IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

THE MEDICINES COMPANY, Plaintiff, v. DAVID KAPPOS, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office; UNITED STATES PATENT AND TRADEMARK OFFICE; MARGARET A. HAMBURG, in her official capacity as Commissioner of the United States Food and Drug Administration; UNITED STATES FOOD AND DRUG ADMINISTRATION; KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No. 1:10-CV-00286-CMH/JFA ECF Case

MEMORANDUM IN SUPPORT OF MOTION OF APP PHARMACEUTICALS, LLC'S MOTION FOR LEAVE TO INTERVENE UNDER FEDERAL RULE OF CIVIL PROCEDURE 24

APP Pharmaceuticals, LLC ("APP") submits this memorandum in support of its Motion for Leave to Intervene under Federal Rule of Civil Procedure 24.

INTRODUCTION

APP has a direct and substantial interest in the outcome of this action. To protect that interest, APP previously sought, and was granted, leave to participate in this action as an *amicus curiae* opposing Plaintiff's motion for summary judgment and supporting Defendants' cross-motion for summary judgment. (D.I. 29-31, 37, 39, 40.) APP's *amicus curiae* brief addressing APP's specific interests, together with Defendants' defense in this action, previously adequately protected APP's interests.

On August 11, 2010, however, counsel for APP received a letter from counsel for Defendants indicating that Defendants have not decided whether they will appeal the Court's August 3, 2010, Order and judgment for Plaintiff in this action. (Ex. 1.) APP no longer can reasonably expect that APP's interests will be adequately represented (or represented at all) by Defendants.

APP therefore seeks leave to intervene for purposes of appeal. On appeal, APP may argue for reversal of this Court's August 3, 2010, Order (D.I. 55) based on arguments (1) made by APP in its *amicus curiae* brief (D.I. 40), (2) made by Defendants and *amicus curiae* Teva Pharmaceuticals USA, Inc. in this action, which APP adopts (*e.g.*, D.I. 17-24, 26, 38, 42, 43, 49, 52), (3) made by Defendants in the previous Action No. 01:10-cv-81, which APP also adopts (*e.g.*, D.I. 13, 17, 19, 22, 24), and (4) newly implicated by the Court's August 3, 2010, order and memorandum opinion. (*See* Ex. 2 (APP's proposed Answer).)

BACKGROUND

Under the Hatch-Waxman Act, companies may develop generic versions of listed drugs[1] without liability for infringement, for purposes of submitting information to the United States Food and Drug Administration ("FDA"), before patents covering the listed drugs ("listed patents") expire. 35 U.S.C. § 271(e)(1). However, liability for infringement may be based on the submission of an Abbreviated New Drug Application ("ANDA") seeking permission to market a generic version of a drug "claimed in a patent." 35 U.S.C. § 271(e)(2)(A). Drug companies must disclose all patents covering a listed drug. 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA provides a list of all such patents in a publication commonly known as the "Orange Book."

[1] A drug becomes a "listed drug" on approval of its New Drug Application. 21 U.S.C. § 355(j)(2)(A)(i).

Thus, generic drug makers like APP rely on the expiration dates of patents listed in the Orange Book to inform their business decisions about whether and when to invest in development of a given generic drug. These are significant strategic decisions in terms of time, money, and people. Investing money and assigning personnel to develop one drug means that opportunities to develop other generic drugs for the public are foregone. Unpredictable extensions of patent terms due to retrospective changes in the rules of the United States Patent and Trademark Office ("PTO") would undermine the ability of generic drug companies to make critical business decisions. Such extensions also could cause years of delay in marketing already-developed generic drugs, thus harming the public.

APP is a leading manufacturer of generic and branded injectable pharmaceutical products for acute medical care both in ambulatory and in-patient settings. APP markets over 115 generic drug products. As such, APP has an interest in and relies on the promulgation, maintenance, and enforcement of consistent rules and procedures by the PTO and the FDA.

