UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, Inc. Plaintiff, v. MICHAEL O. LEAVITT, in his official capacity as Secretary of Health and Human Services; ANDREW C. VON ESCHENBACH, M.D., in his official capacity as Commissioner of Food and Drugs; UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants, MYLAN PHARMACEUTICALS INC., Intervenor-Defendant.	Case No. 08-395-RML

TEVA PHARMACEUTICALS USA, INC.'S OPPOSITION TO APOTEX, INC.'S MOTION TO INTERVENE FOR PURPOSES OF APPEAL

Apotex chose to sit on its rights while others intervened to protect their interests, and now Apotex wishes it hadn't sought a free ride on its competitor's coattails. But that is no reason to allow Apotex to intervene at this late date. Litigants who wait to intervene until an adverse judgment has been entered face an especially heavy burden—and Apotex has not come close discharging that burden here. Apotex does not claim that it was unaware of this case before the Court rendered judgment. Apotex does not assert that it has a new interest in the outcome of this case that emerged only as a result of this Court's judgment. Apotex does not seriously contend that its interests in this case meaningfully diverge from Mylan's. And Apotex does not dispute that the United States Department of Justice is more than capable of doing whatever can be done to defend FDA's letter decision in the face of this Court's well-reasoned judgment.

Instead, Apotex has moved to intervene nearly two months after Teva filed its complaint because FDA and Mylan have taken one week—***one week!***—to digest this Court's decision and perfect their appeals. No court has ever granted a post-judgment motion to intervene on such a thin demonstration of need, and this Court should not wield its substantial discretion to become the first.

ARGUMENT

Post-judgment motions to intervene are disfavored. Indeed, motions "for 'intervention after judgment will usually be denied where a clear opportunity for pre-judgment intervention was not taken.'" *Associated Builders & Contractors, Inc. v. Herman*, 166 F.3d 1248, 1257 (D.C. Cir. 1999) (quoting *Dimond v. District of Columbia*, 792 F.2d 179, 193 (D.C. Cir. 1986)); *see also Massachusetts Sch. of Law v. United States*, 118 F.3d 776, 783 n.5 (D.C. Cir. 1997) ("[S]ome would-be intervenors may inexcusably neglect to try to enter the proceedings before judgment, at a time when notice of their arguments would have enabled the district court to avert the alleged errors. Then, post-judgment intervention for the purpose of challenging those supposed defects on appeal would rightly be denied as untimely."). For that reason, "'motions for intervention made after entry of final judgment will be granted only upon a strong showing of entitlement and of justification for failure to request intervention sooner.'" *UAW v. Lyng*, 651 F. Supp. 855, 856 (D.D.C. 1986) (quoting *United States v. Associated Milk Producers, Inc.*, 534 F.2d 113, 116 (8th Cir. 1976)) (emphasis omitted).

Apotex does not deny that it had "'a clear opportunity for pre-judgment intervention'" in this case. *Herman*, 166 F.3d at 1257. Instead, Apotex seeks to discharge the heavy burden of justifying its delay by asserting that the need for its intervention arose only after the entry of judgment—because Mylan and FDA have taken a few days to assess their options and craft their appellate strategy. Apotex thus analogizes this case to *Smoke v. Norton*, 252 F.3d 468 (D.C. Cir.

2001), in which it claims the D.C. Circuit authorized a post-judgment intervention for purposes of appeal "when it became apparent that the government might not appeal the District Court's decision." Apotex Br. at 5.

Smoke, however, offers no support for Apotex's belated request to intervene in this litigation. In that case, the parties opposing intervention not only conceded in their district court pleadings that the would-be intervenors likely were "'correct that the [federal government] will not take an appeal from this Court's September 30 decision,'" but represented that "'senior [federal] officials have told [the opponents] that they have no interest in … pursuing an appeal.'" *See* Appellants' Brief, *Smoke v. Norton*, Nos. 00-5061 & 00-5062, *available at* 2001 WL 36038044 at *14 (D.C. Cir. filed Jan. 22, 2001) (quoting Plaintiffs' Opp. to Mot. to Intervene, *Ranson v. Babbitt*, No. 98-cv-01422-CKK)). Perhaps more important, the *Smoke* defendants then ***withdrew*** their protective notice of appeal before the intervenors filed their opening appellate brief. *Id*. at *8.

