IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COBALT LABORATORIES, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 08 CV 798 (RBW)
FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants.	)	

ROXANE LABORATORIES' MOTION TO INTERVENE

Pursuant to Rule 24 of the Federal Rules of Civil Procedure, Plaintiff Roxane Laboratories, Inc. ("Roxane") respectfully moves this Court for leave to intervene to protect its interests in the above-referenced action. In support of this motion, Roxane is submitting a memorandum of points and authorities and a proposed order.[1]

Counsel for Roxane has notified plaintiffs Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals, Inc. (collectively, "Cobalt") and defendants Food and Drug Administration, Michael O. Leavitt and Andrew von Eschenbach (collectively, "FDA") of its intention to seek to intervene in this matter. Both FDA and Cobalt have consented to Roxane's intervention in this case.

[1] Federal Rule of Civil Procedure 24(c) and Local Civil Rule 7(j) require that this Motion be accompanied by a pleading that sets "the claim or defense for which intervention is sought." Roxane is filing its opposition to Cobalt's Motion for Temporary Restraining Order tomorrow. That opposition sets forth Roxane's substantial interest in this case and the legal arguments that Roxane will be making to protect those interests.

Dated: May 8, 2008

Respectfully submitted,

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FOR THE DISTRICT OF COLUMBIA

COBALT LABORATORIES, INC., *et al.*, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 08 CV 798 (RBW)

ROXANE LABORATORIES' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION TO INTERVENE

I. INTRODUCTION

Pursuant to Rule 24 of the Federal Rules of Civil Procedure, Roxane Laboratories, Inc. ("Roxane") respectfully moves to intervene to protect its interests in this very important case.

Roxane is a generic drug manufacturer with an approved abbreviated new drug application ("ANDA") for a generic form of Precose® (acarbose), a drug to treat Type II diabetes. Plaintiffs Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals, Inc. (collectively, "Cobalt") have brought this action seeking an order that Defendants Food and Drug Administration, Michael O. Leavitt, and Andrew von Eschenbach (collectively, "FDA") to compel FDA to withdraw its May 7, 2008 approval of Roxane's ANDA on the ground that 1) such approval is barred by the 180 days of marketing exclusivity that Cobalt believes it has earned; and 2) on May 7, FDA wrongly denied a citizen petition filed by Cobalt that argued that FDA may not approve any ANDA for acarbose absent certain scientific data (the "Cobalt Petition").

FDA's May 7 actions comply with the Federal Food, Drug and Cosmetic Act ("FFDCA"). Cobalt's challenge to those decisions threatens Roxane with immediate, substantial, and irreparable economic harm that will result from further delay in Roxane's ability to market its generic acarbose. Because Roxane is uniquely situated to address the harm to it that would be caused by entry of a temporary restraining order, it has an important interest in the outcome of this litigation that is not adequately represented by FDA.

Roxane's motion to intervene is timely, and its participation as an intervenor would not prejudice the interests of the other parties in this case. Consistent with the facts of this case and extensive precedent granting intervention in closely analogous circumstances, the Court should grant Roxane's intervention of right under Fed. R. Civ. P. 24(a)(2), or alternatively, permissive intervention under Fed. R Civ. P. 24(b).

II. BACKGROUND

A. Factual Background

On September 6, 1995, FDA approved Bayer Pharmaceuticals' new drug application (NDA No. 20-482) for acarbose tablets under the brand name Precose®. As part of that application, Bayer submitted to FDA information about a patent, patent number 4904769 ("the '769 patent"), that Bayer had obtained for Precose®.[1] As required by statute, FDA listed such patent information in its publication, the Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book").

On March 22, 2005, Cobalt submitted to FDA the first substantially complete ANDA for a generic version of Precose®. Cobalt's ANDA also contained a "Paragraph IV" certification for acarbose tablets, making it initially eligible for 180 days of generic exclusivity upon approval.

[1] The '769 patent had an original expiration date of February 27, 2007. The expiration date was later extended to September 6, 2009.

On August 30, 2006, Roxane submitted its ANDA for acarbose tablets. Roxane included a Paragraph IV certification that the '769 product was invalid, not infringed, and unenforceable. On December 20, 2006, Bayer filed with the United States Patent and Trademark Office a notice of disclaimer for all claims in the '769 patent. *See* http://www.uspto.gov/go/og/2007/week09/patdisc.htm (notice posted on Feb. 27, 2007). Consistent with that action, on April 16, 2007, Bayer requested that FDA withdraw the '769 patent from the Orange Book. FDA noted that request in the Orange Book section of its website. *See* Orange Book Precose® Data; Telefax from Gary J. Buehler, Director, Office of Generic Drugs, Ref. No. OGD #07-1254 (Sept. 26, 2007).

