IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES INC. and MYLAN PHARMACUETICALS INC. Plaintiffs, v. MICHAEL O. LEAVITT, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and ANDREW C. VON ESCHENBACH, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, and UNITED STATES FOOD AND DRUG ADMINISTRATION Defendants.	Civil Action No.

MYLAN'S EMERGENCY APPLICATION FOR A
TEMPORARY RESTRAINING ORDER TO PRESERVE THE STATUS QUO

Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") respectfully submit this emergency application for a temporary restraining order ("TRO") enjoining defendants, the U.S. Food and Drug Administration ("FDA") and Andrew C. von Eschenbach, M.D., in his official capacity as Commissioner of Food and Drugs (collectively, "FDA") from taking any action that would affect the status of the FDA's final approval of

Mylan's Abbreviated New Drug Application ("ANDA") for an important blood pressure medication known as amlodipine besylate ("amlodipine").

The bases for the present emergency application for a temporary restraining order are fully set forth in the accompanying Statement of Points and Authorities.

Dated: March 23, 2007

Respectfully submitted,

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STATEMENT OF POINTS AND AUTHORITIES IN SUPPORT OF MYLAN'S EMERGENCY APPLICATION FOR A TEMPORARY RESTRAINING ORDER TO PRESERVE THE STATUS QUO

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I. INTRODUCTION AND LEGAL STANDARD

Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") respectfully submit this statement in support of their emergency application for a temporary restraining order ("TRO") enjoining defendants, the U.S. Food and Drug Administration ("FDA") and Andrew C. von Eschenbach, M.D., in his official capacity as Commissioner of Food and Drugs (collectively, "FDA") from taking any action that would affect the status of the FDA's final approval of Mylan's Abbreviated New Drug Application ("ANDA") for an important blood pressure medication known as amlodipine besylate ("amlodipine").

Mylan asks that the Court enter a TRO to maintain the status quo pending a resolution of all appeals and motions before the United States Court of Appeals for the Federal Circuit specifically including, but not limited to, Mylan's pending motion to stay an injunction issued by the U.S. District Court for the Western District of Pennsylvania. That injunction was based on the Pennsylvania Court's determination that the Pfizer patent covering amlodipine was valid and enforceable. The injunction is improper and should be stayed, because the Federal Circuit yesterday held Pfizer's patent to be invalid in Pfizer Inc. v. Apotex, Inc., Docket No. 2006-1261. See Declaration of Minaksi Bhatt ("Bhatt Decl."), Exh. 1.

Despite the Federal Circuit's ruling yesterday holding the Pfizer patent invalid, the FDA advised Mylan late yesterday afternoon that it would convert Mylan's amlodipine ANDA approval status from "final" to "tentative" by "midday" today, unless the Federal Circuit orders otherwise. Mylan asks that the Court enjoin the FDA from prematurely taking any action with respect to Mylan's final approval to market amlodipine or converting that final approval to a tentative approval based on the Pennsylvania Court's injunction until such time that the Federal Circuit rules on pending matters.

"To obtain a temporary restraining order, a plaintiff bears the burden of demonstrating: '1) a substantial likelihood of success on the merits, 2) that [plaintiff] would suffer irreparable injury if the injunction is not granted, 3) that any injunction would not substantially injure other interested parties, and 4) that the public interest would be served by the injunction.'" Canales v. Paulson, No. 06-1330 (GK), 2006 U.S. Dist. LEXIS 61915, *8 (D.D.C. August 30, 2006) (granting temporary restraining order to preserve the status quo pending court's ruling on an application for a preliminary injunction) (quoting Katz v. Georgetown Univ., 246 F.3d 685, 687-88 (D.C. Cir. 2001)). Plaintiffs do not need to prevail on each of these four factors because the factors "'interrelate on a sliding scale and must be balanced against each other.'" Id. (quoting Serono Lab. v. Shalala, 158 F.3d 1313, 1318 (D.C. Cir. 1998)). Furthermore, "'[i]f the arguments for one factor are particularly strong, a temporary restraining order may issue even if the arguments in other areas are rather weak.'" Id. (quoting CityFed Fin. Corp. v. Office of Thrift Supervision, 58 F.3d 738, 747 (D.C. Cir. 1995)). Therefore, injunctive relief may be granted "'where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury.'" Id. See also Zantop Int'l Airlines, Inc. v. Engen, 601 F. Supp. 667, 669 (D.D.C. 1985) (ordering existing temporary restraining order to "remain in effect . . . to preserve the status quo until such time as the Court of Appeals is able to rule on a motion for stay.").

