IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD., AND ALLERGAN, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 11-1171-SLR
APOTEX INC. AND APOTEX CORP.,	)	
Defendants.	)	

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MEMORANDUM OPINION

Dated: September 17, 2012
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

Senju Pharmaceutical Co., Ltd. ("Senju") and Kyorin Pharmaceutical Co., Ltd. ("Kyorin") are co-owners of United States Patent No. 6,333,045 ("the '045 patent"), which is directed to aqueous liquid pharmaceutical compositions comprising gatifloxacin and disodium edetate, as well as various methods utilizing these compositions. Allergan, Inc. ("Allergan") is the exclusive licensee of the '045 patent for ophthalmic uses and the holder of two New Drug Applications ("NDAs") that cover gatifloxacin ophthalmic solutions. (D.I. 1 at ¶¶ 16, 26)

The current case is related to prior litigation ("the first litigation") over the '045 patent in this court between Senju, Kyorin, and Allergan (collectively, "plaintiffs") and Apotex Inc. and Apotex Corp. (collectively, "the Apotex entities" or "defendants") that was based on defendants' Abbreviated New Drug Application ("ANDA") for an allegedly infringing product. (D.I. 1 at ¶ 30) The court entered final judgment in that case against plaintiffs on December 20, 2011. *See Senju Pharma. Co. v. Apotex Co.*, 836 F. Supp. 2d 196 (D. Del. 2011).

Plaintiffs, meanwhile, were engaged in reexamination proceedings for the '045 patent with the United States Patent and Trademark Office ("PTO") without the court's knowledge. (D.I. 13 at 1) Following reexam, plaintiffs filed the instant action against the same defendants on November 28, 2011. (D.I. 1) Plaintiffs seek a declaratory judgment of infringement based on the same ANDA filing at issue in the first litigation. (*Id.* at ¶¶ 18, 36-37, 45-46) However, plaintiffs are now alleging infringement of the claims that were added or amended during the reexamination of the '045 patent, namely

claims 6 and 12-16. (*Id.* at ¶¶ 36, 39, 46-47)

The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a). Presently before the court is defendants' motion to dismiss for failure to state a claim upon which relief can be granted, filed on January 9, 2012. (D.I. 8) For the reasons that follow, the court grants defendants' motion to dismiss.

II. BACKGROUND

A. The Parties

Senju and Kyorin are corporations organized under the laws of Japan and having principal places of business in Japan. (D.I. 1 ¶¶ 2-3) Allergan is a Delaware corporation with its principal place of business in California. (*Id.* at ¶ 4)

Apotex Corp. is a Delaware corporation, having its principal place of business in Florida. (*Id.* at ¶ 5) Apotex Inc. is a corporation formed under the laws of Canada, having its principal place of business in Ontario, Canada. (*Id.* at ¶ 7)

B. The First Litigation

Apotex Inc. is allegedly formulating or planning to formulate gatifloxacin ophthalmic solution to be marketed and sold in the United States by Apotex Corp. (*Id.* at ¶ 9) In connection with this product, the Apotex entities filed ANDA No. 79-084 on July 19, 2007. (*Id.* at ¶ 28) The Apotex entities notified plaintiffs of their ANDA filing on October 17, 2007. (*Id.* at ¶ 29) Pursuant to the Hatch-Waxman Act, plaintiffs then commenced the first litigation, asserting that the product in the ANDA filing would infringe claims 1-3, 6, 7, and 9 of the '045 patent. (*Id.* at ¶¶ 29-30)

Following a bench trial, the court entered judgment on June 21, 2010 that claims

1-3 and 6-9 of the '045 patent were invalid as obvious. *Senju Pharma.*, 717 F. Supp. 2d 404, 433 (D. Del. 2010). Plaintiffs filed a post-trial motion for a new trial, which was denied without prejudice, but the court reopened the judgment on claim 7 of the '045 patent to allow for further submission of evidence. *Senju Pharma.*, 2010 WL 4538265 (D. Del. Nov. 3, 2010). On December 20, 2011, after reviewing the additional evidence, the court issued a final judgment confirming the invalidity of claim 7, thereby closing the case. *See Senju Pharma.*, 836 F. Supp. 2d at 210-11.[1]

