UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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UNIGENE LABORATORIES, INC. and
UPSHER-SMITH LABORATORIES, INC.,

Plaintiffs,

06 CV. 5571 (RPP)

- against -

OPINION AND ORDER

APOTEX INC. and
APOTEX CORP.,

Defendants.
----------X

ROBERT P. PATTERSON, JR., U.S.D.J.

Defendants Apotex Inc. and Apotex Corp. filed this motion to compel discovery by Plaintiffs Unigene Laboratories, Inc., and Upsher-Smith Laboratories, Inc., and seek to abrogate the attorney-client and work product privileges based on evidence of fraud. For the following reasons, Defendants' motion (Doc. No. 63) is denied.

BACKGROUND

A. Procedural Background

On August 27, 2002, the U.S. Patent and Trademark Office (the "PTO") issued U.S. Patent No. 6,440,392 (the "'392 patent"), entitled "Nasal Calcitonin Formulations." (Wayda Decl., Ex. A, cl.1.) Plaintiff Unigene Laboratories, Inc. ("Unigene"), is the owner of the '392 patent by assignment from Dr. William Stern, the sole inventor of the '392 patent. The patented calcitonin formulation is currently sold as a nasal spray under the trademark Fortical®.

Plaintiff Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), is a licensee of Unigene under the '392 patent with exclusive rights to market and distribute Fortical® in the United States. Prior to obtaining its license, Upsher-Smith engaged a patent attorney, Daniel Schulte, Esq., to perform due diligence with respect to the '392 patent. As a result of his search, Mr. Schulte provided approximately ten references, including U.S. Patent No. 6,087,338 (the "'338 patent") and U.S. Patent No. 5,912,014 (the "'014 patent"), to Ostrolenk, Faber, Gerb, and Soffen, LLP ("Ostrolenk"), the firm that had prosecuted the '392 patent for Unigene.

Upon receiving these references from Mr. Schulte, Ostrolenk became aware that the '338 patent might anticipate one of the claims of the '392 patent. (Wayda Decl., Ex. H, 65:3-24.) On February 5, 2004, Ostrolenk filed a reissue application of the '392 patent (Pokotilow Decl., Ex. S), canceling claims anticipated by the '338 patent and amending and adding other claims. Included with the reissue application was a new Information Disclosure Statement (id., Ex. T), which cites a number of relevant patents and publications. Among the cited patents was the '014 patent, also invented by Dr. Stern. (Id., Ex. T at Sheet 3 of 5.)

The reissue application is still pending at the PTO. On February 11, 2005 and March 7, 2007, the Examiner issued a first Office Action (Wayda Decl., Ex. J) and a second Office Action (id., Ex. L), rejecting all of the amended and new claims over a number of references on a variety of grounds, but not rejecting any of the pending reissue claims over the '014 patent (see id., Ex. J at 2-7 & Ex. L at 2-7). At oral argument, the Court was advised that the Examiner has continued to examine the claims in the reissue application, but has not yet based a rejection of a claim on the '014 patent.

On August 29, 2007, Dr. Stern and Mr. William Gray, Esq., of Ostrolenk interviewed with the Examiner. (Id., Ex. M at 14.) At the interview, Dr. Stern and Mr. Gray informed the Examiner of errors in the specification and tables of the '392 patent (id., Ex. M at 16), of which Dr. Stern has stated he first became aware while collecting documents for production in the instant litigation (id., Ex. C, 55:1-20, 88:0-89:24). Specifically, the Examiner was informed of an incorrect entry in Table 3 (id., Ex. M at 16), which represents the effect of various concentrations of citric acid on the shelf life of salmon calcitonin (id., Ex. A, cl.6, tbl.3). The number 20 was incorrectly entered instead of the number 52 for the percent salmon calcitonin recovered after fifteen days of storage at 50 ºC for the sample containing 100 millimoles (mM) of citric acid. (See id., Ex. M at 8.)

On September 7, 2007, Mr. Gray submitted an Amendment/Submission in response to the March 7, 2007 Office Action (Wayda Decl., Ex. M), accompanied by a second declaration of Dr. William Stern (id., Ex. N). In the Amendment/Submission, Mr. Gray corrected the errors in the specification and tables and substantively responded to each of the Examiner's rejections. (Id., Ex. M.) The Examiner has not yet responded to the September 7, 2007 submissions.

