UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04 Md. 1603 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES, Plaintiffs, -against- RANBAXY INC., RANBAXY PHARMACEUTICALS INC., RANBAXY LABORATORIES LTD., ACTAVIS ELIZABETH LLC, MYLAN PHARMACEUTICALS INC., and MYLAN INC., Defendants.	OPINION & ORDER This document relates to: 10 Civ. 3734 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES, Plaintiffs, -against- IMPAX LABORATORIES, INC., Defendant.	13 Civ. 684 (SHS)

SIDNEY H. STEIN, U.S. District Judge.

Plaintiffs have sued defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan") and Impax Laboratories, Inc. for patent infringement as defined by the Hatch-Waxman Act. Defendants have filed counterclaims for declaratory judgment, asserting that defendants will not

infringe plaintiffs' patents and that those patents are invalid. An action by the Food and Drug Administration during the pendency of these actions has raised the issue of whether they are moot. For the reasons set forth below, the Court holds that the claims of infringement and the counterclaims asserting non-infringement are moot. The Court also declines to exercise jurisdiction over those of defendants' counterclaims that assert invalidity. As a result, these actions are dismissed.

I. BACKGROUND

Plaintiffs (collectively "Purdue") manufacture, market, and sell OxyContin, a brand-name controlled-release oxycodone medication for the treatment of moderate to severe pain. The original formulation of OxyContin was the subject of New Drug Application ("NDA") 20-553, which the Food and Drug Administration initially approved in December 1995. *See* Determination that the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn from Sale for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23,273, 23,273 (Apr. 18, 2013) (hereinafter "FDA Determination"). Purdue now manufactures and sells "Reformulated OxyContin," which is more resistant to abuse than original OxyContin. Reformulated OxyContin is the subject of NDA 22-272, initially approved by the FDA in April 2010. As of August 2010, Purdue no longer sells original OxyContin in the United States. *See id.*

The FDA Orange Book entries for original and Reformulated OxyContin list several patents that cover these drugs. As relevant to this order, three patents—the so-called "Low-ABUK Patents"—cover both original and Reformulated OxyContin.[1]

Mylan and Impax each filed Abbreviated New Drug Applications ("ANDAs") with the FDA, seeking to make generic versions of original OxyContin. *See* 21 U.S.C. § 355(j). Both ANDAs included a "Paragraph IV" certification, which asserted that the patents claiming original OxyContin—including the Low-ABUK Patents—were "invalid or will not

---

[1] The Low-ABUK Patents are U.S. Patent Nos. 7,674,799; 7,674,800; and 7,683,072.

be infringed by the manufacture, use, or sale" of defendants' proposed generics. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). After Purdue received notice of defendants' ANDAs, it brought these suits for patent infringement in the U.S. District Court for the Southern District of New York. Defendants filed counterclaims for declaratory judgment, asking the Court to rule that Purdue's patents would not be infringed or were invalid.

Mylan and Impax have also filed ANDAs seeking to make generic versions of Reformulated OxyContin. In these ANDAs as well, defendants certified to the FDA that the patents that claimed Reformulated OxyContin—again, including the Low-ABUK Patents—are invalid or would not be infringed. Once more Purdue sued for infringement in the Southern District of New York, and defendants asserted counterclaims for declaratory judgment as to non-infringement and invalidity. *See Purdue Pharma L.P. v. Impax Labs., Inc.*, No. 11 Civ. 2400 (S.D.N.Y.); *Purdue Pharma L.P. v. Mylan Pharm. Inc.*, No. 12 Civ. 2959 (S.D.N.Y.).

In April 2013, before any of these cases had reached a final resolution,[2] the FDA determined in April 2013 that original OxyContin had been withdrawn from sale for reasons of safety or effectiveness. This determination means that original OxyContin is no longer a "listed drug" that can be the subject of an ANDA. *See* 21 U.S.C. § 355(j)(2)(A)(i), (j)(7)(C). As such, the FDA announced that it would "not accept or approve ANDAs that refer to" original OxyContin. FDA Determination, 78 Fed. Reg. at 23,275.

In light of the FDA Determination, this Court ordered Mylan and Impax to show cause as to why the suits concerning original OxyContin should not be dismissed as moot. Mylan filed a two-page response saying simply that the FDA Determination did not moot its declaratory judgment counterclaim for invalidity. Impax did not respond at all.

---

[2] The Court did hold a trial in three actions in November 2012: *Purdue Pharma L.P. v. Ranbaxy Inc.*, No. 10 Civ. 3734; *Purdue Pharma L.P. v. Ranbaxy Inc.*, No. 11 Civ. 2401; and *Purdue Pharma L.P. v. Ranbaxy Inc.*, No. 11 Civ. 7104. Mylan is a named defendant in the 2010 action, but did not participate at trial.

