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.	)	
SANDOZ INC., ACTAVIS ELIZABETH LLC, ACTAVIS LLC, TEVA PHARMACEUTICALS USA, INC., APOTEX INC., APOTEX CORP., AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, SAWAI PHARMACEUTICAL CO., LTD., SAWAI USA, INC., PRINSTON PHARMACEUTICAL INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US INC., SOLCO HEALTHCARE US, LLC, WINDLAS HEALTHCARE, PVT. LTD.,WINDLAS BIOTECH LTD., ZYDUS PHARMACEUTICALS (USA), INC., CADILA HEALTHCARE LTD. (d/b/a ZYDUS CADILA), LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.	)	
Defendants.	)	

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:

THE PARTIES

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

1. 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.

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 API.

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 API.

B. Sandoz Inc. ("Sandoz")

4. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 College Road West, Princeton, NJ 08540. On information and belief, Sandoz 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.

5. By a letter dated September 9, 2016 ("Sandoz's Notice Letter"), Sandoz notified Plaintiffs that Sandoz had submitted to the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 209441 for mirabegron extended-release tablets, 25 mg and 50 mg ("Sandoz ANDA"), a drug product that is a generic version of

Myrbetriq® extended-release tablets, in the 25mg and 50mg strengths ("Sandoz's ANDA Product"). On information and belief, the purpose of Sandoz's submission of the Sandoz ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA Product prior to November 4, 2023.

6. In Sandoz's Notice Letter, Sandoz notified Plaintiffs that, as a part of the Sandoz ANDA, Sandoz 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 some of the then-listed patents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"), asserting that they are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Sandoz's ANDA Product.

7. On the basis of Sandoz's Notice Letter, Plaintiffs filed suit against Sandoz for infringement of some of the then-listed patents in the Orange Book. *Astellas Pharma Inc. et al. v. Sandoz Inc.*, C.A. No. 16-952 (D. Del.), D.I. 1.

8. In its Answer, Sandoz did not dispute at least subject matter jurisdiction under 35 U.S.C. § 271(e)(2)(A), personal jurisdiction or venue. *Astellas Pharma Inc. et al. v. Sandoz Inc.*, C.A. No. 16-952 (D. Del.), D.I. 12 at ¶¶ 7-8, 13.

9. Astellas and Sandoz reached a settlement and the case was dismissed. *Astellas Pharma Inc. et al. v. Actavis Elizabeth LLC et al.*, C.A. No. 16-905-JFB-CJB (Cons.) (D. Del.), D.I. 604.

C. Actavis Elizabeth LLC, Actavis LLC and Teva Pharmaceuticals USA, Inc. (collectively, "Actavis")

10. On information and belief, Defendant Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of

business at 200 Elmora Avenue, Elizabeth, New Jersey, 07202. On information and belief, Actavis Elizabeth LLC 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.

11. On information and belief, Defendant Actavis LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at Morris Corporate Center Ill, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis LLC 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.

12. On information and belief, Defendant Teva Pharmaceuticals USA Inc. ("Teva") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva 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.

13. On information and belief, on or about August 2, 2016, Teva acquired Actavis's Generics business, including Actavis Elizabeth LLC and Actavis LLC.

14. On information and belief, Actavis Elizabeth LLC is a wholly owned subsidiary of Actavis LLC, which is a wholly owned subsidiary of Teva.

15. By a letter dated August 24, 2016, ("Actavis's Notice Letter") Actavis notified Plaintiffs that Actavis had submitted to the FDA ANDA No. 209368 for Mirabegron Extended-Release Tablets, 25 mg and 50 mg ("Actavis ANDA"), a drug product that is a generic version of

Myrbetriq® extended-release tablets, in the 25mg and 50mg strengths ("Actavis's ANDA Product"). On information and belief, the purpose of Actavis's submission of the Actavis ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis's ANDA Product prior to November 4, 2023.

16. In Actavis's Notice Letter, Actavis notified Plaintiffs that, as a part of the Actavis ANDA, Actavis 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 some of the then-listed patents in the Orange Book, asserting that they are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Actavis's ANDA Product.

17. On the basis of Actavis's Notice Letter, Plaintiffs filed suit against Actavis for infringement of some of the then-listed patents in the Orange Book. *Astellas Pharma Inc. et al. v. Actavis Elizabeth LLC. et al.*, C.A. No. 16-905 (D. Del.), D.I. 1.

18. In its Answer, Actavis did not dispute jurisdiction or venue. *Astellas Pharma Inc. et al. v. Actavis Elizabeth LLC. et al.*, C.A. No. 16-905 (D. Del.), D.I. 16 at ¶¶ 11-12, 14-16, 21.

19. Astellas and Actavis reached a settlement and the case was dismissed. *Astellas Pharma Inc. et al. v. Actavis Elizabeth LLC et al.*, C.A. No. 16-905-JFB-CJB (Cons.) (D. Del.), D.I. 11, 28, 587.

20. On information and belief, and consistent with their past practices, Actavis Elizabeth LLC and Actavis LLC acted collaboratively in the preparation and submission of ANDA No. 209368.

21. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 209368, Actavis Elizabeth LLC, Actavis LLC and Teva will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that

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