IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPN") (collectively "Plaintiffs" or "Janssen"), for their Complaint against Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively, "Defendants" or "Sun"), 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 Abbreviated New Drug Application ("ANDA") No. 217818 by Sun Ltd. to the United States Food and Drug Administration ("FDA") seeking approval to market proposed generic versions of JPI's Invega Sustenna® brand products ("Sun's Proposed Generic 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, Sun Ltd. is a corporation organized and existing under the laws of the Republic of India, having a place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India, 400063.

6. On information and belief, Sun Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 2 Independence Way, Princeton, New Jersey 08540.

7. Upon information and belief, Sun Inc. is a wholly owned subsidiary of Sun Ltd. Upon information and belief, Sun Inc. acts at the direction of, under the control of, and for the benefit of Sun Ltd., and is controlled and/or dominated by Sun Ltd. Upon information and belief, Sun Inc. and Sun Ltd. have at least one officer and/or director in common.

8. Upon information and belief, Sun Inc. is in the business of, among other things: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware; (ii) alone or in concert with and/or through its parent and various subsidiaries, including Sun Ltd., the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) alone or in concert with and/or through its parent and various subsidiaries, including Sun Ltd., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

9. Upon information and belief, Sun Inc. is an agent and/or affiliate of Sun Ltd. and is the authorized United States agent for ANDA No. 217818.

10. On information and belief, Sun Ltd. and Sun Inc. are pharmaceutical companies that develop, manufacture, market, and distribute pharmaceutical products, including generic pharmaceutical products, for sale in the State of Delaware and throughout the United States.

11. On information and belief, Sun Ltd. is acting on behalf of itself and on behalf of Sun Inc. with respect to Sun's ANDA No. 217818.

JURISDICTION AND VENUE

12. 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.

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

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

Sun Ltd.

15. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, Sun Ltd. 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 Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of ANDA No. 217818, Sun Ltd. will, directly or through its affiliates, make, use, import, sell, and/or offer for sale Sun's Proposed Generic Products in the United States, including in Delaware, prior to the expiration of the 906 Patent.

16. Exercising personal jurisdiction over Sun Ltd. in this district would not be unreasonable given Sun Ltd.'s contacts in this district and this district's interest in resolving disputes related to products to be sold herein.

17. This Court also has personal jurisdiction over Sun Ltd. because Sun Ltd. has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Sun Ltd. regularly and continuously transacts business within Delaware, either directly or through its affiliates, including by selling pharmaceutical products in Delaware. On information and belief, Sun Ltd. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

18. On information and belief, Sun Ltd., either directly or indirectly through Sun Inc., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

19. Sun Ltd. has consented to or did not contest the jurisdiction of this Court in at least the following District of Delaware actions: *Exelixis, Inc. v. Sun Pharmaceuticals Industries Ltd. et al.*, No. 24-1208-RGA (D. Del.); *Otsuka Pharmaceutical Co., Ltd. et al. v. Sun Pharmaceutical Industries Limited et al.*, No. 24-789-JLH (D. Del.); *Veloxis Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd. et al.*, No. 24-00726-MN (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Sun Pharmaceutical Industries Limited et al.*, No. 21-1573-CFC (D. Del.).

20. Sun Ltd. has also purposefully availed itself of the rights and benefits of Delaware law by suing or filing counterclaims in the District of Delaware. *See, e.g.*, *Exelixis, Inc.*

v Sun Pharmaceuticals Industries Ltd. et al., No. 24-1208-RGA (D. Del.); *Veloxis Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd. et al.*, No. 24-00726-MN (D. Del.).

21. In the alternative, this Court has personal jurisdiction over Sun Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

22. Sun Ltd. has consented to or did not contest venue in patent cases in this Judicial District in at least the following exemplary District of Delaware actions: *Exelixis, Inc. v. Sun Pharmaceuticals Industries Ltd. et al.*, No. 24-1208-RGA (D. Del.); *Otsuka Pharmaceutical Co., Ltd. et al. v. Sun Pharmaceutical Industries Limited et al.*, No. 24-789-JLH (D. Del.); *Veloxis Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd. et al.*, No. 24-00726-MN (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Sun Pharmaceutical Industries Limited et al.*, No. 21-1573-CFC (D. Del.).

23. Venue is proper in this Judicial District for Sun Ltd. pursuant to 28 U.S.C. §§ 1391(c) and 1400(b), including, for example, because Sun Ltd. is a company organized and existing under the laws of the Republic of India and may be sued in any judicial district.

Sun Inc.

24. On information and belief, Sun Inc., either directly or indirectly through Sun Ltd., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

25. On information and belief, Sun Inc. has substantial, continuous, and systematic contacts with Delaware, including, but not limited to, being incorporated there.

26. The Court has personal jurisdiction over Sun Inc. because, *inter alia*, on information and belief, Sun Inc. 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

Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of ANDA No. 217818, Sun Inc. will, directly or through its affiliate Sun Ltd., make, use, import, sell, and/or offer for sale Sun's Proposed Generic Products in the United States, including in Delaware, prior to the expiration of the 906 Patent.

