

## Zydus Pharmaceuticals (USA) Inc.

508 Carnegie Center, First Floor,  
Princeton, NJ 08540 USA  
Phone: 609-275-5125  
Fax: 609-716-6002

May 26, 2006

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23 (HFA-305)  
12420 Parklawn Drive  
Rockville, MD 20857

Re: Citizen's Petition to the FDA Regarding the Decision of the U.S. District Court for the District of Columbia in *Ivax Pharmaceuticals, Inc. and Ranbaxy Laboratories Ltd. v. Michael O. Leavitt, et al.* Civil Action No. 05-1838 (RWR)  
Docket Nos. 2005P-0008; 2005P-0046

### CITIZEN'S PETITION

The undersigned submits this Petition under the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301 *et seq.*, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 C.F.R., Part 5.10) to request that the Commissioner of Food and Drugs appeal the Decision of Summary Judgment awarded to Plaintiffs, Ivax Pharmaceuticals, Inc. (hereinafter "Ivax") and Ranbaxy Laboratories Limited (hereinafter "Ranbaxy"), by the Honorable Richard W. Roberts of the U.S. District Court of the District of Columbia, in Civil Action No. 05-1838 (RWR).

#### A. ACTION REQUESTED

This Petition is respectfully submitted to request that the FDA file an Appeal to the Order of U.S. District Judge Richard W. Roberts of the U.S. District Court for the District of Columbia in Civil Action No. 05-1838 (RWR) of April 30, 2006. Additionally, this Petition asks the FDA again to deny the Citizen's Petitions of Ivax and Ranbaxy and to approve all other complete simvastatin ANDAs upon expiration of U.S. Patent No. 4,444,784.

#### B. STATEMENTS OF GROUNDS

Petitioner, Zydus Pharmaceuticals USA, Inc. (hereinafter "Zydus"), a Delaware Corporation, produces and sells generic drugs by its approved ANDAs. Zydus has its corporate headquarters located in Princeton, New Jersey. By this Petition, Zydus respectfully

2006P-0241

CP1

submits that the FDA acted properly in denying the Petitions of Ivax and Ranbaxy, and that their Petitions are without merit. Zydus requests that the FDA file an Appeal, because Zydus supports the FDA's Decision that the Agency has properly de-listed the above-mentioned Patents from the Orange Book. Zydus respectfully disagrees with the Court Order granting Summary Judgment to Ivax and Ranbaxy for the following reasons: (a) Zydus believes that, through their Petitions, Ivax's and Ranbaxy's intentions are only directed to keeping other generic (simvastatin tablets) from entering the market, and to thwarting competition so that lower drug costs are not achieved; (b) moreover, the withdrawal letter of October 21, 2005 by Teva (Exhibit A) of its letter to the FDA dated June 8, 2005 (Exhibit B) in support of the FDA's Decision to de-list the Patents attests to Zydus's position that Ivax's and Ranbaxy's intent is to keep other simvastatin generics from entering the market. Zydus is suspicious that Teva withdrew its letter seeking denial of the Ivax and Ranbaxy Petitions and providing support for the FDA's de-listing of the Patents around the time it began negotiations to purchase/merge with Ivax.

Erroneously awarding the 180 day exclusivity to Ivax/Teva and Ranbaxy will effectively preclude smaller generic companies such as Zydus from having any opportunity to introduce their generic version of the drug in a fair and timely manner. Such will also not help to lower drug prices to the public, as Congress intended, and will set a bad precedent.

Merck & Co. Inc. (hereinafter "Merck") is the New Drug Application ("NDA") holder of its Zocor® (simvastatin) tablets by NDA No. 019866. In accordance with the Food, Drug and Cosmetic Act ("FDCA," 21 C.F.R. § 355(b)(1)), Merck listed three Patents with its NDA. i.e., U.S. Patents Nos. 4,444,784, RE 36,481 and RE 36,520. U.S. Patent No. 4,444,784 relates to this compound and will expire on June 23, 2006 due to a six-month pediatric exclusivity extension awarded by the FDA.

Ivax and Ranbaxy were the first Applicants to file an ANDA for simvastatin tablets, i.e., ANDA Nos. 076532 and 076285, respectively. Both Ivax and Ranbaxy filed Paragraph III Certifications with respect to U.S. Patent No. 4,444,784, and Paragraph IV Certifications with respect to U.S. Patents Nos. RE 36,481 and RE 36,520.<sup>1</sup> Merck did not file suit for Patent Infringement against any Applicant for Paragraph IV ANDA within the relevant statutorily required 45-day periods after receiving Ivax's, Ranbaxy's and other Applicants' Paragraph IV Notifications.