Defendant Apotex Inc. is a large Canadian pharmaceutical company that manufactures generic pharmaceuticals and distributes them in the United States. Its subsidiary, Defendant Apotex Corp., assists Apotex Inc. in obtaining U.S. Food and Drug Administration ("FDA") approval for the pharmaceuticals Apotex Inc. plans to manufacture and distribute. On or about June 1, 2006, Apotex Inc. submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking FDA approval to

engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Fortical® before the expiration of the '392 patent. (Compl. ¶¶ 21, 25.) The same day, Apotex Inc. sent a Certification Letter to Plaintiffs, pursuant to federal statute, advising that Defendants had submitted an ANDA for a salmon calcitonin nasal spray and stating the grounds on which Defendants believe the '392 patent is invalid and unenforceable. (Id. ¶¶ 24, 26.)

On July 24, 2006, Unigene and Upsher-Smith filed a complaint against Apotex Inc. and Apotex Corp. (collectively "Apotex"), claiming that Apotex is liable for the infringement of the '392 patent by virtue of its activities supporting its ANDA. The litigation is now in the discovery phase. Defendants assert that Plaintiffs, invoking the attorney-client privilege and work product privilege, have refused to produce certain documents in response to document requests and refused to answer many questions during depositions of Unigene's counsel, Upsher-Smith's counsel, and Dr. Stern. With the instant motion, Defendants seek to abrogate the attorney-client privilege and work product privilege based on the crime-fraud exception and to compel discovery by Plaintiffs of "all documents including [privileged documents] referring to, mentioning or relating to the prosecution of the '392 patent." (Defs.' Mem. Supp. Mot. Compel Disc. at 1.)

B. Description of the Relevant Patents

The '014 patent, entitled "Oral Salmon Calcitonin Pharmaceutical Products," is directed to enteric-coated solid pharmaceutical formulations comprising salmon calcitonin that are intended for oral administration. (Wayda Decl., Ex. F, cl.1.) The '392 patent, or the patent in suit, is directed to intranasal pharmaceutical formulations

comprising calcitonin and specific concentrations of citric acid or a salt thereof acting as both a stabilizer and an absorption enhancer. (Id., Ex. A, cl.1.) Both patents are directed to formulations containing the active ingredient salmon calcitonin, a peptide hormone used to treat a variety of bone-related diseases and calcium disorders, including osteoporosis. The '014 patent is directed to oral pharmaceutical compositions containing salmon calcitonin in tablet or capsule form (id., Ex. F, cl.1), while the '392 patent is directed to nasal spray formulations containing salmon calcitonin (id., Ex. A, cl.1). Both patents were invented by Dr. Stern and assigned to Unigene.

The main objective of the '014 patent is to overcome a significant problem of oral administration of salmon calcitonin—degradation of the calcitonin by proteolytic enzymes in the stomach and intestines that render the calicitonin ineffective before it can be absorbed into the bloodstream. (Id., Ex. F, cl.1.) As described in the '014 patent, the composition comprises (1) salmon calcitonin, (2) a pH-lowering agent, which reduces the degradation of salmon calcitonin by intestinal proteases, (3) an absorption enhancer, which aids the transport of the salmon calcitonin from the intestine to the bloodstream, and (4) an enteric coating capable of transporting the salmon calcitonin, pH-lowering agent, and absorption enhancer through the stomach while protecting the salmon calcitonin from degradation by stomach proteases, and releasing the salmon calcitonin, pH-lowering agent, and absorption enhancer in the intestine. (Id., Ex. F, cls.3-4.) The enteric coating protects the salmon calcitonin from degradation by stomach proteases which are most active at acidic pH, and the pH-lowering agent protects the salmon calcitonin from degradation by intestinal proteases which are most active at basic to neutral pH. (See id., Ex. F, cl.2; see also Oral Argument Tr., Nov. 6, 2007, at 39-40.)

The ‘014 patent lists citric acid as one of more than fifty pH-lowering compounds that can be used to lower the pH in the intestinal tract. (Wayda Decl., Ex. F, cl.5.)

