HellerEhrman LLP

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March 26, 2007

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: Citizen Petition: Refrain From Granting Final Approval to Further ANDAs for Amlodipine Besylate Tablets, 2.5 mg, 5 mg or 10 mg

PETITION FOR STAY OF ACTION

Mylan Pharmaceuticals Inc. ("Mylan") submits this petition pursuant to 21 C.F.R. § 10.35.

Decision Involved

This Petition for Stay of Administrative Action is being submitted to request that the Food and Drug Administration ("FDA") refrain from taking any action to issue final approval to any Abbreviated New Drug Application ("ANDA") submitted for amlodipine besylate tablets in contravention of the FDA's award of final approval to ANDA 76-418, and 180-day exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv) (2002).

Action Requested

Because Mylan Pharmaceuticals Inc. ("Mylan") is entitled to 180 days of generic marketing exclusivity for amlodipine besylate tablets, 2.5 mg, 5 mg and 10 mg ("Amlodipine"), which commenced on March 23, 2007, the FDA must not approve any additional Abbreviated New Drug Applications ("ANDAs") for generic Amlodipine products until after Mylan's 180-day exclusivity expires on September 23, 2007. 21 U.S.C. § 355(j)(5)(B) (2002).

Because other applicants may be improperly requesting final approval for their generic Amlodipine ANDAs, it is critical that the FDA immediately confirm that it will not approve any such ANDAs until Mylan's 180-day exclusivity expires. As the FDA and the courts have recognized, the 180-day exclusivity right is extremely valuable and is an integral component of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 501 *et seq.* ("FDCA"). *See, e.g., Mylan Pharms. v. Shalala*, 81 F. Supp. 2d 30, 33 (D.D.C. 2000) (explaining that Congress created the 180-day exclusivity provision to "encourage generic drug makers to incur the potentially substantial litigation costs associated with challenging pioneer

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drug makers' patents."). Any unwarranted deprivation or shortening of the 180-day exclusivity period will cause Mylan immediate and irreparable harm. Therefore, Mylan reserves the right, and intends, to take immediate legal action to enjoin any further approvals that the FDA might grant before Mylan's 180-day exclusivity expires.

Statement of Grounds

On May 22, 2002, Mylan was the first ANDA applicant to submit a substantially complete application containing a Paragraph IV certification to the patents listed in the Orange Book for the reference listed drug, Norvasc® (amlodipine besylate tablets). The NDA holder and patentee, Pfizer, did not sue Mylan within 45 days of receipt of Mylan's notice of Paragraph IV certification and, therefore, Mylan's ANDA was eligible for immediate final approval. The FDA granted final approval to Mylan's Amlodipine ANDA on October 3, 2005.

The FDA confirmed in its October 3, 2005 final approval letter that because Mylan was the first applicant to file an ANDA with a Paragraph IV certification, "Mylan is eligible for 180 days of market exclusivity." October 3, 2005 letter from Gary J. Buehler to Mylan at 2 (copy attached hereto as Exhibit 1). The FDA's approval letter further states, consistent with the plain language of the FDCA and the FDA's own regulations, that Mylan's 180-day generic marketing exclusivity "will begin to run from the earlier of commercial marketing or court decision dates identified in [21 U.S.C.] section 355(j)(5)(B)(iv)." Mylan commenced commercial marketing of its generic Amlodipine product on March 23, 2007, and notified FDA of this fact. *See* March 23, 2007 General Correspondence from Mylan to Gary J. Buehler and associated Form FDA 356h (copy attached as Exhibit 2).

Because Mylan filed its Amlodipine ANDA prior to the date of enactment of the *Medicare Prescription Drug, Improvement and Modernization Act* ("MMA") on December 8, 2003, the award of 180-day exclusivity to Mylan is governed by the version of the FDCA as in effect prior to December 8, 2003. *See* Exhibit 1 at p.2, n.2 (*citing* MMA § 1102(b)(1)). Accordingly, the statutory language of 21 U.S.C. § 355(j)(5)(B)(iv) as in effect in 2002, governs the application of 180-day generic market exclusivity to Mylan. This statutory language is plain and unambiguous and specifically provides that, once exclusivity has been granted and triggered, that exclusivity lasts for 180 days.[1] Nothing in the statute as it existed prior to December 8,

[1] At a minimum, as long as the '303 patent remains listed in the Orange Book, Mylan's 180-day exclusivity applies. It is the FDA's policy that "the Agency may approve the ANDA on the date the district court issues a judgment that the patent is invalid, unenforceable, or not infringed pursuant to a mandate issued by a court of appeals." *Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* (March 2000) at 4. Therefore, at a minimum, Mylan is entitled to be the exclusive marketer until the mandate is issued to the District Court.

