IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CEPHALON FRANCE,	)	
Plaintiffs,	)	
v.	)	Civil Action No.:
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc. and Cephalon France (collectively "Cephalon") bring this action for patent infringement against Defendant Sandoz Inc. ("Sandoz"). 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, Sandoz is a corporation organized and existing under the laws of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

4. On information and belief, Sandoz is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware, where it is licensed and registered to distribute pharmaceuticals, and throughout the United States.

JURISDICTION AND VENUE

5. 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).

6. This Court has personal jurisdiction over Sandoz by virtue of, *inter alia*, its 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

7. 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. 200-511 filed by Sandoz 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

8. 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.

9. 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 A.

10. Upon information and belief, Sandoz filed ANDA No. 200-511 with the FDA under 21 U.S.C. § 355(j), originally seeking approval for the commercial manufacture, use, and sale of armodafinil tablets in 50 mg, 150 mg, and 250 mg dosage strengths ("Sandoz's 50, 150, and 250 mg generic armodafinil products") before the expiration of the '570 patent ("patent-in-suit"). On information and belief, as part of its ANDA, Sandoz filed a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the patent-in-suit is "invalid or will not be infringed by the manufacture, use, or sale of" Sandoz's 50, 150, and 250 mg generic armodafinil products that are the subject of Sandoz's ANDA No. 200-511.

11. Sandoz's 50, 150, and 250 mg generic armodafinil products, and Cephalon's claims that these products will, if approved and marketed, infringe at least one claim of U.S. Patent No. 7,297,346, U.S. Reissue Patent No. RE37,516 E, and the '570 patent, are the subject of Civil Action No. 1:10-cv-55-GMS, currently pending in the District of Delaware, now consolidated into MDL Docket No. 1:10-md-2200-GMS.

12. Upon information and belief, Sandoz has amended its ANDA No. 200-511, to now seek FDA approval to sell in the United States, in addition to Sandoz's 50, 150, and 250 mg generic armodafinil products, armodafinil tablets in 100 mg and 200 mg dosage strengths

("Sandoz's 100 and 200 mg generic armodafinil products"). On information and belief, as part of its ANDA amendments, Sandoz filed a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the patent-in-suit is "invalid or will not be infringed by the manufacture, use, or sale of" Sandoz's 100 and 200 mg generic armodafinil products that are now also the subject of Sandoz's ANDA No. 200-511.

13. Sandoz caused to be sent to Cephalon a letter ("the Notice Letter"), dated July 27, 2011, notifying Cephalon that Sandoz had amended its ANDA No. 200-511 to now also seek approval to market Sandoz's 100 and 200 mg generic armodafinil products prior to the expiration of the patent-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 28, 2011.

COUNT I FOR INFRINGEMENT OF THE '570 PATENT

14. Cephalon realleges and incorporates by reference paragraphs 1-13.

15. Sandoz has filed or caused to be filed Sandoz's ANDA amendment with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Sandoz's 100 and 200 mg generic armodafinil products before the expiration of the '570 patent. On information and belief, Sandoz 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.

16. By submitting its ANDA amendment 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 Sandoz's 100 and 200 mg generic armodafinil products before the expiration of the '570 patent, Sandoz has infringed the '570 patent under 35 U.S.C. § 271(e)(2).

17. Upon information and belief, Sandoz intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Sandoz's 100 and 200 mg generic armodafinil products with a product insert that will direct physicians and patients in the use of Sandoz's 100 and 200 mg generic armodafinil products.

18. Upon information and belief, Sandoz's 100 and 200 mg 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.

19. Upon FDA approval of Sandoz's ANDA No. 200-511, Sandoz will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Sandoz's 100 and 200 mg generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

20. Upon information and belief, Sandoz will actively aid, abet, encourage, and induce others in the production, importation, sale, offer for sale, and use of Sandoz's 100 and 200 mg generic armodafinil products.

21. Upon information and belief, Sandoz will actively participate in the production, importation, sale, offer for sale, and use of Sandoz's 100 and 200 mg generic armodafinil products.

22. Upon information and belief, the offer to sell, sale, and/or importation of Sandoz's 100 and 200 mg 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.

23. Upon information and belief, Sandoz 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.

24. As a result of Sandoz'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), Sandoz's submission to the FDA of ANDA No. 200-511 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's 100 and 200 mg generic armodafinil products before the expiration of United States Patent No. 7,132,570 was an act of infringement;

B. A declaration that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Sandoz's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-511, including Sandoz's ANDA amendment, to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Sandoz's 100 and 200 mg generic armodafinil products before the expiration of United States Patent No. 7,132,570 were acts of infringement of the patent-in-suit;

C. A declaration that Sandoz would infringe one or more claims of United States Patent No. 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 Sandoz's 100 and 200 mg

generic armodafinil products prior to expiration of said patent-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 Sandoz, 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 patent-in-suit with Sandoz's 100 and 200 mg generic armodafinil products prior to the expiration date of United States Patent No. 7,132,570, and any additional dates of exclusivity;

E. A permanent injunction enjoining Sandoz and all persons acting in concert with Sandoz from seeking, obtaining, or maintaining approval of Sandoz's ANDA No. 200-511 until the expiration date of United States Patent No. 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 Sandoz's 100 and 200 mg generic armodafinil products is not to be earlier than the expiration date of United States Patent No. 7,132,570;

G. A declaration that Sandoz 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

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

Dated: September 6, 2011

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

4463985