IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	Case No.: 08-cv-7231
v.	)	Judge Robert M. Dow, Jr.
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company LLC (collectively "Pfizer") have moved to stay proceedings in this case pending a Delaware District Court's decision addressing personal jurisdiction over Apotex Inc. in a related case [43]. The parties have fully briefed the motion to stay [45, 65, 80]. Having given full consideration to the arguments presented in the briefs, the Court grants the motion [43] and enters a stay of this litigation pending the resolution of the jurisdictional dispute in Delaware.

I. Background

On November 4, 2008, Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") notified Pfizer that they had filed an Abbreviated New Drug Application ("ANDA") with the FDA to market a generic version of Pfizer's cholesterol-lowering drug Lipitor®. Under the Hatch-Waxman Act of 1984, Pfizer was required to file suit against Apotex within 45 days of receiving that notice in order to obtain a statutorily mandated 30-month stay of FDA approval of

Apotex's ANDA. See 21 U.S.C. § 355(j)(5)(B)(iii). On December 17, 2008, Pfizer filed suit against Apotex in the Delaware District Court alleging that Apotex's ANDA infringed Pfizer's '995 patent. Pfizer correctly anticipated that one of the Apotex defendants – Apotex Inc. – would challenge personal jurisdiction in Delaware. Therefore, Pfizer filed an identical patent infringement suit in this Court just hours after filing the Delaware action. Pfizer asserts that it filed the action in this Court only to protect itself in the event that it loses the jurisdictional fight in Delaware after the 45 day filing period has expired. Pfizer now seeks to stay this action pending the outcome of the jurisdictional dispute in Delaware. If the Delaware court determines it has personal jurisdiction over the Defendants, Pfizer will move to transfer this case to Delaware.

II. Legal Standard

A. Motion To Stay

"[T]he power to stay proceedings 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 American Co.*, 299 U.S. 248, 254 (1936). In deciding whether to enter such a stay, courts consider the following factors: (i) whether a stay will unduly prejudice or tactically disadvantage the non-moving party, (ii) whether a stay will simplify the issues in question and streamline the trial, and (iii) whether a stay will reduce the burden of litigation on the parties and on the court. *Tap Pharmaceutical Prods., Inc. v. Atrix Laboratories, Inc.*, 2004 WL 422697, at *1 (N.D. Ill. Mar. 3, 2004). "[I]f there is even a fair possibility that the stay * * * will work damage to some one else," the party seeking the stay "must make out a clear case of hardship or inequity in being required to go forward." *Landis*, 299 U.S. at 255.

Courts in this district have recognized that when two related cases are pending in separate federal courts, either of those courts may exercise that inherent power to stay the proceedings before it in deference to the related action. See *GE Business Financial Services Inc. v. Spratt*, 2009 WL 1064608, at *1 (N.D. Ill. Apr. 20, 2009); *Whirlpool Fin. Corp. v. Metropolis Capital Group*, 1991 WL 212112, at *3 (N.D. Ill. Oct. 7, 1991). Indeed, this Court has a "duty * * * to avoid duplicative litigation in more than one federal court." *Whirlpool Fin. Corp.*, 1991 WL 212112, at *3 (citing *Colorado River Water Conservation District v. United States*, 424 U.S. 800, 817 (1976)). Therefore, the Seventh Circuit not surprisingly has advised that "[a] district court has 'an ample degree of discretion' in deferring to another federal proceeding involving the same parties and issues to avoid duplicative litigation." *Trippe Mfg. Co. v. American Power Conversion Corp.*, 46 F.3d 624, 629 (7th Cir. 1995).

B. The "First To File" Rule

When duplicative actions are filed in different federal courts, "the general rule favors the forum of the first-filed suit." *Schwarz v. Nat'l Van Lines, Inc.*, 317 F.Supp.2d 829, 832 (N.D. Ill. 2004). "[D]istrict courts normally stay or transfer a federal suit for reasons of wise judicial administration whenever it is duplicative of a parallel action already pending in another federal court." *GE Business Financial Services Inc.*, 2009 WL 1064608, at *2 n.1.

However, the presumption in favor of the first-filed suit is "not absolute." *MLR, LLC v. U.S. Robotics Corp.*, 2003 WL 685504, at *1 (N.D. Ill. Feb. 26, 2003); *Trippe Mfg. Co.*, 46 F.3d at 629 ("[t]his circuit does not rigidly adhere to a 'first-to-file' rule"); *Electronics for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1347 (Fed. Cir. 2005) (stating that exceptions to the first-filed rule are not rare). As the Seventh Circuit has explained, "[n]o mechanical rule governs the handling of overlapping cases," and therefore "the judge hearing the second-filed case may conclude that

it is a superior vehicle and may press forward." *Blair v. Equifax Check Services, Inc.*, 181 F.3d 832, 838 (7th Cir. 1999). Nevertheless, where deference to the first-filed action is consistent with "considerations of judicial and litigant economy, and the just and effective disposition of disputes," the first to file rule provides courts seeking to avoid duplicative litigation with some guidance. *MLR, LLC*, 2003 WL 685504, at *1 (quoting *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed.Cir.1993)); see also *Serlin v. Arthur Andersen & Co.*, 3 F.3d 221, 223 (7th Cir. 1993) (favoring first-filed action is appropriate where doing so constitutes "wise judicial administration").

