IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACTAVIS SOUTH ATLANTIC, LLC and ACTAVIS, INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Avanir Pharmaceuticals, Inc. ("Avanir") by its undersigned attorneys, for its Complaint against defendants Actavis South Atlantic LLC and Actavis, Inc. (collectively, "Actavis"), 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 Actavis'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 Actavis South Atlantic LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325.

4. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960. On information and belief, Actavis, Inc. is the parent company of Actavis South Atlantic LLC.

5. On information and belief, Actavis South Atlantic LLC and Actavis, Inc. acted collaboratively in the preparation and submission of ANDA No. 202-934 to the FDA. On information and belief, Actavis South Atlantic LLC's preparation and submission of ANDA No. 202-934 to the FDA was done at the direction, under the control, and for the direct benefit of Actavis, Inc.

6. On information and belief, following any FDA approval of ANDA No. 202-934, Actavis South Atlantic LLC and Actavis, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 202-934 throughout the United States, and/or import such generic products into the United States.

7. On information and belief, Actavis has incorporated in the State of Delaware, and maintains a registered agent for service of process in Delaware. On information and belief, Actavis has regularly transacted business within this judicial district. Further, on information and belief, Actavis has developed numerous generic drugs for sale and use throughout the United States, including in this judicial district.

Jurisdiction and Venue

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

9. This Court has personal jurisdiction over Actavis South Atlantic LLC because it is a corporation organized and existing under the laws of the State of Delaware and, by virtue of,

inter alia, having availed itself of the rights and benefits of Delaware law, and having engaged in systematic and continuous contacts with the State of Delaware.

10. This Court has personal jurisdiction over Actavis, Inc. because it is a corporation organized and existing under the laws of the State of Delaware and, by virtue of, *inter alia,* having availed itself of the rights and benefits of Delaware law, and having engaged in systematic and continuous contacts with the State of Delaware.

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

The Patent-in-Suit

12. 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

13. 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.

14. 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

15. Actavis filed ANDA No. 202-934 ("Actavis's ANDA") 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 ("Actavis's Proposed Product") before the patent-in-suit expires.

16. Upon information and belief, in connection with the filing of its ANDA, Actavis 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 Actavis's ANDA.

17. No earlier than August 17, 2012, Actavis sent written notice of its ANDA certification to Avanir ("Actavis's Notice Letter"). Actavis's Notice Letter alleged that the claims of the '484 patent are invalid and/or will not be infringed by the activities described in Actavis's ANDA. Actavis's Notice Letter also informed Avanir that Actavis seeks approval to market Actavis's Proposed Product before the patent-in-suit expires.

Count I: Infringement of the '484 Patent

18. Avanir repeats and realleges the allegations of paragraphs 1-17 as though fully set forth herein.

19. Actavis'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).

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

21. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will infringe the '484 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Actavis's Proposed Product in the United States.

22. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will induce infringement of the '484 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Actavis's Proposed Product in the United States. On information and belief, upon FDA approval of Actavis's ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '484 patent and knowledge that its acts are encouraging infringement.

23. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will contributorily infringe the '484 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Actavis's Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge that Actavis's Proposed Product is especially adapted for a use that infringes the '484 patent and that there is no substantial non-infringing use for Actavis's Proposed Product.

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

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

26. 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 Actavis has infringed the '484 patent by submitting ANDA No. 202-934 to the FDA;

B. A Judgment be entered that Actavis has infringed, and that Actavis's making, using, selling, offering to sell, or importing Actavis'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. 202-934 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 Actavis 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 Actavis'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 Actavis, 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 Actavis engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis'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.

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