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

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, on behalf of itself and all others similarly situated,	:	
Plaintiff,	:	Civil Action No.
v.	:	
CEPHALON, INC.; BARR LABORATORIES, INC.; MYLAN LABORATORIES, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; RANBAXY LABORATORIES, LTD.; and RANBAXY PHARMACEUTICALS, INC.,	:	CLASS ACTION JURY TRIAL DEMANDED
Defendants.	:	

CLASS ACTION COMPLAINT

Plaintiff, Pennsylvania Employees Benefit Trust Fund, on behalf of itself and the class of End-payors as defined below, upon personal knowledge as to facts pertaining to itself, and upon information and belief and upon the investigation of their counsel as to all other matters, alleges as follows:

NATURE OF THE ACTION

1. This is a nationwide class action alleging violations of federal antitrust law and state antitrust and unfair and deceptive trade practices acts arising from the manufacture and marketing by Cephalon, Inc. ("Cephalon") of the brand-name drug Provigil, a drug used as a "wakefulness promoting agent." The generic name for Provigil is modafinil. Plaintiffs are consumers and third-party payors (such as insurers and employee benefit plans) who paid some or all of the price of modafinil for use and not for resale.

2. As detailed below, Cephalon engineered a conspiracy to restrain trade, and a scheme to monopolize the U.S. market for pharmaceutical products with modafinil as the active ingredient (the "modafinil market"), by substantially delaying the onset of generic competition for Provigil, its top selling drug. Among other aspects of its exclusionary scheme, Cephalon entered into agreements with its prospective generic competitors Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. ("Teva"), Barr Laboratories, Inc. ("Barr"), Mylan Laboratories, Inc. ("Mylan"), Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy") (collectively the "Generic Defendants"), whereby Cephalon agreed to pay the Generic Defendants a total of up to $136 million, as well as provide other compensation, in exchange for agreements by the Generic Defendants not to sell their generic versions of Provigil until October 2011 (or April 2012, under certain circumstances described below).

3. Generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generics and brand name drugs is that generic drugs are substantially cheaper for consumers and third-party purchasers.

4. Faced with litigation challenging the validity of its underlying patents, Cephalon engineered a scheme whereby it would, *inter alia*: (a) make significant payments to the Generic Defendants in exchange for their agreements to refrain from selling their less expensive generic versions of Provigil until either 2011 or 2012 (*i.e.*, for up to at least 6 ½ years); and (b) disguise these "exclusion payments" as payments for: (i) licenses and/or supply agreements regarding modafinil (regarding Teva, Barr and Ranbaxy); or (ii) product development agreements for unrelated products (regarding Mylan). Defendants intentionally concealed the true purpose and

nature of these exclusion payments in an attempt to shield their exclusionary agreements from antitrust scrutiny.

5. Absent the illegal agreements not to compete with the Generic Defendants, generic competition for the sale of modafinil would have commenced in or about January 2006, and Plaintiff and other end-payor purchasers of modafinil would have been able to purchase modafinil at significantly lower prices than they were forced to pay because of Defendants' illegal acts to delay generic competition.

6. As a result of their illegal scheme, Defendants: (1) illegally maintained Cephalon's monopoly power in the market for modafinil in the United States; (2) fixed, raised, maintained, and/or stabilized the price of modafinil at supra-competitive levels; and (3) overcharged Plaintiff and other end-payor purchasers of Provigil from Cephalon by millions of dollars by depriving them of the results of competition from cheaper generic versions of Provigil.

7. Defendants' "exclusion payment" agreements constitute horizontal market allocation agreements, which are *per se* violations of Section 1 of the Sherman Act and analogous state laws. Defendants' conduct also constitutes a conspiracy to restrain trade, in violation of Section 1 of the Sherman Act and analogous state laws.

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

9. In Count I of this Complaint, Plaintiff, on behalf of itself and all others who are End-Payors of Provigil, seek equitable, injunctive and declaratory relief against Defendants based

on allegations of monopolization of, and an attempt to monopolize, the market for Provigil and its generic bioequivalents, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §1 and § 2.

10. Counts II and III are brought by Plaintiff on behalf of itself and those Class members who purchased or paid for Provigil and its generic bio-equivalents in Arizona, California, the District of Columbia, Florida, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin (the "Indirect Purchaser States"). Counts II and III are brought pursuant to the antitrust and unfair and deceptive trade practices acts of the Indirect Purchaser States.

11. Count IV is brought by Plaintiff on its own behalf and on behalf of the Class, seeking a constructive trust and disgorgement of the unjust enrichment of Defendants.

JURISDICTION AND VENUE

12. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of the federal antitrust laws, particularly Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 26. In addition, this Court has jurisdiction over the state law claims pursuant to 28 U.S.C. § 1332(d), as amended in 2005, and 28 U.S.C. § 1367.

13. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because Defendants transact business, are found, and/or have agents in this district; because a substantial portion of the affected trade and commerce described below has been

carried out in this district; because Defendants brought one of the sham litigations which forms an integral part of these claims in this district; and because other related actions are pending in this district.

14. The illegal monopolization and attempt to monopolize the market for Provigil and generic versions of Provigil, as alleged herein, have substantially affected interstate and foreign commerce.

RELEVANT MARKET

15. As to the claims so requiring, the relevant product market is the market for the manufacture and sale of Provigil, modafinil, and all generic bioequivalents rated "AB" by the FDA. The relevant geographic markets are the United States and its territories as a whole (Counts I and IV) and the Indirect Purchaser States (Counts II and III). At all relevant times, Defendants' market share in the relevant product and geographic markets was 100%.

PARTIES

16. Plaintiff, Pennsylvania Employees Benefit Trust Fund ("The Fund"), is a labor-management trust fund duly organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 150 South 43rd Street, Suite 1, Harrisburg, Pennsylvania 17111-5700. The Fund provides comprehensive healthcare benefits, including prescription drug coverage, to over 270,000 participants and beneficiaries, which includes active and retired employees of the Commonwealth of Pennsylvania and their spouses and dependents. Participants and beneficiaries of the Fund live in Pennsylvania and a number of other states. During the Class Period as described herein, Plaintiff has paid for some or all of the purchase price of Provigil prescribed to one or more of its participants or beneficiaries during the Class

Period, and has thereby been injured, and continues to be injured, as a result of Defendants' conduct.

17. 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, PA 19355. Cephalon develops, manufactures, and markets pharmaceuticals and related products in the United States.

18. Defendant Barr is a company incorporated under the laws of the State of New York, with its principal place of business at Two Quaker Road, Pomona, New York 10970. Barr principally develops, manufactures and markets generic versions of brand name drugs.

19. Defendant Mylan is a company incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan's subsidiary, Mylan Pharmaceuticals, Inc., is located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan principally develops, manufactures and markets generic versions of brand name drugs.

20. Teva Pharmaceutical Industries, Ltd. is an Israeli company. 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 19454. Teva principally develops, manufactures and markets generic versions of brand name drugs.

21. Ranbaxy Laboratories, Ltd. is a company operating under the laws of India. Ranbaxy Pharmaceuticals, Inc., a wholly-owned subsidiary of Ranbaxy Laboratories, Ltd., with its principal place of business located at 600 College Road East, Suite 2108, Princeton, New Jersey 08540. Ranbaxy principally develops, manufactures and markets generic versions of

brand name drugs.

INTERSTATE TRADE AND COMMERCE

22. During all or part of the Class Period, one or more Defendants manufactured and sold substantial amounts of Provigil in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Abbott maintained an exclusive license to market and sell Provigil in the United States.

23. At all material times, Provigil was manufactured and sold by one or more Defendants, shipped across state lines, and sold to customers located outside its state of manufacture.

24. During all or part of the Class Period (defined below), Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Provigil.

25. In furtherance of its efforts to monopolize and/or restrain competition in the market for Provigil and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

26. Defendant's efforts to monopolize and restrain competition in the market for Provigil alleged herein has substantially affected interstate and foreign commerce.

FACTUAL ALLEGATIONS

A. Brand-Name Drugs vs. Generic Drugs

27. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40%

of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at a rate of 14% to 18% per year, and the cost of drugs dispensed in the United States for the year 2001 was in the range of $160 billion to $170 billion.

28. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs.

29. To be deemed a therapeutical equivalent and assigned an "AB" rating by the FDA, the generic drug must contain the same active ingredient(s); dosage form and route of administration; and strength. If so, the generic drug, as a therapeutical equivalent, can be substituted (and in some instances must be substituted) for the pioneer or brand-name drug at the pharmacy dispensing the drug.

30. Generic drugs are normally priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party payors between $8 billion and $10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed, "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs."

31. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the

brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

32. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug's market share in just the first year of sale.

B. The Federal Scheme For Approval Of Pioneer Drugs

33. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act"), approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "brand-name" drug, must be sought by filing a New Drug Application ("NDA") with the FDA, demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 ("Hatch-Waxman Act").

34. In addition to information on safety and efficacy, NDA applicants must submit to the FDA a list of all "prior art," as well as patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted. "Prior art" is the term used in patent law to refer to that body of previous knowledge and technology against which a patent application is judged to

determine whether the claim is sufficiently novel to merit patent protection. When the NDA is approved, the FDA "shall publish" the patent information submitted by the NDA applicant. 21 U.S.C. § 355(b)(1).

