IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC., AVANIR HOLDING COMPANY, and CENTER FOR NEUROLOGIC STUDY,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Avanir Pharmaceuticals, Inc. ("Avanir Pharmaceuticals"), Avanir Holding Company, and Center for Neurologic Study ("CNS"), by their undersigned attorneys, for their Complaint against defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc., allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Watson's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval commercially to market a generic version of Avanir Pharmaceuticals' NUEDEXTA® drug product prior to the expiration of United States Patent Nos. 7,659,282 (the "'282 patent") and RE38,115 (the "'115 patent").

The Parties

2. Plaintiff Avanir Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Enterprise, Suite 200, Aliso Viejo, California 92656.

3. Plaintiff Avanir Holding Company is a corporation organized and existing under the laws of the State of California, having a principle place of business at 20 Enterprise, Suite 200, Aliso Viejo, California 92656. Avanir Holding Company is a wholly-owned subsidiary of Avanir Pharmaceuticals, Inc.

4. Plaintiff Center for Neurologic Study is a not-for-profit corporation organized and existing under the laws of the State of California, having a principle place of business at 9850 Genesee Avenue, Suite 320, La Jolla, California 92037.

5. On information and belief, defendant Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. On information and belief, defendant Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, CA 92880, and another place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. On information and belief, defendant Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07960.

8. On information and belief, Watson Laboratories and Watson Pharma are wholly owned subsidiaries of Watson Pharmaceuticals. On information and belief, Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals share a common place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals also each share with the others common employees, officers and directors. Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are collectively referred to herein as "Watson."

Jurisdiction and Venue

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. On information and belief, Watson Pharmaceuticals organizes its operations by divisions—Global Generics, Global Brands and Distribution—and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. On information and belief, Watson Pharmaceuticals consolidates its financial results with, among other entities, Watson Laboratories and Watson Pharma, in its most recent SEC filings, and does not separate financial reports for each Watson subsidiary.

11. On information and belief, the Global Generics division is responsible for developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals each act as agents of each other and/or work in concert with each other to further the aims of the Global Generics division. On information and belief, the Global Generics division, which is responsible for, *inter alia*, developing and submitting ANDAs to the

FDA, relies on contributions from Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals.

12. On information and belief, the Global Generics division's ANDAs are submitted by Watson Laboratories, the Global Generics division's products are also manufactured by Watson Laboratories, and the Global Generics division's products are marketed and sold throughout the United States, including in Delaware, by Watson Pharma.

13. On information and belief, Watson Laboratories has purposefully availed itself of the rights and benefits of Delaware law and this Court. This Court previously determined in *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 629 F.Supp. 2d 338, 348 (D. Del. 2009), that Watson Laboratories "'regularly does or solicits business' in Delaware or engages in a 'persistent course of conduct' in Delaware."

14. On information and belief, Watson Pharmaceuticals, through its own actions and the actions of one or more Watson subsidiaries, actively engages in a concerted effort to sell generic products throughout the United States, including in Delaware.

15. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma participated in, contributed to, aided and/or induced the submission to the FDA of Watson's ANDA. For instance, by letter dated January 26, 2012, Watson Laboratories directed Avanir Pharmaceuticals and CNS to send any written notice regarding confidential access concerning Watson's ANDA to Matthew O. Brady, who is Associate Vice President, Intellectual Property for Watson Pharmaceuticals. Mr. Brady is also registered with the U.S. Patent and Trademark Office as an attorney employed by Watson Pharmaceuticals.

16. On information and belief, Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories, as part of Watson Pharmaceuticals' Global Generics division, will work in

concert with one another to manufacture, market, and/or sell within the United States the generic product that is the subject of ANDA No. 203-538 ("Watson's Proposed Product") if FDA approval is granted.

17. On information and belief, if Watson's ANDA is approved by the FDA, Watson's Proposed Product, which is charged with infringing the '282 and '115 patents, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

18. This Court has personal jurisdiction over defendants Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals by virtue of, *inter alia*, the above-mentioned facts. They demonstrate that Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals either directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware. These activities further demonstrate that Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals have continuous and systematic contacts in Delaware.

19. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents-in-Suit

20. On February 9, 2010, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '282 patent, entitled "Pharmaceutical Compositions Comprising Dextromethorphan and Quinidine for the Treatment of Neurological Disorders" to inventors Gerald Yakatan, James Berg, Laura Pope, and Richard Smith. A copy of the '282 patent is attached hereto as Exhibit A.

21. On May 6, 2003, the USPTO duly and lawfully issued the '115 patent, entitled "Dextromethorphan and an Oxidase Inhibitor for Treating Intractable Conditions" to inventors Richard Smith and Jonathan Licht. A copy of the '115 patent is attached hereto as Exhibit B.

The NUEDEXTA® Drug Product

22. Avanir Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for dextromethorphan hydrobromide/quinidine sulfate capsules (NDA No. 21-879), which it sells under the trade name NUEDEXTA®. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical formulations containing dextromethorphan hydrobromide/quinidine sulfate or methods of using same. Avanir Pharmaceuticals is the assignee of the '282 patent. CNS is the assignee of the '115 patent. Avanir Holding Company is an exclusive licensee of the '115 patent, and Avanir Pharmaceuticals is an exclusive sub-licensee of the '115 patent.

23. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '282 and '115 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NUEDEXTA®.

Acts Giving Rise to this Suit

24. Pursuant to Section 505 of the FFDCA, Watson filed ANDA No. 203-538 ("Watson's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 20 mg dextromethorphan hydrobromide/10 mg quinidine sulfate capsules ("Watson's Proposed Product") before the patents-in-suit expire.

25. In connection with the filing of its ANDA, as described in the preceding paragraph, Watson has provided a written certification to the FDA, as called for by Section 505

of the FFDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA.

26. No earlier than January 26, 2012, Watson sent written notice of its ANDA certification to Avanir Pharmaceuticals ("Watson's Notice Letter"). Watson's Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA. Watson's Notice Letter also informed Avanir Pharmaceuticals that Watson seeks approval to market Watson's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '282 Patent

27. Plaintiffs repeat and reallege the allegations of paragraphs 1-26 as though fully set forth herein.

28. Watson's submission of its ANDA to the FDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of dextromethorphan hydrobromide/quinidine sulfate capsules, prior to the expiration of the '282 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

29. There is a justiciable controversy between the parties hereto as to the infringement of the '282 patent.

30. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '282 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

31. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '282 patent under 35 U.S.C. § 271(b) by making, using,

offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, upon FDA approval of Watson's ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the '282 patent and knowledge that its acts are encouraging infringement.

32. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '282 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson's Proposed Product is especially adapted for a use that infringes the '282 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

33. Plaintiffs will be substantially and irreparably damaged and harmed if Watson's infringement of the '282 patent is not enjoined.

34. Plaintiffs do not have an adequate remedy at law.

35. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '115 Patent

36. Plaintiffs repeat and reallege the allegations of paragraphs 1-35 as though fully set forth herein.

37. Watson's submission of its ANDA to the FDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of dextromethorphan hydrobromide/quinidine sulfate capsules, prior to the expiration of the '115 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

38. There is a justiciable controversy between the parties hereto as to the infringement of the '115 patent.

39. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '115 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

40. Plaintiffs will be substantially and irreparably damaged and harmed if Watson's infringement of the '115 patent is not enjoined.

41. Plaintiffs do not have an adequate remedy at law.

42. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that Watson has infringed the '282 and '115 patents by submitting ANDA No. 203-538 to the FDA;

(B) A Judgment be entered that Watson has infringed, and that Watson's making, using, selling, offering to sell, or importing Watson's Proposed Product will infringe one or more claims of the '282 and '115 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 203-538 be a date which is not earlier than the later of the expiration of the '282 and '115 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Watson and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Watson's Proposed Product until after the expiration

of the '282 and '115 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Watson, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods claimed in the '282 patent, or from actively inducing or contributing to the infringement of any claims of the '282 patent, until after the expiration of the '282 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Watson's Proposed Product will directly infringe, induce and/or contribute to infringement of the '282 and '115 patents;

(G) If Watson engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Watson's Proposed Product prior to the expiration of the '282 and '115 patents, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(H) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(I) Costs and expenses in this action; and

(J) Such further and other relief as this Court may deem just and proper.

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