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. 07-779-SLR
APOTEX INC. and APOTEX CORP.	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 17th day of November, 2010, having considered the materials in connection with plaintiffs' motion for a new trial or, alternatively, to amend the judgment (D.I. 126; D.I. 127; D.I. 128);

IT IS ORDERED that plaintiffs' motion is dismissed without prejudice to renew.

IT IS FURTHER ORDERED that the record of this litigation is opened pursuant to Fed. R. Civ. P. 59(a)(2) so that the parties may present additional testimony with respect to the following specific questions regarding the validity of claim 7 of U.S. Patent No. 6,333,045 ("the '045 patent").

1. **Background**. Plaintiffs are co-owners of the '045 patent, which is directed to aqueous liquid pharmaceutical compositions comprising gatifloxacin and disodium edetate, as well as various methods utilizing these compositions. Gatifloxacin is within the family of quinolones, which are broad spectrum antibacterial compounds that share a common core chemical structure. (*See* DTX 37 at col. 1:7-10; D.I. 107 at 326-28) Briefly, plaintiffs brought this patent infringement action in response to multiple

Abbreviated New Drug Applications ("the ANDAs") filed by defendants. Plaintiffs alleged that the ANDAs infringed multiple claims of the '045 patent, including claim 7.[1] A bench trial was conducted from January 12 to January 14, 2010, and the court issued a memorandum opinion on June 14, 2010 to address the issues presented by the parties' post trial briefs.[2] (*See* D.I. 122) In the memorandum opinion, the court concluded that, *inter alia*, defendants had demonstrated, by clear and convincing evidence, that a 1989 article by Riley et al. ("the Riley reference"), in view of U.S. Patent Nos. 4,980,470 ("the '470 patent") and 4,551,456 ("the '456 patent"), rendered claim 7 of the '045 patent obvious. (*Id.* at 37-38)

a. The court predicated this conclusion of invalidity upon multiple findings of fact with respect to these prior art references. Specifically, the court found that the Riley reference proposed simulated solubility profiles for quinolone compounds. (*Id.* at 7) According to the Riley reference, quinolones with similar pK_a values exhibit a U-shaped solubility curve with an inflection point about each of the pK_a values. (*Id.*) The Riley reference further teaches that the addition of carboxylic acids of various molecular weights and structures to a quinolone solution maintained at pH 5 resulted in an increase in the solubility of the quinolone.

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[1]Claim 7 claims

> [a] method for preventing precipitation of gatifloxacin crystals which comprises incorporating disodium edetate into an aqueous liquid preparation containing gatifloxacin or its salt.

[2]The reader is directed to the memorandum opinion for a more comprehensive understanding of the parties' positions in this litigation. *See Senju Pharm. Co. Ltd. v. Apotex, Inc.*, Civ. No. 07-779-SLR, 2010 WL 2380735 (D. Del. June 14, 2010).

b. The '456 patent discloses a quinolone ophthalmic solution comprising an aqueous solution of 0.3 w/v% of the prior art quinolone norfloxacin and 0.01 w/v% disodium edetate. Disodium edetate is disclosed by the '456 patent in a list of 8 excipients described as "conventional ingredient[s]" in ophthalmic compositions. ('456 patent at col. 2:5-10) The '470 patent, which discloses the compound gatifloxacin, explains that pharmaceutical formulations of gatifloxacin follow "the routes well known . . . ." with respect to "oral[] and parenteral[] administration," including ". . . . liquids [and] eye drops . . . ." ('470 patent at col. 7:21-26)

c. The combination of these prior art references led the court to conclude that

> one of ordinary skill in the art would predict that gatifloxacin, having a pK_a value similar to [prior art quinolones disclosed by the '456 patent], would likewise display a similar and predictable solubility profile. Because gatifloxacin can be expected to behave similarly to these prior art quinolones in solution, one of ordinary skill would find apposite a further teaching of the Riley reference - that the addition of carboxylic acid will increase the solubility of a quinolone in the relevant pH range for topical ophthalmic administration.[] The record demonstrates that the ability to increase the solubility of a quinolone using carboxylic acid bears a direct relationship to the ability to prevent or inhibit the quinolone from precipitating out of a solution.

