IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO.: _____

CEPHALON, INC. and
CEPHALON FRANCE,

Plaintiffs,

v.

APOTEX CORP. and
APOTEX INC.,

Defendants.
_____/

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc. and Cephalon France (collectively "Cephalon"), for their complaint against Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex"), state as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 20-1514 submitted by Apotex to the United States Food and Drug Administration ("FDA") for approval to market generic copies of Cephalon's successful Nuvigil® pharmaceutical products that are sold in the United States. Nuvigil® (armodafinil) is a prescription drug widely used to improve wakefulness in patients

with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder.

PARTIES

2. Cephalon, Inc. is a Delaware corporation having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon, Inc. is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

3. Cephalon France is a société par actions simplifiée ("SAS") under the laws of France, a wholly-owned subsidiary of Cephalon, Inc., and located at 20 Rue Charles Martigny, 94701 Maisons-Alfort Cedex, France.

4. Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. On information and belief, the acts of Apotex Corp. complained of herein were done at the direction of, with the authorization of, and/or the cooperation, participation, and assistance of, and at least in part for the benefit of, Apotex Inc.

JURISDICTION AND VENUE

7. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b).

8. On information and belief, this Court has personal jurisdiction over Apotex Corp. and Apotex Inc. by virtue of their consent and/or contacts with this forum, including, *inter alia*,

marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

9. In a prior, unrelated litigation, Apotex admitted that this District has personal jurisdiction over both Apotex Corp. and Apotex Inc. *Alcon v. Apotex Inc. & Apotex Corp*., C.A. No. 1:06-cv-01642-RLY-TAB, D.I. 23 at 7 (S.D. Ind. Dec. 13, 2006).

10. On information and belief, Apotex Corp. has its principal place of business in this District and has designated the Corporation Service Company, 1201 Hays Street, Tallahassee, Florida 32301, as its registered agent in Florida for service of process.

11. On information and belief, Apotex Corp. and Apotex Inc. both regularly conduct business in this judicial district.

12. On information and belief, Apotex Corp. and Apotex Inc. each have continuous and systematic general business contacts with this judicial district.

13. On information and belief, Apotex Inc. is in the business of formulating, manufacturing, and commercializing generic pharmaceutical products, which it distributes, markets, and/or sells in this judicial district and throughout the United States.

14. On information and belief, Apotex Corp. is the marketing and sales agent for Apotex Inc. in the United States.

15. On information and belief, Apotex Inc., itself and through its agent, Apotex Corp., distributes, markets, and/or sells generic drugs in this judicial district and throughout the United States.

16. On information and belief, Apotex Inc., itself and through its agent, Apotex Corp., derives substantial revenue from the sale of Apotex Inc. products, including from sales of Apotex Inc. products in this judicial district and throughout the United States.

17. Apotex Inc.'s U.S. website states that Apotex Corp. is a wholly owned affiliate of Apotex Inc.

18. On information and belief, Apotex Corp. and Apotex Inc. are two arms of the same business group, operate in concert with each other, and enter into agreements with each other that are nearer than arms length.

19. On information and belief, Apotex Corp. and Apotex Inc. are jointly controlled by Dr. Bernard C. Sherman through a series of shell corporations: Apotex Corp. is a wholly-owned subsidiary of Aposherm Inc., which is a wholly-owned subsidiary of Apotex Holdings; Apotex Holdings owns all of the outstanding capital stock of Apotex Inc. such that Apotex Corp. and Apotex Inc. are sister corporations owned by Apotex Holdings, which is controlled by Dr. Bernard C. Sherman through The Bernard Sherman 2000 Trust.

20. On information and belief, the web site of Apotex Corp., *www.apotexcorp.com*, is registered to "Apotex, 150 Signet Drive, Weston, ON M9L 1T9, CA", and the administrative and technical contact listed by the internet registrar for apotexcorp.com is an employee of Apotex Inc. The website *www.apotexcorp.com* automatically directs users to *www.apotex.com/us/en*. On further information and belief, Apotex Inc.'s website directs U.S. customers to the same web address, *www.apotex.com/us/en*.

21. On information and belief, Apotex describes itself as a worldwide pharmaceutical company employing a global strategy of vertical integration. Apotex further describes itself as the largest pharmaceutical company in Canada, serving customers and partners in the U.S.

market as well as in 115 countries globally. Apotex describes itself as a leader in the North American generic pharmaceutical market in terms of prescriptions filled, sales volume, and value, and its preference is to develop, manufacture, and market its own products—from API to finished dosage form to marketing and distribution.

22. On information and belief, the Florida Department of State Division of Corporations lists, as Apotex Corp.'s corporate address, Apotex Inc.'s address in Canada. In addition, Apotex Corp.'s 2010 For Profit Corporation Annual Report filed with the Florida Secretary of State, provides a mailing address of "c/o 150 Signet Drive, Weston, Ontario Canada M9L 1T9, ON M9L1T9" and lists only Bernard C. Sherman and Jack Kay as its officers and directors. On information and belief, Bernard C. Sherman is Chairman of the Board, Director, and Chief Executive Officer of Apotex Inc., and Jack Kay is President and Chief Operating Officer of Apotex Inc.