In a letter to the FDA dated November 3, 2003, Steven J. Lee, Esq. of Kenyon & Kenyon LLP notified the FDA pursuant to 21 C.F.R. § 314.53(f) that the information published by the FDA in the Orange Book, namely, the listing of U.S. Patents Nos. RE 36,481 and RE 36,520 with respect to Zocor®, was inaccurate and irrelevant (Exhibit C). Mr. Lee also asks the FDA to provide the letter to Applicant, Merck, to consider withdrawal of the Patents from the Orange Book, because such Patents claim metabolites of simvastatin, which

---

<sup>1</sup> The FDCA requires that an ANDA contain a Certification that each Patent listed in the Orange Book for the innovator drug. The Certification must state one of the following: I) that the required patent information relating to such Patent has not been filed; II) that such Patent has expired, III) that the Patent will expire on a particular date; or IV) that such Patent is invalid or will not be infringed by the drug, for which approval is being sought.

did not meet the requirements for patent submissions according to the proposed rules at the time (68 Fed. Reg. 36675, 33680, June 18, 2003). Following issuance of the final rule, brand name companies such as GlaxoSmithKline asked the FDA to remove listed Patents from the Orange Book for NDAs related to Paxil®, and Bristol-Myers Squibb asked the FDA to remove Patents claiming metabolites in their Buspar® and Serzone® NDAs (Exhibit D).

Merck subsequently asked the FDA to de-list U.S. Patents Nos. RE 36,481 and RE 36,520 with respect to Zocor®. In accordance with Merck's request, in September, 2004 the FDA removed U.S. Patents Nos. RE 36,481 and RE 36,520 from the Orange Book listing. As a result of de-listing the Patents, all ANDA Applicants were required to amend their Paragraph IV Certifications with respect to these two Reissue Patents, as required by 21 C.F.R. § 314.94(a)(12)(viii)(B).

On January 5, 2005, Ivax filed a Citizen Petition. On February 1, 2005, Ranbaxy also filed a Citizen Petition. In their Petitions, Ivax and Ranbaxy requested that the Food and Drug Administration reverse its Decision to de-list from the Orange Book U.S. Patent Nos. RE 36,481 and RE 36,520 for which Ivax and Ranbaxy had previously filed Paragraph IV Certifications in their respective Abbreviated New Drug Applications ("ANDA") for generic versions of Merck's Zocor® (simvastatin) tablets. Their Petitions also request that the FDA delay approval of any other ANDA Application for simvastatin tablets until 180 days after the first commercial marketing of their respective simvastatin products covered by their ANDAs. On October 24, 2005, the FDA denied their Petitions, deciding that it would not relist the disputed Patents, and reiterated its position that no Applicant was eligible for 180-day exclusivity for those Patents. It also indicated that the FDA would approve all subsequent ANDAs for simvastatin when they are otherwise eligible for approval.

In Teva's letter of June 8, 2005, signed by Deborah A. Jaskot (Exhibit B), entitled "Response to Citizen Petitions by Ivax Pharmaceuticals, Inc. and Ranbaxy Laboratories Limited," regarding their ANDAs for Zocor®, Teva requested that the FDA deny the Petitions and stated that "Ivax's and Ranbaxy's Petitions are without merit and should be denied, because the patents at issue were improperly listed in the first instance as they do not claim the listed drug." Teva also asserted that "[e]rrors that occur with respect to the listing of Patents should always be subject to correction, and should not be the basis for a 180-day exclusivity period." Teva vehemently argued that the statutory regulations only give rise to exclusivity when an ANDA contains a Paragraph IV Certification against a **reference listed drug**. Teva also asserted that the FDA had not acted inconsistently in prior de-listing situations and that incorrectly listed Patents cannot support exclusivity.

Ivax and Ranbaxy sued the FDA in September 2005, claiming that the FDA improperly nullified Ranbaxy's and Ivax's rights to a 180-day period of exclusive marketing of a generic drug. (*Ranbaxy Laboratories Ltd., et al. v. Michael O. Leavitt, et al.*, Civ. Action No. 05-1838 (RWR) (U.S. D.C., DC April 30, 2006).

