IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD. & ROYALTY PHARMA COLLECTION TRUST,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and Royalty Pharma Collection Trust (collectively, "Plaintiffs") file this Complaint for patent infringement against Defendant Par Pharmaceutical, Inc. ("Par") under 35 U.S.C. §§ 271(e)(2), (b) and (c). This patent action concerns the pharmaceutical drug product Savella®. Plaintiffs hereby state as follows:

JURISDICTION AND PARTIES

2. Plaintiff Forest Laboratories, Inc. ("Forest Labs.") is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York, 10022.

3. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Columbia House, 1 Victoria Street, Hamilton HM11, Bermuda (referred to herein, together with Forest Labs. as "Forest").

4. Plaintiff Royalty Pharma Collection Trust ("Royalty Pharma") is a Delaware trust having a principal place of business at Rodney Square North, 1100 North Market Street, Wilmington, Delaware 19890-0001.

5. On information and belief, Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

6. Par is thus a Delaware corporation. By virtue of its incorporation in Delaware, this Court has personal jurisdiction over Par.

7. On information and belief, Par is a pharmaceutical company that formulates, manufactures, packages and markets generic drug products for distribution in the District of Delaware and throughout the United States.

8. Par is registered with the Delaware Board of Pharmacy as "Distributer/Manufacturer CSR" (License No. DM-0007883) and "Pharmacy-Wholesale" with (License No. A4-0001326) pursuant to DEL. CODE. ANN. tit 24 § 2530 (West 2012).

9. On information and belief, Par derives substantial revenue from the sale of its products in Delaware and throughout the United States.

10. On information and belief, this Court has personal jurisdiction over Par by virtue of its consent and/or contacts with this forum, including, *inter alia*, marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

11. On information and belief, Par has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Par has filed suit for patent infringement and has filed counterclaims for declaratory judgment.

12. This Court has personal jurisdiction over Par, by virtue of, among other things: (1) its incorporation in the state of Delaware; (2) its sale and distribution of generic drugs in

Delaware; (3) its registration to do business in Delaware, including its appointment of a registered agent in Delaware for the receipt of service of process; (4) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiffs Forest Labs. and Royalty Pharma, which are Delaware corporations; and (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute.

13. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq*. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

14. Plaintiffs reallege and incorporate by reference paragraphs 1-13.

15. United States Patent No. 6,602,911 ("the '911 patent"), titled "Methods of Treating Fibromyalgia," was duly and legally issued to inventors Jay D. Kranzler and Srinivas G. Rao by the United States Patent and Trademark Office ("PTO") on August 5, 2003. The '911 patent is currently assigned to Royalty Pharma and expires on January 14, 2023. This expiration date includes a 435 day patent term extension granted by the PTO pursuant to 35 U.S.C. § 156. A true and correct copy of the '911 patent is attached as Exhibit A. A true and correct copy of the Certificate Extending Patent Term is attached as Exhibit B.

16. United States Patent No. 7,888,342 ("the '342 patent"), titled "Methods of Treating Fibromyalgia Syndrome, Chronic Fatigue Syndrome and Pain," was duly and legally issued to inventors Jay D. Kranzler and Srinivas G. Rao by the PTO on February 15, 2011. The

’342 patent is currently assigned to Royalty Pharma and expires on November 5, 2021. A true and correct copy of the ’342 patent is attached as Exhibit C.

17. United States Patent No. 7,994,220 (“the ’220 patent”), titled “Milnacipran for the Long-Term Treatment of Fibromyalgia Syndrome,” was duly and legally issued to inventors Srinivas G. Rao, Michael Gendreau, and Jay D. Kranzler by the PTO on August 9, 2011. The ’220 patent is currently assigned to Royalty Pharma and expires on September 19, 2029. This expiration date includes a 1089 day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the ’220 patent is attached as Exhibit D. A true and correct copy of the Issue Notification reflecting the patent term adjustment is attached as Exhibit E.

18. New Drug Application (“NDA”) No. 022256 is directed to the use of Savella® in the management of fibromyalgia. The FDA approved NDA No. 022256 on January 14, 2009. The ’911, ’342, and ’220 patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 022256.

19. Plaintiff Forest is the exclusive licensee of the ’911, ’342, and ’220 patents. Plaintiff Forest is the exclusive distributor of tablets containing 12.5 mg, 25 mg, 50 mg, and 100 mg of the active ingredient milnacipran hydrochloride in the United States, which are sold under the brand name Savella®.

20. On information and belief, Par filed, or caused to be filed, ANDA No. 205062 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of milnacipran hydrochloride tablets in 12.5 mg, 25 mg, 50 mg, and 100 mg dosage strengths in the United States before the expiration of the ’911, ’342, and ’220 patents.