35. Once the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in a publication known as the *Approved Drug Products With Therapeutic Equivalence Evaluations*. This publication is commonly called the "*Orange Book*." 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 name manufacturer, but trusts that the manufacturer will be truthful.

36. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug which has been approved by the FDA is available.

C. Prescriptions for Generic Drugs

37. Generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

38. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications,

the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-rated generic at a lower price.

39. Once a physician writes a prescription for a brand-name drug such as Provigil, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

D. Abbreviated New Drug Applications For Generic Drugs

40. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted by the manufacturer of the original, pioneer drug. The Hatch-Waxman Act also provides an economic incentive to the first ANDA filer for a particular generic drug: a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its drug free from competition from other generic manufacturers.

41. The ANDA must include information concerning the applicant's position *vis-a-vis* the patent that the pioneer drug manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications:

I. that no patent for the pioneer drug has been filed with the FDA (a

"Paragraph I Certification");

II. that the patent for the pioneer drug has expired (a "Paragraph II Certification");

III. that the patent for the pioneer 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 pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV Certifications.

42. If the ANDA contains a Paragraph IV Certification, the ANDA applicant must provide notice to the owner of each patent that is referred to in the certification, and to the holder of the approved NDA to which the ANDA refers. *See* 21 U.S.C. § 355(j)(2)(B)(I). The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's assertion that the patent is not valid or will not be infringed by the generic product. *See id.*; 21 C.F.R. § 314.95.

43. The brand-name drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(5)(iii). If no action is initiated within 45 days, the process for FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is

automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.

44. Accordingly, brand-name drug patent holders need only to file a patent infringement lawsuit within 45 days of receipt of Paragraph IV Certification in order to automatically block an ANDA applicant's generic drug from entering the market for up to 30 months.

45. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. 355(j)(5)(B)(iv). This 180 day exclusivity against other generic competitors is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity.

46. Hatch-Waxman also provides brand name 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 five years of exclusivity from the date of approval of the NDA. In addition, if an NDA drug treats a rare condition, the FDA may, if appropriate, grant an additional two years of "Orphan Drug" exclusivity.

47. As detailed below, Cephalon sought and obtained both NCE and Orphan Drug

exclusivity for Provigil. These exclusivities expired on December 24, 2003 and December 24, 2005, respectively.

E. Defendants' Unlawful Scheme to Quash Generic Competition

1. Provigil

48. Provigil is a brand name drug manufactured by Cephalon. Provigil is marketed as a "wakefulness promoting agent" and is used in the treatment of certain sleep disorders, including narcolepsy and shift work sleep disorder. The active pharmaceutical ingredient in Provigil is modafinil.

49. Modafinil is a psychostimulant that enhances wakefulness and vigilance but its pharmacological profile, and thus its side effect and efficiency profile, is significantly different than drugs such as amphetamines and methylphenidate (also known as Ritalin). These drugs are not AB-rated to Provigil, and are not reasonably interchangeable with modafinil.

50. The FDA approved Cephalon's NDA for Provigil on December 24, 1998, and Cephalon began selling Provigil shortly thereafter. Because modafinil was an NCE, Cephalon received five years of NCE exclusivity. Provigil's NCE exclusivity expired on December 24, 2003.

51. 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.

52. In anticipation of the expiration of Provigil's NCE and/or Orphan Drug exclusivities, each of the Generic Defendants developed AB-rated generic versions of Provigil and filed an ANDA seeking FDA approval for such generic versions. Each Generic Defendant

filed its ANDA on December 24, 2002, the first day that ANDAs for generic version of Provigil could be filed under the applicable provisions of Hatch-Waxman. Thus, each of the Generic Defendants shared the 180 days of generic exclusivity that is provided by Hatch-Waxman to the first generic challenger(s) to file ANDAs with Paragraph IV certifications.

53. Each of the Generic Defendants received tentative approval from the FDA for its generic version of Provigil prior to December 24, 2005, the date that Orphan Drug exclusivity for Provigil expired: Barr on January 7, 2004; Ranbaxy on February 18, 2004; Mylan on February 9, 2005; and Teva on December 16, 2005. "Tentative approval" means that an ANDA is deemed by FDA to be safe, effective and bioequivalent to its brand name counterpart, but the existence of some legal or regulatory barrier (such as legal exclusivity) precludes the FDA from granting final approval to sell the generic product at issue.

54. As further detailed below, absent 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 - 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.

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

55. 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.

56. Rules governing patent prosecution impose a duty of candor and good faith on

those dealing with the United States Patent & Trademark Office ("PTO"), "which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56. The rule provides that:

> Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

57. 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 PTO. Because the compound modafinil was prior art, the '124 Application could not validly claim broadly the compound modafinil. Instead, the '124 Application narrowly claimed very specific formulations of modafinil, as well as certain uses of those narrow formulations.

