UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Northern Division)

NOVARTIS CORPORATION 180 Park Avenue Florham Park, NJ NOVARTIS PHARMACEUTICALS CORPORATION One Health Plaza East Hanover, NJ and NOVARTIS INTERNATIONAL AG Lichtstrasse 35 CH-4056 Basel, Switzerland, Plaintiffs, v. LUPIN LTD. Laxmi Towers, "B" Wing, 5th Floor Bandra Kurla Complex Mumbai, 400 051 India and LUPIN PHARMACEUTICALS, INC. Harborplace Tower 111 South Calvert Street Baltimore, MD 21202, Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG (collectively, "Novartis"), by their attorneys White & Case LLP and Hogan & Hartson LLP, for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), herein allege:

THE PARTIES

1. Plaintiff Novartis Corporation is a New York corporation having a principal place of business at 180 Park Avenue, Florham Park, New Jersey.

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

3. Plaintiff Novartis International AG is a Swiss corporation having a principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. On information and belief, Lupin Ltd. is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Mumbai, 400 051, India.

5. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary, agent, and alter-ego of Lupin Ltd, organized and existing under the laws of the State of Virginia, and has a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

JURISDICTION AND VENUE

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

7. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. are in the business of making and selling generic drug products.

8. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. conduct business in Maryland and sell various drug products in the United States, including the State of Maryland.

9. On information and belief, Lupin Ltd. manufactures generic drugs for sale and use throughout the United States, including the State of Maryland, alone and/or through its wholly-owned subsidiary, agent, and alter-ego Lupin Pharmaceuticals, Inc.

10. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. have in the past been sued in the United States District Court for the District of Maryland.

11. Upon information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in Maryland, with Maryland Department of Assessments and Taxation business identification number F07655434.

12. Upon information and belief, Lupin Pharmaceuticals, Inc. has appointed Vinita Gupta, Lupin Pharmaceuticals, Inc., Harborplace Tower, 21st Floor, 111 South Calvert Street, Baltimore, Maryland 21202 as its resident agent for the receipt of service of process.

13. Lupin Ltd. and Lupin Pharmaceuticals, Inc. are subject to personal jurisdiction in this 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") duly and lawfully issued 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 Corporation. The '802 patent will expire on December 19, 2017. A copy of the '802 patent is attached hereto as Exhibit A.

16. Novartis Corporation exclusively licensed the '802 patent to Novartis International AG, which in turn exclusively licensed the '802 patent to Novartis Pharmaceuticals Corporation.

17. 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®

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

19. 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®.

Lupin's ANDA and Amendment

20. On information and belief, Lupin submitted Abbreviated New Drug Application ("ANDA") No. 78-466 to the FDA pursuant to 21 U.S.C. § 355(j) (the "Lupin

ANDA"), and subsequently an amendment thereto (the "Lupin Amendment"), seeking approval to market amlodipine besylate and benazepril hydrochloride capsules (the "Lupin Product"). On information and belief, Lupin Ltd. designated Lupin Pharmaceuticals, Inc. as its United States agent in connection with the Lupin ANDA and the Lupin Amendment.

21. On information and belief, the Lupin ANDA and the Lupin Amendment refer to and rely upon Novartis' NDA for Lotrel® and purport to contain data showing bioequivalence of the Lupin Product with Lotrel®.

22. Novartis received from Lupin a letter, dated October 30, 2006, and attached memorandum (collectively, the "First Lupin Notification"), stating that Lupin filed the Lupin ANDA seeking approval to market the Lupin Product in 2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg, and 10 mg/20 mg dosage strengths.

23. Novartis received from Lupin a letter, dated November 29, 2006, and attached memorandum (collectively, the "Second Lupin Notification"), stating that Lupin filed the Lupin Amendment seeking approval to market the Lupin Product in 5 mg/40 mg and 10 mg/40 mg dosage strengths.

24. By the First Lupin Notification and the Second Lupin Notification, Lupin states that, pursuant to section 21 U.S.C § 355(j)(2)(A)(vii)(IV), the Lupin ANDA and the Lupin Amendment certify that the '802 patent is invalid and/or will not be infringed by the manufacture, use, offer of sale, or sale of the Lupin Product.

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

25. Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-24 of this Complaint.

26. Lupin 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. 78-466, and the Lupin Amendment, which each include a Paragraph IV Certification as to the '802 patent and which seek approval from the FDA to engage in the commercial manufacture, use, or sale of the Lupin Product prior to the expiration of the '802 patent.

27. On information and belief, Lupin has knowingly and willfully infringed the '802 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG pray for judgment in their favor and against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., jointly and severally, as follows:

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

B. Entering judgment permanently enjoining Lupin from making, using, offering to sell, selling, or importing the Lupin Product described in ANDA No. 78-466 and the Lupin Amendment 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 21 U.S.C. § 355(a).

C. Determining that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs their reasonable attorneys' fees, costs and expenses.

D. Awarding Plaintiffs such other relief as the Court deems just and proper.

Dated: December 14, 2006

Respectfully submitted,

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