C. Reexamination of the '045 Patent

On February 25, 2011, before final judgment was entered in the first litigation, Senju and Kyorin filed a request for reexamination of claims 1-3, 6, 8, and 9 of the '045 patent with the PTO. (D.I. 1 at ¶ 23) The request was granted on April 28, 2011. (*Id.*) Plaintiffs did not inform defendants about the reexamination proceedings at the time and waited until they received a notice of intent to issue a reexamination certificate from the PTO before informing the court about the reexamination. (D.I. 9 at 4; D.I. 13 at 1) During the reexamination prosecution, plaintiffs submitted the prior art, the arguments relied upon by the court and defendants in the first litigation, and the court's opinion in that case. (*Id.* at ¶ 24) On October 25, 2011, the PTO issued a reexamination certificate for the '045 patent, which canceled claims 1-3 and 8-11, allowed amended claim 6, and added claims 12-16. (*Id.* at ¶ 25)

Claim 1 of the '045 patent, as originally issued, claimed an aqueous liquid

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[1] Plaintiffs have filed for appeal in the United States Court of Appeals for the Federal Circuit. *See* Notice of Appeal, Civ. No. 07-779, D.I. 154.

pharmaceutical composition which comprises gatifloxacin or its salt and disodium edetate ("EDTA"). Claim 2 limited claim 1 to a composition with a pH within the range of 5 to 8, and claims 3 and 9 taught the eye drop form of the compositions taught by claims 1 and 2, respectively. New reexamined claim 12 incorporates claims 1, 2, 3, and 9 and adds further limitations, teaching "[a]n aqueous liquid pharmaceutical eye drop composition which comprises from about 0.3 to about 0.8 w/v% gatifloxacin or its salt, about 0.01 w/n% disodium edetate, and wherein the aqueous liquid pharmaceutical composition has a pH of from about 5 to about 6."

New reexamined claims 13 and 14 are dependent on claim 12 and further specify particular concentrations of gatifloxacin or its salt.[2] Claim 15 teaches an aqueous liquid pharmaceutical eye drop composition according to claim 12, "comprising at least one isotonic agent selected from the group consisting of sodium chloride, potassium chloride, glycerin, mannitol and glucose." Claim 16 teaches an aqueous liquid pharmaceutical eye drop composition according to claim 14, "wherein the at least one isotonic agent is sodium chloride."

Finally, claim 6 was amended to include limitations that were not in any of the original claims. These limitations relate to the amount of gatifloxacin or its salt, a new range of pH, and the amount of EDTA. (D.I. 13 at App'x A1)

III. STANDARD OF REVIEW

In reviewing a motion to dismiss filed under Federal Rule of Civil Procedure

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[2] Claim 13 teaches: "The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising about 0.3 w/v% gatifloxacin or its salt." Claim 14 teaches: "The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising about 0.5 w/v% gatifloxacin or its salt.

12(b)(6), the court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). A court may consider the pleadings, public record, orders, exhibits attached to the complaint, and documents incorporated into the complaint by reference. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384-85 n.2 (3d Cir. 1994). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007) (interpreting Fed.R.Civ.P. 8(a)) (internal quotations omitted). A complaint does not need detailed factual allegations; however, "a plaintiff's obligation to provide the 'grounds' of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 545 (alteration in original) (citation omitted). The "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Id.* Furthermore, "[w]hen there are well-ple[d] factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1950 (2009). Such a determination is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Id.*

IV. DISCUSSION

Defendants seek dismissal of the current infringement action based on the doctrine of res judicata, or claim preclusion. (D.I. 8) Their motion to dismiss argues that dismissal is proper because the claims of the current lawsuit are precluded by the judgment in plaintiffs' first litigation against them. (D.I. 9 at 5-8)

A. Applicable Law

The issue of claim preclusion in the context of patent infringement cases requires the application of both regional circuit and Federal Circuit law. "Because the general principles of res judicata are not unique to patent law," the court looks "to regional circuit law for guidance applying those principles." *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1341 n.1 (Fed. Cir. 2012) (citing *Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1323 (Fed. Cir. 2008)). However, the more particular question of whether asserting reexamined patent claims in a second suit constitutes the same legal claim or cause of action is unique to patent cases, so Federal Circuit law applies to that issue. *See Acumed*, 525 F.3d at 1323 (citing *Hallco Mfg. Co. v. Foster*, 256 F.3d 1290, 1294 (Fed. Cir. 2001)).

