UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, Inc. Plaintiff, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services; MARGARET HAMBURG, M.D., in her official capacity as Commissioner of Food and Drugs; UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants;	Case No. 1:09-cv-01111-GK

TEVA PHARMACEUTICALS USA, INC.'S OPPOSITION TO APOTEX, INC.'S MOTION TO INTERVENE

This Court should deny Apotex's motion to intervene in this case. Apotex's generic losartan potassium ANDAs have not yet received "tentative approval" from FDA, meaning that Apotex has yet to prove that either of the company's proposed generic products is bioequivalent to its brand-name counterpart, or that either of those products meets the other stringent standards for obtaining the final, effective approval required to market a generic drug. At this stage, the prospect that Apotex's ANDAs will ever be approved by FDA—much less that Apotex's ANDAs will be approved before the conclusion of Teva's exclusivity periods for these products—is purely speculative. Accordingly, Apotex lacks standing to intervene in this action as of right or by permission of the Court. If Apotex would like to express its views on the merits, it is free to participate as an *amicus curiae*. But it has no business assuming party status, because it has no legal standing to exercise the rights to which intervening parties otherwise are entitled.

ARGUMENT

Apotex properly notes that in order to intervene as of right, an applicant must satisfy several prerequisites: (1) the motion must be timely; (2) the applicant must claim an interest in the subject matter of the case; (3) the disposition of the case must threaten to impair that interest, and (4) the applicant's interest must not adequately be protected by the existing parties. Apotex Mem. 4; *see also Fund for Animals v. Norton*, 322 F.3d 728, 731 (D.C. Cir. 2003); *Van Valin v. Locke*, --- F. Supp. 2d ----, 2009 WL 1796773, at *8 (D.D.C. June 25, 2009); Fed. R. Civ. P. 24(a). In addition, as Apotex notes in part, permissive intervention under Rule 24(b) may be granted—in the Court's discretion—if the applicant's claims share a common question of law with the underlying action and if intervention will not cause undue delay or prejudice to the existing parties. Apotex Mem. 4; *see also Nat'l Ass'n of Home Builders v. U.S. Army Corp of Eng'rs*, 519 F. Supp. 2d 89, 93 (D.D.C. 2007).

What Apotex fails to mention, however, is that intervention is not permitted under either Rule 24(a) or Rule 24(b) unless the proposed intervenor also has Article III standing to pursue the claims it wishes to raise. As the D.C. Circuit has long held, "because a Rule 24 intervenor seeks to participate on an equal footing with the original parties to the suit, [it] must satisfy the standing requirements imposed on those parties." *City of Cleveland v. Nuclear Regulatory Comm'n*, 17 F.3d 1515, 1517 (D.C. Cir. 1994) (citing *So. Christian Leadership Conf. v. Kelley*, 747 F.2d 777 (D.C. Cir. 1984)); *see also Fund for Animals*, 322 F.3d at 731-32 (same); *Envtl. Def. v. Leavitt*, 329 F. Supp. 2d 55, 68 (D.D.C. 2004) (denying motion to intervene as of right under Rule 24(a) for lack of standing); *Van Valin*, 2009 WL 1796773, at *9 (denying permissive intervention under Rule 24(b) in part for lack of standing).

As a result, "a prospective intervenor—like any party—must show (1) injury-in-fact, (2) causation, and (3) redressability." *Fund for Animals*, 322 F.3d at 732-33 (citing *Lujan v.*

