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IN THE UNITED STATED DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS INDUSTRIES, LTD.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPN") (collectively "Plaintiffs"), for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva Pharms. USA") and Teva Pharmaceuticals Industries, Ltd. ("Teva Pharms. Indus.") (collectively, "Teva"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 9,439,906 ("the 906 Patent").

2. This action relates to the submission of an Abbreviated New Drug Application ("ANDA") by Teva to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of JPI's Invega Sustenna® brand products prior to the expiration of the 906 Patent.

THE PARTIES

3. JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. JPN is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340 Beerse, Belgium.

5. On information and belief, Teva Pharms. USA is a corporation organized under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

6. On information and belief, Teva Pharms. Indus. is a company organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

7. On information and belief, Teva Pharms. USA is a pharmaceutical company that develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

8. On information and belief, Teva Pharms. USA is a wholly-owned subsidiary of Teva Pharms. Indus.

9. On information and belief, Teva Pharms. USA is acting on behalf of Teva Pharms. Indus. with respect to Teva's ANDA No. 211149.

JURISDICTION AND VENUE

10. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b).

13. By email dated January 10, 2018, through its counsel, Teva Pharms. USA stated that Teva Pharms. USA "would consent to jurisdiction and Venue in the District Court of New Jersey" "for purposes of this potential litigation only."

14. This Court has personal jurisdiction over Teva Pharms. USA because, *inter alia*, Teva Pharms. USA has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 211149, Teva Pharms. USA will make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's

Invega Sustenna® brand products in the United States, including in New Jersey, prior to the expiration of the 906 Patent.

15. Exercising personal jurisdiction over Teva Pharms. USA in this district would not be unreasonable given Teva Pharms. USA's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

16. The Court also has personal jurisdiction over Teva Pharms. USA because Teva Pharms. USA has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Teva Pharms. USA regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Teva Pharms. USA derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

17. On information and belief, Teva Pharms. USA employs people throughout New Jersey, including at at least the following locations: 8 Gloria Lane, Fairfield, NJ 07004; 208 Passaic Avenue, Fairfield, NJ 07004; and 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677.

18. On information and belief, Teva Pharms. USA has substantial, continuous and systemic contacts with New Jersey, it is registered to do business in New Jersey, has appointed a registered agent in New Jersey for receipt of service of process, and is registered as a drug manufacturer and wholesaler in New Jersey.

19. This Court also has personal jurisdiction over Teva Pharms. USA because, *inter alia*, this action arises from actions of Teva Pharms. USA directed toward New Jersey. For example, Teva Pharms. USA's counsel sent a letter dated August 1, 2017 to JPI, a corporation with its principal place of business in this Judicial District stating that Teva Pharms. USA had

submitted ANDA No. 211149 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Sustenna® brand products prior to the expiration of the 906 Patent. If Teva Pharms. USA succeeds in obtaining FDA approval, it would sell its proposed generic versions of JPI's Invega Sustenna® brand products in New Jersey and other states, causing injury to Plaintiffs in New Jersey.

20. On information and belief, Teva Pharms. Indus., directly or through Teva Pharms. USA, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

21. On information and belief, Teva Pharms. Indus. has substantial, continuous and systematic contacts with New Jersey, including, but not limited to, the direction of the operation and management of Teva Pharms. USA.

22. On information and belief, Teva Pharms. USA and Teva Pharms. Indus. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

23. On information and belief, Teva Pharms. USA and Teva Pharms. Indus. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Teva's ANDA Product for which they have sought approval from the FDA.

24. On information and belief, Teva Pharms. Indus. and Teva Pharms. USA are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing

and/or selling pharmaceutical products throughout the United States and will do the same with respect to Teva's ANDA Product for which they have sought approval from the FDA.

25. On information and belief, Teva Pharms. Indus., together with its affiliate and/or agent, Teva Pharms. USA, filed the Teva ANDA with the FDA that is at issue in this patent infringement suit.

26. On information and belief, Teva Pharms. Indus. alone and/or together with its affiliate and/or agent Teva Pharms. USA has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including to JPI, which is a New Jersey company, in New Jersey.

27. This Court has personal jurisdiction over Teva Pharms. Indus. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey; and (4) its conduct by and through, and in concert with, Teva Pharms. USA.

28. In the alternative, this Court has personal jurisdiction over Teva Pharms. Indus. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

THE PATENT-IN-SUIT

29. On September 13, 2016, the 906 Patent, titled "Dosing Regimen Associated With Long Acting Injectable Paliperidone Esters" was duly and legally issued to JPN as assignee. A copy of the 906 Patent is attached as Exhibit A.

30. JPI holds approved NDA No. 022264 for paliperidone palmitate extended release injectable suspension, which is prescribed and sold under the trademark Invega Sustenna®.

31. Pursuant to 21 U.S.C. § 355(b)(l), the 906 Patent is listed in the United States FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering JPI's Invega Sustenna® brand paliperidone palmitate extended release suspension products.

