IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CEPHALON FRANCE,	)	
	)	
Plaintiffs,	)	CIVIL ACTION NO.
	)	
v.	)	
	)	
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc. and Cephalon France (collectively "Cephalon") bring this action for patent infringement against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva"). This action concerns patents related to Cephalon's pharmaceutical Nuvigil®, a prescription drug widely used and indicated 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, Teva Pharmaceuticals USA, Inc. ("Teva USA") 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.

4. On information and belief, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a corporation organized and existing under the laws of Israel, with a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

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

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

7. On information and belief, Teva Ltd., itself and through its wholly-owned subsidiary and agent Teva USA, is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware 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 Teva USA and Teva Ltd. 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 THE 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. 200-152 filed by Teva 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. 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 A.

13. Cephalon, Inc. is the owner by assignment, and has the right to sue for infringement, of U.S. Patent No. 7,297,346 B2 ("the '346 patent"), entitled "Pharmaceutical Formulations of Modafinil." The '346 patent was duly and legally issued by the United States Patent and Trademark Office on November 20, 2007. A true and correct copy of the '346 patent is attached as Exhibit B.

14. 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 C.

15. Upon information and belief, Teva filed ANDA No. 200-152 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, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths ("Teva's generic armodafinil products") before the expiration of the '516, '346, and '570 patents (collectively, the "patents-in-suit"). On information and belief, as part of its ANDA, Teva 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, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's generic armodafinil products that are the subject of Teva's ANDA No. 200-152.

16. Teva caused to be sent to Cephalon a letter ("the Notice Letter") dated October 19, 2009, notifying Cephalon that Teva USA had filed ANDA No. 200-152 seeking approval to market Teva'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 October 20, 2009.

17. The Notice Letter included a statement which contained allegations of a license defense with respect to the '516 and '346 patents, and which contained no allegations of non-infringement of one or more claims of the '570 patent.

COUNT I FOR INFRINGEMENT OF THE '516 PATENT

18. Cephalon realleges and incorporates by reference paragraphs 1-17.

19. Teva has filed or caused to be filed ANDA No. 200-152 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Teva's generic armodafinil products before the expiration of the '516 patent. On information and belief, Teva 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.

20. By submitting ANDA No. 200-152 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 Teva's generic armodafinil products before the expiration of the '516 patent, Teva USA has infringed the '516 patent under 35 U.S.C. § 271(e)(2).

21. Upon information and belief, Teva Ltd. has acted in concert with Teva USA, actively supporting, participating in, encouraging, and inducing Teva USA's filing of ANDA No. 200-152 for Teva's generic armodafinil products, and in the preparation to sell in the United States Teva's generic armodafinil products.

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

23. Upon information and belief, Teva'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.

24. Upon FDA approval of Teva's ANDA No. 200-152, Teva will infringe the '516 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Teva'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).

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

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

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

28. Upon information and belief, Teva 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.

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

30. The Notice Letter lacks any legal or factual basis for non-infringement of any claim of the '516 patent.

31. Teva has knowledge of the '516 patent and is knowingly and willfully infringing the '516 patent.

32. As a result of Teva'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 '346 PATENT

33. Cephalon realleges and incorporates by reference paragraphs 1-32.

34. Teva has filed or caused to be filed ANDA No. 200-152 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Teva's generic armodafinil products before the expiration of the '346 patent. On information and belief, Teva 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 '346 patent are invalid, unenforceable, or not infringed.

35. By submitting ANDA No. 200-152 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 Teva's generic armodafinil products before the expiration of the '346 patent, Teva USA has infringed the '346 patent under 35 U.S.C. § 271(e)(2).

36. Upon information and belief, Teva Ltd. has acted in concert with Teva USA, actively supporting, participating in, encouraging, and inducing Teva USA's filing of ANDA No. 200-152 for Teva's generic armodafinil products, and in the preparation to sell in the United States Teva's generic armodafinil products.