The objective of the ‘392 patent is to provide a nasal formulation of salmon calcitonin that does not irritate the nasal passages and that optimizes both the stability (i.e., shelf-life) of the multiple-dose nasal spray applicator and the bioavailability (i.e., absorption into the bloodstream) of the calcitonin. (Id., Ex. A, cls.1-2.) The salient feature of the claimed invention is that citric acid or a salt thereof in a concentration from about 10 mM to about 50 mM increases the stability of calcitonin and enhances nasal absorption characteristics of calcitonin, thereby achieving the goal of maximizing both shelf-life and bioavailability levels. (Id., Ex. A, cl.2.)

DISCUSSION

A party seeking to vitiate the attorney-client privilege[1] based on the crime-fraud exception must make a prima facie showing that the privileged communication was made in furtherance of a crime or fraud. In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 807 (Fed. Cir. 2000) (holding that a prima facie showing of inequitable conduct, a lesser offense than “knowing and willful” fraud, is insufficient to vitiate the attorney-client privilege). Fraud in this context is common law fraud, also known as Walker Process fraud. See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) (holding that proof that a patentee has obtained a patent by “knowingly and willfully misrepresenting facts to the Patent Office” deprives a patentee of the antitrust immunity it would otherwise enjoy).

[1] The parties do not dispute that the documents and answers in depositions that Defendants seek are protected by the attorney-client privilege and the work product privilege. The Court agrees that they are indeed protected by these privileges.

Common law fraud exists where the following elements are present:

> "(1) representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation."

In re Spalding Sports Worldwide, Inc., 203 F.3d at 807 (quoting Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069-70 (Fed. Cir. 1998)).[2] A finding of common law fraud "'must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission.'" Id. (quoting Nobelpharma, 141 F.3d at 1070, 1071). Fraudulent omissions, as well as fraudulent misrepresentations, may support a finding of common law fraud. Nobelpharma, 141 F.3d at 1070. To state a prima facie case of common law fraud, the party seeking to vitiate the attorney-client privilege must present enough evidence to allow the Court to infer the fact at issue—i.e., the commission of fraud—and rule in the party's favor. See Black's Law Dictionary (8th ed. 2004).

Defendants contend that Unigene omitted and misrepresented material facts during the prosecution of the '392 patent with intent to deceive the PTO and that the '392

[2] The U.S. Patent and Trademark Office has provided the following definition of "materiality":

> [I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
> (i) Opposing an argument of unpatentability relied on by the Office, or
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2007); see also E. Am. Trio Prods., Inc. v. Tang Elec. Corp., 97 F. Supp. 2d 395, 403 (S.D.N.Y. 2000).

patent would not have issued but for the omission and misrepresentation. To make their prima facie case, Defendants specifically point to (1) Unigene's failure to cite the '014 patent in the initial prosecution of the '392 patent and (2) the error in Table 3 of Unigene's application for the '392 patent.

A. Failure to Cite the '014 Patent

In their first assertion to support a prima facie showing of common law fraud, Defendants allege that Dr. Stern of Unigene intentionally omitted a citation to the '014 patent, of which he must have had knowledge as its co-inventor, during the prosecution of the '392 patent. Defendants contend the '014 patent is material to the patentability of the '392 patent and that Dr. Stern would have known as much.

It is clear that Dr. Stern had knowledge of the '014 as its co-inventor. The questions are whether the '014 patent is material to the patentability of the '392 patent and whether Dr. Stern would have or should have known of its materiality. According to Defendants' expert Professor Alexander M. Klibanov, there are multiple reasons why these questions should be answered in the affirmative. First, both patents deal with forms of "transmucosal"[3] calcitonin delivery—oral in the case of the '014 patent, and nasal in the case of the '392 patent. (Klibanov Decl. ¶ 25.) And, according to an article[4] co-authored by J.R. Robinson (the "Robinson article") cited by Professor Klibanov, "conceptually similar . . . biological barriers limit the nasal and oral absorption of peptide drugs" such as calcitonin. (Id. ¶ 26). Second, although the '014 patent is directed toward solid formulations, it is material because it shows the effect of citric acid on the

[3] Transmucosal means entering through, or across, a mucous membrane.
[4] David Harris & Joseph R. Robinson, Bioadhesive Polymers in Peptide Drug Delivery, 11 Biomaterials 652 (1990).

bioavailability of salmon calcitonin and discloses liquid formulations in the cited experiments. (Id. ¶¶ 30-31.)[5] An examination of the patents, however, does not support these assertions.

