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.	Civil Action No. 01:10-cv-286-CMH/JFA **PLAINTIFF'S BRIEF IN OPPOSITION TO MOTION OF APP PHARMACEUTICALS LLC FOR LEAVE TO INTERVENE**

Peter D. Keisler (*pro hac vice*)
Jeffrey P. Kushan (VSB # 34452)
C. Frederick Beckner III (*pro hac vice*)
Lowell J. Schiller (*pro hac vice*)
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Tel: (202) 736-8000
Fax: (202) 736-8711
pkeisler@sidley.com

Craig C. Reilly (VSB # 20942)
111 Oronoco Street
Alexandria, Virginia 22314
Tel: (703) 549-5354
Fax: (703) 549-2604
craig.reilly@ccreillylaw.com

Attorneys for Plaintiff THE MEDICINES COMPANY

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES, REGULATIONS, AND RULES

TREATISES

INTRODUCTION

After participating in the litigation before this Court solely as an *amicus curiae*, APP Pharmaceuticals LLC ("APP") now moves for leave to intervene after judgment in an effort to appeal this Court's August 3, 2010 decision (Doc. 54) in favor of Plaintiff The Medicines Company ("MDCO"). The extraordinary relief that APP seeks—essentially to step into the shoes of the government in defending the results of an *ex parte* patent term extension proceeding in which APP had no right to participate—should be denied.

APP seeks to intervene because it believes the government may choose not to appeal this Court's decision. But it is hornbook law that a party may not intervene to pursue an appeal in the absence of the principal party on its side unless it can establish both prudential and Article III standing. And APP's motion fails even to *mention* these requirements, much less to show that they are satisfied here. In fact, APP has neither prudential nor constitutional standing.

APP lacks prudential standing under Federal Circuit precedent because it is outside the "zone of interests" protected by the relevant statutes and may not take over the role of the government in Administrative Procedure Act ("APA") litigation relating to an *ex parte* U.S. Patent and Trademark Office ("PTO") proceeding. As the Federal Circuit has observed, it would be "unprecedented" to allow third parties to bring challenges to the results of PTO proceedings, like the patent term extension proceedings here, that are conducted *ex parte* and for which Congress provides third-parties with no statutory right of direct review. *Syntex (U.S.A.) Inc. v. PTO*, 882 F.2d 1570, 1575 (Fed. Cir. 1989), *affirming* No. 08-527-A (E.D. Va. July 22, 1988) (Hilton, J.). The Federal Circuit has also made clear that if a third party could not challenge an agency's decision directly, it should not be permitted to step into the shoes of the government to continue an appeal that the government declines to pursue. *See Boeing Co. v. Comm'r of Patents & Trademarks*, 853 F.2d 878, 882 (Fed. Cir. 1988).

Most fundamentally, this APA action is simply not the right forum for a third party like APP to attempt to challenge MDCO's patent term extension. In 35 U.S.C. § 282, Congress expressly provided that the "[i]nvalidity of the extension of a patent term" because of a material failure to comply with the requirements of 35 U.S.C. § 156 "shall be a defense in any action involving the infringement of a patent during the period of the extension of its term." Further, in the Hatch-Waxman Act, Congress specified the precise procedures that apply in an infringement suit when a generic applicant files an abbreviated new drug application ("ANDA") that challenges the validity of a patent. Those procedures are designed to ensure that generic producers can gain patent certainty without exposing themselves to damages claims, and APP itself has used them in litigation against MDCO. APP may not circumvent this "clear, comprehensive scheme," *Syntex*, 882 F.2d at 1576, by attempting to take over the government's case here. To the extent APP wishes to challenge the validity of MDCO's patent term extension, it is limited to trying to do so under § 282 and the Hatch-Waxman Act, as Congress intended.

Additionally, APP cannot demonstrate Article III standing. It has not alleged—let alone established through cognizable evidence—a non-speculative injury that would be redressed by a favorable decision on appeal. Indeed, APP has not even obtained tentative approval from the FDA to offer a generic version of ANGIOMAX®. Thus, even in the absence of the patent at issue in this proceeding, APP could not currently enter the market, and its ability to do so in the future is speculative.

Even setting aside the standing requirements applicable when a party intervenes to pursue an appeal on its own, APP cannot satisfy even the ordinary prerequisites for either mandatory intervention under Federal Rule of Civil Procedure 24(a) or permissive intervention under Rule

24(b). Accordingly, APP's motion for leave to intervene should be denied whether or not the government chooses to file an appeal.

APP fails to satisfy the requirements for intervention as of right in numerous respects. Most notably, APP cannot show that it has a legally sufficient interest that would be impaired absent intervention. Because APP was not—and could not have been—a party to the agency proceeding below, it does not have the kind of legally protectable interest in the PTO's resolution of MDCO's patent term extension application necessary to support intervention as of right. It is just a third party hoping to obtain a financial windfall if MDCO's patent rights are prematurely cut short and it is able to obtain FDA approval and enter the market. APP also cannot show that its interests would be impaired if it is not permitted to intervene here. In *Chapman v. Manbeck*, 931 F.2d 46 (Fed. Cir. 1991), the Federal Circuit held that the impairment requirement for mandatory intervention was not satisfied where, as here, the party seeking to intervene in an APA challenge to a PTO decision could raise in infringement litigation its contention that the patent at issue had lapsed.

Finally, APP's request for permissive intervention should be denied for multiple reasons. Most notably, APP cannot establish an independent jurisdictional basis for its proposed intervention. It has not asserted—and would be unable to raise—a claim under the APA or the Patent Act. Moreover, APP's intervention would inject irrelevant issues into this case because APP seeks to defend the PTO on a ground not asserted by the agency during administrative proceedings.

For all of these reasons, APP's motion to intervene should be denied.

