IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

APOTEX, INC. AND APOTEX CORP.,)
Plaintiffs,)
٧.)) Civ. No. 12-196-SLR
SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD., AND ALLERGAN, INC.,	/))
Defendants.	,)

Francis J. Murphy, Esquire of Murphy & Landon, Wilmington, Delaware. Counsel for Plaintiffs. Of Counsel: Alan B. Clement, Esquire, Keith D. Parr, Esquire, Michael J. Gaertner, Esquire, Scott B. Feder, Esquire, David B. Abramowitz, Esquire, and Patrick C. Gallagher, Esquire of Locke Lord LLP.

Richard D. Kirk, Esquire, and Stephen B. Brauerman, Esquire of Bayard, P.A., Wilmington, DE. Counsel for Defendant Senju Pharmaceutical Co., Ltd. Of Counsel: William F. Sondericker, Esquire, Keith D. Nowak, Esquire, and Gerald W. Griffin, Esquire of Carter, Ledyard & Milburn LLP; Derrik K. Takeuchi, Esquire of Greenberg, Whitcombe & Takeuchi, LLP.

David E. Ross, Esquire, and Benjamin J. Schladweiler, Esquire of Seitz Ross Aronstam & Moritz LLP, Wilmington, Delaware. Counsel for Defendant Kyorin Pharmaceutical Co., Ltd. Of Counsel: John M. Majoras, Esquire, Kevin D. McDonald, Esquire, and Rosanna K. McCalips, Esquire of Jones Day.

Jack B. Blumenfeld, Esquire, and Regina S.E. Murphy, Esquire of Morris, Nichols, Arsht & Tunnell LLP, Wilmington, Delaware. Counsel for Defendant Allergan, Inc. Of Counsel: M. Sean Royall, Esquire, Ashley E. Johnson, Esquire, and Jeffrey T. Thomas, Esquire of Gibson, Dunn & Crutcher.

MEMORANDUM OPINION

Dated: February **1** , 2013 Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

This antitrust litigation arises following a series of patent lawsuits between Apotex, Inc. and Apotex Corp. (collectively, "Apotex") and Senju Pharmaceutical Co., Ltd. ("Senju Pharma"), Kyorin Pharmaceutical Co., Ltd. ("Kyorin"), and Allergan, Inc. ("Allergan") (collectively, "Senju") regarding aqueous liquid pharmaceutical compositions for treating bacterial conjunctivitis. Allergan is the holder of two approved New Drug Applications ("NDAs") that cover a 0.3% ophthalmic solution of gatifloxacin, sold under the trade name Zymar®, and a 0.5% ophthalmic solution of gatifloxacin, sold under the trade name Zymaxid®. (D.I. 1 at ¶¶ 21-22, 39, 45)¹ Senju Pharma, Kyorin, and Allergan are the owners or licensees of U.S. Patent Nos. 6,333,045 ("the '045 patent") and 5,880,283 ("the '283 patent"), which are listed in the United States Food and Drug Administration's ("FDA's") publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") for Zymar® and Zymaxid®.² (Id. at ¶¶ 29, 46) After Apotex filed Abbreviated New Drug Applications ("ANDAs") for generic 0.3% and 0.5% ophthalmic solutions of gatifloxacin, Senju initiated several patent actions against Apotex in this court asserting infringement of the '045 patent and/or the '283 patent - Civ. Nos. 07-779, 11-1171, and 12-159 (collectively, "the related proceedings"). As will be discussed in more detail *infra*, the related proceedings are currently at various stages of litigation.

¹Unless otherwise noted, a citation to a docket item refers to a docket item in the instant case.

²The Orange Book must list "each drug which has been approved for safety and effectiveness through an NDA." *See* 21 U.S.C. § 355(j)(A)(ii).

