IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

RITE AID CORPORATION, RITE AID HDQTRS. CORP., JCG (PJC) USA, LLC, ECKERD CORPORATION, MAXI DRUG, INC. D/B/A BROOKS PHARMACY, AND CVS CAREMARK CORPORATION,	:	CIVIL ACTION NO. ____
Plaintiffs,	:	
v.	:	JURY TRIAL DEMANDED
CEPHALON, INC., BARR PHARMACEUTICALS, INC.; MYLAN PHARMACEUTICALS, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., RANBAXY LABORATORIES, LTD. AND RANBAXY PHARMACEUTICALS, INC.,	:	
Defendants.	:	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Rite Aid Corporation, Rite Aid HDQTRS. Corp., JCG (PJC) USA, LLC, Eckerd Corporation, Maxi Drug, Inc. d/b/a Brooks Pharmacy, and CVS Caremark Corporation, (collectively "Plaintiffs") bring this civil action against defendants Cephalon, Inc., ("Cephalon"), Barr Pharmaceuticals , Inc. (formerly known as Barr Laboratories, Inc.) ("Barr"), Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. ("Teva"), Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), and Mylan Pharmaceuticals, Inc. ("Mylan"), (collectively "Defendants"), and for their Complaint allege as follows:

NATURE OF THE ACTION

1. This is a civil antitrust action under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, seeking treble damages arising out of Defendants' unlawful exclusion of generic competition from the market for modafinil, a prescription drug marketed by Cephalon as a "wakefulness promoting agent," and indicated for the treatment of certain sleep disorders, including narcolepsy. Modafinil is sold by Cephalon under the brand name Provigil. Provigil sales totaled nearly $850 million in 2008.

2. As detailed below, Cephalon entered into a conspiracy with each of its generic competitors to restrain trade, and engineered a larger, overall conspiracy in restraint of trade and a scheme to monopolize the United States market for modafinil. The purpose and effect of the conspiracies and scheme were to prevent and delay generic competition for Provigil. Because generic versions of brand name drugs are typically much less expensive than their brand name counterparts, and because purchasers typically switch rapidly from a brand to a generic once the generic becomes available, wrongful suppression of generic competition, as occurred here, results in enormous overcharge damages to all purchasers of the drug at issue. Here, Cephalon, *inter alia*, entered into a series of unlawful, non-competition agreements, or horizontal market allocation agreements, with its prospective generic competitors, Defendants Teva, Barr, Mylan and Ranbaxy (collectively the "Generic Defendants"), whereby Cephalon agreed to pay the Generic Defendants more than $200 million, as well as provide other compensation, in exchange for agreements by the Generic Defendants not to sell their generic versions of Provigil until April 2012 (the "Exclusion Agreements").

3. Generic versions of brand name drugs contain the same active ingredients, and are found by the Food and Drug Administration ("FDA") to be as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics typically cost 30% less than their brand counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market.

4. The launch of a generic drug usually brings huge cost savings for all drug purchasers, but those same savings are viewed as a grave threat by brand name drug companies such as Cephalon. FDA-approved, AB-rated generic versions of brand drugs typically take 80% or more of the sales of the brand product soon after generic entry.

5. Drug companies, including Defendants here, are acutely aware of the dramatic and predictable effects of generic competition. These effects have been extensively studied by government and academic researchers, and by the drug companies themselves. Accordingly, Cephalon, knowing that it would lose enormous sales and profits on Provigil once generics entered, paid all of its generic competitors to stay out of the market and delay launching their generic versions of Provigil for years (no generic version of Provigil is available today). Cephalon engineered a scheme whereby it entered into non-competition agreements with each of the Generic Defendants, agreements which provided for large payments to the Generic Defendants in exchange for their agreement to refrain from selling their less expensive generic versions of Provigil until 2012 (*i.e.*, for up to at least 6½ years). These payments (frequently called "exclusion payments" or "reverse payments") were disguised as payments for: (i) licenses and/or supply agreements for the active ingredient in Provigil (with respect to Teva, Barr and Ranbaxy); or (ii) product development

agreements for unrelated products (with respect to Mylan). Defendants intentionally concealed the true purpose and nature of their exclusion payments. These acts of concealment, themselves, underscore and demonstrate the anticompetitive purpose and effects of Defendants' agreements.

6. The Exclusion Agreements purported to settle patent infringement suits that Cephalon had filed against the Generic Defendants. As detailed below, although Cephalon had sued the Generic Defendants for allegedly infringing a patent related to Provigil, Cephalon knew that its patent and its patent infringement claims were weak. Cephalon also knew that it would not be able to use its patent to obtain a court injunction to stop the Generic Defendants from launching their generic versions of Provigil once Cephalon's various market exclusivities relating to Provigil expired on December 24, 2005. In November 2005, just before agreeing to pay the Generic Defendants to stay off the market, Cephalon expressly and publicly disclosed that it expected to face generic competition for Provigil in 2006. After executing its unlawful agreements with the Generic Defendants, however, Cephalon immediately and significantly increased its projected sales and earnings for 2006, because it knew that the Exclusion Agreements precluded competition from the Generic Defendants until 2012.

7. Likewise, the Generic Defendants knew that they could make as much or more money by agreeing *not* to compete with Cephalon than by actually launching their generic products. But for the unlawful agreements at issue here, the Generic Defendants likely would have prevailed in the patent suits brought against them by Cephalon, and/or the Generic Defendants would have launched their generic products as early as 2006, after Cephalon's regulatory exclusivity had expired.

8. Had the four Generic Defendants all launched generic versions of Provigil, as they were preparing and poised to do, however, they would have competed and rapidly driven down the price of generic Provigil. Once there are multiple generic versions of the same brand drug available, the generic behaves like a commodity, with little or nothing to distinguish one generic from another except price. Price competition between generics is responsible for much of the dramatic price drops that accompany generic entry. The Generic Defendants were well aware of these market dynamics, and knew that they could likely make as much or even more money by agreeing to withhold their generic products in favor of, in effect, splitting Cephalon's monopoly profits from Provigil. And that is precisely what happened.

9. The success of Defendants' conspiracy hinged on getting *all* the Generic Defendants to go along. From Cephalon's perspective, if any of the Generic Defendants launched, Cephalon would still lose most of its Provigil sales to the generic. Hence, Cephalon needed to pay all the Generic Defendants not to compete. For the Generic Defendants, if any one of them launched before the others, that company would obtain a significant advantage over the others and stand to reap much higher profits from its generic. Hence, each of the Generic Defendants needed assurance that its fellow generic competitors would not come to market earlier.

10. Absent Defendants' illegal agreements not to compete, generic versions of Provigil would have become available as early as January 2006, and Plaintiffs and other purchasers of Provigil would have been able to purchase generic modafinil at significantly lower prices than they were forced to pay for Provigil because of Defendants' illegal acts to delay generic competition.

11. Defendants' agreements not to compete constitute horizontal market allocation and price-fixing agreements, which are *per se* violations of Section 1 of the Sherman Act. Defendants' conduct also constitutes a conspiracy to restrain trade, in violation of Section 1 of the Sherman Act.

12. Similarly, as alleged in more detail below, Defendants violated § 2 of the Sherman Act through their scheme to improperly maintain and extend Cephalon's monopoly power by foreclosing or delaying competition from lower-priced generic versions of Provigil.

13. Cephalon's monopoly power in the modafinil market was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a legally obtained valid patent, other legally obtained market exclusivity, a superior product, business acumen or historical accident.

JURISDICTION AND VENUE

14. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a).

15. Defendants transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

THE PARTIES

16. Plaintiffs Rite Aid Corporation and Rite Aid HDQTRS. Corp. (collectively "Rite Aid") are corporations organized and existing under the laws of the State of Delaware with a principal place of business in Camp Hill, Pennsylvania. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 4,900

drugstores owned and operated by its affiliates. During the relevant period of time, Rite Aid has purchased Provigil from wholesaler McKesson. McKesson purchases Provigil directly from Defendant Cephalon and has assigned to Rite Aid the antitrust claims with respect to Provigil that was subsequently resold to Rite Aid. Rite Aid brings this action in its own right and as the assignee of McKesson.

17. Plaintiff JCG (PJC) USA, LLC (JCG USA") is a Delaware limited liability corporation with a principal place of business in Camp Hill, Pennsylvania. On June 4, 2007, JCG USA became a wholly-owned subsidiary of Rite Aid Corporation. JCG USA is the parent corporation of Plaintiffs Maxi Drug, Inc. d/b/a Brooks Pharmacy ("Brooks") and Eckerd Corporation ("Eckerd"), both of which are Delaware corporations. JCG USA, Brooks and Eckerd hereafter are collectively referred to as "Brooks/Eckerd." Brook/Eckerd purchased substantial quantities of pharmaceutical products and other goods for resale to the public through its retail stores. During the relevant period of time, Brooks/Eckerd purchased Provigil from wholesaler McKesson. McKesson purchased Provigil directly from Cephalon, and Brooks/Eckerd is the assignee of McKesson's antitrust claims with respect to Provigil that was subsequently resold to Brooks/Eckerd. Brooks/Eckerd brings this action in its own right and as the assignee of McKesson.

18. Plaintiff CVS Caremark Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Caremark Corporation and its affiliates (collectively, "CVS Caremark") purchase substantial quantities of pharmaceutical products and other goods for resale to the public through more than 6,900 drugstores. During the relevant period of time, CVS Caremark has purchased Provigil from wholesalers Cardinal Health, Inc. and McKesson

Corporation. Cardinal and McKesson purchase Provigil directly from Defendant Cephalon and have assigned to CVS Caremark the antitrust claims with respect to Provigil that was subsequently resold to CVS Caremark. CVS Caremark brings this action in its own right and as the assignee of Cardinal and McKesson.

19. Defendant Cephalon is a company incorporated under the laws of the State of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania. Cephalon develops, manufactures, and markets pharmaceuticals and related products in the United States.

20. Defendant Barr is a company incorporated under the laws of the State of Delaware, with its principal place of business at 225 Summit Avenue, Montvale, New Jersey. Barr principally develops, manufactures and markets generic versions of brand name drugs.

