IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTRICALS L.P. and RHODES TECHNOLOGIES,	)	
Plaintiffs,	)	
v.	)	Civ. No. 15-260-SLR
COLLEGIUM PHARMACEUTICAL, INC.,	)	
Defendant.	)	

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MEMORANDUM OPINION

Dated: August 6, 2015
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On March 25, 2015, plaintiffs Purdue Pharma L.P, The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue"), filed this patent infringement action against Collegium Pharmaceutical, Inc. ("Collegium"). Purdue alleges that Collegium has infringed three patents listed in the FDA Orange Book relating to an improved active pharmaceutical ingredient ("API"): U.S. Patent Nos. 7,674,799, 7,674,800, and 7,683,072 ("the listed patents"). Additionally, plaintiffs allege infringement of one patent relating to an abuse deterrent feature of an extended-release opioid formulation, U.S. Patent No. 8,652,497 ("the '497 patent"), which is not listed in the FDA Orange Book. Presently before the court is Collegium's motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York. (D.I. 8) The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a). For the reasons that follow, Collegium's motion is granted in part and denied in part.

II. BACKGROUND

A. The Parties

Purdue Pharma L.P. is a Delaware limited partnership with its principal place of business in Stamford, Connecticut. The P.F. Laboratories is a New Jersey corporation with its principal place of business in Totowa, New Jersey. Purdue Pharmaceuticals L.P. is a Delaware limited partnership with its principal place of business in Wilson, North Carolina. Rhodes Technologies is a Delaware general partnership with its principal place of business in Coventry, Rhode Island.

Collegium is a Virginia corporation with its principal place of business in Canton, Massachusetts. Collegium incorporated as an entity under the laws of the State of Delaware on April 10, 2002, and then under the laws of the Commonwealth of Virginia on July 1, 2014.

B. Background

In a case before Judge Sidney H. Stein in the Southern District of New York, Purdue sued Teva Pharmaceuticals for infringement of the three listed patents (hereinafter, "the New York litigation"). *See Purdue Pharma L.P. v. Teva Pharms., USA, Inc.*, 994 F. Supp. 2d 367, 409, 437-38 (S.D.N.Y. 2014). In a 2014 decision, Judge Stein found Purdue's listed patents invalid for obviousness. Purdue appealed the invalidity rulings to the Federal Circuit, and briefing was scheduled to close on June 19, 2015. *See Purdue Pharma L.P. v. Epic Pharma, LLC*, No. 2014-1294, Order (Fed. Cir. Apr. 15, 2015).

In 2014, Collegium filed a new drug application ("NDA") under § 505(b)(2) of the Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), with the intent to market and sell an abuse-deterrent, extended-release formulation of oxycodone. (D.I. 9 at 1) Collegium designed the branded product, Xtampza ER™, to be available for patients who have difficulty swallowing pills. *Id.* The FDA committed to act on Collegium's 505(b)(2) application for its Xtampza ER™ product by October 12, 2015. (D.I. 12 at ¶ 4) On that date, the FDA will issue an action letter, which will consist either of an approval of Collegium's proposed 505(b)(2) product or a complete response letter, describing deficiencies that must be corrected in order to receive approval. (D.I. 24, ex. 2 at 2)

Purdue states that it holds data exclusivity for Oxycontin®'s abuse-deterrent clinical studies until April 2016, precluding FDA approval until that point.[1] (D.I. 18, ex. B)

On February 12, 2015, Purdue received Collegium's Paragraph IV Notice Letter and, pursuant to 21 U.S.C. § 271(e)(2) of the Hatch-Waxman Act ("Hatch-Waxman"), Purdue filed suit against Collegium in Delaware on March 25, 2015.[2] (D.I. 17 at 7) By filing suit in Delaware, Purdue triggered a 30-month stay of FDA approval for Xtampza ER™, set to expire in September 2017. 21 U.S.C. § 355(j)(5)(B)(iii). On March 26, 2015, Purdue filed a protective suit in Massachusetts. Purdue has indicated that it seeks to stay litigation of the listed patents pending a final decision in its appeal of the invalidity finding in the New York litigation regardless of whether the present case is litigated in Delaware, New York, or Massachusetts. (D.I. 17 at 16)

