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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PRINSTON PHARMACEUTICAL, INC., Plaintiff, v. NOVEN THERAPEUTICS, LLC, Defendant.	**ELECTRONICALLY FILED DOCUMENT** Civil Action No. _____ **COMPLAINT**

Plaintiff Prinston Pharmaceutical Inc. ("Prinston"), by its attorneys, Tressler LLP, for its Complaint against Defendant Noven Therapeutics, LLC ("Noven"), alleges:

JURISDICTION AND VENUE

1. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

3. This Court has personal jurisdiction over Noven by virtue of, *inter alia*: (1) its systematic and continuous contacts with New Jersey, including its substantial and ongoing sale of pharmaceutical products in New Jersey; (2) its assertion of related patents against the same Abbreviated New Drug Application ("ANDA") No. 207188 and consent to jurisdiction in this judicial district in Civil Action No. 2:14-cv-7400; and (3) its

assertion of related patents and consent to jurisdiction in this judicial district in Civil Action No. 2:14-cv-6414.

4. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PARTIES

5. Plaintiff Prinston is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

6. Upon information and belief, Defendant Noven is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 11960 S.W. 144th Street, Miami, Florida 33186.

FACTUAL BACKGROUND

Orange Book Listing of the '447, '271, '663, and '251 Patents

7. U.S. Patent No. 5,874,447 (the "'447 Patent"), entitled "4-Phenylpiperidine Compounds for Treating Depression," indicates on its face that it was issued by the United States Patent and Trademark Office ("USPTO") on February 23, 1999. The '447 patent indicates on its face that it is assigned to Synthon BV, but a July 7, 2015 search for patent assignments on the United States Patent and Trademark Office website indicates the most recent assignment was to Noven and was recorded on March 2, 2010.

8. U.S. Patent No. 7,598,271 (the "'271 patent"), entitled "Crystalline Paroxetine Methane Sulfonate," indicates on its face that it was issued by the USPTO on October 6, 2009. The '271 patent indicates on its face that it is assigned to Noven.

9. U.S. Patent No. 8,658,663 (the "'663 patent"), entitled "Method of Treating Thermoregulatory Disfunction with Paroxetine," indicates on its face that it was issued by the USPTO on February 25, 2014. The '663 patent indicates on its face that it is assigned to Noven.

10. U.S. Patent No. 8,946,251 (the "'251 patent"), entitled "Method of Treating Thermoregulatory Dysfunction with Paroxetine," indicates on its face that it was issued by the USPTO on February 3, 2015. The '251 patent indicates on its face that it is assigned to Noven. A copy of the '251 patent is attached as Exhibit A.

11. Upon information and belief, Noven is the current holder of approved New Drug Application ("NDA") No. 204516 for paroxetine mesylate capsules in 7.5 mg dosage. Noven sells drug products under NDA 204516 in the United States, including in this District, under the trade name BRISDELLE®.

12. 21 U.S.C. §§ 355(b)(1) and (c)(2) of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act require NDA holders to disclose to the United States Food and Drug Administration ("FDA") the patent numbers and expiration dates of those patents that the holders believe claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug."

13. Upon information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), Noven caused the FDA to publish the '447, '271, and '663 patents in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") in connection with NDA No. 204516. As of December 31, 2014, no other patents were listed in the Orange Book for NDA No. 204516. A copy of excerpts from the electronic version of the Orange Book through December 31, 2014 is attached as Exhibit B.

14. Upon information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), Noven caused the FDA to publish the '251 patent in the Orange Book in connection with NDA No. 204516 in February 2015. A copy of the electronic version of the Orange Book Cumulative Supplement for February 2015 is attached as Exhibit C.

15. By maintaining the listing of the '447, '271, '663, and '251 patents in the Orange Book, Noven represents that these patents could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. 21 U.S.C. § 355(b)(1)(G).

Prinston's Abbreviated New Drug Application

16. Pursuant to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 355(j), Prinston submitted Abbreviated New Drug Application ("ANDA") No. 207188 ("Prinston's ANDA") seeking FDA approval to engage in the manufacture, use, or sale within the United States of a generic 7.5 mg paroxetine mesylate capsule product ("Prinston's proposed product").

17. Prinston's ANDA refers to NDA No. 204516 and contains data that Prinston believes demonstrates bioequivalence of Prinston's proposed product and BRISDELLE®.

18. Prinston sent a notice letter dated October 16, 2014 ("2014 Notice Letter") to Noven and others, stating that Prinston had submitted ANDA No. 207188 for Prinston's proposed product. Prinston's 2014 Notice Letter stated that Prinston's ANDA contains a Paragraph IV certification that Prinston's manufacture, use, importation, sale, or offer for sale of Prinston's proposed product will not infringe any valid or enforceable claim of the '447, '271, and '663 patents. With its 2014 Notice Letter, Prinston provided a detailed statement of the factual and legal bases that the '447, '271, and '663 patents are

invalid, enforceable, and/or not infringed. Prinston also provided with the 2014 Notice Letter an Offer of Confidential Access to Prinston's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

19. In response to Prinston's ANDA filing and Paragraph IV certification against the '447, '271, and '663 patents, Noven filed an infringement action under 35 U.S.C. § 271 (a), (b), and/or (c) and a declaratory judgment action under 28 U.S.C. §§ 2201 and 2202 in this judicial district in Civil Action No. 2:14-cv-7400-CCC-JBC on November 26, 2014.

