IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., & ROYALTY PHARMA COLLECTION TRUST,	)	
Plaintiffs,	)	C.A. No.:
v.	)	
GLENMARK GENERICS INC., USA, GLENMARK GENERICS LTD., GLENMARK PHARMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., (collectively, "Forest") and Royalty Pharma Collection Trust (all collectively, "Plaintiffs") file this Complaint for patent infringement against Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. (collectively "Glenmark") 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.

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, Glenmark Generics Inc., USA ("Glenmark USA") is a Delaware corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 750 Corporate Drive, Mahwah, NJ 07430.

6. On information and belief, Glenmark USA 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. Glenmark USA is also qualified to do business in Delaware and appointed a registered agent in Delaware for service of process.

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

8. On information and belief, Glenmark USA is amenable to litigating in this forum based on Glenmark USA's conduct in numerous other litigations in this District. In particular, Glenmark USA has elected not to contest personal jurisdiction on several different occasions as a defendant in this District, and has previously availed itself of this Court by asserting counterclaims, and filing a declaratory judgment action in other civil actions initiated in this jurisdiction.

9. This Court has personal jurisdiction over Glenmark USA by virtue of, among other things: (1) its incorporation in Delaware; (2) its registration to do business in Delaware, including appointment of a registered agent; (3) its sale and distribution of generic drugs in

Delaware; (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 in other patent litigations.

10. On information and belief, Glenmark Generics Ltd. ("Glenmark Generics") is an Indian company having a place of business at Glenmark House, HDO-Corporate Building, Wing- A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099.

11. On information and belief, Glenmark Generics is a pharmaceutical company that directly or indirectly through its affiliates and agents, including Glenmark USA and Glenmark Pharmaceuticals Ltd., formulates, manufactures, packages and markets generic drug products for distribution in the District of Delaware and throughout the United States.

12. On information and belief, Glenmark USA is a subsidiary of Glenmark Generics, and Glenmark USA acts as an agent for Glenmark Generics in connection with the sale of pharmaceutical products in the United States, including the State of Delaware.

13. On information and belief, Glenmark Generics is amenable to litigating in this forum based on Glenmark Generics' conduct in numerous other litigations in this District. In particular, Glenmark Generics has elected not to contest personal jurisdiction on several different occasions as a defendant in this District, and has previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. This Court has personal jurisdiction over Glenmark Generics by virtue of, among other things: (1) its sale and distribution of generic drugs in Delaware; (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 in other patent litigations.

15. On information and belief, Glenmark Pharmaceuticals Ltd. ("Glenmark Pharmaceuticals") is an Indian company having a place of business at Glenmark House, HDO-Corporate Building, Wing- A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099.

16. On information and belief, Glenmark Pharmaceuticals is a pharmaceutical company that conducts its North American operations, in part, through Glenmark USA 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.

17. On information and belief, Glenmark USA, Glenmark Generics, and Glenmark Pharmaceuticals operate as an integrated business ultimately controlled by Glenmark Pharmaceuticals. *See e.g.,* http://us.glenmark-generics.com/about-us.aspx (noting that "Glenmark Generics Inc., USA (GGI) is the North American division of Glenmark Generics Ltd.") Further, a press releases states that Glenmark Generics Limited (GGL) is a subsidiary of Glenmark Pharmaceuticals Limited and aims to be a global integrated Generic and API leader.

18. On information and belief, Glenmark USA is a wholly-owned subsidiary of Glenmark Generics, which in turn is a wholly-owned subsidiary of Glenmark Pharmaceuticals. Glenmark USA and Glenmark Generics act as agents for Glenmark Pharmaceuticals in connection with the sale of pharmaceutical products in the United States, including the State of Delaware. *See* http://www.glenmarkpharma.com/GLN_NWS/pdf/GG_medicis_final.pdf.

