IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
v.	)	C.A. No. _____
	)	
RANBAXY LABORATORIES LIMITED and RANBAXY INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Avanir Pharmaceuticals, Inc. ("Avanir"), by its undersigned attorneys, for its Complaint against Defendants Ranbaxy Laboratories Limited ("Ranbaxy Labs.") and Ranbaxy Inc. (together, "Ranbaxy"), 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 Ranbaxy'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 Nos. 7,659,282 (the "'282 patent") and 8,227,484 (the "'484 patent"), all owned by Avanir (collectively, "the Patents-in-Suit").

The Parties

2. Plaintiff Avanir 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, Ranbaxy Labs. is a company organized and existing under the laws of India, having a principal place of business at 12th Floor, Devika Towers, 6 Nehru Place, New Delhi, India

4. On information and belief, Ranbaxy Labs. is registered to do business in the State of Delaware, and regularly transacts business within this judicial district. On information and belief, Ranbaxy Labs. develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. On information and belief, Ranbaxy Labs. also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

5. On information and belief, Ranbaxy Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 600 College Road East, Princeton, New Jersey 08540.

6. On information and belief, Ranbaxy Inc. regularly conducts business in this judicial district, including marketing and selling pharmaceutical products. Further, on information and belief, Ranbaxy Inc. is an authorized agent for Ranbaxy Labs., and a wholly-owned subsidiary of Ranbaxy Labs.

7. On information and belief, Ranbaxy Labs. and Ranbaxy Inc. acted collaboratively in the preparation and submission of ANDA No. 204196 to the FDA. On information and belief, Ranbaxy Labs.'s submission of ANDA No. 204196 to the FDA was done at the direction, under the control, and for the direct benefit of Ranbaxy Inc.

8. On information and belief, following any FDA approval of ANDA No. 204196, Ranbaxy Labs. and Ranbaxy 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. 204196 throughout the United States, and/or import such generic products into the United States.

Jurisdiction and Venue

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

10. This Court has personal jurisdiction over Ranbaxy Labs. by virtue of, inter alia, its systematic and continuous contacts with the State of Delaware. On information and belief, Ranbaxy Labs. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware and deriving revenue from such activities. Further, on information and belief, Ranbaxy Labs. has customers in the State of Delaware. Ranbaxy Labs. has also previously admitted that it is subject to this Court's jurisdiction. *See, e.g., Forest Labs., Inc. v. Ranbaxy Inc.*, No. 13-cv-1607, D.I. 14 (D. Del. Dec. 6, 2013); *Merck & Co. v. Ranbaxy Inc.*, No. 07-cv-229, D.I. 10 (D. Del. June 21, 2007); *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. 07-cv-138, D.I. 7 (D. Del. Mar. 29, 2007). Further, Ranbaxy Labs. has purposefully availed itself of this forum by filing counterclaims in lawsuits filed against it in this judicial district. *See, e.g., Merck & Co. v. Ranbaxy, Inc.*, No. 07-229, D.I. 10 (D. Del. June 21, 2007) and *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. 07-cv-138, D.I. 7 (D. Del. Mar. 29, 2007).

11. This court has jurisdiction over Ranbaxy Inc. because Ranbaxy Inc. is a Delaware corporation. Further, Ranbaxy Inc. has purposefully availed itself of this forum by filing counterclaims in lawsuits filed against it in this judicial district. *See, e.g., Pfizer Inc. v. Watson Pharms., Inc.*, No. 10-357, D.I. 26 (D. Del. July 26, 2010).

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

The Patents-in-Suit

13. 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. Avanir is the assignee of the '282 patent. The '282 patent expires on August 13, 2026. A copy of the '282 patent is attached hereto as Exhibit A.

14. On July, 24, 2012, the 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. Avanir is the assignee of the '484 patent. The '484 patent expires on July 17, 2023. A copy of the '484 patent is attached hereto as Exhibit B.

The NUEDEXTA® Drug Product

15. 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 Patents-in-Suit cover, inter alia, pharmaceutical formulations containing dextromethorphan hydrobromide/quinidine sulfate or methods of using same.

16. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patents-in-Suit 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

17. Ranbaxy filed ANDA No. 204196 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 ("Ranbaxy's Proposed Product") before the Patents-in-Suit expire.

18. Upon information and belief, in connection with the filing of its ANDA, Ranbaxy provided written certifications to the FDA, pursuant to Section 505 of the FFDCA, alleging that the claims of the Patents-in-Suit are invalid and/or will not be infringed by the activities described in ANDA No. 204196.

