

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNIGENE LABORATORIES, INC., AND
UPSHER-SMITH LABORATORIES, INC.,

Plaintiffs
- against -

06 CV 5571 (RPP)

**OPINION AND
ORDER**

APOTEX, INC., AND APOTEX CORP.,
Defendants.

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The Court’s opinion of August 31, 2009, granting the Plaintiffs’ motion for summary judgment and directing that judgment be entered in favor of the Plaintiffs, is reinstated for the reasons stated herein.

I. Facts and Proceedings

In July of 2006, Unigene and Upsher-Smith (“Plaintiffs”) filed a complaint alleging that Apotex, Inc. and Apotex Corp. (“Apotex” or “Defendants”) had infringed U.S. Patent No. 6,440,392 (“the ‘392 patent”), which Unigene owned and licensed to Upsher-Smith for marketing and sales. (Complaint, at ¶¶ 11-29.) The patent, entitled “nasal calcitonin formulations,” covered a calcitonin salmon nasal spray, marketed and sold under the brand-name FORTICAL. *Id.*, at ¶15. In September 2006, Apotex filed its answer, denying many allegations and asserting various affirmative defenses and counterclaims. In October 2006, Plaintiffs filed a reply to the answer’s counterclaims.¹ On October 6, 2006, the Court entered a scheduling order proposed by the parties

¹ In May 2007, Defendants filed an amended answer and counterclaims; that same month, the Plaintiffs filed their reply.

providing, *inter alia*, that fact discovery would end August 31, 2007, all expert witnesses would be designated by October 5, 2007. The *Markman* hearing was to be held after January 4, 2008, and a joint pretrial order was to be submitted within thirty days after the Court decided any dispositive motion.

On August 17, 2007, fact discovery was extended to September 14, 2007, at the Defendants' request. In October 2007, Defendants moved the Court to "compel discovery of assertedly privileged documents based on the crime-fraud exception." After extensive briefing, the Court issued an opinion on February 4, 2008, holding that the Defendants had failed to make out a prima facie case of fraud and thus denied the Defendants' motion. Following this decision, the Court received claim construction memoranda and held a *Markman* hearing on July 14-15, 2008. In August 2008, the Court issued an opinion and order construing Claim 19 of the '392 patent.

On September 22, 2008, the Court issued a scheduling order for the completion of expert discovery and providing for termination of expert discovery by February 23, 2009. On October 23, 2008, Plaintiffs moved for a preliminary injunction to prevent Defendants' manufacture and sale of its generic version of FORTICAL. On November 7, 2008, Defendants filed their opposition papers, arguing that Plaintiffs' patent was invalid for obviousness. After receipt of Plaintiffs' reply, Defendants submitted a sur-reply on November 26, 2008. Although the motion for a preliminary injunction was settled by stipulation of the parties on December 1, 2008, no outstanding defense, other than obviousness, was mentioned or alluded to by the Defendants in these papers.

On March 16, 2009, the parties agreed that the United States Patent and Trademark Office ("USPTO") would reissue the '392 patent as Reissue Patent No.

RE40812 (“the RE812 patent”) and agreed to the substitution of the new reissue Claim 19 in the RE812 patent for Claim 19 in the '392 Patent for all litigation purposes. On June 30, 2009, the USPTO reissued the '392 patent as the RE812 patent. On July 2, 2009, the Court entered a consent order that allowed Plaintiffs to amend the complaint by substituting Claim 19 in the RE812 patent for Claim 19 in the '392 patent; that same day, the Plaintiffs filed the amended complaint. At no time did any party indicate that discovery should be re-opened or that additional expert reports would be required, in view of the stipulations. The Defendants’ answer to the amended complaint was filed on July 20, 2009 and contains eight new inequitable conduct claims, and the non-infringement, invalidity, and inequitable conduct claims contained in the original answer.

On April 17, 2009, the Defendants filed for summary judgment on the issue of obviousness, and on April 23, 2009, Plaintiffs cross-moved for summary judgment on the lack of obviousness. The Court heard oral argument on the summary judgment motions on July 16, 2009. On August 31, 2009, the Court issued an opinion and order, deciding that the Claim 19, the single claim at issue in both the '392 patent and the reissued patent, was non-obvious, denying the Defendants’ summary judgment motion, granting Plaintiffs’ summary judgment motion, and entered judgment in favor of Plaintiffs.