On February 16, 2012, Apotex filed the instant action against Senju alleging antitrust violations under the Sherman Act. (D.I. 1) Apotex asserts that Senju used the related proceedings and other alleged anticompetitive conduct to unlawfully delay and frustrate Apotex's entry into the market for gatifloxacin ophthalmic solutions, thereby denying consumers access to its low-cost generic gatifloxacin ophthalmic product. (*Id.* at ¶¶ 59, 72, 74-75, 79-80, 95-96, 112-13, 129-30) Presently before the court are various motions: Senju's motion to stay the case pending resolution of the related proceedings (D.I. 17); Senju Pharma and Kyorin's motion to dismiss for failure to state a claim³ (D.I. 11); and Allergan's motion to dismiss based upon failure to allege antitrust injury.⁴ (D.I. 14) The court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1337(a), and 15 U.S.C. § 15.

II. BACKGROUND

A. The Parties

Apotex, Inc. is a corporation organized under the laws of Canada, with a place of business in Ontario, Canada. (D.I. 1 at \P 1) Apotex Corp. is a Delaware corporation with a place of business in Florida. (*Id.* at \P 2) Senju Pharma and Kyorin are corporations organized under the laws of Japan with principal places of business in Japan. (*Id.* at \P 3-4) Allergan is a Delaware corporation with a principal place of

³Allergan has joined Senju Pharma and Kyorin's motion to dismiss in part. (D.I. 15 at 1 n.1)

⁴Senju Pharma and Kyorin have joined in Allergan's motion to dismiss. (D.I. 12 at 3 n.2)

business in California. (*Id.* at $\P\P$ 5, 7) Because the instant action arises from a history of litigation between the parties in this court, a brief summary will help frame the issues.

B. The Development of 0.3% Gatifloxacin Ophthalmic Solution

Apotex characterizes gatifloxacin as a quinolone antibiotic that was first patented in 1990 by Kyorin researchers in U.S. Patent No. 4,980,470 ("the '470 patent"). (*Id.* at ¶ 10) The '470 patent, which expired in 2010, claims the gatifloxacin molecule and teaches that gatifloxacin can be formulated in various dosage forms, including as eye drops. In 1997, Kyorin entered into a license agreement with Senju Pharma that, inter alia, required any patent filed by Senju Pharma in gatifloxacin ophthalmic formulations to be jointly assigned to Kyorin and Senju Pharma. (*Id.* at ¶ 13) In 2001, Senju Pharma obtained the '045 patent claiming aqueous liquid ophthalmic formulations comprising gatifloxacin and disodium edetate and methods for preparing these formulations; the patent was assigned to Kyorin and Senju Pharma. (*Id.* at ¶¶ 15-16, 18)

Senju Pharma and Kyorin licensed to Allergan the right to practice the '045 patent and to market aqueous liquid gatifloxacin ophthalmic products in the United States. (*Id.* at \P 20) In 2002, Allergan filed NDA No. 21-493 for a 0.3% gatifloxacin ophthalmic solution (*Zymar*®), and the FDA approved it in 2003.⁵ (*Id.* at $\P\P$ 21-22) Domestic sales for Zymar® allegedly reached approximately \$100 million by 2009. (*Id.* at \P 24)

C. The 07-779 Action

⁵The '470, '283 and '045 patents are listed in the Orange Book in connection with Zymar®. (D.I. 1 at \P 29)

On July 18, 2007, Apotex filed ANDA No. 79-084 seeking FDA approval for a generic 0.3% gatifloxacin ophthalmic solution ("generic 0.3% product").⁶ (*Id.* at ¶ 30) Pursuant to 21 U.S.C. § 355(j)(2)(B), Apotex notified Senju that it had submitted the ANDA with a Paragraph IV certification alleging that the '283 and '045 patents are invalid and/or will not be infringed by the generic 0.3% product.⁷ (*Id.* at ¶ 32) In response, Senju initiated Civ. No. 07-779 ("the 07-779 action") against Apotex in this court, alleging infringement of the '283 and '045 patents. (*Id.* at ¶ 33)

Senju eventually dismissed its claims related to the '283 patent and, following a bench trial, the court found claims 1-3 and 6-9 of the '045 patent invalid as obvious. *Senju Pharm. Co. v. Apotex Co.*, 717 F. Supp. 2d 404, 433 (D. Del. 2010). After reopening the judgment on claim 7 and reviewing additional evidence, the court issued a final judgment confirming the invalidity of claim 7. *Senju Pharm. Co. v. Apotex Co.*, 836 F. Supp. 2d 196, 201-11 (D. Del. 2011). On October 5, 2012, the Federal Circuit affirmed the court's decision. *Senju Pharm. Co. v. Apotex, Inc.*, 485 F. App'x 433 (Fed. Cir. 2012).