2003[2], FDA's regulations, or case law interpreting the FDCA says otherwise or supports a contrary interpretation.

Although the FDA has expressed the view that eligibility for 180-day exclusivity cannot extend beyond the expiration date of the patent from which that exclusivity derives, that policy does not and cannot apply in situations where the 180-day exclusivity has already been awarded and triggered. Mylan does not request that the FDA reverse any position that it has publicly announced with respect to the effect of the 180-day exclusivity after patent expiration. Instead, the situation presented in this Citizen Petition is one that, to Mylan's knowledge, has never been addressed by the Agency. Specifically, what is the impact, if any, of patent expiration on the 180-day exclusivity afforded to a first-filed ANDA that is finally approved at the time the patent expires.

In *Dr. Reddy's Laboratories, Inc. v. Thompson*, 302 F. Supp. 2d 340 (D.N.J. 2003), the District Court approved the FDA's interpretation of §355(j)(5)(B)(iv) insofar as it relates to *tentatively* approved ANDAs. That rationale is that, upon patent expiration, a Paragraph IV certification in a tentatively approved ANDA is no longer accurate and it converts *de facto* or *de jure* to a Paragraph III certification at the moment the patent expires. *Id.* at 351. However, the FDA has made clear that a holder of a fully *approved* ANDA, like Mylan's, is under no obligation to amend a patent certification upon patent expiration. *See* Letter from Gary Buehler dated June 22, 2004 (attached as Exhibit 3) at 3 ("An application with full effective approval has no continuing obligation to update its patent certifications. *See* 21 C.F.R. 314.94(a)(12)(viii)(C) (obligation to amend certification applies before effective date of approval.)". The FDA's prior administrative rulings in situations like cisplatin (August 6, 1999) or omeprazole (November 16, 2001), involved ANDAs that were *tentatively-approved* when a patent expired, and the FDA was deciding whether a first-filer retained *eligibility* for 180-day exclusivity.

Unlike the situations that the FDA has addressed previously, Mylan's ANDA was fully approved and the 180-day exclusivity period had been triggered before patent expiration. As the Agency has previously concluded, Mylan's Paragraph IV certification did not change when the patent expired. Therefore, Mylan's ANDA fully complies with the language of §355(j)(5)(B)(iv), as it "is for a drug for which a previous application has been submitted under this subsection [containing] such [subclause IV] certification." This makes a significant difference, because § 505(j)(5)(B)(iv) makes it clear that once exclusivity has been triggered, the FDA may not approve additional ANDAs for 180 days. The FDA's previously announced positions do not and should not preclude Mylan's 180-day exclusivity extending beyond the expiration of Pfizer's patent.

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[2] The MMA included, for the first time, language to the effect that generic marketing exclusivity ends when the patent to which the Paragraph IV certification was made, and from which the exclusivity derives, expires. No such language appears in the pre-MMA version of the statute that applies to Mylan's Amlodipine ANDA.

Therefore, Mylan respectfully requests that the Agency honor the full 180-day generic marketing exclusivity to which Mylan is entitled by law, and that the FDA not approve other ANDAs for Amlodipine tablets until at least 180 days after Mylan's exclusivity was triggered, September 23, 2007.

Environmental Impact

As provided in 21 C.F.R. § 15.30 neither an environmental assessment nor an environmental impact statement is required.

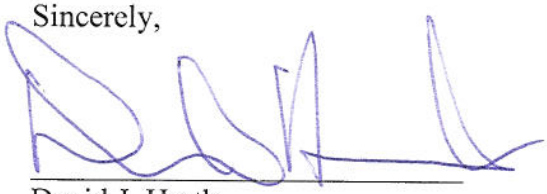
Economic Impact

As provided in 21 C.F.R. § 10.30(b) economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

Certification

The undersigned certifies that to the best of his knowledge and belief, this petition relies on and includes representative data and information known to the petitioner that is unfavorable to the petition.

Sincerely,



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