58. In conjunction with filing the '124 Application, the named inventors assigned their interests to Cephalon and submitted declarations acknowledging their duty of candor 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, as well as 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").

59. 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, FDA approved NDA No. 20-717. Shortly thereafter, Cephalon began commercially marketing Provigil.

60. 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"). The filing of the RE '166 Application 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.

61. 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

62. 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.

63. On or about February 25, 2003, Teva notified Cephalon that it had filed ANDA No. 76-596 seeking to market generic versions of Proviigil 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.

64. 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.

65. On March 28, 2003, Cephalon filed suit in the United States District Court for the District of New Jersey, alleging infringement of the RE '516 Patent by the Generic Defendants.

66. During discovery, as recited immediately below, 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 the patent's claims; and (3) the strength of Cephalon's infringement theory.

67. For example, despite representations, declarations and/or suggestions to the contrary, the modafinil compositions and methods claimed in the '845 Patent and the RE '516 Patent (collectively the "Cephalon Patents") were manufactured and developed by scientists at Labortoire L. Lafon ("Lafon"), rather than scientists at Cephalon. 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. To the contrary, 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 to properly disclose these facts, but again intentionally declined to do so.

68. The named inventors and prosecuting attorneys similarly did not inform the PTO

that Lafon sold and delivered modafinil tablets to Cephalon prior to the Cephalon Patents' critical date of October 6, 1993, under a Supply Agreement and a License Agreement executed in January of 1993. The modafinil tablets and modafinil active pharmaceutical ingredient ("API") sold and delivered to Cephalon prior to the critical date fall within some, if not all, of the composition claims recited in the Cephalon Patents. The sale and delivery of modafinil tablets and modafinil API under the Supply Agreement were highly material to patentability and 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 to properly disclose these facts, but again intentionally declined to do so.

69. The named inventors and/or prosecuting attorneys for the Cephalon Patents intentionally misrepresented in the patent specification, and in Peter Grebow's September 26, 1995 declaration, that certain domestic and foreign clinical trials had followed the same protocol. In fact, 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. During patent prosecution, Cephalon relied upon the existence of purported differences in adverse effects in the domestic and foreign trials in support of patentability, without telling the PTO Examiner about the critical protocol change. The protocol change was material in part because it offered an explanation for the alleged adverse effects different than the explanation advanced by Cephalon in support of patentability. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

70. 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 reality, Lafon informed Cephalon in February 1993 that a single 600 mg dose of modafinil may cause adverse effects, a fact specifically known to Peter Grebow. Furthermore, the named inventors report in the specification that no clinically significant adverse events occurred in the foreign clinical trials conducted by Lafon. In fact, numerous serious adverse events were observed during those foreign clinical trials. Grebow was aware of those instances of adverse events and even forwarded Lafon's "serious adverse event" information to a Canadian counterpart.

71. 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 both the critical date and the alleged conception date. The subjects of the first United States 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. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

72. 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 was still pending and before the RE '516 Patent was filed), concluded that there was no statistically significant difference in the peak plasma levels as a function of modafinil particle size. 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 opportunity to properly disclose these facts, but again intentionally declined to do so.

73. The named inventors and/or prosecuting attorneys also 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 modaf nil API Lafon sold and delivered to Cephalon, including API Lot 003. 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. 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. In fact, Lafon scientists 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, 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 1993, more than one year prior to the filing date, which suggests that modafinil bioavailability differences may be caused by the particle size distribution. These misrepresentations and omissions were material to patentability. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

74. In February 2005, the Generic Defendants filed amended answers alleging in detail the facts above supporting their inequitable conduct defenses and counterclaims. Many of these same facts supported a finding that some or all of the claims of the RE '516 Patent were invalid.

75. Based on the facts and circumstances alleged above, in August and September 2005, the Generic Defendants filed a series of 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.

76. 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 clear and 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. Most of the information relevant to these non-infringement claims is not publicly available.

77. 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 a judicial resolution of the defenses the Generic Defendants had raised.

78. As a result of the facts and circumstances detailed above, each of the Defendants knew or should have known that, because Cephalon's patent claims were weak, and the Generic Defendants' patent defenses were strong, that absent settlements, it was highly likely that Cephalon would have lost the patent litigations involving Provigil on the merits.

3. The Prelude to the "Exclusion Payment" Agreements

79. Cephalon began selling Provigil in December 1998. Cephalon was the only company permitted to sell modafinil from December 1998 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).

