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.	)	
AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, ACTAVIS ELIZABETH LLC, ACTAVIS LLC, TEVA PHARMACEUTICALS USA, INC., 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:

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 Applications ("ANDAs") 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 generic pharmaceutical products.

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. Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC (collectively, "Aurobindo")

5. On information and belief, Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India. On information and belief, Aurobindo Pharma Ltd. 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 Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. On information and belief, Aurobindo Pharma USA, 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.

7. On information and belief, Defendant Aurolife Pharma LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 2400 Route 130 North, Dayton, New Jersey 08810. On information and belief, Aurolife Pharma 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.

8. By a letter dated March 9, 2021, ("Aurobindo's Notice Letter") Aurobindo notified Plaintiffs that Aurobindo had submitted to FDA ANDA No. 209413 for 50 mg mirabegron extended-release tablets ("Aurobindo ANDA"), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 50 mg strength ("Aurobindo's ANDA Product"). On information and belief, the purpose of Aurobindo's submission of the Aurobindo ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo's ANDA Product prior to the expiration of the '780 Patent.

9. In Aurobindo's Notice Letter, Aurobindo notified Plaintiffs that, as a part of the Aurobindo ANDA, Aurobindo 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 Aurobindo's ANDA Product.

10. On information and belief, and consistent with their past practices, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC acted collaboratively in the preparation and submission of ANDA No. 209413.

11. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 209413, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 209413 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

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

12. 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.

13. 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.

14. 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 400 Interpace Parkway, Parsippany, New Jersey 07054. 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.

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

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

17. By a letter dated March 16, 2021 ("Actavis's Notice Letter"), Actavis notified Plaintiffs that Actavis had submitted to 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 25 mg and 50 mg 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 the expiration of the '780 Patent.

18. 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 the '780 Patent, asserting that it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Actavis's ANDA Product.

19. 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.

20. 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

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