

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICALS, INC., and
JANSSEN PHARMACEUTICA NV,

Plaintiffs,
v.

Civil Action No. _____

ACCORD HEALTHCARE, INC., ACCORD
HEALTHCARE, LTD., and INTAS
PHARMACEUTICALS, LTD.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceuticals, Inc. (“JPI”) and Janssen Pharmaceutica NV (“JPN”) (collectively “Plaintiffs” or “Janssen”), for their Complaint against Defendants Accord Healthcare, Inc., Accord Healthcare, Ltd., and Intas Pharmaceuticals, Ltd. (collectively, “Accord” or “Defendants”), 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 Accord to the United States Food and Drug Administration (“FDA”) seeking approval for Defendants to market a generic version of JPI’s Invega Sustenna® brand products in the United States 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, Accord Healthcare, Inc. is a corporation organized under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, NC 27703. Upon information and belief, Accord Healthcare, Inc. is an agent or affiliate of Accord Healthcare, Ltd., and is a wholly-owned subsidiary of Intas Pharmaceuticals, Ltd.

6. On information and belief, Accord Healthcare, Ltd. is a corporation organized under the laws of India, having its principal place of business at Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad 380054, Gujarat, India. Upon information and belief, Accord Healthcare, Ltd. is an agent or affiliate of Accord Healthcare, Inc., and is a wholly-owned subsidiary of Intas Pharmaceuticals, Ltd.

7. On information and belief, Intas Pharmaceuticals, Ltd. is a corporation organized under the laws of India, having its principal place of business at Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad 380054, Gujarat, India. Upon information and belief, Intas Pharmaceuticals, Ltd. is the parent company of Accord Healthcare, Inc. and Accord Healthcare, Ltd.

8. On information and belief, Accord Healthcare, Inc., Accord Healthcare, Ltd., and Intas Pharmaceuticals, Ltd. are pharmaceutical companies that develop, manufacture,

market, and distribute pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

9. On information and belief, Accord Healthcare, Inc., Accord Healthcare, Ltd., and Intas Pharmaceuticals, Ltd. are acting in concert to develop, manufacture, market, and/or distribute generic pharmaceutical products, including the proposed generic version of Inviga Sustenna described in ANDA No. 216674, for sale in the State of New Jersey and throughout the United States.

10. On information and belief, Accord Healthcare, Inc., Accord Healthcare, Ltd., and Intas Pharmaceuticals, Ltd., along with other subsidiaries of Intas Pharmaceuticals, Ltd., 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.

11. On information and belief, Accord Healthcare, Inc., Accord Healthcare, Ltd., and Intas Pharmaceuticals, Ltd. 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 the product for which they have sought approval from the FDA in ANDA No. 216674.

12. On information and belief, Accord Healthcare, Inc., together with its affiliates and/or agents Accord Healthcare, Ltd., and Intas Pharmaceuticals, Ltd., filed the Accord ANDA No. 216674 with the FDA that is at issue in this patent infringement suit.

13. On information and belief, Accord Healthcare, Inc. is acting on behalf of itself and on behalf of Accord Healthcare, Ltd. and Intas Pharmaceuticals, Ltd. with respect to ANDA No. 216674.

JURISDICTION AND VENUE

14. 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.

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

16. This Court has personal jurisdiction over Accord Healthcare, Inc., Accord Healthcare, Ltd., and Intas Pharmaceuticals, Ltd., because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and intend 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. 216674, Defendants will make, use, sell, and/or offer for sale their proposed generic versions of JPI's Invega Sustenna® brand products in, or import those products into, the United States, including in New Jersey, prior to the expiration of the '906 Patent.

17. Exercising personal jurisdiction over Defendants in this district would not be unreasonable given their contacts with this district and this district's interest in resolving disputes related to products to be sold in New Jersey.

18. This Court also has personal jurisdiction over Defendants because they have purposefully availed themselves 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, Defendants regularly and continuously transact business within New Jersey, either directly or through their affiliates and/or agents, including by selling pharmaceutical products in New Jersey. On information and belief, Defendants derive substantial revenue from the sale of those

products in New Jersey and have availed themselves of the privilege of conducting business within New Jersey.

19. This Court also has personal jurisdiction over Defendants because, *inter alia*, this action arises from their actions directed toward New Jersey. For example, Accord Healthcare, Inc. sent a letter dated January 10, 2022 to Plaintiffs stating that Accord Healthcare, Inc. had submitted ANDA No. 216674 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 Accord Healthcare, Inc. succeeds in obtaining FDA approval, it will sell its proposed generic versions of JPI's Invega Sustenna® brand products in New Jersey and other states, either directly or through its affiliates and/or agents Accord Healthcare, Ltd. and/or Intas Pharmaceuticals, Ltd., causing injury to Plaintiffs in New Jersey.

20. In addition, this Court has personal jurisdiction over Accord Healthcare, Inc., because Accord Healthcare, Inc. has agreed by stipulation not to contest personal jurisdiction for purposes of this action.

21. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b) with respect to Accord Healthcare, Inc., because, *inter alia*, Accord Healthcare, Inc., has agreed by stipulation not to contest venue for purposes of this action, and has previously consented to venue in this district. *See Eagle Pharmaceuticals, Inc., v. Accord Healthcare, Inc.*, No. 2:19-cv-09031 (CCC) (MF) (D.N.J.); *Otsuka Pharmaceuticals Co., Ltd., v. Intas Pharmaceuticals Ltd. et al.*, No. 1:16-cv-05743 (JBS) (KMW) (D.N.J.).

22. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b) with respect to Accord Healthcare, Ltd., because, *inter alia*, on information and belief,

Accord Healthcare, Ltd. is a foreign corporation and, as such, may be sued in any judicial district in which it is subject to personal jurisdiction.

23. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b) with respect to Intas Pharmaceuticals, Ltd., because, *inter alia*, on information and belief, Intas Pharmaceuticals, Ltd. is a foreign corporation and, as such, may be sued in any judicial district in which it is subject to personal jurisdiction. Venue is also proper against Intas Pharmaceuticals, Ltd., because Intas Pharmaceuticals, Ltd. has previously consented to venue in this district. *See Otsuka Pharmaceuticals Co., Ltd., v. Intas Pharmaceuticals Ltd. et al.*, No. 1:16-cv-05743 (JBS) (KMW) (D.N.J.).

THE PATENT-IN-SUIT

24. 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.

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

26. Pursuant to 21 U.S.C. § 355(b)(1), 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.

27. 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 ACCORD'S ANDA FOR INVEGA SUSTENNA®**

28. Plaintiffs re-allege paragraphs 1-27 as if fully set forth herein.
29. An actual controversy exists between the parties as to whether Defendants' proposed sale of their generic paliperidone palmitate extended-release injectable suspension products infringe claims 1-21 of the '906 Patent.
30. By letter dated January 10, 2022 ("Accord Notice Letter"), Accord Healthcare, Inc. notified Plaintiffs that it had submitted ANDA No. 216674 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Accord Notice Letter stated that ANDA No. 216674 seeks FDA approval 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. 216674 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.
31. ANDA No. 216674 includes a Paragraph IV Certification that the claims of the '906 Patent are invalid, unenforceable, and/or not infringed.
32. Upon information and belief, the Accord Notice Letter was sent to Plaintiffs via overnight mail no earlier than January 10, 2022.
33. The Accord Notice Letter was subsequently received by Plaintiffs on January 12, 2022, and Plaintiffs are commencing this action within 45 days of the date of receipt of the Accord Notice Letter.

34. The Accord Notice Letter purports to include a Notice of Certification for ANDA No. 216674 under 37 C.F.R. § 314.95(c)(6) as to the '906 Patent. The Accord Notice Letter did not include a detailed statement of allegations of non-infringement as to any claims of the '906 Patent.

35. Defendants have actual knowledge of the '906 Patent, as shown by the Accord Notice Letter.

36. On information and belief, Defendants' generic products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, claims 1-21 of the '906 Patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

37. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed claims 1-21 of the '906 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 216674 seeking approval to manufacture, use, offer to sell or sell in, or import into, the United States, Defendants' generic products before the expiration date of the '906 Patent. Upon information and belief, the products described in ANDA No. 216674 would infringe, either literally or under the doctrine of equivalents, claims 1-21 of the '906 Patent under 35 U.S.C. § 271(e)(2)(A).

38. On information and belief, upon approval of ANDA No. 216674, physicians and/or patients will directly infringe claims 1-21 of the '906 Patent by use of Defendants' generic products.

39. On information and belief, upon approval of ANDA No. 216674, Defendants will take active steps to encourage the use of Defendants' generic products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients in a manner that infringes claims 1-21 of the '906 Patent

for the pecuniary benefit of Defendants. Pursuant to 21 C.F.R. § 314.94, Defendants are required to copy the FDA-approved Invega Sustenna® labeling. Defendants specifically intend their generic paliperidone palmitate products to be used according to their proposed labeling in a manner that infringes claims 1-21 of the '906 Patent. Upon information and belief, Defendants will thus induce the infringement of claims 1-21 of the '906 Patent.

40. On information and belief, if the FDA approves ANDA No. 216674, Defendants will sell or offer to sell their generic products specifically labeled for use in practicing claims 1-21 of the '906 Patent, wherein Defendants' generic products are a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by Defendants in practicing claims 1-21 of the '906 Patent, and wherein Defendants' generic paliperidone palmitate extended-release injectable suspension products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Defendants' generic paliperidone palmitate extended-release injectable suspension products are specifically designed for use in a manner that infringes claims 1-21 of the '906 Patent. On information and belief, Defendants will thus contribute to the infringement of claims 1-21 of the '906 Patent.

41. On information and belief, the actions described in this Complaint relating to Accord's ANDA No. 216674 were done by and for the benefit of Defendants.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following relief:

- A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed claims 1-21 of the '906 Patent through Defendants' submission of ANDA No. 216674 to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell Defendants' proposed generic versions of JPI's Invega Sustenna® brand product 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 Defendants' commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' 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), or (c);
- C. Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 216674 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 Defendants, their affiliates, officers, agents, servants, and employees, and those persons in active concert or participation with Defendants, are preliminarily and permanently enjoined from manufacturing, using, importing, offering for sale, and selling Defendants' proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint, and any other product that infringes 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 Defendants engage 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 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 attorneys' fees; and
- G. Award such further and other relief that the Court deems proper and just.

Dated: February 16, 2022

s/ Keith J. Miller
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding, except for the prior matters *Janssen Pharmaceuticals, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 2:18-cv-00734 (CCC) (LDW), *Janssen Pharmaceuticals, Inc., et al. v. Mylan Laboratories Ltd.*, Civil Action No. 2:19-cv-16484 (CCC)(LDW), and *Janssen Pharmaceuticals, Inc., et al. v. Pharmascience Inc., et al.*, Civil Action No. 2:19-cv-21590 (CCC)(LDW) in this Judicial District, and the prior matter *Janssen Pharmaceuticals, Inc., et al. v. Tolmar Inc., et al.*, Civil Action No. 1:21-cv-1784 pending in the District of Delaware, all of which involve the same plaintiffs and the same patent.

Dated: February 16, 2022

s/ Keith J. Miller

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