As a threshold matter, plaintiffs challenge the applicability of claim preclusion in this case and proffer an issue preclusion analysis. (D.I. 13 at 5) The court, however, agrees with defendants that claim preclusion applies. The Supreme Court has distinguished the two doctrines:

> Issue preclusion refers to the effect of a judgment in foreclosing relitigation of a matter that has been litigated and decided. . . . Claim preclusion refers to the effect of a judgment in foreclosing litigation of a matter that never has been litigated, because of a determination that it should have been advanced in an earlier suit.

Migra v. Warren City School District Board of Education, 465 U.S. 75, 77 n.1 (1984) (citation omitted).

Plaintiffs argue that claim preclusion does not apply because the patent claims they are now asserting against defendants are different than the patent claims in the first litigation. (D.I. 13 at 6-10) However, this fact is inapposite to the application of a claim preclusion analysis. Claim preclusion bars any new legal claim based on the same cause of action previously asserted. *See Churchill v. Star Enters.*, 183 F.3d 184, 194-95 (3d Cir. 1999). Each **patent**, not patent claim, gives rise to an independent and distinct legal claim or cause of action. *See Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555-56 (Fed. Cir. 1996); *Abbey v. Mercedes Benz of N. Am., Inc.*, 138 Fed. App'x 304, 306-07 (Fed. Cir. 2005).

B. Claim Preclusion

Under Third Circuit law, claim preclusion requires: "(1) a final judgment on the merits in a prior suit involving; (2) the same parties or their privities; and (3) a subsequent suit based on the same cause of action." *CoreStates Bank, N.A. v. Huls America, Inc.*, 176 F.3d 187, 194 (3d Cir. 1999). Here, there is no question that the prior litigation ended in a final judgment on the merits and that the current suit involves the exact same parties. The question in this case resolves around the third requirement for the same cause of action.

Whether two infringement suits are the same cause of action is an issue particular to patent law, so Federal Circuit law applies. *See Acumed*, 525 F.3d at 1323 (citing *Hallco Mfg.*, 256 F.3d at 1294). In determining whether two patent suits are

actually the same cause of action, the Federal Circuit has looked primarily at (1) whether the accused products are "essentially the same" and (2) whether the patent claims being asserted are the same or substantially the same. *See Aspex Eyewear*, 672 F.3d at 1342.

As noted above, for claim preclusion to apply, the accused products in the two suits must be essentially the same. *See Nystrom v. Trex Co.*, 580 F.3d 1281, 1285 (Fed. Cir. 2009); *Acumed*, 525 F.3d at 1324; *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 480 (Fed. Cir. 1991). Plaintiffs at bar are alleging infringement by the same proposed product that was at issue in the first litigation–a gatifloxacin ophthalmic solution that is the subject of ANDA No. 79-084. (D.I. 1 at ¶¶ 28, 36) Plaintiffs contend that the accused product may have changed because defendants have offered no evidence as to whether they have amended or supplemented the related ANDA. (D.I. 13 at 13-14) However, plaintiffs offer no basis for their speculation, and the public record indicates that the product that has been approved by the FDA is the same or, at minimum, essentially the same as the product accused in the first litigation.[3] Therefore, the only remaining question for claim preclusion is whether plaintiffs' assertion of the new and amended claims of the reexamined '045 patent is enough to constitute a new cause of action.

Plaintiffs argue in this regard that they could not have asserted new reexamined claims 12-16 and amended claim 6 of the '045 patent in the first litigation because the claims were not in existence at the time. (*Id.*) While literally true, plaintiffs' argument is

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[3] *See FDA Approved Drug Products*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails (last visited Sept. 13, 2012) (search ANDA No. 79-084).

flawed because they could have asserted the equivalent of the new and amended claims in the first litigation. In other words, plaintiffs were free to construe the patent more narrowly than they did.

For support, plaintiffs cite cases in their brief where courts have allowed a party to bring a second suit based on a patent obtained through reissue. (D.I. 13 at 11-12) (citing *Tech. Licensing Corp. v. Thomson*, 738 F. Supp. 2d 1096, 1101 (E.D. Cal. Aug. 27, 2010); *Antonius v. Wilson Sporting Goods Co.*, 1990 U.S. Dist. LEXIS 15428 (N.D. Ill. Nov. 13, 1990)). In doing so, plaintiffs try to equate reexamination with reissue, arguing that a reexamined patent, like a reissued patent, is a new patent because it results in new claims and a new patent number. (*Id.* at 8) The cases that plaintiffs rely on, however, are inapplicable because of the difference between reissue and reexamination.

