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

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

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INTRODUCTION

Both the Plaintiff and the Government fundamentally misunderstand, or misrepresent, the grounds for APP's motion to intervene. APP is not seeking to challenge the PTO's action on Plaintiff's application for extension of the '404 patent's term. APP is not seeking to insert itself into the patent term extension process. APP does not claim to be harmed by, and does not wish to appeal, the underlying agency decision. Instead, APP seeks to appeal the decision of this Court changing the timeliness requirements for patent term extension applications retroactively, a decision that harms APP, in substantial ways that will be explained below.

APP's injury here directly arises from this Court's orders directing the PTO to extend the '404 patent term. But for those orders, the '404 patent would have expired on March 23, 2010. Now, however, if APP's activities stray from those permitted by the patent infringement safe harbor of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(1), then APP would be exposed to suit by Plaintiff for patent infringement. Put another way, the Court's orders continued the term of the '404 patent, which otherwise would have expired March 23, 2010. The extension destroyed APP's freedom to run its business free from any threat from the '404 patent after March 23, 2010. That is not a speculative injury. It is an actual injury, flowing from the Order.

In addition, the Court's orders deprive APP of a substantial right – the right to market a generic version of Angiomax immediately upon FDA approval. As a consequence, APP must now either (1) wait to launch its generic Angiomax until after the '404 patent's new expiration date, or (2) amend its ANDA to challenge validity and/or infringement of the '404 patent, which would trigger a lawsuit against APP by MedCo. (*See* Plaintiff's Opposition to Motion of APP Pharmaceuticals LLC for Leave to Intervene ("Plaintiff's Opp'n") at 19 n.12.) In addition, if

APP so amends its ANDA and Plaintiff files suit, a statutory stay triggered by Plaintiff's filing would prohibit FDA from approving APP's product for marketing for 30 months. (*Id.*)

The immediate and practical effects of this Court's August 3 Order on APP and similarly situated generic drug companies will be to (1) compel APP to bear the cost of another ANDA patent infringement lawsuit if it wants to market a generic version of Angiomax before sometime in 2015, and (2) delay market entry of generic Angiomax products for years, impairing APP's recoupment of investments in developing generic Angiomax products. This delay will also harm the public by delaying access to lower-cost generic Angiomax products.

Instead of dealing straightforwardly with this issue, and addressing the harm to APP from this Court's ruling, Plaintiff and the Government both conjure up a straw man, suggesting that APP is attempting to insert itself as a third party in an *ex parte* agency action, taking issue with the ruling of the PTO. Then they argue at length about the law of intervention generally, and urge irrelevant policy considerations against allowing third parties to intervene in *ex parte* proceedings. In doing so, they miss the points of APP's brief: (1) the harm to APP results from *this Court's ruling*, not the underlying agency ruling, and (2) the *controlling Fourth Circuit authorities* cited by APP in its opening brief *require intervention* on the facts here.

Contrary to the parties' responsive briefs, the actual controversy at issue is quite simple. Years ago the PTO entered its Final Decision denying Plaintiff's application to extend the '404 patent term. As a consequence, the expiration date of the '404 patent was confirmed as March 23, 2010. That Final Decision was consistent with the PTO's longtime and well-known policies effectuating the patent term extension provision of the Hatch-Waxman Act (*i.e.*, 35 U.S.C. § 156). The PTO's Decision affirmed the ***right*** of APP to market a generic version of Angiomax subject to FDA approval after March 23, 2010, without fear of litigation based on

'404 patent. This Court's Order of August 3, 2010 (and underlying related orders), ***revoked that right***.

APP is not seeking to interfere in PTO *ex parte* proceedings. Indeed, APP does not seek review of any administrative proceeding or resulting administrative agency decisions. Nor is APP intending to "take over the role of the government" in this matter. Rather, APP seeks intervention to restore on appeal the right this Court's ruling took away — to be free of the '404 patent as of March 23, 2010. Thus, the extensive legal support and argument the parties submit for the proposition that APP may not intervene to challenge *ex parte* agency action is simply irrelevant to the situation here. By way of example, the "zone of interests" prudential standing analysis urged by the parties is a red herring because that doctrine applies ***only*** where a party seeks intervention to challenge an agency determination.

