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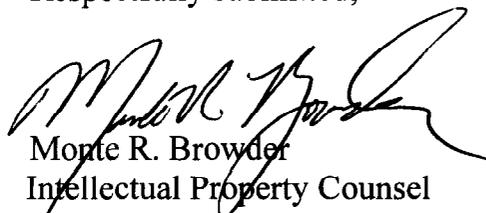
May 23, 2005

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

Re: Update to Docket No. 2005P-0008

This letter is a request to update Docket No. 2005P-0008 – Citizen Petition submitted by IVAX Pharmaceutical, Inc., (IPI), on January 5, 2005. The petition contains three (3) attachments; A, B and C. The second page of attachment B was inadvertently omitted and a copy is enclosed herewith.

Respectfully submitted,



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Intellectual Property Counsel
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Tim Gilbert

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does not claim an approved use of gabapentin in *Warner-Lambert v. Apotex, Inc.*, No. 02-1073 (Fed. Cir. Jan. 16, 2003).

The mirtazapine situation is materially different. As you note, a district court has found in private patent infringement litigation that U.S. Patent No. 5,977,099 (the '099 patent) claims only an unapproved use for mirtazapine, not an approved use for which the ANDA applicants were seeking approval. *Organon, Inc. and Akzo Nobel N.V. v. Teva Pharmaceuticals, Inc.*, C.A. 01-2682 (Dec. 18, 2002 D.N.J.); *appeal docketed*, CA 03-1218 (Fed. Cir.). In addition, on February 13, 2003, counsel for Organon notified FDA that, although Organon still believes the '099 patent meets the requirements of section 505(b) of the Act for listing in the Orange Book, "[n]onetheless, Organon herewith requests the '099 patent be removed from the Orange Book." However, unlike with the '479 gabapentin patent, there has been no admission by the patent holder to FDA that the patent does not claim an approved use. Likewise, there has been no litigation involving FDA in which the court has expressly found that a section viii statement is the correct submission for the listed patent.

You argue that the gabapentin and mirtazapine situations are nevertheless the same and require the same outcome. Your position is that, to be consistent, FDA either 1) must require all mirtazapine ANDA applicants to now change existing paragraph IV certifications under section 505(j)(2)(A)(vii) to the '099 patent to section viii statements under section 505(j)(2)(A)(viii), and deny any applicant 180-day exclusivity as to that patent, or 2) must reverse its decision that no gabapentin ANDA applicant is eligible for 180-day exclusivity as to the '479 patent.

FDA disagrees. These are not analogous situations, and do not require the same regulatory treatment. As Judge Huvette noted, the gabapentin situation involved "unique factual circumstances" that warranted special treatment by the court. In that case, the court found – in part on the basis of the use statements addressing the scope of the '479 patent – that the NDA sponsor never intended to assert that the '479 patent claims the approved use of the listed drug. In addition, as the court noted, Pfizer admitted as much in its December 13, 2002, letter to FDA. Therefore, the district court found that an ANDA applicant was entitled to file a section viii statement to that patent. In the mirtazapine case, we have no such admission to FDA by the NDA sponsor, and no specific court decision regarding the submission of a section viii statement.

Neither Judge Huvette's narrow decision based on unique factual circumstances nor FDA's January 28, 2003, decision requires a change in established FDA practice regarding 180-day exclusivity. FDA's practice under section 505(j)(5)(B)(iv) and 21 C.F.R. § 314.107(c) is to grant 180-day exclusivity to the ANDA applicant that was first to file a valid paragraph IV certification to a listed patent, and for that exclusivity to be triggered, in certain cases, by a court decision in litigation resulting from a paragraph IV certification finding the patent invalid or not infringed. If the triggering court decision finds the patent invalid, FDA will leave the patent in the Orange Book for 180 days to give the first applicant the benefit of its exclusivity. 21 C.F.R. 314.94(a)(12)(viii); 59 Fed. Reg. 50338, 50348 (Oct. 3, 1994). As FDA explained in its rulemaking, to permit removal of the patent immediately upon a court decision of patent invalidity would deprive the first applicant of the benefit for which it is eligible by being first to challenge the patent. *Id.* Similarly, it would be unreasonable to either remove the '099 patent