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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVEN THERAPEUTICS, LLC, Plaintiff, v. ACTAVIS LABORATORIES FL, INC., ACTAVIS PHARMA, INC., ANDRX CORP., and ACTAVIS, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Noven Therapeutics, LLC ("Noven" or "Plaintiff"), in its Complaint of patent infringement against Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc. (collectively, "Actavis" or "Defendants"), states as follows:

THE PARTIES

1. Noven is a Delaware limited liability company with a principal place of business at 11960 S. W. l 44th Street, Miami, Florida 33186.

2. Upon information and belief, defendant Actavis Laboratories FL, Inc. is a Florida corporation with a principal place of business at Morris Corporate Center Ill, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. Upon information and belief, defendant Actavis Laboratories FL, Inc. is in the business of preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the state of New Jersey.

4. Upon information and belief, defendant Actavis Pharma, Inc. is a Delaware corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. Upon information and belief, defendant Actavis Pharma, Inc. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

6. Upon information and belief, defendant Andrx Corp. is a Delaware corporation with a principal place of business at 4955 Orange Drive, Davie, FL 33314.

7. Upon information and belief, defendant Andrx Corp. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

8. Upon information and belief, defendant Actavis, Inc. is a Nevada corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

9. Upon information and belief, defendant Actavis, Inc. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

10. Upon information and belief, defendant Actavis Laboratories FL, Inc. is a wholly-owned subsidiary of defendant Andrx Corp. In turn, upon information and belief, defendants Andrx Corp. and Actavis Pharma, Inc. are wholly-owned subsidiaries of defendant Actavis, Inc.

NATURE OF THE ACTION

11. This is a civil action for patent infringement of U.S. Patent No. 8,946,251 (the "'251 patent" or the "patent-in-suit"), arising under the United States Patent Laws, Title 35, United States Code § 100, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 207139, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market a generic copy of Noven's BRISDELLE® product, which is sold in the United States.

JURISDICTION AND VENUE

12. This is a civil action for patent infringement and declaratory judgment arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

13. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

14. This Court has personal jurisdiction over Defendants by virtue of their specific acts in, and their systematic and continuous contacts with, the State of New Jersey.

15. Upon information and belief, Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Actavis, Inc. have their principal place of business in Parsippany, New Jersey.

16. Upon information and belief, Defendants are registered to do business in the state of New Jersey, and purposefully avail themselves of this forum by making, using, importing, selling or offering to sell pharmaceutical products in the state of New Jersey, or causing others to do the same, and therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts.

17. Upon information and belief, Actavis, Inc., the parent company of the other Defendants in this matter, holds a current and valid New Jersey "Wholesale Drug & Medical Devices" registration, No. 5003854.

18. Upon information and belief, Defendants collectively share common directors, officers, and facilities, operate as agents of each other, and act in concert in the design, development, manufacture, distribution, and sale of pharmaceutical products throughout the United States, including New Jersey.

19. Upon information and belief, Defendants collectively participated in the preparation, development and filing of ANDA No. 207139 and its underlying subject matter, which occurred in the state of New Jersey.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

21. The ’251 patent, entitled “Method of Treating Thermoregulatory Dysfunction With Paroxetine,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on February 3, 2015. Noven is the owner of all title, right, and interest in and to the

'251 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '251 patent is attached as Exhibit A.

22. Noven is the holder of New Drug Application ("NDA") No. 204516 for the manufacture and sale of paroxetine mesylate capsules in 7.5 mg dosage, which Noven markets and sells under the registered trademark BRISDELLE®. Pursuant to Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(l) ("FFD&C Act") and corresponding FDA regulations, Noven has listed the '251 patent in the FDA's Orange Book as covering the BRISDELLE® drug and methods for using it.

23. Upon information and belief, pursuant to FFD&C Act 21 U.S.C. § 505(j), Defendants filed ANDA No. 207139 with the FDA. Defendants' ANDA seeks FDA approval to market and sell within the United States a generic 7.5 mg paroxetine mesylate capsule product (the "generic product") prior to the expiration of the '251 patent.