32. Invega Sustenna is indicated for treatment of schizophrenia in adults and treatment of schizoaffective disorder in adults as a monotherapy and as an adjunct to mood stabilizers or antidepressants.

COUNT I- INFRINGEMENT OF THE 906 PATENT BY TEVA'S ANDA FOR INVEGA SUSTENNA®

33. Plaintiffs re-allege paragraphs 1-32 as if fully set forth herein.

34. An actual controversy exists between the parties as to whether Teva's proposed sale of its generic paliperidone palmitate extended-release injectable suspension products infringes at least one claim, including claim 1 of the 906 Patent.

35. By letter dated December 5, 2017, ("Teva Notice Letter") Teva Pharms. USA notified Plaintiffs that it had submitted ANDA No. 211149 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter stated that ANDA No. 211149 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic paliperidone palmitate extended-release injectable suspension products prior to the expiration of certain of JPN's Orange Book listed patents. ANDA No. 211149 specifically seeks FDA approval to market generic versions of JPI's Invega Sustenna® brand paliperidone palmitate extended-release injectable suspension products in 39 mg, 78 mg, 117 mg, 156 mg, and 234 mg doses prior to the expiration of the 906 Patent.

36. On information and belief, ANDA No. 211149 includes a Paragraph IV Certification that the claims of the 906 Patent are invalid, unenforceable, and/or not infringed.

37. Plaintiffs commenced this action within 45 days of the date of receipt of Teva's Notice Letter.

38. The Teva Notice Letter purports to include a Notice of Certification for ANDA No. 211149 under 37 C.F.R. § 314.95(c)(6) as to the 906 Patent. The Teva Notice Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the 906 Patent.

39. Teva has actual knowledge of the 906 Patent, as shown by the Notice Letter.

40. On information and belief, Teva's generic products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the 906 Patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

41. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim, including at least claim 1 of the 906 Patent by submitting, or causing to be submitted, to the FDA, ANDA No. 211149 seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the 906 Patent. Upon information and belief, the products described in ANDA No. 211149 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the 906 Patent under 35 U.S.C. § 271(e)(2)(A).

42. On information and belief, physicians and/or patients will directly infringe at least one claim, including at least claim 1 of the 906 Patent by the use of Teva's generic products upon approval.

43. On information and belief, upon approval, Teva will take active steps to encourage the use of Teva's generic products by physicians and/or patients with the knowledge and intent that Teva's generic products will be used by physicians and/or patients, in a manner that infringes at least one claim, including at least claim 1, of the 906 Patent for the pecuniary benefit of Teva. Pursuant to 21 C.F.R. § 314.94, Teva is required to copy the FDA approved Invega Sustenna® labeling. Teva specifically intends its generic paliperidone palmitate products to be used according to its proposed labeling in a manner that infringes at least one claim, including at least claim 1, of the 906 Patent. Upon information and belief, Teva will thus induce the infringement of at least one claim, including at least claim 1 of the 906 Patent.

44. On information and belief, if the FDA approves ANDA No. 211149, Teva will sell or offer to sell its generic products specifically labeled for use in practicing at least one claim, including at least claim 1 of the 906 Patent, wherein Teva's generic products are a material part of the claimed invention, wherein Teva knows that physicians will prescribe and patients will use Teva's generic products in accordance with the instructions and/or label provided by Teva in practicing at least one claim, including at least claim 1 of the 906 Patent, and wherein Tevs's generic paliperidone palmitate extended-release injectable suspension products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Teva's generic paliperidone palmitate extended-release injectable suspension products are specifically designed for use in a manner that infringes at least one claim, including at least claim 1, of the 906 Patent. On information and belief, Teva will thus contribute to the infringement of at least one claim, including at least claim 1 of the 906 Patent.

45. On information and belief, the actions described in this Complaint relating to Teva's ANDA No. 211149 were done by and for the benefit of Teva.

46. Plaintiffs will be irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

47. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Teva on the patent infringement claims set forth above and respectfully request that this Court:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the 906 Patent through Teva's submission of ANDA No. 211149 to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell Teva's proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint in the United States before the expiration of the 906 Patent;

B. Enter judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Teva's proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint, prior to the expiration of the 906 Patent, constitutes infringement of one or more claims of the 906 Patent under 35 U.S.C. § 271 (a), (b) and/or (c);

C. Order that pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 211149 be a date that is not earlier than the expiration date of the 906 Patent, or such later date as the Court may determine;

D. Order that Teva, its officers, agents, servants, and employees, and those persons in active concert or participation with Teva, are preliminarily and permanently enjoined from

commercially manufacturing, using, importing, offering for sale, and selling Teva's proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the 906 Patent, prior to the expiration of the 906 Patent, or such later date as the Court may determine;

E. If Teva engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint prior to the expiration of the 906 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement together with interest;

F. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees; and

G. Award such further and other relief as this Court deems proper and just.

Respectfully Submitted,

Dated: January 17, 2018

s/Keith J. Miller
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CERTIFICATE PURSUANT TO RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: January 17, 2018

Respectfully Submitted,

s/Keith J. Miller
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