The Robinson article does not establish the materiality of the '014 patent or that Dr. Stern should have known of its materiality. While the article describes three principal factors that make peptide pharmaceuticals difficult to administer through any route (Klibanov Decl., Attach. 2 at 652) and that must be considered when developing peptide pharmaceuticals generally, the article does not demonstrate that the barriers in the gastrointestinal system and the nasal cavity are biologically similar (see Kwan Decl. ¶ 52). According to Dr. Kwan, there are important differences between the nasal cavity and intestinal tract, particularly the different enzymatic environments and pH environments. (Id. ¶ 54.) The Robinson article acknowledges these differences: it describes the enzymatic degradation of peptide drugs in the gastrointestinal system as "possibly the biggest single obstacle to the development of orally-effective peptide delivery systems, although this enzymatic barrier is probably less significant in buccal, *nasal*, and ocular delivery." (Klibanov Decl., Attach. 2 at 657 (emphasis added).) Enzymatic degradation of calcitonin is the key problem the '014 patent seeks to overcome (see Wayda Decl., Ex. F, cl.1), but notably, the Robinson article "ignore[s] enzymatic degradation of peptide drugs" in its calculations because it is difficult to quantify and its effects are difficult to predict (Klibanov Decl., Attach. 2 at 657, 653). Defendants therefore cannot rely on the Robinson article to demonstrate the similarity

[5] Defendants' expert also contends that a person of ordinary skill in the art would understand that citric acid is a buffering agent and therefore can enhance the stability of formulations containing calcitonin by maintaining their pH at the optimal level. (Klibanov Decl. ¶ 42.) As this argument does not go directly to the materiality of the '014 patent to the '392 patent or the issue of fraud, it will not be addressed here.

between oral and nasal delivery of calcitonin or the materiality of the '014 patent to the '392 patent.

Defendants' contention that the '014 patent teaches the effects of citric acid on the bioavailability of salmon calcitonin is not supported by the patent. According to the '014 patent, citric acid does not significantly increase bioavailability; rather, absorption enhancers are necessary to increase bioavailability. Table 1 demonstrates that when salmon calcitonin is mixed with citric acid alone, the absolute bioavailability of calcitonin increases by less than 1% as the pH of the citric acid formulation is lowered from 5 to 3.[6] (Wayda Decl., Ex. F, cl.10, tbl.1.) Tables 2 and 3 demonstrate that when absorption enhancers are added to the formulation, the absolute bioavailability of salmon calcitonin increases by a significant degree, with either a marginally increasing or a constant amount of citric acid. (See id., Ex. F, cl.11, tbls.2, 3.) These data support the invention claimed in the '014 patent: citric acid lowers the basic pH environment of the intestinal region and thereby deactivates the intestinal proteases that would otherwise degrade the salmon calcitonin before the absorption enhancers can work to transport a therapeutically significant amount of salmon calcitonin through the intestinal mucus to the bloodstream. (Id., Ex. F, cls.5-6.) Defendants fail to show that the use of citric acid to lower the pH environment of the intestines is material to the bioavailability of calcitonin when administered through the nasal cavity.

Defendants next argue that Plaintiffs cannot credibly rely on the distinction between solid and liquid formulations to demonstrate the immateriality of the '014 patent to the '392 patent when the '014 patent discloses experiments in which a liquid

[6] Table 1 reports an increase in absolute bioavailability from 0.02% to 0.64% of salmon calcitonin in the bloodstream. (Wayda Decl., Ex. F, cl.10, tbl.1.)

formulation of salmon calcitonin and citric acid was directly injected into the duodenum[7] of a rat. (See Wayda Decl., Ex. F, tbls.1-5.) But, as Plaintiffs explain, such formulations are disclosed only in the context of "proof of principle" experiments intended to test the potential effects of the formulations once they have reached the duodenal region of the intestine. (Pls.' Mem. Opp'n Defs.' Mot. Compel Disc. at 15.) A liquid formulation of salmon calcitonin and citric acid was used only because it is impossible to inject powder into the intestine (Oral Argument Tr. at 42), and not because the '014 patent is directed toward liquid formulations.

