UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

THE MEDICINES COMPANY, Plaintiff, vs. DAVID J. KAPPOS, in his official capacity as Under Secretary for Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, *et al.*, Defendants.	)	Civil Action No. 1:10cv286 (CMH/JFA)

DEFENDANTS' RESPONSE TO APP PHARMACEUTICALS, LLC'S MOTION FOR LEAVE TO INTERVENE

Pursuant to Local Rule 7(F)(1), Defendants David Kappos, the United States Patent and Trademark Office ("USPTO"), Margaret Hamburg, the United States Food and Drug Administration ("FDA"), Kathleen Sebelius, and the United States Department of Health and Human Services ("Defendants") respectfully submit this Response to APP Pharmaceuticals, LLC's Motion for Leave To Intervene.

INTRODUCTION

Given its two prior decisions, this Court is certainly well-familiar with the events and circumstances that have brought forth this litigation. In its instant motion, an entity that already has been provided the opportunity to participate as *amicus curiae* – APP Pharmaceuticals, Inc. ("APP") – now seeks to intervene into this civil action as a party defendant. APP continues to maintain (as it did in seeking *amicus* participation) that it has made investments to develop a

generic version of ANGIOMAX®, and that, as a result of this Court's opinion, if it were to market that generic drug, plaintiff the Medicines Company ("MDCO") might file a patent infringement lawsuit against it. Mtn. (Dkt. No. 58), at 4-5. But APP now contends that because the Solicitor General of the United States has not yet decided whether to take an appeal of this Court's entry of summary judgment against the defendants[1] (and ultimately might elect *against* any such appeal) it must intervene into this action as a party defendant. That way, APP provides, *it* can appeal this Court's judgment – in an Administrative Procedure Act ("APA") case against federal government entities – to the Federal Circuit and continue to litigate the pertinent legal questions against MDCO as a private business competitor.

Put simply, the instant motion seeks to transform this litigation into one between two competing entities within the pharmaceutical industry. But in engaging in the type of statutory interpretation that is the subject of this action, the United States Patent & Trademark Office ("USPTO") must act a neutral arbiter without involving itself in putative business disputes that often animate private patent interests or litigation. In order to preserve that essential role, defendants do not take an official position on APP's motion to intervene.

Nevertheless, APP's motion raises questions concerning, *inter alia*, APP's capacity or ability to maintain this action on its own accord in the absence of the original governmental-defendants. Defendants therefore believe it important to provide a brief explanation of some of

[1]As this Court is aware, decisions regarding whether the United States will appeal adverse judgments entered by the District Court of the United States are generally committed to the Solicitor General and Attorney General. See generally 28 U.S.C. § 518. And the Federal Rules of Appellate Procedure provide the United States (as well as its agencies and officers) with 60 days within which to notice such appeals in part to allow the Solicitor General to engage in that fulsome decision-making process. See FED. R. APP. P. 4(a)(1)(B).

the thorny legal issues raised through APP's motion, including the analytical framework and pertinent decisional authority that play a role – at least in part[2] – in this Court's adjudication of the motion.

DISCUSSION

APP asserts that it has elected to file its motion to intervene at this time – after this Court has issued its decision on the merits – because were the Solicitor General to elect against appeal of this Court's adverse judgment, defendants would no longer adequately represent APP's interests. In other words, APP's instant motion is exclusively premised upon the notion that the federal defendants would *no longer* be parties to this civil action, and that APP would essentially – through intervention – take the place of the federal defendants for purposes of appeal.

This issue is not entirely unplowed jurisprudential territory. In Diamond v. Charles, 476 U.S. 54 (1986), the Supreme Court considered circumstances that – at least facially – are rather similar to those presented here. In Diamond, a series of plaintiffs brought a civil action against a state government seeking to challenge the constitutionality of a state statute. See id. at 57-58. During district court proceedings, a private third-party was allowed to intervene as a party defendant. See id. The state government ultimately elected not to appeal an adverse judgment that invalidated – on constitutional grounds – a large portion of the state statute. See id. at 58-61. The Supreme Court held that the state's decision against appeal (just like the United States' *potential* decision against appeal here) had consequences for the private, third-party's continued intervention:

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[2]Defendants do not intend to suggest that the issues discussed in this paper are the *only* issues relevant to an adjudication of APP's motion.

> Had the State sought review . . . [the] intervening defendant below[] also would be entitled to seek review, enabling him to file a brief on the merits, and to seek leave to argue orally. But this ability to ride "piggyback" on the State's undoubted standing exists only if the State is in fact an appellant before the Court; in the absence of the State in that capacity, there is no case for [the intervenor] to join.

