IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. KATHLEEN SEBELIUS, et al., Defendants.	Case No. 1:09-cv-01111 (RMC)

MOTION OF APOTEX, INC. TO INTERVENE AS A DEFENDANT

Apotex, Inc. ("Apotex") respectfully requests that this Court permit it to intervene as a defendant in this lawsuit pursuant to Fed. R. Civ. P. 24(a)(2), or in the alternative, Rule 24(b)(1)(B).

In this case the plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") seeks a declaration that it has not forfeited 180-day exclusivity for its Abbreviated New Drug Applications ("ANDAs") for generic Cozaar® (losartan potassium) and Hyzaar® (losartan potassium hydrochlorothiazide). Teva Pharmaceuticals USA, Inc.'s Mot. for Prelim. Injunctive Relief. The relief Teva seeks would prevent the U.S. Food and Drug Administration ("FDA") from approving other generic drug applications for losartan until 180 days after Teva brings its product to market.

Apotex has filed ANDAs seeking approval to market its generic losartan potassium and losartan potassium hydrochlorothiazide products and expects that FDA will approve its ANDA in time to launch its products in April 2010. If Teva were to obtain the exclusivity it seeks, Apotex would not be able to sell its losartan products for six months beyond April 2010. Apotex

will be harmed by this delay while Teva enjoys a monopoly as the sole supplier of generic losartan.

Apotex makes this timely motion to intervene to safeguard its legal and economic interests in the outcome of this litigation. Those substantial interests may be impaired unless Apotex is entitled to participate in this case. FDA, as a regulatory authority, cannot be expected to represent fully Apotex's interests. Teva and Apotex interests' are directly adverse. Thus, Teva does not adequately represent Apotex's interests.

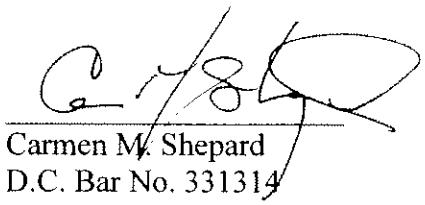
If the Court grants Apotex's motion to intervene, Apotex will not seek to delay the proceedings. If its motion to intervene is granted, Apotex intends to abide by the current schedule and is submitting an opposition to Teva's pending motion for preliminary injunctive relief today.

Apotex's counsel has advised Teva's counsel and counsel for FDA that it intends to file this motion to intervene. FDA does not oppose this motion to intervene. Teva's counsel has stated that Teva opposes Apotex's motion to intervene and intends to file an opposition.

For the reasons set forth above, and explained more fully in the accompanying Memorandum of Points and Authorities, Apotex respectfully requests that this Court grant its motion to intervene.

Dated: July 1, 2009

Respectfully submitted,



Carmen M. Shepard
D.C. Bar No. 331314
Kate C. Beardsley
D.C. Bar No. 416806
Buc & Beardsley, LLP
919 Eighteenth Street, N.W.
Suite 600
Washington, D.C. 20006
(202) 736-3600

Counsel for Apotex, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. KATHLEEN SEBELIUS, et al., Defendants.	Case No. 1:09-cv-01111 (RMC)

MEMORANDUM OF POINTS AND AUTHORITIES IN
SUPPORT OF MOTION BY APOTEX, INC. TO INTERVENE

Apotex, Inc. ("Apotex") has moved to intervene in this action because it has an interest in the subject matter of this action, its interest may be impaired by disposition of the action, and its interest is not adequately represented by the existing parties. As explained below, Apotex has submitted Abbreviated New Drug Applications ("ANDAs") to market generic losartan potassium ("losartan") tablets and losartan potassium hydrochlorothiazide tablets ("losartan HCTZ"). Its ANDAs are under review by FDA and Apotex expects to receive approval to begin marketing its losartan and losartan HCTZ products when the brand name's patent and associated exclusivities expire on April 6, 2010. Teva Pharmaceuticals USA, Inc. ("Teva") also anticipates approval of its ANDAs for losartan and losartan HCTZ by April 2010. Teva brings this action seeking a declaration that Teva has not forfeited, and therefore is entitled to, an award of 180-day generic drug marketing exclusivity that would enable it to be the sole supplier of generic losartan and losartan HCTZ and would prevent Apotex and other competitors from marketing generic losartan products for an additional six months beyond April 2010.