On September 15, 2009, Defendants filed a motion to vacate the judgment “to permit remainder of affirmative defenses and counterclaims to be tried,” alleging that a number of counterclaims and affirmative defenses remained at issue. On September 28, 2009, Defendants filed a notice of appeal to the Federal Circuit. Although the Court was under the clear impression that non-obviousness had been the sole remaining issue, it vacated its August 31 opinion, subject to reinstatement, in a decision issued October 30,

2009, held that it retained jurisdiction because the appeal to the Federal Circuit was premature, and directed the parties to file memoranda relating to the existence of any outstanding claims.

Plaintiffs and Defendants have each submitted memoranda and exhibits in reference to the Court's order of October 30, 2009. The Defendants assert that twelve affirmative defenses/counterclaims remain at issue in this case. These claims generally fall into three categories: noninfringement; invalidity; and inequitable conduct. Because of the numerosity of the Defendants' affirmative defenses/counterclaims and the Court's concern that the Defendants may be using their greater economic circumstances to increase the Plaintiffs' legal costs in this matter and thus pressure Plaintiffs to settlement, the Court has reviewed all filings, sealed and unsealed, in this matter, so that each of the Defendants' arguments could be subjected to scrutiny.

II. Non-Infringement (Count I)²

In each of their pleadings, Defendants raised, as a defense and as a counterclaim, that "[t]he '392 patent would not be infringed by a product made in accordance with the ANDA No. 078200 because an invalid patent cannot be infringed." (Answer, at 11, 17; Amended Answer, at 12, 18; Answer to Amended Complaint, at 14, 24.) Defendants now argue that the Court erred in finding that Defendants had conceded infringement, pointing in part to these affirmative defenses/counterclaims.

² Defendants submitted three sets of pleadings; certain counterclaims are numbered differently in the three sets of pleadings; wherever there is any inconsistency, this opinion refers to the number given to that counterclaim in the Defendants' answer to the amended complaint. Note also that the answer to the amended complaint refers to the "RE812 patent" rather than the "'392 patent."

In their papers, Defendants argue that actual non-infringement (i.e. whether the product to be made by Defendants would actually infringe the '392 and RE812 patent) remains at issue. However, in their pleadings, Defendants claimed that the non-infringement was "because an invalid patent cannot be infringed," not because the proposed product would not fall within the terms of the patent. This is, in itself, grounds for finding that this claim was never raised and that actual infringement was conceded. Moreover, Defendants did not raise these statements in pleading a counterclaim or an affirmative defense. Defendants do not raise a specific ground of non-infringement, and instead rely on broad language of patent invalidity, which is not in compliance with Rule 8 of the Federal Rules of Civil Procedure. Rule 8 requires that Defendants state in short and plain terms the defenses to claims asserted against it. Fed. R. Civ. P. 8(b)(1)(A). The defense must be simple, plain and direct. Broad claims of non-infringement due to invalidity do not preserve a claim of actual non-infringement under this standard. As stated in *Unigene Laboratories, Inc. v. Apotex Inc.*, No. 06-cv-5571, 2009 WL 2762706, at *15 (S.D.N.Y. Aug. 31, 2009), and in light of the Defendants' briefing on Plaintiffs' motion for a preliminary injunction in which they failed to raise a claim of non-infringement, the only conclusion to be reached was that the Defendants had conceded infringement.

Therefore, this affirmative defense/counterclaim is no longer at issue, and Defendants' claims to the contrary are denied.

