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Cephalon, Inc. and Cephalon France

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CEPHALON, INC. and CEPHALON FRANCE, Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC. and NATCO PHARMA LIMITED, Defendants.	CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc. and Cephalon France (collectively "Cephalon") bring this action for patent infringement against Defendants Breckenridge Pharmaceutical, Inc. ("Breckenridge") and Natco Pharma Limited ("Natco Ltd.") (collectively "Defendants"). 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, Breckenridge is a corporation organized and existing under the laws of Florida, having a principal place of business at 1141 South Rogers Circle, Suite 3, Boca Raton, FL 33487.

4. On information and belief, Breckenridge is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in New Jersey, and throughout the United States.

5. On information and belief, Breckenridge has a sales office in New Jersey located at 1 Passaic Avenue, Fairfield, NJ 07004.

6. On information and belief, Breckenridge has previously submitted to this Court's jurisdiction. *See, e.g., Bradley Pharmaceuticals, Inc. v. Breckenridge Pharmaceutical, Inc.* (D.N.J.), No. 2:06-cv-02442; *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical, Inc.* (D.N.J.), No. 2:06-cv-04199.

7. On information and belief, Natco Ltd. is an Indian company located at Natco House, Road No. 2, Banjara Hills, Hyderabad-500 033, India.

8. On information and belief, Natco Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in New Jersey, and throughout the United States.

9. On information and belief, Natco Ltd. has previously submitted to this Court's jurisdiction. *See, e.g., Celgene Corp. v. Natco Pharma Ltd.* (D.N.J.), No. 2:10-cv-5197; *Gilead Sciences et al. v. Natco Pharma Ltd. et al.* (D.N.J.), No. 2:11-cv-04969.

10. On information and belief, the acts of Natco Ltd. 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, Breckenridge.

11. On information and belief, Natco Ltd. is registered to do business, and has a registered agent, in New Jersey.

12. On information and belief, Breckenridge has a registered agent in New Jersey.

JURISDICTION AND VENUE

13. 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).

14. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their continuous and systematic contacts with corporate entities within this judicial district and 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.

15. On information and belief, and as previously noted, Natco Ltd. is registered to do business, and has a registered agent, in New Jersey. On information and belief, and as previously noted, Breckenridge has a sales office in New Jersey located at 1 Passaic Avenue, Fairfield, NJ 07004. Defendants have thus availed of the laws of the State of New Jersey and engaged in a course of conduct in the State of New Jersey. By virtue of these activities, this Court has personal jurisdiction over Defendants.

NATURE OF THIS ACTION

16. 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. 202768 filed by Defendants 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

17. 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.

18. 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.

19. Upon information and belief, Defendants filed ANDA No. 202768 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 ("Defendants' generic armodafinil products") before the expiration of the '570 patent ("patent-in-suit"). On information and belief, as part of its ANDA, Defendants 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 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic armodafinil products that are the subject of Defendants' ANDA No. 202768.

20. Defendants caused to be sent to Cephalon a letter ("the Notice Letter"), dated September 22, 2011, notifying Cephalon that Defendants had filed ANDA No. 202768 seeking approval to market Defendants' generic armodafinil products prior to the expiration of the patent-in-suit, and were providing information to Cephalon pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Cephalon received the Notice Letter on or about September 23, 2011.

COUNT I FOR INFRINGEMENT OF THE '570 PATENT

21. Cephalon realleges and incorporates by reference paragraphs 1-20.

22. Defendants have filed or caused to be filed ANDA No. 202768 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Defendants' generic armodafinil products before the expiration of the '570 patent. On information and belief, Defendants 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.

23. By submitting ANDA No. 202768 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 Defendants' generic armodafinil products before the expiration of the '570 patent, Defendants have infringed at least one claim of the '570 patent under 35 U.S.C. § 271(e)(2).

24. Upon information and belief, Breckenridge will be the exclusive marketer of Defendants' generic armodafinil products, under the Breckenridge label, in the United States.

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

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

27. Upon FDA approval of Defendants' ANDA No. 202768, Defendants will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Defendants' generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

28. Upon information and belief, Defendants will actively aid, abet, encourage, and induce others in the production, importation, sale, offer for sale, and use of Defendants' generic armodafinil products.

29. Upon information and belief, Defendants will actively participate in the production, importation, sale, offer for sale, and use of Defendants' generic armodafinil products.

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

31. Upon information and belief, Defendants had knowledge of the '570 patent and know or should know that they will aid and abet another's direct infringement of at least one claim of the '570 patent, either literally or under the doctrine of equivalents.

32. As a result of Defendants' 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), Defendants' submission to the FDA of ANDA No. 202768 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Defendants' 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), Defendants' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 202768 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation

into the United States of Defendants' 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 Defendants 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 Defendants' 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 Defendants, 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 Defendants' 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 Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of Defendants' ANDA No. 202768 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 Defendants' generic armodafinil products is not to be earlier than the expiration date of United States Patent No. 7,132,570;

G. A declaration that Defendants have 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,

Dated: November 3, 2011

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is the subject of *Cephalon, Inc. and Cephalon France v. Breckenridge Pharmaceutical, Inc. and Natco Pharma Limited*, C.A. No. 1:11-cv-1070, filed on November 2, 2011, in the U.S. District Court for the District of Delaware, and yet to be assigned to a judge. This related matter involves the same ANDA and patent (U.S. Patent No. 7,132,570).

Related cases involving the same patent (U.S. Patent No. 7,132,570) but different ANDAs include the following cases, all pending in the U.S. District Court for the District of Delaware before Chief Judge Gregory M. Sleet:

(1) *Cephalon Inc. and Cephalon France v. Mylan Pharmaceuticals Inc.*, C.A. No. 1:09-cv-954-GMS;

(2) *Cephalon Inc. and Cephalon France v. Watson Laboratories, Inc.*, C.A. No. 1:10-cv-7-GMS;

(3) *Cephalon Inc. and Cephalon France v. Sandoz Inc.*, C.A. Nos. 1:10-cv-55-GMS and 1:11-cv-782-GMS;

(4) *Cephalon Inc. and Cephalon France v. Lupin Limited*, C.A. No. 1:10-cv-210-GMS;

(5) *Cephalon Inc. and Cephalon France v. Apotex Corp. and Apotex Inc.*, C.A. Nos. 1:10-cv-695-GMS and 1:10-cv-1078-GMS; and

(6) All of the above cases except C.A. No. 1:11-cv-782 have been consolidated under In re: Armodafinil Patent Litigation, MDL Docket No. 1:10-md-2200-GMS, which has been assigned to the Honorable Gregory M. Sleet.

Dated: November 3, 2011

Respectfully submitted,

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