amount of EUR 2.5 million should be allocated to the recognition of Teva's launch costs and which part to the licence.[737]

(442) Cephalon replied that no allocation between launch preparation costs and the Intellectual Property Rights was made. It added that, "*as best* [it] *can now determine, the payment was made primarily in connection with launch costs*."[738] Later, Cephalon added on Teva's alleged launch costs: "[Teva's launch costs] *are likely to have included costs incurred by Teva in connection with its own product, which had been launched and supplied to the wholesalers at the time of settlement, such that (inter alia) certain stocks would need to be recalled and/or destroyed*." Cephalon concluded that it was *"unable to provide the Commission with any greater specificity (including contemporaneous documents) in relation to the negotiation of this provision with Teva*." [739]

(443) Teva replied that it had not separately allocated any portion of the EUR 2.5 million up-front payment to distinct distribution, marketing, or licensing categories, and that it did not have any contemporaneous documentation reflecting any such allocation.[740] Teva later confirmed again that "[The one-time payment] *was not divided into a separate remuneration in recognition of the costs and expenses involved in Teva's launch preparation and a separate remuneration in recognition of the license to the IPRs*".[741]

(444) The Commission also asked the Parties to indicate how the amount of EUR 2.5 million was calculated. Neither party answered the question clearly.[742] Teva however replied to the Commission:

"*Up-front payments in connection with the entry of a supply, distribution or licensing agreement can be negotiated for a variety of reasons. An up-front payment could be used to allocate compensation to the beginning of the distribution relationship. That is, the distributor could obtain a higher up-front payment in exchange for a lower percentage distribution margin on each unit sold. For example, if the up-front payment in Teva's UK distribution agreement with Cephalon were added to Teva UK's per unit distribution margin, the total per unit distribution margin to Teva would be slightly above 25%, which is within the range of margins that Teva typically receives in similar arrangements.*

In addition, up-front payments could be used to offset the risk to the distributor that sales throughout the distribution period may be less than expected at the time the distribution is executed. Teva UK's distribution agreement with Cephalon, for example, does not provide for an adjustment of the parties' revenue sharing

737 The Commission also requested the Parties to provide contemporaneous documents confirming that the proposed allocation corresponds to their internal considerations at the time.
738 ID 1318, p. 7. See also SO Reply, p. 42.
739 ID 1436, p. 14. See also in Recital (448). SO Reply, p. 42.
740 ID 1330, p. 6.
741 ID 2151, p. 17. SO Reply, p. 42.
742 ID 1318, p. 7-8; ID 1330, p. 5-6. SO Reply, p. 42.

arrangement in the event of a market demand for Provigil that is less than anticipated."[743]

"*Another reason would be to incentivize a non-exclusive distributor to promote sufficiently the supplier's product (e.g. Teva's distribution agreement with […] in 2008 which involved an up-front payment of EUR 550,000).*"[744]

(445) When the Commission asked Teva the same question again in the Article 18 Request of 6 July 2015, namely to specify how the one-time payment was calculated, making explicit any assumptions on which the calculation was based,[745] Teva said:

"*Also due to the passage of time, Teva does not recall specifically how the one-time payment of EUR 2.5 million was calculated. This payment was generally designed to reimburse Teva for its launch costs and was not paid until commercial launch was complete. The commercial launch itself thus was a service in return for the EUR 2.5 million payment*".[746]

4.7.5.3.3. Teva's alleged launch costs

(446) Replying that the one-time payment had been made primarily for Teva's launch costs (see Recital (439)), Cephalon clarified: "*These* [expenses] *are likely also to have included costs incurred by Teva in connection with its own product (for example, dealing with stocks held by wholesalers).*"[747]

(447) Later the Commission asked Cephalon whether Teva had provided it with any calculation of its costs related to launch of Cephalon's modafinil product in the United Kingdom or any other explanation regarding the amount of EUR 2.5 million, and whether Cephalon had required from Teva such calculation/explanation during the negotiations of the Settlement Agreement or the Teva Distribution Agreement.[748] Cephalon did not answer specifically this question, it did however provide more detail with regard to its above explanation of Teva's alleged launch costs: "[Teva's launch costs] *are likely to have included costs incurred by Teva in connection with its own product, which had been launched and supplied to the wholesalers at the time of settlement, such that (inter alia) certain stocks would need to be recalled and/or destroyed.*" Cephalon concluded that it was *"unable to provide the Commission with any greater specificity (including contemporaneous documents) in relation to the negotiation of this provision with Teva*".[749]

(448) Although Teva attributed in its latest reply to the Commission the one-time payment to the launch cost (see Recital (446)), it was not able, "[G]*iven the passage of time… to quantify with more specificities the costs that Teva incurred in relation to the preparatory steps that Teva undertook to launch Cephalon Modafinil and the costs and other calculations regarding the license to the IPRs.*"[750]

---

743 ID 1330, p. 6. See also SO Reply, p. 43.

744 ID 1330, p. 6, footnote 2. SO Reply, p. 42.

745 The Commission also requested Teva to submit any internal or external documents containing details as to the calculation of this amount or supporting the assumptions.

746 ID 2151, p. 17. This is closer to Cephalon's explanation in Recital (443). SO Reply, p. 42.

747 ID 1318, p. 7.

748 The Commission also requested the relevant contemporaneous documents.

749 ID 1436, p. 14.

750 ID 2151, p. 17.

4.7.5.3.4. Services provided for the one-time payment

(449) In the Article 18 request of 8 November 2010 and then again in the Article 18 request of 27 May 2011, the Commission asked the Parties what services Teva provided for the one-time payment. Neither of the Parties specified any services provided for the payment nor did they provide any document to this end.[751]

(450) In its reply to the Article 18 Request of 27 May 2011, Teva stated that "[A]n upfront payment can be negotiated for a variety of reasons, and is not necessarily provided as a consideration for the performance of specific services to be rendered by the beneficiary of such payment."[752] However, in its response to the Article 18 Request of 6 July 2015, Teva said that the commercial launch itself was a service in return for the one-time payment, explicitly referring to its launch costs (Recital (446)). The Parties seem to assume this apparently contradictory position also in the SO Reply, saying on the one hand, that up-front payments can be negotiated for variety of reasons and not necessarily in consideration for specific services (and repeating the same set of potential reasons that they indicated in their earlier replies to Article 18 Requests (see Recitals (443), (445)-(446)), and trying, on the other hand, to explain the up-front payment as reimbursement for Teva's costs incurred in relation to launch of Cephalon's modafinil.[753]

4.7.5.4. Distribution margin

(451) In the SO Reply, the Parties argue that, as a general matter, Teva negotiates a […] margin for agreements similar to the Teva Distribution Agreement.[754] In that regard, the 20% margin of the Teva Distribution Agreement, or the 25% margin (including the up-front payment) was well within the range.[755] Similarly, the Parties draw attention to certain Cephalon's distribution agreement across the EEA that provided for a substantially higher margin than the margin granted to Teva under the Teva Distribution Agreement (such as […] and […] margin granted to [*company name*] in Italy, or […] margin granted to [*company name*] in certain Eastern Europe and Balkan countries).

(452) However, as the Parties themselves acknowledge, the distribution margin varies in relation to the scope of services provided by the distributor. Under the Teva Distribution Agreement, Teva was only responsible for selling and distributing modafinil in the United Kingdom.[756] [*company name*] and [*company name*], unlike Teva, were also responsible for marketing, promotion and packaging, which explains the difference in margin.[757] Concerning those, very broad range of purported margins

---

751 See ID 1330, p. 5-6; ID 1428, p. 5; ID 1318, p. 6-8; ID 1436, p. 13-14.

752 ID 1428, p. 5. The parties repeated this answer in the SO Reply, SO Reply, p. 42.

753 SO Reply, p. 42.

754 SO Reply, paragraph 139.

755 SO Reply, paragraph 139.

756 See Teva Distribution Agreement, ID 227. Teva's activities as distributor consisted solely of taking orders for products of customers, making orders and corresponding payments to Cephalon, receiving the products from Cephalon, warehousing, storage, physical distribution of products to customers and receiving payments in respect of sales (see in particular Articles 2.2, 3, 5.5, 10.3 and 10.6 of the Teva Distribution Agreement). All other activities including transportation of products to Teva's warehouse, packaging of products, marketing, advertising and promotion of products, as well as holding and maintaining of the product license (marketing authorisation) are carried out only by Cephalon (see in particular Articles 4, 5 and 8 of the Teva Distribution Agreement).

757 See SO Reply, p. 43-44 and Section 4.1.3.

in Teva's distribution agreements, the Commission notes that the Parties do not give any specific examples of similar distribution agreements that would make possible a reasonable comparison of the margins. Finally, the Commission notes the comparison of the margins in the Teva and […] distribution agreements. However, the difference – not material – in the margins cannot alter the Commission's conclusion that Cephalon would not have granted the distribution of modafinil products to Teva, the closest competitor and rival on the market for modafinil in the United Kingdom (see Section (6.6.5.4)).

4.7.6. Teva Generic Rights

(453) In Article 3 of the Settlement Agreement, Cephalon committed to granting to Teva a non-exclusive right under the Listed Patents[758] to manufacture, use, market and sell its generic modafinil product in the United States and other markets (including EEA), and to do the same with respect to the provision of modafinil API for finished pharmaceutical products which have modafinil as an active ingredient, as of 2011 in the United States and as of 2012 in other markets, including the EEA ("Teva Generic Rights").[759] Article 3.1.1 of the Settlement Agreement establishes that Teva Generic Rights shall be effective the earlier of 6 October 2012 or the date which is three calendar years prior to the expiration of the applicable patents and exclusivities in such markets ("Effectiveness Date").[760] In terms of compensation, Teva should pay to Cephalon a royalty equal to 10% of all net profits of all generic modafinil products sold by Teva (Recital (248)). Articles 3.1.2 and 3.1.3 addressed, *inter alia,* mechanisms triggered by possible earlier entry of third parties to modafinil markets. These provisions allowed Teva to launch its own generic version of modafinil as soon as any other generic company entered the market, irrespective of whether Cephalon had authorised such entry. Should Teva, pursuant to the above-mentioned provisions, put its generic product in the market before the Effectiveness Date, it would be obliged to pay increased royalties of 15% (entry authorised by Cephalon) or of 20% (entry at risk by other generics) during the relevant time (see Recital (249)). The scenarios considered in the provision include Cephalon seeking a temporary restraining order or other relief, (see Recital (249)). In these cases, Teva Generic Rights would be suspended (Article 3.1.3.3(a)) and Cephalon would buy back inventory from Teva at agreed upon prices (3.1.3.3(b)). The Licence Agreement foreseen in Article 3.2 of the Settlement Agreement, that would implement the provisions of Article 3, was never concluded (Recital (220)) since Teva acquired Cephalon in 2011, that is well before the planned effective data of the licence.

(454) The terms of the Teva Generic Rights were negotiated by the Parties at the same time with other elements of the Settlement Agreement (see Sections 4.5.1 and 4.8.1.1).[761] Drafts of the Settlement Agreement (for example, draft Settlement Agreement dated

---

758 See footnote 389.

759 For more details, see Recital (248)

760 For Effectiveness Date of Teva Generic Rights in the By-Object Countries, see Recital (686).

761 Cephalon's Board of Directors discussed the Teva Generic Rights along with other transactions as part of the package offered to Teva in the Settlement Agreement (see Section 4.5.1). In the same vein, Teva considered the licence providing for its entry a part of the Settlement Agreement and referred explicitly to it as to an element of the Settlement Agreement "*creating value*" for it (see in particular Recital (471)).

2 December 2005)[762] show that the main elements of the Teva Generic Rights were included already in early stages of the process. Subsequent discussions focused on fine tuning of specific clauses and on introduction of provisions aimed to clarify the scope of the Parties' obligations.[763] Teva was particularly concerned with the fact that there were multiple Cephalon patents surrounding modafinil while Article 3 provided solely for a licence under the Listed Patents ("*Cephalon has more patents out there. I would be happy if the agreement would cover those too (= in case we launch, they don't sue us)…*" (Recital (207)). As a result, and following Cephalon's proposal of 8 December 2005, Article 3.8 of the Settlement Agreement includes Cephalon's covenant not to sue Teva for sales of generic Provigil under any patents owned "*on or after*" the Effective Date of the Settlement Agreement.[764]

(455) Cephalon recognised two tools that could be engaged to counter generic entry – the launch of a second generation product, armodafinil-based Nuvigil, and agreeing a settlement with the generic companies. However, as explained in Sections 4.2.3.1 and 4.2.3.2, Cephalon saw the risks around a fast-tracked entry of Nuvigil in 2006 and acknowledged that this strategy was "*not an Advised Course of Action*". The Modafinil Settlements (including the Settlement Agreement with Teva) provided for generic entry only in 2011/2012, and at the same time reduced incentives for other generic companies to enter the market, since any independent generic entry would be immediately faced with generic competition by a licensee incumbent "sponsored" by Cephalon's Modafinil Settlements.[765] Apart from allowing Cephalon to maintain and increase Provigil revenues for an extended period of time, this strategy gave Cephalon the time to prepare the switch from modafinil to armodafinil products, and to launch Nuvigil at the most convenient time. As Cephalon noted in a document following the Settlement Agreement:

"*It would be fantastic if we have PROVIGIL for the next 6 years, really changes the landscape for Cephalon in the short and long term. The reality is that if we achieve exclusivity, it will dramatically change what we do with NUVIGIL. We are evaluating any number of options which could mean quite frankly launching or not launching…The good news is we have a great opportunity in front of us and the potential of NUVIGIL in the wings as we better understand the best options for Cephalon*".[766]

---

762 ID 2841-962. The Commission notes that this draft Settlement Agreement provides that royalties payable by Teva amount to 50% of all Net Sales in all scenarios of Teva's entry provided for in the Article 3.1. However, already on 4 December 2005, the royalty structure has been settled in the following manner: (i) in a default setting (that is Teva's entry in October 2012) Teva shall pay Cephalon a royalty equal to 10% of all Net Profits of all generic modafinil products sold by Teva; (ii) if Teva's Generic Rights are accelerated as a consequence of entry by any other entity based on Cephalon's licence/permission, Teva shall pay Cephalon a royalty equal to 15% of all Net Profits; and (iii) if Teva's Generic Rights are accelerated as a consequence of entry at risk by any other entity, Teva shall pay Cephalon a royalty equal to 20% of all Net Profits (see, for example, ID 2841-973, p.1).

763 By way of example, ID 2841-153 reveals that Teva insisted on the provisions (i) safeguarding Teva's pre-existing modafinil contractual relationships or modafinil marketing efforts (Article 3.6 of the Settlement Agreement) and (ii) allowing Teva a reasonable preparation time prior to the effective date of the licence (Article 3.5 of the Settlement Agreement).

764 ID 2841-1042. The Commission notes that the covenant not to sue clearly refers solely to the sales of generic Provigil (and not, for example, Nuvigil).

765 ID 2841-1323, p. 3. See also Section 6.9.1.2.

766 ID 2841-1323, p. 4.

(456) As explained in Recital (211) and footnote 378 and in further detail in Section 4.8.1.3, Cephalon granted a similar non-exclusive licence to launch generic modafinil product as of 2011/2012 also to three other generic companies with which it settled the modafinil litigations in the United States (namely, [*company name*], [*company name*] and [*company name*]). The main difference between Teva Generic Rights and the licences to the other companies was that the latter were granted only for the United States market (the three above-mentioned companies were involved in modafinil litigations with Cephalon only in the United States, and therefore, the respective settlement agreements were limited to the United States market). […][767]

4.8. Facts following the Settlement Agreement

(457) This Section sets out the events that followed the conclusion of the Settlement Agreement. First, it describes Cephalon's and Teva's respective ex post assessments of the Settlement Agreement and their respective reactions following its conclusion (Section 4.8.1), including Cephalon's subsequent settlements with other generic contenders in the United States. Second, it recalls certain relevant regulatory decisions and court proceedings that followed the Settlement Agreement, including the Commission's Decision approving Teva's acquisition of Cephalon in 2011 and court proceedings relating to patent litigation raised by Cephalon in the United Kingdom and other EEA countries (Section 4.8.2)

4.8.1. Cephalon's and Teva's reactions following the Settlement Agreement

4.8.1.1. Cephalon's reactions

(458) In an immediate reaction to the Settlement Agreement, Cephalon's Chairman and CEO addressed the Board of Directors for their meeting on 31 January 2006 with this Executive Summary:

"*As of this date we have made substantial progress in settling the Provigil litigation with three of the four first to file generic competitors. Our expectation is to settle with the four and those discussions are continuing…*[768] *The impact of these settlements will be transforming to us. For the past few years we have been preparing to reposition the company away from Provigil and have invested extensively into the development of new products each of which is expected to be launched later this year. The prospect of maintaining the Provigil market (which is now the operating imperative) for another six years significantly changes the course of this company. It will add significant unexpected revenue to the top line which will significantly impact the bottom line and operating margin growth of the company in 2006 and 2007. The growth prospects for us beyond the next two years are dependent on new product approvals which we are confident will occur in 2006*."[769]

(459) Cephalon's CEO also observed publicly with regard to the Modafinil Settlements: "*We were able to get six more years of patent protection. That's $4 billion in sales that no one expected…*",[770] and declared on another occasion in early 2007: *"We've got*

---

767 See ID 254, p. 14 and subsequent for settlement agreement with [*company name*], ID 254, p. 80 and further for the settlement agreement with [*company name*], and ID 254, p. 124 and subsequent for the settlement agreement with [*company name*].

768 Concerning other Cephalon's Modafinil Settlements that followed the Settlement Agreement with Teva see Section 4.8.1.3.

769 ID 2144-62, p. 1.

770 ID 2236, p. 12.

Provigil through 2012. You know the history of the company. We didn't expect to be there."[771] In its quarterly Earnings Conference Call in February 2006, Cephalon told investors that it expected "*to market Provigil until at least 2011 unfettered by generic competition*".[772]

(460) Similarly, at the JPMorgan 24th Annual Healthcare Conference on 10 January 2006, Cephalon's CEO announced: "But Provigil's been the mainstay of the company and I am fortunate enough to keep Provigil for another six years or so, its going to continue to grow, continue to allow us to… dominate our performance over the next several years. Speaking of Provigil continuing to grow. Most of you realize we settled with a number of the groups litigating against us. We announced Ranbaxy a few weeks back and today we announced that we settled our mitigation with Mylan Laboratories. So three of the first four generic filers are already settled. We're pretty excited about that result, as you can imagine, and if we're fortunate enough to settle with the fourth. Provigil will be with us for many more years to come."[773]

(461) Cephalon's document drafted after the conclusion of the Settlement Agreement (and of the Modafinil Settlements with Mylan and Ranbaxy, see Section 4.8.1.3) made a more thorough analysis of Cephalon's position:

771 ID 2215, paragraph 83.
772 ID 2237, p. 2.
773 ID 2841-554, p. 3.

"2. PROVIGIL

(a) What's really happening with these generic companies? Is this real?

There is absolutely a real possibility that we will have PRO VIGIL longer than anyone expected — a little [it] *like pulling a rabbit out of a hat... Fantastic opportunity to sell and grow — we all should be excited.*

The great news is that our executive management has been extremely proactive to defend our flagship product – unprecedented in what they have accomplished with the generic companies. As a result we have a chance for a second life for PRO VIGIL…

Terms:

(2) - Allows Cephalon exclusivity through October 2011 or April 2012 (pediatric exclusivity)

(3) - At the end of this period, Cephalon will grant a non-exclusive royalty bearing right to market / sell a generic version of PRO VIGIL.

(4) - The license becomes effective October 2011 or April 2012 (pediatric exclusivity)

(5) - The only way T, R, M, B? May enter the market prior to this time is if another generic version comes on to the market

(6) - Liklihood [sic] of another entrant is considered unlikely... (need legal input)

(7) - Subject to review by FTC…

To take advantage of the opportunity, we have to continue to deliver the message…

(a) b. It's terrific PROVIGIL may have an extended life... could other generic companies follow?

We don't believe it is likely that another generic company would enter the market. Could they, yes. The question is why would they? Any new filer is guaranteed that 4-5 other generic houses would enter almost simultaneously, forcing the price downward and in reality, creating an unattractive financial situation.

3. Implications for PROVIGIL
a. Refocus 2006 / reinvigorating the selling effort
b. Providing the [the] *resources to support the re*[k]*newed focus*

Given the recent events, we are working to make sure that the resources exist to support the new focus… to develop tools that help keep the excitement up, the message fresh and ultimately allow us to sell more Provigil.

4. If we keep PRO VIGIL, what will we do with NUVIGIL?
a. Will it get approved?
b. How will it fit with PROVIGIL?

Notes: It would be fantastic if we have PROVIGIL for the next 6 years, really changes the landscape for Cephalon in the short and long term. The reality is that if we achieve exclusivity, it will dramatically change what we do with NUVIGIL. We are evaluating any number of options which could mean quite frankly launching or not launching.

Honest answer is we honestly do not know yet. What we can tell you is that we still feel that NUVIGIL is a viable product that will get approved. As a company we need to determine how it fits. The good news is we have a great opportunity in front of us and the potential of NUVIGIL in the wings as we better understand the best options for Cephalon.

5. PROVIGIL / Sparlon
a. Incentivized

Until Sparlon, it is simple – 100% PRO VIGIL

Given the recent chain of events and the apparent opportunity we are facing… don't be surprised if PROVIGIL is larger than we previously expected as a proportion of the incentive – Not out of the realm of possibilities that it could be 50 / 50 with Sparlon. All to be determined.

6. Bottom Line –

NUVIGIL currently under review FDA. Plan is to come, honestly we don't have an answer yet, given the recent events – Stay tuned Sparlon will come when it comes. We have every confidence that Sparlon with launch — waiting for an update on the time frame – it's a matter of when.

In the mean time – What we know now is PROVIGIL. PROVIGIL is the clear opportunity – With all of your efforts, we can take a $600 Mil product to over $l billion in the next few years.

400 + focus our resources – it's about what we are gaining – 1 product focus
It's a great situation to be in!

So we come full circle – It's about BALANCE – balancing all the moving pieces and the uncertainty around timing."[774]

(462) In the "modafinil hand-over document" of December 2006 for Cephalon United Kingdom's Regulatory Officer, the IP Section indicated: "Modafinil was first approved in France in 1992. There is, therefore, no data exclusivity in the EU although Cephalon Inc has done deals with generic companies to minimise risks to market."[775]

(463) While reviewing 2006 accounts of Cephalon UK, Cephalon's auditors had difficulties understanding the payments made by Cephalon under the Settlement Agreement:

"*It is still not clear to me… how come the Company started* [patent infringement] *proceedings* [against Teva] *but in the end paid the defendants of the case… Please can you clarify if the fee paid was for non-compete arrangement (is stopping the other companies entering the UK market with a generic product) or just avoidance of*

774 ID 2841-1323, p. 5.
775 ID 265, p. 12. The same document as ID 280, p. 28-34 and ID 281, pp. 4-10.

the legal costs, etc. As part of the settlement proceedings, has Teva… agreed to give up some rights or committed to do something in favour of the Company?"[776]

(464) The employee of Cephalon UK involved in the drafting of the above-mentioned 2006 accounts, but not familiar with the context of the Settlement Agreement also inquired with a legal director at Cephalon UK:

"(P)*lease see [question from the auditors quoted above], this was an agreement made between Ceph INC and Teva during 2005… Do you have sight of the contract? If so are you able to explain why we ended up paying a settlement…*"[777]

(465) In response to these questions, the note to the 2006 accounts of Cephalon UK, drafted in June 2008, was revised to read: "*Exceptional Item – Administrative expenses: The exceptional item related to a litigation settlement: in July 2005 the Company commenced patent infringement proceedings against Tenlec Pharma Limited and Teva UK Limited following the grant of a UK product license for a generic form of Modafinil in December, 2005. The infringement proceedings were subsequently withdrawn as part of a settlement between the Cephalon group companies and the Teva group companies. As part of the settlement, certain payments were made by Cephalon group companies to Teva group companies in respect of, inter alia, a non-exclusive worldwide license to certain intellectual property rights held by Teva group companies related to Modafinil, and the savings inuring to Cephalon [group companies??] in terms of the avoidance of costs, and expenditure of time and resources associated with prosecuting such litigation.*"[778]

(466) Cephalon's in-house counsel commented on this wording: "I don´t disagree with your suggested language… You could also want to note that… we entered a modafinil supply arrangement as part of the consideration for the settlement."[779]

(467) Cephalon's internal document "Global Product Supply Strategy" of April 2008 sets out: "In early 2006, several agreements were reached with generic competitors that had challenged the Provigil patents. These agreements allowed three generic competitors to supply 35 MT of modafinil annually. This also allowed Provigil to remain on the US market."[780]

(468) The minutes of the meeting of the Central Worker's Council of Cephalon France stated: "Generic threat to Provigil in the US: since 2003, challenge of the validity of the modafinil patents by the generics in the US and filing of their approval applications. Potential risk of loss of 65% of the revenues in 12 months, or approximately USD 350 million. In 2006, a settlement agreement is thus concluded with the generics which temporarily protect the product until 2011 (no generic entry

---

776 ID 189, p. 89. The quoted wording appears in the e-mail sent by the employee of Cephalon Europe to the Cephalon's auditors. However, the response by the Cephalon's auditors indicated that their comments had been made directly in the text of the initial e-mail. The Commission therefore considers that the statement should be attributed to the Cephalon's auditors.

777 *Ibid*, p. 88.

778 ID 189, p. 87.

779 ID 189, p. 85.

780 ID 196, p. 5.

in the US market). In return for this, the generic manufacture a part of active pharmaceutical ingredient for Cephalon."[781]

(469) A presentation prepared for the same meeting of the Central Worker's Council of Cephalon France of 18 September 2008 explained further: "*Provigil (Modafinil) the first product of Cephalon Group in 2004… Major risk of brutal loss of revenues from Provigil… Settlement agreements concluded in 2006 with the generics, protecting the product until 2011. Within the framework of the agreements, the supply contracts for the warranted volume of 35 tons of modafinil were signed.*"[782]

4.8.1.2. Teva's reactions

(470) Less than two weeks after the signing of the Settlement Agreement, on 19 December 2005, Teva's CEO gave a presentation to Teva's Board of Directors in which he drew conclusions from the Settlement Agreement. The learnings of the modafinil type of cases are that they "*create value…* [by creating] *timing certainty and 'early' entry,* [they] *reduce risk*… [and they] *leverage other Teva's businesses and geographies*."[783] He further clarified:

"*We have already begun to use these 'learnings' to create value. I would like to give an example. We recently signed a deal with Cephalon. In fashioning this deal we applied much of what we learned about their strategic needs and their life cycle options, combined with our increased understanding of how to apply our own corporate resources in an integrated way.*

What did we achieve?

(1) We settled patent disputes in the US and UK

(2) We cross licensed – obtaining rights to their modafinil, and giving Cephalon rights to our API patents.

(3) We will receive fees of over $30 million

(4) We will receive royalties on their brand (including any life cycle extensions they launch)

(5) We signed an agreement to supply raw material

Our increased understanding of the complexity of our environment as well as of the needs of our innovators and generic competitors helps us to bring these [types] *of solutions.*"[784]

---

781 ID 1604, p. 3: "*Menace Générique sur Provigil aux US : dès 2003 contestation sur la validité des brevets de modafinil par des génériques aux US et dépôt de dossiers d'enregistrement. Risques potentiels de perte de 65% du CA en 12 mois, soit environ 350 millions USD. En 2006, un accord transactionnel est donc conclu avec les génériques protégeant provisoirement le produit jusqu'en 2011 (pas d'entrée de générique sur le Marché US). En contre parti les génériques produisent une partie du produit actif pour Cephalon.*"

782 ID 1605, p. 19: "*Provigil (modafinil) 1er produit du Groupe Cephalon en 2004… Risque majeur de perte brutale du chiffre d´affaires de Provigil… Accord transactionnels conclus en 2006 avec les génériques, protégeant le produit jusqu´en 2011. Dans le cadre de ces accords, des contrats de fourniture d´un volume garanti de 35 tonnes de modafinil ont été signés.*"

783 ID 2166-97, p. 13.

784 *Ibid*, p. 13-14.

(471) Teva United States' CEO presented on the same day to the same Board of Directors "*Cephalon Agreement* [that] *illustrates the complexities and opportunities we face*". The "*complexities and opportunities*" of the Settlement Agreement with Cephalon include dismissal of patent litigations in the United States and the United Kingdom and all related commercial transactions (modafinil distribution agreement for the United Kingdom, licence to CEP-1347 Data, supply agreement for modafinil API, licence of Teva's Intellectual Property Rights to Cephalon as well as Teva's modafinil entry three years prior to Cephalon's patent expiry) and all payments that Teva obtained through the Settlement Agreement.[785]

(472) Teva's Patent Department drafted a presentation of the work of the Intellectual Property litigation team between 2005 and 2008 comparing, *inter alia*, the results for the company of the concluded settlements, successful litigation and launches at risk. It made the following comments concerning the settlements: "(T)*he profits resulting from the settlements are high. This is because they concern big products that we started selling a while ago + Teva UK Limited is the exclusive distributor in the United Kingdom for all Cephalon Modafinil Products…*"[786]

4.8.1.3. Cephalon reaches settlements with three other generic contenders in the United States

(473) Soon after the Settlement Agreement, Cephalon entered into modafinil settlements with three other generic manufacturers: the settlement agreement with Ranbaxy of 22 December 2005 ("Ranbaxy Settlement Agreement"),[787] the settlement agreement with Mylan of 9 January 2006 ("Mylan Settlement Agreement 2006"),[788] and the settlement agreement with Barr of 1 February 2006 ("Barr Settlement Agreement").[789]

(474) In contrast to the Settlement Agreement, which has worldwide scope, the Ranbaxy, Mylan and Barr settlements are limited to the United States market.

(475) The four modafinil settlements also share certain common features. First, […].[790]

(476) Second, all four Modafinil Settlements include, further transactions between the contracting parties, as follows:[791]

(a) Ranbaxy Settlement Agreement:

– […].[792] […].[793]

– […][794]

---

785 ID 2166-38, p. 28.

786 ID 146, p. 1.

787 ID 254, p. 3 and subsequent.

788 ID 254, p. 73 and subsequent.

789 ID 254, p. 100 and subsequent.

790 Article 3.1 of the Settlement Agreement with Teva, Article 3.1 of the Ranbaxy Settlement Agreement, Article 3.1 of the Mylan Settlement Agreement 2006, Article 3.5 of the Barr Settlement Agreement and the modafinil Licence and Supply Agreement of 1 February 2006 between Cephalon and Barr, ID 254, p. 118 and subsequent. […]. ID 254, p. 126

791 The facts concerning the commercial transactions pursuant to the Settlement Agreement are described in particular in Sections 4.6 and 4.7.

792 ID 254, Article 2.3 of the Ranbaxy Settlement Agreement.

793 ID 3694-13, p. 30-31.

794 ID 254, Article 2.5 of the Ranbaxy Settlement Agreement.

(b) Mylan Settlement Agreement 2006:

– […][795]

(c) Barr Settlement Agreement:

– […].[796]

– […][797] […].[798]

- […].[799]
- […].[800]
- […].[801]

(477) Finally, all modafinil settlements provide for the settlement of the respective litigations. […].[802]

4.8.1.4. Cephalon postpones the switch from Provigil to Nuvigil

(478) After the modafinil settlements, Cephalon postpones the launch of its second-generation modafinil product armodafinil (Nuvigil) to focus on maintaining the Provigil market.

(479) In its Annual Report for 2005, Cephalon states: "Most importantly, we settled litigation with four companies that had been challenging our exclusive right to market PROVIGIL for wakefulness… Now, we intend to reinvigorate our clinical and commercial programs for PROVIGIL and continue to build this brand."[803]

(480) The Modafinil Settlements led to a change of plan to launch the second-generation armodafinil (Nuvigil). As summed-up in the internal e-mail of Cephalon's armodafinil contract supplier [*company name*], […].[804]

(481) In September 2005, Cephalon worked on an assumption of 2006 annual sales of Nuvigil of USD 262 million which "*would force Provigil use to go to zero…*",[805] and kept this high-end estimate for 2006 Nuvigil sales as an option until December 2005.[806] However, on 28 December 2005, a senior supply manager of Cephalon calculated requirements for modafinil API based on a "*potential increase to Provigil Sales*" as well as on the fact that: "*Sales/Marketing is planning to heavily promote Provigil in first half of 2006-additional samples may be needed.*"[807] He

---

795 ID 2215, p. 18, paragraph 70.

796 ID 254, Article 3.4 of the Barr Settlement Agreement.

797 ID 212, p. 76 and subsequent.

798 ID 2215, p. 19, paragraph 74.

799 ID 212, Article I.6 of the […] Supply Agreement.

800 ID 212, Article II of the […] Supply Agreement.

801 ID 2215, p. 20, paragraph 75.

802 ID 254, Article 2.2 of the Ranbaxy Settlement Agreement, Article 2.2 of the Mylan Settlement Agreement 2006, Article 3.3 of the Barr Settlement Agreement.

803 ID 2777, p. 5. See also Cephalon's Annual Report for 2006, ID 2241, p. 4: "*With the future secure for Provigil (modafinil)… we begin to reinvigorate* [Provigil] *marketing programs*."

804 ID 1836, p. 10.

805 ID 1587, p. 2.

806 ID 1570, p. 2. As a result of this estimate Cephalon's supply managers realised, with the Settlement Agreement already concluded, that the high modafinil API requirements for Nuvigil could jeopardize sales in Provigil or Sparlon. ID 1570, p. 1.

807 ID 1570, p. 2.

therefore suggested "*slow down (stop) R-modafinil production for 2-3 months to build up some Modafinil supply to support any increases to Provigil and Sparlon*."[808] The meeting of Cephalon's Technical Operations Executive Committee of 13 February 2006 reveals that, first, the earlier plan to launch Nuvigil is postponed.[809] Second, the Committee therefore assumed the commercial sales of Nuvigil in the United States for 2006 of only USD 32 million, while sales estimate for Provigil soared to USD 650 million[810]. Due to regulatory difficulties, the FDA approved Nuvigil only in June 2007[811].

(482) However, Cephalon launched the product in the United States only two years later, in June 2009.[812] The draft Nuvigil Launch Platform document of 6 February 2007 indicates that "*Past examples of transition strategies – across therapeutic categories – provide insights on requirements for success: differentiation…; sufficient time prior to generics (sufficient time to impact prescriber preferences; accelerated promotional commitment…; use economics to reinforce switch (price discount, rebates to drive transition and change preference).*" It then refers to "*Current Nuvigil Strategy and Assumptions*", distinguishing between "*Shorter-term launch strategy*" and "*Longer-term expansion strategy*". The short-term strategy implies "*Intercept and transition current franchise business*", referring, amongst others, to "*anticipate Provigil exclusivity expiration in April 2012; launch Nuvigil at least 24 months prior (Q1 2010); …; further support for Nuvigil transition (Phase IV studies)*".[813] Accordingly, Cephalon informed in its Annual Report for 2006: *We are planning to transition our wakefulness franchise to NUVIGIL around 2010, prior to the April 2012 license effectiveness dates under the generic settlement agreements related to PROVIGIL.*"[814]

(483) In a document of April 2008 Cephalon summarised its decision to put the Nuvigil project aside at the moment, linking that decision directly to the outcome of the Modafinil Settlements:

"*With Provigil remaining on the market, the US launch of Nuvigil was postponed. This allowed time for additional clinical indications for Nuvigil to be evaluated*."[815]

(484) In line with the strategy to delay the launch of Nuvigil, Cephalon terminated the armodafinil API supply agreements.[816] For example, Cephalon informed [*company name*] about its intention to terminate the supply agreement already on 17 February 2006,[817] namely immediately after the modafinil settlements (and well before the regulatory delay of Nuvigil, see Recital (482)). [*company name*], later told the Commission:

---

808 ID 1570, p. 1.

809 ID 2144-3, p. 15.

810 ID 2144-3, p. 16.

811 The unfavourable side-effect profile of Sparlon delayed the FDA's approval proceedings concerning Nuvigil; see also ID 1726, p.15-16; ID 2325, p.5.

812 ID 1726, p. 16. In this reply to the Article 18 Request, there is a reference to Cephalon's Decision to "*gather additional clinical data*". See however other evidence quoted in this Section.

813 ID 238, p. 2.

814 ID 2235, p. 6. See also ID 2241, p. 6.

815 ID 196, p. 6. An earlier version of this passage, deleted in later draft, read: "*It was* [also] *decided to delay the launch of Nuvigil in the US*." *Ibid*.

816 See Section 4.2.3., Recital (363).

817 ID 1803, p. 6, ID 1836, p. 7, ID 1832, p. 3.

[…] [818]

(485) Similarly, another contracted armodafinil supplier, [*company name*], made the following internal assessment upon the termination of the armodafinil API supply agreement by Cephalon:

[…][819]

(486) Since 2008, Cephalon started progressively increasing prices of Provigil in the United States. In 2008, Provigil became 74% more expensive than in 2004, [820] and in 2009, its price was further increased by 29%.[821] Consequently, at its 2009 launch, Nuvigil was cheaper than Provigil. Such a Cephalon's pricing policy certainly contributed to Nuvigil's success and Cephalon's Head of United States Pharmaceutical Operations confirmed in February 2010 that "*about four out of every five prescriptions for Nuvigil is a conversion from Provigil and about one out of every five is new to wake therapy going to Nuvigil*."[822] Cephalon's CEO told at the same time to investors: "*We exceeded certainly my expectations of where Nuvigil should be at the end of 2009 and I know for a fact that given where everybody's estimates were, we exceeded Wall Street's expectations on where Nuvigil should be at the end of 2009. So we are way ahead of a plan to do what we need to do with Nuvigil.*"[823] Nuvigil world-wide (that is United States) sales in 2009 were about USD 73 million compared to over USD 1 billion of Provigil world-wide sales.[824] In 2013, Cephalon registered sales of Nuvigil of USD 320 million compared to USD 91 million sales of Provigil (the overall decrease in combined sales can be attributed to several factors, including the loss of approved indications for modafinil and the introduction of generic modafinil in the United States in 2012).[825]

4.8.1.5. Teva implements the non-compete commitments from the Settlement Agreement

(487) After the conclusion of the Settlement Agreement, Teva took measures to comply with its obligation pursuant to Article 2.5 thereof not to compete with Cephalon's modafinil product in those Contracting Parties to the EEA Agreement where Cephalon held modafinil patent rights. At the beginning of January 2006, the General Counsel of Teva Pharmaceuticals Europe distributed to Teva's European General Managers this instruction:

"*Dear all,*

Effective as of December 4, 2005, Teva Israel and Teva USA entered into an agreement with Cephalon concerning modafinil. In broad terms, the agreement contains an obligation on Teva and its affiliates to negotiate an agreement with Cephalon if Teva and its affiliates would like to introduce modafinil. This obligation lasts until the earlier of October 6, 2012 or the date three years prior to the expiration of the applicable patents, whichever is the earlier.

818 ID 1803, p. 8. See also ID 1836, p. 10.
819 ID 2325, p. 5. See also ID 1836, p. 7.
820 ID 2240.
821 ID 2239.
822 ID 2238, p. 15.
823 ID 2238, p. 17.
824 ID 2206, p. 46.
825 ID 2234, p. 68.

Agreements existing with third parties concluded prior to 4 December 2005 are excluded.[826] *At your request I can provide you with more details.*"[827]

(488) In the following discussion between Teva's managers in various Contracting Parties to the EEA Agreement, the Export Logistic Director for Europe summarised in the e-mail of 25 January 2006:

"*There is an agreement Modafinil* – [Settlement Agreement] *with Cephalon which is a general agreement including US and Europe markets.*

The significance of the agreement is that Modafinil Teva can't be marketed in Europe.

I understood from [General Counsel of Teva Pharmaceuticals Europe] *that he already informed the General managers in Europe some time ago of the existence of the agreement and of the fact that they cannot conclude any agreements with any other third parties.*"[828]

(489) In February 2006, Teva's patent lawyer recapped Teva's position with regard to envisaged launch preparation in Czechia :

"*The relevant patent is in force in the Czech Republic until October 4, 2015. According to the agreement, we cannot launch our generic Modafinil product until 3 years prior to the expiration of this patent, i.e. October 4, 2012.*

However, the agreement calls for both Teva and Cephalon to consider in good faith in order whether resale and distribution agreement (such as the one negotiated by Teva UK for the UK market) may be feasible in other countries, such as Czech Republic. This is the avenue to pursue, if any."[829]

(490) Cephalon monitored that Teva complied with its non-compete commitments pursuant to the Settlement Agreement. At the meeting between representatives of Teva UK and Cephalon UK on 3 February 2006 discussing the prospective distribution agreement in the United Kingdom "(*C*)*ephalon explained that there still appeared to be Teva modafinil product on the shelves in the UK and expressed concern that certain Teva sales representatives in the UK are apparently still informing customers that Teva's modafinil product is 'temporarily unavailable' rather than 'no longer supplied*'."

(491) A solution was then adopted: "Action point: Teva agreed to look into this problem and take the necessary steps to ensure that the correct message is conveyed."[830]

(492) On 11 December 2006, Cephalon's attorney addressed Teva United States' Senior Associate General Counsel with the following query:

"(I) *need to bring another matter to your attention rather urgently. We have received reports that Teva may currently be seeking approval for a generic modafinil product in France and has apparently also recently sought such approvals in Spain and Germany.*

---

826 According to Article 3.6 of the Settlement Agreement, Teva's sales of modafinil prior to the Settlement Agreements in countries where Cephalon held modafinil patent rights should not have been deemed a breach of the Settlement Agreement, provided that Teva used its best efforts to effect an orderly and timely cessation of such sales. See also ID 457, p. 4.

827 See ID 457, p. 6; ID 981, p. 29, ID 979, p. 71-72.

828 ID 457, p. 7. See also ID 180, p. 77-78. ID 180, p. 82 concerns a query with respect to the Netherlands.

829 ID 457, p. 2.

830 ID 187, p. 123.

As you know, under the terms of our Settlement Agreement, Teva has agreed that until the Date Certain, it will not make, use, or sell or induce or assist anyone else to make, use or sell a generic version of Provigil in any country in Europe wherein Cephalon has applicable IP rights. We simply seek to remind Teva of its obligations and seek assurance that Teva is aware of the restrictions and does not intend to make, use or sell, or to induce or assist anyone else to make, use or sell product in contravention of our agreement.

Thank you for your prompt attention to this matter."[831]

(493) Teva's Associate Director for Legal Affairs forwarded Cephalon's above e-mail to Teva's Patent Department, asking:

"*Please see the e-mail… from Cephalon below. They noticed Teva is seeking approval for generic modafinil in France, Spain and Germany and want our confirmation that subsequent to the Agreement between Teva and Cephalon, Teva EU does not intend to market this product in any EU markets where Cephalon has IP rights as defined therein.*

Can you confirm?"[832]

Teva's General Counsel for Europe replied:

"*Seems very strange to me given the correspondence I had with many people in various countries over the last months.*[833]

[Three first names of sales managers]: *seeking approvals means that you are violating the agreement with Cephalon. Please inform me immediately what is going on here*."[834]

In response, one of the addressed sales managers' remarks:

"*We were never asked to stop* [regulatory] *activity but if this is what you require just say so.*"[835]

To which the General Counsel for Europe reacts:

"*Thanks. We should stop the activity because we are not allowed to market, distribute and /or sell this product*."[836]

Later that day, the General Counsel for Europe deemed necessary to clarify for Teva's staff the company's present policy towards modafinil:

"*All*

As it was not necessarily clear to all I would like to clarify that in light of agreement with Cephalon, Teva cannot launch our own product until the end of said agreement which, I believe is in 2012.

You do have the right to negotiate with Cephalon directly for the distribution rights in your country to their product."[837]

---

831 ID 171, p. 4-5.
832 ID 171, p. 4.
833 This refers to the instruction and subsequent discussion shown in Recital (489).
834 ID 171, p. 3.
835 ID 171, p. 2.
836 *Ibid.*
837 ID 171, p. 1.

(494) In April 2008, Cephalon was asked by its Spanish distributor to take the necessary steps to ask Teva to withdraw its generic modafinil that was approved, as, otherwise, this would lead to immediate and automatic 30% cuts in the price of Provigil.[838]

4.8.2. Regulatory decisions and court proceedings

4.8.2.1. The European Commission restricts Provigil's indications

(495) Provigil was approved in various Contracting Parties to the EEA Agreement between 1997 and 2010 (see Section 4.1.1). However, based on a referral by the United Kingdom health authority, in 2009-2010, the EMA reviewed the efficiency/safety profile of modafinil-containing medicines because of a number of safety concerns, relating to psychiatric disorders, skin and subcutaneous tissue reactions as well as significant off-label use and potential for abuse.

(496) On 22 July 2010, the EMA recommended that Provigil's use be restricted to the treatment of narcolepsy, and that it should no longer be used for three other indications (obstructive sleep apnoea, shift work sleep disorder, idiopathic hypersomnia) because of the side-effect concerns. Following a re-examination and confirmation of this recommendation, the European Commission adopted on 27 January 2011 a Decision that obliged the concerned Member States to maintain and amend national MA's for modafinil-based medicines on the basis of the EMA's conclusions.[839] Following the Decision (and also due to other factors) the sales of Provigil started falling rapidly.[840]

4.8.2.2. United Kingdom court declares Cephalon Particle Size Patents invalid and non - infringed

(497) On 4 September 2010, Generics (UK) Limited (trading as Mylan – "Mylan") announced that it was offering modafinil 100 mg tablets in the United Kingdom. The manufacturer of Mylan's product was Orchid Europe Limited ("Orchid").[841]

(498) On 14 September 2010, Cephalon[842] filed a patent infringement lawsuit with the England and Wales High Court of Justice (Patents Court) against Mylan and Orchid. Cephalon asserted infringement of its EP '698 Patent (claims 1 and 2) and of the EP '962 Patent (claims 1 and 16) – that is the same Particle Size Patents that Cephalon had invoked against Teva in the United Kingdom 2005 patent proceedings – as well as of its European patent No. EP 1 088 549 (EP '549 Patent) which was granted only after the Settlement Agreement (claim 1).[843] In addition, Cephalon sought a preliminary injunction restraining Mylan from selling or offering for sale its modafinil product. By way of counterclaim, Mylan claimed revocation of all three patents.[844]

838 ID 187, p. 84-88.

839 Commission Decision C(2011)578 concerning MA for modafinil.

840 See Recital (487).

841 Both Mylan and Orchid obtained MA's on 22 January 2010. See ID 1396, p. 2, paragraphs 3-4.

842 Cephalon, Inc, Cephalon France and Cephalon UK.

843 This patent was granted on 9 July 2008 and also its claims are construed around the size of modafinil particles. See footnote 121.

844 ID 1396, p. 2, paragraph 7; ID 1660, p. 2, paragraph 8 and p. 4-5, paragraphs 21 and subsequent.

(499) In the judgment of 19 November 2010,[845] the Patents Court dismissed Cephalon's application for the preliminary injunction.[846]

(500) The Patents Court served the judgment in the main proceedings on 24 June 2011,[847] in which the Court concluded that Cephalon's patents were not infringed: "*It was common ground that if Mylan's construction of the claims was the correct one, there was no infringement. The Orchid API falls outside the scope of all the claims if they are construed to mean the particle size in the input API as opposed to the tablet. It has a 95% cumulative particle size of greater than 220 µm. there is accordingly no infringement.*"[848]

(501) Regarding the question of validity of Cephalon's patents, the Patents Court came to the conclusion that the inventive concept of each of the relevant patent claims relied upon by Cephalon was obvious in the light of the literature and common general knowledge.[849] In addition, the Patents Court established that the claims of EP '962 Patent and EP '549 Patent (but not those of EP '698 Patent) would also be invalid on grounds of insufficiency.[850] For all these reasons, the Court invalidated Cephalon's respective patents concluding: "*The Cephalon patents are all invalid for obviousness over Drugs of the Future* [European Commission: scientific publication] *and common general knowledge. Had they been valid they would not have been infringed*."[851]

(502) Cephalon appealed the first instance judgment and received grant of leave to appeal on 1 November 2011. Before the main proceedings, the Parties settled their dispute out of court.[852]

4.8.2.3. Court proceedings in other EEA Contracting Parties

(503) In addition to the court proceedings in the United Kingdom against Mylan, Cephalon initiated patent litigation concerning its Particle Size Patents in the Netherlands and France (against […]), Sweden and Denmark (against […]), in Spain (against […]), and in Germany (against […]). In addition, Cephalon launched court proceedings to

---

845 England and Wales High Court of Justice, Cephalon Inc, & Ors v Orchid Europe Ltd. & Anor, [2010] EWHC 2945 (Pat) (19 November 2010), ID 1396.

846 ID 1396, p. 11, paragraph 70. The Court also assessed whether Cephalon had an arguable case of patent infringement and validity. Concerning the first, the Court found that Cephalon's evidence was very weak and fell "*a long way short of persuading me on the balance of probabilities that the Particle size within the* [Mylan's] *composition is within the* [Cephalon's] *claimed range*." However, the Court also admitted that a final decision cannot be reached at this stage of the proceedings. The Court concluded: "*In the end, and not without difficulty, I have concluded that the evidence just about clears the threshold of establishing that there is a serious question to be tried.*" *Ibid*, p. 6 (paragraphs 32-35). Concerning the patent validity, the Court similarly stated that it did not think "*it is realistic to suggest, even at this stage, that the dosage of modafinil was not common general knowledge, or at least knowledge that the skilled person would immediately acquire…*" However, "*[E]xperience teaches that the most unpromising-looking claim at the interim stage may turn out to be valid…*" *Ibid*, p. 7 (paragraphs 41-42).

847 England and Wales High Court of Justice, Cephalon Inc, & Ors v Orchid Europe Ltd. & Anor [2011] EWHC 1591 (Pat) (24 June 2011), ID 1660.

848 ID 1660, p. 14, paragraph 50. The Court stated already in the decision concerning interim injunction: "*If the claim were to be construed as referring to the API I would have no hesitation in saying that the claimants had not established an arguable case of infringement*." ID 1396, p. 4.

849 ID 1660, p. 19, paragraphs 75-81.

850 ID 1660, p. 20- 21, paragraphs 87-93.

851 ID 1660, p. 21, paragraph 94.

852 ID 1724, p. 7.

declare null and void the MA for modafinil in Portugal issued to […] (see Recital (513)).

(504) As regards modafinil litigations in the Netherlands and France, Cephalon started court proceedings against […] in the Netherlands on 1 October 2010, and in France, on 5 November 2010. Consequently, […] introduced counterclaims to invalidate Cephalon's Particle Size Patents. The Dutch court granted Cephalon, on 5 December 2011, an interim injunction whereby […] was only allowed to supply modafinil products worth up to EUR 50,000 until the decision on the merits.

(505) […] and Teva, which had meanwhile acquired Cephalon, settled the court proceedings in both countries […] ("[…] Settlement Agreement 2012").[853] The […] Settlement Agreement 2012 allowed […] to market and sell modafinil products in the EEA […]. The […] Settlement Agreement 2012 provided that […].[854] Notably, […].

(506) As regards Sweden, on 4 June 2010, Cephalon France SAS (later Teva Santé SAS) filed a lawsuit against […] ("[…]"), a […], which had been selling modafinil product in Sweden since April of that year[855], asserting an infringement of its Particle Size Patents and also applied for an interim injunction.

(507) The Swedish court granted the injunction on 2 November 2010. In the motion of 29 March 2012, […] made invalidity claim against Cephalon's EP '962 Patent.[856]

(508) As regards Denmark, on 30 June 2010, Cephalon, and Cephalon France SAS (later Teva Santé SAS) initiated court proceedings against […], which had been selling modafinil in Denmark since April 2010, alleging infringement of the Particle Size Patents. Cephalon also asked the court for granting of a preliminary injunction, which the court eventually granted following Cephalon's appeal.[857] In the patent infringement proceedings, […] made a counter-claim of invalidity of the Particle Size Patents.[858]

(509) The litigations in Sweden and Denmark were put to an end by the Settlement and Licence Agreement […].[859] In consideration of the withdrawal of the court proceedings, Teva granted to […] a non-exclusive, royalty-free licence in Denmark and Sweden as from the date of execution of the Settlement and Licence Agreement.[860] […].[861]

(510) As regards the modafinil litigation in Spain, Cephalon initiated court proceedings against the generic company […] in order to establish facts showing infringement of

---

853 ID 2282.

854 Article 3, ID 2282.

855 Similarly as with Mylan in the United Kingdom (Section 4.8.2.2), the product marketed by […] in Sweden and Denmark […], ID 1396, p. 2, paragraph 3. […] also obtained an MA for modafinil in Germany (22 July 2009) and in Norway (20 January 2010), ID 1225, p. 13.

856 ID 2178, p. 8. See also the Settlement and Licence Agreement of 11 June 2014, Appendix 1, ID 2283, p. 10.

857 ID 1729 and ID 1728; ID 1731 and ID 1730.

858 ID 2178, p. 2. See also the Settlement and Licence Agreement of 11 June 2014, Appendix 2, ID 2283, p. 11-12.

859 ID 2283. The settlement was recorded and the proceedings discharged by the relevant courts on 12 June 2014 (Sweden), ID 2182, and on 16 June 2014 (Denmark), ID 2179.

860 Article 3.1 of the Settlement and Licence Agreement, ID 2283, p. 3.

861 Article 4.1 of the Settlement and Licence Agreement, ID 2283, p. 3.

its Particle Size Patents (the so-called "*diligencias*"). The court granted the "*diligencias*" on 13 December 2010.[862] Following submission of a report drafted by the court-appointed expert, the court ruled on 31 January 2012 that there was no likelihood of infringement and declared the end of the proceedings.[863]

(511) As regards Germany, Cephalon filed a lawsuit against […] on 28 September 2010 for infringement of its German modafinil patents. After […] gave a declaration that they would not launch generic modafinil, the proceedings were withdrawn on 10 November 2010.[864]

(512) As regards Portugal, on 29 July 2010, Cephalon started court proceedings to declare null and void the MA for modafinil granted by the Portuguese National Authority for Medications and Health Products ("Infarmed") to a generic company […].[865] Cephalon had already in June requested preliminary injunction to suspend the efficacy of the MA, which the Court granted only after an appeal in February 2011.[866] […] was active only as a distributor in Portugal of a finished modafinil product bought from […][867]. The company had already launched the generic modafinil in the market prior to the start of the proceedings.[868]

(513) As the question before the Court concerned the so-called patent linkage, that is whether a state authority competent for issuing the MA has to consider the existence of intellectual property rights when deciding on the grant of the MA, the Court explained "*Infarmed was not responsible for monitoring intellectual property rights, but only for monitoring the medical and therapeutic quality of drugs*"[869] and dismissed Cephalon's action. Subsequently, on 14 March 2014, the court declared that the preliminary injunction had expired.[870]

4.8.2.4. Teva/Cephalon merger

(514) On 13 October 2011, the European Commission approved the acquisition of Cephalon by Teva, subject to conditions.[871]

(515) To address serious doubts expressed by the Commission as regards the compatibility of the notified transaction with the internal market and the EEA-Agreement,[872] Teva

862 ID 1735.
863 ID 1736. See also ID 2178, p. 7.
864 ID 2178, p. 3.
865 Legislation in Portugal allowed for the practice linking the granting of MA and pricing and reimbursement status for generic medicinal product to the status of a patent for the originator reference product ("patent linkage") which in turn led to relatively high number of litigations initiated by the originator seeking the annulments of the MA issued to the generic (Commission Report on the Pharmaceutical Sector Inquiry (8 July 2009), pp. 319, 330 and 331). Portuguese Law 62/2011 published on 12 December 2011 provides that an originator must initiate arbitration proceedings within 30 days of the publication of an MA application by a generic company. If they do not comply with this provision, the originators then lose the ability to assert their intellectual property rights. Hence, originators in Portugal are, since 2012, obliged to systematically bring arbitration proceedings against all generics applying for MA's (European Commission, DG Competition: 6th Report on the Monitoring of Patent Settlements, 2 December 2015, p. 8). ID 2178, p. 5-6.
866 ID 2178, p. 5.
867 ID 1827, p. 4.
868 ID 2186, p. 6.
869 ID 2181, p. 13; ID 2186, p. 12.
870 ID 2180; ID 2187, p. 2.
871 Case M.6258 -*Teva/Cephalon*.
872 Case M.6258 - *Teva/Cephalon*, paragraph 153.

committed to divest Cephalon's generic modafinil pipeline product and related rights("Divestment Business")[873] and/or to covenant not to sue the approved purchaser of the Divestment Business for infringement of any modafinil patents owned by Teva or Cephalon for the manufacture or the sale by the purchaser of a generic modafinil product in the EEA as of 6 October 2012 ("covenant not to sue").[874] The Commission accepted these commitments.[875]

(516) By letter of 17 January 2012, Teva proposed [*company name*] for approval by the Commission as counterparty to the covenant not to sue.[876] As [*company name*] already supplied a generic modafinil in the EEA, it did not need to purchase the Divestment Business from Teva.[877] On 4 April 2012, the Commission approved [*company name*] as a suitable counterparty to the covenant not to sue.[878]

4.8.2.5. United States court declares Cephalon's US '516 Patent invalid and finds that Cephalon obtained the patent through deliberate deception

(517) On 26 June 2006, Apotex Inc., a generic drug manufacturer, commenced declaratory action against Cephalon alleging non-infringement, invalidity and unenforceability of Cephalon's US '516 patent (that is the US Particle Size Patent, see Recital (88)). Apotex' primary argument was that the US '516 patent was invalid and unenforceable because Lafon invented the claimed subject matter.[879]

(518) On 7 November 2011, the United States court declared the US '516 patent invalid pursuant to the on-sale bar, for derivation, for obviousness, and for lack of written description. The court also declared the patent unenforceable due to Cephalon's inequitable conduct in its prosecution of the patent.[880] The court saw as demonstrated that:

(a) Cephalon misinterpreted or omitted certain information in applying for the patent,

(b) such information was material, and

---

873 For the full definition of the Divestment Business, see Case M.6258 - *Teva/Cephalon,* paragraph 157, and annexed Commitments, in particular its Schedule 2. Generic modafinil product is defined as any Modafinil Product that is not marketed under the trademarks Provigil, Modiodal, Vigil, and Modasomil.

874 For a detailed description of the commitments, see Case M.6258 - *Teva/Cephalon,* paragraphs 155-160, as well as attached Teva's commitments proposal in the letter of 22 September 2011, the Schedules 1 and 2 enclosed to Teva's letter. The Commission stated in paragraph 161 of the Decision in Case M.6258 - *Teva/Cephalon* that "*due to the possibility to rely only on the covenant not to sue, i.e. in the absence of an obligation to purchase the whole Divestment Business, the Commitments are also suitable to remove competition concerns if the prospective buyer already has a generic modafinil product*".

875 Case M.6258 - *Teva/Cephalon*, paragraph 167.

876 Case M.6258 - *Teva/Cephalon*, paragraph 5: Approval of [*company name*] as counterparty to the Covenant not to sue.

877 Case M.6258 - *Teva/Cephalon*, paragraph 21.

878 Case M.6258 - *Teva/Cephalon*, paragraph 23.

879 ID 2216, p. 2-3.

880 *Ibid*, p. 51.

(c) Cephalon made the misinterpretation or omission with the specific intent to deceive the PTO to obtain a patent that otherwise would not have been granted.[881]

(519) The United States court established inter alia that Cephalon failed to disclose material information to the PTO concerning its patent application: "*Had the PTO been aware of this information, it would not have allowed the patent to issue*."[882] The court also explained:

"*The claim history with the PTO is also probative of Cephalon's intent. The PTO initially rejected Cephalon's patent application as obvious. (Fact 107.) The examiner concluded that the prior art included smaller particle modafinil, and the scientific references in the field suggested that it would have been obvious to reduce particle size to achieve better bioavailability… In response to that office action, and subsequent office actions continuously rejecting the application as obvious, Cephalon asserted that the prior art and studies on that art would not have motivated one of ordinary skill in the art to modify or manipulate the particle size of the drug substance like Cephalon's inventors had done. (Facts 109, 110, 112.) This response not only served to further conceal, despite the fact that it was central to the examiner's challenge, but was an affirmative misrepresentation in that, as has been mentioned previously, Cephalon did not modify, manipulate or improve any of the modafinil it received from Lafon. (Fact 113.) Without a logical explanation for making such misrepresentations, I conclude that Cephalon made those unsupported claims with the intention of convincing the patent examiner to change his mind and issue the patent… Thus, Cephalon acted with the intent to deceive when it represented that it undertook a course of action which never in fact occurred.*"[883]

The court concluded:

"[G]*iven the unmistakable importance of the Lafon information, the inexplicable concealment of that information from the PTO, even after the examiner's obviousness challenge unequivocally alerted Cephalon to its importance, as well as the direct misrepresentations made by Cephalon to the PTC, the only reasonable inference to be drawn is that Cephalon made a deliberate choice to deceive the PTO about the origin of its claimed invention.*"[884]

(520) It is noteworthy that the court declined to credit a declaration by Dr. […], Cephalon's scientist, which had been submitted to the PTO for the purposes of rebutting the objections over the obvious character of the claimed invention. The court appreciated Dr. […] declaration as misleading and contributing to the finding that Cephalon acted with the intention to deceive.[885] It is noteworthy that Cephalon produced the same Dr. […] declaration to the EPO to overcome its objections during

---

881 These are three criteria to meet the legal standard for finding of inequitable conduct. Ibid. p. 44 ff. The same arguments as successfully made by Apotex in this litigation, concerning both the invalidity and unenforceability of Cephalon's US '516 Patent, had Teva made already during the patent litigation in December 2004 (see Recital (124)).

882 Ibid, p. 48.

883 Ibid, p. 49.

884 Ibid, p. 50.

885 See *ibid*, p. 22-23, p. 42 and p. 49 (see also footnote 212).

the EPO patent application examination procedure regarding the obviousness of the claimed invention for the purpose of obtaining its EP '698 Patent.[886]

4.8.2.6. United States antitrust proceedings against Cephalon / Teva

(521) In early 2006, closely following Cephalon's Modafinil Settlements, Provigil and health insurance plans wholesalers in the United States filed antitrust actions against Cephalon and the four generic competitors (Teva, Mylan, Ranbaxy and Barr), the parties to the modafinil settlement agreements.[887] They claimed in particular damages suffered through overpriced Provigil as a result of those agreements.

(522) In 2008, the FTC filed an antitrust lawsuit against Cephalon with respect to the modafinil settlements.[888]

(523) On 21 April 2015, Teva (as a legal successor of Cephalon) announced that it had agreed with the direct purchasers on a settlement of their antitrust action. As a part of the settlement, Teva committed to pay USD 512 million to the plaintiffs. The settlement was preliminarily approved by the Court on 27 July 2015.

(524) On 28 May 2015,[889] the FTC and Teva reached a settlement of the FTC's antitrust action. According to the United States competition settlement rules, there is no admission of liability or any wrongdoing on the part of Cephalon. However, according to this settlement, Teva (as Cephalon's legal successor) agreed to make a total of USD 1.2 billion available to compensate purchasers, including drug wholesalers, pharmacies, and insurers, who overpaid because of Cephalon's conduct.[890]

(525) Moreover, in the FTC settlement Teva accepted behavioural commitments: "Under the [FTC] order for permanent injunction, Teva is prohibited from engaging in the types of reverse payment agreements […] that Cephalon used, that is, business transactions entered at the same time as the settlement that serve as a form of compensation. In this case, Cephalon agreed to pay the generics principally for active pharmaceutical ingredients and intellectual property rights, business deals the FTC was prepared to prove at trial made no economic sense for Cephalon except as payments not to compete. The order bars Teva from entering into a business deal with a competitor within 30 days of, or expressly conditioned on, a patent litigation settlement that restricts that competitor's generic entry."[891]

(526) The United States District Court for the Eastern District of Pennsylvania approved the FTC/Teva settlement on 17 June 2015.

(527) In the SO Reply (paragraphs 18-19) the Parties argue that the Commission's assessment of the Settlement Agreement should be based solely on the facts of the case and EU law, and not on any aspects of the United States proceedings concerning the Settlement Agreement. According to the Parties, Teva agreed to settle on the

886 ID 2826, p. 3 and p. 9 and subsequent.

887 The plaintiffs involved King Drug Company of Florence, Inc. (Civil Action No. 2:06-cv-1797), Vista Healthplan, Inc. (Civil Action No. 2:06-cv-1833) and Apotex, Inc. (Civil Action No. 2:06-cv-2768). Apotex was not buyer of Provigil but another Cephalon's generic competitor.

888 ID 2215.

889 Four days before the full bench trial in the Cephalon antitrust case which was scheduled for 1 June 2015.

890 ID 2233.

891 *Ibid*.

express condition that it did not admit any liability and the Commission's attempt to predicate liability where Teva expressly denied it is to misuse the FTC settlement in a manner contrary to its express language. The Parties also explain that concerns raised by the FTC were driven by specific features of the United States regulatory regime. These are not applicable in the EEA.

(528) The Parties objections are unfounded. As follows from the Recitals (522) - (527), the Commission is well aware of the legal context and implications (including non-admission of liability) of the settlement with the FTC. The Commission does not attempt to "*predicate liability where Cephalon expressly denied it*". While facts gathered and established in the United States administrative and judicial proceedings were considered (where relevant for Europe) as part of the Commission's factual analysis, the Commission does not base its conclusions on the (legal) analysis and outcome of the United States proceedings but rather on an independent factual and legal analysis based on EU law, as presented in this Decision.

5. ASSESSMENT UNDER ARTICLE 101 TFEU OF SETTLEMENT AGREEMENTS AS RESTRICTIONS OF COMPETITION BY OBJECT: APPLICABLE PRINCIPLES AND CONTEXT

5.1. Introduction

(529) The General Court and the Court of Justice in a number of cases assessed patent settlement agreements between a manufacturer of originator medicines and a manufacturer of generic medicines under Article 101 TFEU. The Union Courts confirmed in these cases that where the originator and the generic manufacturer are at least potential competitors and where the generic manufacturer undertakes not to enter the market and not to challenge the validity of the originator's patent in return for a transfer of value from the originator that is sufficiently significant to induce the generic manufacturer to make such an undertaking, the patent settlement agreement constitutes a restriction of competition by object.[892]

(530) Chapter 5 recalls the legal principles and framework identified by the Union Courts for assessing whether patent settlement agreements between originator and generic manufacturers constitute a restriction of competition by object. Chapter 6 applies these principles and framework to the facts of the present case and establishes that the Settlement Agreement between Cephalon and Teva amounts to such a restriction of competition *by object*. Chapters 7 and 8 address and establish the restriction of competition *by effect* that is also contained in the Settlement Agreement.

(531) This present Chapter 5, in setting out the general principles of the application of Article 101 TFEU, first recalls how the exercise of intellectual property rights and specifically patent settlements is subject to the Treaty prohibition of anticompetitive agreements (Section 5.2). It then recalls the jurisprudence of the Union Courts on the notion of "potential competitors" within the meaning of Article 101 TFEU (Section 5.3) as well as the general principles for assessing restrictions of competition by object (Section 5.4). Finally, Sections 5.5, 5.6 and 5.7 set out the elements that are particularly relevant to apply these principles in the specific context

892 Judgment of 8 September 2016, *Lundbeck v Commission*, T-472/13, EU:T:2016:449, paragraph 435, Judgment of 12 December 2018, *Servier and Others v. Commission*, T-691/14, EU:T:2018:922, paragraphs 273-275; Case C-307/18, *Generics (UK) and Others*, paragraph 111.

of patent settlement agreements, namely: (i) the economic and legal context of patent settlement agreements; (ii) the restrictions on generic manufacturers in a patent settlement agreement and (iii) the value transfers that induce a generic manufacturer to accept such restrictions.

5.2. Application of Article 101 TFEU to patent settlement agreements as a form of exercising intellectual property rights

(532) The Court has consistently held that an exercise of an industrial or commercial property right, including patents, can fall within the ambit of the prohibitions contained in the Treaty if it manifests itself as the subject, the means or the consequence of an agreement or concerted practice.[893]

(533) In order for there to be an agreement within the meaning of Article 101(1) TFEU it is sufficient that the undertakings in question should have expressed their joint intention to conduct themselves on the market in a specific way. It is not necessary that the agreements are actually implemented.[894] An agreement within the meaning of Article 101(1) TFEU can be regarded as having been concluded where there is a concurrence of wills on the very principle of a restriction of competition, even if the specific features of the restriction envisaged are still under negotiation.[895]

(534) Patent settlement agreements are, just like any other agreements, voluntarily concluded by a meeting of the free will of two or more parties – patent holders on one side and generic challengers on the other. Patent holders are free to rely on their patents to exclude competitors from practising the patented invention.[896] Undertakings are also generally entitled to settle litigation including patent litigation. Patent settlements may benefit both the parties to the dispute and, more generally, society, by allowing for a more efficient allocation of resources than if all litigation were to be pursued to judgment.[897]

(535) However, such agreements are fully subject to competition law as "Article 101(1) TFEU makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind".[898] Also settlement agreements resolving a genuine dispute are subject to competition law. While a patent holder has the right to oppose a possible infringement of its patent and while

---

893 Case C-307/18, *Generics (UK) and Others*, paragraph 79 and case-law cited therein.

894 Judgment of 17 December 1991, *SA Hercules Chemicals v Commission*, T-7/89, EU:T:1991:75, paragraph 256; Judgment of 20 March 2002, *HFB and Others v Commission*, T-9/99, EU:T:2002:70, paragraph 199.

895 See, to that effect, Case T-9/99, *HFB and Others v Commission*, paragraphs 151-157, 206.

896 Save for vexatious practices (see Judgment of 17 July 1998, *ITT Promedia v Commission*, T-111/96, EU:T:1998:183, paragraph 60, and Judgment of 13 September 2012, *Protégé International v Commission*, T-119/09, EU:T:2012:421, paragraph 49).

897 See for example Commission Report on the Pharmaceutical Sector Inquiry (8 July 2009), paragraph 707.

898 Case C-307/18, *Generics (UK) and Others*, paragraph 80. See also Judgment of 13 July 1966, *Consten and Grundig v Commission*, Joined cases C-56/64 and C-58/64, EU:C:1965:60, paragraph 346; Judgment of 14 September 1982, *Keurkoop v Nancy Kean Gifts*, C-144/81, EU:C:1982:289, paragraphs 24, 26; Judgment of 12 May 1989, *Ottung v Klee & Weilbach and Others*, C-320/87, EU:C:1989:195, paragraphs 13 and 18; Judgment of 8 June 1971, *Deutsche Grammophon v Metro SB*, C-78/70, EU:C:1971:59, paragraph 6; Judgment of 18 February 1971, *Sirena v Eda*, C-40/70, EU:C:1971:18, paragraph 5; and Judgment of 30 January 1985, *BAT v Commission*, C-35/83, EU:C:1985:32, paragraph 33, Judgment of 25 February 1986, *Windsurfing International v Commission*, C-193/83, EU:C:1986:75, paragraphs 26-28.

companies in principle have the right to reach an agreement on their patent disputes just as they have the right in principle to conclude other kinds of agreements, even if they are actual or potential competitors, and notwithstanding the fact that settlement agreements may be encouraged as a matter of public policy and that the vast majority may not raise competition law issues, such agreements can nonetheless infringe Union competition law.[899]

(536) In this context, the Court of Justice emphasised in the Generics (UK) and Others case that "settlement agreements whereby a manufacturer of generic medicines that is seeking to enter a market recognises, at least temporarily, the validity of a patent held by a manufacturer of originator medicines and gives an undertaking, as a result, no longer to challenge that patent and not to enter that market are liable to have effects that restrict competition since challenges to the validity and scope of a patent are part of normal competition in the sectors where there exist exclusive rights in relation to technology".[900]

(537) The General Court in Lundbeck similarly concluded: "Although the applicants were entitled to enter into settlements with the generic undertakings in order to avoid the costs of potential litigation, they could not, on that ground, substitute their own assessment of the validity of their patents and the infringing nature of the generic undertakings' products for that of an independent judge while paying the generic undertakings to comply with that assessment and refrain from entering the market for a certain period."[901]

5.3. Potential competition

(538) According to well-established case-law of the Union Courts, the examination of conditions of competition on a given market must be *"based not only on existing competition between undertakings already present on the relevant market but also on potential competition, in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to penetrate the relevant market and compete with the undertakings already established"*.[902]

(539) To qualify an undertaking which is not present in a market as a potential competitor, the Commission is required to establish if there are "*real concrete possibilities*" for an undertaking to enter and compete on the relevant market.[903] As concluded by the

---

899 Joined cases C-56/64 and C-58/64, *Consten and Grundig v Commission*, paragraph 346; Case C-144/81, *Keurkoop v Nancy Kean Gifts*, paragraphs 24, 26; Case C-320/87, *Ottung v Klee & Weilbach and Others*, paragraphs 13 and 18; Case C-78/70, *Deutsche Grammophon v Metro SB*, paragraph 6; Case C-40/70, *Sirena v Eda*, paragraph 5; Case C-35/83, *BAT v Commission*, paragraph 33; and Case C-193/83, *Windsurfing International v Commission*, paragraphs 26-28.

900 Case C-307/18, *Generics (UK) and Others*, paragraph 81. Similarly, while an originator is entitled to rely on its intellectual property rights, it cannot shield itself from challenges to such rights since such challenges constitute the exercise of potential competition (Case C-307/18, *Generics (UK) and Others*, paragraph 100).

901 Case T-472/13, *Lundbeck v Commission*, paragraph 390.

902 Judgment of 15 September 1998, *European Night Services and Others v Commission*, Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94, EU:T:1998:198, paragraph 137. This case relates to the assessment of restrictions by effect.

903 Case C-307/18, *Generics (UK) and Others*, paragraph 36. See also, Judgment of 14 April 2011, *Visa Europe and Visa International Service v Commission*, T-461/07, EU:T:2011:181, paragraph 166.

Court of Justice in the *Generics (UK) and Others* case*:* "*Such a criterion means that there can be no finding of a potential competitive relationship as an inference merely from the purely hypothetical possibility of such entry or even from the mere wish or desire of the manufacturer of generic medicines to enter the market. Conversely, there is no requirement that it must be demonstrated with certainty that that manufacturer will in fact enter the market concerned and, a fortiori, that it will be capable, thereafter, of retaining its place there.*"[904]

(540) A conclusion on the existence of real and concrete possibilities must not be based on a "purely hypothetical possibility" but rather "be carried out having regard to the structure of the market and the economic and legal context within which it operates".[905] In the specific context of pharmaceutical markets, this implies taking due account of the regulatory constraints (such as that medicinal products may only be placed on the market after they have obtained a MA), relevant intellectual property rights, in particular any secondary patents protecting the relevant product and finally, of the perception of the manufacturer of originator medicines.[906]

(541) In this context it is necessary to establish whether, at the time when that the agreement was concluded, "the manufacturer of generic medicines had taken sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicines."[907] These preparatory steps may include actions by the generic manufacturer to obtain necessary regulatory approvals (MAs),[908] building an adequate stock of the generic product, securing necessary third-party supplies, challenging patents protecting the originator product or a range of marketing activities. These preparatory steps indicate that a manufacturer of generic medicines has "a firm intention and an inherent ability to enter the market".[909]

(542) In addition, it is necessary to determine if the market entry of such a manufacturer of generic medicines is in fact prevented by insurmountable barriers. In this context, the Court of Justice clarified in the *Generics (UK) and Others* case, that an existence of

---

904 Case C-307/18, *Generics (UK) and Others*, paragraph 38. See also Judgment of 12 July 2011, *Hitachi and Others v Commission*, T-112/07, EU:T:2011:342, paragraph 160.

905 Case C-307/18, *Generics (UK) and Others*, paragraph 38-39. See also, Case T-461/07, *Visa Europe and Visa International Service v Commission*, paragraph 167 and case-law cited therein.

906 Case C-307/18, *Generics (UK) and Others*, paragraph 40-42. See also Case T-461/07, *Visa Europe and Visa International Service v Commission*, paragraph 169.

907 Case C-307/18, *Generics (UK) and Others*, paragraph 43. With respect to the time-frame within which potential entry should take place, the General Court stated in Visa: "*…the essential factor is the need for the potential entry to take place with sufficient speed to form a constraint on market participants...*" (Case T-461/07, *Visa Europe and Visa International Service v Commission*, paragraph 189). The General Court held, in this respect, that a period of one year mentioned in the Commission's Guidelines on horizontal cooperation agreements was merely illustrative.

908 The absence of a MA for some markets does not suggest that a product was not capable of reaching the market. In merger review, the Commission has considered that generic products in development generally constitute "*pipeline*" competition as a form of potential competition to an already marketed originator product, in particular in view of the high likelihood that such generic products would eventually be brought to the market (Commission Decision of 27 May 2005 in Case M.3751-*Novartis/Hexal*, Recital 106; Commission Decision of 4 February 2009 in Case M.5253-*Sanofi-Aventis/Zentiva*, Recital 194; Commission Decision of 28 January 2015 in Case M.7275-*Novartis/GlaxoSmithKline Oncology Business*, Recital 33 and Commission Decision of 10 March 2016 in Case M.7746-*Teva/Allergan Generics*).

909 Case C-307/18, *Generics (UK) and Others*, paragraph 44.

secondary patent protecting a medicinal product or interim injunctions granted by a national court prohibiting a manufacturer of generic medicines from entering the market cannot, as such, be regarded as insurmountable barriers.[910] Specifically, the existence of a patent does not mean that it is necessarily infringed, or that the validity of a patent may not be challenged. Even more, "*the presumption of validity of a patent for an originator medicine does not amount to a presumption that a generic version of that medicine properly placed on the market is illegal*".[911] Even in a situation in which a generic product is found to have infringed a valid secondary patent, this may still not prevent the generic from entering the market. Rather than using a patent protected process, the generic can also switch to a different manufacturing process which does not infringe that patent.

(543) Finally, the Court of Justice held that the perception of the established operator as is "a factor that is relevant to the assessment of the existence of a competitive relationship between that party and an undertaking outside the market since, if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market."[912] Similarly, the conclusion of an agreement between undertakings, operating at the same level in the production chain, some of which had no presence in the market concerned, as well as "the intention, made known by a manufacturer of originator medicines and acted upon, to make transfers of value to a manufacturer of generic medicines in exchange for the postponement of the latter's market entry" constitute "strong indications" of a competitive relationship.[913]

5.4. Restriction of competition by object – general principles

(544) Restrictions "*by object*" are those which, "*by their very nature*", can be regarded as being injurious to the proper functioning of normal competition.[914] In *Groupement des cartes bancaires,* the Court of Justice re-affirmed that certain types of coordination between undertakings "*reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects* " because they "*can be regarded, by their very nature, as being harmful to the proper functioning of normal competition.*"[915]

(545) In order to determine that a particular agreement may be considered a restriction of competition "by object", "regard must be had to the content of its provisions, its

---

910 Case C-307/18, *Generics (UK) and Others*, paragraphs 45-46 and 53. See also, Judgment of 21 May 2014, *Toshiba Corporation v Commission*, T-519/09, EU:T:2014:263, paragraph 230 and Judgment of 20 January 2016, *Toshiba Corporation v Commission*, C-373/14 P, EU:C:2016:26, paragraphs 31-35.

911 Case C-307/18, *Generics (UK) and Others*, paragraph 51.

912 Case C-307/18 *Generics (UK) and Others*, paragraph 42.

913 Case C-307/18, *Generics (UK) and Others*, paragraphs 55-56. See also, Case T-519/09, *Toshiba Corporation v Commission*, paragraph 231; Judgment of 28 June 2016, *Portugal Telecom v Commission*, T-208/13, EU:T:2016:368, paragraphs 180 and 181 and Judgment of 28 June 2016, *Telefónica v Commission*, T-216/13, EU:T:2016:369, paragraphs 221 and 227.

914 Judgment of 11 September 2014, *Groupement des cartes bancaires (CB) v Commission*, C-67/13 P, EU:C:2014:2204, paragraph 50; Judgment of 1 February 1978, *Miller v Commission*, C-19/77, EU:C:1978:19, paragraph 7; and Judgment of 20 November 2008, C-209/07, *Beef Industry Developmentand Barry Brothers*, EU:C:2008:643, paragraph 17.

915 Case C-67/13 P, *Groupement des cartes bancaires (CB) v Commission*, EU:C:2014:2204, paragraphs 49 and 50 and case-law cited therein.

objectives and the economic and legal context of which it forms a part."[916] With respect to the context, "it is also appropriate to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question."[917]

(546) The clauses of an agreement can be an important indication of a restriction by object, to the extent that they may reveal *"the precise purpose of the agreement."*[918] In addition, although the parties' intention is not a necessary factor in determining whether an agreement involves a restriction of competition by object, there is nothing preventing the Commission or the Courts of the Union from taking that aspect into account.[919] Thus the anticompetitive object of an agreement may be deduced not only from the content of its clauses but also from the intention of the parties as it arises from the "*genesis*" of the agreement and/or manifests itself in the "*circumstances in which it was implemented*" and in the "*conduct*" of the companies concerned.[920]

(547) The fact that an agreement may also have had other, entirely legitimate objectives, such as settling a legal dispute over patents, does not bar the possibility of finding a restriction by object:

"*In addition, it must be recalled that, according to the case-law, an agreement is not exempt from competition law merely because it concerns a patent or is intended to settle a patent dispute (see, to that effect, judgment of 27 September 1988 in Bayer and Maschinenfabrik Hennecke, 65/86, ECR, EU:C:1988:448, paragraph 15). Furthermore, an agreement may be regarded as having a restrictive object even if it does not have the restriction of competition as its sole aim but also pursues other legitimate objectives (see the BIDS judgment, cited in paragraph 341 above, EU:C:2008:643, paragraph 21 and the case-law cited).*" [921]

(548) If accordingly the anticompetitive object of the agreement is established, it is not necessary to examine its effects on competition.[922] It is only when the analysis of the content of the agreement does not reveal a sufficient degree of harm to competition, the effects of the agreement should then be considered.

---

916 Case C-67/13 P *Groupement des cartes bancaires (CB) v Commission*, EU:C:2014:2204, paragraph 53 and case-law cited therein.

917 Judgment of 14 March 2013, *Allianz Hungária Biztosító and Others*, C-32/11, EU:C:2013:160, paragraph 36 and case-law cited therein. See also Judgment of 2 April 2020, *Budapest Bank and Others*, C-228/18, EU:C:2020:265, paragraph 51.

918 Judgment of 30 June 1966, *Société Technique Minière v Maschinenbau Ulm*, C-56/65, EU:C:1966:38, page 249.

919 See, to that effect, Judgment of 8 November 1983, *IAZ v Commission*, joined cases C-96-102, 104, 105, 108 and 110/82, paragraphs 23-25. See also Judgment of 6 October 2009, *GlaxoSmithKline Services and Others v Commission and Others*, joined cases C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 58. See also Case C-228/18, *Budapest Bank and Others*, paragraph 53.

920 See Joined cases C-96-102, 104, 105, 108 and 110/82, *IAZ v Commission*, paragraphs 23-25. See also Judgment of 28 March 1984, *CRAM v Commission*, joined cases C-29 and 30/83, EU:C:1984:130, paragraph 26; Judgment of 16 July 2015, *ING Pensii*, C-172/14, EU:C:2015:484, paragraphs 30-34 and case-law cited there; Opinion of Advocate General Tizzano of 25 October 2005 in Case C-551/03 P, *General Motors BV v Commission*, EU:C:2005:639, paragraphs 77-78, and case-law cited there.

921 Case T-472/13, *Lundbeck v Commission*, paragraph 427. See also Joined cases C-96-102, 104, 105, 108 and 110/82, *IAZ v Commission*, paragraph 25. See also in the same vein, Case C-228/18, *Budapest Bank and Others*, paragraph 52.

922 See Case T-472/13, *Lundbeck v Commission*, paragraph 339.

(549) Finally, as part of the assessment under Article 101(1) TFEU, it should also be examined whether an agreement has any "*proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient harm to competition*" that could put into question such characterisation of the agreement as "by object" restriction.[923] In this regard, it should be noted that "*[…] the mere existence of […] pro-competitive effects cannot as such preclude characterisation as a 'restriction by object'*".[924] For such effects to be able to put into question the characterisation as a "by object" restriction of competition under Article 101(1) TFEU, they would have to be *"not only demonstrated and relevant, but also specifically related to the agreement concerned"*, as well as "*sufficiently significant*" and not "*only minimal*" or "*uncertain*".[925]

(550) On the basis of these general principles, Sections 5.5, 5.6 and 5.7 will address specific elements of the assessment of patent settlement agreements as restrictions of competition by object: (i) economic and legal context of patent settlement agreements; (ii) restrictions on generic manufacturer in a patent settlement agreement and (iii) value transfers inducing a generic manufacturer to accept the restrictions.

5.5. General economic and legal context of patent settlement agreements

(551) The competitive process leading to generic entry in the pharmaceutical sector consists of two main stages. Potential competition starts when generic API producers begin developing a commercially viable production process which may occur even several years before expiry of exclusivity on the primary patent. As stated by the General Court in *Lundbeck*, "[…] *case-law confirms that potential competition already exists before the expiry of patents protecting a medicinal product and that the steps taken before that expiry are relevant in assessing whether that competition was restricted.*"[926]

(552) Competitive pressure is obviously stronger after the expiry of the compound patent, even if the originator company still enjoys some protection by a number of other, secondary patents. Such patents offer more limited protection than the compound patent as their scope only extends to the specific form or formulation, or to the manufacturing process covered by the patent (including any products directly obtained from them). As the General Court stated for a formulation patent in *AstraZeneca*: *"the ability of a formulation patent to confer exclusivity on a product is not equivalent, in any event, to that of a substance patent, since an active substance can be incorporated into different formulations"*.[927]

(553) In this second phase of potential competition, suppliers of generic medicines (which, as in the case of Teva, may also be the API producer itself) will prepare for actual entry by applying for MA's, by ordering supplies (if necessary), and by developing strategies for commercial market entry in one or more markets in the EEA.

---

923 Case C-307/18, *Generics (UK) and Others*, paragraph 111.

924 Case C-307/18, *Generics (UK) and Others*, paragraph 106. Cf. also Case C-228/18, *Budapest Bank and Others*, paragraph 52.

925 Case C-307/18, *Generics (UK) and Others*, paragraphs 105, 107 and 110.

926 Case T-472/13, *Lundbeck v Commission*, paragraph 164. See also Case C-307/18, *Generics (UK) and Others*, paragraph 51 and Judgment of 6 December 2012, *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 108.

927 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, EU:T:2010:266, paragraph 607. The same reasoning applies to patents for manufacturing processes, specific forms of API etc.

(554) Finally, upon entry, generic undertakings price their product lower, and often considerably lower, than the originator's product[928], as otherwise distributors, pharmacies, prescribers, patients and health insurers would have little reason to choose their product, given that the generic product uses the same active ingredient as the original product that has already established itself in the market. The only significant way for generic undertakings to compete with the originator's product and with each other's products is therefore on price. The more generic companies enter, the stronger price competition will tend to become and the faster prices will tend to fall. Moreover, as discussed in Section 2.4.3, pricing and/or reimbursement legislation exists in most Member States of the EEA to impose or stimulate price reductions for medicines for which generic alternatives exist.

(555) The very significant price reductions that result from widespread generic entry means that the mere ability of suppliers of generic medicines to enter a market following expiry of the compound patent in itself poses a significant competitive threat to the incumbent originator undertaking, irrespective of the precise intentions of specific generic undertakings and irrespective of whether one or more of them are more likely to infringe any remaining secondary patents than others. The originator has a strong incentive to protect its product exclusivity from generic entry, as its market position can otherwise erode rapidly. To confront generics upon expiry of the compound patent, originators often put in place strategies to create and enforce a comprehensive set of additional patents protecting other aspects of the product (production process, forms, formulations etc.).

(556) The economic context shows that it may be in the interest of the originator undertaking to induce, with a significant value transfer, the generic undertaking to stay out of the market for a period of time and in the interest of the generic undertaking to agree to stay out of the market in exchange for that value transfer. In fact, both parties may do better with such an agreement than if they had continued their own independent commercial course and rivalry.

