IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG,
Plaintiffs,
v .
WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC,
Defendants.

Civil Action No. 12-1032-GMS

MEMORANDUM

I. INTRODUCTION

Plaintiffs Bayer Intellectual Property GMBH and Bayer Pharma AG (collectively, "Bayer") brought this patent infringement suit against defendants Warner Chilcott Company, LLC, Warner Chilcott (US), LLC, and Warner Chilcott plc (collectively, "Warner Chilcott") on August 13, 2012, alleging infringement of U.S. Patent No. 5,980,940 ("'940 patent"). (D.I. 1.) Four months later, Bayer filed a First Amended Complaint that added a claim for patent "interference" under 35 U.S.C. § 291 between the '940 patent and Warner Chilcott's U.S. Patent No. 7,704,984 ("'984 patent). (D.I. 5.) Warner Chilcott then filed the present Rule 12(b)(1) Motion to Dismiss, or in the Alternative to Stay, Count II (Interfering Subject Matter under 35 U.S.C. § 291) on March 18, 2013. (D.I. 7.) For the reasons that follow, the court denies Warner Chilcott's motion to dismiss and motion to stay.

II. BACKGROUND

The patents in this lawsuit concern contraceptive regimens. Bayer markets an oral contraceptive called YAZ, which embodies the '940 patent. (D.I. 11 at 4.) Warner Chilcott sells its own oral contraceptive called Lo Loestrin FE, which embodies the '984 patent. (*Id.* at 6.) Bayer alleges both that Warner Chilcott's Lo Loestrin FE product infringes the '940 patent, and that the '984 patent purportedly covering Lo Loestrin FE interferes with the '940 patent. (D.I. 5.)

Generic-drug manufacturers Lupin and Watson are seeking to market a generic version of Lo Loestrin FE. (D.I. 8 at 6-7.) Warner Chilcott is currently involved in patent litigation with those companies in New Jersey¹ ("the New Jersey litigation"), asserting the '984 patent and another patent against the generics. (*Id.*) In response, Lupin has raised the defense, *inter alia*, that the claims of the '984 patent are invalid over Bayer's '940 patent. (D.I. 8 at 6-7.)

III. STANDARDS OF REVIEW

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction

Federal Rule of Civil Procedure 12(b)(1) allows for dismissal where the court lacks subject matter jurisdiction over an action. Motions brought under Rule 12(b)(1) may raise either a facial or factual challenge to the court's jurisdiction. "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). However, the party asserting subject matter jurisdiction bears "the burden of proof that jurisdiction does in fact exist." *Mortensen v. First Fed. Sav. and Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

¹ See Warner Chilcott Co., LLC v. Lupin Ltd. et al., No. 3:11-cv-5048 and Warner Chilcott Co., LLC v. Amneal Pharms., LLC, No. 3:12-cv-2928.

B. Motion to Stay

A decision to stay litigation lies within the sound discretion of the court and represents an exercise of the court's "inherent power to conserve judicial resources by controlling its own docket." *Cost Bros., Inc. v. Travelers Indem. Co.*, 760 F.2d 58, 60 (3d Cir. 1985). The court performs a balancing analysis using the following three factors to determine if a stay is appropriate: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *First Am. Title Ins. Co. v. McLaren LLC*, No. 10-363-GMS, 2012 WL 769601, at *4 (D. Del. Mar. 9, 2012). This court has recognized that "[u]ndue prejudice and clear tactical disadvantage are more likely to exist where the grant of a stay imposes a greater burden on the non-movant than its denial would inflict on the movant." *ImageVision.Net, Inc. v. Internet Payment Exch., Inc.*, No. 12-054-GMS-MPT, 2012 WL 5599338, at *3 (D. Del. Nov. 15, 2012).

IV. DISCUSSION

A. Subject Matter Jurisdiction Under 35 U.S.C. § 291

Section 291 provides in pertinent part:

The owner of an interfering patent may have relief against the owner of another by civil action, and the court may adjudge the question of the validity of any of the interfering patents, in whole or in part.