20. Additionally, pending the entry of the Discovery Confidentiality Order in Civil Action No. 2:14-cv-7400-CCC-JBC, Prinston produced Prinston's ANDA on an outside counsel eyes only basis pursuant to L. Pat. R. 2.2. Prinston's ANDA was produced on January 12, 2015, and Noven has had access to Prinston's ANDA since that time. For the avoidance of doubt, with regard to the present action, Prinston extends permission to Noven to review on an outside counsel eyes only basis pursuant to L. Pat. R. 2.2 Prinston's ANDA, including all amendments and subsequent FDA correspondence submitted thereto.

21. Prinston sent a notice letter on March 3, 2015 ("2015 Notice Letter") to Noven and others, stating that Prinston had submitted ANDA No. 207188 for Prinston's proposed product. Prinston's 2015 Notice Letter stated that Prinston's ANDA contains a Paragraph IV certification that Prinston's manufacture, use, importation, sale, or offer for sale of Prinston's proposed product will not infringe any valid or enforceable claim of the '251 patent. Prinston provided with the 2015 Notice Letter a detailed statement of the factual and legal bases that the '251 patent is invalid, enforceable, and/or not infringed.

Prinston also provided with the 2015 Notice Letter an Offer of Confidential Access to Prinston's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

THE CONTROVERSY

U.S. Patent No. 8,946,251

22. On February 24, 2015, Prinston amended its Paragraph IV certification to include the '251 patent, which Noven had caused to be listed in the Orange Book.

23. Prinston sent its 2015 Notice Letter to Noven and others on March 3, 2015. Prinston's 2015 Notice Letter was delivered on March 4, 2015.

24. To date, Noven has not filed any action alleging that the filing of Prinston's ANDA infringes any claims of the '251 patent.

25. More than 45 days have elapsed since Noven received Prinston's 2015 Notice Letter informing Noven of the filing of Prinston's ANDA and providing the detailed bases for Prinston's Paragraph IV certification against the '251 patent. 21 U.S.C. § 355(j)(5)(C).

26. Prinston intends to launch Prinston's proposed product in the United States as soon as legally permissible.

27. Noven's filing of an action against Prinston in the District of New Jersey asserting infringement of the '447, '271, and '663 patents demonstrates Noven's intent to enforce its patent rights against Prinston.

28. Based on Noven's ongoing litigation against Prinston regarding the ''447, '271, and '663 patents, its representation to the FDA and the public regarding the scope of coverage of the '447, '271, '663, and '251 patents, Noven's failure to bring suit against Prinston to resolve the questions of infringement regarding the '251 patent and Prinston's intent to launch Prinston's proposed product as soon as legally permissible,

under all the circumstances, an actual, substantial, and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Prinston and Noven as to whether the claims of the '251 patent are not infringed by Prinston's proposed product.

COUNT I

Declaration of Non-Infringement of United States Patent No. 8,946,251

29. Prinston repeats and incorporates by reference each of the foregoing paragraphs 1-28 of this Complaint as if fully set forth herein.

30. This Count arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the manufacture, use, offer for sale, sale, or importation of Prinston's proposed product will not infringe any valid claim of the '251 patent.

31. Noven, through its listing of the '251 patent in the Orange Book, asserts that the manufacture, use, offer for sale, or sale of Prinston's proposed product may infringe one or more claims of the '251 patent.

32. Prinston's proposed product does not infringe, literally or under the doctrine of equivalents, any claim of the '251 patent because Prinston's proposed product does not meet all of the limitations of the claims of the '251 patent.

33. Thus, the manufacture, use, offer for sale, or sale of Prinston's proposed product does not and will not infringe any valid claim of the '251 patent.

34. A present genuine, justiciable controversy exists between Prinston and Noven regarding the issue of whether the manufacture, use, offer for sale, or sale of Prinston's proposed product would infringe any valid claim of the '251 patent.

35. Prinston is entitled to a declaration that the manufacture, use, offer for sale, or sale of Prinston's proposed product does not and will not infringe any valid claim of the '251 patent.

COUNT II

Declaration of Invalidity of United States Patent No. 8,946,251

36. Prinston repeats and incorporates by reference each of the foregoing paragraphs 1-28 of this Complaint as if fully set forth herein.

37. This Count arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claim of the '251 patent are invalid.

38. A present genuine, justiciable controversy exists between Prinston and Noven regarding the issue of whether the claims of the '251 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including failure to comply with one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

39. Prinston is entitled to a declaration that the claims of the '251 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including failure to comply with one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

PRAYER FOR RELIEF

WHEREFORE, Prinston prays that the Court enter judgment in its favor and against Noven as follows:

A. Enter a declaratory judgment that Prinston's proposed product does not infringe any valid claim of the '251 patent;

B. Enter a declaratory judgment that the claims of the '251 patent are invalid; and

C. Grant such other and further relief as the Court deems proper and just.

Dated: July 7, 2015

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LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, Prinston Pharmaceutical Inc. 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); and Noven Therapeutics, LLC v. Actavis Laboratories FL, Inc., Actavis Pharma Inc., Andrx Corp., and Actavis, Inc., 2:14-cv-06414 (CCC-JBC).

Dated: July 7, 2015

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