Defendants' contention that the '014 patent is material because it teaches that citric acid affects stability also lacks support in the '014 patent. While Table 1 evaluates the effect of pH on bioavailability using a single concentration of citric acid and demonstrates an increase of less than 1% (Wayda Decl., Ex. F, cl.10, tbl.1), the effect of citric acid on stability was not determined in the '014 patent (Kwan Decl. ¶ 73; see Wayda Decl., Ex. F). Thus the '014 patent provides an insufficient basis on which to draw conclusions regarding the stability of salmon calcitonin in these formulations. (Kwan Decl. ¶ 73.)

The '014 patent is also immaterial, or at least cumulative, to the '392 patent because the formulations described in Tables 2, 4, and 5 of the '014 patent are considerably different than the formulations used in the '392 patent. For example, as Dr. Kwan pointed out, the concentrations of citric acid utilized in the '014 patent (100 mM to 802 mM) are significantly higher than those utilized in the '392 patent (10 mM to 50 mM), and the formulations used in the '014 patent contain substances not used in the '392 patent. (Kwan Decl. ¶¶ 69-70.) In view of these differences and those discussed

[7] The duodenum is the first part of the small intestine.

earlier, Defendants have not demonstrated the materiality of the '014 patent to the patentability of the '392 patent.

With respect to the element of intent, Defendants' unsupported allegation that Dr. Stern and Unigene intentionally omitted the '014 patent during the initial prosecution of the '392 patent is insufficient to state a prima facie case of fraud. In In re Spalding Sports Worldwide, Inc., the Federal Circuit made clear that "[a]lthough the party seeking to overcome the attorney-client privilege need not conclusively prove fraud, or necessarily submit direct evidence to make a prima facie showing of fraud, [a] mere allegation of [the patentee's] failure to cite a reference to the PTO will not suffice." 203 F.3d at 808 (holding that a patentee's invention record submitted to patent counsel and citing prior art undisclosed in the patent application was protected by the attorney-client privilege). Here, Defendants point only to the fact that Dr. Stern knew of the '014 patent, which he co-invented prior to the '392 patent, and failed to cite it in the '392 patent application.

Defendants argue that Dr. Stern's lack of credibility is demonstrated by his statement at his August 22, 2007 deposition that, at the time the '392 patent was being prosecuted, he believed the '014 patent was irrelevant to the invention claimed in the '392 patent because the '392 patent was directed to liquid formulations, not solid formulations. (See Wayda Decl., Ex. C, 27:20-28:3.) In view of the significant differences between the two patents and because liquid formulations were not taught by the '014 patent, Dr. Stern's statement is quite credible.

Defendants allege that Unigene's citation to the '014 patent in the reissue application "is hidden among a large number of patents in the Information Disclosure

Statement." (Defs.' Mem. Supp. Mot. Compel Disc. at 19.) This allegation, however, is also insufficient to pierce the attorney-client privilege. Cf. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1183-84 (Fed. Cir. 1995) (holding that patentee's disclosure of a material prior art reference to the PTO in a document containing numerous other prior art references after patent had issued was not inequitable conduct, where the reference was not mischaracterized, and the examiner initialed each reference in the reexamination proceeding and stated he considered all cited prior art). In Unigene's reissue Information Disclosure Statement, the citation to the '014 patent appears on the third page of only a five-page document and is not mischaracterized in any way. (See Pokotilow Decl., Ex. T; Wayda Decl., Ex. S.)

Defendants argue that Dr. Stern was obligated to call the Examiner's attention specifically to the '014 patent cited in the reissue Information Disclosure Statement. The Federal Circuit has rejected this same argument where the Examiner, as here, had the citation before him or her in the reissue application. See Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991) (rejecting the argument that the patentee should have brought an abstract cited in the prior art statement to the specific attention of the Examiner because "[w]hen a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner"). Defendants present no other evidence based on which the Court can infer that Dr. Stern or Unigene had fraudulent intent to withhold or bury reference to the '014 patent.

