IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. MICHAEL O. LEAVITT, Secretary of Health and Human Services, ANDREW C. VON ESCHENBACH, Commissioner of Food and Drugs, and U.S. FOOD AND DRUG ADMINISTRATION, Defendants, MYLAN PHARMACEUTICALS INC., Intervenor-Defendant.	Case No. 08-cv-395 (RCL)

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)(2) for the purpose of pursuing an appeal of this Court's decision.

In this case the Court granted Plaintiff Teva Pharmaceuticals USA, Inc.'s ("Teva's") request for an injunction awarding Teva 180 day exclusivity for its risperidone tablet Abbreviated New Drug Application ("ANDA") and preventing the U.S. Food and Drug Administration ("FDA") from approving other generic drug applications for risperidone tablets until 180 days after Teva brings its tablets to market. Apotex has filed an ANDA seeking approval to market generic risperidone tablets. Apotex expected to receive approval of its ANDA in time to launch its generic risperidone tablets by June 29, 2008 and to begin

commercial marketing immediately. Under this Court's ruling, Apotex, a direct competitor of Teva, would be denied approval of its application to market risperidone tablets on June 29, 2008 when the listed patents and exclusivities for the brand drug, Risperidal, expire.

Apotex makes this timely motion to intervene to safeguard its substantial interests in the outcome of this litigation. Apotex's interests can only be protected if the Court of Appeals stays this Court's ruling pending appeal or is able to review this Court's decision and Order prior to June 29, 2008. If this motion is granted, Apotex intends to file a notice of appeal and immediately pursue the appropriate appellate remedies to obtain a stay of the District Court's ruling pending appeal, and/or review of the ruling on an emergency or expedited basis prior to the June 29, 2008 launch date.

The Federal Defendants and Mylan Pharmaceutical Inc. ("Mylan") defended FDA's administrative ruling denying Teva's request for exclusivity during the proceedings in this Court, but their actions following this Court's ruling are no longer adequate to safeguard Apotex's interest. Accordingly, Apotex's grounds to intervene arose post-judgment, when it became apparent that neither the Federal Defendants nor Mylan would immediately appeal this Court's decision, and that even if they appeal, may not prosecute the appeal timely so as to try to dissolve or stay the injunction prior to June 29, 2008. Under these circumstances, intervention as of right is appropriate. See, e.g., Smoke v. Norton, 252 F.3d 468 (D.C. Cir. 2001).

Throughout the proceedings before this Court, Mylan and the Federal Defendants defended FDA's administrative decision. As long as they did so, Apotex's interests were consonant with those of the Federal Defendants and Mylan, and its interests were adequately represented by the Federal Defendants and Mylan. Apotex, therefore, had no reason to

intervene. As of Friday, April 18, 2008, a week after the judgment was entered, however, neither has pursued an appeal.

FDA, as a regulatory authority, can no longer be expected to fully represent Apotex's interests. The Federal Defendants must complete an internal deliberative process in order to determine whether to appeal. It is not certain that the Federal Defendants will appeal. Moreover, FDA has no economic interest in this matter and, therefore, even if it appeals, it has no reason to seek to review or a stay of this Court's order pending appeal prior to June 29, 2008.

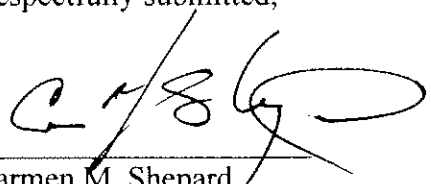
Mylan, for reasons that are not known to Apotex, has neither noticed an appeal nor taken immediate steps to ensure any appellate review can be completed prior to June 29, 2008. As of April 17, 2008, Mylan's counsel represented that Mylan had not decided whether to appeal the Court's Order. Delay may be in Mylan's interest, but is not in Apotex's interest. Thus, Mylan no longer represents Apotex's interests. Mylan and Apotex apparently have different commercial interests, as each seeks to maximize its share of the market for risperidone tablets. How Mylan will seek to do so appears now to depend on facts that are unique to its situation. Mylan's interest may be affected by such factors as its ability to enter into agreements with other pharmaceutical companies, or the effect of the ruling on other Mylan ANDAs. Apotex's interests can only be protected if the Court of Appeals is able to review this Court's decision prior to June 29, 2008 or stays this Court's ruling pending appeal. Mylan's delay in pursuing any appellate relief evidences its divergence from Apotex's interests. For these reasons, Mylan's participation in this litigation is no longer adequate to represent Apotex's interests.

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 as a defendant for purposes of pursuing an appeal.[1]

FDA's counsel stated that the Federal defendants do not oppose Apotex's motion to intervene. Counsel for Teva advised that Teva opposes the motion and intends to file an opposition. Apotex's counsel telephoned and e-mailed counsel of record for Mylan on Friday, April 18, 2008, and telephoned again on Monday, April 21, 2008, to ascertain Mylan's position on the motion. Mylan has not yet responded to these communications.