21. Defendant Mylan is a company incorporated under the laws of the State of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania. Mylan's subsidiary, Mylan Pharmaceuticals, Inc., is located at 781 Chestnut Ridge Road, Morgantown, West Virginia. Mylan principally develops, manufactures and markets generic versions of brand name drugs.

22. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli company. Defendant Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd., is a company incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania. Teva principally develops, manufactures and markets generic versions of brand name drugs.

23. Defendant Ranbaxy Laboratories, Ltd. is a company operating under the laws of India. Defendant Ranbaxy Pharmaceuticals, Inc., is a wholly-owned subsidiary of Ranbaxy

Laboratories, Ltd., with its principal place of business located at 600 College Road East, Suite 2100, Princeton, New Jersey. Ranbaxy principally develops, manufactures and markets generic versions of brand name drugs.

FACTUAL BACKGROUND

A. Federal Regulation of Pharmaceutical Products

24. Under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*., (the "FD&C Act"), approval by the FDA is required before a new drug may be sold in interstate commerce. Premarket approval for a new drug must be sought by filing a New Drug Application ("NDA") with the FDA, under either section 355(b) or section 355(j) of the Act, demonstrating that the drug is safe and effective for its intended use.

25. In 1984, Congress amended the FD&C Act by enacting the Drug Price Competition and Patent Term Restoration Act, , Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the "Hatch-Waxman Amendments" or the "Hatch-Waxman Act." The Hatch-Waxman Act simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need for generic companies to file lengthy and costly NDAs in order to obtain FDA approval. Instead, such companies are permitted to file Abbreviated New Drug Applications ("ANDAs") and rely on the safety and efficacy data already supplied to the FDA by the brand-name manufacturer. The Hatch-Waxman Act also added a number of patent-related provisions to the statutory scheme, as described below. Congress's principal purpose in enacting the Hatch-Waxman Act was "to bring generic drugs onto the market as rapidly as possible." *Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

26. When the FDA approves a brand name manufacturer's NDA, the FDA publishes any compound patents that (according to the brand manufacturer) cover the approved drug in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A)(iii). For other types of patents (including method of use patents), the FDA lists in the Orange Book any patents that (according to the brand manufacturer) claim the approved drug for its approved method of use. In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand manufacturer, but relies on the manufacturer's representations. After the NDA is approved, the brand manufacturer may list any other new patents in the Orange Book as related to the NDA if the brand manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents).

27. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand drug), a generic manufacturer must certify that its generic drug will not infringe any patents listed in the Orange Book. Accordingly, under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

I. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

II. that the patent for the brand name drug has expired (a "Paragraph II certification");

III. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

IV. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

28. If a generic manufacturer files a paragraph I, II, or III certification, it can take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

29. If a generic manufacturer files a Paragraph IV certification stating that a patent listed in the Orange Book is invalid or will not be infringed by the proposed generic, a brand manufacturer has an opportunity to delay final FDA approval of the ANDA and the sale of the competing generic drug on the market. The generic manufacturer must provide prompt notice of its ANDA and Paragraph IV certification to the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, the FDA may not grant final approval of the ANDA until the earlier of: (a) 30 months from the date the ANDA filer notified the NDA holder; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing suit within 45 days of receiving a Paragraph IV certification, a brand drug manufacturer may delay generic entry. During the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the 30-month stay.

30. Under the regulatory scheme outlined above, brand drug companies have strong financial incentives to: (a) list patents in the Orange Book, regardless of whether such patents are truly eligible for listing; and (b) then sue any generic competitor that files an ANDA with a Paragraph IV certification, regardless of whether the suit has merit, because merely filing suit provides the brand company the equivalent of a 30-month preliminary injunction preventing the generic from launching its product, yet the brand obtains this protection from competition without having to make any showing that its patent suit is likely to succeed (and without having to satisfy any of the other normal burdens associated with obtaining a preliminary injunction from a court). In addition, prior to a change in the Hatch-Waxman regulations, brand companies could, and did, bring multiple infringement suits (based on multiple patents listed in the Orange Book) against a single ANDA, thereby obtaining independent 30-months stays associated with each suit. This practice was curtailed by a change in FDA regulations mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which, due to repeated abuses by brand manufacturers of the type described here, limited brand manufacturers to a single stay per ANDA. *See* 21 C.F.R. §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

31. Hatch-Waxman also provides brand manufacturers with other opportunities to obtain protection from generic competition. For example, if the FDA approves an NDA involving a new chemical entity ("NCE"), the brand manufacturer filing the NDA may obtain up to five years of exclusivity from the date of approval of the NDA. Moreover, under the NCE provision, no generic may even file an ANDA with a Paragraph IV certification until four years of the NCE exclusivity have elapsed. In addition, if an NDA drug treats a rare condition, the FDA may grant an additional

two years of Orphan Drug exclusivity to brand manufacturers, a period that is tacked on to any other marketing exclusivity the company may have.

32. Cephalon sought and obtained both NCE and Orphan Drug exclusivity for Provigil. These exclusivities expired on December 24, 2003, and December 24, 2005, respectively.

B. Generic Versions of Brand Name Drugs are Significantly Less Expensive Than Their Brand Name Counterparts, and Quickly Take Significant Sales Directly From The Brand

33. Typically, generic drugs are priced significantly below their brand name counterparts. Because of the price differentials and other institutional features of the pharmaceutical market, bioequivalent, AB-rated generic drugs are rapidly and extensively substituted for their brand name counterparts. As more generic manufacturers enter the market for a given brand drug, prices for generic versions predictably decrease even more because of price competition among the generic manufacturers, and the loss of sales by the brand name drug to the corresponding generic accelerates. Generic competition also results in some reduction in prices of brand drugs.

34. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (*i.e.*, Hatch-Waxman) and most state legislatures (which have enacted Drug Product Selection, or DPS laws), pharmacists may substitute an AB-rated generic version of a drug for the brand name version automatically, without having to seek or obtain permission from the prescribing doctor (unless the prescription states "Dispense as Written," or "DAW"). Both Congress and state legislatures have encouraged generic substitution because generic drugs provide enormous cost savings to purchasers and consumers, and because they

recognize that generic products need marketing assistance since generic manufacturers do not engage in the type of heavy promotion or "detailing" typically done by brand manufacturers.

35. Generic competition enables all purchasers of a prescription drug, including Plaintiffs, to purchase the drug at substantially lower prices, by purchasing the generic and/or by purchasing the brand at a lower price. Because of institutional features in the marketing and sale of prescription drugs, there is comparatively little price competition between brand drugs, even for treatment of the same medical condition. Thus, before generics enter the market, brand manufacturers can and do charge prices far above competitive levels (*i.e.*, far above the prices that prevail for the drug after generic entry) without losing all or a substantial portion of their brand sales. Consequently, brand manufacturers have strong financial incentives to try to block or delay generics from entering the market by any means possible.

36. Hatch-Waxman also rewards the first generic to file an ANDA with a Paragraph IV certification with 180 days of marketing exclusivity. *See* 21 U.S.C. § 355(j)(2)(A)(vii). During that 180-day period, no other generic is allowed by the FDA to enter with an AB-rated generic version of the same drug.

37. Obtaining the 180-day exclusivity period and being "first to market" are important goals for generic companies like Defendants Teva, Mylan, Ranbaxy, and Barr. Typically, a brand drug is priced far above its marginal cost, or the cost of the active chemical ingredient itself and the cost of manufacture (as well as costs of marketing). Accordingly, a generic company that is first to launch a generic version of a popular brand drug, and that obtains generic exclusivity can price its generic substantially below the price of brand (30% lower, for example) yet still earn substantial profits and a high profit margin because the cost of the drug is so low. To illustrate, suppose a

brand name drug is priced at $10 per pill, and suppose the cost of the chemical in the drug and the cost of manufacturing and marketing is $2 per pill. A generic company can price its generic at $7 per pill, capture most of the brand's sales, and yet still earn a $5 per-pill profit. When multiple companies are selling generic versions of the same brand drug, however, the price is driven down towards its cost, or $2 per pill in this illustration, because the generics behave like commodities and try to differentiate themselves from each other largely or exclusively on the basis of price. Defendant Teva, for example, has stated that being first to market with a generic drug and obtaining exclusivity is a primary corporate goal: "To the extent that we succeed in being the first to market a generic version of a significant product, and particularly if we obtain the 180-day period of market exclusivity for the U.S. market provided under the Hatch-Waxman Act, *our sales, profit and profitability can be substantially increased in the period following the introduction of such product* . . ." Teva Pharmaceutical Industries, Ltd. Form 20-F, at 6 (Dec. 31, 2005) (emphasis added). During a period of generic exclusivity, in fact, a generic company can reap "*near-monopoly profits*." *See* Intervenors' Supplemental Brief Regarding the Adequacy of Any Potential Bond, *Mylan Pharmaceuticals Inc. v. Tommy G. Thomspon, et al*., Civ. A. No. 1:01CV23 (N.D. W. Va.) (filed Feb. 20, 2001 on behalf of Teva Pharmaceuticals, USA, Inc.) (emphasis added). *See also* Mylan Laboratories, Inc., Form 10-Q, at 21-22 (Nov. 4, 2005) (having the exclusivity period "generally results in higher market share, net revenues and gross margin"); Barr Pharmaceuticals Inc. Form 10-K, at 34 (Sept. 13, 2005) (Barr "typically experience[s] significant revenues and profitability associated with that product for the six-month exclusivity period," and then "experience[s] significant decreases in our revenues and market share . . . as other generic competitors enter the market.").

38. Where (as here), multiple generic companies file ANDAs with Paragraph IV certifications on the same day, the FDA has ruled that each company is entitled to launch its generic during the 180-day period, and the exclusivity is therefore shared. *See Guidance for Industry on 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day*, 68 Fed. Reg. 45252, 45255 (Aug. 1, 2003). All first-filing generic companies "share" exclusivity and other, successive generic companies (such as Apotex, Inc. ("Apotex") – *see* below) must wait until the 180-day period expires before they can launch. Such "shared" exclusivity, however, means that the typical value associated with generic exclusivity – the ability of a generic to significantly underprice the brand yet still reap "near monopoly" profits for itself – does not exist. As Defendant Mylan has explained, being "required to share our exclusivity period with other ANDA sponsors with Paragraph IV certifications" can have a "material adverse effect on our ability to market that product profitably and on our financial position and results of operations, and the market value of our common stock could decline." Mylan Laboratories, Inc., Form 10-Q, at 22 (Nov. 4, 2005).