The New York litigation did not involve the '497 patent asserted in the instant litigation. The listed patents are directed to and claim the API oxycodone with very low levels of potentially genotoxic impurity, while the '497 patent discloses and claims the use of irritants in the formulation of a drug susceptible to abuse. (D.I. 1, ex. A-D) The New York litigation involved abuse-deterrence mechanisms such as increased breaking

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[1] Collegium argues that Purdue's claim of data exclusivity will not block FDA approval of Collegium's product, because Collegium conducted its own clinical study. (D.I. 21 at 6)

[2] Without going into great detail about the Hatch-Waxman paradigm, submission of an application in order to engage in the commercial manufacture, use or sale of a patented drug "shall be an act of infringement." 21 U.S.C. § 271(e)(2). By enacting Hatch-Waxman, Congress attempted to "fairly balance[ ] the rights of" patentees/branded drug companies (who were given the right to initiate infringement lawsuits before market entry) and companies developing new and/or generic drugs (who were given greater protection during the development and experimentation process). *See, e.g.*, H.R. Rep. No. 98-856, pt. 1, at 28 (1984).

strength and gel formation. *See Teva*, 994 F. Supp. 2d at 377; *Purdue Pharma L.P. v. Amneal Pharms., LLC*, Civ. No. 13-3372, slip op. at 1-2 (S.D.N.Y. Apr. 8, 2015).

III. STANDARD OF REVIEW

A. Personal Jurisdiction

Rule 12(b)(2) directs the court to dismiss a case when the court lacks personal jurisdiction over the defendant. Fed. R. Civ. P. 12(b)(2). When reviewing a motion to dismiss pursuant to Rule 12(b)(2), a court must accept as true all allegations of jurisdictional fact made by the plaintiff and resolve all factual disputes in the plaintiff's favor. *Traynor v. Liu,* 495 F. Supp. 2d 444, 448 (D. Del. 2007). Once a jurisdictional defense has been raised, the plaintiff bears the burden of establishing, with reasonable particularity, that sufficient minimum contacts have occurred between the defendant and the forum to support jurisdiction. *See Provident Nat'l Bank v. Cal. Fed. Sav. & Loan Ass'n,* 819 F.2d 434, 437 (3d Cir. 1987). To meet this burden, the plaintiff must produce "sworn affidavits or other competent evidence," since a Rule 12(b)(2) motion "requires resolution of factual issues outside the pleadings." *Time Share Vacation Club v. Atlantic Resorts, Ltd.,* 735 F.2d 61, 67 n.9 (3d Cir. 1984).

To establish personal jurisdiction, a plaintiff must produce facts sufficient to satisfy two requirements by a preponderance of the evidence, one statutory and one constitutional. *See id.* at 66; *Reach & Assocs. v. Dencer,* 269 F. Supp. 2d 497, 502 (D. Del. 2003). With respect to the statutory requirement, the court must determine whether there is a statutory basis for jurisdiction under the forum state's long-arm statute. *See Reach & Assocs.,* 269 F. Supp. 2d at 502. The constitutional basis requires the court to determine whether the exercise of jurisdiction comports with the defendant's right to due

process. *See id.*; *see also Int'l Shoe Co. v. Washington,* 326 U.S. 310, 316, 66 S.Ct. 154, 90 L.Ed. 95 (1945).

Pursuant to the relevant portions of Delaware's long-arm statute, 10 Del. C. § 3104(c)(1)-(4), a court may exercise personal jurisdiction over a defendant when the defendant or its agent:

> (1) Transacts any business or performs any character of work or service in the State;
> (2) Contracts to supply services or things in this State
> (3) Causes tortious injury in the State by an act or omission in this State;
> (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State.