35 U.S.C. § 291. The Federal Circuit has established that "the sole basis for jurisdiction under § 291 is whether the patents do in fact interfere." *Kimberly-Clark Corp. v. Proctor & Gamble Dist. Co., Inc.*, 973 F.2d 911, 914 (Fed. Cir. 1992); *see also Albert v. Kevex Corp.*, 729 F.2d 757, 760-

61 (Fed. Cir. 1984) (holding a "court has no jurisdiction under § 291 unless interference is established."). The *Albert* court explained that "[t]wo or more patents 'interfere' . . . when they claim the same subject matter." *Id.* at 758 n.1. "Where interference exists between two patents, a court has jurisdiction to determine the validity and priority of the interfering patents." *Datex-Ohmeda, Inc. v. Hill-Rom Services, Inc.*, 185 F. Supp. 2d 407, 410 (D. Del. 2002). And the court provides "relief" under § 291 through "a declaration of priority and the subsequent elimination of an invalid patent that claims the same subject matter as claimed in one's patent" *Kimberly-Clark*, 973 F.2d at 914.

Here, Warner Chilcott makes a facial subject matter jurisdiction challenge to Bayer's § 291 interference claim. It argues that Bayer has not alleged any "injury in fact" or "real-world consequences" traceable to the alleged interference between the patents to satisfy the "case or controversy" requirement of Article III of the United States Constitution.² (D.I. 8 at 1.) Specifically, Warner Chilcott argues that Bayer's First Amended Complaint "fails to allege the necessary priority dispute required to establish subject matter jurisdiction under § 291."³ (*Id.* at

² The federal "judicial power" extends only to "Cases" or "Controversies." U.S. Const. art III, § 2. The "case or controversy" requirement demands that a cause of action before a federal court present a "justiciable" controversy, and "no justiciable controversy is presented . . . when the question sought to be adjudicated has been mooted by subsequent developments . . ." *Flast v. Cohen*, 392 U.S. 83, 95, 88 S. Ct. 1942, 20 L. Ed. 2d 947 (1969). "Article III requires that a plaintiff's claim be live not just when he first brings the suit but throughout the entire litigation, and once the controversy ceases to exist the court must dismiss the case for lack of jurisdiction." *Lusardi v. Xerox Corp.*, 975 F.2d 964, 974 (3d Cir. 1992).

³ Warner Chilcott cites 3V, Inc. v. CIBA Specialty Chems. Corp., 587 F. Supp. 2d 641, 646 (D. Del. 2008) to support its argument. The court is not persuaded and finds the underlying facts in 3V are distinguishable from the present case. In 3V, the Board of Patent Appeals and Interferences ("the Board") found that a CIBA European patent application had priority of invention over 3V's patent, but that claims 16-27 in CIBA's later-filed U.S. application were not entitled to the benefit of the European application and were anticipated by 3V's patent. Id. at 642. 3V challenged the Board's ruling and CIBA initiated a separate action under § 291 asking the court to determine whether claims 16-27 in its U.S. patent application over 3V's patent. Id. at 642-43. During the course of the

9.) Warner Chilcott further argues the First Amended Complaint does not allege that the '984 patent interferes with Bayer's ability to license the '940 patent, or that Warner Chilcott has sued or threatened to sue Bayer for infringing the '984 patent. (*Id.* at 5.)