(D.I. 122 at 30-31) After determining that plaintiffs had failed to demonstrate secondary considerations that would rebut defendants' prima facie case, the court concluded that the Riley reference, in view of the '456 and '470 patents, rendered claim 7 of the '045 patent obvious. (*Id.* at 37-38)

d. Citing to evidentiary deficiencies, plaintiffs have moved pursuant to Fed. R. Civ. P. 52, 59 and 60 for a new trial or, alternatively, to amend the court's judgment with respect to claim 7. Specifically, plaintiffs argue that the court improperly

relied upon the opinions of defendants' expert, Dr. Paul Myrdal ("Dr. Myrdal"), in finding that the Riley reference discloses any link between the solubility of a compound and its precipitation from solution. (D.I. 126 at 5) The alleged impropriety of Dr. Myrdal's opinion stems from his reliance upon "arbitrary" solubility curves prepared for trial and used to demonstrate the interplay between solubility and precipitation. Plaintiffs contend that these solubility curves were not properly vetted through the discovery process and that the court, in fact, cautioned defendants against designating any such evidence as foundational in an invalidity theory.[3]

2. **Plaintiffs' Motion for a New Trial**. Upon motion for a new trial, the court's broad discretionary powers allow it to "open the judgment if one has been entered, take additional testimony, amend findings of fact and conclusions of law or make new ones, and direct the entry of a new judgment." Fed. R. Civ. P. 59(a)(2). The court may grant a new trial after a non-jury trial "for any reason for which a rehearing has heretofore been granted in a suit in equity in federal court." Fed. R. Civ. P. 59(a)(1)(B). A motion for reconsideration, which permits a rehearing in this district, may be granted "to correct a clear error of law or fact or to prevent manifest injustice." *Max's Seafood Cafe by Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). However, "Rule 59 is not a vehicle for relitigating old issues, presenting the case under new theories, securing a

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[3]In response to an objection by plaintiffs at trial, the court noted:

> If this becomes a critical part of the post-trial briefing, and I determine that it wasn't appropriately vetted through discovery, then [defendants are] at risk for paying for a retrial. So [plaintiffs may note the] objection. . . . [Defendants] may go forward if [the solubility curves are] helpful without being critical.

(D.I. 107 at 315)

rehearing on the merits, or otherwise taking a 'second bite at the apple' . . . ." *Sequa Corp. v. GBJ Corp.*, 156 F.3d 136, 144 (2d Cir. 1998).

3. **Discussion**. Plaintiffs' motion calls into question what defendants (and this court) have operated upon as a basic principle of science, to wit, that solubility and precipitation bear, to some extent, an inverse relationship to each other. Upon review of the record, the development of this concept seems to have generated very little attention during discovery. Plaintiffs point to a single statement bearing upon this relationship in the invalidity portion of Dr. Myrdal's expert report, in which he cites to a treatise by Martin et al. ("the Martin reference") for the basis of his opinion that

> [a] person of ordinary skill in the art at the time the '045 patent was applied for would have known that one method for preventing precipitation of the active ingredient in a solution, such as those disclosed in the '456 and '465 patents, under set conditions, is to modify the formulation to raise the active ingredient's solubility.

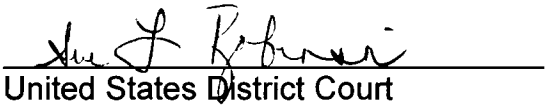
(D.I. 126, ex. 1 at ¶ 88) The court agrees with plaintiffs that the Martin reference discusses solubility and does not explicitly disclose a link to precipitation.

a. In his opinion as to the enablement of the '045 patent, Dr. Myrdal notes that whether gatifloxacin precipitates is "predominantly controlled" by its solubility at a given pH and temperature. (D.I. 127, ex. 2 at ¶ 65) Similarly, in Dr. Myrdal's rebuttal noninfringement report, he consistently submits that "a person of ordinary skill in the art would understand that temperature and pH affect the solubility of a drug and, thus, whether it precipitates." (*Id.*, ex. 3 at ¶ 63) These opinions did not elicit a specific line of questioning during plaintiffs' deposition of Dr. Myrdal as to the interplay between these two properties. It is clear from this record that plaintiffs did not attribute as much

significance as did defendants to the relationship between solubility and precipitation and, consequently, this issue was not properly vetted during discovery.

b. Ultimately, defendants bear the burden of demonstrating the invalidity of claim 7 by clear and convincing evidence. However, the court will not grant a new trial on the validity of claim 7 based solely on defendants' failure of proof with respect to a basic principle of science. Due to the errors made by both parties, the court concludes that it is instead appropriate to open the record pursuant to Fed. R. Civ. P. 59(a)(2) to allow further evidence on the relationship between precipitation and solubility.

4. **Conclusion**. For the reasons explained, plaintiffs' motion is dismissed without prejudice to renew, and the record of this litigation is opened pursuant to Fed. R. Civ. P. 59(a)(2) so that the parties may present additional evidence regarding the relationship between precipitation and solubility. The court will conduct a telephone conference in this regard on November 29, 2010 at 3:00 p.m., with defendants' counsel initiating the call.



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