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. _____
APOTEX CORP. and APOTEX 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 Apotex Corp. and Apotex Inc. (collectively "Apotex") 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, Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto Ontario M9L 1T9, Canada.

6. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

7. On information and belief, the acts of Apotex Corp. complained of herein were done at the direction of, and at least in part for the benefit of, Apotex Inc.

8. On information and belief, this Court has personal jurisdiction over Apotex Corp. and Apotex Inc. by virtue of their 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.

9. On information and belief, Apotex Corp. is a Delaware corporation. By virtue of its incorporation in Delaware, this Court has personal jurisdiction over Apotex Corp.

10. On information and belief, Apotex Inc. is amenable to litigating in this forum based on Apotex Inc.'s conduct in numerous other litigations in this District. In particular, Apotex Inc. has brought declaratory judgment actions in this District, and has elected not to contest personal jurisdiction on at least eleven (11) different occasions as a defendant in this District. Indeed, Apotex Inc. has previously admitted, without qualification, that this Court has personal jurisdiction over both Apotex Corp. and Apotex Inc. *Allergan, Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 07-278-GMS, D.I. 8 at 3 (D. Del. June 11, 2007).

11. On information and belief, Apotex Inc. is in the business of formulating, manufacturing, and commercializing generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States. Apotex Inc. has previously admitted that it manufactures generic drug products for sale, distribution and use throughout the United States, including this judicial district. *Boehringer Ingleheim Pharm., Inc. v. Apotex Inc. & Apotex Corp.* C.A. No. 08-65-SLR, D.I. 7 at 2 (D. Del. Feb. 21, 2008).

12. On information and belief, Apotex Corp. is the marketing and sales agent for Apotex Inc. in the United States.

13. On information and belief, Apotex Corp., itself and on behalf of Apotex Inc., derives substantial revenue from the sale of Apotex Inc. products in Delaware and throughout the United States.

14. On information and belief, Apotex Corp. and Apotex Inc. are two arms of the same business group, operate in concert with each other, and enter into agreements with each other that are nearer than arm's length.

15. On information and belief, Apotex Corp. and Apotex Inc. are jointly controlled by Dr. Bernard C. Sherman through a series of shell corporations. Apotex Corp. is a wholly-owned subsidiary of Aposherm Inc., which is a wholly-owned subsidiary of Apotex Holdings. Apotex Holdings owns all of the outstanding capital stock of Apotex Inc. such that Apotex Corp. and Apotex Inc. are sister corporations owned by Apotex Holding, which is controlled by Dr. Bernard C. Sherman through the Bernard Sherman 2000 Trust.

16. Apotex's U.S. website states that Apotex Corp. is a wholly owned affiliate of Apotex Inc.

17. On information and belief, Apotex Corp. is the U.S. agent for Apotex Inc. for purposes of making regulatory submissions to the FDA, including ANDA No. 205362 at issue in this litigation. In particular, Apotex Inc. has acted in concert with Apotex Corp. with respect to the preparation and filing of ANDA No. 205362 for Apotex's generic milnacipran products, and in preparation to sell those products in the United States and in this judicial district.

18. On information and belief, Apotex Inc. and Apotex Corp. have a nearer than arm's length relationship such that Apotex Corp.'s contacts with Delaware can be imputed to Apotex Inc.

19. On information and belief, this Court has personal jurisdiction over Apotex Corp. by virtue of, among other thing: (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; (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (6) its admission that it is subject to the Court's jurisdiction.

20. On information and belief, this Court has personal jurisdiction over Apotex Inc. by virtue of, among other things: (1) its presence in Delaware, including through Apotex Corp.; (2) 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; (3) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; (4) its admission that it is subject

to the Court's jurisdiction; and (5) its admission that it manufactures generic drug products for sale and distribution in the district.

21. 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

22. Plaintiffs reallege and incorporate by reference paragraphs 1-21.

23. 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.

24. 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.

25. 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. 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.

26. 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.

27. 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®.

28. On information and belief, Apotex filed, or caused to be filed, ANDA No. 205362 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 (“Apotex’s generic milnacipran product”) in the United States before the expiration of the ’911, ’342, and ’220 patents.

29. On information and belief, ANDA No. 205362 contains a Paragraph IV certification alleging that the claims of the ’911, ’342, and ’220 patents are invalid.

30. Apotex sent, or caused to be sent, to Plaintiffs a letter dated August 20, 2013 (“the Apotex Notice Letter”) notifying Plaintiffs that Apotex had submitted ANDA No. 205362, 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.

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

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

33. On information and belief, Apotex has knowledge of the ’911, ’342, and ’220 patents and has filed ANDA No. 205362 seeking authorization to commercially manufacture, use, offer for sale, and sell Apotex’s generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205362, physicians, health care providers, and/or patients will use Apotex’s generic milnacipran product in accordance with the instructions and label provided by Apotex and will directly infringe one or more claims of the ’911, ’342, and ’220 patents.

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

35. On information and belief, if the FDA approves ANDA No. 205362, Apotex 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 Apotex's generic milnacipran product is a material part of the method claimed, wherein Apotex knows that physicians will prescribe and patients will use Apotex'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. Apotex will thus contribute to the infringement of the '911, '342, and '220 patents.

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

COUNT II FOR DECLARATORY JUDGMENT

37. Plaintiffs reallege and incorporate by reference paragraphs 1-36.

38. 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.

39. The manufacture, sale, offer for sale, and/or importation of Apotex'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.

40. On information and belief, Apotex has knowledge of the '911, '342, and '220 patents and has filed ANDA No. 205362 seeking authorization to commercially manufacture,

use, offer for sale, and sell Apotex's generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205362, physicians, health care providers, and/or patients will use Apotex's generic milnacipran product in accordance with the instructions and/or label provided by Apotex and will directly infringe one or more claims of the '911, '342, and '220 patents.

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

42. On information and belief, if the FDA approves ANDA No. 205362, Apotex 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 Apotex's generic milnacipran product is a material part of the method claimed in the '911, '342, and '220 patents, wherein Apotex knows that physicians will prescribe and patients will use Apotex'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. Apotex will thus contribute to the infringement of the '911, '342, and '220 patents under 35 U.S.C. § 271(c).

43. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Apotex as to liability for the infringement of the claims of the '911, '342, and '220 patents. Apotex's actions have created in Plaintiffs a

reasonable apprehension of irreparable harm and loss resulting from Apotex'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), Apotex infringed United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 by submitting ANDA No. 205362 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Apotex's generic milnacipran product prior to the expiration of said patents;

c) declare that Apotex's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of Apotex'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 Apotex'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 Apotex, and all persons acting in concert with Apotex, from seeking, obtaining, or maintaining final approval of ANDA No. 205362 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 Apotex and all persons acting in concert with Apotex, from commercially manufacturing, using, offering for sale, or selling Apotex's generic milnacipran product within the United States, or importing Apotex'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

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