

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO.,)
LTD., KYORIN PHARMACEUTICAL)
CO., LTD., AND ALLERGAN, INC.,)
)
Plaintiffs,)
)
v.)
)
LUPIN LIMITED AND LUPIN)
PHARMACEUTICALS, INC.,)
)
Defendants.)

Civ. No. 11-271-SLR (Consol.)

SENJU PHARMACEUTICAL CO.,)
LTD., KYORIN PHARMACEUTICAL)
CO., LTD., AND ALLERGAN, INC.,)
)
Plaintiffs,)
)
v.)
)
HI-TECH PHARMACAL CO., INC.,)
)
Defendants.)

MEMORANDUM ORDER

At Wilmington this 14th day of December, 2012, having considered defendants Lupin Limited and Lupin Pharmaceuticals, Inc.'s (collectively, "defendants") motion for leave to file second amended answer and the papers submitted therewith;

IT IS ORDERED that said motion (D.I. 110) is granted, as follows:

1. **Background.** This patent infringement litigation was initiated on March 31, 2011 by Senju Pharmaceutical Co., Ltd. ("Senju") , Kyorin Pharmaceutical Co., Ltd.

("Kyorin"), and Allergan Inc. ("Allergan") (collectively, "plaintiffs"). (D.I. 1) Senju and Kyorin are corporations organized under the laws of Japan and having principal places of business in Japan. (D.I. 33 at ¶¶ 2-3) Allergan is a Delaware corporation with its principal place of business in California. (*Id.* at ¶ 4)

2. Plaintiffs filed a complaint against defendants alleging infringement of U.S. Patent Nos. 6,333,045 ("the '045 patent") and 5,880,283 ("the '283 patent") by defendants' Abbreviated New Drug Application ("ANDA") No. 202-653.¹ (D.I. 1) The '045 patent is directed to aqueous liquid pharmaceutical compositions comprising gatifloxacin and disodium edetate, as well as various methods utilizing these compositions. (*Id.* at ex. A)

3. On May 23, 2011, plaintiffs amended their complaint, adding that Senju and Kyorin had filed a request for reexamination of claims 1-3, 6, 8 and 9 of the '045 patent. (D.I. 10 at ¶¶ 47-48) Defendants filed an answer and counterclaim on June 6, 2011. (D.I. 11) Defendants admitted to jurisdiction in their answer. (*Id.* at ¶¶16-18) Plaintiffs filed an answer to the counterclaim on June 27, 2011. (D.I. 16)

4. On November 21, 2011, plaintiffs further amended their complaint to allege infringement of the '045 patent as reexamined by defendants' ANDA No. 202-653 and

¹ Defendants filed a stipulation on January 26, 2012, entered on February 7, 2012, consolidating the instant case with Civ. Nos. 11-926-SLR and 11-1059-SLR for all purposes. (D.I. 47) The '283 patent is directed to a sesquihydrate compound and various processes for its production. (D.I. 1 at ex. B) Subsequently, plaintiffs and defendants filed a stipulation on May 21, 2012 to dismiss all claims and counterclaims related to the '283 patent, which was entered on May 22, 2012. (D.I. 84) Plaintiffs and Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") also filed a stipulation on August 27, 2012, entered on August 28, 2012, to dismiss all claims and counterclaims related to the '283 patent. (D.I. 97)

also by defendants' ANDA No. 202-709. (D.I. 33; D.I. 35) Defendants answered the amended complaints and counterclaimed to each on December 21, 2011. (D.I. 37; D.I. 38) Plaintiffs filed answers to the counterclaims on January 11, 2012. (D.I. 41; D.I. 42) Currently before the court is defendants' motion for leave to further amend their answers, filed October 12, 2012, to add an affirmative defense of intervening rights. (D.I. 105)

5. **Standard.** "[L]eave to amend 'shall be freely given when justice so requires.'" *Foman v. Davis*, 371 U.S. 178, 182 (1962) (quoting Fed. R. Civ. P. 15(a)). The court may exercise its discretion to deny leave to amend in situations in which the moving party has delayed seeking leave and the delay "is undue, motivated by bad faith, or prejudicial to the opposing party." *Bjorgung v. Whitetail Resort, LP*, 550 F.3d 263, 266 (3d Cir. 2008) (citation omitted). Put another way, where the non-moving party will not suffer "substantial or undue prejudice," "denial [of leave to amend] must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment." *USX Corp. v. Barnhart*, 395 F.3d 161, 166 (3d Cir. 2004) (quoting *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1413-14 (3d Cir. 1993)). Delay is "undue" when an unwarranted burden is placed on the court or when the requesting party has had previous opportunities to amend. *See Estate of Oliva ex rel. McHugh v. New Jersey*, 604 F.3d 788, 803 (3d Cir. 2010) (citation omitted).

6. **Discussion.** The doctrine of intervening rights recognizes the public's right to use what is not specifically identified in a patent as originally filed. *See, e.g., Seattle*

Box Co., Inc. v. Indus. Crating and Packing Inc., 756 F.2d 1574, 1579 (Fed. Cir. 1985). Claims amended during reexamination, if they are legally “identical” to the claims of the original patent,² can be enforced for the period prior to the issuance of the reexamination certificate. See, e.g., *Minco, Inc. v. Combustion Eng’g, Inc.*, 95 F.3d 1109, 1115 (Fed. Cir. 1996); *Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 976 (Fed. Cir. 1986). On the other hand, an infringer who was engaged in allegedly infringing activities (or “substantial preparation was made by the infringer” to do so) before a reexamination certificate issued may continue to infringe said claims, if the court determines that the reexamined claims are broader in scope than the original claims, and to the extent and under such terms as the court deems equitable for the continued manufacture, use or sale of an allegedly infringing product. See, *Seattle Box*, 756 F.2d at 1579. Therefore, the doctrine of intervening rights is a defense to infringing activity occurring after reexamination. See, e.g., *Fortel Corp. v. Phone-Mate, Inc.*, 825 F.2d 1577, 1580 (Fed. Cir. 1987).

7. Although the parties agree that defendants’ motion to amend was timely filed, plaintiffs argue that such amendment would be futile, apparently because defendants have not conceded that they have engaged in infringing activity. The court agrees with defendants that, at this stage of the proceedings, defendants need not so concede, but may advance the defense of intervening rights based on plaintiffs’ allegation that “[d]efendants have made, and will continue to make, substantial preparation in the

² “Identical” does not mean verbatim, but rather means without substantive change. See e.g., *Westvaco Corp. v. Int’l Paper Co.*, 991 F.2d 735, 741 (Fed. Cir. 1993).

United States to manufacture, sell, offer to sell, and/or use within the United States, and/or import into the United States the [d]efendants' gatifloxacin ophthalmic solution which is the subject of ANDA" No. 202-653 and No. 202-709. (D.I. 33 at 10; D.I. 35 at 10) Further, defendants contend that each ANDA sets forth preparation steps sufficient to allow the proposed affirmative defense. (D.I. 128 at 6-7)

8. **Conclusion.** As defendants have shown that there is at least some evidence to support an affirmative defense of intervening rights, defendants' motion for leave to file second amended answers is granted. Defendants' second amended answers attached to their motion are deemed filed and served as of the date of this order. (D.I. 111 at ex. A, ex. C)


United States District Judge