III. Discussion

Turning first to the three factors that courts consider in deciding whether to enter a stay, the Court concludes that those factors weigh in favor of granting a stay in this case. First, the Court considers whether a stay will unduly prejudice the non-moving party. Apotex contends that it will be prejudiced by a stay because any delay in this litigation will delay FDA approval of its ANDA, which currently is stayed pending the resolution of this action (or 30 months, whichever is shorter). Apotex is correct in asserting that resolution of this case on the merits will be delayed by some months if this action is stayed and the Delaware court determines that it does not have jurisdiction over all parties in the related case. However, the Court cannot conclude that a delay of limited duration to resolve a jurisdictional motion filed by Apotex itself would cause Apotex *undue* prejudice.

Second, the Court is persuaded that a stay very well may simplify the litigation. Indeed, staying this action in favor of the Delaware action may eliminate entirely the need for any further proceedings whatsoever in this Court.

Third, and most significantly, it hardly can be disputed that a stay would preserve the resources of the parties, including Apotex, and reduce the burden of litigation on the court. There simply is no reason for identical actions – particularly complex pharmaceutical patent cases that doubtless will require a considerable amount of the Court's time and the parties' money – to proceed simultaneously in two federal courts.[1] Indeed, this Court has an obligation to avoid such wasteful duplicative litigation. Moreover, in addition to consuming the limited resources of the judiciary, allowing both actions to proceed simultaneously presents the risk of conflicting decisions.

In addition to the factors noted above, the "first to file" presumption also counsels in favor of a stay in this case. To be sure, the fact that the Delaware action was filed before this action is not dispositive. Yet, where it is consistent with principles of "wise judicial administration" and the "interests of justice," *Schwarz*, 317 F.Supp.2d at 833, the first-filed principle provides practical guidance for courts faced with the possibility of duplicative litigation. See *Asset Allocation and Management Co. v. Western Employers Ins. Co.*, 892 F.2d 566, 573 (7th Cir. 1989) (district courts should "not to countenance the simultaneous litigation of identical claims in two federal courts"). As discussed above and amplified below, the interests of justice do not favor proceeding in this case, and therefore the first to file rule weighs in favor of granting the motion to stay.[2]

[1] As Apotex correctly notes, Pfizer's argument that Delaware is a superior forum because the Delaware court has handled other cases involving the patent in suit is not persuasive in view of the transfer of the Delaware case to a judge who was not involved in the prior Lipitor® litigation. However, even if Delaware is not an inherently better forum, it nevertheless is the case that only one of the parallel actions should go forward at this time. There is no suggestion that a motion to stay has been filed in the Delaware proceeding, and therefore only this Court is in position to prevent duplicative litigation.

[2] The Seventh Circuit does not appear to accept Apotex's contention that the first to file presumption does not apply where, as here, a single plaintiff files two identical suits. See *Blair*, 181 F.3d at 838 ("Sometimes the same plaintiff will file in two courts * * * Judges sometimes stay proceedings in the

While Apotex raises a number of objections to Pfizer's motion to stay, none provides a sufficient basis for overcoming the factors analyzed above that favor the entry of a stay. Apotex's primary argument is that the purpose of the Hatch-Waxman Act – which Apotex contends is to expedite the approval of ANDA's and the availability of generic drugs – counsels against a stay. For its contention that a stay would violate Congress' intent, Apotex relies on 21 U.S.C. § 355(c)(3)(C), which provides that a court may shorten or lengthen the 30-month stay period if "either party to the action failed to reasonably cooperate in expediting the action."

As the Supreme Court explained in *Eli Lilly and Co. v. Medtronic, Inc*., 496 U.S. 661, 669 (1990), the Hatch-Waxman Act "was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval." One of those two distortions occurred at the close of the patent term as a result of the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984). As the Supreme Court noted, the *Roche* court held that the use of a patented invention during the patent term, even for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval, constituted infringement. *Eli Lilly and Co.*, 496 U.S. at 670. Therefore, generic drug companies that planned to compete with the patentee could not even begin to develop generic alternatives until after the expiration of the patent term. *Id.* The result was "an effective extension of the patent term." *Id.* To eliminate that extension, "and to enable new drugs to be marketed more cheaply and quickly," Congress

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more recently filed case to allow the first to proceed"); *Serlin*, 3 F.3d at 223 (where plaintiff filed identical actions before two federal judges in the same district, affirming dismissal of the second-filed action based on the "general rule * * * [that] a federal suit may be dismissed * * * 'whenever it is duplicative of a parallel action already pending in another federal court'") (citation omitted). In any event, the "rule" is not really a "rule," but simply one of several factors that courts weigh in considering whether to stay a case in the circumstances presented here.

"authorize[d] abbreviated new drug applications (ANDA's), which would substantially shorten the time and effort needed to obtain marketing approval." *Id.* at 676.