II. DISCUSSION

"Article III of the Constitution restricts the power of federal courts to 'Cases' and 'Controversies.' Accordingly, to invoke the jurisdiction of a federal court, a litigant must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision." *Chafin v. Chafin*, 133 S. Ct. 1017, 1023 (2013) (quotation marks and alteration omitted). "A case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III—when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome. No matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute is no longer embedded in any actual controversy about the plaintiffs' particular legal rights." *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 726–27 (2013) (quotation marks and citation omitted).

There can be no doubt that Purdue's infringement actions and defendants non-infringement counterclaims are moot. The FDA Determination meted out all of the infringement-related relief that is available in these Hatch-Waxman Act actions.[3] *See* 35 U.S.C. § 271(e)(4); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1346–47 (Fed. Cir. 2003) (challenge to legality of regulation concerning Hatch-Waxman Act 30-month stays was mooted when the FDA removed all the stays at issue).

Whether the FDA Determination mooted defendants' declaratory judgment counterclaims for invalidity is a separate question. For purposes of this Opinion, the Court presumes that defendants' invalidity counterclaims are not moot, *see Alvater v. Freeman*, 319 U.S. 359, 363 (1943), but the Court declines to exercise its discretionary jurisdiction to hear these claims.

---

[3] Because the FDA, and not this Court, changed the legal relationship among the parties, none of them is a "prevailing party" for the purposes of awarding attorneys' fees. *See* 35 U.S.C. §§ 271(e)(4), 285; *Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1347–48 (Fed. Cir. 2012); *Highway Equip. Co., Inc. v. FECO, Ltd.*, 469 F.3d 1027, 1034–35 (Fed. Cir. 2006).

This Court has the discretion to decline to exercise jurisdiction over a Hatch-Waxman Act declaratory judgment action, even though the Court has constitutional jurisdiction over that action. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1338 n.3 (Fed. Cir. 2007). The Court can make this discretionary decision even if the dismissed claim is at an advanced procedural posture. *See Wilton v. Seven Falls Co.*, 515 U.S. 277, 288 (1995); *Apple, Inc. v. Motorola, Inc.*, 869 F. Supp. 2d 901, 924 (N.D. Ill. 2012) (Posner, J.) (stating that the court would decline to exercise declaratory judgment jurisdiction following its decision of motion for summary judgment).

The Federal Circuit requires that a court base its discretionary decision to decline jurisdiction on sound legal and factual grounds, and for reasons that are not "clearly unreasonable, arbitrary, or fanciful." *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 905 (Fed. Cir. 2008). In addition, "[i]f a district court's decision is consistent with the purposes of the Declaratory Judgment Act and considerations of wise judicial administration, it may exercise its discretion to dismiss" the case. *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1288 (Fed. Cir. 2007). "The purpose of the declaratory action is to allow a party who is reasonably at legal risk because of an unresolved dispute, to obtain judicial resolution of that dispute without having to await the commencement of legal action by the other side." *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352, 1354 (Fed. Cir. 2004) (quotation marks omitted).

The purpose underlying declaratory judgment actions and wise judicial administration both counsel in favor of dismissing defendants' invalidity counterclaims. Defendants' currently infringing conduct—their ANDAs seeking to make generic versions of Reformulated OxyContin—has already prompted Purdue to initiate separate lawsuits against them. *See Purdue Pharma L.P. v. Impax Labs., Inc.*, No. 11 Civ. 2400 (S.D.N.Y.); *Purdue Pharma L.P. v. Mylan Pharm. Inc.*, No. 12 Civ. 2959 (S.D.N.Y.). These suits will give defendants the opportunity to contest the validity of the Low-ABUK Patents in this district. Further, allowing the actions concerning defendants' Reformulated OxyContin ANDAs to go forward will not cause any of the parties to expend any additional resources. In short, the actions concerning defendants' Reformulated OxyContin

ANDAs are more fit for adjudication than the actions concerning original OxyContin. Defendants—and the Low-ABUK Patents—will still have their day in Court.

III. Conclusion

For the reasons set forth above, Purdue's actions for infringement and defendants' declaratory judgment counterclaims for non-infringement are moot. The Court presumes that defendants' declaratory judgment counterclaims for invalidity are not moot, but the Court nonetheless declines to exercise jurisdiction over those claims. These actions are hereby dismissed.

Dated: New York, New York
July 18, 2013

SO ORDERED:

Sidney H. Stein, U.S.D.J.