

April 9, 2002

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Mr. Daniel Troy
Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane
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Re: FTC Citizen Petition
Docket No. 01P-0248

Dear Mr. Troy:

On May 16, 2001, the Federal Trade Commission submitted a citizen petition requesting confirmation of FTC's understanding of the requirements of 21 U.S.C. § 355(b)(1) and FDA's corresponding regulation (21 C.F.R. § 314.53(b) for the listing of patents in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"). FTC's petition stated that the commission was seeking FDA's guidance in connection with a broad investigation of possible anticompetitive practices in the drug industry.

On July 19, 2001, GlaxoSmithKline Corporation submitted a response to the citizen petition. On July 24, 2001, we submitted a response to the petition on behalf of Apotex, Inc.

Although the 180-day period for FDA's response to FTC's citizen petition under 21 C.F.R. § 10.30(e)(2) expired sometime ago, FDA has not yet answered the petition. FDA's silence is difficult for us to understand, because the guidance that FTC is seeking does not involve any issue that FDA has not already addressed in its regulation on the patents that are eligible for listing in the Orange Book.

FDA's regulation, 21 C.F.R. § 314.53 (b), exactly mirrors the explicit and unambiguous requirements of the statute. Under 21 U.S.C. § 355(b)(1), a patent is eligible for listing in the Orange Book only if the patent:

claims the drug for which the applicant submitted the application or claims a method of using such drug....

Under 21 U.S.C. § 355(c)(2), a patent that issues after an NDA has been approved may be listed only if the patent:

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claims the drug for which the application was submitted or claims a method of using such drug....

The focus of these subsections is obviously on the NDA and the specific characteristics of the drug substance and drug product that FDA has approved. When FDA approves an NDA, the agency approves the specific chemical entity that is the drug substance and the analytical controls required to assure its identity and purity, based upon the extensive information required by 21 C.F.R. § 314.50(d)(1). The drug product of an approved NDA is similarly defined by the detailed information required by 21 C.F.R. § 314.50(d)(2).

Neither the statute, nor FDA's regulation leaves any room for the listing of patents that claim drug substances or drug products that FDA has not approved under the NDA.

Moreover, the clear and unambiguous text of the statute exactly corresponds to Congress's objective in the Hatch-Waxman Amendments of encouraging research and innovation in the form of new drugs for the benefit of the public. It is obvious that the public does not benefit from an unapproved drug substance or drug product that may be claimed in a patent. *See, Pfizer, Inc. v. FDA*, 753 F. Supp. 17, 177 (D.Md. 1990) ("There is nothing in the legislative history to indicate that Congress intended to provide that protection [of Orange Book listing and the opportunity to file a Hatch-Waxman statutory patent infringement action] as to a product Pfizer has chosen not to make available to the American public.").

There is a striking contrast between FDA's silence in the many months since FTC filed its citizen petition and FDA's conduct in recent patent listing litigation, where the agency promptly advised the court of the relationship between the scope of an NDA approval and the propriety of the listing of a patent in the Orange Book as soon as the essential facts regarding the patent in question emerged. In *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, Nos. 01-6194-CIV and 01-6548-CIV (S.D. Fla.), the NDA-holder told the court that it was reformulating its active ingredient to correspond to a formulation consisting of a quick-release component and a delayed release component that was claimed in a recently listed patent. FDA then filed a brief in which the agency pointed out that it had not approved the new formulation and that it would require the NDA-holder to file a supplement to the NDA before any change in the original formulation was made. Federal Defendants' Notice of Change of Position, Feb. 28, 2001, at 2-3. FDA further stated that the patent in question did not claim the approved drug product as required by the statute. *Id.*

The same requisite relationship between the scope of an NDA approval and the patents that qualify for listing in the Orange Book lie at the heart of FTC's citizen petition.

Apotex supports FTC's investigation of possible anticompetitive practices in the drug industry and has a vital interest in its outcome. While Apotex has no direct knowledge of the status of FTC's investigation, Apotex is concerned that FDA's delay in responding to the citizen petition

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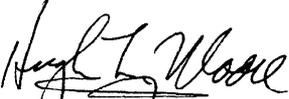
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may be delaying the progress of that investigation. Apotex urges FDA to provide a response to the citizen petition.

Pursuant to 21 C.F.R. § 10.30(d), a copy of this letter is being filed with the Dockets Management Branch for inclusion in the file in Docket No. 01P-0248.

Very truly yours,

LORD, BISSELL & BROOK



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HLM:sk

cc: Dockets Management Branch ✓
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