C. Provigil

39. The active pharmaceutical ingredient in Provigil, modafinil, is a psychostimulant that enhances wakefulness and vigilance. Modafinil's pharmacological profile, and thus its side effect and efficiency profile, are significantly different than drugs such as amphetamines and methylphenidate (Ritalin). These other drugs are not AB-rated to Provigil, cannot be automatically substituted for Provigil by pharmacists, and are not economic substitutes for, nor reasonably interchangeable with, modafinil.

40. On December 27, 1996, Cephalon filed new drug application no. 20-717 ("NDA No. 20-717") with the FDA seeking to market 100mg and 200mg strengths of modafinil under the brand name Provigil for the treatment of narcolepsy. On December 24, 1998, the FDA approved NDA No. 20-717. Shortly thereafter, Cephalon began commercially marketing Provigil.

41. Because modafinil constituted a new chemical entity, Cephalon received five years of NCE exclusivity. Provigil's NCE exclusivity expired on December 24, 2003. Likewise, because Cephalon represented to the FDA that modafinil was a drug to treat a rare disorder (narcolepsy), Cephalon received Orphan Drug exclusivity, which expired on December 24, 2005.

42. In anticipation of the expiration of Provigil's NCE and/or Orphan Drug exclusivities, each of the Generic Defendants developed and filed an ANDA seeking FDA approval for AB-rated, generic versions of Provigil. Each Generic Defendant filed its ANDA with a Paragraph IV certification on December 24, 2002, the first day that ANDAs for generic versions of Provigil could be filed under the NCE provisions of Hatch-Waxman. Thus, each of the Generic Defendants shared the 180 days of generic exclusivity provided by Hatch-Waxman.

43. Each of the Generic Defendants received tentative approval from the FDA for its generic version of Provigil before December 24, 2005, the date that Orphan Drug exclusivity for Provigil expired. Barr received tentative approval on January 7, 2004; Ranbaxy on February 18, 2004; Mylan on February 9, 2005; and Teva on December 16, 2005.

44. "Tentative approval" means that the proposed generic has been deemed by the FDA to be safe, effective and bioequivalent to its brand name counterpart, but the existence of some unexpired legal or regulatory barrier (such as Orphan Drug exclusivity) precludes the FDA from

granting final approval. Put another way, the approval would be final and not "tentative" but for the unexpired regulatory exclusivity.

45. But for Defendants' wrongful and exclusionary conduct, each of the Generic Defendants would have obtained final FDA approval, and would have begun selling its generic version of Provigil in competition with Cephalon and each other – at prices significant below the price of brand name Provigil – on or shortly after the expiration of Provigil's Orphan Drug exclusivity on December 24, 2005.

46. On or about March 28, 2006, Cephalon received a six-month pediatric exclusivity extension from the FDA. This extension, however, applied only to exclusivities which had not yet expired. Since Cephalon's Orphan Drug exclusivity for Provigil expired on December 24, 2005, Cephalon's receipt of a pediatric extension on March 28, 2006, would not have prevented the Generic Defendants from obtaining final FDA approval to sell their generic versions of Provigil prior to Cephalon's receipt of the pediatric extension.

D. Defendants' Wrongful Scheme to Delay Generic Competition

1. Cephalon's Provigil Patent and the Patent Litigation Against the Generic Defendants

47. The drug substance modafinil is an acetamide derivative. Both the compound modafinil and its neuropsychopharmacological profile have been known since at least the late 1980s.

48. The modafinil compound itself is no longer protected by any U.S. patent. The patent on the compound itself was issued in 1979 and expired in 2001.

49. On October 6, 1994, Cephalon scientists Peter Grebow, Vincent Corvari, and David Stong filed United States Application Serial No. 08/319,124 ("the '124 Application") titled "Acetamide Derivative Having Defined Particle Size" with the United States Patent & Trademark Office ("PTO"). Because the basic modafinil compound already had been patented, the '124 Application could not claim the compound again. Instead, the '124 Application narrowly claimed very specific formulations of modafinil, as well as certain uses of those narrow formulations.

50. In conjunction with filing the '124 Application, the named inventors (*i.e.*, Grebow, Corvari and Stong) assigned their interests to Cephalon and submitted declarations to the PTO acknowledging their duty of candor (*i.e.*, the duty to disclose all material information) to the PTO and affirming that they were the true and properly named inventors for the '124 Application. This duty of candor extended to all named inventors, and to others such as patent attorneys and declarants substantively involved in the prosecution of the '124 Application. On April 8, 1997, the '124 Application issued as United States Patent No. 5,618,845 ("the '845 Patent"). Like all PTO patent reviews, the '124 Application was reviewed and the '845 Patent was issued by the PTO in an *ex parte* manner. The PTO does not solicit opposition or responses to patent applications from other parties who might present evidence or arguments to the PTO that the application should not be granted.

51. On or before April 1, 1999, Cephalon concluded that the '845 Patent was wholly or partly inoperative or invalid. Seeking to remedy perceived defects in the '845 Patent, Cephalon filed a reissue application ("the RE '166 Application"). This filing triggered new duties of candor for those individuals substantively involved in the prosecution of the RE '166 Application. On January 15, 2002, the PTO issued reissue patent no. 37,516 ("the RE '516 Patent"), and Cephalon

surrendered the '845 Patent. (We refer to the RE '516 Patent and the '845 Patent, collectively, as the "Cephalon Patents").

52. Because Cephalon's RE '516 Patent claims only certain narrow formulations relating to particle sizes of modafinil and certain uses of modafinil, but does not claim the compound itself, the RE '516 Patent could not be used to block all generic versions of Provigil. Generic competitors could invent around the RE '516 Patent, which would enable them to avoid claims of infringement. Indeed, a consultant advised Cephalon in 2002 that "all generic companies know . . . that the [RE '516 Patent] may be easily circumvented" by manufacturing their generic products to contain a distribution of modafinil particle sizes different than covered by Cephalon's patent. Such non-infringing, generic versions of Provigil therefore would be completely outside the claimed scope of the RE '516 Patent.

53. Because Cephalon's RE '516 Patent could be easily circumvented, generic companies were eager to apply to market generic versions of Provigil. On December 24, 2002, the first day that the FDA could accept an ANDA for generic Provigil, the four Generic Defendants each submitted applications (three of these Defendants literally camped out in the FDA's parking lot waiting to be the first to file when the doors opened at 7 AM). Each of the Generic Defendants certified that its generic version of Provigil did not infringe Cephalon's RE '516 Patent, that the RE '516 Patent was invalid, or both.

54. Under the FDA's interpretation of applicable law, the Generic Defendants would share the 180-day exclusivity period because they all filed ANDAs on the same day. This meant that if the FDA approved their generic products, all four Generic Defendants could simultaneously launch and market generic versions of Provigil during the 180-day exclusivity period. The

"exclusivity" period would be shared, but would still block *other* generic companies such as Apotex from launching until the period had expired. Shared exclusivity also meant that if one Generic Defendant marketed its generic before any other Generic Defendants did so, the 180-day exclusivity period for *all* of the Generic Defendants would begin to run, regardless of whether the other companies also had launched. *See Guidance for Industry on 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day*, 68 Fed. Reg. 45252, 45255 (Aug. 1, 2003).

55. On or about February 12, 2003, Mylan notified Cephalon that it had filed ANDA No. 76-594, seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil, the active ingredient in Provigil. Mylan's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of the RE '516 Patent.

56. On or about February 20, 2003, Barr notified Cephalon that it had filed ANDA No. 76-597, seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Barr's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the RE '516 Patent.

57. On or about February 25, 2003, Teva notified Cephalon that it had filed ANDA No. 76-596, seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Teva's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the RE '516 Patent.

58. On or about March 21, 2003, Ranbaxy notified Cephalon that it had filed ANDA No. 76-595, seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Ranbaxy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of the RE '516 Patent.

59. On March 28, 2003, Cephalon filed suit against the Generic Defendants in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging infringement of the RE '516 Patent by the Generic Defendants.

60. During discovery, the Generic Defendants uncovered facts supporting a host of defenses that cast serious doubt on: (1) the enforceability of the RE '516 Patent; (2) the validity of its claims; and (3) the strength of Cephalon's infringement allegations.

61. For example, despite representations, declarations and/or suggestions to the contrary, the modafinil compositions and methods claimed in the Cephalon Patents were manufactured and developed by scientists at a different, French company, Labortoire L. Lafon ("Lafon"), and not by scientists at Cephalon. These facts were material to patentability because they related to, *inter alia*, derivation, inventorship, and obviousness. In other words, Cephalon should not have sought a patent on someone else's discovery and/or for something that was already known. And despite their duty of candor, neither the named inventors of the '845 Patent nor the prosecuting attorneys informed the PTO about this material information during the prosecution of the '845 Patent, although they were obligated to do so under applicable law and PTO regulations. This material information was intentionally withheld from the PTO. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity (and another obligation) to properly disclose these facts, but again intentionally failed to do so.

62. The named inventors and prosecuting attorneys also failed to inform the PTO that Lafon had sold and delivered modafinil tablets to Cephalon before October 6, 1993, under a Supply Agreement and a License Agreement executed in January of 1993. The October 6, 1993 date is one year before the '124 Application was filed with the PTO. The modafinil tablets and modafinil active pharmaceutical ingredient ("API") sold and delivered to Cephalon prior to October 6, 1993, fell within some, if not all, of the composition claims recited in the Cephalon Patents. The sale and delivery of modafinil tablets and modafinil API by Lafon to Cephalon were highly material to patentability because those transactions relate to, *inter alia*, whether what Cephalon was seeking to patent was too obvious to be patentable. Moreover, a patent application may be denied (and an issued patent later ruled invalid) if in fact the claimed invention had already been "on-sale" more than a year before the patent application was filed, under 35 U.S.C. § 102(b). These critical facts were intentionally withheld by individuals substantively involved in the prosecution of the '845 Patent. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity and obligation to properly disclose these facts, but again intentionally failed to do so.

