CARACO PHARMACEUTICAL LABORATORIES, LTD.

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GENERAL CORRESPONDENCE

April 4, 2007

Fax and Courier

Mr. Gary J. Buehler, Director
Office of Generic Drugs
FDA/Center for Drug Evaluation & Research
Metro Park North II
7500 Standish Place
Rockville, MD 20855

Re: March 29, 2007 Letter Regarding Pending ANDAs for Amlodipine Besylate Tablets - Request for Comments

Dear Mr. Buehler:

Reference is made to your faxed letter received March 29 2007, addressed to Mr. Robert Kurkiewicz, Sr. VP, Caraco Pharmaceutical Laboratories, Ltd (Caraco), regarding our pending ANDA (#78-231) for Amlodipine Besylate Tablets 2.5 mg, 5 mg, and 10 mg. Your letter refers to the March 26, 2007 complaint filed by Mylan Laboratories, Inc. against the FDA seeking to enjoin FDA from immediately approving abbreviated new drug applications for Amlodipine Besylate products. (*Mylan Laboratories, Inc. v. Michael Leavitt, C.A No. 07-579 (RMU) (D.D.C.*). Your letter stated that FDA is soliciting comments from interested parties before rendering a decision in this matter.

As Caraco is an interested party in this matter, we welcome the opportunity to provide input regarding the issues raised in your letter. The following pages include our comments in response to each issue.

If you require additional information to assist with our request, please contact me at (313) 871-8400 ext. 103.

Sincerely,

Derrick Mann
Director, Regulatory Affairs

cc: Daniel Movens, CEO, (Caraco)
Robert Kurkiewicz, Sr. VP, Regulatory Affairs (Caraco)

Enclosure

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1. ***What date controls FDA's giving effect to the decision in Pfizer Inc. v Apotex, Inc., No. 2006-1261 (Fed. Cir. March 22, 2007) ("Apotex decision") holding that Pfizer's patent 4,879,303 ("the '303 patent") is invalid? Can FDA treat the '303 patent as invalid as of March 22, 2007, or must FDA await the issuance of the mandate? Is the answer the same for all purposes, that is, for determining the applicability of pediatric exclusivity, the triggering of 180-day exclusivity, and the eligibility of other ANDA applicants for final approval?***

Caraco Response: Triggering of exclusivity: Mylan filed its ANDA under old law. Mylan's exclusivity is triggered by its commercial launch on March 23, 2007. Because Mylan's exclusivity was triggered on March 23, 2007, it will expire on Sep 23, 2007 even if Mylan's approval is rescinded because of Pfizer's pediatric exclusivity.

Eligibility of other applicants for final approval: Other applicants become eligible under the provisions of the Act after the expiry of Mylan's exclusivity.

Pediatric exclusivity: FDA can only consider the patent to be invalid after a final decision except for a Supreme Court decision. Pfizer has a right to the pediatric extension of the patent until Sep 25, 2007 unless the mandate rejecting it's petition for a rehearing. The Act states:

> *...If the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 355 of this title, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 355(c)(3) of this title or section 355(j)(5)(B) of this title shall be extended by a period of six months after the date the patent expires (including any patent extensions).*

Therefore, FDA should await the issuance of mandate. If the mandate is against Pfizer then Mylan's ANDA becomes eligible for final approval immediately. The approval already given contravenes the above provision.

2. ***If FDA must await the issuance of the mandate, does pediatric exclusivity bar approval of all unapproved ANDAs in the meantime?***

Caraco Response: Yes

3. ***When the Apotex decision is implemented, what is the effect of the decision that the '303 patent is invalid on the obligation of an ANDA applicant to change its certification? Must Pfizer delist its patent, so that certifications can be withdrawn? Or can FDA treat an invalid patent as delisted as a matter of law, and presume the withdrawal of the certifications? Or must the ANDA applicants file paragraph II certifications stating that the '303 patent has expired?***

   Caraco Response: FDA and ANDA applicants may treat the patent as delisted if all the claims of the patent that would be individually allowable to be listed in the Orange Book are held invalid. For example, if all the product claims covering the NDA product are held invalid but process claims have not been held invalid nevertheless the patent may be treated as delisted. When Apotex decision is implemented the '303 patent may be treated as delisted as the above conditions apply.

4. ***If and when the Apotex decision is implemented and the patent is treated as invalid, does pediatric exclusivity attach to the '303 patent with respect to any unapproved ANDAs? Does it matter whether the ANDA applicant filed a paragraph III or IV certification before patent expiration?***

   Caraco Response: Because the '303 patent would be invalid and treated as delisted so also there can be no pediatric extension applied to the same.

5. ***Does 180-day exclusivity triggered before a patent expires continue to bar approvals of other ANDAs after the patent expires, even if other ANDA applicants change their certifications to paragraph II or withdraw their certifications altogether?***

   Caraco Response: Through commercial marketing Mylan triggered it's own exclusivity therefore the exclusivity will expire on Sep 23, 2007.