I. APP CANNOT ESTABLISH EITHER PRUDENTIAL OR CONSTITUTIONAL STANDING

APP's primary goal in seeking intervention is to attempt to appeal this Court's August 3 Order if the government elects not to do so. It is well established, however, that if the losing party at trial chooses to forgo an appeal, a potential intervenor seeking to appeal in its place must not only satisfy the usual requirements of Rule 24, but also demonstrate that it has independent standing. The Supreme Court has long held that "an intervenor's right to continue a suit in the absence of the party on whose side the intervention was permitted is contingent upon a showing by the intervenor that it fulfills the requirement of Art[icle] III," *Diamond v. Charles*, 476 U.S. 54, 68 (1986), and has further confirmed that this requirement applies where, as here, an intervenor seeks "to defend on appeal in the place of [the] original defendant," *Arizonans for Official English v. Arizona*, 520 U.S. 43, 64 (1997).[1] In addition to complying with Article III, such an intervenor must also show "that it satisfies the … prudential requirements" for standing. *Boeing*, 853 F.2d at 882 (dismissing appeal because the intervenor-appellant's alleged injury was not "within the 'zone of interests' protected by" the relevant statutes); *see also Associated Builders & Contractors v. Perry*, 16 F.3d 688, 690-691 (6th Cir. 1994) (listing "self-imposed prudential limits" as among the standing requirements that an intervenor must satisfy in order to pursue an appeal).

[1] *See also, e.g., Dillard v. Chilton County Comm'n*, 495 F.3d 1324, 1330 (11th Cir. 2007); *Willis v. GAO*, 448 F.3d 1341, 1344 (Fed. Cir. 2006); *Providence Baptist Church v. Hillandale Comm., Ltd.*, 425 F.3d 309, 317-318 (6th Cir. 2005); *Kitty Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 457 (5th Cir. 2005); *Cox Cable Commc'ns, Inc. v. United States*, 992 F.2d 1178, 1181 (11th Cir. 1993); *see generally* 7C Wright, Miller, & Kane, *Federal Practice & Procedure* § 1908 (online ed. 2010) ("[F]or an intervenor to continue the litigation on appeal when the party on whose side it has intervened has not appealed, the intervenor must have standing.").

APP does not even attempt to demonstrate that it has prudential and constitutional standing. Nor, as explained below, could it make the necessary showing.

A. APP Lacks Prudential Standing

To establish prudential standing under the Federal Circuit's decision in *Boeing*, a prospective intervenor "must show that his complaint 'fall[s] within the 'zone of interests' to be protected or regulated by the statute or constitutional guarantee in question.'" 853 F.2d at 882 (quoting *Valley Forge Christian Coll. v. Americans United for Separation of Church & State*, 454 U.S. 464, 474-475 (1982)). APP's motion for leave to intervene does not remotely satisfy this standard. Indeed, *Boeing* itself found that prudential standing was lacking in circumstances nearly identical to those at issue here.

In the *Boeing* case, Boeing filed a suit challenging a PTO decision invalidating its patent after a reexamination proceeding. After Boeing and the PTO agreed to a remand of the proceeding, the competitor that had originally requested the reexamination—and intervened as a defendant in the district court without objection—sought to appeal without the agency. The Federal Circuit dismissed the appeal, agreeing with the PTO that the intervenor lacked both constitutional and prudential standing. *See* 853 F.2d at 882. With respect to prudential standing, the Federal Circuit explained that the competitor was not within the zone of interests protected by the relevant statutes because those statutes gave it "no right [after its initial request and a reply] to participate in the reexamination process." *Id.* at 881. The Federal Circuit also found a lack of prudential standing because the competitor "was not entitled by statute to seek judicial review of the reexamination." *Id.* at 881. In other words, because the competitor could not have filed a suit seeking review of a reexamination decision in Boeing's favor, the Federal Circuit held that the competitor could not accomplish essentially the same result by continuing to defend on appeal a reexamination decision that the PTO itself had abandoned. *See id.* at 882.

Precisely the same result follows here. Like the intervenor in *Boeing*, APP is a competitor seeking to defend on appeal a PTO decision adverse to MDCO that APP fears the agency itself may abandon. As in *Boeing*, APP is not within the zone of interests of the relevant statute—here, 35 U.S.C. § 156—because that statute gives it no right to participate in patent term extension proceedings before the PTO. Indeed, APP's right to participate in the underlying PTO proceedings was even more limited than the competitor's right to participate in the reexamination proceeding at issue in *Boeing* because—as this Court has recognized, *see* Mem. Op. 12-13 (Doc. 54)—patent term extension proceedings before the PTO are entirely *ex parte*.[2]

Moreover, like the competitor in *Boeing*, APP also would not have been able to obtain direct judicial review of a PTO decision granting MDCO's requested patent term extension. Indeed, courts have repeatedly held that third parties like APP may not seek direct judicial review of *ex parte* PTO determinations like the patent term extension decision at issue here. For example, in *Syntex (U.S.A.) Inc. v. PTO*, the Federal Circuit affirmed this Court's holding that a third party who had requested a patent reexamination could not seek judicial review of the PTO's