23. On information and belief, Apotex Corp. is the U.S. agent for Apotex Inc. for purposes of making regulatory submissions to the FDA, including ANDA No. 20-1514 at issue in this litigation. In particular, Apotex Inc. has acted in concert with Apotex Corp. with respect to the preparation and filing of ANDA No. 20-1514 for Apotex's generic armodafinil products, and in preparation to sell those products in the United States and in this judicial district. *See infra* ¶ 30.

24. On information and belief, Apotex Inc. and Apotex Corp. have a nearer than arm's length relationship such that Apotex Corp.'s contacts with Delaware can be imputed to Apotex Inc. For at least this reason, jurisdiction over Apotex Inc. is proper in this District.

BACKGROUND

25. Cephalon, Inc. is the holder of approved New Drug Application ("NDA") No. 21-

875 for the use of Nuvigil® (armodafinil) tablets in 50 mg, 150 mg, and 250 mg dosage strengths, as indicated to improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder.

26. Cephalon France is the owner by assignment, and has the right to sue for infringement, of U.S. Patent No. 7,132,570 B2 ("the '570 patent"), entitled "Method for the Production of Crystalline Forms and Crystalline Forms of Optical Enantiomers of Modafinil." The '570 patent was duly and legally issued by the United States Patent and Trademark Office on November 7, 2006. A true and correct copy of the '570 patent is attached as Exhibit A.

27. Cephalon, Inc. is the owner by assignment, and has the right to sue for infringement, of U.S. Reissued Patent No. RE37,516 E ("the '516 patent"), entitled "Acetamide Derivative Having Defined Particle Size." The '516 patent was duly and legally issued by the United States Patent and Trademark Office on January 15, 2002. A true and correct copy of the '516 patent is attached as Exhibit B.

28. Upon information and belief, Apotex filed ANDA No. 20-1514 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of armodafinil tablets in 50 mg, 150 mg, and 250 mg dosage strengths ("Apotex's generic armodafinil products") before the expiration of the '570 and '516 patents (collectively the "patents-in-suit"). On information and belief, as part of its ANDA, Apotex filed a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the patents-in-suit are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's generic armodafinil products that are the subject of Apotex's ANDA No. 20-1514.

29. Apotex caused to be sent to Cephalon a letter ("the Notice Letter"), dated July 6, 2010, notifying Cephalon that Apotex had filed ANDA No. 20-1514 seeking approval to market

Apotex's generic armodafinil products prior to the expiration of the patents-in-suit, and was providing information to Cephalon pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Cephalon received the Notice Letter on or about July 7, 2010.

30. The Notice Letter defined "Apotex" as "Apotex Corp. and Apotex Inc." and stated that "Apotex" had submitted ANDA No. 20-1514 to engage in the commercial manufacture, use, importation, offer for sale, or sale of "Apotex's proposed product."

COUNT I FOR INFRINGEMENT OF THE '570 PATENT

31. Cephalon incorporates by reference paragraphs 1-30, above.

32. Apotex has filed or caused to be filed ANDA No. 20-1514 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Apotex's generic armodafinil products before the expiration of the '570 patent. On information and belief, Apotex also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '570 patent are invalid, unenforceable, or not infringed.

33. By submitting ANDA No. 20-1514 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Apotex's generic armodafinil products before the expiration of the '570 patent, Apotex has infringed the '570 patent under 35 U.S.C. § 271(e)(2).

34. Upon information and belief, Apotex Inc. has acted in concert with Apotex Corp., actively supporting, participating in, encouraging, and inducing Apotex Corp.'s filing of ANDA No. 20-1514 for Apotex's generic armodafinil products, and in the preparation to sell in the United States Apotex's generic armodafinil products.

35. Upon information and belief, Apotex intends, soon after the FDA has approved the ANDA, to begin manufacturing, importing, marketing, selling, and offering to sell Apotex's generic armodafinil products with a product insert that will direct physicians and patients in the use of Apotex's generic armodafinil products.

36. Upon information and belief, Apotex's generic armodafinil products, when offered for sale, sold, and/or imported, and when used as directed, would directly infringe at least one of the claims of the '570 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

37. Upon FDA approval of Apotex's ANDA No. 20-1514, Apotex will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Apotex's generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

38. Upon information and belief, Apotex Inc. will actively aid, abet, encourage, and induce Apotex Corp. and others in the production, importation, sale, offer for sale, and use of Apotex's generic armodafinil products.

39. Upon information and belief, Apotex Inc. and Apotex Corp. will both actively participate in the production, importation, sale, offer for sale, and use of Apotex's generic armodafinil products.