(557) Indeed, on the one hand, originator's losses from generic entry may exceed generic company's expected gains from competing. The difference would accrue to the consumer. It can certainly make commercial sense for an originator company to simply pay the generic undertaking the money than it could hope to gain by entering the market, or more, on condition that the generic undertaking stays out of the market. The incentive to do so is even higher if the originator perceives an appreciable risk that its patent(s) will be held invalid and/or not infringed by a court.

(558) On the other hand, from the perspective of the generic company, a patent settlement agreement with a significant reverse payment is normally also attractive and will affect its incentives to compete. As a result of such a deal, the generic company can make a significant amount of money without even entering the market. It avoids the efforts and risks attached to market entry, including the risks of litigation with the originator undertaking, risks associated with obtaining the regulatory approval and risks of competing on the market. Thus, the generic company is compensated for not entering, effectively through obtaining a share of the originator's exclusivity rents.

---

928 See also case C-307/18, *Generics (UK) and Others*, paragraph 69: *"[Generic] entry leads, in the short term, to a very appreciable fall in the sale price"*.

(559) Consumers, however, will be considerably worse off in this situation, as they are deprived from benefitting, whether through their health insurance premium or the public health budget, from the lower prices that would have followed generic entry. In such a situation, a patent settlement compensating the generic company for not entering thus represents a form of collusion "*equivalent to … market-sharing or market-exclusion agreements*"[929] between (potential) competitors at the expense of the consumer.

5.6. Restrictions on the generic manufacturer in a patent settlement agreement to enter the market

(560) Patent settlement agreement typically impose a number of covenants on the contracting parties. These covenants may direct parties' actions with respect to the pending patent dispute (such as an obligation to undertake actions necessary to terminate the court proceedings, an obligation to withdraw an appeal, etc.) or impose restrictions on the parties' behaviour outside the context of the pending court proceedings. For example, a manufacturer of generic medicines that is seeking to enter the market may give an undertaking not to enter this relevant market and an undertaking not to challenge the patent held by a manufacturer of originator medicines. As confirmed by the Court in the *Generics (UK) and Others* case, such non-compete and non-challenge commitments are liable to restrict competition.[930]

(561) Such commitments may constitute "*in-scope restrictions*", that is to say restrictions that the patent holder may, in the absence of the settlement, possibly have been able to obtain in court on the basis of the strength of its patents. However, even if the restrictions on the parties included in the patent settlement remain within the scope of the patent, a settlement agreement may, under certain circumstances, have to be considered as contrary to EU competition law.

(562) As such, a "*scope of the patent test*"[931] was explicitly rejected by the General Court in *Lundbeck* and by the Court of Justice in the *Generics (UK) and Others* case [932] as relevant to determine an infringement of Article 101 TFEU. The General Court explained in *Lundbeck* that the "*scope of the patent test*" does not provide a safe harbour, and that, even if the restrictions on generics in a patent settlement are within the scope of the innovator's patent, such a settlement agreement would still need to be subject to a case-by-case assessment and may infringe Article 101 TFEU.[933] It should be noted that in the case of secondary patents, it will often be very difficult to

---

929 Case C-307/18, *Generics (UK) and Others*, paragraph 77.

930 Case C-307/18, *Generics (UK) and Others*, paragraphs 81 and 82.

931 According to the "*scope of the patent test*" (that used to be advocated), if a restriction falls within the temporal, territorial and substantive scope of the patent in question, then the agreement imposing such a restriction would supposedly be compatible with the competition rules. In the United States case *Actavis*, the Eleventh Circuit set forth and applied the "scope of the patent test" as follows: "*absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent"* (Judgment of the United States Court of Appeals for the eleventh circuit of 25 April 2012, In *Re: Federal Trade Commission v. Watson Pharmaceuticals, Inc*, 677 F.3d 1298.). The United States Supreme Court subsequently reversed this judgment and rejected the "scope of the patent test" in the ruling of 17 June 2013 in *Re: Fderal Trade Commission, Petitioner v. Actavis, Inc., et al*, 186 L. Ed. 2d 343.

932 Case C-307/18, *Generics (UK) and Others*, paragraph 97.

933 Case T-472/13, *Lundbeck v Commission*, paragraph 401; see also case C-307/18, *Generics (UK) and Others*, paragraph 97.

determine in advance, in the absence of any court ruling, whether a particular product has been produced in a manner that falls within the scope of a process patent or not.

(563) In particular, the restrictions on the parties constitute a breach of Article 101 of the Treaty when these restrictions cannot be justified and do not result from the parties' assessment of the merits of the patent itself, but result from a transfer of value overshadowing and distorting this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market. When an agreement is concluded in which the generic undertaking accepts to exit or not to enter the market for a certain period of time (in which case one would expect, if anything, a payment by the generic undertaking to compensate the originator undertaking for any damages it may have suffered) but instead the originator undertaking transfers a considerable value to the generic undertaking, then such an agreement, whether referred to as a patent settlement or not, merits the full scrutiny of competition law. The reason is that such a constellation could mean that the originator undertaking has paid the generic undertaking to accept to give up, at least for the term of the agreement, its independent efforts to enter the market. Because of the unexpected direction of the payment, such payments are referred to in literature as "*reverse*" payments (see Section 5.7).

(564) The restrictions on the Parties are all the more likely to infringe the competition rules when, as in the present case (see Section 6.5.1), they actually do go *beyond the substantive scope* of the patent.[934] This is the case when the same restrictions could not have been obtained by the patent holder's right to oppose possible infringements before the court. If the restriction agreed in a patent settlement agreement covers not only the allegedly infringing process used by the generic undertaking at that point in time, but extends to future processes which may not even exist yet and which may or may not be covered by the patent holder's patents, then it becomes all the more clear that the generic undertaking's willingness to give up its efforts to seek market entry was not based on any analysis of possible patent infringement but on the financial incentives offered by the originator undertaking. Even if the generic undertaking was firmly convinced that the invoked patent was valid and that the generic's product or process was infringing the patent, it would normally not, in the absence of a payment, accept to also bind itself for other (future) products or for other processes that are not covered by the scope of the litigated patent and that therefore cannot be infringing it.

5.7. Value transfer inducing a generic manufacturer to accept the restrictions

(565) A key condition identified by the Union Courts for a patent settlement between originator and generic manufacturers to amount to a restriction of competition by object is that the restriction on the generic manufacturer not to compete must have

934 See Case T-472/13, *Lundbeck v Commission*, paragraph 386 where the General Court concluded that out of scope restrictions may allow the Parties to "*maintain higher prices for their products, to the detriment of consumers and the healthcare budgets of States, even though such an outcome could not have been obtained if the national courts had confirmed the validity of their patents and the products of the generic undertakings had been held to be infringing. Such an outcome would be manifestly contrary to the objectives of the treaty provisions on competition, which are intended inter alia to protect consumers from unjustified price increases resulting from collusion between competitors.*"

been induced by a significant (unjustified) value transfer from the originator to the generic.[935]

5.7.1. Rationale of the value transfer: replacing the uncertainty of court litigation with the certainty of no competition

(566) Where parties disagree on the validity of a particular patent or whether that patent has been infringed and where there is genuine uncertainty as to the outcome of litigation, it can be reasonable to reach a patent settlement, notwithstanding the utility of having judicial decisions. When a settlement is reached on the basis of each party's assessment of the strength of the patent case before them, such a patent settlement may not infringe competition law even though it may contain an obligation on the generic undertaking not to use the invention covered by the patent during the period of patent protection. Non-compete commitments and/or commitments not to challenge the patent concerned in court (such as a non-challenge clause) will in these cases not run counter the competition rules. Although in such cases certain limitations on the commercial behaviour of the generic undertaking are agreed between the parties to the patent dispute, they directly and exclusively result from the strength of the patent litigation case, as perceived by each party, and are not driven by a transfer of value from the originator to the generic.

(567) The situation is decidedly different when the generic undertaking's incentives to seek market entry are reduced or eliminated through a payment, namely a transfer of value by the originator undertaking. The generic undertaking may then willingly accept market exclusion, which it would not accept without the inducement. In other words, in the absence of the inducement and hence based solely on its assessment of its chances to succeed in the patent dispute, that is to say on the merits of the patent case, the generic company as a reasonable economic operator would not accept the commercial limitation to stay out of the market and would instead act independently and resort to more pro-competitive solutions (for example, continued litigation, acceptance of a royalty free immediate entry, settlement without any restrictions).

(568) In such cases the result of market exclusion is therefore not achieved by the strength of the patent, but by the value of the transfers constituting "*exclusion*" payments.[936] This remains true whether or not the same exclusion might have been achieved if the originator undertaking had gone to court.

(569) It is the uncertainty of possible generic market entry, including through patent litigation, which reflects potential competition. This potential competition is eliminated through the commitment of the generic not to compete, which has been induced by a transfer of value. The payment induced non-compete commitment thus transforms the uncertainty of possible market entry into the certainty of no competition.

---

935 Case C-307/18, *Generics (UK) and Others*, paragraphs 85-95; Case T-472/13, *Lundbeck v Commission*, paragraph 355; Case T-691/14, *Servier and Others v Commission*, paragraphs 273-275.

936 Because of the unexpected direction of the payment to the alleged infringer of the patent, such payments are sometimes referred to as "reverse" payments. When an agreement is concluded in which the generic undertaking accepts to exit or not to enter the market for a certain period of time one would normally expect, if anything, a payment by the generic undertaking to compensate the originator undertaking for any damages it may have suffered.

(570) As the Court of Justice emphasised, it is precisely this uncertainty about the outcome of the court proceedings and the resulting possibility of successful generic entry "*which contributes, for as long as it lasts, to the existence of a situation of at least potential competition between the two parties to those proceedings*.[937] This at least potential competition from generics is the key source of competition during this phase of the development of the market after expiry of the primary patent, a source of competition that is protected by Article 101(1) TFEU.

(571) Also in the context of assessing patent settlements as a restriction of competition by object the Court of Justice underlined that "*in accordance with settled case-law, each economic operator must determine independently the policy which he intends to adopt on the internal market*"[938] and not replace the uncertainty and risk of (potential) competition with the certainty of cooperation. As Advocate-General Kokott explained in the same context, where a "*patent holder pays a generic manufacturer to refrain from entering the market and from challenging the patent*", this "*means precisely that those operators no longer determine independently their conduct in relation to the implications of that patent, but, on the contrary, agree on a concerted position in that regard*."

5.7.2. All forms of value transfer that are sufficiently beneficial to induce

(572) A transfer of value to the generic manufacturer can take different forms. It can be pecuniary, that is to say consist of the payment of money. It can, however, also be non-pecuniary.[939]

(573) A value transfer can, in particular, be indirect and result, for instance, "from profits to be obtained by the manufacturer of generic medicines from a distribution contract concluded with the manufacturer of originator medicines"[940]. It can also consist in other forms of commercial transactions that are sufficiently beneficial to the generic manufacturer to be induced not to independently enter the relevant market.

(574) To fulfil the objective of inducing the generic manufacturer, the unjustified net gain resulting from the value transfer needs to be "*sufficiently large actually to act as an incentive to the manufacturer concerned of generic medicines to refrain from entering the market concerned*"[941], namely there needs to be a significant inducement.

(575) As the Court of Justice emphasised, "taking into account the uncertainty as to the outcome of those proceedings, there is no requirement that the transfers of value should necessarily be greater than the profits which the manufacturer of generic medicines would have made if it had been successful in the patent proceedings. All that matters is that those transfers of value are shown to be sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits with the manufacturer of originator medicines concerned"[942].

---

937 Case C-307/18, *Generics (UK) and Others*, paragraph 100.
938 Case C-307/18, *Generics (UK) and Others*, paragraph 78.
939 Case C-307/18, *Generics (UK) and Others*, paragraph 90.
940 Case C-307/18, *Generics (UK) and Others*, paragraph 91.
941 Case C-307/18, *Generics (UK) and Others*, paragraph 93.
942 Case C-307/18, *Generics (UK) and Others*, paragraph 94, see also Opinion of Advocate General Kokott of 22 January 2020 in Case C-307/18, *Generics (UK) and Others*, EU:C:2020:28, paragraph 120.

5.7.3. The value transfer has no other explanation than the aim to induce

(576) As observed by the Court of Justice, in specific circumstances, even value transfers from the originator to the generic undertaking "*may prove to be justified, that is, appropriate and strictly necessary having regard to the legitimate objectives of the parties to the agreement.*"[943] This may in particular be the case where the manufacturer of generic medicines receives compensation for the costs of or disruption caused by the litigation, or remuneration for the actual supply of goods or services, or discharge of (financial) undertakings, such as a cross-undertaking in damages.[944]

(577) To establish that the value transfer is not "justified", or, in other words, that it "cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits"[945] it is – as mentioned – important to consider all transfers of value made between the parties, whether those were pecuniary or non-pecuniary, including any indirect transfers. Further, it is necessary to assess whether the net gain arising from the transfers of value may be justified by the existence of any quid pro quo by the manufacturer of generic medicines that are proven and legitimate. While the Court of Justice considered that a value transfer could be justified if it corresponds to the normal remuneration for the actual supply of goods or services,[946] this is not the case when the remuneration paid to the generic undertaking could not have been obtained under normal market conditions, either because a particular transaction would not have been concluded at all under normal market conditions or not under the same terms. In such cases, the value transfer is not in line with "normal competitive conditions",[947] and can be presumed to pursue the objective of inducing the generic undertaking not to independently enter the relevant market. In this respect, the General Court has found that "[t]he fact that a commercial agreement, which does not normally have the settlement of a dispute as its subject matter, and which serves as a vehicle for a transfer of value from the originator company to the generic company, is, (…) linked with a settlement agreement containing competition-restricting clauses is a strong indication of the existence of a reverse payment".[948]

5.7.4. Value transfers with no other explanation indicate a restriction of competition by object

(578) If it thus established that the sole consideration for a significant transfer of value is the aim to induce the generic undertaking not to enter the market and no longer to challenge the patent, then the settlement agreement must in principle be characterised as a 'restriction by object'.[949]

(579) Patent holders are not entitled to pay generic companies to keep them off the market and reduce the risks of competition, whether in the context of a patent settlement

---

943 Case C-307/18, *Generics (UK) and Others*, paragraph 85.
944 Case C-307/18, *Generics (UK) and Others*, paragraph 86.
945 Case C-307/18, *Generics (UK) and Others*, paragraph 87.
946 C-307/18, *Generics (UK) and Others*, paragraph 86.
947 Judgment of 12 December 2018, *Krka v. Commission*, T-684/14, EU:T:2018:918, paragraph 173.
948 Case T-684/14, *Krka v Commission*, paragraph 170.
949 Case C-307/18, *Generics (UK) and Others*, paragraphs 89-92.

agreement or otherwise.[950] In essence, settlement agreements rewarding a competitor for staying out of the market distinctly pursue the object to restrict competition. It is well established that agreements excluding competitors from the market, notably in the form of discontinuing or delaying the generics' independent efforts to enter the market as part of a strategy to maintain the originators market power, constitute a restriction by object under Article 101 TFEU. As concluded by the General Court in *Lundbeck*, such agreements are *"comparable to market exclusion agreements, which are among the most serious restrictions of competition. The exclusion of competitors from the market constitutes an extreme form of market sharing or of limitation of production."*[951]

(580) Similarly, in the Krka case the General Court emphasised that such agreements "must … be regarded as market exclusion agreements, in which the 'stayers' are to compensate the 'goers'. Such agreements actually constitute a buying-off of competition and must therefore be classified as restrictions of competition by object … [The exclusion of competitors from the market] reveals a degree of harm which is all the greater since the companies excluded are generic companies, the market entry of which is, as a rule, favourable to competition and which also contributes to the public interest in lowering the cost of healthcare."[952]

6. APPLICATION TO THE CASE: THE SETTLEMENT AGREEMENT AS A RESTRICTION OF COMPETITION BY OBJECT

6.1. Introduction

(581) Based on the principles and case-law set out in Chapter 5, this Chapter shows that the Settlement Agreement constitutes a restriction of competition by object within the meaning of Article 101(1) TFEU, because it had the anticompetitive object to exclude a potential competitor, Teva, from the market in exchange for a significant transfer of value. The Commission's assessment of the Settlement Agreement's content, objectives and the economic and legal context has taken, in particular, into account that:

– the generic undertaking Teva and the originator undertaking Cephalon were at least potential competitors; and

– Teva committed itself in the Settlement Agreement to stop, for the duration of the agreement, its independent efforts to enter one or more markets in the EEA with a generic product, in exchange for

– receiving a transfer of value from Cephalon as a significant and sufficiently beneficial inducement to remove Teva's incentives to independently pursue its efforts to enter one or more EEA markets with a generic product. In this context, all elements of the transfer of value made between the Parties have been considered, whether those were pecuniary or non-pecuniary, direct or

---

950 If a naked payment (namely without any patent settlement) was made from an originator to a generic company in return for generic's commitment to exit or stay out of the market, then Article 101 TFEU would also apply. The fact that the value transfer is made as part of a patent settlement agreement does not shelter it from the application of Article 101 of the TFEU. Case T-472/13, *Lundbeck v Commission*, paragraph 427.

951 Case T-472/13, *Lundbeck v Commission*, paragraph 401. See also Case C-307/18, *Generics (UK) and Others*, paragraph 95.

952 Paragraph 150 of Case T-684/14, *Krka v Commission*.

indirect, easily quantifiable or not, and it was analysed if they had any plausible explanation other than the commercial interest of the Parties not to engage in competition on the merits.

(582) In addition, other factors have also been taken into consideration, even if they are not necessary conditions for establishing a restriction of competition by object. These include, in particular, the fact that during the negotiations Cephalon and Teva considered, in order to reach a certain value transfer that was sufficient to induce Teva, various transactions that were in principle unrelated; the fact that Cephalon could not have obtained the limitations on entry through enforcement of its process patents as the obligations on Teva in the Settlement Agreement went beyond the scope of the rights granted to holders of process patents; and the fact that the Settlement Agreement imposed a non-challenge obligation on Teva that lasted until the very end of the patents.

(583) This Chapter 6 is structured as follows. Section 6.2 sets out that the Settlement Agreement provides a framework for several arrangements, all of which together constitute a single agreement between undertakings. Section 6.3 describes the economic and legal context of the Settlement Agreement and the events and negotiations that led to its conclusion. The Section, in particular, describes the Parties' contemporary views that there was a significant risk that Cephalon's patents would not be upheld in court and the fact that Cephalon saw the Settlement Agreement as creating a "window of opportunity" to switch wakefulness patients successfully to Cephalon's new medicine Nuvigil (still benefitting from exclusivity protection). Section 6.4 establishes that Cephalon and Teva were at least potential competitors.

(584) Against this background, Section 6.4 establishes that Cephalon and Teva were at least potential competitors. Next, Section 6.5 establishes that under the Settlement Agreement Teva committed to restrict its efforts to enter and compete in one or more EEA markets with its generic product until the Effectiveness Date of the Teva Generic Rights, and to refrain from *independently* competing and from challenge Cephalon's patents for the entire duration of the Settlement Agreement.

(585) Section 6.6 reveals, based on a comprehensive analysis of each of the individual commercial transactions contained in Article 2 of the Settlement Agreement, that the package of transactions resulted in a value transfer from Cephalon to Teva. Furthermore, taking into account the negotiations regarding the package of transactions, the wording of the Settlement Agreement including all transactions, and the Parties' own views of the package, Section 6.7 demonstrates that the value transfer brought about by this package of transactions was a *quid pro quo*, paid by Cephalon to Teva, the sole consideration for which is Teva's non-compete and non-challenge commitments. As Section 6.8 concludes, that consideration, irrespective of its exact quantification and the actual contribution of each transaction to the overall value transfer, constituted a significant inducement for Teva to agree to non-compete and non-challenge commitments.

(586) Finally, Section 6.9 shows that the Settlement Agreement did not produce any pro-competitive effects sufficiently significant and relevant to justify a reasonable doubt regarding its characterisation as a restriction by object. Section 6.10 concludes and finds that the Settlement Agreement constitutes a restriction of competition by object within the meaning of Article 101(1) TFEU.

(587) The geographic scope of the restriction of competition by object is determined by the scope of the Settlement Agreement between Cephalon and Teva and, most importantly, by the geographic scope of Teva's non-compete commitment under Article 2.5(a) of the Settlement Agreement.[953] Pursuant to this provision, the territorial scope of Teva's non-compete commitment is defined as "*the United Kingdom or any other country where Cephalon holds modafinil patent rights*". At the time of the Settlement Agreement Cephalon held Particle Size Patents[954] (or their national counterparts) in 25 Member States and Contracting Parties to the EEA Agreement while in (i) Cyprus, (ii) Finland and (iii) Hungary Cephalon held other patents that fall within the scope of "modafinil patent rights".[955] Therefore, the finding of a restriction of competition by object within the meaning of Article 101 TFEU relates to the following 28 Member States and Contracting Parties to the EEA Agreement: Austria, Belgium, Bulgaria,[956] Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom. These countries are hereinafter referred to as the By-Object Countries.

6.2. One single agreement between undertakings

(588) This Section shows that the Settlement Agreement constitutes "*an agreement between undertakings*" under Article 101(1) TFEU. In addition, it shows that the transactions contemplated under the Settlement Agreement as well as the Implementing Agreements entered into by the Parties represent, together with the Settlement Agreement, one single agreement.

(589) The Settlement Agreement was concluded between Cephalon, Inc., on the one hand, and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc., on the other, on 8 December 2005. The Parties entered the Settlement Agreement also for their affiliate companies.[957]

(590) With regard to the concept of undertaking, the Court of Justice has held that it "encompasses every entity engaged in an economic activity regardless of the legal status of the entity and the way in which it is financed".[958] In the present case, Cephalon and Teva are undertakings as these companies are engaged in activities

---

953 On Teva's non-compete commitment see Section 4.6.3.1 and Section 6.5.1

954 Particle Size Patents were the patents at issue in the United Kingdom litigation between Cephalon and Teva and the only patents mentioned in discussions between the Parties on whether Teva's entry on the modafinil markets would infringe Cephalon's intellectual property rights. They also represent European counterparts of the US '516 Patent, which was not only the patent relevant for United States litigation proceedings but also the most important of the patents falling within the scope of the Settlement Agreement. As regards the definition and importance of the Particle Size Patents see Section 4.1.2.1.2, Section 4.3 and Section 6.3.2.

955 See Section 4.1.2.1.3. and Section 4.1.2.1.4.

956 In Bulgaria and Romania Article 101 TFEU is applicable as of 1 January 2007 which was the date of their accession to the EU (Article 4(2) of the TFEU between Member States of the European Union and the Republic of Bulgaria and Romania concerning the Accession of the Republic of Bulgaria and Romania to the European Union (OJ L 157, 21.6.2005, p. 11) and Article 2 of the Act concerning the Conditions of Accession of the Republic of Bulgaria and Romania and the Adjustments to the Treaties on which the European Union is Founded (OJ L 157, 21.6.2005, p. 203)).

957 See Section 4.6.1.

958 Judgment of 23 April 1991, *Höfner and Elser v Macrotron*, C-41/90, EU:C:1991:161, paragraph 21.

"consisting in offering goods or services on a given market" as set out in Section 2.1.[959]

(591) The Settlement Agreement was concluded as a single legally enforceable agreement representing a basis for all the Parties' actions described therein and therefore qualifies as an agreement pursuant to Article 101(1) of the Treaty.[960] The Settlement Agreement is not excluded from the application of Article 101 TFEU merely because its purpose is to settle patent litigation, as Article 101 TFEU makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind.[961]

(592) The Settlement Agreement includes provisions under which Cephalon and Teva committed to immediately discontinue their pending modafinil litigations in the United States and in the United Kingdom. In addition, the Settlement Agreement as a framework agreement includes, among others, provisions for: (i) commitments with respect to manufacturing, marketing and sale of modafinil products (Teva's non-compete and non-challenge commitments (Articles 2.1, 2.5(a) and 8.12 of the Settlement Agreement) and Teva Generic Rights (Article 3 of the Settlement Agreement)); (ii) Cephalon's payments of money to Teva based on the avoided litigation costs (Articles 2.5(b) and 2.5(c) of the Settlement Agreement) and (iii) related commercial transactions between Cephalon and Teva (Cephalon's purchase of Teva's modafinil related intellectual property rights (Article 2.2 of the Settlement Agreement), Teva's licence to use CEP-1347 data (article 2.3 of the Settlement Agreement), modafinil API supply agreement (Article 2.4 of the Settlement Agreement) and Teva's appointment as an exclusive distributor of Cephalon's modafinil products in the United Kingdom (article 2.6 of the Settlement Agreement). All these elements were negotiated by the Parties as a single and interrelated package,[962] which was included as a package in the single Settlement Agreement[963] and were subsequently assessed by the Parties as a single package.[964]

(593) In this context, it is important to recall that Article 3.2 of the Settlement Agreement provides that the Parties agreed to "*prepare and execute whatever documents are necessary to carry out the terms of the Sections 2* [Obligations of the Parties] *and 3* [Teva Generic Rights]" of the Settlement Agreement within thirty days following the Settlement Agreement.[965] This provision included express references to the following Implementing Agreements: (i) Licence Agreement with respect to Teva Generic Rights (namely Licence Agreement under Cephalon's Listed Patents[966]); (ii) Licence to Teva's Intellectual Property Rights; (iii) Teva Distribution Agreement; and (iv) Modafinil API Supply Agreement. However, Article 3.2 of the Settlement

---

959 Judgment of 12 September 2000, *Pavlov and Others*, Joined cases C-180/98 to C-184/98, EU:C:2000:428, paragraph 75.

960 See, for an example of the broad interpretation of the concept of agreement Judgment of 15 July 1970, *Chemiefarma v Commission*, C-41/69, EU:C:1970:71.

961 See, to that effect, Judgment of 27 September 1988, *Bayer v Süllhöfer*, C-65/86, EU:C:1988:448, paragraph 15; see Section 5.6.

962 See Section 4.5.

963 Teva's non-compete commitments and the related transactions are all set out in the same Article 2 of the Settlement Agreement under the heading "Obligations of the Parties".

964 See Sections 4.8.1.1 and 4.8.1.2.

965 This deadline was subsequently prolonged until 28 February 2006 (ID 2841-932, p. 1 and ID 2841-1080, p. 1).

966 See footnote 389.

Agreement included a safety provision providing that "*subject to applicable laws, the terms and conditions contained* [in the Settlement Agreement] *are binding notwithstanding the failure of the parties to enter into the* [Implementing Agreements]". While the Modafinil API Supply Agreement and the Teva Distribution Agreement were concluded after the Settlement Agreement,[967] the Parties never entered into the envisaged separate licence agreements concerning Teva Generic Rights and Teva's Intellectual Property Rights.[968]

(594) The main parameters of the Implementing Agreements were already fixed in the Settlement Agreement. Most importantly, the amount of royalty to be paid to Teva for licence to the Intellectual Property Rights is set out in detail in the Article 2.2(b) of the Settlement Agreement. Article 2.4 defines payments due to Teva for API supply. Also, Article 2.6(a) of the Settlement Agreement sets the purchase price payable to Cephalon as a function of Teva's actual resale price thus guaranteeing to Teva a margin of 20% under Teva Distribution Agreement. Finally, Article 3 defines the timeline and the conditions of Teva's market entry under the modafinil licence from Cephalon. At the date of the Settlement Agreement, Teva therefore had a clear understanding of the significance of the consideration to be received via the Implementing Agreements.[969]

(595) All of the transactions provided for in the Settlement Agreement were contemplated as a package and the aggregate value transferred by Cephalon to Teva as envisaged by the Settlement Agreement forms the consideration for the entirety of the non-compete and non-challenge commitments Teva undertook under the Settlement Agreement which excluded and which prevented Teva's independent entry in the market. The existence of the package is not only established by the design and language of the Settlement Agreement, but is also evidenced by a number of statements by the Parties at the time of the negotiations of the Settlement Agreement.

(596) The Parties set out to conclude a comprehensive settlement deal[970] and discussed several possibilities[971] of transactions in order to achieve a "*fit for Teva*".[972] The Parties negotiated the transactions in an interlinked manner. By way of example, Cephalon's royalty payments under the Licence to Teva's Intellectual Property Rights were tied to the payments for API supply,[973] the access to CEP-1347 data was

---

967 The Modafinil API Supply Agreement was concluded on 7 November 2006 pursuant to the Article 2.4 of the Settlement Agreement. The Teva Distribution Agreement was concluded on 7 August 2006 pursuant to the Article 2.6 of the Settlement Agreement.

968 The licence agreement in the context of Teva's generic rights became obsolete following the merger between Teva and Cephalon in 2011 and was never concluded by the Parties. As to the Licence to Teva's Intellectual Property Rights, even though a formal, separate licence agreement was never entered into, Cephalon fully paid to Teva USD 125 million envisaged in the Settlement Agreement (see Section 6.6.3

969 The intended value transfer occurred even though some of the Implementing Agreements were not signed (for example, with respect to the Licence to Teva's Intellectual Property Rights see Section 6.6.3).

970 ID 979, p. 41.

971 ID 2144-49, p. 2. The addressees included Chief Financial Officer and Head of Business Development of Cephalon Europe, Cephalon Inc.'s Vice-President for Commercial Operations, and Cephalon Inc.'s Vice-President for Worldwide Facilities and Corporate Engineering.

972 ID 2144-49, p. 1.

973 ID 1621, p. 1.

used to facilitate the "*final* [agreement] *on settlement*"[974] and the decision to appoint Teva as a distributor in the United Kingdom "*was taken in the context of the overall settlement agreement negotiations*".[975] Cephalon internally discussed and approved the transactions as one single package resolving the United States and United Kingdom litigation, together with litigation in the other Contracting Parties to the EEA Agreement.[976] Similarly, less than two weeks after the signing of the Settlement Agreement, on 19 December 2005, Teva's CEO presented the Settlement Agreement to Teva's Board of Directors as a comprehensive package of several transactions.[977]

(597) The Parties' ex post assessments leave no doubt as to the fact that all of the transactions formed a single package. By way of example, in the draft note to the 2006 accounts of Cephalon UK, drafted in June 2008, it was stated that: "*The infringement proceedings were subsequently withdrawn* ***as part of a settlement*** *between the Cephalon group companies and the Teva group companies.* ***As part of the settlement****, certain payments were made by Cephalon group companies to Teva group companies in respect of, inter alia, a non-exclusive worldwide license to certain intellectual property rights held by Teva group companies related to Modafinil, and the savings inuring to Cephalon [group companies??] in terms of the avoidance of costs, and expenditure of time and resources associated with prosecuting such litigation.*"[978] (emphasis added)

(598) The Commission therefore concludes that the negotiation history of the Settlement Agreement, its wording as well as the Parties' ex post assessments show that the Implementing Agreements were not independent business deals and that they formed a package, included in the Settlement Agreement with the purpose of contributing to the value transfer made to Teva. This value transfer was made in exchange for Teva's acceptance of the non-compete and non-challenge commitments (see Sections 6.6, 6.7 and 6.8).

6.3. The economic and legal context of the Settlement Agreement

(599) This Section describes (6.3.1) the situation in the modafinil markets before the Settlement Agreement; (6.3.2) the Parties' contemporaneous views of the patent situation; (6.3.3) Cephalon's strategy to switch to Nuvigil; and (6.3.4) the interrelated negotiation of the transactions in Article 2 of the Settlement Agreement.

(600) The analysis described in this Section shows that Cephalon's modafinil product Provigil was its most important product by far and that Teva was the most advanced generic threat to Provigil in the EEA. Both Cephalon and Teva had doubts about the strength of Cephalon's Particle Size Patents and their ability to prevent entry of a generic modafinil product. In fact, Teva was convinced that the Particle Size Patents were invalid. Cephalon was preparing for market entry of generic competitors by contemplating a product switching strategy to Nuvigil. The negotiation history shows that all individual transactions contemplated under the Settlement Agreement were negotiated at the same time and in an interrelated manner with a view of reaching a

974 ID 2843-30, p. 4.
975 ID 1436, p. 15.
976 ID 2144-5, p. 1, ID 2144-48, p. 2.
977 ID 2166-97, p. 13.
978 ID 189, p. 87. For additional evidence on ex post assessment of the Settlement Agreement see Sections 4.8.1.1 and 4.8.1.2.

comprehensive Settlement Agreement. The individual transactions were aimed at reaching a package solution leading to a value transfer that, irrespective of its exact quantification, was sufficiently beneficial to induce Teva to accept the commitment not to independently enter and compete in the markets for modafinil.

6.3.1. The situation in the modafinil markets before the Settlement Agreement

(601) As explained in the Section 4.2.1, at the time the Settlement Agreement was concluded, modafinil-based Provigil was Cephalon's most important product by far. Cephalon's sales of modafinil in the year before the Settlement Agreement (that is 2004) had generated USD 439,667 million (approximately EUR 354 million; year-on-year annual growth of 51%), accounting for approximately 42-43% of its total sales. Profits flowing from Provigil guaranteed the growth of the company and served the company's debt. More than 90% of Provigil's sales occurred in the United States market. In the United Kingdom, Provigil accounted for 73% of Cephalon UK's annual turnover in 2004.[979] In its Annual Reports of 2003 and 2004, Cephalon admitted that the company's "*future success is highly dependent on obtaining and maintaining patent protection for our products… The loss of patent protection on any of our existing products, whether by third-party challenge, invalidation or circumvention or by patent expiration, would materially impact our results of operations.*"[980]

(602) Owing to the compound patent protecting modafinil and ensuring market exclusivity, Cephalon was the only producer of modafinil-based medicines since it entered the markets in 1998.[981] The period of Cephalon's market exclusivity ended in the United States in 2003 and in the EEA in 2005, at the latest.[982] The compound patent on modafinil expired in 2001 in the United States and in 2003 in the United Kingdom and other Contracting Parties to the EEA Agreement (with exception of France where the patent remained in force until February 2005). Accordingly, since then Cephalon's product was mainly protected by the Particle Size Patents or their national counterparts (set to expire in 2014 in the United States and in 2015 in the EEA). As process patents, these did not provide the same high level of protection as the compound patent did.[983]

(603) Teva launched its modafinil product in the United Kingdom in June 2005 at a price undercutting Cephalon's price by 50%, and also applied for MA in fourteen other Member States and Contracting parties to the EEA Agreement based on the mutual recognition proceedings with the United Kingdom as reference country.[984] Teva was at the time the only generic competitor to Cephalon's modafinil product in the EEA that Cephalon was aware of. In the United Kingdom, 93% of the relevant prescriptions were written for the pharmaceutical ingredient modafinil rather than for Cephalon's branded Provigil, thus particularly exposing Provigil to generic

---

979 See Section 4.1.3. For detailed description of modafinil sales in main European markets see Section 8.1.1.4.

980 ID 2200, p. 12.

981 See Section 4.1.1.

982 See Recital (173) and footnote 307.

983 See Section 4.1.2

984 Teva applied for MA for its generic modafinil medicine in the United Kingdom on 31 March 2003. In addition, Teva applied for MA in France on 29 March 2003. Details of national MA applications are included in the Recital (166).

competition. Teva expected to gain at least 80% market share in the United Kingdom.[985]

(604) In July 2005, Cephalon initiated patent court proceedings against Teva in the United Kingdom. Cephalon UK's managing director stated for the court that the market entry of Teva's modafinil product would lead to "*irrecoverable price erosion for Provigil*" which would be followed by "*significant long-term market share erosion*". The price spiral would occur even faster if there were other generic competitors waiting to launch. "*Given that Provigil is Cephalon UK's flagship product, a serious loss of sales would have a significant and substantial impact on the general business activities and expenditure of Cephalon UK.*"[986] In addition, Cephalon expected that losing the litigation in the United Kingdom could negatively impact the outcome of the court proceedings in the United States.[987]

6.3.2. The patent situation: the Parties' contemporaneous views

(605) As explained in detail in Section 4.2.2, Cephalon had doubts that the Particle Size Patents could protect its Provigil.[988] Cephalon admitted that these patents "*might be found invalid if challenged by a third party, or a potential competitor could develop a competing product or product formulation that avoids infringement of these patents…*"[989] and estimated the probability of generic companies being able to design their modafinil products around the patents at 50%.[990] External consultants advised Cephalon that "*all generic companies know* [that the Particle Size Patents] *may be easily circumvented.*"[991]

(606) When, at the end of 2002, four generic companies (including Teva) applied for regulatory authorisation to market their generic modafinil products in the United States, Cephalon initiated patent infringement proceedings against them in the United States, but acknowledged that its litigation "*efforts will be both expensive and time*

---

985 See Recital (169).

986 ID 1627, p. 10 (paragraph 29 and 30). See also ibid. p. 14 (paragraph 46). See also the conclusion in ibid. p.15 (paragraph 50).

987 See Recitals (186) and (190).

988 The considerations on strength of the Particle Size Patents equally apply to the national counterparts of the Particle Size Patents issued in the By-Object Countries (see Section 4.1.2.1.2). As to the importance of the other Cephalon's modafinil patents (see Section 4.1.2.1.3), documents available to the Commission do not contain any reference to the protective strength and importance of these other modafinil patents issued in the By-Object Countries. The Parties also did not raise any arguments regarding the importance of these other patents in their SO Reply. The Commission notes that licence to Teva under Article 3 of the Settlement Agreement might provide some indication of importance of these other patents for entry to the modafinil markets. Article refers to the "Listed Patents" which are defined as "*the RE '516 Patent, United States Patent No. 4,927,855, and any other patent that may be listed in the FDA Orange Book for PROVIGIL®, and for markets outside of the United States, the foreign counterparts of such patents*" (Article 1.12 of the Settlement Agreement". US '855 Patent is an armodafinil patent (see Section 4.1.2.2) and was not asserted by Cephalon against the generic entrants. US '346 Patent was added in the Orange Book for Provigil only in 2008. It therefore follows other Cephalon's modafinil patents are not relevant for assessment of Cephalon's ability to prevent Teva from entering the modafinil markets.

989 ID 2200, p. 4. See also ID 267, p. 2.

990 In an internal presentation of December 2005, Cephalon evaluated the strength of its Particle Size patent: "*Inability to Design Around: 50%;* [Probability of successful] *Defending: 50%.*" (ID 1595, p. 25).

991 ID 2215, paragraph 35.

consuming and, ultimately, may not be successful."[992] Cephalon estimated the probability of a successful defence of the Particle Size Patents at 50%. Such assessment reflects a significant business uncertainty and business risk concerning Cephalon's core product. Anticipating a loss of exclusivity, Cephalon prepared a "Transition plan" to shift patients and thus its business away from Provigil to Cephalon's second-generation medicine Nuvigil (see Section 6.3.3); in addition, Cephalon significantly reduced marketing expenses for Provigil in 2005 (see Recital (138)).

(607) Industry analysts shared the view that there was a serious litigation risk, and they actually expected that the final judgment on the Particle Size Patents would end Cephalon's exclusivity in the United States market (see Section 4.2.2**)**. Moreover, Cephalon advised investors and analysts in 2005 that Provigil is "*going away*" and that the generic versions of modafinil will enter the market mid-2006.[993]

(608) In the same vein, when Teva challenged Cephalon's modafinil in the EEA and Cephalon initiated patent infringement litigation in the United Kingdom, Cephalon's European director stated that "(*F)rom what I heard and learned in the Q3 conference call, there is a 50% chance of a successful outcome*…" (see Recital (186)). Cephalon's United Kingdom distribution partner […] did not believe in the strength of the Particle Size Patents either and […] (see Section 4.3.3).

(609) The above facts demonstrate that Cephalon did not have confidence in the ability of the Particle Size Patents to protect Provigil from the generic competition and thus that it was facing significant uncertainty as to the outcome of the patent litigation.

(610) Teva was, for its part, confident that the Particle Size Patents did not block market entry of its generic modafinil product, because of its own "*strong position on the validity and non-infringement of the patent*."[994] Teva's launch of generic modafinil at risk in the United Kingdom in June 2005 manifested this confidence.

(611) Concerning the patent invalidity, Teva considered that the technology patented by Cephalon with regard to the Particle Size Patents was obvious,[995] making it not a patentable innovation. Also in a letter to Cephalon following the United Kingdom market entry, Teva maintained that Cephalon's European Particle Size Patents are

---

992 ID 2200, p. 20. In this context, the Commission recalls that a United States court later declared Cephalon's Particle Size Patent not only for invalid – which also a United Kingdom court did, see Section 4.8.2.2 – but found that Cephalon procured the patent through misrepresentation and misleading information, thus making "*a deliberate choice to deceive*" the patent office, see Recital (520) Although the United States judgment was served six years later, Cephalon had knowledge of the facts on which the court was deciding long before the Settlement Agreement. This knowledge could not have strengthened its expectations that the Particle Size Patents would be found valid.

993 See Recital (127).

994 ID 979, p. 46.

995 The veracity of this position was confirmed by ruling of the patent court in the United Kingdom in 2011 declaring the European Particle Size Patents invalid for obviousness (see Section 4.8.2.2). In addition, it should be recalled that Teva raised the obviousness argument also in the patent proceedings in the United States concerning the United States Particle Size Patent (counterpart of the European Particle Size Patents). Moreover, Teva argued in the United States court proceedings in 2004 that Cephalon had obtained the United States particle size patent by inequitable conduct, that is with intent to deceive the patent examiner (see Recital (155)). Both Teva's positions on obviousness and the intent to deceive were later confirmed by the United States court (see Section 4.8.2.5).

"*plainly invalid*".[996] With regard to Teva's claim of non-infringement, Teva's scientist declared already in 2003 that they had succeeded in formulating a bioequivalent material outside the scope of the Cephalon patent (Recital (158)). The independent expert tests conducted on Teva's modafinil samples during the patent proceedings in the United Kingdom showed that Teva's product did not fall into the scope of the Particle Size Patents[997] and thus strengthened this view.

(612) In the SO Reply, the Parties argue that at the time of the Settlement Agreement, Teva and Cephalon were engaged in a genuine patent litigation both in the United States and in the United Kingdom and that both Parties recognized the inherent uncertain outcome of this litigation. On one hand, according to the Parties, "50%" likelihood of prevailing in the patent litigation does not support Cephalon's perception of the weakness of its position. On the other hand Teva may, just as Cephalon did, have expressed internally the view that it has a strong patent position but this does not imply that it was certain to prevail.

(613) These arguments of the Parties are not convincing. First, they contradict the contemporaneous evidence, including internal documents, showing that Cephalon and Teva had doubts about the strength of the Particle Size Patents and their ability to prevent entry of a generic modafinil product (see above in this Section). Moreover, the fact that the Settlement Agreement resolved the underlying patent dispute does not in any way (i) exclude the Settlement Agreement from the application of Article 101(1) TFEU or (ii) prevent finding that the Settlement Agreement restricts competition.[998]

(614) The Commission takes full account of the context of the patent litigation including the uncertainty regarding its outcome. Quite contrary to the Parties' assertions, this Decision expressly recognises this uncertainty and concludes that the Parties chose to replace it with the certainty of restricting competition to the benefit of both of them. From Cephalon's perspective, this certainty follows from Teva's commitment not to independently enter and compete on the modafinil markets and not to challenge Cephalon's patents. From Teva's perspective, the possibility of successful market entry, resulting from its possible success in the patent litigation, was eliminated in exchange of the certainty to receive a substantial value transferred by Cephalon through the package of commercial transactions.

6.3.3. Cephalon's strategy to switch to Nuvigil

(615) Cephalon planned to preserve its "*wakefulness franchise*"[999] by employing a product switching strategy, that is to say by using the time gained through the Modafinil Settlements to re-direct patients from Provigil to its second-generation product Nuvigil before the Effectiveness Date of the Teva Generic Rights (See Recital (686)). This switch would have shielded Cephalon's wakefulness business

---

996 ID 214, p. 1. Similarly, Teva's letter of 24 June 2005 (including also non-infringement position), ID 273, p. 19-21.

997 This result differed from earlier tests made for the purpose of the court proceedings in the United States. On that basis, Cephalon attacked the sampling method used in the process of testing which showed non-infringement. However, this question remained unanswered because Cephalon and Teva concluded the Settlement Agreement before the second round of testing could have been finished.

998 Case C-307/18, *Generics (UK) and Others*, paragraph 98.

999 ID 2422, p. 3.

from generic competition.[1000] Whereas in the United States Cephalon implemented the product switch to Nuvigil in 2009, it was ultimately not able to do so in the EEA due to specific regulatory hurdles. However, evidence shows that ex ante, at the time of the Settlement Agreement, Cephalon still was planning to launch Nuvigil in the EEA.

6.3.3.1. Strategy and situation in the United States

(616) Since 2003-2004, Cephalon envisaged a strategy – and indeed started implementing it – to counter the entry of generic modafinil by replacing Provigil by switching the patients to the follow-on product Nuvigil that still benefitted from exclusivity (see Section 4.2.3).

(617) The market introduction of Nuvigil was designed to concur with the phasing out of Provigil and to precede the launch of generic modafinil in order to protect Cephalon's wakefulness business. Cephalon claimed that Nuvigil, based on the API armodafinil, was twice as efficient as Provigil, thereby enabling the medicine to be administered only once-a-day (as compared to the twice-a-day intake of Provigil), and reducing the side effects of the medicine (Recital (134)). The implementation of the strategy would imply that by the time when Teva would enter the markets under Cephalon's modafinil licence in 2012, patients would not benefit anymore from the resulting limited modafinil competition because they would previously have been pushed to switch from the modafinil product (Provigil) to the second generation Nuvigil.[1001]

(618) Initially, Cephalon had believed that the switch to Nuvigil could happen in the first half of 2006 which would coincide with the expected generic entry (see Section 4.2.3). However, Cephalon became aware of significant business risks surrounding the "*fast-tracked*" launch of Nuvigil[1002] and found that it needed more time given the uncertainty around key issues,[1003] Cephalon concluded that launching Nuvigil in 2006 is "*not an Advised Course of Action*" (Recital (141)). An alternative strategy was needed. The "*alternative to launch Nuvigil* [was] *settle with generic competitors*" (Recital (131)). Hence, the alternative in 2005 to the immediate launch of Nuvigil was to gain time by settling with potential modafinil generic competitors.

(619) The Modafinil Settlements created for Cephalon a "*window of opportunity*" by making it possible to postpone the launch of Nuvigil and undertake all preparations required for its successful market entry still well ahead of the start of generic modafinil competition in 2012. Following the Modafinil Settlements, Cephalon announced that it would "*reinvigorate our clinical and commercial programs for*

1000 See Section 4.2.3.

1001 It is important to note that Teva's generic rights pursuant to the Article 3.1 of the Settlement Agreement did not include a licence to market generic armodafinil as it was covered with the patents not falling within the scope of the licensed Listed Patents (footnote 389). By way of example, US '570 Patent does not appear in the Orange Book for Provigil and is therefore not encompassed by the definition of the Listed Patents pursuant to the Article 1.12 of the Settlement Agreement. On importance of the US '570 Patent for Nuvigil see Section 4.1.2.2. For explanation of Teva's generic rights see Section 4.6.4. See also ID 132, p. 1,

1002 "*[F]ast-tracked, forced switch strategy is risky and highly time dependent*" (ID 194, p. 61). Cephalon perceived this as "*[N]ot an advised Course of Action...*" (ID 194, p. 72).

1003 ID 194, p. 24.

PROVIGIL" (Annual Report 2005)[1004] and that it was "*planning to transition our wakefulness franchise to NUVIGIL around 2010*" (Annual Report 2006)[1005] prior to the April 2012 license effectiveness dates under the generic settlement agreements related to PROVIGIL. In 2008, Cephalon summed up: "*With Provigil remaining on the market, the US launch of Nuvigil was postponed*."[1006]

(620) Although Nuvigil was granted marketing approval in the United States on 19 June 2007, Cephalon waited for another two years to launch it in June 2009 (see Recitals (483) and (487)). At the beginning of 2010, Cephalon's senior executives assessed that "*about four out of every five prescriptions for Nuvigil is a conversion from Provigil*" and concluded: "W*e exceeded certainly my expectations of where Nuvigil should be at the end of 2009… we are way ahead of a plan to do what we need to do with Nuvigil.*" (Recital (487)).

6.3.3.2. Situation in the EEA

(621) In Cephalon's strategic planning with regard to switching to Nuvigil, the United States strategy appeared more prominently than the EEA strategy, mainly due to the larger size of the United States market (the United States market being more mature, it registered more than 90% of sales of Cephalon's total modafinil products). Nevertheless, Cephalon undertook the first steps to prepare Nuvigil entry in the EEA at about the same time as in the United States, namely around 2003. In this year, Cephalon applied in the EEA for the armodafinil crystalline Form 1 patent which in its opinion provided for a strong protection for developing the Nuvigil market. In July 2003, Cephalon expressed "*a strong interest in the development of Armodafinil as part of the future oriented life cycle management (LCM) programme for Modafinil*" for Germany, Austria and Switzerland (Recital (144)).

(622) In 2004, Cephalon started assessing the regulatory landscape in the EEA with the view of obtaining the MA and ten years of data protection for Nuvigil. The result of the analysis was however that the applicable regulation, in particular the Directive 2001/83, as amended by the Directive 2004/27,[1007] created an unfavourable regulatory environment for Nuvigil. Cephalon saw a risk that it might not be able to demonstrate a difference between Nuvigil and Provigil. Nuvigil might not be recognized by the authorities in Contracting Parties to the EEA Agreement as a new pharmaceutical substance and therefore might not be granted data protection as such.[1008] There was a possibility that Nuvigil might be substitutable with Provigil (in other words, that Nuvigil might be exposed to competition from generic versions of Provigil) in which case the switching strategy to prevent generic competition on

---

1004 ID 2777, p. 5.

1005 ID 2241, p. 6.

1006 ID 196, p. 6. An earlier version of this passage, deleted in later draft, read: "*It was* [also] *decided to delay the launch of Nuvigil in the US*." Ibid.

1007 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30/04/2004, p. 34-57) which entered into force on 30 October 2005..

1008 Data protection for Nuvigil was critical for its protection from generic competition. The patent protection was not as solid in this regard because it could not prevent a potential entry at risk (also, the patent on armodafinil crystalline Form 1 was not granted even if the application had been filed). This is different from the situation in the United States where the fact that a product is protected by patent can lead in principle to postponement of grant of the generic MA by 30 months provided that an earlier court judgment would not find the patent invalid or not infringed.

Cephalon's wakefulness products in the EEA as from 2012 might be ineffective in the end.

(623) Despite these perceived risks, Cephalon did not give up the launch of Nuvigil in the EEA, as demonstrated by its extensive patenting activity in respect of armodafinil, the ongoing internal discussions (in which Cephalon Europe's president insisted that the plans for potential launch of Nuvigil should be maintained), as well as by Cephalon's considerations whether the potential substitution between racemic modafinil and armodafinil could be prevented by withdrawal of MA for its own modafinil to block market entry of generic modafinil (Section 4.2.3.2).

(624) In the SO Reply, the Parties argue that the development of Nuvigil is irrelevant for the assessment of the Settlement Agreement as it represented Cephalon's unilateral strategy. In addition, the Parties argue that the Nuvigil strategy was never implemented in any of the By Object Countries and was delayed by unexpected regulatory hurdles. However, development of Nuvigil is an essential element of the factual context in which the Settlement Agreement was negotiated and agreed and cannot therefore be ignored. It helps in understanding the content and objectives of the particular provisions of the Settlement Agreement, especially those which, according to the Parties, were proposed and mostly shaped by Cephalon (such as provisions on Teva Generic Rights). In this context, contrary to the Parties' assertions, Cephalon's Nuvigil related strategy should be taken into account as a part of the economic and legal context of the Settlement Agreement irrespective of its unilateral character.[1009] Most importantly, Cephalon viewed the Nuvigil strategy and the settlement agreements as complementary tools serving the same goal: delaying or reducing the impact of generic entry on its business. [1010] In addition, the Nuvigil strategy clearly indicates that Teva's entry under Teva Generic Rights would benefit only a very limited patient population (namely those that would not have been switched to Nuvigil) and that therefore any alleged pro-competitive effects of Teva Generic Rights, as envisaged by Cephalon, would be minimal.

(625) Finally, Cephalon's ultimate goal was to minimize the impact on its "*wakefulness franchise*" from the generic competition by introducing Nuvigil. In the context of the EEA markets this goal is apparent, for example, from the link that Cephalon made between the exclusivity periods granted by armodafinil patents and Teva Generic Rights in the internal presentation of 29 May 2008 "*Patent protection on Nuvigil*".[1011] Although Nuvigil was later not launched in the EEA, in 2009 Cephalon still envisaged that Nuvigil would be launched in 2013 (Recital (150)).

(626) The evidence quoted in this Section 6.3.3 demonstrates that Cephalon contemplated the switching strategy both in the United States and in the EEA at the time of the Settlement Agreement. This strategy was implemented in the United States but ultimately not in the EEA where the regulatory situation seemed less favourable for a successful switch. Nonetheless, at the time of the Settlement Agreement, Cephalon

---

1009 Case C-67/13 P, *Groupement des cartes bancaires (CB) v Commission*, paragraph 53.

1010 Cephalon made a direct connection between Nuvigil and its settlements with the generic contenders: "*If a generic applies for* [MA] *in US, if you sue for patent infringement, you can stop FDA from issuing a license for 30 months. Ceph. sues generics. At same time, Ceph starts looking at Nuvigil. Alternative to launch Nuvigil = settle with generic competitors.*" ID 187, p. 129.

1011 See Recital (149); See also Recital (148) for the link between the "*Extended Modafinil life cycle*" and "*a possible switch strategy*".

was actively exploring a strategy to minimize the impact of generics by introducing Nuvigil in the EEA at least until 2009 and had an interest in delaying any generic entry at least until such switching strategy could be implemented.

6.3.4. Interrelated negotiation of the transactions in Article 2 of the Settlement Agreement

(627) This Section shows that all individual transactions contemplated under the Settlement Agreement were, although in principle unrelated to each other, negotiated at the same time and in interrelated manner with a view of reaching a comprehensive package solution.

(628) The facts described in the Sections 4.1.4 and 4.1.5 and the assessment presented in this Section 6.3 show that Cephalon's modafinil products were the key source of its income and the principal driver of its business, and that Cephalon believed that its exclusivity would come to an end in 2006 as a result of the generic entry having a profound detrimental effects on its business. Cephalon had doubts about the strength of the Particle Size Patents and their ability to prevent entry of a generic modafinil product. Although preparing for countering the generic challenge by a strategy of switching to the second-generation Nuvigil, this was not Cephalon's preferred option because of the importance of the product and many risks and uncertainties surrounding the introduction of the second generation product, especially in the EEA (see Sections 4.1.4, 4.1.5 and 4.1.6).

(629) In this context it is important to recall that Cephalon's CEO acknowledged that losses expected due to a generic entry (around 75% of Provigil sales) would be devastating for the company.[1012] In the United Kingdom (the first EEA market where Teva actually entered with its modafinil product,[1013] and where Provigil accounted for 73% of sales in 2004[1014]), Cephalon UK expected "*drastic effect on the sales of Provigil if their challenge is successful.*"[1015] The managing director of Cephalon UK presented to the United Kingdom court, which had to decide on the modafinil patent litigation with Teva a testimony in which she predicted that entry of Teva's cheaper product "*would inevitably result in immediate and irrecoverable price erosion for Provigil*", followed by significant long-term market share erosion. "*Given that Provigil is Cephalon UK's flagship product, a serious loss of sales would have a significant and substantial impact on the general business activities and expenditure of Cephalon UK.*"[1016]

(630) Throughout the negotiations on the Settlement Agreement, Cephalon made clear to Teva that its proposals for value transfers are made "*solely for purposes of our settlement discussions…*" mentioning expressly that, to Cephalon's understanding, Teva "*may be interested in one or more of the following: (i) access to the CEP-1347 data in connection with your product application, (ii) engagement to manufacture api for one or more of our cancer therapeutic compounds in development, and (iii) possible cross license of our respective patents covering polymorphs contained in modafinil as a means of avoiding an interference*

1012 ID 2215, paragraph 39.
1013 See Section 4.3.2
1014 ID 1627, p. 14.
1015 ID 285, p. 113.
1016 ID 1627, p. 14, paragraph 46.

proceeding."[1017] Internally, Cephalon was discussing what deals it could offer and was considering what "*might be a fit for Teva*".[1018]

(631) Teva shared Cephalon's view of the purpose of the individual transactions under the Settlement Agreement. Already when it approached Cephalon with the first settlement proposal in July 2005, Teva linked the potential settlement to economic advantages that it was seeking in return.[1019] Throughout the negotiations, Teva was putting together "*several moving parts… representing a different value proposition*"[1020] and analysed them as one package. The internal report of 3 December 2005, prepared by Teva´s chief negotiator to Teva´s team just five days before the signing of the Settlement Agreement, considers the outcome of the negotiations as a single complex deal consisting of the settlements of pending litigations and of a series of value transfers directed to Teva.[1021]

(632) In the SO Reply (paragraph 50), the Parties claim that Teva's top priority was to settle instead of extracting value from Cephalon. While indeed at least one of Teva's objectives may have been to settle with Cephalon, this does not in any way alter the Commission's assessment that the value transferred by Cephalon induced Teva to accept the non-compete and non-challenge commitments (see Section 6.7).

(633) The conditionality of individual transactions on the settlement of the patent litigations is well illustrated for example in discussions concerning the licence to CEP-1347 data[1022] where on 28 November 2005 Cephalon's negotiator stated: "*I am willing to provide access under the* [Confidentiality agreement] *for purposes of facilitating final* [agreement] *on settlement…*"[1023] Teva later explicitly confirmed to the Commission that "*Cephalon took the apparently firm position that it would not provide any data to Teva for its meeting with the FDA until Teva and Cephalon had fully and finally resolved all pending litigation and other issues relating to modafinil. Teva agreed to commence promptly settlement negotiations with Cephalon with a view of resolving all outstanding issues and obtaining access to the CEP-1347 data.*"[1024]

(634) This link between the transactions and the Settlement Agreement existed not only in terms of structure, but also in terms of value. The discussions on other individual transactions also reveal that they were negotiated as inseparable elements of the

---

1017 ID 1616, p. 2.

1018 ID 2144-49, p. 1 in relation to possible API supply and final product manufacturing arrangements.

1019 On 11 July Teva's external lawyer reported back to Teva: "*Have now spoken to* [the partner at Cephalon's external law firm] *I outlined to him the proposed terms i.e. T to distribute C product with revenue split 50/50 plus licence under prospective T patent.*" (ID 338, p. 1.) Under the "*prospective T patent*" is meant the "Sulphone" patent, that is to say in particular Teva's United States patent applications covering method for preparing highly pure modafinil, crystalline forms of modafinil and methods of preparing the crystalline forms, to which Cephalon purchased a licence from Teva according to Article 2.2 of the Settlement Agreement.

1020 ID 979, p. 36.

1021 ID 979, p. 38-39.

1022 See Section 4.7.2. Licence to the CEP-1347 Data was particularly valuable for Teva. Teva first approached Cephalon with request for grant of the CEP-1347 Data already in August 2005 but the request was refused (see Recitals (340) and (341)).

1023 ID 2166-81, p. 4-5.

1024 ID 1330, p. 2. With respect to the other transactions please see Sections 6.6 and 6.7.

overall consideration offered to Teva[1025] rather than as independent business deals. By way of example, although Cephalon had shown little interest in Teva's Intellectual Property Rights and appeared to believe that they were of limited purpose for Cephalon,[1026] Cephalon accepted a licence for such intellectual property against payment of a significant amount of USD 125 million to Teva as an integral part of the Settlement Agreement.[1027]

(635) During the negotiations several transactions were linked. On 3 December 2005 Cephalon's and Teva´s chief negotiators discussed the grant by Cephalon of the CEP-1347 data to Teva, the licence to Teva´s Intellectual Property Rights and the modafinil API supply arrangement. Teva's negotiator starts by expressing his concerns about Cephalon's delay to transfer to Teva the clinical data and expresses that the intellectual property part of the transaction is "*tied somewhat to the API piece*".[1028] Cephalon's negotiator at one point expressly confirmed that Cephalon "*will go forward with the earlier discussed royalty structure if you accept this refinement of your proposal on api.*"[1029] In this context, the royalties payable by Cephalon, rather than being negotiated independently and with regard to the (purported) value of the licence, were made to depend on the negotiation of the modafinil API transaction which Cephalon was not keen to accept. In addition, the fact that the Parties capped the royalties to USD 125 million indicates that the royalty payable by Cephalon reflected the Parties' understanding about the value transfer to be made to Teva as part of the Settlement Agreement (rather than the value that the Parties might have had attached to the licence or the value of sales of Cephalon's products made under the licence).

(636) When internally summarizing the status of negotiations on 3 December 2005, Teva's chief negotiator indicated: "They [Cephalon] would also like to settle the UK litigation for a payment to Teva of 4MM (release of the bond we have in place today) and entry by Teva with its product on the earlier of (i) a favourable court decision in any other generic case (ii) generic entry or (iii) 2011. Also they would be prepared to have Teva starting in 06 distribute their product on commercially reasonable terms for "physical distribution".[1030] It is noteworthy that, even though Cephalon proposed to release to Teva the amount of the security bond, it was not mentioned that this should be for the avoided litigation costs as subsequently claimed. To the contrary, the statement made an explicit link between the payment and the Settlement Agreement.

1025 Cephalon's attorney sent on 8 December 2005 the revised draft Settlement Agreement to Chief Legal Counsel of Cephalon Europe and another Cephalon Europe's attorney with the comment expressly indicating that "*the consideration in the UK includes a distribution and supply agreement, which would be effective once the […] arrangements are concluded in the UK in July.*" (ID 277, p. 57.)

1026 See Recital (304) ff. The conclusion that Cephalon did not need licences to the generic companies' (including Teva's) modafinil-related intellectual property rights to manufacture or sell Provigil or planned successor products was also endorsed by FTC (see ID 2215, Recital (57)).

1027 "*Teva's top priority is to settle with Cephalon and to add to the table also the Sulphone patent.*" (ID 95, p. 46); Sulphone patent means in particular Teva's United States patent applications covering method for preparing highly pure modafinil, crystalline forms of modafinil and methods of preparing the crystalline forms). See also footnote 1019.

1028 ID 1621, p. 1.

1029 ID 2166-78, p. 2.

1030 ID 979, p. 38-39.

(637) Such an understanding that the individual transactions were interrelated is also shared by the Parties in their *ex post* assessments of the concluded Settlement Agreement.[1031] Less than two weeks after the signing of the Settlement Agreement, on 19 December 2005, Teva's CEO gave a presentation to Teva's Board of Directors in which he set out the various benefits that Teva had realized through the Settlement Agreement, for example including receiving fees, receiving royalties on current and future products and being rewarded an API production contract (see Section 4.1.16). Teva's Patent Department commented in a draft presentation on a number of settlements (including the one on modafinil) that: "(T)*he profits resulting from the settlements are high. This is because they concern big products that we started selling a while ago (…)"* (see Section 4.1.16).

(638) In its immediate reaction to the conclusion of the Settlement Agreement (along with the other three Modafinil Settlements),[1032] Cephalon saw the impact as transforming for the company: "*For the past few years we have been preparing to reposition the company away from Provigil and have invested extensively into the development of new products… The prospect of maintaining the Provigil market (which is now the operating imperative) for another six years significantly changes the course of this company. It will add significant unexpected revenue to the top line which will significantly impact the bottom line and operating margin growth of the company in 2006 and 2007.*"[1033] Similarly, Cephalon's CEO stated on another occasion: "*We were able to get six more years of patent protection. That's $4 billion in sales that no one expected*…"[1034] His summary: "*We've got Provigil through 2012. You know the history of the company. We didn't expect to be there.*"[1035]

6.3.5. Conclusion on the economic and legal context

(639) The Commission concludes, in view of the facts of the case and their assessment in this Section, that the economic and legal context leading up to the conclusion of the Settlement Agreement demonstrates in particular that:

(a) the modafinil-based Provigil was Cephalon's most important product by far. Teva was the most advanced generic threat to Provigil in the EEA;

(b) both Cephalon and Teva had doubts about the strength of the Particle Size Patents and their ability to prevent market entry of a generic modafinil product. In fact, Teva was convinced that the Particle Size Patents were invalid;

(c) Cephalon was preparing for market entry of generic competitors by contemplating a product switching strategy, that is to say a strategy whereby patients would be re-directed from Provigil to its second-generation product Nuvigil; and

(d) all individual transactions contemplated under the Settlement Agreement, although in principle unrelated to each other, were negotiated at the same time and in an interrelated manner with a view of reaching a comprehensive

---

1031 See , for example, ID 224, p. 3; ID 226, p. 7; ID 264, p. 15; ID 2166-97, p. 13-14; ID 189, p. 87 and ID 189, p. 85, specifically mentioning "*a modafinil supply arrangement as part of the consideration for the settlement.*"

1032 See Section 4.1.15

1033 ID 2144-62, p. 1.

1034 ID 2236, p. 12.

1035 ID 2215, paragraph 83.

package deal of a certain value satisfactory to Teva. Such package led to a value transfer that, irrespective of its exact quantification, was sufficiently beneficial to induce Teva to accept the commitment not to independently enter and compete in the markets for modafinil.

6.4. Teva as potential competitor

(640) Teva was an actual competitor to Cephalon for modafinil in the United Kingdom during June and July 2005 and a potential competitor in the By-Object countries at the time of the Settlement Agreement. Teva had entered and had real and concrete possibilities to enter the markets in the By-Object Countries with a generic modafinil product and Cephalon's remaining patents did not represent an insurmountable barrier for Teva's market entry.

(641) Teva had put in place strategies to enter the market with generic modafinil, one of its "*Platinum*" products, a "*must have in Europe*" where the company has a "*competitive advantage*" in view of an exclusive (or semi-exclusive) *T*[eva]*API, niche and first to market.*[1036] Teva started working on a generic version of modafinil since at least 2000, also expanding efforts to establish a portfolio of modafinil related intellectual property rights[1037] and since 27 July 2001, started filing patent applications related to modafinil worldwide, including in the By-Object Countries.[1038] By the beginning of 2003, Teva considered that it had developed a modafinil product in a way not infringing Cephalon's Particle Size Patents[1039] and in March 2003 it was the first generic company that applied for MA's for its modafinil product in the United Kingdom and France.[1040]

(642) Teva UK received MA for its finished modafinil product in the United Kingdom on 6 June 2005 and immediately launched at risk, offering its generic modafinil product to two big pharmacy chains in the United Kingdom (the […]).[1041] According to Teva's estimates, the development costs for the EEA launch of modafinil (100 mg) incurred by Teva amounted to USD 485,135 (approximately EUR 437,540) while the costs of the regulatory work for the EEA launch of modafinil could be evaluated to around EUR 100,000.[1042] Teva was therefore an actual competitor, making sales on the market in the United Kingdom, between at least 6 June 2005 until at least

---

1036 See Recital (168).

1037 See Sections 4.3 and 4.7.1.1.

1038 ID 1330, p. 10- 11.

1039 See in particular e-mail by a chemist at Teva dated 20 April 2003 (ID 979, p. 91-92): "*Concerning the* [particle size distribution] *Teva has succeeded in showing bioequivalence by formulating a material which is outside the scope of the Cephalon patent.*" See also e-mail by Teva's Patent Department dated 24 April 2003 (ID 979, p. 90) containing details of the particle size distribution specification of Teva's modafinil product which is claimed to be outside the scope of Cephalon's Particle Size Patents. See also e-mail by Teva's Patent Department dated 20 April 2003, ID 979, p. 92-93. In this context, it is also interesting to note that Cephalon Inc.'s Vice-President and Chief Patent Counsel noted in an e-mail of 3 October 2006 that Cephalon's third Particle Size Patent, which was only granted after the settlement with Teva, would "*provide significantly more protection for modafinil in Europe*" (ID 221, p. 5).

1040 See Recital (164).

1041 Teva achieved sales in the amount of approximately GBP 300,000. Its generic offer of GBP 34.2, estimated by Cephalon to be GBP 30, amounted to an almost 50% reduction of the list price offered by […] on behalf of Cephalon UK (see Section 4.3.2).

1042 ID 2166-252, p. 5-6.

6 July 2005, when Cephalon commenced patent infringement proceedings and applied for an interim injunction.[1043]

(643) Apart from the United Kingdom, Teva was also preparing to launch its generic modafinil in other markets. In the Europe Development List dated 17 October 2004, Teva had assessed modafinil as "*low cost to add to [Teva's] range*" and categorised its generic modafinil entry as "*strategic priority A*".[1044] It predicted an average annual growth in the EU of 18.5% for the 100 mg tablets.[1045] As indicated in Section **4.3.2**, Teva had applied in March 2003 for a MA in France (MA was granted in November 2006) and in July 2005 in 14 other By-Object Countries.[1046] These applications were filed based on the mutual recognition procedure with the United Kingdom as the reference Member State. Teva could have relied on the mutual recognition procedure to facilitate issuance of MAs in all other Contracting Parties to the EEA Agreement as well (see Section 2.4.2).[1047]

(644) Contemporaneous documents indicate Teva's intention to launch its generic modafinil in a number of Contracting Parties to the EEA Agreement. In the minutes of a retail meeting in September 2005 "*modafinil tabs*" appear in a table on "*mutual recognition proc*" in which the 14 countries are mentioned under "*estimated day 0*" September / October 2005,[1048] suggesting that Teva intended to launch its modafinil product in those countries in fall 2005. Another internal document of Teva from January 2005 suggests launch dates in these countries (as well as in France) between May 2006 and January 2007.[1049] This illustrates that Teva had advanced and concrete plans to actually compete in the Contracting Parties to the EEA Agreement with generic modafinil within one to two years. As a large and established company in the generic medicines markets, Teva had its distribution network for generic medicines already in place and could easily start supplying its modafinil after it had obtained a MA.[1050]

(645) Finally, in the very beginning of the negotiations with Cephalon (November 2005) Teva was internally assessing which elements might be included in the "*comprehensive settlement*".[1051] In this context, in reply to the question of Teva's chief negotiator on "*planned activities outside of the UK and the US*" Teva's patent counsel confirmed that Teva has "*projected launches throughout Europe starting*

1043 Teva agreed not to sell generic modafinil products in the United Kingdom, just prior to the hearing on the request for interim injunctions scheduled for 11 July2005 (ID 273, p. 29). The fact that Teva was an actual competitor during several weeks in June/July 2005 (namely in a year when the Settlement Agreement was concluded) shows that the barriers to entry were not insurmountable for Teva (See, for example, Case T-519/09, *Toshiba v Commission*, paragraph 232).

1044 ID 333, p. 379.

1045 ID 333, p. 18.

1046 Austria, Belgium, Czechia, Denmark, Germany, Spain, Ireland, Italy, the Netherlands, Poland, Norway, Portugal, Slovakia and Sweden.

1047 With respect to the Bulgaria and Romania the mutual recognition procedure became available on 1 January 2007 as the date of their accession to the EU (Article 52 of the Act concerning the Conditions of Accession of the Republic of Bulgaria and Romania and the Adjustments to the Treaties on which the European Union is Founded (OJ L 157, 21.6.2005, p. 203).

1048 ID 333, p. 253.

1049 ID 333, p. 18-19. See also an August 2005 document covering the 2006-2008 launch plans in BE, ES, NL, IT, CZ, SK, United Kingdom, FR, DE and SE with launch plans for modafinil (100 mg and 200 mg tablets) between April 2006 and July 2008 in these ten countries. ID 333, p. 350- 356.

1050 See Section 4.3.2.

1051 ID 979, p. 41

next year and up until 2008 depending on the different EU countries."[1052] Therefore, at the time of the Settlement Agreement Teva had undertaken significant preparatory steps allowing it to enter the modafinil markets and thus had "*a firm intention and an inherent ability*"[1053] to enter those markets.

(646) Cephalon was aware that the United Kingdom was only a gateway for generic competition in other countries, including other By Object countries. In June 2005, the President of Cephalon Europe internally noted "*We all know UK is very often the entry, but then it does not take too long for a generic to go into other countries*."[1054] Cephalon anticipated generic entry in June/July 2006 worldwide.[1055]

(647) Cephalon's secondary patents did not represent an insurmountable barrier to entry. As mentioned above, the compound patents for modafinil expired in the United States in 2001 and in the United Kingdom and several other Member States on 3 March 2003. In France, the patent remained in force until February 2005.[1056] At the time of the Settlement Agreement Cephalon held Particle Size Patents or national counterparts of the Particle Size Patents in 25 By-Object Countries while in Cyprus, Finland and Hungary Cephalon held other modafinil patent rights.[1057] However, the evidence shows that there was a genuine doubt both on the side of Cephalon and on the side of Teva as to whether Cephalon could successfully enforce its patents. Cephalon internally admitted that its modafinil patents could be invalidated or circumvented.[1058] Teva at the same time was confident to have "*succeeded in showing bioequivalence* [with Cephalon's modafinil] *by formulating a material which is outside the scope of the Cephalon patent.*"[1059]

(648) Similarly, other market participants as well as independent observers were convinced that Cephalon's Particle Size patents did not prevent generic entry. For example, […], Cephalon's distribution partner in the United Kingdom, noted in December 2005 that "*[…]*"[1060] and confirmed later (Reply to the Article 18 Request of 20 July 2010) […].[1061] Likewise, an October 2005 report from Lazard Capital Markets forecasted: "*Our projections assume that there will be shared generic exclusivity for Provigil and that final (FDA) approval will be awarded… (i.e. in mid-2006). At this*

1052 Ibid, p. 40.

1053 Case C-307/18, *Generics (UK) and Others*, paragraph, 44.

1054 ID 1030, p. 2.

1055 ID 194, p. 19.

1056 See Section 4.1.2; ID 206, p. 11.

1057 See Section 4.1.2. The considerations on strength and effects of the Particle Size Patents equally apply to the national counterparts of the Particle Size Patents. On the other hand, documents available to the Commission do not contain any reference to the protective strength and effects of the other modafinil patents issued in these By-Object Countries. It follows therefore that these other modafinil patents were not even considered as relevant as the Particle Size Patents.

1058 ID 2215, paragraph 35, ID 2200, p. 4. See also ID 267, p. 2.

1059 ID 979, p. 92. This analysis confirms the view of Teva's patent lawyer taken in same conversation (Ibid. p. 93). More detailed description of Cephalon's and Teva's assessment of the Cephalon's patent position is included in Sections 4.2 and 4.3, respectively.

1060 ID 2537, p. 4.

1061 ID 2521, p. 7.

point, generic(s) will launch at risk."[1062] It should also be noted that the data exclusivity period for Provigil had already expired at the latest by January 2005.[1063]

(649) It follows that modafinil markets were in principle open to competition at the time of the Settlement Agreement. As described in particular in Section **4.3** , at that time, Teva was a generic undertaking with a modafinil product, with its own infrastructure for API manufacturing, a functioning distribution network and developed business plans. In addition, Teva held an MA in the United Kingdom and could rely on the mutual recognition procedure to facilitate issuance of MAs in the near future in other Contracting Parties to the EEA Agreement.[1064] Teva therefore had real and concrete possibilities to enter the modafinil markets in the EEA within reasonably short period of time.

(650) In this context, a generic undertaking, such as Teva, wanting to enter the modafinil market in the near future had several alternatives open to it that could lead to market entry even in the presence of Cephalon's patents, each of which represented potential competition if the option was available not just in theory, but as a real concrete possibility, as an economically viable strategy: (i) launching at risk the product it had and facing Cephalon's patent challenge; (ii) requesting a declaration of non-infringement from a national court before entering the market; (iii) claiming patent invalidity before the national courts, in particular as a counter-claim to a claim by Cephalon of (imminent) patent infringement; (iv) opposing a patent before national patent bodies or the EPO, with the request to revoke or narrow the patent; (v) changing the API manufacturing process in such a way as to eliminate or reduce the risk of infringement of Cephalon's patents; (vi) possibly switching to another API supplier.

(651) The mere fact that Teva's entry would have been at the risk of patent litigation and interim injunction, does not affect the conclusion that Teva was a potential competitor.[1065] Patent litigation on secondary patents such as the Particle Size Patents is very common and accounts for nearly two thirds of all patent litigation in the EU.[1066] As described in Section 5.5, originators often apply for patents late in the life cycle of the product, close to the expiry of the compound patent and/or data exclusivity. For their part, generics have incentives to enter the market as soon as possible, usually after the compound patent expires. Generics are in competition with each other to reap the higher profits which are usually associated with being the first generic on the market. While much of the generics' development work focuses on manufacturing compounds in ways that do not infringe originators' patents, litigation on patent infringement/validity may be unavoidable. In that kind of situation, as

---

1062 ID 2215, paragraph 51. Expectations of the immediate generic entry included also the national markets within EEA. See in particular the analysis of Cephalon's distribution partner in the United Kingdom and Ireland […] of June – July 2005 in Section 4.3.2.

1063 See Recital (172).

1064 Teva's market capabilities and thus Teva's position of at least a potential competitor were acknowledged by the Parties: "*At the relevant time (i.e. late 2005), Teva was considered to be an obvious candidate to take over the UK distribution activities, given its evident capability (having already launched its own product in the UK)…*" (ID 1436, p. 14).

1065 By way of example, shortly before the sampling of Teva modafinil material, a Teva's executive noted: "*Should the results of psd (particle size distribution) test turn out to be non–infringing we intend to move to the Court to lift the injunctions and re – enter market a.s.a.p*." (ID 979, p. 41-42).

1066 Commission Report on the Pharmaceutical Sector Inquiry (8 July 2009), p. 234 and subsequent.

explained in Section 5.3, patent litigation may be an expression of independent efforts of the generic undertakings to enter the market and therefore a form of competition in the pharmaceutical sector. Likewise, patent litigation is also an expression of competition from the side of the originator undertaking, which is in this way trying to defend its market position against generic competition.

(652) Contrary to the Parties' claims in the SO Reply, the Commission does not dispute that there was genuine uncertainty regarding the outcome of the patent litigation and that either of the Parties had some chance of prevailing in the patent litigation. However, as clarified by the Court of Justice, in presence of "*a genuine dispute, the outcome of which is uncertain, between the manufacturer of the originator medicine and a manufacturer of the generic version of that medicine who seeks to obtain access to the market for that medicine, the genuineness of their dispute, particularly when it is the subject of court proceedings far from precluding the existence of any competition between them, rather constitutes evidence of the existence of a potential competitive relationship between them*".[1067] In addition, the decisive element for the finding of whether Teva was a potential competitor is that there were real concrete possibilities of Teva's independent entry with generic modafinil at the time of the Settlement Agreement, and that Cephalon viewed Teva as a real threat and as a potential entrant. Finally, the very fact that the Settlement Agreement contained a non-compete obligation is in itself a strong indication of a competitive relationship between Cephalon and Teva.[1068]

(653) Events subsequent to the Settlement Agreement may provide additional support to the above *ex ante* analysis of the exclusionary strength of Cephalon's Particle Size Patents. Cephalon filed a number of actions for patent infringement against other generic companies in the United Kingdom, other Member States[1069] and the United States (see Sections 4.8.2.2, 4.8.2.3 and 4.8.2.5). In the SO Reply, the Parties argue that except in Spain, interim injunctions requested by Cephalon were systematically granted (unless the litigation was settled) and that this confirms that Cephalon had a reasonable chance of defending the validity of particle Size Patents.

(654) First, even if there was a "reasonable chance of defending", this does not mean that there would be no potential competition. As noted above (see Recital (653)), the uncertainty as to the outcome of the patent litigation does not prevent a finding of potential competition but is actually an evidence of a potential competitive relationship between the Parties. Moreover, while in four countries (the Netherlands, Sweden, Denmark and Portugal) Cephalon succeeded in securing preliminary injunctions against generic competitors in 2010/2011, the Commission is not aware of any judgment or other decision actually finding that Cephalon's Particle Size Patents would be valid and enforceable against potential generic entrants in modafinil markets or that Teva was infringing any of Cephalon's modafinil patents

---

1067 Case C-307/18, *Generics (UK) and Others*, paragraph 52.

1068 Case C-307/18, *Generics (UK) and Others*, paragraphs 55-56. See also, Case T-519/09, *Toshiba Corporation v Commission*, paragraph 231; Case T-208/13, *Portugal Telecom v Commission*, paragraphs 180 and 181 and Case T-216/13, *Telefónica v Commission*, paragraph 221 and 227.

1069 ID 2178. Legal and regulatory background of these proceedings varied significantly. By way of example, in Portugal Cephalon started court proceedings to declare null and void MA for modafinil granted to a generic company […]. The question at issue in both the injunction and the main proceedings was not an infringement and/or validity of the Particle Size Patents but the patent linkage. Cephalon's action was dismissed in the end.

in force in the EEA.[1070] Due to the Settlement Agreement, the court actions brought against Teva (including Teva's counterclaim) were withdrawn prior to any court decision on their substance.

(655) Quite to the contrary, a court decision in modafinil patent dispute between Cephalon and the company […] in Spain on 31 January 2012 actually concluded that there was no likelihood of infringement of Cephalon's patents by a product from the generic competitor.[1071]

(656) The mere allegation of infringement, without a court decision on the merits,[1072] does not allow drawing the conclusion that the generic product actually infringes a valid patent.[1073] The presumption of validity of patents "*for an originator medicine does not amount to a presumption that a generic version of that medicine properly placed on the market is illegal*", which is why the Court of Justice held that a potential competition is not prevented by existence of (presumably valid) patents.[1074]

(657) Moreover, in the United Kingdom proceedings concerning the relevant Particle Size Patents, the competent court concluded on 24 June 2011 that the inventive concept of each of the patent claims relied upon by Cephalon was obvious in the light of the literature and common general knowledge. The United Kingdom Court therefore concluded that the Cephalon patents were all invalid for obviousness. Similarly, a Court in the United States on 7 November 2011declared the US 516 patent[1075] invalid pursuant to the on-sale bar, for derivation, for obviousness, and for lack of written description. The United States Court also declared the patent unenforceable due to Cephalon's inequitable conduct in its prosecution of the patent.[1076] In the context of the assessment of Teva's competitive position, it is important to note that Teva raised essentially identical objections to Cephalon's patents in December 2004 in the United States modafinil litigation initiated by Cephalon against Teva and other generic challengers.[1077]

(658) The Parties' assertion that "*'elimination' of 'potential competition' is intrinsic to every bona-fide settlement agreement*" is not convincing. First, there are settlement agreements that do not include restrictions on generic entry and they do not necessarily eliminate potential competition. Second, the Commission recognizes that patent settlement agreements without value transfers are unlikely to violate

---

1070 See also Section 4.4.2 on the results of initial tests showing the United Kingdom modafinil samples falling outside the scope of Cephalon's Particle Size Patents (including the European '962 Patent).

1071 See Recital (511).

1072 Grant of a preliminary injunction in the proceedings cannot be equated with the decision on the merits of the dispute. By way of example, Cephalon initially secured a preliminary injunction from the Administrative Court in Portugal. However, Cephalon's claims in the main proceedings were dismissed subsequently (ID 2178 p. 5-6).

1073 This position is consistent with the Technology Transfer Guidelines, for the reasons explained above. The Technology Transfer Guidelines state in point 33 that: *"Particularly convincing evidence of the existence of a blocking position may be required where the parties have a common interest in claiming the existence of a blocking position in order to be qualified as non–competitors* […]" Communication from the Commission—Guidelines on the application of Article 101 of the TFEU on the Functioning of the European Union to technology transfer agreements, OJ C 89, 28.3.2014, p. 3, point 33.

1074 Case C-307/18, *Generics (UK) and Others*, paragraph 51. See also Case T-472/13, *Lundbeck v Commission*, paragraph 121.

1075 For more details on the patent situation for Cephalon's modafinil see Section 4.1.2.

1076 See Sections 4.8.2.2 and 4.8.2.5.

1077 See Recital (155).

Article 101(1) TFEU either by-object or by-effect. Absent value transfers inducing the potential generic competitor to accept restrictive commitments that it would otherwise not be willing to accept, a patent settlement agreement is likely to merely reflect the strength of the disputed patents. However, as the General Court concluded in Lundbeck, "*where a reverse payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry, the Commission rightly took the view that it was possible to consider that such a limitation did not arise exclusively from the parties' assessments of the strength of the patents but rather was obtained by means of that payment constituting, therefore, a buying-off of competition*." Hence, the question is not whether the settlement agreement contains some limitation to potential competition, but whether such limitation follows from value transfers from the incumbent to the potential competitor that undermine the latter's incentive to independently enter the market and compete.

(659) In summary, Teva was an actual competitor to Cephalon for modafinil in the United Kingdom during June and July 2005. The evidence also demonstrates that Teva had real concrete possibilities to enter the other By-Object countries with generic modafinil within reasonably short period of time and that Cephalon's secondary patents did not represent an insurmountable barrier for such entry. In addition, Cephalon was aware of this and perceived Teva as an important competitive constraint in relation to modafinil in the EEA.

6.5. Restrictions on Teva's independent behaviour and ability to compete

(660) In this Section the Commission demonstrates that Teva's non-compete and non-challenge commitments blocked its independent efforts to enter markets in the By-Object Countries with generic product until the Effectiveness Date of the Teva Generic Rights (Section 6.5.1) and restricted its independent behaviour and ability to compete for the duration of the Settlement Agreement (Section 6.5.2). These restrictive commitments ensured that there was no competitive pressure from Teva until 2012 and that Teva's entry in 2012 would be a controlled one, softening any competition between Cephalon and Teva (see Section 6.9).

6.5.1. Non-compete commitments

(661) The Settlement Agreement includes two provisions setting out Teva's non-compete commitments. Article 2.1 of the Settlement Agreement prescribes the non-compete commitments related to the United States while Article 2.5(a) defines Teva's obligations on the markets in the United Kingdom and "*any other country where Cephalon holds modafinil patent rights*". Article 2.5(a) is therefore the relevant provision for the assessment under this Decision.

Content

(662) Under Article 2.5(a) of the Settlement Agreement Teva undertook not to "make, use, offer to sell, or sell or actively induce or assist any other entity to make, use, offer to sell, or sell any finished drug which has modafinil as an active ingredient within the United Kingdom or any other country where Cephalon holds modafinil patent rights (other than in the United States market […]) or to import or cause to be imported any finished drug which has modafinil as an active ingredient into the United Kingdom or any other country where Cephalon holds modafinil patent rights (other than the United States market […])". Article 2.5(a) further explains that terms "'assist' and 'induce' shall include Teva's provision of modafinil API to parties it knows or has

reason to know will make, use, offer to sell, sell, import or cause to be imported any finished drug which has modafinil as an active ingredient into the United Kingdom or any other country where Cephalon holds modafinil patent rights".

(663) The notion of "*any finished drug which has modafinil as an active ingredient*" remains undefined in the Settlement Agreement.[1078] Taking into account that both Provigil and Sparlon have modafinil as their active ingredient, the Commission concludes that Teva's commitment arising under Article 2.5(a) of the Settlement Agreement refers to generic versions of Provigil and Sparlon.[1079] [1080]

(664) In addition to Article 2.5(a), several other provisions of the Settlement Agreement are relevant for assessing the content of Teva's non-compete commitment. By way of example, Article 3.4 of the Settlement Agreement[1081] states that if Cephalon anticipates acceleration of Teva Generic Rights[1082], it will notify Teva so that Teva has "*adequate time to prepare for launch*", implying that in the meantime Teva will not undertake actions preparing for the launch of generic modafinil products.