D. Reexamination of the '045 Patent

On February 25, 2011, before final judgment was entered by this court in the 07-779 action, Senju Pharma and Kyorin filed an ex parte request for reexamination of claims 1-3, 6, 8, and 9 of the '045 patent with the U.S. Patent and Trademark Office ("PTO"). (D.I. 1 at ¶ 56) As part of the request, portions of the record from the 07-779

⁶Apotex also filed a Paragraph III certification, certifying that it would not market its generic 0.3% product until the '470 patent expired. (D.I. 1 at \P 31) Apotex received tentative approval of ANDA No. 79-084 on June 12, 2009. (*Id.* at \P 38)

⁷See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

action that were favorable to the patent owners' position were provided, but other information unfavorable to patentability was allegedly withheld or misrepresented. (*Id.* at ¶¶ 57-63) A reexamination certificate was issued for the '045 patent on October 25, 2011, cancelling claims 1-3 and 8-11, amending claim 6, and adding new claims 12-16. (*Id.* at ¶ 69)

E. The 11-1171 Action

On November 28, 2011, Senju filed a second lawsuit, Civ. No. 11-1171 ("the 11-1171 action"), against Apotex alleging that the same generic 0.3% product accused of infringement in the 07-779 action infringes the reexamined '045 patent. (*Id.* at ¶ 77) The 11-1171 action was dismissed by this court on grounds of claim preclusion, or res judicata. *Senju Pharm. Co. v. Apotex Inc.*, Civ. No. 11-1171, 2012 WL 4062325, at *6 (D. Del. Sept. 17, 2012). The dismissal is currently on appeal at the Federal Circuit. (Civ. No. 11-1171, D.I. 24)

F. The 12-159 Action

During the pendency of the 07-779 action, Allergan filed NDA No. 22-548 and received FDA approval for a 0.5% gatifloxacin ophthalmic solution (Zymaxid®).⁸ (D.I. 1 at ¶¶ 39, 45) According to Apotex, Zymaxid® is substantially similar to Zymar® – except that the concentration of gatifloxacin is 0.5% instead of 0.3% – and "does not possess any clinical or therapeutic benefit or superiority in comparison to Zymar®." (*Id.* at ¶¶ 40, 47-49)

⁸The '283 and '045 patents are listed in the Orange Book in connection with Zymaxid®. (D.I. 1 at \P 46)

Apotex subsequently filed ANDA No. 203-523 for a generic 0.5% ophthalmic solution of gatifloxacin ("generic 0.5% product").⁹ (Civ. No. 12-159, D.I. 1 at ¶ 33) Pursuant to 21 U.S.C. § 355(j)(2)(B), Apotex notified Senju in a letter dated January 13, 2012 that it had submitted the ANDA with a Paragraph IV certification. (Civ. No. 12-159, D.I. 1 at ¶ 34) In response, on February 10, 2012, Senju filed Civ. No. 12-159 ("the 12-159 action") against Apotex, alleging that the generic 0.5% product infringes the '045 and '283 patents. (Civ. No. 12-159, D.I. 1) The court recently granted in part and denied in part a motion to dismiss and to strike Apotex's invalidity and inequitable conduct defenses in that case. (Civ. No. 12-159, D.I. 44)

G. The Instant Litigation

In the instant litigation, Apotex claims that Senju unlawfully delayed Apotex's entry into the market for gatifloxacin ophthalmic solutions, fraudulently obtained reexamination of the '045 patent, and filed the NDA for Zymaxid® in order "to exclude further competition" and to execute a "product switching strategy to deny patients access to Apotex's low cost generic [0.3% product]." (D.I. 1 at ¶¶ 41-42, 75, 79-80) In this regard, the complaint focuses on four categories of alleged anticompetitive conduct by Senju: (1) "sham" litigation regarding the filing of the 07-779 action and post-trial

