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. _____
HETERO USA INC., HETERO LABS LIMITED UNIT V & HETERO LABS LIMITED,	)	
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 Defendants Hetero Labs USA Inc., Hetero Labs Limited Unit V, and Hetero Labs Limited (collectively "Hetero") 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, Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1031 Centennial Avenue, Piscataway, NJ, 08854.

6. By virtue of its incorporation in Delaware, this Court has personal jurisdiction over Hetero USA Inc.

7. On information and belief, Hetero USA 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.

8. On information and belief, Hetero USA Inc. is registered to do business in Delaware and has appointed a registered agent in Delaware for the receipt of service of process.

9. This Court has personal jurisdiction over Hetero USA Inc. 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; (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (6) its prior admission that it is subject to the Court's jurisdiction. *See Forest Laboratories, Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, C.A. No. 12-305 (D. Del. April 4, 2012) at D.I. 41, paragraph 42.

10. On information and belief, Hetero Labs Ltd. is an Indian corporation having a principal place of business at 7-2-A-2, Hetero Corporate Industrial Estate, Sanathnagar Hyderabad 500018 Andhra Pradesh, India.

11. On information and belief, Hetero Labs Limited Unit V is an Indian corporation and a division of Hetero Labs Ltd. having a principal place of business at Polepally, Jadcherla, Mahabubnagar - 509301, Andhra Pradesh, India. Hetero Labs Ltd.'s website located at http://www.heterodrugs.com/mfg-formulation-facilities.shtml, describes Unit V as a manufacturing facility of Hetero Labs Ltd.

12. On information and belief, Hetero Labs Ltd. and Hetero Labs Ltd. Unit V, directly or through Hetero USA Inc. and/or through one or more of its subsidiaries, are in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

13. On information and belief, Hetero USA Inc. acts as the agent of Hetero Labs Ltd. and Hetero Labs Ltd. Unit V.

14. In its letter dated August 26, 2013, notifying Plaintiffs of its submission to the FDA of ANDA No. 205147 for Hetero's generic milnacipran tablets, 12.5 mg, 25 mg, 50 mg, and 100 mg ("Hetero's generic milnacipran product"), Hetero USA Inc. described itself as "the U.S. Regulatory Agent for Hetero Labs Limited Unit V" for purposes of making regulatory submissions to the FDA. Hetero Labs Ltd. and Hetero Labs Ltd. Unit V have thus acted in concert with Hetero USA Inc. with respect to the preparation and filing of ANDA No. 205147 for Hetero's generic milnacipran products, and in preparation to sell those products in the United States and in this judicial district.

15. On information and belief, the acts of Hetero USA Inc. complained of herein were done at the direction of, or with the authorization of, and/or with the cooperation, participation, and assistance of Hetero Labs Ltd. and Hetero Labs Ltd. Unit V.

16. On information and belief, Hetero USA Inc. itself, and on behalf of Hetero Labs Ltd and Hetero Labs Ltd. Unit V, derives substantial revenue from the sale of Hetero USA Inc.'s products in Delaware and throughout the United States.

17. Hetero USA Inc.'s acts and continuous and systematic contacts with the state of Delaware, as agent of Hetero Labs Ltd. and Hetero Labs Ltd. Unit V, are also attributable to Hetero Labs. Ltd. for jurisdictional purposes.

18. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Ltd and Hetero Labs Ltd. Unit V.

19. On information and belief, Hetero Labs Ltd., Hetero Labs Ltd. Unit V, and Hetero USA Inc. operate as an integrated business ultimately controlled by Hetero Labs Ltd.

20. Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit V have a nearer than arm's length relationship such that Hetero USA Inc.'s contacts with Delaware can be imputed to Hetero Labs Ltd. and Hetero Labs Ltd. Unit V.

21. This Court has personal jurisdiction over Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit V 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.

22. Hetero Labs Ltd., and Hetero Labs Ltd. Unit V are amenable to litigating in this forum based on their conduct in numerous other litigations in this District. For example, Hetero

Labs Ltd. has admitted, without qualification, that this Court has jurisdiction over it in *Forest Laboratories, Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, C.A. No. 12-305 (D. Del. April 4, 2012), specifically in paragraph 42 of D.I. 28 it admits "[t]his Paragraph contains legal conclusions to which no response is required. To the extent that an answer is required, Hetero admits that the Court has jurisdiction over Hetero . . . ." In addition, Hetero Labs Ltd. has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Hetero Labs Ltd. has filed counterclaims for declaratory judgment.