[2] Under the reexamination statute at issue in *Boeing*, the party requesting a reexamination initiates the administrative proceeding and has a right to reply to any response by the patent holder. *See Boeing*, 853 F.2d at 881; *see also* 35 U.S.C. §§ 302, 304. In contrast, the statute and regulations governing patent term extension proceedings before the PTO provide *no* role for third parties, stating that "[a] determination that a patent is eligible for extension may be made by the Director [of the PTO] solely on the basis of the representations contained in the application for the extension." 35 U.S.C. § 156(e)(1); *see also* 37 C.F.R. § 1.741 (same). The only third-party participation permitted by § 156 is limited to proceedings before the U.S. Department of Agriculture or the Food and Drug Administration ("FDA") regarding its determination of the *length* of the extension period. 35 U.S.C. § 156(d)(2)(B)(ii). That Congress granted third parties such limited rights to participate only in the calculation of the length of the extension period and not in the underlying patent term extension eligibility determination underscores that APP is not within the zone of interest of the statutory provision at issue in this case. *See* Brief for PTO 16 n.13, *Syntex*, No. 88-1652 (Fed. Cir. Jan. 25, 1989) ("[S]ince the earliest patent acts, PTO proceedings involving patent applications have been conducted *ex parte*. 2 Op. Att'y Gen. 454 (1831). When Congress intended for proceedings in this area to be *inter partes* it has provided so explicitly.").

ultimate ruling. *See* 882 F.2d 1570 (Fed. Cir. 1989), *affirming* No. 08-527-A (E.D. Va. July 22, 1988) (Hilton, J.). The Federal Circuit explained that "[t]he creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be unprecedented." *Id.* at 1574-1575; *see also Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991) ("[W]e find nothing in the law which gives rise to a right in nonapplicants to object to the way in which patent applications of others are prosecuted."). The court in *Syntex* then held that, as a general rule, a third party seeking to challenge a PTO decision granting or maintaining a patent may raise its arguments only as a defense in infringement suits instituted by the patent owner:

> [E]very perceived injury caused by improper agency action does not carry a right to immediate judicial redress. A right to immediate judicial review must be granted or reasonably inferred from a particular statute. For example, a potential infringer may not sue the PTO seeking retraction of a patent issued to another by reason of its improper allowance by the PTO. *A remedy must await confrontation with the patent owner* [in an infringement suit].

Syntex, 882 F.2d at 1576 (emphasis added).

Similarly, in *Hallmark Cards, Inc. v. Lehman*, 959 F. Supp. 539 (D.D.C. 1997), the court held that a third party had no right to judicial review of the PTO's issuance of a certificate of correction. As the court explained, given the limited extent to which third parties can participate in such proceedings and the ability of the third party to "confront[]" the patent holder in infringement litigation, Congress did not "intend[] to grant third party requesters a right to judicial review." *Id.* at 544. And in *Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3 (D.D.C. 1991), the court held that a third party who had submitted a protest in a PTO patent reissuance proceeding had no right to seek judicial review of the PTO's decision. It explained that "[t]he Patent Statute is addressed to patent owners and patent applicants. The patent examination process is an *ex parte* proceeding, not an adversarial one …. Title 35 contains no provision

expressly authorizing administrative or judicial review of a PTO decision at the behest of a third-party protestor." *Id.* at 8.

These precedents make clear that third parties such as APP may not seek direct judicial review of the PTO's patent term extension decisions. Section 156 does not grant third parties any "right to immediate judicial review," *Syntex*, 882 F.2d at 1576, and such a right cannot be "reasonably inferred" from the statute, *id.* To the contrary, Congress expressly provided an entirely different remedy for a third party to try to challenge the validity of a patent term extension: Under 35 U.S.C. § 282, it can raise the issue as a defense in infringement proceedings. That section provides that the "[i]nvalidity of the extension of a patent term" because of a material failure to comply with the requirements of 35 U.S.C. § 156 "shall be a defense in any action involving the infringement of a patent during the period of the extension of its term."[3]

In the context of this case, moreover, APP need not even expose itself to patent damages to litigate its challenge. Under the Hatch-Waxman Act, a generic manufacturer that wants to enter the market without conducting its own safety and effectiveness studies and challenge a patent claiming a drug must file an ANDA with a "paragraph IV" certification that explains why the patent is invalid and/or will not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii). Congress defined the mere filing of an ANDA containing a paragraph IV certification as a statutory act of infringement. *See* 35 U.S.C. § 271(e)(2). The purpose of creating this "highly artificial act of infringement," *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990), was "to enable adjudication of issues of patent validity and infringement in the absence of actual manufacture,

[3] *See Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371, 1384-1385 (Fed. Cir. 2004); *King Pharms., Inc. v. Teva Pharms. USA, Inc.*, 409 F. Supp. 2d 609 (D.N.J. 2006).

sale, or use of the product," *Glaxo Wellcome, Inc. v. Andrx Pharms., Inc.*, 344 F.3d 1226, 1228 (Fed. Cir. 2003), meaning that "there are no infringement damages for the patent holder to recover," *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206-207 (2d Cir. 2006).

Congress also carefully specified the procedures that govern such litigation. The patentee has 45 days to decide whether to file an infringement suit against the ANDA applicant. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee files suit within that time, the FDA may not approve the ANDA for at least 30 months, unless the court reaches a decision earlier. *Id*. But if the patentee fails to file within 45 days, the ANDA filer may bring a declaratory judgment action to obtain "patent certainty." *Id*. § 355(j)(5)(C). Such an action must "be brought in the judicial district where [the patentee] has its principal place of business or a regular and established place of business." *Id*. § 355(j)(5)(C)(i)(II).

APP is familiar with all of these procedures. It is currently engaged in Hatch-Waxman Act litigation against MDCO in which it has used § 282 to challenge the validity of two recently issued patents relating to ANGIOMAX. *See* D. Del. Dkt. No. 09-cv-750. There is no reason why APP should not be required to follow the same procedure here to the extent it wishes to challenge MDCO's patent term extension. APP cannot circumvent the framework created by Congress by challenging the PTO's patent term extension determinations directly. *See Hitachi Metals*, 776 F. Supp. at 12 & n.18 (noting, in holding that a third party may not obtain direct review of a PTO reissue decision, that "Congress explicitly provided for the redress of injuries such as those alleged by [the third party] by authorizing targets of infringement suits to raise the defense of patent invalidity in any infringement action"). And because APP cannot challenge a patent term extension decision directly, it necessarily follows from *Boeing* that it may not

intervene to defend on appeal a decision that the PTO itself has abandoned. *See Boeing*, 853 F.2d at 881-882.

