

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF ARKANSAS  
WESTERN DIVISION**

**NOVARTIS AG, NOVARTIS  
PHARMACEUTICALS CORPORATION,  
MITSUBISHI TANABE PHARMA  
CORPORATION, and MITSUI SUGAR  
CO., LTD.**

**PLAINTIFFS**

**v.**

**Case No. 4:15-cv-00095 KGB**

**EZRA VENTURES, LLC**

**DEFENDANT**

**ORDER**

Before the Court is plaintiffs' motion to stay (Dkt. No. 26). Defendant has responded in opposition to the motion (Dkt. No. 28), and plaintiffs have replied (Dkt. No. 32). Plaintiffs also filed a notification to the Court regarding their motion to stay (Dkt. No. 34). For the following reasons, the Court grants plaintiffs' motion to stay and hereby stays this action.

**I. Background**

Plaintiffs Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co. hold the rights, including various patents, to the drug fingolimod, popularly known as Gilenya®. On January 2, 2015, defendant Ezra Ventures, LLC ("Ezra") informed plaintiffs that it had filed an Abbreviated New Drug Application ("ANDA") with the Federal Drug Administration ("FDA") seeking permission to market a generic version of Gilenya®. Plaintiffs then filed suit against Ezra in the Federal District Court for the District of Delaware on February 11, 2015, pursuant to the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j)(5)(B)(iii). Plaintiffs state that their Delaware action against Ezra is the third case they have filed in Delaware involving the same patent and similar proposed generic drugs at issue

here. *See Novartis AG, et al. v. Actavis Inc., et al.*, Case No. 14-01487 LPS (D. Del.); *Novartis AG, et al. v. HEC Pharm. Group, et al.*, Case No. 15-00151 LPS (D. Del.).

Two days after filing suit against Ezra in Delaware, plaintiffs filed in this Court an action against Ezra, also pursuant to the Hatch-Waxman Act. The parties do not dispute the fact that the claims raised in the Delaware action are identical to those raised in this action. Plaintiffs state that the purpose of this action is “to protect Plaintiffs’ rights should the first case be dismissed for lack of personal jurisdiction” (Dkt. No. 27, at 2-3). Plaintiffs’ suit in this Court is the effect of certain peculiarities of the Hatch-Waxman act.

Under the Hatch-Waxman Act, the holder of a drug patent who receives notice that a generic drug manufacturer has filed an ANDA with the FDA must file a protective suit against the generic drug manufacturer within 45 days of receiving such notice. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent holder fails to file such an action within the 45 day window, it will lose its claims to the patent. *See Eli Lilly & Co. v. Teva Pharms. United States, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009). Once a protective suit is filed, the Hatch-Waxman Act bars the FDA from approving the ANDA until the suit either is resolved in favor of the generic drug manufacturer or 30 months elapses after the patent holder’s receipt of notice of the ANDA application. *See id.* “The court entertaining the suit has discretion under the statute to order a shorter or longer stay [of the FDA’s approval] if ‘either party to the action fail[s] to reasonably cooperate in expediting the action.’” *Id.* (quoting 21 U.S.C. § 355(j)(5)(B)(iii)).

Because a patent holder will lose its patent claims if it fails to maintain a suit against the generic drug manufacturer, patent-holder plaintiffs in Hatch-Waxman Act cases often “file protective ANDA suits in multiple jurisdictions as a hedge against the risk of dismissal for want of jurisdiction.” *Pfizer, Inc. v. Mylan, Inc.*, Case No. 1:09-cv-79, 2009 WL 10270101, at \*1

(N.D. W. Va. Nov. 20, 2009). Thus, if the patent holder's first-filed suit is dismissed for lack of jurisdiction, the patent holder may maintain the Hatch-Waxman Act litigation in the jurisdiction of the second-filed suit without threat of losing its patent claims for failure to maintain a suit against the generic drug manufacturer in the first-filed suit.