(665) Likewise, Article 3.5 of the Settlement Agreement states that Teva has the right to "*commence manufacturing activities*" a "*reasonable period of time*" before the

---

1078 The Settlement Agreement includes *inter alia* the following definitions. Cephalon Modafinil Product is defined as "*all finished pharmaceutical products that contain the compound modafinil, including, without limitation, its salts, esters, enantiomers, isomers and polymorphs, including without limitation, PROVIGIL®, SPARLON® and NUVIGIL®, sold by Cephalon, its Affiliates distributors and resellers.*" Conversely, Teva Generic Modafinil Product is defined as "*any Subject Modafinil Product marketed and sold by Teva pursuant to the terms of this Agreement or the same or similar finished pharmaceutical product that contains modafinil as the active ingredient marketed and sold by Teva in a jurisdiction other than* the United States." Subject Modafinil Product is defined as "any finished pharmaceutical product containing modafinil that is manufactured or sold pursuant to (a) NDA 20- 717 and all of its current and future supplements, or (b) an ANDA for which the reference listed drug is (i) PROVIGIL®, (ii) any other product that is the subject of NDA 20- 717 and all of its current or future supplements, or (iii) any other Cephalon Modafinil Product that is the subject of an NDA or supplemental NDA filed or held by Cephalon for which the RE '516 Patent is listed in the Orange Book."

1079 Sparlon is Cephalon's modafinil based medicine for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). See Section 4.2.3.1.

1080 The question whether Teva's commitment arising under Article 2.5(a) of the Settlement Agreement extends to generic versions of Nuvigil does not need to be conclusively answered. Nuvigil has armodafinil (and not modafinil) as the active ingredient and therefore would arguably not fall within the scope of the term "any finished drug which has modafinil as an active ingredient". However, arguments may be put forward to support a conclusion that Nuvigil indeed falls within the scope of the Article 2.5(a) of the Settlement Agreement. First, it appears that the Parties themselves assessed the non-compete commitments under the Settlement Agreement as covering generic Nuvigil (for example, ID 2144-56, p. 54 and ID 132, p. 1). In addition, the Teva Distribution Agreement which was entered into in compliance with the obligations arising under the Article 2.6 of the Settlement Agreement clearly extends to Nuvigil. Distribution of Nuvigil is entrusted to Teva as is the distribution of Provigil (Articles 1.1 and 2.2 of the Teva Distribution Agreement and Article 2.6 of the Settlement Agreement). In addition, Article 12.2 of the Teva Distribution Agreement which essentially imports Teva's non-compete obligation into the Teva Distribution Agreement, does not make any difference between Teva's intention to launch generic version of Provigil and Teva's intention to launch generic version of Nuvigil. However, due to the fact that Cephalon never launched Nuvigil within EEA, the question of whether Teva's non-compete commitments under the Settlement Agreement extend to Nuvigil is not relevant for the Commission's assessment in this Decision.

1081 Articles mentioned in this Recital are among the provisions of the Settlement Agreement detailing Teva's generic rights (see Section 4.6.4).

1082 Teva Generic Rights could be accelerated as a consequence of, for example, market entry by any other entity based on Cephalon's licence/permission (see Section 4.6.4 or 4.7.6).

effectiveness of Teva Generic Rights, implying that the non-compete commitments indeed prevented Teva from modafinil manufacturing activities until such time. In addition, in case of acceleration of Teva Generic Rights where other generic competitors enter at risk ("acceleration clause"), if Cephalon is successful in obtaining an injunction or any other measure sufficient to stop the generic(s) from selling modafinil, Teva Generic Rights will also be suspended (Article 3.1.3.3(a) of the Settlement Agreement) and Cephalon will buy back from Teva any inventory at agreed upon prices and levels (Article 3.1.3.3(b) of the Settlement Agreement).

(666) Article 3.6 of the Settlement Agreement does not prohibit any pre-existing contractual relationships between Teva and third parties for the supply of API, provided however that Teva does not continue relationships or enter into any new API supply agreements which "*would be reasonably likely to operate to cause Teva to breach its obligations*" under the settlement Agreement. To the extent that Teva was currently selling modafinil in any country other than the United States or the United Kingdom where Cephalon holds modafinil patent rights, Teva was required to "*use its best efforts to effect an orderly and timely cessation from such market*". These provisions contributed to excluding Teva from the market by prohibiting Teva to enter new markets (and even to prepare for market entry) with modafinil API and by mandating Teva to use its best efforts to leave the market and to sell its inventory to Cephalon.

Teva's commitment exceeds the scope of Cephalon's patents

(667) In compliance with the terms of the non-compete clause of the Settlement Agreement, Teva undertook not to produce, commercialize or import any finished drug which has modafinil as an active ingredient. Teva Export Logistic Director for Europe emphasised "*The significance of the agreement is that Modafinil Teva can't be marketed in Europe*" (see Recital (489)). Teva's product was "*no longer supplied*" rather than being "*temporarily unavailable*" (see Recital (491)) and Teva needed "*to negotiate an agreement with Cephalon if Teva and its affiliates would like to introduce modafinil*" (see Recital (488)). As summarized by its General Counsel for Europe, "*Teva cannot launch our own product until the end of said agreement which, I believe is in 2012*." (see Recital (494)).

(668) The commitment installed a general limitation on the Teva's ability to pursue any commercial activities regarding any finished product which had modafinil as an active ingredient, including by seeking to enter the market with its own generic version of the originator product in a viable and timely manner. Moreover, in the same provision, Teva also undertook not to assist any entity to make or sell any finished drug which has modafinil as an active ingredient. This included in particular supplying such entity with modafinil API.[1083] The commitment not to compete ensured that Teva would discontinue all manufacturing and marketing of modafinil products, irrespective of whether or not the manufacturing process was based on technology that infringed Cephalon's existing patents.

(669) Accordingly, the commitment that Teva undertook under the Settlement Agreement was not limited to a commitment not to infringe the Particle Size Patents or any other

[1083] See Section 4.6.3.1.

modafinil patent held by Cephalon.[1084] It should be recalled that Article 2.5(a) of the Settlement Agreement refers to "*any finished drug*" as opposed to any finished product that may infringe the modafinil patents held by Cephalon. Teva's commitment is therefore an agreement concerning Teva's market conduct, Teva's entry or exit from the market and not simply a commitment not to infringe Cephalon's patents. Cephalon could never have legally obtained such broad non-compete commitments through successful enforcement of the Particle Size Patents in the underlying litigation. Teva's commitment goes thus beyond the scope of Cephalon's modafinil patent rights.

(670) The Settlement Agreement contained the same out of scope restrictions both when referring to the United States and when referring to the rest of the world. It is unlikely that these out of scope restrictions were unintentional especially since in a prior draft of the United States Settlement Agreement, the non-compete commitments related to the patent dispute only. Such limitation to the scope of the dispute was later deleted.[1085]

(671) In the SO Reply, the Parties dispute the Commission's out of scope finding. According to the Parties, the Commission's "allegation assumes that Teva could have launched a non-infringing version of modafinil before the Effectiveness Date of Teva Generic Rights". However, "at the time of the Settlement Agreement, all generic modafinil products that were in development, particularly including Teva's products, likely infringed Cephalon's Particle Size Patents, and Cephalon certainly would have sued any generic launch at risk" not only on the basis of the Particle Size Patents but also on the basis of any other modafinil patent.[1086]

(672) The Parties' arguments are not convincing. First, it simply follows from the wording of the Settlement Agreement that Teva was prohibited from entering modafinil markets rather than from infringing Cephalon's modafinil patents. In this context, the scope of obligation clearly exceeds the exclusion scope of any possible court judgment concluding the United Kingdom patent litigation in Cephalon's favour.

(673) Second, the Parties now claim that it was "*likely*" that all generic modafinil products and "*particularly*" Teva's products infringed the Particle Size Patents. However, this is contradicted by contemporaneous evidence showing that (i) even Cephalon believed that the chances of litigation success against Teva are at best at 50%; (ii) Teva considered that it has succeeded in "*showing bioequivalence* [with Cephalon's modafinil] *by formulating a material which is outside the scope of the Cephalon patent*",[1087] (iii) tests on Teva's sample from 2005 did not show infringement of Cephalon's patents; and that (iv) Teva was convinced of the

---

1084 The Commission notes that both Parties understood the non-compete commitments under Article 2.5(a) of the Settlement Agreement as including the prohibition for Teva to apply for MAs as evidenced by an email from Cephalon's attorney to Teva in December 2006 and subsequent Teva internal correspondence categorizing MA applications as infringements of the Settlement Agreement (See Recital (493)) although (i) the Settlement Agreement does not stipulate anything about applying for MAs and although (ii) applying for a MA is not considered an act of patent infringement).

1085 See also the Draft Settlement Agreement of 7 December 2005, ID 277, p. 25, Article 2.1 which limited the non-compete commitments to "*Subject Modafinil Product that would infringe the RE ´516 Patent within the United States…*"

1086 SO Reply, paragraphs 86 and 87.

1087 ID 979, p. 92.

invalidity of Cephalon's Particle Size Patents.[1088] In the present case the competent court had not given a ruling on infringement yet and the burden of proving an infringement of the patent would have been on Cephalon. In this context, Teva's modafinil products could be considered at most as "*potentially infringing*".

(674) Even if Teva's existing product infringed Cephalon's patents (quod non), Teva could have developed one that would not since the file reveals that a modafinil product which would not infringe Cephalon's patents was not only a theoretical possibility. More specifically, competent courts in separate proceedings decided that both […] and […] (Recital 1145) succeeded in formulating and marketing generic modafinil products outside the scope of Cephalon's patents. It should also be recalled that the Particle Size Patents were indeed found invalid by the United Kingdom court on 24 June 2011 and by the United States court on 7 November 2011.

(675) A non-compete commitment between potential or actual competitors that goes beyond what could have been legally obtained through opposing a possible infringement of its rights in the underlying litigation is already a strong indication that the purpose of the Settlement Agreement was to restrict competition.[1089]

(676) However, even if the Settlement Agreement had only contained commitments that were claimed to be "*within the scope*" of Cephalon's modafinil patents, this would not exclude a finding of a by object restriction.[1090] That is because the objective aim of the Settlement Agreement was to keep Teva off the market through value transfers that induced Teva to postpone its independent efforts to enter the market. Such an agreement on the future market conduct of potential competitors has as its object to restrict competition and infringes Article 101(1) TFEU irrespective of whether or not, under patent law, Cephalon may have been able to obtain the same exclusion through an appropriate court decision.[1091]

(677) The restriction of competition by object identified in this Decision exists exactly because, instead of reaching an outcome based on the merits of the patents, the Parties decided to bypass any uncertainty by agreeing to a transfer of considerable value to Teva. Therefore, contrary to what is asserted by the Parties, the Commission does take into account the genuine uncertainty as to the outcome of the patent litigation. The Commission concludes that the Parties chose to replace the uncertainty of the outcome of the modafinil litigation with the certainty of Teva's limited entry in 2012 induced by a number of value transfers as compensation for Teva's non-compete and non-challenge commitments.

(678) Finally, the Commission notes that pursuant to the Article 2.5(a) of the Settlement Agreement Teva entered into the non-compete obligation "*as an express inducement to Cephalon to enter into the settlement of the UK Action, and the settlement of*

1088 See Sections 4.3.2 and 4.4.2.

1089 See also Case T-472/13, *Lundbeck v Commission*, paragraph 386 where the General Court concluded that out of scope restrictions may allow the Parties to "*maintain higher prices for their products, to the detriment of consumers and the healthcare budgets of States, even though such an outcome could not have been obtained if the national courts had confirmed the validity of their patents and the products of the generic undertakings had been held to be infringing. Such an outcome would be manifestly contrary to the objectives of the treaty provisions on competition, which are intended inter alia to protect consumers from unjustified price increases resulting from collusion between competitors.*"

1090 Case C-307/18, *Generics (UK) and Others*, paragraph 97.

1091 See for example. Case T-472/13, *Lundbeck v Commission*, paragraph 491 and ff.

potential litigation and disputes in other countries where Cephalon holds modafinil patent rights". In this context, Teva's non-compete commitment (as well as non-challenge commitment)[1092] represent Teva's consideration for Cephalon's obligations, in particular the value transfer through the package of transactions, assumed under the Settlement Agreement.

Territorial scope

(679) As to the territorial scope of the clause, Article 2.5(a) of the Settlement Agreement refers to the "*United Kingdom or any other country where Cephalon holds modafinil patent rights*". The Commission notes that the wording of Article 2.5(a) refers only to "*patent rights*" while the definition of the Intellectual Property Rights (Article 1.20 of the Settlement Agreement) includes an express reference to the patent applications. The Commission therefore concludes that Teva's non-compete commitments under the Article 2.5(a) of the Settlement Agreement relates to all countries in which Cephalon held patents related to modafinil (as opposed to pending patent applications) at the time of the Settlement Agreement. The Commission notes that the term "*modafinil patent rights*" is sufficiently broad to encompass any number of modafinil related patents held by Cephalon at the time of the Settlement Agreement.[1093]

(680) As described in Section 4.1.2, Cephalon's Provigil was no longer protected by compound patents as these patents expired in the United States in 2001[1094] and in the United Kingdom and several other Member States on 3 March 2003. In France, the patent remained in force until February 2005.[1095]

(681) However, at the time of the Settlement Agreement Cephalon held Particle Size Patents in Austria, Belgium, Denmark, Germany, Greece, France, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom and national counterparts of the Particle Size Patents in Bulgaria, Czechia, Iceland, Latvia, Lithuania, Norway, Poland, Romania, Slovakia and Slovenia. In addition, at the time of the Settlement Agreement, Cephalon held other modafinil related patents falling within the scope of the non-compete clause in Cyprus, Finland and Hungary. It is therefore concluded that Teva's non-compete commitments under Article 2.5(a) of the Settlement Agreement covered all of these Contracting Parties to the EEA Agreement.

Duration

(682) Finally, as to the temporal scope of Teva's non-compete commitments, Article 2.5(a) of the Settlement Agreement provides that this Teva obligation is limited by "*the license granted by Cephalon in connection with this Agreement*". In other words, Teva's non-compete obligation started on 4 December 2005 with the entry into force of the Settlement Agreement and ended with the effectiveness of the Teva Generic Rights. The following specifically address in more detail the end date of Teva's non-compete obligation.

1092 See Section 6.5.2.

1093 For details on the patent situation for modafinil see Section 4.1.2.

1094 Section 4.1.2.1.See also, for example, ID 267, p. 2.

1095 Ibid.

(683) In order to ascertain the end date of Teva's non-compete obligation, Article 2.5(a) of the Settlement Agreement should be read in conjunction with Article 3 of the Settlement Agreement (especially Article 3.1.1). With respect to "*any market outside the United States*" (namely with respect to the markets relevant for the Commission's assessment in this Decision), Article 3.1.1 of the Settlement Agreement provides that Teva Generic Rights (that is to say Cephalon's licence to Teva) shall be effective "*the earlier of October 6, 2012 or the date which is three calendar years prior to the expiration of the applicable patents and exclusivities in such markets*".

(684) The term "*applicable patents and exclusivities*" is not defined in the Settlement Agreement and the available documents do not provide guidance on its scope. It is worded in broad enough terms so as to include not only the Particle Size Patents and their national counterparts but also other "*modafinil patent rights*" that serve to define the territorial scope of Teva's non-compete commitment (see Recitals (680)-(681)).

(685) Accordingly, (i) in those By-Object Countries where at the time of the Settlement Agreement Cephalon held a modafinil patent set to expire on or after 6 October 2015, the end of the non-compete obligation and thus the Effectiveness Date of Teva Generic Rights was 6 October 2012; (ii) in those By-Object Countries where at the time of the Settlement Agreement Cephalon held only Particle Size Patents or their national counterparts (the date of their expiry being 4 October 2015) and no other modafinil patent, the Effectiveness Date of Teva Generic Rights was 4 October 2012; and (iii) in those By-Object Countries where at the time of the Settlement Agreement Cephalon did not hold Particle Size Patents or their national counterpart but held modafinil patents set to expire before 4 October 2015 the Effectiveness Date of Teva Generic Rights was three calendar years before the expiry of the relevant modafinil patent (together "Effectiveness Date of Teva Generic Rights").[1096]

(686) Taking into account the patent situation as described in Section 4.1.2.1.4 and the dates of expiry of the relevant patents,[1097] the Commission concludes that (i) Teva's non-compete commitment lasted until 6 October 2012 in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and United Kingdom; (ii) Teva's non-compete commitment lasted until 4 October 2012 in Bulgaria, Czechia, Iceland, Latvia, Lithuania, Norway, Poland, Romania, Slovakia and

---

1096 As described in Section 4.6.4 and 4.7.6 under the Teva Generic Rights, Cephalon granted to Teva a non-exclusive right under the Listed Patents to manufacture, use, market and sell its generic modafinil product in the United States and other markets (including EEA), and to do the same with respect to provision of modafinil API for finished drug which has modafinil as an active ingredient, as from 2011 (United States) or 2012 (other markets including EEA) under a royalty-bearing licence. For the assessment of Teva Generic Rights see Section 6.9.1

1097 The Particle Size Patents were set to expire on 4 October 2015. The national counterparts of the Particle Size Patents were set to expire on 4 October 2015 as well (these are relevant for assessment of duration in the following By-Object Countries: Bulgaria, Czechia, Iceland, Latvia, Lithuania, Norway, Poland, Romania, Slovakia and Slovenia). European patent EP1251842 was set to expire on 29 January 2021 (this patent is relevant for assessment of duration in the following By-Object Countries: Austria, Belgium, Cyprus, Germany, Denmark, Greece, Spain, Finland, France, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Sweden and United Kingdom). Hungarian patent HU216731 was set to expire on 14 June 2014.

Slovenia; and (iii) Teva's non-compete commitment lasted until 14 June 2011 in Hungary.[1098]

Implementation

(687) In accordance with Article 4 of the Settlement Agreement,[1099] the Parties ended their pending modafinil patent litigations before competent courts in the United States and in the United Kingdom. For Cephalon, this eliminated not only the risk of Teva's market entry but also the threat of invalidation of its modafinil patents that would have opened the markets for broad generic competition.

(688) Further, Teva implemented its non-compete commitments stemming from the Settlement Agreement. In doing that, it was actively assisted by Cephalon which monitored Teva's conduct. In addition, Teva did not challenge Cephalon's modafinil patents, either in the EEA or in other markets, as foreseen in the Agreement.

(689) Cephalon, on the other hand made the payments set out in the Settlement Agreement and performed under the agreed transactions.[1100] As a whole, Cephalon's actions induced Teva to assume the non-compete and non-challenge commitment.[1101]

6.5.2. Non-challenge commitment

(690) Patent challenges are an essential part of the competitive process in the pharmaceutical sector, both for generic companies seeking market entry and for originator companies that invoke process patents or other patents against such market entry.[1102] Competition – actual or potential – from generic undertakings trying to enter the market by inventing around the outstanding process and other patents, having to defend themselves against alleged infringement, seeking declarations of non-infringement or trying to invalidate process patents or other patents still held by the originator undertaking, or indeed by generic entry at risk, is the essence of competition in this sector. Preventing patent challenges, whether in the form of pre-litigation disputes, court litigation, or opposition procedures may therefore seriously impact the competitive process. The restriction of the freedom to challenge an intellectual property right is not part of the specific subject-matter of an intellectual property right and may restrict competition.[1103] This is even more so if the non-

---

1098 In the United States, the non-compete commitment was set to last until 6 April 2012. See footnote 420.

1099 See Section 4.6.5.

1100 Article 3.2 of the Settlement Agreement includes an obligation of the Parties to ""*prepare and execute whatever documents are necessary to carry out the terms of the Sections 2* [Obligations of the Parties] *and 3* [Teva Generic Rights]" of the Settlement Agreement. It expressly refers to (i) Licence Agreement with respect to Teva's Generic Rights; (ii) Licence to Teva's Intellectual Property Rights; (iii) Teva Distribution Agreement; and (iv) Supply Agreement. Plantex Supply Agreement and Teva Distribution Agreement were concluded after the Settlement Agreement. Separate licence agreement concerning Cephalon's purchase of licence to Teva's modafinil Intellectual Property Rights was never concluded but Cephalon made the royalty payments to Teva prescribed under the Article 2.2 of the Settlement Agreement (see Section 4.6.3.2). Licence Agreement in the context of Teva's Generic Rights became obsolete following the merger between Teva and Cephalon.

1101 While Teva's non-compete and non-challenge commitments installed restrictions on Teva's independent behaviour that lasted until the effectiveness of Teva's Generic Rights and until the end of the Settlement Agreement respectively, the infringement assessed under this Decision finished when the Commission cleared Teva's acquisition of control over Cephalon (see Chapter 14).

1102 See, for example, case C-307/18, *Generics (UK) and Others*, paragraph 81.

1103 See, for example, case C-307/18, *Generics (UK) and Others*, paragraph. 82, Case T-472/13, *Lundbeck v Commission*, paragraph 487 (see also paragraph 390) and jurisprudence cited therein; Case C-65/86,

challenge clause relates to the intellectual property that is subsequently invalidated since it is in the interest of undistorted competition and in accordance with the principles underlying the protection of intellectual property that invalid intellectual property rights should be eliminated.[1104]

(691) Teva's non-challenge undertaking is expressed in Article 8.12 (b) of the Settlement Agreement which stipulates that "nothing in this Agreement shall operate or be construed as a waiver by Teva of any right to challenge any patent owned by Cephalon other than the Listed Patents." Consequently, Teva committed, for the duration of the Settlement Agreement not to challenge Cephalon's Listed Patents defined as "the RE '516 Patent, United States Patent No. 4,927,855, and any other patent that may be listed in the FDA Orange Book for PROVIGIL®, and for markets outside of the United States, the foreign counterparts of such patents."[1105]

(692) With the non-challenge undertaking Cephalon acquired certainty that Teva would not represent a competitive threat through its challenge to Cephalon's patent position for the duration of the Settlement Agreement. Teva committed not to challenge what were considered the main patent barriers to the entry into the modafinil market. Teva's non-challenge obligation as incorporated in Article 8.12 (b) of the Settlement Agreement lasted throughout the duration of the Settlement Agreement, that is to say Teva committed not to challenge also during the period of the intended Teva Generic Rights as stipulated in Article 3.1 of the Settlement Agreement.

(693) It should be recalled that Teva undertook the non-challenge commitment in a situation where Teva considered Cephalon's patent position to be weak. Even more, before concluding the Settlement Agreement, Teva had submitted evidence in the United States litigation that Cephalon's patents were invalid and obtained by deception (see Recital **(124)**). The Parties' claim that the non-challenge clause is inherent in every patent settlement agreement does not alter the Commission's assessment and cannot rebut the Commission's conclusion that the Settlement Agreement represents a restriction of competition by object.[1106] The non-challenge clause together with the non-compete commitment installed limitations on Teva's

---

Bayer v Süllhöfer, paragraph 16. See also, Communication from the Commission—Guidelines on the application of Article 101 of the TFEU on the Functioning of the European Union to technology transfer agreements, OJ C 89, 28.3.2014, p. 3, point 243 that further emphasise that competition law scrutiny of non-challenge clauses "*may also be necessary if the licensor, besides licensing the technology rights, induces, financially or otherwise, the licensee to agree not to challenge the validity of the technology rights*".

1104 See, for example. Case T-472/13, *Lundbeck v Commission*, paragraph 487 and Case C-193/83, *Windsurfing International v Commission*, paragraph 92.

1105 See Settlement Agreement, Article 1.12. The RE '516 Patent and United States Patent No. 4,927,855, are in this Decision referred to as US '516 Patent and US '855 Patent (see Section 4.1.2). The patents that were listed in the Orange Book for Provigil since 2005 are the US '855 Patent, (European counterpart EP 0233106), US '516 Patent (European counterparts Particle Size Patents) and US '346 Patent (European counterpart EP139712). See Section 4.1.2.1.

1106 "*[Characterization of a settlement agreement as a 'restriction by object'] cannot be rebutted, first, on the ground that the undertakings that have entered into such agreements argue either that settlement agreements such as those at issue in the main proceedings do not exceed the scope and the remaining period of validity of the patent to which they relate and, therefore, are not anticompetitive, or that restrictions stemming from such agreements are merely ancillary within the meaning of the judgment of 11 July 1985, Remia and Others v Commission (42/84, EU:C:1985:327).*" (Case C-307/18, *Generics (UK) and Others*, paragraph 96).

independent efforts to compete with Cephalon and was accepted only against a significant value transfer made by Cephalon (see Sections 6.6, 6.7 and 6.8).

6.6. The value transfer

(694) The analysis in this Section 6.6 of, in particular, contemporaneous evidence shows that the package of commercial transactions in Article 2 of the Settlement Agreement resulted overall in a significant transfer of value from Cephalon to Teva. This value transfer was, as described in the subsequent Sections 6.7 and 6.8, a consideration sufficient to induce Teva to enter into the non-compete and non-challenge commitments.

(695) As emphasised by the Union Courts and summarised in Chapter 5 above, the fact that a non-compete and non-challenge commitment has been induced by a transfer of value to the generic manufacturer is a key consideration for identifying a patent settlement as a restriction of competition by object. The presence of a value transfer shows that the settlement is not reached on the basis of each party's assessment of the strength of the patent case, but that it is artificially incentivised through a payment (the transfer of value) to the generic manufacturer.

(696) A transfer of value to the generic manufacturer can take different forms. It does not have to be a direct payment of money. It can also be indirect and embedded in commercial transactions between the originator and the generic manufacturer. Such commercial transactions can grant benefits to the generic undertaking, in particular the profit margin (net gain) resulting from such transactions (but also other direct or indirect benefits), that under normal circumstances the generic undertaking would not obtain.[1107] This can be either because such a transaction would not have been realised at all under normal market conditions, or because such transaction has been realised at more favourable terms than would have been the case under normal market conditions.

(697) As the Court of Justice emphasised, to find that a settlement agreement like the present one represents a restriction of competition by object, it is necessary to establish that the value transferred to the manufacturer of generic medicines is not "*justified*", or, in other words, that it "*cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits*".[1108]

(698) The Parties argue, in this context, that there could only be a value transfer if the Commission demonstrated that the price paid was not within "*a range of reasonableness*" and not the result of "*arm's length bargaining*"[1109]. In evidentiary support, the Parties strongly rely on the analysis in a report, dated 24 January 2018, by […], that the Parties had commissioned for the purposes of the present case.[1110]

1107 See the case-law cited in Section 5.7.3

1108 Case C-307/18, *Generics (UK) and Others*, paragraphs 85, 87, 89 and 92.

1109 SO Reply, section II.3; SSO Reply, section 1.2.1.

1110 Annex 1 of the SO Reply; see also the multiple reference in the SSO Reply. The report by […] appears to be based on (and reproducing content from) the expert report that […] had produced on 10 June 2011 for Cephalon in the United States antitrust litigation concerning the settlement with Teva and other generic manufacturers. In these US court proceedings, expert reports had also been produced by experts commissioned by the plaintiffs, including the United States Federal Trade Commission (FTC) as competent antitrust authority. As it is apparent from the public court

(699) The Commission notes, in the first place, that none of the concepts referred to by the Parties appear in the legal test set out by the Court of Justice in the *Generics (UK) and Others* case. The Parties base their view mainly on references to the judgment of the General Court in *Krka*.[1111] In that case, the General Court indeed referred, when assessing a value transfer (reverse payment) received by the generic company, to the concept of "*at arm's length*" negotiation. The Court pointed out, however, that this concept is "*similar to*" the concept of "*normal competitive conditions*" that it is regularly used in the case-law on State aid.[1112] Pursuant to this case-law, to determine whether a public measure involves the grant of State aid, it is relevant "*whether the recipient undertaking receives an economic advantage which it would not have obtained under normal market conditions*".[1113]

(700) This is precisely the question that the Commission has been assessing in the present case: would Teva have obtained the economic advantages (such as profit margins, or other advantages) from the commercial transactions in question under normal market conditions, that is to say without committing to Cephalon that it would not compete on modafinil markets and not challenge Cephalon's secondary patents? The answer to this question can be negative even if the price paid in a transaction has been within "*a range of reasonableness*", It is indeed possible that a transaction with a reasonable ("normal") remuneration and a reasonable profit margin grants Teva an economic advantage that Teva would otherwise not have obtained, for instance if under normal market conditions the transaction would not have occurred, either at all or not at the same terms. It is therefore indeed necessary, as the General Court explained in *Krka*, to consider specifically for each transaction whether it was "*concluded … on the basis of economic considerations limited to the economic value of the asset traded, that is to say, for example, to its prospects of profitability*" and not driven by extraneous considerations such as the aim to induce a generic to stay out of the market.

(701) Accordingly, the Court of Justice affirmed that profits from a commercial agreement that in fact involves an actual supply of goods and services (namely an actual *quid pro quo*), such as the profits from a distribution agreement, can amount to an unjustified value transfer.[1114] This will particularly be the case when the assessment shows that the generic undertaking could not have expected to obtain these profits

---

documents in these court proceedings (which ended with a settlement under which Cephalon paid USD 1.2 billion), experts commissioned by the plaintiffs (for example, the expert report by Professor […], Boston, dated 11 June 2011) reached different conclusions in analysing the same facts than […], concluding for instance that Cephalon's conduct leading up to the licence of Teva's Intellectual Property was "outside industry norms", see the ruling of the District Court for the Eastern District of Pennsylvania, Goldberg, J., Memorandum Opinion, 28 January 2015, p. 29, available at: https://www.ftc.gov/system/files/documents/cases/150128cephalonopinion.pdf
The Commission requested in 2011, 2018 and 2019 the expert reports submitted in the United States antitrust proceedings both by the FTC (and other plaintiffs) and by Cephalon/Teva. According to the Parties, they were not able to deliver the expert reports produced in the United States porceedings as they were subject to the Court's Protective Order of 9 November 2009. In 2019 the Parties maintained that they "*are of the view that the protective order still does not permit [them] to produce the* ***plaintiffs' reports***" (emphasis by the Commission; ID 3904, p.1; see also ID 3736 and ID 1436, p. 15).

1111 Specifically, paragraphs 171 and 173 of that judgment of the General Court in Case T-684/14, *Krka v Commission*.

1112 Case T-684/14, *Krka v Commission*, paragraph 173.

1113 Judgment of 11 July 1996, *SFEI and Others*, C-39/94, EU:C:1996:285, paragraph 60.

1114 Case C-307/18, *Generics (UK) and Others*, paragraphs 91 and 92.

under normal market conditions, that is without entering into anticompetitive clauses in a settlement agreement. If, however, the transaction would have been concluded also without the generic entering into anticompetitive clauses, then the transaction has another plausible explanation than the commercial interest of the originator and the generic not to engage in competition on the merits.

(702) It follows that the presence of a value transfer giving rise to a reverse payment should be established by examining, in the light of the specific circumstances of the case and the perspectives and interests of the Parties, whether Cephalon transferred to Teva a value that it would not have received under normal market conditions (in the absence of the Settlement Agreement with its non-compete and non-challenge clauses).

(703) Contrary to the Parties' claim, the Commission does not "*distort the [Generics UK] test by introducing a specious counterfactual analysis*"[1115]. A counterfactual analysis, namely asking what would have happened in a hypothetical alternative scenario, is inherent in the framework for the legal assessment of value transfers established by the General Court and the Court of Justice.[1116] In order to establish whether value has been transferred to the generic manufacturer that cannot have any other plausible explanation than the inducement of the generic undertaking not to independently enter the market, it is necessary for the Commission to assess whether, the different transactions mentioned in Article 2 of the Settlement Agreement would have occurred at all, or on the same terms, under normal market conditions, that is to say without Teva's commitment not to compete and not to challenge in the Settlement Agreement. In other words, to assess whether each of the commercial transactions had as their sole plausible explanation the objective to induce Teva or whether they would have occurred in any event, that is to say also under other circumstances, it is inevitable to compare what actually happened with what would have happened in the absence of the Settlement Agreement with its restrictive commitments.

(704) In this respect, the Court of Justice explained that in order to assess the possible value transfers contained in a settlement agreement, it is important to consider *all* the transfers of value made between the Parties, whether those were pecuniary or non-pecuniary, direct or indirect.[1117]

(705) The Commission, in this Section, therefore analyses the circumstances of each transaction in detail and assesses, in particular, the value that Teva could expect to obtain from each transaction at the moment of concluding the Settlement Agreement and whether Teva would have been able to conclude each transaction without engaging in the non-compete and non-challenge commitments (Teva's interest). The Commission also assesses the interest that Cephalon had in each transaction and whether, in light of that interest, each transaction would have occurred at all or on the same terms absent the Settlement Agreement (Cephalon's interest). For each transaction, the Commission analyses thus each Party's incentives to enter into the transaction, taking into account both the terms of the transactions and the broader context at the time of signing the Settlement Agreement.

1115 SSO Reply, section 1.3.2

1116 See, for example, SSO Reply, paragraphs 26-27.

1117 Case C-307/18, *Generics (UK) and Others*, paragraphs 90-91.

(706) In doing so and contrary to what is claimed by the Parties, the Commission does not ignore evidence that allegedly would show that the transactions were concluded to address legitimate business interests. The Commission conducts an individual analysis of each transaction included in the Article 2 of the Settlement Agreement and assesses its possible business rationale and especially every explanation provided by the Parties during the proceedings. This assessment cannot however follow the mechanic approach proposed by the Parties where each and every transaction is looked at in isolation and outside of its context.[1118] Quite to the contrary, in order to establish whether a particular transaction would have occurred under normal market conditions, the Commission has to take into consideration not only the terms and conditions of a particular transaction but also its relevant context.[1119]

(707) On the basis of a comprehensive and detailed assessment of each commercial transaction, the Commission has reached the conclusion that alternative explanations put forward by the Parties are simply not plausible and that under normal circumstances, that is absent the Settlement Agreement and without the aim of inducing Teva to refrain from competing, Cephalon would not have entered into the transactions with Teva, its most advanced generic rival in the EEA. The analysis shows that the package of transactions in Article 2 of the Settlement Agreement had the objective aim of transferring value from Cephalon to Teva and inducing Teva's commitment, in the Settlement Agreement, not to independently enter and compete in the market for modafinil and not to challenge Cephalon's modafinil property rights.

(708) The following Sections set out, for each individual commercial transaction, the evidence and analysis that have led to this conclusion.

6.6.1. Modafinil API Supply Agreement

6.6.1.1. Introduction

(709) This Section assesses Cephalon's and Teva's incentives to enter into the Modafinil API Supply Agreement at the time of concluding the Settlement Agreement, taking into account both the terms of the transaction and its context. From the perspective of Teva, this Section shows that the Modafinil API Supply Agreement generated value for Teva that it would not have been able to appropriate from Cephalon absent the Settlement Agreement. From the perspective of Cephalon, the evidence reveals that the commercial transaction for the API supply pursuant to the Modafinil API Supply Agreement ("API transaction") did not have any plausible explanation other than serving as an unjustified value transfer from Cephalon to Teva in consideration of the

---

1118 For example, see paragraph 292 of the SO Reply with respect to the royalties payable under Licence to Teva's Intellectual Property Rights.

1119 For example, it is not possible to assess if Cephalon would have had agreed to pay for fixed quantities of modafinil API to Teva without establishing, based on contemporaneous documents rather than on ex post clarifications, Cephalon's then existing and potential alternative suppliers and their prices, Cephalon's demand estimates or Cephalon's investment in own production facilities (which had been abandoned after modafinil supply contracts with generic challengers (including Teva)). Similarly, it was not possible to establish if Cephalon would have paid a significant amount of money (USD 125 million) for Teva's intellectual property (the most valuable part of which was, according to the Parties, a pending patent application) without first establishing, based on contemporaneous evidence rather than on subsequently commissioned expert reports, if Cephalon at any time prior to the Settlement Agreement internally or externally expressed any concerns about the risks for Provigil arising from Teva's intellectual property or any interest in acquiring it.

commitments of Teva not to independently enter the modafinil markets and compete with Cephalon and not to challenge its patents.

6.6.1.2. Clause

(710) According to Article 2.4 of the Settlement Agreement, Cephalon committed to purchase fixed annual quantities of modafinil API from Teva between 2007 and 2011 for prices defined in this provision. The purchasing arrangement was implemented by the Modafinil API Supply Agreement of 7 November 2006 between Cephalon and Teva's subsidiary Plantex USA.

(711) In Article 2.4 of the Settlement Agreement, as further detailed in the Modafinil API Supply Agreement, Teva agreed to supply and Cephalon agreed to purchase an annual minimum of 10,000 kg of modafinil API yearly, which made a total of at least 50,000 kg for the five-year term of the Supply Agreement.

(712) The prices ranged from USD 650/kg in the first year to USD 500/kg in the last two years amounting to a total of at least USD 28 million for the duration of the agreement (see Section 4.6.3.4). Cephalon committed to buy modafinil API without any tender or any other form of call for quotations by potential suppliers for the volumes agreed in the Modafinil API Supply Agreement.[1120]

(713) Teva represented to Cephalon that the price in the first year reflected its approximate manufacturing cost plus an added 30% by way of mark-up. Evidence shows that the 30% mark-up was representative for the whole duration of the supply arrangement (Recital (407)).

6.6.1.3. Teva's interest

(714) First, pursuant to Article 2.4 of the Settlement Agreement, Teva was entitled in the first year of supplies (2007) to a 30% mark-up over its manufacturing cost, and this mark-up was representative for the whole duration of the supply agreement (see Recital (407)). Cephalon committed to purchase a minimum annual volume of 10,000 kg of modafinil API during the years 2007-2011 for prices ranging from USD 650/kg to USD 500/kg, namely at least 50,000 kg for an aggregate price of at least USD 28 million. This combined with the above-mentioned mark-up of 30%,[1121] the Modafinil API Supply Agreement generated, from an ex ante perspective, value (profit) for Teva of approx. USD 6.5 million; namely EUR 5.5 million.[1122] These findings were not contested by the Parties in the SO Reply.

1120 Modafinil API Supply Agreement therefore represented a "take–or–pay" contract. In such a contract the company either takes the product from the supplier or pays the supplier a penalty. For any product the company takes, they agree to pay the supplier a certain price. It was also understood so by Cephalon, see, for example, ID 2841-1129, p. 3.

1121 See Recital (240).

1122 Eventually, Plantex supplied under the terms of the Plantex Supply Agreement Cephalon with approximately 55,000 kg for the price approximately USD 30 million (or, approximately EUR 21.7 million), during the period between 2006 and 2010 (Recitals (405) - (406)). Hence, Teva's aggregated margins from supplying API to Cephalon reached in the end EUR 5.009 million. Nevertheless, Teva's expectations at the moment of concluding the Settlement Agreement are the relevant indication of Teva's incentive to enter into the Settlement Agreement. The difference between the lower total margin in EUR for actually supplied modafinil API against the provisions of the Plantex Supply Agreement – while in fact Teva supplied to Cephalon more modafinil API than was the contractual minimum – is explained by changes in USD-EUR exchange rate. The expected (contractual)

(715) The Commission considers that Teva had an interest in keeping its API manufacturing facility operating at guaranteed volumes in 2006 and onwards. The non-compete commitment accepted by Teva in the Settlement Agreement for 2006-2012 implied that Teva's dedicated manufacturing capacity became futile. Such capacity running idle would have been suboptimal for Teva's operations and might have prevented it from obtaining any returns on the investments done earlier in view of a market launch of its modafinil product (see Section 4.3). Teva's chief Settlement negotiator voiced explicitly this concern during the negotiations on the Settlement Agreement and demanded a binding modafinil arrangement: "*[U]nderstand that we have some dedicated capacity issues there and soft language where we agree to agree is not giving* [Teva's employees in charge of API operations] *much*." In the light of the above facts, the API Supply Agreement provided Teva ex ante with a guaranteed revenue stream for fixed volumes of modafinil API at fixed prices for five years, irrespective of market developments (Cephalon's purchase obligation was worded as take-or-pay commitment).

(716) Absent the API transaction, a continuation of the modafinil API operations would not have been certain, on the one hand, due to the pending modafinil litigation with Cephalon. On the other hand, even in the case that Teva had prevailed in the litigation, it could have been faced with competition by other potential generic entrants (for example, Ranbaxy, Mylan, Barr) making its future modafinil market shares uncertain and thus also its modafinil API revenues. This uncertainty, characteristic of competition, was replaced with the certainty of revenue streams from Cephalon for Teva's API.

(717) Teva could not have hoped to conclude this or a similar modafinil API Supply Agreement with Cephalon absent the non-compete and non-challenge commitments in the Settlement Agreement, because Cephalon already had sufficient capacity in its existing supply chain, providing it with modafinil API at terms better than those offered by Teva/Plantex (see Sections 4.7.3 and 6.6.1.4).

(718) In summary, at the conclusion of the Settlement Agreement, Teva could expect to receive significant value (profits) as a result of the API transaction, which it would not have been able to appropriate from Cephalon absent the non-compete and non-challenge commitments in the Settlement Agreement.

6.6.1.4. Cephalon's interest

(719) Cephalon would not have entered into the Modafinil API Supply Agreement outside the context of the Settlement Agreement. The supply agreement did not have a plausible explanation other than to contribute to the value transfer inducing Teva to commit not to enter the modafinil markets and not to challenge the patents. This is shown, in particular, by the evidence on file, the terms of the transaction, as well as its context including especially Cephalon's modafinil demand and supply situation as perceived by Cephalon at the time of the Settlement Agreement.

<u>The Modafinil API Supply Agreement as an important part of the Settlement Agreement</u>

---

total margin is calculated on the USD-EUR rate in 2005 while the actual total margin is calculated (and converted in EUR) on year-by-year basis of supplies and respective payments.

(720) Cephalon internally brought up the idea of a modafinil API supply agreement with Teva in November 2005 for the purpose of the settlement negotiations: *"to discuss potential opportunities… that may be relevant to the settlement of the Provigil Patent litigation*" and in this regard, *"to consider what might be a fit for Teva*". This quote from contemporaneous documents show that Cephalon's motivation to discuss a supply deal with Teva was to include it in the inducement package offered in exchange of Teva's non-compete and non-challenge commitments in the Settlement Agreement. It was only in the settlement context that Cephalon stated that *"Modafinil manufacturing for conversion to R-modafinil could be a possibility for Teva as well*", and not in a context of discussing a need for a new modafinil supplier, as the Parties now allege.

(721) Moreover, during the negotiations of the Settlement Agreement, Cephalon initially refused concluding a binding modafinil API supply agreement with Teva. On 3 December 2005, Cephalon's chief negotiator told Teva: "*I think we should forget about api other than* [agreement] *to continue discussions*."[1123] However, Teva's chief negotiator insisted on a binding supply commitment, as shown in a communication of 3 December 2005: "*I'd appreciate your checking with your* [operations] *guys on the API – understand that we have some dedicated capacity issues there and soft language where we agree to agree is not giving them much.*"[1124]

(722) Eventually Cephalon agreed to a binding agreement on the modafinil API supply for fixed volumes and for the term of five years, even though throughout the negotiations it kept trying to minimise purchase commitments (Section 4.5).

Cephalon forecasted that it had sufficient and secure modafinil sources

(723) Cephalon's forecasts before the Settlement Agreement showed that its supply chain had sufficient capacity to provide it with secure supplies of modafinil for all modafinil-based products.

(724) Since 2002 Cephalon made significant investments in the development of its supply chain for modafinil API. First, Cephalon increased its in-house manufacturing capacity at Mitry-Mory.[1125] Initially, Mitry-Mory ran one manufacturing plant (C-1) but in 2002 Cephalon decided to increase the capacity by building a new C-2 plant: "*In 2002, the sales forecasts in the US market, the steady increase in sales in the European market, as well as the Sparlon project led the group to an investment of EUR 32 million in Mitry-Mory into a construction of a new production facility…*".[1126] The C-2 plant was not supposed to replace C-1 but to add capacity to Mitry-Mory's overall manufacturing capabilities.[1127]

1123 This was a similar approach that Cephalon took when it agreed with Teva in Article 2.6 of the Settlement Agreement to "undertake to consider in good faith" whether both companies could conclude resale and distribution arrangements in other countries than the United Kingdom, and in Article 2.7 of the Settlement Agreement, according to which "(T)he parties agree to discuss commercially reasonable terms" for "a potential commercial supply agreement" for the API contained in Cephalon's cancer medicine Treanda (see Sections 4.5.1 and 4.6.1) These agreements were never concluded even if, at least with respect to the distribution arrangements in Europe, Teva showed an interest in doing.

1124 Section 4.5.

1125 Also called Orsymonde.

1126 Recital (357).

1127 Section 4.7.3.1.

(725) Upon completion of works in C-2, Cephalon stated in its 2004 Annual Report: "This new state-of-the-art facility significantly increases our capacity to manufacture modafinil and other active drug ingredients. The facility also enables us to prepare for production of Nuvigil (armodafinil) and will allow greater control over our entire manufacturing and supply systems."[1128]

(726) A second investment flowed into , an external manufacturer that Cephalon selected in 2003 through an RFP. The cooperation implied that Cephalon transferred modafinil manufacturing technology to [*contract manufacturer*], which lacked such technology. Cephalon incurred further costs in terms of money and time expenditure in the process of regulatory approval for [*contract manufacturer*] as its source of modafinil and in internal validation processes (quality assurance).[1129] As result of these investments, [*contract manufacturer*] was able to supply modafinil to Cephalon.[1130]

(727) From the perspective of Cephalon, [*contract manufacturer*] was compared to Mitry-Mory already only "*a secondary source of supply in case there were supply disruptions from Mitry-Mory.*"[1131] According to Cephalon's planning of November 2005, once the C-2 plant could manufacture modafinil for commercial supplies, Cephalon wished to receive "*as much modafinil as possible from Orsymonde* [that is Mitry-Mory] *and take advantage of the improved economics…*"[1132] Cephalon's internal presentation of 11 November 2005 summarised in respect of the supply chain: "*No practical constraint on modafinil production volume.*"[1133] Already in January 2004, Cephalon told [*potential contract manufacturer*], another […] company interested in becoming Cephalon's modafinil API supplier,[1134] that the modafinil project "*is not a very high priority…* [Cephalon's] *current source, which is manufactured by their French facility, is building additional capacity which will come on line in 2004 and an additional outside source is currently running a validation campaign.*"[1135]

(728) Cephalon forecasted that its existing supply chain provided it with secure future supplies in respect of all of its (both existing and pipeline) modafinil requirements. This is demonstrated in detail by the company's demand and supply forecasts for 2006-2008.[1136] For example, for 2007, Cephalon estimated demand between 117,000 and 146,000 kg of modafinil API, while it could have access to […] kg of supply from Mitry-Mory and . Similarly, for 2008, the highest demand was estimated at 160,000 kg, while its existing sources could have supplied […]% more ([…] kg) (see Recital (392)).

Short-term supply concern in 2006

(729) Notwithstanding Cephalon's forecasts which suggest that supply would meet demand in every scenario (see Sections 4.7.3.4 - 4.7.3.6), some internal communication of

---

1128 Recital (358).
1129 Section 4.7.3.2. This was also confirmed by the Parties in the SO Reply.
1130 See Section 4.7.3.2.
1131 Recital (354).
1132 Recital (396).
1133 Recital (393).
1134 See Section 4.7.3.3.
1135 Recital (376).
1136 See Sections 4.7.3.4 and 4.7.3.6.

Cephalon in December 2005 may suggest that Cephalon was to some extent concerned about a short-term issue regarding the modafinil demand/supply situation in the first half of 2006. This resulted from two concurring factors. First, on the demand side, during the run up to the Settlement Agreement (and the other modafinil settlements in the United States) in November 2005, Cephalon's managers included into the maximum potential modafinil requirements high-demand scenarios for both Nuvigil and Provigil, since they did not know whether the generic contenders would enter the modafinil market in June 2006.[1137] Second, on the supply side, the Mitry-Mory's C-2 plant was scheduled to start commercial operations only in the third quarter of 2006, and hence could not contribute to the maximum demand scenario for the first half of 2006.[1138]

(730) Contrary to what the Parties appear to suggest in the SO Reply,[1139] this internal Cephalon correspondence reveals that a potential supply concern was – from the relevant perspective of Cephalon at the time of the Settlement Agreement – limited to the first two quarters of 2006. This short-term concern ("*next couple of months*") surfaced in the conversation within Cephalon's Technical Operations team regarding the modafinil demand forecast of 28 December 2005. In his comments to the requirement estimates, Cephalon's supply manager concluded: "[B]*ased on the increased input from and Orsymonde we will be able to support the modafinil needs for all 3 products* [that is Provigil, Nuvigil and Sparlon]… *My concern is for the short term (next couple of months) and suggesting that we slow down (stop) R-modafinil production for 2-3 months to build up some Modafinil supply to support any increases to Provigil and Sparlon*."[1140] Cephalon's associate director for production planning followed-up: "*We will be able to support all 3, but the large SMB* [simulated moving bed, a process of manufacturing of R-modafinil for Nuvigil] *will only be able to run to the extent of* [C1] *output in Q1 and Q2. The issue we are having is balance. The current consumption schedule assumes 100 procent consumption of Modafinil… And we will be hand-to-mouth. If anything changes (e.g. Provigil Samples, increase in Sparlon sales, desire to increase Provigil inventory to higher than 2 months), we won't be in a position to do it. Based on current Nuvigil forecast, it just doesn´t make sense to continue to devote this much Modafinil to R-modafinil conversion when we could be jeopardizing sales in Provigil or Sparlon*."[1141]

(731) In any event, the Commission notes that even if Cephalon's supply managers were concerned at the time of the Settlement Agreement about a potential short-term supply concern for the first two quarters of 2006, the Modafinil API Supply Agreement with Teva could not have been a solution for the issue. Supply from Teva would never have been capable of solving the situation sufficiently in time. According to Article 2.4 of the Settlement Agreement, the initial year of the supply agreement was 2007, that is the supplies were scheduled to start when the potential

---

1137 As it was shown above, in reality the high-demand scenarios for both products could not co-exist (see Section 4.7.3)

1138 See Section 4.7.3.1 and Section 4.7.3.6.

1139 ID 3694-26, p. 88 and subsequent, see in particular the quotes on p. 91, paragraph 337.

1140 ID 1570, p. 1.See also Recital (394).

1141 ID 1570, p. 1. See also Recital (395).

short-term supply constraint in the first half of 2006 was already expected to be long over (see also Recital (396)).[1142] [1143]

The Parties' arguments regarding the sufficient and secure modafinil sources

(732) The Parties claim that the Modafinil API Supply Agreement was economically rational from Cephalon's perspective, as it provided additional modafinil API volume and insurance against an API shortage when: (a) Cephalon anticipated a significant increase in demand for modafinil API with the pending regulatory approvals and launches of Sparlon and Nuvigil, two modafinil-based products; and (b) Cephalon faced uncertainty with respect to its existing sources of supply.[1144]

(733) With regard to the (a) assertion of the anticipated significant increase in Cephalon's demand for modafinil API, the Commission notes that Cephalon planned and prepared for these launches long before its supply arrangement with Teva. First, the Phase III clinical trials for both Sparlon and Nuvigil commenced in the United States in 2003 (Section 4.2.3.1). Second, the construction of the new C-2 manufacturing plant at Mitry-Mory and the API supply agreement with [*contract manufacturer*] as a secondary source of supply were designed prior to any discussion on the Settlement Agreement to meet Cephalon's increased modafinil demands, as explicitly acknowledged in Cephalon's contemporaneous documents (see Section 4.7.3.1). Third, when [*potential contract manufacturer*] offered to Cephalon modafinil manufacturing, Cephalon replied that the modafinil project "*is not a very high priority with Cephalon. Their* [Cephalon's] *current source, which is manufactured by their French facility, is building additional capacity which will come on line in 2004 and an additional outside source is currently running a validation campaign*." (Section 4.7.3.3).

(734) In light of the above, the Commission finds that Cephalon anticipated increased demand for modafinil API and adjusted its modafinil supply chain for this purpose by investing into new C-2 Mitry-Mory plant and concluding a modafinil API supply agreement with [*contract manufacturer*] at least from 2003, that is to say well before and independently of the Settlement Agreement.

1142 For the sake of completeness, the actual modafinil supply agreement with Teva's subsidiary Plantex was concluded only on 7 November 2006. The United States regulatory approval to commercialise Teva's modafinil API was granted only on 20 December 2007. See Recital (761).

1143 As for the substance of the conversation in Recital (731), the Technical Operations team confirmed that the existing suppliers were able to support all products, while acknowledging a temporary strain on demand in the first two quarters of 2006 as a result of unnecessary high quantities devoted to r-modafinil. Cephalon's managers suggested an internal re–balancing of modafinil API requirements between Nuvigil, Provigil and Sparlon that would reflect Cephalon's actual needs, as opposed to finding an additional source of supplies. The start of operation in Mitry-Mory's C-2 in the third quarter of 2006 would put an end to the short-term concern, as also recognised by Cephalon, see ID 1570.

1144 SO Reply, paragraphs 7, 310 and 314, ID 3694-26, p. 10 and 84. See also the [*Expert report of 23 January 2018*], paragraphs 46, 47 and 49, ID 3694-19, p. 16-18. The [*Expert report of 23 January 2018*] states that the increase in demand between June and November 2005 was largely because of increased forecasts for Sparlon (paragraph 47). However, in their SO Reply, the Parties note that the increase was due to jumps in demand for both Nuvigil and Sparlon (SO Reply, paragraph 310). Indeed, the increase in demand for Nuvigil (from 45.000 kg in June to 70.500 kg in November 2005) was much steeper than the increase for Sparlon (from 40.000 kg to 57.000) but also the estimates for modafinil requirements varied by +/ - 10.000 kg. See IDs 1568, 1569 and 1585.

(735) Regarding the Parties' argument concerning (b) Cephalon's alleged uncertainty with its existing sources of supply, the SO Reply specifies that Cephalon's modafinil sources at the time of the Settlement Agreement (namely both Mitry-Mory's plants and [*contract manufacturer*]) were insufficient.[1145] According to the Parties, the Commission omits the "key statement" that Cephalon faced a real fear that, even if Mitry-Mory and [*contract manufacturer*] could meet demand, its modafinil supply would be tight, that Cephalon would be "*hand to mouth*" and that "*if anything changes (e.g. Provigil samples, increase in Sparlon sales, desire to increase Provigil inventory to higher than 2 months), we won't be in a position to do it.*"[1146]

(736) The Commission considers that the Parties use the quotes selectively and out of context. The conversations between Cephalon's employees related only to the potential so-called "*short-term concern*" with respect to the first half of 2006 (Section 4.7.3.6). The contemporary documents also show that Cephalon's supply managers nevertheless believed that the existing supply chain can supply the required volumes of modafinil and did not consider adding a new supplier(s) to the chain. Internally, Cephalon's supply managers rather proposed that the available modafinil API supplies should be more efficiently redistributed between Nuvigil, Provigil and Sparlon (reflecting lower demand for Nuvigil following the Settlement Agreement) and that the short-term concern would be resolved after the start of operations at Mitry-Mory's C 2 in 2006 (see Section 4.7.3.6).

(737) The Parties further argue in the SO Reply that the combined long-term available API capacity of both Mitry-Mory and [*contract manufacturer*] at the time of the Settlement Agreement was at best […] kg annually, well below the internal high (148,500 kg) and low-side (138,500 kg) demand forecast of 21 November 2005. This […] kg capacity estimate was, according to the Parties, a best case scenario because it depended on several risky assumptions (that [*contract manufacturer*] would be able to operate at full capacity, Mitry-Mory's C-2 would obtain FDA approval as planned, all of the available capacity of C-2 could be allocated to modafinil, and neither [*contract manufacturer*] nor C-2 would face significant manufacturing issues).[1147]

(738) The Commission notes, regarding the calculation of the figure of […] kg of modafinil API (which the Parties do not explain), it appears that the SO Reply combines the estimated manufacturing capacity of Mitry-Mory's C-2 plant for 2007 (45,000 kg) with expected supplies from [*contract manufacturer*] as of 2006 onwards ([…] kg). The contemporaneous evidence however shows that Cephalon's managers expected C-2 to produce 74,000 kg of modafinil API as from 2007, and while [*contract manufacturer*] committed to supply […] kg of modafinil API in 2006, it also indicated a supply capacity of […] kg from 2007 onwards (Cephalon itself assumed that it could demand from [*contract manufacturer*] […] kg if necessary (see Recitals (379)-(380)). More importantly, the calculation of the Parties appears to exclude any possible supplies by Mitry-Mory's C-1 plant. However, contrary to the Parties' assertions, that C-1 plant was scheduled for phase-out by the end of the

1145 SO Reply, paragraph 328 and subsequent, ID 3694-26, p. 88 and subsequent. See also Response to the LoF, points 18-22 (ID 3763).

1146 SO Reply, paragraph 337, quoting ID 1570, p. 1.

1147 SO Reply, paragraph 338.

first quarter of 2007,[1148] Cephalon's own contemporaneous documents include supplies of 37,000 kg of modafinil API from the C-1 plant in 2006 and Cephalon's estimate for 2007 and 2008 again explicitly included supplies of 37,000 kg of modafinil API from the C-1 plant[1149].

(739) With regard to the C-2 Mitry-Mory plant, the Parties contend that in early 2005, although C-2 was expected to provide annual capacity of approximately 45,000 kg per year (which reflected about 80% of full capacity), it had not yet obtained FDA approval. Hence, according to the Parties, the Commission's calculation assumes a greater capacity for C-2 than was standard, and assumes that the C-2 plant could operate at 100% capacity prior to the FDA approval. According to the Parties, the SO ignored the uncertainty presented by both C-1 and C-2 and assumed, without any basis that, at the time of the Settlement Agreement, Cephalon had been planning for 100,000 kg from the Mitry-Mory facilities alone.[1150] The Parties support their assertions about the allegedly low C-2 capacity by reference to Meeting Notes of Cephalon's technical operations team of 18 May 2006[1151] and by a presentation for Cephalon's Budget meeting on 25 July 2006.[1152]

(740) The Commission points again to the above-mentioned contemporaneous evidence that plainly shows that Cephalon estimated Mitry-Mory's overall manufacturing capacity for 2006 at approximately 63,000 kg, and from 2007 at approximately 100,000 kg (see in particular Recital (360) and Sections 4.7.3.1, 4.7.3.4). The evidence also demonstrates that Cephalon incorporated fully and without reservations its plans that C-2 plant would become operational in the third quarter of 2006 into all its contemporaneous supply estimations (Sections 4.7.3.1, 4.7.3.4 and 4.7.3.6). Subsequently, the C-2 plant indeed became operational according to the plan in 2006. Finally, the Parties' reference to the annual capacity of C-2 of 45,000 kg (at 80% of full capacity) misinterprets the two documents to which the Parties refer (see Recital (740)). The documents originate from May and July 2006, several months after the conclusion of the Settlement Agreement with Teva. They reflect lower modafinil API production planning after the conclusion of the Modafinil Settlements (for example, 117,000 kg of modafinil API for 2007[1153]). In this light, the figure of 45,000 kg mentioned in the SO Reply does not reflect the real annual manufacturing capacity of C-2 in 2007 but rather the manufacturing plans adjusted after the Settlement Agreement with Teva and settlements with other generic companies.

(741) Based on the evidence set out above, the Commission concludes that the Parties argument that the modafinil API supplies, as estimated at the time of the Settlement Agreement, were not sufficient is not supported by the evidence on the file.

(742) In light of the above, the Commission concludes that, as a result of significant investments made in-house at Mitry-Mory and externally with [*contract manufacturer*], Cephalon forecasted its modafinil supply chain to be sufficient and secure. Another result of these investments was that [*contract manufacturer*] and

---

1148 SO Reply, paragraph 331. See also Response to the LoF, points 13-14 (ID 3763).
1149 ID 2010-24, p. 1.
1150 SO Reply, paragraph 332-333.
1151 ID 2166-16, p. 2.
1152 ID 2166-17, p. 9.
1153 ID 2166-16, p. 2. See also ID 2166-17, p. 6 and subsequent.

Mitry-Mory supplied modafinil at a much lower price than that of Teva/Plantex. From Cephalon's perspective, it would thus have been in its interest to continue supplies from these sources to make economic use of the investments (see also Section 4.7.3.9, Recitals (750)-(762)) rather than to switch to Teva for its supplies.

Inflexible five-year agreement whilst future demand was uncertain

(743) In the words of Cephalon's senior supply manager, by entering into series of supply agreements with the generic companies in the United States (including the one with Teva, hereinafter "generic modafinil supply agreements"),[1154] Cephalon created "*a supply chain nightmare*" for itself.[1155]

(744) This statement was prompted by the supply chain that was created on top of the existing (adequate) suppliers through the Modafinil API Supply Agreement with Teva and other generic modafinil API agreements adding several additional suppliers.

(745) Cephalon entered into the Modafinil API Supply Agreement (and the API supply agreements with other generic manufacturers) before obtaining United States regulatory approval for the commercialisation of its modafinil-based pipeline products Sparlon and Nuvigil.[1156] The Modafinil API Supply Agreement was a five-year, inflexible take-or-pay agreement, according to which Cephalon was bound to purchase from Teva fixed annual volumes of modafinil at fixed prices.[1157] Given that the expected production of Nuvigil and Sparlon was, according to the Parties, the only reason for increased modafinil API requirements,[1158] the conclusion of the Modafinil API Supply Agreement on the above-mentioned terms (along with the other generic modafinil supply agreements) created an important risk of oversupply tried to anticipate for Cephalon.

(746) If the two pipeline products were not launched as planned (anything but a merely theoretical risk, see below), Cephalon knew that it would be obliged to purchase fixed quantities of modafinil API for the next five years (without a possibility of altering the terms of the supply agreement). This would have increased its modafinil inventories of which only part could be commercialised (modafinil devoted to Provigil production) while the other part (modafinil for Sparlon and armodafinil necessary for Nuvigil production) could not, since it would not be approved for marketing. That would have put a significant burden on Cephalon's supply chain management (on top of the difficulties of coordinating the supplies from several suppliers). Cephalon would either have to pay, possibly[1159] for years, for the storage of excess material, part of which it might never be able to sell in form of the final

---

1154 Cephalon also concluded modafinil supply agreements with […] and […]. Similarly to the supply agreement with Teva, the supply agreements with […] and […] were concluded for a five-year term, for fixed annual volumes of modafinil API at fixed prices. See Section 4.8.1.3 and Section 4.7.3.

1155 Recital (415).

1156 In 2005, the applications for regulatory approval for Nuvigil and Sparlon were filed only in the United States. See Section 4.2.3.1.

1157 Section 4.6.3.4.

1158 See Recital (352).

1159 The products refused by the FDA, in particular Nuvigil, could have been approved later.

product,[1160] or it would have to re-structure its existing supply chain. Considering the inflexible five-year term of the generic modafinil supply agreements, such restructuring would target in the first place the commercially attractive existing suppliers [*contract manufacturer*] and Cephalon's own facility at Mitry-Mory.

(747) This foreseeable situation actually materialised when the FDA refused to approve Sparlon and delayed approval for Nuvigil. Cephalon soon found that its existing inventories of modafinil API together with its purchase commitments pursuant to the generic modafinil API supply agreements went far beyond its actual needs.[1161] In response, Cephalon did not extend its supply agreement with [*contract manufacturer*] and sharply reduced supplies from Mitry-Mory. Because of that, Cephalon's in-house supplier lost a crucial part of its business, and since it was not able to find an alternative source of revenue, Cephalon eventually sold the Mitry-Mory facility in 2011.[1162] Cephalon not only lost two suppliers that provided it with modafinil API at the lowest prices (approximately 3-4 times lower than prices from Teva/Plantex), but Cephalon also forfeited, in whole or in part, its recent investments into both Mitry-Mory (USD 32 million for C-2 plan construction) and [*contract manufacturer*] (transfer of technology, cost of qualification and validation) (see Recitals (725) and (727)).[1163]

(748) The risk of the described supply chain issues was foreseeable at the time of concluding the Settlement Agreement. Cephalon concluded with Teva the five-year[1164] inflexible modafinil API Supply Agreement with a take or pay commitment at a time when the future demand for its pipeline products Nuvigil and Sparlon was not certain due to missing regulatory approvals for the products. Cephalon knew *ex ante* about the risk that eventually materialised and caused serious difficulties for its modafinil supply management and resulted in additional costs for Cephalon in the form of higher prices for modafinil API (see Recitals (750) - (752)) as well as the loss of its significant previous investments in its modafinil supply chain.

Teva's prices were considerably higher than the prices of existing suppliers

(749) It is important to recall that, from the relevant ex ante perspective, the prices for Teva/Plantex' modafinil API were 100-300 % higher than the prices paid to [*contract manufacturer*], or the Mitry-Mory's in-house prices (or manufacturing cost). Teva's prices were even higher than the prices offered in alternative proposals by [*contract manufacturer*] for a possible new supply agreement, or by [*potential contract manufacturer*].[1165]

(750) While Teva's prices according to the Modafinil API Supply Agreement ranged between USD 650/kg – USD 500/kg[1166] during the five-year term, considering an

---

1160 According to the Parties, modafinil has shelf-life of five years, and if converted into the final product within this period, it could be stock-piled for another five years. During this time, however, such inventories would not contribute to Cephalon's business (other than causing costs).

1161 See Sections 4.7.3.10.

1162 See Section 4.7.3.10. Fact not disputed by the Parties.

1163 In the United States, Cephalon also paid contractual penalty of USD 13.5 million to […] in exchange for reduction of purchase commitments from […]. See Recital (414).

1164 For the term of the [*contract manufacturer*] API supply agreement see Recital (361).

1165 See Section 4.7.3.9.

1166 As stipulated in the Modafinil API Supply Agreement, see Recitals (240) and (263); it would correspond approximately to EUR 520/kg – EUR 400/kg at the ECB average exchange rate in 2005.

overall annual supply of 10,000 kg of modafinil API (paid prices EUR 549/kg-340/kg[1167]), according to the […], the price was approximately EUR […]/kg for the same annual volume,[1168] and [*potential contract manufacturer*] offered EUR […]/kg for a supply of up to 10,000 kg.[1169] Cephalon's in-house API manufacturing facility Mitry-Mory had average manufacturing costs of EUR 138/kg, so given that an in-house manufacturer is in principle always the preferred supplier, Cephalon could use captive API at significantly lower cost than Teva's prices under Modafinil API Supply Agreement.

(751) Moreover, it is recalled that within a few weeks after the Settlement Agreement, Cephalon entered into modafinil settlements with two other generic manufacturers that contained also API supply agreements that had been negotiated in parallel with Teva's API Supply Agreement, namely the agreements with […] and […] (see Section 4.8.1.3 and, in particular, Recital (477)). Accordingly, by concluding three different supply arrangements for rather smaller quantities of the modafinil API (Teva/Plantex – 10,000 kg/year, […] – […] kg/year; […] – […] kg/year, see Recital (477)) rather than either extending its existing arrangements ([*contract manufacturer*], Mitry-Mory) or concluding a larger volume supply arrangement ([*potential contract manufacturer*] offered much lower prices for "*quantities considerably higher than 20 tons*"[1170]), Cephalon failed to obtain better prices through benefitting from economies of scale. It should be recalled in this context that all (existing or potential) suppliers except for Teva/Plantex (and the other generic modafinil API suppliers) offered to Cephalon sliding ("tiered") prices in inverse proportion to the API quantities supplied.

The Parties' arguments regarding the prices

(752) The Parties argue in the SO Reply that prices according to the Modafinil API Supply Agreement were bona fide and the result of genuine negotiations.[1171]

(753) The Commission notes that it is not material that Cephalon was able to negotiate down the price of Teva's/Plantex' modafinil API, for example, compared to Plantex' initial unsolicited offer from October 2005. At the end of the "negotiations", the price was still considerably higher than the price for modafinil API from [*contract manufacturer*], the manufacturing costs from Mitry-Mory or the price offer from [*potential contract manufacturer*] – namely from other supply sources available to Cephalon.

(754) In their SO Reply, the Parties further argue that there were other entities (such as […] or […]) that were offering modafinil at much higher prices than Teva.[1172]

1167 The lowest recorded price for which Cephalon bought a certain volume of modafinil API from Teva, was EUR 324/kg in 2009 (see Table 12 in Section 4.7.3.9).

1168 Approx. […]/kg. ID 1727, p. 25; ECB average exchange rate in 2005 and in 2006. See also Table 12 in Section 4.7.3.9.

1169 See Table 12 in Section 4.7.3.9.

1170 ID 1817. [*potential contract manufacturer*] repeated the same in the offer of 13 January 2004 (ID 1820) and in a letter of 30 August 2005, ID 1579.

1171 SO Reply, paragraph 377.

1172 See SO Reply, the table at p. 97-99. For example modafinil API prices from […] to […] in 2008: EUR […]; […] prices in 2005-commercial quantities: EUR […]; […] prices in 2005-R&D quantities: EUR […]; […] offer to Cephalon of 2005: EUR […]).

(755) The Commission considers that it is not relevant whether there were other entities offering worse terms than Teva. What matters is that there were sources of supply able to deliver much better terms than Teva.[1173] Besides, the Commission notes that "*Cephalon declined to contract with […] due to the high price*", according to the SO Reply[1174] and that […] supplied the modafinil API in small "*R&D quantities*"[1175] and not for commercial purpose. It should also be remembered that Cephalon was the dominant company in the modafinil market buying the biggest volumes of modafinil for commercial purposes.[1176] This should have effectively put it in a strong negotiation position vis-à-vis the suppliers, normally allowing it to negotiate down the offer from any given supplier, including Teva.

(756) Another point raised in the SO Reply concerns the comparison of the low price of [*contract manufacturer*] with the high price of Plantex. The Parties point to an expert opinion they commissioned and argue that drawing such comparison was a conceptual error because [*contract manufacturer*] relied extensively on Cephalon's manufacturing know-how and Cephalon invested substantial resources to transfer its technology to [*contract manufacturer*]. The cost of the technology transfer was borne by Cephalon. The Parties' expert argues that the price that Cephalon paid [*contract manufacturer*] does not properly account for Cephalon's cost of developing and transferring the technology to [*contract manufacturer*].

(757) What matters is what prices other companies were offering to Cephalon. How the price offers had been calculated by these other companies is secondary. Moreover, even if the technology transfer saved potential costs to [*contract manufacturer*] (and might have been reflected in the price of modafinil API to Cephalon), and, conversely, generated costs for Cephalon, these costs were already sunk and were not material for Cephalon's assessment of the prices of [*contract manufacturer*] and Teva at the time of the Settlement Agreement. If anything, the fact that Cephalon invested in [*contract manufacturer*], should have been an incentive for continuing to source from [*contract manufacturer*] at lower prices (thus recuperating the investment) rather than adding a new source with considerably higher prices (see Recital (727)).

(758) Finally, the Parties argue that Teva was an attractive option as an API supplier for Cephalon from a qualitative standpoint, which would justify its higher price. According to the Parties, Plantex had experience with modafinil API because it was Teva's modafinil supplier, and, unlike [*contract manufacturer*], had its own manufacturing process and therefore would not require any transfer of technology. Cephalon did not expect any significant amount of work or cost in qualifying the modafinil manufactured by Teva with the FDA. The SO Reply explains that though there was no certainty that Teva would be able to supply FDA-qualified modafinil in

---

1173 Provided that the terms included comparable volumes of supply and comparable quality of the material. This was the case for both [*contract manufacturer*] and [*potential contract manufacturer*]. [*contract manufacturer*] was Cephalon's established modafinil API supplier (see Sections 4.7.3.1 and 4.7.3.2). The offers by [*potential contract manufacturer*] were seriously considered by Cephalon (and [*potential contract manufacturer*] was also Cephalon's established supplier with regard to another API, […], see Section 4.7.3.3).

1174 SO Reply, p. 98.

1175 *Ibid*.

1176 Cephalon's Vice-President acknowledged that the offers made by […] or Plantex were made for lower supply volumes. ID 3694-13, p. 38

the short term, Teva at least presented the possibility of an efficient qualification process without the technology transfer or other cost that would be presented by other suppliers.[1177]

(759) The Commission recalls that between December 2005 and February 2006, Cephalon entered into three supply arrangements by means of modafinil settlement agreements with three generic firms – Teva, […][1178] and […] (see Section 4.8.1.3). At that time, Cephalon knew that it would take administratively at least one year to receive FDA approval to use Teva's API (as well as the API of […] and […]) in its final products.[1179] Moreover, Cephalon was also aware that the approval proceedings would raise issues with the particle size of Teva's material.[1180] In fact, Cephalon's Vice-President for Global Manufacturing confirmed explicitly: "*We knew that there would be an issue most likely with the particle size*."[1181]

(760) Cephalon's Vice-President for Global Manufacturing remembered that […][1182] At the time of his testimony to the FTC on 14 June 2007[…][1183] Cephalon's Vice-President acknowledged that […][1184] Indeed, the FDA approved Teva as a new Cephalon's modafinil API supplier on 20 December 2007.[1185]

(761) In the light of the above facts, the Commission finds that the Parties' argument that, at the time of the Settlement Agreement, Teva was an attractive or even superior option as a modafinil API supplier is not convincing. In addition, the difficulties and delays faced by Cephalon to qualify Teva (and other generic companies) as its modafinil API suppliers demonstrate that the alleged technical issues raised by the Parties in connection with reliability of [*contract manufacturer*] and [*potential contract manufacturer*], if any, were not (or would not be in the case of [*potential contract manufacturer*]) out of the ordinary (see Section 4.7.3.2).

(762) In the SO Reply, the Parties argue that the […] and […] arrangements were concluded after the Modafinil API Supply Agreement and are irrelevant to assess Cephalon's rationale for entering into the Modafinil API Supply Agreement.[1186] The Commission considers that the fact that Cephalon concluded the API supply arrangements with […] and […] very short time after it concluded the Modafinil API Supply Agreement with Teva does not diminish the relevance of the former two as factual context for the assessment of the latter. All three modafinil supply agreements

---

1177 SO Reply, paragraphs 371-372, ID 3694-26, p. 99-100.

1178 In fact, […] was not an API supplier. The API was supplied to […] by […] API manufacturer […] and […] re-sold the API according to its modafinil API supply agreement to Cephalon.

1179 As acknowledged by Cephalon's Executive Vice-President for Technical Operations. ID 3694-14, p. 114.

1180 In its application for United States marketing approval for modafinil from December 2002 as well as in the ensuing United States patent court proceedings, as well as in the United Kingdom court proceedings, Teva always argued that it manufactured modafinil API with different particle size than Cephalon's modafinil API and its product was therefore outside the scope of Cephalon's particle size patents. This however meant, once Cephalon accepted Teva as its modafinil API supplier that Teva's product did not comply with the specifications of Cephalon's approved product.

1181 ID 3694-13, p. 40.

1182 ID 3694-13, p. 41.

1183 *Ibid*, p. 42.

1184 *Ibid*, p. 43.

1185 […] and […] were approved by the FDA only in December 2008 (Article 18 Request to Cephalon of May 2011).

1186 ID 3694-26, p. 80.

were signed as parts of the respective settlements in a very close time succession: Settlement Agreement with Teva on 8 December 2005, […] Settlement Agreement on 22 December 2005 and the […] Settlement Agreement / […] Supply Agreement on 1 February 2006.[1187] The provisions of all settlement agreements stipulated the main terms of the API supply arrangements (that is supply / purchase obligations, annual supply volumes of modafinil API, exact prices for each year and duration of the agreements (see Sections 4.6.3.4 and 4.8.1.3).

(763) The modafinil settlement agreements between Cephalon and the generic companies, including the API supply deals, were negotiated in parallel. In this regard, as shown further in this Recital, internal statements by Cephalon show that all these negotiations were part of Cephalon's single strategy to protect its modafinil franchise. Cephalon's Board of Directors of 1 December 2005 discussed "*Prospective Settlement Issues*" in relation to each of Teva, Barr, Ranbaxy and Mylan and described the "*Current Status of Negotiations*" with all the generic companies, including "*possibly non-exclusive API manufacturing rights/requirements contract for modafinil*" for Teva and […].[1188] The interconnected nature of the negotiations with the generics was further recognised in the reaction by the president of Cephalon Europe to the information about the settlement discussion with Teva: "*Teva is one piece of the equation and if we can settle that this* (is) *great…*"[1189] Similarly, Cephalon internally stated following the settlements: "[O]*ur executive management has been extremely pr*[o]*active to defend our flagship product-unprecedented in what they have accomplished with the generic companies. As a result we have a chance for second life for PROVIGIL…*"[1190]

(764) Therefore, the Commission considers that the API supply agreements that Cephalon concluded with […] and […] constitute a relevant factual background for the assessment of the Modafinil Supply Agreement.

(765) In light of the above, the Commission concludes that by entering into the Modafinil API Supply Agreement with Teva, Cephalon chose to buy modafinil API at prices much higher (100-300 %) not only than those of its existing suppliers, but also than those of potential other suppliers. The Commission also notes that at the time of the Settlement Agreement, some manufacturers offered Cephalon prices even below those that it paid to its existing suppliers, namely the prices in the new offer by [*contract manufacturer*] and the offer by [*potential contract manufacturer*].[1191]

No request for proposals

(766) Before the Settlement Agreement, Cephalon developed an internal procedure involving the issue of RFPs for the selection of prospective API suppliers.[1192]

(767) Cephalon internally discussed that an RFP would be issued to potential modafinil suppliers in 2005. These considerations were driven by an effort to push down prices

---

1187 […] Supply Agreement was part of Cephalon's settlement with […] which was concluded on the same day as the […] Supply Agreement. On 9 January 2006 Cephalon concluded the Settlement Agreement with […], which was […]. For details see Section 4.8.1.3.

1188 Section 4.5.1 , ID 2144-48.

1189 ID 1020, p. 1; Recital (209).

1190 ID 2841-1323, p. 2; Recital (462).

1191 See Sections 4.7.3.3, 4.7.3.9. Cephalon was open to negotiations with [*potential contract manufacturer*] before conclusion of the Settlement Agreement (see also Recital (769)).

1192 ID 3694-13, p. 17

rather than by any supply constraint.[1193] As proposed by Cephalon's Vice-President for Global Manufacturing in preparation for a November 2005 meeting with [*contract manufacturer*] (namely exactly the period when Cephalon was negotiating with Teva without any RFP): "*I would tie the RFP into the last item on his* [[*contract manufacturer*] representative's] *agenda, the discussion on the* [renewal] *Modafinil Supply Agreement. Let´s see what they come up with before we inform them. If they come back with a cost reduction, we need to think if the RFP is needed. If they don´t propose one, then, I think we tell them of our intention to start an RFP during mid/late 1Q06.*"[1194]

(768) Similarly, Cephalon's Vice-President for Global Manufacturing discussed an RFP in connection with an offer for modafinil supplies by […] company […] of 30 August 2005: "*[…]* [Cephalon's Executive Vice-President for Global Technical Operations], *FYI. At* […] *is about* […] *but I bet we could get them down to less than* […]*! At 40 tons, this could be* […]. *If you agree, […] and I will bring this up during our discussions next week and try a squeeze play. If not, then start an RFP in 4Q this year to get another site approved*."[1195]

(769) Eventually, Cephalon concluded the Modafinil API Supply Agreement with Teva (as well as the generic modafinil supply agreements) without any RFP. It thus departed from its RFP practice developed in the years just before the Settlement Agreement was concluded[1196] and contrary to its plans that it internally discussed in 2005 before the start of the settlement negotiations with Teva. With the conclusion of the Modafinil API Supply Agreement, Cephalon accepted considerably higher prices than those paid to [*contract manufacturer*], even though Cephalon's intention to organise an RFP was driven by the desire to achieve prices better than those by [*contract manufacturer*] and to "*try a squeeze play*".

Multisourcing

(770) The Parties argue that a diversity of supply sources is beneficial.[1197] The Parties cite the [Expert *report of 24 January 2018*] which explains that "*[s]ourcing from multiple suppliers, or "multi-sourcing," is a well-established industry practice to diversify supply chain risk. Multi-sourcing lessens a buyer's reliance on any one supplier, potentially increasing shorT-term costs, but decreasing vulnerability to a supply chain failure, shortage, or defect.*"[1198] According to the Parties, at the time of

---

1193 See Section 4.7.3.7.

1194 ID 1572, p. 1.

1195 [*potential contract manufacturer*] was an experienced API contractual manufacturer and Cephalon's established supplier of […] API for Cephalon's […]. [*potential contract manufacturer*] was ready to start supplies within one year and offered Cephalon a supply capacity of at least 20,000 kg of modafinil API annually. Cephalon's Vice-President for Global manufacturing stated later about Cephalon's relationship with [*potential contract manufacturer*]: "*We were working towards* [signing a supply agreement]. [*potential contract manufacturer*] *had already been part of the early RFP process that was done by France, and they were familiar with the process.*" See Section 4.7.3.3.

1196 The only documented case when a Cephalon's executive expressed preference for a certain bidder without possibly organizing an RFP was the case of [*potential contract manufacturer*] whose price offer was very low. See Section 4.7.3.3.

1197 ID 3694-26, p. 97.

1198 [*Expert report of 24 January 2018*], paragraph 92, ID 3694-1, p. 40.

the Settlement Agreement, Cephalon was at risk because it relied on a single outside supplier in the face of increasing API needs.[1199]

(771) This argument is unfounded. Cephalon was already multi-sourcing at the time of the Settlement Agreement. Its primary source of modafinil API was in-house via its Mitry-Mory facility and its secondary source was [*contract manufacturer*]. The contemporaneous evidence shows that Cephalon considered this structure sufficient and secure. Cephalon made significant investments in building its modafinil supply chain (see Recitals (724)-(728)). In addition, Cephalon had already other potential options for an additional source of modafinil API supply ([*potential contract manufacturer*]), at significantly better conditions than those offered by Teva.

(772) Moreover, Cephalon's decision to conclude generic modafinil supply agreements with three additional outside suppliers for relatively small annual volumes of modafinil API (10,000 kg-15,000 kg per supplier) instead of concluding a single additional modafinil supply agreement with one supplier (for example, through extending the […] as proposed by, or a supply agreement discussed with [*potential contract manufacturer*] in 2003-2005) should also be viewed in the context of the costs related to technology transfer, validation, qualification and to the necessary quality controls. Moreover, although Cephalon arranged in all its API supply agreements for tiered pricing (that is decreasing price relative to increased volumes of purchased API), by concluding three supply agreements for fixed small volumes of modafinil at fixed prices Cephalon incurred substantial opportunity costs (giving up any savings through economies of scale).

(773) Furthermore, the Commission recalls that Cephalon's senior supply manager in 2008-2009 noted that by entering into a series of modafinil API supply agreements with Teva and other generic manufacturers, Cephalon created "*a supply chain nightmare*".[1200] In addition, the Commission notes that the true benefits of multisourcing were not only not appreciated internally, but the decision to enter into additional supply agreements also ultimately led to terminating the supply relationship with the existing suppliers, that is [*contract manufacturer*] and Mitry-Mory business.

(774) The Commission therefore finds that the Parties' argument that multi-sourcing is beneficial cannot alter the Commission's conclusion. The above facts show that Cephalon was already multi-sourcing and that concluding three additional modafinil supply agreements with the generic companies, including the Modafinil API Supply Agreement was not in Cephalon's commercial interests.

Reliability of [*contract manufacturer*] and [*potential contract manufacturer*]

(775) The Parties also put in doubt the reliability of [*contract manufacturer*] and [*potential contract manufacturer*] as modafinil API suppliers. According to the SO Reply, [*contract manufacturer*] history with Cephalon was short and inconsistent, and its long-term reliability uncertain. Cephalon encountered issues with the technology

1199 ID 3694-26, p. 98.

1200 ID 2215, paragraph 57, p. 15.

transfer, which was finalised one year behind the initial plan, and other problems with the manufacturing of modafinil.[1201]

(776) The evidence on file offers an opposite picture. Although it is true that there had been problems and delays during the transfer of modafinil manufacturing technology to [*contract manufacturer*], the issues were caused by Cephalon's subsidiary Mitry-Mory and not by [*contract manufacturer*]. Cephalon's Vice-President for Global Manufacturing wrote in an e-mail of 14 January 2005 to the Executive Vice-President for Technical Operations: "*I truly believe that Cephalon has been bordering on being 'unprofessional' in our workings with Orsymonde. This began with the transfer from Orsymonde, their lack of support of control to the tech transfer process and continues today from a* [manufacturing] *and quality perspective*. *I have never seen contracts and* [quality technical agreements] *take over a year to negotiate!*"[1202] The e-mail further specified: "*We have committed volumes* [for supply of modafinil API and DMSAM] *to* [*contract manufacturer*], *given them firm forecasts* [for production] *and not submitted purchase orders*. *Several* [*contract manufacturer*] *staff have approached me 'off the record' on how to improve the manufacturing and quality relationship. These issues continue to put me in an awkward position with them from a technical perspective. I really believe there is a total lack of leadership with this regard.*" The e-mail ended: "*It is clear to me that Cephalon does not have depth in the* [Chemistry, Manufacturing and Controls] *development experience*."[1203] In sum, according to Cephalon's Vice-President, the technical team in Mitry-Mory "*was not living up to the expectations*" and "*they weren't doing a good job, so* [*contract manufacturer*] *was looking for help from the US group…* [*contract manufacturer*] *were looking to get the project moving again. The project had stalled*" as a result of Cephalon's own conduct.[1204] It took "*at least a year*" to correct the problems, including removing the responsible Mitry-Mory's staff from their positions or terminating their employment.[1205]

(777) Cephalon's experience with [*contract manufacturer*] as a partner was, according to the contemporaneous documents, positive. It also awarded [*contract manufacturer*]sinn an excellence award for the process of qualification and validation of modafinil API. In this context, Cephalon's Vice-President for Global Manufacturing, who was directly dealing with [*contract manufacturer*] during the technology transfer and regulatory proceedings, wrote on 14 March 2005 to [*contract manufacturer*]: "*The entire* [*contract manufacturer*] *team has been a great support to Cephalon and certainly serves as a model for a working partnership*." Cephalon's director of regulatory affairs wrote: "*I can personally attest to the cooperation, communication and professionalism of our* [*contract manufacturer*] *colleagues in working on the DMSAM* and *modafinil* [drug master file]."[1206] On 19 August 2005, Cephalon's Vice-President for Global Manufacturing addressed Cephalon's the Executive Vice-President for Technical Operations and Cephalon's head of finance in an internal e-mail regarding [*contract manufacturer*] upcoming visit at Cephalon:

1201 SO Reply, Recitals 335-336, ID 3694-26, p. 90- 91. Also, Teva's Response to the LoF, point 17 (ID 3763).

1202 ID 3694-11, p. 39-40. He explained to the FTC on 12 January 2011 that *[…]*

1203 *Ibid*, p. 41.

1204 *Ibid*, p. 40- 41.

1205 *Ibid*, p. 40.

1206 See Section 4.7.3.2

"[*contract manufacturer*] *are currently approved for modafinil supply and have been a good partner*."[1207] In January 2006, the same Vice-President internally reported to Cephalon's Chief Financial Officer (and later CEO): "*Our experience with* [*contract manufacturer*] *has been uniformly positive delivering what I consider superb responsiveness to Cephalon's needs and exhibits a flexibility to deal with both the challenges and opportunities of Cephalon's aggressive and opportunistic style*."

(778) With regard to [*potential contract manufacturer*], the Commission notes that Cephalon negotiated a potential API supply agreement on 30 August 2005 (that is before the start of the Settlement negotiations), Cephalon's Vice-President for Global Manufacturing showed a clear interest in [*potential contract manufacturer*] offer: " [Cephalon's Executive Vice-President for Global Technical Operations], *FYI. At* […] *is about* […] *but I bet we could get them down to less than* […]*! At 40 tons, this could be* […]. *If you agree, […] and I will bring this up during our discussions next week and try a squeeze play.*" Cephalon's Vice-President for Global Manufacturing later confirmed: "*We were working towards* [signing a supply agreement]. [*potential contract manufacturer*] *had already been part of the early RFP process that was done by France, and they were familiar with the process.*"[1208] In fact, Cephalon considered to work with [*potential contract manufacturer*] on the basis of an "*integrated supply chain*", in which [*potential contract manufacturer*] would be in charge of sourcing of the starting materials formodafinil (benzhydrol, DMSAM), manufacturing of modafinil API and converting it into tablets which would be shipped to Cephalon in the United States.[1209]

(779) Cephalon also expressed its trust in [*potential contract manufacturer*] because at the time of their discussions about a potential modafinil supply agreement, the […] company was already Cephalon's established contract manufacturer of […], the API for Cephalon's […]. In this regard, Cephalon's Vice President for Global manufacturing stated: "*We have already used them for […]… The European […] API supply had been going on since its first approval. So eight years.*"[1210]

(780) The Commission also notes that during the qualification and validation process of the generic API suppliers (Plantex, […] and […]), Cephalon encountered technical difficulties, costs and delays that show that any purported issues with [*contract manufacturer*] or [*potential contract manufacturer*] were not out of the ordinary for this kind of process. In fact, the delays with qualification of the modafinil API manufactured by Teva and other generic companies were even longer than the delays during the same process with [*contract manufacturer*] (see Section 4.7.3.2 and Recital (761)). In sum, the evidence on the file rebuts the Parties' argument that [*contract manufacturer*] and [*potential contract manufacturer*] would have proven to be unreliable manufacturers and that this would have affected Cephalon's decision to conclude the Modafinil API Supply Agreement with Teva. In any event, the Parties' argument does not explain why it would have made sense for Cephalon to shut down its captive source of supply at Mitry-Mory in favour of sourcing modafinil API from the generic suppliers.