Also irrelevant here are the parties' treatises about whether APP will have standing on appeal if the Government chooses not to participate. There is no dispute that the Government has not decided whether it will appeal. And that question will not be answered until the Government files (or does not file) its appellate brief. If the Government chooses not to appeal, it will be the responsibility of the Federal Circuit to assess whether APP's interest is sufficient to support subject matter jurisdiction. That question is not ripe for determination by this Court.

In addition to the incorrect factual predicate for the parties' responses to APP's Motion, they rely on inapplicable legal precedent. The controlling law for adjudicating APP's request is uncontrovertibly that of the Supreme Court and the Fourth Circuit. As reflected in *Teague*, the Fourth Circuit takes the view that contingent interests suffice for intervention to appeal a court's order, and APP has such an interest. The parties, however, improvidently rely on decisions such

as *Teva Pharms. USA, Inc. v. Sebelius* by courts that disagree with the Fourth Circuit, and in several places do not even attempt to distinguish the controlling law cited by APP.

As demonstrated in its opening brief and below, APP has met its burden of showing why intervention is mandatory, or at least should be permitted, under the controlling law. Neither Plaintiff nor the Government effectively rebuts APP's showing. Indeed, while in effect arguing against APP's intervention, the Government formally declined to oppose intervention.

I. THE LAW OF THE FOURTH CIRCUIT CONTROLS

The law of the Fourth Circuit, and not of any other circuit, governs APP's request for leave to intervene. The Federal Circuit, the court that would decide any appeal of this action, acknowledges as much. *See Stauffer v. Brooks Bros., Inc.*, Nos. 2009-1428, -1430, and -1453, 2010 U.S. App. LEXIS 18144, at *20 (Fed. Cir. Aug. 31, 2010) ("We review the district court's denial of intervention under Rule 24 under regional circuit law, in this case that of the Second Circuit."). The law of circuits other than the Fourth Circuit is inapplicable here where it conflicts with controlling Fourth Circuit precedent, such as *Teague*.

II. THE STANDING ISSUE IS NOT RIPE AND, IN ANY EVENT, APP HAS STANDING TO INTERVENE

As a preliminary matter, the standing issues raised by the parties are not ripe for adjudication by this Court. Both Plaintiff and the Government argue at length that APP would not have standing to appeal if the Government chooses not to do so. (*See* Plaintiff's Opp'n at 4-13; *see also* Defendants' Response to APP Pharmaceuticals, LLC's Motion for Leave to Intervene ("Defendants' Resp.") at 2-9.) The Government's response to APP's Motion, however, makes clear that the Government may indeed pursue an appeal. (*See* Defendants' Resp. at 3 (reminding the Court of "the *potential* decision against appeal") (emphasis in original).) The answer to this question will not be known with certainty until the Government

actually participates (or chooses not to participate) in an appeal, and even then, not until the appeal process is completed.

If the Government does participate in or complete an appeal APP would have standing to participate as well. *Diamond v. Charles*, 476 U.S. 54, 64 (1986) (stating that intervenor can "'piggyback' on the [existing parties'] undoubted standing" if they are parties to appeal). The parties do not seriously dispute this proposition. (*See generally* Plaintiff's Opp'n; *see also* Defendants' Resp. at 3 (mischaracterizing APP's Motion as "exclusively premised upon the notion that the federal defendants would *no longer* be parties" on appeal and then limiting its "Response" accordingly).) Whether there would be standing on appeal if the Government chooses not to participate in or complete the appeal is an issue for the Federal Circuit, not this Court, to decide. This issue is not yet ripe for adjudication. *Id.*

Further, even if standing, Constitutional or otherwise, to intervene in this matter is required, APP's standing is clear. APP is not seeking to challenge the PTO's agency action or to "take over the role of the government" in this matter. Rather, APP is seeking to restore its right, taken away by this Court's rulings, to operate its business without fear of suit based on the '404 patent after March 23, 2010. The loss of that right is a sufficiently concrete injury to support standing.

