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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS CORPORATION, NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS INTERNATIONAL AG, Plaintiffs, v. MYLAN LABORATORIES INC. and MYLAN PHARMACEUTICALS INC., Defendants.	Civil Action No. _____ **COMPLAINT** *Filed electronically.*

On or around September 10, 2007, Plaintiffs Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG (collectively, "Novartis") received from Mylan Pharmaceuticals, Inc., a letter dated September 7, 2007, with an attached memorandum (together, "First Mylan Notification"), stating that it had filed Abbreviated New Drug Application ("ANDA") No. 77-375 seeking approval to market amlodipine besylate and benazepril hydrochloride capsules (the "Mylan Products") in three dosage strengths: 2.5/10 mg,

5/20 mg, and 10/20 mg. On October 11, 2007, Novartis filed a Complaint with this Court alleging infringement of United States Patent No. 6,162,802 (the "'802 patent") by the submittal of the ANDA. Based upon the representations of the First Mylan Notification, Novartis' October 11, 2007 Complaint alleged infringement of the '802 patent for the 2.5/10 mg, 5/20 mg, and 10/20 mg dosage strengths of the Mylan Products. On or around November 21, 2007, Novartis received another letter from Mylan Pharmaceuticals, Inc., dated November 20, 2007, with an attached memorandum (together, "Second Mylan Notification"), stating that it had filed ANDA No. 77-375 actually seeking approval to market the Mylan Products in four dosage strengths: 2.5/10 mg, 5/10 mg, 5/20 mg, and 10/20 mg. As a result of the new information provided in the Second Mylan Notification, Novartis herein files this Complaint to allege infringement of the '802 patent by the 5/10 mg dosage strength of the Mylan Products.

Therefore, Plaintiffs Novartis, by their attorneys White & Case LLP and Gibbons P.C., for their Complaint against Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan"), 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, Mylan Laboratories Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principal place of business at

1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

5. On information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. On information and belief, Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Laboratories Inc., and the acts of Mylan Pharmaceuticals Inc. complained of herein were aided and abetted by and done with the cooperation, participation, and assistance of Mylan Laboratories Inc.

7. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. have officers and directors in common.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

9. On information and belief, Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. are in the business of making and selling generic drug products.

10. On information and belief, Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. conduct business in New Jersey and sell various drug products in the United States, including the State of New Jersey.

11. On information and belief, Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. are registered to do business in New Jersey and have appointed Corporation Service Company, 830 Bear Tavern Rd., West Trenton, NJ 08628, as their registered agent.

12. On information and belief, Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. have sued and been sued in the United States District Court for the District of New Jersey.

13. On information and belief, Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. have submitted to the jurisdiction of the United States District Court for the District of New Jersey.

14. Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. are subject to personal jurisdiction in this judicial district.

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

The '802 Patent

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

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

18. 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®

19. Novartis Pharmaceuticals Corporation holds an approved New Drug Application for amlodipine besylate and benazepril hydrochloride combination capsules, in 2.5/10 mg (amlodipine besylate/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®.

20. 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®.

Mylan's Notifications and ANDA

21. On information and belief, Mylan submitted ANDA No. 77-375 to the FDA pursuant to 21 U.S.C. § 355(j) (the "Mylan ANDA"), seeking approval to market the Mylan Products.

22. On information and belief, the Mylan ANDA refers to and relies upon Novartis Pharmaceutical Corporation's NDA for Lotrel® and purports to contain data showing bioequivalence of the Mylan Products with Lotrel®.

23. On or about September 10, 2007, Novartis received from Mylan the First Mylan Notification, stating that Mylan had filed the Mylan ANDA seeking FDA approval to market the Mylan Products in 2.5/10 mg, 5/20 mg, and 10/20 mg dosage strengths.

24. On October 11, 2007, Novartis filed a Complaint with this Court alleging infringement of the '802 patent based upon the representation of the First Mylan Notification that under ANDA No. 77-375 FDA approval was sought to market the Mylan Products in 2.5/10 mg, 5/20 mg, and 10/20 mg dosage strengths.

25. On or about November 21, 2007, Novartis received from Mylan the Second Mylan Notification, stating that Mylan had filed ANDA No. 77-375 actually seeking FDA approval to market the Mylan Products in dosage strengths of the previously disclosed 2.5/10 mg, 5/20 mg, and 10/20 mg strengths, as well as the newly disclosed 5/10 mg strength.

26. By the Second Mylan Notification, Mylan states that, pursuant to 21 U.S.C. § 355(j)(2)(A), the Mylan ANDA certifies that the '802 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer to sell, or sale of the Mylan Products in the 5/10 mg strength, in addition to the previously disclosed 2.5/10 mg, 5/20 mg, and 10/20 mg dosage strengths.

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

27. Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-26 of this Complaint.

28. Mylan 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. 77-375, 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, or sale of the Mylan Product in the 5/10 mg dosage strength prior to the expiration of the '802 patent.

29. Upon information and belief, Mylan has knowingly and willfully infringed the '802 patent.

30. Novartis will be irreparably harmed if Mylan 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 Mylan Laboratories Inc. and Mylan Pharmaceuticals 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 Mylan from making, using, offering to sell, selling, or importing the Mylan Products described in ANDA No. 77-375 or offering to sell or selling the Mylan 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: December 11, 2007
Newark, New Jersey

Respectfully submitted,

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