In August 2007, Roxane's application was proceeding through the regulatory review process at FDA and all pending questions from FDA had been answered. From the Agency's response and communications regarding Roxane's acarbose ANDA, Roxane reasonably believed that FDA soon would approve the application for marketing. Roxane therefore prepared to be ready to market its product at the earliest possible time should the first Paragraph IV filer forfeit its exclusivity by failing to market its product on or before September 22, 2007. Accordingly, between August and October 2007, Roxane proceeded with commercialization activities, investing over $1 million to prepare commercial inventory for launch.

By September 22, 2007, 30 months after the filing of Cobalt's ANDA for acarbose, FDA had not given Cobalt marketing approval for its ANDA, and therefore Cobalt had not commenced marketing acarbose tablets. This 30-month period is significant, because this is the date upon which FDA has ruled that Cobalt forfeited its exclusivity.

On November 9, 2007, about six weeks *beyond* its 30-month deadline to market its acarbose product or forfeit 180-day exclusivity, Cobalt filed its citizen petition, which argued

that FDA may not approve an acarbose ANDA that does not contain data demonstrating *in vivo* bioequivalence[2] to the reference listed drug, Precose®. Cobalt simultaneously petitioned FDA to stay approval of any acarbose ANDAs without such data.

On January 15, 2008, FDA informed Roxane that the Agency would not grant final approval on its ANDA until it considered and resolved the issues raised by the Cobalt Petition. *See* Letter from Gary Buehler, OGD, to Roxane (Jan 15, 2008). Under FFDCA § 505(q), FDA was required to rule on the Cobalt Petition within 180 days of its submission, a period that ended May 7, 2008. *See* 21 U.S.C. § 355(q).

On May 7, 2008, FDA denied the Cobalt Petition and confirmed that Cobalt (or any other party) is no longer eligible for 180-day exclusivity for acarbose. That same day, FDA gave final approval to the acarbose ANDAs for both Roxane and Cobalt.

On May 8, 2008, Cobalt filed the above-captioned action, challenging FDA's May 7 decisions. Roxane therefore seeks to intervene in this action because it has a substantial interest in protecting its ability to immediately begin commercial marketing of its acarbose tablets.

III. ARGUMENT

Roxane has a substantial interest in the outcome of this case and meets the standard for both intervention of right and permissive intervention under Fed. R. Civ. P. 24, as discussed below. This Court should grant Roxane's motion to intervene.

[2] The FFDCA defines two drugs as "bioequivalent" when their respective rates and extent of absorption do not differ significantly when administered in the same dose under similar experimental conditions. *See* 21 U.S.C. § 355(j)(8)(B)(i). *In vivo* data derive from tests performed using a whole living organism.

A. Roxane Should Be Permitted to Intervene as of Right.

Federal Rule of Civil Procedure 24(a) provides:

> (a) Intervention of Right. On timely motion, the court must permit anyone to intervene who: . . .
>
> (2) claims an interest relating to the property or transaction that is the subject of the action, and is so situated that the disposition of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.

Fed R. Civ. P. 24(a). A non-party has a right to intervene under Rule 24(a)(2) if four requirements are met: (1) the application to intervene is timely; (2) the applicant has demonstrated a legally protectable interest in the action; (3) the action threatens to impair that interest; and (4) no party to the action will be an adequate representative of the applicant's interests. *Smoke v. Norton*, 252 F.3d 468, 470 (D.C. Cir. 2001); *see also Schoenborn v. WMATA*, 247 F.R.D. 5, 7 (D.D.C. 2007) (noting four elements of standard for intervention of right). All of those requirements are satisfied here.

This Court routinely allows generic and brand name drug companies to intervene to protect their interests in cases where a party seeks to enjoin FDA from enforcing a decision regarding a generic drug product. *See, e.g., Collagenex Pharm. v. Thompson*, 2005 WL 256561 (D.D.C. Jan. 19, 2005); *Biovail Corp. v. FDA*, 519 F. Supp. 2d 39 (D.D.C. 2007); *Apotex, Inc. v. FDA*, 508 F. Supp. 2d 78 (D.D.C. 2007); *Mylan Pharms. Inc. v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000). It should do so here as well.

1. Roxane's Motion is Timely.

Cobalt filed this action on May 8, 2008. Roxane is filing this motion to intervene within hours of the time that it learned that the suit was filed. Therefore, this motion is timely filed.