Denying Apotex the opportunity to market its product beginning in April 2010 and instead awarding Teva the opportunity to be the exclusive marketer of generic losartan potassium products for six months would significantly harm Apotex and consumers. Because the remedy sought by Teva would deprive Apotex of a right to market product beginning in April 2010, Apotex is entitled to intervene as of right pursuant to Fed. R. Civ. P. 24(a). Apotex also satisfies the standards of Fed. R. Civ. P. 24(b) for permissive intervention.

I. Factual Background.

Teva and Apotex market generic drugs. Before a company can market a generic drug, it must submit to FDA, and FDA must approve, an abbreviated new drug application ("ANDA"). 21 U.S.C. § 355(j). Both Teva and Apotex have submitted ANDA applications for generic losartan drug products. Declaration of Ellen Gettenberg ("Gettenberg Dec.") ¶ 10; Complaint ¶¶ 54-55. No ANDA has received final approval from FDA, but both Apotex and Teva expect that FDA will approve their respective ANDAs in April 2010. See id.

Both Teva's and Apotex's drugs are generic versions of Merck's drugs, Cozaar® and Hyzaar®. When a brand company obtains FDA approval for a drug, it must file the patents that it believes claim the approved drug. See 21 U.S.C. § 355(b)(1). Merck originally filed three patents with FDA as claiming each losartan drug but subsequently requested that FDA withdraw one patent, U.S. Patent No. 5,608,075 ("the '075 patent") from the list of patents that claim Cozaar and Hyzaar.

An ANDA applicant may be eligible for a 180-day period of exclusive generic marketing if it is the first to challenge a patent that the innovator company has filed with FDA as claiming the drug which is the subject of the ANDA. See 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity will be forfeited, however, if certain conditions are not met. See 21 U.S.C. § 355(j)(5)(D). Teva

believes that it was the first to challenge the '075 patent that Merck has withdrawn, and is therefore entitled to 180 days as the only generic marketer of losartan. Complaint ¶ 56.

Under the Hatch Waxman provisions, an ANDA applicant that becomes eligible for 180-day exclusivity will forfeit exclusivity if it fails to market the drug within certain definite time periods. In this case, Teva has forfeited any claim to exclusivity based on the '075 patent because it did not market any of its losartan drug products within the statutory window. As a result, there will be full competition for generic losartan and losartan HCTZ products. FDA can approve all otherwise eligible ANDAs once the relevant patent and associated exclusivities for Cozaar and Hyzaar expire in April 2010.

Apotex has already begun to commit significant human and capital resources preparing for the anticipated launch of its losartan products. If Teva prevails in this litigation and is able to obtain a declaration that it has not forfeited and therefore is entitled 180-day exclusivity for its losartan and losartan HCTZ ANDAs, approval of Apotex's ANDAs will be delayed for six months while Teva is the sole marketer of these generic losartan products. Teva will reap a windfall at the expense of Apotex and other competitors. The harm to Apotex from a six month exclusion from the market will be serious and irreparable. Even the grant of a preliminary injunction will harm Apotex.