B. APP Lacks Article III Standing

APP has also failed to demonstrate that it has Article III standing. A "party invoking federal jurisdiction"—including a third party that seeks to intervene for purposes of continuing litigation on appeal—"bears the burden of establishing" that (1) it suffered "injury in fact" that is "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." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992) (internal quotation marks and brackets omitted); *see also Diamond*, 476 U.S. at 68 ("right to continue a suit" is "contingent upon a showing *by the intervenor* that he fulfills the requirements of Art[icle] III" (emphasis added)).

As an initial matter, APP's motion fails because it has not submitted any evidence to support its claims of injury, causation, and redressability. The elements of Article III standing "are not mere pleading requirements," and "each element must be supported in the same way as any other matter on which [a party] bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561. Thus, as litigation progresses past the pleadings stage, the entity seeking to establish standing cannot rely on "mere allegations, but must set forth by affidavit or other evidence specific facts" supporting its standing. *Id*. (internal quotation marks omitted).

Here, the Court has already granted MDCO's motion for summary judgment, and it is therefore far too late for APP to rely on unsubstantiated allegations of harm. Indeed, had APP attempted to intervene at an earlier stage of the proceeding, it would have been required to carry its burden of proof on standing before the entry of final judgment, and it cannot avoid that

requirement through its late filing. Accordingly, APP's failure to submit any affidavits or supporting evidence, by itself, precludes it from intervening to appeal in the absence of the government. *Cf. Washington State Farm Bureau v. Nat'l Marine Fisheries Serv.*, No. C06-388Z, 2006 WL 4914810, at *5-6 (W.D. Wash. Dec. 20, 2006) (party that did not submit any affidavits or other evidence failed to carry its burden of demonstrating standing). Nor may APP cure the defect through the belated submission of such evidence with its reply brief. *See Sierra Club v. EPA*, 292 F.3d 895, 900-901 (D.C. Cir. 2002). Because "full development of the arguments for or against standing requires the same tried and true adversary procedure [courts] use for the presentation of arguments on the merits," an entity "whose standing is not self-evident should establish its standing by the submission of its arguments and any affidavits or other evidence appurtenant thereto at the first appropriate point in the review proceeding," not "in its reply." *Id*. at 900.

Even apart from this failure, APP's allegations in support of its motion are far too vague and conditional to support standing. APP alleges that it made "substantial investments to develop a generic version of Plaintiff's Angiomax®," APP Mem. 3, and that this effort "required time, money, and people that APP could have allocated to develop other generic drugs," *id*. at 4.[4] But these expenditures would have to be incurred regardless of *when* APP enters the market, and APP has not explained how these *past* expenditures demonstrate present or imminent harm.

[4] APP also alleges that it "has an interest in and relies on the promulgation, maintenance, and enforcement of consistent rules and procedures by the PTO and FDA." APP Mem. 3. "An interest shared generally with the public at large in the proper application of the Constitution and laws," however, does not establish the particularized injury in fact needed to support Article III standing. *Arizonans for Official English*, 520 U.S. at 64. Moreover, as this Court's decision makes clear, prior to this case, the PTO had never addressed, much less adopted a clear rule on, whether after-hours approvals should be treated as received on the next business day. Thus, the Court's decision hardly gives rise even to the amorphous injury that APP asserts.

Tellingly, particularly in light of its on-going patent litigation with MDCO, APP never alleges that it actually intends, and will be prepared and able, to enter the market promptly if the Federal Circuit reverses this Court's decision and MDCO's requested patent term extension is denied. Indeed, APP's ANDA has not even received tentative approval from the FDA.[5] Thus, it is speculative, at best, whether APP would be able to enter the market even if it were to intervene and succeed on appeal. It has failed to demonstrate either a concrete injury fairly traceable to the district court's decision or a non-speculative possibility that its injury would be addressed by a favorable decision. *See, e.g.*, *Teva Pharms. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42, 58 (D.D.C. 2009) (putative intervenor lacked Article III standing because its "expectation of final approval depend[ed] on the FDA's completion of scientific review of [its] ANDAs and finding [of] no deficiencies"), *rev'd on other grounds*, 595 F.3d 1303 (D.C. Cir. 2010); *see also Pfizer Inc. v. Shalala*, 182 F.3d 975, 978 (D.C. Cir. 1999) (challenge to acceptance of ANDA for processing was not ripe because "the FDA m[ight] never approve [the] application—whether because it decides in the end that the dosage form … is different … or for some entirely different reason, such as a lack of bioequivalence"); *Prasco v. Medicis Pharm. Corp.*, 537 F.3d 1329,

[5] A generic manufacturer that submits an ANDA does not have to duplicate the safety and effectiveness studies submitted by the pioneer that first secured FDA approval. The FDA, however, reviews the ANDA closely to determine, among other things, whether "the methods used in, or the facilities and controls used for, the manufacturing, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity," 21 U.S.C. § 355(j)(4)(A); whether the active ingredient or ingredients are the same as the approved drug, *id*. § 355(j)(4)(C); whether the "route of administration, dosage form, or strength of the drug" is different from the approved drug, *id*. § 355(j)(4)(D); whether the drug is "bioequivalent" to the approved drug, *id*. § 355(j)(4)(F); whether the composition or inactive ingredients of the drug are unsafe, *id*. § 355(j)(4)(H); and whether there is sufficient safety and effectiveness data to permit use of a different active ingredient, route of administration, dosage form, or strength, *id*. § 355(j)(2)(C). To the extent an application meets these criteria but cannot be approved because of an exclusivity period, the FDA will grant "tentative approval" under § 355(j)(5)(B)(iv)(II)(dd)(AA). Where tentative approval has not been granted, it may mean that other barriers besides exclusivity currently prevent the application from entering the market.