Dated: April 21, 2008

Respectfully submitted,



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1. Pursuant to Rule 24(c) of the Federal Rules of Civil Procedure and Local Rule 7(j), the Motion to Intervene is accompanied by an Answer, attached as Exhibit A. If its Motion to Intervene is granted, Proposed-Intervenor Apotex will file a Notice of Appeal. See Exhibit B.

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MEMORANDUM OF POINTS AND AUTHORITIES IN
SUPPORT OF MOTION BY APOTEX, INC. TO INTERVENE AS
A DEFENDANT FOR THE PURPOSE OF PURSUING AN APPEAL

Apotex, Inc. ("Apotex") has moved to intervene in this action post-judgment for the purpose of pursuing an appeal. Apotex's considerable interest in the subject matter of this action is no longer being adequately represented by the existing parties. Accordingly, 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.

This Court's April 11, 2008 Order awarded 180 day exclusivity to Teva Pharmaceuticals USA, Inc. ("Teva") for its risperidone Abbreviated New Drug Application ("ANDA") and enjoined the Food and Drug Administration ("FDA") from approving any applications for generic risperidone until Teva has exhausted this exclusivity. Apotex has filed an ANDA to market risperidone. It expects to be eligible for approval in time to begin the commercial

marketing of its generic risperidone tablets by June 29, 2008. Apotex therefore has an interest in the subject matter of this litigation which will be impaired unless this Court's Order is timely reviewed by the appellate court and/or this Court's order is stayed pending appeal.

While the existing parties' interests were consonant with those of Apotex prior to judgment, that is no longer the case. Apotex cannot be certain that the Federal Defendants or Mylan will move expeditiously to pursue immediate review and/or for a stay of this Court's final judgment and Order. Indeed, as of April 18, 2008, one week after entry of judgment, no defendant even had reached a decision as to whether it would appeal. Delay is not in Apotex's interest. Accordingly, Apotex's interests are no longer adequately represented by the parties.

Apotex's motion is timely and its participation will not delay these proceedings. As explained more fully below, the Court of Appeals for the District of Columbia Circuit has held intervention for the purpose of pursuing an appeal is appropriate under these circumstances.

I. Factual Background

The facts of this case have been extensively briefed by FDA, Mylan and Teva in the proceedings before this Court. Therefore, except for the facts directly bearing on Apotex's motion to intervene, they will not be repeated here.

Apotex is one of several generic manufacturers that have submitted abbreviated new drug applications (ANDAs) to market generic versions of risperidone tablets to compete with Janssen's risperidone product, Risperdal®. Declaration of Shashank Upadhye ("Upadhye Dec."), Exhibit C to Motion by Apotex, Inc. to Intervene as a Defendant at ¶7. Janssen Pharmaceutica, Inc. ("Janssen") is the holder of the original approval (the "NDA") for risperidone. FDA Response to Teva's Citizen Petition ("Resp."), Docket No. 2007 P-0316/CPI and CRI, Teva's Mot. for Ex. Prelim. Inj. Relief, Exh. 2 at 4.

When an applicant such as Janssen submits an NDA, it is required to provide information on patents that claim the drug for which the applicant is submitting the application. 21 U.S.C. § 355(b)(1). Janssen submitted patent information to FDA regarding U.S. Patents Nos. 4,804,633

("the '663 patent") and 5,158,952 ("the '952 patent"). Resp. at 4. By June of 2001, Janssen had withdrawn the patent information on the '952 patent. Id. Currently, only the '663 patent has been identified by Janssen as a patent that claims the drug.

When an applicant submits an ANDA, it must provide a certification to all patents that claim the drug. 21 U.S.C. § 355(j)(2)(A)(vii) (2001). Teva submitted an ANDA containing certifications to both the '663 and '952 patents. FDA rejected the certification to the '952 patent because Janssen had withdrawn the information on that patent, and Teva corrected the ANDA by changing its certification to the '952 patent. Resp. at 5. Other ANDA applicants, including Apotex, submitted certifications only to the '663 patent.

Until June 29, 2008, no ANDA for a generic version of risperidone may be approved. On that date, the '663 patent will no longer bar generic approvals. Anticipating the date for ANDA approvals, Teva filed a citizen petition with FDA asserting that FDA should have accepted its certification to the '952 patent, and that, as the first ANDA applicant to make a paragraph IV certification to the '952 patent, it is entitled to 180 days of exclusivity. See Teva's Mot. for Exp. Prelim. Inj. Relief at Exh. 1. Teva argued that FDA should have accepted its certification to the '952 patent because, even though Janssen had withdrawn the information on the '952 patent, FDA had not published that information in printed form. Id. When FDA denied the citizen petition, explaining that it made decisions based on the information currently available, Teva filed this action. This Court disagreed with FDA's decision, accepted Teva's argument, and has enjoined FDA from approving any other ANDA during Teva's exclusivity. Order, Apr. 11, 2008.

