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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KYOWA KIRIN CO., LTD. and KYOWA KIRIN, INC., Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC., Defendants.	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Kyowa Kirin Co., Ltd. and Kyowa Kirin, Inc. (collectively, "KKC" or "Plaintiffs"), for their Complaint against Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, "Sun" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Kyowa Kirin Co., Ltd. ("Kyowa Ltd.") is an entity organized and existing under the laws of Japan, with a principal place of business at 1-9-2 Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan.

2. Plaintiff Kyowa Kirin, Inc. ("Kyowa Inc.") is an entity organized and existing under the laws of Delaware, with a principal place of business at 510 Carnegie Center Dr. Suite 600, Princeton, NJ 08540.

3. Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is an entity organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1 Western Express Highway, Goregaon (E), Mumbai-400063, Maharashtra, India.

4. Defendant Sun Pharmaceutical Industries, Inc. ("Sun Inc.") is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

5. Upon information and belief, Sun Inc. is a wholly owned subsidiary of Sun Ltd.

6. Upon information and belief, Sun Inc. acts at the direction, and for the benefit, of Sun Ltd. and is controlled and/or dominated by Sun Ltd.

7. Upon information and belief, Sun Ltd. and Sun Inc. work in concert, either directly or indirectly, with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

NATURE OF THE ACTION

8. This is a civil action for infringement of U.S. Patent No. 7,727,993 ("the '993 patent").

9. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this action is an actual controversy within the Court's jurisdiction.

11. Upon information and belief, Sun Ltd. and Sun Inc., either directly or through one or more of their agents, develop, manufacture, market, distribute, sell, and/or import generic versions of branded pharmaceutical products throughout the United States, including in this Judicial District.

12. Sun sent Plaintiffs a letter dated September 30, 2025 ("Sun's Notice Letter"), stating that Sun Ltd. filed Abbreviated New Drug Application ("ANDA") No. 220691 seeking approval from the United States Food and Drug Administration ("FDA") to engage in the commercial manufacture, use, or sale within the United States, including, upon information and belief, in this Judicial District, of a generic version of Plaintiffs' Nourianz® (istradefylline) tablets, 20 mg and 40 mg ("Sun's ANDA Product"), before the expiration of the '993 patent.

13. Upon information and belief, Sun Ltd. and Sun Inc. are agents of each other with respect to importing pharmaceutical products into the United States and are commercially manufacturing, marketing, distributing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to Sun's ANDA Product that is the subject of ANDA No. 220691, for which Sun has sought approval from the FDA.

14. Upon information and belief, Sun Ltd. and Sun Inc. are acting in concert with each other with respect to importing pharmaceutical products into the United States and are commercially manufacturing, marketing, distributing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to Sun's ANDA Product that is the subject of ANDA No. 220691, for which Sun has sought approval from the FDA.

15. Upon information and belief, Sun filed or caused to be filed ANDA No. 220691 with the FDA. Sun Inc. maintains distribution channels throughout the United States, including in this Judicial District, which will be used by Sun to commercially manufacture, use, offer to sell, sell, and/or import Sun's ANDA Product. If Sun's ANDA No. 220691 is approved by FDA, Sun will use the above-mentioned distribution channels to distribute Sun's ANDA Product.

16. This Court has personal jurisdiction of Sun Ltd. because, *inter alia*, Sun Ltd.: (1) has purposely availed itself of the privilege of doing business in this Judicial District directly or indirectly through its subsidiary, agent, and/or alter ego; (2) upon information and belief, maintains pervasive, continuous, and systematic contacts with this Judicial District, including the marketing, distribution, and/or sale of generic pharmaceutical drugs; (3) upon information and belief, derives substantial revenue from the sale of its products in this Judicial District; and (4) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Sun's ANDA Product in this Judicial District.

17. Sun Ltd. has further availed itself of the jurisdiction of this Judicial District by initiating litigation in this Judicial District. *See, e.g.*, *Sun Pharmaceutical Industries Ltd., et al. v. Novartis Pharmaceuticals Corp., et al.*, Civil Action No. 19-21733 (D.N.J.); *Sun Pharmaceutical Industries Ltd. v. Pfizer Inc., et al.*, Civil Action No. 19-09330 (D.N.J.); *Sun Pharmaceutical Industries Ltd., et al. v. VistaPharm, Inc.*, Civil Action No. 19-07536 (D.N.J.).

18. Alternatively, this Court may exercise jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*: (1) Plaintiffs' claims arise under federal law; (2) Sun Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Sun Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, by submitting or causing to be submitted various ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products throughout the United States, such that this Court's exercise of jurisdiction over Sun Ltd. satisfies due process.

19. This Court has personal jurisdiction over Sun Inc., because, *inter alia*, Sun Inc.: (1) has a principal place of business New Jersey; (2) has employees in the place of business that it maintains in New Jersey; (3) has purposely availed itself of the privilege of doing business in this Judicial District, including, *inter alia*, by registering with the State of New Jersey's Division of Revenue and Enterprise Service to do business in New Jersey under Business ID Nos. 0100970132 and 0100954087 and securing a New Jersey manufacturer's and wholesale drug distributor's license under Registration Nos. 5003437, 5003826 and 5003941; (4) imports generic versions of branded pharmaceutical products for sale and use throughout the United States, including in this Judicial District; (5) markets, distributes, and sells generic versions of branded pharmaceutical products throughout the United States, including in this Judicial District; (6) intends to market, sell, or distribute Sun's ANDA Products to residents of this Judicial District; and (7) upon information and belief, derives substantial revenue from the sale of its products in this Judicial District.

