

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PFIZER, INC.,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,
MARK B. McCLELLAN, M.D., Ph.D.,
Commissioner, Food and Drug Administration,
and TOMMY G. THOMPSON, Secretary
of Health and Human Services,

Defendants,

and

DR. REDDY'S LABORATORIES, INC., et al.

Proposed Intervenor-Defendants.

Case No. 03-02346 (RCL)

FEDERAL DEFENDANTS' MOTION FOR STAY OF PROCEEDINGS

Federal defendants, U. S. Food and Drug Administration (FDA), Mark B. McClellan, Commissioner, FDA, and Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services (HHS), through their undersigned attorneys, move to stay the proceedings in this case. In this action, plaintiff Pfizer, Inc. (Pfizer) challenges FDA's approval of a new drug application (NDA) submitted by Dr. Reddy's Laboratories Ltd. (Reddy) for amlodipine maleate tablets (NDA 21-435) under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2) (a 505(b)(2) application). In its request for relief, Pfizer seeks a declaration that FDA's approval of NDA 21-435 was unlawful and an order vacating its approval. See Complaint, Docket Item (D.I.) 1, at 15. On February 5, 2004, FDA stayed the effective date of

the approval of NDA 21-435 to conduct a reevaluation of the basis for that approval to ensure that any approval is based on appropriate data. Once the reevaluation of the data is completed, FDA will determine whether the approval should be maintained.

Federal defendants request that the Court stay proceedings in this case to promote the efficient resolution of this case and avoid the issuance of an advisory opinion. If FDA ultimately determines that the approval of NDA 21-435 was in error and should be withdrawn, this case will be moot. If FDA reaffirms its initial approval of the NDA, it will then be able to complete the administrative record in this case and promptly proceed with litigation. As discussed below, until FDA has made such a determination and completed the administrative record, the administrative decision in this case is not yet ripe for review.

BACKGROUND

Prior to the initial approval of Reddy's product, Pfizer (and others) submitted citizen petitions to FDA challenging FDA's policies regarding section 505(b)(2) applications in general and consideration of Reddy's 505(b)(2) application for amlodipine maleate specifically. 2001P-0323/CP1 submitted by Morgan, Lewis & Bockius, LLP, on behalf of Pfizer Inc. and Pharmacia Corporation (2001 Pfizer petition) (attached as Exhibit A); 2002P-0447/CP1 submitted by Morgan, Lewis & Bockius, LLP on behalf of Pfizer Inc. (2002 Pfizer petition) (attached as Exhibit B). On October 14, 2003, FDA issued a partial response to Pfizer's citizen petitions, as well as citizen petitions filed by other parties, addressing the legal bases and policy reasons for its interpretation and application of section 505(b)(2) (October 2003 Petition Response) (attached as Exhibit C). In the October 2003 Petition Response, FDA reserved its response to the specific scientific arguments raised by certain of the petitions, including Pfizer's challenge to NDA 21-

435. See October 2003 Petition Response, Exhibit C, at 1 n.1 ("Because this application is not approved, FDA cannot comment on the scientific issues raised in this petition. (See 21 CFR 314.430.)").

On October 31, 2003, FDA approved NDA 21-435. On November 13, 2003, Pfizer filed its Complaint. See D.I. 1. Reddy moved to intervene, see D.I. 4, and the federal defendants have filed their Answer, see D.I. 5. The parties have discussed filing cross-motions for summary judgment after FDA's submission of the administrative record. At this point in the litigation, however, the record has not been filed and no party has filed a motion on the merits of the case.

During the course of preparing its Citizen Petition response to Pfizer's scientific challenge to NDA 21-435 and collecting the administrative record for the response, FDA became aware that a first line reviewer made reference to certain studies of Pfizer's in the documentation of his review of NDA 21-435. In light of this discovery, FDA determined that it should reevaluate whether the approval of NDA 21-435 was based upon data from appropriate sources. Thus, on February 5, 2004, FDA issued an Administrative Stay of Approval (attached as Exhibit D) pending its reevaluation of the source of the data FDA relied on in approving NDA 21-435. If FDA determines upon reevaluation that the approval of NDA 21-435 is appropriate, FDA will promptly complete its Citizen Petition response to Pfizer's scientific challenge to FDA's approval of NDA 21-435 and will lift the Administrative Stay.

Both Pfizer, the plaintiff, and Reddy, the proposed intervenor, have asked FDA to provide a deadline by which the reevaluation process will be complete. FDA has informed the parties it intends to conduct the process expeditiously, but cannot provide a definitive time for its completion. However, at this time, FDA anticipates that the process will be completed within

approximately two months. Pfizer had informed the federal defendants that it could not take a position on the motion to stay without a commitment by the federal defendants regarding the length of the stay. Reddy opposes a stay as proposed by the federal defendants and is not prepared at this time to agree to a stay of any set duration.

DISCUSSION

A stay of proceedings will promote judicial efficiency, avoid the potential for an advisory opinion, and serve the interests of justice. As noted above, if FDA determines that NDA 21-435 should not have been approved and proceeds to withdraw the approval, this case will be moot. If FDA reaffirms its initial approval of the NDA, it will then be able to complete its Citizen Petition response to Pfizer's challenge to FDA's approval of NDA 21-435 and the administrative record for that response. That, in turn, will allow FDA to complete and file the administrative record for this case. Once the administrative record is submitted, this case will be ready for summary judgment briefing. By contrast, any briefing now would be conducted on an incomplete record.

Proceeding with the case prior to the completion of the administrative record would be contrary to the ripeness doctrine. "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Pfizer v. Shalala, 182 F.3d 975, 978 (D.C. Cir. 1999) (citations omitted). Thus, the ripeness requirement serves "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Id. (citations omitted). Those requirements will not be

met for the purposes of this litigation until FDA completes its reevaluation of the basis for approval of Reddy's NDA.

Under controlling law, where FDA's determination on an approval decision is not certain, a claim by one of the applicant's competitors that FDA violated the law during the approval process is not yet ripe. See, e.g., id. at 978-79 (Pfizer's challenge of FDA's acceptance of a drug application for processing is not ripe for review until approval decision is made). This legal conclusion is based on several grounds. First, FDA's future actions could make judicial review unnecessary. See id. at 979. Second, premature judicial review could deprive the agency of the opportunity to apply its expertise and correct any mistakes it may have made. See id. Third, a competitor cannot claim economic injury required to sustain the action until FDA has made a final determination on the approval decision. See id. All of these grounds apply to the instant case.