1207 ID 3694-11, p. 42.
1208 Section 4.7.3.3.
1209 ID 3694-13, p. 35.
1210 *Ibid*, p. 36.

6.6.1.5. Conclusion

(781) As regards the Modafinil API Supply Arrangement, the Commission has thus established that:

(a) With regard to Teva:

– Teva had an interest to conclude the Modafinil API Supply Agreement with Cephalon because the agreement provided Teva ex ante with a guaranteed revenue stream for fixed volumes of modafinil API at fixed prices for five years, irrespective of market developments. At the conclusion of the Settlement Agreement, Teva could expect to receive through the transaction a value in the range of EUR 5 million; and, importantly,

– Teva would not have been able to conclude this or a similar modafinil API Supply Agreement without agreeing to the non-compete and non-challenge commitments in the Settlement Agreement.

(b) With regard to Cephalon:

– Cephalon did not show any desire to commit to a firm modafinil API supply agreement with Teva before the settlement negotiations. It accepted the transaction only as a part of the package of deals included in the Settlement Agreement;

– Before the conclusion of the Settlement Agreement, Cephalon forecasted that its existing sources of supply would be able to provide it with sufficient and reliable future supply of modafinil API for all its modafinil-based products (both existing and pipeline). In order to develop its modafinil API supply chain, Cephalon made significant investments into Mitry-Mory (C-2 plant) and the contract manufacturer [*contract manufacturer*], which it had to sacrifice following the conclusion of the Modafinil API Supply Agreement;

– Cephalon concluded the Modafinil API Supply Agreement with a "take or pay" purchase commitment for fixed volumes of modafinil API, even though at that time its future demand was uncertain because Cephalon's modafinil-based pipeline products did not have a marketing approval;

– The prices agreed in the Modafinil API Supply Agreement were considerably higher (100%-300%) than the prices/manufacturing costs of Cephalon's existing suppliers, and also much higher than other alternatives available to Cephalon (new [*contract manufacturer*] proposal, [*potential contract manufacturer*] proposal).

– Cephalon's alternative sources of supply, including its captive production at Mitry-Mory and the external suppliers [*contract manufacturer*] and [*potential contract manufacturer*] were reliable.

– Cephalon awarded the Modafinil API Supply Agreement to Teva without any RFP, contrary to its established procedure for selecting new API suppliers. Cephalon also internally discussed in 2005 a possibility of launching a modafinil RFP to achieve lower prices but through the terms of the Modafinil API Supply Agreement with Teva, it actually accepted considerably higher prices.

(782) On the basis of the above, the Commission concludes that the API Modafinil Supply Agreement generated value for Teva that it would not have been able to appropriate

from Cephalon absent the non-compete and non-challenge commitments included in the Settlement Agreement and that Cephalon would not have entered into a Modafinil API Supply Agreement with Teva absent the non-compete and non-challenge commitments in the Settlement Agreement. Accordingly, the Commission concludes that the Modafinil API Agreement contributed to the overall unjustified value transfer inducing Teva to accept non-compete and non-challenge commitments for modafinil.

6.6.2. Clinical data CEP-1347 (Azilect)

6.6.2.1. Introduction

(783) This Section assesses Cephalon's and Teva's incentives to enter into the CEP-1347 data transaction at the time of the Settlement Agreement, taking into account both the terms of the transaction and its context. This Section shows that the transaction regarding the CEP-1347 data generated value for Teva that it would not have been able to appropriate from Cephalon absent the non-compete and non-challenge commitments included in the Settlement Agreement. The Section also shows that the transaction would not have occurred at all or on the same terms under the normal market conditions, that is absent the Settlement Agreement. Accordingly, the CEP-1347 data transaction served as an unjustified transfer of value from Cephalon to Teva in consideration of the commitments of Teva not to independently enter the modafinil markets and compete with Cephalon.

6.6.2.2. Teva's interest

(784) The CEP-1347 clinical data that Teva obtained from Cephalon allowed Teva to enter the market for Azilect more swiftly. By entering into the Settlement Agreement, Teva could expect to appropriate significant value generated through obtaining the licence to the clinical data, that it would not have been able to appropriate from Cephalon without entering into the non-compete and non-challenge commitments of the Settlement Agreement.

(785) As indicated in Section 4.7.2, not having succeeded to carry out its own study on the relation between melanoma and Alzheimer patients at the time of the Settlement Agreement, Teva sought other ways to obtain the necessary information. Teva was convinced that the CEP-1347 data could help it to convince the FDA and obtain FDA's regulatory approval to launch its new innovative drug Azilect in the United States.[1211] In particular, the CEP-1347 clinical data served the purpose of helping to convince the FDA to approve Azilect and not to require a warning label identifying an increased risk of melanoma associated with Azilect. If Teva were able to convince the FDA, this would speed up the commercial launch of Azilect. The only source of the data known to Teva was Cephalon/ […].

(786) Failing to obtain regulatory approval as soon as possible would result in significant delays in launching the product in the United States market, reducing the remaining time of available market exclusivity and therefore eroding revenues and profits for Teva on its Azilect product. As Teva had not been able to produce the necessary

[1211] Teva had scheduled a meeting with the FDA on 7 December 2005. During this meeting Teva wanted to convince the FDA to approve Azilect.

clinical data itself or to obtain equivalent clinical data from other suppliers, Teva crucially needed the data from Cephalon.[1212]

(787) The design of the Cephalon-[…] drug study included a dermatological exam for enrolled patients: "To the best of our knowledge (published information) the Cephalon-[…] drug study had a derm [i.e. "dermatological"], the issue is one of melanoma, (that is skin cancer) exam at screening and after one year." [1213] Cephalon's clinical study had required more than one year to produce the CEP-1427 clinical data that Teva was interested in (see Recital (339)). Producing similar clinical data through its own clinical study to address the FDA's concerns regarding the link between melanoma and the new medicine would have implied for Teva a significant postponement in obtaining regulatory approval and launching Azilect.[1214]

(788) In Teva´s sales projections for the first years of Azilect, Teva forecasted sales of approximately USD 17 million in 2006, USD 70 million in 2007, USD 130 million in 2008 and USD 200 million in 2009.[1215] These projections show the value that early introduction of Azilect had to Teva. The end date of the Azilect patent and hence the end date of exclusivity on the market was fixed. Early introduction of Azilect would enable to start uptake of the product earlier. Given the fixed end of the exclusivity period, such earlier uptake of the medicine meant that Teva would have benefited from a longer period of commercial exclusivity, meaning significant larger expected total profits from the product.

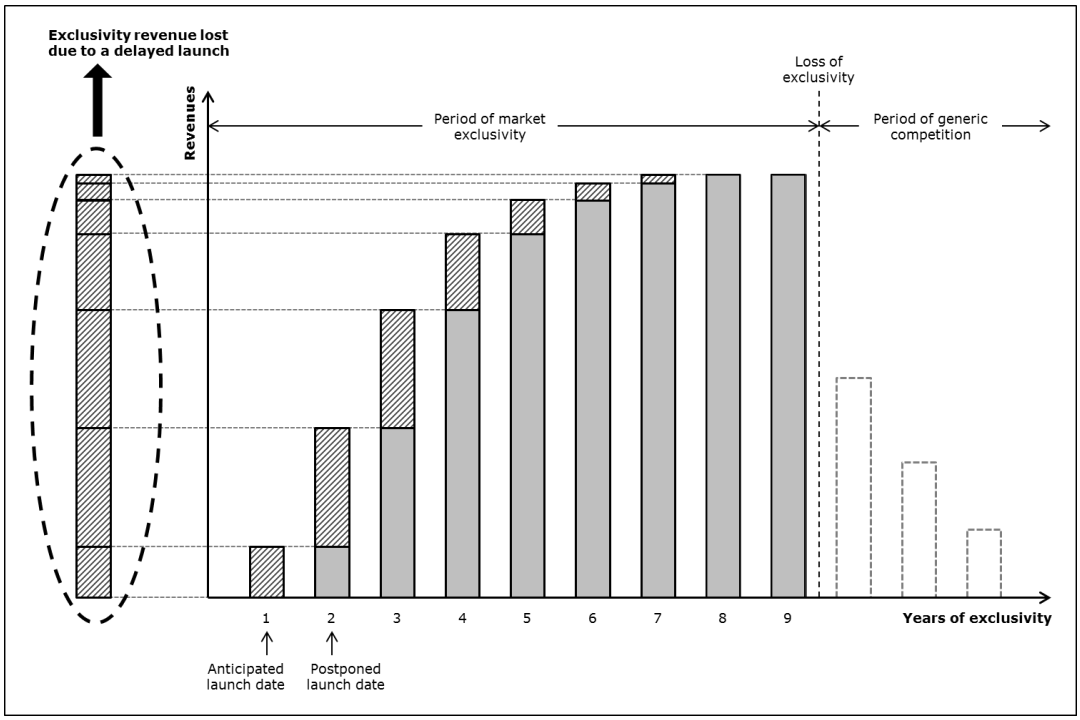
1212 As explained above (see footnote 551), […] refused to provide the CEP-1347 data to a third party without Cephalon's consent.

1213 Teva's internal e-mail of 11 July 2005, ID 2166-40, p.1. It could even have taken as long as four years (see reference to […] in footnote 1217).

1214 Such a study could also not have been completed before the 7 December 2005 meeting with the FDA Agreement.

1215 ID 1641, p. 1.

Figure 1: Illustration of the ex ante expected lost revenues due to a delay in market launch of Azilect (European Commission)



(789) Figure 1 illustrates the impact of having to postpone market launch of Azilect on the revenues that Teva expected to earn during the period of exclusivity. The patterned rectangles in the graph show each year's lost revenue due to a postponed launch. The patterned rectangle on the left hand side shows the accumulated lost revenues throughout the entire exclusivity period. As illustrated by the figure, a delay in market launch would ex ante be expected to lead to the loss of revenue equal to the revenue expected during the last year before loss of exclusivity, when the market sales have reached the highest level.[1216] The Commission's file does not hold projections of Teva beyond 2009 but a conservative assumption is that they would have stayed at least at the 2009 level. Based on Teva's own ex ante forecasts the yearly revenues were expected to reach an order of magnitude of about USD 200 million by 2009. Hence, a one year delay would have been expected to cause a revenue loss in the order of USD 200 million for Teva, which is a considerable magnitude. Consequently, Teva had a strong interest in obtaining the data as soon as possible.

(790) Although it is possible that Teva might have convinced the FDA on other grounds or that it might have obtained regulatory approval with a delay of less than the time it would have taken Teva to conduct the necessary clinical trials, the Commission considers that even a short delay in market introduction would already have been

1216 Upon launch of a new drug to the market, clinicians and patients gradually adopt the new drug, often switching from their previous treatment to the new one. This gradual uptake does not typically depend on the date of launch, but on the time that the clinical community needs to familiarise with the new drug and incorporate it to guidelines and clinical practice. It is therefore reasonable to expect that a similar time would be needed to gradually increase sales after market launch.

very costly to Teva. [1217] A relatively swift introduction of Azilect in the United States market had a large value to Teva and any delay put significant value at risk. A revenue loss of this order of magnitude (that is USD 200 million) for a one-year delay, when distributed across 52 weeks in a year, represents an expected loss of almost USD 4 million a week. It follows that Teva had an urgency to obtain the data as soon as possible.

(791) While Teva's expectations at the moment of concluding the Settlement Agreement, represented by its sales projections, are the relevant indication of Teva's incentive to pay for the licence to Cephalon's CEP-1347 data, the fact that the data was vital for Teva was also confirmed ex post by the Executive Director and Head of Global Pipeline Development Global Innovative R&D at Teva on 6 December 2005 (just before the meeting with the FDA): "*The new data is the first and only breakthrough in this saga",*[1218] as well as on 8 December 2005 (one day after the meeting): *"The outcome of the meeting was very positive, totally different from the pessimistic expectations"; "no doubt that the data submitted was very instrumental;*" and *"I do not think we could have reached this outcome without the data*".[1219] Thanks to the Settlement, Teva was able to submit the data to the FDA before the meeting. Teva received approval from the FDA for Azilect in May 2006.

(792) Actual sales data for Azilect that were observed ex post confirm Teva's ex ante view. The data shows that Teva's sales of Azilect actually reached approximately USD 219.5 million in 2014 (for actual sales data, COGS and profits of Azilect see also Table 7 in Recital (349). This confirms that Teva's ex ante view that the sales and thus profits for this product over its exclusivity period would be significant was reasonable.[1220] This also shows that the Commission´s assumption that Azilect revenues would stay at the level expected for 2009 is conservative and may actually underestimate the ex ante expected loss of revenue due to a delay in the launch of Azilect.

(793) The Parties argue that the clinical data were not critical for Teva at the time of the Settlement Agreement. The Parties also argue that Teva did not expect Azilect to become a blockbuster, that Teva expected Azilect gross sales to be in the order of USD 16/17 million in 2006 and that the fact that Azilect grew significantly is irrelevant to assess Teva's expectations. The Parties argue that, on the contrary, Teva did not expect delays in the launch of Azilect to have substantial impact on expected profit and that a short delay would not have been costly to Teva. Therefore, they argue, that Teva could not have expected to gain significant value possibly in the order of USD 200 million.

(794) The argument that at the time of the Settlement Agreement Teva regarded the clinical data as not critical is not in line with the evidence on file. Teva internally observed

---

1217 See ID 2166-90, p. 1: *[…] told us after reviewing all the documents (before seeing the new data) that he thinks that the division will require a simple randomized study before approval. He believes that the Cephalon data is very important and may change the FDA request to post approval. His opinion is that our best achievement will be if Rusty does not finish the meeting with FDA decision that the study needs to be completed prior to approval'*.

1218 ID 2154-203.

1219 ID 2166-93.

1220 ID 1641. From *actual sales data* it follows that Teva gained USD 219,493,000 by getting the data before 7 December.

that the data was "*crucial*"[1221] (see Section 4.7.2). Also, in their SO Reply the Parties omit the fact that, absent the Settlement Agreement, Teva would have found itself in the situation of continued litigation with Cephalon, possibly with launch at risk of Teva's modafinil product. In that situation Cephalon would not – as is set out in the facts and not denied by the Parties – have been prepared to give access to the clinical data: "*Cephalon (…) refused to consider providing that data to a litigation adversary*".[1222] That would have led inevitably to a delay of approval of Azilect in the United States.

(795) The Commission based its assessment on Teva's expectations and forecasts for this product. These forecasts show that Teva expected to gain significant profits from marketing its own originator product Azilect.

(796) The forecasts also show that a short delay would have been costly and Teva could have expected that. Even a short delay would have meant for Teva less profits over the total exclusivity period before the loss of Azilect's exclusivity. Therefore, contrary to what the Parties claim, a small delay would have been costly: based on the above-mentioned projections of Teva itself this would be in the order of a magnitude of almost EUR 4 million per each week of delay.

(797) The Parties also state that the SO does not provide evidence that Teva's launch would have been delayed for a full year. In arguing so, the Parties do not deny the fact that – as is explained above – even a shorter delay would have had a negative impact on Teva's profits from Azilect. Besides, this assumes that Teva could have found a way to work around the need for the CEP-1347 within the time frame of a year, in order to convince the FDA to grant regulatory approval. This does not seem plausible, because Teva tried to conduct its own test but did not succeed, and Cephalon's clinical study had taken more than one year (see Section 4.7.2).

(798) The Parties furthermore state that Teva was not certain that the clinical data would be sufficient to convince the FDA and that […] only confirmed that the data 'may' be useful.[1223] However, (i) Teva knew that Cephalon's data might indicate a higher prevalence of melanoma among the Parkinson's disease population, thereby rebutting a causal relationship between Azilect and melanoma; (ii) Teva valued Cephalon's data as "crucial"; and (iii) the clinical data appears to have been an integral part of the Settlement Agreement negotiations. As early as of 7 November 2005, Teva spoke with Cephalon on the clinical data, and the clinical data formed part of negotiation talks in several instances. These facts are not denied by the Parties. Therefore, it cannot be held that Teva thought that the data might not be useful.

(799) In view of the above, the Commission concludes that from the perspective of Teva, the transaction whereby Teva obtained the CEP-1437 data contributed considerably to the value that Teva gained from the Settlement Agreement and which it would not have been able to appropriate from Cephalon (or at least not at the same terms)

1221 ID 2166-40 p. 1

1222 ID 1330, p. 1-2.

1223 The Parties also state that the rights granted to Teva in relation to the CEP data were restricted in scope. Although this is in itself true, the significance of the value of the clinical data from the perspective of Teva, lies in the fact that it enabled Teva to assist getting approval for its Azilect product on a certain date.

absent the non-compete and non-challenge commitments included in the Settlement Agreement.

6.6.2.3. Cephalon's interest

(800) This Section shows that absent the Settlement Agreement, Cephalon would not have given access to CEP-1347 data to Teva at all or on the same terms. The Section also analyses and concludes that the explanations for the transaction and its terms as provided by the Parties are not plausible.

(801) Before Teva approached Cephalon for the Azilect data, Cephalon did not have an intention to sell the clinical data to Teva.[1224] When Teva showed interest in Cephalon's CEP-1347 data, Cephalon took the position that it would not provide the data to Teva.[1225] In August 2005, before the start of negotiations of the Settlement Agreement and after some going back and forth between Teva and Cephalon, Cephalon communicated its final refusal to provide the clinical data to Teva, being its adversary in the modafinil litigation (see Recitals (340)-(343)).[1226] However, when the access of Teva to the Azilect data became part of the settlement package, Cephalon offered to provide access to Teva.

(802) The fact that Teva sought to get access from Cephalon to the clinical data already for some time, the fact that Cephalon understood that Teva was interested in the data and the fact that Cephalon was only willing to provide the access to the clinical data for facilitating the Settlement Agreement shows that Cephalon understood that the data had a significant value to Teva and shows that the transaction on these terms was foremost initiated because it contributed to putting a strong incentive on Teva to enter into the non-compete and non-challenge commitments of the Settlement Agreement. However, Cephalon obtained USD 1 million in consideration for the licence of the CEP-1347 data (see Section 4.7.2).

(803) In the SO Reply, the Parties submit that the payment of USD 1 million for the CEP-1347 data was determined by genuine negotiations and reflected a reasonable value from Teva's perspective and constituted a significant net benefit to Cephalon.[1227] The Parties, in particular, argue that Cephalon could not have extracted more than USD 1 million, that the file does not show that Cephalon thought it could extract more, that Cephalon could not assess the value from Teva's perspective and that the arrangement was concluded based on arm's length discussion in light of information available. The Parties also claim that the Commission's assessment hinges on the fact that Cephalon would likely not have entered into this arrangement absent the Settlement Agreement. They contend that the SO disregards the fact that Cephalon initially refused to supply the data justified by the fact that Cephalon would not

---

1224 Cephalon did not often conclude transactions on the sale of clinical data. There was no market for the CEP-1437 clinical data in the sense that neither anyone else had previously shown an interest to purchase these data, nor Cephalon had done any effort to find a potential purchaser. Cephalon concluded one other transaction concerning clinical data between 2000 and July 2015, namely with […].in 2006, ID 2166-251, p. 19.

1225 See Recital (343) and, in addition, ID 1330, p. 2, 4 and 5.

1226 Holding on to the clinical data as a leverage for starting negotiations on modafinil risked making the clinical data less valuable to Teva. However, it was rational for Cephalon to delay the granting of the licence to the data, because as long as Cephalon did that, it had leverage vis-à-vis Teva with regard to the negotiations on settling the litigation on modafinil.

1227 SO Reply, paragraph 7, ID 3694-26, p. 10.

pursue business with a party with which Cephalon was in patent litigation. The Parties argue that the 1 million USD payments constituted net revenue for Cephalon and that Cephalon had *de minimis cost* to provide the data. Moreover they contend that Cephalon had no plan for the potential use of the data.

(804) However, the Parties do not support any of these assertions by contemporaneous evidence. The Commission, on the other side, draws the attention to the evidence to the contrary, namely showing that Cephalon did use the granting of the licence to the CEP-1347 data as a leverage (together with other transactions) to induce Teva to enter into the non-compete and non-challenge commitments.

(805) First, there is no evidence on file that significant negotiating took place on the price of the access to the clinical data or that Cephalon ever evaluated (even in broad terms) how much it should extract from Teva for the access to CEP-1347 data.[1228] Further, there was no independent negotiation about the licence to the CEP-1347 data for Teva but the Parties negotiated the licence as a part of the overall package of payments and side deals within the framework of the Settlement Agreement.[1229]

(806) Second, Cephalon was aware that Teva had an interest in getting quick access to the clinical data.[1230] Cephalon also tried to find out the urgency that the access to the clinical data had for Teva.[1231]

(807) Third, Cephalon's negotiator stated that Cephalon was "*willing to provide access* (…) *for the purposes of facilitating* [agreement] *on the settlement*".[1232] Similarly the Parties' own expert acknowledged that "*Teva's need to use the CEP-1347 data was urgent and expedited the settlement negotiations.*"[1233]

(808) Fourth, Teva itself conceded that it "agreed to commence promptly settlement negotiations with Cephalon with a view of… obtaining access to the CEP-1347 data" because "Cephalon…refused to consider providing that data to a litigation adversary." (Recital (343)).

(809) The arguments of the Parties therefore find no ground in the evidence in the file. If anything, it transpires from the negotiation history, based on the contemporaneous (ex ante) internal considerations of Cephalon and Teva that there is no other plausible explanation for the CEP-1347 data transaction other than the inducement of Teva to enter into the Settlement Agreement and to commit not to independently enter and compete in the modafinil markets.

1228 An early draft of the Settlement Agreement contains the amount of USD 3 million, but the Parties have not evidenced that the final number of USD 1 million was the result of negotiations.

1229 See, for example, document quoted in the Recital (196) where Cephalon's chief negotiator offers to Teva the access to the Data along with other transactions "*solely for purposes of our settlement discussions*"; document quoted in the Recital (197), according to which Cephalon's chief negotiator replied to Teva's request for the Data "*I'm willing to provide access under the* [confidentiality agreement] *for purposes of facilitating final* [agreement] *on settlement…*" and the correspondence quoted in the Recital (201).

1230 ID 1616, p. 1-2.

1231 ID 1616, p. 1-2.

1232 ID 2166-81, p.4-5.

1233 [Expert report of 24 January 2018], Annex 1 to the SO Reply, paragraph 43, ID 3694-1, p. 22.

6.6.2.4. Conclusion

(810) The assessment above shows that access to Cephalon's CEP-1347 data was very valuable for Teva, because it could accelerate the commercial launch of Azilect, from which Teva could expect significant additional sales and profits. The assessment also shows that Cephalon did not evaluate or negotiate independently the price for providing access to the CEP-1347 data and used the data as leverage in the negotiations on the Settlement Agreement, refusing to grant a licence until the Settlement Agreement was finalised.

(811) Therefore, the Commission concludes, that it is not plausible that Cephalon would have given access to the CEP-1347 data in December 2005 absent the non-compete and non-challenge commitments in the Settlement Agreement, and at least not at the same terms. Accordingly, the Commission concludes that the CEP-1347 transaction was an unjustified value transfer that contributed to inducing Teva to enter into these commitments in the broader context of the Settlement Agreement.

6.6.3. Licence to Teva's Intellectual Property Rights

6.6.3.1. Introduction

(812) This Section assesses Cephalon's and Teva's incentives to enter into the transaction granting Cephalon a licence to Teva's Intellectual Property Rights at the time of concluding the Settlement Agreement, taking into account both the terms of the transaction and its context. From Teva's perspective, this Section shows that the Licence to Teva's Intellectual Property Rights generated value for Teva that it would not have been able to appropriate from Cephalon without committing to the non-compete and non-challenge obligations in the Settlement Agreement. From Cephalon's perspective, the facts strongly suggest that Cephalon would not have entered into this transaction at all or on the same terms absent the Settlement Agreement and that the transaction had the objective aim of serving as a transfer of value from Cephalon to Teva in consideration of the commitments of Teva not to independently enter the modafinil markets and compete with Cephalon.

6.6.3.2. Clause

(813) According to Article 2.2(a) of the Settlement Agreement, Cephalon purchased from Teva a non-exclusive, worldwide licence to Teva's modafinil-related intellectual property rights solely for the manufacture, development, formulation, use, sale, offer for sale, and importation of finished pharmaceutical products that contain the compound modafinil. The provision explicitly included Cephalon's products Provigil, Sparlon and Nuvigil. In addition, in Article 2.2 (a) Cephalon committed not to challenge or dispute any issued patents included in the Intellectual Property Rights.

(814) The licensed Intellectual Property Rights are defined in Article 1.20 of the Settlement Agreement and listed in Annex 1.20 to this Agreement (see Recitals (234) and (235)). At the moment of the Settlement Agreement, Teva's patent rights consisted in particular of the US '120 Patent claiming a method for preparing highly pure modafinil, US '227 Patent Application claiming crystalline forms of modafinil, and a

number of patent applications in the EEA and elsewhere that were derived from the US '120 Patent and US '227 Patent Application.[1234]

(815) In Article 2.2 (b) of the Settlement Agreement, Cephalon undertook to pay the following royalty payments:[1235]

(a) Upfront lump sum of USD 15 million within five business days of the Effective Date of the Agreement (that is 4 December 2005, see Recital (215)),

(b) Two lump sums of USD 7.5 million each, due upon achievement of sales of Cephalon Modafinil Product[1236] of USD 100 million or USD 200 million, respectively,[1237]

(c) Lump sum of USD 3 million on the date of the first commercial launch of Sparlon, and

(d) Starting from 1 January 2006, a running royalty in the amount of 3% of all worldwide net sales of Cephalon's modafinil products. This royalty was payable until the last to expire of any issued patents covered by the Intellectual Property Rights containing a valid and enforceable claim, or until such time as the cumulative sum of all royalties in (a)-(d) of this Recital shall have reached a total of USD 125,000,000 (approximately EUR 92.9 million)[1238], the so-called Royalty Cap. The Royalty Cap was reached in 2009, before the expiry of the last patent (see Section 4.7.1.7).

(816) The Settlement Agreement also clarified that Teva's Intellectual Property Rights were deemed valid and enforceable unless determined otherwise by a final non-appealable decision of a court of competent jurisdiction.

(817) In sum, by virtue of Article 2.2 of the Settlement Agreement, Cephalon agreed to purchase from Teva a licence to the latter's Intellectual Property Rights for an aggregate sum of USD 125 million, or approximately EUR 92.9 million.[1239]

6.6.3.3. Teva's interest

(818) Pursuant to Article 2.2 of the Settlement Agreement, in a sequence of quarterly payments between December 2005 and September/November 2009, Teva received a significant amount of money (approximately an amount of EUR 92.9 million).[1240] The price obtained by Teva for the licence to its Intellectual Property Rights was positively assessed internally by the Senior Assistant of Teva's General Patent Counsel who characterized the negotiated royalty as a particularly good deal: "*Also (this is more out of curiosity), it sounds like they are paying a huge sum for our IP*

1234 See Section 4.7.1.1.

1235 See Section 4.6.3.2.

1236 Footnote 409.

1237 With respect to the three lump sum payments listed under Recital (816)(a)-(816)(b), it should be noted that in their negotiations preceding the Settlement Agreement, the Parties first reached an agreement on the total sum of USD 30 million which was divided only later for the purposes of the wording of the Settlement Agreement. See footnote 410.

1238 See Recitals (232) and (329), Table 5.

1239 The royalties were paid in several quarterly payments in the period 2006-2009. The Commission applied the average exchange rate relevant for the respective year to each payment. See Recital (329).

1240 See Section 4.7.1.7.

(30MM plus royalties?!) Am I missing something here? Or could we have got more?"[1241]

(819) By licensing the Intellectual Property Rights, Teva did not incur any costs. It also did not incur any opportunity costs since the subject-matter of the purchase was a non-exclusive licence (Article 2.2 (a) of the Settlement Agreement). This means that Teva did not forfeit its right to continue using the Intellectual Property Rights as well as the right to grant the same licence to other licensees. Therefore, Teva did not forego any potential earnings by selling a non-exclusive licence to Cephalon.[1242]

(820) Teva's costs associated with the development and prosecution of the Intellectual Property Rights of EUR 1,352,621.11[1243] were sunk at the moment of negotiating the licence with Cephalon, meaning that Teva had already incurred them. Those costs were not dependent in any way on the conclusion of the licence agreement. Therefore, such costs are not attributable to Teva's act of granting the licence to Cephalon. The Commission's findings about Teva's costs related to the licensing and development and prosecution of the Intellectual Property Rights have not been contested by the Parties.

(821) Also, both before and after conclusion of the Settlement Agreement, Teva did not engage in any negotiations concerning the grant of a licence to the Intellectual Property Rights to other companies than Cephalon. Parties did not submit any evidence that any company expressed, either before or after the Settlement Agreement, an interest in a licence to Teva's Intellectual Property Rights, be it on an exclusive or non-exclusive basis. Outside the context of the Settlement Agreement, Teva was thus unlikely to expect any revenue from licensing out its intellectual property rights.

(822) By relying on ex post explanations and expert reports, in the SO Reply (paragraph 292) the Parties argue that the royalty amount and the royalty cap was reasonable and in line with at arm's length negotiations. The Parties' arguments are not convincing. First, the evidence shows that the terms of the Licence to Teva's Intellectual Property Rights were favourable to Teva and did not reflect the respective positions of strength of the Parties, indeed the terms do not seem to have been the subject of any detailed negotiations (see Recitals (849)-(859)). Second, the evidence also shows that the Licence to Teva's Intellectual Property Rights would not have occurred under normal market conditions.[1244] Finally, the fact that a given transaction involves a real transfer of assets or provision of services or that the price paid in a transaction is within "a range of reasonableness", does not exclude that it at the same time represents a consideration for Teva's non-compete and non-challenge commitments.[1245]

(823) In the light of the above, the Commission concludes that by granting the licence to its Intellectual Property Rights, Teva did not incur costs that would diminish the value transferred by the Licence to Teva's Intellectual Property Rights. Through the

---

1241 ID 979, p. 37.

1242 It should be recalled that the non compete commitments in the Settlement Agreement prevented Teva from entering the modafinil markets (see Section 6.5.1).

1243 See Recital (334).

1244 See Section 6.6.3.4

1245 See Section 6.6.

royalty payments for the Intellectual Property Rights, Teva received an amount of approximately EUR 90 million that it would not have been able to appropriate from Cephalon without entering into the non-compete and non-challenge commitments of the Settlement Agreement.

6.6.3.4. Cephalon's interest

(824) The Commission concludes, on the basis of analysing the evidence on the file, that Cephalon had no interest to pay significant amounts for a licence to Teva's Intellectual Property Rights, since they had at most very limited value to it. Therefore, the transaction can be explained only as contributing to the value transfer to Teva in consideration for entering into the non-compete and non-challenge commitments.[1246]

Cephalon did not consider Teva's Intellectual Property Rights as a significant threat to Provigil and never showed any interest in acquiring Teva's Intellectual Property Rights

(825) Provigil was Cephalon's most important product and Cephalon was well aware of the modafinil patent landscape. Despite this, the Parties never submitted any contemporaneous evidence showing that Cephalon was indeed concerned about alleged threat caused by Teva's Intellectual Property Rights or that Cephalon needed to undertake any actions to alleviate this threat.

(826) Concerning the modafinil polymorphs claims specifically, Cephalon's patent counsels were confident that "(*W*)*e have predating records of invention of these polymorphs*." In this sense, Cephalon's Chief Patent Counsel confirmed in August 2005, only a few months before the conclusion of the Settlement Agreement: "(*W*)*e know the patent landscape for modafinil and formulations of modafinil and are not aware of any potential infringement problems*."[1247] (see Section 4.7.1.3.) Therefore, contrary to the Parties' allegations, all pieces of contemporaneous evidence available to the Commission suggest that Cephalon at the time was confident that Teva's Intellectual Property Rights did not represent a significant threat to Provigil. The Parties did not submit any other contemporaneous evidence suggesting the contrary. [1248]

(827) In the SO Reply (paragraph 209 and following), the Parties submit an expert opinion from January 2018 ([*Expert report of 24 January 2018*]) suggesting that the polymorphic form claimed in Teva's patent application is equivalent to the polymorphic form claimed by the Cephalon patent and that there was a risk of detection of different polymorphs (including those claimed in Teva's patent applications) in Cephalon's final product or during the manufacturing process and

---

1246 Contrary to the Parties' claims (SO Reply, paragraph 200), the Commission does not assert that the Licence to Teva's Intellectual Property Rights was a condition for conclusion of the Settlement Agreement. They royalty paid by Cephalon to Teva under the Licence to Teva's Intellectual Property Rights was part of the value transfer and contributed to the value transfer inducing Teva to enter into the non-compete and non-challenge clauses of the PSA.

1247 See Recitals (304) and (307).

1248 Although the Commission has invited the Parties on more than one occasion to provide contemporaneous documents evidencing that Cephalon was concerned about infringement risks relating to Teva's Intellectual Property Rights, the Parties have not produced any evidence relating to (i) Cephalon's appraisal of difficulties in proving prior art; or (ii) Cephalon's appraisal of risk that Cephalon would be deemed to have been suppressing or concealing the invention.

that Cephalon was well aware of this. According to the Parties, patent positions for polymorphs are important both for innovator life cycle reasons and for potential infringement reasons. The Parties argue that these findings coupled with the fact that Cephalon faced a heavy burden of proof in any interference or litigation proceedings against Teva demonstrate that Teva's Intellectual Property Rights represented a significant infringement risk for Cephalon.[1249] The Parties also argue that obtaining the freedom to operate was an important goal for Cephalon in general and from a company with a reputation for aggressively pursuing patent strategies (Teva) in particular.

(828) It is apparent that the fact that the modafinil crystalline form may have been instable and the fact that there may have been an identity between polymorph forms claimed by Teva's patent application and Cephalon's patent application did not translate into a significant infringement risk for Cephalon. Likewise, Cephalon being aware of the possibility that the modafinil polymorph claimed in Teva's patent application might appear in Cephalon's modafinil API or even in the final product, did not necessarily imply that Cephalon had been aware of an infringement risk, as the Parties claim. This is so for the following reasons:

(829) First, Cephalon was convinced that its records of invention predated the priority date of Teva's patent application. It explicitly stated this in the context of legal proceedings in 2003: Cephalon's patent application of 7 August 2003 included an affidavit of Cephalon's scientists confirming that their invention predated Teva's priority date (27 July 2000).[1250] Second, Cephalon's modafinil product – Provigil – which Teva's patent application allegedly jeopardized, was approved in the United States on 24 December 1998, and subsequently placed on the market (namely before the priority date claimed in Teva's patent application). Third, at the time of the Settlement Agreement, Cephalon had not detected any traces of modafinil polymorph Form III either in the modafinil API or in the final product Provigil[1251] (see also Recitals (308)-(314)).

(830) The Parties also failed to submit any contemporaneous evidence demonstrating the alleged interest of Cephalon in Teva's Intellectual Property Rights or internal discussions on a possible licence from Teva.

(831) Even when Teva made its first offer in July 2005 expressly mentioning possible cross-licence of modafinil patents,[1252] Cephalon never replied to this offer (Recital (193)).[1253] When Cephalon agreed to negotiate the licence, it was solely for

---

1249 See also Response to the LoF (ID 3763, points 31-39) emphasising that the evidence on predating records of invention "**would likely** have been inadmissible" (emphasis added) under the United States law and that there was a risk of finding that Cephalon had abandoned the subject matter of the patent application. However, the Parties again fail to provide any contemporaneous evidence indicating that at the time of the Settlement Agreement (or before) anyone in Cephalon expressed or discussed such or similar doubts regarding Cephalon's legal position in the likely interference proceedings. The Parties' ex post explanations which are not supported with the corresponding evidence do not put into question Commission's conclusions drawn from the available contemporaneous documents.

1250 ID 3738, p. 12-19.

1251 [*Expert report of 24 January 2018*], paragraph 21 and 67, ID 3694-12, p. 5 and 21.

1252 See Recital (192).

1253 The Parties' reliance on correspondence from November 2005 (for example, SO Reply, paragraph 200) in order to show Cephalon's initiative with respect to the Licence to Teva's Intellectual Property Rights

purposes of discussing the Settlement Agreement,[1254] having understood "*that* [Teva]…may *be interested*".[1255] Any Cephalon's internal discussions about Teva's modafinil patent rights – that, according to the Parties, supposedly posed an existential threat to Cephalon's core business activity, generating more than 40% of its revenues[1256] – were limited to the circle of Cephalon's scientists and patent counsels and not business executives.[1257]

(832) It is also important to put the Parties' claims in perspective. The Parties' argue that Teva's Intellectual Property Rights and especially Teva's polymorph patent once issued, were capable of not only distorting Cephalon's processes but also completely blocking market access for Provigil. According to the Parties, Cephalon was aware of this alleged infringement risk and the alleged weaknesses of its patent position. In other words, the Parties' argument means that Cephalon would have been aware that Teva's Intellectual Property Rights threatened market access of, as Cephalon called it, *"Cephalon's present and planned highest grossing products worldwide.*"[1258]

(833) This line of argument is not reconcilable with the evidence on the Commission's file. Most importantly, when analysed in light of the available evidence (such as the fact that, as early as in 2003 Cephalon assumed that Teva's polymorph patent will issue and lead to interference proceedings), the Parties' arguments imply that ever since 2003 (that is at least two years before the Settlement Agreement) Cephalon would have been aware of a patent position capable of preventing market access of Provigil and other modafinil products. Even so, Cephalon would have failed to undertake any step to remedy this significant obstacle (for example, internal discussions on possible approaches to Teva, contacts with Teva regarding the licence, discussions on changes to the manufacturing process to mitigate the infringement risk, etc.). It is apparent that such inactivity by Cephalon on an issue allegedly capable of jeopardizing the company's most important product could not be explained if the alleged threat that the Parties now emphasise in their SO Reply had really existed at the time.

(834) Had Cephalon genuinely believed that Teva's patent rights put its business at a significant risk as claimed by the Parties, Cephalon would have had many opportunities from April 2002, when Cephalon first internally mentioned Teva's patent application or at least from 2003, when Cephalon first assumed that Teva's polymorph patent will lead to the interference proceedings, to July 2005, when the Licence to Teva's Intellectual Property Rights was first proposed by Teva, to contact Teva and explore a possibility of a licence or a cross-licence. However, Cephalon never contacted Teva and there is no evidence that Cephalon, at least internally, contemplated doing so before the negotiations on the Settlement Agreement started. Even more, it was not Cephalon but Teva who took the initiative to discuss, as a part

---

is misplaced. The licence was first mentioned by Teva in July 2005 and then in October 2005 without any response from Cephalon.

1254 See Recital (196).

1255 *Ibid*.

1256 See Recital (114).

1257 First mention by Cephalon's Senior Vice-President and General Counsel (and chief negotiator) of a possible Teva's licence is from 28 November 2005, and mentions a possible cross-licence between Teva's and Cephalon's patents, see Recital (322).

1258 ID 2153, p. 10.

of the Settlement Agreement, a transaction involving Teva's modafinil patent rights.[1259]

(835) Cephalon's *ex post* assessment of the Settlement Agreement presents the same picture. In the *ex post* assessments of the Settlement Agreement Cephalon never, either internally (such as when Cephalon's Chairman and CEO addressed the Board of Directors on 31 January 2006) or externally (such as in communication to the investors) mentioned the licence to Teva's Intellectual Property Rights.

(836) Had Cephalon indeed believed that Teva's Intellectual Property Rights presented a significant threat (that is that Teva held a patent position that could have blocked Cephalon's modafinil products) and that the Settlement Agreement (namely Licence to Teva's Intellectual Property Rights included in the Settlement Agreement) had alleviated this risk, one would also expect that the transaction saving Cephalon's modafinil business from such a supposed threat would have figured prominently in Cephalon's communications, at least in the internal ones. The Commission did not find any contemporaneous evidence showing that it did and the Parties did not submit any such evidence either. Quite to the contrary, Cephalon's *ex post* assessments and communications focused solely on delayed generic entry (Section 4.8.1.1). This could be contrasted with Teva's *ex post* assessments where the Licence to Teva's Intellectual Property Rights is expressly included among the "*value creating*" elements of the Settlement Agreement (Section ex post Teva).

Allowance of Cephalon's polymorph patent in September 2005 did not change Cephalon's assessment of risks arising from Teva's Intellectual Property Rights

(837) The Parties also argue that the notice of allowance issued to Cephalon in September 2005 changed Cephalon's assessment of Teva's Intellectual Property Rights since it only then became obvious that Teva's polymorph patent would be issued and that it would enjoy priority over Cephalon's patent.[1260] Therefore, according to the Parties, all Cephalon's statements expressing lack of concern which predate the September notice of allowance would be irrelevant for the assessment of Cephalon's interest during the settlement negotiations (November-December 2005). However, the Parties did not submit any contemporaneous evidence reflecting the alleged change in Cephalon's risk assessment.

(838) Moreover, the Parties' claim that the September notice significantly altered Cephalon's risk assessment is in contrast with available contemporaneous evidence. Most importantly, as soon as Cephalon learned about Teva's patent application (that is already in 2003), its risk assessment was immediately based on the assumption that Teva's patent will eventually be issued and that Teva and Cephalon would engage in interference proceedings. This is obvious from the internal Cephalon presentation by its Vice-President of Worldwide Chemical R&D from 2003. This presentation clearly states that "[Cephalon has] *filed our US patent application covering*

1259 See Recital (190) and Section 4.7.1.4. In the SO Reply, paragraph 290, the Parties emphasise importance of Teva's Intellectual Property Rights by pointing that projected sales for Provigil in 2006-2010 only were in the range of USD 4 billion, sales for Sparlon in 2006-2008 in the range of USD 805 million and for Nuvigil USD 256 million and that the expectations of the whole life cycle including all modafinil products would be much higher. Such forecasts only underscore the Commission's conclusions in this Section.

1260 The Parties argue that issuance of the Cephalon's patent clarified that the United States PTO will allow patents in polymorphs.

[modafinil polymorphs claimed by Teva] *and* ***expect an interference proceeding in the US in 2-3 years****. We have* ***predating records of invention*** *of these polymorphs.*"[1261] (emphasis added by the Commission)

(839) In other words, as early as 2003 Cephalon assumed that Teva's patents would issue and that polymorph patent dispute between Teva and Cephalon would be resolved in interference proceedings. Based on this assumption (namely that Teva's patent would issue) Cephalon made its risk assessment and never expressed any concerns regarding the infringement risks or any interest in acquiring Teva's Intellectual Property Rights.

(840) Therefore, since Cephalon expected issuance of Teva's patents and related interference proceedings with Teva already since 2003, the grant of Cephalon's patent in September 2005 did not suddenly convince Cephalon that Teva's patent will issue or altered Cephalon's assessment of infringement risks, as the Parties now argue. Quite to the contrary, the grant of Cephalon's patent in September 2005 and subsequent initial rejection of Teva's competing patent application may have only strengthened Cephalon's belief in the strength of its patents.

Other explanations for entering into the Licence to Teva's Intellectual Property Rights are not plausible

(841) The Parties argue that the acquisition of Teva's process patent and acquisition of Teva's other (including future) modafinil patent rights may explain Cephalon's interest in the Licence to Teva's Intellectual Property Rights. However, these other patent rights represented at most a very limited value to Cephalon and do not alter the Commission's conclusion that the transaction can be explained only in the broader context of the Settlement Agreement as a consideration for entering into the non-compete and non-challenge commitments. This for the following reasons:

(842) First, as mentioned, Cephalon never expressed any interest in acquiring Teva's process patent before the Settlement Agreement. Nonetheless, the Parties argued *ex post* that the process patent was of "*considerable interest*"[1262] and that it offered freedom to operate, affirmative synergies and significant manufacturing efficiencies. They did not submit any contemporaneous evidence that, at the (relevant) time of the negotiations for the Settlement Agreement, Cephalon would have seen such "*considerable interest*" or even a lesser degree of interest in the process patent.

(843) The claim that this patent would be of "considerable interest" is in contradiction with Cephalon's analysis from 2003 which does not mention that Cephalon needed the technology or contemplated approaching Teva concerning the process patent. This internal presentation by Cephalon's Vice-President of Worldwide Chemical R&D concludes that "*[T]hese Teva claims should have no substantive impact on*

1261 ID 2144-67, p. 3. An interference is an administrative contest between an application and either another application or a patent before the PTO. It serves the purpose of determining priority, that is, which party first invented the commonly claimed invention.

1262 ID 1318, p. 3. Reply to the Article 18 Request of 9 December 2010. Teva's claims to crystalline (polymorph) forms of modafinil were, as Cephalon explained to the Commission, "[B]*y far the most important to Cephalon*". Conversely, Teva's modafinil process claims, although issued as patent (unlike claims to polymorph forms) were less important and would not justify the price for the licence, or a substantial part of it. The Commission assumes that the major part of the royalty sum was paid for the licence to patent applications for modafinil polymorphs, based on Cephalon's explanation that it regarded those claims as key for its whole business. (Section 4.7.1)

Cephalon's manufacturing of modafinil as currently practiced." Moreover, the analysis confirms that "*Current manufacturing process will not infringe any Teva claims.*"[1263]

(844) Cephalon informed the Commission that at the time of Cephalon's internal discussions about Teva's applications (that is in 2003), its scientists, including the Vice-President of Worldwide Chemical R&D, were examining technical benefits of the process claimed by Teva, concluding that employing this process could lead to cost efficiencies (see Recital (297) and also Recital (291)(b)). However, it was not able to locate written studies or analyses relating to this investigation. The only contemporaneous evidence available on the Commission's file is a presentation by Cephalon's Vice-President of Worldwide Chemical R&D from 2003 concluding: "*Teva claims a process which we do not use (we oxidize the sulfide-ester).*[…] *Cephalon's improved process patent application will be filed shortly and is distinct from the above. These Teva claims should have no substantive impact on Cephalon's manufacturing of modafinil as currently practiced.*" (see Section 4.7.1.3, in particular Recital (304))

(845) In addition, even if Cephalon had a certain interest for Teva's protected process, such interest never materialised in any type of communication towards Teva, or in any type of internal discussions at Cephalon on whether such technical interest would merit a possible acquisition of Teva's process patent. The Parties did not submit any contemporaneous evidence to the contrary. It should also be recalled that Cephalon never actually used the technology in-licensed from Teva at all (see Section 4.7.1.2.2).

(846) Second, regarding Teva's other (including future) modafinil patent rights as the alleged reason for the purchase of Teva's licence, the Parties maintained that the licence would eliminate the risk that Teva could disrupt Cephalon's current or future supply or sale of modafinil through patent rights that it might have acquired in the future. The Parties also note that Teva did file patent applications for Nuvigil in 2007.

(847) However, this does not sufficiently explain Cephalon's interest in the licence and the Parties did not submit any contemporaneous evidence supporting this explanation. A purchase of rights that might or might not be acquired in the future, and of inventions that still needed to be invented does not appear to be supported by a clear business rationale from Cephalon's perspective. This is also supported by the fact that the possible future Intellectual Property Rights were purchased *en bloc* and without any further specification as to their scope or usefulness for Cephalon.

Terms of the Licence to Teva's Intellectual Property Rights are favourable to Teva and do not reflect the Parties' respective positions of strength

(848) In order to fully assess the purpose of the Licence to Teva's Intellectual Property Rights, the Commission carefully reviewed the terms of the licence as agreed between the Parties in the Settlement Agreement.[1264] This is especially important since the Parties argue that the terms of the Licence to Teva's Intellectual Property Rights and especially the royalty payable by Cephalon should be looked at in

---

1263 See Recitals (304)-(307).

1264 The Commission notes that the Parties never entered into a separate, proper licence agreement as envisaged by Article 3.2 of the Settlement Agreement.

isolation from the context of the Settlement Agreement and that such assessment would show that the terms are reasonable and cannot represent a value transfer from Cephalon to Teva.

(849) In order to appropriately reply to the Parties' arguments it is worthwhile to recall the elements that would have constituted the background of the negotiating positions of Teva and Cephalon with respect to the Intellectual Property Rights. At the time of the negotiations on the Settlement Agreement (November/December 2005):

(a) In September 2005, the PTO informed Cephalon that it would grant Cephalon a patent on modafinil crystalline forms.[1265] Conversely, in October 2005 the PTO rejected in the first instance all claims of Teva's competing patent application.[1266] In other words, Teva was offering to Cephalon (and Cephalon accepted) a licence to what was at that time formally a rejected patent application.[1267] It should be recalled that it was exactly this patent over modafinil crystalline forms that, according to the Parties, constituted the most important element of the Licence to Teva's Intellectual Property Rights (see Recital (291));

(b) Cephalon's product Provigil was placed on the market before Teva submitted an allegedly blocking patent application and Cephalon relied on its predating records of invention.[1268] Cephalon seemed confident in the strength of its own legal position *vis-à-vis* Teva's patent application;

(c) Following the PTO's Notice of Allowance, Cephalon's top management (namely the CEO, the Senior Vice-President and General Counsel and the Vice-President and Chief Patent Counsel) even contemplated a strategic use of this patent against Teva as a defendant in the pending patent infringement cases;[1269]

(d) Cephalon has never shown any concern about, or interest in, Teva's Intellectual Property Rights and it was actually Teva who initiated the discussion on the licence;

(e) Although the Parties argue that other potential modafinil entrants faced constraints arising from Teva's Intellectual Property Rights, no other company

---

1265 See Section 4.7.1.5.

1266 *Ibid*.

1267 Teva's patent counsel expressed doubts in July 2005 whether Teva's polymorph patent could be granted in the EEA. Also at the time of the negotiations on the Settlement Agreement, they were sceptical whether an offer of a licence to a patent application would be of sufficient value for Cephalon (Section 4.7.1.4). For the sake of accuracy, the Commission notes that the quotes of Teva's lawyers were made in the context of the European part of the modafinil dispute between the Parties and that it appears that when the lawyers comment on the patent application, they refer primarily to the applications filed with the EPO. Nevertheless, the comments regarding the "*attractiveness*" of a patent application for Cephalon are general in nature and their logic is the same for the Teva's US '227 Patent Application. Hence, Cephalon was in this respect buying a licence to a mere patent application for a significantly large sum, without a certainty that patent(s) would be granted, and in fact admitting that the patent might not be issued for all claims filed by Teva. This finding is underscored by the fact that Article 2.2 did not give Cephalon any guarantee for the case of non-issuance.

1268 This is evidenced by, for example, Cephalon's patent application of 7 August 2003 which included an affidavit of Cephalon's scientists confirming that their invention predated Teva's priority date, see Recital (830).

1269 ID 2144-24, p. 1-2.

ever inquired about licence to allegedly blocking Teva's patents or patent applications.[1270].[1271]

(850) The above elements show that Cephalon would have enjoyed a negotiating position of strength against Teva. One would therefore have expected from Cephalon to use the leverage and negotiate licence terms that would have sufficiently protected Cephalon as a licensee. However, the following elements of the actual negotiations and the terms of the Licence to Teva's Intellectual Property Rights contradict the Parties' allegations about its supposed arm's length nature.

(851) Cephalon could have insisted on entering into the separate, detailed licence agreement rather than proceeding based solely on Article 2.2 of the Settlement Agreement. It should be recalled that the Settlement Agreement expressly provided for the conclusion of the separate Intellectual Property Licence Agreement (Article 3.2). However, Cephalon did not insist on the elaborate licence agreement which would adequately protect its position as a licensee. Quite contrary, Cephalon proceeded to make the substantial payment to Teva relying solely on Article 2.2 of the Settlement Agreement which, as shown below, was quite favourable to Teva as the licensor.

(852) Article 2.2 of the Settlement Agreement does not contain provisions that would be expected, in particular where the licensee is in a stronger bargaining position and tries to secure its legal position. Conversely, Article 2.2 of the Settlement Agreement

---

1270 Since the end of 2002 there were at least four other companies, besides Teva, aiming to enter modafinil markets in the United States ([…], […], […] and […]). Since 2012, more generic competitors have entered the United States market. The Parties did not submit any evidence showing that any of these companies would ever inquire about Teva's Intellectual Property Rights.

1271 The Parties (SO Reply, paragraph 255 and ff) argue that other market participants were facing similar issues resulting from patent applications on modafinil polymorphs. The Parties specifically rely on concerns expressed by an employee of the pharmaceutical company […] that claims of crystallisation patents form III and IV seemed "*too close to our process*" and that they may inadvertently "*run into a protected polymorphs*" (ID 2816-8662, p. 1). However, these concerns directly relate to polymorphic claims in Cephalon's patent application and not to those in Teva's patent application which may imply […] assessment of the relative importance of Cephalon's and Teva's competing patent applications. In addition, the Parties omit to quote earlier e-mail from the another […] employee (this e-mail belongs to the same e-mail chain as the e-mail relied upon by the Parties) who after initial review of the Cephalon patent application stated: "(*T)his patent does not pose any problem to us.*" (ID 2816-8662, p. 2). Finally, the Commission has no indication that following the assessment of the patent claims […] ever inquired with Cephalon (or with Teva) about a possible licence to the polymorph patent. In addition, evidence on the Commission's file includes answers from other companies that commercially manufactured modafinil that they did not consider to be constrained by Teva's Intellectual Property Rights (for example, […] ID 2368, p. 4, […], ID 1829 p. 3, […] ID 1760 p. 4-5 (Q5-6)). In the Response to the LoF the Parties make a number of arguments striving to put into question relevance of the statements relied on by the Commission. The Parties thus claim that the statement by […] is taken out of context, that the statement by […] is not sufficiently elaborated and that the statement by […] is limited only to a certain of Teva's Intellectual Property rights and does not cover other (see ID 3763, points 44-51). However, there is nothing in the Parties' arguments that contradicts the fact that (i) the Commission reached out to other modafinil manufacturers, (ii) inquired about the risks they were facing from Teva's Intellectual Property Rights and that (iii) none of the contacted modafinil manufacturers identified any constraints arising from Teva's modafinil Intellectual Property Rights or any actions (for example, licence inquiries) to alleviate such possible constraints. This is in stark contrast with the Parties' assertion (SO Reply, paragraph 255 and ff) that other market participants were facing issues resulting from patent applications on modafinil polymorphs which is supported by a single quote of an employee of the pharmaceutical company […] which statement, as explained above, directly refers to Cephalon's rather than to Teva's patent application.

included provisions which were important from Teva's perspective: schedule of payments and non-challenge clause.

(853) The absence of any warranties in favour of the licensee (Cephalon) is in stark contrast with the fact that the licensed Intellectual Property Rights came with significant uncertainties: (i) they dominantly included patent applications rather than actual patents (19 out of 21),[1272] and (ii) Teva's patent application concerning the most important element of the licensed Intellectual Property Rights (claims on modafinil crystalline forms) was formally rejected by the PTO just before conclusion of the Settlement Agreement (in October 2005). In order to mitigate uncertainties always inherent in pending applications, Cephalon could have insisted on some of the following provisions: (i) provisions setting deadlines for Teva to obtain the patents, (ii) provisions making the payment of royalties contingent on the progress in the patent proceedings, or (iii) claw-back or reduced royalty provisions for the case of non-issuance of the patents. However, the Settlement Agreement did not include any such provision protecting Cephalon.

(854) Finally, with respect to Teva's process patent, Cephalon could have asked for engineering or technical consultancy support or for the transfer of related know-how as it is usual in the case of licensing agreements that transfer technology. There was not a subsequent technical collaboration between Cephalon and Teva concerning the modafinil process. In fact, Cephalon did not apply the technology in-licensed from Teva at all.

Cephalon did not undertake formal due diligence of the Intellectual Property Rights or their formal evaluation

(855) Cephalon could have undertaken at least basic legal due diligence of the Intellectual Property Rights under the licence to mitigate, for example, risk that they potentially might be encumbered by legal defects (such as Teva's rightful ownership title). Lack of formal due diligence is surprising given the significant amount of USD 125 million paid for the licence. Even Teva internally characterised the negotiated royalty as "*a huge sum for our IP (30MM plus royalties?!)*".[1273]

(856) Cephalon could have also evaluated the Intellectual Property Rights it intended to acquire. The Commission's file however does not contain any indication that Cephalon ever estimated a value of Teva's Intellectual Property Rights. The Minutes of Cephalon's Board of Directors meetings of 4 December 2005 just mention that the licence was "*discussed*" (along with the other transactions forming part of the Settlement Agreement) without giving any more specific information, while the Minutes of Meeting of 1 December 2005 attribute the purchase of Teva's licence to considerations given to Teva in exchange for the terms of the Settlement Agreement.

(857) Cephalon did not produce any other internal documents analysing the purchase of Teva's licence and its value for the company, even if explicitly asked by the Commission (see Section 4.7.1.6 and in particular Recital (326)). Despite the lack of clear evaluation, Cephalon nevertheless proceeded to pay to Teva royalties in the amount of USD 125 million.

[1272] Out of 21 Intellectual Property Rights listed in Annex 1.20 of the Settlement Agreement, 19 were patent applications (see Recital (235)).

[1273] ID 979, p. 37.

(858) The Parties argue that the fact that there was no due diligence does not call into question the justification of the licence and its value to Cephalon. Cephalon did not have the ordinary practice to prepare formal due diligence for each transaction, and no formal due diligence was prepared in this case in line with its normal practice. Moreover Cephalon's in-house scientist and outside counsels had already analysed the Teva applications as soon as they became aware of them. However, these Parties' arguments do not call into question the Commission's conclusion that the wording of the licence included in the Settlement Agreement as well as its negotiating history and overall context indicate that the certainty of the consideration obtained by Teva (namely certainty of royalty payments) was by far more important for the Parties than the scope and value of the license obtained by Cephalon (namely strength, validity and utility of in-licensed intellectual property rights). More specifically, Cephalon explicitly confirmed to the Commission that no formal diligence report was prepared in advance of the Teva Licence (Section 4.7.1.6). Consequently, Cephalon took the risk with respect to scope and validity of the Intellectual Property Rights which is surprising given the significant amount of USD 125 million it paid for the Licence.

Dynamics of royalty payments favoured Teva

(859) At odds with the Parties' argument on arm's length nature of the negotiations between the Parties is the fact that the schedule of royalty payments included in the Settlement Agreement ensured that Teva would unconditionally and swiftly receive the contemplated value transfer. Cephalon paid to Teva the amount of USD 125 million for the Intellectual Property Rights.[1274] Almost 40% of the total royalty (USD 45,794,515) was paid before November 2006 (when the Notice of Allowance for issue of the patent in the United States was delivered to Teva, see Recital (321)) and almost 50% of the total royalty (USD 57,775,226) was still paid before the actual issuance of the United States polymorph patent (See Recital 232 ff.).[1275] It should be recalled that this patent was, according to the Parties, the most important element of the licensed Intellectual Property Rights (see Recital (291).

(860) Cephalon could have simply insisted on the payment of royalties contingent on the issuance of Teva's patent or could have included any other protective mechanism mentioned in Recital (853). However, the Parties did not submit any evidence of such or similar negotiating requests by Cephalon. In other words, contrary to the Parties' claims on the supposed arm's length nature of the negotiations, Cephalon did not use the main leverage it had as a licensee (that is payment of royalties) to hedge a risk of a non-issuance of Teva's patents.

(861) In addition, the Commission notes that Article 2.2 of the Settlement Agreement provides for calculating running royalties payable to Teva based on the sales of all Cephalon Modafinil Products, namely Provigil, Sparlon and Nuvigil regardless of actual infringement risks related to a specific product and regardless of the actual use

---

1274 Under the […] Settlement Agreement Cephalon committed to pay up to USD […] for purchase of licence to […] modafinil-related patent applications. Under the Barr Settlement Agreement Cephalon committed to pay USD 1 million for purchase of licence to Barr's modafinil-related patent applications. Under the […] Supply Agreement linked with the Barr Settlement Agreement Cephalon committed to pay USD 4 million for purchase of licence to […] a modafinil-related patent and patent applications.

1275 In this context, the Commission notes that the patent for Teva's modafinil polymorphs claims was never granted in the EEA. Section 4.7.1.1

of in-licensed technology. In this context it is worthwhile recalling that, according to the Parties alleged infringement risks were detected solely with respect to Provigil and Sparlon and not with respect to Nuvigil (SO Reply, paragraphs 213 and 286) and that Cephalon never actually used Teva's in-licensed process technology (Section 4.7.1.1.2). It follows that Cephalon was at least partially paying royalties even though it only used its own technology.[1276]

(862) As to the non-challenge obligation, this commitment served as an assurance for Teva that Cephalon would not terminate its royalty payments through a successful challenge of Teva's patents. It should be recalled that Cephalon assumed the non-challenge obligation with respect to Intellectual Property Rights which could have potentially conflicted with its own intellectual property and thus, according to the Parties, hampered Cephalon's business endeavours (see Recital (233). Moreover, the combination of Teva's non-challenge commitment vis-à-vis Cephalon's modafinil patents (see Section 6.5.2) and Cephalon's non-challenge commitment vis-à-vis Teva's Intellectual Property Rights increased entry barriers for other potential competitors on the modafinil markets.[1277] Based on the findings presented above the Commission therefore concludes that the royalties payable to Teva under the Licence to Teva's Intellectual Property Rights cannot be explained outside the overall context of the Settlement Agreement as a part of consideration for Teva's commitments.

(863) Finally, the negotiations of the licence appear to have been extremely brief (a matter of days) and the Commission's file does not contain any indication that the Parties did discuss any details of the licence other than the price in great detail. The licence was always discussed in close connection to the Settlement Agreement and together with other transactions under the Settlement Agreement as Teva's chief negotiator confirmed with respect to the API: "*And [Licence to Teva's IP] is in some respects tied to our API.*"[1278]

6.6.3.5. Conclusion

(864) In view of the above, the Commission concludes that Teva obtained a significant value by licensing its Intellectual Property Rights to Cephalon. Cephalon in turn was neither interested in nor had a real need to acquire Teva's Intellectual Property Rights prior to the Settlement Agreement. Cephalon had no incentive to pay

---

1276 The Commission's Technology Transfer Guidelines state: "*The hardcore restriction contained in Article 4(1)(a) TTBER also covers agreements whereby royalties are calculated on the basis of all product sales irrespective of whether the licensed technology is being used. Such agreements are also caught by Article 4(1)(d) according to which the licensee must not be restricted in its ability to use its own technology rights (see point (116) of these guidelines). In general such agreements restrict competition since the agreement raises the cost of using the licensee's own competing technology rights and restricts competition that existed in the absence of the agreement*". See *Communication from the Commission—Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements*, OJ C 89, 28.3.2014, p. 22, point 101.

1277 See the statement of Teva's senior manager in Europe in the initial phases of the Settlement Agreement negotiations cited in Recital (190): "*Teva's top priority is to settle with Cephalon and to add to the table also the Sulphone patent that we have. In my opinion the combination of the two patents may lock any realistic option to anyone else to get into the market. I strongly believe that a settlement is optimal for both companies.*"

1278 See Recital (201) and subsequent. Also, Article 2.6 (a)(i) of the Settlement Agreement indicates that a reason for the one-time payment under the Teva Distribution Agreement was a consideration for the licence to Teva's Intellectual Property Rights, thus making an express connection between these two transactions. However, this connection was *ex post* denied by the Parties (see Recital (913)).

significant amounts for a licence to Intellectual Property Rights that had no, or at most a limited value to Cephalon. The facts strongly suggest that Cephalon would not have entered into this transaction at all or on the same terms absent the Settlement Agreement and that the transaction had the objective aim of serving as a transfer of value from Cephalon to Teva in consideration of the commitments of Teva not to independently enter the modafinil markets and compete with Cephalon. Alternative explanations for the transaction provided by the Parties are not plausible. The Licence to Teva's Intellectual Property Rights thus involved an unjustified value transfer to Teva that it would not have been able to obtain absent the Settlement Agreement.

6.6.4. Cash payment for avoided litigation costs

6.6.4.1. Introduction

(865) This Section assesses Cephalon's and Teva's incentives to enter into the transaction on the cash payments for avoided litigation costs at the time of concluding the Settlement Agreement, taking into account both the terms of the transaction and its context. The Court of Justice considered in *Generics (UK) and Others* case that *"where the manufacturer of generic medicines receives from the manufacturer of the originator medicine sums that correspond in fact to compensation for the costs of or disruption caused by the litigation between them"* such transfers of value may be justified in the light of the objectives of the Parties to the agreement.[1279] In the case at hand, the Commission establishes that cash payment for avoided litigation costs was not associated with the actual costs related to the dispute between the Parties or the disruption caused by the litigation between them. In particular, from the perspective of Teva, this Section shows that the transaction likely generated value for Teva that it would not have been able to appropriate from Cephalon absent the non-compete and non-challenge commitments in the Settlement Agreement. From the perspective of Cephalon, the facts strongly suggest that in the broader context of the Settlement Agreement the transaction had the objective to serve as a transfer of value from Cephalon to Teva in consideration of the commitments of Teva not to independently enter the modafinil markets and compete with Cephalon, and not to challenge Cephalon's patents.

6.6.4.2. Clause

(866) Article 2.5 of the Settlement Agreement stipulates Cephalon's obligation to make two payments to Teva allegedly in recognition of Cephalon's savings (avoidance of costs, expenditure of time and resources etc.) as a result of the discontinuance of ongoing litigation in the United Kingdom and avoidance of potential modafinil litigations between the two Parties in other markets:

(a) Payment of GBP 2.1 million (approximately EUR 3.07 million[1280]) for ending the pending litigation in the United Kingdom (Article 2.5 (b)), and

(b) Payment of EUR 2.5 million for avoiding potential future patent or other litigation in European and other markets outside of the United States or the United Kingdom (Article 2.5 (c)).[1281]

1279 Case C-307/18, *Generics (UK) and Others*, paragraph 86.

1280 Based on the average GBP-EUR exchange rate in 2006.

1281 For more details concerning both payments see Section 4.6.3.5.

(867) Pursuant to Article 2.5.(b), the release of the relevant bond was in recognition of avoidance of future costs that Cephalon would have incurred – "*savings inuring to Cephalon in terms of the avoidance of cost, expenditure of time and resources, disruption and burden associated with prosecuting such litigation in the United Kingdom*".

(868) According to Article 4.2 of the Settlement Agreement, both Cephalon and Teva bore their own costs with respect to the settlement of the litigation in the United Kingdom.

(869) Accordingly, the Settlement Agreement did not provide for compensation to Teva for actually incurred litigation costs. The payments in value of EUR 5.57 million served to end litigation in the United Kingdom and to abstain from any future litigation between the parties in other markets outside the United Kingdom and the United States.

6.6.4.3. Teva's interest

(870) The Parties have not contested that Teva gained a value of EUR 5.57 million via Cephalon's payment to Teva. Teva obviously had an interest in receiving a payment for which it did not have to make any counter-performance.

(871) First, the alleged time and cost savings for Cephalon valued at EUR 5.57 million do not involve a counter-performance by Teva and the cash payments of EUR 5.57 million are not related to any costs incurred by Teva. Accordingly, these cash payments cannot "*correspond … to compensation for the costs of or disruption caused by the litigation*" as envisaged in the jurisprudence of the Union Courts.[1282]

(872) Indeed, it cannot be considered that a party to a litigation can reasonably have a claim to "compensation" for own costs that it did not incur, or a claim to non-incurred litigation costs of the opposing party. The transfer of such amounts cannot reasonably be considered as a justified gain.

(873) Second, in the present case the payments were dissociated from the costs of any actual or potential litigation. The contemporaneous evidence suggests that the Parties were rather looking for a legal form which could justify this specific value (money) transfer. For example, internally, Teva discussed whether the relevant amount could be transferred by any other means instead of releasing the bond issued by Cephalon to Teva in the context of the United Kingdom proceedings. In particular, Teva considered whether it was necessary to transfer the value by finding another '(commercial) route': "*The enclosed* (Court Order) *releases both parties from the undertaking* (such as the GBP 2 million bond) *to the Court. Does that mean that we would go about getting the 2.1MBP of the undertaking from Cephalon in a different route (commercial), or will we be able to 'cash' the undertaking as part of the dismissal?"*[1283]

(874) Third, the Parties have not been able to provide any calculations or assumptions on which the amounts of GBP 2.1 million (approximately EUR 3.07 million) and EUR 2.5 million were based. Teva submitted without further substantiation that the amount was "*negotiated at arm's length*" with Cephalon.[1284] Absent the non-compete and non-challenge commitments included in the Settlement Agreement it cannot be

---

1282 Case C-307/18, *Generics (UK) and Others*, paragraph 86.

1283 ID 153, p. 2.

1284 ID 2166-252, p. 3.

explained what these amounts cover and hence why Cephalon made the commitment for this transfer. In other words, there is no plausible explanation for the payments other than the aim of inducing Teva to commit to the non-compete and non-challenge clauses. Consequently, the payments to Teva allegedly aimed at covering for litigation costs can only be considered as pure cash payments to Teva with the aim of inducing the latter into concluding the Settlement Agreement.

(875) In light of the above, the Commission thus concludes that, from Teva's perspective both payments in question are pure value transfers that Teva would not have been able to extract from Cephalon outside the Settlement Agreement.

6.6.4.4. Cephalon's interest

(876) Regarding the payment for alleged avoided litigation costs in the United Kingdom, Cephalon paid Teva an amount of GBP 2.1 million (approximately EUR 3.07 million).

(877) As explained above (Section 6.6.4.3), the alleged time and cost savings for Cephalon are not a counter-performance by Teva, for which Teva should be compensated. As such, the payments to Teva at issue cannot be considered "*compensation for the costs of or disruption caused by the litigation*".[1285]

(878) Further, there is no other plausible explanation from Cephalon's perspective for the payment of the amounts at issue to Teva other than to induce Teva to commit to the non-compete and the non-challenge commitments. This is for the reasons set out below.

(879) The actual payment of the EUR 3.07 million under Article 2.5b of the Settlement Agreement was made as an automatic conversion of a bond (and interest) that was issued by Cephalon in connection to the United Kingdom court proceedings. The bond for the same value as the payment under the Settlement Agreement was issued as security for any damages that Teva expected to suffer through blocked sales of its modafinil product during the trial period, should the case be decided in its favour.[1286] The amount of EUR 3.07 million was based on Teva's anticipated modafinil sales in the United Kingdom during the court proceedings and unrelated to any possible avoided litigation costs. The Parties have not been able to explain how the amount of avoided litigation costs exactly matches the amount of Teva's estimated anticipated sales of modafinil.

(880) In addition, Cephalon consistently estimated its own costs of the expected litigation in the United Kingdom at between GBP 1 million to GBP 1.5 million,[1287] which is a significantly lower amount than the payment made. The paid amount is thus not based on a reasonable estimate for Cephalon's litigation cost in the United Kingdom. The title "*avoided litigation costs*" hence appears to be a pretext for transferring the amount to Teva on account of another reason. On the amount of litigation cost that Cephalon thought it would be avoiding, the Parties bring forward in the SO Reply that Cephalon's forecast of litigation costs was no more than an uncertain estimate, as is the case for all pre-trial estimates. The Parties also state that their early estimate of GBP 1-1.5 million was meant to cover the expected costs of the procedure up to

1285 Case C-307/18, *Generics (UK) and Others*, paragraph 86.
1286 See Recital (185).
1287 See Recital (424).

the High Court and did not include any additional expenses thereafter[1288]. The Parties argue that the SO ignores the "non-monetary" costs that Cephalon would have incurred, such as the significant time and effort. The Parties claim that estimates for litigation costs are often on the low side and that it was reasonable, when negotiating the payment, to agree upon a slightly higher sum.

(881) Similarly, Cephalon's own statement seems to suggest that the release of the bond was a mere vehicle of transferring the amount of GBP 2.1 million from Cephalon to Teva. Cephalon stated in its response to the Article 18 Request dated 6 July 2015: "*The decision to release the bond as a means of payment for the GBP 2.1 million was made for efficiency reasons*".[1289] This shows that the payment was *not* based on calculations or estimates of litigation costs in the United Kingdom, but was merely transferred because of "efficiency reasons".

(882) Regarding the payment for avoided litigation costs in other countries, Cephalon paid Teva an amount of EUR 2.5 million.

(883) Cephalon has not been able to provide calculations or assumptions on which this amount transferred for avoided litigation costs were based, and it never substantiated how the amount of EUR 2.5 million reflected any potential savings for Cephalon from avoiding litigations in other European markets. In this context, it is recalled that a draft version of the Settlement Agreement still suggested that Cephalon would have to pay to Teva an amount of EUR 1 million in return for the avoided litigation costs in European and other markets.[1290] The Parties did not provide any explanation that could reconcile those amounts.

(884) In the SO Reply, the Parties argue that payments that are agreed upon to reflect avoided litigation costs are not reverse payments. Absent a settlement agreement, they argue, by definition, there would have been no saving of litigation costs. However, for the reasons set out above, the Commission finds that the payments at issue cannot be considered as a compensation for Teva's litigation costs in the first place since Teva never incurred such costs.

(885) The Parties also claim that in its judgment in *Lundbeck* case, the General Court did not condemn payments for avoided litigation costs to the extent that they are objectively justified.[1291]

(886) However, the judgment in *Lundbeck* case does not provide any support for the Parties' claim. In that case, the General Court found that the relevant agreements in that case did not even enable the resolution of the underlying patent disputes and, thus, the claim that the agreements could avoid litigation costs was not corroborated by the facts in the first place. [1292] In any event, in the present case, there is no evidence that the cash payments were based on calculations or estimates of the cost of litigation. More importantly, the Parties did not provide any plausible explanation

---

1288 SO Reply, paragraph 155.

1289 ID 2166-251, p. 1.

1290 ID 290, p. 19

1291 And the Parties point out that in contrast with the Citalopram settlement of Lundbeck, the Settlement Agreement in the present case was designed to resolve all ongoing and potential litigations between Teva and Cephalon. SO Reply, paragraph 146, referring to Case T-472/13, *Lundbeck v Commission*, paragraph 718.

1292 Case T-472/13, *Lundbeck v Commission*, paragraphs 718-719.

regarding this value transfer, and in particular, that the amount received by Teva corresponds *"in fact to compensation for* [its] *costs of or disruption caused by the litigation between them"*[1293], in other words the payment was not related to any costs incurred by Teva.

(887) The Parties also argue that in the United States, payments in recognition for saved litigation costs have been approved under the antitrust rules.[1294] However, under European competition law, including the recent case-law of the Union Courts, only compensations by originator for actual litigation or other costs incurred by a generic manufacturer can be considered justified and as such not to constitute reverse payments. In the case at hand, while the payments were labelled as payments related to avoided litigation costs, for the reasons set out above, the amounts were actually pure cash payments that had no other plausible explanation but to induce Teva into the non-compete and non-challenge restrictions.

(888) The Parties argue that this was all the more so because a specific amount was already set aside and "on the shelf" in the form of the GBP 2.1 million bond. The GBP 2.1 million bond was agreed by Cephalon just before the interim injunctions hearing, in exchange for Teva agreeing not to sell modafinil in the United Kingdom until the outcome of the trial. According to the Parties, it was designed to compensate Teva for lost profits in case Teva would prevail at trial. Thus, so the Parties argue, from Cephalon's perspective, this amount had already been set aside for litigation purposes.

(889) As regards the EUR 2.5 million payment for litigation outside the United States and the United Kingdom, the Parties argue that the amount was reasonable and in line with the litigation costs that Cephalon could anticipate. Cephalon was ready to introduce legal actions in every country where Teva was planning to launch generic modafinil. According to the Parties, Teva was aware that Cephalon would file such lawsuits. In light of Cephalon's anticipated litigations in so many jurisdictions, the EUR 2.5 million estimate was well below the saved litigation costs that Cephalon could expect (compared, for example, to the costs in the United Kingdom). The Parties argue that the amount of EUR 2.5 million was understated by a large measure.[1295]

(890) The Commission notes that, contrary to the Parties' argument, the evidence suggests that the amount of approximately EUR 3.07 million have not been set aside for litigation. This amount served to compensate Teva for lost sales, as also indicated in the draft version of the Settlement Agreement.

1293 Case C-307/18, *Generics (UK) and Others*, paragraph 86.

1294 The Parties refer to the Actavis judgment, or specifically with respect to Teva and Cephalon, to the exclusion of avoided litigation costs from potentially reverse payments by the United States FTC (if they are less than USD 7 million). According to the Parties, in the Settlement Agreement, the cash payments were limited (in any case below the USD 7 million threshold), and generally in line with the litigation costs that pharmaceutical companies can reasonably estimate for patent litigations in Europe. See SO Reply, paragraphs 150-151.

1295 The Parties also claim that in arguing that Teva and Cephalon failed to provide "*any contemporaneous documents supporting the* [EUR 2.5 million] *figure*", the SO wrongly shifts the burden of proof from the Commission to the defendants. However, the Commission invited the Parties to provide contemporaneous documents supporting the figure because there appears not to be any counterperformance by Teva. The fact that the Parties were not able to provide these documents is not shifting the burden of proof.

(891) Accordingly, the amount of EUR 3.07 million indicated in the Settlement Agreement appears not to have been based on litigation costs:

– it appears rather to have been based on Teva's anticipated modafinil sales in the United Kingdom during the court proceedings;

– the draft version of the Settlement Agreement mentions that Cephalon pays the amount "*also in recognition of Teva's lost revenues*";

– Teva internally considered whether it was necessary to transfer the value by finding another '(commercial) route'; and

– Cephalon has not been able to provide convincing calculations explaining how this amount would cover litigation costs.

(892) As regards the payment of EUR 2.5 million, the Commission notes that this payment related to potential litigation between the Parties in the future that had not even started, for which the Parties did not provide any contemporaneous evidence substantiating these costs even in broad terms. In any event, they did not explain what was relevant Teva's counter-performance or which costs Teva incurred that could justify a compensation.

(893) Furthermore, the Commission notes, with respect to the amount of EUR 2.5 million for avoiding potential future litigation in European and other markets (other than the United States and the United Kingdom), that a prior draft settlement agreement suggested another distribution of payments – proposing a payment of only EUR 1 million for the avoided litigation costs pursuant to Article 2.5 (c) and a payment of EUR 4 million as a one-time payment associated with the start of the distribution by Teva of Cephalon's modafinil product in the United Kingdom pursuant to Article 2.6 (a)(i) of the Settlement Agreement.[1296] It was only in the final version of the Settlement Agreement of 8 December 2005 that both aforementioned payments, that is to say the payment for the avoided litigation costs in the European and other markets and the payment under the Distribution Agreement, were set at EUR 2.5 million (see Sections 4.6.3.5, 4.6.3.6 and Recital (911)). While the sum of both payments combined, that is EUR 5 million, remained unchanged, the re-allocation of amounts between two ostensibly unrelated payments shows that the Parties clearly intended to transfer somehow EUR 5 million to Teva and that the amount of EUR 2.5 million pursuant to Article 2.5 (c) of the Settlement Agreement was not established on the basis of an estimation of likely litigation costs avoided elsewhere in Europe (the Parties were unable to point to any such estimation).

(894) In their SO Reply, the Parties argue that the Commission's conclusion is incorrect. According to the Parties, all transactions were negotiated simultaneously in a relatively short period of time in light of Teva's urgent need for the CEP-1347 data. The consideration paid in each transaction evolved due to the at arm's length negotiation. Given that no liquid market existed for the subject matter of any of the transactions, including distribution costs, some variation in consideration due to negotiation should be expected. This does not imply that any transaction was not concluded for reasonable consideration.

1296 See Recital (911) and subsequent.

(895) The Parties thus seem to argue that the independent arm's length negotiation of the Teva Distribution Agreement and the litigation costs was the reason for the decrease of the one-time payment under the Teva Distribution Agreement from EUR 4 million to EUR 2.5 million (that is for 37.5 percent) and for the simultaneous 150% increase of the value of avoided litigation costs for the exact same amount (from EUR 1 million to EUR 2.5 million). This argument is unconvincing. The Parties offer no evidence to substantiate their claim of intense negotiations on this point or to explain the sudden depreciation of the services provided in relation to the start of the distribution and the equally sudden (and substantive) raise in supposedly expected avoided litigation costs. The simultaneous adjustment of these supposedly non-connected payments for the same amount rather indicates that the transactions under the Settlement Agreement constitute a single package that serves no other plausible aim than to induce Teva into committing to the non-compete and non-challenge commitments.

(896) Finally, the Parties argue in the SO Reply that an initial figure of the draft Settlement Agreement (of 6-7 December 2005) is irrelevant assessing the reasonableness of the payment that was later agreed.[1297] The Parties claim that the earlier draft shows that the payments were subject to arm's length negotiations.

(897) However, the draft shows precisely that the amount was not based on any estimates of avoided litigation cost. If anything, it shows that the Parties aimed at a certain value transfer through the transactions. This is evidenced by the fact that after the draft a simultaneous decrease of the value of Teva's Distribution Agreement (from EUR 4 million to EUR 2.5 million) and increase of avoided litigation cost occurred at the same amount (from EUR 1 million to EUR 2.5 million). The draft only shortly pre-dates the final Settlement Agreement and the differences between the relevant amounts are considerable. This shows that the value transfer was moreso an outcome of negotiations on the Settlement Agreement than the amount paid in recognition of litigation costs.

6.6.4.5. Conclusion

(898) The bond of EUR 3.07 million that was released to Teva as an alleged payment for avoided litigation costs likely represented Teva's expected lost profits from not entering the modafinil market in the United Kingdom and had no relevance to any actual litigation costs incurred by Teva. Likewise, the Parties have not substantiated how the amount of EUR 2.5 million reflected any avoided litigation costs in other European markets, nor indicated any counter-performance of Teva, which could justify such transfer. Accordingly, the payment of this amount was valuable for Teva, which it would not have been able to obtain absent the Settlement Agreement, because such payment cannot be regarded as a compensation that is justified and that excludes the existence of a reverse payment.

(899) From Cephalon's perspective the payments according to Article 2.5 (b) and (c), that is GBP 2.1 million (approximately EUR 3 million) and EUR 2.5 million, being in total approximately EUR 5.5 million, do not have any other plausible explanation than Teva's inducement by Cephalon to commit to the non-compete and non-challenge commitments and should therefore be considered as an unjustified value transfer to Teva.

[1297] SO Reply, paragraph 165.

6.6.5. Teva Distribution Agreement

6.6.5.1. Introduction

(900) This Section assesses Cephalon's and Teva's incentives with respect to entering into the Teva Distribution Agreement at the time of the Settlement Agreement. This Section shows that the Teva Distribution Agreement likely generated value for Teva that it would not have been able to appropriate from Cephalon absent the Settlement Agreement. This Section also shows that the Teva Distribution Agreement had no other plausible explanation from Cephalon's perspective either. Accordingly, the Section concludes that the Teva Distribution Agreement served as an unjustified value transfer that induced Teva to enter into the Settlement Agreement.

6.6.5.2. Clause

(901) In accordance with Article 2.6 of the Settlement Agreement, Cephalon committed to appoint Teva UK (or another Teva subsidiary) as an exclusive distributor in the United Kingdom for "*all Cephalon Modafinil Product*"[1298] for a period of five years commencing on or about 1 July 2006. The implementing Teva Distribution Agreement was executed on 7 August 2006 and the actual distribution started in September 2006.[1299]

(902) According to Article 2.6 (a) of the Settlement Agreement (and Article 7.1 of the Teva Distribution Agreement), Cephalon undertook to supply its modafinil product to Teva at a price equal to 80% of Teva's actual resale price in the United Kingdom, after any deductions, discounts, credits, rebates, returns and allowances. In addition, pursuant to Article 2.6 (a)(i) of the Settlement Agreement Cephalon undertook to make a one-time payment of EUR 2.5 million to Teva upon Teva's commercial launch of Cephalon's modafinil product in the United Kingdom under the Teva Distribution Agreement, "*in recognition of the costs and expense involved in Teva's preparation for such launch and in recognition of the license to the Intellectual Property Rights*."[1300]

(903) In Article 2.6 (b) of the Settlement Agreement, the Parties undertook to "*consider in good faith*" whether a similar resale and distribution services arrangement as in the United Kingdom might be feasible in other countries.

6.6.5.3. Teva's interest

(904) Teva estimated the market value for the relevant modafinil products in the United Kingdom at roughly EUR 8 million annually. Teva also assessed the market as "*rapidly growing*" (see Recital (169)).

(905) Since Teva expected no generic entry before the end of the Teva Distribution Agreement in 2011 (that is to say that Cephalon's modafinil products would account

---

1298 The Settlement Agreement defines the Cephalon Modafinil Products as encompassing "*all finished pharmaceutical product that contain compound modafinil…, including without limitation Provigil, Sparlon and Nuvigil…*" This is in line with the definition of "*Product*" or "*Products*" in Article 1.1 of Teva Distribution Agreement. The distributed products were to be set out in Schedule 1 of the Teva Distribution Agreement, "*as automatically amended from time to time*". This Schedule included only 100 mg and 200 mg formulations of Provigil during the entire term of the Teva Distribution Agreement (that is to say Teva distributed only Provigil during that period; see also Recital (428)).

1299 See Section 4.6.3.6.

1300 ID 176. For the definition of the Intellectual Property Rights see Recitals (234)-(235).

for the total value of the market; see Recital (168)), it follows that Teva expected that sales of Cephalon's Modafinil Products for the five year duration of Teva Distribution Agreement would amount to at least EUR 40 million. Based on Article 2.6 (a) of the Settlement Agreement Teva was entitled to a margin of 20% of sales of Cephalon's Modafinil Products. Therefore, at the time of the Settlement Agreement Teva expected to earn at least EUR 8 million from the Teva Distribution Agreement.

(906) This Commission's finding is not contested by the Parties. In addition, actual sales of modafinil observed *ex post* provide further confirmation of Teva's expectations. During the Teva Distribution Agreement, total sales of Cephalon's modafinil products achieved by Teva UK amounted to approximately EUR 44.7 million with the marginal costs of distribution of EUR 36.5 million.[1301] The marginal costs of distribution included the price that Teva UK paid to Cephalon UK for the modafinil products[1302] (and on which it gained its 20% margin), and other cost related to the distribution (such as transport costs).[1303] Teva therefore earned a profit of EUR 8.2 million.

(907) In addition to the distribution margin, Teva received a one-time payment of EUR 2.5 million pursuant to Article 2.6 (a)(i) of the Settlement Agreement. The Parties failed to identify and specify any costs that Teva would have incurred in connection with this payment (see Section 4.7.5.3).

(908) Finally, contrary to the Parties' arguments, the fact that the Teva Distribution Agreement allowed Teva to act as a real distributor for Cephalon's modafinil or the fact that the terms of the Teva Distribution Agreement may be typical for pharmaceutical distribution agreements and might be negotiated at arm's length (*quod non*) would not alter the conclusion that the Teva Distribution Agreement contributed to inducing Teva to accept restrictive commitments in the context of the Settlement Agreement. The Parties here again promote a mechanical approach where each and every transaction encompassed within the Settlement Agreement is looked at in isolation and outside of its context. As shown in Section 6.3.4 and Section 4.5, all transactions in the Settlement Agreement, including the Teva Distribution Agreement, were contractually linked. As regards in particular the Teva Distribution Agreement, the one-time payment payable to Teva (see Recital (903)) was explicitly linked to Teva granting to Cephalon a licence to its Intellectual Property Rights (see Section 6.6.3.). Further, all transactions in the Settlement Agreement stood in intrinsic connection to each other in the mind of the Parties and were a consideration for Teva committing not to independently enter and compete in the modafinil markets. In this context, the fact that the specific terms of a particular transaction when looked in isolation may appear as resulting from the arm's length negotiations, is of no relevance. As explained above (Recital (701)), a profitable transaction can grant an abnormal economic advantage, not only if it is concluded at conditions more favourable than market terms, but also if under normal market conditions (absent the

---

1301 See Recital (436), Table 12. While Teva's expectations at the moment of concluding the Settlement Agreement, based on the terms of the Teva Distribution Agreement, are the relevant indication of Teva's incentive to enter into the agreement, actual sales of modafinil observed *ex post* provide further confirmation of the reasonableness of Teva's expectations.