63. The named inventors and/or prosecuting attorneys for the Cephalon Patents intentionally misrepresented in the patent specification, and in Peter Grebow's declaration dated September 26, 1995, that certain domestic and foreign clinical trials of modafinil formulations had followed the same dosing protocol. The U.S. and foreign trials actually used different protocols. It was the difference in protocols – the foreign clinical trial conducted by Lafon administered half of the daily dose of modafinil in each of two daily doses, whereas the domestic clinical trial conducted by Cephalon administered the entire daily dose in a single dose – that could, for example, explain

the alleged difference in adverse effects in the U.S. trial. Cephalon had relied on the alleged difference in adverse effects between the U.S. and European trials in support of patentability (*i.e.*, that Cephalon's formulation of modafinil was sufficiently distinguishable from existing formulations) but failed to inform the PTO about the difference in protocols (which could have accounted for the difference in results of the trials and which would have weighed against patentability). Cephalon's failure to inform the PTO of these facts was therefore material. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity and obligation to properly disclose these facts, but again intentionally failed to do so.

64. The inventors and their attorneys misrepresented to the PTO in the Cephalon Patents' specification that the adverse events observed in the domestic clinical trial at 800 mg doses were completely unexpected. Peter Grebow, a named inventor, further misled the PTO when he reiterated that contention in his September 26, 1995 declaration in support of patentability. In fact, Lafon had informed Cephalon in February of 1993 that a single 600 mg dose of modafinil may cause adverse effects, a fact known to Peter Grebow. Furthermore, the named inventors reported in the specification that no clinically significant adverse events occurred in the foreign clinical trials conducted by Lafon. However, numerous serious adverse events were observed during those foreign clinical trials. Peter Grebow was aware of those instances of adverse events and even forwarded Lafon's "serious adverse event" information to a Canadian counterpart. This information was material to patentability (it relates to inventorship, utility, derivation, and obviousness) because it contradicts representations made by the patentee to the PTO to secure the allowance of the claims of the Cephalon Patents.

65. The named inventors and prosecuting attorneys at Cephalon also intentionally concealed from the PTO that the domestic clinical trial described in the Cephalon Patents, which used modafinil compositions covered by at least one of the composition claims, and which followed the method of administration falling within at least one of the method claims, occurred prior to October 6, 1993, and the alleged conception date. The subjects of the first U.S. clinical trial were members of the public, and they were under no obligation of confidentiality to Cephalon or the clinical investigators. The non-confidential, public clinical trial was material to patentability because it constituted a public use of the claimed inventions more than one year before the filing date for the patent, which bars patentability of the claims under 35 U.S.C. § 102(b). During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity and obligation to properly disclose these facts, but again intentionally failed to do so.

66. The named inventors and prosecuting attorneys also intentionally misrepresented to the PTO that the dog plasma level data discussed in the Cephalon Patents demonstrated that the claimed small particle modafinil compositions result in higher peak plasma levels than the large particle modafinil compositions of the prior art. Notwithstanding their representations to the PTO, the named inventors and prosecuting attorneys knew that the test results were not statistically significant. Indeed, the contrary was true. Cephalon's DM-93-014 report to the FDA includes representations directly contradictory to those made to the PTO. That report, completed at least as early as November 8, 1996 (*i.e.*, while the '845 Patent application was still pending and before the RE '516 Patent application was filed), concluded that there was no statistically significant difference in the peak plasma levels as a function of modafinil particle size. This information

suggests, *inter alia*, that there was no basis to believe that Cephalon's formulation of modafinil was different than the prior art, and expressly contradicts an argument asserted in favor of patentability.

67. Cephalon agents with a duty of candor intentionally withheld the FDA report and the contradictory representations therein from the PTO during prosecution of the '845 Patent. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another obligation and opportunity to properly disclose these facts, but again intentionally failed to do so. The Cephalon Patents give the false impression that Cephalon was the first to measure particle size for modafinil and the first to recognize the importance of particle size. However, the named inventors and/or prosecuting attorneys intentionally withheld the fact that Lafon had already considered the importance of maintaining particle size controls over modafinil drug products prior to Cephalon's alleged invention. Lafon provided Cephalon with particle size information for all of the lots of modafinil API Lafon sold and delivered to Cephalon, including API Lot 003. The named inventors and their attorneys also misrepresented to the PTO that one or more of the named inventors had discovered that the dissolution rate of modafinil increases with a decrease in particle size. Lafon scientists had discovered the relationship between modafinil dissolution rate and particle size in 1989. Moreover, Lafon had communicated the relevant dissolution and particle size data to Cephalon in March of 1993. In addition, Peter Grebow represented to the PTO that there were no publications suggesting that the utility of modafinil could be improved by reducing its particle size when in fact he knew of a document published in September of 1993, more than one year prior to the patent filing date, which suggests that modafinil bioavailability differences may be caused by the particle size distribution. These misrepresentations and omissions were material to patentability because they all contradicted Cephalon's contention that its narrow formulation based

on particle size was novel and patentable. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity and obligation to properly disclose these material facts, but again intentionally failed to do so. These misrepresentations and omissions were material to patentability because they relate to inventorship, derivation, obviousness and prior publication under 35 U.S.C. §§ 102(a) and 102(b).

68. In February 2005, Mylan, Ranbaxy and Teva filed amended answers alleging in detail the facts above. These Generic Defendants asserted that the RE '516 Patent was invalid, unenforceable, and not infringed. Mylan, Ranbaxy and Teva also asserted that they were entitled to an award of attorney's fees and costs under 35 U.S.C. § 285 against Cephalon. Many of these same facts supported a finding that some or all of the claims of the RE '516 Patent were invalid and/or unenforceable due to inequitable conduct. In August and September 2005, the Generic Defendants filed motions seeking summary judgment that some or all of the claims of the RE '516 patent were invalid as a matter of law. Those motions were fully briefed as of November 14, 2005.

69. Moreover, the Generic Defendants argued, in summary judgment motions filed with the patent court under Fed. R. Civ. P. 11, that their evidence of non-infringement was so strong that the Generic Defendants were entitled to a finding, as a matter of law, that their generic products did not infringe the RE '516 Patent because their generics contained distributions of modafinil particles having more large particles than the formulation claimed in Cephalon's patent. (Most of the information relevant to these non-infringement claims is not publicly available.)

70. In addition, Ranbaxy and Mylan each argued in summary judgment papers that Cephalon's RE '516 patent was invalid, for several reasons. Ranbaxy argued that Cephalon's patent claims were invalid under 35 U.S.C. § 112 as indefinite because their scope was unclear. Mylan

argued that Cephalon was not entitled to a patent because it merely bought modafinil containing the claimed distribution of small particles from Lafon and did not "invent" anything itself, making the patent invalid under 35 U.S.C. § 102(f). Ranbaxy and Mylan both argued that Lafon's sale of modafinil to Cephalon raised an "on-sale bar" that invalidated the patent under 35 U.S.C § 102(b).

71. Cephalon bore the burden of proving that each of the four generic products to be sold by the four Generic Defendants was within the scope of and infringed the RE '516 Patent. Cephalon had not met its burden at the time it settled the patent litigation and instead agreed to pay the Generic Defendants millions of dollars not to compete. Had the patent litigation proceeded, Cephalon was unlikely to have prevented generic entry by the Generic Defendants. To do so, using just its patent rather than pay-offs, Cephalon had to show that each of the generic modafinil products infringed its patent and defeat each of the generic companies' invalidity arguments. If Cephalon failed to prove that even one of the generic products infringed its narrow patent, generic entry would have occurred. And if any one of the generic' invalidity arguments prevailed, the patent would be invalidated and could not have prevented the entry of any generic product. Consequently, Cephalon had to settle with *all* of the Generic Defendants to protect its monopoly.

72. In Hatch-Waxman patent litigation, generic firms have prevailed, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration, at 20 (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf. Cephalon was no doubt aware that both as a general matter, and because of the particular and severe problems it faced in its patent litigation against the Generic Defendants, that it most likely would

not be able to keep the Generic Defendants off the market solely by using its patent (by, for example, obtaining an injunction from a court).

73. The Generic Defendants had their own reasons to accept Cephalon's money instead of competing. As discussed, the four Generic Defendants were to share marketing exclusivity, meaning that the four firms would compete against each other and drive down the price for generic Provigil, substantially reducing the Generic Defendants' potential revenues and profit. Entering into non-competition agreements with Cephalon in return for large cash payments permitted the Generic Defendants to share Cephalon's monopoly profits on Provigil without having to enter the market and compete.

74. Significantly, it was in the economic self-interest for each of the Generic Defendants to settle only if they *all* settled. Absent an understanding that the other Generic Defendants also would agree to stay off the market, a lone settling Generic Defendant would run the risk that one or more of its fellow generic competitors would continue to litigate and either prevail and/or enter "at risk" after the 30-month stay (or any exclusivity) had expired.

75. Starting in December 2005, Cephalon began settling its claims against the Generic Defendants. Each settlement culminated in a dismissal with prejudice, thereby allowing Cephalon to avoid judicial scrutiny and resolution of the defenses and facts the Generic Defendants had raised and brought to light. Significantly, each of the individual agreements provided the same entry date (April 6, 2012) and contained a "Most Favored Nation" ("MFN") clause that guaranteed to each Generic Defendant that no other Generic Defendant would receive an earlier entry date, *i.e.*, the licensed entry date would be advanced if any other Generic Defendant did not settle or agree to the same entry date and entered earlier.

76. As a result of the facts and circumstances detailed above, each of the Defendants knew (or should have known) that absent the Exclusion Agreements, it was highly likely that Cephalon would have lost on the merits in all of the patent litigation involving Provigil.

2. Defendants Expected Cephalon to Lose the Patent Litigation and for Generic Modafinil to be Introduced in Early 2006

77. Cephalon was granted FDA approval to sell modafinil, as Provigil, in December 1998. Cephalon was the only company permitted to sell modafinil through December 2005 – first, because it obtained five years of NCE exclusivity (which expired in December 2003), and then because it obtained two additional years of Orphan Drug exclusivity (which expired in December 2005). Sales of Provigil grew substantially, exceeding $420 million in 2004 and $500 million in 2005, and climbing to nearly $850 million in 2008.