Id. at 64. And here, in the event that the United States elected against appeal of an adverse judgment in an APA case that challenged one of its regulatory decisions, "there is no case for [APP] to join," unless APP – as a third-party that did not (and could not have) participated in the underlying administrative proceedings before the USPTO – could have independently been a party to this litigation in the absence of the federal defendants.[3] Related issues have already been adjudicated by the Federal Circuit, and the instant response will now turn to an explanation of that decisional authority.

1. Article III of the United States Constitution extends the jurisdiction of federal courts only to "cases or controversies." U.S. CONST. art. III; see also Whitmore v. Arkansas, 495 U.S. 149, 154-55 (1990). One element of the case or controversy requirement is "standing" – the tenet that constitutionally ensures that "the litigant is entitled to have the court decide the merits of the dispute or of particular issues." Warth v. Seldin, 422 U.S. 490, 498 (1975); see also Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 925 (Fed. Cir. 1991). Standing is similarly a requirement of appellate jurisdiction. See Boeing Co. v. Comm'r, 853 F.2d 878, 880 (Fed. Cir. 1988). To determine whether a party has standing to assert a cause of action, a court must

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[3]Before proceeding any further, it is important to recognize that the Federal Circuit has now conclusively held that the APA cannot be utilized to challenge the USPTO's *ex parte* administrative decisions in civil patent litigation between two private entities, see Aristocrat Techs. Australia Pty Ltd, et al. v. Int'l Game Tech., 543 F.3d 657, 663 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 2791 (2009) – the very "private party vs. private party" scenario that would occur if the federal defendants were to elect against appeal and APP were to intervene as a party defendant.

undertake a two-step analysis that involves both constitutional and prudential considerations. Id.

In order to satisfy the requirements of Article III of the Constitution, a plaintiff must establish the following:

> (1) [he] 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 of the defendant; 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)). Prudential standing, on the other hand, dictates, *inter alia*, that a litigant must demonstrate that it "[f]all[s] within the 'zone of interests' to be protected or regulated by the statute or constitutional guarantee in question." Valley Forge Christian College v. Americans United for Separation of Church and State, 454 U.S. 464, 475 (1982). Typically, a litigant must assert his own legal rights or interests and cannot rest his claim on the rights or interests of third parties. See, e.g., McKinney v. U.S. Dep't of Treasury, 799 F.2d 1544, 1550-51 (Fed. Cir. 1986).

2. Even before Congress promulgated the most recent incarnation of the Patent Act (in 1952), the statutes and regulations governing USPTO decision-making in the patent arena have required that administrative proceedings (with particularized and limited exceptions) move forward on an *ex parte* basis – between USPTO and the patent applicant/owner. See, e.g., Williams Mfg. Co. V. United Shoe Mach. Corp., 121 F.2d 273, 277 (6th Cir. 1941), aff'd, 316 U.S. 364 (1942). As such, courts have rejected attempts by third parties (*e.g.*, an entity such as APP that wishes to manufacture and sell a generic version of the drug product on which another entity [MDCO] holds a patent) to challenge USPTO decision-making in this *ex parte* context.

See Godtfredsen v. Banner, 503 F. Supp. 642, 646 (D.D.C. 1980) (holding that judicial modification of the statutory *ex parte* process would "revolutionize patent practice"). Thus, the Patent Act generally does not provide for any involvement by a putative third-party generic drug manufacturer in the administrative process to determine whether a drug sponsor for a human drug product is entitled to a patent term extension.[4] See 35 U.S.C. § 156(e)(1) (noting that "[a] determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension"); see also Portney v. CIBA Vision Corp., SACV07-854-AG, 2009 WL 5064701, at *5 (C.D. Cal. Dec. 23, 2009) (noting that patent term extension proceedings are *ex parte*).

In fact, Congress has demonstrated that when it wants to involve third parties in the administrative review of patent issues, it knows how to do so. For instance, Congress has specifically provided that third parties are entitled to bring prior art references to USPTO's attention that might be relevant to a given patent, see 35 U.S.C. § 301, and third parties may petition USPTO either to undertake *ex parte* reexamination, see id. at § 302, or to participate in *inter partes* reexamination. See id. § 311. Each of the instances in which Congress has expressed its desire to involve third parties in the USPTO's administrative process relate to a particularized issue—the review of an issued patent on substantive patentability grounds. Congress has expressly chosen not to authorize involvement by third parties in the USPTO's administrative review of whether a drug sponsor is entitled to receive a patent term extension—a

[4] The *only* third-party participation that 35 U.S.C. § 156 permits is limited to proceedings before the United States Department of Agriculture or the FDA regarding the *length* of a patent term extension period, see 35 U.S.C. § 156(d)(2)(B)(ii), as opposed to the issue implicated here – *whether* MDCO is entitled to a patent term extension at *all*.

decision consistent with the general rule reflected in the Patent Act that third-party participation in proceedings before USPTO is limited to extremely narrow situations that have been specifically articulated by Congress. Cf. Animal Legal Defense Fund, 932 F.2d at 930 (concluding that the court found "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. A third party has no right to intervene in the prosecution of a particular patent application to prevent issuance of an allegedly invalid patent").

