

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, Dr. Reddy's Laboratories, Inc. is organized and existing under the laws of the State of New Jersey, having a principal place of business at 200 Somerset Corporate Blvd., 7th Floor, Bridgewater, New Jersey 08807.
5. On information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India and having a principal place of business in Hyderabad, India.

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, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are in the business of making and selling generic drug products.
8. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. conduct business in New Jersey and sell various drug products in the United States, including the State of New Jersey.

9. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have sued and been sued in the United States District Court for the District of New Jersey.

10. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have submitted to the jurisdiction of the United States District Court for the District of New Jersey.

11. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are subject to personal jurisdiction in this judicial district.

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

The '802 Patent

13. On December 19, 2000, the United States Patent and Trademark Office (the "PTO") 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.

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

15. 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[®]

16. 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[®].

17. 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[®].

Dr. Reddy’s ANDA

18. On information and belief, Reddy submitted Abbreviated New Drug Application (“ANDA”) No. 77-183 to the FDA pursuant to 21 U.S.C. § 355(j) (the “Reddy ANDA”), seeking approval to market amlodipine besylate and benazepril hydrochloride capsules (the “Reddy Products”).

19. On information and belief, the Reddy ANDA refers to and relies upon Novartis Pharmaceutical Corporation’s NDA for Lotrel[®] and purports to contain data showing bioequivalence of the Reddy Products with Lotrel[®].

20. Novartis received from Reddy a letter, dated May 30, 2007, and attached memorandum (collectively, the “Reddy Notification”), stating that Reddy filed the Reddy

ANDA seeking approval to market the Reddy Products in 2.5 mg base/10 mg, 5 mg base/10 mg, 5 mg base/20 mg, and 10 mg base/20 mg dosage strengths.

21. By the Reddy Notification, Reddy states that, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), the Reddy ANDA certifies that the '802 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer to sell, sale, or importation into the United States of the Reddy Products.

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

22. Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-21 of this Complaint.

23. Reddy 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. 77-183, 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, or sale of the Reddy Products prior to the expiration of the '802 patent.

24. Upon information and belief, Reddy has knowingly and willfully infringed the '802 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG pray for a judgment in their favor and against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. 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 Reddy from making, using, selling, offering to sell, selling, or importing the Reddy Products described in ANDA No. 77-183 or offering to sell or selling the Reddy Products for use in a method which would infringe the '802 patent until after the expiration of the '802 patent;
- C. Determining that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs their reasonable attorneys' fees, costs and expenses; and
- D. Awarding Plaintiffs such other relief as the Court deems just and proper.

Dated: July 12, 2007
Newark, New Jersey

Respectfully submitted,

GIBBONS P.C.

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