78. Although Cephalon received two years of Orphan Drug exclusivity by representing to the FDA that Provigil was a niche drug used to treat a rare disorder (and thus supposedly had a limited potential market), the federal government investigated Cephalon for improperly inflating its Provigil sales by allegedly illegally promoting or marketing Provigil for uses other than the limited/specific uses approved by the FDA – *i.e.*, for "off label" uses. Cephalon pled guilty and was fined $425 million. *See* http://www.usdoj.gov/opa/pr/2008/September/08-civ-860.html.

79. Prior to December 2005, Cephalon recognized the likelihood that, despite the existence of its patent and its patent suits against the Generic Defendants, Cephalon would lose its modafinil monopoly at or about the time that its Orphan Drug exclusivity expired on December 24, 2005. Three of the Generic Defendants had obtained tentative approval of their ANDAs for their

generic versions of Provigil by January 2005. (The fourth Generic Defendant, Teva, received tentative approval on December 16, 2005.) As discussed, tentative approval means that: (a) the FDA has determined that the generic product is safe, effective and bioequivalent to its brand name counterpart; and (b) the only barrier to final approval is the existence of some form of legal or regulatory exclusivity – such as Orphan Drug exclusivity.

80. Cephalon knew that when its Orphan Drug exclusivity expired, the Generic Defendants would come to market with their generic versions of Provigil, immediately or shortly thereafter, regardless of the patent litigation. Cephalon knew that its RE '516 Patent would not preclude the Generic Defendants from coming to market on or shortly after December 24, 2005, because: (a) the 30 month stays, which Cephalon had obtained automatically merely by filing its meritless patent suits against the Generic Defendants, had expired in September 2005, and its Orphan Drug exclusivity expired in December 2005; (b) Cephalon's patent did not give it an automatic right to exclude its generic competitors, but rather a right to attempt to obtain a court order excluding or enjoining generic competition; and (c) under controlling patent law, Cephalon would have been required to establish, *inter alia*, that it was likely to succeed on the merits of its patent suit to obtain an injunction keeping the Generic Defendants off the market after expiration of the 30 month stay and any exclusivity. However, the weakness of Cephalon's patent claims, and the strength of the patent defenses raised by the Generic Defendants, precluded Cephalon from obtaining a court order enjoining generic competition. Cephalon could not have established a likelihood of success on the merits because it was highly likely that, but for the Exclusion Agreements, Cephalon would have lost the patent cases on the merits.

81. Furthermore, it was well-known within the drug industry that the Generic Defendants were willing to enter "at risk," that is, while Cephalon's patent suits were still pending. Indeed, Defendant Ranbaxy represented, in its First Amended Answer To [Cephalon's] Complaint and Counterclaims, filed Feb. 22, 2005, that "Ranbaxy admits that it presently intends to manufacture, use, sell and offer to sell drug products for which the ANDA has been submitted once the FDA approves the ANDA." In other words, Ranbaxy told Cephalon (and represented to the court) that it would launch its generic "once the FDA approv[ed]" it – *i.e.*, Ranbaxy was willing and intended to launch at risk, because final FDA approval would occur upon expiration of Cephalon's Orphan Drug exclusivity, and did not need to await final resolution of the patent case. Likewise, Defendants Barr and Teva agreed in September 2005 to launch a generic version of Allegra prior to resolution of the patent litigation, see Press Release, "Teva and Barr Announce Launch of Generic Allegra Tablets By Teva Under Agreement With Barr," *available at* http://www.tevapharm.com/pr/2005/pr_544.asp. Defendant Teva, along with generic manufacturer Alphapharma, launched a generic version of Neurontin at risk in October 2004. *See* Press Release, "Teva Announces Approval and Launch of Gabapentin Tablets," *available at* http://www.teva.co.il/pr/2004/pr_496.asp. And Defendant Barr launched its generic version of Mircette at risk in April 2002, see News Release, "Barr Receives Final Approval For Generic Mircette Oral Contraceptive Company Will Launch Product Immediately Under Kariva Trademark," *available at* http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=338900&highlight.

82. The Generic Defendants expected to enter the market, even if that meant launching their generic products at risk. Each of the Generic Defendants prepared internal projections that

assumed a generic launch date by June 2006 and planned for a generic launch. For example, Barr, which believed an even earlier launch was possible, ordered substantial quantities of active ingredient from its supplier in late 2005.

83. Similarly, Wall Street analysts projected generic Provigil entry in 2006. A September 2005 report from American Technology Research noted that "current Street expectations are for generic competition to Provigil in the mid-2006 time frame." An October 2005 report from Lazard Capital Markets detailed one such expectation: "Our projections assume that there will be shared generic exclusivity for Provigil and that final [FDA] approval will be awarded with Summary Judgment motions still pending [in mid-2006]. At this point, generic(s) will launch at risk."

84. Cephalon's management was so convinced that generic competition was imminent, that they informed the investment community in November 2005 that Cephalon was projecting a substantial reduction of sales of Provigil in 2006, specifically because it expected generic competition in 2006. Cephalon's management also told securities analysts in November 2005 that Cephalon had reduced promotional spending on Provigil in late 2005 because it expected that generic competition would soon begin. As Cephalon's CEO explained to investment analysts, "we expected not to have [Provigil] in our portfolio." Therefore, "we haven't spent any money [in the] second half of '05 on Provigil." Brand drug companies commonly reduce promotional spending and detailing (visiting prescribing physicians) for a brand name drug at or shortly before they expect generic competition because brand companies (like Cephalon) know that once the generic enters, most of the brand sales will be lost to the generic regardless of continued brand promotion. By contrast, a brand company that reduces brand promotion in the absence of imminent generic competition would only hurt itself, since the reduction in promotion by itself could lead to reduced

brand sales. Thus, Cephalon's decision to reduce promotion for Provigil in 2005 made economic sense only if Cephalon expected generic competition to begin at that time or shortly thereafter.

85. Another tactic employed by Cephalon in light of expected generic competition was to develop, and seek FDA approval for, a new formulation of modafinil, which it called Nuvigil. Nuvigil purportedly has a longer-lasting effect than Provigil. Analysts, however, believed that Nuvigil was not a significant or meaningful improvement over Provigil, but simply a way for Cephalon to attempt to maintain its modafinil sales by attempting to convert demand for modafinil from Provigil, which faced imminent AB-rated generic competition, to Nuvigil, which, upon information and belief, would not be AB-rated to – and therefore not subject to substitution for – the proposed generic versions of Provigil.

86. From as early as the release of Cephalon's 2003 Annual Report, until the first settlements with the Generic Defendants were announced in December 2005, Cephalon publicly and repeatedly announced its intent to: (a) seek prompt FDA approval of Nuvigil; (b) begin selling Nuvigil upon such approval; and (c) convert the market demand for modafinil from Provigil to Nuvigil. Cephalon's plans regarding Nuvigil were well known in the pharmaceutical industry – and thus were known by the Generic Defendants when they commenced settlement negotiations with Cephalon.

87. After executing its anticompetitive Exclusion Agreements, however, Cephalon changed tactics and delayed the launch of Nuvigil.

88. Cephalon has been open about its plan to convert the market from Provigil to Nuvigil prior to generic entry. As Cephalon's Vice President of Investor Relations told investment analysts: "You should expect that we will likely raise Provigil prices to try to create an incentive to

reimbursers to preferentially move to Nuvigil." The Wall Street Journal detailed Cephalon's plan and labeled it an "extreme example" of attempts to boost profits and deter the use of less expensive generics by cannibalizing Provigil sales and converting them into prescriptions for Nuvigil. Cephalon expects that by the time the Generic Defendants actually launch their generic versions of Provigil in 2012, most Provigil users already will have switched to Nuvigil, which is under patent protection through 2023. Under this Nuvigil-conversion plan, any purported pro-competitive "benefit" of Defendants' unlawful agreements – *i.e.*, that they permit the Generic Defendants to launch generic Provigil before the expiration of the RE '516 Patent – would become completely illusory. *See* Jonathan D. Rockoff, *How a Drug Maker Tries to Outwit Generics*, WALL STREET JOURNAL, Nov. 18, 2008, at B1.

89. Expecting entry by other generics, Cephalon also made plans to launch its own generic version of Provigil (a so-called "authorized generic" product). Typically, a pharmaceutical company will prepare to launch a generic version of its own brand product only if it expects imminent generic entry from *AB-rated* products. Otherwise, an authorized generic would simply cannibalize the sales of the brand.

3. The Negotiation and Execution of Defendants' Unlawful Market Allocation Agreements

90. Upon information and belief, in late 2005, Cephalon began negotiating settlements of its patent suits with some, if not all, of the Generic Defendants. Cephalon's primary goal was simple – to delay generic competition for Provigil for as long as possible.

91. Because Cephalon's patent infringement claims against the Generic Defendants were so weak and the defenses of the Generic Defendants were so strong, the existence of those claims

would not have deterred the Generic Defendants from coming to market upon expiration of Cephalon's Orphan Drug exclusivity. The Generic Defendants would have to receive something of immediate and substantial value in order to induce them to delay or forego their right to launch their generics.

92. To maintain its monopoly over modafinil, Cephalon had to induce *all* the Generic Defendants to refrain from selling their generic versions of Provigil, because even one generic would quickly take the majority of Provigil sales. Given the enormous profits at stake, Cephalon set out to engage in just such a scheme to protect its monopoly.

93. Cephalon sought to delay generic entry both to protect its Provigil monopoly and to buy time to permit it to switch purchasers to Nuvigil before generic Provigil became available.

94. From the Generic Defendants' perspective, none would want to agree to a delayed entry date unless all the others agreed to the same date as well. None of the Generic Defendants would agree to stay off the market if there was the possibility that one or more of its competitors could enter earlier. Consequently, starting in December 2005, Cephalon entered into seriatim settlement agreements that contained the same entry date and an MFN clause that would permit earlier entry if any of the remaining Generic Defendants did not settle and/or entered earlier. The MFN clause not only guaranteed each Generic Defendant that no competitor would receive an earlier entry date but also effectively eliminated any incentive for a generic to enter at risk since the other, settling Generic Defendants would be able to enter at the same time with a license.

