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. 11-271-SLR (Consol.)
LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

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

MEMORANDUM ORDER

At Wilmington this 7th day of December, 2012, having considered defendants Lupin Limited and Lupin Pharmaceuticals, Inc.'s (collectively, "Lupin") Rule 12(c) motion for judgment on the pleadings and the papers submitted therewith;

IT IS ORDERED that said motion (D.I. 105) is granted in part and denied in part, 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 Lupin alleging infringement of U.S. Patent Nos. 6,333,045 ("the '045 patent") and 5,880,283 ("the '283 patent") by Lupin's 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) Lupin filed an answer and counterclaim on June 6, 2011. (D.I. 11) Lupin admitted to jurisdiction in its 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 filed two second amended complaints. The

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[1] Lupin 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 Lupin 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)

first amended the original complaint alleging infringement of the '045 patent as reexamined. (D.I. 33) The next alleged infringement of the '045 patent as reexamined by Lupin's ANDA No. 202-709. (D.I. 35) Lupin filed answers to both second 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 Lupin's motion for judgment on the pleadings, filed October 8, 2012. (D.I. 105)

5. **Standard**. When deciding a Rule 12(c) motion for judgment on the pleadings, a district court must view the facts and inferences to be drawn from the pleadings in the light most favorable to the non-moving party. *Green v. Fund Asset Mgmt., L.P.*, 245 F.3d 214, 220 (3d Cir. 2001); *Janney Montgomery Scott, Inc. v. Shepard Niles, Inc.*, 11 F.3d 399, 406 (3d Cir. 1993). The motion can be granted only if no relief could be afforded under any set of facts that could be provided. *Turbe v. Gov't of the Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991); *see also Southmark Prime Plus, L.P. v. Falzone*, 776 F. Supp. 888, 891 (D. Del. 1991); *Cardio-Medical Associates, Ltd. v. Crozer-Chester Medical Ctr.*, 536 F. Supp. 1065, 1072 (E.D. Pa. 1982) ("If a complaint contains even the most basic of allegations that, when read with great liberality, could justify plaintiff's claim for relief, motions for judgment on the pleadings should be denied."). However, the court need not adopt conclusory allegations or statements of law. *In re General Motors Class E Stock Buyout Sec. Litig.*, 694 F. Supp. 1119, 1125 (D. Del. 1988). Judgment on the pleadings will only be granted if it is clearly established that no material issue of fact remains to be resolved and that the

movant is entitled to judgment as a matter of law. *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290 (3d Cir. 1988).

6. In *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971), the Supreme Court held that, in the patent context, defensive collateral estoppel may be used if the accused infringer shows: "(1) that a patent was found invalid in a prior case that had proceeded through final judgment and in which all procedural opportunities were available to the patentee; (2) that the issues litigated were identical; and (3) that the party against whom estoppel is applied had a full and fair opportunity to litigate." *Abbott Labs. v. Andrx Pharma., Inc.*, 473 F.3d 1196, 1203 (Fed. Cir. 2007). Regional Circuit law controls the determination of whether prior findings invoke collateral estoppel pursuant to these guidelines. *Id.* at 1202-03.

7. In this regard, the Third Circuit has held that collateral estoppel applies when "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (citations omitted). The Third Circuit has also considered whether the party being precluded had "a full and fair opportunity to litigate the issue in question in the prior litigation" and, in addition, whether the issue was determined by final judgment. *Id.* (citations omitted).

8. A judgment of invalidity in one patent action operates to bar relitigation of the validity of the same patent in a subsequent action, by collateral estoppel. *See Blonder-*

Toungue, 402 U.S. at 349-50. Further, unadjudicated patent claims may be barred by collateral estoppel if "'the issue of invalidity common to each action is substantially identical.' It is the issues litigated, not the specific claims around which the issues were framed, that is determinative." *Westwood Chem., Inc. v. United States*, 525 F.2d 1367, 1372 (1975). Collateral estoppel may also operate to bar relitigation of common issues in actions involving different but related patents. *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1310 (Fed. Cir. 2001).