1302 This price equalled to 80% of Teva's actual resale price in the United Kingdom pursuant to Article 2.6 of the Settlement Agreement, see Section 4.6.3.6.

1303 See Recital (436), Table 13.

settlement) the transaction would not have occurred, either at all or not at the same terms. In other words, the fact that a given transaction involves a real transfer of assets or provision of services, does not exclude that it represents a consideration for Teva's non-compete and non-challenge commitments, if under normal market conditions such transaction would not have been realised and there is no other plausible explanation for it other than the need to induce Teva into these commitments.

6.6.5.4. Cephalon's Interest

(909) Based on an analysis of Cephalon's interest, the Commission concludes, that the appointment of Teva UK as exclusive distributor of modafinil products in the United Kingdom and payments made in connection with this appointment do not appear to be the result of commercial negotiations between a supplier and a (potential) distributor, but instead had no other plausible explanation but to contribute to an unjustified value transfer that would induce Teva into concluding the Settlement Agreement.

Cephalon did not receive any value in exchange for the one-time payment

(910) Article 2.6 (a)(i) of the Settlement Agreement stipulates: "Upon Teva's commercial launch of Cephalon's modafinil product in the United Kingdom under this distribution agreement, Cephalon shall make a one-time payment of 2.5 million Euros to Teva Israel, in recognition of the costs and expense involved in Teva's preparation for such launch and in recognition of the license to the Intellectual Property Rights."[1304]

(911) Cephalon did not receive anything of value, or any commercial benefit in exchange for this one-time payment, or any part of it.

(912) First, the Parties themselves acknowledged to the Commission that the payment was not made as a consideration for licence to the Intellectual Property Rights although Article 2.6 (a)(i) of the Settlement Agreement indicates this as one of the reasons of the one-time payment.[1305] This acknowledgement is not surprising if one recalls that Cephalon was already a rightful holder of this licence pursuant to Article 2.2 of the Settlement Agreement and agreed to pay royalties to Teva in the maximum amount of USD 125 million (see Section 6.6.1.)

(913) Second, nothing in the contemporaneous evidence indicates (i) how the Parties determined Teva's "*costs and expense involved in Teva's preparation for [launch of Cephalon's modafinil product]*" that should have been compensated by Cephalon; (ii) what was the exact amount of these costs; or (iii) which services Cephalon could have expected from Teva against the payment of EUR 2.5 million.

(914) Teva's United Kingdom distribution model confirms that Teva did not provide services to Cephalon in connection with the launch, nor did it incur the distribution launch costs for which it was allegedly compensated by Cephalon. Teva's tasks as distributor under the Teva Distribution Agreement were limited to taking orders of

---

1304 The one-time payment was not stipulated in the Teva Distribution Agreement, but in the Settlement Agreement which set out on the one hand Teva's commitments not to compete with Cephalon's products and not to challenge its modafinil patents and on the other hand all payments and transactions between the Parties.

1305 See Recitals (443) for Cephalon and (446) for Teva.

customers, making orders to Cephalon, receiving the products from Cephalon, warehousing and storing the products and ensuring their transportation to customers. All other tasks including transportation of products to Teva's warehouse, packaging of products, marketing, advertising and promotion activities as well as holding and maintaining of MA were performed by Cephalon. In addition, Teva simply added Cephalon's modafinil product to its already existing distribution operations and existing list of products which were available for wholesalers and pharmacists to order.

(915) Finally, the Commission notes that the alleged reasons for the payment (compensation of Teva's costs and recognition of the licence to the Intellectual Property Rights) were added in the final version of the Settlement Agreement by Cephalon's antitrust counsel. The draft Settlement Agreement dated 6-7 December 2005 (that is one to two days before the signing of the Settlement Agreement) did not specify any reasons for Cephalon's one-time payment (see Recital (266).[1306]

The Parties never provided any specific explanation for the one-time payment

(916) Since the very beginning of the investigation, the Commission has repeatedly asked the Parties to explain the business rationale for the one-time payment. The Parties were not able to identify any services that Cephalon would have received in consideration of the one-time payment. They were also not able to specify how the amount was calculated or to show that Cephalon asked for any specification of Teva's costs during the negotiations of the Settlement Agreement (see Section 4.7.5.3).

(917) Moreover, the argument repeated by the Parties in their SO Reply – that the payment served to compensate Teva for costs of recall and destruction of certain stocks of Teva's generic products – confirms that the one-time payment indeed served as a consideration for Teva's non-compete and non-challenge commitments. By virtue of Article 2.5 of the Settlement Agreement Teva undertook, *inter alia*, not to sell any finished drug which has modafinil as an active ingredient in the United Kingdom (or any other country where Cephalon holds modafinil patent rights). An arrangement between the Parties to recall and/or destruct Teva's modafinil products would guarantee that the generic product was not in the market anymore and would amount to implementation of Teva's non-compete obligation. Dealing with the stock of Teva's generic modafinil (including product recall or destruction) has nothing to do with the distribution launch and Cephalon received no other commercial benefit from the withdrawal of Teva's product but for the implementation of the non-compete and non-challenge commitments of the Settlement Agreement.

1306 According to the draft Settlement Agreement of 6-7 December 2005, the provisions concerning Cephalon's obligation to appoint Teva UK as an exclusive distributor in the United Kingdom and the one-time payment formed part of Article 2.5 "*UK Action Settlement and UK Supply and Distribution Agreement*". In addition, the same draft Settlement Agreement provided that Cephalon should pay to Teva the amount of EUR 4 million (rather than EUR 2.5 million). As already explained (see Recital (894)), simultaneously with the decrease of the one-time payment in relation to the distribution arrangement under Article 2.6 (a)(i) of the Settlement Agreement by EUR 1.5 million, the Parties increased the amount payable to Teva under Article 2.5 (c) for avoiding potential future litigation in European and other markets (other than the United States and the United Kingdom) by the exact same amount of EUR 1.5 million. The total amount payable to Teva under these two provisions remained the same – EUR 5 million.

(918) In their SO Reply, the Parties also explain that they do not recall how the one-time payment was calculated and negotiated due to the passage of time and that almost 12 years after the facts at issue, Teva is not able to quantify the Provigil launch costs. According to the Parties, it seems that Teva did not separately allocate any portion of the EUR 2.5 million one-time payment to distinguish distribution, marketing, or licensing functions.

(919) However, contrary to the Parties' allegations, the Commission asked for explanations of the one-time payment for the first time already at the very beginning of the investigation (in the Article 18 Requests sent to the Parties in 2010 and 2011; see Section 4.7.5.3). Even then the Parties were not able to identify any value received by Cephalon in return for the one-time payment (for example, in terms of services provided by Teva) or specify any costs incurred by Teva that should be reimbursed by Cephalon (see Section 4.7.5.3).

Alternative ex post explanations of the one-time payment are not convincing

(920) As described in the preceding sections, (i) there is no contemporaneous evidence indicating what type of benefits Cephalon received in return for the one-time payment to Teva in the amount of EUR 2.5 million and (ii) the Parties never provided any specific explanation for this payment.

(921) In their SO Reply, the Parties however tried to explain that one-time payments are not uncommon in the pharmaceutical sector. According to the Parties, in 2003-2006, Teva was party to three other distribution agreements with up-front one-time payments.[1307]

(922) The Commission notes that the examples provided by the Parties are not comparable to the situation under the Settlement Agreement and cannot be used to justify the one-time payment. First, in two of the three distribution agreements with up-front payments mentioned by the Parties (one with Caber and the other with Combino), the payments were made from exclusive distributors to principals in consideration of the grant of the exclusivity. Hence, they were made in the opposite direction of the one-time payment under the Settlement Agreement which was made from Cephalon (principal) to Teva (distributor).

(923) Second, in the only example of one-time payment flowing from the principal to the distributor (agreement between Teva and […] which provided for an upfront payment of EUR 550,000; see Recital (445)), the reason for the up-front payment was to incentivise a non-exclusive distributor to promote sufficiently the supplier's product. It should be recalled that Teva UK was appointed as an exclusive distributor and did not need this type of additional incentive. The distribution agreement with […] therefore cannot be relied on for explaining the one-time payment pursuant to Article 2.6 (i) of the Settlement Agreement.

(924) The Parties continue to explain that up-front payments in connection with the entry of a supply, distribution, or licensing agreement can be negotiated for a variety of reasons, not necessarily in consideration for the performance of specific services. For example, a distributor can obtain a higher up-front payment in exchange for a lower percentage distribution margin on each unit sold or up-front payments may

[1307] See SO Reply, paragraph 132 and ID 1329. The Commission relies on the information provided by the Parties and in the table (ID 1329) produced by Teva.

encourage distributors to promote the products or offset the risk faced by the distributor. The Parties also claim that both of these explanations are likely applicable to the Teva Distribution Agreement.

(925) These alternative explanations are not convincing. They are presented as purely hypothetical reasons for any up-front payment that may or may not appear in any distribution agreement. Given that these explanations are not detailed in relation to the Teva Distribution Agreement and not based on contemporaneous evidence or otherwise substantiated and supported by evidence, they remain speculative. Moreover, these alternative explanations are different from and not related to the grounds for payment laid down in Article 2.6 of the Settlement Agreement or in the explanations presented by Teva and Cephalon during the investigations. These explanations retroactively add new elements that were not foreseen and not manifested at the time of conclusion of the Settlement Agreement and can accordingly not reflect the Parties' considerations at that time.

(926) In the Commission's view, the lack of any contemporaneous information on the calculation of the one-time payment is a strong indication for the artificial and ex post character of the justifications (both those incorporated in the Settlement Agreement and those raised by the Parties) for the one-time payment. They are therefore not plausible.

Cephalon did not select Teva as the most commercially suitable option

(927) Between 2000 and 2006, Cephalon used […] as distributor of Provigil in the United Kingdom on the basis of the […] Distribution Agreement, within a broader collaboration between Cephalon and […] (the […] Collaboration, see Section 4.1.3). The Collaboration Agreement, together with the […] Distribution Agreement, was formally terminated by […] (see Recital (174)).

(928) Contrary to the Parties' assertion set out in the SO Reply,[1308] the Commission does not allege that the termination of the […] Collaboration was motivated by the desire to appoint Teva as distributor in the United Kingdom. As described in detail in this Decision (see Sections 4.1.3 and 4.3.2), the termination of the […] Collaboration was […]. The Commission does not dispute that the imminent termination of […] might have therefore created a legitimate business need for Cephalon to appoint a new distributor.

(929) However, this does not in any way affect the Commission's conclusion that Cephalon selected Teva as a part of the consideration for Teva's acceptance of the non-compete and non-challenge commitments under the Settlement Agreement.

(930) More specifically, Teva was Cephalon's closest competitor at the time of the Settlement Agreement. From Cephalon's perspective, Teva had launched generic modafinil in violation of Cephalon's patents thus jeopardizing Cephalon's most important product (Provigil) and had to be enjoined by Cephalon. In the Commission's view, outsourcing the distribution of modafinil products to the biggest rival on the market would create a conflict of interest. Absent Teva's non-compete and non-challenge clauses that effectively put an end to Teva's independent modafinil activities worldwide (including the United Kingdom), it would not appear economically rational for Cephalon to grant the distribution of modafinil products to

[1308] ID 3763, points 5 and 6.

Teva, the closest competitor and rival on the market for modafinil in the United Kingdom.

(931) However, under the Settlement Agreement Cephalon instantaneously undertook to appoint Teva as its modafinil distributor in the United Kingdom without even considering any other possible solutions. It should also be recalled that it was Teva who contacted Cephalon after the start of the United Kingdom litigation in July 2005 with the proposal to settle the litigation in exchange for, *inter alia*, Teva becoming a distributor of Cephalon's product on a profit sharing basis.[1309]

(932) The Parties never submitted any evidence that Cephalon actively looked for alternative distributors, organized a tender (or otherwise invited potential candidates to manifest their interest) or attempted to obtain any alternative offers to compare and assess Teva's proposal.

(933) Contrary to the Parties' allegations in the SO Reply, the Commission does not claim that Cephalon should have organized a tender for modafinil distribution. However, the Commission notes that without evidence of Cephalon soliciting and considering alternative options to Teva (even if for the sole purpose of leveraging Teva into offering better distribution conditions) and without any due diligence having been conducted (which would be the standard commercial approach) the Parties' arguments that Teva was selected as the most suitable option are not credible.

(934) In their SO Reply, the Parties acknowledge that from Cephalon's perspective, concluding the Teva Distribution Agreement while patent litigation on Cephalon's main product was pending would not have been economically rational. In that regard, the Teva Distribution Agreement was indeed depending upon the Settlement Agreement.

(935) However, the Parties further explain that once it was clear that Teva and Cephalon would conclude the Settlement Agreement, Teva was an attractive distribution partner in the United Kingdom: Teva had launched its own modafinil product prior to being enjoined. The Parties also argue that Teva's expertise and experience was confirmed by […].

(936) The Parties' arguments are not convincing. According to the Parties, it was the fact that Teva had launched its generic modafinil that made Teva an attractive distribution partner. However, the Parties failed to submit any contemporaneous evidence suggesting that Cephalon considered this characteristic as attractive. In addition, none of the other Cephalon's European distributors for modafinil, even those that were assigned multiple countries such as […] or […] (see Recital (109)) had its generic modafinil product launched before becoming Cephalon's distributor.

(937) As to the Parties' claim that Teva's expertise and experience was confirmed by impressive growth in modafinil sales, it should be recalled that the Teva Distribution Agreement restricted Teva's role and that it was Cephalon who was responsible for all marketing, advertising and promotion activities. In this context, any increase in modafinil market in the United Kingdom is more likely the consequences of Cephalon's rather than of Teva's activities.

1309 See Section 4.4.2.

Cephalon did not appoint Teva as modafinil distributor in any other European country

(938) Article 2.6 (b) of the Settlement Agreement provides that the Parties should also consider "*in good faith*" whether a similar resale and distribution services arrangement as in the United Kingdom might be feasible in other countries (see Recital (247). However, no other distribution agreement between Cephalon and Teva was ever concluded.

(939) Teva showed an interest in such distribution agreements and wrote to Cephalon on 12 January 2006: "(W)e have been discussing the situation with colleagues [at Teva] regarding the rest of Europe (clause 2.6.(b)). We need the name of a commercial contact within Cephalon… to take forward not just the UK agreement but also possible similar arrangements in Europe. Therefore I would be grateful if you would provide the name of this commercial contact as soon as possible…" However, following this inquiry, Cephalon's Vice-President and Associate General Counsel addressed colleagues at Cephalon with an e-mail of 13 January: "Our obligation is pretty soft in this area. The fact that Teva has brought up the idea I think requires us to talk with them, but no more. I do not believe that we expected that we would actually enter into any of these arrangements."[1310]

(940) It is clear from this evidence that Cephalon, once it had achieved to obtain Teva's non-compete and non-challenge commitments in the Settlement Agreement, did not have any real interest in, and did not seriously consider, appointing Teva as a distributor outside of its obligations under the Settlement Agreement. This further shows that Cephalon did not see Teva as an attractive candidate for becoming its distributor and that the Teva Distribution Agreement was not the result of a normal commercial relationship but instead, had all the features of a consideration, paid by Cephalon, which contributed to inducing Teva not to independently enter modafinil markets and compete with Cephalon.[1311]

Through the Teva Distribution Agreement Cephalon monitored Teva's compliance with the non-compete and non-challenge commitments

(941) The terms of the Teva Distribution Agreement supported the non-compete and non-challenge commitments assumed by Teva in the Settlement Agreement. First, Teva was appointed as the exclusive distributor in the United Kingdom with a guaranteed margin. This provided additional incentive to Teva not to challenge Cephalon's patents. The continuing existence of these patents strengthened Teva's ability to share with Cephalon its monopoly rents from a high-price product in the market without competition. On the other hand, a potential invalidation of Cephalon's patents (see Section 4.3) would attract other generic competitors, and this would inevitably lead to a price drop, loss of market shares and hence to erosion not only of Cephalon's revenues as manufacturer but also of Teva' revenues as a distributor.

1310 ID 2144-9, p. 1-2.

1311 According to the Parties, the distribution in the rest of the EEA is not relevant to assessing Teva's role as a distributor in the United Kingdom. However, the Commission does not assess Teva's role as distributor in the United Kingdom, but rather Cephalon's interest in appointing Teva as a distributor in the context of the Settlement Agreement. The Commission assesses the role played by the Teva Distribution Agreement in the settlement arrangement and comes to the conclusion that the transaction contributed to value transfer that was a consideration for Teva to enter into the non-compete and non-challenge commitments under the Settlement Agreement.

(942) Second, the termination clauses of Article 2.6 (b) of the Settlement Agreement and Article 12.2 of the Teva Distribution Agreement made sure that Teva's launch of its own modafinil product would lead to the termination of the Teva Distribution Agreement. The construction envisaged by the Settlement Agreement (as implemented by the Teva Distribution Agreement) also anticipated a smooth transition for Teva from the position of Cephalon's exclusive distributor until 2011 to Cephalon's licensee from 2012, in the market protected by Cephalon's modafinil patents until 2015. The conclusion of the Teva Distribution Agreement on the terms laid down in the Settlement Agreement (and in the Teva Distribution Agreement itself) was therefore in Cephalon's interest in the sense of offering Teva an attractive business deal as part of the consideration for its obligation not to enter as an independent competitor in the modafinil markets.

Cephalon's own characterisation of the Teva Distribution Agreement confirms the Commission's findings

(943) In its assessment of the Settlement Agreement and Teva's appointment as an exclusive distributor, Cephalon was always clear that Teva's United Kingdom distribution rights form part of the consideration of the Settlement Agreement. Contemporaneous evidence makes this connection very explicitly (see Section 4.7.5.1).

(944) For example, on 8 December 2005 (the day of signing of the Settlement Agreement) Cephalon's attorney commented to the Chief Legal Counsel of Cephalon Europe and another Cephalon Europe's attorney in an email entitled "*Teva/Cephalon – Draft Agreement*" that "*the consideration in the UK includes a distribution and supply agreement, which would be effective once the […] arrangements are concluded in the UK in July*.q".[1312] Similarly, Cephalon's presentation prepared for the United Kingdom sales review of August 2006 and for the Provigil Marketing Plan of September 2006 concludes: "*In UK Teva will distribute Provigil and in return will not launch a generic modafinil until 2012.*"[1313]

(945) The Commission therefore concludes that the appointment of Teva UK by Cephalon as its exclusive distributor of modafinil products in the United Kingdom and payments made in connection with this appointment can be plausibly explained only in the broader context of the Settlement Agreement as contributing to consideration for Teva to enter into the non-compete and non-challenge commitments. The alleged alternative explanations offered by the Parties are not plausible.

6.6.5.5. Conclusion

(946) The assessment above shows that the Teva Distribution Agreement was valuable for Teva because Teva expected to earn at least the amount of EUR 10.5 million based on its appointment as exclusive distributor in the United Kingdom (that is one-time payment of EUR 2.5 million and EUR 8 million profits as a distributor), which under normal market conditions it would not have been able to obtain, at least not for the full amount, absent the Settlement Agreement. The facts also strongly indicate that, from Cephalon's perspective, the transaction does not have any other plausible explanation other than Teva's inducement into concluding the Settlement Agreement. As such, the transaction has, therefore, contributed to the unjustified value transfer that was a consideration for Teva to enter into the commitments in the broader context of the Settlement Agreement.

6.7. The package of transactions was a consideration for the non-compete and non-challenge commitments

(947) Section 6 demonstrated that the transactions in Article 2 of the Settlement Agreement (that is the transactions on the Licence to Teva's Intellectual Property Rights, the licence to CEP-1347 data, the Modafinil API Supply Agreement, the cash payments for litigation costs and the Teva Distribution Agreement) led to an overall transfer of value that was unjustified as the transactions did not have another plausible explanation than to serve as an inducement of Teva. The present Section shows that

---

1312 ID 277, p. 57. The email included an attachment that was entitled "*discussion draft — cephalon and teva — provigil — dec 7--6pm.DOC*".

1313 ID 224, p. 3; ID 226, p. 7. See also ID 264, p. 15. See also Recital (192).

value transfer, irrespective of its exact quantification, represented a consideration, a *quid pro quo*, which was sufficient for Teva to enter into the non-compete and non-challenge commitments of the Settlement Agreement. Contrary to the claim of the Parties, the Commission does not only base its conclusion on the mere concurrence of the value transfer and the Settlement Agreement. Rather the link between the package of transactions leading to a significant value transfer, on the one hand, and the non-compete and non-challenge commitments, on the other, is evidenced by the conduct of the negotiations regarding the package of transactions, the wording of the Settlement Agreement, and especially the Parties' own contemporaneous views of the package of transactions.

(948) First, as it was shown in Section 6.3.4, all individual transactions under the Settlement Agreement were negotiated at the same time and in an interrelated manner with a view of reaching a comprehensive Settlement Agreement.

(949) The Parties were discussing various options for those *in principle* unrelated transactions in order to arrive at a certain overall value to be transferred from Cephalon to Teva that Teva viewed as sufficient consideration for making its non-compete and non-challenge commitments under the Settlement Agreement. This value transfer did not reflect Cephalon's commercial gains from the transactions but rather served to reward Teva for staying out of the modafinil markets with its generic product. The fact that different building blocks with different content were contemplated, discussed and modulated in the negotiations on the Settlement Agreement in order to reach a certain overall level,[1314] indicates that Cephalon aimed at proposals that, as a whole, would offer Teva a sufficient value to agree to the non-compete and non-challenge commitments. To this end, various value options were conceived, and sometimes dismissed, during the negotiations. Cephalon tried to compile a number of transactions that would be enough to induce Teva to enter into the Settlement Agreement containing the non-compete and non-challenge commitments. In turn, Teva aimed at achieving a combination of transactions that, as a whole, it perceived as sufficiently beneficial to accept the non-compete and non-challenge commitments. Teva was trying to "*get*" a relative large value from these transactions because the Settlement Agreement concerned a relatively "*big product*" that "*Teva started selling a while ago*".[1315]

(950) Both Teva and Cephalon contemplated which alternative side deals could be concluded. Evidence on file includes Teva considering internally, for example, API production, access to clinical data and entry in certain modafinil markets at various possible dates as transactions that could be concluded (see Section 4.5.1). Cephalon considered, for example, that API production in certain cancer medicines or sterile injectables would be a fit for Teva. Various potential transactions were discussed (See Sections 4.5 and 6.3.4). These were considered and contemplated as "*moving parts"*, as Teva´s chief negotiator called them, during the negotiations.[1316] By way of example, the Parties simultaneously (that is to say in the same draft the Settlement Agreement of 6-7 December 2005) decreased the one-time payment under

---

1314 Teva's negotiator for instance noted: "*In the end there are several moving parts here, each representing a different value proposition, and we will lose leverage in my opinion if we don't work in a comprehensive manner*" (ID 979, p. 36).

1315 ID 146, p. 1.

1316 ID 979, p. 36.

Article 2.6 (a)(i) of the Settlement Agreement for EUR 1.5 million and increased the amount payable to Teva under Article 2.5 (c) for avoiding potential future litigation in European and other markets (other than the United States and the United Kingdom) for the exact same amount of EUR 1.5 million. The total amount payable to Teva under these two provisions remained the same: EUR 5 million (see Recital (894).

(951) Teva enjoyed a strong negotiating position towards Cephalon. This was due to various factors, including Cephalon's uncertainty about the outcome of the patent litigation against Teva's confidence about its own patent position, Teva's actual entry of Teva in the United Kingdom, and Teva's position as multi-product company for which modafinil products were not an as essential part of its product portfolio as it was for Cephalon, for which Provigil had indeed existential value for its business. Based on this position of strength, Teva was confident that it could attain the value it was aiming at in exchange for its non-compete and non-challenge commitments. In this light, Teva took the initiative concerning the kind and size of the transactions traded in the negotiations, outlined to Cephalon its desired outcome and was able to assert its negotiation goals.[1317]

(952) Second, the aim of the negotiations was reflected in the wording of the Settlement Agreement itself, which shows that the conclusion of the transactions and the ensuing transfer of value were a consideration by Cephalon for Teva entering into the non-compete and non-challenge commitments.

(953) Thus the Preamble of the Settlement Agreement clarified the Parties' aim and this interlinkage of the transactions: "Whereas, to avoid the time and expense of further litigation, and in compromise of the disputed claims set forth above[1318] the parties now desire to resolve their disputes on a worldwide basis, including, but not limited to, with respect to the litigation matters pending in the United States and the United Kingdom, by settlement and to enter into such licensing or other commercial arrangements as shall fairly effect an amicable resolution of such unfiled disputes to avoid the time and expense of future potential litigation" (emphasis added).

(954) Furthermore, according to Article 2.1, the Settlement Agreement "*includes a settlement which is a compromise of disputed claims*". Article 2.1 then continues to state that as an incentive to *"Cephalon to enter into this settlement, in consideration of the terms hereof, Teva hereby warrants, represents and agrees that Teva"* [does not independently enter and compete in the United States]. In addition, under Article 2.2 (a) Cephalon committed not to challenge Teva's Intellectual Property Rights "*[a]s an express inducement to Teva to enter into* [the Settlement Agreement]*, in consideration of the terms hereof*" (see Sections 4.6.3.2 and 6.6.3). Article 2.5 then subsequently defines that the same settlement includes a non-compete for the United Kingdom and other markets. The Settlement Agreement is hence formulated in a way that the non-compete and non-challenge clauses were agreed to in consideration of the transactions taken as a whole.

1317 By way of example, with regard to the binding Cephalon's commitment to purchase fixed modafinil API volumes, see Section 4.5.

1318 "[Disputed] *claims set forth above*" means Cephalon's and Teva's modafinil-related patent rights described in preceding Recitals of the Preamble. See Section 4.6.2. Footnote added by the European Commission.

(955) Third, also Cephalon's internal view on the Settlement Agreement explicitly acknowledged that the transactions were considerations given to Teva in exchange for its acceptance of the terms of the Settlement Agreement. In this context, Cephalon's Board of Directors considered (on 1 December 2005) that reversed payments to the generic competitors may be restricting competition: "*Increasing number of generic patent infringement lawsuit settlements driven by desire for certainty. FTC has indicated its displeasure with certain of these settlements (e.g. those involving payments to generic firms), but several US Courts of Appeals have sided with proprietary firms and upheld these arrangements. US Supreme Court has not yet decided whether to review 11th Circuit case involving Schering-Plough. Although outright payments to generic firms will be viewed as suspect, it is permissible to structure terms at arms' length related to other business interests between the companies (e.g. manufacturing, licensure, other disputes)*."[1319] Cephalon was therefore well aware that "*outright payments*" to the generic competitors are "*suspect*". However, as shown in the Section 6.6, Cephalon nevertheless decided to proceed with transfer of value to Teva through transactions "*related to other business interests between the companies*" that it incorrectly characterized as "*permissible*".[1320]

(956) The draft note to the 2006 accounts of Cephalon UK, drawn up in June 2008, stated[1321]: "As part of the settlement, certain payments were made (…) in respect of, inter alia, a non-exclusive worldwide license to certain intellectual property rights held by Teva group companies related to Modafinil, and the savings inuring to Cephalon" The draft note was reviewed by Cephalon's in-house counsel who commented: "(…) You could also want to note that… we entered a modafinil supply arrangement as part of the consideration for the settlement."[1322]

(957) The minutes of the meeting of the Central Worker's Council of Cephalon France of 18 September 2008 also confirmed that: "(…) since 2003, challenge of the validity of the modafinil patents by the generics in the US and filing of their approval applications. Potential risk of loss of 65% of the revenues in 12 months, or approximately USD 350 million. In 2006, hence, settlement agreement is concluded with the generics which temporarily protect the product until 2011 (no generic entry

---

1319 ID 2144-48, p. 2. Cephalon's legal assessment was based on its knowledge of the United States law and the enforcement practice of the United States FTC. The Commission recalls in this context that the Settlement Agreement is worldwide in nature, covering United States, EEA and other markets, but that at the time relevant for the present proceedings more than 90% of worldwide sales of Cephalon's modafinil products were realized in the United States, with the rest essentially in the EEA. From the business point of view, the centre of gravity of the Settlement Agreement laid in the United States.

1320 See also Judgment of 18 June 2013, *Schenker & Co. and Others*, C-681/11, EU:C:2013:404, paragraph 38 confirming that "*the fact that the undertaking concerned has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine in so far as it could not be unaware of the anticompetitive nature of that conduct.*"

1321 The employee of Cephalon United Kingdom involved in the drafting of the above-mentioned 2006 accounts, had difficulties with understanding the transaction: "*(…) how come the Company started* [patent infringement] *proceedings* [against Teva] *but in the end paid the defendants of the case… Please can you clarify if the fee paid was for non-compete arrangement (…)?*"[1321]

1322 ID 189, p. 85.

in the US market). In return for this, the generic manufacture a part of active pharmaceutical ingredient for Cephalon."[1323]

(958) Cephalon's attorney commented on the draft Settlement Agreement: "[The Agreement] is designed to settle both the United States and United Kingdom litigation and to settle any as yet unfiled disputes that may arise in Europe or elsewhere (assuming we have patents in those markets). However, as I believe […] is aware, the consideration in the United Kingdom includes a distribution and supply agreement, which would be effective once the […] arrangements are concluded in the United Kingdom in July."[1324] The same is evidenced in a presentation prepared for United Kingdom sales review of August 2006 and for Provigil Marketing Plan of September 2006: "Agreement made with major generic houses in United States and Europe. In United Kingdom Teva will distribute Provigil and in return will not launch a generic modafinil until 2012."[1325] (See Recitals (431) or (433) regarding Teva Distribution Agreement).

(959) These statements confirm that Cephalon regarded the package of transactions as consideration for the non-compete and non-challenge and the value that was embedded in the transactions aimed at inducing Teva to enter into these commitments.

(960) Also from the perspective of Teva it is clear that the transactions were regarded as consideration for Teva's commitments not to independently enter and compete in the markets for modafinil. The Settlement Agreement gave Teva, through the package of transactions in Article 2, the value that it wanted to gain. At the moment of concluding the Settlement Agreement, Teva perceived this package as a whole as sufficiently beneficial to accept the non-compete and non-challenge commitments, irrespective of how much each transaction actually contributed to the overall value of the package of transactions and irrespective of its precise quantification. Teva's immediate internal reactions to the result of the negotiations on the Settlement Agreement show satisfaction with the "*great job*" done and the "*good deal*" for the company.[1326] In a presentation to Teva's Board of Directors two weeks after the conclusion of the Settlement Agreement, Teva's CEO presented that:

"In fashioning this deal we applied much of what we learned about their strategic needs and their life cycle options, combined with our increased understanding of how to apply our own corporate resources in an integrated way.

What did we achieve?

(1) We settled patent disputes in the US and UK

1323 ID 1604, p. 3: "*Menace Générique sur Provigil aux US : dès 2003 contestation sur la validité des brevets de modafinil par des génériques aux US et dépôt de dossiers d'enregistrement. Risques potentiels de perte de 65% du CA en 12 mois, soit environ 350 millions USD. En 2006, un accord transactionnel est donc conclu avec les génériques protégeant provisoirement le produit jusqu'en 2011 (pas d'entrée de générique sur le Marché US). En contre parti les génériques produisent une partie du produit actif pour Cephalon.*"

1324 ID 277, p. 57.

1325 ID 224, p. 3; ID 226, p. 7. See also ID 264, p. 15.

1326 See Recital (207). Concerning specifically the royalty sum of USD 125 million for the licence to Teva's Intellectual Property Rights, the Senior Assistant of Teva's General Patent Counsel voiced its surprise: (*I)t sounds like they are paying a huge sum for our IP (30MM plus royalties?!) Am I missing something here? Or could we have got more?*" ID 979, p. 37.

(2) We cross licensed-obtaining rights to their modafinil, and giving Cephalon rights to our API patents.

(3) We will receive fees of over $30 million

(4) We will receive royalties on their brand (including any life cycle extensions they launch)

(5) We signed an agreement to supply raw material

Our increased understanding of the complexity of our environment as well as of the needs of our innovators and generic competitors helps us to bring these [types] *of solutions.*"[1327]

(961) This shows that Teva considered the various transactions to be a consideration that was achieved in the 'deal' and that the (unjustified) value obtained through the transactions considered as a whole led Teva to accept the non-compete and non-challenge commitments, which were the sole consideration for the value transfer. Irrespective of the specific contribution of the different transactions and of the exact quantification of this value transfer, it was sufficiently significant for Teva to accept those anticompetitive commitments.[1328]

(962) The Parties misrepresent and simplify the Commission's comprehensive assessments by claiming that the Commission infers the restrictive object of the Settlement Agreement solely from the existence of the "*value transfer*" which distorts the settlement process. The Commission notes that the existence of a significant and non-justified value transfer from the originator to the generic distorts the generic's assessment of whether or not to settle (a decision that should be based on "*assessing its chances of success in the court"*[1329]) is indeed one of the relevant factors taken into account in assessment of the settlement agreements. An agreement by which a generic undertaking accepts to give up its independent efforts to enter the market for a certain period of time in exchange for the transfer of a considerable value, thereby eliminating potential competition, in principle falls under Article 101 TFEU.[1330]

(963) The evidence on the file point to this exact conclusion: Cephalon paid Teva to give up its independent efforts to enter the modafinil markets in the By-Object countries. Value transfers in the Settlement Agreement amount to payments for market "exclusion". This conclusion is arrived at only after careful assessment of multiple factors outlined in Section 6.8.

6.8. Conclusion regarding the value transfer that was a significant inducement not to compete

(964) As shown in Sections 6.6 and 6.7, the package of transactions included in Article 2 of the Settlement Agreement (namely the transactions on the Licence to Teva's Intellectual Property Rights, the licence to CEP-1347 data, the Modafinil Supply Agreement, the cash payments for litigation costs and the Teva Distribution

---

1327 ID 2166-97, p. 13-14.

1328 The Commission notes that this would be valid even if some of the transactions were not considered to specifically contribute to the value transfer embedded in the overall package of transactions, which was in any event regarded by Teva as sufficient for accepting the non-compete and non-challenge commitments, regardless of how much each individual transaction contributed.

1329 Case C-307/18, *Generics (UK) and Others*, paragraph 84.

1330 See Recital (564).

Agreement) transferred value to Teva which was a consideration paid by Cephalon to Teva in exchange of entering into the non-compete and non-challenge commitments of the Settlement Agreement.

(965) On the basis of a thorough consideration of all available evidence and, in particular, after careful assessment of the alternative explanations put forward by the Parties, the Commission considers that Cephalon would not have entered, just after expiry of its main patents in Europe, into these transactions with its most advanced generic rival absent the Settlement Agreement, either not at all or at least not at the same terms. Conversely, under normal circumstances, namely absent the Settlement Agreement, Teva would not have obtained the value it received through this package of transactions. Absent the value transfer embedded in the package of transactions, Teva would not have accepted the commitment not to independently enter and compete in the market and not to challenge Cephalon's modafinil property rights. The package of transactions has no plausible explanation other than the commercial interest of the Parties not to engage in competition on the merits, and therefore the embedded transfer of value represents an unjustified net gain[1331] for Teva. Contrary to the Parties' suggestion, the fact that it was not only the originator (Cephalon) that took the initiative to start discussions does not alter this assessment: the result was that Teva's incentives were changed through the Settlement Agreement.

(966) It is not possible to quantify precisely in pecuniary terms the value transferred to Teva through the package of transactions. Such exact quantification is in any case not necessary for a conclusion that the value transfer was indeed a significant inducement not to compete: all that matters is that the package of transactions is shown to be sufficiently beneficial to induce the generic undertaking to refrain from entering the market, accepting the non-compete and non-challenge commitments.[1332] It is also not necessary that the value transferred exceeds the gains expected by the generic undertaking from entering the market.[1333]

(967) However, based on both contemporary and ex post evidence, the Commission conservatively and broadly estimates that through this package of transactions Teva could have expected to obtain (and indeed obtained) a net gain well exceeding EUR 100 million for those transactions whose value could broadly be estimated in pecuniary terms (the purchase by Cephalon of Teva's Intellectual Property Rights, the Modafinil Supply Agreement, the payments for avoided litigation costs and the Teva Distribution Agreement).[1334] The value obtained through Cephalon's licence to the CEP-1347 Data is more difficult to estimate in pecuniary terms, but was considered by Teva important in the negotiation of the Settlement Agreement and clearly contributed to induce Teva to accept the non-compete and non-challenge commitments (see also Sections 4.7.2 and 6.6.2.2).

1331 As discussed in Case C-307/18, *Generics (UK) and Others*, paragraph 92.

1332 Case C-307/18, *Generics (UK) and Others*, paragraph 94.

1333 Ibid.

1334 The amount is calculated in the following manner: (i) the net gain that Teva received with respect to the purchase by Cephalon of Teva's Intellectual Property Rights is approximately EUR 90 million. (Section 6.6.3.3); (ii) the net gain that Teva received with respect to the purchase by Cephalon of Teva's modafinil API is approximately EUR 5 million (Section 6.6.1.3); (iii) the net gain that Teva received with respect to the avoided litigation costs is approximately EUR 5.5 million (Section 6.6.4.3); and (iv) the net gain that Teva received with respect to distribution of Cephalon's modafinil product in the United Kingdom is approximately EUR 10.5 million (Section 6.6.5.3).

(968) Moreover, through the Settlement Agreement, Teva gained not only the value that was transferred through the package of transactions, but also the upfront certainty to earn this value without the associated business risks of actually entering the modafinil markets and the risks resulting from potential competition from other generics and Cephalon. [1335]

(969) The analysis of the negotiations between the Parties, the wording of the Settlement Agreement and the Parties' own views of the package of transactions, confirms that the sole consideration for the value transfer arising from the financial and economic advantages given to Teva are the non-compete and non-challenge commitments entered into by Teva. The Parties compiled this value transfer by contemplating various in principle unrelated transactions in order to reach a certain level that was sufficiently beneficial to induce Teva not to independently enter and compete in the market for modafinil and not to challenge Cephalon's modafinil property rights. It was the overall package that was considered sufficiently beneficial to induce Teva to accept the non-compete and non-challenge commitments, irrespective of how much each transaction individually and actually contributed to the overall value of the package and of the precise quantification thereof.

(970) The Parties claim that conditionality of the transactions is not sufficient for transactions to serve as a value transfer. The Parties also claim that the Commission fails to support the conclusion that the transactions were not justified and that their terms did not reflect arm's length negotiations. Contrary to the Parties' assertions, the above assessment of each transaction in Section 6.6, from the perspective of both Teva's and Cephalon's interest shows that the Settlement Agreement granted advantages given to Teva, which it could not have obtained outside of the context of the Settlement Agreement, by Cephalon, which would likewise not have granted such advantages absent the Settlement Agreement. These advantages, i.e an unjustified net gain obtained by Teva, formed an inducement to accept the non-compete and non-challenge undertakings set out in the Settlement Agreement. In other words, the above assessment reveals exactly what the Parties onerously claim is missing from the Commission's analysis: that the transactions would not have been concluded at all or on the same terms absent the Settlement Agreement and its restrictive covenants.

(971) The Settlement Agreement prompted a value transfer between Cephalon and Teva in return for which Teva committed not to independently enter and compete in the markets for modafinil. In doing so, the Parties replaced the risks of competition with a practical cooperation between them consisting of an agreement that Teva would refrain from independently entering modafinil markets and competing with Cephalon.[1336]

1335 Case C-307/18, *Generics (UK) and Others*, paragraph 94.

1336 The Parties also note that in *Groupement des cartes bancaires* (paragraph 81) the Court also concluded that in case of "the uncertainty as to the nature of the agreement" the Commission should pursue a by-effects analysis and that the Settlement Agreement stands in stark contrast with the cartel agreements since it was completed to resolve bona-fide patent litigation. In addition, the Parties assert that *Groupement des cartes bancaires* and *Intel* imply that when the competitive impact of the conduct, by virtue of its content and the relevant market circumstances, may reasonably be ambiguous, the Commission is obliged to carry out a thorough analysis of its likely effects. These Parties' arguments are not convincing. First, after careful assessment of the economic and legal context of the Settlement Agreement, content and objective of the Settlement Agreement as well as of the intentions of the

(972) Based on the above considerations, the Commission concludes that the value transfer embedded in the transactions in Article 2 of the Settlement Agreement was a significant inducement of Teva. This value transfer was a consideration paid by Cephalon to Teva and that constituted actually the sole consideration for Teva to accept to no longer independently pursue its efforts to enter one or more EEA markets with its generic modafinil product.

(973) As the Court of Justice emphasised, "taking into account the uncertainty as to the outcome of those proceedings, there is no requirement that the transfers of value should necessarily be greater than the profits which the manufacturer of generic medicines would have made if it had been successful in the patent proceedings. All that matters is that those transfers of value are shown to be sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits with the manufacturer of originator medicines concerned"[1337].

6.9. No pro-competitive effects raising doubts on the characterisation as a restriction "by object"

(974) This Section explains that there are no pro-competitive effects stemming from the Settlement Agreement that would be demonstrated, relevant, sufficiently significant and not uncertain to give rise to a reasonable doubt as to its anticompetitive object.

(975) First, the Section addresses the Teva Generic Rights and shows that the non-exclusive licence granted to Teva by Cephalon to enter the modafinil market as of 2012 is far from entailing relevant, sufficiently significant and not uncertain pro-competitive effects (Section 6.9.1). On the contrary, the Teva Generic Rights shielded Cephalon from independent unrestricted generic competition and thereby contributed to the restrictions created by the Settlement Agreement. Second, this Section shows that the commercial transactions concluded between Cephalon and Teva and included in Article 2 of the Settlement Agreement as well as the settlement of the patent dispute between Cephalon and Teva as such do not involve any pro-competitive effects that are demonstrated, relevant, sufficiently significant and not uncertain (Section 6.9.2).

Parties, the Commission concludes that under the Settlement Agreement Cephalon paid Teva to keep it off the market and reduce the risks of competition. There is therefore no uncertainty as to the nature of the Settlement Agreement which is "*comparable to market exclusion agreements, which are among the most serious restrictions of competition. The exclusion of competitors from the market constitutes an extreme form of market sharing or of limitation of production*." In addition, the Settlement Agreement simply did not have "ambivalent effects" as the Parties assert. In any event, nowhere in *Groupement des cartes bancaires* did the Court of Justice adopt the view that agreements with ambivalent effects on the market should not (even if they are market-sharing agreements) be regarded as by object restrictions. That proposition is inconsistent with the case-law expressly relied on by the Court of Justice in *Groupement des cartes bancaires* (*Irish Beef*, *Allianz*) and with its subsequent judgment in *ING*. Finally, Advocate General Wahl pointed out in his Opinion in *Groupement des cartes bancaires* that that case did not concern market-sharing arrangements (where, as he accepted, it was "well established" that they "entail[ed] a restriction of competition by object". (Opinion of Advocate General Wahl of 27 March 2014 in Case C-67/13 P, *Groupement des cartes bancaires (CB) v Commission*, EU:C:2014:1958, paragraph 81).

1337 Case C-307/18, *Generics (UK) and Others*, paragraph 94, see also Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraph 120.

6.9.1. The Teva Generic Rights do not involve demonstrated, sufficiently significant and not uncertain pro-competitive effects

(976) The Teva Generic Rights do not involve demonstrated, sufficiently significant and not uncertain pro-competitive effects, that is to say effects capable of putting into question the by object character of the restriction of competition at issue. Instead, the Teva Generic Rights actually shielded Cephalon from immediate and full-fledged independent generic competition and allowed both Parties to soften competition on the modafinil market to their benefit.

6.9.1.1. The Teva Generic Rights would have led only to delayed and controlled entry

(977) The granting of the Teva Generic Rights allowed Cephalon to replace the uncertainty and the potential imminence of Teva's entry into the modafinil markets with the certainty of (i) no entry until 2012[1338] and (ii) only limited and controlled entry of Teva under Cephalon's licence as of 2012. The Teva Generic Rights, therefore, delayed Teva's entry until 2012 and as of 2012 allowed Teva to enter the modafinil market but not as an independent generic entrant, namely an entrant that would embark on head-to-head competition with Cephalon. Accordingly, already as such the Teva Generic Rights cannot be said to have pro-competitive effects that would be demonstrated, sufficiently significant and not uncertain.

(978) As explained in Section 6.4, absent the Settlement Agreement, Teva had real and concrete possibilities (and expected) to enter the modafinil markets much earlier than 2012 as a fully independent generic entrant, possibly around the time of the Settlement Agreement. The Teva Generic Rights as part of the Settlement Agreement guaranteed that this possible full-fledged generic entry could not occur before 2012 (or for as long as no other generic third party entered the market[1339]). A contractual mechanism that effectively delays Teva's entry into the market cannot be considered pro-competitive. In any event, the Commission notes that such commitment not to enter between 2005 and 2012 is different from the situation in the *Generics (UK)* case where the Court of Justice considered possible pro-competitive effects from generics starting to sell the products (in dependency from the originator GSK) *directly* after concluding the settlement agreement with GSK.

(979) Even as of 2012, Teva's entry would only be based on a right derived from Cephalon (a licence). As such, Teva's entry would not be comparable to the full-fledged entry of an independent source of competition. By virtue of the Settlement Agreement[1340], Teva would in particular be required to pay Cephalon royalties amounting to 10% of Teva's net profits from the sale of all generic modafinil products, which would increase (in terms of percentage on these net profits) if other entities entered the relevant modafinil markets before 2012, reaching up to 20% of Teva's net profits from the sale of generic modafinil.[1341] The Parties themselves acknowledge that such royalties are "*significant*".[1342] Accordingly, contrary to the Parties claims,[1343] it is clear that Teva's ability to compete on price (the principal form of competition that

---

1338 Unless the "acceleration clause" would be triggered prior to the start of Teva's licence in 2012 due to earlier entry of other generic companies. See Recitals (249) and (454).

1339 See Article 3.1 of the Settlement Agreement.

1340 See Articles 3.1.1., 3.1.2. and 3.1.3.1. of the Settlement Agreement.

1341 See Articles 3.1.1., 3.1.2. and 3.1.3.1.of the Settlement Agreement.

1342 SO Reply, paragraph 507.

1343 See SSO Reply, paragraph 75.

normally results from generic entry) in the modafinil markets would likely be curtailed under the Teva Generic Rights, compared to genuinely independent entry, due to the increased costs associated with the royalties payable to Cephalon.

(980) The payment of material royalties to Cephalon under the Teva Generic Rights also aligned the interests of the Parties to a considerable extent, softening price competition and benefiting both Parties to the detriment of consumers as compared to a completely uncoordinated outcome of the competitive process. On the one hand, since Cephalon would extract profits from Teva's modafinil sales, Cephalon had no incentives, or at least considerably lower incentives, to engage in price competition with Teva. Teva, on the other hand, had also lower incentives to engage in aggressive pricing with Cephalon compared to a true independent generic entrant, since it faced higher costs due to the important royalty payments. Since Teva would have to bear the significant costs stemming from the royalties and still remain profitable, it is likely that it would not have the incentives to engage in aggressive pricing with Cephalon that could erode its profits. Consequently, contrary to the Parties' arguments,[1344] the significant royalty payments would have ensured less competitive pressure on the Parties than in a situation of independent generic entry, and would be likely to allow modafinil prices to remain higher.

(981) Finally, as regards Articles 3.1.3.3. and 3.1.3.6. of the Settlement Agreement, while these provisions concern the pre-2012 period, they, nevertheless, further show, contrary to the Parties' claims,[1345] that the Teva Generic Rights were not designed to allow for Teva's entry as a full-fledged and independent competitor and in that sense they are relevant in the context of the present assessment. Indeed, in case Teva had entered the modafinil market before 2012 (that is, prior to the Effectiveness Date of Teva Generic Rights pursuant to the "acceleration clause" in Article 3.1.2.,), Cephalon would have the right to ultimately force Teva to exit the market.[1346]

6.9.1.2. The Teva Generic Rights arrangement rendered entry by other generic companies less likely

(982) In addition, the Teva Generic Rights rendered entry by other generic players less likely: first and most importantly, Teva, the best-placed generic player to challenge Cephalon's patent position, had committed not to undertake any such challenges until the very end of the Settlement Agreement, thereby contributing to maintaining the patent-based hurdles for other generics to enter. Second, the the Teva Generic Rights created for Teva an 'incumbent position' on the market compared to other generic players which was likely to have a negative impact on their incentives to enter.

(983) While, upon Teva's entry, the non-*compete* commitment would cease to have effect, after its entry, Teva was, under the Teva Generic Rights arrangement, still bound by the non-*challenge* commitment. Teva committed not to challenge what were considered the main patent barriers to any entry into the modafinil market and this commitment lasted until the very end of the Settlement Agreement.[1347]

1344 See SSO Reply, paragraph 76.

1345 See SSO Reply, paragraph 75.

1346 See also Recital (249).

1347 Teva's non-challenge commitment (incorporated in Article 8.12 (b) of the Settlement Agreement) lasted throughout the duration of the Settlement Agreement, that is to say Teva committed not to challenge

(984) The non-challenge commitment (in combination with the Teva Generic Rights) represented for Cephalon an extra safeguard, in that it gave complete certainty for the entire duration of the Settlement Agreement that Teva would not pose a threat through challenging Cephalon's patent position and thereby potentially clearing the way also for other generics (see Section 6.5.2). Before the Settlement Agreement, Teva had actually filed a counterclaim before the English High Court seeking to declare Cephalon's secondary patents as invalid.[1348] By removing the most likely challenger for Cephalon's patents, which, if successful, would likely facilitate generic entry by multiple suppliers, the Settlement Agreement clearly renders entry by other generic companies less likely.

(985) This also means that, contrary to the Parties' claims that the Settlement Agreement promoted competition,[1349] the Teva Generic Rights were likely to negatively impact the incentives of other generic companies to enter the market, because they would allow Teva to keep a first-mover advantage (as the first licensee on the market), without allowing other generic companies to benefit from Teva's successful entry. Without the Settlement Agreement and its restrictions, that is in the scenario of continued litigation, there were real concrete possibilities that Teva would succeed in removing the patent barriers, which, in turn, would have immediately opened the way for other generics to also enter. The Settlement Agreement, in contrast, created a situation where Teva could enter first and build up market presence, whilst the other generics would still face patent barriers. When another generic would eventually manage to enter, it would immediately face the threat of generic competition from Teva, which, as a result of the Teva Generic Rights, could respond from its established market position as first licensee to any other generic entry by pushing down the prices and margins. The threat of such reaction to entry is likely to make market entry less attractive for other potential generic competitors. The first-mover advantage of the first non-originator entrant compared to subsequent generic entrants is particularly pronounced where the first non-originator enters on the basis of a licence, because in this scenario, entry has not occurred following the expiry or invalidation of the originator's patents, which would have removed an important hurdle for generic entry generally. In these circumstances, the first non-originator entrant is likely to have sufficient time to establish a strong position on the market (e.g. with customers and sales channels), before other generic companies enter, since

---

Cephalon's Listed Patents also during the period of the intended Teva Generic Rights. See Recitals (692)-(693). Article 3.1.1 of the Settlement Agreement provides that the royalty for the Teva Generic Rights is payable to Cephalon "*until the later of (i) the expiration of all Listed Patents (as applicable) or (ii) the end of any paediatric extension on the Patent in Suit, or with respect to any market outside of the United States, the equivalent later date in such market*". Paediatric extension on the Patent in Suit (as per Article 1.18 of the Settlement Agreement, Patent in Suit means US '516 Patent) expired on April 6, 2015. On the other side, the definition of the Listed Patents includes a reference to "*any other patent that may be listed in the FDA Orange Book for Provigil*". As explained in Section 4.1.2.1, the patents that were listed in the Orange Book for Provigil since 2005 are the US '855 Patent which expired on 22 October 2010 (European counterpart is patent EP 0233106, expired on 19 January 2007), the US'516 Patent which expired on 6 October 2013 (European counterparts are Particle Size Patents, expired on 4 October 2015) and US '346 Patent set to expire on 29 November 2023 (European counterpart is EP139712, set to expire on 11 September 2023). However, Article 3.1.1 opened a possibility for Cephalon to include additional patents in the FDA Orange Book for Provigil and thus possibly prolong the duration of the Teva Generic Rights and of the Settlement Agreement.

1348 See Recital (184).

1349 SSO Reply, paragraph 77.

they would still first have to overcome the originator's patents before being able to enter the market.

(986) Indeed, in the pharmaceutical sector, the incentives for a generic to enter are greater where there is only the originator in the market and the generic for a certain period would be the only generic competitor in the market. Accordingly, by allowing entry of Teva as a licensee, Cephalon and Teva not only softened competition amongst themselves, but also generated a competitive advantage for Teva as first licensee that would likely have a negative impact on entry incentives for subsequent generics. Given that entry by multiple generics generally leads to increased competitive pressure on prices, reducing entry chances and incentives for entry by subsequent generics leads to less competitive pressure on prices. Consequently, also this element of the Teva Generic Rights contributed to shielding Cephalon from full-fledged (that is independent) and timely generic competition, which again shows that it is not capable of giving rise to demonstrated, sufficiently significant and not uncertain *pro-competitive* effects.

(987) The Commission does not argue that the existence of a licensed generic necessarily increases the barriers to entry for other generics, but that, as explained in Recital (986), the existence of a first-mover non-originator entrant on the basis of a licence is likely to negatively impact the incentives of other generic companies to enter. Nor does the Commission argue that other generic undertakings were absolutely excluded from entering the modafinil markets as a consequence of the Settlement Agreement or that entry barriers were insurmountable. However, the mechanism in the EEA that was established in the Settlement Agreement combined the non-challenge commitment for the entire remaining duration of the patent term with granting to Teva the limited right to enter the market as a licensee as of the Effectiveness Date of Teva Generic Rights. Such a mechanism cemented the unique position of Teva as most advanced potential entrant and made it more likely that Teva would be the only generic in the market as of 2012 to the benefit of both Teva and Cephalon.

(988) The Parties' argument that the Settlement Agreement promoted competition through the "*significant royalties imposed on Teva*" (presumably because the thus increased the costs of Teva would lead to higher prices and attract further generic entry) does not convince.[1350] First, it is hard to consider that the Settlement Agreement was pro-competitive when the Parties' themselves seem to acknowledge that the royalties imposed on Teva would lead to higher prices being sustained (compared to independent entry by Teva), which is the corollary of ineffective price competition. Second, by rendering entry by *other* potential competitors less likely as explained above (despite the higher cost base of Teva), Cephalon and Teva could expect to enjoy less intense competition until 2015. Third, the very same Settlement Agreement including the Teva Generic Rights restricted competition by delaying Teva's *independent* entry and thus the start of genuine competition, a commitment that Teva accepted in return for a transfer of value. The very same cost increase for Teva actually meant that Cephalon would be exposed to less price competition, as explained above (Recital (980).

(989) The Parties further argue that the fact "that Teva would not 'clear the way for other generics' had no bearing on Teva's own pro-competitive entry as of 2012" and that

1350 SO Reply, paragraph 507.

the non-challenge commitment "did not diminish the pro-competitive benefits of the Teva Generic Rights".[1351] This is not convincing either. First, Teva's entry as of 2012 cannot be characterized as pro-competitive in a situation where Teva's entry would be in legal dependency from Cephalon (by way of the licence agreement) and financially influenced (by way of the royalties) by Cephalon, as explained in Recital (980). Second, an agreement cannot be said to have *significant* and *proven* pro-competitive effects within the meaning of the case-law of the Union Courts, if it may merely appear to bring some benefits to competition (allegedly, Teva's controlled entry after 2012) when in fact at the same time it has severe anticompetitive effects (delaying and softening the impact of Teva's entry on price competition, and making the entry of other generics less likely). The Teva Generic Rights are a constituent part of the Settlement Agreement: they contribute to the restrictive nature of this agreement and, contrary to the Parties' conviction of the opposite[1352], cannot be assessed in isolation.

(990) The Parties also recall the *Servier* case to argue that experience shows that generic players enter new markets despite the existence of other licensed generics.[1353] The Commission recalls that in the *Servier* case, there were several generics as potential competitors with real and concrete possibilities of entering, and that Servier reached reverse payment settlements with all of them. In the present case, other generic companies in the EEA were much more remote from entering than Teva. At the time of conclusion of the Settlement Agreement these other generic companies still had not made substantial sunk investments to reach an advanced stage of product development that positioned them close to market entry (See Sections 8.2.2 and 8.2.3). In these circumstances, it would be much harder for such other entrants, if any, to enter the market compared to the *Servier* case, because important investment decisions would still need to be taken for which likely returns were crucial. Therefore, the factual findings in the *Servier* case do not allow drawing any conclusions in the present case, the facts being crucially distinct.

(991) The Parties also erroneously claim that the Commission's position is that "any early entry agreement would be anticompetitive because it would diminish the incentives of other generic companies to enter the market".[1354] The Commission is not suggesting that, as a general matter, any early entry agreement is illegal or, as the Parties suggest[1355], that the impact of generic competition is anticompetitive under Article 101 TFEU. First of all, referring to an "early entry" by Teva is misleading because independent entry was never allowed and entry under licence was allowed only several years later than the moment when Teva's independent entry could have occurred in the absence of the non-compete commitment.[1356] Second, the Commission assessed the Teva Generic Rights and concluded that an alleged pro-competitive agreement that includes a non-challenge clause and conditions as those of the Teva Generic Rights, including significant royalties and the "acceleration

---

1351 See Reply SSO, paragraph 73.

1352 See SO Reply, paragraphs 509-510 and SSO Reply, paragraph73.

1353 See SO Reply, paragraph 502, which refers to Commission Decision of 9 July 2014 in Case AT.39612-*Perindopril (Servier)*, points 1531 and 1533.

1354 See SSO Reply, paragraph 77.

1355 See SO Reply, paragraph 501.

1356 See in particular Sections 4.2.2, 4.3.1, 4.3.2 and 4.3.3.

clause", is capable of limiting generic competition, such that it does not include demonstrated, sufficiently significant and certain pro-competitive effects.

(992) The Parties also argue that despite the Teva Generic Rights, several other generic entrants continued their efforts to enter the modafinil markets in the EEA after the conclusion of the Settlement Agreement. The Parties contend that the Commission (in Recital 800 of the SO) relies on the conclusions made within the specific United States regulatory context and that a similar regulatory environment does not exist in the EEA. The Parties also bring forward that the Commission itself had concluded in its *Servier* Decision that "*Teva had taken into account the possibility that it will not be the first generic entrant and had not given up on marketing its product for this reason.*"[1357]

6.9.1.3. Cephalon's Nuvigil strategy undermined any of the alleged pro-competitive effects from the Teva Generic Rights

(993) As explained in Section 6.3.3., at the time of the Settlement Agreement, Cephalon planned to preserve its wakefulness business from generic competition by re-directing patients from its original modafinil-based Provigil to its second-generation product Nuvigil, based on armodafinil. Cephalon was experiencing delays in getting approval for Nuvigil and needed more time to implement this switching strategy. Through the Settlement Agreement, Cephalon bought the necessary time to have most chances to succeed in switching patients to Nuvigil before any generic entry. The Settlement Agreement provided for controlled generic entry only in 2012. This gave Cephalon, apart from maintaining and increasing Provigil revenues for an extended period of time, also the time to switch patients from Provigil to Nuvigil and shield its profits from generic competition also this way.

(994) In light of this switching strategy, the Teva Generic Rights would at most have allowed Teva to enter under licence in what was still remaining of the market of *modafinil* patients by 2012, without being able to contest patients that Cephalon would have already successfully switched to the new *armodafinil* product Nuvigil. This means that, even if there had been any pro-competitive effects in the Teva Generic Rights, *quod non*, these would have been limited and therefore not sufficiently significant to put into doubt the characterisation of the Settlement Agreement as a restriction of competition by object.

(995) In light of the above, contrary to the Parties' contentions[1358], Cephalon's alleged switching strategy is relevant for assessing the Settlement Agreement and, in particular, the Teva Generic Rights and shows that any alleged pro-competitive effects from Teva's entry would be in any event limited and certainly not sufficiently significant, considering the serious restrictions of competition stemming from the non-compete and non-challenge commitments.

6.9.1.4. The Teva Generic Rights were not the main purpose of the Settlement Agreement

(996) The Parties argue that the Teva Generic Rights and the settlement of litigation were the main competitive elements of the Settlement Agreement and that the non-

---

1357 See SO Reply, paragraph 502, which refers to Commission Decision of 9 July 2014 in Case AT.39612-*Perindopril (Servier)*, points 1531 and 1533.

1358 See SSO Reply, paragraph 78.

challenge and non-compete commitments were only ancillary.[1359] They argue that the Teva Generic Rights are an integral part of the competition-related terms of the Settlement Agreement. The Parties claim that the Commission tries to disaggregate the settlement and the Teva Generic Rights.

(997) It should be noted from the outset that the Parties' position is at odds with the case-law of the European Court of Justice. As the Court held in the *Generics (UK) and Others* case, a finding of a restriction by object "*cannot be rebutted (…) on the ground (…) that restrictions stemming from such agreements are merely ancillary (…)*".[1360]

(998) The Commission has nevertheless given full consideration to the arguments of the Parties. The analysis, however, shows that the Teva Generic Rights cannot be regarded to have been pro-competitive, but to the contrary contributing to the restriction of competition through the Settlement Agreement. As part of a package of transactions that induced Teva not to independently enter and compete in the markets for modafinil, they served – to shorten rather than to extend the period in which unrestricted competition would take place.

(999) As explained above, first, the Teva Generic Rights allowed a controlled entry only several years later than the moment when Teva's independent entry could have occurred in the absence of the non-compete commitment. Moreover, the Teva Generic Rights had a likely negative impact on the incentives of potential competitors' and ensured Teva's market position as a first entrant. Second, because of the Teva Generic Rights combined with the non-challenge commitments, making entry by other potential competitors less likely, Cephalon and Teva could expect to enjoy less intense competition until 2015. The fact that Cephalon raised Teva's costs through the royalties in the licence further contributed to less competitive pressure on Cephalon's prices.

(1000) The Commission does not dispute the above Parties' arguments in that a patent settlement agreement may indeed include provisions allowing for entry that is not immediate. However, such provisions should be agreed on the basis of the Parties' perception of the patent's strength and must not be induced or distorted by value transfers the sole consideration for which is the acceptance of non-compete and non-challenge commitments. In the present case, as is set out, the Teva Generic Rights formed part of a set of transactions. Teva's restrictive commitments were induced by the value transferred through this package of transactions that substantially reduced the Teva's incentives to pursue its efforts to independently enter and compete in one or more EEA modafinil markets (see Sections 6.6, 6.7 and 6.8). By aligning the interests of the Parties, the Settlement Agreement, including the Teva Generic Rights, significantly softened price competition compared to an uncoordinated competitive process, resulting in both Teva and Cephalon gaining to the detriment of consumers.

(1001) The Settlement Agreement not only prevented any generic competition until 2012, but it did also not allow for independent, royalty free and unrestricted generic entry in the markets for modafinil before patent expiry. It only allowed for controlled generic entry under licence, with significant payable royalties, in the reduced market

---

1359 See SO Reply, paragraphs 514, 551 and 564, element (a).

1360 Case C-307/18, *Generics (UK) and Others*, paragraph 96.

segment consisting of patients that were not expected to have been yet switched to Nuvigil three years before patent expiry.

6.9.1.5. The Teva/Cephalon merger Decision offers no basis to accept pro-competitive effects stemming from the Teva Generic Rights

(1002) The Parties argue that in the Teva/Cephalon merger Decision "the Commission found that Teva Generic Rights improved Teva's chances of early entry in comparison to other generic entrants that had no such agreement and thus caused Teva to become 'the most significant competitive constraint, particularly in the period after October 2012'".[1361] According to the Parties, this suggests that in the Teva/Cephalon merger Decision the Commission acknowledged the pro-competitive effects of the Teva Generic Rights.

(1003) The conclusion that the Parties draw from the Teva/Cephalon merger Decision is incorrect because the Parties factually misrepresent its contents. First, the Teva/Cephalon merger Decision does not assess the Settlement Agreement at all, and in particular does not consider the restrictions stemming from the non-compete and non-challenge commitments induced by the value transfer during the period of infringement. The reference framework in the Teva/Cephalon merger Decision and in this Decision is different. While this Decision assesses the restriction of competition caused by the Settlement Agreement and compares its impact to a counterfactual of the Settlement Agreement not having been concluded, the Teva/Cephalon merger Decision takes as a starting point that the Settlement Agreement was in place and assesses the likely impact of the Parties' merger on competition in the foreseeable future under EU merger control rules as of 2011. Second, and importantly, the Teva/Cephalon merger Decision did not conclude that Teva's agreed entry in 2012 under the Teva Generic Rights would have had pro-competitive effects. The Teva/Cephalon merger Decision merely considered that Teva was at the time "*the most likely competitive constraint on Cephalon at least in the period from October 2012 to October 2015*" and took into account that the merger, if concluded, would eliminate this constraint.

(1004) Accordingly, the Teva/Cephalon merger Decision did not find that Teva's prospects of entry in the modafinil market improved, as a consequence of the Settlement Agreement, compared to the situation before the Settlement Agreement. The Decision simply found that after (and despite) the conclusion of the Settlement Agreement, Teva – who was already the first generic to start selling modafinil product in the EEA in June 2005, that is to say before the Settlement Agreement – continued to be the best placed potential generic entrant. The Teva/Cephalon merger Decision, does not in any way state that the Settlement Agreement had pro-competitive effects. On the contrary, the Teva/Cephalon merger Decision states that "*as a result of a patent settlement agreement reached in 2005 with Cephalon, Teva has agreed to postpone entry until 6 October 2012 […]*".

6.9.2. The commercial transactions in Article 2 of the Settlement Agreement also do not call into question the finding of a restriction "by object"

(1005) As regards the package of transactions included in Article 2 of the Settlement Agreement, similarly to the Teva Generic Rights, these do not involve pro-

[1361] See SSO Reply, paragraph 79; see also SO Reply, paragraphs 495-498.

competitive effects that are proven, sufficiently significant and not uncertain to raise doubts as to the anticompetitive object of the Settlement Agreement. First, as shown in Sections 6.6, 6.7 and 6.8, the transactions listed in Article 2 of the Settlement Agreement were overall aimed at, and worked towards, inducing Teva to agree to the non-compete and non-challenge clauses of the Settlement Agreement. As they constitute the inducement to stay out of the market, it is difficult to see how these transactions would produce any significant pro-competitive effects. Second, when looking at the facts surrounding each of these transactions, it is evident that they were unlikely to have pro-competitive effects on the relevant modafinil markets that would be capable of giving rise to a reasonable doubt that the Settlement Agreement "*reveals a sufficient degree of harm to competition*" that is required for a characterisation of a restriction "by object".[1362] This is for the following reasons.

(1006) First, as regards the CEP-1347 licence arrangement, any alleged pro-competitive effects linked to it, even if assumed proven, certain and sufficiently significant (*quod non*), they would be irrelevant for drawing conclusions on the anticompetitive object of the Settlement Agreement that restricts competition on the modafinil markets. Such alleged pro-competitive effects would concern exclusively the markets on which Azilect is traded that are very much distinct from and unrelated to the modafinil markets. Therefore they would not be "relevant" regarding the markets concerned in the present case, as required by the Court of Justice. Therefore, the CEP-1347 licence as such cannot give rise to any reasonable doubt that the Settlement Agreement "*reveals a sufficient degree of harm to competition*" on the markets concerned in the present case.[1363]

(1007) Second, as regards the licence to Teva's Intellectual Property Rights, the Commission's analysis in Section 6.6.3.4 shows that this transaction was in fact not driven by the freedom to manufacture modafinil products but was rather designed to serve as a reverse payment from Cephalon to Teva (see Recital (865)). Cephalon's product, Provigil, was already present on the relevant market for many years without Teva's Intellectual Property Rights hindering Cephalon in its ability or incentives to compete on the markets for modafinil. Cephalon never (either internally or externally) showed any concerns about the infringement risks allegedly arising due to Teva's Intellectual Property Rights. Even more, at the time of the Settlement Agreement, the PTO rejected Teva's patent application while it granted at the same time Cephalon's competing patent (see Recitals (838)-(841)). In addition, Cephalon did not apply the technology in-licensed from Teva at all, neither for Nuvigil nor for Provigil (see Recitals (842)-(848)). Therefore, the alleged pro-competitive effects arising from the Licence to Teva's Intellectual Property Rights cannot be deemed as proven, certain and sufficiently significant.

(1008) Third, as regards the Modafinil API Supply Agreement, the Commission's analysis in Section 6.6.1.4 shows that Cephalon appeared not to be in need of additional sources of modafinil API in the relevant period. Accordingly, if anything, the Modafinil API Supply Agreement could lead to unnecessary additional capacity on

---

1362 See Case C-67/13 P, *Groupement des cartes bancaires (CB) v Commission*, paragraphs 49 and 53. See Case C-307/18, *Generics (UK) and Others*, paragraph 103.

1363 See Case C-307/18, *Generics (UK) and Others*, paragraphs 103 and 105-107. See also Case C-67/13 P, *Groupement des cartes bancaires (CB) v Commission*, paragraphs 49 and 53.

the modafinil markets, which, as a general matter, is not pro-competitive but rather prone to disincentivising entry by others.[1364]

(1009) Fourth, as regards the Teva Distribution Agreement, as explained above (Section 6.6.5.4.), Cephalon did not organise a call for offers (or similar selection procedure) to seek the most effective and efficient distribution solution for its modafinil products in the United Kingdom. Instead, Cephalon directly chose Teva, its closest competitor on the market, as an exclusive distributor for these products, thereby eliminating it as an independent competitor. The Teva Distribution Agreement therefore had, if anything, rather the effect of less competition than with a distributor that was not a (potential) competitor of Cephalon on the modafinil market in the United Kingdom.

(1010) Fifth, the settlement of an allegedly genuine patent dispute between Cephalon and Teva and the alleged potential avoidance of associated litigation costs cannot as such be considered as involving proven, certain and sufficiently significant pro-competitive effects, as required by the Court of Justice. The overall settlement and the arrangement on litigation costs may lead to certain cost savings for the two litigating parties. However, these costs are not proven and, even if they were, they are part of the competitive process, especially in pharmaceutical markets. Eliminating this part of the competitive process to replace it by an anti-competitive agreement can hardly be considered as a pro-competitive effect and in any event it cannot amount to a pro-competitive effect that would be proven, certain and sufficiently significant to give rise to a reasonable doubt as to whether the Settlement Agreement revealed a sufficient degree of harm to competition.

(1011) In this regard, the Parties' argument that the Teva Generic Rights include "intrinsic pro-competitive benefits associated with the settlement of a genuine patent litigation"[1365] and that "the settlement of the litigation and the Teva Generic Rights (…) constituted significant pro-competitive effect"[1366] cannot be upheld. If this were accepted, it would mean that any patent litigation settlement agreement would be immune from competition rules, even the most straightforward pay for delay settlement. Moreover, as the Court of Justice emphasised in the Generics (UK) and Others case, "the fact that there is uncertainy as to the validity of the patent, whether that is due to the existence of a genuine dispute (…) [or] the existence of court proceedings prior to the conclusion of the settelement agreement at issue (…) is again of no relevance to the question of whether characterisation as a 'restriction by object' can be ruled out".[1367] Accordingly, the removal of the legal uncertainty of a genuine patent litigation cannot in itself be considered as sufficiently pro-competitive to put into question the characterisation of the Settlement Agreement as a restriction of competition by object.

1364 In fact, the various modafinil API supply agreements that Cephalon concluded with generic suppliers, including the Modafinil API Supply Agreement, led to a modafinil API overproduction for Cephalon, which in turn resulted in the closure of its Mitry-Mory facility. See Section 4.7.3.10 and footnote 696.

1365 See SSO Reply, paragraph 87.

1366 See SSO Reply, paragraph 86

1367 Case C-307/18, *Generics (UK) and Others*, paragraph 98.

6.9.3. Conclusion on pro-competitive effects

(1012) Based on the above, the Commission concludes that the Settlement Agreement could not produce pro-competitive effects that would be "*demonstrated*", "*relevant*", "*sufficiently significant*" and not "*uncertain*" so that they would be capable of casting reasonable doubt as to its anticompetitive object.

6.10. Conclusion: the Settlement Agreement restricted competition by object

(1013) The modafinil-based Provigil was by far Cephalon's most important product. At the time, Teva was the most advanced generic threat to Provigil in the EEA. Cephalon and Teva were at least potential competitors in the markets for modafinil products in each of the By-Object Countries (see Sections 6.3.1 and 6.4). Cephalon was not convinced that its patents could prevent market entry of a generic modafinil product (Section 6.3.2) and was preparing itself for market entry of generic competitors by contemplating a product switching strategy, namely a strategy whereby the patients would be re-directed from Provigil to its patent-protected second-generation product Nuvigil before the Effectiveness Date of Teva Generic Rights (see Section 6.3.3). Evidence on file shows that Teva was convinced that its product did not infringe Cephalon's Particle Size Patents and that it believed that in any event such patents were invalid and obtained by deception (see Section 6.3.2).

(1014) Nonetheless, Teva undertook in the Settlement Agreement a commitment not to compete on modafinil markets in the By-Object Countries until the Effectiveness Date of Teva Generic Rights (see Section 6.5.1). In addition, the Commission concludes that Teva assumed an undertaking not to challenge Cephalon's Listed Patents including Particle Size Patents that lasted for the duration of the Settlement Agreement (see Section 6.5.2). Therefore, the Commission concludes that the Settlement Agreement contains restrictions of competition in that Teva committed itself in an agreement to limit its independent efforts to enter one or more EEA markets with generic product by accepting a non-compete commitment that lasted until the Effectiveness Date of Teva Generic Rights[1368] and a non-challenge commitment that lasted for the duration of the Settlement Agreement. Cephalon and Teva implemented these obligations resulting from the Settlement Agreement and thus prevented generic entry by Teva in the By-Object Countries.

(1015) As a consideration, a *quid pro quo* paid to Teva for agreeing to these non-compete and non-challenge commitments in the Settlement Agreement, the Parties concluded a number of transactions financially and economically beneficial to Teva. These transferred sufficient value to induce Teva to accept the non-compete and non-challenge undertakings (see Sections 6.6, 6.7 and 6.8). The Parties composed this value transfer by considering various in principle unrelated transactions in order to reach a certain overall level of value that was significant enough to reduce Teva's incentives to independently compete. This is in particular apparent from the negotiation history of these transactions (see Sections 6.3.4 and 6.7). The fact that the transactions were negotiated, considered and concluded together with the Settlement Agreement, as a package, and were included in the contract as a consideration for the restrictive clauses of the Settlement Agreement that Teva committed itself to, is in itself already a strong indication that these transactions served as an inducement for Teva.

[1368] See also Section 6.9.1, where Teva Generic Rights are assessed in more detail.

(1016) The Commission's analysis of each individual transaction from the perspective of both Parties and in the context of potential competition at the time of the Settlement Agreement makes it clear that the value transfer was not the result of a regular commercial relationship between suppliers under normal market circumstances, namely absent the aim to induce the generic to stay out of the market. This analysis also demonstrates that the alternative explanations put forward by the Parties are simply not plausible. In other words, and under normal circumstances, that is to say absent the restrictive clauses of the Settlement Agreement, Cephalon would not have entered into the transactions with Teva, its most advanced generic rival in the EEA and Teva would not have been able to appropriate the value from Cephalon, which it was able to obtain via the Settlement Agreement. Even if one of the transactions may have in the end added little or no value to the overall value transfer, the package of transactions was in any event significant enough, such as to lead Teva to accept the commitments not to independently enter and compete in the modafinil markets.

(1017) Hence, the Commission concludes that the package of transactions had the content and objective aim of serving as a value transfer, as a reverse settlement payment from Cephalon to Teva. The value transfer served to reward Teva for staying out of the modafinil markets and for not independently competing with its generic product. The Settlement Agreement thus was akin to a market exclusion agreement in which the potential competitor is rewarded for not competing and which, therefore, is a restriction of competition by its very nature. In this context, the Settlement Agreement constitutes by its very nature an appreciable restriction on competition.[1369] There are no pro-competitive effects in the Settlement Agreement that would be sufficient to cast reasonable doubt as to the anticompetitive object of the Settlement Agreement (see Section 6.9).

(1018) Based on the above considerations, the Commission concludes that the Settlement Agreement constitutes a restriction of competition by object within the meaning of Article 101 TFEU.

7. ASSESSMENT UNDER ARTICLE 101 TFEU OF SETTLEMENT AGREEMENTS AS RESTRICTIONS OF COMPETITION BY EFFECT: APPLICABLE PRINCIPLES AND CONTEXT

(1019) The previous Chapter 6 concluded that the Settlement Agreement constitutes a restriction of competition by object under Article 101 TFEU. Pursuant to the jurisprudence of the Union Courts, where it is established that an agreement has as its object the restriction of competition, there is then no need to take account of the effects of that.[1370] Nonetheless, the Commission proceeded to examine the anticompetitive effects of the Settlement Agreement and establishes that it restricted competition by effect, within the meaning of Article 101(1) TFEU (see Chapter 8). Prior to this analysis, Chapter 7 sets out the principles applicable to the Commission's assessment and the relevant context.

1369 Case T-472/13, *Lundbeck v Commission*, paragraph 741.

1370 See among others, Case C-56/65, *Société Technique Minière v Maschinenbau Ulm*, page 249; Joined cases C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, *GlaxoSmithKline Services and Others v Commission and Others*, paragraph 55; Judgment of 4 June 2009, *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraph 29.

7.1. General principles

(1020) In order to establish whether an agreement constitutes a restriction of competition by effect within the meaning of Article 101(1) TFEU, the Court of Justice has consistently held that *"the competition in question should be assessed within the actual context in which it would occur in the absence of the agreement in dispute."*[1371] In other words, the competition in question should be compared with the degree of competition that would have existed if the agreement had not been concluded, in other words how the competition "*would have operated in the market*"[1372] absent the agreement. In particular, when assessing the restrictive effects of the agreement on competition account should be taken of the economic and legal context in which the undertakings concerned operate, the nature of the product concerned and the real conditions of the functioning and structure of the market concerned.[1373]

(1021) Accordingly, this analysis looks at the restriction not in isolation or in the abstract, but under the real conditions on the relevant market in particular as regards the competitive structure of the market, entry and prevailing market forces.[1374] Where appropriate, the likely developments that would occur on the market in the absence of the agreement may be taken into account.[1375]

(1022) As a result, to establish whether an agreement is caught by Article 101(1) TFEU as a restriction of competition by effect, *"it is necessary to show — by a comparison between the competition that existed when the agreement was in force and the competition that would have occurred if that agreement had not been concluded — that the competitive situation was worse when that agreement was in force."*[1376]

(1023) The restrictive effects on competition may be both potential and actual effects.[1377] In accordance with settled case-law, "*the restrictive effects on competition may be both real* [actual] *and potential, but they must, in any event, be sufficiently appreciable*".[1378] Advocate General Kokott explained: "[…] *the assessment of the effects of an agreement is not limited to actual effects alone, but must also take*

1371 Judgment of 11 September 2014, *MasterCard and Others v Commission*, C-382/12 P, EU:C:2014:2201, paragraph 161; Case C-56/65, *Société Technique Minière v Maschinenbau Ulm*, p. 250; Judgment of 11 December 1980, *L'Oréal v De Nieuwe AMCK*, C-31/80, EU:C:1980:289, paragraph 19; Judgment of 6 April 2006, *General Motors*, C-551/03 P, EU:C:2006:229, paragraph 72.

1372 Opinion of Advocate General Tesauro of 16 June 1994 in Case C-250/92, *Gøttrup-Klim e.a. Grovvareforeninger v Dansk Landbrugs Grovvareselskab*, EU:C:1994:413, paragraph 16.

1373 Case C-382/12 P, *MasterCard and Others v Commission*, paragraph 165 and the case-law cited; Case C-307/18, *Generics (UK) and Others*, paragraph 116.

1374 See, for example, Judgment of 26 November 2015, *Maxima Latvija*, C-345/14, EU:C:2015:784, paragraphs 27 and 28.

1375 Case C-382/12 P, *MasterCard and Others v Commission*, paragraph 166. Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraph 191.

1376 Case T-684-14, *Krka v Commission*, paragraph 315.

1377 Judgments of 17 November 1987, *BAT and Reynolds v Commission*, C-142/84 and 156/84, EU:C:1987:490, paragraph 54; of 28 May 1998, *Deere v Commission*, C-7/95 P, EU:C:1998:256, paragraph 77; of 9 July 1969, *Voelk v Vervaecke*, C-5/69, EU:C:1969:35, paragraph 7, and of 23 November 2006, *Asnef-Equifax*, C-238/05, EU:C:2006:734, paragraph 50; Case C-307/18, *Generics (UK) and Others*, paragraph 117, see also Communication from the Commission - Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11, 14.01.2011 ("Horizontal Guidelines"), paragraph 26.

1378 Case C-307/18, *Generics UK and Others*, paragraph 117.

account of potential effects. Moreover, that is only logical since, […], *Article 101 TFEU protects not only actual competition, but also potential competition without which the entry of new entrants to the market could never take place"*.[1379]

(1024) More specifically, the Guidelines on Article 101(3) TFEU explain that for an agreement to be restrictive by effect, it must affect either actual or potential competition to such an extent that on the relevant market negative effects on competition parameters, such as prices, output, innovation or the variety or quality of goods may be expected with a reasonable degree of probability.[1380] Agreements can have such effects of appreciably reducing competition between the parties to an agreement where they "*reduce the parties' decision-making independence*", for example, *"due to obligations contained in the agreement"*.[1381]

(1025) Restrictive effects on competition must be established with a sufficient degree of probability and this depends on factors such as "*the nature and content of the agreement, the extent to which the parties individually or jointly have or obtain some degree of market power, and the extent to which the agreement contributes to the creation, maintenance or strengthening of that market power or allows the parties to exploit such market power"*.[1382] While market power is a relevant factor, as regards the degree of market power, there is no threshold under Article 101(1) TFEU that must be met to establish restrictive effects on competition. According to settled case-law, the Commission must carry out an objective analysis of the impact of the agreement on the competitive situation.[1383]

(1026) Finally, for an agreement to fall within the scope of Article 101(1) TFEU, the potential or actual effects on existing or potential competition must be sufficiently appreciable.[1384]

7.2. Restrictive effects in relation to potential competition in general and in relation to patent dispute settlement agreements in particular

(1027) The examination of conditions of competition on a given market must not be based solely on existing competition between the undertakings already present on the relevant market, but must extend also to examining the effects on potential competition, that is to say competition from undertakings that are not yet present on the market.[1385] The Court of Justice maintained in *Generics (UK) and Others* case, that to have a negative and appreciable effect on competition with respect to

---

1379 Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraph 198.

1380 Communication from the Commission – Notice: Guidelines on the application of Article [101(3)] of the Treaty, OJ C 101, 27.4.2004, page 97 ("Guidelines on Article 101(3) TFEU"), point 24.

1381 Horizontal Guidelines, point 27.

1382 Horizontal Guidelines, point 28. See also, Guidelines on Article 101(3) TFEU, point 25.

1383 Judgment of 2 May 2006, *O2 Germany v Commission*, T-328/03, EU:T:2006:116, paragraph 77.

1384 Joined cases C-142/84 and C-156/84, *BAT and Reynolds v Commission*, paragraph 54; Case C-7/95 P, *Deere v Commission*, paragraph 7; Case C-5/69, *Voelk v Vervaecke*, paragraph 7; Case C-238/05, *Asnef-Equifax*, paragraph 50; Case C-307/18, *Generics (UK) and Others*, paragraph 117; see also Case T-461/07, *Visa Europe and Visa International Service v Commission*, paragraph 125.

1385 Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94, *European Night Services and Others v Commission*, paragraph 137; Case T-461/07, *Visa Europe and Visa International Service v Commission*, paragraph 68; Judgment of 28 February 1991, *Delimitis v Henninger Bräu*, C-234/89 , paragraph 21; Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraph 58; Case C-307/18, *Generics (UK) and Others*, paragraphs 31-32.

horizontal cooperation agreements, *"the coordination involves undertakings who are in competition with each other, if not in reality, then at least potentially"*.[1386]

(1028) Where undertakings are potential competitors, an agreement may constitute restriction of competition by effect within the meaning of Article 101(1) TFEU if the agreement eliminates that potential competition between the undertakings, and consequently the real concrete possibilities to enter the market.[1387] To determine if there is potential competition it is necessary to ascertain whether "*there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to penetrate the relevant market and compete with the undertakings already established."*[1388] Such analysis "*must not be based on a mere hypothesis, but must be supported by evidence or an analysis of the structures of the relevant market"* and the economic and legal context within which it operates.[1389] Accordingly, when potential competition has been established, an agreement is capable of restricting competition when it eliminates the possibility for the potential competitor to enter the market. That implies that there are no insurmountable barriers to enter the market, which as a matter of fact would exclude any potential competition.

(1029) The Court of Justice established in relation to the assessment of restrictive effects based on potential competition that the fact that an undertaking concludes an agreement with an undertaking that is not actually competing on a specific market in order to keep that undertaking away or delay its entry on that market serves as a strong indication of a competitive relationship between them.[1390] Furthermore, as the Court of Justice stated in the *Generics (UK) and Others* case: "*A further* […] *indication* [of a competitive relationship] *is the intention, made known by a manufacturer of originator medicines and acted upon, to make transfers of value to a manufacturer of generic medicines in exchange for the postponement of the latter's market entry, even though the former claims that the latter is infringing one or more of its process patents.*"[1391]

(1030) To establish the existence of restrictive effects on competition, it is sufficient to determine the potential effects of the agreement on competition.[1392] In other words, the agreement must have, with a sufficient degree of probability, anticompetitive effects on competition.[1393]

1386 Case C-307/18, *Generics (UK) and Others*, paragraphs 31-32.

1387 Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraphs 196-197.

1388 Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94, *European Night Services and Others v Commission*, paragraph 137; see also Case C-307/18, *Generics (UK) and Others*, paragraph 36.

1389 Case T-461/07, *Visa Europe and Visa International Service v Commission*, paragraph 167; Case C-307/18, *Generics (UK) and Others*, paragraph 39.

1390 Case C-373/14 P, *Toshiba Corporation v Commission*, paragraphs 33 and 34; see also, Case T-472/13, *Lundbeck v Commission*, paragraph 144; Case C-307/18, *Generics (UK) and Others*, paragraphs 55-56; see also in this context Case T-461/07, *Visa Europe and Visa International Service v Commission*, paragraphs 127, 169.

1391 Case C-307/18, *Generics (UK) and Others*, paragraph 56.

1392 Case C-7/95 P, *Deere v Commission*, paragraph 77; Case C-5/69, *Voelk v Vervaecke*, paragraph 7, and Case C-238/05, *Asnef-Equifax*, paragraph 50; Case C-307/18, *Generics (UK) and Others*, paragraph 117. Horizontal Guidelines, points 27 and 28. See also Guidelines on Article 101(3) TFEU, point 24.

1393 Guidelines on Article 101(3) TFEU, paragraph 24. See also Case C-234/89, *Delimitis v Henninger Bräu*, paragraph 21.