A. APP Has Constitutional Standing to Intervene

APP satisfies all the criteria with respect to Constitutional standing in order to intervene in this matter:

> (1) it has suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action . . . ; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc., 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

With respect to the first prong, APP has suffered a particularized injury-in-fact. That injury was caused by this Court's orders, not by agency action. The PTO's Final Decision refusing to extend the '404 patent's term, grounded in the longstanding PTO policy interpreting and implementing Section 156, affirmed the absolute right of APP to pursue marketing of generic Angiomax free from potential litigation involving the '404 patent any time after March 23, 2010. That right was abrogated by direct legal operation of this Court's orders. APP is entitled to appeal that order because it has a direct stake in the outcome of this litigation.[1]

As to the second prong, destruction of that right is not only fairly—but directly—traceable to the challenged action, this Court's August 3, 2010 Order. Finally, as to the third prong, a favorable decision obtained by APP on appeal will unquestionably redress its injury, as a reversal of the Order would result in the '404 patent being deemed to have expired as of March 23, 2010.

B. APP Has Any Requisite Prudential Standing to Intervene Because APP Has Suffered Direct Harm

The argument by Plaintiff and the Government that APP lacks "prudential standing" to intervene is a red herring. (*See* Plaintiff's Opp'n at 5-10; Defendants' Resp. at 5.) Prudential

[1] *See Bryant v. Yellen*, 447 U.S. 352, 367-68 (1980) (affirming intervention where intervenors have "a sufficient stake in the outcome of the controversy"); *Teague v. Bakker*, 931 F.2d 259, 261 (4th Cir. 1991) ("Intervenors stand to gain or lose by the direct legal operation of the *district court's judgment*…." (emphasis added)); *W. Watersheds Project v. Kraayenbrink*, Nos. 08-35359, -35360, 2010 U.S. App. LEXIS 18250, at *18-19 (9th Cir. Sept. 1, 2010) ("To invoke this court's jurisdiction on the basis of an injury *related to the judgment*, Intervenors must establish that the *district court's judgment* causes their members a concrete and particularized injury. . ." (citation omitted) (emphasis added)); see also *Rutherford Cnty. v. Bond Safeguard Ins. Co.*, 1:09cv292, 2009 U.S. Dist. LEXIS 127842, at *12 (W.D.N.C. Dec. 3, 2009) (citing *Teague*, 931 F.2d at 261) ("Where the intervenor ***stands 'to gain or lose by the direct legal operation of the district court's judgment***,' the intervenor's interest in the subject matter of the litigation is significantly protectable.").

standing, with its "zone of interest" analysis, is only required when a third party seeks to overturn an agency action, which APP does not seek to do.

First, the parties are incorrect that APP is seeking intervention in this matter in an effort to supplant the Government or step into its shoes. Instead, APP wants to intervene so that it can fight for *its own* rights and interests that were directly abrogated by this Court's orders.[2] Second, ***APP is not challenging any administrative decision*** but rather the Court's decision overruling an administrative decision. The "zone of interest" analysis therefore does not apply. As explained by the Supreme Court,

> [t]he ***"zone of interest" test is a guide for deciding whether***, in view of Congress' evident intent to make agency action presumptively reviewable, ***a particular plaintiff should be heard to complain of a particular agency decision***. In cases where the plaintiff is not itself the subject of the contested regulatory action, the test denies a right of review if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.

Clarke v. Sec. Indus. Ass'n, 479 U.S. 388, 399 (1987) (emphasis added). Where intervenors challenge a court order overruling an agency action, rather than the underlying agency action itself, the standing inquiry examines the nature of the injury caused by the court order rather than whether there would have been standing to challenge the agency decision. *W. Watersheds Project*, 2010 U.S. App. LEXIS 18250, at *18-19. So, the "zone of interest" analysis has no application in this case.