20. On information and belief, Sun Inc. has not contested jurisdiction in this Judicial District in one or more prior cases arising out of the filing of its ANDAs. *See, e.g.*, *Incyte Corp., et al., v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 25-13225 (D.N.J);

TherapeuticsMD, Inc., et al. v. Sun Pharmaceutical Industries Limited, et al., Civil Action No. 24-07974 (D.N.J.); *Astellas Pharma Inc. v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 22-07357 (D.N.J.); *Orexo AB, et al. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 21-17941 (D.N.J); *Orexo AB, et al. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 20-12588 (D.N.J.); *Merck Sharp & Dohme BV, et al. v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 20-03007 (D.N.J.).

21. This Court also has personal jurisdiction over Sun Inc. because, *inter alia*, Sun Inc. has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in this Judicial District, that have led to foreseeable harm and injury to Plaintiffs in this Judicial District.

22. Venue is proper in this Court as to Sun Ltd. under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Sun Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which Sun Ltd. is subject to the court's personal jurisdiction.

23. Venue is proper in this Court as to Sun Inc. under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because Sun Inc. has a principal place of business in New Jersey, and has committed and will commit further acts of infringement in this Judicial District.

24. Venue is proper in this Court as to Sun Ltd. and Sun Inc. for the additional reasons set forth above and for other reasons that will be presented to the Court if such venue is challenged.

THE '993 PATENT

25. Kyowa Inc. is the holder of New Drug Application ("NDA") No. 022075, pursuant to which the FDA first granted approval for istradefylline tablets, 20 mg and 40 mg, marketed in the United States under the trade name Nourianz®.

26. Nourianz® (istradefylline tablets, 20 mg and 40 mg) is FDA-approved, and indicated as an adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease experiencing "off" episodes.

27. Pursuant to 21 U.S.C. § 355(b)(l), the '993 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as "the Orange Book") as covering Nourianz® (istradefylline tablets, 20 mg and 40 mg).

28. Kyowa Ltd. owns the '993 patent, which was duly and legally issued on June 1, 2010, and is titled "*Administering Adenosine A_{2A} Receptor Antagonist to Reduce or Suppress Side Effects of Parkinson's Disease Therapy.*" A copy of the '993 patent is attached as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

29. Upon information and belief, Sun filed with the FDA ANDA No. 220691, which includes a certification with respect to the '993 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Product before the expiration of the '993 patent.

30. On or about September 30, 2025, Sun sent Sun's Notice Letter to Plaintiffs, in which it represented that Sun had filed ANDA No. 220691 for Sun's ANDA product, including a

Paragraph IV Certification with respect to the '993 patent, and that it is seeking approval of ANDA No. 220691 before the expiration of the patent.

31. Separate and apart from certain contentions regarding alleged patent invalidity, Sun's Notice Letter does not identify any factual basis for, or any position of, noninfringement of claims 1-12 of the '993 patent.

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

COUNT I – INFRINGEMENT BY SUN

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

34. By seeking approval of ANDA No. 220691 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Product before the expiration of the '993 patent, Sun has infringed the '993 patent under 35 U.S.C. § 271(e)(2)(A).

35. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 220691 be a date that is not earlier than the expiration date of the '993 patent, including any patent term extensions and/or patent term adjustments, and the period of any pediatric exclusivity, associated with the '993 patent to which Plaintiffs are or may become entitled.

36. The commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Product, if approved by the FDA before the expiration of the '993 patent for use in accordance with its proposed labeling, would directly and/or indirectly infringe and/or induce and/or contribute to the infringement of the '993 patent.

37. Upon information and belief, Sun knows and intends that healthcare professionals and/or patients will use Sun's ANDA Product in accordance with the labeling sought by Sun's ANDA, and Sun will therefore contribute to the infringement of and/or induce the direct infringement of one or more claims of the '993 patent under 35 U.S.C. §§ 271 (b) and/or (c).

38. Plaintiffs are entitled to a declaration that, if Sun commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Sun's ANDA Product, or induces or contributes to any such conduct, it would further directly and/or indirectly infringe the '993 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

39. Upon information and belief, Sun was aware of the existence of the '993 patent and was aware that the submission of Sun's ANDA No. 220691 to the FDA constituted an act of direct and/or indirect infringement of the '993 patent.

40. Upon information and belief, Sun was aware that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Product before the expiration of the '993 patent would constitute an act of direct and/or indirect infringement of the '993 patent.

41. Plaintiffs will be irreparably harmed by Sun's direct and/or indirect infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. a Judgment that Sun has infringed the '993 patent by submitting ANDA No. 220691 to the FDA;

B. a Judgment that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Product will infringe, or induce or contribute to the infringement of, the '993 patent;

C. a Judgment that this case is exceptional and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

D. a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 restraining and enjoining Sun, its directors, officers, agents, attorneys, affiliates, divisions, successors, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of any drug product, or use thereof, claimed in the '993 patent;

E. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 220691 be a date that is not earlier than the expiration date of the '993 patent, including any patent term extensions and/or patent term adjustments, and the period of any pediatric exclusivity associated with the '993 patent to which Plaintiffs are or may become entitled; and

F. such other and further relief as the Court may deem just and proper.

Dated: November 13, 2025

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy is not related to any other matter currently pending in this Judicial District.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 13, 2025

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