

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

SUMITOMO DAINIPPON PHARMA CO., LTD.
and SUNOVION PHARMACEUTICALS INC.,

Plaintiffs,

v.

MACLEODS PHARMACEUTICALS LTD. and
MACLEODS PHARMA USA, INC.

Defendants.

C.A. No. _____

**PLAINTIFFS SUMITOMO DAINIPPON PHARMA CO., LTD.
AND SUNOVION PHARMACEUTICALS INC.'S
COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo”) and Sunovion Pharmaceuticals Inc. (“Sunovion”) (collectively, “Plaintiffs”), for their complaint against Defendants Macleods Pharmaceuticals Ltd. (“Macleods Ltd.”) and Macleods Pharma USA, Inc. (“Macleods Inc.”) (collectively, “Defendants” or “Macleods”), allege as follows:

NATURE OF ACTION

1. This is an action for infringement of United States Patent Nos. 9,815,827 (the “’827 patent”) and 9,907,794 (the “’794 patent”) (collectively, the “Asserted Patents”) under 35 U.S.C. § 271(e)(2) and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271 (a), (b), and (c) relating to Plaintiffs’ commercially successful product, Latuda®. A true and accurate copy of the ’827 patent is attached hereto as Exhibit A. A true and accurate copy of the ’794 patent is attached hereto as Exhibit B.

THE PARTIES

2. Plaintiff Sumitomo is a company organized and existing under the laws of Japan, with a principal place of business at 6-8, Doshomachi 2-chome, Chuo-ku, Osaka, Osaka 541-0045, Japan.

3. Plaintiff Sunovion is a corporation organized and existing under the laws of Delaware, with a principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

4. On information and belief, Defendant Macleods Ltd. is a company organized and existing under the laws of India with a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400059, India.

5. On information and belief, Defendant Macleods Inc. is a company organized and existing under the laws of the state of Delaware with a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

6. On information and belief, Macleods Inc. is a wholly-owned subsidiary of Macleods Ltd.

7. On information and belief, Macleods is in the business of developing, manufacturing, distributing and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Macleods is working to achieve final approval by the U.S. Food and Drug Administration (“FDA”) of Abbreviated New Drug Application (“ANDA”) No. 212124.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.*, including §§ 271(e)(2), 271(a), 271(b), 271(c), and 28

U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

9. This Court has personal jurisdiction over Macleods Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Macleods Ltd. regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Macleods Ltd. derives substantial revenue from the sale of pharmaceutical products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Macleods Ltd.'s filing of its ANDA (submitted, on information and belief, in concert with Macleods Inc.) and the causes of action Plaintiffs raise here, as alleged herein.

10. On information and belief, Macleods Ltd. wholly owns Macleods Inc.

11. Further, this Court has personal jurisdiction over Macleods Ltd. because Macleods Ltd. has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Macleods Ltd. intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Macleods Ltd., either directly or through its subsidiaries, agents, and/or affiliates, manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Macleods Ltd. developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Macleods Ltd., in concert with Macleods Inc., filed ANDA No. 212124, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

12. On information and belief, Macleods Ltd. intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

13. On information and belief, Macleods Ltd.'s conduct has or will cause foreseeable harm and injury to Plaintiffs.

14. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Macleods Ltd. to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

15. Further, this Court has personal jurisdiction over Macleods Ltd. because Macleods Ltd. has previously been sued in this district and has not challenged personal jurisdiction, and Macleods Ltd. has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Otsuka Pharm. Co., Ltd. v. Macleods Pharms. Ltd.*, 1:15-cv-5109 (D.N.J.); *AstraZeneca AB v. Macleods Pharms. Ltd.*, 3:16-cv-1682 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. v. Macleods Pharms. Ltd.*, 3:17-cv-13130 (D.N.J.).

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over Macleods Ltd., this Court may exercise jurisdiction over Macleods Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Macleods Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) Macleods Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the

United States; and (d) Macleods Ltd. filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over Macleods Ltd. satisfies due process.

17. This Court has personal jurisdiction over Macleods Inc. by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Macleods Inc. regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Macleods Inc. derives substantial revenue from the sale of pharmaceutical products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Macleods Inc.'s filing of its ANDA (submitted, on information and belief, in concert with Macleods Ltd.) and the causes of action Plaintiffs raise here, as alleged herein.

18. On information and belief, Macleods Inc. has a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536. On information and belief, Macleods Inc. conducts business in New Jersey as a pharmaceutical manufacturer and wholesaler (New Jersey Business Entity ID No. 0101021236). On information and belief, Macleods Inc. is currently licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration No. 5004370).

19. Further, this Court has personal jurisdiction over Macleods Inc. because Macleods Inc. has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Macleods Inc. intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Macleods Inc., either directly or

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