In *Western Watersheds Project*, Plaintiffs were a conservation group that brought suit to invalidate new grazing regulations promulgated by the Bureau of Land Management ("BLM"). Intervenors were ranching associations who intervened on behalf of the BLM to defend the new

[2] *But see W. Watersheds Project*, 2010 U.S. App. LEXIS 18250, at *18-19 (observing that "the government is not the only party who has standing to defend the validity of federal regulations"); *Schulz v. Williams*, 44 F.3d 48, 52 (2d Cir. 1994) (stating that "various circuits have recognized situations in which a private individual has standing to defend on appeal a law or regulation even though the government has acquiesced in a district court's determination of invalidity").

regulations. The district court granted summary judgment in favor of Plaintiffs and permanently enjoined implementation of the BLM regulations. Both the BLM and the Intervenors appealed. Shortly afterwards, however, the BLM moved to dismiss its appeal, acquiescing in the court's ruling. The Intervenors maintained their appeal. Plaintiffs subsequently attacked Intervenors' standing to appeal, and "the BLM submitted an amicus brief in support of Plaintiffs' argument that Intervenors' lack[ed] Article III standing to maintain their appeal absent the government." *Id*., at *17.

Despite the original parties' protests, the appellate court held that Intervenors had standing to pursue the appeal in the absence of original defendant BLM:

> [T]he government is not the only party who has standing to defend the validity of federal regulations. *See, e.g., Kootenai Tribe of Idaho v. Veneman*, 313 F.3d 1094, 1110 (9th Cir. 2002) (holding that intervenors could appeal and challenge the grant of injunctive relief by defending the government's action against alleged violations of NEPA when the federal defendants decided not to appeal); *see also Didrickson v. U.S. Dep't of the Interior*, 982 F.2d 1332, 1339 (9th Cir. 1992) (holding that environmental groups had standing to defend government regulations on appeal, despite the government's dismissal of its appeal). . . .
>
> Absent the government, however, Intervenors must now, ***and for the first time***, establish Article III standing. *See Diamond v. Charles*, 476 U.S. 54, 68 (1986) ("[A]n intervenor's right to continue a suit in the absence of the party on whose side intervention was permitted is contingent upon a showing by the intervenor that he fulfills the requirements of Art. III."); *see also Didrickson* , 982 F.2d at 1338 ("An interest strong enough to permit intervention is not necessarily a sufficient basis to pursue an appeal abandoned by the other parties.").
>
> ***In these circumstances, Intervenors' standing need not be based on whether they would have had standing to independently bring this suit, but rather may be contingent on whether they have standing now based on a concrete injury related to the judgment.*** *See Didrickson*, 982 F.2d at 1338; *see also Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1398 (9th Cir. 1995). To invoke this court's jurisdiction on the basis of an injury related to the judgment, Intervenors must establish that the district court's judgment causes their members a concrete and particularized injury that is actual or imminent and is likely to be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992).

Id., at *18-19 (emphasis added).

Western Watersheds Project had a fact pattern nearly identical to that now before the Court: (1) the district court granted judgment to Plaintiffs, enjoining the agency action, (2) the Intervenors sought to intervene for purposes of defending the administrative action and ultimately to overturn the judgment on appeal, (3) the Government ultimately did not participate in the appeal, and (4) the Government contested the Intervenors' pursuit of appeal on their own. On those identical facts, the appellate court held that the Intervenors had standing to pursue the appeal in the absence of the Government.[3]

The analysis employed by *Western Watersheds Project* is aligned with controlling precedent of the Fourth Circuit, where standing to intervene hinges on the nature of the interest at issue. *Teague*, 931 F.2d at 260-61, provides the courts of the Fourth Circuit with a three-part test to be used to assess the propriety of intervention by third parties: "(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 existing parties to the litigation." *Id.* (citing *Donaldson v. United States*, 400 U.S. 517, 531 (1971) to clarify that in requiring an interest in the subject matter of the action "what is obviously meant . . . is a significantly protectable interest" in a Constitutional sense). Courts of this circuit have found that "a significantly protectable interest" also meets the Fourth Circuit's standing requirement. *United States v. ExxonMobil Corp.*, 264 F.R.D. 242, 245 (N.D. W. Va. 2010) ("Generally, to intervene as a matter of right a party must have a 'significantly protectable interest' in the outcome of the litigation. Courts have also characterized this element as a 'standing requirement.'" (citations omitted)).