40. Upon information and belief, the offer to sell, sale, and/or importation of Apotex's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '570 patent, either literally or under the doctrine of equivalents.

41. Upon information and belief, Apotex had knowledge of the '570 patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '570 patent, either literally or under the doctrine of equivalents.

42. As a result of Apotex's infringement of the '570 patent, Cephalon has been and will continue to be damaged unless said infringement is enjoined by this Court. Cephalon has no adequate remedy at law.

COUNT II FOR INFRINGEMENT OF THE '516 PATENT

43. Cephalon incorporates by reference paragraphs 1-42, above.

44. Apotex has filed or caused to be filed ANDA No. 20-1514 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Apotex's generic armodafinil products before the expiration of the '516 patent. On information and belief, Apotex also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '516 patent are invalid, unenforceable, or not infringed.

45. By submitting ANDA No. 20-1514 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Apotex's generic armodafinil products before the expiration of the '516 patent, Apotex has infringed the '516 patent under 35 U.S.C. § 271(e)(2).

46. Upon information and belief, Apotex Inc. has acted in concert with Apotex Corp., actively supporting, participating in, encouraging, and inducing Apotex Corp.'s filing of ANDA No. 20-1514 for Apotex's generic armodafinil products, and in the preparation to sell in the United States Apotex's generic armodafinil products.

47. Upon information and belief, Apotex intends, soon after the FDA has approved the ANDA, to begin manufacturing, importing, marketing, selling, and offering to sell Apotex's generic armodafinil products with a product insert that will direct physicians and patients in the use of Apotex's generic armodafinil products.

48. Upon information and belief, Apotex's generic armodafinil products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '516 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

49. Upon FDA approval of Apotex's ANDA No. 20-1514, Apotex will infringe the '516 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Apotex's generic armodafinil products in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c).

50. Upon information and belief, Apotex Inc. will actively aid, abet, encourage, and induce Apotex Corp. and others in the production, importation, sale, offer for sale, and use of Apotex's generic armodafinil products.

51. Upon information and belief, Apotex Inc. and Apotex Corp. will both actively participate in the production, importation, sale, offer for sale, and use of Apotex's generic armodafinil products.

52. Upon information and belief, the offer to sell, sale, and/or importation of Apotex's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '516 patent, either literally or under the doctrine of equivalents.

53. Upon information and belief, Apotex had knowledge of the '516 patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '516 patent, either literally or under the doctrine of equivalents.

54. Upon information and belief, the offer to sell, sale, and/or importation of Apotex's generic armodafinil products would contributorily infringe under 35 U.S.C. § 271(c) at least one of the claims of the '516 patent, either literally or under the doctrine of equivalents.

55. As a result of Apotex's infringement of the '516 patent, Cephalon has been and will continue to be damaged unless said infringement is enjoined by this Court. Cephalon has no adequate remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiffs Cephalon, Inc. and Cephalon France pray for judgment and relief including:

A. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of ANDA No. 20-1514 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Apotex's generic armodafinil products before the expiration of United States Patent No. 7,132,570 B2 and United States Reissued Patent No. RE37,516 E, was an act of infringement;

B. A declaration that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Apotex's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 20-1514 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Apotex's generic armodafinil products before the expiration of United States

Patent No. 7,132,570 B2 and United States Reissued Patent No. RE37,516 E were acts of infringement of the patents-in-suit;

C. A declaration that Apotex would infringe one or more claims of United States Patent No. 7,132,570 B2 and United States Reissued Patent No. RE37,516 E, under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Apotex's generic armodafinil products prior to expiration of said patents-in-suit and any additional dates of exclusivity therefor;

D. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Apotex, and all officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing any claims of the patents-in-suit with Apotex's generic armodafinil products prior to the expiration date of United States Patent No. 7,132,570 B2 and United States Reissued Patent No. RE37,516 E, and any additional dates of exclusivity;

E. A permanent injunction enjoining Apotex and all persons acting in concert with Apotex from seeking, obtaining, or maintaining approval of Apotex's ANDA No. 20-1514 until the expiration date of United States Patent No. 7,132,570 B2 and United States Reissued Patent No. RE37,516 E, and any additional dates of exclusivity;

F. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Apotex's generic armodafinil products is not to be earlier than the latest of: (i) the expiration date of United States Patent No. 7,132,570 B2 and (ii) the expiration date of United States Reissued Patent No. RE37,516 E;

G. A declaration that Apotex has no legal or equitable defense to Cephalon's allegations of infringement;

H. An award declaring this case exceptional pursuant to 35 U.S.C. § 285 and granting Cephalon its attorney's fees;

I. An award of Cephalon's costs and expenses in this action; and

J. An award of any further and additional relief as this Court may deem just and proper.

Dated: August 19, 2010.

Respectfully submitted,

s/John A. Camp

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