

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Christine M. Arguello**

Civil Action No. 09-cv-02392-CMA-MJW

PFIZER, INC.,
PFIZER PHARMACEUTICALS, LLC,
PFIZER IRELAND PHARMACEUTICALS,
PFIZER LIMITED, and
C.P. PHARMACEUTICALS INTERNATIONAL C.V.,

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

SANDOZ INC.,

Counterclaim Plaintiff,

v.

PFIZER INC.,
PFIZER PHARMACEUTICALS, LLC,
PFIZER IRELAND PHARMACEUTICALS,
PFIZER LIMITED,
C.P. PHARMACEUTICALS INTERNATIONAL C.V.,
WARNER-LAMBERT COMPANY, and
WARNER-LAMBERT COMPANY LLC.

Counterclaim Defendants.

**ORDER GRANTING IN PART AND DENYING IN PART
MOTION TO TRANSFER OR STAY**

This matter is before the Court on Plaintiffs Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Limited, and C.P. Pharmaceuticals International C.V.'s Motion to Transfer or Stay this action.¹ (Doc. # 14). For the following reasons, the Court GRANTS IN PART and DENIES IN PART Plaintiffs' Motions to Transfer or Stay.

I. BACKGROUND

This case arises under the Drug Price Competition and Patent Term Restoration Act of 1984, (the "Hatch-Waxman Act"). The Hatch-Waxman Act sets forth procedures for pharmaceutical companies to obtain approval from the Food and Drug Administration ("FDA") to manufacture and market generic versions of patented drugs, which procedures include the filing of Abbreviated New Drug Applications ("ANDAs"). See 21 U.S.C. § 355. In pertinent part, upon receipt of notice of an ANDA filing, patent-holders have 45 days in which to commence an infringement action. *Id.* "According to 35 U.S.C. § 271(e)(2), the filing of an ANDA...provides a federal court with subject matter jurisdiction to adjudicate infringement on a prospective basis, before the ANDA applicant has made, used, sold, or offered to sell its generic product in the United States." *Shire LLC v. Sandoz, Inc.*, No. 07-cv-197, 2008 WL 4402251, at *1 (D. Colo. Sept. 24, 2008).

¹ Plaintiffs have filed a nearly-identical Motion to Transfer or Stay Sandoz's Complaint for Declaratory Relief in the related case No. 09-cv-2457 ("Colorado II Action") (Doc. # 13). The Court has issued a similar order granting Plaintiffs' Motion to Transfer the Colorado II Action. The arguments raised in the parties' briefs in both cases are essentially identical and will be addressed together in this Order.

On October 6, 2009, Plaintiffs filed in Delaware a patent infringement action against Defendant Sandoz Inc., alleging that Defendant infringed U.S. Patent No. 6,455,574 (the “574 Patent”) when it filed ANDA No. 91-462 (hereinafter, “Defendant’s ANDA”), which sought permission from the FDA to market a generic version of Pfizer’s hypertension and hyperlipidemia drug sold under the brand name Caduet, pursuant to 35 U.S.C. § 271(e)(2). (Doc. # 14, Ex. 2) (hereinafter, the “Delaware Action”). As set forth in Plaintiffs’ Motion to Transfer or Stay, Caduet contains two active ingredients: (1) amlodipine besylate and (2) atorvastatin calcium. (Doc. # 14 at 2).

On October 7, 2009, Plaintiffs initiated in this Court the above-captioned action, Case No. 09-cv-02392, which is essentially identical to the Delaware Action. (Doc. # 1) (hereinafter, the “Colorado I Action”).

On October 16, 2009, in the Colorado I Action, Defendant filed its Answer, Affirmative Defenses, and Counterclaims against Plaintiffs and two new Counterdefendants, Warner-Lambert Company and Warner-Lambert Company LLC, both allegedly wholly owned subsidiaries of Pfizer, Inc., and assignees of certain patents raised in the Counterclaims.² (Doc. # 6). In pertinent part, in its Counterclaims, Defendant contends that the ‘574 Patent is invalid and non-infringed. (Doc. #10 at 12-13). Defendant also alleges the invalidity and non-infringement of three patents not included by Plaintiffs in their Complaint: Patent Nos. 6,126,971 (the “971 Patent”),

² On October 19, 2009, Defendant re-filed its Answer, in order to properly add the two new Counterdefendants, Warner-Lambert Company and Warner-Lambert Company LLC. (Doc. # 10). The Court notes that these new “counterdefendants” would be more appropriately classified as third parties and Defendant’s claims against them, “third party claims”.