80. Despite the fact that Cephalon received the 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), sales of Provigil grew substantially, exceeding $420 million in 2004 and $500 million in 2005. The federal government is currently investigating whether Cephalon improperly inflated 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.

81. 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. There are several reasons why Cephalon knew before December 2005 that generic competition was imminent. First, 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 explained above, 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 the grant of final approval to sell the generic product is the existence of some form of legal or regulatory exclusivity - such as Orphan Drug exclusivity.

82. Since Cephalon knew that its Orphan Drug exclusivity was set to expire on December 24, 2005, it also knew that if it did nothing, (a) the Generic Defendants were likely to obtain final approval of their ANDAs and come to market with their generic versions of Provigil on or shortly after December 24, 2005; and (b) Cephalon would quickly lose the vast majority of its Provigil sales because purchasers would switch to the bioequivalent - but substantially less expensive - generic versions of Provigil.

83. Second, 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, automatically obtained by Cephalon merely by filing their meritless patent suits against the Generic Defendants (within 45 days of receipt of the generics' Paragraph IV Certifications), expired by no later than September 2005; (b) Cephalon's patent did not give it an automatic right to exclude its generic competitors, but rather a right to use its patent 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 the underlying suit in order to obtain an injunction order to keep the Generic Defendants off the market after expiration of the 30 month stay. However, the weakness of Cephalon's patent claims, and the strength of the patent defenses raised by Generic Defendants in the underlying patent cases, precluded Cephalon from obtaining a court order enjoining generic competition. In fact, as detailed above, Cephalon could not have established a likelihood of success on the merits, because it was highly likely that, but for the settlements, Cephalon would have lost the patent cases on the merits.

84. Indeed, Cephalon management was so convinced that generic competition was imminent prior to December 2005 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 to emerge in 2006.

85. Moreover, and significantly, Cephalon management also told securities analysts in November 2005 that Cephalon had reduced its promotional spending on Provigil in late 2005 because of its expectation that generic competition would commence promptly. It is common practice in the pharmaceutical industry for brand name manufacturers to reduce detailing for a brand name drug at or shortly before they expect generic competition. Such a reduction in promotion activity makes rational economic sense only if generic competition is expected in the very near future, because the reduction in promotion, by itself, could lead to substantially reduced sales and profits for the brand name manufacturer.

86. Third, 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 did not constitute a significant or meaningful improvement over Provigil, but was simply a vehicle by which Cephalon could 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 readily substitutable for - the existing generic versions of Provigil.

87. 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, which did not face imminent generic competition. Therefore, Cephalon's plans regarding Nuvigil were well known in the pharmaceutical industry - - and thus were known by the Generic Defendants -- when the Generic Defendants commenced settlement negotiations with Cephalon.

4. The Negotiation and Execution of Defendants' Market Allocation Agreements

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

89. Because Cephalon's patent infringement claims against the Generic Defendants were weak, the existence of these claims would not deter 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 forego their right to profit from the sale of their generic versions of Provigil after Cephalon's Orphan Drug exclusivity expired.

90. In order to protect and maintain its monopoly power in the modafinil market, it would have to induce all of the Generic Defendants to refrain from selling their generic versions of Provigil, because the entry of even a single generic product would quickly cause the majority of modafinil purchases to switch from Cephalon's branded Provigil to the substantially less expensive, but bioequivalent, generic version(s) of Provigil.

91. On December 9, 2005, Cephalon announced that it had reached an agreement to settle its patent litigation with Teva. The settlement agreement was not made available to the public. According to Cephalon's and Teva's press releases, however, under the agreement, Teva must keep its generic version of Provigil off the market until 2011 (or 2012, if Cephalon obtained a six-month pediatric exclusivity extension), unless another generic manufacturer enters the market prior to that time. Teva also received substantial (but undisclosed) cash payments.

92. The purpose and effect of the agreement was to delay generic competition to Provigil for 6 years or more, and thereby maintain and extend Cephalon's modafinil monopoly well past the date by which generic entry previously had been expected. In fact, following the settlements, Cephalon's Chief Executive Officer, Frank Baldino, Jr., candidly explained the rise in Cephalon's stock price following the announcements of the settlements as follows:

> "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."

Philadelphia Business Journal, March 20, 2006.

93. Defendants claim the cash payments to Teva were in exchange for: (1) licenses to Teva's worldwide intellectual property "relating to the manufacture, development and formulation of modafinil"; and (2) "certain agreements with Teva relating to Teva's manufacture and supply of the active pharmaceutical ingredient modafinil." In fact, however, these payments were in exchange for Teva's agreement to keep its generic version of modafinil off the market until 2011 or 2012 (*i.e.*, for up to 6 ½ years).