In its ruling, the Court granted Ivax's and Ranbaxy's Summary Judgment Motion and denied the FDA Motion. The Court also ordered that the Decision be remanded to the FDA and stated that the Order is appealable. According to the Court, the FDA failed to give full

effect to the unambiguous intent of Congress regarding the statutory provisions with respect to de-listing of Patents. The Court concluded that the FDA acted contrary to the clear intent of Congress in its Decision to deny Plaintiffs' Citizen Petitions.

Zydus strongly believes that the Court Decision granting Summary Judgment to Ivax and Ranbaxy is completely erroneous. Zydus supports the FDA's assertions that "an ANDA application does not have a 'vested' right to exclusivity just by filing a Paragraph IV submission." As Ivax and Ranbaxy ANDAs only had tentative approval of their submissions, Zydus believes that the FDA acted correctly and in the best interest of the public by de-listing the improperly listed Patents in the Orange Book.

Zydus further supports the FDA's position that a Patent should be de-listed at the request of the NDA holder except for limited circumstances such as when it is the subject of litigation, and that even though successful defense of a Patent Infringement lawsuit is not a factor in eligibility for exclusivity, Zydus considers that the FDA is reasonable in interpreting a Patent listing and 180-day exclusivity provisions of the FDCA to permit the FDA to leave a Patent listed only when a lawsuit has been filed as a result of a Paragraph IV Certification. Zydus submits its full support to the FDA Decision to approve all ANDA Applicants upon expiration of U.S. Patent 4,444,784.

Zydus objects to an FDA Decision that would award 180-day exclusivity to Teva and Ranbaxy for their simvastatin ANDA. Teva's recent purchase of Ivax, Zydus submits, is a blatant example of how larger generic companies will keep smaller generic companies from competing in the market, and impeding the realization of lower costs for prescription drugs in the marketplace. This is evident by Teva's withdrawal of its original assertions regarding their June 8, 2005 request to the FDA to deny Ivax's and Ranbaxy's Petitions. Zydus fully supports Teva's letter of June 8, 2005 and its statements therein. As clearly stated in Teva's letter to the FDA, which Zydus supports, "Petitioners' [Ivax and Ranbaxy] position would require FDA to grant and enforce exclusivity based on Paragraph IV Certifications to patents that do not claim the listed drug. This would be legally improper and bad policy." Zydus additionally supports statements made in Teva's letter that "the clear statutory mandate precludes the interpretation proffered by the Petitioners [Ivax and Ranbaxy] by limiting 180-day exclusivity *solely* to ANDAs that contain the first Paragraph IV Certification *to a patent that claims the reference listed drug*. Specifically, the statutory exclusivity provision 21 U.S.C. § 355(j)(5)(B)(iv), gives rise to exclusivity only where an ANDA contains a certification 'described in' 21 U.S.C. § 355(j)(2)(A)(vii)(IV)." It is also Zydus's position that, where a Patent is submitted and listed incorrectly for a reference drug, and the Patent does not claim the reference drug, such as is the case for Zocor®, Zydus asserts Teva's original position that "no ANDA applicant was ever lawfully entitled to exclusivity as to the Patent. In such an instance, it is appropriate that the NDA sponsor be permitted to de-list the patent(s)."

Zydus respectfully requests that the FDA expeditiously appeal the Decision of the U.S. District Court for the District of Columbia and deny Ivax/Teva's and Ranbaxy's Petitions.

C. ENVIRONMENTAL IMPACT

The action requested by this Petition qualifies for a categorical exclusion under 21 C.F.R. § 25.31(a). Therefore, we submit, an environmental assessment is not required.

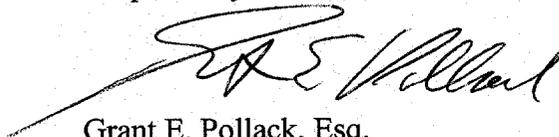
D. ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 10.30(b), information on the economic impact of this action requested by this Petition will be submitted if requested by the Commissioner.

E. CERTIFICATION

The undersigned certifies that, to the best of their knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which is unfavorable to the Petition.

Respectfully submitted,



Grant E. Pollack, Esq.  
POLLACK, P.C  
The Chrysler Building  
132 East 43rd Street, Suite 760  
New York, NY 10017  
(646) 265-1468

Attorneys for  
Zydus Pharmaceuticals USA, Inc.

Dated: May 26, 2006