⁹Although the 12-159 action is not mentioned in the complaint, it is pending before this court, and Apotex and Senju both addressed it in their briefing on the motion to stay.

conduct in that case;¹⁰ (2) sham litigation regarding the filing of the 11-1171 action;¹¹ (3) fraud on the PTO to obtain reexamination of the '045 patent; and (4) an anticompetitive product-switching scheme. (*Id.* at ¶¶ 33-80) Under the alleged product-switching scheme, Allergan stopped marketing Zymar® and began marketing Zymaxid®, encouraging physicians to switch their prescriptions for gatifloxacin ophthalmic solution from Zymar® to Zymaxid®. (*Id.* at ¶¶ 46, 73-75) Apotex alleges that, "[d]uring the delay resulting from Allergan's anticompetitive conduct, Allergan's efforts were successful in effectively removing Zymar® from the market. The intended and actual effect of this conduct was to deny consumer access to a low-cost generic gatifloxacin ophthalmic solution product." (*Id.* at ¶ 75)

Apotex brings three claims for relief: (1) monopolization in violation of section 2 of the Sherman Act; (2) conspiracy to monopolize in violation of section 2 of the Sherman Act; and (3) unreasonable restraint of trade in violation of section 1 of the Sherman Act. In each of those claims, Apotex alleges that, "[a]s a result of [Senju's] anticompetitive conduct, consumers have been deprived of a low-cost generic gatifloxacin ophthalmic solution product. . . . Apotex has been further damaged and will not be able to enjoy the benefits . . . that it would otherwise have enjoyed but for [Senju's] unlawful conduct." (*Id.* at ¶¶ 95-96, 112-13, 129-30)

III. STANDARD OF REVIEW

¹⁰Specifically, Apotex alleges Senju brought the 07-779 action with knowledge that the asserted claims were invalid or not infringed and later filed a baseless motion for new trial in an effort to buy time to switch Zymar® sales to Zymaxid®. (D.I. 1 at ¶¶ 33-37, 50-55)

¹¹Specifically, Apotex alleges that Senju initiated the 11-1171 action despite knowledge that it was barred.

Motions to stay invoke the broad discretionary powers of the court. See Dentsply

Int'l, Inc. v. Kerr Mfg. Co., 734 F. Supp. 656, 658 (D. Del. 1990) (citing Bechtel Corp. v.

Laborers' Int'l Union, 544 F.2d 1207, 1215 (3d Cir. 1976)); see also Monsanto Co. v.

Syngenta Seeds, Inc., Civ. No. 04-305, 2006 U.S. Dist. LEXIS 84963, at *3 (D. Del.

Nov. 8, 2006) (citing In re Innotron Diagnostics, 800 F.2d 1077, 1085 (Fed. Cir. 1986)).

Three general factors inform the court in this regard:

(1) whether the granting of a stay would cause the non-moving party to suffer undue prejudice from any delay or allow the moving party to gain a clear tactical advantage over the non-moving party; (2) whether a stay will simplify the issues for trial; and (3) whether discovery is complete and a trial date set.

Enhanced Security Research, LLC v. Cisco Sys., Inc., Civ. No. 09-571, 2010 WL

2573925, at *3 (D. Del. June 25, 2010) (citing St. Clair Intellectual Prop. Consultants v.

Sony Corp., Civ. No. 01-557, 2003 WL 25283239, at *1 (D. Del. Jan. 30, 2003)).

IV. DISCUSSION

Senju urges the court to stay the antitrust litigation pending the outcome of all of

the related proceedings "in order to avoid duplication of work, conserve judicial

resources, and save costs and expenses of the parties."¹² (D.I. 18 at 1) Apotex

counters by arguing that such an indefinite stay would be prejudicial to its position,

would not lead to judicial efficiency, and would permit Senju to further exploit its

anticompetitive advantage. (D.I. 24 at 1)

¹²In the alternative, Senju urges the court to stay the case pending only the outcome of the appeal in the 07-779 action. (D.I. 28 at 1) The Federal Circuit affirmed this court's decision in the 07-779 action on October 5, 2012, shortly after briefing on the motion to stay was completed. Therefore, Senju's request to stay pending the resolution of the 07-779 action is moot.