And from this premise, courts have consistently held that third parties, like APP, cannot seek *direct* judicial review (*i.e.*, against the government) of *ex parte* decisions by USPTO concerning patents held by other individuals or entities. For instance, in Syntex (U.S.A.) Inc. v. USPTO, 882 F.2d 1570 (Fed. Cir. 1989), the Federal Circuit held—in the context of whether the court had subject matter jurisdiction pursuant to 5 U.S.C. § 701(a)—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*," and refused to allow the third party resort to the APA. See id. at 1574-75 (emphasis added). Moreover, in Hallmark Cards, Inc. v. Lehman, 959 F. Supp. 539 (D.D.C. 1997), a third party sought APA review of USPTO's decision to issue a "certificate of correction" with respect to a patent that had already been issued pursuant to 35 U.S.C. § 255. See id. at 541-42. After noting that the administrative proceedings with respect to a patent owner's request for a certificate of correction were completely *ex parte*, the district court held "that Congress did not intend that third parties have the right to judicial review of Certificates of Correction issued by the PTO." Id. at 544. Moreover, the Hallmark court also held that the type of administrative action at issue was pertinent to whether Congress had

precluded judicial review:

> [I[t would strain credulity to conclude that Congress did not provide for judicial review by third parties of PTO decisions when the PTO conducts a thorough and comprehensive review of a patent in reissue and reexamination proceedings, but intended that third parties have the right to judicial review when the PTO issues Certificates of Correction, which involves a far less intrusive examination of a patent for minor, typographical, and clerical errors.

Id. at 543.

As previously discussed, administrative proceedings with respect to determining whether a patent qualifies for a PTE are of a similar ilk, as neither the Patent Act nor USPTO's implementing regulations provide for "any participation by third parties." Id. at 544. Further, the type of administrative action at issue here—decisions whether an applicant qualifies for a PTE—are exactly the type of "procedural minutiae" that are far divorced from the analytically-laden determinations that USPTO undertakes in the substantive examination context. See id. at 543. Moreover, the statutory scheme does not authorize a third party generic drug manufacturer such as APP to file a lawsuit challenging the decision of USPTO to grant or deny a PTE application. Accordingly, had USPTO *initially* granted MDCO's PTE application, APP would not be entitled to challenge that decision in this Court. Cf. Aristocrat, 543 F.3d at 663 (holding that authorizing use of the APA in purely private litigation "would inundate [USPTO and] the courts with arguments relating to every minor transgression [third parties] could comb from the file wrapper" in an attempt to invalidate a given patent).[5]

[5]Defendants similarly do not intend to suggest that such a hypothetical lawsuit would be precluded – whether jurisdictionally or otherwise – *only* by the principles espoused in this paper. In all candor, other additional reasons (not necessarily implicated by APP's present intervention motion) would prevent such a civil action from proceeding. The somewhat unique nature of the circumstances surrounding APP's intervention request therefore do not require a full exposition of each of these issues.

Nor are the issues raised in APP's present motion entirely foreign to the Federal Circuit's decisional authority. In fact, in Boeing Co. v. Commissioner, 853 F.2d 878 (Fed. Cir. 1988), a third-party who had requested that the USPTO "re-examine" a patent held by another[6] intervened into a resulting district court civil action brought by the patent holder after the USPTO invalidated the patent. See id. at 879-80. After the USPTO and the patent holder entered into an agreed disposition of that civil action (that would have resulted in a remand to the agency for further administrative proceedings), the intervenor noticed its own appeal. See id. at 880. The Federal Circuit, after recognizing that the intervenor was "required to independently establish its own standing" because it could not "rely on its intervenor status where the parties to the district court action have not appealed," held that as a third-party, the intervenor lacked both constitutional and prudential standing to maintain the appeal on its own accord. See id. at 881-82.

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[6]As stated above, see supra p.6, re-examination is another example of those limited instances in which the Patent Act authorizes third-parties to seek administrative action from the USPTO with respect to a patent held by another entity.

CONCLUSION

In engaging in the complex task of statutory interpretation, the United States and its agencies – in particular, the USPTO – are required to act as neutral arbiters and must eschew involvement in disputes amongst competitors in any given industry. For that reason, the federal defendants here have elected against taking any formal position on APP's attempt to intervene as a party defendant in this action. The federal defendants nevertheless respectfully believe that, in considering the weighty issues APP's motion implicates, it was appropriate to provide the above identification of those issues and the decisional authority concerning the same.

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CERTIFICATE OF SERVICE

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