

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division**

LUPIN LIMITED,

Plaintiff,

v.

Civil Action No. 3:06cv400

ABBOTT LABORATORIES,
and ASTELLAS PHARMA, INC.,

Defendants.

ABBOTT LABORATORIES,
and ASTELLAS PHARMA, INC.,

Counterclaim Plaintiffs,

v.

LUPIN LIMITED, AND LUPIN
PHARMACEUTICALS, INC.,

Counterclaim Defendants.

MEMORANDUM OPINION

This matter is before the Court on Plaintiff's Motion for Summary Judgment on Noninfringement and Invalidity for U.S. Patent No. 4,935,507 (Docket No. 208). For the reasons set forth below, the motion is granted in part and denied in part.

BACKGROUND

This action involves U.S. Patent No. 4,935,507 ("507 patent"), which covers Crystal A, a particular form of the

antibiotic cefdinir. (See Docket No. 188, Mem. Op. at 23.) Astellas Pharma, Inc. ("Astellas") obtained the '507 patent in 1990, five years after it had obtained U.S. Patent No. 4,559,334 ("'334 patent"), which also covered forms of cefdinir. The '334 patent expired on May 6, 2007, and the '507 patent is set to expire on December 4, 2011.¹

Because the '334 patent expired on May 6, 2007, Astellas can no longer prevent competitors from producing forms of cefdinir not covered by the '507 patent, which is limited in scope to Crystal A. Abbott Laboratories ("Abbott") holds a license from Astellas to practice the '507 patent. Pursuant to that license, Abbott makes and markets Crystal A in a branded cefdinir product called Omnicef®, which currently has annual sales exceeding \$600 million. Seizing on the expiration of the '334 patent, Lupin Limited ("Lupin") is now marketing a generic form of cefdinir to compete with Omnicef®, and seeks a declaration that its product "has not infringed, does not infringe, and will not infringe any valid and enforceable claim of" the '507 patent. (Compl. for Declaratory J. at 1.) Abbott and Astellas have each filed counterclaims against Lupin, alleging infringement of the '507 patent. (Dockets No. 18 and 21.)

¹ Astellas received a patent term extension (PTE) for the '507 patent on January 19, 2001. Without that PTE, the '507 patent would expire on August 8, 2008. Whether the '507 patent's PTE is enforceable is disputed by the parties, but the parties have agreed to dismiss this claim in a Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349).

Lupin seeks summary judgment on six independent grounds: (1) non-infringement of Claims 1-5 of the '507 patent, both literally and under the doctrine of equivalents; (2) invalidity of the '507 patent for obviousness; (3) invalidity of the '507 patent for anticipation; (4) invalidity of the '507 patent for improper inventorship; (5) invalidity of the '507 patent for lack of enablement; (6) the absence of legal or equitable remedy for trace infringement. (See Lupin Limited's Mem. of Law in Supp. of Mot. for Summ. J. of Noninfringement and Invalidity for U.S. Patent No. 4,935,507 and Supplemental Declaration of Amy D. Brody ("Lupin Mem.")) Abbott and Astellas oppose Lupin's motion, and contend that summary judgment is inappropriate on any of those bases. (See Abbott Laboratories' and Astellas Pharma, Inc.'s Mem. in Resp. to Lupin's Mot. for Summ. J. ("Abbott and Astellas Mem.")) Oral argument was heard on May 21, 2007 and, for the reasons that follow, the Court now grants Lupin's summary judgment motion with respect to the literal infringement of Claims 2-5 and the infringement of all claims under the doctrine of equivalents.

DISCUSSION

Summary judgment is appropriate in a patent case, as in other cases, when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Nike Inc. v. Wolverine World Wide, Inc., 43 F.3d 644, 646 (Fed. Cir. 1994). When analyzing a summary judgment

motion, the facts must be construed in the light most favorable to the non-movant, and all reasonable inferences must be drawn in the non-movant's favor. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

A. Infringement

A determination of infringement requires a two-step, claim-by-claim analysis. See Amazon.com, Inc. v. Barnesandnoble.com, Inc., 139 F.3d 1343, 1351 (Fed. Cir. 2001). First, the court must properly construe the claim; second, "the claim as properly construed must be compared to the accused device or process." Gart v. Logitech, Inc., 254 F.3d 1334, 1339 (Fed. Cir. 2001). An infringement issue is properly decided upon summary judgment when no reasonable jury could find, by a preponderance of the evidence, that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents. Id.