(1031) Accordingly, where the agreement in question affects potential competition by removing the real and concrete possibility that competition on the market will occur, it negatively affects the effective competitive process. An agreement preventing the entry on the market of a potential competitor precludes from the outset any chance of the benefits of competition from materialising, in terms of lower prices, more output, or better quality and innovation. As the Court of Justice, in the context of Article 102 TFEU, explained with respect to a set of agreements restricting manufacturers of generic medicines from entering a market, the possible anticompetitive effect on the market lies in *"depriving the consumer of the benefits of entry into that market of potential competitors manufacturing their own medicine and, therefore, reserving that market directly or indirectly to the manufacturer of the originator medicine concerned"*.[1394] Indeed, eliminating possible entry by a competitor preserves the incumbent's market power and maintains the incumbent's ability to continue charging supracompetitive prices.

(1032) In relation to patent dispute settlement agreements in the pharmaceutical sector, and specifically as regards the competitive relationship between the parties to such an agreement, Advocate-General Kokott noted that the patent dispute is the very *"expression of the existence of potential competition between patent holders and generic manufacturers"*.[1395] Accordingly, provided that the existence of a potential competitive relationship between the generic manufacturer and the originator is established, it is then possible for a competition authority to show that the agreement settling a patent dispute has restrictive effects on competition if it eliminates that *"potential competitor, and, in doing so, the possibility that the latter might become an actual competitor by entering the market"*.[1396]

(1033) A patent settlement agreement that prohibits a generic manufacturer from entering and competing independently in a market served solely by the originator potentially reduces or even prevents effective competition and renders the opening of the market, which would normally occur with generic entry, less likely. From the perspective of an originator, a settlement agreement which, through a significant value transfer, induces the generic entrant not to compete and not to challenge the originator's patents, eliminates the possibility that generic entry significantly constrains the originator's competitive position. This, in turn, increases the likelihood that the originator undertaking's market exclusivity and ability to charge supra-competitive prices would remain uncontested for a longer period of time. In such case, the likelihood increases that independent generic entry and competition does not materialises or is delayed to the detriment of consumers. As the Court of Justice emphasised in the *Generics (UK) and Others* case, "[the generic] *entry leads, in the short term, to a very appreciable fall in the sale price of medicines containing an active ingredient that are henceforth sold not only by the manufacturer of the originator medicine, but also by manufacturers of generic medicines.*"[1397]

1394 Case C-307/18, *Generics (UK) and Others*, paragraph 157.

1395 Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraph 195.

1396 Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraph 197.

1397 Case C-307/18, *Generics (UK) and Others*, paragraph 69.

(1034) The starting point of the analysis of how competition "*would have operated in the market*"[1398] absent the Settlement Agreement is the factual situation and the Parties' perspective at the time the agreement was concluded.[1399] The principle of legal certainty mandates that the parties to an agreement should be able to determine whether the conduct may raise antitrust liability at the time of the conduct itself.[1400] Nonetheless, the facts posterior to the agreement may be informative with regard to the solidity of the parties' expectations at the time of concluding the agreement, and are to this extent considered by the Commission. The occurrence of unexpected events after the agreement has been concluded, however, does not by itself disprove of the actual or potential effects of their agreements upon competition, having regard to reasonably foreseeable events at the time of entering into the agreement.

(1035) In the present case, the Settlement Agreement significantly changed Teva's ability and incentives to compete with Cephalon,[1401] and what actually happened is therefore hardly a guide to what would have happened absent that Settlement Agreement. Notwithstanding, the Commission also considered how the Settlement Agreement was actually implemented and the market developments that ensued. The evidence in this regard shows that the market developments do not contradict the *ex ante* individual assessment of the market conditions of the Parties at the time of the Settlement Agreement.

(1036) The counterfactual scenario of what would likely have happened absent the agreement must be sufficiently realistic and plausible, and therefore not merely theoretical in light of all the relevant factors such as, in particular, the nature of the products or services concerned, the positions of the parties on the agreement on the relevant market, the structure of the market and also the economic, legal and technical context governing its functioning.[1402]

1398 Opinion of Advocate General Tesauro of 16 June 1994 in Case C-250/92, *Gøttrup-Klim and Others Grovvareforeninger v Dansk Landbrugs Grovvareselskab*, EU:C:1994:413, paragraph 16.

1399 As a matter of precedent, the anticompetitive nature of its acts must be evaluated at the time when those acts were committed. See Case C-457/10 P, *AstraZeneca v Commission*, paragraph 110. Similarly, see the Judgment of 17 September 2007, *Microsoft v Commission*, T-201/04, EU:T:2007:289, paragraph 914; Case T-472/13, *Lundbeck v Commission*, paragraphs 138-141.

1400 Judgment of 14 October 2010, *Deutsche Telekom v Commission*, C-280/08 P, EU:C:2010:603, paragraph 202; Judgment of 21 March 2012, *RENV-Ireland v Commission*, T-50/06, EU:T:2012:134, paragraph 62; Case C-457/10 P, *AstraZeneca v Commission*, paragraph 110.

1401 It may be noted that an adverse effect on competition is demonstrated not just by showing that, absent the Settlement Agreement, Teva would be likely to have entered the market but also by showing that, absent the Settlement Agreement, it would have remained a potential competitor, as a major generic company with a viable generic alternative to Cephalon's product and one with a good chance of withstanding any patent infringement action brought by Cephalon.

1402 Opinion of Advocate General Mengozzi of 30 January 2014 in Case C-382/12 P, *MasterCard and Others v Commission*, paragraph 53; the Court of Justice found that it was likely that absent the MIF (interchange fees between banks), the MasterCard system would have been maintained by a prohibition of *ex post* pricing: the prohibition of *ex post* pricing was "*economically viable*" in the context of the MasterCard system but also plausible or indeed likely because it was "*common ground*" that MasterCard would have preferred to introduce the prohibition of *ex post* pricing rather than let its system collapse (Case C-382/12 P, *MasterCard and Others v Commission*, paragraph 173). In the judgment under appeal in case C-382/12P, the Court stated that the Commission was, however, not obliged to demonstrate that market forces would compel the issuing and acquiring banks themselves to adopt a rule less restrictive of competition than the MIF (Judgment of 24 May 2012, *MasterCard and Others* v *Commission*, T-111/08, EU:T:2012:260, paragraph 99). In the present case, absent the Settlement Agreement, and its inducement to forego independent behaviour on the market, Teva would

(1037) In particular with regards to the patent dispute settlement agreements as possible restrictions of competition by effect, the Court of Justice in the *Generics (UK) and Others* case, explained that the *"sole purpose of the counter-factual is to establish the realistic possibilities with respect to that manufacturer's conduct in the absence of the agreement at issue"*.[1403] The Court of Justice further clarified that *"... to establish the existence of appreciable potential or real effects on competition"* does not require a finding that "*the manufacturer of generic medicines who is a party to that agreement would probably have been successful in the proceedings relating to the process patent at issue*".[1404]

(1038) Accordingly, while patent law is part of the actual context in which the Settlement Agreement was concluded between the Parties, when establishing competition conditions that would have existed absent the agreement, the Commission is not required to assess and predict the likelihood of which party would have prevailed in the ongoing patent litigation.[1405] Similarly, the Court of Justice established that it is not necessary to take into account whether *"the parties to that agreement would probably have concluded a less restrictive settlement agreement"*.[1406] The Commission, however, may take account of the individual assessment of each of the Parties as to their chances of success in the dispute to define the actual context for the assessment.[1407]

8. APPLICATION TO THE CASE: THE SETTLEMENT AGREEMENT AS A RESTRICTION OF COMPETITION BY EFFECT

(1039) In accordance with the principles and framework set out in Chapter 7, this Chapter establishes that the Settlement Agreement also constitutes a restriction of competition by effect within the meaning of Article 101(1) TFEU.

(1040) A comparison of the competition that existed when the Settlement Agreement was in force with the potential or actual competition that would have existed if that agreement had not been concluded shows that there was less competition on the market when the Settlement Agreement was in force. The non-compete and non-challenge restrictions contained in the Settlement Agreement prevented Teva from selling modafinil products in the EEA and this resulted in removing Teva as a potential competitor. It replaced the uncertainty of Teva's entry on the market with the certainty of non-entry and no competition. The Settlement Agreement furthermore had the likely effect of Cephalon preserving its market power more generally: without the Settlement Agreement, Teva could have succeeded in invalidating Cephalon's relevant patents so that not only Teva itself, but also other generic companies could have entered the modafinil markets, thereby undermining Cephalon's market power and its ability to maintain high prices.

---

have remained a competitive threat and would have continued to prepare market entry, as will be shown in Section 8.4.2.

1403 Case C-307/18, *Generics (UK) and Others*, paragraph 120.

1404 Case C-307/18, *Generics (UK) and Others*, paragraph 122.

1405 Case C-307/18, *Generics (UK) and Others*, paragraph 119-120; Opinion of Advocate General Kokott of in Case C-307/18, *Generics (UK) and Others*, paragraphs 192-194.

1406 Case C-307/18, *Generics (UK) and Others*, paragraph 122.

1407 Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraph 200.

(1041) This finding of a restriction of competition by effect is based, first, on an assessment of the characteristics and delineation of the modafinil markets concerned in France, Germany, the Netherlands, Spain, Sweden and the United Kingdom (the "By-Effect Countries")[1408] (Section 8.1). Second, the assessment continues with the description of the prevailing market structure at the time when the Settlement Agreement was concluded, and the establishment, in particular, of (i) Cephalon's very strong market position and (ii) Teva's position as Cephalon's most advanced potential competitor on these markets (Section 8.2). Third, the Commission recalls the restrictive non-compete and non-challenge clauses in the Settlement Agreement, how they were concluded and how they influenced Teva's conduct in the market (Section 8.3). Against this background, fourth, an analysis of the degree of potential or actual competition that would have existed absent the Settlement Agreement in comparison to the competitive situation which resulted from the conclusion of that agreement demonstrates that the Settlement Agreement contained a restriction of competition by effect (Section 8.4). The Commission concludes in Section 8.5.

8.1. Characteristics and delineation of the markets concerned

(1042) Before assessing, in Section 8.2, Cephalon's position on the relevant markets concerned and the position of its (potential) competitors, and to assess, in Section 8.4, the effects of the Settlement Agreement on these markets, Section 8.1 first analyses and delineates the relevant product (Section 8.1.1) and geographical markets (Section 8.1.2).

8.1.1. The relevant product market

(1043) The Market Definition Notice[1409] states in paragraph 2, that "the main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face". More specifically, the objective is "to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behaviour and of preventing them from behaving independently of effective competitive pressure".

(1044) The Market Definition Notice also provides that "[f]rom an economic point of view, for the definition of the relevant market, demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a given product".[1410] In order to assess demand substitution, an "analysis of the product characteristics and its intended use allows the Commission, as a first step, to limit the field of investigation of possible substitutes", but this is not sufficient to determine whether two products are demand substitutes. Moreover, the "functional interchangeability or similarity of characteristics may not, in themselves, provide sufficient criteria, because the responsiveness of customers to relative price changes may be determined by other considerations as well".[1411] The type of evidence relevant to assess whether two products are demand substitutes includes "evidence of substitution in the recent

---

1408 See Recital (1137) for the reasons for focussing on these six Member States.

1409 Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997, page 5 (the "Market Definition Notice").

1410 Market Definition Notice, paragraph 13.

1411 Market Definition Notice, paragraph 36.

past". When this type of evidence is available "it will normally be fundamental for market definition".[1412]

(1045) It must be recalled that the relevant market is not determined on the basis that certain products competed against each other in a broad sense but on the basis of whether such products were sufficiently substitutable to significantly constrain each other. A significant degree of differentiation in terms of therapeutic use may limit the strength of the competitive constraint that such products can exert on each other. In order to carry out the assessment whether the Settlement Agreement infringed Article 101 TFEU by effect, the relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure, even if some products may show some degree of substitutability.[1413]

(1046) However, the elements described above are neither pre-set, nor exhaustive. Each case will depend on its own facts, and it is necessary to examine the particular circumstances of each case in order to establish whether the investigated product competes with others and to what extent the latter exert a significant competitive constraint on the former.

8.1.1.1. Description of Excessive Daytime Sleepiness (EDS)

(1047) Modafinil-containing medicines (such as Provigil) are intended for patients who suffer from mild to moderate excessive daytime sleepiness (EDS). EDS is a condition in which a person has trouble staying awake during the day.[1414]

(1048) EDS is a symptom of (i) narcolepsy with or without cataplexy,[1415] (ii) disturbed night-time sleeping patterns or (iii) unknown causes (in which case it is called idiopathic hypersomnia). The three primary origins are discussed below in more detail.

(1049) The first cause associated with EDS is narcolepsy. Narcolepsy is a particular form of hypersomnia (excessive sleepiness) of central origin. It usually appears in patients at the age of 20-25, but it also occurs later in adult patients. Often, it impacts daily activities and requires pharmacological treatment. Behavioural therapies can enhance the pharmacological treatment, yet they cannot substitute drugs administration in a large majority of cases.[1416]

(1050) Cataplexy is a symptom unique to some forms of narcolepsy in which the patient experiences a sudden loss of muscle tone for tens of seconds to minutes, provoked by emotional situations such as laughter, fear, or anger. Cataplexy varies in intensity and duration. Conscious awareness of the environment is preserved in patients during an

---

1412 Market Definition Notice, paragraph 38. In addition, the Market Definition Notice states in paragraph 20 that supply-side substitutability may also be taken into account when defining markets in those situations in which its effects are equivalent to those of demand substitution in terms of effectiveness and immediacy (namely that suppliers are able to switch production to the relevant products and market them in the short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices).

1413 Market Definition Notice, paragraph 3.

1414 American Academy of Sleep Medicine. The international classification of sleep disorders: diagnostic & coding manual (2nd ed). Westchester, IL: American Academy of Sleep Medicine, 2005:xviii, 297 p.

1415 ID 2824.

1416 IDs 2823, 2232.

attack of cataplexy, although it might appear that the patient has fainted.[1417] As a separate symptom from excessive sleepiness, cataplexy is typically addressed with a distinct treatment.

(1051) Second, EDS can also be a symptom of disturbed night-time sleeping patterns due to work-shift or can be observed in those who suffer from obstructive sleep apnoea. Sleep apnoea is a sleep disorder characterized by pauses in breathing or periods of superficial breathing. Breathing pauses can last from a few seconds to several minutes and happen multiple times in a single night. These breathing pauses disrupt normal sleep, resulting in sleepiness during the day in those affected. Children may also be confronted with problems in school or hyperactivity as a result of this.[1418]

(1052) There are three forms of sleep apnoea: obstructive ('OSA'), central ('CSA'), and a combination of the two. OSA is the most common form. In OSA, breathing is interrupted by a blockage of airflow, while in CSA breathing stops due to a lack of effort to breathe.[1419] Sleep apnoea can be diagnosed with an overnight sleep study. While no pharmacological treatment is associated with the disturbed night-time sleep patterns due to apnoea[1420], the treatment of this indication include lifestyle changes, mouthpieces, breathing devices, and surgery. Breathing devices include the use of a machine, such as a machine that applies continuous positive airway pressure ('CPAP') to ease breathing during sleep.[1421] Lifestyles changes may include avoiding alcohol, weight loss or stopping from smoking.

(1053) Patients of disturbed night-time patterns have problems with EDS and impaired alertness. In other words, common effects of sleep apnoea include daytime fatigue, a slower reaction time, and vision problems.

(1054) Third, EDS can also be caused by unknown causes. In these cases it is called idiopathic hypersomnia. The Diagnostic and statistical manual of mental disorders, Fourth Edition (DSM-IV) defines idiopathic hypersomnia as EDS without narcolepsy or the associated features of other sleep disorders. It occurs in the absence of medical problems that can cause secondary hypersomnia, and it occurs "*despite normal quality and quantity of night time sleep (and sometimes despite exceptionally long periods of night time sleep). Primary Hypersomnia is thought to arise from problems with the brain's systems that regulate sleep and wake*."[1422] For idiopathic hypersomnia pharmacological treatment is possible.[1423]

(1055) Apart from stemming from these three primary origins, EDS can also be caused by disorders such as clinical depression, multiple sclerosis, epilepsy, autoimmune disorders, etc. EDS is in these cases a secondary symptom to these disorders. These so called 'secondary hypersomnia' are numerous.[1424]

1417 ID 2819.

1418 ID 2817 and ID 2818.

1419 Ibid.

1420 ID 2818.

1421 According to the National Center on Sleep Disorders Research, CPAP is the primary treatment for OSA. However, approximately 30 percent of patients that use CPAP continue to experience EDS, for which Provigil may be an appropriate adjunctive treatment. ID 2200, p. 4.

1422 Diagnostic and statistical manual of mental disorders: DSM-IV-. Washington, DC: American Psychiatric Association. 2000. ISBN 0-89042-025-4.

1423 ID 2290.

1424 ID 2817. ID 2820.

8.1.1.2. Modafinil and its ATC classification

(1056) In previous cases, the Commission has taken as a starting point for market definition in the pharmaceutical sector the Anatomical Therapeutic Chemical ("ATC") division of medicines by therapeutic use devised by the European Pharmaceutical Marketing Research Association ("EphMRA") maintained by EphMRA and Intercontinental Medical Statistics. The ATC classification has the advantage of being developed and maintained for commercial use and provides ready access to statistics. It is based on finished dose pharmaceutical products and their approved indications in different countries, which may in some instances, vary from one country to another. In the ATC system, medicines are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.[1425]

(1057) The ATC system classifies medicines into groups at five different levels. The ATC1 level refers to the anatomical main group. The ATC2 level covers the therapeutic main group. The ATC3 level allows medicines to be grouped in terms of their therapeutic/pharmacological indications. The ATC4 level normally takes into consideration the mode of action. Finally, the ATC5 level defines the narrowest classes, namely individual active substances.

(1058) In particular, the Commission has, in past Decisions, referred to the ATC3 level as the starting point for defining the relevant product market. However, in a number of cases, the Commission found that the ATC3 level classification did not yield the appropriate market definition.[1426] Belonging to the same ATC category does not necessarily imply an overlap in therapeutic uses. There is thus no systematic correspondence between a given ATC category and the relevant product market in a given case.[1427] In recent pharmaceutical merger Decisions involving *generic competitors*, the Commission has also concluded on the basis of the assessment of competitive constraints that the relevant product market could consist only of products based on the same "*molecule*" or "*API*".[1428]

1425 Both the World Health Organization (WHO) and EphMRA maintain ATC classification systems. It should be noted, for the avoidance of confusion, that the EphMRA ATC classification, whilst similar to the ATC classification maintained by the World Health Organization (WHO), is not exactly the same as the latter. The WHO classification uses similar categories but is based on active ingredients and serves a scientific, rather than commercial, purpose. Thus, a given active ingredient is classified in only one place in the WHO classification, whereas products based on it may be classified in more than one class of the EphMRA ATC classification, depending on formulation and approved use in a given country.

EphMRA classification: http://www.ephmra.org/Anatomical-Classification

WHO classification: http://www.whocc.no/atc/structure_and_principles

Comparison of the WHO ATC classification & EphMRA/PBIRG anatomical classification; Version January 2013, document available at: http://www.ephmra.org/user_uploads/who-atc%202013%20final.pdf.

1426 OJ C 372, 9.12.1997, p. 5.

1427 See for example Commission Decision of 3 August 2010 in Case M.5865-*Teva/Ratiopharm*; Commission Decision of 5 October 2012 in Case M.6613-*Watson/Actavis* and Commission Decision of 28 January 2015 in Case M.7379-*Mylan/Abbott*.

1428 For example Commission Decision of 16 March 2016 in Case M.7480-*Actavis/Allergan*, or Case M.6613-*Watson/Actavis*.

(1059) In the ATC classification system, modafinil is recorded under the code N06BA07. The N stands for nervous system (ATC1) and N06 for psychoanaleptics (ATC2). N06B[1429] comprises psychostimulants, agents used for Attention Deficit Hyperactivity Disorder ("ADHD") and nootropics (ATC3). ATC3 category N06B is further subdivided into three ATC4 categories: centrally acting sympathomimetics (A), xanthine derivatives (C) and other psychostimulants and nootropics (X).

(1060) Modafinil is defined as a centrally acting sympathomimetic in ATC4 category N06BA, which also includes: dexamfetamine, metamfetamine, methylphenidate, pemoline, fencamfamin, fenozolone, atomoxetine, fenetylline, dexmethylphenidate, and lisdexamfetamine. Sodium oxybate is classified in N07 'other nervous system drugs' (ATC2).

8.1.1.3. Therapeutic substitutability of modafinil as a differentiated product

(1061) The exact mode of action of modafinil is unknown. Modafinil is structurally different from amphetamines-like stimulants and its mode of action differs greatly from the latter. Modafinil is a long-acting wake-promoting agent. Modafinil appears to produce its effect via different neural mechanisms than conventional stimulants or other psychotropic drugs. Modafinil is a chemically unrelated compound to amphetamines-like drugs and, for example, sodium oxybate.[1430]

(1062) The list of approved indications and medical guidelines for a given drug provides a more precise description of its therapeutic uses than the ATC categorisation. An assessment of therapeutic uses of medicines may provide a better identification of potentially substitutable products for the purpose of market definition. The fact that two or more medicines share approved indications indicates a certain degree of interchangeability, but is not necessarily sufficient to conclude on this point. Different medicines can share approved indications while not being interchangeable in their therapeutic use, for instance if they are used at different stages of the therapeutic path or for distinct patient groups.

(1063) Moreover, sharing therapeutic uses does not necessarily imply any particular economic substitution patterns between products and therefore also does not necessarily determine the boundaries of the relevant product market. In fact, the Commission has observed that generic versions of a medicine are typically the closest substitute to originator's product based on the same molecule and that they are specifically designed to compete with those originator products.[1431] In such cases, the constraints posed by competing generics were the basis of product market definitions at molecule level, even if products based on other molecules shared the same therapeutic use.[1432] The observed impact of generic entry both on market shares and on prices can illustrate that the main competitive constraint of a given product is exercised by potential generic entry.

1429 In *Novartis/Hexal*, the Commission assessed the market at N06B level. However, the assessment was limited to the Netherlands, where the N06B, ATC3 class, consists exclusively of methylphenidate based medicines used to treat ADHD. That case therefore concerned only methylphenidate-based medicines and could therefore by no means be interpreted as implying that modafinil is in the same relevant market as methylphenidate. See Case M.3751-*Novartis/Hexal*.

1430 ID 2821.

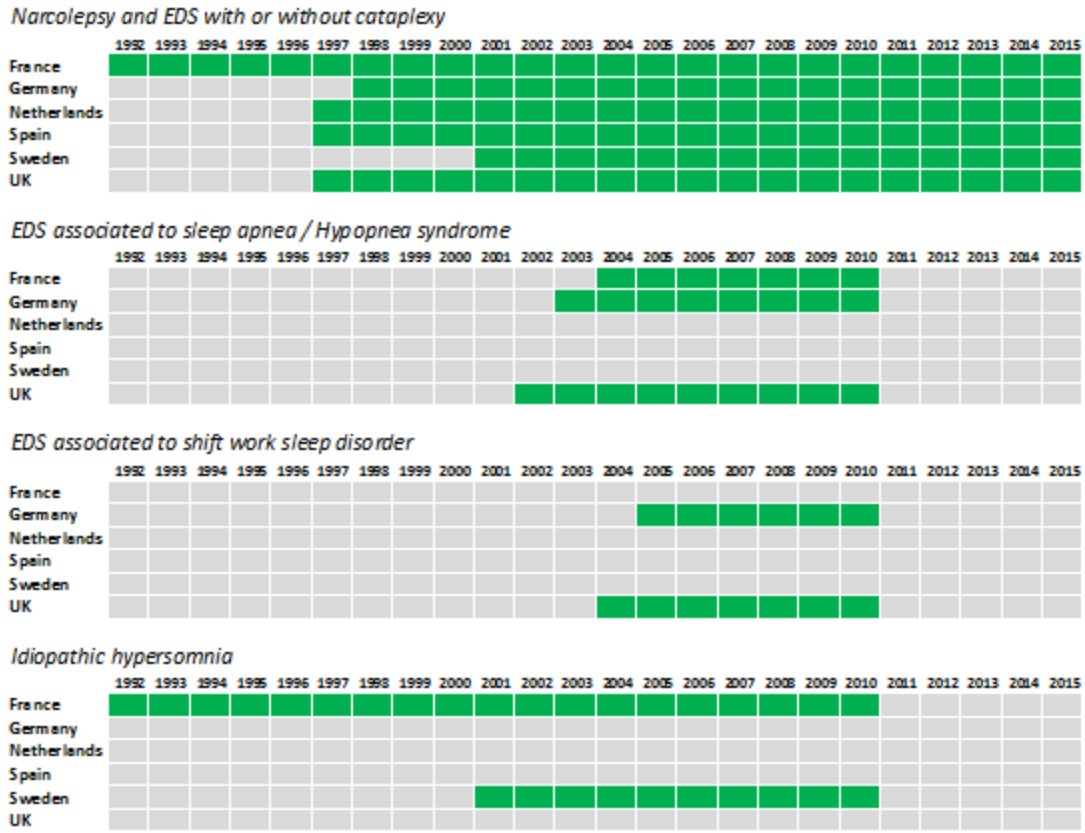
1431 Case M.6258-*Teva/Cephalon*, para. 12.

1432 See for instance Case M.5253-*Sanofi-Aventis/Zentiva*.

8.1.1.3.1. Approved indications for modafinil

(1064) Since the market launch of modafinil, narcolepsy (with or without cataplexy) has been the main approved indication of the product and the only one that remains valid today. Other indications were approved in some Member States until 2011, including EDS associated with Obstructive Sleep Apnoea ("OSA"), EDS associated with moderate to severe shift work sleep disorder ("SWSD"), and idiopathic hypersomnia ("IH") (see Section 4.1.1). Figure 2 reports the periods during which these indications were approved in the By-Effect Countries.[1433]

Figure 2: Modafinil approved indications in the By-Effect Countries



Source: Commission on the basis of responses from national health authorities.[1434]

(1065) Cephalon submitted a report elaborated by IMS Health (now IQVIA)[1435] with estimated proportions of modafinil prescriptions by indication within a number of

---

1433 In response to the Article 18 Request of 11 October 2010, Teva submitted that modafinil has been at some point approved for narcolepsy in Austria, Belgium, Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Poland, Portugal, Slovakia, Spain, Sweden and the United Kingdom; for IH in France, Norway and Sweden; for OSA in Austria, Germany, France, Ireland and the United Kingdom; and for SWSD, in the United Kingdom. See ID 1290, page 1 of 2. For the situation in 2002, see ID 210, p. 4-13.

1434 France: ID 2557, ID 2558, ID 2559, ID 2560, ID 2561, ID 2562, ID 2563, ID 2564 and ID 2565; Germany: ID 2576; the Netherlands: ID 2566; Spain: ID 2584, Sweden: ID 2598; United Kingdom: ID 2570, ID 2571, ID 2572, ID 2573, ID 2574 and ID 2575.

1435 As explained in the report: "*The IMS MIDAS database was used to estimate the proportion of modafinil prescriptions by indication within each Member State where available. The data collection methodology for MIDAS differs by country in order to account for the various healthcare systems; however, the principles behind the data collection are similar. In general, a panel of physicians within*

Member States, including the following By-Effect Countries: France,[1436] Germany,[1437] the Netherlands,[1438] Spain,[1439] and the United Kingdom[1440]. The report suggests that, at least in 2009, modafinil was used to some extent for other indications, such as multiple sclerosis[1441].

(1066) On 18 November 2010, the Committee for Medicinal Products for Human Use ("CHMP") of the EMA issued certain conclusions and recommendations regarding indications that could be treated by modafinil.[1442] Following this, on 27 January 2011, the European Commission adopted a Decision concerning MA's for modafinil-based medicines.[1443] The Commission ordered the Member States to maintain and amend national MA's for modafinil-containing medicines on the basis of the scientific conclusions of the Committee. Consequently, since January 2011, the use of modafinil in the EEA is indicated only for the treatment of narcolepsy, excluding the use of modafinil in patients with uncontrolled hypertension or irregular heartbeat and in children. The use of modafinil is no longer indicated to treat idiopathic hypersomnia, obstructive sleep apnoea and shift work sleep disorder since January 2011.

8.1.1.3.2. Medical guidelines in relation to modafinil

(1067) Medicines sharing the same therapeutic indications can be used in clinical practice in a distinct way. If such a distinct use in practice is observed, it must be taken into consideration when assessing the competitive landscape in which a medicinal product is marketed and thus for market definition.

(1068) The role of a given medicine in the therapeutic strategy is typically described in medical guidelines and consensus papers published by leading practitioners in the relevant areas. The purpose of these medical guidelines is educational, aiming to offer balanced information to practitioners to help them make decisions in everyday practice. They are also intended for public health authorities, to raise awareness and improve treatment. They are based on all the available sources of scientific evidence, including large clinical trials and their meta-analysis. As regards EDS, before and

---

each country agrees to provide records of patients who they have treated over a defined period. The needed records are extracted by IMS. The prescription information obtained is then used to project use patterns for the entire country. However, the confidence of any projection of product use by indication is directly related to the number of prescriptions recorded within the records." ID 1293. IMS Health merged with Quintiles in 2016 and the resulting company was named QuintilesIMS. The company was renamed to IQVIA in 2017.

1436 The report estimated that 45% of modafinil prescriptions were related to 'Narcolepsy and cataplexy' and another 40% to 'Hypersomnia' in France in 2009.

1437 The report estimated that 46% were related to 'Narcolepsy and cataplexy' and another 12% to 'Sleep apnoea' in 2009, while 24% of prescriptions could not be assigned to any specific therapeutic use.

1438 The report estimated that 45% were related to 'Narcolepsy and cataplexy', 35% to 'Hypersomnia' and the remaining 19% to 'Multiple sclerosis' in 2009.

1439 The report estimated that 60% were related to 'Multiple sclerosis', 21% to 'Narcolepsy and cataplexy' and another 14% to 'Hypersomnia' in 2009.

1440 The report estimated that 27% of modafinil prescriptions were assigned to 'Multiple sclerosis' and 14% for unspecified brain disorders, while it was unable to identify the therapeutic use of 32% of modafinil prescriptions in 2009.

1441 As regards multiple sclerosis (and other disorders), EDS is a secondary symptom to these disorders.

1442 The first conclusions of the CHMP concerning this matter were taken in July 2010. Cephalon submitted detailed grounds for the re-examination, and on 18 November 2010, the CHMP confirmed its earlier findings.

1443 Commission Decision C(2011)578 concerning MA for modafinil, see also Section 4.8.2.1.

during the period concerned by this Decision, there were a number of medical guidelines published.

(1069) In 2006, the European Federation of Neurological Societies ("EFNS") published the first pan-European guidelines on the management of narcolepsy ("EFNS 2006 Guidelines").[1444] The authors explained that modafinil had been used for over 10 years with the consequence of decreasing the need to use amphetamine and amphetamine-like stimulants for the treatment of EDS and that in 2006 in Europe only modafinil and methylphenidate had been approved for narcolepsy. At the time of the publication of the EFNS 2006 Guidelines, sodium oxybate had already been approved for the treatment of cataplexy, but not yet for the treatment of any of the EDS causes[1445].

(1070) The EFNS 2006 Guidelines recommended that the first line pharmacological treatment for EDS should rely on modafinil. Second line pharmacological treatment would be methylphenidate. In 2011, the EFNS produced updated guidelines for the management of narcolepsy in adults ("EFNS 2011 Guidelines").[1446] These updated guidelines recommended that modafinil should be prescribed as a first line treatment when the most disturbing symptom was EDS, based on its efficacy, limited adverse effects and easiness of manipulation.

(1071) The EFNS 2006 Guidelines and the EFNS 2011 Guidelines include only modafinil (as the first line treatment) and sodium oxybates and methylphenidates in their recommendations, no other drugs being recommended for the indications approved for modafinil.[1447] The medical guidelines hence specify the recommended use of modafinil and limit its substitutability with methylphenidate and sodium oxybate, as is explained in the next Section.

8.1.1.3.3. Modafinil is a differentiated product

Methylphenidate is not a substitute for modafinil

(1072) Methylphenidate is a medicine that was and is primarily used to treat children between 6 and 18 years of age who have ADHD. Methylphenidate belongs to a group of so-called psychostimulants and is thought to work by enhancing the activity of areas of the brain that control attention and concentration.[1448] Methylphenidate is indicated as part of a comprehensive treatment programme when remedial measures alone prove insufficient. Treatment must be under the supervision of a specialist in childhood behavioural disorders. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10 and should be based on a complete history and evaluation of the patient. Methylphenidate treatment is not indicated in all children with ADHD and the decision to use the drug must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the

1444 ID 2231.
1445 ID 2231, see also Recital (1049).
1446 ID 2232.
1447 ID 2231, p. 5, ID 2232, p. 7.
1448 EMA/444166/2013 rev. 1.

child's age. Methylphenidate should always be used according to the licensed indication and according to prescribing / diagnostic guidelines.[1449]

(1073) Medical guidelines provide a more complete view regarding the medical use of various medicines than the list of approved indications. They show that although some methylphenidates were also licensed for narcolepsy in some By-Effect Countries (for example, 10 mg Ritalin of Novartis), methylphenidates and modafinil were not seen as valid alternatives for this indication in practice.

(1074) Methylphenidate was only recommended by the EFNS 2011 Guidelines if modafinil was insufficiently active and if sodium oxybate was not recommended.[1450] The short-acting effect of methylphenidate is considered of interest to supplement modafinil at specific times of the day or in situations where a maximum of alertness is required, but methylphenidate and modafinil were not considered as substitutes.[1451]

(1075) In France, methylphenidates were approved to treat narcolepsy with or without cataplexy, but only in case of inefficiency of modafinil in adults and for treatment of narcolepsy with or without cataplexy in children of 6 years and more.[1452] This concerned only the 10 mg dosage of the brand medicine Ritalin.[1453] In the Netherlands, only the 10 mg immediate release dosage of the manufacturer Novartis was approved for narcolepsy in adults.[1454] As indicated above, the primary usage of methylphenidate was used for treating ADHD. Modafinil has always been the primary treatment for narcolepsy. Treatment with methylphenidate was recommended where sodium oxybate was not indicated and where modafinil was insufficiently active.[1455] In the other By-Effect Countries, methylphenidates were not indicated for narcolepsy.[1456]

(1076) These observations illustrate that even if modafinil and methylphenidates were to a limited level functionally interchangeable, they were used in different circumstances and for different patient groups. Hence, both medicines could not exert competitive pressure on each other. The objective characteristics of the products differ, as well as their role in the therapeutic strategy, as shown by the medical guidelines. It

---

1449 Committee for Medicinal Products for Human Use "Elements recommended for inclusion in Summaries of Product Characteristics for methylphenidate-containing medicinal products authorised for the treatment of ADHD in children aged six years and above and adolescents", 22 January 2009.

1450 ID 2232, p. 7.

1451 According to the National Center on Sleep Disorders Research, CPAP is the primary treatment for OSA (Obstructive Sleep Apnoea/Hypopnea Syndrome). However, approximately 30 percent of patients that use CPAP continue to experience EDS, for which Provigil may be an appropriate adjunctive treatment. ID 2200, p. 4.

1452 In other countries, sometimes methylfenidates may have been prescribed for children as well, off-label. See Case M.6258-*Teva/Cephalon*, paragraph 89.

1453 ID 2605, ID 2690, ID 2691, ID 2761, ID 2762, ID 2763 and ID 2764.

1454 ID 2781.

1455 Modafinil on the other hand has been used as a second line off-label treatment for ADHD, where patients are irresponsive to methylphenidate, see Case M.6258-*Teva/Cephalon*, paragraph 89. However, for the purposes of this Decision, the degree of competitive constraint from modafinil on methylphenidate is not relevant, what matters are constraints in the other direction, that is to say from methylphenidate on modafinil, which has been considered to have significant limitations, in the Decision in Case M.6258-*Teva/Cephalon*, paragraph 91.

1456 Germany: ID 2631, ID 2634, ID 2635, ID 2636, ID 2637, ID 2638, ID 2639, ID 2640, ID 2654; Spain: ID 2686, ID 2699, ID 2701; Sweden: ID 2646, ID 2647, ID 2648; United Kingdom ID 2809, ID 2810, ID 2811, ID 2812 and ID 2813.

therefore appears that there are significant limitations on the substitutability of modafinil with methylphenidate.

Sodium Oxybate is not a substitute for modafinil

(1077) To this date, only one other medicine was approved by the EMA for the treatment of EDS as a symptom of cataplexy: sodium oxybate. Sodium oxybate was not approved for EDS as a symptom of narcolepsy without cataplexy, for EDS as a symptom of disturbed night-time sleeping patterns or EDS due to unknown causes ("idiopathic hypersomnia").

(1078) Sodium oxybate-based products are sedatives. Sodium oxybate is taken during the night in order to induce night time sleep, whilst reducing the periods of daytime sleep. Sodium oxybate was recommended for the treatment of cataplexy in combination with narcolepsy. While the EFNS 2006 Guidelines considered the possibility of using sodium oxybate as a first line pharmacological treatment in the future, they did not recommend it as sodium oxybate had not yet been approved for the treatment of EDS. The EFNS 2006 Guidelines stated that in severe cases of EDS, the use of modafinil and sodium oxybate in combination appeared to be effective. Pursuant to the EFNS 2011 Guidelines, sodium oxybate is recommended when EDS coexists with cataplexy and poor sleep.[1457] However, the more delicate manipulation of sodium oxybate required additional vigilance. Moreover, the EFNS 2011 Guidelines stressed that sodium oxybate combined with modafinil was generally more successful than sodium oxybate alone.

(1079) Sodium oxybates and modafinil, therefore, cannot be regarded as closely substitutable medicines either. Sodium oxybate is a strong hypnotic medication. Sodium oxybate helps to consolidate and improve the quality of night-time sleep, which is of particular benefit to patients with narcolepsy who suffer frequent night-time awakenings.[1458] While modafinil is a wakefulness promoting agent, sodium oxybate consolidates sleep. In addition, it provides relief of cataplexy during one's waking hours. The way in which sodium oxybate treats EDS is hence diametrically opposite from modafinil. A distinct segment of patients may use modafinil instead of sodium oxybate in case of narcolepsy – if at all: for example a patient in charge of a baby may need to stay sufficiently alert during the night and hence may need to avoid taking strong sedatives. Moreover, modafinil has a milder and more targeted effect on the central nervous system. Sodium oxybates are also generally more complex to administer than modafinil. Sodium oxybate has to be administered in more doses, one of which is administered during the night.

(1080) Moreover, sodium oxybate was believed to have more troublesome side effects. It is therefore most often prescribed for patients with severe cataplexy symptoms during daytime or in cases where there is failure to respond to modafinil or where troublesome side effects of the use of modafinil are present.[1459] Although they share the approved therapeutic indication, their therapeutic interchangeability is limited in practice as shown by the medical guidelines. The very different ways in which sodium oxybates and modafinil operate is the reason why they are used in

1457 ID 2232, p. 7.
1458 Case M.6258-*Teva/Cephalon*, paragraph 89.
1459 Case M.6258-*Teva/Cephalon*, paragraph 89.

combination for patients with cataplexy, because each of them adds a distinct contribution to the management of the patient's condition.[1460]

(1081) All these specificities indicate that sodium oxybate does not exert significant competitive pressure on modafinil for the treatment of EDS as a symptom of narcolepsy. If anything, they must be seen as therapeutic complements rather than substitutes. Sodium oxybate products are therefore not capable of significantly constraining modafinil.[1461]

Other psychostimulants are not substitutes for modafinil

(1082) Other psychostimulants included in the N06B class (for example, dexamphetamine based products) were not indicated in the EFNS Guidelines as a first line treatment of narcolepsy with or without cataplexy.[1462] In addition, amphetamines are classified as controlled drugs and associated with higher level of risks and more troublesome side effects.[1463] Pemoline[1464] on the other hand showed no or only limited therapeutic improvements[1465] and has been withdrawn from the market in most countries due to potential lethal hepatotoxicity.[1466] According to the EFNS 2006 Guidelines, the role of other compounds became fairly limited and only recommended in case the preferred treatments failed.[1467]

(1083) Accordingly, other psychostimulants do not exert significant competitive pressure on modafinil.

Conclusion

(1084) Modafinil is therefore a clearly differentiated product, in terms of both its objective chemical attributes and its distinct role in the therapeutic strategy for the treatment of EDS. Due to the significant degree of differentiation, methylphenidates, sodium oxybate or other psychostimulants cannot exert a strong competitive constraint on modafinil.

(1085) The above is also underlined by Cephalon's own view on the product market. Cephalon assessed Provigil as a "novel wakefulness promoting compound that offers the patient improved functioning and quality of life without detrimental side effects and [which] provides the physician with an easy to use, cost/effective and well tolerated option for their sleepy patients."[1468] Modafinil was considered to be the "gold standard" for the treatment of EDS. Cephalon's CEO described Provigil as a unique drug that "created the category of wakefulness products" and "faces no competition".[1469] Provigil was said to have a favourable benefit and side-effect

---

1460 ID 2817. ID 2819.

1461 Case M.6258-*Teva/Cephalon*, paragraph 89.

1462 ID 2231, p. 2, ID 2232, p. 7.

1463 ID 2231, p. 4, ID 2232, p. 5.

1464 This drug was tested for use on narcoleptic patients (ID 2232, p. 7), it is not an amphetamine, but a drug of the oxazolidinone class (ID 2232, p. 7).

1465 ID 2231, p. 5, ID 2232, p. 7.

1466 ID 2232, p. 7.

1467 ID 2231, p. 6.

1468 ID 314, p. 2. (United Kingdom) Provigil Marketing Plan 2004, discussed at 04/11/2003 meeting.

1469 ID 2215, paragraph 27.

profile when compared to other amphetamine-like stimulants.[1470] Provigil users are supposed to face reduced risk of addiction or unwanted side-effects.

(1086) In internal documents, Cephalon pointed out that modafinil was indicated for the treatment of EDS, associated with pathological disorders (including narcolepsy). According to Cephalon's internal documents EDS could be associated with many medical conditions in three distinct but overlapping areas. It describes these areas as, disorders of sleep wake regulation (narcolepsy), disorders of sleep disruption and disorders of circadian alignment. Cephalon stated that at the time there were no specific treatments for these disorders, apart from amphetamines.[1471] However, it regarded amphetamines not as a substitute because they would only be used as a second line option. Amphetamines (such as dexedrine and methylphenidate) were, according to Cephalon mainly used in 'reserve', that is to say for those who showed insufficient response to higher doses of modafinil.[1472]

(1087) In December 2008, an internal Cephalon document notes, with respect to the United Kingdom, "*One direct competitor - Xyrem (sodium oxybate) with 2% of the market in branded* [Excessive sleepiness] *products.*"[1473] A March 2009 internal Cephalon document covering Europe, indicates the first line treatment nature of Provigil for narcolepsy-associated excessive sleepiness, OSA/HS-associated excessive sleepiness and Shift Work Sleep Disorder-associated excessive sleepiness.[1474] An Irish Marketing Plan of 2010 states: "*No direct competitors. Only competitor might be Xyrem (sodium oxybate). Indicated for treatment of narcolepsy with cataplexy in adult*".[1475] A presentation of a National Sales Meeting Ό6 mentions: "*Right now, we have no direct competition. Sure there are stimulants and caffeine, but in terms of pharmaceutical agents designed to address excessive sleepiness, Provigil is it*".[1476]

(1088) On the basis of the above, the Commission concludes that there is no significant therapeutic substitutability between modafinil and any other products included in the ATC 3 class N06B. Modafinil is a differentiated product that faces at most limited competitive constraints from non-modafinil based products. This conclusion applies for all approved indications of modafinil.[1477]

(1089) However, as will be discussed in the following Sections, even if methylphenidates, sodium oxybates and/or amphetamines exert a limited competitive constraint on modafinil, this would not change the analysis of the effects of the Settlement Agreement. In this context, it will be shown that Cephalon held some degree of market power even if, for some specific patient groups, modafinil could be substituted with methylphenidate, sodium oxybate or amphetamines.

1470 However, as explained further below, in a recent review, the CHMP noted that modafinil is strongly linked to a risk of serious, life-threatening skin reactions, especially in children. The CHMP also noted a link between modafinil and psychiatric adverse reactions, such as suicidal thoughts, depression, psychotic episodes and between modafinil and cardiovascular adverse reactions, such as hypertension and irregular heartbeat.

1471 See, for example, ID 314, p. 4 and p. 6.

1472 See, for example, ID 314, p. 10.

1473 ID 221, p. 54.

1474 ID 221, p. 85-94 and in particular p. 87-88.

1475 ID 408, p. 40.

1476 ID 2841-1226, p.4.

1477 See, for example, ID 2288, ID 2289 and ID 2290; see also ID 1908.

8.1.1.4. Generic substitutability of modafinil as the main competitive constraint

(1090) Competitive constraints from undifferentiated products competing on price tend to be stronger than the constraints that a differentiated product can exert. This is the reason why in most pharmaceutical markets generics constitute the main source of competitive pressure as soon as their entry becomes a real prospect. The Court of Justice in the *Generics (UK) and Others* case, stated: *"the interchangeability or substitutability of products are naturally dynamic, in that a new supply of products may alter the conception of the products considered to be interchangeable with a product already present on the market or as substitutable for that product and, in that way, justify a new definition of the parameters of the relevant market".*[1478] The Court of Justice further explained that provided that the generic manufacturer are *"in position to present themselves within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of the originator medicine already on the market", "there is sufficient degree of interchangeability between the originator medicine and the generic medicines concerned",* particularly where generic manufacturers *"have formed a prior effective strategy for market entry, have taken steps necessary to achieve it, suh as, for example, lodging of an MA application or the obtaining of such an MA […]"*.[1479] Accordingly, regardless of the finding that the originator relies on its process patents capable of possibly preventing the market entry of generics and the validity of which remains uncertain, *the generic versions of an originator medicine containing an active ingredient which is in the public domain* […] *must be taken into account for the purposes of the relevant market"*.[1480]

(1091) It is important to assess the degree of therapeutic substitutability between Cephalon's modafinil and generic modafinil products, in order to assess the likely source of the main competitive constraint faced by Cephalon's modafinil at the time of the Settlement Agreement.

(1092) Generic pharmaceutical companies typically produce copies of originator drugs which therefore can normally be viewed as the closest substitute to those drugs. In regulatory approval procedures, a generic drug manufacturer has to demonstrate that the generic version of the originator drug has identical quality and purity and is biologically equivalent to the originator drug. Indeed, generic versions of originator medicines are specifically designed to compete with those medicines and normally represent the closest substitute to them. As explained in Section 2.3.3, when generic entry occurs, price tends to drop significantly (sometimes up to 80%-90%) and volume shifts to generics.[1481] This leads to the elimination of the high margin that the originator enjoyed during the period before generic entry. Regulatory systems usually have measures stimulating direct price competition between the originator product and generic products or anticipate statutory price cuts on generic entry, via substitution rules or incentives for pharmacies.

(1093) The assessment of the evolution of originator and generic modafinil sales in the period before and after generic entry in a number of Member States is a useful

---

1478 Case C-307/18, *Generics (UK) and Others*, paragraph 130 referring to AG Kokott Opinion in the case, point 222.

1479 Case C-307/18, *Generics (UK) and Others*, paragraphs 132-134.

1480 Case C-307/18, *Generics (UK) and Others*, paragraphs 136-138.

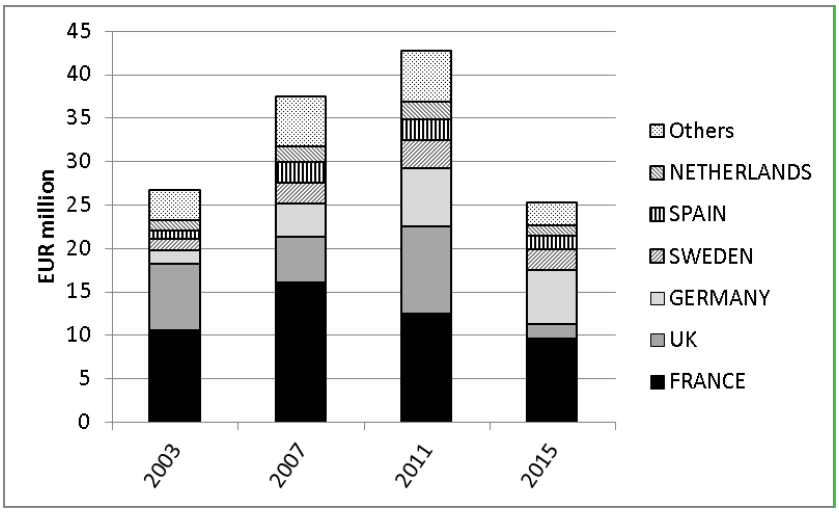
1481 Report on the pharmaceutical sector inquiry, 8 July 2009, European Commission.

exercise to show the particular relevance of generics as a competitive constraint in the case of modafinil, especially in the situation where other differentiated products based on different molecules exerted only limited competitive pressure on modafinil-based products.

(1094) Since market launch, Cephalon's worldwide sales of Provigil have grown substantially to a maximum of USD 1.125 billion in 2010. Value sales in the EEA followed a similar growth trend but remained of a relatively small scale as, in the entire period, United States value sales accounted for more than 90% of total value sales. Modafinil value sales in the EEA as a whole increased during the years preceding the Settlement Agreement and continued to increase until 2010, which is the year of maximum expansion of modafinil value sales in the EEA. According to data from IQVIA,[1482] yearly value sales of modafinil in the EEA was EUR 18.4 million in 2002 and reached EUR 50.4 million in 2010. This represents a yearly average growth of 13.7% over the period 2002-2010 in the EEA. Similarly, volume sales increased at an average yearly rate of 15.5% in the same period in the EEA.

(1095) Modafinil value sales have been unevenly distributed across the EEA, with the By-Effect Countries (France, Germany, the Netherlands, Spain, Sweden and the United Kingdom) accounting for more than 85% of the value sales in the area for the period 2002-2014 (including the entire period of infringement 2006-2011).

Figure 3: Value sales of modafinil in the EEA by By-Effect Countries



Source: Commission's calculations based on IQVIA data and data submitted by the companies in the United Kingdom

(1096) In the following Sections 8.1.1.4.1-8.1.1.4.7, the Commission provides for each of the By-Effect Countries the evolution of Cephalon's and generic modafinil sales in

1482 For this and all subsequent references to the IQVIA data, it must be noted that data and other information obtained from IQVIA, a provider of pharmaceutical data services, that is cited or used in this Decision (including empirical analyses performed by the Commission) were partially submitted by Cephalon in response to the Article 18 Request of 16 December 2013, and partially obtained by the Commission through direct purchase of the data from IQVIA. IQVIA has not acted as an advisor, expert or consultant on behalf of the Commission in connection with this proceeding. For the United Kingdom, the Commission has used data submitted directly by the companies active in the modafinil market in the United Kingdom, for the reasons explained in footnote 1489.

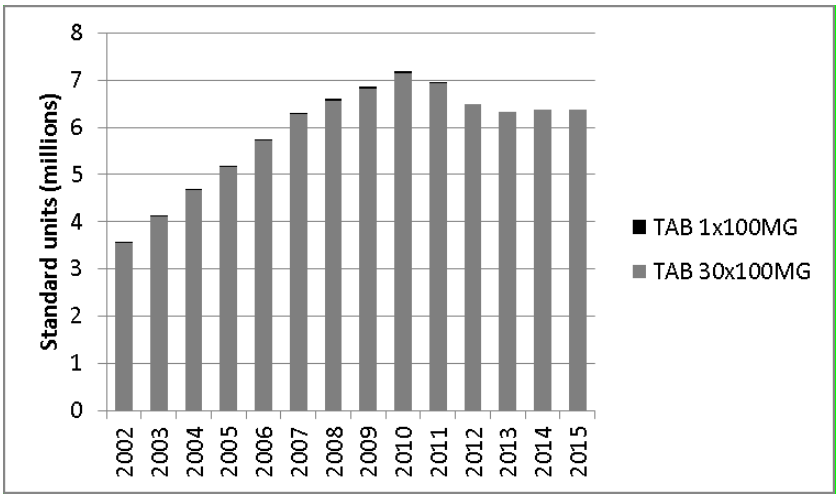
the period before and after the generic entry, that is to say *effective* generic entry[1483], to illustrate the competitive constraints of the generic modafinil on the originator modafinil, including in terms of its effects on prices. In addition, the Commission shows that the Parties' claims regarding incompleteness or defectiveness in the Commission's analysis of the sales and prices of modafinil in the By-Effect Countries are unfounded because the examples selected by the Parties allegedly supporting their claim concern a misinterpretation by the Parties of the evidence and of the Commissions' analysis.

8.1.1.4.1. Modafinil sales and prices in France

(1097) France was not only the first country were modafinil was launched, but it has also been the largest EEA market for modafinil. The French market for modafinil grew from EUR 9.1 million in 2002, to EUR 18.3 million in 2010. By the end of 2013, yearly sales had decreased to EUR 11.3 million, partly due to a reduction in the volumes of modafinil sold since 2010 and partly to a reduction in the average price for modafinil in France.

(1098) The main modafinil formulation marketed in France is the 100 mg tablet in packs of 30 tablets ("*30x100 mg formulation*"). This formulation was the only modafinil formulation with recorded sales in France in 2013.

Figure 4: Volume sales of modafinil in France by formulation



Source: Commission's calculations based on IQVIA data

(1099) The Parties submit that the reason why volume sales of modafinil in France decreased as of 2010 may have been that a significant number of patients switched to substitutable products as of 2011[1484]. The Parties' description is not supported by the facts. Data in Figure 4 show a sudden reduction in volume sales in 2011-2013, right after the regulatory withdrawal of approved indications for modafinil by the EMA in 2010, as explained in Section 8.1.1.3.1 and illustrated in Figure 2. The loss of approved indications restricted the number of patients eligible for modafinil-based therapy, negatively impacting on the use of modafinil. Modafinil volume sales in France remained largely stable between 2013 and 2015. The sudden decrease in

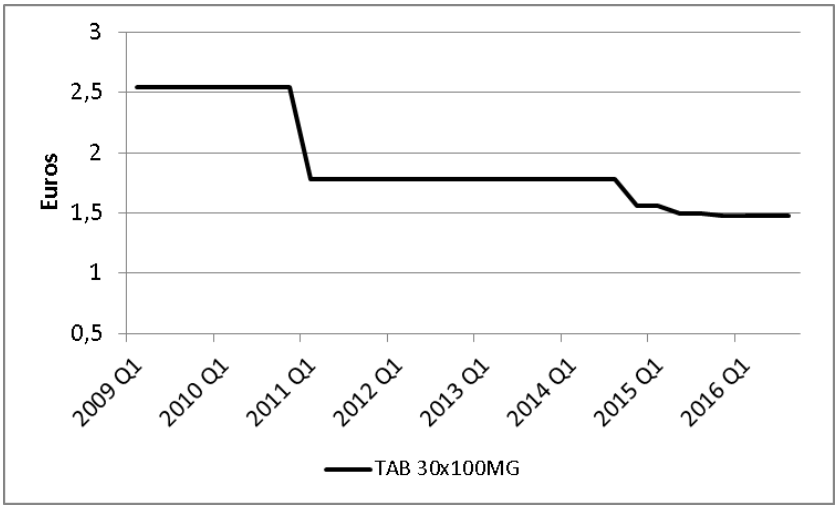
1483 *Effective* generic entry is determined on the basis of the generic modafinil sales registered in the IQVIA database.

1484 SO Reply, paragraph 531.

volume sales in 2011-2012, immediately after loss of approved indications in 2010, reflects a regulatory change, not any competitive interaction between modafinil and any other product.

(1100) The average price of the 30x100 mg formulation remained stable at EUR 2.54 per tablet in France until the effective entry of generic competitors in the third quarter of 2011, as indicated by the data on generic sales. Generic entry was accompanied by a 30% reduction of its average price. As of 2011 and until 2015, Cephalon and all generic entrants sold the 30x100 mg formulation at the same new price of EUR 1.78 per tablet. This generic entry happened in a context in which, *ex-post*, the provisions of the Settlement Agreement soon after ceased to apply because of the merger between Cephalon and Teva. At the time of the Settlement Agreement, there was no *ex-ante* expectation that such would be the market context in 2011. This *ex-post* observation of generic entry illustrates the actual impact of independent generic entry in the modafinil market in France.

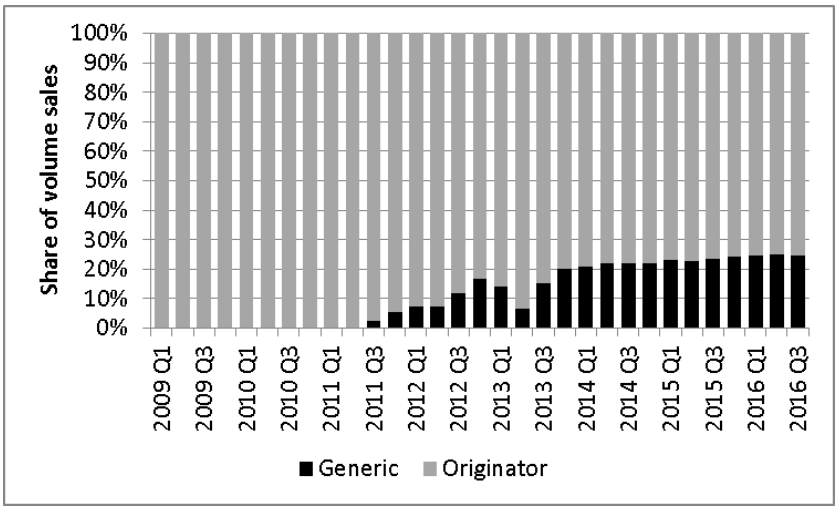
Figure 5: Average price per tablet in France, by formulation



Source: Commission's calculations based on IQVIA data

(1101) Since the launch of generic versions of modafinil in 2011, generics have gradually gained market share in France. Generic modafinil attained a 22% share of sales, both in volume and value terms, in 2014. Such a moderate level of generic penetration may be partly explained by the fact that originator and generics have been sold at the same price, which did not incentivise the switching from the originator to generic versions of modafinil. Savings from generic entry in France, therefore, appear to have resulted mainly from the price drop that generic entry triggered for all versions of modafinil.

Figure 6: Market share of generics in France, by volume



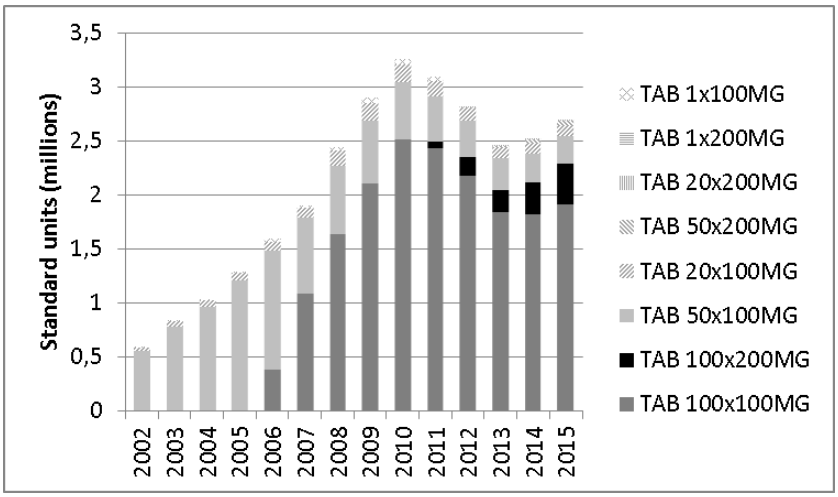
Source: Commission's calculations based on IQVIA data

8.1.1.4.2. Modafinil sales and prices in Germany

(1102) The German market for modafinil grew from EUR 1.1 million in 2002, up to EUR 6.8 million in 2010. By the end of 2013, yearly sales had decreased to EUR 6.6 million, partly due to a reduction in the volumes of modafinil sold since 2010 and partly to a moderate reduction of around 10% in the average price for modafinil in Germany (see Figure 7 below).

(1103) The main modafinil formulation marketed in Germany was the 100 mg tablet in packs of 50 tablets ("50x100 mg formulation") in 2002, but sales shifted over the following years towards the packs of 100 tablets ("100x100 mg formulation"). This formulation represented 75% of all modafinil tablets sold in Germany in 2013.

Figure 7: Volume sales of modafinil in Germany by formulation



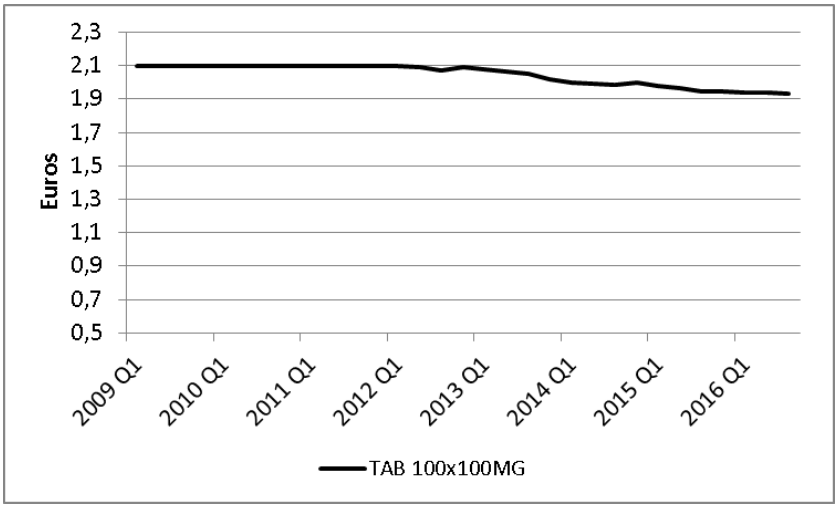
Source: Commission's calculations based on IQVIA data

(1104) The Parties submit that the reason why volume sales of modafinil in Germany decreased as of 2010 may have been that a significant number of patients switched to substitutable products as of 2011. The Parties' description is not supported by the facts. Data in Figure 7 show a sudden reduction in volume sales in 2011-2013, right after the regulatory withdrawal of approved indications for modafinil by the EMA in 2010, as explained in Section 8.1.1.3.1 and illustrated in Figure 2. The loss of

approved indications restricted the number of patients eligible for modafinil-based therapy, negatively impacting on the use of modafinil. Modafinil volume sales in Germany started to increase again in 2014. The sudden decrease in volume sales in 2011-2013, immediately after loss of approved indications in 2010, reflects a regulatory change, not any competitive interaction between modafinil and any other product.

(1105) The 50x100 mg and 100x100 mg formulations of modafinil have been sold at the same average price per tablet throughout the period 2002-2014 in Germany. The average price was EUR 1.87 per tablet before it increased first to EUR 2.05 in 2005 and subsequently to EUR 2.10 in 2009. The average price started slightly to decrease following generic entry in 2012. While Cephalon continued to sell both formulations at EUR 2.10 per tablet for the remainder of the period under analysis, generic competitors launched their own formulations to the market in 2012 at EUR 1.86 per tablet, that is, 11% lower than the originator. This *ex-post* observation of generic entry illustrates the actual impact of independent generic entry in the modafinil market in Germany.

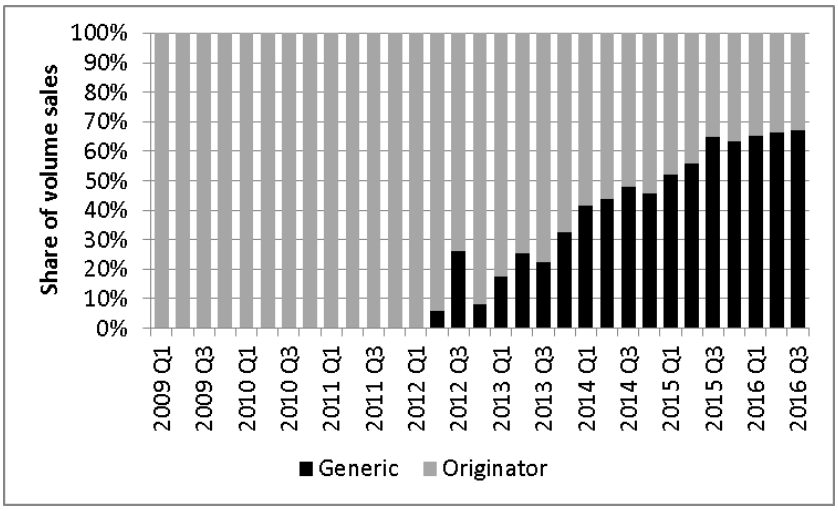
Figure 8: Average prices per tablet in Germany, by formulation



Source: Commission's calculations based on IQVIA data

(1106) Since the launch of generic versions of modafinil in 2012, generics have gained substantial market shares in Germany. Generic modafinil attained a 48% share of sales in volume and a 44% market share in value by the third quarter of 2014. Such level of generic penetration may be partly explained by the price differential between originator and generic modafinil, which has incentivised the switching from the originator to generic versions of modafinil. Savings from generic entry in Germany, therefore, appear to have resulted mainly from generics undercutting the originator price and gaining substantial market shares.

Figure 9: Market share of generics in Germany, by volume



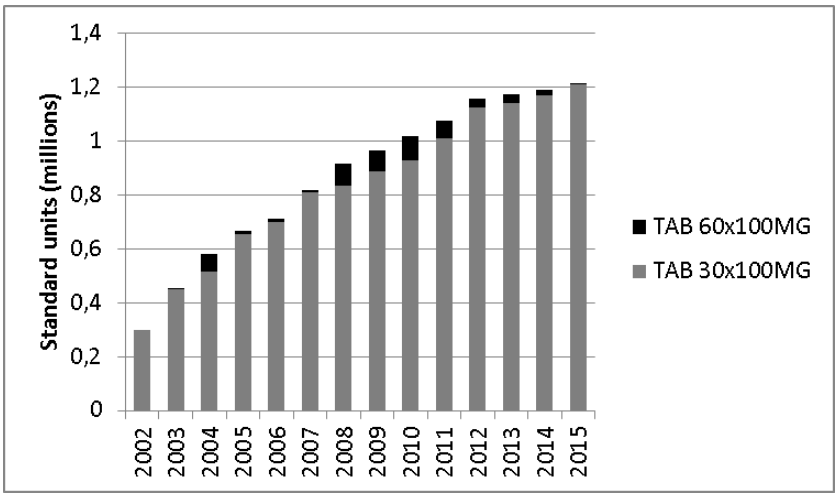
Source: Commission's calculations based on IQVIA data

8.1.1.4.3. Modafinil sales and prices in the Netherlands

(1107) The Dutch market[1485] for modafinil grew from EUR 0.7 million in 2002, up to EUR 1.9 million in 2011. By the end of 2013, yearly sales had decreased to EUR 1.6 million, partly due to a reduction in the volumes of modafinil sold since 2010 and partly to a reduction in the average price for modafinil in the Netherlands.

(1108) The main modafinil formulation marketed in the Netherlands is the 30x100 mg formulation. This formulation represented 99% of all modafinil tablets sold in the Netherlands in 2013.

Figure 10: Volume sales of modafinil in the Netherlands by formulation



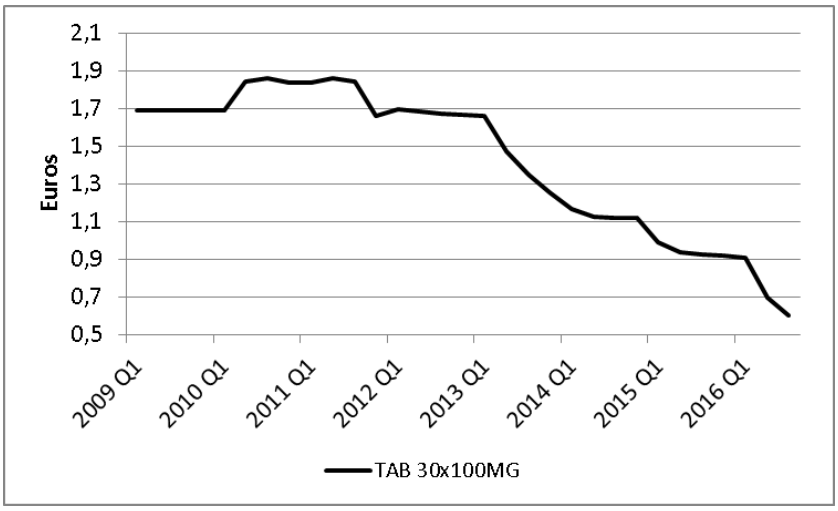
Source: Commission's calculations based on IQVIA data

(1109) The average price of the 30x100 mg formulation in the Netherlands decreased over the period 2002-2014. After being consistently at or above EUR 2.30 per tablet until mid-2007, the average price fluctuated between EUR 1.70 and 1.85 in the period prior to generic entry (corresponding to the difference in price in the range of 20-

[1485] With regard to the Netherlands, occasional parallel imports appear in the IQVIA data.

26%). Since the beginning of 2013, the average price dropped gradually as generics progressively gained market share and attained EUR 1.10 per tablet in 2014 and even lower EUR 0.65 in 2016. This represents a price drop of 65% compared to the average prices prior to generic entry. This ex-post observation of generic entry illustrates the actual impact of independent generic entry in the modafinil market in the Netherlands.

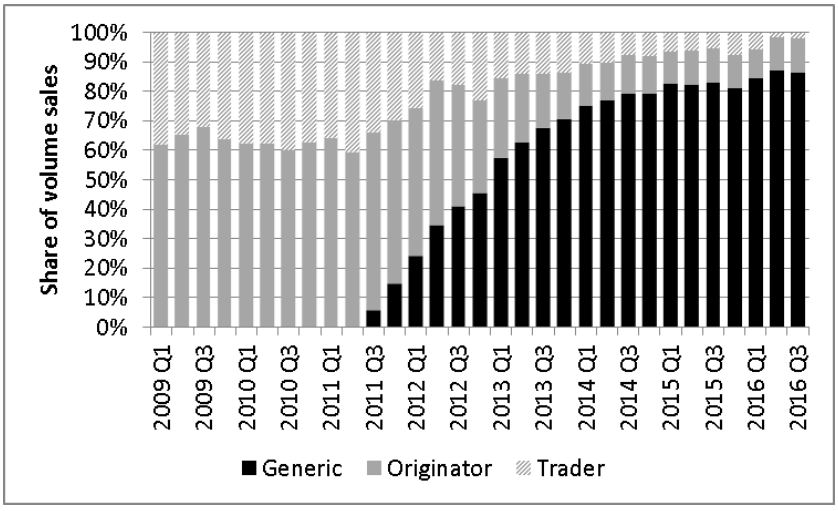
Figure 11: Average price per tablet in the Netherlands, by formulation



Source: Commission's calculations based on IMS data

(1110) Since the effective entry of generic versions of modafinil in 2011, generics have rapidly gained substantial market shares in the Netherlands. Generic modafinil attained an 81% share of sales in volume and a 74% market share in value by the third quarter of 2014. Such level of generic penetration may be partly explained by the price differential between Cephalon and the generics, which has incentivised the switching from the originator to generic versions of modafinil. Savings from generic entry in the Netherlands, therefore, appear to have resulted mainly from generics undercutting the originator price and gaining substantial market shares.

Figure 12: Market share of generics in the Netherlands, by volume



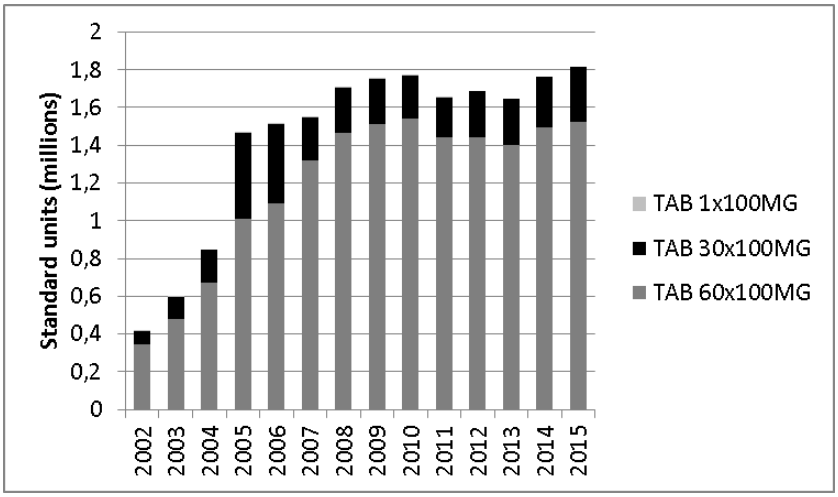
Source: Commission's calculations based on IQVIA data

8.1.1.4.4. Modafinil sales and prices in Spain

(1111) The Spanish market for modafinil grew from EUR 0.7 million in 2002 to EUR 2.7 million in 2010. By the end of 2013, yearly sales had decreased to EUR 1.5 million, partly due to a reduction in the volumes of modafinil sold since 2011 and partly to a reduction of more than 40% in the average price for modafinil in Spain (see Figure 13 below).

(1112) The main modafinil formulation marketed in Spain is the 100 mg tablet in packs of 60 tablets ("60x100 mg formulation"). This formulation represented 85% of all modafinil tablets sold in Spain in 2013.

Figure 13: Volume sales of modafinil in Spain by formulation



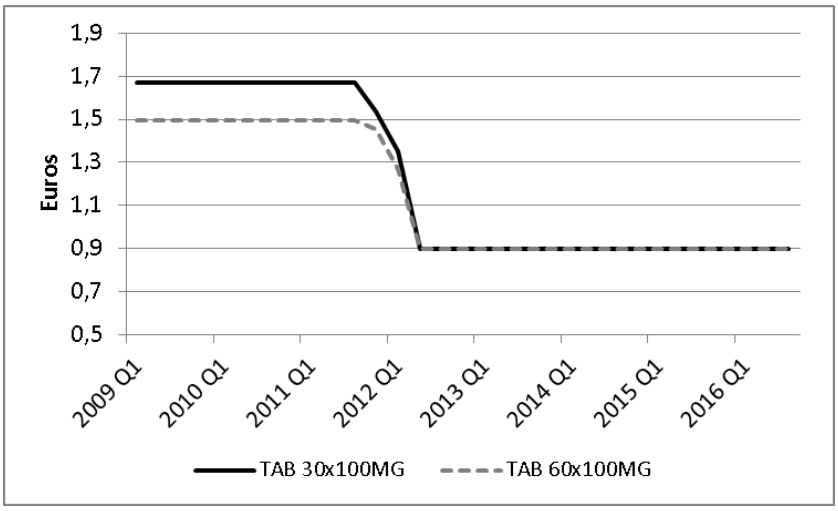
Source: Commission's calculations based on IQVIA data

(1113) The Parties submit that the reason why volume sales of modafinil in Spain decreased as of 2010 may have been that a significant number of patients switched to substitutable products as of 2011[1486]. The Parties' description is not supported by the facts. Data in Figure 13 show a slight reduction in volume sales in 2011, right after the regulatory withdrawal of approved indications for modafinil by the EMA in 2010, as explained in Section 8.1.1.3.1 and illustrated in Figure 2. The loss of approved indications restricted the number of patients eligible for modafinil-based therapy, negatively impacting on the use of modafinil. Modafinil volume sales in Spain show certain stability in 2012 and 2013, before increasing again as of 2013. Volume sales of modafinil in 2015 in Spain were the highest ever observed. The decrease in volume sales in 2011, immediately after loss of approved indications in 2010, reflects a regulatory change, not any competitive interaction between modafinil and any other product.

(1114) The average price of the 60x100 mg formulation in Spain remained stable first at EUR 1.60 per tablet until 2005 and then at EUR 1.5 per tablet until generic entry in 2012. Since generic entry and for the remainder of the period under analysis, modafinil tablets of 100 mg were sold at EUR 0.90 per tablet, that is, 40% below the pre-generic entry price. This ex-post observation of generic entry illustrates the actual impact of independent generic entry in the modafinil market in Spain.

1486 SO Reply, paragraph 531.

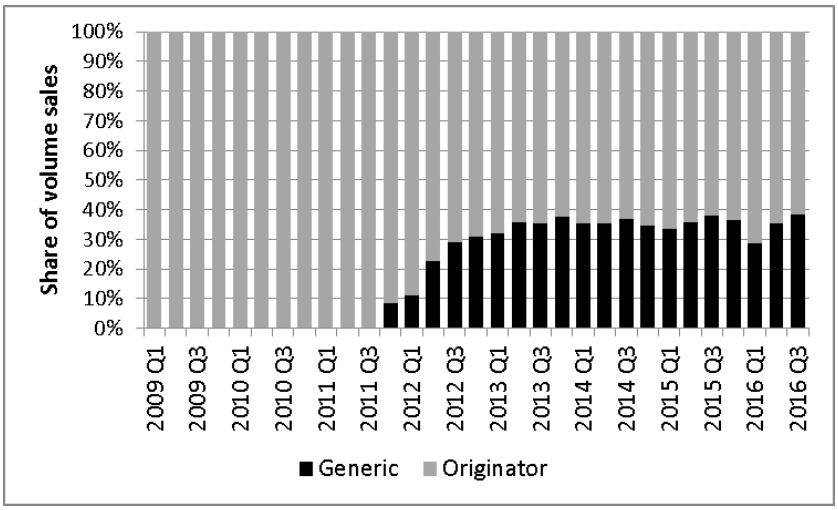
Figure 14: Average prices per tablet in Spain, by formulation



Source: Commission's calculations based on IQVIA data

(1115) Since the launch of generic versions of modafinil in 2011, generics first gradually gained market share until 2012 and then stabilised at approximately 35% share of sales, both in volume and value terms. Given that Cephalon and the generics have been sold at the same price, savings from generic entry in Spain appear to have resulted mainly from the price drop that generic entry triggered for all versions of modafinil.

Figure 15: Market share of generics in Spain, by volume



Source: Commission's calculations based on IQVIA data

8.1.1.4.5. Modafinil sales and prices in Sweden

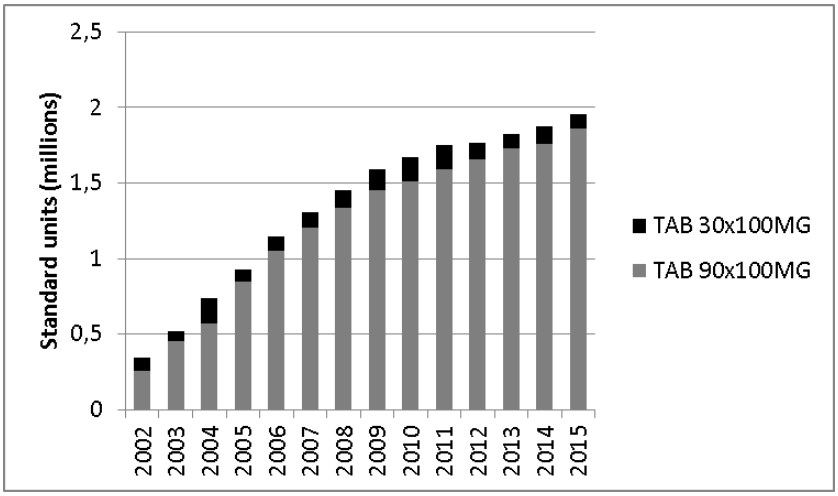
(1116) The Swedish market[1487] for modafinil grew from EUR 0.9 million in 2002 to EUR 3.3 million in 2012. By the end of 2013, yearly sales had decreased to EUR 2.7 million due to a reduction in the average price for modafinil in Sweden.

(1117) The main modafinil formulation marketed in Sweden is the 100 mg tablet in packs of 90 tablets ("90x100 mg formulation"), which got increasingly consolidated over the

[1487] With respect to Sweden, occasional parallel imports appear in the IQVIA data.

period 2002-2013. This formulation represented 95% of all modafinil tablets sold in Sweden in 2013.The other formulation marketed in Sweden is the 30 mg tablet.

Figure 16: Volume sales of modafinil in Sweden by formulation



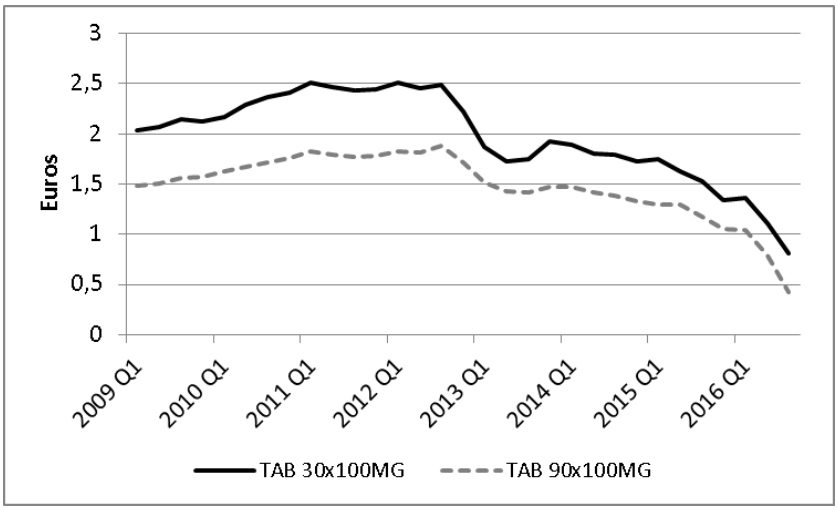
Source: Commission's calculations based on IQVIA data

(1118) The Parties submit that volume sales of modafinil in Sweden may have decreased as of 2010 because a significant number of patients switched to substitutable products as of 2011[1488]. The Parties' description is not supported by the facts. Data in Figure 16 show that volume sales of modafinil in Sweden increased without interruption during the period observed, from 2002 until 2015.

(1119) The evolution of average prices of these two formulations in Sweden differed during the period 2002-2014. While both formulations were sold at the same average price at or above EUR 2.50 per tablet until the last quarter of 2005, since 2006 the average price of the 90x100 mg formulation has been significantly lower than that of the 30x100 mg formulation. The average price of the 90x100 mg formulations fluctuated between EUR 1.5 and EUR 1.9 per tablet between 2006 and 2012. The average price of the 30x100 mg formulations fluctuated between EUR 2.0 and EUR 2.5 per tablet between 2006 and 2012. After generic entry in 2012, prices of both formulations have dropped to EUR 1.4 per tablet for the 90x100 mg formulation and to EUR 1.80 per tablet for the 30x100 mg formulation in 2015, and further decreased to EUR 0.61 and EUR 0.96 respectively in 2016. This represents a reduction of up to 26% and 28% respectively in 2015 and of 67% and 62% respectively in 2016, compared to pre-generic entry prices. This ex-post observation of generic entry illustrates the actual impact of independent generic entry in the modafinil market in Sweden.

1488 SO Reply, paragraph 531.

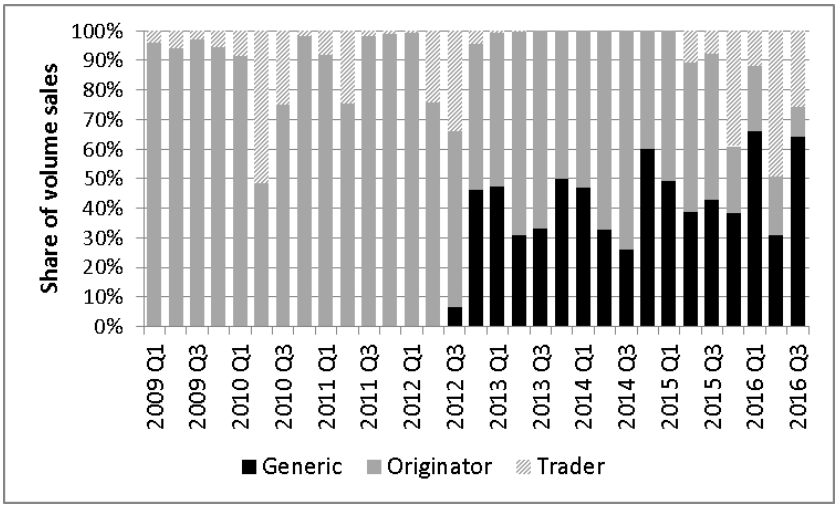
Figure 17: Average prices per tablet in Sweden, by formulation



Source: Commission's calculations based on IQVIA data

(1120) Generics have consistently shown significant levels of penetration in Sweden since 2013, with market shares between 25% and 50% of sales, both in volume and value terms. Generic uptake was accompanied by a significant drop in average prices. The lack of a clear trend and the significant year-to-year variation in generic market shares may be reflective of the regulatory framework in Sweden, linking reimbursement to the lowest available price of substitutable products and establishing compulsory substitution for the cheapest available version. Savings from generic entry in Sweden appear to have resulted both from generics undercutting the originator price and gaining substantial market shares and from the originator itself lowering its price.

Figure 18: Market share of generics in Sweden, by volume



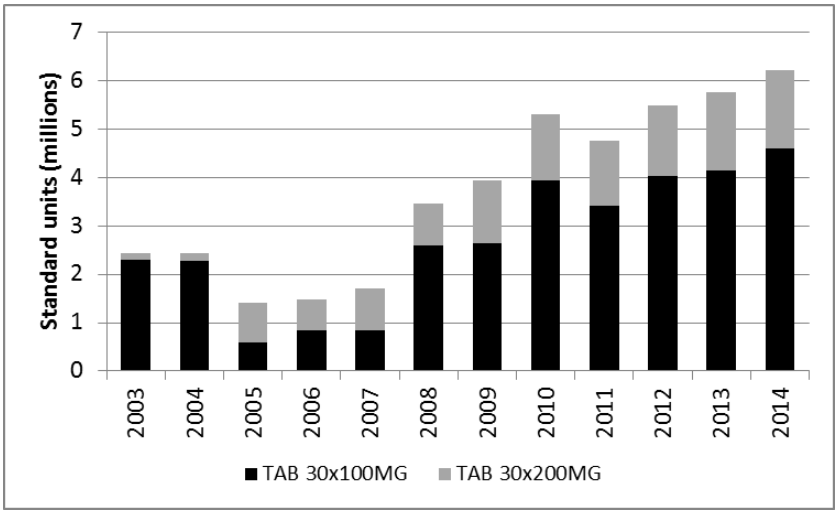
Source: Commission's calculations based on IQVIA data

8.1.1.4.6. Modafinil sales and prices in the United Kingdom

(1121) According to the data submitted by the Parties,[1489] the United Kingdom market went from EUR 7.6 million in 2003 to EUR 4.1 million in 2006 and then grew to EUR 10.1 million in 2011. By the end of 2014, yearly sales had decreased to EUR 3.3 million, partly due to a reduction in the volumes of modafinil sold since 2011 and partly to a very significant reduction of more than 80% in the average price for modafinil in the United Kingdom since generic entry (see Figure 19 below).

(1122) The main modafinil formulation marketed in the United Kingdom is the 30x100 mg formulation, although the packs of 30 tablets of 200 mg ("30x200 mg formulation") also represent a significant share of the market. The 30x100 mg formulation represented 74% of all modafinil tablets sold in United Kingdom in 2014, while the 30x200 mg formulation represented the remaining 25%.

Figure 19: Volume sales of modafinil in the United Kingdom by formulation



Source: Commission's calculations based on data submitted by the companies (and IQVIA data for 2010)[1490]

(1123) The Parties submit that the reason why volume sales of modafinil in the United Kingdom decreased as of 2010 may have been that a significant number of patients switched to substitutable products as of 2011[1491]. The Parties' description is not supported by the facts. Data in Figure 19 show a sudden reduction in volume sales in 2011, right after the regulatory withdrawal of approved indications for modafinil by

1489 With regard to the United Kingdom, the IQVIA data appeared to suffer from several gaps in the data series due to methodological changes in the data collection and adjustment procedures. Large shifts in absolute values for modafinil sales in the relevant time period seemed to indicate that the IQVIA data was not faithfully reflecting market dynamics for modafinil in the United Kingdom. The Commission has therefore requested companies active in the sale of modafinil in the United Kingdom during the investigated period to submit their own sales data. The analysis presented in this section is therefore based on the sales data submitted directly by pharmaceutical companies (including Teva/Cephalon, […], […], […] and […]), not on IQVIA data. Although occasional parallel imports appear in IQVIA data in the United Kingdom, they are of very limited magnitude. See also Recitals (1155) - (1156).