In this case, however, Mylan already has manifested its intention to appeal this Court's judgment by moving in open court for a stay pending appeal. *See* April 11 Transcript at 6 ("MR. RAKOCZY: William Rakoczy for Mylan Pharmaceuticals. Your Honor, to preserve Mylan's right to potentially move for an injunction pending appeal, it's required to exhaust remedies before this Court, so Mylan at the time would orally move to stay Your Honor's injunction. THE COURT: That request is denied, so you all can get straight to the Court of Appeals."). Moreover, senior FDA officials have repeatedly informed counsel for Teva that they fully intend to appeal this Court's decision—and that they actively are moving forward on that front.

Apotex nonetheless asserts that it cannot wait for FDA or Mylan to lodge their appeals because its "independent interest in the outcome of this case … can only be protected by immediate pursuit of all its appellate remedies." Apotex Br. at 5-6. Indeed, Apotex speculates,

Mylan might cut a deal with Janssen and choose not to appeal, and FDA might then decline to seek a stay of this Court's decision when it does appeal. *Id*. But those speculative risks were both present and well-known at the outset of this case, when Apotex decided to sit on the sidelines and let its competitor Mylan and the federal government take the laboring oars. After all, Teva's lawsuit against FDA was well-covered in the national news media,[1] industry periodicals,[2] and widely read blogs,[3] and the whole generic industry understood that FDA's February 28 response to Teva's Citizen Petition created a possibility that the D.C. Circuit might not decide an appeal before June 29.

Had Apotex intervened before judgment was entered, it could have guarded itself against the market-timing risks on which its post-judgment motion to intervene is based. Apotex instead opted to gamble with its rights, figuring that FDA would prevail in this Court and that Teva would bear those risks. But post-judgment intervention is not an insurance policy for bad bets on litigation outcomes, and this Court should not create the moral hazard that Apotex's motion invites.

Because the timeliness of an applicant's motion for intervention is a threshold prerequisite, and because Apotex offers no sound excuse for its delay in moving to intervene, there is no need for this Court to address the remaining intervention factors. *Herman*, 166 F.3d at 1257 ("If the motion was not timely, there is no need for the court to address the other factors

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1 *See, e.g.*, Ransdell Pierson, *Teva sues FDA on Generic Form of J&J's Risperdal*, Reuters (Mar. 4, 2008).

2 *See, e.g.*, *Teva Sues FDA Over Generic Risperdal Exclusivity*, 5 FDANEWS DRUG DAILY BULLETIN 51 (Mar. 13, 2008); Amanda Ernst, *Teva Sues FDA Over Delisted Risperdal Patent*, IP LAW 360 (Mar. 5, 2008).

3 *See, e.g.*, Patent Baristas, *FDA: Don't Do As We Say or You're Out of Luck*, at http://www.patentbaristas.com/archives/2008/03/07/fda-dont-do-as-we-say-or-youre-out-of-luck/ (posted Mar. 7, 2008); FDA Law Blog, *Teva Sues FDA After the Agency Refuses to Relist RISPERDAL Patent and Recognize the Company's 180-Day Exclusivity Eligibility*, at http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/03/teva-sues-fda-a.html (posted Mar. 7, 2008).

that enter into an intervention analysis.") (citing *NAACP v. New York*, 413 U.S. 345, 369 (1973)). Apotex's motion should be denied.

Dated: April 22, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2008, I caused a copy of TEVA PHARMACEUTICALS USA, INC.'S OPPOSITION TO APOTEX, INC.'s MOTION TO INTERVENE to be served upon the following attorneys through the Court's ECF filing system and by email:

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