II. Legal Standard for a Motion to Intervene.

Federal Rule of Civil Procedure 24 sets forth the requirements for intervention as of right and permissive intervention. In relevant part, Rule 24(a) provides that:

> On timely motion, the court must permit anyone to intervene who [...] claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing 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)(2). Thus, a prospective intervenor must be permitted to intervene if the applicant claims an interest in the subject matter of the case, if the disposition of the case stands to impair that interest, and if the applicant's interest is not adequately represented by the existing parties. Acree v. Republic of Iraq, 370 F.3d 41, 49 (D.C. Cir. 2004). Alternatively, an applicant may be permitted to intervene pursuant to Rule 24(b)(1)(B) if its claim shares a question of law or fact in common with the underlying action and if the intervention will not unduly delay or prejudice the rights of the original parties. Id. These requirements for intervention are construed liberally in favor of intervention. Wilderness Soc'y v. Babbitt, 104 F. Supp. 2d 10, 18 (D.D.C. 2000) ("[T]he D.C. Circuit has taken a liberal approach to intervention . . . .").

As shown below, Apotex has met the requirements for intervention as of right under Rule 24(a)(2) and for permissive intervention under Rule 24(b)(1)(B).

III. Apotex Has An Interest in the Subject Matter of the Case Which Could Be Impaired by Disposition of This Case.

Apotex has a substantial interest in this action because it has pending ANDAs for generic losartan and is preparing to launch its losartan products immediately upon approval. This commercial and legal interest constitutes an interest in the property or transaction which is the subject of the action sufficient to satisfy Rule 24(a)(2). This Court has routinely allowed competing drug manufacturers to intervene in actions involving FDA drug approval and exclusivity decisions so that manufacturers may protect their unique and substantial interests. See, e.g., Hi-Tech Pharmacal Co. v. FDA, 587 F. Supp. 2d 1 (D.D.C. 2008); Mylan Labs., Inc. v. Leavitt, 495 F. Supp. 2d 43 (D.D.C. 2007); Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26 (D.D.C.

2006); Torpharm, Inc. v. Thompson, 260 F. Supp. 2d 69 (D.D.C. 2003), aff'd sub nom., Puerpac Pharm. Co. v. TorPharm Inc., 354 F.3d 877 (D.C. Cir. 2004); Purepac Pharm. Co. v. Thompson, 238 F. Supp. 2d 191 (D.D.C. 2002), aff'd sub nom., 354 F.3d 877; Teva Pharms., Indus., LTD v. FDA, 355 F. Supp. 2d 111 (D.D.C. 2004). See also Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1074-1076 (D.C. Cir. 1998).

If Teva prevails in this action, Apotex's interest will be impaired. To determine whether an interest will be impaired, the court must look at the "'practical consequences' of denying intervention . . . ." Fund for Animals, Inc. v. Norton, 322 F.3d 728, 735 (D.C. Cir. 2003), quoting Natural Resources Defense Council v. Costle, 561 F.2d 904, 909 (D.C. Cir. 1977). In this case, if Teva were to prevail, Apotex's launch of its losartan products would be delayed by six months, while Teva would enjoy a period of marketing exclusivity. Apotex would be harmed as a result of its inability to market both through the immediate loss of sales, as well as suffer long term harm as the result of the head start Teva would receive from any award of exclusivity. See Gettenberg Dec. ¶¶ 14-18. Apotex, therefore, would face the immediate loss of substantial revenue that would likely be unrecoverable. The injury to Apotex is fairly traceable to the regulatory action Teva seeks to compel – an award of 180-day exclusivity for its losartan products. A decision rejecting Teva's legal challenge would prevent that loss from occurring. Thus, Apotex can demonstrate both the substantial interest and impairment necessary to satisfy Rule 24(a)(2).

IV. Apotex's Interest Is Not Adequately Represented By the Existing Parties.

The requirement that an intervenor show that the existing defendants do not adequately represent the proposed intervenor is not onerous. Dimond v. District of Columbia, 792 F.2d 179, 192 (D.C. Cir. 1986). An intervenor need only show that representation of its interest "may be"

inadequate – not that it will in fact be inadequate, id., and the burden of making this showing is "minimal," Trbovich v. United Mine Workers of Am., 404 U.S. 528, 538 n.10 (1972) (citing 3B James W. Moore et al., Moore's Federal Practice ¶ 24.09-1 [4] (1969)). Apotex amply satisfies this showing.