Defenders of Wildlife, 504 U.S. 555, 560-61 (1992)). That requires the intervenor to do more than assert an "abstract injury"; rather, the applicant must show a "direct injury" resulting from the challenged conduct. *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-102 (1983). Moreover, that injury "cannot be conjectural, hypothetical, remote, speculative or abstract; it must be ***certainly impending***." *Williams v. District of Columbia*, 530 F. Supp. 2d 119, 125 (D.D.C. 2008) (emphasis added) (citing *Nat'l Treasury Employees Union v. United States*, 101 F.3d 1423, 1427 (D.C. Cir. 1996)). As this Court and the D.C. Circuit have made clear, standing does not exist "where the court 'would have to accept a number of very speculative inferences and assumptions in any endeavor to connect the alleged injury with [the challenged conduct].'" *Appalachian Voices v. Bodman*, 587 F. Supp. 2d 79, 85 (D.D.C. 2008) (quoting *Winpisinger v. Watson*, 628 F.2d 133, 139 (D.C. Cir.1980)); *see also Winpisinger*, 628 F.2d at 139 ("Courts are powerless to confer standing when the causal link is too tenuous."). Moreover, an "increased risk" of injury is not sufficient to confer standing. *Williams*, 530 F. Supp. 2d at 125 (citing *Randolph v. ING Life Ins. & Annuity Co.*, 486 F. Supp. 2d 1 (D.D.C. 2007)); *Middleton v. Kelly*, No. 08-0560, 2008 WL 859189, at *1 (D.D.C. Apr. 1, 2008).

Apotex does not come close to satisfying this irreducible constitutional requirement, because it cannot demonstrate a concrete, non-hypothetical injury-in-fact that is directly linked to Teva's lawsuit against the FDA. While Apotex claims that a decision in Teva's favor will prevent Apotex from obtaining final approval of its losartan ANDAs (and thus from being able to sell its losartan products) during Teva's 180-day exclusivity period, *see* Apotex Mem. 4-5, those alleged harms are purely speculative at this stage. That is so because Apotex's two generic losartan ANDAs apparently do not meet the scientific standards necessary to secure a final, effective approval under the Hatch-Waxman Act, and Apotex thus may not obtain an final,

effective approval to market its drug products before the conclusion of Teva's exclusivity period—or, indeed, ever.

More specifically, the Hatch-Waxman Act provides for two types of approvals: a "tentative approval" and a "final approval" (also known as "effective approval"). The statute defines "tentative approval" as a "notification to an applicant by [FDA] that an [ANDA] meets the requirements of [21 U.S.C. § 355(j)(2)(A)] but cannot receive effective approval" until some future date because there is a patent-based or regulatory exclusivity period barring the ANDA's approval (such as 180-day exclusivity). 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA). In turn, Section 355(j)(2)(A) lays out the substantive scientific standards that each ANDA must satisfy before it can be tentatively or finally approved, including provisions relating to manufacturing methods, product labeling, dosage forms and routes of administration, and bioequivalence to a previously approved drug. *Id.* § 355(j)(2)(A)(i)-(vii); *see also* 21 C.F.R. § 314.127 (providing further guidance on the requirements for ANDAs).

Tentative approval is thus a critical threshold in the ANDA process: it signifies that FDA's scientific review of an ANDA is complete, and represents FDA's conclusion that the proposed generic drug product is safe, effective and ready to be marketed—provided no patent-based or regulatory barriers remain. As its name suggests, however, mere tentative approval is not sufficient to entitle a manufacturer to market its product:

> FDA will approve an abbreviated new drug application and send the applicant an approval letter if none of the reasons … for refusing to approve the abbreviated new drug application applies. The approval becomes effective on the date of the issuance of the agency's approval letter unless the approval letter provides for a delayed effective date. An approval with a delayed effective date is tentative and does not become final until the effective date.

21 C.F.R. § 314.105(d).

By contrast, a "final approval" represents FDA's conclusive sign-off permitting a manufacturer to lawfully market its proposed drug product. It can be issued only after (a) the applicant has met the scientific standards for approval, and (b) every remaining patent-based or other regulatory barrier to generic entry has been felled—that is, that all relevant patents have expired or been held invalid, not-infringed, or unenforceable, and that no statutory or regulatory exclusivity period prevents the applicant from marketing its proposed drug product. *See* 21 C.F.R. § 314.105(d) ("A new drug product approved under this paragraph may not be introduced or delivered for introduction into interstate commerce until approval of the abbreviated new drug application is effective.").