10 Del. C. § 3104(c)(1)-(4). With the exception of (c)(4), the long-arm statute requires a showing of specific jurisdiction. *See Shoemaker v. McConnell,* 556 F. Supp. 2d 351, 354, 355 (D. Del. 2008). Subsection (4) confers general jurisdiction, which requires a greater number of contacts, but allows the exercise of personal jurisdiction even when the claim is unrelated to the forum contacts. *See Applied Biosystems, Inc. v. Cruachem, Ltd.,* 772 F. Supp. 1458, 1466 (D. Del. 1991).

If defendant is found to be within the reach of the long-arm statute, the court then must analyze whether the exercise of personal jurisdiction comports with due process, to wit, whether plaintiff has demonstrated that defendant "purposefully avail[ed] itself of the privilege of conducting activities within the forum State," so that it should "reasonably anticipate being haled into court there." *World–Wide Volkswagen Corp. v. Woodson,* 444 U.S. 286, 297 (1980) (citations omitted). For the court to exercise specific personal jurisdiction consistent with due process, plaintiff's cause of action must

have arisen from the defendant's activities in the forum state. *See Burger King Corp. v. Rudzewicz,* 471 U.S. 462, 472 (1985). For the court to exercise general personal jurisdiction consistent with due process, plaintiff's cause of action can be unrelated to defendant's activities in the forum state, so long as defendant has "continuous and systematic contacts with the forum state." *Applied Biosystems, Inc.*, 772 F. Supp. at 1458.

B. Venue

Section 1404(a) of Title 28 of the United States Code grants district courts the authority to transfer venue "[f]or the convenience of parties and witnesses, in the interests of justice . . . to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). Much has been written about the legal standard for motions to transfer under 28 U.S.C. § 1404(a). *See, e.g., In re Link_A_Media Devices Corp.*, 662 F.3d 1221 (Fed. Cir. 2011); *Jumara v. State Farm Ins. Co.*, 55 F.3d 873 (3d Cir. 1995); *Helicos Biosciences Corp. v. Illumina, Inc.*, 858 F. Supp. 2d 367 (D. Del. 2012).

Referring specifically to the analytical framework described in *Helicos*, the court starts with the premise that a defendant's state of incorporation has always been "a predictable, legitimate venue for bringing suit" and that "a plaintiff, as the injured party, generally ha[s] been 'accorded [the] privilege of bringing an action where he chooses.'" 858 F. Supp. 2d at 371 (quoting *Norwood v. Kirkpatrick*, 349 U.S. 29, 31 (1955)). Indeed, the Third Circuit in *Jumara* reminds the reader that "[t]he burden of establishing the need for transfer . . . rests with the movant" and that, "in ruling on defendants' motion, the plaintiff's choice of venue should not be lightly disturbed." 55 F.3d at 879 (citation omitted).

The Third Circuit goes on to recognize that,

> [i]n ruling on § 1404(a) motions, courts have not limited their consideration to the three enumerated factors in § 1404(a) (convenience of parties, convenience of witnesses, or interests of justice), and, indeed, commentators have called on the courts to "consider all relevant factors to determine whether on balance the litigation would more conveniently proceed and the interests of justice be better served by transfer to a different forum.

Id. (citation omitted). The Court then describes some of the "many variants of the private and public interests protected by the language of § 1404(a)." *Id.*

> The private interests have included: plaintiff's forum of preference as manifested in the original choice; the defendant's preference; whether the claim arose elsewhere; the convenience of the parties as indicated by their relative physical and financial condition; the convenience of the witnesses - but only to the extent that the witnesses may actually be unavailable for trial in one of the fora; and the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum).
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> The public interests have included: the enforceability of the judgment; practical considerations that could make the trial easy, expeditious, or inexpensive; the relative administrative difficulty in the two fora resulting from court congestion; the local interest in deciding local controversies at home; the public policies of the fora; and the familiarity of the trial judge with the applicable state law in diversity cases.

Id. (citations omitted).