With respect to the element of reliance, it cannot be inferred that the '392 patent would not have issued but for the omission of a citation to the '014 patent in Unigene's

initial '392 patent application. The proceedings thus far in Unigene's pending reissue application weigh against a finding of reliance: the Examiner reviewing Unigene's reissue application has rejected a number of Dr. Stern's additional claims, but none of the rejections so far have been based on the '014 patent. (See Wayda Decl., Ex. J & Ex. L.) In an inequitable conduct case, the Federal Circuit held that "the result of a PTO proceeding that assesses patentability in light of information not originally disclosed can be of strong probative value in determining whether the undisclosed information was material." Molins PLC, 48 F.3d at 1179; accord In re Rhone-Poulenc Rorer, Inc., 1998 U.S. App. LEXIS 33103, *6 (Fed. Cir. 1998) ("To be sure, the fact that the JACS article was disclosed to the examiner in the reissue prosecution but did not lead the examiner to reject the application is relevant evidence favoring Rhone-Poulenc on the issue of materiality.") Although the reissue application is still pending in this case, there is no inference to date that the Examiner relied on the omission of a citation to the '014 patent in issuing the '392 patent.

B. The Errors in Table 3 of the '392 Patent

In their second assertion to support a prima facie showing of common law fraud, Defendants allege that Unigene intentionally misrepresented material data in Table 3 of the '392 patent. Specifically, Defendants contend that Table 3 intentionally misreports that only 20% of salmon calcitonin was recovered after fifteen days when stored at 50 ºC in a formulation containing 100 mM of citric acid, when in fact 52% of salmon calcitonin was recovered.[8] They argue that the '392 patent would not have issued but for this error.

[8] The other error is typographical: the heading of the fourth column of Table 3 should be 25 mM of citric acid instead of 20 mM of citric acid.

To demonstrate the materiality of the error in Table 3 of the '392 patent, Defendants point to the representation by Unigene's counsel that the range of 10 mM to 50 mM of citric acid in the formulation was essential to the claimed invention's patentability. (Defs.' Mem. Supp. Mot. Compel Disc. at 17-18.) Specifically, Unigene's counsel responded to the Examiner's rejection of a number of claims prior to the issuance of the '392 patent by stating that "citric acid concentrations between 10 and 50 mM were essential in improving the stability of a liquid calcitonin pharmaceutical composition since citric acid concentrations outside the claimed range (either higher or lower than the claimed range) were relatively unstable." (Pokotilow Decl., Ex. J at bate stamp 0226244.) According to Defendants, the range of 10 mM to 50 mM concentration of citric acid only appeared to be critical when the data point for 100 mM concentration of citric acid at 15 days misreported 20% recovery of salmon calcitonin, and it cannot be considered critical when the correct data point of 52% salmon calcitonin is entered.[9] (Oral Argument Tr. at 7-10.)

As noted by Plaintiffs' expert Dr. Kwan, even with the corrected data point, Table 3 as a whole still demonstrates that there is a significant, if less dramatic, decrease in shelf stability of salmon calcitonin when the amount of citric acid is increased to 100 mM

[9] Below is a reproduction of Table 3 of the '392 patent showing corrections of the errors.

EFFECT OF THE CONCENTRATION OF CITRIC ACID ON THE STABILITY OF sCT STORED FOR VARYING PERIODS AT 50º C (Percent sCT Recovered)					
Citric Acid (pH 3.7)	0 mM	10 mM	~~20~~ 25 mM	50 mM	100 mM
Days at 50º C					
0	100	100	100	100	100
3	83	94	91	90	87
6	53	90	87	83	77
9	24	82	78	73	66
15	22	74	68	61	~~20~~ 52

(See Wayda Decl., Ex. F, cl.6, tbl.2.)

from 50 mM. (Kwan Decl. ¶ 86.) The corrected Table 3 still supports the invention claimed in the '392 patent, which is that optimal stability and bioavailability of the salmon calcitonin nasal spray are achieved with citric acid concentrations between 10mM and 50 mM, and that citric acid concentrations above this range result in formulations that are "*relatively* unstable." (Pokotilow Decl., Ex. J at bate stamp 0226244 (emphasis added); see also Oral Argument Tr. at 67.) As Dr. Kwan stated, regardless of whether 20% or 52% recovery of salmon calcitonin is reported, the trend remains the same. (Kwan Decl. ¶ 87.) Thus the error, which is not inconsistent with the position Unigene has taken with respect to the patentability of the '392 patent, cannot be considered material.