The court has stayed antitrust litigation where there was a possibility that the resolution of underlying patent claims could moot, narrow, or otherwise simplify the antitrust claims. See, e.g., Masimo Corp. v. Philips Elecs. N. Am. Corp., Civ. No. 09-80, 2010 WL 925864, at *3 (D. Del. Mar. 11, 2010) (staying discovery of antitrust counterclaims pending trial on patent issues); Eurand Inc. v. Mylan Pharm. Inc., Civ. No. 08-889, 2009 WL 3172197, at *2 (D. Del. Oct. 1, 2009) (staying discovery on antitrust counterclaims because those claims "may be rendered moot by resolution of the patent infringement issues"); Monsanto, 2006 U.S. Dist. LEXIS 84963, at *3-4 (staying an antitrust case pending resolution of the underlying patent claims on appeal because there was "at least a minimal overlap between the patent case and the antitrust case; therefore, the outcome of the patent appeal necessarily w[ould] affect the complexion of the antitrust case to some extent"); accord Mitsubishi Heavy Indus. Ltd. v. Gen. Elec. Co., 720 F. Supp. 2d 1061, 1069 (W.D. Ark. 2010) ("Because the decisions in [pending] actions could render this [antitrust] case moot or narrow the issues considerably, this Court's discretion is best exercised in granting a stay.").

A stay on antitrust claims may potentially simplify the issues in various ways. For example, if a patent holder ultimately prevails on any of its infringement claims, it would have a legal entitlement to exclude a competitor from the marketplace. *See Dentsply Int'l, Inc. v. New Tech. Co.,* Civ. No. 96-272, 1996 WL 756766, at *3 (D. Del. Dec. 19, 1996) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." (alteration in original) (internal quotation marks omitted)). The "resulting capacity to provide [a party] with a defense to . . . antitrust []claims turns, at least in part, on the scope of [the

underlying patents]," which can be determined by resolving related patent litigation. Masimo, 2010 WL 925864, at *4. In addition, the outcome of an underlying lawsuit can shed light on allegations of sham litigation - that litigation was "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961). Proving sham litigation requires an antitrust claimant to first show that a lawsuit is "objectively baseless" and then show that the litigant's "subjective motivation" was to try to use the litigation process as an "anticompetitive weapon" to interfere with a competitor's business. Professional Real Estate Investors v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61 (1993) (quoting City of Columbia v. Omni Outdoor Adver., Inc., 499 U.S. 365, 380 (1991)) (internal quotation marks omitted). "A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." Id. at 60 n.5. On the other hand, a losing lawsuit does not necessarily mean that the litigation was a sham because "a party may have an entirely reasonable ground for bringing suit." Id. (internal quotation marks omitted). As the 07-779 action has been resolved on appeal, the court turns to whether the instant litigation should be stayed pending resolution of the 11-1171 action and/or the 12-159 action. For the reasons below, the court will grant the motion to stay pending resolution of the appeal in the 11-1171 action.

A. Resolution of the Appeal in the 11-1171 Action

With respect to the 11-1171 action, an affirmance of the court's dismissal on res judicata grounds would prevent Senju from prevailing on any of its infringement claims against Apotex regarding the generic 0.3% product. In other words, such an outcome would shed light on the scope of the reexamined '045 patent and Senju's right to exclude Apotex from the market at any specific time.¹³ An affirmance may further clarify Apotex's burden of demonstrating that the 11-1171 action was a sham litigation by suggesting whether a plaintiff could have realistically expected success on the merits. On the other hand, a reversal by the Federal Circuit could also shed light on the antitrust allegations because a determination that the action was not legally barred by res judicata would render moot any assertion that Senju brought the action knowing it was barred.

