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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, and MITSUI SUGAR CO., LTD.<br><br>Plaintiffs,<br><br>v.<br><br>AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,<br><br>Defendants. | : | Civil Action No. _____<br><br>Document Filed Electronically |

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**PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo"), hereby allege as follows:

## Nature Of The Action

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to Abbreviated New Drug Application ("ANDA") No. 207983 filed by Aurobindo Pharma Ltd. with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of Fingolimod 0.5 mg capsules, a generic version of Novartis's GILENYA® Capsules, 0.5 mg, prior to expiration of U.S. Patent No. 5,604,229 ("the '229 patent").

## PARTIES

2. Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

3. Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

4. Mitsubishi Tanabe Pharma Corporation ("MTPC") is a corporation organized and existing under the laws of Japan, having an office and place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan.

5. Mitsui Sugar Co., Ltd. ("Mitsui") is a corporation organized and existing under the laws of Japan, having an office and place of business at 36-2, Nihonbashi-Hakozakicho, Chuo-ku, Tokyo, Japan.

6. Upon information and belief, Aurobindo Pharma Ltd. is a company organized and existing under the laws of India, having a registered office at Plot No. 2 Maitrivihar, Ameerpet, Hyderabad 500038, India and a principal place of business at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hitech City, Hyderabad 50084, Telangana, India.

7. Upon information and belief, Aurobindo Pharma Ltd. itself, and through its wholly-owned subsidiary and agent, Aurobindo Pharma USA, Inc., develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

8. Upon information and belief, Aurobindo Pharma USA, Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

9. Upon information and belief, Aurobindo Pharma USA, Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Ltd. and is controlled and/or dominated by Aurobindo Pharma Ltd. Upon information and belief, Aurobindo Pharma USA, Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Aurobindo Pharma Ltd.

10. Upon information and belief, Aurobindo Pharma Ltd. established Aurobindo Pharma USA, Inc. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

11. Upon information and belief, Aurobindo Pharma Ltd. operates in the United States through Aurobindo Pharma USA, Inc.

12. Upon information and belief, and consistent with their past practices, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. acted collaboratively in the preparation and submission of ANDA No. 207983.

13. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207983, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. 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. 207983 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

14. NPC and Novartis AG are collectively referred to hereafter as "Novartis."

## JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

16. This Court has personal jurisdiction over Aurobindo Pharma Ltd. because, among other things, it has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 207983 that has led to foreseeable harm and injury to NPC, a corporation with a principal place of business in New Jersey.

17. This Court also has personal jurisdiction over Aurobindo Pharma Ltd. because, on information and belief, Aurobindo Pharma Ltd. develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district, through various directly or indirectly owned operating subsidiaries, including its wholly owned subsidiary Aurobindo Pharma USA, Inc. Moreover, on information and belief, upon receiving FDA approval, Aurobindo Pharma Ltd. intends to market and sell the proposed generic products at issue in this litigation in this judicial district.

18. This Court also has personal jurisdiction over Aurobindo Pharma Ltd. because, upon information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. work in concert for purposes of developing, formulating, manufacturing, marketing and selling its generic drug products throughout the United States, including New Jersey, and New Jersey is a likely destination of Aurobindo Pharma Ltd.'s generic products. Moreover, on information and belief, Aurobindo Pharma Ltd. has purposely availed itself of the rights and benefits of the laws of the State of New Jersey, by, among other things, selecting the State of New Jersey as the principal place of business for Aurobindo Pharma USA, Inc. and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey. *See e.g., Takeda Pharmaceutical Co. Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 15-cv-07635 (MLC)(TJB) (D.N.J.); *Shionogi & Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 15-cv-00319 (MAS)(LHG) (D.N.J.).

19. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because Aurobindo Pharma USA, Inc., as a company with its principal place of business in New Jersey, has purposely availed itself of the rights and benefits of the laws of the State of New Jersey. Moreover, on information and belief, Aurobindo Pharma USA, Inc. has engaged in systematic

and continuous contacts with the State of New Jersey and has previously admitted jurisdiction and asserted counterclaims in lawsuits filed in the United States District Court for the District of New Jersey. *See e.g., Takeda Pharmaceutical Co. Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 15-cv-07635 (MLC)(TJB) (D.N.J.); *Shionogi & Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 15-cv-00319 (MAS)(LHG) (D.N.J.).

20. Upon information and belief, Aurobindo Pharma USA, Inc. is in the business of, among other things, formulating, developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the U.S. market, including in this judicial district. This Court also has jurisdiction over Aurobindo Pharma USA, Inc. because, on information and belief, upon receiving FDA approval, Aurobindo Pharma USA, Inc. intends to market and sell the proposed generic products at issue in this litigation in this judicial district.

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

## THE PATENT-IN-SUIT AND GILENYA®

22. On February 18, 1997, the U.S. Patent and Trademark Office duly and legally issued the ’229 patent, entitled “2-Amino-1,3-Propanediol Compound and Immunosuppressant.” A true and correct copy of the ’229 patent is attached hereto as Exhibit A. The claims of the ’229 patent are valid and enforceable. The ’229 patent is owned by Mitsui and MTPC and exclusively licensed to Novartis. Plaintiffs have the right to sue for and obtain equitable relief and damages for infringement of the ’229 patent.

