IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES INC. 1500 Corporate Drive Canonsburg, PA 15317, and MYLAN PHARMACUETICALS INC. 781 Chestnut Ridge Road Morgantown, WV 26505 Plaintiffs, v. MICHAEL O. LEAVITT, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W. Washington, DC 20204, and ANDREW C. VON ESCHENBACH, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, 200 C Street, S.W. Washington, DC 20204, and UNITED STATES FOOD AND DRUG ADMINISTRATION 5600 Fishers Lane Rockville, MD 20857 Defendants.	Civil Action No.

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

Plaintiffs Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan"), by and through counsel, respectfully submit this Complaint against Michael O. Leavitt, in his official capacity as Secretary of Health and Human Services, Andrew C. Von

Eschenbach, in his official capacity as Commission of Food and Drugs, and the United States Food and Drug Administration ("FDA"). In support thereof, Plaintiffs allege as follows:

INTRODUCTION

1. Mylan specifically asks this Court to enjoin the FDA from taking any action, pursuant to the Order of Court and Amended Judgment entered on March 16, 2007 by the United States District Court for the Western District of Pennsylvania ("the Pennsylvania District Court"), that would change the effective date of Mylan's final approval to March 25, 2007, or otherwise disturb the final approval granted to Mylan's Abbreviated New Drug Application ("ANDA") until the United States Court of Appeals for the Federal Circuit has had an opportunity to rule on all matters pending before the Federal Circuit specifically including, but not limited to, Mylan's Emergency Motion to Stay the District Court's Injunction.

THE PARTIES

2. Plaintiff, Mylan Laboratories Inc., is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania and has a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

3. Plaintiff, Mylan Pharmaceuticals Inc., is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505-4310. Mylan is engaged in the research, development, manufacture and distribution of generic pharmaceutical products.

4. Defendant, Michael O. Leavitt, is Secretary of Health and Human Services ("HHS"), having offices at 200 Independence Avenue, S.W., Washington, DC 20204. Defendant Leavitt is responsible for supervising the activities of HHS and is being sued in his official capacity.

5. Defendant, Andrew C. Von Eschenbach, is Commissioner of the FDA, having offices at 200 C Street, S.W., Washington, DC 20204 and 5600 Fishers Lane, Rockville, MD 20857. Upon information and belief, Defendant Eschenbach, is responsible for supervising FDA's activities, and is being sued in his official capacity.

6. Defendant FDA is an agency within the Public Health Service, which is part of HHS. The FDA has offices at 5600 Fishers Lane, Rockville, MD 20857.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§555, 701 *et seq.*; and 28 U.S.C. § 1331 (federal question). The relief requested is also authorized pursuant to 28 U.S.C. § 2201 (declaratory relief); and 28 U.S.C. §2202 (further relief).

8. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

STATEMENT OF FACTS

9. Since November 1992, Pfizer has marketed amlodipine besylate tablets under the brand name Norvasc®.

10. Mylan filed its ANDA on May 22, 2002 and certified under 21 U.S.C. §355(j)(2)(A)(vii)(IV) that the manufacture, use or sale of Mylan's amlodipine products would not violate Pfizer's U.S. Patent No. 4,572,909 ("the '909 patent") and U.S. Patent No. 4,879,303 ("the '303 patent") because they were invalid, unenforceable, or not infringed. The '909 patent has already expired, and the '303 patent will expire on March 25, 2007, two days from now.

11. Mylan also timely sent the required notices to Pfizer, as required by §355(j)(2)(B) on July 23, 2002. On September 20, 2002, Pfizer filed suit against Mylan before the

Pennsylvania District Court, alleging that the filing of Mylan's ANDA was an act of infringement of the '909 and '303 patents.

12. Upon the FDA's finding that Mylan's amlodipine products were safe, effective and therapeutically equivalent to Norvasc,® the FDA issued final approval to Mylan on October 3, 2005.

13. The Pennsylvania District Court held a non-jury trial in November and December 2006 to address questions of inequitable conduct and patent invalidity with respect to the '303 patent. The Pennsylvania District Court issued Findings of Fact and Conclusions of Law on February 27, 2007, finding that the '303 patent was valid and that Mylan's amlodipine products are infringing.