94. The payments to Teva were, in fact, payments to exclude Teva's generic modafinil, based on several factors. First, prior to the settlement, Cephalon had been selling modafinil since February 1999 in the United States, and since 1998 in Europe, without a license under Teva's intellectual property. Thus, Cephalon had no need or use for a license from Teva - other than to use such a license as a subterfuge to conceal the fact that it was paying Teva not to compete in the modafinil market for up to 6 ½ years.

95. Second, according to published reports, Cephalon also paid for a supply agreement from Teva for the active ingredient modafinil. 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, and did not suddenly need such an agreement in December 2005. Again, Teva's agreement to supply Cephalon with modafinil was simply a subterfuge to conceal the fact that Cephalon was paying Teva not to compete with Cephalon's Provigil product for up to 6 1/2 years.

96. Third, since Cephalon's patent claims were very weak, Teva's agreement to stay off the market until 2011 (or 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 of those nine remaining years. Thus, logic and economic rationality dictate that: (a) Teva must have received compensation for its agreement to stay off the market until 2011 (or 2012); 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 compensation for these payments.

97. Fourth, as of the date of its settlement with Cephalon, Teva was well aware that its ability to market a generic version of Provigil in 2011 (or 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 prior to the entry of generic versions of Provigil; and (2) Teva's generic product would not be AB-rated to Nuvigil (since Nuvigil had a different dosage strength and/or formulation than Provigil), and thus would not be substitutable by pharmacists. Thus, Teva knew that by the time it was permitted under its settlement 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.

98. 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, while continuing to market Provigil. After the agreements, however, Cephalon publicly stated that its intent was: (a) to delay marketing Nuvigil until 2010 - a year before the Generic Defendants were permitted to sell generic versions of Provigil under the agreements; and (b) to stop promoting/selling Provigil at that point, and to convert market demand for modafinil from Provigil to Nuvigil prior to the market entry of generic Provigil.

99. The announcement of Cephalon's first settlement (with Teva) created expectations that Cephalon would settle with the other Generic Defendants. These expectations were reasonable because, as explained above, it made little economic sense for Cephalon to settle with less than all of the Generic Defendants, since any one of them would have toppled Cephalon's modafinil monopoly if they had come to market with an AB-rated generic equivalent to modafinil.

100. As expected, Cephalon in fact settled with the remaining Generic Defendants shortly after announcing its settlement with Teva.

101. Specifically, Cephalon settled with Ranbaxy on December 22,2005; with Mylan on January 10, 2006; and with Barr on February 1, 2006. Like the Teva settlement, the Ranbaxy and Barr settlement agreements were not made publicly available. However, according to the parties' press releases and SEC filings, the Ranbaxy and Barr agreements, like the Teva agreement: (a) required the generic manufacturers to keep their generic versions of Provigil off the market until 2011 or 2012 (unless another generic enters the market before them); but (b) provided cash payments to the generic manufacturers purportedly for licenses to the generics' worldwide intellectual property relating to modafinil and for supply/inventory purchase agreements with the generics.

102. Indeed, according to Cephalon's 200510-K, the payments to Teva, Ranbaxy and Barr will total up to $136 million.

103. Moreover, like the Teva agreement, the licenses and the supply agreements in the Ranbaxy and Barr agreements were merely subterfuges to conceal the fact that the payments to Ranbaxy and Barr were actually in exchange for their agreements to keep their generic versions of Provigil off the market for up to 6 ½ years.

104. While the press releases regarding the Mylan settlement did not disclose specific terms (other than Mylan's agreement to stay off the modafinil market until 2011 or 2012), upon information and belief, Cephalon similarly provided compensation to Mylan in exchange for its agreement not to compete. Indeed, not coincidentally, on the same day as Cephalon and Mylan executed their settlement agreement, the two companies executed two purported "product development collaboration agreements," under which Cephalon would make royalty payments to Mylan, purportedly on net sales of products unrelated to modafinil.

105. For the reasons detailed above, it would be economically irrational for Mylan to agree to keep its generic version of Provigil off the market for up to 6 1/2 years unless it was receiving substantial compensation in exchange for its agreement not to compete.

106. Absent the Generic Defendants' illegal agreements not to compete with Cephalon for up to 6 1/2 years, each and all of the Generic Defendants would have obtained final FDA approval to sell their generic versions of Provigil, and would have commenced selling their less expensive generic versions of Provigil, by no later than January 2006. Absent the illegal "exclusion payments" they received from Cephalon, the Generic Defendants would have been motivated to begin selling its generic version of Provigil as soon as possible, in order to reap a

substantial return on the significant investment each had made in developing and seeking FDA approval for their generic versions of Provigil. Moreover, absent the exclusion payments they received from Cephalon, each of the Generic Defendants would have been motivated to come to market promptly because each knew that, if it did not come to market, the other Generic Defendants would likely do so, and capture the sales of generic Provigil that it otherwise would have obtained if it had come to market.