1338 n.6 (Fed. Cir. 2008) ("underlying inquiry" into "whether the complained-of-conduct has an immediate and substantial impact" "is the same regardless of whether labeled standing [or] ripeness" (internal quotation marks omitted)).

* * *

Because APP lacks prudential and Article III standing, it cannot intervene in this case for the purpose of taking an appeal if the government itself does not appeal.

II. APP CANNOT SATISFY THE REQUIREMENTS FOR MANDATORY OR PERMISSIVE INTERVENTION UNDER RULE 24

APP's failures to show that it has prudential or constitutional standing constitute two independent reasons why it should not be permitted to intervene to appeal in the absence of the government. In addition to these shortcomings, APP cannot satisfy the requirements for either mandatory or permissive intervention under Rule 24. Accordingly, its motion should be denied whether or not the government elects to appeal.

A. APP Is Not Entitled To Intervene As Of Right

In order to intervene as of right under Rule 24, an applicant must demonstrate that: (1) the applicant has an interest in the subject matter of the action; (2) the denial of the motion to intervene would impair or impede the applicant's ability to protect its interest; (3) the application to intervene is timely; and (4) the applicant's interest is not adequately represented by existing parties to the litigation. *See, e.g.*, *Houston Gen. Ins. Co. v. Moore*, 193 F.3d 838, 839 (4th Cir. 1999); *Teague v. Bakker*, 931 F.2d 259, 260-261 (4th Cir. 1991); *United States v. B.C. Enters., Inc.*, 667 F. Supp. 2d 650, 655 (E.D. Va. 2009). An applicant may not intervene as of right unless it satisfies *all* of these requirements. *Houston General Ins.*, 193 F.3d at 839; *Virginia v. Westinghouse Elec. Corp.*, 542 F.2d 214, 216 (4th Cir. 1976); *Dairy Maid Dairy, Inc. v. United States*, 147 F.R.D. 109, 110 (E.D. Va. 1993). APP does not meet any of them.

1. APP Lacks A Legally Cognizable Interest In The Subject Matter Of This Action

APP does not have a sufficient interest in the subject matter of this action to warrant intervention as of right. APP bears the burden of showing that it has a "legally protectable interest" in the outcome of the litigation between MDCO and the government. *American Maritime Transp., Inc. v. United States*, 870 F.2d 1559, 1561 (Fed. Cir. 1989) (internal quotation marks omitted). A "general interest in the subject matter of pending litigation" "does not constitute a protectable interest within the meaning of Rule 24(a)(2)." *Dairy Maid*, 147 F.R.D. at 111. To be sufficient, an interest must be one that the "substantive law recognizes as belonging to or being owned by the applicant." *American Maritime Transp.*, 870 F.2d at 1562 (internal quotation marks and emphasis removed). Moreover, "the putative intervenor's claim must bear a close relationship to the dispute between the existing litigants and therefore must be direct, rather than remote or contingent." *Dairy Maid*, 147 F.R.D. at 111. In other words, the intervenor's interest must be "'of such a *direct* and *immediate* character that [it] will either gain or lose by the direct legal operation and effect of the judgment.'" *American Maritime Transp.*, 870 F.2d at 1561 (quoting *United States v. AT&T*, 642 F.2d 1285, 1292 (D.C. Cir. 1980)).

For many of the same reasons that APP is not within the "zone of interests" protected by the statute and therefore lacks prudential standing, it does not have a "legally protectable interest" in having the PTO reach a particular result in its *ex parte* review of MDCO's patent term extension application. APP's interest is in competing with MDCO, not in the dispute between MDCO and the PTO over whether the PTO's decision violates the APA. APP has no legally cognizable interest in a PTO determination it would not have been permitted to challenge,

arising out of PTO proceedings in which it was not permitted to participate. *See supra* § I.A.[6] At most, APP has an indirect economic interest in the outcome of this matter—*i.e.*, a decision finding that MDCO is not entitled to a patent term extension may enhance APP's still-contingent ability to offer a generic competitor to MDCO's drug ANGIOMAX. But the courts have repeatedly made clear that such a contingent economic interest is not sufficient to permit intervention as of right.[7]

These cases have particular force here because APP's asserted economic injury is speculative. As explained above in Section I.B, the FDA has not even tentatively approved APP's ANDA. It is thus entirely speculative whether a decision reversing this Court's ruling would, in fact, permit APP to offer an alternative product to ANGIOMAX. Courts have

[6] APP suggests that this Court previously recognized that APP has a "significantly protectable interest" when it granted APP leave to file a brief as *amicus curiae* in this action. APP Mem. 1. That is incorrect. A motion to appear as an *amicus* before the district court is not governed by any specific standard under the Federal Rules of Civil Procedure and is instead addressed to the court's discretion. *See Tafas v. Dudas*, 511 F. Supp. 2d 652, 659 (E.D. Va. 2007). When exercising that broad discretion, the court may weigh a number of factors, including whether the proposed *amicus*'s suggested arguments are merely "helpful" or "useful" to the Court, whether the proposed amicus has a "special interest" in the matter, and the timeliness of the proposed *amicus*'s motion. *See, e.g.*, *id.* (internal quotation marks omitted); *Long v. Coast Resorts, Inc.*, 49 F. Supp. 2d 1177, 1178 (D. Nev. 1999). This Court's May 3, 2010 Order granting APP's motion made no finding as to whether APP had an interest sufficient to satisfy the requirements of Rule 24.