Because the Pennsylvania Court's order is based on a finding that Pfizer's patent was not invalid, and because the Federal Circuit yesterday held that Pfizer's patent is invalid, any action by the FDA to change Mylan's approval status prior to resolution of all pending matters would be arbitrary and capricious and contrary to law.

Mylan is entitled to a TRO because: (1) it has a very high likelihood of ultimately establishing that it is entitled to its final approval, based on yesterday's Federal Circuit decision holding the patent upon which the Pennsylvania Court's injunction is based invalid; (2) Mylan will be severely and irreparably harmed by a premature revocation or conversion of Mylan's final approval; (3) the public will be deprived of a low-cost generic version of Pfizer's expensive Norvasc® product until Mylan's final approval is restored; and (4) neither the FDA nor any private party can show any legally cognizable harm from competition by Mylan.

II. FACTUAL BACKGROUND

Pfizer is the assignee of U.S. Patent No. 4,879,303 ("the '303 patent"), which covers amlodipine besylate. Since November 1992, Pfizer has marketed—without any competition—amlodipine besylate tablets under the brand name Norvasc®. The '303 patent will expire on March 25, 2007, two days from now.

In 2002, Mylan submitted an abbreviated new drug application ("ANDA") to the FDA seeking approval to market its amlodipine product as a generic equivalent to Pfizer's Norvasc® product. Mylan's ANDA was the first to contain a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) that the Pfizer patent was invalid. Because Pfizer failed to bring a patent infringement action against Mylan within forty-five days of its being notified of Mylan's ANDA, under the provisions of the so-called Hatch-Waxman amendments to the Federal Food, Drug and Cosmetic Act ("FD&C Act"), Mylan received final FDA approval of its ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). That approval was received in October 2005. Declaration of Brian S. Roman at ¶ 4. Mylan was, until the Pennsylvania court's order, entitled to market its amlodipine product commercially pursuant to that final approval.

Although Pfizer did not sue Mylan within forty-five days, it did ultimately sue Mylan in the U.S. District Court for the Western District of Pennsylvania, alleging that the filing of the ANDA was an act of infringement. Earlier this year, that court entered judgment against Mylan, holding that Pfizer's patent was valid, enforceable and infringed. Bhatt Decl., Exh. 2. The Pennsylvania court entered an order pursuant to 35 U.S.C. §§271(e)(4)(A) and (B) ordering that the approval of Mylan's ANDA be effective no earlier than the expiration date of Pfizer's patent and enjoined Mylan from the commercial manufacture or sale of amlodipine until patent expiration. Id., Exh. 3.

Mylan has appealed the Pennsylvania court's decision to the United States Court of Appeals for the Federal Circuit and has moved for a stay of the injunctive relief. Mylan supplemented its motion yesterday following receipt of the Federal Circuit's decision, discussed below, holding the Pfizer patent to be invalid. Mylan's motion is pending.

Pfizer sued another generic drug company, Apotex, Inc., in the Northern District of Illinois for infringement of its patent. Although the Mylan case was filed first, the Apotex case was tried first. As in the Mylan case, the Illinois court also held the '303 patent to be valid, enforceable and infringed. During the pendency of Mylan's case in Pennsylvania, Apotex appealed the Illinois court's decision to the Federal Circuit. Yesterday morning, March 22, 2007, the Federal Circuit issued its opinion in Pfizer v. Apotex, Inc., Docket No. 2006-1261 (Bhatt Decl., Exh. 1). In a unanimous decision authored by Chief Judge Michel, the Federal Circuit held that claims 1-3 of the '303 patent (the same claims asserted by Pfizer against Mylan) were "invalid for obviousness." Id., slip op. at 40. The Federal Circuit did not remand for further proceedings. It reversed and held that the '303 patent is invalid as a matter of law.