III. Invalidity (Counts II, V)

Defendants concede that Count III (invalidity due to obviousness) was decided by this Court, and thus is no longer outstanding. (Def. Mem., at 6.) Defendants contend, however, that Count IV (invalidity due to lack of enablement) is outstanding, but they have affirmed to the Court that they “do not intend to assert lack of enablement.” (*Id.*) That claim is thus waived.

a. Count II: This counterclaim/defense was raised in each of Apotex’s answers. The Court reads: “The ‘392 patent is invalid under one or more provisions of 35 U.S.C. § 101, *et seq.*” (Answer, at 11, 17; Amended Answer, at 12, 18; Answer to Amended Complaint, at 14, 24.) This is a broad, general statement encompassing all defenses under the patent laws and does not comply with Rule 8(a)(2) or 8(d)(1) of the Federal Rules of Civil Procedure and absent further specificity is deemed waived.

b. Count V: This counterclaim/defense was raised in each of Apotex’s pleadings. The Court reads: “The ‘392 patent is invalid under 35 U.S.C. § 112, ¶ 2, for indefiniteness because the claims of the ‘392 patent are not reasonably discernable to one of ordinary skill in the art and, therefore do not particularly point out and distinctly define the scope of the invention.” (Answer, at 12, 18; Amended Answer, at 12, 19; Answer to Amended Complaint, at 14, 25.)

Plaintiffs argue, correctly, that this defense/counterclaim was not developed during discovery, which closed in February 2008. (Plaint. Mem., at 5-8.) However, the Defendants did not concede definiteness in their papers submitted prior to the *Markman* hearings. (Def. Exh. 11, at 2.) And during the *Markman* hearings, counsel for Defendants raised the specific argument that claim 19 of the patent was invalid due to indefiniteness. (Def. Exh. 12, at 2.) The Defendants raised indefiniteness in their

responses to the Plaintiff's interrogatories on August 30, 2007, describing their contentions: "Claim 19 of the patent-in-suit is invalid due to the patent applicant's failure to specify sodium chloride (NaCl) in the formulation for either that claim or Example 3, thereby violating 35 U.S.C. § 112." (Def. Exh. 7, at 10.) The Defendants are, of course, limited by their response to the contentions interrogatories. Count V, as constrained by the Defendants' response to the contentions interrogatories, cannot survive, because this Court has already held that Claim 19 does not reference or contain sodium chloride.

Unigene Laboratories, Inc. v. Apotex Inc., No. 06-cv-5571, 2009 WL 2762706, at *14 (S.D.N.Y. Aug. 31, 2009). And Example Three, which contains Table 3, has already been determined to have no material or fraudulent omissions. Opinion and Order (Feb. 4, 2008), at 14-18. Therefore, this Claim, as limited by the Defendants' responses to the contentions interrogatories, is barred by previous decisions issued by this Court.

IV. Inequitable Conduct (Counts VI, VII, VIII, IX, X, XI, XII, XIII and XIV)

Defendants contend that Count XV (misrepresentation by "teaching away") is outstanding, but they affirm to the Court that they do not intend to assert this counterclaim/defense, and it is thus deemed to have been waived. (Def. Mem., at 15.)

a. Count VI: This counterclaim/defense was raised in each of the Defendants' pleadings. (Answer, at 13, 18-19; Amended Answer, at 12, 18; Answer to Amended Complaint, at 14, 24.) This claim is that the patent is unenforceable due to Plaintiffs' materially, intentionally misleading statements that the citric acid range of 10 to 50 mM was essential for stability. (*Id.*) The amended answer does allege several specific instances of inequitable conduct: (1) Plaintiffs did not inform the USPTO that there was

data inconsistent with the information provided in Table 3 of the '392 and RE 812 patents, namely data showing that at room temperature there was no difference in stability between compositions of 10 mM and 100 mM of citric acid; (2) the same tables do not provide enough data to analyze stability using the Arrhenius equation; (3) Plaintiffs "intended to deceive the USPTO by not providing data comparing the stability of the '392 and RE812 patents' compositions to those of the '893 patent, nor any other patent cited by the USPTO;" (4) Plaintiffs knew of, but did not disclose, "data regarding the stability of calcitonin at 50 °C, measured at a pH in the range 3.70-3.76, in the presence of 10 mM and 100 mM citric acid, and was aware that this data was inconsistent with the results in Table 3 of the '392 and the RE812 patents;" and (5) Plaintiffs' assertion that 10 mM of citric acid "was critical as a lower limit" was not supported by the data in Table 3 of the patents. (Answer to Amended Complaint, at 27.) These claims were also generally described in the Defendants' responses to Plaintiffs' interrogatories on August 30, 2007, describing their contentions. (Def. Exh. 7, at 16, 21.)