107. On or about March 28, 2006, Cephalon received a six-month pediatric exclusivity extension from the FDA. This extension, however, applies only to exclusivities which have not yet expired on the date that the extension is granted. Since Cephalon's Orphan Drug exclusivity for Provigil expired on December 24, 2005, Cephalon's receipt of a pediatric extension on March 28, 2006, over 90 days after the expiration of Cephalon's Orphan Drug exclusivity, 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.

G. Effects on Competition and Damages to Plaintiff and Class

108. Defendants' exclusionary conduct has delayed or prevented the sale of generic modafinil in the United States, and unlawfully enabled Defendants to sell Provigil at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of Provigil capsules by January 2006, and additional generic competitors would have entered the market thereafter.

109. If manufacturers of generic modafinil had entered the marketplace and effectively competed with Defendants earlier, as set forth above, Plaintiff and other members of the Class 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.

110. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Provigil directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiff and the other Class members paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; (2) Class members paid artificially inflated prices for generic modafinil and/or (3) the price of branded Provigil was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

CLASS ACTION ALLEGATIONS

111. Plaintiff brings this action on behalf of itself and as representative of a Class defined as follows:

> All persons or entities throughout the United States and its territories who purchased and/or paid for Provigil or generic versions of Provigil during the period December 23, 2003 to the present ("the Class Period") for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class"). For purposes of the Class definition, persons and entities "purchased" Provigil if they paid some or all of the purchase price.

Excluded from the Class are all Defendants, their officers, subsidiaries and affiliates; all

government entities (except for government-funded employee benefit plans); all persons or entities that purchased Provigil for purposes of resale, or directly from any of the Defendants or their affiliates; and the judge in this case and any members of his/her immediate family.

112. Plaintiffs seek class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to declaratory and equitable relief sought herein, and Rule 23(b)(3) as to the damages sought herein.

113. Although Plaintiff does not know the exact number of class members, it believes it to be, at a minimum, in the tens of thousands. Provigil has annual U.S. sales of $406 million for the year 2004 and over $475 million in 2005. Thus, members of the Class are numerous and joinder is impracticable. The Class members are identifiable, from information *inter alia,* and records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefits managers, and managed care organizations.

114. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members, in part because Defendants have acted and refused to act on grounds generally applicable to the entire Class, thereby making appropriate equitable, injunctive and declaratory relief with respect to the Class as a whole. Such conduct includes the Defendants' exclusionary and anti-competitive efforts in filing sham litigation and converting the relevant market from one confronted with generic competition to one that is not for the sole purpose of monopolizing and attempting to monopolize the market for Provigil.

115. Questions of law and fact common to the Class include:

(a) whether Defendants maintained or attempted to maintain monopoly power by delaying generic entry;

(b) whether Defendants' agreements constitute illegal market allocation agreements;

(c) whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

(d) to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

(e) whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

(f) whether Defendants' litigation asserting infringement of its patents described herein was baseless;

(g) whether Defendants engaged in sham litigation for the purpose of preventing competition;

(h) whether Defendants intentionally and unlawfully excluded competitors and potential competitors from the market for Provigil and generic bio-equivalents to Provigil;

(i) whether Plaintiff and members of the Class are entitled to declaratory, equitable and/or injunctive relief; and

(j) whether Plaintiff and the Class have been damaged and the aggregate amount of damages.

116. Plaintiff's claims are typical of the members of the Class, in that Plaintiff purchased and/or paid for Provigil throughout the United States, including the Indirect Purchaser States, during the Class Period. Such purchases and payments were made for consumer consumption of Provigil. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

117. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiff are not antagonistic to those of the Class. In addition, Plaintiff is

represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

118. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

119. Plaintiff knows of no difficulty to be encountered by litigating of this action that would preclude its maintenance as a class action.

FIRST CAUSE OF ACTION

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTIONS 1 AND 2 OF THE SHERMAN ACT

120. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

121. Beginning on or about December 9, 2005, Cephalon and each of the Generic Defendants engaged in continuing illegal contracts, combinations and conspiracies 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 version of modafinil in the United States, thereby protecting Provigil from any generic competition for up to 6 ½ years; and (c) fix the price

at which direct purchasers would pay for Provigil at the higher, branded price. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' agreements are horizontal market allocation and price-fixing agreements between actual or potential competitors, and thus are per se violations of Section 1. In the alternative, Defendants' agreements are unreasonable restraints of trade in violation of Section 1, pursuant to a "rule of reason" analysis.