5,969,156 (the “156 Patent”), and 5,686,104 (the “104 Patent”) (collectively, “the Non-Asserted Patents”) (*Id.* at 13-16). All the patents allegedly cover formulations of Caduet’s active ingredients, amlodipine besylate and atorvastatin calcium, and Defendant’s ANDA seeks approval to market certain formulations of amlodipine besylate and atorvastatin calcium. (Doc. # 29 at 2-3). In pertinent part, Defendant’s ANDA included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (hereinafter, the “Paragraph IV Certification”) stating that the ‘574, ‘104, ‘156, and ‘971 patents are either invalid or would not be infringed by the Defendant’s products. (Doc. # 10, ¶ 26). Thus, Defendant’s ANDA implicates the ‘574 Patent and the Non-Asserted Patents.

On the same day that Defendant filed its Answer in the Colorado I Action, Defendant filed a Complaint for Declaratory Relief in this District, seeking a declaratory judgment that the Non-Asserted Patents are invalid and/or not infringed by Defendant’s ANDA. (Case No. 09-cv-2457, Doc. # 1) (hereinafter, the “Colorado II Action”). The parties, causes of action, and relief demanded in the Colorado II Action are identical to those set forth in Defendant’s Counterclaims in the Colorado I Action.

On November 19, 2009, Plaintiffs filed the instant Motion to Transfer or Stay the Colorado I Action (Doc. # 14) and a Motion to Transfer or Stay Sandoz’s Complaint for Declaratory Relief, in the related Colorado II Action. (Case No. 09-cv-2457, Doc. # 13). On December 3, 2009, Defendant filed its Response Briefs. (Doc. # 29; Case No. 09-cv-2457, Doc. # 26). Finally, on December 21, 2009, Plaintiffs filed their Reply Briefs. (Doc. # 36; Case No. 09-cv-2457, Doc. # 31).

Meanwhile, pending before the District of Delaware were Plaintiffs' Motion to Enjoin Defendant Sandoz from Proceeding with its Later Filed Suit in the District of Colorado and Defendant's Motion to Transfer the Delaware Action to this District. On January 20, 2010, the District of Delaware denied Defendant's Motion to Transfer, after balancing the public and private interest factors of proceeding in the District of Delaware versus the District of Colorado and after applying the first-filed rule. (Doc. # 44, Ex. 1 at 7-14) (hereinafter, the "January 20 Delaware Decision"). The court reserved judgment on Plaintiffs' Motion to Enjoin until such time that this Court rules on the instant Motions. (*Id.* at 16).

II. ANALYSIS

While courts typically disfavor the filing of substantially similar lawsuits in multiple jurisdictions, courts have made an exception for patent suits arising from a defendant's ANDA filings, in light of the fact that the Hatch-Waxman Act, the governing statute, is silent as to whether a patent holder loses its right to sue if its suit is dismissed for lack of personal jurisdiction after the 45-day window has expired. *See Pfizer Inc. v. Mylan, Inc.*, No. 09-cv-79, Doc. # 62 (N.D. W. Va. Nov. 20, 2009) ("[A] plaintiff, such as Pfizer, may decide to file protective ANDA suits in multiple jurisdictions as a hedge against the risk of dismissal for want of jurisdiction.") (Doc. # 16, Ex. A); *Pfizer Inc. v. Apotex, Inc.*, 640 F. Supp. 2d 1006, 1010 (N.D. Ill. 2009) ("While the routine filing of protective lawsuits in ANDA cases places an extra burden on the parties and the judicial system, the Court is reluctant to condemn the practice in view of the apparent conundrum that parties in

Pfizer's position otherwise may face."); *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, No. 07-cv-993, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 3, 2007); *PDL Biopharma, Inc. v. Sun Pharma. Indus. Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Schering Co. v. Caraco Pharm. Labs., Ltd.*, No. 06-14386, 2007 WL 1648908 (E.D. Mich. June 6, 2007); *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05-C-6561, 2006 WL 850916, at *8 (N.D. Ill. March 28, 2006).