IV. ANALYSIS

A. General Jurisdiction

In support of finding general jurisdiction, Purdue points to Collegium's long-standing former incorporation in the State of Delaware. (D.I. 1 at ¶ 13) Although Collegium changed its state of incorporation to Virginia prior to filing its NDA, it was incorporated in Delaware from 2002 to 2014. (D.I. 1 at ¶ 13) Collegium states that its present activities are limited to drug development in Massachusetts and business development and investment activities in Massachusetts and New York. (D.I. 9 at 6)

Collegium is not currently registered to do business in Delaware nor has it appointed a registered agent to conduct business on its behalf in Delaware.[3] (D.I. 9 at 11)

The Supreme Court stated in *Daimler AG v. Bauman*, 134 S. Ct. 746, 749 (2014), that the "paradigm all-purpose forums for general jurisdiction are a corporation's place of incorporation and principal place of business." The Court did not hold that a corporation may be subject to general jurisdiction only in one of these locations. The Court, however, did reject the notion that "continuous and systematic" contacts alone could confer general jurisdiction, clarifying that the role of general jurisdiction is to "afford plaintiffs recourse to at least one clear and certain forum in which a corporate defendant may be sued on any and all claims." *Id.* at 760-62. In shifting the standard for general jurisdiction, the traditional grounds for exercising general jurisdiction over drug company defendants in Hatch-Waxman litigation have been narrowed. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 421 (D. Del. 2010).

In this regard, Collegium is not currently incorporated in Delaware, nor is Delaware its principal place of business. No additional evidence suggests that Delaware stands out as a "clear and certain" forum in which Collegium should be sued.[4] Accordingly, the court finds that it does not have general jurisdiction over Collegium.

B. Specific Jurisdiction

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[3] As Collegium is not registered to do business in Delaware, Collegium has not consented to general jurisdiction in Delaware. *See Forest Labs., Inc. v. Amneal Pharm. LLC*, Civ. No. 14-508-LPS, 2015 WL 880599, at *3 (D. Del. Feb. 26, 2015); *see also AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 556-57 (D. Del. 2014).

[4] The court does not rule out the possibility that Collegium may be subject to general jurisdiction outside of Virginia and Massachusetts if its contacts in another state are sufficient to make it stand out as a "clear and certain forum."

Purdue alleges that Collegium's contacts with Delaware are sufficient for the court to exert specific jurisdiction over Collegium. A plaintiff making such a claim must establish "a statutory basis for exercising jurisdiction under the Delaware long-arm statute." *Reach & Assocs.*, 269 F. Supp. 2d at 502. Under Delaware's long-arm statute, the court may exercise personal jurisdiction over a defendant when the defendant "[c]auses tortious injury in the State by an act or omission in this State." 10 Del. C. § 3104(3).

The question of what kind of conduct satisfies the above requirement has evoked multiple analyses, especially in the context of Hatch-Waxman litigation. Courts, for instance, have found contacts sufficient to establish specific jurisdiction based on: (1) sending a Paragraph IV Notice Letter into the state;[5] (2) registration to do business in the state;[6] (3) preparation of the FDA application (NDA or ANDA) in the state;[7] and (4) design and development of the infringing product occurred in the state.[8] In addition, one court has granted jurisdictional discovery based on the alleged existence of a

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[5] *AstraZeneca*, 72 F. Supp. 3d at 559-60.

[6] *Accorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, 2015 WL 186833, at *11 (D. Del. Jan. 14, 2015).

[7] *Pfizer Inc. v. Apotex, Inc.*, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009); *Pfizer Inc. v. Synthon Holding, B.V.*, 386 F. Supp. 2d 666, 675-76 (M.D.N.C. 2005).