[3] Notably, the court conducted a "zone of interest" analysis only in examining the Plaintiffs' standing — not the Intervenors' standing. *Id.,* at *25. This underscores that the prudential "zone of interests" analysis is inapplicable to APP here, challenging the judgment, not the agency action, just as the Intervenors in *Western Watersheds Project*.

As APP explains in its opening brief and in this rebuttal brief, by meeting *Teague*'s "significantly protectable interest" test, APP meets any requirement the Fourth Circuit might impose for standing in this instance. That is, APP "stands 'to gain or lose by the direct legal operation of the district court's judgment'." *Rutherford,* 2009 U.S. Dist. LEXIS 127842, at *12 (finding "the intervenor's interest in the subject matter of the litigation is significantly protectable.").

III. APP SATISFIES THE REQUIREMENTS FOR BOTH MANDATORY AND PERMISSIVE INTERVENTION UNDER RULE 24

A. APP Is Entitled To Intervene As Of Right

APP's opening brief and the standing discussion above provide confirmation that APP meets each prong of *Teague*'s three-part test, entitling APP to intervene as of right in these proceedings. As explained below, Plaintiff's challenge fails because it does not take into account the facts here and because Plaintiff relies on inapposite law. The Government, meanwhile, does not challenge applicability of the *Teague* test to APP, but rather focuses solely on prudential standing.

1. APP has a legally cognizable interest, and it is not the interest identified by Plaintiff

Plaintiff mistakenly asserts that it is APP's economic interests "in competing with" Plaintiff that should serve as the basis for determining whether APP may intervene as of right in these proceedings. (Plaintiff's Opp'n at 14.) While that certainly is an interest of APP's, that is not the interest on which APP relies to establish its right to intervene. Rather, APP relies on its interest in restoring the rights it enjoyed prior to the Court's August 3, 2010 Order. In particular, APP's legally cognizable interest is the right to conduct its business without the specter of infringement litigation based on the '404 patent, including the right to pursue commercial marketing of generic Angiomax immediately upon FDA approval. Prior to this Court's orders,

APP had that right. By direct operation of this Court's orders, APP lost that right. That harm is neither speculative nor contingent. Contrary to Plaintiff, therefore, APP *does* stand "to gain or lose by the direct legal operation of the district court's judgment." (Plaintiff's Opp'n at 17 (citing *Teague*, 931 F.2d at 261).)

Additionally, even if APP's injuries were wholly contingent (which they are not) the contingent injury identified by Plaintiff suffices for intervention in the Fourth Circuit under *Teague*. Plaintiff makes much ado about the fact that APP has not yet received approval from the FDA to market its generic version of Angiomax[4], but an interest contingent on the outcome of another proceeding is a sufficient interest for intervention under controlling Fourth Circuit law. (*See* APP's Opening Br. at 7 (citing *Teague*, 931 F.2d at 259-61).) The Fourth Circuit (with the Eighth and Ninth Circuits following suit) has unequivocally held that a contingent interest may be sufficient to intervene as of right. (*Id*.; *see also Teague*, 931 F.2d at 261 ("We find the reasoning of [various authorities allowing intervention '. . . even when the intervenor's interest is continent . . .'] persuasive.")

Moreover, Plaintiff's argument that APP is attempting to insert itself into the *ex parte* patent term extension proceeding is incorrect. APP's injury arises from this Court's orders, not from the underlying PTO decision. As discussed above, the "zone of interests" analysis therefore is inapplicable. This simple but critical distinction obviates Plaintiff's objections to APP's intervention.

[4] It was improper for Plaintiff to disclose *in a public filing* the confidential status of APP's ANDA. APP has not made that information public, although it was disclosed to Plaintiff's outside litigation counsel in a separate patent infringement action brought by Plaintiff against APP ***subject to the Protective Order in that litigation***. That Protective Order prohibited disclosure of such highly confidential information to in-house counsel at Plaintiff, as well as to any outside counsel not of record in that lawsuit.

2. Protection of APP's interest will be impaired unless APP is permitted to intervene

Plaintiff would have the Court believe that because APP could challenge the propriety of extending the '404 patent term retroactively in a separate litigation, APP cannot show that, absent intervention, protection of APP's interest will be impaired. Not only is that argument illogical, it ignores the realities of the situation here.