As Apotex notes, one goal of the Hatch-Waxman Act is to facilitate the approval of generic drug alternatives. See *Stacel v. Teva Pharmaceuticals, USA*, 2009 WL 703274, at *6 (N.D. Ill. March 16, 2009) ("it is clear that the Hatch-Waxman Amendment was devised to allow generic drug manufacturers to get their drugs to market both cheaply and quickly"). However, it is a substantial leap to conclude, as Apotex does, that *any* delay an ANDA case would be inconsistent with Congress' intent. Indeed, the only provision on which Apotex relies belies that conclusion. Section 355(c)(3)(C) not only allows a court to shorten the 30-month stay period if the brand name drug company fails to expedite the action, but also to lengthen it if the generic drug company engages in delay tactics. Therefore, the Act itself authorizes courts to *delay* the approval of generic drug alternatives under certain circumstances. The Court cannot conclude that the mere fact that this case arises under the Hatch-Waxman Act provides a sufficient basis for refusing to enter a stay, despite the factors weighing in favor of one.[3]

Apotex also complains that Pfizer's strategy in this case – filing two identical cases and then seeking to stay the one in the less favorable forum – constitutes improper forum shopping.

[3] As other courts have recognized, "[t]he case law on ANDA litigation is not settled, and there is no definitive guidance to those district court judges who are charged with handling 'protective' lawsuits such as the one at issue here." *Schering Co. v. Caraco Pharm. Laboratories, Ltd.*, 2007 WL 1648908, at *2 (E.D. Mich. June 6, 2007). The district courts that have considered whether a stay is appropriate under these circumstances are divided. See *PDL Biopharma, Inc. v. Sun Pharm. Indus., Ltd*., 2007 WL 2261386 (E.D. Mich. 2007) (staying second-filed protective suit in ANDA context based on the first-to-file rule, stating "[a]lthough the Court cannot condone the routine use of the filing of 'protective' lawsuits, given the unusual nature of ANDA claims and absent any guidance in the statute or case law regarding the handling of such 'protective' suits, the Court finds that Plaintiff has satisfied its burden for a stay [because a]llowing two identical suits to proceed in a parallel manner would clearly be contrary to the principles of comity and would waste scarce judicial resources"); *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 7, 2007) (staying second-filed ANDA case because "going forward with both actions simultaneously would waste judicial resources and present the possibility of conflicting rulings or judgments"); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 489 (E.D. Va. 2005) (refusing to stay second-filed protective suit in ADNA context, holding that the standard of review for stays is higher in ANDA cases).

According to Apotex, because Pfizer chose to file suit in this Court, any effort to avoid litigating in this forum evinces bad faith on behalf of Pfizer. Pfizer is not alone in adopting this litigation strategy. See *Abbott Laboratories v. Mylan Pharmaceuticals, Inc.*, 2006 WL 850916, at *8 (N.D. Ill. March 28, 2006) (noting "the apparently increasing number of 'protective' suits filed in ANDA-related patent infringement actions"). The filing of so-called protective suits appears to be motivated in large part by the ambiguity of the Hatch-Waxman Act, which imposes "a strict statutory 45-day window in which to file suit after the patent holder receives notice that a generic company has filed an ANDA" but "is silent * * * whether the patent holder loses its right to sue for patent infringement in the event its suit is dismissed for lack of personal jurisdiction after the 45-day period has expired." *Id.* 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.[4]

In view of its obligation to avoid duplicative litigation, the inevitable waste of judicial and party resources that will result if both this action and the identical Delaware action proceed, and its conclusion that a slight delay will not cause Apotex undue prejudice, the Court concludes that the entry of a stay is appropriate in this case.

[4] Courts in factually similar cases have likewise refused to find "bad faith or forum shopping on the part of Plaintiff" where "Plaintiff filed the duplicative actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act" and Plaintiff's belief "that Defendant would challenge personal jurisdiction in Plaintiff's preferred forum." *Adams Respiratory Therapeutics, Inc.*, 2007 WL 4284877, at *2 (quoting *PDL Biopharma, Inc.*, 2007 WL 2261386, at *2).

III. Conclusion

For all of these reasons, Pfizer's motion for stay of the litigation pending the Delaware District Court's decision addressing personal jurisdiction over Apotex Inc. in a related case [43] is granted.[5]

Dated: June 12, 2009

Robert M. Dow, Jr.
United States District Judge

[5] Apotex requests in the alternative that, if the Court grants Pfizer's motion to stay, the Court also terminate the 30-month stay of FDA approval of Apotex's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Congress has authorized courts to lengthen or shorten the 30-month stay period when a "party to the action fails to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(2)(B)(iii). But the Court finds that altering the 30-month stay in this case is not warranted at this time because there has not been a sufficient showing that Pfizer has unreasonably prolonged this litigation. See *Cima Labs, Inc. v. Actavis Group HF*, 2007 WL 1672229, at *10-*11 n.5 (D. N.J. June 7, 2007) (granting motion to stay and rejecting defendant's request that the court condition the stay on the shortening of the 30-month statutory stay, stating that defendant's "reliance on 21 U.S.C. § 355(j)(5)(B)(iii) is misplaced, and it fails to cite any case law to support its argument").