APP has a direct interest in the outcome of this case. APP made substantial investments to develop a generic version of Plaintiff's Angiomax® product while relying on the published expiration date of United States Patent No. 5,196,404 ("the '404 patent"), the only patent Plaintiff had disclosed to the FDA as covering Angiomax® when APP filed its ANDA. Before APP decided to develop a generic version of Angiomax®, the PTO made a final determination that it would not extend the '404 patent's term, thus leaving the expiration date as March 23, 2010. That determination accorded with what the industry understood to be the PTO's longstanding practice. (*E.g.*, D.I. 29-4 (MPEP § 2754.01 (2001) ("The sixty-day period begins on the regulatory agency approval date . . . . For drug products the approval date is the date of a letter by the [FDA] indicating that the application has been approved....")))

APP filed its ANDA for generic Angiomax® in 2007, after the PTO's final agency action denying Plaintiff's patent term extension. (*See* D.I. 29-2 (11/21/2007 ANDA patent certification).) APP reasonably relied on the '404 patent's expiration date, and the PTO's longstanding rules regarding patent term extensions, in deciding to begin and continue development of a generic version of Angiomax® without a concurrent challenge to the '404 patent. With the '404 patent' expiration date only a few years away when APP filed its ANDA, it was unnecessary and inefficient to challenge the '404 patent. APP's development of a generic version of Angiomax® required time, money, and people that APP could have allocated to develop other generic drugs.

On August 3, 2010, this Court granted Plaintiff's motion for summary judgment, ordering that the PTO "consider [Plaintiff's] patent term extension application [for the '404 patent] timely filed and to adopt an interpretation of § 156(d)(1) that includes a next business day construction for filing of a patent term extension application." (D.I. 55; *see also* D.I. 54.) That order caused a retrospective change of PTO rules and procedures that the pharmaceutical industry (other than Plaintiff) has followed and relied upon for many years. As a consequence of the order, the PTO has issued a third interim extension of the '404 patent term (a cumulative extension of more than 16 months to date), while it considers Plaintiff's request for a patent term extension of more than four years. (Ex. 3 (8/5/2010 PTO Order Granting Interim Extension).) Thus, because of the Court's orders, instead of expiring March 23, 2010, the '404 patent now expires August 13, 2011, and may well be extended into late-2014. (*See* Ex. 3 ("An extension of 1,728 days is requested.")

This retrospective change prejudices APP. Under APP's current ANDA filing, the FDA will not permit APP to market its generic version of Angiomax® until the '404 patent expires.

See D.I. 29-2; 21 U.S.C. § 505(j)(2)(A)(vii)(III). Even if APP were to its ANDA to challenge the '404 patent, APP likely would be faced by a lawsuit from Plaintiff and, perhaps, a 30-month delay before the FDA would approve APP's generic version of Angiomax®. Given that Angiomax® has annual sales of almost $400 million, the Court's August 3 Order significantly impacts APP. (*See* D.I. 29-3 (Exhibit 2 to APP's *amicus curiae* brief).)

As shown below, this motion is timely and APP meets all the criteria for intervention as of right (and permissively) under Federal Rule of Civil Procedure 24.

ARGUMENT

I. APP IS ENTITLED TO INTERVENE AS OF RIGHT

A. Legal Standard

Fed. R. Civ. P. 24(a)(2) requires that courts permit intervention by any party that, on a timely motion

> 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.

As construed by the Fourth Circuit, intervention is required if a timely movant shows: "(1) an interest in the subject matter of the action; (2) that the protection of this interest would be impaired because of the action; and (3) that the applicant's interest is not adequately represented by the existing parties to the litigation." *Teague v. Bakker*, 931 F.2d 259, 260-61 (4th Cir. 1991) (citing *Virginia v. Westinghouse Elec. Corp.*, 542 F.2d 214, 216 (4th Cir. 1976)).