The Federal Circuit's decision finally and completely removes any basis for keeping

Mylan off the market. Nevertheless, Pfizer has indicated that it intends to seek rehearing en banc by the Federal Circuit, thereby delaying issuance of that Court's mandate. By so doing, Pfizer hopes to retain six months of additional so-called pediatric exclusivity that will prevent the FDA from approving ANDAs of some generic drug companies.

Upon receipt of the Federal Circuit's decision in the Apotex case, Mylan immediately supplemented its motion to stay the Pennsylvania court's injunctive relief.[1] The Federal Circuit's holding that the Pfizer patent is invalid makes Mylan's ultimate likelihood of success a virtual certainty. While Pfizer undoubtedly will ask the Federal Circuit to reconsider its decision, that Court rehears only a very small percentage of cases and reverses itself very rarely.

Mylan also immediately approached the FDA concerning how it would act with respect to Mylan's final approval status for its amlodopine ANDA in light of the Federal Circuit's decision. As set forth in the accompanying Declaration of Shannon Bloodworth, the FDA's Office of General Counsel advised Ms. Bloodworth that if the Federal Circuit did not grant Mylan's emergency stay motion by midday today (March 23), it would have no choice but to implement the District Court order and convert Mylan's final approval status to "tentative" based on the Pennsylvania Court's order under 35 U.S.C. §271(e)(4)(A) Declaration of Shannon Bloodworth ("Bloodworth Decl.") at ¶ 4. The FDA stated that it felt that it had to take this action promptly to effect a conversion of the approval status before expiration of Pfizer's patent at midnight on Sunday, March 25, 2007. Id.

A revocation of Mylan's final approval or its conversion to tentative approval will severely and irreparably harm Mylan. Were the FDA to revoke Mylan's final approval, Mylan

[1] Mylan also requested that the Pennsylvania court stay its injunction order. When the District Court learned that Mylan had filed a stay motion with the Federal Circuit, the District Court deferred to that Court and denied Mylan's motion.

would likely be excluded from this important market for an indefinite period of time, even if the Federal Circuit promptly stays the Pennsylvania Court's order. The FDA has made clear that once an approval becomes tentative, it will not automatically become final when the patent obstacles are removed:

> Approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform, and an applicant has no vested right to enter the market until the FDA gives its final formal approval.

Ranbaxy Labs. Ltd. v. FDA, 307 F. Supp. 2d 15, 19 (D.D.C. 2004), aff'd, No. 04-5079, 2004 U.S. App. LEXIS 8311, *1 (D.D.C. 2004). While Mylan waits for the FDA to restore its final approval, Mylan will be deprived of the opportunity (which it sought for four years) to sell a lower cost generic version of the Norvasc®—a product worth millions of dollars per day in U.S. sales. In addition, the public will be deprived of Mylan's low-cost generic version of amlodipine, and will have no choice but to continue to purchase Pfizer's costly Norvasc® product, even though the patent that covers that product has now been held to be invalid. Mylan has not legal redress for these losses.

Mylan simply seeks a TRO to maintain the status quo and to prevent premature revocation of Mylan's final approval until the Federal Circuit rules on Mylan's motion to stay the effect of the Pennsylvania court's order. Upon receipt of such a stay, Mylan understands that the FDA will not convert Mylan's ANDA approval from final to tentative. Given the high likelihood that the Pennsylvania court's order will be stayed in view of the fact that it is based on a patent that the Federal Circuit has now held to be invalid, the FDA should be temporarily restrained from upsetting the status quo until the Federal Circuit has ruled.

III. SUMMARY OF ARGUMENT

1. Mylan asks this Court to issue a TRO prohibiting the FDA from altering the status quo with respect to Mylan's ANDA approval status until the Federal Circuit rules on Mylan's Emergency Stay Motion. Mylan seeks such relief, because the FDA has advised Mylan that it is compelled to change Mylan's approval status—even though the Federal Circuit has now held the '303 patent to be invalid for obviousness—because there is an outstanding district court order directing such a result. Mylan submits that such automatic and premature action that ignores the Federal Circuit's holding that the '303 patent is invalid, and is arbitrary, capricious, and contrary to law.
2. If the FDA follows the position it has taken in the past with respect to the steps necessary to convert a tentative approval to a final approval, Mylan could be mired in bureaucracy in an effort to get its final approval restored. The harm to Mylan would be enormous.
3. The harm to the public also would be significant, given that Pfizer currently sells approximately $7 million of Norvasc® per day.
4. If the relief requested is granted, Pfizer would suffer no cognizable harm. That is so because the '303 patent has been held invalid. Thus, Pfizer has no legitimate interest in blocking competition.