[8] *Bristol-Myers Squibb Co. v. Andrx Pharmaceuticals, LLC*, 2003 WL 22888804, at *3 (S.D.N.Y. Dec. 5, 2003); *Reckitt Benckiser Inc. v. Watson Labs., Inc.*, 2009 WL 4756515, at *4 (S.D.N.Y. Dec. 8, 2009); *Intendis, Inc. v. River's Edge Pharm., LLC*, 2011 WL 5513195 at *4 (D.N.J. Nov. 10, 2011).

contract with an in-state API manufacturer, leaving open the question of whether such a contact would be sufficient to establish specific jurisdiction.[9]

Setting aside the debate over whether the artificial regime of Hatch-Waxman litigation should impact the court's jurisdictional analysis,[10] the grounds for establishing specific jurisdiction asserted at bar are not compelling.[11] Collegium did not send its Paragraph IV Notice Letter to Purdue in Delaware; Collegium is not registered to do business in Delaware; Purdue did not prepare its NDA in Delaware. Although Collegium worked with a Delaware corporation to conduct clinical trials for its NDA submission, there is no indication of record that the trials themselves took place in Delaware. (D.I. 13, ex. A) Likewise, although oxycodone, the API used in Collegium's Xtampza ER™ product, is manufactured in Wilmington, Delaware by Noramco, Inc. (D.I. 18, ex. A), oxycodone is a basic API[12] that is the subject of numerous patents ('497 patent, col. 1:42-46) and is commercially available in at least two dosage forms (*id.* at col. 9:14-22). Even if such a contact were held to satisfy Delaware's long-arm statute, the court concludes that it would not pass constitutional muster. Purdue's cause of

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[9] *Senju Pharm. Co. v. Metrics, Inc.*, 2015 WL 1472123, at *11 (D.N.J. Mar. 31, 2015).

[10] I.e., just because Congress wanted to artificially control the trigger for such litigation may not mean that it intended courts to ignore the real conduct of the parties for all other purposes.

[11] The court acknowledges that Purdue, a Delaware corporation, will be deemed to have suffered injury in Delaware by the anticipated sale of an infringing product in Delaware. However, the fact of injury only satisfies the first prong of the test; such injury must be caused by conduct that occurred in Delaware.

[12] The Drug Enforcement Administrated granted Noramco, Inc. registration as a bulk manufacturer of various "basic classes of controlled substances," including oxycodone. Manufacturer of Controlled Substances Registration: Noramco, Inc., 79 Fed. Reg. 60498-02 (Oct. 7, 2015).

action does not arise from the sale of the API to Collegium and, therefore, does not logically establish a reasonable expectation of being haled into a Delaware court based on such sales. There has been no court to date that has exercised specific jurisdiction on this basis. The court concludes that Purdue has failed to carry its burden of persuasion.

C. Venue

The court's conclusion above leaves the question: Where should this case be litigated? Collegium urges the court to transfer the case to the Southern District of New York, because it has consented to personal jurisdiction in that venue. Purdue, having filed a "back-up action" in the District of Massachusetts, argues that if transfer is required, the case should be transferred there.

The court agrees with Purdue. There is no doubt that jurisdiction can be exercised over Collegium in Massachusetts, where Collegium continues to be headquartered and to engage in drug and business development and investment activities. The fact that the court in the Southern District of New York has adjudicated the listed patents is not compelling under the circumstances at bar, where such adjudication is on appeal and the issues presented by the '497 patent are new and distinct.[13]

In sum, under the unusual circumstances of this case, the court will dismiss the instant litigation so that Purdue can pursue its protective lawsuit pending in the District of Massachusetts, an entirely appropriate venue. The court finds that Purdue's litigation

[13] To wit, the listed patents cover the formulation of an oxycodone hydrochloride API with high breaking strength and which gels in water, whereas the '497 patent claims an abuse-deterrent formulation that uses an irritant.

tactics[14] are no better or worse than Collegium's,[15] and that a straightforward venue like Massachusetts is the most reasonable solution to the parties' dispute in this regard.

V. CONCLUSION

For the reasons discussed above, Collegium's motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York, is granted in part and denied in part.

An appropriate order shall issue.

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[14] Filing suit in both Delaware and Massachusetts.

[15] Changing its state of incorporation from Delaware to Virginia on the eve of a litigation-triggering event and consenting to jurisdiction in the Southern District of New York, not because of sufficient contacts but, ostensibly, because of the adverse decision rendered by that court against Purdue and the potential for early market entry based on that decision.