122. In addition, Defendants knowingly and willfully engaged in a course of conduct designated to improperly obtain and extend their monopoly power in the Relevant Markets. This course of conduct included, *inter alia*, the following acts: (i) the prosecution of baseless, sham patent litigation(s) against a potential generic manufacturer(s); (ii) the intentional conversion of the relevant market from one confronting generic competition to one that is not; and (iii) the intentional frustration of generic competition by effectively eliminating the ability for a generic therapeutical equivalent to be substituted for a Provigil product. The result of Defendants' unlawful conduct has been to obtain and extend their monopoly.

123. Defendants intentionally and wrongfully created and maintained a monopoly power in the Relevant Markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

124. Plaintiff and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Provigil, and paying higher prices for such products than they would have paid in the absence of the antitrust violation. The injury to Plaintiff and the Class is the type of injury antitrust laws were designed

to prevent, and the injury flows from Defendants' unlawful conduct.

125. Plaintiff and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

126. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

SECOND CAUSE OF ACTION

FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

127. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

128. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statues §§ 480-2, 480-3, and 480-4.

f. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

g. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

h. Kentucky: The aforementioned practices by Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.,* and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;

i. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.,* and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

j. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

k. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

l. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

m. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.,* and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

n. Mississippi: The aforementioned practices by Defendant were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*;

o. Nebraska: The aforementioned practices by Defendant were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;

p. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;

q. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

r. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

s. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

t. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

u. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.,* and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

v. Tennessee: The aforementioned practices of Defendants were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;

w. Utah: The aforementioned practices of Defendants were and are in violation of the Utah Trade Practices Act, Utah Code Ann. §§ 13-5-1, *et seq.*, the Utah Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1, *et seq.*, and Utah Code Ann. § 76-10-919;

x Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

y. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West

Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

z. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq*.

129. As a result of the conduct described above, Plaintiff and the Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of Provigil, and paying prices for such products that were higher than they would have been but for Defendants' improper actions. The full amount of such damages are presently unknown and will be determined after discovery and upon proof at trial.

130. Plaintiff and the Class seek damages, multiple damages, treble damages, and other damages as permitted by state law, for their injuries caused by these violations pursuant to these statutes.

THIRD CAUSE OF ACTION

FOR INJUNCTIVE AND DECLARATORY RELIEF UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

131. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

132. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statues §§ 480-2, 480-3, and 480-4.

f. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

g. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

h. Kentucky: The aforementioned practices by Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;

i. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*, and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

j. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

k. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

l. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

m. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

n. Mississippi: The aforementioned practices by Defendant were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*;

o. Nebraska: The aforementioned practices by Defendant were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;

p. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the

Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;

q. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

r. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

s. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

t. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

u. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

v. Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;

w. Utah: The aforementioned practices of Defendants were and are in violation of the Utah Trade Practices Act, Utah Code Ann. §§ 13-5-1, *et seq.*, the Utah Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1, *et seq.*, and Utah Code Ann. § 76-10-919;

x. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

y. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

z. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq*.

133. Plaintiff and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Provigil, and paying higher prices for Provigil and generic versions of Provigil than they would have paid but for Defendants' improper actions. The injury to Plaintiff and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

134. Plaintiff and the Class, pursuant to laws of the Indirect Purchaser States, hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition through the scheme set forth herein is unlawful. Plaintiff and the Class further seek equitable and injunctive relief pursuant to the laws of the Indirect Purchaser States to correct for the anti-competitive market effects and other harms to purchasers caused by the unlawful conduct of Defendants, and other relief so as to assure that similar conduct does not occur in the future.

FOURTH CAUSE OF ACTION

FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS

135. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

136. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Specifically, Defendants have been unjustly enriched, to the detriment of Plaintiff and the Class by the receipt of, at a minimum, unlawfully inflated prices and/or illegal monopoly profits on their sale of Provigil.

137. Defendants have benefitted from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for Provigil made by Plaintiff and the Class.

138. Plaintiff and members of the Class are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiff and the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiff and the Class members may make claims on a *pro rata* basis.

WHEREFORE, Plaintiff prays that:

(a) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiff's claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and declare Plaintiff as the representative of the Class;

(b) the conduct alleged herein be declared, adjudged and decreed to be in violation of Sections 1 and 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;

(c) Plaintiff and each member of the Class be awarded damages and, where applicable, treble, multiple, and other damages, according to the laws of the Indirect Purchaser States, including interest;

(d) Plaintiff and each member of the Class recover the amounts by which Defendants have been unjustly enriched;

(e) Defendants be enjoined from continuing the illegal activities alleged herein;

(f) Plaintiff and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law;

(g) Plaintiff and the Class be granted such other and further as the Court deems just and necessary.

JURY DEMANDED

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: June 30, 2006

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