1. Literal Infringement of Claim 1

After oral argument, the Court concluded that there were genuinely disputed issues of material fact which precluded an award of summary judgment on the literal infringement of Claim 1. In a Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349), the parties have agreed to dismiss without prejudice any claims related to the literal infringement of Claim 1. Because that issue has been resolved thusly by the parties, it is not necessary to

address it further.

2. Literal Infringement of Claims 2-5

Claims 2-5 are product-by-process claims. (See Docket No. 188, Mem. Op. at 39.) In an order dated May 10, 2007 (Docket No. 234), the Court informed the parties that the Federal Circuit's decision in Atlantic Thermoplastics Co., Inc. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992) would govern the literal infringement analysis of Claims 2-5. That order was necessary because the parties disagree about whether the product-by-process infringement analysis should be controlled by Atlantic Thermoplastics or Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991).

Scripps and Atlantic Thermoplastics announce conflicting rules respecting the proper analysis of product-by-process claims in an infringement action. In Scripps, a panel of the Federal Circuit determined that "the correct reading of the product-by-process claims is that they are not limited to product prepared by the process set forth in the claims." 927 F.2d at 1583. One year later, the decision in Atlantic Thermoplastics held that "process terms in product-by-process claims serve as limitations in determining infringement." 970 F.2d at 846-47. As district courts have long acknowledged, those two holdings are at odds with one another. See, e.g., Trustees of Columbia Univ. v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16, 31 (D. Mass. 2000).

Scripps and Atlantic Thermoplastics are different in substance as well as in result. While Scripps enunciated its rule without legal citation or significant analysis, see 927 F.2d at 1583, the Atlantic Thermoplastics decision reached its contrary conclusion only after thoroughly examining both the history of product-by-process claims and the relevant precedent from the Supreme Court of the United States and the Federal Circuit pertaining to the infringement of such claims, see id. at 838-47. Indeed, the Scripps analysis was so brief by comparison that the Atlantic Thermoplastics court determined that Scripps would have been decided differently had Supreme Court precedent and other relevant authority been considered. See 970 F.3d at 838 n.2.

Notwithstanding the analytical parsimony in Scripps, some district courts have decided to follow Scripps because it was issued first and has not been overruled *en banc*. See, e.g., Trustees of Columbia Univ., 126 F. Supp. 2d at 32. On the other hand, other district courts have concluded that Atlantic Thermoplastics constitutes a proper statement of the law, and, therefore, should govern the analysis of product-by-process claims. See, e.g., Tropix, Inc. v. Lumigen, Inc., 825 F. Supp. 7, 8-10 (D. Mass. 1993). Abbott and Astellas urge the Court to adopt Scripps, which offers a broader reading of product-by-process claims, while Lupin urges application of Atlantic Thermoplastics.

Having considered the matter further, the Court concludes, as

it did in its order of May 10, 2007, that Atlantic Thermoplastics must control the product-by-process analysis because it, not Scripps, reflects controlling Supreme Court precedent. At oral argument on the motion for summary judgment, Abbott and Astellas disputed the Federal Circuit's interpretation of Supreme Court precedent in Atlantic Thermoplastics. (See Summ. J. Hr'g Tr. 185-89.) Having considered that argument, the Court finds no basis for concluding that the decision in Atlantics Thermoplastics either misconstrued or misapplied the controlling decisions of the Supreme Court. Moreover, a district court is not at liberty to ignore relevant and controlling Supreme Court precedent simply because it was not considered in an appellate decision addressed to the same subject as the Supreme Court's antecedent decisions. Thus, because Atlantic Thermoplastics reflects the relevant and controlling Supreme Court precedent, and Scripps does not, the process terms in Claims 2-5 must "serve as limitations in determining infringement." 970 F.2d at 846-47.

Under the rule set forth in Atlantic Thermoplastics, Lupin's product cannot literally infringe any of Claims 2-5 unless it is made using each of the process limitations set forth in one of those claims. Abbott and Astellas have presented no evidence that Lupin is practicing the process steps set forth in Claims 2-5. Indeed, Abbott and Astellas have conceded that literal infringement of Claims 2-5 cannot be established if the product-by-process

analysis is performed pursuant to the rule in Atlantic Thermoplastics. Therefore, Lupin's motion for summary judgment is granted with respect to the literal infringement of those claims.

3. Doctrine of Equivalents

If Lupin's product does not literally infringe Claims 1-5, it may still infringe under the doctrine of equivalents if there is "equivalence between those elements of the accused product and the claimed limitations of the patent invention that are not literally infringed." Zelinski v. Brunswick Corp., 185 F.3d 1311, 1316 (Fed. Cir. 1999). The test of equivalency is directed to the individual claim limitations, and not to the invention itself. As the Supreme Court explained in Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.: "Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." 520 U.S. 17, 29 (1997).