The Court issued an order on a related matter when it decided the Defendants' motion to compel discovery ("the crime fraud decision"). The crime fraud decision dealt in part with whether the inclusion of an incorrect data point (the stability of salmon calcitonin after 15 days at 50 °C with 100 mM of citric acid) on the '392 patent's table 3 was material. The court concluded that that error was immaterial, because the correction to the table did not disturb the findings that stability was optimal with citric acid concentrations between 10 mM and 50 mM, with concentrations above this range being unstable. Opinion and Order (Feb. 4, 2008), at 15. The claim asserted by the Defendants in their answer to the amended complaint raises issues that are inextricably intertwined

with issues raised in the crime fraud matter (data problems in table 3). Moreover, it appears that the Defendants' claim of failure to disclose data inconsistent with table depends in part on the Miranda notebooks, and the Court has already determined that the Miranda notebooks do not contain data that contradicts table 3. *Id.*, at 17. For these reasons, the factual allegations underlying this claim should have been raised in the Defendants' motion to compel production of privileged documents pursuant to the crime-fraud doctrine. Their failure to do so constituted an abandonment of this claim.

b. Count VII: This claim was raised for the first time in the answer to the amended complaint. (Answer to Amended Complaint, at 15, 28.) The claim is that the patent is unenforceable due to inequitable conduct, namely failing to provide "data comparing the bioavailability of the '392 and the RE812 patents' compositions to those of the '893 patent, nor any other patent cited by the USPTO." (*Id.*, at 28.)

Plaintiffs assert that all defenses/claims raised for the first time in the answer to the amended complaint violate the scheduling order and should be stricken; this argument overlooks the fact that the scheduling order pre-dates the Court's decision to grant Plaintiffs' request to amend the complaint in light of the reissued patent. Order (July 1, 2009), at 1 (allowing Plaintiffs to amend the complaint). Thus, the scheduling order does not constitute a *per se* bar to the addition of new claims via the answer to the amended complaint.

Numerous cases, however, have held that "if an amended complaint does not change the scope or theory of a case, then the responsive pleading cannot add new theories either[;] . . . if the amended complaint adds new theories of recovery or changes the scope of the case, then the defendant is free to plead anew as if the prior pleadings did

not occur.” *GSI Group, Inc. v. Sukup Mfg. Co.*, 2007 WL 757819, at *2 (C.D.Ill. Mar. 08, 2007).³ The amended complaint merely added the reissue patent information and does not change the scope of the complaint. Therefore, the question is whether this claim, added for the first time in the answer to the amended complaint, adds a new theory to the case. The answer to the amended complaint does change the scope of the case dramatically, by asserting issues that could have, and indeed should have, been raised in the answer or amended answer to the original complaint. Moreover, the Plaintiffs sought and were granted leave to file pleadings outside the scheduling order, while the Defendants did not take these steps prior to filing pleadings not contemplated by the scheduling order. While there is evidence that Defendants had given some notice to Plaintiffs of this claim in their original ANDA letter, dated June 1, 2006, their answer was filed several months afterwards and contained no notice of this claim. (Def. Exh. 16, at 9-10.) Thus, it would appear to be abandoned. Defendants argue that they also raised this claim in their summary judgment papers, but this argument is misleading, as the passage they quote was actually an argument about obviousness, rather than inequitable conduct. (See Def. Exh. 17, at 18-19.) Defendants’ Count III adds a new theory to the case; the claim has been improperly brought and is thus not at issue.

c. Count VIII: This claim was raised in all of the Defendants’ pleadings. (Answer, at 14-15, 19-20; Amended Answer, at 16, 22-23; Answer to Amended Complaint, at 17-18, 28-29.) The claim is that the patent is unenforceable due to inequitable conduct on the part of the Plaintiffs, namely failing to disclose the ‘365 patent as material prior art. (Answer to Amended Complaint, at 28-29.)