19. No earlier than May 9, 2014, Ranbaxy sent written notice of its ANDA certification to Avanir ("Ranbaxy Notice Letter"). Ranbaxy's Notice Letter alleged that the claims of the Patents-in-Suit are invalid and/or will not be infringed by the activities described in Ranbaxy's ANDA. Ranbaxy's Notice Letter also informed Avanir that Ranbaxy seeks approval to market Ranbaxy's Proposed Product before the Patents-in-Suit expire.

Count I: Infringement of the '282 Patent

20. Avanir repeats and realleges the allegations of paragraphs 1-19 as though fully set forth herein.

21. Ranbaxy'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).

22. There is a justiciable controversy between Avanir and Ranbaxy as to the infringement of the '282 patent.

23. Unless enjoined by this Court, upon FDA approval of ANDA No. 204196, Ranbaxy will infringe the '282 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States.

24. Unless enjoined by this Court, upon FDA approval of ANDA No. 204196, Ranbaxy will induce infringement of the '282 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States. On

information and belief, upon FDA approval of ANDA No. 204196, Ranbaxy will intentionally encourage acts of direct infringement with knowledge of the ’282 patent and knowledge that its acts are encouraging infringement.

25. Unless enjoined by this Court, upon FDA approval of ANDA No. 204196, Ranbaxy will contributorily infringe the ’282 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ranbaxy’s Proposed Product in the United States. On information and belief, Ranbaxy has had and continues to have knowledge that Ranbaxy’s Proposed Product is especially adapted for a use that infringes the ’282 patent and that there is no substantial non-infringing use for Ranbaxy’s Proposed Product.

26. Avanir will be substantially and irreparably damaged and harmed if Ranbaxy’s infringement of the ’282 patent is not enjoined.

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

28. Ranbaxy’s infringement is willful.

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

Count II: Infringement of the ’484 Patent

30. Avanir repeats and realleges the allegations of paragraphs 1-29 as though fully set forth herein.

31. Ranbaxy’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).

32. There is a justiciable controversy between Avanir and Ranbaxy as to the infringement of the ’484 patent.

33. Unless enjoined by this Court, upon FDA approval of ANDA No. 204196, Ranbaxy will infringe the '484 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States.

34. Unless enjoined by this Court, upon FDA approval of ANDA No. 204196, Ranbaxy will induce infringement of the '484 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States. On information and belief, upon FDA approval of ANDA No. 204196, Ranbaxy will intentionally encourage acts of direct infringement with knowledge of the '484 patent and knowledge that its acts are encouraging infringement.

35. Unless enjoined by this Court, upon FDA approval of ANDA No. 204196, Ranbaxy will contributorily infringe the '484 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States. On information and belief, Ranbaxy has had and continues to have knowledge that Ranbaxy's Proposed Product is especially adapted for a use that infringes the '484 patent and that there is no substantial non-infringing use for Ranbaxy's Proposed Product.

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

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

38. Ranbaxy's infringement is willful.

39. 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, Plaintiff respectfully requests the following relief:

(A) A Judgment be entered that Ranbaxy has infringed the Patents-in-Suit by submitting ANDA No. 204196;

(B) A Judgment be entered that Ranbaxy has infringed, and that Ranbaxy's, making, using, selling, offering to sell, or importing into the United States of Ranbaxy's Proposed Products will infringe one or more claims of the Patents-in-Suit;

(C) An Order that the effective date of FDA approval of ANDA No. 204196 be a date which is not earlier than the later of the expiration of the Patents-in-Suit, or any later expiration of exclusivity to which Avanir is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Ranbaxy and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from making, using, selling, offering to sell, or importing into the United States Ranbaxy's Proposed Products until after the expiration of the Patents-in-Suit, 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 Ranbaxy, its officers, agents, attorneys and employees, and those acting in privity or concert with it, from practicing any methods claimed in the Patents-in-Suit, or from actively inducing or contributing to the infringement of any claim of any of the Patents-in-Suit, until after the expiration of the Patents-in-Suit, or any later expiration of exclusivity to which Avanir is or becomes entitled;

(F) If Ranbaxy engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Ranbaxy's Proposed Product prior to the expiration of the Patents-in-Suit, a Judgment awarding damages to Avanir resulting from such infringement, together with interest;

(G) A Judgment be entered that Ranbaxy's infringement is willful.

(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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