Defendants argue nonetheless that the Examiner relied on the error in issuing the '392 patent. In support of their argument, they point to the Examiner's statement of reasons for allowance: "the prior art does not teach or suggest a liquid pharmaceutical composition containing calcitonin or an acid addition salt thereof and citric acid and/or salt thereof in a concentration from 10 to about 50 mM in a form suitable for nasal administration." (Pokotilow Decl., Ex. O at 2.) It cannot be inferred from this statement, however, that the Examiner was relying on the erroneous data point at 100 mM and not on the trend exhibited by Table 3 as a whole.

Defendants' allegation that Dr. Stern and Unigene misrepresented data in Table 3 of the '392 patent with intent to deceive the PTO is not supported by the evidence in the record to this point. To the contrary, the evidence tends to prove that this error was an honest mistake, though perhaps a careless one. Dr. Stern stated under oath that he did not discover the error in Table 3 until he reviewed data in preparation for his deposition.

(Wayda Decl., Ex. C, 55:1-20; 88:0-89:24.) The testimony of Dr. Stern's technical assistant, who helped run the experiment cited in Table 3, corroborates Dr. Stern's lack of knowledge of the error at the time the '392 patent was being prosecuted. The technical assistant testified that if anyone had discovered an error on a notebook page, a notation to that effect would have been written on the notebook page, and no such notations were made. (Id., Ex. V, 55:24-56:18.)

Nor is the error one that Dr. Stern should have known about because whether the entry is 20% or 52% recovery of salmon calcitonin, the data point indicates a drop-off in stability that is consistent with the pattern demonstrated by the rest of the data. Defendants' expert asserts that Dr. Stern nonetheless should have noticed that the 20% value was "grossly inconsistent" with the results of a prior experiment performed by Edgar Miranda, another scientist at Unigene. (Klibanov Decl. ¶ 53.) Contrary to what Professor Klibanov claims, Miranda's results did not "directly contradict[]" the data in Table 3 (see id. ¶ 49), but rather show the same trend with a less drastic drop-off, similarly to the corrected Table 3 (Kwan Decl. ¶ 89). To the extent that Dr. Stern was aware of the experiment, Miranda's results are not an adequate basis to determine that Dr. Stern knew or should have known of the error in Table 3.

Finally, when Dr. Stern became aware of the error in Table 3, he brought it to the attention of the Examiner of the reissue patent application. On September 7, 2007, Dr. Stern submitted a second declaration in which he explained that an "inadvertent error during automated data analysis resulted in an incorrect number being entered for the percent [salmon calcitonin] recovered in the last row and last column of original Table 3." (Wayda Decl., Ex N, ¶ 18.) He further explained why the error does not affect the

patentability of the '392 patent: "While the new number shows a lesser loss of [salmon calcitonin] than was originally reported, revised Table 3 continues to show that shelf stability of the nasal calcitonin formulation is reduced, independent of any pH effects, by increasing the concentration of citric acid and/or citric acid salt beyond certain low levels." (Id.) The declaration attached a revised Table 3 with the correct numbers. As Plaintiffs disclosed and corrected the error, and Defendants have shown no evidence of intent to deceive the PTO by initially misreporting the data, the Court finds insufficient evidence of fraudulent intent on the part of Plaintiffs to abrogate the attorney-client and work product privileges.

CONCLUSION

Defendants fail to make a prima facie case of fraud that would warrant compelling Plaintiffs to hand over the large number of privileged materials Defendants seek to discover. For the foregoing reasons, Defendants' motion to compel discovery (Doc. No. 63) is denied.

IT IS SO ORDERED.

Dated: New York, New York
February 4, 2008

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

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