B. APP's Motion for Leave to Intervene is Timely

Motions to intervene, whether as of right or permissive, must be timely, based on all the circumstances. Fed. R. Civ. P. 24(a) & (b); *Hill Phoenix, Inc. v. Systematic Refrigeration, Inc.*, 117 F. Supp. 2d 508, 514 (E.D. Va. 2000). The most important consideration in this analysis is

"the prejudice caused to the other parties by the delay" in seeking intervention. *Id.* (citing *Spring Constr. Co., Inc. v. Harris*, 614 F.2d 374, 377 (4th Cir. 1980)).

Here, neither Plaintiff nor Defendants will be prejudiced if APP now intervenes. APP seeks intervention in order to pursue an appeal. Accordingly, APP will not take discovery or otherwise delay this action. As discussed above and in APP's attached proposed Answer, APP plans to present arguments on appeal previously made by Defendants and *Amici Curiae* in this action, and by Defendants in the predecessor action, as well as any new arguments implicated by the August 3 Order that Defendants could raise on appeal if they appealed.

Motions to intervene for the purpose of appeal are timely even when filed post-judgment, if filed within the applicable time for filing a notice of appeal. *See, e.g., United Airlines, Inc. v. McDonald*, 432 U.S. 385, 395-96 & 396 n.16 (1977). Here, judgment has not been entered. Further, if the August 3 Order is deemed to be entry of judgment, then the time for filing a notice of appeal has not yet expired. *See* Fed. R. App. P. 4(a)(1)(B) (specifying that a notice of appeal may be filed by any party "within 60 days after the judgment or order appealed from is entered").

As discussed above, APP has filed its motion to intervene within a week after receiving a letter from the Government suggesting that Defendants may not pursue an appeal regarding the August 3 Order. That is timely action:

> Here the appellants claim that in moving to intervene they were prompted by the post-judgment prospect that the Government might not appeal. Prior to the entry of judgment, the appellants say, they had no reason to intervene; their interests were fully consonant with those of the Government, and those interests were adequately represented by the Government's litigation of the case. We agree. In these circumstances a post-judgment motion to intervene to prosecute an appeal is timely (if filed within the time for appeal) because "the potential inadequacy of representation came into existence only at the appellate stage."

Smoke v. Norton, 252 F.3d 468, 471 (D.C. Cir. 2001) (reversing district court order that denied motion for leave to intervene as untimely).

C. APP has an Interest in the Subject Matter of the Action Sufficient to Intervene as of Right

To intervene as of right, a petitioner must have "a significantly protectable interest." *Donaldson v. U.S.*, 400 U.S. 517, 531 (1971). In the Fourth Circuit, this includes interests that are contingent on the outcome of other proceedings. For example, in *Teague v. Bakker*, a district court denied an insurance company's motion for leave to intervene as of right because its interest was contingent on the outcome of other pending litigation. *Teague*, 931 F.2d at 259-61. The Fourth Circuit reversed, finding that intervention should be permitted "even when the intervenor's interest is contingent on the outcome of other litigation." *Id.* at 261.

APP's interest in the present matter is sufficient for Rule 24(a) intervention. As discussed above, APP has invested substantial resources to develop its generic version of Angiomax® and pursue marketing approval from the FDA. Angiomax® generates over one million dollars a day in revenues for Plaintiff. Every day that APP is delayed in launching its generic product is a day that APP cannot compete in the marketplace with Plaintiff for a share of those revenues. As explained above, APP believes the Court's August 3 Order will significantly delay APP's ability to launch its product, frustrating APP's reasonable expectations and causing economic prejudice.

D. The Protection of APP's Interest Would be Impaired by Disposition of this Action

"In order to successfully intervene, [the applicant] 'must show…that without intervention, its interests may be impaired.'" *United Guar. Residential Ins. Co. v. Philadelphia Sav. Fund*, 819 F.2d 473, 474 (4th Cir. 1987) (quoting *Virginia v. Westinghouse Elec. Corp.*, 542 F.2d 214, 216 (4th Cir. 1976)). Impairment is indisputable here. As a direct result of the August 3 Order, the PTO already has issued a one-year extension of the '404 patent term. (Ex. 3.)

