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

APOTEX, INC. 150 Signet Drive Weston, Ontario M9L 1T9 Plaintiffs v. CEPHALON, INC. 41 Moores Road Frazer, PA 19355 and BARR LABORATORIES, Inc. 2 Quaker Road Pomona, NY 10970 and MYLAN LABORATORIES, INC. 1500 Corporate Drive, Suite 400 Canonsburg, PA 15317 and TEVA PHARMACEUTICAL INDUSTRIES, LTD., 5 Basel St. Petach Tikva 49131, Israel and TEVA PHARMACEUTICALS USA, INC. 1090 Horsham Road North Wales, PA 19454 and RANBAXY LABORATORIES, LTD. 19, Nehru Place New Delhi 110 024, India	CIVIL ACTION NO. JURY TRIAL DEMANDED

and :
:
RANBAXY PHARMACEUTICALS, INC. :
600 College Road East, Suite 2108 :
Princeton, NJ 08540 :
:
Defendants :
:

COMPLAINT

Plaintiff Apotex, Inc. ("Plaintiff"), by and through its attorneys, complains against defendants Cephalon, Inc., Barr Laboratories, Inc., Mylan Laboratories, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Ranbaxy Laboratories, Ltd., and Ranbaxy Pharmaceuticals, Inc. (collectively "Defendants"), as follows:

PARTIES

1. Apotex Inc. ("Apotex") is a corporation organized and existing under the laws of Canada, whose principal place of business is located in Ontario, Canada.

2. Cephalon, Inc. ("Cephalon") is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon transacts business and resides in this district.

3. Ranbaxy Laboratories, Ltd. is a company organized and existing under the laws of India with a principal place of business at 19, Nehru Place, New Delhi 110 024, India.

4. Ranbaxy Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware. It is a wholly-owned subsidiary of Ranbaxy Laboratories, Ltd. It has a principal place of business at 600 College Road East, Suite 2108, Princeton, New Jersey 08540. (Collectively, Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals Inc. are referred to herein as "Ranbaxy".)

5. Mylan Laboratories, Inc. ("Mylan") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania.

6. Teva Pharmaceutical Industries, Ltd. is an Israeli company. Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. It is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. (Collectively, Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. are referred to herein as "Teva".)

7. Barr Laboratories, Inc. ("Barr") is a corporation organized and existing under the laws of New York, whose

principal place of business is located at 2 Quaker Road, Pomona, New York 10970.

JURISDICTION AND VENUE

8. This case arises under the Constitution, laws or treaties of the United States, 35 U.S.C. §§1-376 and 15 U.S.C. §§ 1,2,15, and 26, and 21 U.S.C. §355, which provide subject matter jurisdiction under 28 U.S.C. §§1331, 1337(a), and 1338(a) and (b).

9. Venue is proper in this District under 28 U.S.C. § 1391(b).

FACTS COMMON TO ALL COUNTS

10. Cephalon sells a product called Provigil®, which contains Modafinil as its active ingredient. Cephalon has directed the Food and Drug Administration ("FDA") to list United States Patent Numbers 4,927,855 ("the '855 Patent") and RE 37,516, which is a reissue of United States Patent Number 5,618,845 ("the '516 Reissue"), as covering Provigil® in the Orange Book. Cephalon is the owner by assignment of the '516 Reissue.

11. Cephalon sells, markets and distributes Provigil® throughout the United States, including this judicial district, and delivers Provigil® across state lines. Cephalon is engaged in, and its activities substantially affect, interstate commerce.

12. Cephalon obtained approval from the FDA to market its Provigil® product by a New Drug Application ("NDA") 20-717 on December 24, 1998, and began selling Provigil® shortly thereafter.

13. Because Modafinil was considered a new chemical entity ("NCE"), Cephalon received five years of NCE exclusivity. Cephalon's NCE exclusivity for Provigil® expired on December 24, 2003.

14. Because Cephalon represented to the FDA that Modafinil was a drug to treat a rare disorder (narcolepsy), Cephalon received Orphan Drug exclusivity. Cephalon's Orphan Drug exclusivity for Provigil® expired on December 24, 2005.

THE RELEVANT PRODUCT MARKET

15. Modafinil is the relevant product market.

16. Provigil® is the only FDA approved prescription medicine containing Modafinil, as an active ingredient, for treatment of excessive sleepiness associate with obstructive sleep apnea/hyponea syndrome and shift work sleep disorder.

17. There are no other FDA approved medications that are interchangeable with Modafinil to treat sleepiness associated with narcolepsy, treatment of excessive sleepiness associate with obstructive sleep apnea/hyponea syndrome and shift work sleep disorder.

18. Modafinil is the relevant product market because there are no other drugs that have been approved by the FDA as therapeutic equivalents to and/or substitutes for Modafinil.

19. According to the '516 Reissue, "Modafinil has been described as presenting a neuropsychopharmacological spectrum characterized by the presence of excitation with hyperactivity and of hypermotility; and by the absence of stereotypy (except in high doses) and of potentialisation of the effects of apomorphine and amphetamine."

20. Further, according to the '516 Reissue, the "neuropsycopharmacological profile of Modafinil has been distinguished from that of amphetamines."

21. Amphetamines and methylphenidate are schedule II controlled substances with an abuse potential. Modafinil is not a schedule II controlled substance.

22. Modafinal is a psychostimulant that enhances wakefulness and vigilance but its pharmacological profile, and thus its side effects and efficiency profile, is significantly different than drugs such as amphetamines and methylphenidate. Amphetamines and methylphenidate are neither therapeutically equivalent nor reasonably interchangeable with Modafinil.

23. Cephalon has not charged any generic drug manufacturer with infringing the '855 patent. The '855 patent term will expire on May 22, 2007.

24. The '516 Reissue relates to forms of the drug Modafinil. The '516 Reissue patent term will expire on October 6, 2014.

25. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the sales of Provigil® (Modafinil) tablets increased from 417.7 million dollars in 2004 to approximately 587.9 million dollars in 2005.

26. Because no FDA approved products are interchangeable with it, Provigil® (Modafinil) is the relevant product market.

THE GEOGRAPHIC MARKET

27. Cephalon sells its Provigil® (Modafinil) throughout the United States.

28. The United States is a relevant geographical market in which to assess the effects of Defendants' anti-competitive acts with respect to the relevant product market of Modafinil tablets.

