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. _____
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
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 Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") 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, Lupin Limited ("Lupin Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Mumbai, 400 051, India.

6. On information and belief, Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a corporation organized and existing under the laws of Virginia and having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

7. On information and belief, Lupin Pharma 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. Lupin Pharma is also qualified to do business in Delaware and appointed a registered agent for service of process.

8. On information and belief, Lupin Pharma is amenable to litigating in this forum based on Lupin Pharma's conduct in numerous other litigations in this District. In particular, Lupin Pharma has brought declaratory judgment actions in this District, and has elected not to contest personal jurisdiction on several different occasions as a defendant in this District. Lupin Pharma has previously admitted, without qualification, that this Court has personal jurisdiction over Lupin Pharma. *See Forest Laboratories, Inc. v. Cobalt Laboratories, Inc.* C.A. No. 08-021-GMS-LPS, D.I. 35 at ¶ 18 (D. Del. Feb. 4, 2008).

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

10. This Court has personal jurisdiction over Lupin Pharma 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. This Court has personal jurisdiction over Lupin Pharma by virtue of, among other things: (1) its registration to do business in Delaware, including appointment of a registered agent; (2) its sale and distribution of generic drugs in Delaware; (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, including Plaintiffs Forest Labs. and Royalty Pharma, which are Delaware corporations; (4) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (5) its admission that it is subject to the Court's jurisdiction.

12. On information and belief, Lupin Ltd. is a pharmaceutical company that conducts its North American operations, in part, through Lupin Pharma and together they collaborate in formulating, manufacturing, packaging and marketing generic drug products for distribution in the District of Delaware and throughout the United States.

13. On information and belief, Lupin Pharma is a wholly-owned subsidiary of Lupin Ltd. and Lupin Pharma acts as an agent for Lupin Ltd. in connection with the sale of pharmaceutical products in the United States, including the State of Delaware.

14. On information and belief, Lupin Ltd. does business in the State of Delaware and has derived substantial revenue from sales of pharmaceutical products in Delaware.

15. This Court has personal jurisdiction over Lupin Ltd. 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.

16. On information and belief, Lupin Ltd. is amenable to litigating in this forum based on Lupin Ltd.'s conduct in numerous other litigations in this District. In particular, Lupin Ltd. has brought declaratory judgment actions in this District, and has elected not to contest personal jurisdiction on several different occasions as a defendant in this District. Lupin Ltd. has previously admitted, without qualification, that this Court has personal jurisdiction over it. *See Forest Laboratories, Inc. v. Cobalt Laboratories, Inc.* C.A. No. 08-021-GMS-LPS, D.I. 35 at ¶ 18 (D. Del. Feb. 4, 2008).

17. This Court has personal jurisdiction over Lupin Ltd. by virtue of, among other things: (1) its presence in Delaware, including through Lupin Pharma; (2) its sale and distribution of generic drugs in Delaware; (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, including Plaintiffs Forest Labs. and Royalty Pharma, which are Delaware corporations; (4) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (5) its admission that it is subject to the Court's jurisdiction.

18. 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

19. Plaintiffs reallege and incorporate by reference paragraphs 1-18.

20. 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(b). 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.

21. 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.

22. 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.

23. 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.

24. 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®.

25. On information and belief, Lupin filed, or caused to be filed, ANDA No. 205286 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 (“Lupin’s generic milnacipran product”) in the United States before the expiration of the ’911, ’342, and ’220 patents.

26. On information and belief, ANDA No. 205286 contains a Paragraph IV certification alleging that the claims of the ’911, ’342, and ’220 patents are invalid.

27. Lupin sent, or caused to be sent, to Plaintiffs a letter dated September 17, 2013 (“the Notice Letter”) notifying Plaintiffs that Lupin had submitted ANDA No. 205286, 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 patent.

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

29. Under 35 U.S.C. § 271(e)(2)(A), Lupin 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 —Lupin’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 Lupin’s generic milnacipran product.

30. On information and belief, Lupin has knowledge of the ’911, ’342, and ’220 patents and has filed ANDA No. 205286 seeking authorization to commercially manufacture, use, offer for sale, and sell Lupin’s generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205286, physicians, health care providers, and/or patients will use Lupin’s generic milnacipran product in accordance with the instructions and/or label provided by Lupin and will directly infringe one or more claims of the ’911, ’342, and ’220 patents.

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

32. On information and belief, if the FDA approves ANDA No. 205286, Lupin 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 Lupin’s generic milnacipran product is a material part of the method claimed, wherein Lupin knows that physicians will prescribe and patients will use Lupin’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. Lupin will thus contribute to the infringement of the ’911, ’342, and ’220 patents.

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

COUNT II FOR DECLARATORY JUDGMENT

34. Plaintiffs reallege and incorporate by reference paragraphs 1-33.

35. 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.

36. The manufacture, sale, offer for sale, and/or importation of Lupin’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.

37. On information and belief, Lupin has knowledge of the ’911, ’342, and ’220 patents and has filed ANDA No. 205286 seeking authorization to commercially manufacture, use, offer for sale, and sell Lupin’s generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205286, physicians, health care providers, and/or patients will use Lupin’s generic milnacipran product in accordance with the instructions and/or label provided by Lupin and will directly infringe one or more claims of the ’911, ’342, and ’220 patents.

38. On information and belief, Lupin knows and intends that physicians, health care providers, and/or patients will use Lupin’s generic milnacipran product in accordance with the

instructions and/or label provided by Lupin, 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).

39. On information and belief, if the FDA approves ANDA No. 205286, Lupin 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 Lupin’s generic milnacipran product is a material part of the method claimed in the ’911, ’342, and ’220 patents, wherein Lupin knows that physicians will prescribe and patients will use Lupin’s generic milnacipran product for 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. Lupin will thus contribute to the infringement of the ’911, ’342, and ’220 patents under 35 U.S.C. § 271(c).

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request 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), Lupin infringed United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 by submitting ANDA No. 205286 to the

FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Lupin's generic milnacipran product prior to the expiration of said patents;

c) declare that Lupin's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of Lupin'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 Lupin'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 Lupin, and all persons acting in concert with Lupin, from seeking, obtaining, or maintaining final approval of ANDA No. 205286 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 Lupin and all persons acting in concert with Lupin, from commercially manufacturing, using, offering for sale, or selling Lupin's generic milnacipran product within the United States, or importing Lupin'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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Charles E. Lipsey
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Two Freedom Square
11955 Freedom Drive.
Reston, VA 20190-5675
(571) 203-2700

Howard W. Levine
Sanya Sukduang
Courtney B. Casp
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

September 23, 2013