In urging the "separate litigation" alternative to intervention, Plaintiff knows that this "separate litigation" will presumptively trigger an automatic 30-month statutory delay in FDA's approval of APP's ANDA. 21 U.S.C. § 355(c)(3)(C); *see also* Plaintiff's Opp'n at 19 n.12. Thus, regardless of the propriety of extending the '404 patent term, Angiomax will enjoy the benefit of an additional 2½ years of market exclusivity. Plaintiff's annual Angiomax revenues are approximately $400 million. So even if (when) the '404 patent term extension is ultimately deemed invalid, Plaintiff will have earned an additional ***$1 billion*** by expiration of the 30-month stay, at the expense of APP, similarly situated generics, and the public. That is a windfall for Plaintiff of massive proportions.

One of APP's interests is the right to pursue commercial marketing of generic Angiomax as of March 23, 2010 without fear of litigation concerning the '404 patent. By definition, then, ***any "separate litigation" concerning the '404 patent undercuts the very right APP currently seeks to restore through intervention in this matter***. Plaintiff's argument is illogical and untenable. As a matter of law, the avoidance of "separate litigation" is an interest sufficient to award intervention as of right. *See, e.g.*, *Int'l Bhd. of Elec. Workers v. Interstate Commerce Com.*, 862 F.2d 330, 334 (D.C. Cir. 1988) (where prospective intervenors were permitted in order to avoid being "forced to litigate").

3. The Government's representation on appeal, whether or not it decides to pursue one, will be inadequate

Plaintiff states that "if the government *does* decide to appeal, APP has failed to identify any viable basis for rebutting the presumption that the government would adequately represent its interests." (Plaintiff's Opp'n at 20.) This is wrong. APP's opening brief highlights the fact that the Government's ambivalence regarding appeal to date is sufficient as a matter of controlling Supreme Court and Fourth Circuit precedent. (APP's Opening Br. at 8 (citing *Trobovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972) and *United Guar. Residential Ins. Co. v. Philadelphia Sav. Fund*, 819 F.2d 473, 475 (4th Cir. 1987) for the proposition that the burden to show inadequate representation is "minimal" and is satisfied if the applicant shows that the representation of its interests "may be" inadequate).)

Additionally, the Government's "Response" to APP's Motion, purportedly submitted as a "neutral arbiter" with respect to APP's request to intervene, reads like an *amicus* brief supporting Plaintiff. (*See generally* Defendants' Resp. (erroneously implying that APP lacks standing to intervene and misguidedly characterizing APP's interest in this matter as a third-party interest in an *ex parte* proceeding).) In sum, it is not reasonable to assume the Government will adequately represent APP's interests because the Government misconstrues APP's position and, in effect, opposes APP's intervention, .

4. APP timely sought leave to intervene

Plaintiff cites to *Houston Gen. Ins. Co. v. Moore*, 193 F.3d 838, 840 (4th Cir. 1999) for the proposition that "[t]here is considerable reluctance on the part of courts to allow intervention after the action has gone to judgment." What Plaintiff fails to mention, however, is that the court in *Houston General* denied intervention in that instance because the prospective Intervenor filed its request to intervene well after the time to file a notice of appeal had expired. *Id.* Indeed,

where leave to intervene is sought prior to such expiration, Supreme Court precedent cited by APP permits intervention for purposes of appeal, even post-judgment. (*See* APP's Opening Br. at 6 (citing *United Airlines, Inc. v. McDonald*, 432 U.S. 385, 395-96 & 396 n.16 (1977).) According to *United Airlines*, "[t]he critical inquiry in every such case [where leave to intervene is sought post-judgment] is whether in view of all the circumstances the intervenor acted promptly after the entry of final judgment." *Id.* at 395-96.

As stated above, APP's interest in intervening in these proceedings ripened when the Court issued its August 3, 2010 Order. Intervention before August 3, 2010, would have been premature. Additionally, as the intervenor in *United Airlines* had done, APP sought intervention prior to the expiration of time permitted for either party to file a notice of appeal. *See id.* APP therefore timely sought leave to intervene.