27. Exercising personal jurisdiction over Sun Inc. in this district would not be unreasonable given Sun Inc.'s contacts in this district and this district's interest in resolving disputes related to products to be sold herein.

28. This Court has personal jurisdiction over Sun Inc. by virtue of, among other things, the fact that it is organized and exists under the laws of the State of Delaware.

29. This Court also has personal jurisdiction over Sun Inc. because Sun Inc. has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Sun Inc. regularly and continuously transacts business within Delaware, either directly or through its affiliates. On information and belief, Sun Inc. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

30. Sun Inc. has consented to or did not contest the jurisdiction of this Court in at least the following District of Delaware actions: *Exelixis, Inc. v. Sun Pharmaceuticals Industries Ltd. et al.*, No. 24-1208-RGA (D. Del.); *Otsuka Pharmaceutical Co., Ltd. et al. v. Sun Pharmaceutical Industries Limited et al.*, No. 24-789-JLH (D. Del.); *Veloxis Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd. et al.*, No. 24-00726-MN (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Sun Pharmaceutical Industries Limited et al.*, No. 21-1573-CFC (D. Del.).

31. Sun Inc. has also purposefully availed itself of the rights and benefits of Delaware law by suing or filing counterclaims in the District of Delaware. *See, e.g.*, *Exelixis, Inc. v Sun Pharmaceuticals Industries Ltd. et al.*, No. 24-1208-RGA (D. Del.).

32. Venue is proper in this district pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Sun Inc. is incorporated in the State of Delaware, and, therefore, resides in this Judicial District.

33. Sun Inc. has consented to or did not contest venue in patent cases in this Judicial District in at least the following exemplary District of Delaware actions: *Exelixis, Inc. v. Sun Pharmaceuticals Industries Ltd. et al.*, No. 24-1208-RGA (D. Del.); *Otsuka Pharmaceutical Co., Ltd. et al. v. Sun Pharmaceutical Industries Limited et al.*, No. 24-789-JLH (D. Del.); *Veloxis Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd. et al.*, No. 24-00726-MN (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Sun Pharmaceutical Industries Limited et al.*, No. 21-1573-CFC (D. Del.).

Sun Ltd. and Sun Inc.

34. On information and belief, Sun Ltd. and Sun Inc., along with other subsidiaries of Sun Ltd., hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in Delaware and throughout the United States.

35. On information and belief, Sun Ltd. and Sun Inc. 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. 217818.

36. On information and belief, Sun Ltd. and Sun Inc. 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 the product for which they have sought approval from the FDA in ANDA No. 217818.

37. On information and belief, Sun Ltd. and Sun Inc. filed ANDA No. 217818 with the FDA.

THE PATENT-IN-SUIT

38. On September 13, 2016, the 906 Patent, titled "Dosing Regimen Associated With Long Acting Injectable Paliperidone Esters" was duly and legally issued by the United States Patent & Trademark Office to JPN as assignee. A copy of the 906 Patent is attached as **Exhibit A**.

39. JPI holds approved NDA No. N022264 for paliperidone palmitate extended-release injectable suspension, which is prescribed and sold under the trademark Invega Sustenna®.

40. 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 injectable suspension products.

SUN'S NOTICE LETTER AND OFFER OF CONFIDENTIAL ACCESS

41. By letter dated May 28, 2025 ("Notice Letter"), Sun Ltd. notified Plaintiffs that it had submitted ANDA No. 217818 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. 217818 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 into the State of Delaware, of Sun's Proposed

Generic Products prior to the expiration of the 906 Patent. On information and belief, Sun Inc. is the authorized United States agent of Sun Ltd. with respect to ANDA No. 217818.

42. In the Notice letter, Sun Ltd. offered confidential access (Offer of Confidential Access, "OCA") to certain confidential information regarding Sun's Proposed Generic Products. On May 30, 2025, counsel for Plaintiffs contacted Sun Ltd.'s counsel identified on the Notice Letter in an attempt to reach agreement on the terms for confidential access to the Sun ANDA. On June 2, 2025, Plaintiffs sent Sun Ltd.'s counsel a markup of the OCA.

43. Despite multiple emails and a telephone call, Sun Ltd. did not respond to Plaintiffs' proposed mark-up of the OCA until June 16, 2025, when Sun Ltd. categorically rejected Plaintiffs' proposed edits to the OCA without explanation. That same day, Plaintiffs responded by email seeking clarification from Sun Ltd. to determine whether it would be willing to make any changes to the proposed OCA. After multiple prompts from Plaintiffs, Sun Ltd. responded on June 30, 2025 stating it was not willing to negotiate. As of the filing of this Complaint, the parties have not been able to reach an agreement on the terms of the OCA.

44. To date, Sun Ltd. has not provided Plaintiffs with a copy of any portions of ANDA No. 217818 or any information regarding Sun's Proposed Generic Products, beyond the information set forth in the Notice Letter.

