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., Proposed Intervenor-Defendant.	)	Case No. 08-cv-395 (RCL)

MYLAN PHARMACEUTICALS INC.'S
MOTION TO INTERVENE AS A DEFENDANT

Pursuant to Federal Rule of Civil Procedure 24, Mylan Pharmaceuticals Inc. ("Mylan") hereby respectfully moves to intervene as a defendant in this action as a matter of right under Rule 24(a) or, alternatively, to intervene permissibly under Rule 24(b).

Mylan has conferred with counsel for Teva and the Federal Defendants regarding the motion and Mylan's intent to seek the Court's leave to intervene in this matter as a defendant. The Federal Defendants do not oppose Mylan's motion. As of the time of filing, Teva takes no position on the motion.

The grounds for this motion are fully set forth in the accompanying memorandum, filed concurrently herewith and incorporated by reference herein. Pursuant to

Rule 24(c), FED. R. CIV. P., and Local Civil Rule 7(j), a pleading setting forth the claim or defense for which intervention is sought is attached hereto as Exhibit A.

Dated: March 11, 2008.

Respectfully submitted,

MYLAN PHARMACEUTICALS INC.

By: */s/ William A. Rakoczy*
One of its attorneys

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CERTIFICATE OF SERVICE

I, William A. Rakoczy, HEREBY CERTIFY that on this 11th day of March 2008, a true and correct copy of **Mylan Pharmaceuticals Inc.'s Motion to Intervene as a Defendant, supporting Memorandum of Law and Proposed Order** were served via overnight delivery upon the following:

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MEMORANDUM IN SUPPORT OF MYLAN PHARMACEUTICALS INC.'S MOTION TO INTERVENE AS A DEFENDANT

Mylan Pharmaceuticals Inc. ("Mylan") respectfully submits this memorandum in support of its motion to intervene as a defendant in this action as a matter of right, under Rule 24(a) of the Federal Rules of Civil Procedure. Alternatively, Mylan seeks leave for permissive intervention under Rule 24(b). Mylan has conferred with counsel for Teva and the Federal Defendants regarding the motion and Mylan's intent to seek the Court's leave to intervene in this matter as a defendant. The Federal Defendants do not oppose Mylan's motion. As of the time of filing, Teva takes no position on the motion.

INTRODUCTION

This action involves Teva's second attempt to obtain an unlawful and unwarranted period of 180-day generic marketing exclusivity for its generic version of Janssen's

Risperdal® (risperidone) Tablets. Risperdal® Tablets currently are protected from generic competition by a period of pediatric exclusivity that expires on June 29, 2008. At that time, all applicants who have submitted an abbreviated new drug application ("ANDA") for generic risperidone tablets, including Mylan, will be eligible for final approval and immediate market entry, so long as all other substantive requirements for FDA approval have been met. Mylan already has received tentative approval for its risperidone ANDA, indicating that it is positioned for final approval immediately upon expiration of Janssen's pediatric exclusivity. As a result, Mylan is entitled to, and expects to receive, final approval on June 29, 2008, and is preparing for an immediate commercial launch at that time.

Mylan's final approval and market entry are at risk of being substantially delayed, however, because of Teva's baseless lawsuit. In its complaint and motion for preliminary injunction, Teva maintains that it is entitled to an exclusive six-month head-start in the generic risperidone market once the pediatric exclusivity for Risperdal® expires. Teva previously tried to convince the Agency of this legally and factually unsupportable position, but was rightly rejected. Specifically, Teva submitted a citizen petition to FDA arguing that it was entitled to 180-day exclusivity for risperidone tablets by virtue of having submitted with its ANDA (yet, withdrawn) a so-called "paragraph IV certification" to U.S. Patent No. 5,158,952 ("the '952 patent"). FDA denied Teva's petition for the same reason that Teva was asked to withdraw the paragraph IV certification in the first instance—because the '952 patent had been removed from the Agency's patent database at least one month *prior to* Teva's paragraph IV submission. As FDA acknowledged, only a patent included in the Agency's patent database at the time of the applicant's paragraph IV ANDA submission gives rise to a period of 180-day generic exclusivity. Therefore, because the '952 patent had been removed from the database at Janssen's

request well in advance of Teva's paragraph IV submission, FDA concluded that Teva was, and still is, *not* entitled to 180-day exclusivity for this product.