[7] *See, e.g.*, *In re Lease Oil Antitrust Litig.*, 570 F.3d 244, 251 (5th Cir. 2009) ("An economic interest alone," as opposed to a legally protectable interest, "is insufficient to intervene." (internal quotation marks omitted)); *United States v. Metro. St. Louis Sewer Dist.*, 569 F.3d 829, 839 (8th Cir. 2009) ("General economic interests are not protectable and cannot serve as the basis for intervention."); *Medical Liab. Mut. Ins. Co. v. Alan Curtis LLC*, 485 F.3d 1006, 1008 (8th Cir. 2007) ("An economic interest in the outcome of the litigation is not itself sufficient to warrant mandatory intervention."); *Mountain Top Condo. Ass'n v. Dave Stabbert Master Builder, Inc.*, 72 F.3d 361, 366 (3d Cir. 1995) ("In general, a mere economic interest in the outcome of the litigation is insufficient to support a motion to intervene…. Thus, the mere fact that a lawsuit may impede a third party's ability to recover in a separate lawsuit ordinarily does not give the third party a right to intervene.").

routinely denied intervention as of right when the "interest" asserted is the applicant's concern that it may be harmed in the future if the court adopts a particular party's position or interpretation.[8] Such "speculative, competitive injury … does not rise to the level required for intervention as a matter of right." *Media Gen. Fairfax Cable of Fairfax, Inc. v. Sequoyah Condo. Council of Co-Owners*, 721 F. Supp. 775, 779 (E.D. Va. 1989) (denying intervention as of right to a cable television provider seeking to intervene in lawsuit involving interpretation of statute that, if interpreted as proposed by plaintiff, would entitle plaintiff to compete with the prospective intervenor in a condominium complex).

Apparently recognizing the contingent nature of its asserted interest, APP attempts to rely on the Fourth's Circuit statement in *Teague, supra*, that intervention of right has been allowed "'even when the intervenor's interest is contingent on the outcome of other litigation.'" APP Mem. 7 (quoting *Teague*, 931 F.2d at 261). But APP's reliance on *Teague* is misplaced because, unlike APP, the prospective intervenors in that case had a direct and immediate stake in the outcome of the litigation at issue. *Teague* was a declaratory action by an insurance company, which sought a ruling that it had no obligation under an insurance policy to pay claims asserted

[8] *See, e.g.*, *Medical Liab. Mut. Ins.*, 485 F.3d at 1008 ("An interest that is 'contingent on the occurrence of a sequence of events before it becomes colorable' is also not sufficient to satisfy Rule 24(a)(2)." (citations omitted)); *American Maritime Transp.*, 870 F.2d at 1561-1563 (holding that operators of cargo vessels, which sought to intervene as of right, had only an "indirect and contingent" interest because it was based merely "upon the possibility of increased competition" that might result if statute was interpreted to entitle another shipping company to subsidies); *Kitzmiller v. Dover Area Sch. Dist.*, 229 F.R.D. 463, 468 (M.D. Pa. 2005) (Courts "have denied motions to intervene for lack of a sufficiently protectable interest in several instances where the proposed intervenors' only interest was an uncertain and purely economic one."); *Paine, Webber, Jackson & Curtis, Inc. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 564 F. Supp. 1358, 1372 (D. Del. 1983) (rejecting applicant's request to intervene as of right in patent litigation, because the "only interest which he is claiming is that if the … patent is found to be valid he might lose customers to Merrill Lynch because Merrill Lynch is offering a better financial service. This interest, without any factual support, is too speculative and therefore not a direct interest to satisfy Rule 24(a)(2).").

against the declaratory judgment defendants in a separate class action that the prospective intervenors had filed against the same (and other) persons. The intervenors eventually prevailed in the class action and were awarded $129 million in damages. The Fourth Circuit agreed with the intervenors that they had a "significantly protectable" interest in the declaratory judgment action even before they secured the judgment because the insurance company had specifically requested a ruling that it had "no obligation" with respect to the class action, and the proceeds of the insurance policy were assets from which the intervenors hoped to collect their class action judgment. Thus, the intervenors stood "to gain or lose by the direct legal operation of the district court's judgment on [the insurance company's] complaint." 931 F.2d at 261.[9] APP does not remotely satisfy this standard.

2. APP Has Failed To Demonstrate That Denying Intervention As Of Right Would Impair Its Ability To Protect Its Claimed Interests

Even if APP had the requisite interest in the subject matter of the action, it could not show that its interest will be impaired or impeded if intervention is denied. Although APP asserts that its impairment is "indisputable," APP Mem. 7, the only impairment it alleges is that the extension of the '404 patent as the result of this Court's August 3 Order might prevent it from launching a generic competitor to ANGIOMAX. But APP's ability to try to challenge the validity of the extension as a defense in any infringement proceeding under the procedure that

[9] *Teague*'s finding that the intervenors in that case had a legally protectable interest is consistent with the general rule that "injured parties may maintain an action against the alleged tortfeasor's insurer when … the injured party seeks only a declaratory judgment determining insurance coverage." 22 *Appleman on Insurance* § 151.1[A] (online ed. 2010). By contrast, APP has no legally recognized right to file an APA action challenging the *ex parte* patent term extension proceedings at issue here. *See supra* § I.A.

Congress created for that purpose belies any claim that its interest will be impaired if intervention is denied.[10]

Courts have often held that the impairment requirement is not satisfied, and therefore that intervention should be denied, when "the would-be intervenor could protect its interest in a separate action." 7C Wright, Miller & Kane, *supra*, § 1908.2. For example, in *Chapman v. Manbeck*, 931 F.2d 46 (Fed. Cir. 1991), a patent owner filed suit to compel the PTO to reinstate a patent that had lapsed for failure to pay maintenance fees. After the district court ordered the PTO to reinstate the patent, a competitor involved in infringement litigation with the patent owner moved to intervene for purposes of taking an appeal. The district court denied the motion, and the Federal Circuit affirmed. The Federal Circuit held that the competitor was limited to "confront[ing] the patent owner" in an "infringement action." *Id*. at 48 (internal quotation marks omitted). It noted that the decision ordering reinstatement did not bind the court handling the infringement litigation and, therefore, did not "impair" the putative intervenor's "ability to protect its interest." *Id*.