2. Roxane Has a Substantial Interest in this Case and the Action Could Impair That Interest.

Roxane's interest in the outcome of this case is clear: this litigation directly affects Roxane's ability to market its acarbose tablets. While FDA is the named defendant, it is Roxane that will suffer direct, substantial, and irreparable injury from of an injunction or TRO against the Agency. If Cobalt obtains relief requiring that FDA withdraw its approval of the Roxane acarbose ANDA, from either FDA's decision recognizing the forfeiture of 180-day exclusivity for acarbose or FDA's decision to deny the Cobalt Petition, Roxane will remain unsold and unavailable to the consumer.

Roxane is ready – right now – to enter and compete vigorously in this market. Indeed, it has already begun commercialization activity. As described in the Paoletti Declaration, if Cobalt's suit or a TRO causes FDA to withdraw marketing approval for Roxane's ANDA, Roxane will suffer millions dollars of irrecoverable loss of profits and other economic injury. A TRO or adverse decision on the merits of Cobalt's suit will substantially diminish – if not eliminate altogether – any market advantage Roxane earned through diligent pursuit of final approval by September 2007 and its efforts to commence marketing of its generic acarbose immediately upon approval. Thus, Roxane has significant financial and competitive interests that may be significantly affected by an adverse outcome of this litigation. Its motion to intervene should be granted so that it can protect its business, market, and competitive interests.

3. Roxane's Interests Will Not Be Protected by the Parties in the Absence of Intervention.

Roxane's interests will not be adequately protected by the existing parties if Roxane is not permitted to intervene. Roxane will bring specific knowledge and perspective to this case that would be absent without its intervention. For example, one of the elements that the Court will consider in deciding whether a grant of Cobalt's temporary restraining order ("TRO") is warranted is the harm suffered by the parties. Roxane will be the party that suffers substantial irreparable harm, both economically and to its standing in the market, if a TRO is granted, and Roxane is in the best position to present evidence of that harm to the Court. *See generally* Paoletti Declaration. Roxane therefore is uniquely situated to demonstrate the imminent harm it will suffer should the Court grant the relief Cobalt seeks.

Moreover, Roxane has a wealth of knowledge available to it regarding the testing it performed to establish the safety of its product, an issue that will be at the forefront of the argument regarding FDA's denial of the Cobalt Petition. Roxane has spent years developing its generic form of acarbose and it stands ready to provide necessary information to the Court in support of FDA's determination that the Cobalt Petition was without merit and that denial of the Cobalt Petition is consistent with the agency's past, considered scientific judgment that it has applied to numerous product applications, including Roxane's acarbose ANDA. Indeed, it is likely that submissions to the Agency by Roxane will comprise a substantial portion of the administrative record.

Finally, Roxane will present the Court with evidence about its reliance on past Agency practice in developing and perfecting its acarbose ANDA. Roxane therefore offers the Court a perspective as a regulated entity – one that has pursued and met well-established Agency

standards for the very drug at issue – on the critical importance to its own business planning and decisions of consistent Agency decisions.

For all of the foregoing reasons, Roxane is the best source of information that will be critical to the Court's decision in this case.

4. Roxane's Intervention Will Not Prejudice Any of the Parties.

Roxane's intervention will not prejudice any party to this litigation. Roxane's motion is timely and will not delay the proceedings, nor will it present any obstacle in the fair adjudication of all of the relevant issues. The absence of any prejudice to the parties and Roxane's significant interest in this case support a grant of Roxane's motion to intervene as of right.

B. If This Court Denies Intervention as of Right, It Should Grant Permissive Intervention.

If this Court denies Roxane's motion to intervene as of right, Roxane requests that the Court exercise its discretion to allow permissive intervention.

Roxane plainly meets all of the requirements for permissive intervention. *See* Fed. R. Civ. P. 24(b)(2). First, Roxane's motion is timely filed, as noted above. Second, the claims of Roxane and the existing parties have questions of law and fact in common: this case is about the FDA's approval of Roxane's ANDA for acarbose, based entirely on facts already in the administrative record.

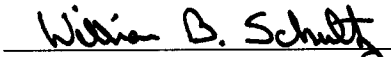
Permissive intervention is discretionary with the Court. In exercising its discretion, the Court considers whether intervention will unduly delay or prejudice the adjudication of the rights of the existing parties. Fed. R. Civ. P. 24(b). As previously discussed, Roxane's participation in this case will neither delay these proceedings nor will it create any prejudice for either existing party.

IV. CONCLUSION

For the foregoing reasons, Roxane respectfully requests that this Court allow its intervention in this case. If the Court denies Roxane's motion to intervene as of right, Roxane requests that this Court grant permissive intervention.

Dated: May 8, 2008

Respectfully submitted,



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