The court finds Warner Chilcott fundamentally misconstrues the prerequisites to an interference action under § 291. The Federal Circuit has established that interfering patents, not a priority dispute, are required to establish jurisdiction under § 291. "Under any construction of § 291, it is impossible to conceive how it could be any clearer that interference between patents is a sine qua non of an action under § 291. Absent interference, a court has no power under § 291 to adjudicate the validity of any patent." *Albert*, 729 F.2d at 760. "Moreover, by its very language, a cause of action under section 291 does not require that 'the owner of an interfering patent' accuse 'the owner of another' of infringement. Rather, section 291 gives patent owners a *separate and distinct basis of jurisdiction if two patents interfere.*" *Kimberly-Clark*, 973 F.2d at 914 (emphasis added). Therefore, when two patents interfere "the validity, priority, and issues relating thereto have a source of jurisdiction under 35 U.S.C. § 291 …." *Id.*⁴

litigation, 3V disclaimed its patent -- thereby rendering moot all issues of priority of invention and invalidity relating to 3V's patent. *Id.* at 645. Nevertheless, CIBA contended that the court must resolve whether claims 16-27 of its U.S. application were entitled to the benefit of the European application such that 3V's now-disclaimed patent would not be prior art. *Id.* The *3V* court found that it did not have jurisdiction because any cause of action stemming from a priority dispute was mooted in light of 3V's disclaimer. *Id.* at 346. The court reasoned that after the disclaimer 3V no longer had a legally cognizable interest in protecting its patent in a § 291 action. *Id.* at 645-46. Thus, the court held that it did not have jurisdiction under § 291 because there were no longer interfering patents.

In contrast, here, there are two allegedly interfering patents. And Bayer has a legally cognizable interest in protecting its patent, even if the priority issue is "moot" because Warner Chilcott does not dispute Bayer's priority of invention.

⁴ In *Kimberly-Clark* the parties entered into a settlement agreement that released one another from past infringement damages, but did not resolve the priority dispute of their respective patents. 973 F.2d at 914 The Federal Circuit recognized that "[t]he jurisdictional question [it] must resolve, *before evaluating the question of priority*, is whether two patent owners, who once did but [were] no longer accusing each

Moreover, the court disagrees with Warner Chilcott that Bayer failed to allege a "priority dispute." Bayer's First Amended Complaint alleges that "[t]he '940 Patent is prior art to the '984 Patent," (D.I. 5, \P 21), and that "[t]he '940 patent is the senior patent because it claims priority to an application from April 8, 1995" while "[t]he '984 patent claims priority to an application from April 22, 2005," (*id.*, \P 27). The Prayer for Relief then requests "[a] declaration that the inventors of the '940 patent are the first inventors of the subject matter in the interfering claims of the '984 and '940 patents." (*Id.* at 8.) By stating there is no priority "dispute," Warner Chilcot apparently concedes that Bayer has priority of invention. Such a concession does not render Bayer's interference claim "moot" and divest the court of jurisdiction under § 291. Rather, if Bayer ultimately proves an interference, it is entitled to "relief" under § 291 through "a declaration of priority and the subsequent elimination of an invalid patent that claims the same subject matter." *Kimberly-Clark*, 973 F.2d at 914.

Viewing the First Amended Complaint in the light most favorable to Bayer, the court finds it has subject matter jurisdiction under 35 U.S.C. § 291. Bayer's First Amended Complaint alleges that: (1) Bayer owns the '940 patent (D.I. 5, ¶ 12); (2) Warner Chilcott owns the '984 patent (*id.*, ¶ 2); and (3) the '940 patent and the '984 patent claim the same or substantially the same subject matter, and therefore, interfere (*id.*, ¶¶ 14-15, 26-30). The court finds Bayer has sufficiently pled the prerequisites for an interference action, and the court therefore has subject matter jurisdiction under 35 U.S.C. § 291. Accordingly, the court must deny Warner Chilcott's

other of patent infringement under section 271, [would] still be entitled to 'relief' under section 291." *Id.* (emphasis added). The court reasoned that "[b]ecause [the patents were] conceded to interfere, the validity, priority, and issues relating thereto ha[d] a source of jurisdiction under 35 U.S.C. § 291, distinct from that of the infringement action." *Id.* The court emphasized that "the sole basis for jurisdiction under § 291 is whether the patents do in fact interfere." *Id.* (citing *Albert*, 729 F.2d at 760-61).

Rule 12(b)(1) Motion to Dismiss Count II (Interfering Subject Matter under 35 U.S.C. § 291).