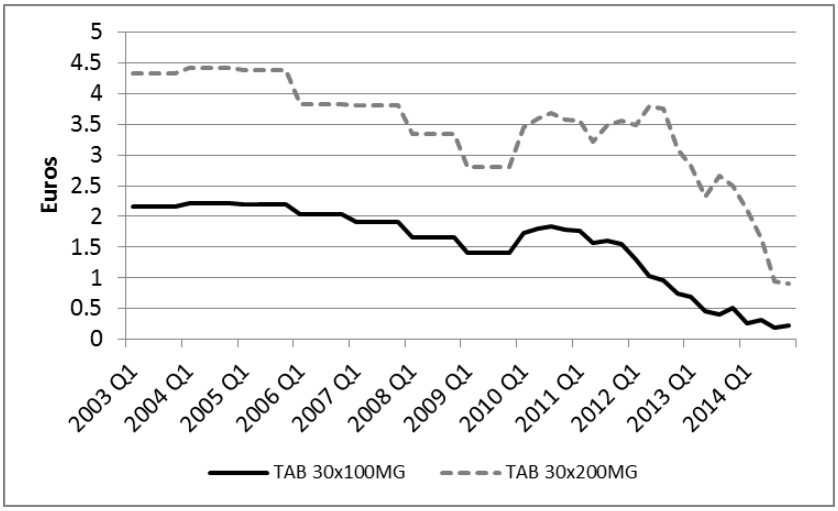
1490 Cephalon did not provide sales data for the United Kingdom in 2010. Despite the inaccuracies detected in the IQVIA data for the United Kingdom, the Commission has completed the United Kingdom reconstruction exceptionally using the IQVIA data to fill the gap in Cephalon's data submissions for 2010. The figure was adjusted following the submission by the Parties (see ID 3630).

1491 SO Reply, paragraph 531.

the EMA in 2010, as explained in Section 8.1.1.3.1 and illustrated in Figure 2. The loss of approved indications restricted the number of patients eligible for modafinil-based therapy, negatively impacting on the use of modafinil. Modafinil volume sales in the United Kingdom continued to increase after 2011. Volume sales of modafinil in 2014 in United Kingdom were the highest ever observed. The decrease in volume sales in 2011, right after loss of approved indications in 2010, reflects a regulatory change, not any competitive interaction between modafinil and any other product.

(1124) The average price of the 30x100 mg formulation decreased over the period 2002-2014 in the United Kingdom. After being consistently at or above EUR 2 per tablet until the last quarter of 2006, average prices of this formulation fluctuated between EUR 1.5 per tablet in 2009 and EUR 1.77 per tablet in 2010 (corresponding to a price drop in the range of 12-25%). In parallel to the increase in generic uptake during 2013 and 2014 the average price per tablet fell to just about EUR 0.2 in 2014, representing a reduction in price in the range of 88% compared to the prices before the entry. This ex-post observation of generic entry illustrates the actual impact of independent generic entry in the modafinil market in the United Kingdom.

Figure 20: Average prices per tablet in the United Kingdom, by formulation

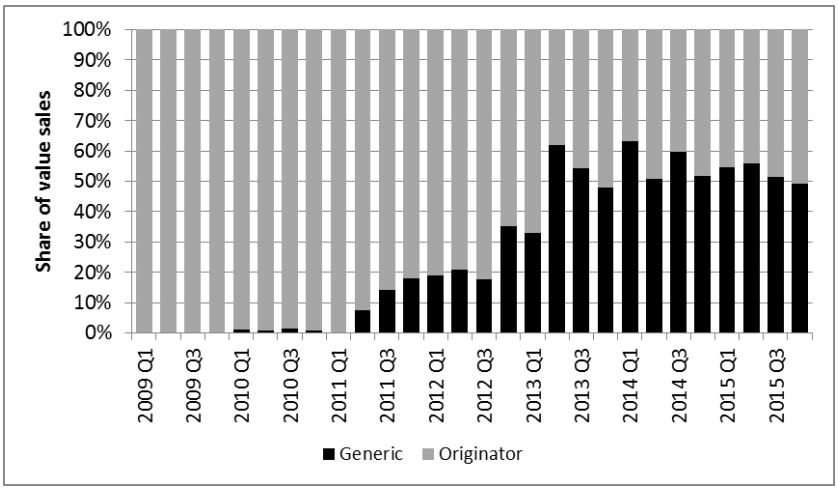


Source: Commission's calculations based on data submitted by the companies (and IQVIA data for 2010)[1492]

(1125) Since the launch of generic versions of modafinil in 2010, generics have gradually gained substantial market shares in the United Kingdom. Generic modafinil remained above 50% share of sales, both in volume and value terms, in most quarters of 2013 and 2014. Savings from generic entry in the United Kingdom appear to have resulted both from generics undercutting the originator price and gaining substantial market shares, as well as from the originator itself lowering its price.

[1492] The figure was adjusted following the submission by the Parties (see ID 3630).

Figure 21: Market share of generics in the United Kingdom, by value



Source: Commission's calculations based on sales data submitted by the companies (and IQVIA data for 2010)

(1126) The data available to the Commission does not include market shares of parallel importers in the United Kingdom. Nonetheless, the price fluctuations prior to generic entry show that parallel imports could have some impact on the originator's price, although this impact was limited in size and only temporary, as shown by the price increases observed in 2010 prior to generic entry. By contrast, from 2011 generic entry was accompanied by permanent, long-lasting, and much larger price drops, delivering price reductions of more than 80% between 2011 and 2014.

8.1.1.4.7. Summary of facts regarding the Evolution of sales in the By-Effect Countries

(1127) Between 1998 and 2006, Cephalon was selling modafinil in the United Kingdom and in at least 14 other Member States and Norway. Yearly sales of modafinil in these 15 countries[1493] were EUR 18.4 million in 2002 and reached EUR 50.4 million in 2010. This represents a yearly average growth of 13.7% over the period 2002-2010. Similarly, volume sales increased at an average yearly rate of 15.5% in the same period in these 15 countries. Modafinil sales have been unevenly distributed across EU Member States, with only six countries accounting for more than 85% of all EU value sales of the entire period 2002-2014: France, Germany, the Netherlands, Spain, Sweden and the United Kingdom. These are the markets described in this section. In those By-Effect Countries, Cephalon's value sales of modafinil showed an increasing trend at first and followed by a gradual decrease. In general, it can be said that in all By-Effect Countries the peak in value sales was around 2010. The prices of modafinil remained relatively stable in a number of By-Effect Countries prior to generic entry (France, Germany, and Spain) in 2011-2012. In other By-Effect Countries, the price level was less stable prior to generic entry, mainly due to regulatory changes and the intermittent presence of parallel imports (the Netherlands, Sweden, and the United Kingdom). However, in all By-Effect Countries, significant generic uptake was observed in 2011 and 2012, in a context in which, ex-post, the provisions of the Settlement Agreement no longer applied or soon ceased to apply because of the merger between Cephalon and Teva. At the time of the Settlement

1493 Including Austria, Belgium, Czechia, Denmark, France, Germany, Ireland, Italy, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden and United Kingdom. The dataset used does not cover Norway.

Agreement there was no ex-ante expectation that such would be the market context in 2011. This observation of generic entry illustrates the actual impact that independent generic entry had in the modafinil markets. Average price decreases for modafinil occurred in all By-Effect Countries since generic entry and were substantial (between 88% and 40%, while in Germany, a moderate reduction of around 10%, see Table 21).

8.1.1.5. Conclusion with regard to the relevant product market of modafinil

(1128) In view of the therapeutic indications and uses and the medical guidelines, as well as internal Cephalon documents quoted in Section 8.1.1.3.3, it can be concluded that there are significant limitations on the therapeutic substitutability of modafinil with other products, in particular methylphenidate or sodium oxybate. Their significant degree of objective differentiation and their usage in distinct circumstances and for distinct patient groups limit both their therapeutic substitutability and the strength of the competitive constraint that they can exert on Cephalon's modafinil.

(1129) This suggests that they do not belong to the same relevant product market, but even if they were to be included in the same relevant product market, such differentiated molecules would not constitute the most relevant competitive constraint faced by Cephalon's modafinil at the moment of the Settlement Agreement. The economic analysis of the market evolution ex-post in the By-Effect Countries upon entry by generic modafinil products indicates that such generic products exerted a uniquely strong competitive pressure on Cephalon's modafinil, which no other product in the market could exert. The observed impact of generic entry both on Cephalon's market shares and on prices of modafinil illustrates that the main competitive constraint faced by Cephalon's modafinil products at the moment of the Settlement Agreement came from potential generic entry.

(1130) The Parties submit that volume sales of modafinil decreased as of 2010 in most By-Effect Countries and that the Commission disregarded the possibility that such decrease may imply that a significant number of modafinil patients switched to substitutable products as of 2011, which would suggest a wider product market. The Commission has shown that the Parties' allegation that modafinil volume sales decreased as of 2010 is not supported by the facts. Modafinil volume sales experienced only a limited sudden and transitory decrease in 2010 in four of the six By-Effect Countries, and modafinil volume sales continued to increase afterwards in all of them but France, where volume sales remained stable. The sudden and transitory decrease in volume sales immediately after loss of approved indications in 2010 reflects a regulatory change that restricted the number of patients eligible for modafinil-based therapy, not any competitive interaction between modafinil and any other product The Commission did not disregard any data or evidence, but accurately illustrated the evolution of modafinil sales and analysed it in light of the relevant regulatory context, notably taking into account the withdrawal of some of modafinil's approved indications in 2010. In this context and contrary to what the Parties submit, the evolution of modafinil volume sales in the By-Effect Countries does not suggest a wider relevant product market.

(1131) Therefore, the Commission considers that for the purpose of determining Cephalon's position on the market, based on the assessment of the relevant competitive

constraints at the moment of the Settlement Agreement, the relevant product market consists of modafinil.[1494]

8.1.2. The relevant geographic market

(1132) In previous Decisions, the Commission found that the relevant geographic market for finished pharmaceutical products was national.[1495] In the present case, the Commission did not find any particular facts that would point to the need to deviate from this established practice.

(1133) The Commission considers that the national scope of pharmaceutical markets derives from a number of factors. These include in particular different price and reimbursement rules, differences between national rules on incentives for cheaper generics and differences in supply and demand or uptake (see Section 8.1.1.4). As an illustration, reference can be made to the varying prices for modafinil in the By-Effect Countries (see Section 8.1.1.4). At this stage, Union law harmonisation as regards pharmaceuticals is mainly limited to rules relating to the authorisation of medicinal products (either nationally or through a centralised EU system), in particular rules aimed at ensuring that the products concerned fulfil requirements in terms of safety, quality and efficacy.

(1134) In terms of geographic scope, the analysis and the finding of a restriction of competition by effect in this Decision focuses, for the reasons set out below, on six Member States of the European Union, namely France, Germany, the Netherlands, Spain, Sweden and the United Kingdom. These countries are referred to as the "By-Effect Countries".

(1135) The Parties submit that limiting the analysis to six Member States is "surprising" and that as a consequence of this choice, the Commission may have overlooked the competitive situations in other Member States that would undermine the Commission allegations. The Parties also argue that if the analysis by effects can be limited to the Member States that represent the majority of sales in the EEA, then the Commission should not have conducted any investigation in the EEA because the sales of modafinil in the United States represented a far greater portion of worldwide sales.

(1136) The Commission notes that these six Member States represented a very large share (over 80%) of the revenues generated by modafinil sales in the EEA in the period under investigation. This means that the overwhelming part of the harm to patients and health systems caused by the conduct of the Parties occurred in these six Member States. Moreover, these six Member States form a substantial part of the internal market. Due to the considerable investigative effort required for the in-depth fact-finding and analysis of each additional market, the Commission considers it appropriate to limit the assessment to the By-Effect Countries where Cephalon achieved the vast majority of its revenues from modafinil sales. These countries were directly concerned by the Settlement Agreement in the sense that (i) Teva committed not to enter in these countries, (ii) Cephalon held Modafinil patent rights for these countries at the time of the Settlement Agreement, and (iii) in these countries, market

---

1494 These findings are in line with the Teva/Cephalon merger Decision, where the Commission concluded that the most likely product market definition in relation to modafinil was that for modafinil-based products. Case M.6258-*Teva/Cephalon*.

1495 See for example Commission Decisions in Case M.5865-*Teva/Ratiopharm*; in Case M.6613-*Watson/Actavis*, and in Case M.7379-*Mylan/Abbott.*

authorisations had been granted to Teva (United Kingdom) or, following Teva's applications for the MAs in France in 2003 and in other By-Effect Countries in July 2005, could have been granted to Teva at any point in time after the Settlement Agreement (see Section 4.3.2).

(1137) The Parties' claim that the Commission may have overseen relevant evidence from other countries is unfounded. While the effects of the Settlement Agreement are assessed and established for the By-Effect Countries, the Commission has duly taken into account all available evidence on the file. The Parties have not identified any specific evidence or fact from countries other than the By-Effect Countries that in their view might have not have been taken into account by the Commission and that could have altered the Commission's findings. Moreover, each of the By-Effect Countries represents a separate relevant geographic market and the restrictive effects found in one national market are independent from the effects in other national markets.

(1138) The Commission also rejects the Parties' submission that the Commission should not have investigated the Parties conduct in the EEA in the first place. The fact that the largest portion of worldwide modafinil sales occurred in the United States by no means implies that the absolute volume of modafinil sales in the EEA would have been negligible. In any event, Article 101 TFEU applies regardless of whether the value or volume of sales in the EEA is particularly high or particularly low, since what matters for the "by effect" analysis is whether the impact of the conduct on competition in the EEA is appreciable, which is the case here (see Recital (1259)).

(1139) The Commission concludes that, for the purpose of this Decision, the degree of market power should be assessed at national level in the six By-Effect Countries. This reflects the specific features that shape competition in the markets for pharmaceuticals nationally and, ensures administrative efficiency by focusing on Member States accounting for over 80% of the value of modafinil sales in the EEA (without Norway) for the period 2002-2014.

8.2. Structure of the markets and the position of Cephalon, Teva and other potential competitors

(1140) As a basis for assessing, in Section 8.4, the degree of potential or actual competition that would have existed in the markets concerned in the absence of the Settlement Agreement and thereby assessing the restrictive effects of that agreement, this Section describes positions of Cephalon, Teva and other potential generic competitors on these markets (Sections 8.2.1 to 8.2.3).

8.2.1. Position of Cephalon as sole producer of modafinil

(1141) The current Section describes Cephalon's market position in the market for modafinil in the By-Effect Countries. The observed impact of generic entry both on Cephalon's market shares and on prices of modafinil illustrates that the main competitive constraint faced by Cephalon's modafinil products at the moment of the Settlement Agreement came from potential generic entry, notably from Teva.

(1142) According to the Guidelines on Article 101(3) TFEU, "[m]arket power is the ability to maintain prices above competitive levels for a significant period of time or to

maintain output in terms of product quantities, product quality and variety or innovation below competitive levels for a significant period of time".[1496]

(1143) In order to assess whether Cephalon held market power, first, the Commission assesses Cephalon's market shares in the market for modafinil in the By-Effect Countries. Second, the Commission assesses to what extent barriers to entry existed and to what extent Cephalon was able to charge prices above competitive levels allowing it to appropriate substantial economic rents to the detriment of customers. Finally, the role of countervailing buyer power is assessed.

8.2.1.1. Market shares

(1144) Market shares provide a useful first indication for the Commission of the market structure and of the relative importance of the various undertakings active on the market. Low market shares are generally a good proxy for the absence of substantial market power. Conversely, the case-law indicates that large market shares, that is of 50% or more, are in themselves, save for exceptional circumstances, evidence of a dominant position, thus *a fortiori* of market power.[1497]

(1145) The market shares presented below are established on the basis of the value of sales in the retail distribution channel as provided by IQVIA for all By-Effect Countries except the United Kingdom, for which data submitted by the suppliers of modafinil in the United Kingdom was used.

(1146) Table 14 shows the market shares of Cephalon and of the other producers of modafinil in France in the period 2004-2014. Cephalon was the only undertaking active prior to 2010 and its market shares for modafinil remained above 70% for the rest of the period analysed. Based on this evidence and given that very large market shares are in itself a clear indication of the existence of market power (Recital (1145)), Cephalon's significant market shares suggest that Cephalon held market power for the entire period 2004-2014 in the modafinil market in France.

1496 Guidelines on Article 101(3) TFEU, point 25.

1497 Judgment of 3 July 1991, *AKZO v Commission*, C-62/86, EU:C:1991:286, paragraph 60; see also Judgment of 12 December 1991, *Hilti v Commission*, T-30/89, EU:T:1991:70, paragraph 92; and Judgment of 30 September 2003, *Atlantic Container Line and Others v Commission*, Joined Cases T-191/98, T-212/98 to T-214/98, EU:T:2003:245, paragraph 907.

Table 14: Market shares (in volume) for modafinil in France

Year	Total market (EUR thousands)	Cephalon	Generics	Parallel traders
2004	11,909	100%	0%	0%
2005	13,189	100%	0%	0%
2006	14,608	100%	0%	0%
2007	16,018	100%	0%	0%
2008	16,787	100%	0%	0%
2009	17,438	100%	0%	0%
2010	18,258	100%	0%	0%
2011	12,382	98%	2%	0%
2012	11,542	89%	11%	0%
2013	11,259	86%	14%	0%
2014	10,994	78%	22%	0%

Source: Commission's calculations based on IQVIA data

(1147) Table 15 shows the market shares of Cephalon and of the other producers of modafinil in Germany in the period 2004-2014. Cephalon was the only undertaking active prior to 2011 and its market shares for modafinil product remained above 50% for the rest of the period analysed. Based on this evidence and given that very large market shares are in itself a clear indication of the existence of market power (Recital (1145)), Cephalon's significant market shares suggest that Cephalon held market power for the entire period 2004-2014 in the modafinil market in Germany.

Table 15: Market shares (in volume) for modafinil in Germany

Year	Total market (EUR thousands)	Cephalon	Generics	Parallel traders
2004	1,929	100%	0%	0%
2005	2,618	100%	0%	0%
2006	3,252	100%	0%	0%
2007	3,898	100%	0%	0%
2008	5,024	100%	0%	0%
2009	6,086	100%	0%	0%
2010	6,828	100%	0%	0%
2011	6,626	100%	0%	0%
2012	6,277	90%	10%	0%
2013	5,551	75%	25%	0%
2014	5,717	55%	45%	0%

Source: Commission's calculations based on IQVIA data

(1148) Table 16 shows the market shares of Cephalon and of the other producers of modafinil in the Netherlands in the period 2004-2014. Cephalon enjoyed market

shares for modafinil well above 50% until 2011. Other than Cephalon, only parallel traders were present prior to 2011. Based on this evidence and given that very large market shares are in itself a clear indication of the existence of market power, Cephalon's significant market shares suggest that Cephalon held market power for the period 2004-2011 in the Netherlands.

(1149) Regarding the role of parallel traders, the Commission observes that by their very nature, parallel traders are not engaged in the marketing of products differing from the original reference product, in this case from Cephalon's modafinil. After repackaging and re-labelling as the case may be, parallel traders in fact sell the originator product which they have obtained, directly or indirectly, from the same originator in another Member State. In the present case, parallel traders were entirely dependent on whether and to what extent Cephalon decided to supply markets in low-price Member States, and on the requirements to meet demand in these low-price Member States. For these reasons, the market shares held by parallel importers at any given time in the markets concerned overstate their actual market power. This is reflected in the substantial volatility of their shares from year to year.

(1150) Moreover, as shown in Figure 11, the drop in average prices observed in the Netherlands was not achieved through competition by parallel traders, but only after the generic entry and in particular, as of 2013. This shows the much stronger intensity of the price competition triggered by generics and illustrates how parallel traders were a much weaker competitive constraint than generic suppliers.

Table 16: Market shares (in volume) for modafinil in the Netherlands

Year	**Total market (EUR thousands)**	**Cephalon**	**Generics**	**Parallel traders**
2004	1,356	57%	0%	43%
2005	1,546	76%	0%	24%
2006	1,648	78%	0%	22%
2007	1,842	76%	0%	24%
2008	408	63%	0%	37%
2009	1,629	65%	0%	35%
2010	1,845	62%	0%	38%
2011	1,929	60%	6%	35%
2012	1,946	42%	37%	21%
2013	1,682	21%	65%	14%
2014	1,354	13%	78%	9%

Source: Commission's calculations based on IQVIA data

(1151) Table 17 shows the market shares of Cephalon and of the other producers of modafinil in Spain in the period 2004-2014. Cephalon was the only undertaking active prior to 2010 and its market shares for modafinil remained well above 50% for the rest of the period analysed. Based on this evidence and given that very large market shares are in itself a clear indication of the existence of market power, Cephalon's significant market shares suggest that Cephalon held market power for the entire period 2004-2014 in the modafinil market in Spain.

Table 17: Market shares (in volume) for modafinil in Spain

Year	Total market (EUR thousands)	Cephalon	Generics	Parallel traders
2004	1,383	100%	0%	0%
2005	2,323	100%	0%	0%
2006	2,337	100%	0%	0%
2007	2,356	100%	0%	0%
2008	2,592	100%	0%	0%
2009	2,665	100%	0%	0%
2010	2,690	100%	0%	0%
2011	2,484	98%	2%	0%
2012	1,683	77%	23%	0%
2013	1,472	65%	35%	0%
2014	1,581	64%	36%	0%

Source: Commission's calculations based on IQVIA data

(1152) Table 18 shows the market shares of Cephalon and of the other producers of modafinil in Sweden in the period 2004-2014. Cephalon enjoyed market shares for modafinil almost at or above 80% until 2011. Other than Cephalon, only parallel traders were present prior to 2012. Cephalon's shares for modafinil product remained well above 50% for the rest of the period analysed. Based on this evidence and given that very large market shares are in itself a clear indication of the existence of market power, Cephalon's significant market shares suggest that Cephalon held market power for the entire period 2004-2014 in the modafinil market in Sweden.

Table 18: Market shares (in volume) for modafinil in Sweden

Year	Total market (EUR thousands)	Cephalon	Generics	Parallel traders
2004	1,962	99%	0%	1%
2005	2,294	84%	0%	16%
2006	2,145	79%	0%	21%
2007	2,366	97%	0%	3%
2008	2,533	97%	0%	3%
2009	2,520	95%	0%	5%
2010	2,929	78%	0%	22%
2011	3,236	91%	0%	9%
2012	3,257	71%	13%	16%
2013	2,678	59%	40%	0%
2014	2,669	59%	41%	0%

Source: Commission's calculations based on IQVIA data

(1153) Table 19 shows the shares of Cephalon and of the other producers of modafinil in the United Kingdom in the period 2004-2014. Cephalon enjoyed market shares for modafinil well above 90% until 2010 and its market shares for modafinil remained well above 50% until 2012. Based on this evidence and given that very large market shares are in itself a clear indication of the existence of market power, Cephalon's significant market shares suggest that Cephalon held market power at least for the period 2004-2012 in the modafinil market in the United Kingdom.

Table 19: Market shares (in volume) for modafinil in the United Kingdom

Year	**Total market (EUR thousands)**	**Cephalon**	**Generics**	**Parallel traders**
2004	5,709	100%	0%	n/a
2005	4,898	100%	0%	n/a
2006	4,124	100%	0%	n/a
2007	5,260	100%	0%	n/a
2008	8,127	100%	0%	n/a
2009	7,982	100%	0%	n/a
2010	12,187	99%	1%	n/a
2011	10,152	87%	13%	n/a
2012	9,181	67%	33%	n/a
2013	6,268	48%	52%	n/a
2014	3,347	44%	56%	n/a

Source: Commission's calculations based on data submitted by companies in the United Kingdom and IQVIA data

(1154) Although from internal documents it can be concluded that parallel traders were present in the United Kingdom, the market reconstruction exercise conducted for the United Kingdom did not allow accounting for parallel traders. Cephalon UK's business plans state that "*parallel imports severely affected ex-factory sales*" in the United Kingdom in 2003 and 2004.[1498] In 2004, Cephalon estimated parallel imports in the United Kingdom at GBP 1.5 million. From internal documents it appears that parallel trade was forecasted at 25% of sales in the United Kingdom in 2006 (37% of 100 mg dosage)[1499], 30% of sales in 2007 (45% of 100 mg dosage)[1500] and 35% of sales in 2008 (52% of 100 mg dosage).[1501] Even taking into account the data on parallel imports in these internal documents, Cephalon's market shares remained significant, above 65%, in the years for which these data are available.

(1155) Although no parallel traders were recorded in IQVIA data before 2011 some price movements were observed in the United Kingdom in that period, as can be seen in Figure 20 (see Recital (1125)). This figure shows in fact that these price movements were not as significant as the price decrease resulting from generic entry. As shown

1498 ID 224, p.5.
1499 ID 315.
1500 ID 316.
1501 ID 318.

in Figure 20, the drop in average prices observed in the United Kingdom after generic entry was not achieved before through competition by parallel traders.[1502] This shows the greater relevance of the price competition triggered by generic suppliers.[1503] As already explained, the market shares held by parallel importers at any given time in the markets concerned, tend to overstate their actual ability to act as a competitive constraint.

(1156) The Parties submit that, while the Commission generally notes that upon the generic entry price of pharmaceuticals tends to drop significantly (sometimes up to 80%-90%), the factual findings on a country-by-country basis show a more nuanced description of price effects.[1504] The Parties also submit that the Commission does not account for the price evolution in the Netherlands that does not match the timing of generic entry.[1505]

(1157) First, the Parties take out of context the Commission's reference to the price effects that generic entry tend to have (see Recital (1093)), which provides useful background for the assessment of the evidence in the case at hand. This does not affect in any way the Commission's thorough analysis of the modafinil market in each By-Effect Country, which was based on the facts and the evidence relevant to each of them. The Commission's findings in this investigation are in line with the statement disputed by the Parties. Thus, the data shows that modafinil prices in the United Kingdom experienced reductions of 74% and 88% after generic entry, depending on the formulation. Moreover, the Commission transparently reports the precise price reductions by country and formulation in Table 21 (see Section 8.4.3). The Parties' allegation that the Commission did not sufficiently take into account the nuanced reporting of the data is therefore unfounded.

(1158) Second, Figure 11 and Figure 12 show the evolution of weighted average modafinil prices and generics' share in the Netherlands. The two figures, observed together, clearly illustrate that the weighted average modafinil price in the Netherlands decreased progressively as the generics' share increased over time. The claims of the parties reveal at least a lack of understanding of the concept of weighted average price. Weighted average prices cannot be expected to show sudden drops immediately upon generic entry whenever the incumbent does not respond by immediately dropping its own price, because they are a composition of originator and generic prices, weighted by their relative volumes. Such sudden drops can only be expected in certain circumstances, for instance when the incumbent chooses to immediately reduce its own price or when regulation imposes automatic price cuts to the originator upon generic entry, as Figures 5 and 14 show for France and Spain. When such automatic price cuts are not observed, as in the Netherlands, weighted average prices only gradually decrease as generics gain market share over time. The gradual decrease in the weighted average price of modafinil in the Netherlands in

---

1502 In the judgment of the High Court in *Cephalon v. Orchid* [2010] EWHC 2945 (Pat) of 19.11.2010 it was concluded, on the evidence, that Cephalon was able to raise its prices for modafinil after lowering them temporarily to compete with parallel importers.

1503 Moreover, in the judgment of the High Court in *Cephalon v. Orchid* [2010] EWHC 2945 (Pat) of 19.11.2010, paragraphs 52-68 in particular, which relies on evidence from Cephalon, it was observed that once a generic s on the market, other generics are encouraged to enter as well. The judgment left open the possibility that his further entry would trigger a further significant price drop.

1504 SO Reply, paragraph 531, second point.

1505 SO Reply, paragraph 531, second point.

parallel to the gradual increase of generics' market share indicates that the lowest prices achieved in the Netherlands over time were the result of generic competition. The evolution of weighted average prices are particularly relevant for the competitive analysis of effects because they reveal the increasing average discounts that Dutch patients and the Dutch health system enjoyed thanks to independent generic competition, once such competition could finally occur. The Parties thus misinterpreted the evidence presented by the Commission. The Commission duly accounted for the price evolution in the Netherlands that matches generic uptake and reveals the uniquely strong price effects that independent generic competition can deliver.

8.2.1.2. Barriers to entry

(1159) Besides the market position of the companies and the concentration in the market, other factors such as the stability of market shares over time, entry barriers and the likelihood of market entry, as well as any countervailing power of buyers also have to be considered. The notion of barriers to entry does not require that barriers are absolute in order to include them in the assessment of Cephalon's market position. For entry to be considered a sufficient competitive constraint on existing market participants, it must be shown to be likely, timely and sufficient to deter or defeat any potential restrictive effects of the agreement.

(1160) During product development, generic companies typically examine options to increase the likelihood that the product would overcome the entry barriers, notably patent barriers, by reducing, to the extent possible, the risk that a given product infringes a patent protecting the originator's product.

(1161) Pharmaceutical markets are generally characterised by the existence of entry barriers. Pharmaceutical products are typically protected by patents and require strict quality control processes, specialised development and manufacturing know-how and specialised distribution networks. It should also be recalled that pharmaceutical markets in the EEA and in the By-Effect Countries are heavily regulated, including also the regulation of prices. Prescription for modafinil products was obligatory. Since patients and physicians do not directly bear most or any part of the prices of prescription medicines, their price elasticity in general, and also for modafinil products in particular was low.

(1162) In order to enter the modafinil market, generic entrants would need to obtain MA (see Section 2.4.2). Obtaining such an authorisation was not impossible for potential generic entrants, but it was costly and time consuming, thereby further decreasing the likelihood of timely entry. As is explained hereinafter in Section 8.2.3, several potential entrants obtained MA's in several Member States in 2009.[1506]

(1163) Moreover, the existence of the Particle Size Patents (see Section 4.1.2.1) held by Cephalon, even if they were regarded as weak by some market participants (such as Teva (Section 4.3.1 and 6.3.2) and […] (see Section 4.3.3 and 6.3.2), decreased the likelihood of entry by generics. Cephalon enforced its patents by means of warning letters sent to the potential entrants informing them about a possible infringement of its patent rights, or by litigating against a generic entrant. Cephalon's court actions

[1506] It should be noted that the data exclusivity period had expired for Provigil in all relevant markets, See Recital (649).

often resulted in interim injunctions (see Section 4.8.2.3). Such litigation is typically very costly, thereby creating a barrier to entry for potential entrants. Finally, as is set out in Section 4.1.2, the Particle Size Patents were not the only secondary patents that Cephalon held. The mere existence of other patents also constituted a barrier to entry.

(1164) Already before the Settlement Agreement, Teva had been capable of developing and launching a generic modafinil product that it believed was not infringing any of the Cephalon's patents. It took Teva several years to develop this particular type of generic modafinil. Teva started the development of a generic version of modafinil in 2000,[1507] and only by the end of 2002 / beginning of 2003 it was confident that it had developed a modafinil product that could enter the markets regardless of Cephalon's Particle Size Patents. After having developed this particular generic modafinil, it would take still some more time to bring it actually to the market. The fact that it took Teva several years to bring its generic modafinil from development to market underlines in itself the fact that the modafinil markets in the EEA were characterised by high entry barriers. Moreover, as indicated above, specialised know-how was needed for the development and manufacturing. Teva had this know–how and capability in-house: Teva sourced modafinil API from its own subsidiary specialised in API manufacturing (TAPI, see Recital (153)). Such capabilities made Teva the frontrunning potential generic competitor already at the time of the Settlement Agreement and without those distinctive capabilities, Teva's entry in a specialised market such as modafinil products would have been undoubtedly less timely and more difficult.

(1165) The Parties submit that the Commission's analysis of barriers to entry contains intrinsic contradictions. This is because Cephalon's patents are described as a significant barrier to entry vis-à-vis generic entrants other than Teva. At the same time those same patents would have allegedly been disregarded when assessing the competitive effects of the Settlement Agreement with respect to Teva, which allegedly was capable of developing generic modafinil not infringing Cephalon's patents.

(1166) The Parties' claim ignores the fact that different potential entrants have distinct capabilities to overcome barriers to enter and to effectively enter a market in a timely and sufficient manner. While patents, irrespective of their perceived strength, constitute an entry barrier, they do not exclude the existence of potential competition as such (see Sections 6.4, 7.2 and 8.2.2) and the very fact that the findings of the case may point to different companies not having the same "real and concrete possibilities" to enter the market at a given point in time. This heterogeneity across potential entrants is of crucial relevance in the case at hand. Section 6.4 describes in detail the unique position of Teva as the most advanced potential generic entrant in the modafinil markets at the time of the Settlement Agreement: Teva had managed to develop a generic version of modafinil that it saw as not infringing Cephalon's patents, engaged in patent litigation based on its view that Cephalon's modafinil patents were invalid, invested significant resources in its effort to independently enter the modafinil market, and even effectively entered the modafinil market in the United Kingdom in 2005. The specific capabilities and actions of Teva show it was a particularly strong potential competitor at the time of the Settlement Agreement,

[1507] ID 979, p. 94.

even considering the existence of Cephalon's modafinil patents and other barriers to entry.

(1167) As explained in detail in Section 8.2.3**,** no other generic producer was ready to launch a modafinil-based generic in any of the By-Effect Countries at the time of the Settlement Agreement or shortly thereafter. Cephalon's own press release of February 2006 stated that generic competition on modafinil markets from Barr and three other companies, namely Teva, Mylan and Ranbaxy, would not be initiated until 2011 at the earliest.[1508] The Commission's file contains no indications that any generic company other than Teva was capable of entering or planning to enter the modafinil markets in any of the By-Effect Countries at the time of the Settlement Agreement. Though the relevant perspective for assessing the restrictive effects is the ex-ante view held by the Parties at the time they concluded the Settlement Agreement, events that occurred at a later stage, if those could be anticipated by the Parties *ex ante*, can be taken into account when assessing the Parties' contemporaneous view on the degree of probability of the scenario that they envisaged when concluding the agreement.

(1168) Indeed, when the Settlement Agreement was concluded Cephalon did not see any specific threat from the generic companies other than Teva (see Sections 8.2.2 and 8.2.3). Furthermore, as explained in Section 8.2.3, at the time of the Settlement Agreement there were no indications showing the preparedness of other generic companies to enter the modafinil markets. It can be observed that other generic companies actually did not enter or attempt to enter the modafinil market in any of the By-Effect Countries at least until 2010. These included entries (all in 2010 or 2011) of […] (in the United Kingdom, the Netherlands and France), […] (in Sweden) and […] (in Spain). Cephalon initiated litigation against each of them, which in certain cases led to interim injunctions that further delayed effective generic entry in those markets. As regards Germany, in 2010 Cephalon initiated patent litigation against […] and obtained the same year its declaration that it will not launch generic modafinil. In Germany, no effective generic entry is observed before 2012 (see Sections 4.8.2.3 and 8.1.1.4.2.) This shows that the mere existence of the patents, regardless of their perceived strength, is a barrier to entry that, as Teva's entry shows, can be overcome, but presented a large barrier to enter timely and effectively in the relevant markets for any other generic producer that was not similarly uniquely positioned as Teva.

(1169) Moreover, Teva's leading role in the efforts to open these modafinil markets to generic competition, enjoying a lead of five years with respect to all other potential generic entrants (Teva's first entry regarding the By-Effect Countries was in the United Kingdom in 2005, whilst other generics managed their first entry only in 2010), illustrates how Cephalon's patents were an effective barrier to entry to a different degree for each potential entrant, depending on the particular capabilities of each of them. Contrary to the Parties' assertion, there is thus no contradiction in concluding that Cephalon's modafinil patents represented at the time of the Settlement Agreement a lesser obstacle to entry for Teva than it did for other generic producers. The Commission's conclusion simply reflects the evidence that Teva was in a unique position as the most advanced generic entrant, being the only one that had even entered at risk and competed with Cephalon.

[1508] ID 2325, p. 5. See also ID 1836, p. 7.

(1170) Given the characteristics of pharmaceuticals markets in general, the patents owned by Cephalon and regulatory requirements to enter the market, the Commission concludes that Cephalon's market position was further protected by important barriers to entry that dissuaded potential competitors from launching generic versions of modafinil for most of the investigated period. The secondary patents required potential competitors to incur additional costs by seeking alternative processes, and exposed them to the threat of litigation with Cephalon.

8.2.1.3. Countervailing power

(1171) The Commission already explained that the demand for prescription medicines in the By-Effect Countries is generated through the interaction of a number of actors: patients, doctors, pharmacists and national health (insurance) systems. This raises the question of countervailing buyer power. For the avoidance of doubt, only the centralised buyer (national health authorities) could conceptually exercise buying power. The other agents involved on the demand side, namely patients, doctors and pharmacists, cannot exert countervailing buyer power given their high degree of fragmentation vis-à-vis the single seller and given that they do not bear the price to be paid.

(1172) The prices of original products are either agreed in the direct bargaining process between national health authorities and the originator companies (for example, France) or are subject to certain forms of caps restricting the amount of public financing via profitability limits (for example, the United Kingdom) or reference pricing (for example, the Netherlands). However, the initial bargaining power of the national health authorities is largely restricted by their objective of sustaining the continuous research and development of new medicines. The Court of Justice recognised this characteristic of the price setting process by stating that *"as the second and third recitals to Directive 89/105 state, the task of the authorities when setting prices of medicines is not only to control expenditure connected with public health systems and to ensure the availability of adequate supplies of medicinal products at a reasonable cost, but also to promote efficiency in the production of medicinal products and to encourage research and development into new medicinal products. As the Advocate General indicated in points 90 to 93 of his Opinion, the level at which the selling price or the amount of reimbursement of a given medicinal product is fixed reflects the relative strength of both the public authorities of the relevant Member State and the pharmaceuticals companies at the time of the price negotiations for that product".*[1509]

(1173) Furthermore, as the General Court confirmed in case AstraZeneca v Commission, "it may be in the strategic interest of pharmaceutical undertakings not to market their products on certain markets, where the prices which national authorities are prepared to pay do not meet their expectations".[1510] However, in the present case, it remains beyond any doubt that Cephalon found it highly profitable to sell its modafinil in each of the By-Effect Countries.

(1174) The lack of real alternative sources of modafinil that could exert significant competitive pressure on Cephalon in the By-Effect Countries during the period of

---

[1509] Judgment of 16 September 2008, *Sot. Lélos kai Sia*, Joined Cases C-468/06 to C-478/06, EU:C:2008:504, paragraph 63.

[1510] See Case T-321/05, *AstraZeneca v Commission*, paragraph 257.

application of the Settlement Agreement, let national health authorities with little alternative but to purchase most volumes of modafinil from Cephalon. Even the presence of parallel importers in some markets, especially the Netherlands, Sweden and the United Kingdom, only delivered limited and temporary price pressure, not comparable to the competitive pressure exerted on prices by generics later on. This prevented national health authorities from using potential alternative sources of modafinil as leverage in their commercial negotiations with Cephalon, greatly undermining any degree of countervailing buyer power they might have. The relatively high stability of modafinil prices prior to generic entry, compared to the price drops observed after generic entry, illustrates the lack of countervailing buyer power of the national health authorities during the period of investigation.

(1175) Against this background, the Commission concludes for the purpose of this Decision that the national health authorities were not able, in any of the By-Effect Countries, to prevent Cephalon from acquiring significant economic rents during the period when it enjoyed exclusivity over modafinil products. Moreover, the authorities were not in the position to influence the entry of cheaper generic products on the market, while as already mentioned, Cephalon proved to be capable of delaying the independent entry and competition of generics via the Settlement Agreement. Therefore, the Commission concludes that the national health authorities did not have any buying power that could counter Cephalon's market power in the By-Effect Countries.

8.2.2. Teva was an important potential competitor at the time of the Settlement Agreement

(1176) At the time of the Settlement Agreement, the only modafinil product on the market in the By-Effect Countries was Cephalon's Provigil. However, at that time, Teva had real and concrete possibilities to enter modafinil markets in each of the By-Effect Countries within a reasonably short period of time. In particular, as explained in Section 6.4 and below, at the time of the Settlement Agreement, Teva had taken significant preparatory actions for entering the modafinil markets in the relevant countries and there were no insurmountable barriers that could have in principle precluded its entry.

(1177) First, Teva developed its own generic version of modafinil, which it firmly considered was not infringing Cephalon's Particle Size Patents.[1511]. In addition, Teva had its own infrastructure for manufacturing modafinil API and a distribution network, which would have enabled it to easily start supplying its modafinil once it obtained MAs.[1512] Furthermore, Teva had developed specific business plans for the launch of its modafinil product to take place between fall 2005 and January 2007 including in each of the By-Effect Countries.[1513]

(1178) Second, Teva took specific preparatory steps to have the necessary regulatory approvals for its generic modafinil. Already in March 2003 it applied for MA's for its modafinil product in the United Kingdom and France.[1514] Teva applied for the MAs in other By-Effect Countries in July 2005.

1511 See Recital (642).

1512 See Section 4.3.2 and Recital (645).

1513 In some other contemporaneous documents Teva envisaged launch in the By-Effect Countries in 2006-2008, see Recitals (642), (644)-(645) and the evidence cited.

1514 See Recitals **(**164**)** and (643)-(644).

(1179) Third, immediately after acquiring the MA in the United Kingdom, Teva entered at risk in the United Kingdom in June 2005. It competed with Cephalon between at least 6 June 2005 and until at least 6 July 2005, when Cephalon commenced patent infringement proceedings and applied for an interim injunction.[1515]

(1180) Fourth, Cephalon's patents did not represent an insurmountable barrier to entry for Teva. In particular, the compound patents for modafinil had expired in most countries by 2003, while in France it remained in force until February 2005.[1516]

(1181) Fifth, the very existence of the Settlement Agreement with value transfers undermining the generic manufacturer's incentive to independently enter the market and compete is in itself a strong indication of a competitive relationship between Cephalon and Teva.[1517] This also suggests that Cephalon perceived Teva as a potential competitor exerting competitive constraint and thus as a real threat to its Provigil franchise.

(1182) In light of the above and as explained in Section 6.4, the Commission finds not only that Teva was a potential competitor in the modafinil market in each of the By-Effect Countries[1518] and that Teva had real and concrete possibilities to enter in each of the By-Effect Countries with its own generic modafinil product. In addition, Cephalon perceived Teva as the main source of competitive pressure in relation to modafinil. Furthermore, as shown in Recitals (1165) to (1169), and further in Section 8.2.3, Teva was the most advanced potential competitor in the By-Effect Countries.

8.2.3. Other generic manufacturers did not exert competitive constraint on Cephalon at the time of the Settlement Agreement

(1183) There was no generic modafinil being commercialised in any of the By-Effect Countries at the time of the Settlement Agreement, except for Teva's entry at risk in the United Kingdom in June 2005.[1519] Cephalon brought Teva to court and sought an interim injunction against Teva. Just prior to the hearing on the request for interim injunctions scheduled for 11 July 2005, Teva agreed not to sell generic modafinil products in the United Kingdom in exchange for a cross-undertaking for damages and a bond of GBP 2.1 million (EUR 3.07 million) as a security for forgone profits.[1520]

(1184) The Commission's file contains no indications that […], […] and/or […] (Sweden, Germany), […] (United Kingdom, the Netherlands), […] (Spain), […] (the Netherlands) or any other generic company was capable of entering or planning to enter the modafinil markets of any of the By-Effect Countries at the time of the Settlement Agreement. All companies were capable to enter only years later, as described below.

1515 Recital (643).

1516 See Section 6.4 and Section 4.1.2.1.1.

1517 Case C-307/18, *Generics (UK) and Others*, paragraphs 55-56. See also, Case T-519/09, *Toshiba Corporation v Commission*, paragraph 231; Case T-208/13, *Portugal Telecom v Commission*, paragraphs 180 and 181 and Case T-216/13, *Telefónica v Commission*, paragraph 221 and 227.

1518 The conclusions in Section 6.4. covering By-Object Countries are pertinent for this section as By-Object Countries include all of the By-Effect Countries.

1519 See Section 4.3.2.

1520 See Section 4.4.

(1185) […] started API development as of 19 January 2005. The Drug Master File ("DMF") batches were taken in December 2005. It filed its DMF only on 4 March 2007 and the applications for MA in the By-Effect Countries were only filed in March 2008. […] wanted to out-license its modafinil product. At the time of the Settlement Agreement, […] did not have distribution or cooperation partners in place in the By-Effect Countries. The modafinil API produced by […] (and also the MA dossier[1521]) was the basis for the attempts for generic entry by […], […][1522] and […],[1523] described hereafter.[1524]

(1186) At the time of the Settlement Agreement, […] was by far not ready to enter the modafinil markets. […] started selling its modafinil product in Sweden only on 1 April 2010. At the end of 2005, […] acquired […] through which it later became active in Germany. […] filed for an MA in March 2008 and obtained the MA for modafinil in Germany (22 July 2009) and in Norway (20 January 2010). The product marketed by […] in Sweden and other countries where […] was active was manufactured by […].[1525] At the time of the Settlement Agreement, […] did not have a modafinil product or a MA in Sweden or Germany.

(1187) Cephalon obtained a patent law based court interim injunction against […] in both countries.[1526] In Germany, […] gave a declaration that it would not launch generic modafinil, after Cephalon filed a lawsuit against it on 28 September 2010 for infringement of its German modafinil patents (see Section 4.8.2.3).[1527] Ultimately, the dispute between […] and Cephalon/Teva was settled in 2014 (see Section 4.8.2.3).

(1188) As a result and as explained in Section 9.1.1.7.2., no generic sales were observed in Germany before 2012. The same holds true for Sweden where there were no sales from any generic market entrant (only sales from a trader) before 2012 (see Section 8.1.1.4.5.).

(1189) At the time of the Settlement Agreement, the generic company […] (trading as […]) was not ready to enter the modafinil markets in the EEA. […] filed for an MA in the Netherlands, Germany, France, and United Kingdom in March 2008. It was only on

---

1521 […] "*Out Licensing & Contract Manufacturing*" letter of March 2009 mentions explicitly as business model "*Out licensing of MA / dossiers followed by supply tie ups for finished formulations*" ID 1001, p. 4-5. For […] this is confirmed by ID 187, p. 89.

1522 ID 1396, p. 2 (paragraphs 3-4)

1523 ID 187, p. 89.

1524 The company […] from Israel (earlier […]) in 2000-2001 had developed a generic version of modafinil in collaboration with […], one of the other generic contenders in the United States with whom Cephalon settled, and also supplied […] with modafinil API. As part of the settlement, […] concluded a modafinil API supply agreement with Cephalon. […] had not been faced with actual or threatened patent litigation (it was not a party in the litigation between Cephalon and […]) and believed it was free to supply modafinil API to any prospective customer (although it focused on the United States, Israel, Australia, Mexico and the United Kingdom as primary markets). […] excluded that until 2010 any modafinil had been launched in any Member State of the EEA on the basis of its product. See also Recital (295). ID 2515, p. 5-6.

1525 ID 1396, p. 2 (paragraph 3).

1526 On 4 June 2010, Cephalon France SAS (later Teva Santé SAS) filed a lawsuit against […] in Sweden asserting an infringement of its Particle Size Patents, see Section 4.8.2.3. The Swedish court granted the injunction on 2 November 2010.

1527 ID 2178, p. 3.

4 September 2010 that […] announced that it was offering modafinil 100 mg tablets in the United Kingdom. Mylan would in-license its modafinil from Orchid.

(1190) On 14 September 2010, Cephalon initiated modafinil proceedings against […] in the United Kingdom, on 1 October 2010 in the Netherlands and on 5 November 2010 in France. […] replied to Cephalon's lawsuits with invalidity claims against the Particle Size Patents. On 5 December 2011, the Dutch court granted Cephalon, an interim injunction whereby […] was allowed to supply modafinil products worth up to a maximum of EUR 50,000 until adoption of the decision on the merits (the interim injunctions were refused in the United Kingdom and in France). Ultimately, […] and Teva settled their European modafinil disputes (see Sections 4.8.2.2 and 4.8.2.3). The […] Settlement Agreement allowed […] to market and sell modafinil products in the EEA as from 13 January 2012 (the date of the agreement).[1528]

(1191) At the time of the Settlement Agreement, Spanish generic company […] was not ready to enter the Spanish modafinil market. In Spain, Cephalon initiated court proceedings against […] in order to establish facts showing infringement of the Spanish counterparts of its Particle Size Patents. Following submission of a report drafted by a court-appointed expert, the court ruled only on 31 January 2012 that there was no likelihood of infringement and declared the end of the proceedings[1529] (see Section 4.8.2.3). As shown in Recitals (1115)-(1116), following the generic entry there was a large price drop for modafinil in Spain. Before 2011 no generic entry was observed in the Spanish market, whereas Teva had concrete launch plans in Spain as from May 2006.[1530]

(1192) At the time of the Settlement Agreement, […] was not capable of entering any modafinil market. It was planning to source modafinil API from […]. The Commission's file shows that […] and […] were still corresponding on the DMF in September 2009. This shows that at the time of the Settlement Agreement, they were further behind in the development than any other potential entrant discussed in this section. […] only obtained a MA via the decentralised procedure in January 2011. In the Netherlands, one of the By-Effect Countries, the date of market authorisation is January 2011.[1531]

(1193) Furthermore, Cephalon did not see any specific threat from any of the discussed generic companies. As Cephalon explained to the Commission, it did not have any information at the time of the conclusion of the Settlement Agreement that indicated that any specific generic manufacturer other than Teva would enter the United Kingdom or any other EEA market with modafinil products.[1532] The views of both Teva and […] (Cephalon's distribution partner until 2006) coincided with Cephalon's market intelligence.[1533]

1528 ID 2282, Section 3.2.

1529 ID 1736. See also ID 2178, p. 7.

1530 ID 333, p. 18.

1531 ID 2519 and based on IQVIA data.

1532 ID 1436, p. 12

1533 ID 979, p. 41-42. Neither Teva, nor Cephalon / [*distributor*] were at the time of Teva's entry in the United Kingdom modafinil market aware of any other generic competitor that would prepare for entering the contested markets in the EEA with modafinil products. Cephalon replied to the Article 18 Request of 27 May 2011, question 8, ID 1436, p. 12: "*Cephalon did not have any information in 2005 that indicated that any specific generic manufacturer other than Teva would enter the UK or other EEA*

(1194) Accordingly, at the time of the Settlement Agreement, the generic companies discussed in this Section were not capable to enter the relevant modafinil markets and the Parties did not expect entry by other generic companies in the modafinil markets of the By-Effect Countries. Accordingly, it appears that at the time of the Settlement Agreement, Teva was the only competitive threat to Cephalon in the markets for modafinil in the By-Effect Countries.

8.2.4. Conclusion on the competitive position of Cephalon and Cephalon's potential competitors

(1195) First, the Commission finds that Cephalon held market power in France, Germany, the Netherlands, Spain, Sweden, and the United Kingdom for the entire period relevant for infringement, that is to say from 2005 until 2011, and, in certain cases specified subsequently, beyond 2011. In particular, in France, Cephalon was the only supplier of modafinil until 2011 and its market share was never lower than 78% between 2011 and 2014. In Germany, Cephalon was the only supplier of modafinil until 2012 and its market share was 90% in 2012, 75% in 2013 and remained at 55% in 2014. In the Netherlands, no generic entered the modafinil market until 2011 and Cephalon's market share remained at or above 60% until 2011. In Spain, no effective generic entry was observed before 2011 and Cephalon's market share was not lower than 64% between 2012 and 2014. In Sweden, no generic effectively entered the modafinil market until 2012[1534] and Cephalon's market share remained at or above 59% until 2014. In the United Kingdom, no generic entered the modafinil market until 2010 and Cephalon's market share remained at or above 67% until 2012 .

(1196) Second, as shown in Sections 8.2.1.2 and 8.2.1.3 Cephalon's market position was strengthened by important barriers to entry and the lack of any buying power that could counter Cephalon's market power in any of the By-Effect Countries during the period under investigation.

(1197) Furthermore, as regards Teva's position and the position of other generic manufacturers, it is shown in Sections 8.2.2 and 8.2.3 that, at the time of the Settlement Agreement, Teva was the most advanced potential competitor, while other generic manufacturers were several years behind in terms of their preparation to enter the modafinil markets in the By-Effect Countries.

(1198) In the context of the persisting barriers to entry and the limited countervailing buyer power, the exclusion of the single generic competitor Teva significantly reduced the likelihood of a timely and effective generic entry and competition, and consequently also likely delayed the transformation of prevailing market structure and outcomes, to the detriment of consumers.

---

markets with modafinil products. Nor did Cephalon have any expectation that any specific generic manufacturer would do so." Teva replied to the Article 18 Request of 27 May 2011, question 2, ID 1428, p. 5: "*Teva expected limited competition in the EEA markets, but was not aware at the time whether other generic manufacturers were planning to launch modafinil products in the UK or other EEA markets. Teva was aware, however, of IMS data showing that […] had launched a modafinil product in the Czech Republic, Poland and Slovakia."* See also ID 2529, p. 1; ID 2539, p. 8. According to the Commission however, IQVIA data do not show the presence of […] in Czechia, Poland or Slovakia at that time.

1534 […] launched in April 2010 in Sweden, however, already in June 2010 Cephalon initiated court proceedings and requested interim injunction against the generic company, which was granted by the Swedish court in November 2010 (see Recitals (507) - (508)).

8.3. The nature, content, impact and context of the restrictive clauses in the Settlement Agreement

(1199) In this Section the Commission sets out the analysis of the restrictive non-compete and non-challenge clauses in the Settlement Agreement, how they came about and how they influenced Teva's conduct in the market. Teva's non-compete and non-challenge restricted Teva's independent behaviour, preventing it from entering modafinil markets, including in the By-Effect Countries, with generic product and restricted its ability to continue challenging Cephalon's patents (Section 8.3.1). Teva committed to this only in return for Cephalon entering into a package of transactions whose purpose was to transfer value to Teva, as an inducement to Teva to accept the non-compete and non-challenge commitments (Section 8.3.2).

8.3.1. Restrictions on Teva's independent behaviour and ability to compete

(1200) This Section establishes that the Settlement Agreement imposed restrictions on the competitive behaviour of Teva and examines their nature, impact and their context (namely their place in the Settlement Agreement and relationship with other elements of the Settlement Agreement). The Commission's analysis of the restrictions imposed on Teva under the Settlement Agreement and their context has been developed in Sections 6.3, 6.5, 6.6, 6.7 and 6.8 and this Section will thus refer to the Commission's findings and conclusions made in these Sections as appropriate. Restrictions on Teva's independent behaviour and ability to compete

(1201) As explained in Section 6.5, by accepting non-compete and non-challenge commitments under the Settlement Agreement, Teva committed itself to limit its independent efforts to enter one or more EEA markets (including all By-Effect Countries)[1535] with generic product until the Effectiveness Date of Teva Generic Rights and accepted restrictions on its ability to compete for the duration of the Settlement Agreement. As the Commission will show, this in turn potentially (if entry occurred) affected the parameters of competition in the By-Effect Countries, in particular price.

8.3.1.1. Non-compete commitment and its impact

(1202) Under Article 2.5(a) of the Settlement Agreement Teva undertook not to "*make, use, offer to sell, or sell or actively induce or assist any other entity to make, use, offer to sell, or sell*" generic versions of Provigil[1536] in any market outside the United States where Cephalon held modafinil rights (including all By-Effect Countries). In addition, Article 2.5(a) prohibited Teva from undertaking any action in preparation for the launch of generic modafinil products and prevented Teva from modafinil manufacturing activities. Teva was also prohibited to enter new markets (and even to prepare for market entry) with modafinil API (see Recitals (662)-(667).

(1203) The commitment prevented Teva from pursuing any commercial activities regarding any finished generic modafinil. It prohibited Teva to seek to enter the market with its generic version of the originator product in a viable and timely manner as well to assist any entity to make or sell any finished drug which has modafinil as an active

---

1535 See Recital (682).

1536 Generic versions of Sparlon fell within the scope of Article 2.5(a) of the Settlement Agreement as well. However, Cephalon never launched Sparlon (see Recital (419)). As to the generic versions of Nuvigil, see footnote 1080.

ingredient, including, in particular, by supplying other companies with modafinil API.

(1204) The commitment that Teva undertook under the Settlement Agreement was by no means limited to a commitment not to infringe the Particle Size Patents or any other modafinil patent held by Cephalon.[1537] Teva's commitment is an agreement concerning Teva's market conduct, that is to say Teva's non-entry or exit from the markets, and not simply a commitment not to infringe Cephalon's patents. Cephalon could never have legally obtained such broad non-compete commitments through successful enforcement of the Particle Size Patents in the underlying litigation. Teva's commitment went thus beyond the scope of Cephalon's modafinil patent rights (see Recitals (668)-(675)).

(1205) Teva's non-compete commitment lasted until 6 October 2012 in all of the By-Effect Countries (see Recital (687)).

8.3.1.2. Non-challenge commitment

(1206) Under Article 8.12 (b) of the Settlement Agreement Teva committed, for the duration of the Settlement Agreement not to challenge Cephalon's Listed Patents defined as any "*patent that may be listed in the FDA Orange Book for PROVIGIL®*," or counterparts of these patents. This definition includes, among others, Cephalon's Particle Size Patents in dispute in the UK litigation pending between the Parties.[1538]

(1207) Teva therefore committed not to challenge what were considered the main patent barriers to the entry into the modafinil market for the duration of the Settlement Agreement. The non-challenge undertaking eliminated Teva as a competitive threat as patent challenges are an essential part of the competitive process in the pharmaceutical sector. Generic undertakings trying to enter the market by inventing around the outstanding process and other patents, having to defend themselves against alleged infringements, seeking declarations of non-infringement or trying to invalidate process patents or other patents still held by the originator undertaking, or indeed by generic entry at risk, is the essence of (actual or potential) competition in this sector.[1539]

(1208) It should be recalled that Teva undertook the non-challenge commitment in a situation where Teva considered that (i) its generic product did not infringe Cephalon's patents and that (ii) Cephalon's patents were invalid and obtained by deception (see Recitals (691)-(694)).

8.3.2. The commitments not to compete and not to challenge were induced by value transfer

(1209) Teva's commitments not to compete and not to challenge were not the result of its views on the strength of the litigated patents, but rather the result of a significant value transfer from Cephalon to Teva. The transactions in Article 2 of the Settlement Agreement (namely Licence to Teva's Intellectual Property Rights, the licence to

---

1537 The Commission notes that both parties understood the non-compete commitments under Article 2.5(a) of the Settlement Agreement as including the prohibition for Teva to apply for MAs although (i) the Settlement Agreement does not stipulate anything about applying for MAs and although (ii) applying for a MA is not considered an act of patent infringement (See Recital (493)).

1538 See Section 4.1.2 and especially Section 4.1.2.1.

1539 Case C-307/18, *Generics (UK) and Others*, paragraph 81, Opinion of Advocate General Kokott in Case C-307/18, *Generics (UK) and Others*, paragraph 71.

CEP-1347 data, the Modafinil API Supply Agreement, the cash payments for avoided litigation costs and the Teva Distribution Agreement) and the ensuing transfer of value were the consideration by Cephalon in exchange for Teva entering into the non-compete and non-challenge commitments of the Settlement Agreement

(1210) The package of commercial transactions in Article 2 of the Settlement Agreement resulted overall in a significant transfer of value from Cephalon to Teva. The Commission analysed in detail the circumstances of each transaction and each Party's incentives to enter into the transactions and concluded that under normal circumstances, that is to say absent the Settlement Agreement with restrictive commitments and without the aim of inducing Teva to refrain from competing, Cephalon would not have entered into these transactions with its most advanced generic rival, at least not at the same terms. Conversely, absent the Settlement Agreement and its restrictive commitments, Teva would not have been able to obtain the value it received through this package of transactions. Moreover, through the Settlement Agreement, Teva gained not only the value that was transferred through the package of transactions, but also the upfront certainty to earn profits without the associated business risks of actually entering the modafinil markets and the risks resulting from potential competition from other generics and Cephalon. The package of transactions in Article 2 of the Settlement Agreement had the objective aim of transferring value from Cephalon to Teva and the sole consideration for this value transfer was Teva's commitments not to independently enter and compete in the market for modafinil and not to challenge Cephalon's modafinil property rights (see Section 6.6)

(1211) As evidenced by the conduct of the negotiations regarding the package of transactions, the wording of the Settlement Agreement and especially the Parties' own contemporaneous views, the package of transactions in Article 2 of the Settlement Agreement and the ensuing transfer of value had to sole aim to induce Teva to enter into the non-compete and non-challenge commitments of the Settlement Agreement. The transactions as an overall package were considered sufficiently beneficial to induce Teva not to independently enter and compete in the market for modafinil and not to challenge Cephalon's modafinil property rights, irrespective of how much each transaction individually and actually contributed to the overall value of the package and of the precise quantification of this overall value (see Sections 6.7 and 6.8).

(1212) The Settlement Agreement prompted a significant value transfer from Cephalon to Teva in return for which Teva committed not to independently enter and compete in the markets for modafinil. In doing so, the Parties replaced the risks of competition with a practical cooperation between them amounting to excluding Teva from the modafinil markets and thus effectively constituting a market exclusion agreement.

8.4. Competition that would have existed without the Settlement Agreement

8.4.1. Introduction

(1213) The Commission concluded in the previous sections that Cephalon had market power on the market for modafinil products in each of the By-Effect Countries and that Teva was its most advanced competitive threat (Section 8.2). The Commission also recalled that the non-compete and non-challenge commitments in the Settlement Agreement were not the result of a genuine assessment based on the perceived strength of the patent, but induced by the significant value transfer embedded in the transactions in Article 2 of the Settlement Agreement and that they eliminated Teva's

independent market behaviour and its ability to compete with Cephalon (Section 8.3).

(1214) On this basis, and in light of the principles recalled in Chapter 7, this Section assesses the competitive situation that would have existed in the absence of the Settlement Agreement. It leads the Commission to conclude that due to the Settlement Agreement a lesser degree of competition existed in the modafinil markets of the By Effect Countries and that the Settlement Agreement therefore had as its effect the restriction of competition within the meaning of Article 101(1) TFEU. This conclusion is based on comparing the competitive situation arising under the Settlement Agreement with the likely competitive scenario that would have arisen absent the Settlement Agreement.

8.4.2. Absent the Settlement Agreement Teva would have sought to enter the modafinil markets independently of Cephalon

(1215) Taking into account the economic and legal context in which the Parties operated and especially their own contemporaneous views on the relevant patent situation[1540] as well as the real conditions of the functioning and the structure of the modafinil markets, including Teva's position as Cephalon's most advanced competitive threat,[1541] the Commission considers that the likely counterfactual in the absence of the Settlement Agreement is a continued patent litigation between the Parties. Absent the Settlement Agreement Teva would have been likely to continue to defend its position in litigation and to continue its efforts to enter the modafinil market independently of Cephalon. It was expected that the trial in the UK would start in March 2006 at the earliest and the judgment would be served within three to four weeks, still before the decision in the litigation in the United States. Cephalon was of the view that "*Teva may be intentionally seeking a UK judgement prior to US*".[1542] Teva would therefore have been likely to continue to exert strong competitive pressure on Cephalon.

(1216) At the time of the Settlement Agreement, Teva had planned to enter the modafinil markets in various countries in the EEA and had launched already in one European country. Teva was prepared to market its modafinil product in these markets and planned a roll-out through various means, such as starting mutual recognition procedures to obtain MAs.[1543]

(1217) Teva UK received the MA for its finished modafinil product in the United Kingdom on 6 June 2005 and immediately launched at risk, offering its generic modafinil product to two big pharmacy chains in the United Kingdom (the Boots Company and Alliance Unichem/Moss).[1544] Apart from the United Kingdom, Teva was also

---

1540 See Section 6.3. The detailed factual description and assessment of the economic and legal context of the Settlement Agreement set out in the context of the analysis of the Settlement Agreement as a by-object restriction of competition is applicable also in the context of the analysis of the Settlement Agreement as a by-effect restriction of competition.

1541 See Sections 8.1 and 8.2.

1542 ID 2531, p. 2. See also Recital (186).

1543 ID 1848, p. 11. An internal document of Teva sets out [mentioned] launch dates in these countries between May 2006 and January 2007 (ID 333, p. 18). See also ID 1848, ID 1846, ID 1847.

1544 Teva achieved sales in the amount of approximately GBP 300,000. Its generic offer of GBP 34.2, estimated by Cephalon to be GBP 30, amounted to an almost 50% reduction of the list price offered by […] on behalf of Cephalon UK (see Section 4.3.2).

preparing to launch its generic modafinil in other markets. In the Europe Development List dated 17 October 2004, Teva had assessed modafinil as "*low cost to add to [Teva's] range*" and categorised its generic modafinil entry as "*strategic priority A*".[1545] It predicted an average annual growth in the EU of 18.5% for the 100 mg tablets.[1546]

(1218) Teva had applied in March 2003 for an MA in France (the MA was granted in November 2006) and in July 2005 in all other By-Effect Countries. These applications were filed based on the mutual recognition procedure with the United Kingdom as the reference Member State.

Table 20: MA filing dates in the By-Effect Countries

Country concerned	**Date of filing**	**Date of grant**
France	29/03/2003	21/11/2006
United Kingdom	31/03/2003	06/06/2005
Germany	07/07/2005	12/092006
Spain	07/07/2005	24/03/2008
The Netherlands	07/07/2005	03/11/2009
Sweden	07/07/2005	05/06/2008

Source: ID 1844, p. 5-6.

(1219) Teva was well placed and capable to launch its generic modafinil product, since it had gained over many years vast experience in introducing generic medicines in the EEA, including in the By-Effect Countries. Teva was a leading generics manufacturer in several EEA countries (including the United Kingdom and the Netherlands) and one of the largest generic manufacturers in others. Teva also had operations in Germany (through Teva Pharmaceuticals Germany GmbH).[1547] In 2004, Teva established subsidiaries in, among others, Spain and Sweden, which started their commercial activities in 2005. In 2005, Teva realized significantly higher European sales of generic products (resulting from new product launches) as well as an increase in net sales in every Contracting Party to the EEA Agreement in which Teva operated (including all By-Effects Countries). Following the acquisition of IVAX Corporation (completed on 26 January 2006), Teva significantly boosted its

1545 ID 333, p. 379.

1546 ID 333, p. 18.

1547 Even in the countries which were referenced as smaller operations for Teva (such as Czechia), it was the Settlement Agreement that was understood as the reason preventing launch of Teva's generic modafinil product rather than the inadequacy of Teva's operations (for example, ID 460, p. 2). Teva's operations in Germany in 2005 were sufficient enough to support "*significant sales increases*" of Copaxone, Teva's leading product and its first major innovative drug (Germany was termed as the largest multiple-sclerosis market in the EEA) (ID 2275, p. 25).

presence and reach in, *inter alia*, Western Europe (for example, in France and the United Kingdom).[1548]

(1220) Modafinil was termed as one of Teva's "Platinum Products. These are the potentially large selling products or products in which [Teva] ha[s] competitive advantage (patent, exclusivity, […]) for a short or long term. We must have them in Europe (at least in few markets) in order to grow substantially our business."[1549] The specific reasons as to why modafinil has platinum status are "T[eva] API, niche and first to market".[1550] To be included as a platinum product, the source of the material must be "TAPI exclusive or semi exclusive and others".[1551]

(1221) At the time of the Settlement Agreement, Teva had also the ability to supply API and the ability to efficiently distribute pharmaceutical products in the By-Effect Countries (see Section 4.3). At the time of the Settlement Agreement, Teva had already invested considerable resources and time in developing a process to manufacture and launch its modafinil product that was in Teva's firm conviction not infringing any intellectual property rights.[1552] Absent the Settlement Agreement, Teva would have retained the competitive ability and incentives to pursue commercial strategies independently of Cephalon, taking into account the patent situation.

(1222) In addition, Teva would likely have remained involved in litigation with Cephalon. Teva was convinced of its own strong patent position which allowed according to its own assessment for entry without infringement. The fact that Teva had started regulatory MA procedures and was also starting to approach potential customers (such as potential API purchasers; see Recital (158)) further underlines that Teva was determined to start competing on the modafinil markets. There is no contemporary evidence suggesting that Teva would not have continued to do so absent the Settlement Agreement.

(1223) At the time of the Settlement Agreement, Teva was also convinced that Cephalon's Particle Size Patents were invalid and obtained by deception (see Sections 4.4.1. and 6.3.2). The Commission notes that, ultimately, in the United Kingdom proceedings initiated by Cephalon against Mylan, the competent court concluded on 24 June 2011 that the Particle Size Patents are indeed invalid for obviousness. Similarly, in the declaratory proceedings initiated by Apotex against Cephalon in 2006, on 7 November 2011 a Court in the United States declared the US '516 patent invalid pursuant to the on-sale bar, for derivation, for obviousness, and for lack of written description.

(1224) As confirmed by the Court of Justice, patent challenges are an essential part of the competitive process in the pharmaceutical sector, both for generic companies seeking market entry and for originator companies that invoke process patents or other patents against such market entry.[1553]

1548 ID 2275, p. 13, 18, 19, 38, 39 and 40. The Commission notes that the fact that Teva intended to acquire IVAX Corporation had been known already at the time of the Settlement Agreement (ID 351, p. 240).

1549 ID 2089-120, p. 3. Document distributed to participants at EPRM meeting on 25-26 August 5, 2004.

1550 ID 2089-125, p. 3. Document of 26 August 2005.

1551 ID 2089-120, p. 3.

1552 ID 979, p. 94.

1553 Case C-307/18, *Generics (UK) and Others*, paragraphs 81-82.

(1225) Had Teva continued with the pending litigation and continued defending its product launch, other generic suppliers could have been attracted to enter. The ongoing litigation process would have preserved (rather than deferred) the potential for independent generic competition and associated price declines.[1554]

(1226) In addition to removing the otherwise continued potential competition from Teva, the Settlement Agreement also had an impact on the likelihood of other possible suppliers of generic modafinil to prepare for and undertake entry. Absent the non-challenge commitment and the provisions in the Settlement Agreement disincentivising Teva to independently compete, the independent entry of other generic suppliers in the market would have been more likely.

(1227) By eliminating Teva's efforts to seek an independent market entry, the likely effect of the Settlement Agreement was also to assist Cephalon in preserving the patent entry barriers faced by potential entrants which would continue to face the prospect of litigation. The Settlement Agreement rendered an independent generic modafinil launch by any third entity more difficult. The combination of Cephalon's non-challenge commitment vis-à-vis Teva's modafinil patent and, especially, Teva's non-challenge commitment vis-à-vis Cephalon's modafinil patents (see Section 6.5.2.) contributed to maintain entry barriers for other potential competitors on the modafinil markets.[1555] The Settlement Agreement thus gave Teva an outstanding market position where it had the certainty to be able to supply modafinil without being under threat of patent infringement litigation by Cephalon, while the barriers to entry for other generics remained high, albeit not insurmountable.[1556] (See also Section 8.2)

(1228) In the Settlement Agreement, Teva, on the one hand, agreed not to develop, market or sell generic versions of Provigil and it agreed not to develop, market or sell generic equivalents, second generation products or any other products containing modafinil as an active ingredient. On the other hand, Teva undertook not to challenge Cephalon's modafinil patents. Therefore, the Settlement Agreement effectively terminated all competitive pressure from Teva, not only in terms of the likelihood of Teva's own entry but also in terms of Teva continuing to challenge Cephalon's patents and thereby facilitating entry for other generic competitors.

(1229) The Parties submit, first, that the Commission's assessment would not deny the objective *bona fides* nature of the patent dispute and the genuine uncertainty as to its outcome. The Parties also note that at no point the Commission explicitly assert that, in the absence of the Settlement Agreement, Teva would have won the patent litigation or even would have been likely to invalidate Cephalon's patents or prove its non-infringing case and that Teva's successful challenge of Cephalon's patents remained a theoretical possibility. They submit that the Commission would not even claim that the Settlement Agreement actually did delay Teva's entry in light of the legal and economic context of the case, or was likely to delay Teva's entry.

1554 Case C-307/18, *Generics (UK) and Others*, paragraphs 69-70.

1555 See the statement of Teva's senior manager in Europe in the initial phases of the Settlement Agreement negotiations cited in Recital (190): "*Teva's top priority is to settle with Cephalon and to add to the table also the Sulphone patent that we have. In my opinion the combination of the two patents may lock any realistic option to anyone else to get into the market. I strongly believe that a settlement is optimal for both companies.*"

1556 Also other generic companies could in theory for example enter at risk or litigate.

According to the Parties, the Commission bases its effect case on the sole assumption that an alleged "value transfer" distorted the settlement process.

(1230) Second, the Parties also consider that the Commission ignores the pro-competitive benefits of the Settlement Agreement, in particular by allegedly not examining the licence allowing Teva into the modafinil markets as of 2012. They also submit that the Settlement Agreement had the reasonable prospect of being pro-competitive by replacing the uncertainty of Teva's entry before 2012 or after 2015 with the certainty of Teva's allegedly full-blown, pro-competitive, entry as of 2012. Hence, according to the Parties, the Commission analysis does not show any restrictive effects.

(1231) Finally, according to the Parties, in its *Teva/Cephalon* merger Decision, the Commission would have found that the Settlement Agreement improved the prospect of Teva's entering the market from 2012 as compared to other generic players that confronted the uncertainties of the on-going patent litigations until 2015 and it would also have concluded that by virtue of the Settlement Agreement Teva remained the most likely competitive constraint on Cephalon.

(1232) The Commission agrees that there was uncertainty at the time of the Settlement Agreement regarding the outcome of the patent litigation between Cephalon and Teva. However, the *bona fides* nature of the patent dispute and the genuine uncertainty as to its outcome is immaterial regarding the assessment of the effects of the Settlement Agreement on competition. As emphasised by the Court of Justice and recalled in Section 7.2, it is not for the Commission to assess the subject-matter of the patent litigation and conclude on its likely outcome and such a balance of probabilities concerning the outcome of the patent litigation is not necessary to find that the Settlement Agreement was likely to have restrictive effects on competition from an *ex ante* perspective. The Court of Justice expressly held that a finding that a patent settlement agreement has appreciable effects on competition does not presuppose a finding "*that the manufacturer of generic medicines who is a party to that agreement would probably have been successful in the patent proceedings.*"[1557]

(1233) At the same time, the possibility of Teva prevailing in the patent litigation and entering the modafinil markets independently immediately afterwards was not a mere theoretical possibility, but a plausible and actual possibility based on the evidence in the file and on the expectations of the Parties at the time of the Settlement Agreement (see Section 4.3). The Commission has shown in Section 8.2. that Cephalon and Teva were potential competitors at the time of the Settlement Agreement, in the sense that Teva had real concrete possibilities of entering the market with generic modafinil, that Cephalon's secondary patents did not represent an insurmountable barrier for Teva's market entry and that Cephalon was aware of this and perceived Teva as the main competitive threat to its modafinil business. Had Teva not been induced by the value transfer to accept the non-compete and non-challenge commitments (see Section 8.3), the prospect of independent entry and competition by Teva would have been maintained. The potential competition of Teva vis-à-vis Cephalon would have continued to exist.

(1234) As to the Parties' arguments on alleged pro-competitive effects of the Settlement Agreement and the conclusions drawn from the Commission's analysis of Teva-Cephalon merger, these are assessed and refuted in detail in Section 6.9 and

[1557] Case C-307/18, *Generics (UK) and Others*, paragraph 121.

Section 10 of this Decision. It suffices to note here that the Parties' arguments on the alleged pro-competitive effects of the Settlement Agreement concern the assessment of the Settlement Agreement as a restriction of competition by object[1558] and its assessment under Article 101(3) TFEU. They cannot alter the Commission's finding that the Settlement Agreement had the effect of restricting competition on modafinil markets in the By-Effect Countries.

(1235) As regards other conceivable alternative scenarios of less restrictive settlement agreements, the Commission notes that any such alternative counterfactual scenario would have to involve a settlement reflecting solely the Parties' *ex ante* assessment of strength of the litigated patents. In other words, such alternative settlement should not have been distorted by value transfers made in exchange for the restrictive commitments and would reflect an undistorted competition (not distorted by a value transfer).

(1236) The Parties do not elaborate on possible less restrictive settlement agreements. The only alternative settlement agreement put forward by the Parties is a settlement without "*competition-related terms of the Settlement Agreement*"[1559], that is to say without non-compete and non-challenge commitments that was introduced by the Parties in their SSO Reply (their most recent substantive submission).

(1237) In such a scenario, much like in the counterfactual of a continued litigation (i.e. without a settlement), Teva would not have been constrained by the non-compete and non-challenge clauses and would have retained significantly more ability and incentive to compete and challenge Cephalon's position on the market, notably allowing for earlier and more intense generic competition. This also follows from Cephalon's own appreciation of Teva's potential entry in the relevant markets. Cephalon considered that entry of Teva on modafinil markets would have a major impact on its own modafinil business (see Sections 4.2 and 4.3).

(1238) The Parties submit that the lack of evidence that an alternative agreement to settle litigation was considered by the Parties at the time of the Settlement Agreement constitutes a necessary failure of an effects assessment. The Parties note that Cephalon was unwilling to compromise on the Effectiveness Date of Teva Generic Rights and conclude that the Commission's own analysis undermines the relevance of the effect of the alleged value transfers.

(1239) The Parties' arguments do not convince. First, the fact that there is no evidence of a particular alternative agreement being considered or discussed by the Parties at the time of the Settlement Agreement does not imply that such an alternative agreement cannot have been a realistic possibility in the absence of the Settlement Agreement. This is precisely the purpose of a counterfactual analysis: to establish competitive scenarios that have not materialized because the Parties decided to enter into the Settlement Agreement.

(1240) Second, as noted above, given the importance of the exclusivity regarding modafinil, conferred by patent protection, for Cephalon and given Teva's advanced development of its generic product and it being convinced that it did not infringe any valid patents, the Commission considers that the more likely counterfactual is

---

1558 Case C-307/18, *Generics (UK) and Others*, paragraphs 103 and ff.

1559 SSO Reply, paragraph 56.

continued litigation between Teva and Cephalon (namely no settlement at all). However, in terms of the assessment of the likely effects of the Settlement Agreement, both the most likely counterfactual of continued litigation and the counterfactual of settling without value transfers on less restrictive terms lead to the same conclusion, because both would reflect the ex-ante prospects of competition by Teva without the restrictive commitments induced by the package of transfers. This does not constitute a failure of the analysis by effect, on the contrary, it makes the conclusions of the Commission's assessment less dependent on one specific counterfactual scenario and therefore more robust. Either a less restrictive agreement without the non-compete and non-challenge commitments was a possible alternative scenario, then the Commission's analysis confirms the finding of effects on competition (namely in the absence of non-compete and non-challenge commitments). Or it was not a possible alternative scenario, then it is irrelevant for the counterfactual analysis and the finding of effects under the counterfactual analysis in Recitals (1216)-(1235) remains unaffected and conclusive. The Commission recalls that the Parties did not put forward, as relevant for the effects analysis, any further counterfactuals in which Teva's assessment was not distorted through a value transfer[1560].

(1241) Finally, the evidence in the file shows that at least Teva contemplated at the time of the Settlement Agreement various alternative agreements with less restrictive terms. For instance, Teva internally mentioned the possibility of settling with immediate entry in the United Kingdom and entry in France as of 2007, without some of the other transactions that were finally included in the Settlement Agreement (see Recital (205)).

(1242) The Parties' claim that Cephalon was unwilling to compromise any further on the Effectiveness Date of Teva Generic Rights is indeed reflected in a lack of evidence on any discussions between the Parties on this issue. This is exactly why the Commission considers this scenario a less likely possible scenario. The evidence shows indeed that Cephalon was instead rather willing to compromise on the other transactions that contributed to the overall value transfer inducing Teva to accept the non-compete and non-challenge commitments than to move on the date. The negotiation between Cephalon and Teva (see Section 4.5) focused on the contributions to the overall value transfer and on the vehicles through which such transfer would take place, namely, the various transactions in Article 2 of the Settlement Agreement as a consideration for Teva's acceptance of the restrictive commitments. The evidence shows that the various transactions are directly linked to the restrictive effects of the Settlement Agreement, inasmuch as they were a necessary condition for the non-compete and non-challenge commitments to be accepted by Teva.

(1243) Therefore, absent the Settlement Agreement, Teva would have retained significantly more ability and incentive to compete and challenge Cephalon's position on the

---

1560 It is important to note that, for the purposes of assessing whether the present Settlement Agreement with its value transfer induced commitments not to compete and challenge restricted competition by effect, the point of comparison can only be a counterfactual scenario without commitments induced by value transfers. Only counterfactual scenarios in which the Parties independently determine their conduct in view of the strength of the patents and in which they are not induced in their decision-making and conduct by a transfer of value can allow to draw conclusions about the effects on competition that the Settlement Agreement in its current form is likely to have had.

market allowing for earlier and more intense generic competition. In other words, at the time of the Settlement Agreement, Teva constituted the most significant competitive threat for Cephalon. In the absence of the Settlement Agreement, this threat of potential competition would have been maintained; and if entry had indeed occurred, a decrease in the price of modafinil in the By-Effect Countries would have been likely. However, the Settlement Agreement – through clauses that were induced by a value transfer to Teva – eliminated this competitive threat and preserved Cephalon's market power and therefore had the effect of restricting competition.

8.4.3. Cephalon's preserved market power and associated rents illustrate the effect of the Settlement Agreement on competition

(1244) As shown above, Teva was the most important potential generic competitor of Cephalon at the time of the Settlement Agreement. No other potential generic competitor was even close to exerting a comparable competitive constraint on Cephalon (Section 8.2). This important potential competition, that would have existed in the counterfactual, was effectively removed by the Settlement Agreement. Absent the Settlement Agreement, Teva would have continued its patent litigation and its strive for entry due to its advanced product development (Section 8.4.2.). The removal of Cephalon's most advanced potential competitor produces potential restrictive effects. This restriction of competition is further illustrated by looking at the impact of the Settlement Agreement on Cephalon's market position, manifesting itself in Cephalon's ability to continue extracting significant economic rents on the modafinil markets in the By-Effect Countries.

(1245) By removing Cephalon's main competitive constraint that would have existed in the counterfactual, the Settlement Agreement had the likely effect of shielding Cephalon from price competition by generic competitors in the By-Effect Countries. Had Teva entered, it would (this is the business model of generic entrants) been likely to compete with Cephalon on prices, with the likely result of lower prices. The price competition that can (and usually does) occur after generics have gained an effective presence on the market is shown, for purely illustratively purposes, in Table 21 below, which sets out separately for each By-Effect Member State the difference in prices before and after effective entry by generic competitors, and in Figures 5, 8, 11, 14, 17 and 20 above, which illustrate the development of the average price for modafinil in each of the By-Effect Countries.

Table 21: Price differentials before and after generic entry (per tablet)

Member State	**Formulation concerned**	**Pre-entry Cephalon's price (EUR)**	**Post-entry average price (EUR)**	**Price decrease (relative to pre-entry price).**
France	TAB 30 x 100 mg	2.54	1.48	42%
Germany	TAB 50 x 100 mg	2.10	1.94	8%
Germany	TAB 100 x 100 mg	2.10	1.93	8%
Netherlands	TAB 30 x 100 mg	1.85	0.65	65%
Spain	TAB 30 x 100 mg	1.67	0.90	46%
Spain	TAB 60 x 100 mg	1.49	0.90	40%
Sweden	TAB 30 x 100 mg	2.48	0.96	62%
Sweden	TAB 90 x 100 mg	1.82	0.61	67%
United Kingdom	TAB 30 x 100 mg	1.77	0.21	88%
United Kingdom	TAB 30 x 200 mg	3.56	0.93	74%

Source: The Commission's calculation based on IQVIA data and data submitted by companies in the United Kingdom.

(1246) The Settlement Agreement ensured that Teva would not enter the modafinil market as an independent competitor in any of the By-Effect Countries, while this was a real possibility absent the Settlement Agreement. This prevented the possibility of Teva's independent entry and of competition arising that would have been likely to reduce the price levels that Cephalon was able to maintain in the By-Effect Countries. The Settlement Agreement contributed to preserving Cephalon's prominent market position by muting Teva's competitive constraint.

(1247) The position of economic strength enjoyed by Cephalon is further shown by the rents that Cephalon managed to extract until generic entry effectively took place between 2011 and 2012 in the By-Effect Countries. For the avoidance of doubt, the notion of rents in this context refers to the difference between the actual returns obtained and the returns obtained when operating under effective competition. Substantial such rents are an indication of exercise of market power and can be referred to as "market power rents". Persistent significantly high returns relative to those which would prevail in a competitive market can be appropriated only by an undertaking holding market power by exploiting this position and preventing effective competition. Such

market power includes the ability to charge high prices independently from its (potential) competitors.[1561]

(1248) There is no evidence or *a priori* reason to believe that the originator companies suffer from higher average production (or distribution) costs than their generic competitors. The Parties have not submitted any reasons and evidence in this respect. Thus, the steady post-generic entry price covers costs, both of the generic and originator companies. The gap between prices before and after generic entry provides an indication of the rents extracted by Cephalon prior to generic entry. A steady post-generic entry price in the long run reflects effective competition. The observed post-generic entry price in the first years after generic entry (before prices had stabilised) can therefore be assumed to be only a conservative estimate (that is an upper bound) of the effective competitive price level because the prices would in all likelihood continue to decrease.

(1249) Prior to generic entry, Cephalon due to its singular position on the modafinil markets was able to charge on average prices that were substantially higher than the above mentioned steady post-generic entry prices, which provide a conservative estimate of the competitive price level for the purpose of estimating the economic rents enjoyed by Cephalon. Table 21 summarises the relevant data for each of the By-Effect Countries. It sets out Cephalon's average price per standard unit at the average level from the last six months before effective generic entry.[1562] The post generic entry price was calculated as a weighted average price of modafinil per standard unit in the second and third quarters of 2016, the last quarters for which data was available at the time of the SO, as a conservative approximation to the competitive price level in each market.[1563] It is a conservative approximation because by 2016 prices may not have yet (fully) stabilised[1564] (which usually takes some years in markets that become subject to generic competition). The percentage price decreases in Table 21 therefore give a conservative lower bound of the extra margin that Cephalon was able to enjoy on each of the By-Effect Countries prior to generic entry. They indicate that Cephalon was able to appropriate substantial economic rents prior to generic entry.

(1250) The Parties submit that the Commission's above analysis contains discrepancies and inconsistencies. In this respect, the Commission considers that the Parties overlook the detailed description in Section 8.1.1.4[1565] regarding the methodology used to calculate the price reductions after generic entry that are reproduced here in Table 21 To ensure consistency across the By-Effect Countries and robustness to different possible choices of time periods for price comparison within each country, the Commission compared average prices of six months before generic entry in each country with average prices of the last six months observed in the available data at the time of the SO. This approach has not been contested by the Parties. In particular,

---

1561 See Judgment of 13 February 1979, *Hoffmann-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 38.

1562 This approach ensures robustness and avoids sensitivity to monthly variations due to possible accounting irregularities.

1563 For the United Kingdom, data on prices for the third and fourth quarters of 2014 have been used, the last periods for which data was available. Given the downward trend of prices observed, this is therefore likely to underestimate the price drop for the United Kingdom.

1564 See data on prices in the By-Effects Countries presented in Section 8.1.1.4

1565 This description of methodology was set out in the SO, Section 9.1.3 SO.

the alleged inconsistency with respect to prices in Sweden does not exist: the price reductions between 2009 and 2016 of 67% and 62% reported in Table 21 are entirely consistent with the price reductions between 2009 and 2014 of 36% and 28% observed in Figure 17. The figures simply reflect how prices continue to drop over time as a result of generic competition. With respect to the Netherlands, drops in weighted average prices are apparent both in Figure 11 and in Table 21

(1251) In view of the foregoing, the Commission finds that, after and because of the Settlement Agreement, Cephalon was in a position to continue extracting after the Settlement Agreement significant market power rents above the effectively competitive price level since the Settlement Agreement enabled it to operate without being constrained by generic competitors in the By-Effect Countries. Also, lack of constraints by generic competitors generally reduces the incentives for originator companies to engage in innovation, since generic entry serves to effectively enforce the end to their market exclusivity.[1566] The evolution of prices shows that the most effective constraint in restricting Cephalon in terms of its ability to charge higher prices and therefore to appropriate market power rents was effective generic competition. Until entry by generics became effective in the By-Effect Countries and as a result of the Settlement Agreement, Cephalon was not only in the position to operate without facing any significant constraints, but also had an interest in exercising its market power and appropriating the associated rents by sustaining supracompetitive prices at the expenses of national health systems and ultimately to the detriment of patients' welfare.