An element in the accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art. DeMarini Sports, Inc. v. Worth, Inc., 239 F.3d 1314, 1331-32 (Fed. Cir. 2001). A difference may be "insubstantial" if the accused product's element "performs substantially the same function in substantially the same way to obtain the same result as the claim limitation." Eagle Comtronics,

Inc. v. Arrow Comm'n Laboratories, Inc., 305 F.3d 1303, 1315 (Fed. Cir. 2002) (citation and internal quotations omitted). Under no circumstances, however, is this element-focused equivalency inquiry "allowed such broad play as to effectively eliminate [any] element in its entirety." Warner-Jenkinson, 520 U.S. at 29.

Notwithstanding the foregoing well-established, element-focused dispositive principles, Abbott and Astellas contend that Lupin's product infringes Claims 1-5 "because Lupin's product performs substantially the same function, in substantially the same way, to produce substantially the same result as the claimed crystalline cefdinir." (Abbott and Astellas Mem. at 12 (emphasis added).) Abbott and Astellas focus, in particular, on the "bioequivalence" and "stability and solubility" similarities between Lupin's product and Crystal A. (Id. at 12-13.) Even if Abbott and Astellas are correct about the functioning of Lupin's product, no reasonable jury could conclude, based on a product-focused analysis, that Lupin's product contains elements insubstantially different from each and every limitation in one of Claims 1-5 (which focus on peak positions and process steps, not stability, solubility, or other characteristics associated with Crystal A as a whole). See Schoell v. Regal Marine Indus., Inc., 247 F.3d 1202, 1210 (Fed. Cir. 2001) (noting that similarities between products as a whole do not, by themselves, allow inferences respecting the equivalence of individual elements and claim

limitations). To the extent that Abbott and Astellas rely on characteristics of Lupin's product unrelated to the individual limitations set forth in Claims 1-5, their doctrine of equivalents theory is without merit.

However, Abbott and Astellas make three arguments which, at least, loosely relate to the individual limitations contained in Claims 1-4.² First, Abbott and Astellas claim that "the peak positions in Lupin's products are at most insubstantially different from the positions of the peaks claimed in the patent." (Abbott and Astellas Mem. at 14.) They base that argument entirely on a single paragraph in Dr. Atwood's first expert report. (See id.) In paragraph 50 of that report, Dr. Atwood states the following:

Even a crystal of cefdinir with 6.0 - 7.5% w/w water in the lattice would contain the peaks recited in claim 1 of the '507 patent, but they would at most be insubstantially shifted by virtue of the expansion of the crystal lattice along the c direction upon the insertion of additional water molecules. In every material respect, crystalline cefdinir monohydrate and crystalline cefdinir hydrate containing 6.0-7.5% w/w water are substantially the same as each other.

(First Expert Report of Jerry L. Atwood ¶ 50.) Under the doctrine of equivalents, this paragraph alone is insufficient to allow a reasonable jury to conclude by a preponderance of the evidence that

² Abbott and Astellas make no element-focused contentions with respect to Claim 5. (See Abbott and Astellas Mem. at 14-15.) That being the case, summary judgment is appropriate for noninfringement of Claim 5 under the doctrine of equivalents notwithstanding the merits of any element-focused arguments made by Abbott and Astellas with respect to Claims 1-4.

Lupin's product infringes Claim 1. First, Dr. Atwood makes no mention whatsoever of Lupin's particular product. Instead, he offers a theoretical discussion comparing abstract hydrated forms of crystalline cefdinir that might share characteristics with Lupin's product. Second, Dr. Atwood does not conduct an element-by-element analysis of Claim 1 as compared to Lupin's product. For example, he does not say which particular peak in Lupin's product corresponds with the peak that must exist at about 14.7 and why the difference between the two peak positions is "insubstantial" to a person of ordinary skill in the art.³ Thus, while Dr. Atwood's statements relate to the individual limitations in Claim 1 (the existence and position of peaks), he nevertheless "has not opined in a sufficient manner regarding infringement under the doctrine of equivalents." Microstrategy, Inc. v. Business Objects, S.A., 331 F. Supp. 2d 432, 445 (E.D. Va. 2004). Without more, Dr. Atwood's conclusory and abstract opinion is simply insufficient to support a finding of infringement under the doctrine of equivalents with respect to Claim 1. See Schoell, 247 F.3d at 1210 ("The doctrine of equivalents is not a talisman that entitles a patentee to a jury trial on the basis of suspicion; it is a limited remedy available in special circumstances, the evidence for which is the

³ Moreover, Dr. Atwood's conclusory opinion does not enable the Court to determine whether his theory of equivalence would "entirely vitiate" a particular claim element or otherwise render the peak limitations in Claim 1 impermissibly meaningless. Warner-Jenkinson, 520 U.S. at 39 n.8.

responsibility of the proponent.”)