First, the plaintiff's interests in obtaining exclusivity for its product are squarely adverse to Apotex. Teva seeks to deny Apotex its entitlement to begin marketing its losartan products beginning in April 2010. Accordingly, it does not in any way represent Apotex's interests.

Second, FDA represents a different set of interests from those Apotex seeks to protect. Apotex, and presumably FDA if FDA determines Teva is not entitled to exclusivity, will seek to show that the plaintiff's arguments are inconsistent with the Hatch Waxman scheme, language, legal precedent, and Congressional intent. Nevertheless, FDA has neither a commercial nor financial interest in this case. Its interest lies in exercising the authority delegated by Congress. Apotex, by contrast, has an independent commercial and financial interest in the outcome of this case. As the D.C. Circuit has concluded, "governmental entities do not adequately represent the interests of aspiring intervenors." Fund for Animals, 322 F.3d at 736; see also People for the Ethical Treatment of Animals v. Babbitt, 151 F.R.D. 6, 8 (D.D.C. 1993).

V. Apotex's Motion is Timely and Will Not Unduly Delay the Proceedings.

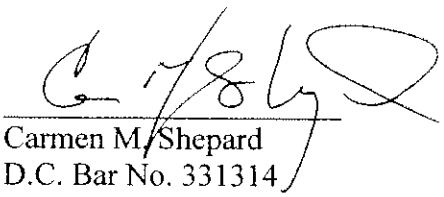
The last requirement for intervention is that the intervention be timely. In this case, there can be no doubt that Apotex's motion is timely. Apotex filed this motion within days after learning that Teva filed this suit. Apotex is prepared to comply with the briefing schedule set by this Court. Accordingly, there will be no delay from granting Apotex's motion to intervene.

Conclusion

For the reasons set forth above, Apotex meets the test for intervention as of right and its motion to intervene should be granted. In the alternative, the Court should allow Apotex to intervene pursuant to Rule 24(b)(1)(B).

Dated: July 1, 2009

Respectfully submitted,



Carmen M. Shepard
D.C. Bar No. 331314
Kate C. Beardsley
D.C. Bar No. 416806
Buc & Beardsley, LLP
919 Eighteenth Street, N.W.
Suite 600
Washington, D.C. 20006
(202) 736-3600

Counsel for Apotex, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the Motion of Apotex, Inc. to Intervene as a Defendant, the Memorandum of Points and Authorities in Support of Apotex, Inc.'s Motion to Intervene, Proposed Order, the Answer of Proposed Intervenor-Defendant Apotex, Inc., the Opposition of Apotex, Inc. to Plaintiff Teva Pharmaceuticals USA, Inc.'s Motion for Preliminary Relief, exhibits annexed thereto, Proposed Order, and Certificate Under LCvR 7.1, were served today, July 1, 2009, as follows:

By first class mail, postage pre-paid, and by electronic mail upon:

Jay P. Lefkowitz, P.C.
Michael D. Shumsky, Esq.
Gregory L. Skidmore, Esq.
Kirkland & Ellis, LLP
655 15th Street, NW
Washington, D.C. 20005
e-mail: jlefkowitz@kirkland.com
e-mail: mshumsky@kirkland.com
e-mail: gskidmore@kirkland.com

Drake S. Cutini, Esq.
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 307-0044
e-mail: drake.cutini@usdoj.gov

Michael M. Landa, Esq.
Acting Chief Counsel
Eric M. Blumberg, Esq.
Deputy Associate General Counsel
Elizabeth Dickinson, Esq.
Shoshana Hutchinson, Esq.
Office of Chief Counsel
Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-7138
e-mail: michael.landa@fda.hhs.gov
e-mail: eric.blumberg@fda.hhs.gov
e-mail: elizabeth.dickinson@fda.hhs.gov
e-mail: shoshana.hutchinson@fda.hhs.gov

Carmen M. Shepard