21. On information and belief, ANDA No. 205062 contains a Paragraph IV certification alleging that the claims of the ’911, ’342, and ’220 patents are invalid.

22. Par sent or caused to be sent to Plaintiffs a letter dated September 4, 2013 (“the Par Notice Letter”) notifying Plaintiffs that Par had submitted ANDA No. 205062, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges invalidity of claims 1-7 of the ’911 patent, claims 1-10 of the ’342 patent and claims 1-7 of the ’220 patent. The notice letter did not allege noninfringement of the claims of the ’911, ’342, or ’220 patents.

23. On information and belief, Par seeks approval of at least one indication for Par’s generic milnacipran product that is claimed in the ’911, ’342, and ’220 patents.

24. Under 35 U.S.C. § 271(e)(2)(A), Par infringed one or more claims of the ’911, ’342, and ’220 patents, in violation of Plaintiffs’ patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the ’911, ’342, and ’220 patents—Par’s generic milnacipran product, the use of which would directly infringe one or more claims of the ’911, ’342, and ’220 patents, and the manufacture and sale of which would contribute to or induce the direct infringement of one or more claims of the ’911, ’342, and ’220 patents by users of Par’s generic milnacipran product.

25. On information and belief, Par has knowledge of the ’911, ’342, and ’220 patents and has filed ANDA No. 205062 seeking authorization to commercially manufacture, use, offer for sale, and sell Par’s generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205062, physicians, health care providers, and/or patients will use Par’s generic milnacipran product in accordance with the instructions and/or label provided by Par and will directly infringe one or more claims of the ’911, ’342, and ’220 patents.

26. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's generic milnacipran product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more of the claims of the '911, '342, and '220 patents with the requisite intent.

27. On information and belief, if the FDA approves ANDA No. 205062, Par will sell or offer to sell its generic milnacipran product specifically labeled for use in practicing one or more of the method claims of the '911, '342, and '220 patents, wherein Par's generic milnacipran product is a material part of the method claimed, wherein Par knows that physicians will prescribe and patients will use Par's generic milnacipran product in practicing one or more of the methods claimed in the '911, '342, and '220 patents, and wherein milnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Par will thus contribute to the infringement of the '911, '342, and '220 patents.

28. Plaintiffs will be substantially and irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT

29. Plaintiffs reallege and incorporate by reference paragraphs 1-28.

30. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

31. The manufacture, sale, offer for sale, and/or importation of Par's generic milnacipran product so labeled, if approved by the FDA, will induce and contribute to the

infringement of one or more claims of the ’911, ’342, and ’220 patents under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs’ patent rights.

32. On information and belief, Par has knowledge of the ’911, ’342, and ’220 patents and has filed ANDA No. 205062 seeking authorization to commercially manufacture, use, offer for sale, and sell Par’s generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205062, physicians, health care providers, and/or patients will use Par’s generic milnacipran product in accordance with the instructions and/or label provided by Par and will directly infringe one or more claims of the ’911, ’342, and ’220 patents.

33. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par’s generic milnacipran product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more of the claims of the ’911, ’342, and ’220 patents with the requisite intent under 35 U.S.C. § 271(b).

34. On information and belief, if the FDA approves ANDA No. 205062, Par will sell or offer to sell its generic milnacipran product specifically labeled for use in practicing one or more of the method claims of the ’911, ’342, and ’220 patents, wherein Par’s generic milnacipran product is a material part of the method claimed in the ’911, ’342, and ’220 patents, wherein Par knows that physicians will prescribe and patients will use Par’s generic milnacipran product in practicing one or more of the methods claimed in the ’911, ’342, and ’220 patents, and wherein milnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Par will thus contribute to the infringement of the ’911, ’342, and ’220 patents under 35 U.S.C. § 271(c).

35. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Par as to liability for the infringement of the claims of the '911, '342, and '220 patents. Par's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Par's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment in its favor as follows:

(a) declare that United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 are valid;

(b) declare that, under 35 U.S.C. § 271(e)(2)(A), Par infringed United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 by submitting ANDA No. 205062 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Par's generic milnacipran product prior to the expiration of said patents;

c) declare that Par's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of Par's generic milnacipran product prior to the expiration of United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271 (b) and/or (c);

d) order that the effective date of any FDA approval of Par's generic milnacipran product shall be no earlier than the expiration date of United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Par, and all persons acting in concert with Par, from seeking, obtaining, or maintaining final approval of ANDA No. 205062 until the expiration of United

States Patent Nos. 6,602,911, 7,888,342, and 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled;

f) enjoin Par and all persons acting in concert with Par, from commercially manufacturing, using, offering for sale, or selling Par's generic milnacipran product within the United States, or importing Par's generic milnacipran product into the United States, until the expiration of United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);

g) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

h) grant Plaintiffs such further and additional relief that this Court deems just and proper.

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