IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Northern Division)

CEPHALON, INC. 41 Moores Road Frazer, Pennsylvania 19355 and CEPHALON FRANCE, 20 Rue Charles Martigny 94701 Maisons-Alfort Cedex, France Plaintiffs, v. LUPIN LIMITED Harborplace Tower 111 South Calvert Street 21st Floor Baltimore, Maryland 21202 and LUPIN PHARMACEUTICALS, INC. B/4 Laxmi Towers Bandra Kurla Complex Bandra (W) Mumbai, 400 051, India Defendants.	CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc. and Cephalon France (collectively "Cephalon") bring this action for patent infringement against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("Lupin"). This action concerns patents related to Cephalon's pharmaceutical product, Nuvigil® (armodafinil), 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

1. 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.

2. 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.

3. On information and belief, Lupin Limited ("Lupin Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India.

4. On information and belief, Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a corporation organized and existing under the laws of Virginia and having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

5. On information and belief, Lupin Pharma. is a wholly-owned subsidiary and agent of Lupin Ltd.

6. On information and belief, Lupin Pharma, itself and on behalf of its parent corporation Lupin Ltd., distributes, markets, and/or sells generic drugs in Maryland and throughout the United States.

7. On information and belief, Lupin Ltd., itself and through its wholly-owned subsidiary and agent Lupin Pharma, is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Maryland and throughout the United States.

JURISDICTION AND VENUE

8. 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).

9. This Court has personal jurisdiction over Lupin Ltd. and Lupin Pharma by virtue of, *inter alia*, their 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.

NATURE OF THIS ACTION

10. 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. 200751 filed by Lupin with 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.

BACKGROUND

11. Cephalon, Inc. is the holder of approved New Drug Application ("NDA") No. 21-875 for the use of Nuvigil® (armodafinil) tablets in 50 mg, 100 mg, 150 mg, 200 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.

12. Cephalon, Inc. is the owner by assignment, and has the right to sue for infringement, of U.S. Reissue 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 A.

13. Cephalon France is the owner by assignment, and has the right to sue for infringement, of U.S. Patent No. 7,132,570 ("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 B.

14. Upon information and belief, Lupin filed ANDA No. 200751 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of armodafinil capsules in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths ("Lupin's generic armodafinil products") before the expiration of the '516 and '570 patents ("patents-in-suit"). On information and belief, as part of its ANDA, Lupin 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 or will not be infringed by the

manufacture, use, or sale of" Lupin's generic armodafinil products that are the subject of Lupin's ANDA No. 200751.

15. Lupin caused to be sent to Cephalon a letter ("the Notice Letter"), dated February 5, 2010, notifying Cephalon that Lupin Ltd. had filed ANDA No. 200751 seeking approval to market Lupin'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 February 8, 2010.

COUNT I FOR INFRINGEMENT OF THE '516 PATENT

16. Cephalon realleges and incorporates by reference paragraphs 1-15.

17. Lupin has filed or caused to be filed ANDA No. 200751 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Lupin's generic armodafinil products before the expiration of the '516 patent. On information and belief, Lupin also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '516 patent is invalid, unenforceable, or not infringed.

18. By submitting its ANDA No. 200751 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 Lupin's generic armodafinil products before the expiration of the '516 patent, Lupin Ltd. has infringed the '516 patent under 35 U.S.C. § 271(e)(2).

19. Upon information and belief, Lupin Pharma has acted in concert with Lupin Ltd., actively supporting, participating in, encouraging, and inducing Lupin Ltd.'s filing of ANDA No. 200751 for

Lupin's generic armodafinil products, and in the preparation to sell in the United States Lupin's generic armodafinil products.

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

21. Upon information and belief, Lupin'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.

22. Upon FDA approval of Lupin's ANDA No. 200751, Lupin will infringe the '516 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Lupin'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).

23. Upon information and belief, Lupin Pharma will actively aid, abet, encourage, and induce Lupin Ltd. and others in the production, importation, sale, offer for sale, and use of Lupin's generic armodafinil products.