95. Each Generic Defendant became aware of the existence, purpose, and scope of the deals Cephalon was striking with its fellow Generic Defendants, and each Generic Defendants'

agreement was not an isolated deal but part of a larger arrangement to restrain trade. Defendants nevertheless adhered to the scheme and participated in it.

a. Teva

96. On December 9, 2005, Cephalon announced it had reached an agreement to settle its patent litigation with Teva. A complete version of the agreement was not made publicly available but was produced to the FTC during its investigation. According to Cephalon's and Teva's press releases, under the agreement, Teva was required to keep its generic version of Provigil off the market until a "Date Certain" which is defined as: "in the event that Cephalon obtains a pediatric extension on the Patent in Suit, April 6, 2012 (which is three years prior to the expiration of the pediatric extension, if obtained.)" On information and belief, the agreement prohibits Teva not only from selling the versions of generic Provigil at issue in the patent litigation, but also from developing and marketing any other generic versions of Provigil *and* generic equivalents of successor products. The agreement also contains an effective MFN clause that advances the entry date should, among other reasons, Cephalon grant an earlier license to any of the other Generic Defendants or should any Generic Defendant enter at risk. In exchange, Teva received substantial cash payments (reportedly up to $125 million).

97. The purpose and effect of the agreement was to delay generic competition to Provigil for 6 years or more, and thereby wrongfully maintain and extend Cephalon's modafinil monopoly well past the date by which generic entry previously had been expected and would have occurred. Following execution of the Exclusion Agreements, Cephalon's Chief Executive Officer, Frank Baldino, Jr., candidly explained the rise in Cephalon's stock price following the announcements of the agreements:

> A lot of [Wall Street's enthusiasm for Cephalon's stock] is a result of the patent litigation getting resolved for Provigil. **We were able to get six more years of patent protection. That's $4 billion in sales that no one expected.**

John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006.

98. Defendants claim the cash payments to Teva were for: (1) licenses to Teva's worldwide intellectual property "relating to the manufacture, development and formulation of modafinil" (including purported patent licenses and patent applications relating to modafinil); and (2) "certain agreements with Teva relating to Teva's manufacture and supply of the active pharmaceutical ingredient modafinil."

99. The payments to Teva were, in fact, payments to exclude Teva's generic modafinil from the market. Cephalon had been selling modafinil since February 1999 in the United States, and since 1998 in Europe, without any license from Teva. Thus, Cephalon had no need or use for a license from Teva. Cephalon already had all it needed to successfully manufacture and sell Provigil and any planned successor products, including Nuvigil. Cephalon knew about Teva's patent applications for over three years before it showed any alleged interest in a license, and only became interested because the license was tied to Teva's agreement to refrain from marketing generic Provigil until April 2012. Cephalon used the licenses as subterfuge to conceal the fact that it was paying Teva not to compete in the modafinil market for 6 years or more.

100. According to published reports, Cephalon also paid for a supply agreement from Teva for the active ingredient in Provigil, modafinil, to purchase the chemical at prices higher than Cephalon was paying its existing supplier. Prior to its agreement with Teva, however, Cephalon had been able to obtain sufficient amounts of modafinil to meet market demand for almost seven

years without a supply agreement from Teva, and did not suddenly need such an agreement in December 2005. At one point, Cephalon even suggested that Teva "forget about api" until after a settlement had been reached. Teva, however, insisted that such a term be included in the settlement, and ultimately Cephalon agreed to a supply term that guarantees Teva a revenue stream until 2012, when Teva is permitted to market its generic version of Provigil.

101. Since Cephalon's patent claims were very weak, Teva's agreement to stay off the market until 2012 does *not* reflect a reasonable compromise of the patent suit based on the respective strength of Cephalon's claims and Teva's defenses. At the time of the settlement, there were approximately nine years remaining on Cephalon's patent, which is set to expire on October 6, 2014. Even though Teva was highly likely to win the patent case, it agreed to stay off the market for six or more of those nine remaining years. Thus, logic and economic rationality dictate that: (a) Teva must have received compensation for its agreement to delay entry; and (b) the above-described payments to Teva were, in fact, for its agreement to keep its generic version of Provigil off the market, rather than for the licenses and supply agreements that Defendants claim were the consideration for these payments.

102. As of the date of its agreement with Cephalon, Teva was well aware that its ability to market a generic version of Provigil in 2012 likely would be worth little (or nothing) because: (1) it knew of Cephalon's well-publicized efforts to convert all or most of the market demand for modafinil from Provigil to Nuvigil before the entry of generic versions of Provigil; and (2) Teva's generic product would not be AB-rated to – and thus would not be substitutable by pharmacists for – Nuvigil. Thus, Teva knew that by the time it was permitted under its agreement to sell its generic version of Provigil, its generic product was likely to generate little (if any) sales and profits, since it

was likely that by that time, most (or all) of the demand for modafinil would have been converted to Nuvigil.

103. The agreement was intentionally structured in a manner that would buy Cephalon the time necessary to: (a) obtain FDA approval of its Nuvigil product; and (b) convert the market demand for modafinil from Provigil to Nuvigil. Indeed, prior to the agreement with Teva (and the agreements with the other Generic Defendants), Cephalon had publicly stated its plan to launch Nuvigil in early 2006. After the four Exclusion Agreements were secured, however, Cephalon publicly stated that its intent was: (a) to delay marketing Nuvigil; and (b) to stop promoting/selling Provigil at that point, and to convert market demand for modafinil from Provigil to Nuvigil before entry of generic Provigil. Thus, any alleged "pro-competitive" effect of the Defendants' Exclusion Agreements – *i.e.*, that they allow Teva and the other Generic Defendants to launch generic Provigil prior to patent expiration – is completely illusory.

b. Ranbaxy

104. On December 22, 2005, Cephalon and Ranbaxy entered a written agreement to settle their patent litigation. On information and belief, this agreement prohibits Ranbaxy not only from selling the versions of generic Provigil at issue in the patent litigation, but also from developing and marketing any other generic versions of Provigil. The agreement also provides for the same "Date Certain" licensed entry date as Teva and the same MFN clause, permitting Ranbaxy to come to market sooner if another generic company did so.

105. Ranbaxy would not have entered into this agreement unless it received significant compensation. Ranbaxy's chief negotiator sought to obtain "$20-30 million" in value from the

settlement. He would not have recommended the settlement to Ranbaxy management absent this compensation "because the economics of the settlement would be quite different."

106. Cephalon agreed to provide this compensation, though it disguised part of the payment as a supply agreement. Cephalon agreed to purchase modafinil API from Ranbaxy, even though Ranbaxy does not manufacture modafinil API itself, but rather obtains the API from a third-party manufacturer in India. Ranbaxy will pass API on to Cephalon at a substantial markup, and Cephalon will pay prices substantially higher than the price Cephalon paid to its existing supplier. The supply agreement is nothing more than a pretextual sham, a conduit of cash from Cephalon to Ranbaxy in exchange for Ranbaxy's agreement not to compete.

107. Cephalon also agreed to pay Ranbaxy up to $5 million in exchange for a license to patent applications Ranbaxy held related to modafinil, even though Cephalon did not need the license to manufacture or sell Provigil or planned successor products, including Nuvigil.

c. Mylan

108. On January 9, 2006, Cephalon and Mylan entered a written agreement to settle their patent litigation. On information and belief, this agreement prohibits Mylan not only from selling the versions of generic Provigil at issue in the patent litigation, but also from developing and marketing any other generic versions of Provigil *and* generic equivalents of successor products. The agreement also provides for the same "Date Certain" licensed entry date as Teva and Ranbaxy and the same MFN clause, permitting Mylan to come to market sooner if another generic company did so.

109. In December 2005, just before settling, Mylan prepared a written projection with a 100% "probability factor" of launching its generic version of Provigil by June 2006. Mylan was

therefore unwilling to refrain from competing until April 2012 absent significant compensation. At Mylan's urging, Cephalon agreed to enter into simultaneous product development deals that provide significant guaranteed compensation for Mylan, purportedly based on net sales of products unrelated to modafinil. Not coincidentally, these purported "product development collaboration agreements," were executed the same day Cephalon and Mylan executed their settlement agreement. Under these deals, Cephalon has paid Mylan, to date, at least $45 million. Prior to its agreement with Mylan, Cephalon had expressed no interest to Mylan in the technology Mylan contributed to the product development deals.

110. The compensation Cephalon agreed to provide Mylan was designed to, and did, induce Mylan to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

d. Barr

111. On February 1, 2006, Cephalon entered written agreements with Barr and Barr's partner and co-conspirator, Chemagis, Ltd. (together with its affiliates, "Chemagis") to settle Cephalon's patent litigation with Barr. On information and belief, this agreement prohibits Barr not only from selling the versions of generic Provigil at issue in the patent litigation, but also from developing and marketing any other generic versions of Provigil. The agreement also provides for the same "Date Certain" licensed entry date as Teva, Ranbaxy and Mylan, and the same MFN clause, permitting Barr to come to market sooner if another generic company did so.

112. Barr was unwilling, however, to settle the Provigil patent litigation based solely on terms that required Barr to refrain from marketing generic Provigil until April 2012 without compensation. Cephalon therefore agreed to (1) pay Barr $1 million for a license to a patent

application Barr held related to modafinil that Cephalon did not need to manufacture or sell Provigil or planned successor products, including Nuvigil; (2) purchase modafinil API directly from Chemagis (and indirectly from Barr via Barr's profit-sharing arrangement with Chemagis) at prices substantially higher than the price Cephalon paid to its existing supplier; and (3) settle unrelated patent litigation on terms favorable to Barr.

113. Since Barr had developed its generic version of Provigil with Chemagis, which supplied modafinil API to Barr, any patent litigation settlement with Cephalon effectively required the assent of both Barr and Chemagis. Therefore, to secure Barr's agreement to refrain from marketing generic Provigil until April 2012, Cephalon also was willing to provide significant compensation to Chemagis.

114. At the time it entered the patent agreement with Barr, Cephalon agreed to pay Chemagis $4 million in exchange for a license to a patent and patent application Chemagis held related to modafinil, but that Cephalon did not need to manufacture or sell Provigil or planned successor products, including Nuvigil. Cephalon also entered into a product development deal with Chemagis. Under that deal, the parties agreed to collaborate on two projects. The first was the use of Chemagis drug delivery technology with an existing Cephalon drug product, for which Cephalon agreed to make $20 million in guaranteed payments to Chemagis. The second was a project to be named later. Cephalon agreed to pay Chemagis at least $20 million for the project to be named later.

