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. _____
FIRST TIME US GENERICS LLC,	)	
Defendants.	)	

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 First Time U.S. Generics LLC ("First Time") 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, First Time US Generics LLC is a corporation organized and existing under the laws of Florida, having a principal place of business at 505 Park Way, Suite 6, Broomall, PA 19008.

6. On information and belief, First Time is subject to personal jurisdiction in the District of Delaware.

7. On information and belief, First Time 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. On information and belief, upon approval of ANDA No. 205071, First Time will sell its milnacipran hydrochloride tablets in 12.5 mg, 25 mg, 50 mg, and 100 mg dosage strengths ("First Time's generic milnacipran product") in Delaware and throughout the United States and will derive substantial revenue from such sales.

9. On information and belief, this Court also has personal jurisdiction over First Time because, among other things, First Time will place its products into the stream of commerce with the reasonable expectation and/or knowledge and the requisite intent that purchasers and users of such products who are located within this judicial district will purchase and use them. Specifically, upon information and belief, upon approval of ANDA No. 205071, First Time will place its generic milnacipran products into the stream of commerce with the expectation and requisite intent that such products will ultimately be used by consumers in the State of Delaware.

10. On information and belief, First Time's filing of ANDA No. 205071 with a paragraph IV certification constitutes an act of infringement, which is a tortious act that has, and

will lead to foreseeable harm to Plaintiffs Forest Labs. and Royalty Pharma, which are both Delaware corporations.

11. Accordingly, on information and belief, this Court has personal jurisdiction over First Time, by virtue of, among other things: (1) the sale and distribution of First Time's generic milnacipran products in Delaware upon FDA approval of ANDA No. 205071; (2) the placement of First Time's generic milnacipran products into the stream of commerce with the expectation and requisite intent that such products will ultimately be used by consumers in the State of Delaware upon FDA approval of ANDA No. 205071; and (3) 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 in Delaware, including Plaintiffs Forest Labs. and Royalty Pharma, which are Delaware corporations.

12. 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

13. Plaintiffs reallege and incorporate by reference paragraphs 1-12.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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®.

19. On information and belief, First Time filed, or caused to be filed, ANDA No. 205071 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of First Time's generic milnacipran product in the United States before the expiration of the '911, '342, and '220 patents.

20. On information and belief, ANDA No. 205071 contains a Paragraph IV certification alleging that the claims of the '911, '342, and '220 patents are invalid.

21. First Time sent or caused to be sent to Plaintiffs a letter dated September 23, 2013 ("the First Time Notice Letter") notifying Plaintiffs that First Time had submitted ANDA No. 205071, 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 any claims of the '342, or '220 patents and did not allege noninfringement of claims 1-3 and 5-7 of the '911 patent.

22. On information and belief, First Time seeks approval of at least one indication for First Time's generic milnacipran product that is claimed in the '911, '342, and '220 patents.

23. Under 35 U.S.C. § 271(e)(2)(A), First Time 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—First Time'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 First Time's generic milnacipran product.

24. On information and belief, First Time has knowledge of the '911, '342, and '220 patents and has filed ANDA No. 205071 seeking authorization to commercially manufacture, use, offer for sale, and sell First Time's generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205071, physicians, health care providers, and/or patients will use First Time's generic milnacipran product in accordance with the instructions and/or label provided by First Time and will directly infringe one or more claims of the '911, '342, and '220 patents.

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

26. On information and belief, if the FDA approves ANDA No. 205071, First Time 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 First Time's generic milnacipran product is a material part of the method claimed, wherein First Time knows that physicians will prescribe and patients will use First Time'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. First Time will thus contribute to the infringement of the '911, '342, and '220 patents.

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

COUNT II FOR DECLARATORY JUDGMENT

28. Plaintiffs reallege and incorporate by reference paragraphs 1-27.

29. 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.

30. The manufacture, sale, offer for sale, and/or importation of First Time'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.

31. On information and belief, First Time has knowledge of the '911, '342, and '220 patents and has filed ANDA No. 205071 seeking authorization to commercially manufacture, use, offer for sale, and sell First Time's generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205071, physicians, health care providers, and/or patients will use First Time's generic milnacipran product in accordance with the instructions and/or label provided by First Time and will directly infringe one or more claims of the '911, '342, and '220 patents.

32. On information and belief, First Time knows and intends that physicians, health care providers, and/or patients will use First Time's generic milnacipran product in accordance with the instructions and/or label provided by First Time, 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).

33. On information and belief, if the FDA approves ANDA No. 205071, First Time 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 First Time's generic milnacipran product is a material part of the method claimed in the '911, '342, and '220 patents, wherein First Time knows that physicians will prescribe and patients will use First Time'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. First Time will thus contribute to the infringement of the '911, '342, and '220 patents under 35 U.S.C. § 271(c).

34. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and First Time as to liability for the infringement of the claims of the '911, '342, and '220 patents. First Time's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from First Time'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), First Time infringed United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 by submitting ANDA No. 205071 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States First Time's generic milnacipran product prior to the expiration of said patents;

c) declare that First Time's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of First Time'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 First Time'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 First Time, and all persons acting in concert with First Time, from seeking, obtaining, or maintaining final approval of ANDA No. 205071 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 First Time and all persons acting in concert with First Time, from commercially manufacturing, using, offering for sale, or selling First Time's generic milnacipran product within the United States, or importing First Time'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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