The same is true here. Because APP was not party to the suit, it is not bound by this Court's August 3 decision. That decision also is not binding precedent in other courts. *See* 18 *Moore's Federal Practice* § 134.02[1][d] (online ed. 2010) (district court decisions not binding).[11] The Court's decision therefore does not deprive APP of the ability to seek to challenge the validity of MDCO's extension under 35 U.S.C. § 282. Under *Chapman*, therefore,

[10] As noted above, *see supra* § I.A, APP need not expose itself to patent damages to litigate its challenge.

[11] To be sure, a Federal Circuit decision would be binding on other courts. But that will not be an issue if the PTO and FDA decline to appeal. And if they do appeal, intervention would not be appropriate anyway because, among other things, the government would adequately represent APP's interests, *see infra* § II.A.3, and APP could always seek leave to file an amicus brief.

APP is not entitled to intervene as of right because its interest will not be impaired if intervention is denied.[12]

3. If The Government Elects To Appeal, APP's Motion Is Untimely And APP's Interests Would Be Adequately Protected By The Government

APP seeks leave to intervene whether or not the government ultimately decides to appeal. But APP cannot satisfy Rule 24(a)'s requirements no matter what the government does because APP cannot establish a legally protectable interest in this litigation or show that its interest will be impaired if intervention is denied. Moreover, if the government does *not* appeal, then APP's motion to intervene also would have to be denied for lack of standing. *See supra* § I. If, on the other hand, the government *does* appeal, then APP's request for mandatory intervention should be denied for two additional reasons: (1) it is untimely, and (2) APP has not demonstrated that its interests will be inadequately protected by the government.

As to timing, the Fourth Circuit has stated that "'[t]here is considerable reluctance on the part of the courts to allow intervention after the action has gone to judgment and a strong showing will be required of the applicant.'" *Houston Gen. Ins.*, 193 F.3d at 840 (quoting 7C Wright, Miller & Kane, *supra*, § 1916). APP suggests that it did not previously file a motion to

[12] APP acknowledges at one point that it would be able to challenge MDCO's patent term extension by amending its ANDA to assert that the extension is invalid. *See* APP Mem. 4-5. It implies, however, that its interests would still be impaired if it pursued this course because it "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®." APP Mem. 5. But APP is simply objecting to—and trying to circumvent—the procedures Congress required in order to properly balance the interests of patentees and parties like APP in precisely these circumstances. Moreover, the prospective intervenor in *Chapman* was also forced to incur the delay and expense of litigating its arguments in another proceeding, and the Federal Circuit nonetheless held that its interests were not impaired within the meaning of Rule 24. *See* 931 F.2d at 48. Indeed, as a general matter courts hold that "the practical disadvantage of filing a separate suit and perhaps duplicating some of the efforts in the ongoing action are not sufficient to meet the criteria of the rule." 7C Wright, Miller & Kane, *supra*, § 1908.2.

intervene because it only recently learned that the government "may not pursue an appeal." APP Mem. 6. But if the government decides to appeal, APP's excuse for filing so belatedly disappears.

Likewise, APP has not demonstrated that government will not adequately represent its interests. APP's only basis for questioning the government's ability to represent its interest is its assertion that the government's alleged "uncertainty" over whether to appeal suggests that the government may not vigorously litigate any appeal it does file. APP Mem. 8. But as the government's letter to APP makes clear, *see* Doc. 58-1, the reason that the government has not yet determined whether to take an appeal is that the appeal decision is committed to the Solicitor General, who is currently undertaking the standard process for evaluating whether to authorize an appeal. *See* 28 U.S.C. § 518(a) (granting the Attorney General and the Solicitor General control over the conduct of suits in the courts of appeals "in which the United States is interested"). Moreover, 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. *See, e.g.*, *James City County v. U.S. Envtl. Prot. Agency*, 131 F.R.D. 472, 474 (E.D. Va. 1990); *see also Prete v. Bradbury*, 438 F.3d 949, 956 (9th Cir. 2006) ("In the absence of a very compelling showing to the contrary, it will be presumed that a state adequately represents its citizens[.]" (internal quotation marks omitted)).

B. APP Should Not Be Granted Permissive Intervention

The Court has discretion over whether to permit permissive intervention under Rule 24(b). *See* 6 *Moore's Federal Practice* § 24.10[1] ("[T]he decision regarding whether to grant permissive intervention is always subject to the inherently discretionary considerations of equity and judicial economy."). APP should be denied permissive intervention for at least three independent reasons.

First, as APP acknowledges, a party seeking permissive intervention under Rule 24(b) must "show an independent jurisdictional basis" to support its claim or defense. APP Mem. 8; *Spring Constr. Co. v. Harris*, 614 F.2d 374, 377 (4th Cir. 1980).[13] This requirement reflects the principle that "[i]ntervention presupposes the pendency of an action in a court of competent jurisdiction and cannot create jurisdiction if none existed before." 7C Wright, Miller & Kane, *supra*, § 1917. APP, however, has not established any independent jurisdictional basis for its proposed intervention here. As discussed in Section I.A, *supra*, APP has no independent right to seek judicial review of PTO rulings on applications for patent term extensions filed pursuant to § 156(d)(1). Neither of the statutes that APP cites, *see* APP Mem. 8-9 (citing 28 U.S.C. §§ 1331 & 1338(a)), by itself creates a cause of action. *See, e.g, Jayme v. U.S. Dep't of Homeland Sec.*, No. 07-23022, 2008 WL 1885797, at *3 (S.D. Fla. Apr. 28, 2008) ("28 U.S.C. § 1331 provides no independent basis for subject matter jurisdiction"); *Hallmark Cards*, 959 F. Supp. at 542 (Section 1338(a) "does not create any right of civil action in the first instance"). No language in the patent statute authorizes APP to seek to challenge MDCO's extension except in a separate infringement action.[14]