115. Absent the unlawful Exclusion Agreements, the Generic Defendants would have been motivated to begin selling their generic versions of Provigil as soon as possible, in order to reap an appropriate return on the significant investment each had made in developing and seeking FDA approval for their generic versions of Provigil. Absent the exclusion payments they received

from Cephalon, each of the Generic Defendants would have been motivated to launch promptly because each knew that, if it did not launch, the other Generic Defendants could and would likely do so, and capture the sales of generic Provigil that it otherwise would have obtained if it had come to market.

116. Defendants did not need to resort to payments from Cephalon to the Generic Defendants in order to resolve their patent litigation, however. To the contrary, according to FTC analyses, in 2004 and 2005, twenty-seven out of thirty, or 90% of agreements between brand and generic manufacturers settling patent disputes contained no anticompetitive payment from the brand to the generic manufacturer. *See* FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (2006), *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf; FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by the Bureau of Competition (2005), *available at* http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf. Many of those twenty-seven agreements allowed for sustained entry of a generic drug well before the date of patent expiration. Those agreements took various forms, but many agreements resulted in either: (a) split patent life whereby the generic would enter the market before the expiry of the challenged patent; or (b) unrestricted generic entry immediately upon or very soon after the settlement, sometimes accompanied by a royalty payment from the generic manufacturer to the brand manufacturer. *Id.*

117. On or about March 28, 2006, Cephalon received a six-month pediatric exclusivity extension from the FDA. This extension, however, applied only to exclusivities which had not yet expired. Cephalon's Orphan Drug exclusivity for Provigil expired on December 24, 2005, and so Cephalon's receipt of a pediatric extension on March 28, 2006, would not have prevented the Generic Defendants from obtaining final FDA approval to sell their generic versions of Provigil prior to Cephalon's receipt of the pediatric extension.

E. Defendants' Conduct Also Has Delayed Entry by Apotex

118. On March 30, 2005, Apotex filed its ANDA number 77-667 for a generic version of Provigil. Apotex reportedly produces more than 260 generic pharmaceuticals in over 4,000 dosages and formats and sells in over 115 countries around the world. Apotex has sufficient knowledge, expertise, capital, facilities, marketing prowess, and access to any raw materials necessary to manufacture and sell generic Provigil in the United States.

119. Apotex's ANDA filing included a Paragraph III certification stating that it would not sell its generic until the expiration of the patents then listed for Provigil in the Orange Book. Although Apotex did not originally file a Paragraph IV certification regarding the RE '516 Patent, it believed it had no reason to do so, because four other generic companies (the four Generic Defendants) were already engaged in litigation over that patent.

120. When Apotex learned that the Generic Defendants had settled their lawsuits with Cephalon with an agreement not to pursue their claims that the RE '516 Patent as invalid, Apotex changed its certification from a Paragraph III to a Paragraph IV in March 2006, to specifically state that the RE '516 Patent was either invalid or not infringed by Apotex's planned generic.

121. Apotex received tentative approval for its ANDA on December 29, 2006, and the only known impediment to Apotex's receipt of final FDA approval (and the entry of Apotex's generic Provigil) is that the Generic Defendants have refrained from launching their generics, thereby preventing their shared 180-day exclusivity period from running, thereby preventing the FDA from granting final approval to Apotex. That period would have been triggered had the Generic Defendants either launched their generic products in 2006, as they had planned to do, or if they had continued to prosecute their patent cases to judgment and prevailed (as they would have). Instead, because of the unlawful Exclusion Agreements, all four Generic Defendants have agreed not to enter before April 2012, leaving their 180-day exclusivity period in place and thereby blocking final FDA approval and entry of subsequent generics like Apotex.

122. Although Cephalon received a Paragraph IV certification from Apotex, Cephalon did not sue Apotex under Hatch-Waxman, either because of an express or tacit agreement with the Generic Defendants, or of its own accord. Cephalon knew that bringing suit would again put the RE '516 Patent at risk of a finding of invalidity or non-infringement. By not suing, Cephalon could avoid any determination of the invalidity or non-infringement of its patent because (Cephalon believed) Apotex would lack standing to bring a declaratory judgment action. Cephalon did not need to sue Apotex, however, to prevent Apotex from launching its generic because, as discussed, Defendants agreements precluded Apotex from receiving final FDA approval, and so Apotex could not launch. Nevertheless, on June 26, 2006, Apotex filed an action seeking a declaratory judgment that the RE '516 Patent is either invalid or not infringed by Apotex's generic Provigil. (*Apotex, Inc. v. Cephalon, Inc., et al.*, Civ. A. No. 2:06-cv-02768 (E.D. Pa.)). Cephalon challenged Apotex's right to bring a declaratory judgment action, arguing there was no case or controversy because

Apotex did not face a "reasonable apprehension of imminent suit," which Cephalon argued was a prerequisite for standing under what it termed "clear and controlling" precedent. Cephalon, Inc.'s Motion to Dismiss and to Strike, Civ. A. No. Case 2:06-cv-02768, D.E. # 31, at 54-55 (E.D. Pa.). Thus, Cephalon likely believed that by paying off the four Generic Defendants, and then by refraining from suing Apotex, it could prevent Apotex from launching its generic.

123. Defendants' unlawful conduct, therefore, has delayed not only the launch of less expensive generic versions of Provigil by the Generic Defendants, but has created a bottleneck which has delayed the launch of generic Provigil by Apotex as well.

124. Moreover, the agreements between Cephalon and the Generic Defendants which leave the Generic Defendants' 180-day exclusivity period in place were not necessary for the settlement of the patent litigation and constitute an ancillary restraint of trade.

125. Nearly two years after entering into the Exclusion Agreements with the Generic Defendants, Cephalon obtained another patent, Patent No. 7,297,346 B2 ("the '346 patent") on November 20, 2007 and listed it in the Orange Book. The '346 patent, issued in 2007, obviously could not have been used to block generic entry at the time of the Exclusion Agreements – in December 2005. Nor could the '346 patent, which is extremely narrow, legitimately forestall Apotex's subsequent entry because the '346 patent would not be infringed by Apotex's planned generic.

F. Effect on Interstate Commerce

126. At all material times, Provigil, manufactured and sold by Defendant Cephalon, was shipped across state lines and sold to customers located outside its state of manufacture.

127. During the relevant time period, in connection with the purchase and sale of Provigil, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

128. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

G. Monopoly Power

129. Through the anticompetitive conduct alleged herein, Cephalon was able to profitably charge supracompetitive prices for modafinil without losing substantial sales, and thus, by definition, maintained monopoly power with respect to modafinil sold in the United States.

130. Insofar as Plaintiffs are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is Provigil (in all its forms and dosage strengths), and AB-rated bioequivalent versions of Provigil. There are no reasonably interchangeable drug products available to prescribing physicians for the indications for which modafinil is prescribed. According to Cephalon's CEO, Provigil is a unique drug that "created the category of wakefulness products" and faces "no competition." For the entire period relevant to this case, Cephalon has been able to profitably maintain the price of its branded modafinil product well above competitive levels without losing substantial sales.

131. The relevant geographic market is the United States and its territories.

132. Cephalon's market share in the relevant market is and was 100% at all times relevant to this complaint.

133. Defendants' actions are part of, and in furtherance of, the illegal restraint of trade and monopolization alleged herein, and were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

H. Effects on Competition and Damages to Plaintiffs

134. Defendants' unlawful exclusionary conduct has delayed or prevented the sale of generic modafinil in the United States, and unlawfully enabled Cephalon to sell modafinil (marketed as Provigil) at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Provigil would have occurred prior to April 2012 because (1) one or more of the Generic Defendants would have entered with its generic version of Provigil before conclusion of the patent litigation; (2) Cephalon would not have prevailed against each of the four Generic Defendants in its patent litigation; or(3) Cephalon would have agreed to settle its patent litigation on terms that did not include exclusion payments, but provided for generic entry earlier than April 2012.

135. If the Generic Defendants had launched their generic versions of Provigil, Plaintiffs and other purchasers would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received a lower price (and/or discounts) on some or all of their remaining Provigil purchases.

136. During the relevant period, Plaintiffs (or their assignors) purchased substantial amounts of Provigil directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other purchasers were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs and other purchasers paid prices for modafinil

that were substantially higher than the prices that they would have paid but for the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other purchasers have sustained substantial losses and damage to their business and property in the form of overcharges.

137. Even when generic versions of Provigil eventually enter the market, Plaintiffs may realize few benefits from entry. Prior to its agreements with the Generic Defendants, Cephalon intended to launch Nuvigil upon receiving FDA approval, which occurred in June 2007. Having successfully forestalled generic competition, however, Cephalon delayed Nuvigil's launch until June 2009.

138. Meanwhile, Cephalon is actively working to destroy the market for generic Provigil, and the potential benefits to consumers from generic entry in 2012. As Cephalon's CEO told investment analysts: "[I]f we do our job right [switching the market to Nuvigil] . . . the Provigil number in 2012 that will be genericized will be very, very small."

COUNT I

Contract in Restraint of Trade in Violation of Section 1
Agreement Between Cephalon and Teva Not to Compete

139. Plaintiffs repeat and incorporate by reference all of the allegations above.

140. Beginning no later than December 9, 2005, Cephalon and Teva engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of modafinil in the United States to Cephalon; (b) prevent the

sale of a generic version of Provigil in the United States, thereby protecting Provigil from any generic competition for 6 years or more; and (c) fix the price at which direct purchasers would pay for modafinil at the supracompetitive price of brand name Provigil.

141. By entering into the unlawful agreement, Cephalon and Teva have unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreement constitutes a horizontal market allocation and price-fixing agreement between actual or potential competitors, and thus is a *per se* violation of Section 1. In the alternative, the agreement is an unreasonable restraint of trade in violation of Section 1, under a "quick look" or "rule of reason" analysis.

142. But for the illegal agreement, Teva would have begun marketing generic versions of Provigil in 2006 and/or well before the April 2012 delayed entry date.

143. If Teva had entered the market and competed with Cephalon in a full and timely fashion, Plaintiffs would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

144. Plaintiffs have been injured in their business and property by reason of the unlawful contract, combination and conspiracy. During the relevant period, Plaintiffs purchased substantial amounts of Provigil, and, as a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to

purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by the illegal conduct.