Incredibly, without any new facts or legal support, Teva now seeks the same relief from this Court that was denied by the Agency: namely, injunctive relief requiring FDA to re-list the '952 patent in FDA's Orange Book and an award of 180-day generic exclusivity for Teva's risperidone ANDA. The governing statute, FDA's implementing regulations, and relevant case law all require that the Agency's administrative decision be upheld. Were the Court to award Teva's requested relief, however, approval of Mylan's risperidone ANDA will be withheld, and its market entry delayed, during the entirety of any unlawful period of exclusivity awarded to Teva.

Accordingly, this action, and Teva's associated motion for preliminary injunction, indisputably implicates Mylan's statutory rights, and has the potential to adversely impact Mylan's interest in prompt final approval of its ANDA. Indeed, Teva admittedly filed this suit solely to delay the approvals of Mylan and other prospective competitors. Because FDA can not adequately represent Mylan's interests, and because Mylan's participation as an intervenor will not prejudice or burden the parties or this Court, the Court should permit Mylan to intervene to ensure that its interests are protected.

ARGUMENT

Mylan meets the requirements for both intervention as a matter of right, under Rule 24(a), and permissive intervention, under Rule 24(b), FED. R. CIV. P. 24.

I. The Court Should Permit Mylan To Intervene As Of Right.

Federal Rule of Civil Procedure 24(a) provides that, upon timely motion, the court must permit any party 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). A party thus has the right under Rule 24(a) to intervene in an action if it meets four requirements: (1) the application to intervene is timely; (2) the applicant has demonstrated a legally protected interest in the action; (3) disposition of the action threatens to impair that interest; and, (4) no party to the action can adequately represent the applicant's interests. *See Appleton v. FDA*, 310 F. Supp. 2d 194, 196 (D.D.C. 2004) (granting motions to intervene); *see also Smoke v. Norton*, 252 F.3d 468, 470 (D.C. Cir. 2001) (holding that district court erred in denying motion to intervene); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (finding that applicant was entitled to intervene); *Cook v. Boorstin*, 763 F.2d 1462, 1466-67 (D.C. Cir. 1985) (same). These requirements are construed liberally in favor of intervention. *See Wilderness Society v. Babbitt*, 104 F. Supp. 2d 10, 18 (D.D.C. 2000).

Courts in this Circuit routinely allow competing drug manufacturers to intervene in actions involving potential delays in FDA approval and 180-day generic exclusivity rights under the Federal Food, Drug, and Cosmetic Act ("FFDCA"). *See, e.g., Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1078-79 (D.C. Cir. 2002); *Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1202 n.2 (D.C. Cir. 1998); *Mova*, 140 F.3d at 1074; *Teva Pharms. Indus., Ltd. v. FDA*, 355 F. Supp. 2d 111 (D.D.C. 2004); *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69 (D.D.C. 2003); *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002); *Merck & Co. v. FDA*, 148 F. Supp. 2d 27 (D.D.C. 2001); *Mylan Pharms., Inc. v. Shalala.*, 81 F. Supp. 2d 30, 34 (D.D.C. 2000). Because Mylan has met each of the requirements for intervention as of right, this Court should do the same here.

A. Mylan's Motion To Intervene Is Timely.

First, there can be no question that Mylan's motion to intervene is timely. Intervention is timely where a party seeks to intervene promptly after suit is initiated and/or before the court renders any substantive rulings. *See, e.g.*, *Mova*, 140 F.3d at 1076 (motion was timely when filed a few weeks after complaint was filed and before any substantive rulings); *Admiral Ins. Co. v. Nat'l Cas. Co.*, 137 F.R.D. 176, 177 (D.D.C. 1991) (motion was timely when filed before the major substantive issues had been argued or resolved). Teva filed its complaint and motion for preliminary injunction just one week ago, and the Court has not yet scheduled a hearing on Teva's motion or rendered any substantive rulings. If permitted to intervene, Mylan will seek leave of Court to file a response to Teva's motion. Thus, Mylan's motion to intervene is timely and neither the parties nor this Court will be prejudiced by Mylan's intervention. Nor would Mylan's participation cause any delay in the resolution of this case. As Teva concedes, no generic applicant, including Teva, will be eligible for final approval until June 29, 2008, at the earliest. Thus, Mylan's intervention would still allow ample time for briefing, argument, and resolution of this case well in advance of that date.

