IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD. and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	C.A. No. _____
Plaintiffs,	)	
v.	)	
APOTEX INC. and APOTEX CORP.	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc. (collectively, "Astellas" or "Plaintiffs"), by their undersigned attorneys, hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement of United States Patent No. 10,842,780 ("the '780 Patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to the Abbreviated New Drug Application ("ANDA") submitted by the above-named Defendants under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration ("FDA") approval to market a generic pharmaceutical product.

THE PARTIES

A. Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc.

2. Plaintiff Astellas Pharma Inc. ("API") 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. API was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

3. 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 API.

4. 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 API.

B. Apotex Inc. and Apotex Corp. (collectively, "Apotex")

5. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. On information and belief, Apotex Inc. is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

6. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

7. By a letter dated June 22, 2021, ("Apotex's Notice Letter") Apotex notified Plaintiffs that Apotex had submitted to FDA ANDA No. 209434 for mirabegron extended-release tablets, 25 mg and 50 mg ("Apotex ANDA"), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25mg and 50mg strengths ("Apotex's ANDA Product"). On information and belief, the purpose of Apotex's submission of the Apotex ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's ANDA Product prior to the expiration of the '780 Patent.

8. In Apotex's Notice Letter, Apotex notified Plaintiffs that, as a part of the Apotex ANDA, Apotex had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '780 Patent, asserting it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Apotex's ANDA Product.

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 Apotex because, among other things, Apotex has committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in filing the Apotex ANDA that has led to foreseeable harm and injury to Plaintiffs, and will imminently commit, or aid, abet, contribute to, or participate in the commission of, a tortious act of patent infringement by selling Apotex's ANDA Product which will lead to foreseeable harm and injury to Plaintiffs.

11. This Court also has personal jurisdiction over Apotex because its affiliations with the State of Delaware, including by virtue of Apotex Corp.'s incorporation in Delaware, are so continuous and systematic as to render Apotex essentially at home in this forum.

12. This Court also has personal jurisdiction over Apotex Inc. pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Astellas's claims arise under federal law; (b) as a foreign defendant, Apotex Inc. is not subject to jurisdiction in any state's courts of general jurisdiction; and (c) Apotex Inc. has sufficient contacts within the United States as a whole, including but not limited to preparing and submitting an ANDA to FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

13. This Court also has personal jurisdiction over Apotex because it has frequently availed itself of the legal protections of the State of Delaware by, among other things, Apotex Corp. selecting the State of Delaware as its place of incorporation, and by Apotex admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Bial Portela & CA SA et al. v. Apotex Inc. et al.*, C.A. No. 21-00187 (D. Del.), D.I. 6; *Intercept Pharm., Inc. et al. v. Apotex Inc. et al.*, C.A. No. 20-1105 (D. Del.), D.I. 10.

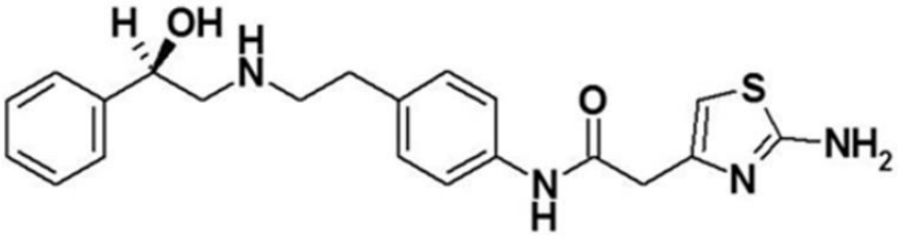
14. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Apotex.

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) and/or Fed. R. Civ. P. 4(k)(2).

MYRBETRIQ® TABLETS

16. APGD holds approved New Drug Application ("NDA") No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron. FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets.

17. Mirabegron has been referred to chemically as, *inter alia*, (R)-2-(2-aminothiazol-4-yl)-4'-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, and 2-(2-aminothiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide. Mirabegron can be depicted as, *inter alia*, the following formula:



18. Myrbetriq® extended-release tablets, containing 25 mg or 50 mg of mirabegron ("Myrbetriq® Tablets"), are indicated for the treatment of overactive bladder ("OAB") with symptoms of urge urinary incontinence, urgency, and urinary frequency.

19. Myrbetriq® Tablets comprise a sustained release hydrogel-forming formulation containing, *inter alia*, polyethylene oxide and polyethylene glycol as inactive ingredients within the tablet formulation, which function as a means for forming a hydrogel and a means for ensuring penetration of water into the tablets.

20. For quality control purposes in the U.S. market, Myrbetriq® Tablets are subjected to dissolution testing using the United States Pharmacopeia ("USP") Apparatus I. A dissolution test evaluates the rate and extent that a compound forms a solution under carefully controlled conditions. Within the context of regulatory approval, the USP dissolution test helps safeguard against the release of drug products that do not perform acceptably. USP Apparatus I (basket) and II (paddle) provide a platform to evaluate the *in vitro* performance of dosage forms using

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