Any delay in obtaining review of this Court's decision, and/or failure to pursue a stay of the order pending appeal would substantially impair Apotex's considerable interests. Apotex seeks to intervene in this action for purpose of pursuing an appeal so its interest can be adequately protected.

II. Legal Standard for a Motion to Intervene.

The requirements for intervention following a judgment for purposes of pursuing an appeal are the same as those governing any intervention. United Airlines v. McDonald, 432 U.S. 385, 395-96 (1977). In relevant part, Rule 24(a) provides that:

> Upon timely application anyone shall be permitted to intervene in an action...when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

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, if the applicant's interest is not adequately represented by the existing parties and if it timely seeks intervention. Acree v. Republic of Iraq, 370 F.3d 41, 49 (D.C. Cir. 2004). Apotex satisfies each of these requirements.

Post judgment intervention is often permitted and is appropriate where the prospective intervenor's interest did not arise until the appellate stage. Acree, 370 F.3d 41, 50 citing to Wright & Miller, § 1916. In Smoke v. Norton, 252 F.3d 468 (D.C. Cir. 2001), for example, the appellants - officers of the Saint Regis Mohawk Tribal Government – did not intervene in an ongoing case to protect their interest while the case was being litigated before the District Court. Instead, they sought to intervene after summary judgment was entered in the case, for the purpose of taking an appeal because it was uncertain whether the Federal Defendants would appeal. The District Court denied their motion to intervene because it deemed the intervention had not been timely filed. The Court of Appeals reversed, holding that the District Court erred in denying the motion to intervene.

The Court of Appeals held that the appellants in Smoke v. Norton had not been required to intervene during the proceedings because, at that time, the government was adequately representing their interests by defending an agency decision. The appellate court held that the

motion to intervene was timely made when it became apparent that the government might not appeal the District Court's decision.

Apotex is in an analogous posture, and like the appellants in Smoke v. Norton, has satisfied the requirements for intervention as of right under Rule 24(a)(2) and for permissive intervention under Rule 24(b)(2).

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

Timeliness is judged in consideration of all circumstances, including the purpose for which intervention is sought and the need for intervention as a means of preserving the applicant's rights. Smoke v. Norton, 252 F.3d at 471, citing United States v. AT&T, 642 F.2d 1285, 1295 (D.C. Cir. 1980). A post-judgment motion to intervene for the purpose of pursuing an appeal is timely when the divergence of interests between the existing parties and the applicant arises after judgment. Smoke v. Norton, 252 F.3d 470. Apotex filed this motion within 10 days after the judgment, and as soon as it became apparent that the existing defendants had delayed in seeking appellate review. See Upadhye Dec. at ¶¶10-12. Under these circumstances, there can be no doubt that Apotex's motion is timely. See United Airlines v. McDonald, 432 U.S. at 385 (holding that intervention for purpose of pursuing an appeal filed less than three weeks after final judgment was timely).

Apotex's intervention clearly will cause no delay in the resolution of this case, as Apotex seeks only to appeal. Apotex does not seek to interject additional arguments or request additional proceedings before the Court. Where a party seeks to intervene only to participate at the appellate stage and not in any further trial proceedings, its intervention does not prejudice any existing parties. Dimond v. District of Columbia, 792 F.2d 179, 193 (D.C. Cir. 1986). The existing parties do not have a legitimate interest in avoiding review. To the contrary, there is a substantial interest in assuring that the Court appropriately interpreted the governing law. See Acree, 370 F.3d at 50 (finding no prejudice arising from intervention that enables appellate review).

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

The requirement that an intervenor show that the existing parties do not adequately represent the proposed intervenor is not onerous. Fund for Animals v. Norton, 322 F.3d 728, 735 (D.C. Cir. 2003). An intervenor need only show that representation of its interest "may be" inadequate – not that it will in fact be inadequate, Dimond v. District of Columbia, 792 F.2d 179, 192 (D.C. Cir. 1986), and the burden of making this showing is "minimal," Trbovich v. United Mine Workers of Am., 404 U.S. 528, 538 n.10 (1972) (quoting Moore's Federal Practice).

The requirement for inadequacy of representation by existing parties is satisfied in this instance. First, the plaintiff's interests in this case are squarely adverse to Apotex's. See Upadhye Dec. at ¶15. Teva seeks to avoid competing with Apotex in the market for risperidone tablets for 180 days. Accordingly, it does not in any way represent Apotex's interests.

