IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEIJIN LIMITED, TEIJIN PHARMA LIMITED, and TAKEDA PHARMACEUTICALS U.S.A., INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MACLEODS PHARMACEUTICALS LTD., and MACLEODS PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Teijin Limited ("Teijin Ltd."), together with its subsidiary Teijin Pharma Limited ("Teijin Pharma Ltd.") (collectively, "Teijin"), and Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") (collectively, "Plaintiffs"), for their Complaint against Defendants Macleods Pharmaceuticals Ltd. ("Macleods Pharmaceuticals") and Macleods Pharma USA, Inc. ("Macleods USA") (collectively "Macleods" or "Defendants"), hereby allege as follows:

PARTIES

1. Plaintiff Teijin Ltd. is a Japanese corporation, having a principal place of business at 6-7, Minami-Hommachi 1-chome, Chuo-ku, Osaka 541-8587, Japan.

2. Plaintiff Teijin Pharma Ltd. is a Japanese corporation, having its principal place of business at 2-1, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo 100-8585, Japan.

3. Plaintiff Takeda is a Delaware corporation, having its principal place of business at 1 Takeda Parkway, Deerfield, Illinois 60015.

4. Upon information and belief, Macleods Pharmaceuticals is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059. Furthermore, upon

information and belief, Macleods Pharmaceuticals, either directly or through an agent acting at its direction, is in the business of, *inter alia*, developing, manufacturing, and packaging active pharmaceutical ingredients and pharmaceutical products for sale in the United States market.

5. Upon information and belief, Macleods USA is the United States division of Macleods Pharmaceuticals. Furthermore, on information and belief, Macleods USA is a corporation organized under the laws of the State of Delaware, having its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

NATURE OF THE ACTION

6. This is a civil action for infringement of U.S. Patent No. 7,361,676 ("the '676 patent" or "patent-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Macleods Pharmaceuticals by virtue of, *inter alia*, the fact that Macleods Pharmaceuticals has committed, or aided, abetted, contributed to, or participated in the commission of, the tortious act of patent infringement under 35 U.S.C. § 271(e)(2), which has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Plaintiff Takeda, a Delaware corporation.

9. Upon information and belief, Macleods Pharmaceuticals has submitted, either directly or through an agent acting at its direction, over sixty Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA"). In addition, Macleods Pharmaceuticals has submitted, either directly or through an agent acting at its direction, over fifty drug master files ("DMF") to the FDA, providing information about

Macleods' manufacture of various drug substances, including but not limited to Macleods' DMF concerning febuxostat "Form-A."

10. Upon information and belief, Macleods Pharmaceuticals and/or its affiliates or agents will market and sell tablets containing 40 and 80 mg of the active ingredient febuxostat ("Macleods Generic Product") in Delaware, and will derive substantial revenue from these activities, upon final approval of ANDA No. 207293 ("Macleods' ANDA") by the FDA.

11. Upon information and belief, Macleods Pharmaceuticals and/or its affiliates or agents will market, offer for sale, and/or sell Macleods Generic Product upon final approval of Macleods' ANDA by the FDA, with the reasonable expectation or knowledge and intent that such product will ultimately be purchased and used by consumers in this District.

12. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Macleods Pharmaceuticals in this action, this Court may exercise jurisdiction over Macleods Pharmaceuticals pursuant to Fed. R. Civil P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Macleods Pharmaceuticals is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Macleods Pharmaceuticals has sufficient contacts with the United States as a whole, including but not limited to submitting various ANDAs and DMFs to the FDA, and manufacturing and selling active pharmaceutical ingredients that are used in pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Macleods Pharmaceuticals satisfies due process.

13. This Court has personal jurisdiction over Macleods USA because, upon information and belief, Macleods USA is incorporated in the State of Delaware. Furthermore, Macleods USA maintains a registered agent in Delaware, known as "Incorp Services, Inc.,"

which is located at 1201 Orange St., Suite 600, One Commerce Center, Wilmington, Delaware 19899. Furthermore, Macleods USA has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with the State of Delaware.

