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Attorneys for Plaintiffs
CEPHALON, INC. and CEPHALON FRANCE

Ballard Spahr, LLP
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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

CEPHALON, INC. and CEPHALON FRANCE

Plaintiffs,

v.

CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. and WATSON PHARMA, INC.,

Defendants.

Plaintiffs Cephalon, Inc. and Cephalon France (collectively "Cephalon") bring this action for patent infringement against Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (collectively "Watson"). This action concerns a patent 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.

Cephalon files this Complaint through its local counsel, Ballard Spahr LLP. Counsel for Cephalon, Finnegan, Henderson, Farabow, Garrett & Dunner, will file a verified Pro Hac Vice Application with the District Court in compliance with LR IA 10-12 within forty-five days.

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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, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of Nevada, with a principal place of business at 311 Bonnie Circle, Corona, California 92880.

4. On information and belief, Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of Nevada, with a principal place of business at 311 Bonnie Circle, Corona, California 92880.

5. On information and belief, Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of Delaware, with a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

6. On information and belief, Watson Pharmaceuticals is the parent corporation of Watson Laboratories and Watson Pharma.

7. On information and belief, Watson Pharmaceuticals, itself and through its wholly-owned subsidiaries, Watson Laboratories and Watson Pharma, is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Nevada 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 Watson Pharmaceuticals, Watson Laboratories, and Watson 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. Additionally, both Watson Pharmaceuticals and Watson Laboratories are corporations organized and existing under the laws of Nevada.

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. 200-156 filed by Watson 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.

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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 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.

13. Upon information and belief, Watson filed ANDA No. 200-156 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 ("Watson's generic armodafinil products") before the expiration of the '570 patent ("patent-in-suit"). On information and belief, as part of its ANDA, Watson 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" Watson's generic armodafinil products that are the subject of Watson's ANDA No. 200-156.

14. Watson Laboratories caused to be sent to Cephalon a letter ("the Notice Letter"), dated November 24, 2009, notifying Cephalon that Watson had filed ANDA No. 200-156 seeking approval to market Watson's generic armodafinil products prior to the expiration of the '570 patent, 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 November 25, 2009.

COUNT I FOR INFRINGEMENT OF THE '570 PATENT

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

16. Watson has filed or caused to be filed ANDA No. 200-156 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Watson's generic armodafinil products before the expiration of the '570 patent. On information and belief, Watson

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.

17. By submitting ANDA No. 200-156 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 Watson's generic armodafinil products before the expiration of the '570 patent, Watson has infringed the '570 patent under 35 U.S.C. § 271(e)(2).

18. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have acted in concert, actively supporting, participating in, encouraging, and inducing Watson Laboratories's filing of ANDA No. 200-156 for Watson's generic armodafinil products, and in the preparation to sell in the United States Watson's generic armodafinil products.

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

20. Upon information and belief, Watson'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.

21. Upon FDA approval of Watson's ANDA No. 200-156, Watson will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Watson's generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

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

23. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma will each actively participate in the production, importation, sale, offer for sale, and use of Watson's generic armodafinil products.

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

25. Upon information and belief, Watson 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.

26. Watson has knowledge of the '570 patent and is knowingly and willfully infringing the '570 patent.

27. As a result of Watson'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.

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PRAYER FOR RELIEF

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

1. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Watson's submission to the FDA of ANDA No. 200-156 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Watson's generic armodafinil products before the expiration of United States Patent No. 7,132,570 was an act of infringement;

2. A declaration that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Watson's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-156 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Watson's generic armodafinil products before the expiration of United States Patent No. 7,132,570 was an act of infringement;

3. A declaration that Watson 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)-(b) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Watson's generic armodafinil products prior to expiration of said patent-in-suit and any additional dates of exclusivity therefor;

4. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Watson, 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 Watson's generic armodafinil products prior to the expiration date of United States Patent No. 7,132,570, and any additional dates of exclusivity;

5. A permanent injunction enjoining Watson and all persons acting in concert with Watson from seeking, obtaining, or maintaining approval of Watson's ANDA No. 200-156 until the expiration date of United States Patent No. 7,132,570, and any additional dates of exclusivity;

6. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Watson's generic armodafinil products is not to be earlier than the latest of the expiration date of United States Patent No. 7,132,570 and any additional dates of exclusivity;

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

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

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

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

Respectfully submitted,

/s/ Jacob D. Bundick

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