B. Mylan Has A Substantial Legal Interest In This Action.

Second, Mylan has a substantial, protectable interest in this action. An intervenor "can be said to have a substantial and direct interest in the subject of [the] litigation" where, if the plaintiff succeeds, a governmental agency's "regulatory decisions, which are obviously in the intervenors' interests, will be set aside." *Natural Res. Def. Council, Inc. v. EPA*, 99 F.R.D. 607, 609 (D.D.C. 1983). Such is the case here.

As FDA concluded in its denial of Teva's petition, as soon as the pediatric exclusivity for Risperdal® Tablets expires on June 29, 2008, all otherwise-approvable risperidone applicants, including Mylan, lawfully are entitled to immediate final approval of their ANDAs.

As noted above, Mylan already has received tentative approval and is committed to bringing its generic risperidone products to market as soon as Janssen's pediatric exclusivity expires. FDA's challenged administrative decision will allow Mylan to do just that.

Teva's requested injunction, however, would prevent Mylan from receiving final approval and earning any sales revenue for its risperidone products for at least another six months. Courts have recognized that a movant's economic or pecuniary interest in the outcome of the litigation constitutes a direct and significant legally protectable interest pursuant to Rule 24(a). *See Cascade Natural Gas Corp. v. El Paso Natural Gas Co.*, 386 U.S. 129, 132-33 (1967) (recognizing that intervention was proper where protection of interests in a competitive system or economic independence is at issue); *Smuck v. Hobson*, 408 F.2d 175, 178-79 (D.C. Cir. 1969) (recognizing that economic interest more than suffices to satisfy intervention "interest" requirement). Mylan has a direct, substantial, and protectable interest in receiving final approval and bringing its products to market in June 2008—not six months later, and thus should be allowed to intervene to protect that interest.

C. Teva's Requested Relief Would Impair Mylan's Ability To Protect Its Interests.

Third, Teva's requested injunction undoubtedly would impair Mylan's ability to protect its interest. To determine whether disposition of an action will impair or impede a protected interest, courts consider the "'practical consequences' of denying intervention, even where the possibility of future challenge to the regulation remains available." *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 735 (D.C. Cir. 2003) (citation omitted). Where, as here, "the task of reestablishing the *status quo* if the [plaintiff] succeeds in [its] case will be difficult and burdensome" and the "loss of revenues during any interim period would be substantial and likely irreparable," this factor is met. *Id*.

If Teva succeeds in this action, FDA approval of Mylan's risperidone ANDA will be withheld for at least another 180 days after Janssen's pediatric exclusivity expires. Teva, meanwhile, will enjoy sole access to the generic risperidone market during this time. As Teva itself recognizes, if Teva is awarded an official six-month "head start" in the market, it will gain a "permanent advantage over subsequent entrants" like Mylan, and likely will enter into long-term contracts that can hurt later entrants well after the exclusivity period expires. (*See* Teva Mem. at 27-28.) As a direct result, Mylan will suffer a substantial loss in sales, revenue, and market share not only during the 180-day period, but also for several months afterward—losses that, as Teva itself has noted, can never be recouped. (*See id*. at 28.) Because this Court will never be able to turn back the clock if Teva is allowed to market its risperidone product without generic competition for 180 days, and because Mylan's resulting losses would be unrecoverable from either FDA or Teva, the Court should allow Mylan to intervene as a Defendant to prevent such losses from occurring in the first instance.

