IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WATSON PHARMACEUTICALS, INC.,	)	
WATSON LABORATORIES, INC., and	)	
WATSON PHARMA, INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Avanir Pharmaceuticals, Inc. ("Avanir") by its undersigned attorneys, for its Complaint against defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc.. (collectively, "Watson"), alleges as follows:

Nature of 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's NUEDEXTA® drug product prior to the expiration of United States Patent No. 8,227,484 (the "'484 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. 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.

4. 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.

5. 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.

6. 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

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

8. 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.

9. 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.

10. 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.

11. 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."

12. 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.

13. 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 ANDA No. 203-538 ("Watson's ANDA"). For instance, by letter dated August, 15, 2012, Watson Laboratories directed Avanir Pharmaceuticals 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.

14. 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 if FDA approval is granted.

15. On information and belief, if Watson's ANDA is approved by the FDA, the generic product that is the subject of ANDA No. 203-538 , which is charged with infringing the '484 patent, 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.

16. 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.

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

The Patent-in-Suit

18. On July, 24, 2012, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '484 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 '484 patent is attached hereto as Exhibit A.

The NUEDEXTA® Drug Product

19. Avanir 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 patent-in-suit cover, *inter alia*, methods of using pharmaceutical formulations containing dextromethorphan/quinidine. Avanir is the assignee of the '484 patent.

20. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '484 patent is 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

21. Watson filed ANDA No. 203-538 seeking the FDA's 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 patent-in-suit expires.

22. Upon information and belief, in connection with the filing of its ANDA, Watson provided a written certification to the FDA, pursuant to Section 505 of the FFDCA, alleging that the claims of the '484 patent are invalid and/or will not be infringed by the activities described in Watson's ANDA.

23. No earlier than August 15, 2012, Watson sent written notice of its ANDA certification to Avanir ("Watson's Notice Letter"). Watson's Notice Letter alleged that the claims of the '484 patent are invalid and/or will not be infringed by the activities described in Watson's ANDA. Watson's Notice Letter also informed Avanir that Watson seeks approval to market Watson's Proposed Product before the patent-in-suit expires.

Count I: Infringement of the '484 Patent

24. Avanir repeats and realleges the allegations of paragraphs 1-23 as though fully set forth herein.

25. 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 '484 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

26. There is a justiciable controversy between the parties hereto as to the infringement of the '484 patent.

27. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '484 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.

28. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '484 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 '484 patent and knowledge that its acts are encouraging infringement.

29. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '484 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 '484 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

30. Avanir will be substantially and irreparably damaged and harmed if Watson's infringement of the '484 patent is not enjoined.

31. Avanir does not have an adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Avanir respectfully requests the following relief:

A. A Judgment be entered that Watson has infringed the '484 patent 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 '484 patent;

C. An Order that the effective date of FDA approval of ANDA No. 203-538 be a date which is not earlier than the expiration of the '484 patent, or any later expiration of exclusivity to which Avanir is or becomes 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 '484 patent, or any later expiration of exclusivity to which Avanir is or becomes 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 '484 patent, or from actively inducing or contributing to the infringement of any claims of the '484 patent, until after the expiration of the '484 patent, or any later expiration of exclusivity to which Avanir is or becomes entitled;

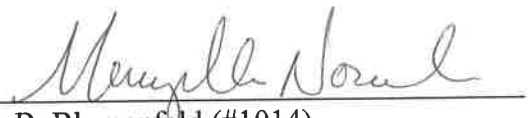
F. If Watson engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Watson's Proposed Product prior to the expiration of the '484 patent, a Judgment awarding damages to Avanir resulting from such infringement, together with interest;

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

H. Costs and expenses in this action; and

I. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNEL, LLP



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