23. NPC is the holder of New Drug Application (“NDA”) No. 022527 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of GILENYA® (fingolimod) Capsules, 0.5 mg. GILENYA® is the first in a new class of

compounds known as sphingosine 1-phosphate receptor (S1PR) modulators. GILENYA® is indicated to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability in patients with relapsing forms of multiple sclerosis. GILENYA® is the first oral drug that has been approved by the FDA for such an indication.

24. GILENYA® and the use of GILENYA® is covered by one or more claims of the '229 patent.

25. The FDA's official publication of approved drugs (the "Orange Book") lists the '229 patent in connection with GILENYA®.

**ACTS GIVING RISE TO THIS ACTION**

26. Plaintiffs incorporate each of the preceding paragraphs 1 - 25 as if fully set forth herein.

27. By letters dated December 8, 2016, ("the Notice Letters"), Aurobindo Pharma Ltd. notified Plaintiffs that Aurobindo Pharma Ltd. had submitted to the FDA ANDA No. 207983 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Aurobindo's ANDA Product"). The purpose of Aurobindo's submission of the 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 Aurobindo's ANDA Product prior to the expiration of the '229 patent.

28. In the Notice Letters, Aurobindo Pharma Ltd. notified Plaintiffs that, as a part of its 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 '229 patent asserting that the '229 is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Aurobindo's ANDA Product.

29. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Notice Letters.

**COUNT 1**
**INFRINGEMENT OF U.S. PATENT NO. 5,604,229**

30. Plaintiffs incorporate each of the preceding paragraphs 1 - 29 as if fully set forth herein.

31. By filing ANDA No. 207983, Aurobindo has necessarily represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and strength as GILENYA®, and will be bioequivalent to GILENYA®.

32. Aurobindo's submission of ANDA No. 207983 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Aurobindo's ANDA Product, prior to the expiration of the '229 patent constitutes infringement of one or more of the claims of the '229 patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, Aurobindo had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 207983 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '229 patent.

34. Upon information and belief, Aurobindo intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Aurobindo's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207983.

35. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '229 patent.

36. Upon information and belief, use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '229 patent.

37. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '229 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

38. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product is especially made or adapted for use in infringing the '229 patent, and that Aurobindo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to the infringement of the '229 patent immediately and imminently upon approval of ANDA No. 207983.

39. The foregoing acts by Aurobindo constitute and/or will constitute infringement of the '229 patent, active inducement of infringement of the '229 patent, and/or contribution to the infringement by others of the '229 patent.

40. Upon information and belief, Aurobindo acted without a reasonable basis for believing that it would not be liable for infringing the '229 patent, active inducement of infringement of the '229 patent, and/or contribution to the infringement by others of the '229 patent.

41. If Aurobindo's infringement of the '229 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

**WHEREFORE**, Plaintiffs pray that this Court grant the following relief:

a. A judgment that one or more claims of the '229 patent is not invalid, is enforceable and is infringed by Aurobindo's submission of ANDA No. 207983, and that

Aurobindo's making, using, offering to sell, or selling in the United States, or importing into the United States of Aurobindo's ANDA Product, will infringe the '229 patent.

b. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 207983 shall be a date which is not earlier than the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

c. An order permanently enjoining Aurobindo, its affiliates, subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Aurobindo's ANDA Product, until after the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

d. Damages or other monetary relief to Plaintiffs if Aurobindo engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Aurobindo's ANDA Product, prior to the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

e. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: January 19, 2017
Newark, New Jersey

Respectfully submitted,

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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is the subject of the following actions:

- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. v. Actavis, Inc. and Actavis Elizabeth LLC*, C.A. No. 1:14-cv-01487-LPS (D. Del.).
- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. v. Actavis, Inc. and Actavis Elizabeth LLC*, C.A. No. 2:14-cv-07849-MCA-JBC (D.N.J.).
- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. v. HEC Pharm Co., Ltd., HEC Pharm Group and HEC Pharm USA Inc.*, C.A. No. 1:15-cv-00151-LPS (D. Del.).
- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. v. Ezra Ventures, LLC*, C.A. No. 1:15-cv-00150-LPS (D. Del.).
- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation and Mitsui Sugar Co. Ltd, v. Ezra Ventures, LLC*, Case No. 4:15-cv-00095-KGB (D. Ark.).
- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. v. HEC Pharm Co., Ltd., HEC Pharm Group, and HEC Pharm USA Inc.*, C.A. No. 2:15-cv-01647-CCC-MF (D.N.J.).

- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. v. Apotex Inc. and Apotex Corp.*, C.A. No. 1:15-cv-00975-LPS (D. Del.).
- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, C.A. No. 1:16-cv-00289-LPS (D. Del.).
- *Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.*, C.A. No. 1:17-cv-00048-LPS (D. Del.).

Dated: January 19, 2017
Newark, New Jersey

Respectfully submitted,

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