24. Upon information and belief, Lupin Pharma and Lupin Ltd. will both actively participate in the production, importation, sale, offer for sale, and use of Lupin's generic armodafinil products.

25. Upon information and belief, the offer to sell, sale, and/or importation of Lupin'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.

26. Upon information and belief, Lupin 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.

27. Upon information and belief, the offer to sell, sale, and/or importation of Lupin'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.

28. Lupin has knowledge of the '516 patent and is knowingly and willfully infringing the '516 patent.

29. As a result of Lupin'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.

COUNT II FOR INFRINGEMENT OF THE '570 PATENT

30. Cephalon realleges and incorporates by reference paragraphs 1-29.

31. Lupin has filed or caused to be filed ANDA No. 200751 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Lupin's generic armodafinil products before the expiration of the '570 patent. On information and belief, Lupin 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.

32. By submitting ANDA No. 200751 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 Lupin's generic armodafinil products before the expiration of the '570 patent, Lupin Ltd. has infringed the '570 patent under 35 U.S.C. § 271(e)(2).

33. Upon information and belief, Lupin Pharma has acted in concert with Lupin Ltd., actively supporting, participating in, encouraging, and inducing Lupin Ltd.'s filing of ANDA No. 200751 for Lupin's generic armodafinil products, and in the preparation to sell in the United States Lupin's generic armodafinil products.

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

35. Upon information and belief, Lupin'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 '570 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

36. Upon FDA approval of Lupin's ANDA No. 200751, Lupin will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Lupin's generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

37. Upon information and belief, Lupin Pharma will actively aid, abet, encourage, and induce Lupin Ltd. and others in the production, importation, sale, offer for sale, and use of Lupin's generic armodafinil products.

38. Upon information and belief, Lupin Pharma and Lupin Ltd. will both actively participate in the production, importation, sale, offer for sale, and use of Lupin's generic armodafinil products.

39. Upon information and belief, the offer to sell, sale, and/or importation of Lupin'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.

40. Upon information and belief, Lupin 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.

41. The Notice Letter lacks any factual basis for non-infringement of any claim of the '570 patent.

42. Lupin has knowledge of the '570 patent and is knowingly and willfully infringing the '570 patent.

43. As a result of Lupin'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.

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), Lupin's submission to the FDA of ANDA No. 200751 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Lupin's generic armodafinil products before the expiration of United States Patent Nos. RE37,516 and 7,132,570 was an act of infringement;

B. A declaration that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Lupin's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200751 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Lupin's generic armodafinil products before the expiration of United States Patent Nos. RE37,516 and 7,132,570 were acts of infringement of each of the patents-in-suit;

C. A declaration that Lupin would infringe one or more claims of United States Patent Nos. RE37,516 and 7,132,570 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 Lupin'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 Lupin, 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 Lupin's generic armodafinil products prior to the expiration date of United States Patent Nos. RE37,516 and 7,132,570, and any additional dates of exclusivity;

E. A permanent injunction enjoining Lupin and all persons acting in concert with Lupin from seeking, obtaining, or maintaining approval of Lupin's ANDA No. 200751 until the expiration date of United States Patent Nos. RE37,516 and 7,132,570, 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 Lupin's generic armodafinil products is not to be earlier than the latest of (i) the expiration date of United States Patent No. RE37,516 and (ii) the expiration date of United States Patent No. 7,132,570.

G. A declaration that Lupin 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.

Respectfully submitted,

/s/ Charles S. Hirsch

Charles S. Hirsch (Bar #06605)
BALLARD SPAHR LLP
300 East Lombard Street
18th Floor
Baltimore, Maryland 21202-3268
(410) 528-5503
Fax: (410) 528-5650
hirsch@ballardspar.com

Attorney for Plaintiffs
CEPHALON, INC. and CEPHALON FRANCE

Of Counsel:

Charles E. Lipsey
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
Two Freedom Square
11955 Freedom Drive
Reston, Virginia 20190
(571) 203-2700

Thomas L. Irving
Barbara R. Rudolph
Mark J. Feldstein
Laura P. Masurovsky
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
(202) 408-4000