The court is concerned that staying Apotex's antitrust claims will "likely devolve into a series of time-consuming and expensive discovery disputes as to whether particular discovery is directed at the patent or antitrust claims." *Masimo*, 2010 WL 925864, at *3 (quoting *Dentsply*, 1996 WL 756766, at *6). Nevertheless, "the court is cognizant of the need to prevent the parties from conducting discovery that will ultimately prove unnecessary." *Id.* Because resolution of the appeal in the 11-1171 action could eliminate or narrow some of the antitrust claims and prevent unnecessary expenditure of time and resources, the court finds that simplifying issues for trial favors a stay pending the appeal in the 11-1171 action. *See id.* at *4-5.

In addition, the procedural posture of the instant litigation also favors a stay; there has not yet been any discovery, scheduling conference, or filing of an answer.

¹³Senju has already lost on its claims in the 07-779 action that the generic 0.3% product infringes the original '045 patent. The reexamined '045 patent, which issued on October 25, 2011, is at issue in the 11-1171 action. Although the reexamined patent's potential to exclude Apotex from the market is narrower than a valid '045 patent would have been, the outcome of the appeal may nonetheless clarify any remaining questions regarding Senju's right to exclude Apotex's generic 0.3% product from the market.

See Cephalon, Inc. v. Sandoz Inc., Civ. No. 10-123, 2011 WL 1750446, at *2 (noting that a stay is disfavored where "discovery is complete and a trial date set"). Furthermore, the court is not persuaded by Apotex's argument that it would be unduly prejudiced by any delay because of fading recollections or vanishing witnesses.¹⁴ Apotex has not proffered any plausible reason why such concerns would be especially relevant in the instant case.¹⁵ Accordingly, the court grants the motion to stay pending resolution of the appeal in the 11-1171 action.¹⁶

B. Resolution of the 12-159 Action

Senju goes further, urging the court to stay the case pending the resolution of the 12-159 as well. The 12-159 action, however, does not have the same potential that the 07-779 action had, or that the appeal in the 11-1171 action has, to eliminate or narrow antitrust allegations. The infringement claims in the 12-159 action involve the generic 0.5% product, whereas Apotex's antitrust allegations focus on anticompetitive conduct directed at preventing entry of the generic 0.3% product. The potential for the 12-159

¹⁴Apotex cites to *Texaco, Inc. v. Borda*, 383 F.2d 607, 609-10 (3d Cir. 1967), in which the Third Circuit found that a district court abused its discretion in staying a private antitrust action pending resolution of a related criminal antitrust action. However, the facts of *Texaco* are distinguishable. The Court in that case found that a stay was inappropriate insofar as it prevented a 71-year-old individual from being deposed regarding an alleged conspiracy that took place 11 years prior; in all other respects, the Court found that the stay was not an abuse of discretion. *Id.*

¹⁵In addition, the court declines to draw an inference that the motion to stay seeks an inappropriate tactical advantage for Senju. It was filed soon after commencement of the litigation (before filing an answer), and Senju has a legitimate concern to minimize the potential burdens and expenses of complex antitrust litigation.

¹⁶The court declines, at this time, to grant the stay pending the ultimate resolution of the 11-1171 action on the merits should the Federal Circuit allow the case to proceed.

action to simplify the antitrust litigation is instead likely limited to any overlap of the inequitable conduct defense in the 12-159 action with the antitrust allegations based on reexamination fraud. Apotex's inequitable conduct counterclaims and affirmative defenses in the 12-159 action, however, have been dismissed without prejudice. (Civ. No. 12-159, D.I. 44) Moreover, given the infancy of the 12-159 action, the delay that would result from a stay pending the resolution of that action is indefinite, at least relative to a pending appeal. Therefore, while the court, in its discretion, finds that a stay pending the outcome of appeal in the 11-1171 action is warranted, a stay pending the resolution of all of the related proceedings is not warranted at this time.

V. CONCLUSION

For the foregoing reasons, the court grants Senju's motion to stay pending the appeal in the 11-1171 action. The pending motions to dismiss (D.I. 11; D.I. 14) are denied without prejudice to renew. An appropriate order shall issue.