This action is plaintiffs' second-filed Hatch-Waxman Act suit against Ezra, with plaintiffs admitting this suit alleges claims identical to those in the first-filed Delaware action. The parties do not dispute that this Court has jurisdiction. In the Delaware action, however, Ezra moved to dismiss for lack of personal jurisdiction. On May 11, 2015, the Delaware district court denied Ezra's motion to dismiss but specified the dismissal was without prejudice to Ezra's right to renew its motion to dismiss, if appropriate, after the Federal Circuit Court of Appeals decides other pending interlocutory appeals that may address certain of the personal-jurisdiction issues raised by Ezra. On that same day, the Delaware district court ordered the parties to participate in a Rule 26(f) conference by May 29, 2015, which the parties held on May 21, 2015.

Ezra moved to certify an appeal of the Delaware district court's decision to the Federal Circuit on May 21, 2015. On May 22, plaintiffs filed their motion to stay in this Court. Ezra answered the plaintiffs' complaint in this action on March 19, 2015, and the plaintiffs' complaint in Delaware on May 27, 2015. Ezra states that, in the Delaware action, plaintiffs have proposed a schedule setting trial for March 2017. In this action, the Court has entered an Initial Scheduling Order tentatively setting trial during the week of April 25, 2016 (Dkt. No. 23). On June 1, 2015, Ezra served written discovery requests in this action. On June 22, 2015, the parties submitted their joint Rule 26(f) Report to this Court (Dkt. No. 33). In their Report, plaintiffs state that, if this Court denies its motion to stay, plaintiffs wish to have the schedule and filings in the Delaware action apply to this action. Ezra disagrees, stating that the Delaware schedule to

which it agreed should only apply to the Delaware action and that the dates as set forth in the initial scheduling order should remain. On June 22, 2015, the Delaware district court denied Ezra's motion for certification of interlocutory appeal of the order denying Ezra's motion to dismiss for lack of personal jurisdiction (Dkt. No. 34).

## **II. Discussion**

Plaintiffs contend that the Court should stay this case under the "first to file" rule and because other considerations weigh in favor of the Court exercising its broad discretion to stay the proceedings in this action. Plaintiffs also cite several district court cases that have granted stays in second-filed protective suits under the Hatch-Waxman Act. *See Pfizer, Inc. v. Mylan, Inc.*, Case No. 1:09-cv-79, 2009 WL 10270101 (N.D. W. Va. Nov. 20, 2009); *Pfizer, Inc. v. Apotex, Inc.*, 640 F. Supp. 2d 1006, 1010-11 (N.D. Ill. 2009); *Schering Corp. v. Caraco Pharm. Labs., Ltd.*, Case No. 06-cv-14386, 2007 WL 1648908, at \*3 (E.D. Mich. June 6, 2007); *PDL Biopharma, Inc. v. Sun Pharm. Indus., Ltd.*, Case NO. 07-cv-11709, 2007 WL 2261386, at \*2-3 (E.D. Mich. Aug 6, 2007); *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, Case No. 1:07-cv-993, 2007 WL 4284877, at \*2-3 (W.D. Mich. Dec. 3, 2007). Ezra argues that the Court should deny the motion to stay because jurisdiction is contested in the Delaware action and because equitable considerations favor denying the stay. Ezra cites one case in which the court denied a motion to stay in a second-filed protective suit when jurisdiction was challenged in the first-filed action. *See Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 491 (E.D. Va. 2005).

The first-to-file rule is an equitable doctrine which provides that, “[i]n all cases of concurrent jurisdiction, the Court which first has possession of the subject must decide it.”<sup>1</sup> *Smith v. McIver*, 22 U.S. 532, 535 (1824). Further, “[t]he ‘first-to-file’ rule is a doctrine of federal comity, intended to avoid conflicting decisions and promote judicial efficiency, that generally favors pursuing only the first-filed action when multiple lawsuits involving the same claims are filed in different jurisdictions.” *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012). Under this rule, the court presiding over the second-filed action must defer to the court presiding over the first-filed action, if the two actions were filed in close chronology, contain similar parties, and involve similar issues. *See Furminator, Inc. v. Munchkin, Inc.*, Case No. 4:08-cv-00367-ERW, 2009 WL 2957952, at \*1 (E.D. Mo. Sept. 10, 2009). Courts also consider whether “jurisdiction over all necessary or desirable parties” is absent in the court presiding over the first action. *Elecs. For Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1348 (Fed. Cir. 2005).