14. On March 8, 2007, Pfizer filed a motion with the Pennsylvania District Court, to amend the injunction. In its moving papers, Pfizer alleged that the FDA had informed Pfizer that it would take action to change Mylan's final approval if Pfizer obtained from the court an order under 35 U.S.C. §271(e)(4)(A). On March 16, 2007 the Pennsylvania district court issued an Order of Court and Amended Judgment ordering that "the effective date of Mylan's [amlodipine ANDA] ... shall be a date not earlier than the expiration of the '303 patent (March 25, 2007)."

15. Mylan appealed the Pennsylvania District Court's decision that the '303 patent is invalid and unenforceable to the United States Court of Appeals for the Federal Circuit.

16. On March 20, 2007, Mylan filed an Emergency Motion to Stay the District Court's Injunction Pending Appeal in the Federal Circuit.

17. On March 22, 2007, the Federal Circuit issued its decision in *Pfizer Inc. v. Apotex Inc.*, No. 2006-1261, holding the '303 patent invalid. Later that day, Mylan filed a supplemental submission with the Federal Circuit concerning the decision that the '303 patent is invalid.

18. In a telephone call with Mylan's counsel on March 22, 2007, FDA counsel stated that FDA would revoke Mylan's final approval and convert it to a tentative approval, if the §271(e)(4)(A) is not stayed by the Federal Circuit by mid-day on March 23, 2007.

19. The FDA's refusal to maintain the status quo until resolution of all matters pending before the Federal Circuit specifically including, but not limited to, Mylan's emergency motion for a stay is arbitrary and capricious and contrary to law—particularly in light of the Federal Circuit's March 22, 2007 decision holding the '303 patent invalid.

20. At the time of the filing of this Complaint, the emergency motion judge at the Federal Circuit had not yet ruled on Mylan's Emergency Motion to Stay the District Court's Injunction.

21. Faced with imminent FDA action that would cause it irreparable harm, Mylan has commenced this action for injunctive relief.

COUNT I

22. Mylan incorporates by reference all allegations contained in paragraph 1-21 of this Complaint.

23. All of the factors necessary for relief support Mylan's motion here: Mylan's substantial likelihood of success on the merits; the overwhelming and irreparable harm to Mylan that would result from the FDA's actions; the absence of any corresponding harm to the FDA; and the serious public interest considerations that favor Mylan.

24. Mylan has a substantial likelihood of success on the merits of this lawsuit. The Federal Circuit's decision in *Pfizer Inc. v. Apotex Inc.*, No. 2006-1261, that the '303 patent is invalid finally and completely removes any basis for keeping Mylan off the market once the

mandates issues. The Federal Circuit's holding that the '303 patent is invalid makes Mylan's ultimate likelihood of success a virtual certainty.

25. The FDA's proposed action would cause irreparable harm to Mylan. The conversion of Mylan's final approval to a tentative approval based on the Pennsylvania district court's order under 35 U.S.C. §271(e)(4)(A) will severely and irreparably harm Mylan. Once the FDA revokes Mylan's final approval, Mylan is likely to be excluded from this important market for an indefinite period of time, even if the Federal Circuit promptly stays the Pennsylvania's district court Order after the approval is revoked.

26. If FDA is not enjoined from revoking the final approval of Mylan's ANDA, Mylan Pharmaceuticals will lose sales that are forecasted to reach the hundreds of millions of dollars, a harm for which there is no legal redress. Mylan therefore faces irreparable economic harm for which there simply is no legal recourse.

27. If Mylan's final approval is revoked, the public will be deprived of a low cost generic version of amlodipine and will have not choice by to continue to purchase Pfizer's costly Norvasc® product, even though the patent that covers that product has now been held to be invalid.

28. Neither the FDA nor any other party faces harms similar to those faced by Mylan.

29. Therefore, Mylan seeks injunctive relief simply to maintain the status quo and to prevent revocation of Mylan's final approval until the Federal Circuit rules on all matters pending before the Federal Circuit specifically including, but not limited to, Mylan's Emergency Motion to Stay the District Court's Injunction.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully pray that this honorable Court:

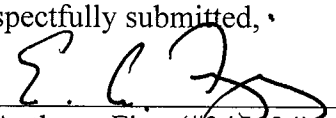
A. Enjoin Defendants from revoking Mylan's final approval until the Federal Circuit has decided all matters pending before the Federal Circuit specifically including, but not limited to, Mylan's Emergency Motion to Stay the District Court's Injunction.

B. Award Plaintiffs their costs and reasonable attorneys fees in this action to the extent authorized by 28 U.S.C. §2412 or as otherwise authorized by law; and

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

Dated: March 23, 2007

Respectfully submitted,



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