D. FDA Can Not Adequately Represent Mylan's Interests.

Finally, FDA can not adequately represent Mylan's interests. Rule 24(a)(2) provides for intervention "unless existing parties adequately represent [the movant's] interest." FED. R. CIV. P. 24(a)(2). The burden of making this showing is "minimal" and "is satisfied if the applicant shows that representation of his interest 'may be' inadequate." *Fund for Animals*, 322 F.3d at 735 (quoting *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972)); *see also Me-Wuk Indian Cmty. of the Wilton Rancheria v. Kempthorne*, 246 F.R.D. 315, 320 (D.D.C. 2007) (Lamberth, J.) (same). Mylan certainly meets this burden.

As the D.C. Circuit has recognized, "the tactical similarity of the present legal contentions of the parties does not assure adequacy of representation or necessarily preclude the

intervenor from the opportunity to appear in its own behalf." *Fund for Animals*, 322 F.3d at 737 (internal quotations and citation omitted). Thus, because FDA's interests here are not squarely aligned with Mylan's, representation by FDA "may be" inadequate. While Mylan supports the Agency's challenged administrative decision denying Teva's request for 180-day exclusivity for risperidone, and both Mylan and FDA share the position that Teva's requested relief is inconsistent with the statutory and regulatory scheme governing patent certifications and 180-day exclusivity, FDA has no proprietary interests to protect and no financial stake in the outcome of this litigation. Mylan, on the other hand, most assuredly does.

Moreover, it is not in FDA's interests to advance the interests of one particular ANDA applicant over those of any other applicant or the public. Rather, as a federal agency, FDA's "obligation 'is to represent the interests of the American people.'" *Friends of Animals v. Kempthorne*, 452 F. Supp. 2d 64, 70 (D.D.C. 2006) (citation omitted). "For this reason, this Circuit has concluded that 'governmental entities do not adequately represent the interests of aspiring intervenors.'" *Id.* (quoting *Fund for Animals*, 322 F.3d at 736); *accord Dimond v. Dist. of Columbia*, 792 F.2d 179, 192 (D.C. Cir. 1986). There is no reason this Court should reach any other conclusion here. Mylan, therefore, should be allowed to appear on its own behalf to defend against Teva's attempt to substantially delay Mylan's approval and market entry.

II. In The Alternative, The Court, In Its Discretion, Should Permit Mylan To Intervene Under Rule 24(b).

For all the reasons discussed above, intervention as of right is appropriate here. If this Court should find otherwise, however, Mylan respectfully requests that it be permitted to intervene under Rule 24(b).

Under Rule 24(b), the Court may permit intervention upon a timely motion when the movant "has a claim or defense that shares with the main action a common question of law or

fact." FED. R. CIV. P. 24(b)(1)(B). Additionally, the Court "must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." FED. R. CIV. P. 24(b)(3).

Here, as explained above, Mylan has filed a timely motion, and has raised a common question of law or fact by claiming an interest in defending FDA's decision denying Teva 180-day exclusivity for risperidone tablets. Mylan's "real economic stake in the outcome of this litigation," moreover, strongly favors intervention. *Textile Workers Union of Am., CIO v. Allendale Co.*, 226 F.2d 765, 769 (D.C. Cir. 1955) (recognizing that, while "establishing a 'claim or defense' for purposes of permissive intervention is . . . not dependent upon a showing of 'direct pecuniary interest' in the litigation," intervention was justified where appellants had shown an economic interest).

Mylan's intervention also will not prejudice the original parties or unduly delay the proceedings. In fact, permitting Mylan to intervene would "promote judicial and administrative convenience by avoiding multiplicity of proceedings and by bringing to the aid of the tribunal the parties who 'may know the most facts and can best explain their implications.'" *Textile Workers Union*, 226 F.2d at 770 (citation omitted). Mylan, whose own ANDA approval is at risk of being significantly delayed, is in the best position to explain the practical implications of Teva's requested injunction. Moreover, should intervention be denied, Mylan would have to consider separate litigation to protect its interests, resulting in multiple related lawsuits. Accordingly, Mylan satisfies the requirements for permissive intervention under Rule 24(b).

CONCLUSION

For the foregoing reasons, Mylan respectfully requests that this Court enter an Order permitting Mylan to intervene in this case as a Defendant.

Dated: March 11, 2008.

Respectfully submitted,

MYLAN PHARMACEUTICALS INC.

By: */s/ William A. Rakoczy*
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