E. APP's Interest is Not Adequately Represented by Defendants

The burden to show that an applicant's interests are not adequately represented is "minimal." *Trobovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972). This burden is satisfied if the applicant shows that representation of its interests "may be" inadequate. *Id.*; *United Guar. Residential Ins. Co.*, 819 F.2d at 475. Defendants recently suggested that they may not pursue an appeal. (Ex. 1.) Even if Defendants now file a notice of appeal, this uncertainty establishes at least that "there is a significant chance that [Defendants] might be less vigorous than [APP] in defending their claim...." *Teague*, 931 F.2d at 262. Defendants may decide to abandon the appeal. Defendants may omit important arguments on appeal. APP's intervention is necessary to safeguard against the potential inadequate representation resulting from the Government's ambivalence.

II. IF THE COURT DENIES INTERVENTION AS OF RIGHT, IT SHOULD ALLOW APP TO INTERVENE PERMISSIVELY

If this Court denies intervention as of right, then APP requests that the Court exercise its discretion to allow APP to intervene permissively under Federal Rule of Civil Procedure 24(b)(1)(B). On a timely motion, Rule 24(b)(1)(B) authorizes the court to permit anyone to intervene who "has a claim or defense that shares with the main action a common question of law or fact." Permissive intervention "requires less" than intervention of right, but the applicant usually must also show an independent jurisdictional basis. *Media General Cable of Fairfax, Inc. v. Sequoyah Condominium Council of Co-Owners*, 721 F. Supp. 775, 779 (E.D. Va. 1989).

APP's defense that the '404 patent has expired and is not entitled to an extension under 35 U.S.C. § 156(d)(1) is shared by Defendants. This defense presents the identical question, and therefore satisfies the common question component of Rule 24(b). This Court has subject matter

jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a). APP therefore meets the two criteria necessary for a court to grant permissive intervention.

If a common question of law or fact and an independent jurisdictional basis are shown, the applicant may be permitted to intervene unless the court determines that intervention will unduly delay the action or prejudice the rights of the original parties. *Media General Cable of Fairfax*, 721 F. Supp. at 779-80. Whether the applicant's delay in moving for intervention has prejudiced the existing parties, and whether the applicant will expand the issues causing further delay, are among the most important criteria in this analysis. *Id*. at 780 (citing *Hill v. Western Elec. Co.*, 672 F.2d 381 (4th Cir. 1982)).

Before receiving the Government's letter, suggesting that Defendants may not appeal, APP had no reason to question that Defendants would vigorously defend this action. Mindful of this Court's requirements for efficiency and practicality, and especially because the Court permitted APP to file an *amicus curiae* brief, APP did not move to intervene before receiving the Government's letter. Now, however, for the first time, the necessity to protect APP's appellate rights is compellingly clear. Thus, there was no delay in filing this motion to intervene.

Nor is there prejudice to the parties. Because APP has already participated in the suit as *amicus curiae*, the existing parties have been on notice of APP's interest in the suit. APP is seeking intervention for the purpose of appeal, and will not expand the issues raised in the present action or delay its resolution. Therefore, APP's motion for leave to intervene is timely and APP's intervention will not prejudice the existing parties.

CONCLUSION

For the reasons discussed above and in the attached proposed pleading, APP respectfully requests that the Court grant APP's motion and deem APP's Answer filed upon the granting of this Motion without requiring a separate filing.

Dated: August 19, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of August 2010, I electronically filed in Case No. 1:10-cv-00286 (CMH/JFA) the foregoing MEMORANDUM IN SUPPORT OF MOTION OF APP PHARMACEUTICALS, LLC'S MOTION FOR LEAVE TO INTERVENE UNDER FEDERAL RULE OF CIVIL PROCEDURE 24 using the CM/ECF system and that service was thereby accomplished on:

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