24. Upon information and belief, Defendants' ANDA No. 207139 identified Noven's BRISDELLE® product and included a written certification, as required by FFD&C Act 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the '251 patent are invalid or otherwise will not be infringed by Defendants' generic product.

25. On or about July 31, 2015, Noven received a letter from Defendants purporting to be a written notice that Defendants have filed ANDA No. 207139 to seek approval of the generic product prior to the expiration of the '251 patent, pursuant to FFD&C Act 21 U .S.C. § 505(j)(2)(B)(iv) (the "Paragraph IV letter"). The Paragraph IV letter included notice of Defendants' allegations that the claims of the '251 patent are invalid, unenforceable and/or not infringed by Defendants' generic product.

26. Defendants' submission of ANDA No. 207139, including the Paragraph IV certification, to the FDA constitutes infringement of the '251 patent under 35 U.S.C. § 271 (e)(2). Moreover, Defendants' anticipated commercial manufacture, use, sale, offer for sale, or importation of the generic product will infringe the '251 patent under 35 U.S.C. § 271(a), (b), and/or (c).

27. Noven commenced this action within 45 days of receiving Defendants' Paragraph IV letter.

COUNT OF INFRINGEMENT OF U.S. PATENT NO. 8,946,251

28. Paragraphs 1-27 are incorporated by reference as though fully set forth herein.

29. Defendants' submission of ANDA No. 207139 and its Paragraph IV certification for FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '251 patent constitutes infringement under 35 U.S.C. § 271(e)(2).

30. Upon information and belief, Defendants will infringe the '251 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 207139.

31. Upon information and belief, Defendants will induce infringement of the '251 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting acts of direct infringement of the '251 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 207139.

32. Upon information and belief, Defendants will contributorily infringe the '251 patent under 35 U.S.C. § 271(c) by making, using, selling, offering to sell, or importing the generic product in the United States, with knowledge of the '251 patent and that there is no

substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 207139.

33. Pursuant to 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Defendants' direct, induced, and contributory infringement of the '251 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

34. Upon information and belief, Defendants were aware of the '251 patent prior to submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '251 patent.

PRAYER FOR RELIEF

WHEREFORE, Noven respectfully prays for:

A. A judgment that Defendants have infringed the '251 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 207139 under the FFD&C Act, and that the commercial manufacture, use, sale, offer for sale, and/or importation of the generic product before the expiration of the '251 patent will constitute acts of infringement of said patent;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 207139 shall be no earlier than the date on which the '251 patent expires, including any regulatory extensions;

C. An injunction under 35 U.S.C. § 271(e)(4)(B), permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their

behalf, from engaging in the commercial manufacture, use, sale, offer to sell, and/or importation within the United States, of any pharmaceutical product covered by the '251 patent;

D. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C) as appropriate;

E. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Noven be awarded reasonable attorneys' fees and costs; and

F. An award of any such other and further relief as the Court may deem just and proper.

Date: August 14, 2015

Respectfully submitted,

/s/ Anne B. Sekel
Anne B. Sekel

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LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, Plaintiff Noven Therapeutics, LLC certifies that the matter in controversy in this action is the subject of the following actions pending before the District Court for the District of New Jersey: Noven Therapeutics, LLC v. Prinston Pharmaceutical Inc., Solco Healthcare U.S., LLC, and Huahai US Inc., 2:14-cv-07400 (CCC-JBC); Noven Therapeutics, LLC v. Actavis Laboratories FL, Inc., Actavis Pharma Inc., and Actavis, Inc., 2:14-cv-06414 (CCC-JBC); Prinston Pharmaceutical, Inc. v. Noven Therapeutics, LLC, 2:15-cv-05308 (CCC-JBC).

Date: August 14, 2015

Respectfully Submitted,

By: /s/ Anne B. Sekel
Anne B. Sekel

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