29. Modafinil cannot be distributed by a pharmacist without a prescription from a physician.

30. Generic versions of branded drugs are drugs that the FDA has concluded are therapeutically equivalent or bio-equivalent to the branded drug. A generic drug is the same as a brand-name drug in dosage, safety, strength, how it is taken,

quality, performance and intended use. The FDA will not approve a generic drug unless it is safe and effective.

31. Because of the acts of the Defendants, no generic form of Provigil® (Modafinil) is currently available for sale in the relevant geographical market, i.e., the United States, and therefore, consumers do not have access to an alternative when obtaining a prescription for Provigil® (Modafinil).

CEPHALON'S VIOLATION OF ITS DUTY OF CANDOR TO THE USPTO WITH REGARD TO THE KNOWN INVALIDITY OF THE '516 REISSUE

32. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the '516 Reissue is unenforceable due to inequitable conduct by the named inventors and others who participated in the prosecution of the applications that resulted in the '516 Reissue. Specifically, the prosecuting attorneys and named inventors, Messrs. Rick Burgoon, Robert Hrubiec, Peter Grebow, Vincent Corvari and David Stong, had knowledge of material facts set forth below relevant to patentability, knew these facts to be material to patentability, and withheld them from or misrepresented them to the United States Patent and Trademark Office ("PTO") with deceptive intent.

33. On October 6, 1994, the prosecuting attorneys and named inventors filed United States Application Serial No. 08/319,124 ("the '124 Application") titled "Acetamide Derivative Having Defined Particle Size" with the PTO. By October 1994,

the compound Modafinil was prior art. Therefore, Cephalon could not validly claim the compound Modafinil in the application resulting in the '516 Reissue.

34. During prosecution of 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. The prosecuting attorneys were also bound by the duty of candor.

35. On April 8, 1997, the '124 Application issued as United States Patent Number 5, 618,845 ("the '845 patent").

36. On April 1, 1999, Cephalon filed a reissue application ("the RE '166 Application") for the '845 patent. During the prosecution of the RE '166 Application, the prosecuting attorneys and named inventors had a duty of candor to disclose all material information related to the RE '166 Application including any material related to whether the named inventors were the true and properly named inventors for the RE '166 Application. On January 15, 2002, the PTO issued Reissue Patent Number 37, 516 ("the '516 Reissue").

37. During the prosecution of both the '124 Application and the prosecution of the RE '166 Application, the duty of candor set forth in 37 C.F.R. §1.56(a) was applicable to anyone "substantively involved in the preparation or prosecution of the

application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." The duty of candor, under 37 C.F.R. §1.56(a), required disclosure of all information material the patentability of these applications, where

> "information ... material to patentability ... 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
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> (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.
>
> A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability."

37 CFR §1.56 further states that

> "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."

38. Any inequitable conduct, including non-disclosure of material information, that occurred in the prosecution of the

’124 Application or the RE ’166 Application renders the ’516 Reissue unenforceable.

39. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the Modafinil tablets used in all of the foreign and U.S. clinical studies and experiments discussed in the ’516 Reissue were previously developed and manufactured, i.e., invented, by scientists at Laboratoire L. Lafon (“Lafon”), and provided by Lafon to the named inventors. The ’516 Reissue is therefore invalid under 35 U.S.C. § 102 or § 103. The prosecuting attorneys and named inventors knew of these facts but did not disclose them to the PTO. However, these facts were material to patentability because they relate to derivation, inventorship, and obviousness of the claimed subject matter of the ’516 Reissue. The withholding of these facts was a breach of the duty of candor rendering the ’516 Reissue unenforceable.

40. For the reasons stated in ¶1-40, the ’516 Reissue is invalid pursuant to 35 U.S.C. § 102 and/or § 103.

41. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Lafon scientists and others in Europe developed the protocols for, and performed the foreign clinical studies discussed in, the ’516 Reissue as well as assisted the named inventors in the development of the protocol used in the U.S. clinical trial

discussed in the ’516 Reissue. The ’516 Reissue is, therefore, invalid under 35 U.S.C. § 102 or § 103. Nonetheless, the prosecuting attorneys and named inventors knew these facts yet failed to disclose them to the PTO. These facts were material to patentability because they relate to derivation, inventorship, and obviousness of the claimed subject matter of the ’516 Reissue. The withholding of these facts was a breach of the duty of candor rendering the ’516 Reissue unenforceable.

42. The specification of the ’516 Reissue gives the false impression that the named inventors developed and manufactured the Modafinil composition and methods described in the ’516 Reissue. Nowhere in the specification or the prosecution history did the named inventors or the prosecuting attorneys inform the PTO that the claimed Modafinil compositions and methods were developed and manufactured by Lafon. The ’516 Reissue is invalid under 35 U.S.C. § 102 or § 103. The prosecuting attorneys and named inventors knew these facts yet failed to disclose them to the PTO. These facts were material to patentability because they relate to derivation, inventorship, and obviousness of the claimed subject matter of the ’516 Reissue. The withholding of these facts was a breach of the duty of candor rendering the ’516 Reissue unenforceable.

43. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Lafon

sold and delivered Modafinil tablets and Modafinil active pharmaceutical ingredient ("API") to Cephalon prior to the critical date of October 6, 1993 (a year prior to the filing date of the '516 Reissue) under a Supply Agreement and a License Agreement executed in January of 1993. The Modafinil tablets and Modafinil API sold and delivered to Cephalon prior to the critical date were covered by some, if not all, of the composition claims recited in the '516 Reissue. The '516 Reissue is therefore invalid under 35 U.S.C. § 102 or § 103. While the prosecuting attorneys and named inventors knew of these facts, they failed to inform the PTO during the prosecution of the '516 Reissue. These facts were material to patentability because they relate to derivation, inventorship, and obviousness of the claimed subject matter of the '516 Reissue. The withholding of these facts was a breach of the duty of candor rendering the '516 Reissue unenforceable.

44. For the reasons stated in ¶¶ 1-44, the '516 Reissue is invalid pursuant to 35 U.S.C. §§ 102 and/or 103.

45. None of the named inventors had any role in the development of the early and late lot Modafinil API and tablets discussed in the '516 Reissue, including *inter alia*, the tablets (lot 006) manufactured from Lafon lot L-1 (003) API. These facts were not disclosed to the PTO by any of the named inventors or prosecuting attorneys. The failure of the

inventors and/or prosecuting attorneys of the ’516 Reissue to disclose Lafon’s role in the alleged invention gives the false and misleading impression that the named inventors developed the Modafinil tablets made from lot L-1 (003) API. The sale and delivery of Modafinil tablets and Modafinil API under the Supply Agreement of 1993 were material to patentability because those transactions relate to anticipation, use, inventorship, obviousness, derivation and the “on-sale” bar pursuant to 35 U.S.C. §§ 102 and 103. The withholding of these facts was a breach of the duty of candor rendering the ’516 Reissue unenforceable.

46. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that none of the named inventors had any role in the foreign clinical study discussed in the ’516 Reissue. This study was the work of Lafon scientists and others in Europe. While the named inventors and prosecuting attorneys knew of these facts, they failed to inform the PTO of them. Their failure to inform the PTO that this information was derived from Lafon gives the false and misleading impression that the foreign clinical study was the work of the named inventors and was a breach of the duty of candor.

47. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Lafon

scientists gave the named inventors verbal and written information and substantial assistance for the development of the protocol the named inventors used in the U.S. clinical trial. The named inventors and prosecuting attorneys knew these facts yet failed to inform the PTO during the prosecution of the '516 Reissue. Their failure to acknowledge Lafon's role in the development of the U.S. clinical trial protocol gave the false and misleading impression that the named inventors alone developed the U.S. clinical trial protocol and was a breach of the duty of candor.

48. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the composition claims of the '516 Reissue read directly on the Modafinil tablets manufactured from "late lot" Modafinil API. Modafinil Lot L-1 (003) API was manufactured and characterized by Lafon scientists, including its particle size distribution. Tablets made from Lot L-1 (003) API were developed and manufactured, i.e., invented by Lafon scientists and subsequently sold and delivered to Cephalon prior to the October 6, 1993 critical date under the supply and license agreements executed in 1993. This material fact was not disclosed to the PTO. The named inventors and prosecuting attorneys knew these facts were material to patentability pursuant to 35 U.S.C. §§102

and 103 and their failure to inform the PTO was a breach of their duty of candor.

49. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Lafon tablets (006) made from Lot L-1 (003) Modafinil API and Lafon's treatment protocols fall within the scope of some, if not all, of the claims in the '516 Reissue. These tablets and protocols were sold and delivered to Cephalon prior to the October 6, 1993 critical date under the supply and license agreements executed in 1993. This sale constitutes *inter alia* an invalidating prior sale and renders the '516 patent invalid under 35 U.S.C. § 102 and § 103. The named inventors and prosecuting attorneys knew these facts were material to patentability but failed to inform the PTO, which was a breach of their duty of candor.

50. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that all of the asserted claims of the '516 Reissue read on compositions and methods used in Cephalon's U.S. clinical trials, which were completed prior to October 6, 1993. The subjects of the U.S. clinical trial were members of the public, and they were under no obligation of confidentiality to Cephalon or the clinical investigators. The U.S. clinical trial thereby constitutes *inter alia* an invalidating public use and renders the '516 Reissue invalid under 35 U.S.C. § 102 and § 103. The named

inventors and prosecuting attorneys knew these facts were material to patentability but failed to inform the PTO, which was a breach of their duty of candor.

51. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the named inventors and prosecuting attorneys misrepresented in the patent specification and in Peter Grebow's September 26, 1995 declaration that the United States and foreign clinical trials discussed in the patent used the same dosing protocols. However, the U. S. clinical trial conducted by Cephalon utilized a once-a-day treatment using a full daily dose of Modafinil, while the foreign clinical trial conducted by Lafon utilized half of the daily dose of Modafinil in each of two daily doses. The difference in dosage protocol explains, at least in part, any discrepancy between the foreign and U.S. clinical trial results observed by the named inventors. These facts render the patent invalid under 35 U.S.C. §§ 101, 102, 103, or 112. The named inventors and prosecuting attorneys knew of the dosing protocol differences and falsely and misleadingly relied upon discrepancies in results to support arguments for patentability without telling the PTO about the dosing protocol differences. This misrepresentation was material to patentability because it relates to utility, derivation, inventorship and obviousness of the claimed subject matter of the '516 Reissue.

52. For the reasons stated in ¶¶ 1-52, the '516 Reissue is invalid pursuant to 35 U.S.C. §§ 102, 103 and/or 112.

53. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that, contrary to what is stated in the '516 Reissue, the named inventors concluded from the results of the bioavailability tests conducted on dogs, that there was not a statistically significant difference in dogs between the bioavailability of large and small particle size Modafinil. This conclusion is shown in and supported by the DM-93-014 report that Cephalon submitted to the FDA. That report, which was completed at least as early as November 8, 1996, concluded that there was no statistically significant difference in the peak plasma levels as a function of Modafinil particle size. Cephalon intentionally withheld that FDA report and the contradictory representations therein from the PTO during the prosecution of both the underlying '845 patent and '516 Reissue. These facts render the '516 Reissue invalid under 35 U.S.C. § 101, 102, 103 or 112. This information was material to patentability because it implicates utility, derivation and obviousness, and expressly contradicts an argument asserted in favor of patentability.

54. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the named inventors were not the first persons to consider the

importance of maintaining particle size controls for Modafinil tablets. Lafon scientists provided to the named inventors particle size information for all of the lots of Modafinil API that it had previously manufactured and provided to Cephalon, including all of the lots discussed in the '516 Reissue, and suggested to the named inventors that differences in bioavailability between the early and late lots of Modafinil API and tablets may have been due to differences in particle size. The 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. These misrepresentations and omissions were material to patentability because they relate to inventorship, derivation, obviousness, and prior publication under §§ 101, 102, 103 and 112.

55. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the patent is false and misleading in failing to identify Lafon scientists as the originators of the idea any differences in bioavailability between the foreign and U.S. Modafinil clinical trials may have been due to differences in particle size. The named inventors and prosecuting attorneys knew these facts were material to patentability but did not inform the PTO, which was a breach of their duty of candor.

56. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the named inventors were not the first to discover that Modafinil is a very slightly soluble compound. This is information they obtained from Lafon. That information renders the patent invalid under 35 U.S.C. § 102 or 103. The named inventors and prosecuting attorneys knew the information was material to patentability but did not inform the PTO, which was a breach of their duty of candor.

57. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Lafon had already considered the importance of maintaining particle size controls over Modafinil drug product 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 '516 Reissue gives 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, 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 documents published in or before September of 1993, more than one year prior to the filing date, which suggest to persons having ordinary skill in the art of the '516 Reissue that differences in Modafinil bioavailability can be caused by differences in particle size. These facts render the '516 Reissue invalid under 35 U.S.C. § 101, 102, 103 or 112. The named inventors and prosecuting attorneys knew these facts were material to patentability but did not inform the PTO, which was a breach of their duty of candor.

