IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES INC. 1500 Corporate Drive Canonsburg, PA 15317, and MYLAN PHARMACEUTICALS 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

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 Commissioner of Food and Drugs, and the United States Food and Drug Administration ("FDA"). In support thereof, Plaintiffs allege as follows:

THE PARTIES

1. 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. Mylan Laboratories Inc is the parent company of Mylan Pharmaceuticals Inc.

2. 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 Pharmaceuticals Inc is engaged in the research, development, manufacture and distribution of generic pharmaceutical products.

3. 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.

4. 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.

5. 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

6. 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).

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

STATEMENT OF FACTS

8. Amlodipine besylate is a drug approved by the FDA for treating hypertension and chronic stable and vasospastic angina. The large pharmaceutical company, Pfizer, held two patents that it contended covered different aspects of amlodipine besylate, U.S. Patent No. 4,572,909 ("the '909 patent") and U.S. Patent No. 4,879,303 ("the '303 patent") The '909 patent expired on July 31, 2002; the '303 patent expired on March 25, 2007.

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

10. In May of 2002, Mylan filed with the FDA an Abbreviated New Drug Application (ANDA) on generic 2.5 mg, 5 mg and 10 mg amlodipine besylate tablets. Mylan's ANDA was and is governed by the provisions of the Hatch-Waxman Act.[1]

11. By letter dated July 23, 2002, Mylan certified pursuant to §505 (j)(2)(A)(vii)(IV) of the Hatch-Waxman Act that the manufacture, use and sale of Mylan's 2.5 mg, 5 mg and 10 mg amlodipine besylate tablets would not violate the '909 patent and the '303 patent because

[1] *Drug Price Competition and Patent Term Restoration Act of 1984*, P.L. 98-417, 98 Stat. 1585 (Sept. 24, 1984), amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 501 *et seq.*

they were invalid, unenforceable, or not infringed. Mylan was the first to file a Paragraph IV certification with respect to amlodipine besylate.

12. On September 20, 2002, Pfizer sued Mylan for patent infringement in the United States District Court for the Western District of Pennsylvania (the "Pennsylvania action").

13. By letter dated October 3, 2005, the FDA notified Mylan that its amlodipine besylate ANDA was approved. *See Declaration of Shannon M. Bloodworth in Support of Mylan's Emergency Application for a Temporary Restraining Order* (*hereinafter* "Bloodworth Decl.") ¶ 2.

14. In that same letter, the FDA provided the following notice:

> With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Amlodipine Besylate Tablets . . . Therefore, with this approval, Mylan is eligible for 180-days of market exclusivity. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv) of the Act

Id., at ¶ 2.

15. The FDA approved Mylan's amlodipine ANDA despite the fact that in November, 2001 the FDA granted Pfizer so-called pediatric exclusivity pursuant to 21 U.S.C. § 355a.

16. In approximately May 2003, generic pharmaceutical company, Apotex Inc. ("Apotex"), filed an ANDA with the FDA seeking approval to sell amlodipine besylate tablets prior to the expiration of Pfizer's '303 patent and certifying pursuant to § 505(j)(2)(A)(vii)(IV) of the Hatch-Waxman Act that the manufacture, use and sale of Apotex's amlodipine besylate tablets would not violate the '303 patent.

17. On July 30, 2003, Pfizer sued Apotex for patent infringement in the United States District Court for the Northern District of Illinois (the "Illinois action"). The FDA has not to date approved Apotex's amlodipine besylate ANDA.

18. Following a bench trial in the Illinois action, on January 29, 2006, the district court entered judgment dismissing Apotex's invalidity and unenforceability defenses and declaring that Apotex's amlodipine besylate tablets infringed the '303 patent. In addition, the district court ordered that the effective date of Apotex's ANDA be no earlier than September 25, 2007 (patent expiration plus six months pediatric exclusivity) and enjoined Apotex from engaging in commercial activities with respect to amlodipine besylate. Apotex appealed the district court judgment to the Federal Circuit.

19. On February 27, 2007, following a bench trial in the Pennsylvania action, the district court entered judgment dismissing Mylan's invalidity and unenforceability defenses and declaring that Mylan's amlodipine besylate tablets infringed the '303 patent. *See Bloodworth Decl.*, at ¶ 3. In addition, the district court ordered that the effective date of Mylan's ANDA be no earlier than March 25, 2007 and enjoined Mylan from engaging in commercial activities with respect to amlodipine besylate until patent expiration on March 25, 2007. *See id.*, at ¶ 4. Mylan appealed the district court judgment to the Federal Circuit.

20. On March 22, 2007, the Federal Circuit issued its decision in the Illinois action, holding the '303 patent invalid for obviousness under 35 U.S.C. § 103. *See Pfizer, Inc. v. Apotex, Inc.*, 2007 U.S. App. LEXIS 6623, 2006-1261 (Fed. Cir. 2007).

21. On March 23, 2007, the Federal Circuit issued a stay of the district court's order in the Pennsylvania action. *See Bloodworth Decl.*, at ¶ 5. Later that same day Mylan began commercial marketing of amlodipine besylate tablets, thereby triggering the 180 days of

exclusivity pursuant to § 505(j)(5)(B)(iv) of the Hatch-Waxman Act and the FDA's approval letter. *See id.*, at ¶ 6.

22. In addition to Mylan and Apotex, there are at least six other generic pharmaceutical companies who have filed ANDAs on amlodipine besylate. All filed after Mylan. None have received final FDA approval.

23. Mylan has learned that the FDA may issue final approvals to Apotex and the other generic ANDA filers before the expiration of Mylan's 180-day exclusivity. *See Declaration of Brian S. Roman in Support of Mylan's Emergency Application for a Temporary Restraining Order, (hereinafter* "Roman Decl.") ¶ 5. Such action would be in direct contravention of § 505(j)(5)(B)(iv) of the Hatch-Waxman Act and therefore *ultra vires* and beyond the FDA's statutory authority.

24. Mylan will be irreparably harmed if the FDA grants additional approvals during its 180-day period of exclusivity. *See* Roman Decl., ¶ 6. Generic exclusivity is a valuable right that the Hatch-Waxman Act provides as an incentive for generic manufacturers to challenge invalid patents, such as Pfizer's '303 patent. *See id.* If the FDA permits other generics into the market during Mylan's 180-day exclusivity period, Mylan will incur substantial losses, losses which it will never be able to recoup, even if the FDA's actions are later overturned. *See id.*

PRAYER FOR RELIEF

Wherefore, Mylan respectfully prays that this honorable Court:

To issue a temporary restraining order and/or a preliminary injunction to enjoin the FDA defendants from taking any action to issue an approval of any Abbreviated New Drug Application for amlodipine besylate products pending the determination of the scope and duration of Mylan's 180-day generic exclusivity.

Dated: March 26, 2007

Respectfully submitted,

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