The first-to-file rule is not intended to be a “rigid mechanical solution[] to questions of forum.” *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993) (internal quotation marks omitted); *see also Orthmann v. Apple River Campground, Inc.*, 765 F.2d 119,

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<sup>1</sup> Plaintiffs contend that Federal Circuit law governs application of the first-to-file rule in this case. *See J.P. Sercel Assocs., Inc. v. New Wave Research*, Case No. 03-331-JD, 2003 WL 22299014, at \*1 (D. N.H. Oct 7, 2003) (“[D]istrict courts follow Federal Circuit precedent in considering the first-filed action rule in patent cases.”). If Federal Circuit law is silent, courts “look to understandings of the doctrine as developed generally in the federal courts.” *Shire U.S., Inc. v. Johnson Matthey, Inc.*, 543 F. Supp. 2d 404, 408 (E.D. Pa. 2008). The cases that plaintiffs cite are primarily patent-infringement cases where a defendant in one action subsequently files a second patent-infringement action in another jurisdiction; these cases do not reflect squarely the situation here—when a plaintiff brings two patent cases in different jurisdictions. Ezra cites *Orthmann v. Apple River Campground, Inc.*, 765 F.2d 119, 121 (8th Cir. 1985), to argue that courts do not apply the first-to-file rule when jurisdiction is “vigorously dispute[d]”; nonetheless, the parties do not argue explicitly that Eighth Circuit law is materially different than Federal Circuit law regarding the first-to-file rule. The Court finds no inconsistencies in any circuit’s law on the first-to-file rule that would change the Court’s decision here.

121 (8th Cir. 1985) (holding that the first-to-file rule is “not intended to be rigid, mechanical, or inflexible, but should be applied in a manner serving sound judicial administration”). “[A]s in any issue of choice of forum,” courts apply exceptions to the first-to-file rule “when justice or expediency requires.” *Genentech*, 998 F.2d at 937. Courts may decline to follow the first-to-file rule if the balance of convenience weighs in favor of the second-filed court’s continued exercise of jurisdiction. *See Ellicott Mach. Corp. v. Modern Welding Co.*, 502 F.2d 178, 181 (4th Cir. 1974). Nonetheless, some courts hold that the court over the first-filed action must determine if an exception to the first-filed rule applies. *Touchstone Research Lab., Ltd. v. Anchor Equip. Sales, Inc.*, 294 F. Supp. 2d 823, 828 (N.D. W. Va. 2003); *Citygroup Inc. v. City Holding Co.*, 97 F. Supp. 2d 549, 557 n.4 (S.D. N.Y. 2000).

A district court’s power to stay an action is “incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936). When deciding whether to stay proceedings, courts consider potential prejudice to the non-moving party, hardship and inequity to the moving party if the matter is not stayed, and economy of judicial resources. *See Benge v. Eli Lilly & Co.*, 553 F. Supp. 2d 1049, 1050 (N.D. Ind. 2008).

This case fits squarely within the first-to-file rule. Plaintiffs filed this action two days after they filed the action in Delaware, and the parties and issues in this action are identical to those in the Delaware action. Furthermore, to the extent that it may decide if any exception to the first-to-file rule applies, the Court finds that equitable considerations weigh in favor of the parties’ dispute continuing in Delaware. Although this Court’s Initial Scheduling Order tentatively set the trial for this matter for the week of April 26, 2016, it is unlikely, based on the complexity of the issues here, that this case would go to trial so quickly. The Initial Scheduling

Order is not a reflection of the Court's understanding of the complexity of the action nor is it a firm timetable. Rather, the parties' agreed-upon schedule in their joint Rule 26(f) Report in Delaware is likely a better indication of the time needed to prepare this case for trial.