58. For the reasons stated in ¶¶ 1-58, the '516 Reissue is invalid pursuant to 35 U.S.C. §§ 101, 102, 103 and/or 112.

THE CONSPIRACY TO MONOPOLIZE THE MARKET FOR MODAFINIL

59. In anticipation of the expiration of Cephalon's NCE and/or Orphan Drug exclusivities for Provigil®, Barr, Ranbaxy, Mylan, and Teva (collectively, "Generic Defendants") each filed an ANDA on December 24, 2002, the first day that ANDAs for generic versions of Provigil® could be filed under the NCE provisions of the Hatch-Waxman Act.

60. Each of the Generic Defendant's ANDA filings included a Paragraph IV certification stating that the commercial manufacture, use and/or sale of its generic Modafinil drug product would not infringe any valid claim of the '516 Patent. Thus, each of the Generic Defendant's 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.

61. Prior to March 28, 2003, each of the Generic Defendant's notified Cephalon that it had filed an ANDA, with the notice letter including a Paragraph IV certification. On or about March 28, 2003, Cephalon filed a complaint in the United States District Court for the District of New Jersey charging Mylan, Teva, Barr and Ranbaxy with infringement of the '516 Reissue.

62. Mylan, Teva, Barr and Ranbaxy responded to the complaint asserting various defenses; however, neither Mylan, Teva, Barr nor Ranbaxy charged that the '516 Reissue had been obtained by inequitable conduct.

63. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that on or before December 14, 2004, Mylan, Teva, Barr and Ranbaxy learned through discovery in the matter that the '516 Reissue was invalid and also unenforceable due to inequitable conduct by the

named inventors and attorneys who prosecuted the applications that led to the '516 Reissue and the original U.S. Patent Number 5,618,845.

64. On or about December 14, 2004, Ranbaxy filed a motion seeking leave to file a first amended answer to the Cephalon complaint and charging that the '516 Reissue was unenforceable due to inequitable conduct by the named inventors and attorneys who prosecuted the applications that resulted in the '516 Reissue and the original U.S. Patent Number 5,618,845.

65. On or about December 17, 2004, Teva filed a motion seeking leave to file a first amended answer to the Cephalon complaint and charging that the '516 Reissue was unenforceable due to inequitable conduct by the named inventors and attorneys who prosecuted the applications that resulted in the '516 Reissue and the original U.S. Patent Number 5,618,845.

66. On or about December 17, 2004, Mylan filed a motion seeking leave to file a first amended answer to the Cephalon complaint and charging that the '516 Reissue was unenforceable due to inequitable conduct by the named inventors and attorneys who prosecuted the applications that resulted in the '516 Reissue and the original U.S. Patent Number 5,618,845.

67. In August and September 2005, the Generic Defendants filed motions for summary judgment that some or all of the claims of the '516 Reissue were invalid, as a matter of law.

68. On September 28, 2005, the 30-month automatic stay, which began with Cephalon filing suit on March 28, 2003 and that prevents generic drug manufacturers from entering the market, expired. However, the Generic Defendants still could not enter the market on September 28, 2005, because Cephalon had obtained Orphan Drug exclusivity blocking entry of any generic until December 24, 2005. Prior to December 24, 2005, the Generic Defendants received tentative approval from the FDA for their generic versions of Provigil® – Barr on January 7, 2004; Ranbaxy on February 18, 2004; Mylan on February 9, 2005; and Teva on December 16, 2005.

69. Tentative approval means that an ANDA is deemed by the FDA to be safe, effective and the bioequivalent of its brand name counterpart, but the existence of some legal or regulatory barrier (such as Orphan Drug exclusivity) precludes the FDA from granting final approval to sell the generic product at issue. Cephalon knew that after December 24, 2005, there would be no barrier precluding the FDA from granting final approval to the generic product at issue, or entry into the market by Barr, Ranbaxy Mylan and/or Teva.

70. As detailed above and below, absent Defendants' wrongful and exclusionary conduct, each, or at least one, of the Generic Defendants would have obtained final FDA approval and would have begun selling its generic Modafinil drug product on

or shortly after Cephalon's Orphan Drug exclusivity for Provigil® expired on December 24, 2005.

71. Had any one of the Generic Defendants begun selling its generic version of Provigil®, it would have triggered the 180-day exclusivity provided to the first generic challenger to file an ANDA with a Paragraph IV certification. Because of the Defendants' wrongful and exclusionary conduct, none of the Generic Defendants have triggered the 180 day exclusivity, meaning that all other generic drug manufacturers, including Plaintiff, are prohibited from entering the Modafinil market.

Teva's Participation in the Conspiracy with Cephalon

72. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that between December 17, 2004, and December 9, 2005, meetings were held between representatives of Cephalon and representatives of Teva concerning Modafinil.

73. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that at those meetings an agreement was reached where Teva agreed not to market a generic Modafinil product until October, 2011, absent a pediatric extension (which has since been granted, extending the exclusion until April 2012) or the entry of another generic Modafinil drug product.

74. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Teva is to receive payments from Cephalon to stay out of the market and said payments being larger than Teva's anticipated profits from its share of the Modafinil market.

Ranbaxy's Participation in the Conspiracy with Cephalon

75. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that between December 17, 2004, and December 22, 2005, meetings were held between representatives of Cephalon and representatives of Ranbaxy concerning Modafinil.

76. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that at those meetings an agreement was reached where Ranbaxy agreed not to market a generic Modafinil product until October, 2011, absent a pediatric extension (which has since been granted, extending the exclusion until April 2012) or the entry of another generic version of Provigil®.

77. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Ranbaxy is to receive payments from Cephalon to stay out of the market and said payments being larger than Ranbaxy's anticipated profits from its share of the market for generic Provigil®.

Mylan's Participation in the Conspiracy with Cephalon

78. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that between December 17, 2004, and January 10 2006, meetings were held between representatives of Cephalon and representatives of Mylan concerning Modafinil.

79. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that at those meetings an agreement was reached where Mylan agreed not to market a generic Modafinil product until October, 2011, absent a pediatric extension (which has since been granted, extending the exclusion until April 2012) or the entry of another generic version of Provigil®.

80. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Mylan is to receive payments from Cephalon to stay out of the market and said payments being larger than Mylan's anticipated profits from its share of the market for generic Provigil®.

Barr's Participation in the Conspiracy with Cephalon

81. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that between December 17, 2004, and February 1, 2006, meetings were held between representatives of Cephalon and representatives of Barr concerning Modafinil.

82. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that at those meetings an agreement was reached where Barr agreed not to market a generic Modafinil product until October, 2011, absent a pediatric extension (which has since been granted, extending the exclusion until April 2012) or the entry of another generic version of Provigil®.

83. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Barr is to receive payments from Cephalon to stay out of the market and said payments being larger than Barr's anticipated profits from its share of the market for generic Provigil®.

Cephalon's Further Participation in the Conspiracy with Teva, Ranbaxy, Mylan and Barr

84. The introduction of a generic version of Provigil® would introduce direct competition against Cephalon's Modafinil product and lead to lower prices for Provigil® and its generic competition.

85. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the Chairman and Chief Executive Officer of Cephalon stated that the absence of generic competition would provide a "new foundation for further accelerating Cephalon's growth over the next several years."

86. Cephalon made these payments to Teva, Mylan, Ranbaxy and Barr to protect its monopoly profits from its sales of Provigil®. By settling with Teva, Mylan, Ranbaxy and Barr and removing the threat of generic competition Cephalon is able to maintain the price of Provigil® artificially higher than it would be with generic competition.

87. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the settlement agreements between Cephalon and each of the Generic Defendants contain a "poison pill," which is a provision that, if anyone else succeeds in a challenge to the patent, the date at which the Generic Defendants parties can launch is accelerated to pre-empt the successful challenger.

APOTEX AND ITS ANDA FOR MODAFINIL TABLETS

88. Apotex manufactures for sale both in Canada and the United States a number of generic drugs. Apotex has become familiar with the regulatory requirements of filing an ANDA and the benefits that the first to file receive.

89. On March 30, 2005, Apotex filed its ANDA number 77-667 for a generic version of Provigil®. Apotex included a Paragraph III certification stating that it would not sell until the patent expired.

90. Apotex did not initially file a Paragraph IV certification because it knew that it would not be the first to

file and that there were four companies who were the first to file. Apotex had a reasonable expectation that when the patent was held invalid by a U.S. District Court it would receive approval and be able to market its generic version of Provigil® at the conclusion of the 180 days of exclusivity to which the first to file was entitled.

91. When Apotex learned through the various press releases that the first filers, Mylan, Teva, Barr and Ranbaxy, had settled the lawsuit with Cephalon with an agreement not to pursue their claims that the '516 Reissue was invalid, Apotex changed its certification from a Paragraph III certification to a Paragraph IV certification.

92. Nonetheless, Apotex will be prevented from receiving final approval for its ANDA and will not be able to sell a generic version of Provigil® because the settlement agreements entered between Cephalon and Mylan, Teva, Barr and Ranbaxy insure that Cephalon will not have the '516 Reissue declared invalid by a court of law. Further, the 180 days of exclusivity from other generic competitors that Mylan, Teva, Barr and Ranbaxy are entitled to as the first to file an ANDA for a generic version of Provigil® will not begin to run until they market their generic version of Provigil® under the settlement agreements with Cephalon ("Cephalon Settlement").

93. The FDA will not give final approval to Apotex's ANDA until 180 days after Mylan, Teva, Barr and Ranbaxy begin to market their generic version of Provigil®.

94. The Cephalon Settlement has an anti-competitive on Apotex. Because of the anti-competitive settlement agreement between Mylan, Teva, Barr, Ranbaxy and Cephalon, Apotex is being denied its right to obtain final approval from the FDA to sell and market its generic version of Provigil® at lower prices to the consumer.

ANTI-COMPETITIVE CONDUCT

95. The first generic company to introduce a generic product usually obtains a large portion of the generic market. Here, the four Generic Defendants would all be allowed to enter the market and potentially enjoy the 180-day exclusivity stemming from being the first to file.

96. If allowed to be first, the Generic Defendants would assume a large portion of the generic market for Modafinil.

97. The agreements between Cephalon and the Generic Defendants, including the "poison pill" thus eliminate any potential value for another generic competitor to challenge Modafinil, thus improperly stifling competition and creating a bottleneck for other generic competitors.

98. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon

listed the ’516 Reissue with the FDA as covering Provigil® with full knowledge that it was obtained by fraud and/or inequitable conduct.

99. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon listed the ’516 Reissue with the FDA as covering Provigil® with full knowledge that it is invalid for failure to comply with one or more provisions of Title 35, United States Code.

100. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon improperly received the two years of Orphan Drug exclusivity.

101. Cephalon represented to the FDA that Provigil® was a niche drug used to treat a rare disorder that would have a limited potential market. However, in fact, Cephalon may have intended to have Provigil® be used for treatments beyond the rare disorders.

102. Cephalon could not have obtained a preliminary injunction against the Generic Defendants preventing them from marketing and/or selling generic versions of Provigil® after December 24, 2005, which is the date that the Orphan Drug exclusivity ended.

103. Cephalon did not seek a preliminary injunction against any of the Generic Defendants.

104. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon and the Generic Defendants all knew that the patent infringement claims made by Cephalon against the Generic Defendants were weak at best. As a result, the existence of the '516 Reissue or the patent litigations alleging infringement could not keep the Generic Defendants out of the market for Provigil®.

105. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon and the Generic Defendants all knew that Cephalon could not maintain its monopoly over the market for Provigil® and/or Modafinil after December, 2005, by enforcing the '561 Reissue patent. Instead of using the '561 Reissue patent to maintain its monopoly, Cephalon and the Generic Defendants entered into settlement agreements whereby, in effect, Cephalon paid the Generic Defendants to maintain its monopoly on Provigil®.

106. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that because they knew that the '561 patent was invalid or unenforceable, the Generic Defendants would not have stayed out of the generic market for Provigil® based on the threat of enforcement of the '561 patent or the then pending lawsuits against them. Instead, 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 Modafinil drug products after Cephalon's Orphan Drug exclusivity expired in December, 2005.

107. In order to maintain its monopoly power in the Modafinil market, Cephalon would have to induce all of the Generic Defendants to refrain from marketing generic versions of Provigil® because entry of even one generic would cause the majority of Modafinil sales to transfer to the FDA-approved, therapeutically equivalent generic Modafinil drug product.

108. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon listed the '516 Reissue with the FDA as covering Provigil® with the improper purpose of creating a barrier to entry into the Modafinil market .

109. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon entered into the agreements with Mylan, Teva, Barr and Ranbaxy for the purpose of creating a barrier to entry into the Modafinil market.

110. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon knew that the Generic Defendants would have entered the Modafinil market in 2006 unless they paid the Generic Defendants to stay out. Cephalon's CEO, Frank Baldino Jr., stated:

> "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.

111. On December 9, 2005, Cephalon announced an agreement with Teva. The settlement agreement was not made available to the public. Based in part on Cephalon and Teva's press releases surrounding the agreement, it is likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that Teva must keep its generic Modafinil drug product off the market until 2012. The agreement also contained a "poison pill" provision that accelerated the date Teva could sell if another generic manufacturer succeeds in challenging the patent.

112. Cephalon also agreed to make a substantial cash payment to Teva. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon and Teva considered the agreement and payment by Cephalon to Teva for the purpose of allowing Cephalon to maintain its monopoly on Modafinil. Teva settled with Cephalon predominantly, if not wholly, because of the cash payment made to it by Cephalon. Teva did not settle because of any fear of enforcement of the '561 Reissue patent. Cephalon's payment was predominantly, if not wholly, to maintain its

monopoly position. Any terms of the agreement providing alternative reasons for the payment are mere pretext meant to hide the fact that the Cephalon and Teva were entering an improper agreement to restrain trade for the drug Modafinil.

113. On December 22, 2005, Cephalon entered into an agreement with Ranbaxy. The settlement agreement was not made available to the public. Based in part on press releases and SEC filings regarding the agreement, it is likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that Ranbaxy must keep its generic Modafinil drug product off the market until 2012. The agreement also contained a "poison pill" provision that accelerated the date Ranbaxy could sell if another generic manufacturer succeeds in challenging the patent.

114. Cephalon also agreed to make a substantial cash payment to Ranbaxy. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon and Ranbaxy considered the agreement and payment by Cephalon to Ranbaxy for the purpose of allowing Cephalon to maintain its monopoly on Modafinil. Ranbaxy settled with Cephalon predominantly, if not wholly, because of the cash payment made to it by Cephalon. Ranbaxy did not settle because of any fear of enforcement of the '561 Reissue patent. Cephalon's payment was predominantly, if not wholly, to maintain

its monopoly position. Any terms of the agreement providing alternative reasons for the payment are mere pretext meant to hide the fact that the Cephalon and Ranbaxy were entering an improper agreement to restrain trade for the drug Modafinil.

115. On December February 1, 2006, Cephalon announced an agreement with Barr. The settlement agreement was not made available to the public. Based in part on Cephalon and Barr's press releases and SEC filings regarding the agreement, it is likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that Barr must keep its generic Modafinil drug product off the market until 2012. The agreement also contained a "poison pill" provision that accelerated the date Barr could sell if another generic manufacturer succeeds in challenging the patent.

116. Cephalon also agreed to make a substantial cash payment to Barr. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon and Barr considered the agreement and payment by Cephalon as a means for Cephalon to maintain its monopoly on Modafinil. Barr settled with Cephalon predominantly, if not wholly, because of the cash payment made to it by Cephalon. Barr did not settle because of any fear of enforcement of the '561 Reissue patent. Cephalon's payment was predominantly, if not wholly, to maintain its monopoly position.

Any terms of the agreement providing alternative reasons for the payment are mere pretext meant to hide the fact that Cephalon and Barr were entering an improper agreement to restrain trade for the drug Modafinil.

117. On January 10, 2006, Cephalon settled with Mylan. The settlement agreement was not made available to the public. Based in part on Cephalon and Mylan's press releases surrounding the agreement and the releases on the agreements between Cephalon and the other Generic Defendants, it is likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that Mylan must keep its generic Modafinil drug product off the market until 2012. The agreement also contained a "poison pill" provision that accelerated the date Mylan could sell if another generic manufacturer succeeds in challenging the patent.

118. Cephalon also agreed to make a substantial cash payment to Mylan. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon and Mylan considered the agreement and payment by Cephalon to Mylan as a means for Cephalon to maintain its monopoly on Modafinil. Mylan settled with Cephalon predominantly, if not wholly, because of the cash payment made to it by Cephalon. Mylan did not settle because of any fear of enforcement of the '561 Reissue patent. Cephalon's payment was

predominantly, if not wholly, to maintain its monopoly position. Any terms of the agreement providing alternative reasons for the payment are mere pretext meant to hide the fact that Cephalon and Mylan were entering an improper agreement to restrain trade for the drug Modafinil.

119. Cephalon paid over $100 million dollars to the Generic Defendants in exchange for the Generic Defendants to stay out of the Modafinil market. It is likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that it was the payment of this money, not anything related to the ’516 Reissue patent, that was the reason the Generic Defendants agreed to stay out of the Modafinil market.

120. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon has effectively paid the Generic Defendants potentially more than they otherwise would have earned by competing in the marketplace by putting out a generic drug. That is because the illegal agreements allow Cephalon to charge an artificially high price for Modafinil. If the Generic Defendants had entered the market, the price of Modafinil would have been reduced to less than half of its selling price.

121. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that absent the Generic Defendant’s illegal agreements not to compete with

Cephalon until 2012 in the Modafinil market, at least one of the Generic Defendants would have obtained final FDA approval to sell a generic Modafinil drug product as a therapeutic equivalent to Provigil® and would have entered the market in early 2006. The agreements are illegal because they are, in effect, exclusion payments to keep the Generic Defendant's out of the market in restraint of trade.

122. Absent the illegal agreements, the Generic Defendant's introduction of a generic Modafinil product would have triggered the 180 day exclusivity period given to the first ANDA filer(s) with a Paragraph IV certification. Apotex would be able to enter the market with its own generic drug after the 180 day exclusivity period would expire in 2006. However, because of the illegal agreements, the FDA will not grant Apotex approval to market its generic version of Modafinil until 2012.

123. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon and Mylan, Teva, Barr and Ranbaxy entered into license agreements to otherwise support the appearance of validity of the '516 Reissue.

124. The '516 Reissue patent was obtained by fraud and/or inequitable conduct, as more particularly set forth in the paragraphs above, which Apotex adopts by reference, repeats, and alleges as though set forth fully herein.

125. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that all of the Defendants knew that the '516 Reissue patent was invalid or enforceable when they entered into the settlement agreements.

INJURY

126. Apotex evidenced its intent to enter the market for Modafinil products by filing its ANDA and changing its Paragraph III certification to a Paragraph IV certification.

127. Cephalon's anti-competitive acts, including those set forth above, have harmed competition and caused injury to Apotex by preventing the FDA from giving Apotex final approval to market its Modafinil drug product as a therapeutic equivalent to Cephalon's Provigil® because the six months of marketing exclusivity given to Mylan, Teva, Barr and Ranbaxy will not run because of Cephalon's anti-competitive acts.

