

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS)
IRELAND CO., LTD., and ASTELLAS)
PHARMA GLOBAL DEVELOPMENT,)
INC.,)

Plaintiffs,)

v.)

C.A. No. _____

SAWAI PHARMACEUTICAL CO., LTD.)
and SAWAI USA, INC.,)

Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, “Plaintiffs”), by their undersigned attorneys, for their Complaint against Defendants Sawai Pharmaceutical Co., Ltd. and Sawai USA, Inc. (collectively “Sawai”), hereby allege as follows:

THE PARTIES

1. Plaintiff Astellas Pharma Inc. is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. Astellas Pharma Inc. was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

2. Plaintiff Astellas Ireland Co., Ltd. (“AICL”) is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff Astellas Pharma Inc.

3. Plaintiff Astellas Pharma Global Development, Inc. (“APGD”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. APGD is a subsidiary of Plaintiff Astellas Pharma Inc.

4. On information and belief, Defendant Sawai USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business in Irvine, California. On information and belief, Sawai USA, Inc., by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

5. On information and belief, Defendant Sawai Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business in Osaka, Japan. On information and belief, Sawai Pharmaceutical Co., Ltd., by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

6. On information and belief, Sawai USA, Inc. is a wholly-owned subsidiary of Sawai Pharmaceutical Co., Ltd.

7. On information and belief, Defendants Sawai Pharmaceutical Co., Ltd. and Sawai USA, Inc. have cooperated and assisted in the preparation and filing of Sawai’s Abbreviated New Drug Application (“ANDA”) No. 209446 and will be involved in the manufacture, importation, marketing and sale of the drug that is the subject of ANDA No. 209446 if it is approved.

NATURE OF ACTION

8. This is an action for patent infringement of United States Patent Nos. 6,346,532 (“the ’532 patent”), 7,342,117 (“the ’117 patent”), 7,982,049 (“the ’049 patent”), 8,835,474 (“the ’474 patent”), and RE44,872 (“the ’872 patent”), arising under the United States patent laws, Title 35, United States Code. This action relates to Sawai’s filing of ANDA No. 209446 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration (“FDA”) approval to market generic pharmaceutical products.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. This Court has personal jurisdiction over each Defendant for purposes of this civil action.

11. This Court has jurisdiction over Sawai Pharmaceutical Co., Ltd. On information and belief, Sawai Pharmaceutical Co., Ltd. is the parent corporation of Sawai USA, Inc.

12. This Court has jurisdiction over Sawai USA, Inc. On information and belief, Sawai USA, Inc. is a Delaware company.

13. On information and belief, Sawai, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this Judicial District. On information and belief, Sawai has purposefully conducted and continues to conduct business in Delaware, and Delaware is a likely destination of Sawai’s generic drug products. On information and

belief, Sawai has purposefully availed itself of the rights and benefits of the laws of the State of Delaware, having engaged in systematic and continuous contacts with the State of Delaware.

14. On information and belief, Sawai USA, Inc. and Sawai Pharmaceuticals Co., Ltd. are agents of each other with respect to the development, regulatory approval, marketing, sale and/or distribution of generic drug products. On information and belief, the acts of Sawai USA, Inc. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of Sawai Pharmaceuticals Co., Ltd.

15. On information and belief, Sawai USA, Inc. filed an abbreviated new drug application seeking approval from the FDA to market and sell pharmaceutical products containing the compound mirabegron as active ingredient, for the treatment of overactive bladder, prior to the expiration of each of the '532, '117, '049, '474, and '872 patents.

16. This lawsuit arises in part from Sawai USA, Inc. sending Plaintiffs, one of which is a Delaware corporate entity, a letter dated September 12, 2016 purporting to be a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act) and 21 C.F.R. § 314.95" ("Notice Letter").

17. When the Notice Letter was sent, Sawai knew or should have known that: (i) APGD is a Delaware corporation; and (ii) Plaintiffs would file suit against Sawai within 45 days of receiving the Notice Letter.

18. Alternatively, assuming that the above facts do not establish personal jurisdiction over Sawai Pharmaceuticals Co., Ltd., this Court may exercise jurisdiction over Sawai Pharmaceuticals Co., Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Sawai Pharmaceuticals Co., Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sawai

Pharmaceuticals Co., Ltd. has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Sawai Pharmaceuticals Co., Ltd. satisfies due process

19. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

A. The '532 Patent

20. The United States Patent and Trademark Office ("PTO") duly and legally issued the '532 patent, entitled "Amide Derivatives or Salts Thereof," on February 12, 2002. On February 24, 2015, after an ex parte reexamination proceeding, the PTO duly and legally issued a reexamination certificate confirming the validity and patentability of the '532 patent. A true and correct copy of the '532 patent is attached as Exhibit A.

21. The '532 patent claims, *inter alia*, the compound mirabegron and compositions containing mirabegron.

22. The '532 patent also claims, *inter alia*, a pharmaceutical composition containing mirabegron as an active ingredient.

23. The Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the expiration date of the '532 patent as March 27, 2022.

B. The '117 Patent

24. The PTO duly and legally issued the '117 patent, entitled " α -Form or β -Form Crystal of Acetanilide Derivative," on March 11, 2008. A true and correct copy of the '117 patent is attached as Exhibit B.

25. The '117 patent claims, *inter alia*, crystal forms of mirabegron.

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