In considering judicial economy, the Court places no value on any party's attempt to color the Delaware court or this Court as the speedier action by delaying or accelerating service of filings or discovery requests. Rather, the Court seeks to conserve scarce judicial resources by avoiding duplicative litigation. Proceeding in this Court while the Delaware action progresses would cause duplicative litigation and waste judicial resources. Moreover, maintaining a single action in Delaware will ensure the uniformity of results and promote a more consistent application of patent law, not only in this litigation, but in other litigation in the District of Delaware involving plaintiffs' rights regarding Gilenya® and other patent-infringement cases under the Hatch-Waxman Act. *See Genentech*, 998 F.2d at 937 (noting "the special obligation of the Federal Circuit to avoid creating opportunities for dispositive differences among the regional circuits" in the interests of "national uniformity in patent cases").

Although courts have not followed the first-to-file rule when jurisdiction is lacking in the first-filed action, nothing before this Court shows that jurisdiction is lacking in Delaware. Instead, the District of Delaware has determined that it has jurisdiction over the parties' action there. This Court will not undermine that ruling. This case is materially different than *Orthmann*, where the Eighth Circuit Court of Appeals did not follow the first-to-file rule because, in part, jurisdiction was "vigorously disputed." 765 F.2d at 121. In *Orthmann*, the Eighth Circuit found that a second-filed Wisconsin case had progressed further than the first-filed Minnesota case, and the court presiding over the first-filed case had already dismissed its action for lack of personal jurisdiction. 765 F.2d at 120. In this case—unlike the facts in

*Orthmann*—the Delaware district court has held that it has jurisdiction, and this Court’s action has not progressed further than the Delaware action.

Further, Ezra’s reliance on *Aventis*, a case in which the district court denied a motion to stay because jurisdiction was unsettled in the first-filed action, does not persuade this Court. In *Aventis*, the defendants’ motion to dismiss for lack of personal jurisdiction was still pending in the first-filed action. 403 F. Supp. 2d at 488, 491. Here, the Delaware district court has already denied Ezra’s motion to dismiss for lack of personal jurisdiction. Regardless, however, the Court finds convincing the analysis in *Mylan*, where the district court rejected *Aventis*, stating as follows:

This Court’s opinion, however, is that [*Aventis*’s] strict approach fails to consider the peculiar enforcement requirements of the Hatch–Waxman Act, which place incredible risks on patent holders who file a protective suit in a single jurisdiction. It is these requirements that have resulted in the widespread proliferation of concurrent filings of protective suits in the federal courts. In light of these circumstances, the Court finds *Mylan*’s argument [to not apply the first-to-file rule] unconvincing, and concludes that Pfizer is not barred from invoking the first-to-file rule in support of its motion to stay or transfer.

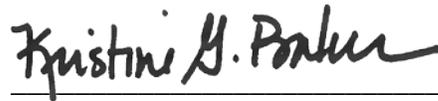
*Mylan, Inc.*, 2009 WL 10270101, at \*2. Moreover, Ezra has pointed to no authority that would prevent the parties from continuing litigation in this Court were the Federal Circuit to overturn the District of Delaware’s determination regarding jurisdiction. Thus, Ezra has not convinced the Court that any potential prejudice to it demands that the action progress further here.

The risks inherent in Hatch-Waxman Act cases, the need for uniform application of patent law, and the goal of avoiding duplicative litigation persuade this Court that maintaining the parties’ action here in this Court would result in hardship and inequity to plaintiffs and waste judicial resources. These interests outweigh any potential prejudice to Ezra caused by a stay. Accordingly, for these reasons, the Court grants plaintiffs’ motion to stay and hereby stays this action pending further resolution of jurisdictional issues, if any, in the District of Delaware.

### **III. Conclusion**

For the foregoing reasons the Court grants plaintiffs' motion to stay (Dkt. No. 26), and hereby stays this action pending further resolution of jurisdictional issues, if any, in the District of Delaware. The Court directs the Clerk of the Court to administratively close this action pending further communication from the parties. If either party seeks to lift the stay and commence this litigation again at a later date, that party should file a motion to do so in this Court referencing this case number.

SO ORDERED this 10th day of July, 2015.



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KRISTINE G. BAKER  
UNITED STATES DISTRICT JUDGE