128. Cephalon's anti-competitive acts, including those set forth above, have created barriers to entry into the relevant markets.

COUNT I
MONOPOLIZATION UNDER THE CLAYTON ACT AND THE SHERMAN ACT

129. Paragraphs 1-129 above are hereby adopted by reference as though they were fully set forth herein.

130. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon at the time it filed suit against Mylan, Teva, Barr and Ranbaxy

knew that the ’516 Reissue was procured by fraud, was invalid and unenforceable.

131. By reason of Cephalon’s anti-competitive acts, Apotex has been and will continue to be injured in its business and property and is entitled to recover three-fold such actual damages as the jury finds Apotex to have incurred, and Apotex’s cost of suit, includes reasonable attorneys’ fees, pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26.

132.The above-described circumstances and conduct by Cephalon constitute monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT II
ATTEMPT TO MONOPOLIZE IN VIOLATION OF THE SHERMAN ACT § 2

133. Paragraphs 1-133 above are hereby adopted by reference as though they were fully set forth herein.

134. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon’s intention in the anti-competitive acts set forth above was to delay entry of generic forms of Modafinil onto the market.

135. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon had no reasonable basis to believe that they would be successful in a patent infringement suit to enforce the ’516 Reissue.

136. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon was aware at all relevant times that the ’516 Reissue was wrongfully and fraudulently listed with the FDA as covering Provigil®.

137. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon knew when it listed the ’516 Reissue with the FDA and when it did not withdraw that listing after settling the litigation with Mylan, Barr, Teva and Ranbaxy that the ’516 patent was wrongfully and fraudulently obtained.

138. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon entered into the settlement agreements and license arrangements with Mylan, Barr, Teva and Ranbaxy for the ’516 Reissue with the specific intent to monopolize or to attempt to monopolize the relevant market for Provigil®.

139. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that by acts including listing ’516 Reissue with the FDA and entering into the agreements with the first generic filers, Mylan, Barr, Teva and Ranbaxy, Cephalon has delayed the FDA administrative process for approval of Apotex’s ANDA.

140. Delay in the approval of Apotex's ANDA application has caused, and is causing substantial damage to Apotex and the public.

141. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that anti-competitive acts by Cephalon (including listing the '516 with the FDA and entering into its agreements with the first generic filers) will have the effect of maintaining the price for Provigil® at artificially high and non-competitive levels through at least 2012, thus causing purchasers including wholesale buyers and ultimate consumers to pay more than they would have had to pay under natural conditions of competition in the absence of illegal restraints and monopoly. It will also have the effect of diminishing and delaying competition in the sale of Provigil® in the United States market, to the detriment of Apotex and the public. Cephalon's anti-competitive acts as set forth above have had and continue to have a substantial effect on interstate commerce.

INTENT TO MONOPOLIZE

142. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon's intention in the anti-competitive acts set forth above was to delay entry of generic forms of Provigil® onto the market.

143. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon had no reasonable basis to believe that it would be successful in a patent infringement suit to enforce the '516 Reissue.

144. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon was aware at all relevant times that the '516 Reissue was wrongfully and fraudulently listed with the FDA as covering Provigil®.

145. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon knew when it listed the '516 Reissue with the FDA that the '516 Reissue was wrongfully and fraudulently obtained.

146. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon listed the '516 Reissue with the FDA, and settled with Mylan, Teva, Ranbaxy and Barr with the specific intent to monopolize or to attempt to monopolize the relevant market for Provigil®.

DANGEROUS PROBABILITY OF SUCCESS AND DAMAGE TO APOTEX

147. By acts including listing the '516 Reissue with the FDA and settling with Mylan, Teva, Ranbaxy and Barr, Cephalon has delayed the FDA administrative process for approval of Apotex's ANDA No. 77-667. By reaching the anti-competitive agreements with Mylan, Teva, Ranbaxy and Barr, Cephalon has

prevented the FDA from approving Apotex's ANDA thereby preventing Apotex from entering the market for Apotex's generic Provigil®.

148. Delay in the approval of Apotex's ANDA application and its entry into the market has caused, and is causing, substantial damage to Apotex and the public.

149. Anti-competitive acts by Cephalon (including listing the '516 Reissue with the FDA and settling with Mylan, Teva, Ranbaxy and Barr will have the effect of maintaining the price for Provigil® at artificially high and non-competitive levels, thus causing purchasers including wholesale buyers and ultimately consumers to pay more than they would have had to pay under natural conditions of competition in the absence of illegal restraints and monopoly. It will also have the effect of diminishing and delaying competition in the sale of Provigil® in the United States market, to the detriment of Apotex and the public. Cephalon's anti-competitive acts as set forth above have had and continue to have a substantial effect on interstate commerce.

150. The above-described circumstances and conduct by Cephalon, Mylan, Teva, Ranbaxy and Barr constitute an attempt to monopolize in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

151. By reason of the anti-competitive acts of Cephalon, Mylan, Teva, Ranbaxy and Barr, Apotex has been and will continue to be injured in its business and property and is entitled to recover threefold such actual damages as the jury finds Apotex to have incurred, and Apotex's costs of suit, including reasonable attorneys' fees, pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26.

COUNT III
UNREASONABLE RESTRAINT OF TRADE IN VIOLATION OF SHERMAN ACT § 1

152. Apotex adopts by reference, repeats, and realleges its specific responses and averments in ¶¶ 1-152 above as though set forth fully herein.

153. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon has conspired, confederated, and combined, together and with Mylan, Teva, Ranbaxy and Barr, in a plan, common design, or understanding with the specific intent to reduce and/or eliminate competition in the market for Provigil®.

154. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the conduct of Cephalon and/or the Generic Defendants constitutes a combination and conspiracy in unreasonable restraint of trade in violation of the Sherman Act, 15 U.S.C. § 1.

155. By reason of Cephalon's anti-competitive acts and these violations, Apotex has been and will continue to be

injured in its business and property and is entitled to recover threefold such actual damages as the jury finds Apotex to have incurred, and Apotex's costs of suit, including reasonable attorneys' fees, pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26.

COUNT IV
FOR DECLARATORY JUDGMENT OF PATENT MISUSE

156. Apotex adopts by reference, repeats, and realleges its specific responses and averments in ¶¶ 1-156 above as though set forth fully herein.