(1252) The prospect that Cephalon could charge substantially higher average prices that produced significant market power rents, motivated Cephalon to offer significant inducements to convince Teva to accept the non-compete and non-challenge commitments. The Commission indeed notes that by means of the Settlement Agreement, Cephalon was capable of delaying the independent entry and competition of cheaper generic products and of deferring the price decreases associated with generic competition. The Settlement Agreement constituted the means by which Cephalon preserved its market power, appropriated the associated rents and transferred part of them to Teva, hence having the effect of restricting competition to the detriment of national health systems and, ultimately, patients.

(1253) As illustrated by the above analysis of Cephalon's market power and ability of extracting the associated rents, the Settlement Agreement had an appreciable effect on competition by removing the competitive pressure from Teva on Cephalon and allowing Cephalon to protect its market power. The Settlement Agreement also significantly reduced any likelihood of Cephalon's market power being challenged by other generic manufacturers. Finally, it also reduced the likelihood that consumers could benefit from lower competitive prices resulting from generic competition.

8.5. Conclusion: the Settlement Agreement restricted competition by effect

(1254) Although, according to the case-law, there is no need to take account of the effects of an agreement if it is established that it has as its object the restriction of

[1566] See Case T-321/05, *AstraZeneca v Commission*, paragraph 367.

competition,[1567] the Commission nonetheless examined the anticompetitive effects of the Settlement Agreement.

(1255) Cephalon had market power on the market for modafinil products in each of the By-Effect Countries. Teva was its most advanced competitive threat and no other generic manufacturer exerted competitive pressure on Cephalon at the time of the Settlement Agreement in the EEA, including in the By-Effect Countries (Section 8.2). The non-compete and non-challenge commitments in the Settlement Agreement were induced by the significant value transfer embedded in the transactions in Article 2 of the Settlement Agreement and eliminated Teva's independent market behaviour and ability to compete with Cephalon (Section 8.3).

(1256) The Settlement Agreement therefore eliminated Teva as a potential competitor and thus appreciably restricted competition between Cephalon and Teva. Absent the Settlement Agreement, Teva would have been likely to continue trying to enter and compete with Cephalon on the modafinil markets. The Settlement Agreement, with its restrictive non-challenge and non-compete commitments, hence appreciably increased the likelihood that Cephalon's position on the modafinil markets remained uncontested for a longer period of time. Teva could no longer compete with Cephalon the way it would have in the absence of the Settlement Agreement despite having developed an advanced generic modafinil product.

(1257) The Settlement Agreement resulted in removing the risk of competition and market entry by the main potential competitor and replacing that uncertainty with the certainty of a significant value transfer to Teva in return for its non-entry in the relevant markets. In the absence of the restrictive provisions of the Settlement Agreement, Teva, which considered Cephalon's remaining patents to be weak and knew it was the most advanced potential generic entrant, was well placed to enter and was the first undertaking involved in infringement proceedings with Cephalon in the EEA, would have remained a competitive threat as a potential generic entrant with modafinil in the By-Effect Countries. Such entry would have the likely effect to decrease prices for modafinil in the By-Effect Countries. The Settlement Agreement preserved Cephalon's market power, allowed Cephalon to maintain its significant rents (and the resulting prices) to the detriment of consumers and health systems and deterred all other generic challengers from entering the market. The Settlement Agreement thus had the potential effect to restrict competition in the internal market.

(1258) Since at the moment of the Settlement Agreement Cephalon held market power in each of the By-Effect Countries and since Teva's generic product was the most advanced potential generic competitor to Cephalon's modafinil, the Settlement Agreement's likely effects on competition were also appreciable.

(1259) On the basis of the foregoing considerations, the Commission concludes that the Settlement Agreement had the effect of appreciably restricting potential competition on the modafinil markets in the By-Effect Countries within the meaning of Article 101(1) TFEU for the duration of the infringement.

[1567] See among others, Case C-56/65, *Société Technique Minière v Maschinenbau Ulm*, page 249; Joined Cases C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, *GlaxoSmithKline Services and Others v Commission and Others*, paragraph 55; Case C-8/08, *T-Mobile Netherlands and Others*, paragraph 28.

9. EFFECT ON TRADE BETWEEN MEMBERS STATES

9.1. Principles

(1260) Article 101(1) TFEU only applies to agreements and practices "*which may affect trade between Member States*". The "*effect on trade*" criterion has three basic elements.[1568]

(1261) First, "trade between Member States" must be affected. The concept of trade covers all forms of economic activity. According to settled case-law[1569] an agreement or practice that has an impact on the competitive structure in more than one Member State is by its very nature capable of affecting trade between Member States. Trade between Member States may be affected also in cases where the relevant market is national.[1570]

(1262) Second, it is sufficient that the agreement or practice "*may*" affect trade, that is to say that it is sufficiently probable that the practices are capable, based on an objective assessment (as well as subjective elements, if any), of having an effect on the patterns of trade, or on the competitive structure. Article 101 of the TFEU "*does not require that agreements referred to in that provision have actually affected trade between Member States*"; however "*it does require that it be established that the agreements are capable of having that effect*".[1571]

(1263) Third, the effect on trade of the agreement or practice must be appreciable. This element requires that the effect on trade between Member States must not be insignificant and it is assessed primarily with reference to the position of the undertaking(s) on the market for the products concerned.

(1264) Finally, it is the course of conduct as a whole that must be capable of affecting trade between Member States. It is not required that each individual practice, each provision of an agreement or each agreement that forms part of a single and continuous infringement is capable of doing so.[1572]

9.2. Application to the case at hand

(1265) In light of the principles set out in the previous section, in the case at hand, the effect on trade between Member States has to be analysed for the Settlement Agreement as a single instrument that brought about comprehensive settlement between the Parties and affected the behaviour of the Parties in a manner relevant for assessment under competition law rules.[1573]

1568 *Commission Notice—Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81-96, point 18.

1569 Judgment of 8 October 1996, *Compagnie maritime belge transports and Others*, Joined cases T-24/93, T-25/93, T-26/93 and T-28/93, EU:T:1996:139, paragraph 203; Judgment of 6 March 1974, *Instituto Chemioterapico Italiano and Commercial Solvents v Commission*, Joined cases C-7/73 and C-6/73, EU:C:1974:18, paragraph 32.

1570 *Commission Notice—Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81-96, points 19-22.

1571 Judgment of 28 April 1998, *Javico v Yves Saint Laurent Parfums*, C-306/96, EU:C:1998:173, paragraphs 16 and 17; see also Joined cases T-374/94, T-375/94, T-384/94 and T-388/94 *European Night Services and Others v Commission*, paragraph 136.

1572 Guidelines on Article 101(3) TFEU, points 12 and 14.

1573 See Section 6.2.

(1266) The Settlement Agreement imposed on Teva a commitment to limit, for the duration of the agreement, its independent efforts to enter modafinil markets in the By-Object Countries, which included (among others) 25 Member States.[1574] Teva's efforts to enter these markets, either on its own or through a cooperation partner, were discontinued and therefore a potential competitor was eliminated from these national markets in the EU, thereby affecting the competitive structure in those markets.

(1267) As such the Settlement Agreement was by its very nature capable of affecting trade between Member States. In view of Cephalon's strong position on the relevant national product markets where it was selling modafinil[1575], the potential impact on trade can be said to be appreciable.

(1268) The Commission, therefore, concludes that the Settlement Agreement was capable of affecting trade between Member States within the meaning of Article 101(1) TFEU.

10. APPLICATION OF ARTICLE 101(3) TFEU

(1269) This Chapter concludes that the Parties have failed to submit the evidence necessary to show that the conditions for the application of Article 101(3) TFEU are met. The Parties have not provided any evidence demonstrating that the production or distribution of goods improved as a result of the Settlement Agreement, thus failing to comply with the requirements outlined in Article 101(3) TFEU (Section 10.1.). While this conclusion is sufficient for the Commission to conclude on the overall non-applicability of Article 101(3) TFEU, the Commission nevertheless, has also assessed the remainder of the Parties' arguments and has similarly concluded that these do not meet the remainder of the conditions of Article 101(3) TFEU (Sections 10.2.2-10.2.4).

10.1. Principles

(1270) Article 101(3) TFEU sets out an exception rule which provides a defence to undertakings against a finding of infringement of Article 101(1) TFEU.[1576] Article 101(3) TFEU reads as follows:

"*The provisions of paragraph 1 [of Article 101 TFEU] may, however, be declared inapplicable in the case of:*

- any agreement or category of agreements between undertakings,

- any decision or category of decisions by associations of undertakings,

- any concerted practice or category of concerted practices,

which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;

1574 See Recital (588).

1575 See Section 8.2.1 and Recital (1137) where it is explained that France, Germany, the Netherlands, Spain, Sweden and the United Kingdom represented over 80% of the revenues generated by modafinil sales in the EEA in the period under investigation.

1576 Guidelines on Article 101(3) TFEU, point 1.

(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question".

(1271) Article 1(2) of Regulation (EC) No 1/2003 provides that agreements caught by Article 101(1) TFEU that satisfy the conditions of Article 101(3) TFEU shall not be prohibited.[1577] Pursuant to Article 2 of Regulation (EC) No 1/2003, "*[t]he undertaking […] claiming the benefit of Article* [101(3) TFEU] *shall bear the burden of proving that the conditions of that paragraph are fulfilled*".[1578] According to the Commission's Guidelines on Article 101(3) TFEU, these conditions are cumulative.[1579]

(1272) As regards the first of the four conditions of Article 101(3) TFEU (namely, the efficiency gains), a party invoking Article 101(3) TFEU must substantiate each efficiency claim so that the following can be verified:[1580]

– the nature of claimed efficiencies;

– the causal link between agreement and claimed efficiencies;

– the likelihood and magnitude of each claimed efficiency; and

– how and when each claimed efficiency would be achieved.[1581]

(1273) In the following Sections, the Commission concludes that the arguments and evidence put forward by the Parties fall short of showing that the Settlement Agreement, including its accompanying commercial transactions, involved likely efficiencies that are sufficient to exempt it from the application of Article 101(1) TFEU.

10.2. Application in the case at hand

(1274) The Parties argue that the four conditions for exemption under Article 101(3) TFEU are fulfilled by the Settlement Agreement.[1582] According to the Parties:

(1) The Settlement Agreement contributed to improving the production and distribution of generic products;

(2) Consumers received a fair share of the resulting benefits;

(3) The alleged restrictions of competition were indispensable to the attainment of these objectives; and

(4) The Settlement Agreement did not eliminate competition in respect of a substantial part of modafinil sales.

1577 Article 53(3) of the EEA Agreement contains a provision that is analogous to Article 101(3) TFEU.

1578 See also Guidelines on Article 101(3) TFEU, point 11.

1579 Guidelines on Article 101(3) TFEU, point 34.

1580 See Guidelines on Article 101(3) TFEU, point 51.

1581 The possibility that an agreement restricting competition may be exempted under Article 101(3) TFEU applies also to agreements restricting competition by object. However, severe restrictions of competition such as market sharing or market exclusion often do not meet the conditions for an exemption under Article 101(3) TFEU because, as the Commission has explained in its Guidelines on Article 101(3) TFEU, point 46, usually they "*neither create objective economic benefits nor do they benefit the consumer*"; instead, they may lead to "*transfers [of] value from consumers to producers […] without producing any countervailing value to consumers…*".

1582 See Section 3 of the SO Reply.

10.2.1. No evidence of contribution to improving the production or distribution of generic modafinil

10.2.1.1. The Settlement Agreement and the Teva Generic Rights delayed independent generic entry and competition instead of facilitating it

(1275) The Parties argue that the outcome of the patent litigation between Teva and Cephalon was "*genuinely uncertain*", that the Teva Generic Rights "*were designed to accelerate Teva's generic entry by three years in the genuinely possible scenario where Cephalon's Particle Size Patents would be upheld*" and that the Commission Decision of October 2011 in case M.6258 - *Teva/Cephalon* acknowledged the pro-competitive effects of the Settlement Agreement.[1583] On this basis the Parties argue that the first condition under Article 101(3) TFEU is satisfied.

(1276) It should be noted from the outset that it is irrelevant in this context whether the Teva Generic Rights were *"designed to accelerate Teva's generic entry by three years*"; what matters under Article 101(3) TFEU is not the intended purpose of an agreement but its likely positive effects for consumers in terms of efficiency gains. Moreover, efficiency claims must be substantiated so that they can be verified.[1584]

(1277) The Commission also notes at the outset that the Parties fail to explain what kind of improvement of production or distribution or what other efficiency (such as an improvement of the product or cost savings) they are referring to with the argument that Teva would be able to enter the market and start competing as of 2012. As explained below, it is indeed not clear what genuine separate efficiency would result from the possibility that Teva enters (under restrictive terms) and starts competing (to a limited extent) in 2012[1585]. What the Teva Generic Rights arrangement really means is that as of 2012 the full non-compete clause and its particularly restrictive effects no longer apply, but not that new efficiencies would be created. The Teva Generic Rights are thus essentially about the scope of the restriction, and the Parties fail to demonstrate that they were likely to bring about a genuine efficiency that without the Settlement Agreement would not have occurred. Already on this basis it can be concluded that the Teva Generic Rights in themselves do not justify an exemption of the Settlement Agreement pursuant to Article 101(3) TFEU.

(1278) However, even if the Teva Generic Rights were to entail some supposed benefits that could be regarded as an efficiency, the Parties have failed to substantiate, as will be explained below, the argument that the Settlement Agreement and the Teva Generic Rights had likely positive effects that were sufficient to meet the criteria for exemption provided for in Article 101(3) TFEU.

(1279) Article 3.1 of the Settlement Agreement and the Teva Generic Rights set out therein should not be assessed in isolation but rather as part of the Settlement Agreement and the context in which it was concluded. Teva assumed in the Settlement Agreement an undertaking not to compete on modafinil markets at all until the Effectiveness Date of Teva Generic Rights and thereafter to operate on modafinil markets under a royalty-bearing licence.[1586] As such, the Settlement Agreement and the Teva Generic Rights allowed Cephalon to remove the uncertainty that is inherent to the

1583 See SO Reply, paragraphs 555-559.
1584 Guidelines on Article 101(3) TFEU, paragraph 55.
1585 See Sections 6.9.1.1 and Recital (1284).
1586 See Sections 4.7.6 and 6.9.1.

competitive process in the sector and replace the real concrete possibility and the potential imminence of Teva's entry into the modafinil markets with the certainty of (i) no entry by Teva at all until 2012[1587] and of (ii) only limited and controlled entry of Teva under Cephalon's licence as of 2012 (see also Section 6.9.1.1).

(1280) It therefore follows, first, that, contrary to the Parties' claims[1588], the Settlement Agreement did not facilitate genuine early entry, but instead it primarily delayed Teva's possible independent entry and then only allowed for restricted, dependent entry. Teva agreed not to manufacture or distribute its own generic product and not to assist any third party to do the same, regardless of whether the specific formulation actually infringed Cephalon's patents, or whether these patents were valid or invalid[1589]. Teva agreed not to launch its own product and not to challenge Cephalon's patents. In other words, Teva agreed not to try to establish its own technology as non-infringing in a situation in which it believed that Cephalon's patents were not infringed.[1590] Cephalon also agreed not to challenge Teva's licensed intellectual property (Recital (216)

(1281) The non-challenge provisions would continue to restrict the independent competitive behaviour of the Parties even beyond the Effectiveness Date of Teva Generic Rights. As explained above (Section 6.9.1), a contractual mechanism that effectively delays the most advanced potential competitor entering into the market for a number of years cannot be considered pro-competitive, let alone giving rise to sufficient efficiencies to qualify for an exemption under Article 101(3) TFEU.

(1282) Further, under the Settlement Agreement, Cephalon transferred significant value to Teva and it was this inducement that influenced the terms of settlement that Teva was willing to accept (Sections 6.7-6.8). This is not consistent with the claim that the Parties genuinely facilitated earlier generic entry purely in view of the (supposed) strength of the patent.

(1283) Second, the Parties have failed to explain and substantiate how any material efficiencies would be produced through Teva's controlled entry as a licensee on the basis of the Teva Generic Rights. As explained above (Section 6.9.1), Teva's entry under the Teva Generic Rights would depend on a right derived from Cephalon (a licence) and would, not be comparable to the full-fledged entry of an independent source of competition. In particular, Teva's ability to compete on the modafinil markets on price would be curtailed due to the significant costs associated with the royalties payable to Cephalon (see further in this respect Section 6.9.1). The significant royalty payments of (at least) 10% of all net profits on all generic

---

1587 Unless the "acceleration clause" would be triggered prior to the start of Teva's licence in 2012 due to earlier entry of other generic companies. See Recitals (249) and (454).

1588 See SO Reply, paragraphs 555-559.

1589 Section 4.6.3.1

1590 It should be recalled that Teva was claiming that relevant Cephalon's patents were invalid. In that respect it is important to recall that, in the interest of undistorted competition and in accordance with the principles underlying the protection of intellectual property, invalid intellectual property rights should be eliminated and that a licensee of a technology right (such as Teva in relation to Cephalon's modafinil patents) is generally in the best position to assess the validity of the licensed intellectual property and to pursue its elimination. Non-challenge clauses related to invalid intellectual property rights are in general likely to be anticompetitive. (Communication from the Commission—Guidelines on the application of Article 101 of the TFEU on the Functioning of the European Union to technology transfer agreements, OJ C 89, 28.3.2014, p. 3, point 134, 142 and 143).

modafinil products sold by Teva raised Teva's costs and already for this reason ensured less competitive pressure on Cephalon than in a situation of independent generic entry, allowing modafinil prices to remain higher.[1591]

(1284) In addition, the licence to Teva, together with the non-challenge commitment, rendered independent entry by generic companies other than Teva more difficult, because it ensured that Cephalon's patents were not invalidated as a result of Teva's actions and because it would allow Teva to keep a first-mover advantage as the first licensee on the market. As explained in Section 6.9.1., as a result of the Teva Generic Rights, a new entrant would immediately face the threat of generic competition from Teva, which from its established market position as first licensee could respond to any other generic entry by pushing down the prices and margins, and the threat of such a reaction by Teva is likely to make entry less attractive for other potential generic competitors. In the pharmaceutical sector, the incentives for a generic to enter are greatest where there is only the originator in the market and where the generic entrant for a certain period would be the only generic competitor in the market. The terms of the Teva Generic Rights thus had a likely negative impact on entry incentives by other generic suppliers and were likely to result in preserving a market structure that does not promote independent competition (see Section 6.9.1.2). This demonstrates once again that the Parties' alleged efficiencies resulting from the Teva Generic Rights cannot be sustained such as would allow for an exemption under Article 101(3) TFEU.

(1285) In addition, Cephalon's strategy concerning Nuvigil in Europe further shows that the Settlement Agreement is unlikely to entail material efficiencies that would outweigh its restrictive effects within the meaning of Article 101(3) TFEU. Although Nuvigil was never actually launched in the EEA, the evidence shows that Cephalon had pursued this option *ex ante*, that is to say at the time of the Settlement Agreement, and although the regulatory situation in the EEA did not prove beneficial for the launch in the end, Cephalon kept this option open as long as until at least 2009 (Section 4.2.3.2). The planned switch to Nuvigil would have shielded Cephalon's wakefulness business from generic competition, as is also explained in Section 6.9.1.[1592] In the context of the Settlement Agreement, the implementation of such strategy would imply that by the time Teva would enter the markets under the Teva Generic Rights in 2012, many customers would not benefit from the effect of Teva's entry on competition, because they would have been re-directed from the modafinil product (Provigil) to the still patent-protected second generation Nuvigil (a low price sensitivity of prescribers would contribute to this)[1593] (see also Sections 6.3.3.1 and 6.3.3.2).[1594] Consequently, even if the Teva Generic Rights had brought genuine entry in 2012 (*quod non*), and besides the fact that the Parties had eliminated all possibility of entry until 2012, the Parties did not demonstrate that Teva's entry in 2012 under the Teva Generic Rights would have brought competitive benefits to consumers, since patients were planned to be largely moved to Nuvigil by 2012.

1591 See on this point also Section 6.9.1.1.

1592 See Section 6.3.3

1593 It is important to note that Teva's generic rights pursuant to the Article 3.1 of the Settlement Agreement did not include a licence to market generic armodafinil (see footnote 1001).

1594 Whereas in the United States Cephalon implemented the product switch to Nuvigil in 2009, it was not able to do so in the EEA due to specific regulatory hurdles.

(1286) This in itself shows that the Parties' claim that the Settlement Agreement would, through generic competition, improve the production or distribution of modafinil with potential benefits for consumer welfare sufficient to meet the conditions of Article 101(3) TFEU cannot stand. The timing of the entry into force of the Teva Generic Rights (three years before patent expiry) was aimed at allowing Cephalon to complete the planned switch of a vast part of patients to the patent protected and thus higher priced Nuvigil. It was very important for Cephalon during the negotiations to achieve this timing of the Teva Generic Rights. The Teva Generic Rights would, therefore, have the likely effect of ensuring that as many patients as possible paid the supra-competitive prices, rather than bringing the benefits of price competition from generic entry to patients and national health systems. Even if such benefits were likely under the Teva Generic Rights arrangement (*quod non*), only a reduced segment of patients would profit from the entry of Teva as a licensee on the modafinil market.

(1287) Hence, contrary to the Parties' claims, the Settlement Agreement did not allow for genuine 'full-blown' generic entry in the markets for modafinil before patent expiry, but just for restricted generic entry under licence, with payable royalties, in the reduced segment of patients that were not expected to have yet been switched to Nuvigil (armodafinil) three years before patent expiry. The Parties fail to explain and substantiate how entry under these conditions and circumstances would entail sufficient pro-competitive effects to outweigh the anticompetitive effects of the Settlement Agreement.

(1288) Finally, contrary to the Parties' claims the Commission's Decision approving the Teva/Cephalon merger offers no basis for accepting any material efficiencies stemming from the Settlement Agreement and the Teva Generic Rights, for the reasons set out in Section 6.9.1.

10.2.1.2. Not all settlement agreements providing for entry prior to patent expiry are pro-competitive

(1289) The Parties also argue that, as a matter of public policy, the Commission should acknowledge that settlement agreements providing for entry prior to patent expiration are beneficial to society as a whole.

(1290) However, patent settlements in the pharmaceutical sector, even if they also contain a clause for authorised generic entry before the end of the patent, may still prove to be problematic from a competition law perspective. In particular, settlements that may lead to a delay of independent generic entry in return for a value transfer (for example, a payment) by the originator company to the generic company, as compared to the situation that would likely prevail absent such settlement, can still restrict competition (see also above Section 6.9.1.). Absent such patent settlement agreement, induced and influenced by the transfer of value to the generic, the parties to a patent litigation would either pursue the litigation or would reach a settlement that reflects their perceived strength of the patent(s) or patent claim(s). In other words, absent a settlement agreement that includes a (significant) value transfer, the parties to that agreement would pursue their respective business strategies without their incentives being distorted by value transfers inducing them to a settlement that does not reflect their objective expectations on the strength of their patent(s) or patent claim(s).

(1291) Where a generic company's entry is at least partly controlled by the originator company through the terms of the licence agreement, this results, as explained in

Section 6.9.1.1., in only limited competition. The situation could be different in case of royalty-free licences that allow generic companies to immediately and independently launch their own product without any further constraints, and where the negotiation of the generic's entry date has not been distorted by a value transfer. However, with regard to the Settlement Agreement between Cephalon and Teva, this is not the case, as shown in Sections 4.7.6, 6.9.1.1. and Chapter 6.

10.2.1.3. The commercial transactions accompanying the Settlement Agreement did not contribute to improving the production or distribution of modafinil

(1292) The Parties claim that the commercial transactions accompanying the Settlement Agreement were not anticompetitive value transfers, but instead "*beneficial, value-enhancing business transactions*".[1595]

(1293) Contrary to the Parties' arguments, the Commission has already shown above that the commercial transactions at issue were overall aimed at, and worked towards, inducing Teva to agree to the non-compete and non-challenge clauses of the Settlement Agreement (Section 6.6). As explained in Recital (1280), the Settlement Agreement together with the Teva Generic Rights and the accompanying commercial transactions needs to be assessed as a whole and not in isolation. As the transactions were motivated by the aim to induce the most advanced potential competitor to stay out of the market, it is already difficult to see how these transactions (that under normal circumstances, that is to say without the promises not to compete and challenge, would not have occurred) would on balance produce material efficiencies on the modafinil markets within the meaning of Article 101(3) TFEU.

(1294) In any event, it should be noted from the outset that, contrary to the Parties' assertions, it is irrelevant for the purposes of applying Article 101(3) TFEU whether or not the transactions represented a certain value for the Parties and were beneficial to them.[1596] What matters under Article 101(3) TFEU is whether or not the transactions were likely to produce material efficiencies for consumers that are sufficient to outweigh the restrictive effect of the agreement at issue. The Parties fail to provide evidence to demonstrate that such material efficiencies are brought about by the commercial transactions concluded between Cephalon and Teva. Indeed, even if the various business transactions involved value for the Parties or had a certain business rationale, this would not necessarily correspond to an efficiency-producing outcome that is sufficiently beneficial and relevant to meet the conditions of Article 101(3) TFEU.

(1295) As regards the CEP-1347 licence arrangement, the alleged efficiencies linked to it, even if assumed proven, would be irrelevant under Article 101(3) TFEU, as they relate to a distinct product market.[1597]

1595 See SO Reply, paragraph 560.

1596 According to the Guidelines on Article 101(3) TFEU, point 49, "*efficiencies are not assessed from the subjective point of view of the parties*".

1597 Guidelines on Article 101(3) TFEU, which at point 43 states: *"[t]he assessment under Article* [101(3)] *of benefits flowing from restrictive agreements is in principle made within the confines of each relevant market to which the agreement relates. (…) Negative effects on consumers in one geographic market or product market cannot normally be balanced against and compensated by positive effects for consumers in another unrelated geographic market or product market*". See also above Section 6.9.2.

(1296) As regards the remainder of the transactions, namely the licence to Teva's Intellectual Property Rights, the Modafinil API Supply Agreement and the Teva Distribution Agreement, the Commission concludes that the Parties failed to show that these transactions involved any material efficiencies that would be sufficient to meet the conditions of Article 101(3) TFEU. In view of the Commission's considerations in Section 6.9.2, the Commission considers it indeed unlikely that the Parties could have shown efficiencies of sufficient magnitude to outweigh the major negative effects of the restriction (the removal of the most advanced potential competitor, resulting in the preservation of Cephalon's market power and the ability to avoid the significant decline of prices normally resulting from generic entry).

(1297) Finally, the mere fact that the patent litigation between Cephalon and Teva was settled also cannot be regarded as producing sufficient efficiencies that are capable of exempting the Settlement Agreement from the application of Article 101(1) TFEU by virtue of Article 101(3) TFEU. The terms under which the Parties settled were not pro-competitive but anticompetitive, replacing the uncertainty and risk of Teva's competition and possible imminent entry, by the certainty of Teva's limited and controlled entry under Cephalon's licence as of 2012. If the argument of the Parties were accepted, it would mean that any patent litigation settlement agreement would be immune to competition rules, even the most straightforward pay for delay settlement.

(1298) Accordingly, the Parties failed to show that the commercial transactions accompanying the Settlement Agreement improved the production or distribution of modafinil or contributed to promoting technical or economic progress to a sufficient degree to meet the conditions of Article 101(3) TFEU.

10.2.2. Consumers did not receive a fair share of the alleged efficiencies

(1299) The Parties argue that the Settlement Agreement benefitted consumers by "*increased generic competition earlier in time*" through the Teva Generic Rights and by efficiencies produced through the commercial transactions that were negotiated at the time of the Settlement Agreement.[1598]

(1300) First, with regard to the Teva Generic Rights, the Commission has already explained that the Parties have not shown that they would likely produce material efficiencies that would be sufficient to meet the conditions of Article 101(3) TFEU and, accordingly, there are no benefits to be passed on to consumers in this respect. In view of the restrictive effect of the Settlement Agreement (see Section 8.5), the Parties have failed to substantiate on the basis of cogent evidence their assertion that the Teva Generic Rights have "*at least compensate[d] consumers for any actual or likely negative impact caused to them by the restriction of competition found under Article [101(1) TFEU]*".[1599] Further, considering Teva's strategy with respect to the launch of Nuvigil (see Sections 6.3.3 and 6.9.1.3), even if there were any benefits for modafinil patients *(quod non*), only a small share of these patients would have received a benefit, with most of patients being switched to Nuvigil.

(1301) Second, with regard to the other commercial transactions the Parties do not provide any evidence as to how exactly a "fair share" of the claimed efficiencies is passed

1598 See SO Reply, paragraphs 561-562.

1599 See Guidelines on Article 101(3) TFEU, point 85.

down to consumers. The Parties merely refer vaguely to "*earlier access to Azilect and more modafinil products to be available through the provision o of additional API capacity and improved manufacturing processes*". Again, the Parties fail to demonstrate how the alleged consumer benefits from these transactions would be high enough to counter the restrictive effects of the Settlement Agreement, thus leading to a neutral "*net effect*".[1600] Azilect is an entirely unrelated medicine and any benefits for Azilect patients would not accrue to consumers of modafinil. As regards the alleged availability of more modafinil on the market, the Parties have failed to demonstrate that any higher volumes sold were the result of the Modafinil API Supply Agreement. To the contrary, as established in Section 6.6.1 above, the supply of API from Teva was not needed to meet demand. As regards improved manufacturing processes allegedly stemming from the individual transactions, even if the Parties could show these, it is difficult to see how consumers would have obtained a fair share of the value these may have had for the Parties: after all, the prices charged by Cephalon for modafinil remained at the previous high levels for many years after the Settlement Agreement was concluded.

(1302) In light of the above, the Commission concludes that the Parties have failed to demonstrate that the condition of consumers receiving a fair share of the claimed efficiencies under Article 101(3) TFEU has been met.

10.2.3. The imposed restrictions were not indispensable

(1303) The Parties claim that the Settlement Agreement meets the "*'indispensability' condition*" of Article 101(3) TFEU.[1601] To support this claim, the Parties argue, first, that the non-compete and non-challenge clauses of the Settlement Agreement were ancillary to the main alleged purpose of the Settlement Agreement, that is resolving the patent litigation between Teva and Cephalon and allowing the early entry of Teva through the Teva Generic Rights.[1602] The Parties also argue that an alternative settlement agreement providing for earlier entry was not considered or likely and that there is no evidence showing that Teva would have achieved earlier entry on the market absent the Settlement Agreement.[1603] Finally, the Parties acknowledge that the commercial transactions would not have taken place absent a settlement between the Parties and on that basis claim that the Settlement Agreement was indispensable for achieving the pro-competitive effects linked to these transactions.[1604]

(1304) The Commission has shown in Sections 10.2.1 and 10.2.2 that the Parties have failed to demonstrate that the Settlement Agreement involves likely efficiencies that outweigh its anti-competitive effects. Even if this alone is sufficient to prevent the application of Article 101(3) TFEU to the case at hand, the Commission nevertheless summarises in this section how the Parties equally failed to show that the condition of indispensability is met.

(1305) As regards the Teva Generic Rights, even if it were to be accepted that they entail sufficient efficiencies within the meaning of Article 101(3) TFEU (*quod non*), the Parties have failed to demonstrate that there were "*no other economically practicable*

1600 See Guidelines on Article 101(3) TFEU, point 85.
1601 See SO Reply, paragraph 564.
1602 See SO Reply, paragraph 564.
1603 See SO Reply, paragraph 564.
1604 See SO Reply, paragraph 566.

and less restrictive means of achieving the [claimed] efficiencies"[1605] and why an alternative, less restrictive Settlement Agreement would be merely "*seemingly realistic*"[1606] or purely hypothetical[1607] and "*significantly less efficient*".[1608] The Parties have limited themselves to vague statements without producing any cogent evidence in support of their claims.[1609] For instance, the Parties failed to demonstrate why a settlement with entry under licence without the restrictive conditions of the Teva Generic Rights was not available as a possibly less restrictive forms of the Settlement Agreement. The Commission recalls that it is for the Parties to produce cogent evidence to demonstrate that the conditions of the defence provided for in Article 101(3) TFEU are met.[1610]

(1306) Moreover, the Commission notes that "the application of the ancillary restraint concept must be distinguished from the application of the defence under Article [101](3) [TFEU] which relates to certain economic benefits produced by restrictive agreements and which are balanced against the restrictive effects of the agreements".[1611] Accordingly, the Parties' arguments that the non-compete and non-challenge clauses of the Settlement Agreement were ancillary to the resolving of the patent litigation between Teva and Cephalon and the early entry date for Teva through the Teva Generic Rights is not relevant under Article 101(3) TFEU.

(1307) In any event, the Commission has shown in Section 6.9.1.4 that the non-compete and non-challenge clauses cannot be considered ancillary to the settlement of the Parties' patent litigation and the Teva Generic Rights. As explained in Recital (1298), the terms under which the Parties settled were not pro-competitive but anticompetitive and as such they cannot in any event be regarded as proportionate to the purported main purpose of the Settlement Agreement. As regards the Teva Generic Rights, in the first place, although they allowed Teva's controlled entry into the modafinil market as of 2012, they actually contributed to the restriction of competition through the Settlement Agreement. In the second place, even if it were assumed that the Teva Generic Rights did not contribute to the restrictive effect of the Settlement Agreement (*quod non*), the Parties have not produced any evidence to show that the non-compete and non-challenge agreements were objectively necessary and proportionate to achieve the alleged efficiencies through the Teva Generic Rights.[1612]

(1308) As regards the other commercial transactions accompanying the Settlement Agreement, the Parties simply argue broadly that "*Cephalon would not transact with Teva while litigation was pending*".[1613] The Parties, however, have not substantiated why it was not possible for them to achieve the efficiencies allegedly associated with these transactions (such as obtaining an additional source of supply of API and greater volumes) by concluding individual transactions without a settlement

---

1605 See Guidelines on Article 101(3) TFEU, point 75.
1606 See Guidelines on Article 101(3) TFEU, point 75.
1607 See SO Reply, paragraph 565.
1608 See Guidelines on Article 101(3) TFEU, point 75.
1609 SO Reply, Section 3.3.
1610 See Guidelines on Article 101(3) TFEU, point 41 and Regulation 1/2003, Article 2.
1611 See Guidelines on Article 101(3) TFEU, point 30.
1612 See Guidelines on Article 101(3) TFEU, point 29: "*[t]he test of necessity implies that the restriction must be objectively necessary for the implementation of the main transaction and be proportionate to it*".
1613 SO Reply, paragraph 566.

agreement or achieving the alleged efficiencies otherwise.[1614] Similarly, and even if it was not possible to achieve the alleged efficiencies without a settlement agreement *(quod non*), the Parties have not demonstrated that the alleged efficiencies stemming from these transactions could not have been achieved as part of a less restrictive form of settlement agreement.[1615]

(1309) In light of the above, the Commission concludes that the Parties have failed to show that the condition of indispensability of Article 101(3) TFEU has been met.

10.2.4. Eliminating competition in a substantial part of the modafinil markets

(1310) The Parties argue that the Settlement Agreement did not afford the possibility to eliminate competition but, instead allowed Teva's "*full-blown, pro-competitive entry*".[1616] The Parties also argue that the Settlement Agreement did not have any impact on the efforts of other generic players to enter the EEA modafinil market, which continued after the conclusion of the Settlement Agreement.[1617] The Commission disagrees with these claims and concludes that the Settlement Agreement did eliminate competition in a substantial part of the modafinil markets. Accordingly, even if the other conditions of Article 101(3) were met (*quod non*), the Settlement Agreement would still not qualify for exemption under this provision.

(1311) Pursuant to the Commission's Guidelines on the application of Article 101(3) TFEU, "[u]ltimately the protection of rivalry and the competitive process is given priority over potentially pro-competitive efficiency gains which could result from restrictive agreements"[1618] and "[t]he more competition is already weakened in the market concerned, the slighter the further reduction required for competition to be eliminated within the meaning of Article [101](3)".[1619]

(1312) As shown in Sections 6.5-6.9, 8.3-8.6 and 6.9.1, the Commission has found that the Settlement Agreement entirely eliminated competition from Teva on the modafinil markets for many years after its conclusion and after 2012 would still contribute to the absence of full-blown independent competitive pressure by Teva and also had a negative impact on the incentives for entry by competitors other than Teva.

(1313) As further explained in Sections 6.9.1 and 10.2.1, the Teva Generic Rights did not allow for Teva's genuine early entry but rather delayed its independent entry. Furthermore, as explained above (Sections 6.9.1 and 10.2.1.1), combining the non-challenge commitment with the Teva Generic Rights rendered potential entry from other generics less likely, since Teva itself could not challenge Cephalon's patents, which would have cleared the way for other generic players. In addition, by allowing Teva to keep a first-mover advantage as the first licensee on the market the Teva Generic Rights had a negative impact on the incentives of other generics to enter the modafinil markets. Even if efforts by other generic suppliers to enter the market

---

1614 The Commission notes that the Parties have not shown why, for example, the conclusion of the Modafinil API Supply Agreement with Teva was objectively more suitable to increase supply volumes than using Cephalon's own recently modernised API production capacity at Mitry-Mory (instead of having to close it eventually) or by working with another API supplier from whom quotes at better conditions had already been obtained, as set out in more detail in Section 6.6.1 above.

1615 See in this regard, Guidelines on Article 101(3) TFEU, point 76.

1616 See SO Reply, paragraph 568.

1617 See SO Reply, paragraph 569.

1618 See paragraph 105.

1619 See paragraph 107.

continued after the conclusion of the Settlement Agreement, the Parties have not demonstrated that these efforts were unaffected by the Settlement Agreement (which, as explained in Sections 10.2.1.1 and 6.9.1.2, is unlikely to have been the case).

(1314) In summary, contrary to the Parties' assertions, by removing Teva as a competitor entirely for several years, by rendering Teva's entry dependent on Cephalon's licence and by making entry by competitors other than Teva less likely, the Settlement Agreement did in fact eliminate competition in a substantial part of the modafinil markets within the meaning of Article 101(3) TFEU.

10.3. Conclusion

(1315) In view of the above, the Commission concludes that the Parties failed to demonstrate that the Settlement Agreement met the four cumulative conditions for exemption under Article 101(3) TFEU.

11. APPLICATION OF ARTICLE 53 OF THE EEA AGREEMENT

(1316) The EEA Agreement between the Union Member States and the European Free Trade Association ('EFTA') countries came into force on 1 January 1994. Article 53 of the EEA Agreement contains a provision on restrictions of competition analogous to Article 101 TFEU.

(1317) Article 53(1) of the EEA Agreement applies to agreements and practices "*which may affect trade between Contracting Parties*" of the EEA Agreement.

(1318) As explained in Section 9.1 in the context of the TFEU, the "effect on trade" criterion is met when (i) there is an impact on the competitive structure in more than one of the Contracting Parties to the EEA Agreement, (ii) it is sufficiently probable that the practices at issue are capable of affecting trade among these Contracting Parties, and (iii) the effect on trade is appreciable.

(1319) In the Settlement Agreement, Teva made the commitment to limit, for the duration of the agreement, its independent efforts to enter the modafinil markets in the By-Object Countries, which included 25 Member States and three EFTA countries (namely, Iceland, Liechtenstein and Norway).[1620] Teva's efforts to enter these markets were discontinued and therefore a potential competitor was eliminated from these national markets in the EEA, thereby affecting the competitive structure in these markets.

(1320) As such, the Settlement Agreement was by its very nature capable of affecting trade between EFTA countries and between Union Member States and EFTA countries. In view of Cephalon's strong market position in the relevant national product markets where it was selling modafinil[1621], the potential impact of the Settlement Agreement on trade can be said to be appreciable.

(1321) The Commission, therefore, concludes that the Settlement Agreement was also capable of affecting trade between Contracting Parties within the meaning of Article 53(1) of the EEA Agreement.

1620 See Recital (588).

1621 Within EFTA, at the time of the conclusion of the Settlement Agreement (2005), Cephalon had launched modafinil in Norway (see Recital (12)), and it did not face actual competition on any EEA national market, as generic entry had not occurred.

(1322) Given that the provisions of Art 101 TFEU and Art 53 EEA are (except for the effect on trade criterion) identical, the Commission concludes that the findings as regards the Settlement Agreement restricting competition by object and also meeting the other conditions of Article 101(1) TFEU and the findings on the inapplicability of Article 101(3) TFEU apply also with respect to Article 53 of the EEA Agreement.

(1323) In light of the above, the Settlement Agreement constitutes a restriction of competition by object that amounts to an infringement of Article 53 of the EEA Agreement.

12. JURISDICTION TO APPLY ARTICLE 101 TFEU AND ARTICLE 53 OF THE EEA AGREEMENT

(1324) In this case, the Commission is the competent authority to apply both Article 101 TFEU and, on the basis of Article 56 of the EEA Agreement, also Article 53 of the EEA Agreement.

12.1. Principles

(1325) According to the case-law of the Union Courts, where the anticompetitive conduct is implemented in the internal market, "*the Community's jurisdiction to apply its competition rules to such conduct is covered by the territoriality principle as universally recognized in public international law*".[1622] In this context, "*the Commission must be able to take proceeding in respect of the repercussions which that undertaking's conduct has had on competition within the internal market (...)*".[1623] Moreover, pursuant to the case-law of the Union Courts, the Commission has jurisdiction over an agreement if it is implemented in the EU market, which is a criterion that "*is satisfied by mere sale within the Community, irrespective of the location of the sources of supply and the production plant*" ("implementation test").[1624] Furthermore, the Union Courts have held that the application of EU competition law is "*justified under public international law when it is foreseeable that the conduct in question will have an immediate and substantial effect in the European Union*" ("qualified effects test"); for this criterion to be satisfied "*it is sufficient to take account of the probable effects of conduct on competition*".[1625]

(1326) For the avoidance of doubt, the Court of Justice has clarified that "as regards the application of Article 101 TFEU, (…) the fact that an undertaking participating in an agreement is situated in a third country does not prevent the application of that provision if that agreement is operative on the territory of the internal market as regards the application of Article 101 TFEU".[1626]

(1327) In light of the above, in order to justify the Commission's jurisdiction, it is sufficient that an agreement is either implemented in the EEA ("implementation test") or is

---

1622 Judgment of 27 September 1988, *A. Ahlström Osakeyhtiö and others v Commission*, Joined Cases C-89/85, C-104/85, C-114/85, C-116/85, C-117/85 and C-125/85 to C-129/85, EU:C:1988:447, paragraph 18.

1623 Judgment of 27 February 2014, *InnoLux v Commission*, T-91/11, EU:T:2014:92, paragraph 70.

1624 Judgment of 25 March 1999, Gencor Ltd v Commission, T-102/96, EU:T:1999:65, paragraph 87; cf. paragraph 69.

1625 Judgment of 6 September 2017, *Intel v Commission*, C-413/14 P, EU:C:2017:632, paragraphs 49 and 51.

1626 Case C-413/14 P, *Intel v Commission*, paragraph 43.

liable to have immediate, substantial and foreseeable effects in the EEA ("qualified effects test").[1627] These two approaches for establishing the Commission's jurisdiction are alternative.[1628]

12.2. Application in the case at hand

(1328) The Commission concludes that it has jurisdiction to apply Article 101 TFEU and Article 53 of the EEA Agreement to the Settlement Agreement, since, as explained below, that agreement was implemented in the EEA.

(1329) The non-compete and non-challenge commitments under Article 2.5(a) of the Settlement Agreement applied to "*the United Kingdom or any other country where Cephalon holds modafinil patent rights*".[1629] The Settlement Agreement was, therefore, applicable and implemented in the United Kingdom and all the other Member States and Contracting Parties to the EEA Agreement in which Cephalon held modafinil patents, and therefore in a substantial part of the EEA market.[1630] Consequently, the Commission's jurisdiction over the Settlement Agreement is established.

(1330) In the SO Reply, the Parties argue that the Commission has no jurisdiction to investigate those commercial transactions accompanying the Settlement Agreement "*that have no European nexus*".[1631] However, the Parties do not put forward any arguments or evidence supporting the claim that any of the commercial transactions discussed in this decision has no European nexus. On the contrary, the Settlement Agreement overall and the transactions mentioned in its Article 2 all had a nexus to the EEA. Further, in respect of certain modafinil API supply agreements that Cephalon concluded in December 2005 and February 2006 in the United States with *other* generic modafinil companies ([…] and […][1632]), the Parties argue that the Commission had no jurisdiction to assess these arrangements because they were "*purely US based*".[1633] In that respect, the Commission notes that it does not assert jurisdiction over the […] and […] Supply Agreements, but only considers them as part of the factual context of the Modafinil API Supply Agreement and the Settlement Agreement with Teva, without undertaking any legal assessment of the other modafinil API supply agreements with […] and […]. The Commission can take into account facts arising outside of the European Union provided that they are relevant for the assessment of practices that affect competition in the EEA (see Recital (1326)). In the present case, although the API supply agreements with […]

1627 Joined Cases 89/85, 104/85, 114/85, 116/85, 117/85 and 125/85 to 129/85 *Ahlström Osakeyhtiö and Others* v *Commission*, EU:C:1988:447, paragraphs 11-18; Case T-102/96 *Gencor* v *Commission* EU:T:1999:65, paragraphs 89-101.

1628 Judgment of 12 July 2019, *Quanta Storage, Inc. v Commission*, Case T-772/15, EU:T:2019:519, paragraph 46; Case C-413/14 P, *Intel v Commission*, paragraphs 40-46.

1629 The Commission notes that Cephalon's contemporaneous statements and actions reveal that the Settlement Agreement was implemented or at least intended to be implemented in the Member States and Contracting Parties to the EEA Agreement. See, for example, Minutes of Cephalon's CADCOM meeting of 9 February 2006 expressly concluding: "*ACTION: assess EU impact from recent modafinil agreements; STATUS: there is no impact to the EU other than the agreement with TEVA which addresses Teva's entry into the EU market*" (emphasis added) (ID 2144-60).

1630 Section 4.1.2.1 describes these 28 Member States and Contracting Parties.

1631 SO Reply, paragraph 93.

1632 See Section 4.8.1.3

1633 SO Reply, paragraph 300.

and […] were concluded and implemented in the United States, they are nonetheless relevant as part of factual context for the assessment of the Modafinil API Supply Agreement between Cephalon and Teva which, as part of the value transfer inducing Teva's non-compete and non-challenge commitment, affected competition in national markets within the EEA (see Section 6.6.1.4).

(1331) In light of the above, the Commission concludes that the Commission is the competent authority to apply both Article 101 of the TFEU and, on the basis of Article 56 of the EEA Agreement, Article 53 of the EEA Agreement in the case at hand.

13. ADDRESSEES

13.1. Liability for the infringement

(1332) Article 101 TFEU addresses undertakings. The concept of "undertaking" has an economic scope and encompasses any entity engaged in an economic activity. The 'undertaking' that committed the infringement can therefore be larger than the legal entity whose representatives actually took part in the infringing activities. As the European Court of Justice ruled in *Akzo Nobel*, "*When such an economic entity infringes the competition rules, it falls, according to the principle of personal responsibility, to that entity [i.e. the undertaking] to answer for that infringement.*"[1634]

(1333) At the same time, an infringement of EU competition law must necessarily be imputed to a legal person on whom fines may be imposed. A decision finding an infringement must therefore be addressed to legal persons.[1635] It is accordingly necessary for the Commission to identify, for each undertaking that is to be held accountable for its infringement of Article 101 TFEU in this case, one or more legal entities that represent the undertaking concerned.

13.2. Addressees of this Decision

(1334) Cephalon Inc. concluded the Settlement Agreement on behalf of all Cephalon group companies. Even though Teva Pharmaceutical Industries Ltd. acquired control over Cephalon Inc. in October 2011,[1636] Cephalon Inc. still exists as a legal person. This Decision is therefore addressed to Cephalon Inc.

(1335) Teva Pharmaceutical Industries Ltd. concluded the Settlement Agreement on behalf of all Teva group companies. Teva Pharmaceutical Industries Ltd. still exists as a legal person. This Decision is therefore also addressed to Teva Pharmaceutical Industries Ltd.

14. DURATION OF THE INFRINGEMENT

(1336) The infringement started on the effective date of the Settlement Agreement, that is on 4 December 2005, with the exception of Bulgaria and Romania, where the

---

1634 Judgment of 10 September 2009, *Akzo Nobel and Others v Commission*, C-97/08 P, EU:C:2009:536, paragraph 56.

1635 Case C-97/08 P, *Akzo Nobel and Others v Commission*, paragraph 57.

1636 See Commission Decision of 13 October 2011 in Case M.6258-*Teva/Cephalon*.

infringement started as of 1 January 2007, when these two Member States joined the EU (see Recital (588) and footnote 956).

(1337) As regards the end date of the infringement, the Commission notes that (i) Teva's non-compete commitment lasted until 6 October 2012 in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and United Kingdom; (ii) Teva's non-compete commitment lasted until 4 October 2012 in Bulgaria, Czechia, Iceland, Latvia, Lithuania, Norway, Poland, Romania, Slovakia and Slovenia; and (iii) Teva's non-compete commitment lasted until 14 June 2011 in Hungary (see Recital (687)). However, on 13 October 2011 the Commission authorised Teva's acquisition of control over Cephalon under the Merger Regulation.[1637] Since the acquisition of control by Teva over Cephalon, the two companies belong to the same group of companies and are no longer independent undertakings, that is to say they form part of the same undertaking for the purposes of Article 101 TFEU and Article 53 of the EEA Agreement. Accordingly, these provisions do not apply to the agreements between Teva and Cephalon as of that point in time.[1638] For this reason, the Commission deems, for the purposes of this Decision, that 12 October 2011 was the last day of the infringement,[1639] with the exception of Hungary, where the last day of the infringement was 14 June 2011.

(1338) Both Cephalon and Teva participated in the infringement for its entire duration.

(1339) In light of the above, the duration of each of Cephalon's and Teva's respective participation in the infringement is five years and ten months (2139 days), with the exception of Hungary, where their participation in the infringement lasted until 14 June 2011 and Bulgaria and Romania, where their participation in the infringement started as of 1 January 2007.

15. REMEDIES AND FINES

15.1. Article 7(1) of Regulation (EC) No 1/2003

(1340) Where the Commission finds that there is an infringement of Article 101 of the TFEU and Article 53 of the EEA Agreement,[1640] it may by decision require the undertakings concerned to bring such infringement to an end, in accordance with Article 7(1) of Regulation (EC) No 1/2003.

1637 See Commission Decision of 13 October 2011 in Case M.6258-*Teva/Cephalon.*

1638 See Judgment of 24 October 1996, *Viho v Commission*, C-73/95 P, EU:C:1996:405, paragraphs 50-51. See also cf. Case C-97/08 P, *Akzo Nobel and Others v Commission*, paragraphs 60-61.

1639 The Commission notes that Teva effectively took control of Cephalon only on 14 October 2011 and that it could, therefore, have taken that date as the last day of the infringement. However, in view of the date indicated in the Statement of Objections as the end date of the infringement (12 October 2011; recital 1086) and to the benefit of the Parties, the Commission deems that the infringement ended on 12 October 2011.

1640 With respect to Article 53 of the EEA Agreement, Article 5 of Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements of implementing the Agreement on the European Economic Area provides that *"the Community rules giving effect to the principles set out in Articles 85 and 86 [now Articles 101 and 102 TFEU] of the EC Treaty […] shall apply mutatis mutandis."* (OJ L 305, 30.11.1994, page 6).

(1341) The infringement found in this Decision has ceased.[1641] Therefore, there is no need to require the Parties to bring the infringement to an end. However, there is a need to expressly confirm the Parties' obligation not to enter into new agreements having the same or a similar object or effect, particularly given that the Parties expressed, during these proceedings, that they do not regard the agreement under review to be anticompetitive.[1642] In these circumstances, there is a real danger that the Parties might commit similar practices as those considered in this Decision in the future.

15.2. Article 23(2) of Regulation (EC) No 1/2003

(1342) Under Article 23(2) of Regulation (EC) No 1/2003, the Commission may by decision impose fines upon undertakings where, either intentionally or negligently, they infringe Article 101 TFEU and Article 53 of the EEA Agreement (Article 23(2)(a)). In accordance with the same provision, for each undertaking participating in an infringement, the fine shall not exceed 10% of its total turnover in the preceding business year.

(1343) In the present case, the Commission concludes that, by entering into the Settlement Agreement, the Parties intentionally or, at the very least, negligently infringed Article 101 TFEU and Article 53 of the EEA Agreement, since both Cephalon and Teva knew or should have known that a combination of Teva's non-compete and non-challenge commitments with Cephalon's value transfer in exchange for these commitments may infringe Article 101 of the TFEU and Article 53 of the EEA Agreement. The Commission intends therefore to impose a fine on each of the Parties.

(1344) Pursuant to Article 23(3) of Regulation (EC) No 1/2003, the Commission, in fixing the amount of the fines, shall have regard to all relevant circumstances, particularly to the gravity and duration of the infringement. In doing so, the Commission will set the fines at a level sufficient to ensure deterrence. Moreover, the role played by each undertaking party to the infringement(s) will be assessed on an individual basis.

(1345) In setting the fines to be imposed in this case, the Commission will also refer to the principles laid down in its Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation (EC) No 1/2003 ("the Guidelines on fines").[1643]

15.3. Arguments raised by the Parties

(1346) In their SO Reply, the Parties raised a number of general arguments as to why no fines or why only symbolic fines should be imposed in the present case. These arguments are not convincing for the reasons set out below.

1641 See chapter 14.

1642 Notably, in the Parties' SO Reply (see, for example, paragraph 6). See in this context, for instance, judgment of 2 March 1983, *GVL v Commission*, C-7/82, EU:C:1983:52, paragraph 27; judgment of 28 April 2010, *Gütermann and Zwicky v Commission*, T-456/05 and T-47/05, EU:T:2010:168, paragraphs 66-67; judgment of 18 June 2008, *Hoechst v Commission*, T-410/03, EU:T:2008:211, paragraphs 199-200.

1643 Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003, OJ C 210, 1.9.2006, page 2.

15.3.1. Intention or negligence

(1347) The Parties argued that "Teva and Cephalon could not anticipate the breadth of the Commission's prohibition of settlement agreements in the pharmaceutical sector at the time of the Settlement Agreement"[1644] and that therefore the Commission should not impose fines or, alternatively, should impose only symbolic ones.

(1348) According to well-established jurisprudence of the Courts of the European Union, "[f]or an infringement of the competition rules to be regarded as having been committed intentionally, it is not necessary for an undertaking to have been aware that it was infringing those rules; it is sufficient that it could not have been unaware that its conduct was aimed at restricting competition".[1645]

(1349) As described in Chapter 4 and legally assessed in Chapters 6 and 8, the infringement consisted of an explicit, written agreement between the Parties, aimed at preventing Teva from selling generic modafinil in several markets in the EEA in exchange for a significant transfer of value from Cephalon. The Commission considers that Cephalon was perfectly aware that the Settlement Agreement was aimed at excluding Teva as Cephalon's competitor on the modafinil markets. This was the very purpose of the Settlement Agreement. Similarly, given the nature and content of the commitments to which it agreed, Teva was fully aware that the aim of the Settlement Agreement was its exclusion, at least temporarily, from the modafinil markets. In line with the findings of the General Court in *Servier*, by combining Teva's non-compete and non-challenge commitments with Cephalon's value transfer in exchange for these commitments, the Parties could have reasonably assumed that their conduct may infringe Article 101 TFEU.[1646] Even if the Parties had not deliberately infringed Article 101 TFEU and Article 53 of the EEA Agreement, at the very least they acted negligently in entering into such an anticompetitive agreement. It is therefore appropriate to impose fines on the undertakings to which this Decision is addressed.

15.3.2. Novelty

(1350) The Parties argued that imposing fines would not be justified in light of the alleged novelty of the case. In the Parties' view, "*Teva and Cephalon could not anticipate the breadth of the Commission's prohibition of settlement agreements in the pharmaceutical sector at the time of the Settlement Agreement.*" According to the Parties, "*the Commission should abstain from imposing a fine on Teva and Cephalon, or should apply only a symbolic fine, in accordance with the relevant decisional practice of the Commission and the case law*"[1647] In support of their

---

1644 SO Reply, paragraph 585.

1645 Judgment of 5 October 2011, *Romana Tabacchi Srl v Commission*, T-11/06, EU:T:2011:560, paragraph 227; Judgment of 14 May 1998, *Enso Española v Commission*, T-348/94, EU:T:1998:102, paragraph 277; judgment of 13 July 2018, *Stührk Delicatessen Import GmbH & Co. KG v Commission*, T-58/14, EU:T:2018:474, paragraphs 226-227.

1646 "*In particular, Servier could assume that by inducing generic companies to accept non-marketing and non-challenge clauses, by themselves restrictive of competition, it rendered the inclusion of such clauses in a patent settlement agreement entirely illegitimate. Indeed, their inclusion was no longer based on recognition by the parties to the agreements of the validity of the patent and thus indicated a misuse of the patent, unrelated to its specific purpose […]. Servier could therefore reasonably have foreseen that its conduct was caught by the prohibition laid down in Article 101(1) TFEU"* (Case T-691/14, *Servier and Others v Commission*, paragraph 1661.)

1647 SO Reply, paragraph 585.

position, the Parties refer to the alleged lack of applicable precedents and the complex nature of the assessment of the settlement agreements from a competition law standpoint.[1648]

(1351) In this context, it is important to recall that in AstraZeneca, the Court of Justice stated the following: "… concerning the novelty of the two abuses of a dominant position, it must be stated that those abuses, as the General Court pointed out at paragraph 900 of the judgment under appeal, had the deliberate aim of keeping competitors away from the market. It is therefore common ground that even though the Commission and the Courts of the European Union had not yet had the opportunity to rule specifically on conduct such as that which characterised those abuses, AZ was aware of the highly anticompetitive nature of its conduct and should have expected it to be incompatible with competition rules under European Union law."[1649]

(1352) Similarly, the General Court concluded in Servier: "In particular, Servier could assume that by inducing generic companies to accept non-marketing and non-challenge clauses, by themselves restrictive of competition, it rendered the inclusion of such clauses in a patent settlement agreement entirely illegitimate. Indeed, their inclusion was no longer based on recognition by the parties to the agreements of the validity of the patent and thus indicated a misuse of the patent, unrelated to its specific purpose […]. Servier could therefore reasonably have foreseen that its conduct was caught by the prohibition laid down in Article 101(1) TFEU (see, to that effect, judgments of 22 October 2015, AC-Treuhand v Commission, C-194/14 P, EU:C:2015:717, paragraph 46, and of 8 September 2016, Lundbeck v Commission, T-472/13, under appeal, EU:T:2016:449, paragraph 764"[1650]

(1353) At the time when the Settlement Agreement was entered into, there may not have been any established precedents specifically in relation to patent settlement agreements under which a generic undertaking commits not to enter the market and not to challenge the originator's patents in return for transfers of value. However, the notion that such agreements, which are aimed at market exclusion in exchange for a value transfer, are anti-competitive and, in particular, are likely to constitute a restriction by object under Article 101 of the TFEU is and was well established and cannot be seen as novel. In relation to a patent settlement agreement, the General Court found, in *Lundbeck*, that *"(…) the applicants' conduct in the present case was clearly not part of normal competition, since they aimed to exclude potential competitors from the market by means of significant reverse payments. The fact that some patent settlement agreements, moreover, may be legitimate and not infringe the provisions of the Treaty on free competition does not alter the fact that, in the present case, the agreements at issue concluded by the applicants were anticompetitive, for the reasons set out by the Commission in the contested decision (…)"*.[1651] Similarly, the General Court underlined in *Servier* that such agreement "*must … be regarded as market exclusion agreements, in which the 'stayers' are to compensate the 'goers'. Such agreements actually constitute a buying-off of competition and must therefore be classified as restrictions of competition by*

1648 SO Reply, paragraphs 587-591.
1649 Case C-457/10 P, *AstraZeneca v Commission*, paragraph 164.
1650 Case T-691/14, *Servier and Others v Commission*, paragraph 1661.
1651 Case T-472/13, *Lundbeck v Commission*, paragraph 783.

object".[1652] The practices at stake in the present case clearly fall within the prohibition of Article 101 TFEU and their characterisation as anticompetitive, based on the assessment of the specific facts and the economic and legal context of the present case, cannot be seen as novel.

(1354) The Parties' reference to certain past cases where the Commission refrained from imposing a fine due to novelty,[1653] is immaterial. First, as already explained above, the present case cannot be considered novel. Second, in any event, in the circumstances of this case the Commission considers it appropriate to impose fines having regard to the need for appropriate sanctioning and deterrence. The former is aimed at ensuring parties do not profit from illegal practices. The latter has a dual objective, ensuring that both the addressees of this Decision specifically and other undertakings generally refrain from entering into such types of anticompetitive agreements. The Commission's discretion in this case is not fettered by its approach in certain other cases. Whilst a consistent approach must be adopted by the Commission within the same case to ensure the respect of the principle of equal treatment, an undertaking cannot rely on the Commission's approach in distinct cases to escape sanctions especially in a case, such as the present one, which involves a market exclusion of a potential competitor.[1654] In any event, the General Court has recognised that the Commission can impose fines in patent settlement cases between originator and generic manufacturers giving rise to an infringement of Article 101 TFEU.[1655]

15.3.3. Legal certainty, legitimate expectations, nulla crimen, nulla poena sine lege and non-retroactivity

(1355) The Parties claim that they were not able to foresee that the Settlement Agreement infringed EU competition law, especially since their infringement was not predictable on the basis of existing case-law. According to the Parties, the imposition of fines in the present case would therefore violate "*the closely related principles of legal certainty, non-retroactivity, legitimate expectations and nulla crimen, nulla poena sine lege*."[1656]

(1356) The Commission has established, contrary to the Parties' assertion, that the Parties entered into the Settlement Agreement with the aim of restricting competition on the modafinil markets and should have been aware that their conduct may violate Article 101 of the TFEU (see Sections 15.2 and 15.3.1). The Parties' arguments should be dismissed for the reasons set out below.

(1357) First, it is settled case-law that the principle of legal certainty requires that rules such as Article 101 TFEU enable those concerned to know precisely the extent of the obligations which are imposed on them and that these persons must be able to ascertain unequivocally what their rights and obligations are and take the appropriate steps accordingly.[1657] Agreements explicitly prohibited by Article 101(1) TFEU

1652 Paragraph 150 of Case T-684/14, *Krka v Commission*.

1653 SO Reply, paragraph 587.

1654 See Case T-91/11, *InnoLux v Commission*, paragraph 144, and the case-law cited therein.

1655 Case T-472/13, *Lundbeck v Commission* and Case T-691/14, *Servier and Others v Commission*.

1656 SO Reply, paragraph 586.

1657 See, for example, udgment of 10 March 2009, *Gottfried Heinrich*, C-345/06, EU:C:2009:140, paragraph 44.

include those which "*limit or control production, markets, technical development, or investment*" or "*share markets or sources of supply*".

(1358) The Parties could not ignore[1658] that the Settlement Agreement with its non-compete, non-challenge commitments was injurious to the proper functioning of normal competition since it barred market entry and allowed Cephalon to maintain its prominent position on the market, at the detriment of competitors and ultimately customers, in exchange for a significant value transfer. The notion that agreements aimed at market exclusion in exchange for a consideration constitute a restriction by object under Article 101 TFEU is one that is well established and therefore enshrined in the TFEU.

(1359) Second, as to the principle of legitimate expectations, according to the case-law of the Union Courts, no one may plead infringement of that principle unless precise, unconditional and consistent assurances, from authorised, reliable sources, have been given to him by the authorities.[1659] In this respect, it suffices to say that the Commission did not at any point give assurances as to the consistency with Union competition law of the conduct undertaken by Cephalon and Teva.[1660]

(1360) Third, it is settled case-law that the principle of *nullum crimen, nulla poena sine lege* cannot be interpreted as prohibiting the gradual clarification of the rules of criminal liability through interpretation by the courts.[1661] It may, however, preclude the retroactive application of a new interpretation of a rule establishing an offence where such an interpretation was not reasonably foreseeable at the time when the offence was committed.[1662] This is not the case here. The type of infringement at stake in this case, namely the exclusion from the market in return for a consideration, was not new and its illegality was foreseeable for the Parties. In addition, the wording of Article 101 TFEU itself even includes an explicit reference to agreements which "*share markets*", thereby further confirming that the type of agreement at issue in this case infringes Union competition law.

(1361) Finally, in their SSO Reply, the Parties also submit that the imposition on Teva of a fine consisting of a fixed amount fine would infringe the principles of legal certainty and legitimate expectations. However, the Commission's approach of imposing a fine on Teva as a fixed amount is fully in line with point 37 of the Guidelines on fines and the applicable jurisprudence (as explained in Section 15.5. The fact that the Commission may in the past not have applied a certain calculation under point 37 cannot create a legitimate expectation that it will not do so in the future.[1663] Moreover, in 2015, the Court of Justice in *AC-Treuhand* explicitly endorsed the approach of determining the fine for an infringer without turnover in the market concerned as a fixed lump sum under point 37, dismissing the applicant's arguments

---

1658 See, for example, Case T-472/13, *Lundbeck v Commission*, paragraph 783.

1659 Case T-456/10, *Timab Industries*, EU:T:2015:296, paragraph 123.

1660 *"In accordance with settled case-law, that principle extends to any individual in a situation where the authorities have caused him to entertain legitimate expectations, it being understood that no one may plead infringement of that principle unless precise, unconditional and consistent assurances, from authorised, reliable sources, have been given to him by the authorities*." (Case T-461/07, *Visa Europe and Visa International Service v Commission*, paragraph 38)

1661 See judgment of 8 July 2008, *AC-Treuhand v Commission*, T-99/04, EU:T:2008:256, paragraph 141.

1662 Judgment of 5 September 2015, *Koninklijke Philips Electronics NV*, T-92/13, EU:T:2015:605, paragraph 136.

1663 Judgment of 7 November 2019, *Campine NV*, T-240/17, EU:T:2019:778, paragraph 370.

questioning this approach.[1664] Similarly, the principle of a fixed lump sum was upheld in the recent judgment in the *ICAP* case[1665] as well as the earlier case *Ordre National des Pharmaciens*.[1666]

15.3.4. Other arguments raised by the Parties

(1362) The Parties argue in the SO Reply that the Commission's conclusions on Teva's and Cephalon's liability for an infringement of Article 101 TFEU were also at odds with the Commission's Pharmaceutical Sector Inquiry and the Commission's Seventh Report on the Monitoring of Patent Settlements for the period January-December 2015, published on 13 December 2016. The Parties specifically refer to the following statements included in that report: "*[s]ettlements [that include a value transfer from the originator to the generic] are likely to attract the highest degree of antitrust scrutiny […]. Nonetheless, this is not to suggest that agreements falling into this category would necessarily be incompatible with EU competition law. This needs to be assessed on the basis of the circumstances of each individual case*" (paragraph 17) and "*an agreement which includes no other limitative provision than determining the date of the generic entry with the originator's undertaking not to challenge such entry (a "pure early entry") is not likely to attract the highest degree of antitrust scrutiny*" (paragraph 12).[1667]

(1363) The Parties' argument is not convincing. First, none of the quoted passages suggests that individual antitrust scrutiny could not occur and lead to the finding of an infringement and the imposition of fines. In the present case the Commission came to the conclusion that the Settlement Agreement represents a restriction of competition by object after a comprehensive and specific analysis of its content and objective as well as of its specific economic and legal context. Second, this analysis has, in any event, shown that the arrangement called Teva Generic Rights does not represent a "pure early entry" as it allowed only for controlled, restricted entry which was intrinsically connected with other restrictive provisions of the Settlement Agreement (see Section 6.9).

(1364) As to the Parties' reliance on what was the prevailing legal view by United States courts at the time of the Settlement Agreement, namely that patent settlements containing restrictions that are within the scope of the patent at issue were not violations of the United States antitrust rules,[1668] it should be recalled that EU law is distinct from United States law, and that therefore decisions by United States bodies are without legal bearing for the application of Article 101 TFEU. There is no precedent under EU competition law that would support such a view (see Section 5.6). In addition, given that the United States case-law was not unanimous at the time of the Settlement Agreement[1669] and given the position of the United States FTC on the issue of the reverse payment settlements at that time, the Parties should

---

1664 Judgment of 22 October 2015, *AC-Treuhand v Commission*, C-194/14, EU:C:2015:350, paragraph 67. The Court confirmed that the Commission was entitled to fix the fine as a lump sum instead of using value of sales as a basis for setting the fine. AC Treuhand, as a consultancy firm, was not active on the markets for tin stabilisers and ESBO/esters, and therefore did not have any sales in those markets.

1665 Judgment of 10 July 2019, *Commission v Icap and Others*, C-39/18 P, EU:C:2019:584.

1666 Judgment of 10 December 2014, *ONP and Others v Commission*, T-90/11, EU:T:2014:1049.

1667 SO Reply, paragraphs 589-590.

1668 SO Reply, paragraph 588.

1669 The "scope of the patent test" was subsequently rejected by the Supreme Court in FTC v. Actavis, Inc., 570 U.S., (2013). See Recital (563).

have been aware of (at least) the possibility that the practices under scrutiny in the present case could have been considered illegal even under United States law.[1670] In any event, it must be recalled that the commitments that Teva assumed under the Settlement Agreement actually exceeded the scope of the litigated Cephalon's Particle Size Patents (see Recitals (668) and subsequent).

(1365) Finally, concerning the Parties' argument that the Settlement Agreement resolved a genuine patent settlement litigation, the Commission recalls that the fact that the Settlement Agreement resolved the underlying patent dispute does not in any way (i) exclude the Settlement Agreement from the application of Article 101(1) TFEU or (ii) prevent a finding that the Settlement Agreement restricts competition.[1671] What matters from a competition law perspective is that, as explained in Section 6.8, at the time when the Settlement Agreement was concluded, there was uncertainty about whether Teva's entry in one way or another would be successful; that this uncertainty of competition was eliminated through the commitments included in the Settlement Agreement; and that these commitments were induced by significant value transfers, rather than by the Parties' perception of the strength of the patents. It is this combination of elements that characterises the Settlement Agreement as anticompetitive.

15.4. The calculation of the fine for Cephalon

(1366) In line with the general methodology set out in the Guidelines on fines, the Commission will first determine the basic amount of the fine (see Section 15.4.1 below). Second, where applicable, the Commission will adjust the basic amount upwards or downwards (see Section 15.4.2 below). Third, the Commission will ensure that the fine does not exceed 10% of the undertaking's total turnover in the preceding business year (see Section 15.4.3 below).

15.4.1. Determination of the basic amount of the fines

(1367) Pursuant to the Guidelines on fines, the basic amount of the fine consists of a variable amount of up to 30% of an undertaking's relevant sales in the EU,[1672] depending on the degree of gravity of the infringement and multiplied by the number of years of the undertaking's participation in the infringement, and – where appropriate – an additional amount of up to 25% of the value of an undertaking's relevant sales, irrespective of duration.[1673]

15.4.1.1. The value of sales

(1368) According to point 13 of the Guidelines on fines, the value of sales consist of the undertaking's sales of goods to which the infringement directly or indirectly relates in the relevant geographic area within the EEA. The Commission normally takes into account the sales made by the undertakings during the last full business year of their participation in the infringement. Since the infringement lasted until 12 October 2011 (see Chapter 14) the last full business year of the Parties' participation in the infringement is 2010.

1670 See also Case T-472/13, *Lundbeck v Commission*, paragraph 801.

1671 Case C-307/18, *Generics (UK) and Others*, paragraph 94

1672 Point 12 of the Guidelines on fines. Relevant sales refer to the value of the undertaking's sales of goods or services to which the infringement directly or indirectly related in the relevant geographic area in the EEA,

1673 See points 19 to 26 of the Guidelines on fines.

(1369) As regards the relevant geographic area, through the infringement in question, Cephalon protected its modafinil sales against generic competition in the By-Object Countries[1674]. The infringement therefore covers the entire EEA except for Estonia and Malta.

(1370) In determining the value of sales by an undertaking, the Commission will take the undertaking's best available figures.[1675] Where the figures made available by an undertaking are incomplete or not reliable, the Commission may determine the value of its sales on the basis of the partial figures it has obtained and/or any other information which it regards as relevant and appropriate.[1676]

(1371) Cephalon has indicated that "*due to the transition of Cephalon to Teva*", it was not in a position to provide 2010 sales (the last full business year of the participation in the infringement) for individual EEA countries.[1677] The best available information as to the relevant sales therefore consists of Cephalon's total sales of modafinil products achieved in 2010 in the entire EEA of approximately EUR 46 455 000.[1678] Since the available data show that Cephalon had no modafinil sales in Estonia and Malta in the relevant period, the Commission takes into account the amount of sales for the entire EEA, that is EUR 46 455 000 as the relevant sales.

15.4.1.2. Gravity

(1372) The gravity of the infringement determines the percentage of the value of sales taken into account in setting the fine. In assessing the gravity of the infringement, the Commission has regard to a number of factors, such as the nature of the infringement and the combined market share of all the undertakings concerned, the geographic scope of the infringement and/or whether or not the infringement has been implemented. In this case, the Commission assesses these elements as follows:

(a) The anticompetitive nature and objective of the infringement:

the Commission considers that the infringement constitutes market exclusion, which must be regarded as a serious infringement of Article 101 TFEU and of Article 53 of the EEA Agreement;

(b) Market share:

at the time when it concluded the Settlement Agreement, Cephalon held a very high market share of the product to which the infringement relates for the geographic areas concerned;

(c) Geographic scope:

the infringement had a wide geographic scope covering the entire EEA except for Estonia and Malta;

(d) Implementation:

the Settlement Agreement was implemented as set out in Sections 4.7 and 4.8.1.5.

1674 For definition of the By Object Countries see Recital (588).
1675 Guidelines on fines, point 15.
1676 Guidelines on fines, point 16.
1677 ID 1771-117.
1678 ID 1771-117.

(1373) The Commission has taken into account the criteria referred to in Recital (1373), namely nature, market share, geographical scope and implementation. It must be recalled that the arrangements constitute a restriction by object and the market exclusion described is considered to be a serious infringement. However, even though there could be no doubt as to the illegality of the conduct, the Commission has nevertheless had regard to the specific circumstances of the case, as described in Chapter 6 and Chapter 8. In view of the specific circumstances of this case, the Commission considers that the proportion of the value of sales to be taken into account should be 11%.

15.4.1.3. Duration

(1374) In its assessment of the duration of the infringement the Commission has taken into consideration that the infringement, as explained above (Chapter 14), started on the Effective Date of the Settlement Agreement, that is 4 December 2005 and finished on 12 October 2011 (see Chapter 14).[1679] The infringement therefore lasted for five years and ten months (2139 days).

15.4.1.4. Additional amount

(1375) The Commission considers that, given that the infringement consisted of a horizontal market exclusion agreement, the provisions of the Guidelines on fines regarding the additional amount should be applied.[1680]

(1376) Taking into account the criteria discussed in Recital (1373), the Commission concludes that an additional amount of 11% of the average annual value of sales should be included in the basic amount for Cephalon.

15.4.2. Adjustments to the basic amount: aggravating and mitigating factors

(1377) The Commission may reflect in the fine imposed any aggravating and/or mitigating factors that result in an adjustment of the basic amount. These factors are listed, in a non-exhaustive way, in points 28 and 29 of the Guidelines on fines.

(1378) No aggravating or mitigating factors apply in the present case.

15.4.3. Application of the 10% turnover limit

(1379) Teva acquired Cephalon in 2011 and Cephalon's results of operations and balance sheet were included in Teva's consolidated reports as of October 2011.[1681] However, Teva and Cephalon were two separate undertakings for the entire duration of the infringement. Therefore, for the purpose of calculating the limit in Article 23(2) of Regulation (EC) No 1/2003, Cephalon's sole worldwide turnover in 2019 (that is to say Cephalon's turnover as subsidiary of Teva) should be taken into account for Cephalon.

(1380) According to information received from the Parties, Cephalon Inc. did not publish (and does not prepare) consolidated accounts. The only available figures used for official purposes are the revenues provided as part of the United States Federal corporate tax returns. The tax returns covering the last fiscal year, which ended on

---

1679 The last day of the infringement with respect to Hungary was 14 June 2011. As regards Bulgaria and Romania the infringement started as of 1 January 2007. Data available to the Commission do not reveal any sales of modafinil products in these countries during the period of infringement

1680 See point 25 of the Guidelines on fines.

1681 See Section 4.8.2.4

31 December 2019, are due only in late 2020. According to the Parties, the current draft tax returns show that the consolidated revenues of Cephalon Inc. for 2019 amounted to […].[1682]

15.4.4. Conclusion: final amount of the fine for Cephalon

(1381) Based on the calculations presented in the Sections 15.4.1 and 15.4.2, the Commission considers that the fine to be imposed on Cephalon should, […].

(1382) Therefore, the Commission considers that the fine to be imposed on Cephalon should be EUR 30 480 000.

15.5. The calculation of the fine for Teva

15.5.1. The application of the general methodology set out in the Fining Guidelines would not enable the Commission to impose a deterrent fine

(1383) Point 37 of the Guidelines on fines allows the Commission to depart from the general methodology of the Guidelines on fines because of the particularities of a given case or the need to achieve deterrence in a particular case.

(1384) In the present case, Teva agreed not to sell generic modafinil in the By-Object Countries and therefore did not have any modafinil sales in the geographic area concerned. Consequently, the application of the general methodology set out in the Guidelines on fines to calculate the fine to be imposed on Teva (in the same manner as for Cephalon), would result in a zero fine, which would not be deterrent, in contrast with what is required by the case-law of the Union Courts and the Guidelines on fines.[1683]

(1385) Accordingly, for the purpose of determining the fine to be imposed on Teva, the Commission considers it necessary to apply point 37 of the Guidelines on fines and thus depart from the general methodology set out in the Guidelines on fines. .

15.5.2. The fining approach followed in previous cases on patent settlement agreements not appropriate to be applied in the present case

(1386) In the *Lundbeck*, *Fentanyl* and *Servier* cases[1684], which concerned a similar situation of patent settlements that infringed Article 101 TFEU and where the generic companies did not have any sales in the relevant markets, the fines were established by taking into account the value transferred to the generic company (as inducement to stay out of the market) without approximating its turnover. In these cases the Commission considered that the value (payment) received by the generic company provided an indication as to (i) the gravity of an infringement, (ii) its duration and (iii) the need to achieve deterrence.

(1387) While the Commission is not bound to follow the same approach as in previous cases nor to motivate its decision with reference to previous cases,[1685] it is nevertheless worth noting that the situation is decidedly different in relation to the fine to be imposed on Teva in the present case. In particular, as assessed in this Decision, the

---

1682 See ID 3908. Conversion using the ECB annual exchange rate for 2019, 1 EUR = 1,1195 USD.

1683 Guidelines on fines, point 4 and Judgment of the Court of 7 June 1983, *Musique Diffusion française and others v Commission*, Joined cases 100 to 103/80, EU:C:1983:158, paragraph 106

1684 Commission Decision of 19 June 2013 in Case AT.39226-*Lundbeck*; Commission Decision of 10 December 2013 in Case AT.39685-*Fentanyl*; Case AT.39612-*Perindopril (Servier)*.

1685 See for example, Case T-240/17, *Campine NV*, paragraph 370 and case-law cited therein.

value transfer from Cephalon to Teva was embedded in the commercial transactions included in Article 2 of the Settlement Agreement (see Sections 6.6). In only four out of five of these transactions has it been possible to estimate the value being transferred to Teva, and even for those transactions, such value can be estimated only broadly and based on conservative assumptions. In this context, the Commission has broadly and conservatively estimated the net gain embedded in the purchase by Cephalon of Teva's Intellectual Property Rights (Section 6.6.3), the Modafinil API Supply Agreement (Section 6.6.1), the payments for avoided litigation costs (Section 6.6.4) and the Teva Distribution Agreement (Section 6.6.5). This estimate showed that the overall value transferred through these transactions was well over EUR 100 million.[1686]

(1388) The Commission further notes that the fifth transaction, namely the grant to Teva of earlier access to the CEP-1347 Data, contributed significantly to the value transfer inducing Teva to accept the non-compete and non-challenge commitments. On the one hand, Teva paid an amount of USD 1 million to Cephalon. On the other hand, at the time of the Settlement Agreement, Teva could expect that the earlier access to the data would result in additional sales of the Azilect drug, possibly reaching USD 200 million, resulting from the introduction of Azilect one year earlier than would have been possible without having acquired the CEP-1347 Data (Recital (790)). However, this value could not be taken into account if the fine for Teva were to be established pursuant to the approach mentioned in Recitals (1387) and (1388). This is because the amount of additional sales of Azilect and the exact price that Cephalon would have been able to extract from Teva in return for granting it earlier access to the CEP-1347 Data without the Settlement Agreement are difficult to even broadly estimate in pecuniary terms.

(1389) These circumstances, in particular the difficulty to even broadly estimate in pecuniary terms the value contribution of the CEP-1347 Data, distinguish the present case from the previous Commission decisions finding similar infringements mentioned in Recital (1384) where the entire value transfer could be readily quantified.[1687]

(1390) Nevertheless, as described in Sections 6.6.2 and 6.7, the value contributed by the CEP-1347 Data transaction to the overall package was considered important by Teva during the negotiation of the Settlement Agreement. Failure to take into account the value transferred to Teva by giving it access to Cephalon's CEP-1347 Data would mean that a value transfer that was important to the Parties in the context of the Settlement Agreement would not be reflected at all in the amount of the fine, and would thereby undermine the deterrent effect of the fine and fail to reflect the gravity

---

1686 See Recital (968).

1687 It should be recalled that the exact quantification of the unjustified net gain is not a prerequisite for finding that the Settlement Agreement indeed restricts competition by object as long as the Commission can show that the "*transfers of value are […] to be sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits*" (Case C-307/18, *Generics (UK) and Others*, paragraph 94). The Commission has indeed shown that the value transfer embedded in the transactions in Article 2 of the Settlement Agreement was a sole consideration paid by Cephalon which was sufficiently beneficial to encourage Teva to accept to no longer independently pursue its efforts to enter one or more EEA markets with its generic modafinil product (see Sections 6.6, 6.7 and 6.8).

of the infringement. The conservative nature of the broad estimate for the other transactions further enhances the risk of undermining the deterrent effect.

(1391) In light of the above, in the present case, the Commission does not consider it appropriate to determine the fine to be imposed on Teva on the basis of the overall value transferred to it.

15.5.3. A fixed amount fine would take due account of the gravity and duration of Teva's infringement and of the need to ensure deterrence

(1392) Due to the imprecise and contingent nature of any estimate of the value of Cephalon's CEP-1347 data and the conservative nature of the estimate for the other transactions, the Commission considers that an appropriate approach in the present case is to establish the fine for Teva as a fixed amount (lump sum).

(1393) In order to establish an appropriate fixed amount, and taking into account the gravity and duration of the infringement, which are the same for both Cephalon and Teva (see Sections 15.4.1.2 and 15.4.1.3), as well as the need to ensure sufficient deterrence, the Commission considers the fine for Cephalon prior to the application of the 10% turnover limit (see Sections 15.4.3 and 15.4.4), as an appropriate point of orientation for establishing an adequate fine for Teva.

(1394) In particular, the Commission considers that the fine for Teva should be comparable to, but not higher than, the fine established for Cephalon prior to the application of the 10% turnover limit. In general, the revenues and profits of a manufacturer of originator medicines (such as Cephalon) protected by an anticompetitive pay-for-delay agreement are typically higher than the revenues and profits foregone by a potential generic entrant (such as Teva).

(1395) At the same time, the following specific characteristics of the present case need to be observed. First, during the time of the infringement, Teva has been a much larger company than Cephalon (see Recitals (7) and (9)). In 2010 (the last full year of the infringement and the year before Teva actually acquired Cephalon), Teva reported a worldwide turnover of approximately EUR 12.16 billion while Cephalon reported worldwide turnover of approximately EUR 2.12 billion.[1688] Second, as detailed in Section 6.7 and Recital (952), Teva enjoyed a strong negotiating position towards Cephalon. Teva actually took the initiative concerning the kind and size of the transactions discussed and agreed in the negotiations, it outlined to Cephalon its desired outcome and was able to assert its negotiation goals (see, for example, Recitals (190), (201)-(203) and (206)-(207)).

(1396) No aggravating or mitigating circumstances apply in the present case.

15.5.4. Application of the 10% turnover limit

(1397) Article 23(2) of Regulation (EC) No 1/2003 provides that the fine imposed on each undertaking shall not exceed 10% of its total turnover relating to the business year preceding the date of the Commission Decision.

15.5.5. Conclusion: final amount of fines for Teva

(1398) On the basis of the application of point 37 of the Guidelines on fines and taking into account the considerations set out in this Section 15.5, the Commission considers

[1688] Case M.6258 – *Teva/Cephalon*.

that the fine to be imposed on Teva should be EUR 30 000 000. This amount does not exceed 10% of the total turnover of Teva in 2019 as the last full business year.[1689]

(1399) Therefore, the fine to be imposed on Teva pursuant to Article 23(2) of Regulation (EC) No 1/2003 should be EUR 30 000 000.

16. CONCLUSION

(1400) In light of the considerations set out in this Decision, the Commission finds that Cephalon, Inc. and Teva Pharmaceutical Industries Ltd. have infringed Article 101 TFEU and Article 53 of the EEA Agreement by concluding and implementing the Settlement Agreement and that fines should be imposed on them pursuant to Article 23(2) of Regulation (EC) No 1/2003.

HAS ADOPTED THIS DECISION:

Article 1

Cephalon, Inc. and Teva Pharmaceutical Industries Ltd. have infringed Article 101 TFEU and Article 53 of the EEA Agreement by participating in an agreement in the pharmaceutical sector covering Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom.

The duration of the infringement was from 4 December 2005 until 12 October 2011, except as regards Bulgaria and Romania where the infringement started on 1 January 2007 and except as regards Hungary where the infringement ended on 14 June 2011.

Article 2

For the infringement referred to in Article 1, the following fines are imposed:

(a) Cephalon, Inc.: EUR 30 480 000

(b) Teva Pharmaceutical Industries Ltd.: EUR 30 000 000

The fines shall be paid, in euros, within six months of the date of notification of this Decision, to the following bank account held in the name of the European Commission:

BANQUE ET CAISSE D'EPARGNE DE L'ETAT
1-2, Place de Metz
L – 1930 Luxembourg

IBAN: LU02 0019 3155 9887 1000
BIC: BCEELULL
Ref.: EC/BUFI/AT.39686

[1689] See ID 3908.

After the expiry of that period, interest shall automatically be payable at the interest rate applied by the European Central Bank to its main refinancing operations on the first day of the month in which this Decision is adopted, plus 3.5 percentage points.

Where an undertaking referred to in Article 1 lodges an appeal, that undertaking shall cover the fine by the due date, either by providing an acceptable financial guarantee or by making a provisional payment of the fine in accordance with Article 108 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[1690].

Article 3

Cephalon, Inc. and Teva Pharmaceutical Industries Ltd. shall refrain from repeating any act or conduct referred to in Article 1 and from any act or conduct having the same or similar object or effect.

Article 4

This Decision is addressed to

– Cephalon, Inc., 145 Brandywine Parkway, West Chester PA 19380, United States of America; and

– Teva Pharmaceutical Industries Ltd., 122 Devorah Hanevia, Tel Aviv 6944038, Israel.

This Decision shall be enforceable pursuant to Article 299 TFEU and Article 110 of the EEA Agreement.

Done at Brussels, 26.11.2020

For the Commission
Margrethe VESTAGER
Executive Vice-President

[1690] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the European Union (OJ L 193, 30.7.2018, p. 80).