Defendant contends that the first-to-file rule should not apply in the instant action because Pfizer has needlessly multiplied the proceedings by filing two actions (the Delaware Action and the Colorado I Action) within a short time period. (Doc. # 29 at 8). In support, Defendant cites to four cases that are all distinguishable from the instant action. Three of these cases do not even concern the unique set of circumstances present in ANDA-based patent lawsuits. See *Employers Reinsurance Corp. v. MSK Ins., Ltd.*, No. 01-2608, 2003 WL 21143105 (D. Kan. Mar. 31, 2003) (dispute over the issuance of a reinsurance certificate); *Universal Premium Acceptance Corp. v. Oxford Bank & Trust*, No. 02-2448, 2002 WL 31898217 (D. Kan. Dec. 10, 2002) (dispute over an indemnification provision in a stock purchase agreement); *United States Fire Ins. Co. v. Goodyear Tire & Rubber Co.*, 920 F.2d 487 (8th Cir. 1990) (breach of contract and fraud claims).

The fourth case, and the lone patent case, cited by Defendant, *Pfizer Inc. v. Apotex, Inc.*, No. 08-cv-948, 2009 WL 2843288 (D. Del. Aug. 13, 2009), is equally distinguishable. In *Apotex*, the District of Delaware chose not to apply the first-to-file

rule where factual and legal issues existed concerning the court's personal jurisdiction over one of the defendants in the first-filed case. *Id.* at *3. In the instant case, Defendant, a Colorado corporation with a principal place of business in New Jersey, suggests that the District of Delaware lacks personal jurisdiction over it. However, as the January 20 Delaware Decision noted, "[a]lthough Defendant has not consented to personal jurisdiction in this Court, the scope of the jurisdictional dispute is much less apparent than in *Apotex*." (Doc. # 44, Ex. 1 at 13). Further, Sandoz's suggestion that the District of Delaware lacks jurisdiction over it is disingenuous. Defendant has admitted that it is licensed to distribute pharmaceuticals in the state of Delaware and is in the business of making and selling generic pharmaceutical products for sale throughout the United States, including Delaware. (Doc. # 14, Ex. 5, ¶ 15). Defendant has also admitted that it is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale". (*Id.*, ¶ 16). Further, the Court notes that Defendant has proceeded with tendering discovery requests upon Plaintiffs in the Delaware Action (Del. Case. No. 09-cv-742, Doc. # 38). Finally, Defendant has admitted that it did not contest personal jurisdiction in an unrelated and earlier case before the District of Delaware. (See Doc. # 14, Ex. 5, ¶ 22). Accordingly, this Court concludes that jurisdictional issues do not preclude the transfer of the Colorado I and II Actions to Delaware and that, given the Hatch-Waxman Act's vagueness, Plaintiffs' protective strategy of filing essentially identical lawsuits in multiple jurisdictions was in good faith and not a means to unnecessarily duplicate proceedings.

Finally, like the District of Delaware, this Court finds that the public and private interest factors of the competing jurisdictions are neutral and that the first-filed rule should prevail. Pursuant to 28 U.S.C. § 1404(a), courts may transfer a case to another district where it might have been brought “[f]or the convenience of parties and witnesses, in the interest of justice.” “[T]here is a strong presumption in favor of hearing the case in the plaintiff’s chosen forum. That presumption is overcome only when the private and public interest factors clearly point towards trial in the alternative forum.” *Gschwind v. Cessna Aircraft Co.*, 161 F.3d 602, 606 (10th Cir. 1998) (internal citations and quotations omitted). Courts in the Tenth Circuit analyze the public and private interest factors set forth in *Texas Gulf Sulphur Co. v. Ritter*, 371 F.2d 145 (10th Cir. 1967). Specifically, courts consider: (1) the plaintiff’s choice of forum; (2) the accessibility of witnesses and other sources of proof, including the availability of compulsory process to insure attendance of witnesses; (3) the cost of making the necessary proof; (4) questions as to the enforceability of a judgment if one is obtained; (5) relative advantages and obstacles to a fair trial; (6) difficulties that may arise from congested dockets; (7) possibility of questions arising in the area of conflict of laws; (8) the advantages of having a local court determine questions of local law; and (9) all other considerations of a practical nature that make a trial easy, expeditious and economical. *Id.* at 147.