157. Cephalon's acts of misuse include causing the '516 Reissue to be listed in the Orange Book as covering Provigil® and bringing this infringement suit.

158. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support of other and further acts constituting misuse.

159. By its acts of misuse, Cephalon has used the '516 Reissue to restrain competitors in Provigil®, even though that patent was invalid and procured by fraud and/or inequitable conduct.

160. By its acts of misuse, Cephalon has impermissibly broadened the scope of the '516 Reissue with anti-competitive effect.

161. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that

Cephalon's acts of misuse were done in bad faith, with knowledge that the patent is invalid and was procured by fraud and/or inequitable conduct, and/or for an improper purpose.

COUNT V
TORTIOUS INTERFERENCE WITH A PROSPECTIVE BUSINESS RELATION

162. Apotex adopts by reference, repeats, and realleges its specific responses and averments in ¶¶ 1-162 above as though set forth fully herein.

163. Apotex has invested time, money, and other resources in development of its generic version of Provigil®.

164. Because of its reasonable investment-backed expectations, Apotex has a protectable economic interest in the commercial right to distribute its generic version of Provigil® after receiving FDA approval.

165. Apotex was in pursuit of the business of seeking the opportunity to distribute its generic Provigil®, by means including its research and development of its product and its prosecution of its ANDA No. 77-667.

166. Cephalon's acts of tortious interference with a prospective business relation include causing the '516 Reissue to be listed in the Orange Book as covering Provigil®.

167. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support of other and further acts constituting tortious interference with a prospective business relation.

168. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Cephalon's acts of tortious interference with a prospective business relation were done intentionally and with malice.

169. Cephalon's acts of tortious interference with a prospective business relation have caused, and are continuing to cause, the loss of Apotex's prospective gain by necessitating the prosecution of this litigation and delaying FDA approval of Apotex's generic version of Provigil®.

170. If there had been no interference, there exists a reasonable probability that Apotex would receive the anticipated economic benefits.

171. Cephalon's acts of tortious interference with a prospective business relation have caused, and are continuing to cause, damage in the form of economic injury in necessitating the prosecution of this litigation and in delaying FDA approval of Apotex's generic version of Provigil®.

COUNT VI
DECLARATORY JUDGMENT OF PATENT INVALIDITY

172. Apotex adopts by reference, repeats, and realleges its specific responses and averments in ¶¶ 1-59 and 89-95 above as though set forth fully herein.

173. Apotex has filed an ANDA with a Paragraph IV certification that the '516 Reissue patent is invalid and/or unenforceable and/or not infringed by Apotex. Apotex intends to

sell Modafinil once it obtains FDA approval. A real, actual, and justiciable controversy exists between Apotex on the one hand and Cephalon on the other hand regarding the invalidity, unenforceability, and non-infringement of the '516 Reissue patent constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

174. Cephalon is estopped from arguing or has waived any argument that it does not intend to sue Apotex for patent infringement of the '516 Reissue patent because it would be inequitable to allow Cephalon to create a barrier to Apotex's entry into the Modafinil market by blocking FDA approval through illegal agreements and then hide behind that blocking action to keep the '516 Reissue patent from being declared invalid, unenforceable and/or not infringed.

175. The '516 Reissue patent is invalid on the grounds specified in United States Code, Title 35, including, but not limited to, failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT VII
DECLARATORY JUDGMENT OF UNENFORCEABILITY

176. Apotex adopts by reference, repeats, and realleges its specific responses and averments in ¶¶ 1-59, 173 and 176 above as though set forth fully herein.

177. As described more specifically above, Cephalon, the named inventors and prosecuting attorneys knew of information that they knew was material to patentability of the '516 Reissue patent but did not inform the PTO of such material during the prosecution of the '516 Reissue or its predecessor. Cephalon thus breached its duty of candor before the PTO, rendering the '516 Reissue patent unenforceable

COUNT VIII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT

178. Apotex adopts by reference, repeats, and realleges its specific responses and averments in ¶¶ 1-59 and 173-178 above as though set forth fully herein.

179. Because all of the claims of the '516 Reissue are invalid and/or unenforceable, that patent will not be infringed by the manufacture, use, or sale of the new drug for which Apotex has submitted an ANDA.

DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

180. WHEREFORE, Apotex prays for judgment:

a. Finding that Apotex has not infringed the '516 Reissue and the '855 patent;

b. Finding that the '516 Reissue is invalid and unenforceable;

c. Finding that the '516 Reissue provides no impediment to any approval of defendant Apotex's application under Section 505(j) of the Federal

Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), and further vacate the 180 day exclusivity period that Mylan, Teva, Ranbaxy and Barr enjoyed as first to file;

d. Finding that this is an exceptional case under 35 U.S.C. § 285;

e. Ordering Cephalon to notify the FDA that the '516 Reissue does not cover Modafinil;

f. Awarding Apotex treble its actual damages incurred by Cephalon's violation of the anti-trust laws in an amount exceeding $150,000;

g. Awarding Apotex its damages actually incurred by Cephalon tortuous interference with Apotex's prospective economic relations in an amount exceeding $150,000;

h. Awarding Apotex its costs, expenses, and reasonable attorneys' fees and other relief the Court deems just;

i. Awarding Apotex 180-day exclusivity to launch a generic version of Modafinil;

j. Ordering the Generic Defendants to notify the FDA that they are waiving the exclusivity;

k. Ordering the FDA to give approval to Apotex to launch a generic version of Modafinil;

l. Ordering that the provision in the agreements between Cephalon and the Generic Defendants which allows for the Generic Defendants to launch generic versions of Modafinil should a third party succeed in a challenge of Cephalon's exclusivity be invalidated and ordering that the Generic Defendants not be allowed to enter the market prior to April, 2012.

DEMAND FOR JURY TRIAL

Apotex demands trial by jury for all issues triable by jury as a matter of right.

Respectfully submitted,

NH1402
Neil J. Hamburg
Michael E. Sacks
I.D. Nos. 32175 and 39774
HAMBURG & GOLDEN, P.C.
1601 Market Street, Suite 3310
Philadelphia, PA 19103-1443
(215) 255-8590

Of Counsel (Motion for Pro Hac Vice Admission Will Be Filed):
A. Sidney Katz
Robert B. Breisblatt
Julie A. Katz
Steven E. Feldman
Brian J. Sodikoff
Michael S. Krol
WELSH & KATZ, LTD.
120 S. Riverside Plaza, 22nd Fl.
Chicago, IL 60606

Attorneys for Plaintiff Apotex, Inc.