Moreover, §§ 1331 and 1338(a) cannot serve as a basis for jurisdiction where "the statutory framework enacted by Congress implicitly precludes a right to the relief sought." *Hallmark Cards*, 959 F. Supp. at 543; *see also Hitachi Metals*, 776 F. Supp. at 8 (judicial review is implicitly precluded when a statute "'provides a detailed mechanism for judicial consideration

[13] *See also, e.g., Francis v. Chamber of Commerce of the U.S.*, 481 F.2d 192, 195 n.6 (4th Cir. 1973); *Media Gen. Cable of Fairfax*, 721 F. Supp. at 779.

[14] *Accord Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1367 (Fed. Cir. 2007) ("Patent law does not 'create' the plaintiffs' cause of action here, because there is no language in the patent statute explicitly authorizing preemption claims.").

of particular issues at the behest of particular persons'" (quoting *Block v. Community Nutrition Inst.*, 467 U.S. 340, 349 (1984)). Because the patent statute "is addressed to patent owners and patent applicants," *id.*, rather than to third parties, courts have uniformly held that they have no jurisdiction under either § 1331 or § 1338(a) to entertain third-party challenges to decisions issued by the PTO in *ex parte* proceedings, where, as here, (1) the patent statute does not expressly provide for such challenges, and (2) the patent statute allows third parties to assert their claims as a defense in an infringement suit. *See, e.g.*, *Hallmark Cards*, 959 F. Supp. at 542-544 (holding that court lacked jurisdiction under § 1338(a) to hear third party's challenge to PTO's issuance of certificates of correction for two patents); *Hitachi Metals*, 776 F. Supp. at 7-10 (holding that court had no jurisdiction under § 1331 to review PTO's decision to reissue patent).

Second, "the requirement of timeliness applies whether intervention is sought as a matter of right or as a matter of discretion." 7C Wright, Miller, & Kane, *supra*, § 1916; *see also* Fed. R. Civ. P. 24(b) (requiring that a request for permissive intervention be "timely"). Just as APP's request is untimely under Rule 24(a) if the government decides to appeal, *see supra* § II.A.3, it is also untimely under Rule 24(b).

Third, discretionary considerations counsel strongly against permitting APP to intervene. In considering a request for permissive intervention, a court has discretion to consider whether the intervenor would significantly contribute to resolution of the issues that may properly be raised in the case. *See, e.g.*, *Washington Elec. Coop. v. Mass. Mun. Wholesale Elec. Co.*, 922 F.2d 92, 98 (2d Cir. 1990); *New Orleans Pub. Serv., Inc. v. United Gas Pipeline Co.*, 732 F.2d 452, 471 (5th Cir. 1984); *Stadin v. Union Elec. Co.*, 309 F.2d 912, 920 (8th Cir. 1962).[15] APP

[15] *See also, e.g.*, *Spangler v. Pasadena City Bd. of Educ.*, 552 F.2d 1326, 1329 (9th Cir. 1977) (court may consider whether intervenor "will significantly contribute to full development of the

has made clear that it intends to present irrelevant or improper arguments. For example, APP states that if intervention is granted, it intends to raise on appeal the "retroactive rulemaking" argument set forth its *amicus* brief. As MDCO explained in its opposition to APP's amicus brief (Doc. 35 at 4-5), this argument cannot be considered because it was not a basis for the PTO's decision. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). Thus, this Court properly did not address APP's argument in its August 3 decision. Because 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. This Court should exercise its discretion to deny permissive intervention.

* * *

Accordingly, APP cannot satisfy the standards for either mandatory or permissive intervention.

CONCLUSION

For the reasons stated herein, APP's motion to intervene should be denied.

Date: September 2, 2010

Respectfully submitted,

/s/ Craig C. Reilly
Craig C. Reilly (VSB # 20942)
111 Oronoco Street
Alexandria, Virginia 22314
Tel: (703) 549-5354

underlying factual issues in the suit"); *Kitzmiller*, 229 F.R.D. at 471 (in determining whether to grant permissive intervention, "courts consider whether the proposed intervenors will add anything to the litigation").

Fax: (703) 549-2604
craig.reilly@ccreillylaw.com

Peter D. Keisler (*pro hac pending*)
Jeffrey P. Kushan (VSB # 34452)
C. Frederick Beckner III (*pro hac pending*)
Lowell J. Schiller (*pro hac pending*)
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Tel: (202) 736-8000
Fax: (202) 736-8711

Attorneys for Plaintiff THE MEDICINES COMPANY

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of September, 2010, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt, including the counsel of record listed below. Parties may access this filing through the Court's system. In addition, I have served the following counsel by hand:

Neil H. MacBride, United States Attorney
Dennis C. Barghaan, Jr., Assistant United States Attorney
OFFICE OF THE UNITED STATES ATTORNEY
EASTERN DISTRICT OF VIRGINIA
Justin W. Williams United States Attorney's Building
2100 Jamieson Avenue
Alexandria, Virginia 22314
Tel: (703) 299-3891
Fax: (703) 299-3983
E-Mail: dennis.barghaan@usdoj.gov

Attorneys for Defendants

/s/ Craig C. Reilly
Craig C. Reilly (VSB # 20942)
111 Oronoco Street
Alexandria, Virginia 22314
Tel: (703) 549-5354
Fax: (703) 549-2604
craig.reilly@ccreillylaw.com

Attorney for Plaintiff
THE MEDICINES COMPANY