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Rec'd 5/1/07
May 1, 2007

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Food and Drug Administration
Office of Generic Drugs, HFD-600
Attn: Gary J. Buehler, Director
7519 Standish Place
Rockville, MD 20855

Re: Apotex Inc. -- ANDA 76-719 (Amlodipine Besylate Tablets)

Dear Mr. Buehler:

This letter is submitted on behalf of our client Apotex Inc. (formerly TorPharm) and addresses an issue posed in the five questions set forth in your letter to Mr. John Ley of Apotex Corp, agent for Apotex Inc.

Effective April 3, 2007, the United States District Court for the Northern District of Illinois lifted its injunction against Apotex relating to the '303 patent. *Order, Pfizer v Apotex*, No. 3-c-5289 (N.D. Ill. Mar. 29, 2007) (attached as Exhibit A). FDA may have the understanding that the injunction in the district court prevents the FDA from approving Apotex's ANDA. However, since April 3, 2007, Apotex has not been enjoined. Apotex does not know if the FDA was aware of this, and asks the FDA to issue final approval of Apotex's ANDA for amlodipine because of that fact.

In its April 18, 2007 decision, the FDA considered Mylan as having final approval despite a district court judgment against Mylan. FDA did so because the Federal Circuit had stayed the injunction against Mylan because of the Federal Circuit March 22, 2007 judgment in favor of Apotex and against Pfizer. Letter from Gary J. Buehler, Director, Office of Generic Drugs, to ANDA Holder/Applicant for Amlodipine Besylate Tablets, at 5 n.4 (Apr. 18, 2007) ("April 18 Decision Letter") (attached as Exhibit B). This is the identical situation that Apotex is in now,

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except that Apotex is the actual winner of the March 22, 2007 judgment, and the stay was by the court that issued the injunction instead of the court of appeals.

In discussing Apotex's situation in the April 18 Decision Letter, FDA indicated that a stay would be a cause for approval of Apotex. This is because FDA applies district court decisions unless they are stayed.

In FDA's view, the phrase "the court determines" in section 355a(c)(2)(B), in the context of a federal court of appeals reversing a district court judgment, should be read as the date the mandate issues for several reasons. When the district court decides a patent issue, ***FDA applies that decision, unless it is stayed, in determining issues related to ANDA approval.***

April 18, Decision Letter, at 7 (emphasis added). This analysis implies that the FDA is treating Apotex as if it were not the beneficiary of a stay. Apotex has a stay.

In its reply brief to all of the preliminary injunction motions in the district court, FDA reiterated its position that it was powerless to convert Mylan's final approval to a tentative approval because of a stay of an injunction, not the reversal or vacating of a judgment. *Government Defendants' Combined Memorandum In Opposition To Motions For Injunctive Relief Filed By Teva, Apotex, And Mylan*, at 16 (hereafter "FDA Mem.") (attached as Exhibit C). FDA also reiterated, and continued to hew to the position that it could not act ***unless the district court was stayed***. FDA Mem. at 24.

In agreement with FDA arguments, the District Court for the District of Columbia upheld FDA's denial of final approval for Apotex's ANDA, stating:

Moreover, the district court's ruling is effective and remains so during the pendency of the appeal ***unless the district court's judgment is stayed*** (either by the district court itself or the appellate court), Fed. R. App. P. 8, or until the Federal Circuit issues its mandate, *Deering Milliken, Inc. v. F.T.C.*, 647 F.2d 1124 (D.C. Cir. 1978). "[T]he vitality of [the district court] judgment is undiminished by pendency of the appeal. ***Unless a stay is granted either by the court rendering the judgment*** or by the court to which the appeal is taken, the judgment remains operative." *Id.* Therefore, the pediatric exclusivity period, triggered by the district court's ruling, remains effective ***until it is formally stayed*** or reversed.

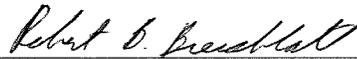
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Memorandum Opinion, Mylan v. Leavitt, No. 07-579, at 13-14 (D.D.C. Apr. 30, 2007) (attached as Exhibit D) (emphasis added).

Apotex asks FDA to immediately approve its ANDA for amlodipine besylate because Apotex has the stay that both the FDA and Judge Urbina have made a condition for approval.

We appreciate the agency's attention to this important matter. If we do not receive a response by the close of business on Wednesday, May 2, we will have no option but to assume that this request for final approval has been denied by FDA and seek appropriate relief from Judge Urbina.

Respectfully submitted,



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