In the instant case, Defendant argues in its opposition brief that the Court’s discretion to transfer cases does not “extend to transferring a case to a district that lacks

personal jurisdiction over a defendant, even where the defendant has consented to the suit.” (Doc. # 29 at 12). However, as previously noted, Defendant’s intimations that the District of Delaware lacks jurisdiction over it are disingenuous. While the Delaware Court has not yet made a final determination on the jurisdictional issue, for the previously-stated reasons, Defendant appears to have sufficient Delaware contacts to subject it to that court’s jurisdiction.

Plaintiffs filed the Colorado I Action as a protective measure, but Plaintiffs’ preferred forum is the District of Delaware, the locale of the first-filed action. This Court agrees with the District of Delaware’s determination that the public and private interest factors of proceeding in either jurisdiction do not weigh in favor of one jurisdiction over the other. Further, in failing to prevail on its Motion to Transfer in the District of Delaware, Defendant itself failed to meet its burden of establishing that Delaware is an inconvenient forum. See *Chrysler Credit Corp. v. Country Chrysler, Inc.*, 928 F.2d 1509, 1515 (10th Cir. 1991) (the party seeking transfer bears the burden of establishing that the existing forum is inconvenient). Moreover, Defendant has explicitly acknowledged that “Colorado and Delaware are equally convenient forums for all parties.” (Doc. # 29 at 15).

In sum, Defendant Sandoz has not overcome the presumption in favor of the Plaintiffs’ preferred choice of forum. Instead, Sandoz essentially argues that it was the first-to-file an action regarding the Non-Asserted Patents (the Colorado II Action) and, therefore, Sandoz’s choice-of-forum for the Colorado II Action should prevail, unless

Plaintiffs show that the chosen forum of this District is inconvenient. (Doc. # 29 at 5-6, 13). However, Sandoz's decision to initiate the Colorado II Action for declaratory judgment in connection with the Non-Asserted Patents³ appears to be nothing other than a tactical maneuver to gain a foothold in its preferred forum. First, Sandoz's allegations and defenses in the Colorado II Action are identical to its Counterclaims in the Colorado I Action. Second, in opposing transfer of the Colorado I and II Actions, Sandoz contends that, "unlike the Delaware Action, the [Colorado Actions] will adjudicate all patents implicated by the Paragraph IV certification in Sandoz's ANDA." (Doc. # 29 at 5). However, no good reason exists for Sandoz's failure to assert identical claims and defenses in the Delaware Action, especially when Sandoz filed its Answer and Counterclaims in the Delaware Action (regarding only the '574 Patent) ten days *after* it filed its pleadings in the Colorado I and II Actions, which pleadings asserted claims and defenses regarding all the patents implicated by the Paragraph IV certification in Sandoz's ANDA, *i.e.*, the '574 Patent and Non-Asserted Patents. This type of tactical maneuvering was not contemplated by the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201, and is disfavored by federal courts. *See Trading Techs. Int'l, Inc. v. CQG, Inc.*, No. 05 C 4811, 2005 WL 3601936, at *3 (N.D. Ill. Oct. 31, 2005) (the DJA's purpose was not to provide alleged infringers with a means to forum shop, but to provide alleged infringers, who have been threatened with a potential lawsuit, with a means to efficiently adjudicate their rights while minimizing the accumulation of injuries);

³ The Colorado II Action also concerns the '574 Patent.

see also *Berry Floor USA, Inc. v. Faus Group, Inc.*, No. 08-cv-44, 2008 WL4610313, at *5 (E.D. Wis. Oct. 15, 2008) (placing less weight on the plaintiff's first-to-file status in light of evidence that the declaratory judgment action was filed as a tactical maneuver). In the instant case, actual lawsuits arising from Defendant Sandoz's ANDA had commenced by the time Sandoz had filed its Complaint for Declaratory Judgment. The threat of litigation arising from Sandoz's ANDA was not potential; the litigation was actual.

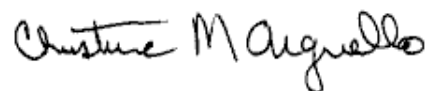
For the foregoing reasons, the Court finds no reason to retain this action.

Accordingly, IT IS ORDERED THAT Plaintiffs' Motion to Transfer or Stay this action (Doc. # 14) is GRANTED to the extent it seeks a transfer to the District of Delaware and DENIED to the extent that it seeks a stay, as the stay request is now moot.

IT IS FURTHER ORDERED THAT this action be transferred to the District of Delaware for further prosecution and adjudication.

DATED: February 08, 2010

BY THE COURT:



CHRISTINE M. ARGUELLO
United States District Judge