The key point here, then, is that Apotex has not obtained a tentative approval of either of its ANDAs for generic Cozaar® and Hyzaar®, and thus has not met the standards for obtaining a final, effective approval that would permit Apotex to market its product even if Teva were ***not*** entitled to 180-day exclusivity. The most Apotex can say is that "[i]ts ANDAs are under review by FDA and Apotex ***expects*** to receive approval to begin marketing its losartan and losartan HCTZ products ... on April 6, 2010." Apotex Mem. 1 (emphasis added). But Apotex provides no support for this "expectation," and indeed, it is entirely speculative. Apotex simply has no way of knowing when—if ever—FDA will complete its comprehensive scientific review of the Apotex ANDAs and determine whether or not one or both of those ANDAs is eligible for approval. *See Pfizer, Inc. v. Shalala*, 182 F.3d 975, 978-79 (D.C. Cir. 1999) (holding that FDA's acceptance of an ANDA is "merely the first step in the agency's approval process" and noting that "the FDA may never approve [the] application").

Apotex's standing to participate as a party to this case thus depends on purely speculative allegations of harm that have no direct relationship to Teva's lawsuit. At best, Apotex can argue

that Teva's victory in this litigation ***may*** cause it harm if (1) FDA completes scientific review of Apotex's ANDAs prior to April 2010; (2) FDA finds no deficiencies in those ANDAs; and (3) FDA grants tentative approval to Apotex's ANDAs. These contingent and conjectural possibilities, which are entirely independent of Teva's lawsuit, do not suffice to establish Apotex's standing. *Winpisinger*, 628 F.2d at 139; *Appalachian Voices*, 587 F. Supp. 2d at 85. While it may be true that a ruling in Teva's favor would increase the risk that Apotex will be injured, this is not enough. *See Williams*, 530 F. Supp. 2d at 125. Because Apotex cannot show a direct relationship between this case and its alleged injury, it does not have standing and cannot intervene as a party to this case—whether as of right, or permissively.

This Court need go no further. But for what it's worth, Apotex's effort to intervene is further flawed because it cannot demonstrate the substantial interest necessary to justify intervention as of right under Rule 24(a)(2). Apotex argues that it "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." Apotex Mem. 4. But, as noted above, Apotex can have no immediate plans to launch a generic losartan product because, without tentative approval, it is not even ***eligible*** for final approval from FDA. Nor has Apotex provided any reason for this Court to grant its request for permissive intervention under Rule 24(b). Putting aside the fact that Apotex has no standing, its brief makes no effort to argue that it meets any of the Rule 24(b) factors that can justify intervention.

At bottom, Apotex at most finds itself positioned to provide additional argument on the issues in this case. But that is not the role of an intervenor; it is the role of an *amicus curiae*.

CONCLUSION

For the foregoing reasons, Teva respectfully requests that this Court deny Apotex's motion to intervene.

Dated: July 8, 2009

Respectfully submitted,

By: Michael D. Shumsky
Jay P. Lefkowitz, P.C. (D.C. Bar No. 449280)*
Michael D. Shumsky (D.C. Bar No. 495078)
Gregory L. Skidmore (D.C. Bar No. 974024)
KIRKLAND & ELLIS LLP
655 15th Street N.W., Suite 1200
Washington, D.C. 20005
(202) 879-5000
(202) 879-5200 fax

*Counsel of Record

Counsel for Teva Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies that on this 8th day of July 2009, he caused a copy of the foregoing **OPPOSITION TO OPPOSITION TO APOTEX, INC.'S MOTION TO INTERVENE** to be served upon the following attorneys by electronic mail and the court's CM/ECF system:

Drake S. Cutini
Department of Justice
Office of Consumer Litigation
P.O. 386
Washington, DC 20044
(202) 307-0044

Eric Blumberg
Elizabeth Dickinson
Shoshanna Hutchinson
Office of the Chief Counsel
Food and Drug Division
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
(301) 827-8579

Counsel for the Federal Defendants

Carmen Mercedes Shepard
Buc and Beardsley
919 18th Street, NW
Suite 600
Washington, DC 20006
(202) 736-3620

Counsel for Proposed Intervenor-Defendant Apotex, Inc.

/s Michael D. Shumsky
Michael D. Shumsky
Counsel for Teva Pharmaceuticals USA, Inc.