The recent *Aspex Eyewear* case explains the difference and provides particularly relevant guidance regarding the effect of reexamination on a claim preclusion analysis. The plaintiff-appellant in *Aspex Eyewear* had previously brought infringement suits against the defendants over a patent teaching magnetic clip-on eyewear. It then obtained reexamination of its patent at the PTO, which resulted in several canceled claims, the addition of one claim, and the amendment of another. After reexam, the plaintiff-appellant filed a new suit against the defendants, asserting infringement of the new claims and making substantially the same arguments as plaintiffs at bar. *Aspex Eyewear*, 672 F.3d at 1338-39.

The Federal Circuit found that, "[u]nlike reissue, reexamination does not result in

the surrender of the original patent and the issuance of a new patent."[4] *Id.* at 1341-42. Therefore, any reliance on cases involving reissue patents is problematic. In addition, the Federal Circuit found that the amended claim "tracked [the] original claim . . . in all respects except for the addition of . . . limiting words" and that the new claim reflected "an insignificant change that, at most, narrow[ed] the scope of the claim in a way that d[id] not affect the products here at issue." *Id.* at 1341. It went on to point out that, by necessity and by statute, new claims resulting from reexamination cannot be broader than the original claims. *See id.*; *see also* 35 U.S.C. § 305; MPEP § 2290. Thus, the Federal Circuit held that reexamination of a patent does not entitle a plaintiff to circumvent claim preclusion because "claims that emerge from reexamination do not create a new cause of action that did not exist before." The claims are "merely new versions of claims that were part of the . . . patent prior to its reexamination." *Aspex Eyewear*, 672 F.3d at 1341.

Similarly, in this case, claims 6 and 12-16 of the '045 patent were added or amended during reexamination. Claim 6 was amended only to add limiting words. Claim 12 is similar to canceled claim 1, except that it adds limiting words providing the gatifloxacin concentration, EDTA concentration, and pH characteristics. Claims 13 through 15 are dependent on claim 12, and claim 16 is dependent on claim 15. Consequently, claims 6 and 12-16 are all narrower in scope than the original claims.

Consistent with *Aspex Eyewear*, the court finds that none of the claims added or

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[4] That a reexamined patent does not result in a new patent is also evidenced by the patent numbering system. A reexamined patent retains the same number and merely obtains a new suffix indicating that the patent was reexamined. In the instant case, the originally issued patent number was 6,333,045 B1, and the reexamined patent number is 6,333,045 C1.

amended during reexamination were broader than their predecessors, and the reexam did not result in a new patent. As such, the new and amended claims of the '045 patent do not create any new cause of action that plaintiffs lacked under the original version of the patent.[5] *See id.* at 1342.

The doctrine of claim preclusion is "a rule of fundamental and substantial justice." *EEOC v. U.S. Steel Corp.*, 921 F.2d 489, 492 (3d Cir. 1990) (quoting *Hart Steel Co. v. Railroad Supply Co.*, 244 U.S. 294, 299 (1917)). It is necessary for the "conclusive resolution of disputes" and conserves judicial resources while minimizing the possibility of inconsistent decisions. *EEOC*, 921 F.2d at 492 (quoting *Montana v. United States*, 440 U.S. 147, 153-54 (1979)). The underlying facts in plaintiffs' cases overlap identically, except for the scope of the patent claims asserted. Plaintiffs were free to construe the claims of the '045 patent more narrowly and could have raised the infringement claims in the instant action in the first litigation. They made a strategic decision not to and lost, and the court will not allow relitigation of the matter.

V. CONCLUSION

For the foregoing reasons, the reexamination of the patent-at-issue did not create a new cause of action against the same previous defendants and accused product. Allowing this case to go forward would open the door to relitigation of a matter that has already been decided on the merits. The court grants defendants' motion to dismiss on

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[5] In a letter to the court, plaintiffs focus on the fact that the Federal Circuit did not ultimately apply claim preclusion in *Aspex Eyewear*. (D.I. 18) However, the disposition was based on that Court's finding that the products at issue were different than in the first litigation. *See Aspex Eyewear*, 672 F.3d at 1344. The Court was clear in its finding that reexamination did not result in a new patent constituting a new cause of action. As discussed, the products at issue are the same in the instant case.

grounds of claim preclusion. An appropriate order shall ensue.