For these reasons, Mylan respectfully requests that the TRO be granted and that the FDA be enjoined from changing Mylan s final approval status until such time as the Federal Circuit rules on Mylan's Emergency Stay Motion and other matters.

IV. MYLAN IS LIKELY TO SUCCEED ON THE MERITS

A unanimous panel of the United States Court of Appeals for the Federal Circuit held yesterday that claims 1-3 of the '303 patent (the only claims asserted against Mylan) are invalid

for obviousness. The Federal Circuit is highly unlikely to reverse its decision. The leading treatise on Federal Circuit practice and procedure reports that the Federal Circuit in the years 1982-1995 heard cases en banc "only 16 times out of more than 11,000 requests." Bhatt Decl., Exh. 4 (Donald R. Dunner, The Court of Appeals for the Federal Circuit: Practice and Procedure, Vol. 1 at §6.06(c) at page 6-73 (2006)).

As a matter of law, a patent cannot be invalid with respect to one accused infringer and valid with respect to another. The Federal Circuit's decision collaterally estops Pfizer from asserting its patent against Mylan or anyone else. Blonder-Tongue Lab. v. Univ. of Ill. Found., 402 U.S. 313, 332-34 (1971); Pharmacia & Upjohn Co. v. Mylan Pharms, Inc., 170 F.3d 1373, 1379-80 (Fed. Cir. 1999). It is therefore overwhelmingly likely that Mylan will ultimately prove that it is entitled to final approval based on the Federal Circuit's March 22, 2007 opinion.

However, the FDA has advised Mylan of its intention to change Mylan's approval status if the Federal Circuit has not acted by midday today. In a rational world, the FDA would read the Federal Circuit opinion in Apotex and conclude that there is no basis on which to change Mylan's approval status from final to tentative. However, the FDA apparently feels constrained by the outstanding improper Pennsylvania court order, thus necessitating this emergency application.

V. MYLAN WILL BE IRREPARABLY HARMED IF A TRO IS NOT ENTERED

Annual U.S. sales of Norvasc® are publicly reported to be approximately $7 million per day ($2.5 billion per year). Bhatt Decl., Exh. 5. Mylan has expended tremendous resources on the development and approval of its amlodipine products, including millions of dollars on materials, studies, overhead and litigation. Roman Decl. at ¶ 3. Mylan anticipates that its sales of generic amlodipine will be about $3 million per day. These are the revenues that Mylan will

irrevocably lose to Pfizer's Norvasc® product if the FDA prematurely revokes Mylan's final approval.

If the FDA prematurely revokes Mylan's final approval by converting it to a tentative approval, Mylan will be delayed from launching its product until the FDA finds the time necessary to restore the final approval. This is so because the FDA has made clear that once an approval becomes tentative, it does not automatically become final when the patent obstacles are removed.

> Approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform, and an applicant has no vested right to enter the market until the FDA gives its final formal approval.

Ranbaxy Labs, 307 F. Supp. 2d at 19. In briefs previously submitted to this Court in other cases, the FDA has explained why a tentative approval is not automatically converted to a final approval:

> [A]pproval of an ANDA cannot occur until FDA conducts a final substantive review of the ANDA for any recent changes, and then issues an approval letter. This period of delay is simply a function of what is required for an ANDA to be approved under the statute. As described above, there are a myriad of scientific, labeling, and other requirements that an ANDA must satisfy to be approved; overcoming patent barriers is only one of many. See 21 U.S.C. §§ 355(j)(2), (j)(4) & (j)(5). . . . Even where the agency has made a tentative determination that an ANDA has satisfied the requirements of the statute, final approval is not inexorable, automatic, or instantaneous. See Barr Labs.[, Inc. v. Thompson, 238 F. Supp. 2d 236, 245-50 (D.D.C. 2002)] (affirming FDA's decision that tentatively approved ANDAs do not have a vested right to immediate approval upon patent expiry) [footnote and record citation omitted]. . . . Instead, before FDA will issue "final" approval of an ANDA, it "will examine the application to determine whether there have been any changes in the conditions under which the application was tentatively approved. [59 Fed. Reg] at 50352.