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

38. Upon information and belief, Teva'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 '346 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

39. Upon FDA approval of Teva's ANDA No. 200-152, Teva will infringe the '346 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Teva's generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

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

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

42. Upon information and belief, the offer to sell, sale, and/or importation of Teva's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '346 patent, either literally or under the doctrine of equivalents.

43. Upon information and belief, Teva had knowledge of the '346 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 '346 patent, either literally or under the doctrine of equivalents.

44. The Notice Letter lacks any legal or factual basis for non-infringement of any claim of the '346 patent.

45. Teva has knowledge of the '346 patent and is knowingly and willfully infringing the '346 patent.

46. As a result of Teva's infringement of the '346 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 III FOR INFRINGEMENT OF THE '570 PATENT

47. Cephalon realleges and incorporates by reference paragraphs 1-46.

48. Teva has filed or caused to be filed ANDA No. 200-152 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Teva's generic armodafinil products before the expiration of the '570 patent. On information and belief, Teva 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.

49. By submitting ANDA No. 200-152 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 Teva's generic armodafinil products before the expiration of the '570 patent, Teva USA has infringed the '570 patent under 35 U.S.C. § 271(e)(2).

50. Upon information and belief, Teva Ltd. has acted in concert with Teva USA, actively supporting, participating in, encouraging, and inducing Teva USA's filing of ANDA No. 200-152 for Teva's generic armodafinil products, and in the preparation to sell in the United States Teva's generic armodafinil products.

51. Upon information and belief, Teva intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Teva's generic

armodafinil products with a product insert that will direct physicians and patients in the use of Teva's generic armodafinil products.

52. Upon information and belief, Teva'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.

53. Upon FDA approval of Teva's ANDA No. 200-152, Teva will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Teva's generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

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

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

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

57. Upon information and belief, Teva 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.

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

59. Teva has knowledge of the '570 patent and is knowingly and willfully infringing the '570 patent.

60. As a result of Teva'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 in their favor as follows:

A. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Teva's submission to the FDA of ANDA No. 200-152 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Teva's generic armodafinil products before the expiration of United States Patent Nos. RE37,516, 7,297,346, and 7,132,570 was an act of infringement of each of the patents-in-suit;

B. A declaration that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Teva's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-152 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Teva's generic armodafinil products before the expiration of United States Patent Nos. RE37,516, 7,297,346, and 7,132,570 were acts of infringement of each of the patents-in-suit;

C. A declaration that Teva would infringe one or more claims of the United States Patent Nos. RE37,516, 7,297,346, 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 Teva's generic armodafinil products prior to expiration of said patents-in-suit and any additional dates of exclusivity therefor, except as may be permitted with respect to the '346 and '516 patents in accordance with any applicable license thereto;

D. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Teva, 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 Teva's generic armodafinil products prior to the expiration date of each of United States Patent Nos. RE37,516, 7,297,346, and 7,132,570, and any additional dates of exclusivity, except as may be permitted with respect to the '346 and '516 patents in accordance with any applicable license thereto;

E. A permanent injunction enjoining Teva and all persons acting in concert with Teva from seeking, obtaining, or maintaining approval of Teva's ANDA No. 200-152 until the expiration date of each of United States Patent Nos. RE37,516, 7,297,346, and 7,132,570, and any additional dates of exclusivity, except as may be permitted with respect to the '346 and '516 patents in accordance with any applicable license thereto;

F. An order pursuant to 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of Teva's generic armodafinil products is not to be earlier than the latest of (i) the expiration date of United States Patent No. RE37,516, except as may be permitted in accordance with any applicable license thereto, (ii) the expiration date of United States Patent No. 7,297,346, except as may be permitted in accordance with any applicable license thereto, and (iii) the expiration date of United States Patent No. 7,132,570;

G. A declaration that Teva 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.

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
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
(202) 408-4000

Respectfully submitted,

/s/ Mary W. Bourke

Mary W. Bourke (#2356)
CONNOLLY, BOVE, LODGE & HUTZ LLP
The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899
(302) 658-9141
mbourke@cblh.com

Attorney for Plaintiffs
CEPHALON, INC. and CEPHALON FRANCE

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