³ See also *Uniroyal Chemical Co., Inc. v. Syngenta Crop Protection, Inc.*, 2005 WL 677806, at *2 (D.Conn. Mar. 23, 2005); *Pereira v. Cogan*, 2002 WL 1822928 (S.D.N.Y. Aug. 7, 2002); *Intermedics, Inc. v. Cardiac Pacemakers, Inc.*, 1998 WL 35253496, at *2 (D. Minn. Jul. 7, 1998);

This claim was not decided by the crime-fraud decision; instead, Plaintiffs claim that the Defendants abandoned this claim by not directing their discovery towards it. (Plaint. Mem., at 11-12.) Defendants did not raise this claim in their responses to Plaintiffs' interrogatories, describing their contentions. (*See* Def. Exh. 7, at 20.) Although their contentions reference the '365 patent, they provide no actual description of the Count VIII claim, and mention the '365 patent only as one of many potential examples of relevant prior art. Defendants are bound by their contentions interrogatory answers, and are required to "supplement or correct [their] . . . response [to an interrogatory] . . . in a timely matter if the party learns that in some material respect the disclosure is incomplete or incorrect" Fed. R. Civ. P. 26(e)(1) – 26(e)(1)(A). In this context, where there is substantial prejudice to the Plaintiffs – namely, not being advised of the contours of this claim until long after the termination of discovery and the filing of dispositive motions – the Defendants' failure to amend their contentions results in this claim being deemed waived. Fed. R. Civ. P. 37(b)(2)(A)(iii), 37(c)(1)(C).

d. Count IX: This claim was raised for the first time in the answer to the amended complaint. (Answer to Amended Complaint, at 18, 29.) The claim is that the patent is unenforceable due to inequitable conduct on the part of the Plaintiffs, namely "implicitly or explicitly asserting that none of the prior art shows the effects of citric acid concentration on bioavailability of calcitonin." (*Id.*, at 29.)

In their filings with the Court, Defendants argue that this claim was raised before the answer to the amended complaint, albeit not in any pleadings prior to answer to the amended complaint. The discovery material shows that Defendants had raised the facts underlying this claim of inequitable conduct and had, at least once prior to filing their

answer to the amended complaint, explicitly argued in interrogatories wherein they described their contentions, that the patent was unenforceable on the basis of this alleged inequitable conduct. (*See, e.g.*, Def. Exh. 7, at 21-22; Def Exh. 18, at 28-29; Def. Exh. 19, at 39-47.) Nevertheless, Defendants failed to move in a timely manner to amend their pleadings to add this claim. Therefore, the Court concludes that Count IX adds a new theory to this case and is not properly at issue in this case.

e. Count X: This claim was raised for the first time in the answer to the amended complaint. (Answer to Amended Complaint, at 18, 29.) The claim is that the patent is unenforceable due to inequitable conduct on the part of the Plaintiffs, namely “implicitly or explicitly asserting that none of the prior art suggests the effects of citric acid concentration on stability of calcitonin.” (*Id.*, at 29.)

Unlike Count IX, this claim was not developed or revealed in the Defendants’ answers to Plaintiffs’ interrogatories. (*See* Def. Exh. 7, at 21.) The underlying facts were raised by the Defendants’ expert declarations, but only in the context of whether or not the patent was obvious. (Def. Exh. 18, at 30-32; Def. Exh. 19, at 60-64; Def. Exh. 20, at 40-41.) Therefore, the Court finds that the claim in Count X adds a new theory to the case and is therefore not properly at issue in this case.

f. Count XI: This claim was raised for the first time in the answer to the amended complaint. (Answer to Amended Complaint, at 18-19, 29-30.) The claim is that the patent is unenforceable due to inequitable conduct on the part of the Plaintiffs, namely “failing to disclose errors in the claims of the ‘392 patent during prosecution of the RE812 patent,” specifically that claim 18 of the ‘392 patent “erroneously contained the term ‘about’ before ‘10 mM citric acid.’” (*Id.*, at 29-30.)