19. On information and belief, Glenmark Pharmaceuticals is amenable to litigating in this forum based on Glenmark Pharmaceuticals' conduct in numerous other litigations in this District. In particular, Glenmark Pharmaceuticals has elected not to contest personal jurisdiction on several different occasions as a defendant in this District, and has previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

20. This Court has personal jurisdiction over Glenmark Pharmaceuticals by virtue of, among other things: (1) its sale and distribution of generic drugs in Delaware; (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 in other patent litigations.

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(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.

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, Glenmark filed, or caused to be filed, ANDA No. 205267 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 ("Glenmark'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. 205267 contains a Paragraph IV certification alleging that the claims of the '911, '342, and '220 patents are invalid and/or not infringed.

30. Glenmark sent, or caused to be sent, to Plaintiffs a letter dated January 2, 2014 ("the Notice Letter") notifying Plaintiffs that Glenmark had submitted ANDA No. 205267, 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 and claims 1-10 of the '342 patent. The Notice Letter did not allege invalidity of the '220 patent. The Notice Letter alleges noninfringement of claim 4 of the '911 patent and claims 1-7 of the '220 patent.

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

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

33. On information and belief, Glenmark has knowledge of the '911, '342, and '220 patents and has filed ANDA No. 205267 seeking authorization to commercially manufacture, use, offer for sale, and sell Glenmark's generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205267, physicians, health care providers, and/or patients will use Glenmark's generic milnacipran product in accordance with the instructions and/or label provided by Glenmark and will directly infringe one or more claims of the '911, '342, and '220 patents.

34. On information and belief, Glenmark knows and intends that physicians, health care providers, and/or patients will use Glenmark's generic milnacipran product in accordance with the instructions and/or label provided by Glenmark, 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. 205267, Glenmark 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 Glenmark's generic milnacipran product is a material part of the method claimed, wherein Glenmark knows that physicians will prescribe and patients will use Glenmark'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. Glenmark will thus contribute to the infringement of the '911, '342, and '220 patents.

36. Plaintiffs will be substantially and irreparably harmed by Glenmark'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 Glenmark'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, Glenmark has knowledge of the '911, '342, and '220 patents and has filed ANDA No. 205267 seeking authorization to commercially manufacture,

use, offer for sale, and sell Glenmark's generic milnacipran product in the United States. On information and belief, if the FDA approves ANDA No. 205267, physicians, health care providers, and/or patients will use Glenmark's generic milnacipran product in accordance with the instructions and/or label provided by Glenmark and will directly infringe one or more claims of the '911, '342, and '220 patents.

41. On information and belief, Glenmark knows and intends that physicians, health care providers, and/or patients will use Glenmark's generic milnacipran product in accordance with the instructions and/or label provided by Glenmark, 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. 205267, Glenmark 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 Glenmark's generic milnacipran product is a material part of the method claimed in the '911, '342, and '220 patents, wherein Glenmark knows that physicians will prescribe and patients will use Glenmark'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. Glenmark 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 Glenmark as to liability for the infringement of the '911, '342, and '220 patents claims. Glenmark's actions have created in Plaintiffs a reasonable

apprehension of irreparable harm and loss resulting from Glenmark'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), Glenmark infringed United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 by submitting ANDA No. 205267 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Glenmark's generic milnacipran product prior to the expiration of said patents;

c) declare that Glenmark's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of Glenmark'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 Glenmark'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);

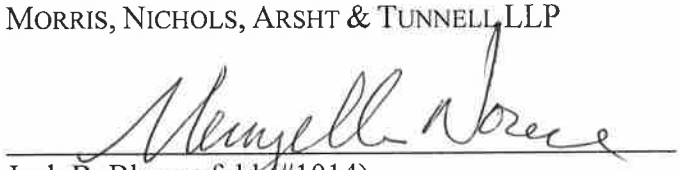
e) enjoin Glenmark, and all persons acting in concert with Glenmark, from seeking, obtaining, or maintaining final approval of ANDA No. 205267 until the expiration of United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled;

f) enjoin Glenmark, and all persons acting in concert with Glenmark, from commercially manufacturing, using, offering for sale, or selling Glenmark's generic milnacipran product within the United States, or importing Glenmark'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



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