See Bhatt Decl., Exh. 6 [excerpt from FDA brief in Ranbaxy case].

These FDA procedures suggest that if the Agency prematurely converts Mylan's final approval to a tentative approval, the delay in restoring the final approval following the Federal

Circuit's ruling could be significant. Irrespective of whether it is days, a week or longer, Mylan's harm will be substantial and irreparable. McGregor Printing Corp. v. Kemp, 1992 U.S. Dist. LEXIS 6717 at *16 (D.D.C. 1992) (irretrievable monetary loss in combination with loss of employment to plaintiff's employees amounted to irreparable injury); Torpharm v. Shalala, 1997 U.S. Dist. Lexis 21983 at *13 (D.D.C. 1997) (irretrievable monetary losses that have a serious effect on plaintiff constitute irreparable harm) (citing Gulf Oil Corp. v Dep't of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981)).

The harm to Mylan would be unrecoverable because there is no remedy at law against FDA. This Court and the D.C. Circuit Court of Appeals have found irreparable harm also in situations where there is no one from whom to recover loss. Bracco Diagnostics Inc. v. Shalala, 963 F. Supp. 20, 29 (D.D.C. 1997) (when the injury is "admittedly economic" but there is no adequate compensatory or other relief, the balance tips in favor of injunctive relief); National Medical Care, Inc. v. Shalala, 1995 U.S. Dist. LEXIS 10074, at *7-8 (D.D.C. 1995); Express One Int'l, Inc. v. USPS, 814 F.Supp. 87, 91 (D.D.C. 1992) (nonrecoverable monetary loss sufficient to justify injunctive relief); O'Donnell Constr. Co. v. District of Columbia, 963 F.2d 420, 428-429 (D.C. Cir. 1992).

The kind of injury that Mylan would suffer cannot be compensated by monetary damages. Even if it could, Mylan would have no way to recoup its losses from the government, which has no financial liability for erroneous decisions in circumstances like these. See Collagenex v. Thompson, 2003 U.S. Dist. LEXIS 12523 at *33 (D.D.C. 2003).

VI. THE PUBLIC WILL BE HARMED IF A TRO IS NOT ENTERED

Not only will Mylan be irreparably harmed by the FDA's premature and unnecessary revocation of Mylan's final approval, but the public will be harmed as well. Mylan expects to

sell its amlodipine products at prices significantly lower than those of Pfizer's branded Norvasc® product. Roman Decl. at ¶ 3. For each day that Mylan is excluded from the market because of the FDA's premature revocation of final approval, the public will be deprived of the benefits of the lower prices for this important drug.

A fundamental purpose of the Hatch-Waxman amendments was to get lower-priced generic versions of expensive branded drugs to the public as quickly as possible. See Apotex Inc. v. FDA, 414 F. Supp. 2d 61, 64 (D.D.C. 2006) ("the statutory purpose [of Hatch-Waxman is to] hel[p] the public gain access to lower-cost drug products more expeditiously . . ."). Here, Mylan is ready, willing and able to launch its product. Depriving the public of this product for an indeterminate period of time merely because the FDA prematurely decides to revoke Mylan's approval based on a demonstrably improper injunction would cause unnecessary and substantial harm to the public.

VII. BALANCING THE HARMS FAVORS ENTRY OF A TRO

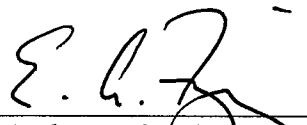
The FDA will suffer no harm as a result of a TRO ordering that it delay revoking Mylan's final approval or converting it to a tentative approval. Moreover, Pfizer will suffer no legally cognizable harm. Pfizer will, of course, lose sales of its expensive Norvasc® product to Mylan's lower cost generic product. But Pfizer cannot complain about competition when the patent that has heretofore precluded such competition has been held invalid by the Federal Circuit. Pfizer has no right to restrain competition and maintain the monopoly prices for its product based on a patent that the Federal Circuit has determined to be invalid because it is obvious over the prior art.

VIII. CONCLUSION

For the foregoing reasons, Mylan respectfully requests that its emergency application for a temporary restraining order be granted.

Dated: March 23, 2007

Respectfully submitted,



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