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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA INC., Defendants.	Civil Action No. _____ **COMPLAINT** *Filed electronically*

Plaintiff Novartis Pharmaceuticals Corporation ("Novartis"), by its attorneys White & Case LLP, Cravath, Swaine & Moore LLP and Gibbons P.C., for its Complaint against Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. (collectively, "Aurobindo") herein allege:

THE PARTIES

1. Plaintiff Novartis is a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, New Jersey.

2. On information and belief, Aurobindo Pharma Limited ("Aurobindo Ltd.") is an Indian corporation having a principal place of business in Hyderabad, Pradesh, India.

3. On information and belief, Aurobindo Pharma USA Limited ("Aurobindo USA") is a wholly-owned subsidiary, agent and alter-ego of Aurobindo Ltd., organized and existing under the laws of the State of Delaware, and has a principal place of business at 2400 U.S. Highway 130, Dayton, New Jersey.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

5. On information and belief, Aurobindo Ltd. and Aurobindo USA are in the business of making and selling generic drug products.

6. On information and belief, Aurobindo Ltd., directly and/or indirectly through Aurobindo USA, develops and manufactures generic drugs that are marketed, distributed, and sold throughout the United States, including New Jersey.

7. On information and belief, Aurobindo Ltd. and Aurobindo USA conduct business in New Jersey and sell various drug products in the United States, including New Jersey.

8. On information and belief, Aurobindo Ltd. has continuous and systematic contacts with New Jersey, including, but not limited to, ongoing communications and contacts with Aurobindo USA.

9. On information and belief, Aurobindo Ltd. is registered to do business in New Jersey as a foreign profit corporation, with filing number 0100904116.

10. On information and belief, Aurobindo USA is registered to do business in New Jersey as a foreign profit corporation, with filing number 0100921223.

11. On information and belief, Aurobindo Ltd. and Aurobindo USA have been sued in the United States District Court for the District of New Jersey.

12. On information and belief, Aurobindo Ltd. and Aurobindo USA have submitted to the jurisdiction of the United States District Court for the District of New Jersey.

13. Aurobindo Ltd. and Aurobindo USA are subject to personal jurisdiction in this judicial district.

14. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The '802 Patent

15. On December 19, 2000, the United States Patent and Trademark Office (the "PTO") granted United States Patent No. 6,162,802 ("the '802 patent"), entitled "Synergistic Combination Therapy Using Benazepril and Amlodipine for the Treatment of Cardiovascular Disorders and Compositions Therefor." The '802 patent has been assigned to, and continues to

be owned by, Novartis. The '802 patent will expire on December 19, 2017. A copy of the '802 patent is attached hereto as Exhibit A.

16. The '802 patent is directed to and claims, inter alia, a pharmaceutical composition consisting essentially of a range of ratios of specified amounts of benazepril and amlodipine (or pharmaceutically acceptable salts of either or both), as well as a method of treating a condition selected from a group consisting of, inter alia, hypertension, in a human, consisting of administering a daily dose of a range of ratios of specified amounts of benazepril and amlodipine (or pharmaceutically acceptable salts of either or both).

Lotrel®

17. Novartis holds an approved New Drug Application for amlodipine and benazepril hydrochloride combination capsules, in 2.5 mg/10 mg (amlodipine/benazepril hydrochloride), 5 mg/10 mg, 5 mg/20 mg, 10 mg/20 mg, 5 mg/40 mg, and 10 mg/40 mg dosage strengths, which it sells under the brand name Lotrel®.

18. Pursuant to 21 U.S.C. §§ 355(b)(1) and attendant United States Food and Drug Administration ("FDA") regulations, the '802 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lotrel®.

Aurobindo's ANDA

19. On information and belief, Aurobindo submitted Abbreviated New Drug Application ("ANDA") No. 20-2239 to the FDA pursuant to 21 U.S.C. § 355(j) (the "Aurobindo ANDA"), seeking approval to market amlodipine besylate and benazepril hydrochloride capsules (the "Aurobindo Product").

20. On information and belief, the Aurobindo ANDA refers to and relies upon Novartis' NDA for Lotrel® and purports to contain data showing bioequivalence of the Aurobindo Product with Lotrel®.

21. Novartis received from Aurobindo a letter, dated October 20, 2010, and attached memorandum (collectively, the "Aurobindo Notification"), stating that Aurobindo had filed the Aurobindo ANDA seeking approval to market the Aurobindo Product in 2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg, 5 mg/40 mg, 10 mg/20 mg, and 10 mg/40 mg dosage strengths.

22. By the Aurobindo Notification, Aurobindo states that, pursuant to 21 U.S.C § 355(j)(2)(A)(vii)(IV), the Aurobindo ANDA certifies that the '802 patent will not be infringed by the manufacture, use, sale, or offer of sale of the Aurobindo Product.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,162,802

23. Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-22 of this Complaint.

24. Aurobindo has infringed, induced the infringement, and contributed to the infringement of the '802 patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 20-2239, which includes a Paragraph IV Certification as to the '802 patent and which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Aurobindo Product for the treatment of hypertension prior to the expiration of the '802 patent.

25. Novartis will be irreparably harmed if Aurobindo is not enjoined from infringing the '802 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Novartis Pharmaceuticals Corporation prays for a judgment in its favor and against Defendants Aurobindo Ltd. and Aurobindo USA, jointly and severally, as follows:

A. Entering judgment for Plaintiff on its Count for Infringement of U.S. Patent No. 6,162,802.

B. Entering judgment permanently enjoining Aurobindo from making, using, selling, offering to sell, or importing the Aurobindo Product described in ANDA No. 20-2239 or active ingredients for use in a method which would infringe the '802 patent until after the expiration of the '802 patent and until after the expiration of any additional exclusivity period provided under the Federal Food, Drug & Cosmetic Act.

C. Awarding Plaintiff such other relief as the Court deems just and proper.

Dated: December 3, 2010
Newark, New Jersey

Respectfully submitted,

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