Second, the Federal Defendants represent a different set of interests from those Apotex seeks to protect. There is no certainty that the Federal Defendants will seek review of this Court's decision. Even if the Federal Defendants appeal, the Federal Defendants have neither a commercial nor financial interest in this case to seek a stay of this Court's order pending appeal. Indeed, in a similar situation, the Federal Defendants did not seek a stay of the District Court order pending appeal. Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120 (D.C. Cir. 2006). Apotex, by contrast, has an independent interest in the outcome of this case that can only be protected by immediate pursuit of all its appellate remedies. Upadhye Dec. at ¶14. 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).

Third, neither Mylan nor any other generic company would adequately represent Apotex's interest. While Apotex's and Mylan's positions initially may have been similar, they now are quite different. First, while Mylan supported FDA's decision before this Court, it failed to take any steps to obtain appellate review for a week after the judgment was entered. Delay is

not in Apotex's interest. Even if Mylan does eventually appeal, its delay in doing so evidences that it no longer adequately represents Apotex's interest. Apotex can have no certainty that Mylan would pursue appellate court review so as to safeguard Apotex's interest.

Second, each generic company faces unique factual situations that may dictate positions that differ in subtle but important respects. Upadhye Dec. at ¶¶12-13. "[A] partial congruence of interests . . . does not guarantee the adequacy of representation." Fund for Animals, 322 F.3d at 737. Mylan and Apotex have different commercial interests, as each will seek to maximize its share of sales. How Mylan will seek to do so will likely depend on facts that are unique to its situation, and may even include the ability to enter into agreements with Teva, Janssen, or other companies. The commercial and financial differences between Apotex and Mylan alone are enough to satisfy the requirements for intervention. As the Court of Appeals for the District of Columbia has held, interests need not be wholly adverse before concluding that existing representation may be inadequate. Id.

V. Apotex Has An Interest in the Subject Matter of the Case Which Will Be Impaired by Failure to Promptly Appeal this Court's Decision.

Apotex has a substantial interest in this action because it is committed to launch its risperidone tablets immediately upon the expiration of the '663 patent and its pediatric exclusivity. See Upadhye Dec. at ¶8. 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). The courts have 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., Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1074-1076 (D.C. Cir. 1998); Torpharm, Inc. v. Thompson, 260 F. Supp. 2d 69 (D.D.C. 2003), aff'd 354 F.3d 877 (D.C. Cir. 2004); Purepac Pharm. Co. v. Thompson, 238 F. Supp. 2d 191 (D.D.C. 2002), aff'd 354 F.3d 877 (D.C. Cir. 2004); Teva

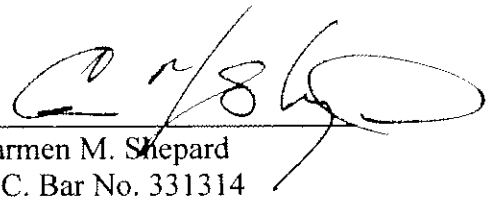
Pharms. Indus., LTD v. FDA, 355 F. Supp. 2d 111 (D.D.C. 2004); Purepac Pharm. Co. v. Friedman, 162 F.3d 1201, 1202 n.2 (D.C. Cir. 1998); Merck & Co. v. FDA, 148 F. Supp. 2d 27 (D.C.C. 2001).

The impairment to Apotex's interest from the Court's ruling if it is not timely stayed or reversed likewise is sufficient to qualify for intervention as of right. Courts must look to the "'practical consequences' of denying intervention" to determine whether an interest will be impaired. Fund for Animals, 322 F.3d at 735. In this case, the consequence of failing to pursue immediate appellate remedies is that Apotex would face the immediate harm to its substantial interests for which it would be unable to obtain recovery. See Declaration of Tammy McIntire, Exhibit D to Motion By Apotex, Inc. to Intervene as a Defendant. The injury to Apotex is directly traceable to the judgment in this case – the grant of 180-day exclusivity and the exclusion of Apotex for 180 days from the market for risperidone. A decision on appeal favorable to the defendants, rejecting Teva's legal challenge, or a stay pending appeal, would prevent that loss from occurring. Thus, Apotex can demonstrate both the substantial interest and impairment necessary to satisfy Rule 24(a)(2).

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)(2).

Respectfully submitted,



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Counsel for Proposed Intervenor-Defendant, Apotex, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of Motion of Apotex, Inc. to Intervene as a Defendant, the exhibits thereto, Memorandum of Points and Authorities in Support of Apotex, Inc.'s Motion to Intervene, Proposed Order, and Certificate Under LCvR 7.1, were served as follows:

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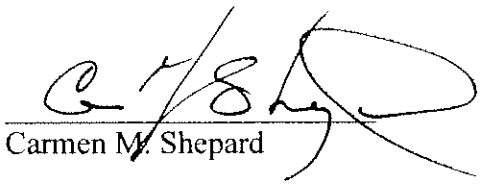

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