45. The limited information relating to Sun's Proposed Generic Products that was provided in the Notice Letter does not demonstrate that Sun's Proposed Generic Products, which Sun Ltd. has asked the FDA to approve for sale in the United States, will not fall within the scope of issued claims of the 906 Patent. On information and belief, Sun's Proposed Generic Products will contain instructions for use that are substantially identical to the instructions for use

for Janssen's Invega Sustenna® products, and therefore fall within the scope of the issued claims of the 906 Patent.

COUNT I:
INFRINGEMENT OF THE 906 PATENT BY SUN'S ANDA FOR INVEGA SUSTENNA®

46. Plaintiffs re-allege paragraphs 1-45 as if fully set forth herein.

47. An actual controversy exists between the parties as to whether Sun's proposed sale of Sun's Proposed Generic Products infringes claims 1-21 of the 906 Patent.

48. In its Notice Letter dated May 28, 2025, Sun Ltd. notified Plaintiffs that it had submitted ANDA No. 217818 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. 217818 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 into the State of Delaware, of Sun's Proposed Generic Products prior to the expiration of the 906 Patent, which is listed in the Orange Book. Upon information and belief, ANDA No. 217818 seeks FDA approval to market Sun's Proposed Generic Products prior to the expiration of the 906 Patent.

49. Upon information and belief, Sun Inc. is the authorized United States agent with respect to ANDA No. 217818.

50. Upon information and belief, ANDA No. 217818 includes a Paragraph IV Certification that the claims of the 906 Patent are invalid, unenforceable, and/or not infringed.

51. Upon information and belief, Sun's Notice Letter was sent to Plaintiffs via overnight mail no earlier than May 28, 2025. The Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of the Notice Letter.

52. Sun's Notice Letter purports to include a Notice of Certification for ANDA No. 217818 under 21 C.F.R. § 314.95(c)(6) as to the 906 Patent. Sun's Notice Letter did not include a detailed statement of allegations of non-infringement as to any claims of the 906 Patent.

53. Sun Ltd. has actual knowledge of the 906 Patent, as shown by the Notice Letter. On information and belief, Sun Inc., as authorized United States agent for ANDA No. 217818, has actual knowledge of the 906 Patent.

54. On information and belief, Sun's Proposed Generic Products, if approved and made, used, offered for sale, or sold within the United States, or imported into the United States, 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).

55. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun has infringed claims 1-21 of the 906 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 217818 seeking approval to manufacture, use, import, offer to sell or sell Sun's Proposed Generic Products before the expiration date of the 906 Patent. Upon information and belief, the products described in ANDA No. 217818 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).

56. On information and belief, upon approval of ANDA No. 217818, physicians and/or patients will directly infringe claims 1-21 of the 906 Patent by use of Sun's Proposed Generic Products.

57. On information and belief, upon approval of ANDA No. 217818, Sun will take active steps to encourage the use of Sun's Proposed Generic Products by physicians and/or patients with the knowledge and intent that Sun's Proposed 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 Sun. Pursuant to 21 C.F.R. § 314.94, Sun is required to copy the FDA-approved Invega Sustenna® labeling. The use of Invega Sustenna® according to its approved labeling meets the elements of claims 1-21 of the 906 Patent. On information and belief, Sun's Proposed Generic Products meet all the formulation elements of claims 17-21. On information and belief, Sun specifically intends Sun's Proposed Generic Products to be used according to its proposed labeling in a manner that infringes claims 1-21 of the 906 Patent. Upon information and belief, Sun will thus induce the infringement of claims 1-21 of the 906 Patent.

58. On information and belief, if the FDA approves ANDA No. 217818, Sun will sell or offer to sell Sun's Proposed Generic Products specifically labelled for use in practicing claims 1-21 of the 906 Patent, wherein Sun's Proposed Generic Products are a material part of the claimed invention, wherein Sun knows that physicians will prescribe and patients will use Sun's Proposed Generic Products in accordance with the instructions and/or label provided by Sun in practicing claims 1-21 of the 906 Patent, and wherein Sun's Proposed Generic Products are not staple articles or commodities of commerce suitable for non-infringing use. Sun's Proposed Generic Products are specifically designed for use in a manner that infringes claims 1-21 of the 906 Patent. On information and belief, Sun will thus contribute to the infringement of claims 1-21 of the 906 Patent.

59. On information and belief, the actions described in this Complaint relating to Sun's ANDA No. 217818 were done by and for the benefit of Sun.

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

61. The case is an exceptional one, and Plaintiffs are entitled to an award of 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 Sun has infringed claims 1-21 of the 906 Patent through Sun's submission of ANDA No. 217818 to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell Sun's Proposed Generic 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 Sun's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Sun's Proposed Generic 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. 217818 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 Sun, its affiliates, officers, agents, servants, and employees, and those persons in active concert or participation with Sun, are preliminarily and permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling Sun's Proposed Generic 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 Sun engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Sun's Proposed Generic Products identified in this Complaint prior to the expiration of the 906 Patent, enter 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.

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