Defendants argue that they raised this as an issue in their briefings to the court on claim construction. (Def. Mem., at 11.) Instead, those briefings reveal that Defendants argued: (1) that the inclusion of the term “about” was “an inadvertent oversight,” and (2) that there was evidence that the patent examiner knew that the inclusion of the term “about” was an error. (Def. Exh. 21, at 19 n.12 (“In claim 18 of the ‘392 patent as issued the term ‘about 10 mM citric acid’ is present. However, there is nothing in the prosecution history of the ‘392 patent that indicates the inclusion of the term ‘about’ before ‘10 mM citric acid’ in claim 18 is anything other than an inadvertent oversight, since the examiner in the Notice of Allowability stated that ‘about’ was to be deleted. Claim 18 of the ‘392 patent should read ‘10 mM’ not ‘about 10 mM citric acid.’”)).) While that argument dealt with the ‘392 patent, these admissions apply also to Count XI (which deals with the Plaintiffs’ actions in the reissue application), as Count XI is premised on the theory that the plaintiffs misled the same examiner as to the proper construction of claim 18 of the ‘392 patent. Therefore, the Court concludes that Count XI is not at issue.

g. Count XII: This claim was raised for the first time in the answer to the amended complaint. (Answer to Amended Complaint, at 19-20, 30-31.) The claim is that the patent is unenforceable due to inequitable conduct on the part of the Plaintiffs, namely that the Plaintiffs knew of and failed to disclose “stability test results showing that stability of a liquid calcitonin pharmaceutical composition was greatest when the concentration of citric acid and/or its salts was 0 mM.” (*Id.*, at 30-31.)

It appears that Defendants did raise this claim, albeit in a very general manner, in their interrogatory responses describing their contentions, as provided in August 2007.

(Def. Exh. 7, 21 (“Applicant [made] false and/or erroneous statements during (and/or subsequent to) prosecution of the patent-in-suit arguing that the data contained in Tables 1 and 3 of the patent-in-suit, and underlying data used to create the Tables, establish the criticality of the range of about 10 to about 50 mM citric acid to the stability and/or bioavailability of the liquid calcitonin composition.”).) A general statement such as this in the interrogatories is insufficient to give notice of the theory or nature of Count XII and fails to and preserve this claim. Instead, this claim would add a new theory to the case. Therefore, the Court concludes that this claim was not properly raised in the Answer to the Amended Complaint.

h. Count XIII: This claim was raised for the first time in the Answer to the Amended Complaint. (Answer to Amended Complaint, at 20-21, 32.) The claim is that the patent is unenforceable due to inequitable conduct on the part of the Plaintiffs, namely failing to disclose the ‘014 patent to the U.S.P.T.O. during the prosecution of the ‘392 patent. (*Id.*, at 32.)

However, the Court already determined that the ‘014 patent was not material to the ‘392 patent in its crime fraud decision. Opinion and Order (Feb. 4, 2008), at 12. Therefore, this claim is barred by the Court’s crime fraud decision.

i. Count XIV: This claim was raised for the first time in the Answer to the Amended Complaint. (Answer to Amended Complaint, at 21-22, 32-33.) The claim is that the patent is unenforceable due to inequitable conduct on the part of the Plaintiffs, namely misleading the U.S.P.T.O by providing erroneous data in Table 3 of the ‘392 patent. (*Id.*, at 32-33.) The allegedly erroneous data was: (1) an erroneous entry for

stability after 15 days with 100 mM citric acid; (2) mislabeling the 25 mM column; and (3) mislabeling the first column (it should have said “1 mM” rather than “0 mM”). (*Id.*)

All three errors were disposed of in the crime-fraud opinion. *See* Opinion and Order (Feb. 4, 2008), at 14 n.8 (finding that a numerical error in the column headings of Table 3 constitutes a mere typographical error) and at 15 n.9 (showing a corrected Table 3). Accordingly, Count XIV raises a claim already decided and is rejected.

V. Conclusion

No claims remain at issue. The Court reinstates its opinion and order of August 31, 2009 in its entirety. Accordingly, judgment will be entered in favor of Plaintiffs.

IT IS SO ORDERED.

Dated: New York, New York

July 6, 2010



Robert P. Patterson, Jr.
U.S.D.J.

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