David E. De Lorenzi
Sheila F. McShane
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4743

WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
(212) 819-8200

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. APOTEX INC. and APOTEX CORPORATION, Defendants.	Civil Action No. _____ **COMPLAINT** *Filed electronically.*

Plaintiff Novartis Pharmaceuticals Corporation, by its attorneys White & Case LLP and Gibbons P.C., for its Complaint against Defendants Apotex Inc. and Apotex Corporation herein alleges:

THE PARTIES

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") is a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, New Jersey 07936.

2. On information and belief, Defendant Apotex Inc. ("Apotex") is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

3. On information and belief, Defendant Apotex Corporation ("Apotex USA") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 N. Commerce Parkway, Suite 400, Weston, Florida, 33326.

4. On information and belief, Apotex USA is the United States subsidiary of Apotex.

5. On information and belief, Apotex conducts business operations in the United States, including in the State of New Jersey, through Apotex USA.

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, Apotex and Apotex USA are in the business of making and selling generic drug products.

8. On information and belief, Apotex and Apotex USA maintain continuous and systematic contacts with the State of New Jersey.

9. On information and belief, Apotex and Apotex USA conduct business in the State of New Jersey and sell various drug products in the United States, including in New Jersey.

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

11. On information and belief, Apotex USA markets and sells drug products in the United States, including in this Judicial District, that are manufactured by Apotex, following FDA approval. On information and belief, Apotex USA has registered as a wholesaler with the New Jersey Department of Health and Senior Services. Upon information and belief, Apotex derives substantial revenue from services or things used or consumed in the State of New Jersey.

12. On information and belief, Apotex and Apotex USA have submitted to the jurisdiction of the United States District Court for the District of New Jersey and have purposefully availed themselves of the District of New Jersey by filing suit and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

13. Apotex and Apotex 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®.

APOTEX'S ANDA

19. On information and belief, Apotex submitted Abbreviated New Drug Application ("ANDA") No. 91431 to the FDA pursuant to 21 U.S.C. § 355(j) (the "Apotex

ANDA"), seeking approval to market amlodipine besylate and benazepril hydrochloride capsules (the "Apotex Product").

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

21. Novartis received from Apotex a letter, dated July 23, 2012, and attached memorandum (collectively, the "Apotex Notification"), stating that Apotex had filed the Apotex ANDA seeking approval to market the Apotex 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. The Apotex Notification states that Apotex has included a certification in the Apotex ANDA, pursuant to 21 U.S.C § 355(j)(2)(A)(vii)(IV), that the '802 patent will not be infringed by the commercial manufacture, use, sale, or offer of sale of the Apotex Product (the "Paragraph IV Certification").

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. Apotex 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. 91431, 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 Apotex Product for the treatment of hypertension prior to the expiration of the '802 patent.

25. Novartis will be irreparably harmed if Apotex 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 Apotex and Apotex 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 Apotex from making, using, selling, offering to sell, or importing the Apotex Product described in ANDA No. 91431 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: September 6, 2012
Newark, New Jersey

Respectfully submitted,

GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Phone: (973) 596-4743
Facsimile: (973) 639-6235

By: s/ Sheila F. McShane
Sheila F. McShane
smcshane@gibbonslaw.com

-and-

WHITE & CASE LLP
Dimitrios T. Drivas
Leslie Morioka
R. Gregory Parker
1155 Avenue of the Americas
New York, New York 10036
Phone: (212) 819-8200
Facsimile: (212) 354-8113

Attorneys for Plaintiff Novartis Pharmaceuticals Corporation