B. Motion to Stay

The court finds that the relevant factors weigh against a stay of the interference claim. The "simplification of issues" factor weighs heavily against a stay because the New Jersey litigation will not likely resolve the interference claim. Bayer is not a party in the New Jersey litigation, and that litigation cannot bind Bayer if Warner Chilcott's '984 patent is found valid in light of Bayer's '940 patent. *See Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1091 (Fed. Cir. 1987) (finding litigant may not be collaterally estopped from challenging the validity of patent claims upheld in a prior infringement suit in which it was not a party). Further, an interference-in-fact inquiry requires a more narrow review of the patent than an invalidity defense against an infringement claim.⁵ Accordingly, the New Jersey litigation would only have a bearing on Bayer's interference claim if that court directly focused on comparing the claims of the parties' respective patents.

Further, the court concludes the remaining factors do not significantly alter the balance analysis. While the current action is in its early stages, the nature of the proceedings does not favor a stay. The separate counts involve the same technology and a stay would not promote the interests of judicial economy. While Warner Chilcott is correct that the interference claim may

⁵ An interference action requires a two-way test that examines whether Warner Chilcott's patent claims are anticipated or obvious in light of Bayer's patent claims and vice versa. *See Noelle v. Lederman*, 355 F.3d 1343, 1351 (Fed. Cir. 2004) ("In order for an interference-in-fact to exist, invention A must anticipate or make obvious invention B, and invention B must anticipate or make obvious invention A, thereby meeting both prongs of the 'two-way' test."); *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002) (stating that under a § 291 analysis courts compare the patents claims, not disclosures). In contrast, anticipation and obviousness analyses for an invalidity defense compare the patent's claims to anything in the prior art to determine if there is disclosure of the claimed invention, as well as evaluating secondary considerations.

be rendered moot if the New Jersey court invalidates the '984 patent, that outcome however would require the court and the parties to wait for a specific trial court opinion and resolution of any subsequent appeals. Warner Chilcott did not move to stay the infringement count, which will require the court to construe one of the two patents in the interference claim. A stay would therefore disjoint the separate infringement and interference counts and eliminate any judicial economy that may be obtained during the pretrial claim construction process.

Additionally, the "undue prejudice" factor does not favor a stay. Although "delay does not, *by itself*, amount to undue prejudice," *ImageVision*, 2012 WL 5599338 at *5, the imminent delay in the present case,⁶ coupled with the unlikely resolution of the interference issue, does prejudice Bayer's interference claim. Further, the court is not persuaded by Warner Chilcott's argument that litigating the interference claim at this time would pose a clear hardship. (D.I. 12 at 9.) It would only be spared the burden of defending against the interference claim if the New Jersey court invalidated its '984 patent and the Federal Circuit affirmed that decision upon appeal.

V. CONCLUSION

For the reasons stated above, the court denies Warner Chilcott's Rule 12(b)(1) Motion to Dismiss, or in the Alternative to Stay, Count II (Interfering Subject Matter under 35 U.S.C. § 291) (D.I. 7.).

Dated: December ____, 2013

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⁶ The New Jersey litigation completed a joint bench trial on October 17, 2013. See Warner Chilcott Co., LLC v. Lupin Ltd. et al., No. 3:11-cv-5048 (D.I. 126), and Warner Chilcott Co., LLC v. Amneal Pharms., LLC, No. 3:12-cv-2928 (D.I. 91). Therefore, any appeal process will likely extend to late 2014, if not early 2015.

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Defendants.

Civil Action No. 12-1032-GMS

ORDER

At Wilmington, this $b^{[\gamma]}$ day of December, 2013, consistent with the Memorandum issued this same date, IT IS HEREBY ORDERED THAT:

Warner Chilcott's Rule 12(b)(1) Motion to Dismiss, or in the Alternative to Stay, Count II (Interfering Subject Matter under 35 U.S.C. § 291) (D.I. 7.) is DENIED.

CHIEF, UNITED STATE RIC/T JUDGE S DIST