9. **Discussion**. Lupin alleges that narrower reexamined claims 6 and 12-16 of the '045 patent are invalid for obviousness and that plaintiffs should be collaterally estopped from relitigating these claims based on this court's findings in *Senju Pharmaceutical Co. Ltd. v. Apotex Inc.*, 717 F. Supp. 2d. 404, 419-27 (D. Del. 2010). (D.I. 106 at 1-2) Plaintiffs argue that the reexamined claims have not been previously litigated and decided, because this court did not consider or determine "the validity of a claim limited to 0.01 w/v%" disodium edetate ("EDTA"). *Id.* at 2-3.[2]

10. In *Senju*, the court construed the EDTA concentration limitation to be from 0.001 to 0.2 w/v%. *Senju*, 717 F. Supp. 2d. at 419 & n.26, 421-23. The court held that the original claim 6 was obvious in light of the prior art as it "would lead one of ordinary skill in the art to reasonably expect that, consistent with the court's construction of claim 6, the step of adding disodium edetate (even at a concentration as low as 0.1 w/v%) to

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[2] Plaintiffs' argument that this court's decision in *Senju Pharm. Co., Ltd. v. Apotex Inc.*, ___ F. Supp. 2d ___, 2012 WL 4062325 (D. Del. Sept. 17, 2012) precludes the application of collateral estoppel is incorrect. (D.I. 119 at 1-2) This court stated that claim preclusion applied to that case, not that issue preclusion could never apply. *Senju Pharm. Co., Ltd. v. Apotex Inc.*, 2012 WL 4062325 at *4.

a solution of gatifloxacin eye drops would demonstrate an increased concentration of gatifloxacin in the aqueous humor."[3] *Id.* at 423.

11. Defendants argued that the original claim 6 was obvious as "one of ordinary skill would have expected disodium edetate to enhance the corneal permeability of gatifloxacin such that it would result in an increased concentration of gatifloxacin in the aqueous humor" based on a 1985 publication by Grass et al. ("the Grass reference").[4] *Id.* at 421. The Grass reference "sought to determine the effect of EDTA on the permeability of organic and inorganic compounds with respect to the corneal epithelia" and suggested "that EDTA concentrations lower than 0.5 w/v% would be effective in view of the increased corneal permeability of the 0.5w/v% EDTA formulation." *Id.* at 411, 421. Plaintiffs' expert testified that the Grass reference had no bearing on the obviousness of the '045 patent because the compounds disclosed were different than gatifloxacin. *Id.* at 422. However, this court concluded that the Grass reference attributed the improved corneal permeability on the ability of EDTA to transport a polar compound across the epithelial layer of the cornea and gatifloxacin was a polar compound with a topical ophthalmic application. *Id.*

12. The court held that "the validity of claim 6 does not hinge . . . upon the

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[3] The Federal Circuit upheld the court's finding that claim 7 was invalid for obviousness. *See Senju Pharmaceutical, Co., Ltd. v. Apotex, Inc.*, No. 2012-1179 (Fed. Cir. Oct. 5, 2012). The court's analysis of the obviousness of claim 7 is instructive for the addition of EDTA to an aqueous solution, but does not address the validity of a claim limited to 0.01 w/v% EDTA or whether such an addition might increase corneal permeability.

[4] Grass George, M., et al., *Effects of Calcium Chelating Agents on Corneal Permeability*, 77 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCI. 3 (1985).

existence of a prior art teaching that EDTA affects the corneal permeability of gatifloxacin specifically, or even quinolones generally." *Id.* Further, "within the finite range of excipients disclosed to be suitable in combination with quinolones, it would be obvious to try one such excipient characterized by the prior art as increasing the corneal permeability of polar compounds." *Id.* at 423. Plaintiffs now argue that reexamined claim 6, with its narrower limitations, is not rendered obvious by the above analysis.[5] (D.I. 119 at 9)

13. **Conclusion.** Although in the '045 patent the concentration of EDTA is limited to from 0.001 to 0.2 w/v%, this court did not specifically make findings for a claim with a limitation of 0.01 w/v% EDTA. *Senju*, 717 F. Supp. 2d. at 419 & n.26, 421-23. Moreover, plaintiffs did not fully litigate a claim with a limitation of 0.01 w/v% EDTA and Lupin has not shown sufficient evidence that this limitation does not lend patentable significance to reexamined claims 6 and 12-16.[6] Therefore, Lupin's motion for judgment on the pleadings is denied as to reexamined claims 6 and 12-16 and granted as to claim 7 of the '045 patent.

United States District Judge

[5] A narrower claim is not rendered invalid by the invalidity of a broader claim. "Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." 35 U.S.C. §282.

[6] Although Lupin's failure to demonstrate that the reexamined claims are substantially identical to the original claim 6 prevents it from prevailing on collateral estoppel grounds, Lupin may later succeed in showing that the reexamined claims are invalid for obviousness.