Confusingly, Plaintiff states that "if the government decides to appeal, APP's excuse for filing so belatedly disappears." (Plaintiff's Opp'n at 20.) Again, Plaintiff misses the issue. APP moved for leave to intervene only 16 days after the Court's August 3, 2010 Order, and it filed its request within days of learning about the Government's ambivalence towards appeal. Whether the Government ultimately decides to appeal has no bearing on APP's timeliness in seeking leave to intervene.

B. Alternatively, APP should be allowed to intervene permissively

As explained in APP's opening brief, permissive intervention "requires less" than intervention by right. It requires "a timely application showing that the proposed intervenor's claim or defense and the main action have a question of law or fact in common." *Media Gen. Cable of Fairfax, Inc. v. Sequoyah Condo. Council of Co-Owners*, 721 F. Supp. 775, 779 (E.D. Va. 1989). It also generally requires an independent jurisdictional basis. *Id*.

Here, APP satisfies both standards because it merely seeks to appeal the Court's August 3, 2010 Order, which is uniquely the province of this Court and, for appellate purposes, the U.S. Court of Appeals for the Federal Circuit because the issue arises from the patent laws. Because the disputed issue arises under the patent laws of the United States, the Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Plaintiff's entire argument against granting APP permissive intervention is built upon the flawed premise that APP is seeking to intervene as a third-party to an *ex parte* proceeding. (*See* Plaintiff's Opp'n at 20-23.) The three reasons Plaintiff provides to deny permissive intervention are therefore without merit.

First, Plaintiff misguidedly states that "APP has no independent right to seek judicial review of PTO rulings on applications for patent term extensions filed pursuant to § 156(d)(1)." (*Id.* at 21.) But again, APP is not seeking judicial review of any PTO ruling and does not contest Plaintiff's standing in its underlying action against the PTO. Instead, APP seeks appellate review of this Court's orders, which impermissibly and retroactively revived the '404 patent from expiration. As a result, permissive intervention "need not be based on whether [APP] would have had standing to independently bring this suit, but rather may be contingent on whether they have standing now based on a concrete injury related to the judgment." *W. Watersheds Project*, 2010 U.S. App. LEXIS 18250, at *19. As explained previously, APP has identified a legally cognizable interest based on a concrete injury related to this Court's orders.

Second, Plaintiff raises the issue of timeliness. (Plaintiff's Opp'n at 22.) Again, APP sought leave to intervene within days after learning that the Government's representation may be inadequate. APP timely sought leave to intervene.

Third, Plaintiff makes an argument "explained in its opposition to APP's amicus brief" (and therefore already rejected by the Court) that raising the "retroactive rulemaking" argument

as set forth in APP's *amicus* brief would be improper. (Plaintiff's Opp'n at 22-23.) Plaintiff asserts that because (1) APP—and not the Government—first articulated the "retroactive ruling making" argument, and (2) "a court deciding an APA challenge is not permitted to consider arguments not given by the agency, there is simply no reason to permit a third party that did not even participate in the *ex parte* proceedings below to intervene in defense of the agency." *Id.* Even if that were true[5], once again, Plaintiff's theory is premised upon the flawed premise that APP is seeking to intervene as a third party to an *ex parte* proceeding. That premise is wrong.

As set forth in APP's Motion, APP has met all the conditions necessary for the Court to grant permissive intervention in this matter should it determine APP cannot intervene as a matter of right.

CONCLUSION

For the reasons discussed above as well as those provided in APP's Motion, APP respectfully requests that the Court grant APP's motion, deem APP's Answer filed upon the granting of this Motion without requiring a separate filing, and transfer the record to the United States Court of Appeals for the Federal Circuit.

[5] In fact, the Government did rely, in part, on this argument to support its decision. (*See* D.I. 38, at 5-6.(Reply Memorandum In Support of Defendants' Motion for Summary Judgment.)

Dated: September 9, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of September 2010, I electronically filed in Case No. 1:10-cv-00286 (CMH/JFA) the foregoing REBUTTAL BRIEF IN SUPPORT 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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