

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AVANIR PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
IMPAX LABORATORIES, INC.,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Avanir Pharmaceuticals, Inc. (“Avanir”) by its undersigned attorneys, for its Complaint against defendant Impax Laboratories, Inc. (“Impax”), 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 Impax’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<sup>®</sup> 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 Impax is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

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

#### **Jurisdiction and Venue**

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

6. This Court has personal jurisdiction over Impax Laboratories, 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.

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

#### **The Patent-in-Suit**

8. 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<sup>®</sup> Drug Product**

9. 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<sup>®</sup>. 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.

10. 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<sup>®</sup>.

#### **Acts Giving Rise to this Suit**

11. Impax filed ANDA No. 203-061 ("Impax'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 ("Impax's Proposed Product") before the patent-in-suit expires.

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

13. No earlier than September 20, 2012, Impax sent written notice of its ANDA certification to Avanir ("Impax's Notice Letter"). Impax's Notice Letter alleged that the claims of the '484 patent are invalid and/or will not be infringed by the activities described in Impax's ANDA. Impax's Notice Letter also informed Avanir that Impax seeks approval to market Impax's Proposed Product before the patent-in-suit expires.

#### **Count I: Infringement of the '484 Patent**

14. Avanir repeats and realleges the allegations of paragraphs 1-13 as though fully set forth herein.

15. Impax'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).

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

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

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

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

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

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

22. 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 Impax has infringed the '484 patent by submitting ANDA No. 203-061 to the FDA;

B. A Judgment be entered that Impax has infringed, and that Impax's making, using, selling, offering to sell, or importing Impax'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. 203-061 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 Impax 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 Impax'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 Impax, 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 Impax engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Impax'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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