14. This Court further has personal jurisdiction over Macleods USA by virtue of, *inter alia*, the fact that Macleods USA has committed, or aided, abetted, contributed to, or participated in the commission of, the tortious act of patent infringement under 35 U.S.C. § 271(e)(2), which has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Plaintiff Takeda, a Delaware corporation.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

16. On April 22, 2008, the '676 patent, titled "Solid Preparation Containing Single Crystal Form," was duly and legally issued. A copy of the '676 patent is attached as Exhibit A.

17. Teijin Ltd. is the owner of the '676 patent. Teijin Pharma Ltd. and Takeda hold exclusive licenses with respect to the '676 patent.

ACTS GIVING RISE TO THIS ACTION

18. Takeda holds New Drug Application ("NDA") No. 21-856 for oral tablets containing 40 or 80 mg of the active ingredient febuxostat. Takeda markets and sells these tablets in the United States under the brand name "Uloric®."

19. Pursuant to 21 U.S.C. § 355(b)(1), the '676 patent is listed in the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Uloric® or its use.

20. Upon information and belief, Macleods submitted ANDA No. 207293 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Macleods' ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of the Macleods Generic Product prior to the expiration of the '676 patent.

21. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Macleods certified in ANDA No. 207293 that the claims of the '676 patent will not be infringed by the commercial manufacture, use, or sale of the Macleods Generic Product, and/or the claims of the '676 patent are invalid.

22. Plaintiffs received written notification of Macleods' ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter ("Macleods' Notice Letter"), dated April 21, 2015 and sent via Federal Express.

23. Macleods' Notice Letter does not refer to a certification with respect to U.S. Patent No. 5,614,520 ("the '520 patent"), and does not provide any detailed statement with regard to the '520 patent. Accordingly, upon information and belief, Macleods' ANDA No. 207293 contains a "Paragraph III" certification with respect to the '520 patent pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(III). The expiration date of the '520 patent is March 25, 2019.

24. Macleods' Notice Letter does not refer to a certification with respect to U.S. Patent No. 6,225,474 ("the '474 patent"), and does not provide any detailed statement with regard to the '474 patent. Accordingly, upon information and belief, Macleods' ANDA No. 207293 contains a "Paragraph III" certification with respect to the '474 patent pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(III). The expiration date of the '474 patent is June 18, 2019.

25. Macleods' Notice Letter does not refer to a certification with respect to U.S. Patent No. 8,372,872 ("the '872 patent"), and does not provide any detailed statement with regard to the '872 patent. Accordingly, upon information and belief, Macleods' ANDA No. 207293 contains a "Paragraph III" certification with respect to the '872 patent pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(III). The expiration date of the '872 patent is September 8, 2031.

26. Macleods' Notice Letter does not deny that the Macleods Generic Product contains febuxostat in the form of polymorph A.

27. Macleods' Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain Macleods confidential information regarding the Macleods Generic Product. Plaintiffs executed Macleods' OCA, in the form provided with Macleods' Notice Letter, and subsequently received access to limited excerpts of Macleods' ANDA on May 19, 2015.

28. The limited information relating to the Macleods Generic Product that has been provided by Macleods to Plaintiffs to date does not demonstrate that the Macleods Generic Product does not and will not fall within the scope of any issued claim of the '676 patent.

INFRINGEMENT OF U.S. PATENT NO. 7,361,676

29. Plaintiffs re-allege paragraphs 1-28 as if fully set forth herein.

30. Upon information and belief, Macleods' submission of ANDA No. 207293 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '676 patent under 35 U.S.C. § 271(e)(2)(A).

31. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Macleods Generic Product, if approved by the FDA prior to the expiration of the '676 patent, including any applicable exclusivities or extensions, would infringe the '676 patent under 35 U.S.C. § 271(a), (b), and/or (c).

32. Upon information and belief, Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Macleods' ANDA No. 207293 be a date that is not earlier than the expiration of the term of the '676 patent, including any extension granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '676 patent to which Plaintiffs are or become entitled.

33. 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.

34. Upon information and belief, Defendants were aware of the existence of the '676 patent, and were also aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '676 patent constituted an act of infringement of the '676 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '676 patent;

B. That pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 207293 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration of the '676 patent, including any applicable exclusivities or extensions;

C. That Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, or importing into the United States the Macleods Generic Product and any other product that infringes or induces or

contributes to the infringement of one or more claims of the '676 patent prior to its expiration, including any exclusivities or extensions;

D. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action; and

E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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