Second, Abbott and Astellas contend that, even if Lupin’s product does not show “peaks” at about 14.7 or about 22.0, it does show “increases in intensity” at those angles. (Abbott and Astellas Mem. at 14.) Abbott and Astellas again invoke Dr. Atwood to argue that those increases in intensity are insubstantially different from peaks. (Id.) However, Dr. Atwood’s third declaration, on which Abbott and Astellas rely for this argument, does not equate “peaks” with mere increases in intensity. (See id. Ex. 9 ¶¶ 9-11.) For example, paragraph 9 of Dr. Atwood’s third declaration depicts features which he labels “peaks,” but, while those “peaks” take slightly different forms, each increase in intensity labeled a “peak” has an apex surrounded by a lower intensity measurement on each side. (Id. ¶ 9.) While paragraphs 10 and 11 of the declaration do discuss the possibility that peaks may overlap, or that a peak may protrude as a “shoulder” from another peak, nothing in paragraphs 10 and 11 indicates that a peak, of any shape or size, may be anything other than an apex immediately preceded by and immediately followed by a lower intensity measurement. (See id. ¶¶ 10-11.) Therefore, Dr. Atwood’s third declaration does not support Abbott’s and Astellas’ contention that mere “increases in intensity” are insubstantially different from peaks.

Even if Dr. Atwood’s third declaration did support that

argument, Dr. Atwood does not point out, on an element-by-element basis, which "increases in intensity" in Lupin's product correspond to the peaks required by Claim 1.⁴ The failure to offer proof on that subject is fatal at this stage.

Third, and finally, Abbott and Astellas argue that Lupin's product infringes Claims 2-4 by equivalents because the processes described by Claims 2-4 may result in both Lupin's product and the crystalline cefdinir covered by the '507 patent. (See Abbott and Astellas Mem. at 15.) Therefore, Abbott and Astellas argue, "any difference between the two crystal forms is insubstantial." (Id.) Again, however, this argument improperly focuses on completed products and not on Lupin's process steps, which are the elements at issue here. In order to demonstrate infringement by equivalents, Abbott and Astellas must offer proof to show why Lupin's processes feature a step that is insubstantially different from each process limitation set forth in one of Claims 2-4. Abbott and Astellas offer no such proof. They certainly do not explain why Lupin's processes are insubstantially different from each process step described in one of Claims 2-4 simply because the processes in Claims 2-4 might produce Lupin's product (among others). Because Abbott's and Astellas' equivalency analysis with respect to Claims 2-4 fails to address the pertinent process steps

⁴ Nor do Abbott and Astellas explain why the claim limitations in Claim 1 would not be rendered totally and impermissibly meaningless if mere "increases in intensity" could serve as infringing equivalents.

- Lupin's - summary judgment for Lupin is required.

In sum, Abbott and Astellas largely make irrelevant product-focused arguments under the doctrine of equivalents, and, where their arguments do properly focus on individual claim elements, they do not offer supporting evidence sufficient to defeat Lupin's motion for summary judgment. Accordingly, summary judgment for Lupin is required with respect to the infringement of Claims 1-5 under the doctrine of equivalents.

B. Validity and Availability of Legal Remedies

After oral argument on the motion for summary judgment, the Court concluded that the existence of genuinely disputed material facts precluded summary judgment on Lupin's contentions respecting invalidity and the availability of remedies. In the Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349), the parties agreed to dismiss without prejudice any claims related to invalidity. Because those issues have been resolved by the parties, it is not necessary to address them further. In addition, because the issues related to infringement have been dismissed or resolved in favor of Lupin, the Court need not consider the availability of legal remedies to Abbott and Astellas.

CONCLUSION

For the reasons set forth above, Lupin's motion for summary judgment is granted with respect to the literal infringement of

Claims 2-5 and infringement of all claims under the doctrine of equivalents. Lupin's motion is otherwise denied.

The Clerk of the Court is directed to send a copy of this Memorandum Opinion to all counsel of record.

It is so ORDERED.

/s/
Robert E. Payne
Senior United States District Judge

Date: June 14, 2007
Richmond, Virginia