

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

Civil Action No. 09-cv-02457-CMA-MJW

SANDOZ, INC.,

Plaintiff,

v.

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

Defendants.

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

This matter is before the Court on Defendants Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Limited, and C.P. Pharmaceuticals International C.V.'s Motion to Transfer or Stay this action.¹ (Doc. # 13). For the following reasons, the Court **GRANTS IN PART** and **DENIES IN PART** Defendants' Motions to Transfer or Stay.

¹ Defendants have filed a nearly-identical Motion to Transfer or Stay in the related and earlier-filed case No. 09-cv-02392 ("Colorado I Action"). (Doc. # 14). In the Colorado I Action, the parties' roles are reversed. Defendants filed that earlier action against the instant Plaintiff Sandoz for patent infringement. In a tactical maneuver, Sandoz filed this action for declaratory judgment. The Court has issued a similar order granting Defendants' Motion to Transfer the Colorado I Action. The arguments raised in the parties' briefs in both cases are essentially identical and will be addressed together in this Order.

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).

On October 6, 2009, Defendants filed in Delaware a patent infringement action against Plaintiff Sandoz Inc. (“Sandoz”), alleging that Sandoz infringed U.S. Patent No. 6,455,574 (the “574 Patent”) when Sandoz filed ANDA No. 91-462 (hereinafter, “Sandoz’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. # 13, Ex. B) (hereinafter, the “Delaware Action”). As set forth in Defendants’ Motion to Transfer or Stay, Caduet contains two

active ingredients: (1) amlodipine besylate and (2) atorvastatin calcium. (Doc. # 13 at 4).

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

On October 16, 2009, in the Colorado I Action, Sandoz filed its Answer, Affirmative Defenses, and Counterclaims against Defendants. (Case No. 09-cv-02392, Doc. # 6). In pertinent part, in its Counterclaims, Sandoz contends that the ‘574 Patent is invalid and non-infringed. (Case No. 09-cv-02392, Doc. #10 at 12-13). Sandoz also alleges the invalidity and non-infringement of three patents not included by Defendants in their Complaint: Patent Nos. 6,126,971 (the “‘971 Patent”), 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 Sandoz’s ANDA seeks approval to market certain formulations of amlodipine besylate and atorvastatin calcium. (Doc. # 29 at 2-3). In pertinent part, 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 Sandoz’s products. (Case No. 09-cv-02392, Doc. # 10, ¶ 26). Thus, Sandoz’s ANDA implicates the ‘574 Patent and the Non-Asserted Patents.

On the same day that Sandoz filed its Answer in the Colorado I Action, Sandoz filed the above-captioned action, a Complaint for Declaratory Relief in this District, seeking a declaratory judgment that the Non-Asserted Patents are invalid and/or not infringed by Sandoz's ANDA. (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 Sandoz's Counterclaims in the Colorado I Action.

On November 19, 2009, Defendants filed a Motion to Transfer or Stay the Colorado I Action (Case No. 09-cv-02392, Doc. # 14) and the instant Motion to Transfer or Stay. (Doc. # 13). On December 3, 2009, Sandoz filed its Response Briefs. (Doc. # 26; Case No. 09-cv-02392, Doc. # 29). Finally, on December 21, 2009, Defendants filed their Reply Briefs. (Doc. # 31; Case No. 09-cv-02392, Doc. # 36).

Meanwhile, pending before the District of Delaware were Defendants' Motion to Enjoin Sandoz from Proceeding with the instant action and Sandoz's Motion to Transfer the Delaware Action to this District. On January 20, 2010, the District of Delaware denied Sandoz'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. (Case No. 09-cv-02392, Doc. # 44, Ex. 1 at 7-14) (hereinafter, the "January 20 Delaware Decision"). The court reserved judgment on Defendants' 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 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.”) (Case No. 09-cv-02392, 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).

Sandoz 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. # 26 at 8).

In support, Sandoz 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 Sandoz, *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, Sandoz, 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 [Sandoz] has not consented to personal jurisdiction in this Court, the scope of the jurisdictional dispute is much less apparent than in *Apotex*." (Case No. 09-cv-02392, Doc. # 44, Ex. 1 at 13). Further, Sandoz's suggestion that the District of Delaware lacks of jurisdiction over it is disingenuous. Sandoz 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. #13, Ex. F, ¶ 15).

Sandoz 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 Sandoz has proceeded with tendering discovery requests upon Defendants in the Delaware Action (Del. Case. No. 09-cv-742, Doc. # 38). Finally, Sandoz has admitted that it did not contest personal jurisdiction in an unrelated and earlier case before the District of Delaware. (See Doc. #13, Ex. F, ¶ 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, Defendants’ 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, one must remember that Defendants initiated the Delaware and Colorado I Actions, both of which precede the instant Colorado II Action. Accordingly, the pertinent question is whether the Defendants' preferred forum, *i.e.*, Delaware, should prevail. Sandoz 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. #26 at 13). However, as previously noted, Sandoz'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, Sandoz appears to have sufficient Delaware contacts to subject it to that court's jurisdiction.

Defendants filed the Colorado I Action as a protective measure, but Defendants' 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, Sandoz 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, Sandoz has explicitly acknowledged that "Colorado and Delaware are equally convenient forums for all parties." (Doc. #26 at 15).

In sum, Sandoz has not overcome the presumption in favor of the first plaintiffs', *i.e.*, the Defendants', 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, its choice-of-forum for the Colorado II Action should prevail, unless Defendants show that the chosen forum of this District is inconvenient. (Doc. #26 at 7-8, 14). However, Sandoz's decision to initiate the Colorado II Action for declaratory judgment in connection with the Non-Asserted Patents² 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

² The Colorado II Action also concerns the '574 Patent.

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. #26 at 6). 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); 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 Sandoz’s ANDA had commenced by the time Sandoz had filed this action. The threat of litigation arising from Sandoz’s ANDA was not potential; the litigation was actual.

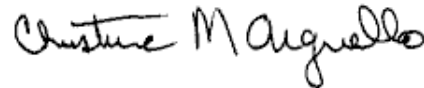
For the foregoing reasons, the Court finds no reason to retain this action.

Accordingly, IT IS ORDERED THAT Defendants' Motion to Transfer or Stay this action (Doc. #13) 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:

A handwritten signature in black ink that reads "Christine M. Arguello". The signature is written in a cursive style with a horizontal line above the text.

CHRISTINE M. ARGUELLO
United States District Judge