23. This Court has personal jurisdiction over Hetero Labs Ltd. by virtue of, among other things: (1) its presence in Delaware, including through Hetero USA; (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; and (4) its admission that it is subject to the Court's jurisdiction.

24. This Court has personal jurisdiction over Hetero Labs Ltd. Unit V by virtue of, among other things: (1) its presence in Delaware, including through Hetero USA; (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) and its purposeful availment of this forum previously for the purpose of litigating a patent dispute.

25. 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

26. Plaintiffs re-allege and incorporate by reference paragraphs 1-25.

27. 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.

28. United States Patent No. 7,888,342 ("the '342 patent"), entitled "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.

29. 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.

30. 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.

31. 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®.

32. On information and belief, Hetero filed, or caused to be filed, ANDA No. 205147 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 ("Hetero's generic milnacipran product") in the United States before the expiration of the '911, '342, and '220 patents.

33. On information and belief, ANDA No. 205147 contains a Paragraph IV certification alleging that the claims of the '911, '342, and '220 patents are invalid.

34. Hetero sent or caused to be sent to Plaintiffs a letter dated August 26, 2013 ("the Hetero Notice Letter") notifying Plaintiffs that Hetero had submitted ANDA No. 205147, 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, claims 1-7 of the '220 patent and noninfringment of claims 6-10 of the '342 patent. The Notice Letter did not allege noninfringement of the '911 and '220 patents.

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

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

37. On information and belief, Hetero has knowledge of the '911, '342, and '220 patents and has filed ANDA No. 205147 seeking authorization to commercially manufacture, use, offer for sale, and sell Hetero's generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205147, physicians, health care providers, and/or patients will use Hetero's generic milnacipran product in accordance with the instructions and/or label provided by Hetero and will directly infringe one or more claims of the '911, '342, and '220 patents.

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

39. On information and belief, if the FDA approves ANDA No. 205147, Hetero 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 Hetero's generic

milnacipran product is a material part of the method claimed, wherein Hetero knows that physicians will prescribe and patients will use Hetero'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. Hetero will thus contribute to the infringement of the '911, '342, and '220 patents.

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

COUNT II FOR DECLARATORY JUDGMENT

41. Plaintiffs reallege and incorporate by reference paragraphs 1-40.

42. 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.

43. The manufacture, sale, offer for sale, and/or importation of Hetero'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.

44. On information and belief, Hetero has knowledge of the '911, '342, and '220 patents and has filed ANDA No. 205147 seeking authorization to commercially manufacture, use, offer for sale, and sell Hetero's generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205147, physicians, health care providers, and/or patients will use Hetero's generic milnacipran product in accordance with the

instructions and/or label provided by Hetero and will directly infringe one or more claims of the ’911, ’342, and ’220 patents.

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

46. On information and belief, if the FDA approves ANDA No. 205147, Hetero 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 Hetero’s generic milnacipran product is a material part of the method claimed in the ’911, ’342, and ’220 patents, wherein Hetero knows that physicians will prescribe and patients will use Hetero’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. Hetero will thus contribute to the infringement of the ’911, ’342, and ’220 patents under 35 U.S.C. § 271(c).

47. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hetero as to liability for the infringement of the claims of the ’911, ’342, and ’220 patents. Hetero’s actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Hetero’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), Hetero infringed United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 by submitting ANDA No. 205147 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Hetero's generic milnacipran product prior to the expiration of said patent;

c) declare that Hetero's commercial manufacture, use or sale, offer for sale, or importation into the United States of Hetero'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 Hetero'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 Hetero, and all persons acting in concert with Hetero, from seeking, obtaining, or maintaining final approval of ANDA No. 205147 until the expiration of United States Patent Nos. 6,602,911, 7,888,342, and and 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled;

f) enjoin Hetero and all persons acting in concert with Hetero, from commercially manufacturing, using, offering for sale, or selling Hetero's generic milnacipran

product within the United States, or importing Hetero'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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