145. This unlawful conduct threatens continuing loss and damage to Plaintiffs if not enjoined by this Court.

COUNT II

Contract in Restraint of Trade in Violation of Section 1
Agreement Between Cephalon and Ranbaxy Not to Compete

146. Plaintiffs repeat and incorporate by reference all of the allegations above.

147. Beginning no later than December 22, 2005, Cephalon and Ranbaxy engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of modafinil in the United States to Cephalon; (b) prevent the sale of generic versions of Provigil in the United States, thereby protecting Provigil from any generic competition for 6 years or more; and (c) fix the price at which direct purchasers would pay for modafinil at the supracompetitive price of brand name Provigil.

148. By entering into the unlawful agreement, Cephalon and Ranbaxy have unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreement constitutes a horizontal market allocation and price-fixing agreement between actual or potential competitors, and thus is a *per se* violation of Section 1. In the alternative, the agreement is an unreasonable restraint of trade in violation of Section 1, under a "quick look" or "rule of reason" analysis.

149. But for the illegal agreement, Ranbaxy would have begun marketing generic versions of Provigil in 2006 and/or well before the April 2012 delayed entry date.

150. If Ranbaxy had entered the market and competed with Cephalon in a full and timely fashion, Plaintiffs would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

151. Plaintiffs have been injured in their business and property by reason of the unlawful contract, combination and conspiracy. During the relevant period, Plaintiffs purchased substantial amounts of Provigil, and, as a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by the illegal conduct.

152. This unlawful conduct threatens continuing loss and damage to Plaintiffs if not enjoined by this Court.

COUNT III

Contract in Restraint of Trade in Violation of Section 1
Agreement Between Cephalon and Mylan Not to Compete

153. Plaintiffs repeat and incorporate by reference all of the allegations above.

154. Beginning no later than January 10, 2006, Cephalon and Mylan engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of modafinil in the United States to Cephalon; (b) prevent the sale of generic versions of Provigil in the United States, thereby protecting Provigil from any

generic competition for 6 years or more; and (c) fix the price at which direct purchasers would pay for modafinil at the supracompetitive price of brand name Provigil.

155. By entering into the unlawful agreement, Cephalon and Mylan have unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreement constitutes a horizontal market allocation and price-fixing agreements between actual or potential competitors, and thus is a *per se* violation of Section 1. In the alternative, the agreement is an unreasonable restraint of trade in violation of Section 1, under a "quick look" or "rule of reason" analysis.

156. But for the illegal agreement, Mylan would have begun marketing generic versions of Provigil in 2006 and/or well before the April 2012 delayed entry date.

157. If Mylan had entered the market and competed with Cephalon in a full and timely fashion, Plaintiffs would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

158. Plaintiffs have been injured in their business and property by reason of the unlawful contract, combination and conspiracy. During the relevant period, Plaintiffs purchased substantial amounts of Provigil, and, as a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by the illegal conduct.

159. This unlawful conduct threatens continuing loss and damage to Plaintiffs if not enjoined by this Court.

COUNT IV

Contract in Restraint of Trade in Violation of Section 1
Agreement Between Cephalon and Barr Not to Compete

160. Plaintiffs repeat and incorporate by reference all of the allegations above.

161. Beginning no later than February 1, 2006, Cephalon and Barr engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of modafinil in the United States to Cephalon; (b) prevent the sale of generic versions of Provigil in the United States, thereby protecting Provigil from any generic competition for 6 years or more; and (c) fix the price at which direct purchasers would pay for modafinil at the supracompetitive price of brand name Provigil.

162. By entering into the unlawful agreement, Cephalon and Barr have unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreement constitutes a horizontal market allocation and price-fixing agreement between actual or potential competitors, and thus is a *per se* violation of Section 1. In the alternative, the agreement is an unreasonable restraints of trade in violation of Section 1, under a "quick look" or "rule of reason" analysis.

163. But for the illegal agreement, Barr would have begun marketing generic versions of Provigil in 2006 and/or well before the April 2012 delayed entry date.

164. If Barr had entered the market and competed with Cephalon in a full and timely fashion, Plaintiffs would have substituted lower-priced generic modafinil for the higher-priced

brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

165. Plaintiffs have been injured in their business and property by reason of the unlawful contract, combination and conspiracy. During the relevant period, Plaintiffs purchased substantial amounts of Provigil, and, as a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by the illegal conduct.

166. This unlawful conduct threatens continuing loss and damage to Plaintiffs if not enjoined by this Court.

COUNT V

Conspiracy In Restraint of Trade In Violation of Section 1 of the Sherman Act Agreement Between All Defendants Not to Compete

167. Plaintiffs repeat and incorporate by reference all of the allegations above.

168. Beginning no later than December 9, 2005, Cephalon and the Generic Defendants engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of modafinil in the United States to Cephalon; (b) prevent the sale of generic versions of Provigil in the United States, thereby protecting Provigil from any generic competition for 6 years or more; and (c) fix the price at which direct purchasers would pay for modafinil at the supracompetitive price of brand name Provigil.

169. By entering into the unlawful agreement, Defendants have unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants' agreement constitutes a horizontal market allocation and price-fixing agreement between actual or potential competitors, and thus is a *per se* violations of Section 1. In the alternative, the Defendants' agreement is an unreasonable restraints of trade in violation of Section 1, under a "quick look" or "rule of reason" analysis.

170. But for Defendants' unlawful conduct, some, if not all, of the Generic Defendants would have begun marketing generic versions of Provigil in 2006, and/or well before the April 2012 delayed entry date.

171. If any of the Generic Defendants had launched their generic versions of Provigil in a full and timely fashion, Plaintiffs would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

172. Plaintiffs have been injured in their business and property by reason of the unlawful contract, combination and conspiracy. During the relevant period, Plaintiffs purchased substantial amounts of Provigil, and, as a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by the illegal conduct.

173. This unlawful conduct threatens continuing loss and damage to Plaintiffs if not enjoined by this Court.

COUNT VI

Conspiracy In Restraint of Trade In Violation of Section 1 of the Sherman Act Agreement Between the Generic Defendants Not to Compete

174. Plaintiffs repeat and incorporate by reference all of the allegations above.

175. Beginning no later than December 9, 2005, Cephalon orchestrated an agreement between and among the Generic Defendants not to compete with each other regarding the sale of generic versions of Provigil.

176. By entering into the unlawful agreement, the Generic Defendants have unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreement constitutes a horizontal market allocation and price-fixing agreement between actual or potential competitors, and thus is a *per se* violation of Section 1. In the alternative, the Generic Defendants' agreement is an unreasonable restraint of trade in violation of Section 1, under a "quick look" or "rule of reason" analysis.

177. But for the illegal agreement, some if not all, of the Generic Defendants would have begun marketing generic versions of Provigil in 2006 and/or well before the April 2012 delayed entry date.

178. If the Generic Defendants had not collectively agreed to stay off the market until April 2012 at least one, if not all of them would have entered the market as early as 2006 and/or well before the April 2012 delayed entry date. Plaintiffs would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil

requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

179. Plaintiffs have been injured in their business and property by reason of the unlawful contract, combination and conspiracy. During the relevant period, Plaintiffs purchased substantial amounts of Provigil, and, as a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by the illegal conduct.

180. This unlawful conduct threatens continuing loss and damage to Plaintiffs if not enjoined by this Court.

COUNT VII

Monopolization in Violation of Section 2 of the Sherman Act Against Cephalon

181. Plaintiffs repeat and incorporate by reference all of the allegations above.

182. Cephalon used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend its monopoly power in the modafinil market, as detailed above.

183. The goal, purpose and/or effect of Cephalon's scheme was to prevent, delay, and/or minimize the success of the entry of generic modafinil competitors who would have sold generic modafinil in the United States at prices significantly below Cephalon's prices for Provigil, which

would have effectively caused the average market price of modafinil (brand plus generic versions) to decline dramatically.

184. The goal, purpose and/or effect of Cephalon's scheme was also to maintain and extend Cephalon's monopoly power with respect to modafinil. Cephalon's illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Provigil enabled Cephalon to continue charging supra-competitive prices for modafinil (sold as Provigil) without a substantial loss of sales.

185. As a result of Cephalon's illegal conduct, Plaintiffs paid more than they would have paid for modafinil, absent Cephalon's illegal conduct. But for Cephalon's illegal conduct, competitors would have begun marketing generic versions of Provigil at least as early as 2006 and/or well before the April 2012 delayed entry date.

186. If manufacturers of generic modafinil had entered the market and competed with Cephalon in a full and timely fashion, Plaintiffs would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

187. During the relevant period, Plaintiffs purchased substantial amounts of Provigil, and, as a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by the illegal conduct.

188. Cephalon's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for modafinil in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

189. This unlawful conduct threatens continuing loss and damage to Plaintiffs if not enjoined by this Court.

COUNT VIII

Conspiracy to Monopolize In Violation of Section 2 of the Sherman Act Against All Defendants

190. Plaintiffs repeat and incorporate by reference all of the allegations above.

191. As detailed above, the Generic Defendants conspired with Cephalon to monopolize the modafinil market by, *inter alia,* agreeing to keep their generic versions of modafinil off the market for 6 years or more, in exchange for substantial cash payments. But for the Defendants' conspiracy to monopolize, some, if not all, of the Generic Defendants would have begun marketing generic versions of Provigil in 2006 and/or well before the April 2012 delayed entry date.

192. During the relevant period, Plaintiffs purchased substantial amounts of Provigil, and, as a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; and/or (2) the price of branded Provigil was artificially inflated by the illegal conduct.

193. This unlawful conduct threatens continuing loss and damage to Plaintiffs if not enjoined by this Court.

194.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A judgment for three times the damages actually sustained by Plaintiffs, as determined by a jury;

B. A declaration that Defendants have violated the antitrust laws in the ways described above;

C. Permanent injunctive relief, which enjoins Defendants from entering into any further illegal agreements and requires them to take affirmative steps to dissipate the anticompetitive effects of their prior violation;

D. The costs of this suit, including a reasonable attorneys' fee; and

E. Such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand trial by jury of all issues so triable.

Dated: August 20, 2009

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