IP 06-1642-C Y/K Alcon v Apotex
Magistrate Tim A. Baker Signed on 11/26/08

NOT INTENDED FOR PUBLICATION IN PRINT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ALCON MANUFACTURING, LTD, ALCON LABORATORIES, INC., KYOWA HAKKO KOGYO CO. LTD., Plaintiffs, vs. APOTEX INC., APOTEX CORP., Defendants.	)	NO. 1:06-cv-01642-RLY-TAB

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ALCON MANUFACTURING, LTD, et al.,	)	
	)	
Plaintiffs,	)	
	)	1:06-cv-1642- RLY-TAB
vs.	)	
	)	
APOTEX INC. et al.,	)	
Defendants.		

ORDER ON SEPTEMBER 26, 2008, DISCOVERY HEARING

I. Introduction.

This patent lawsuit raises several discovery issues, one of which involves an electronically produced document containing privileged information, which requires the Court to consider waiver issues under the new Federal Rule of Evidence 502 and the governing protective order.

The Court held a hearing on these matters on September 26, 2008, at which the parties presented evidence and argument regarding: (1) Plaintiffs' contention that Defendants delete or return the document containing privileged information; (2) Plaintiffs' contention that the document containing privileged information be stricken from the expert's report; (3) Defendants' contention that Plaintiffs should produce consent forms used in clinical trials; and (4) Defendants' contention that Plaintiffs should produce documents relating to what will be termed the '863 patent. Both sides submitted lengthy post-hearing briefs. [Docket Nos. 91, 92.] For the reasons set forth below, the Court finds: (1) all copies of the document containing privileged

information shall be deleted or returned to Plaintiffs and any references to it in any expert report shall be redacted; (2) Plaintiffs shall produce the consent forms used in the clinical trials; and (3) Plaintiffs shall produce documents relating to the '863 patent.

II. Discussion.

A. Use of Exhibit 71.

Plaintiffs contend that Defendants are in violation of the Court's May 18, 2007, protective order because Defendants refuse to return or destroy all copies of a privileged document (Deposition Exhibit 71) inadvertently produced electronically, and because Defendants distributed this document to one or more of its experts. Plaintiffs request the Court to compel Defendants to return the document and redact those portions of the expert witness report that rely upon the document. Defendants acknowledge that the document in question is privileged, but argue that the protective order is not applicable to this document; that even if the protective order is applicable, Plaintiffs have waived attorney-client privilege; and that the crime fraud exception applies to the privilege asserted in this instance.

1. Background.

Plaintiffs allege that Defendants' application to the United States Patent and Trademark Office ("PTO") seeking approval to manufacture and sell a generic version of an ophthalmic solution infringes Plaintiffs' U.S. Patent No. 5,641,805 ("the '805 patent") because this patent has not yet expired. [Docket No. ¶ 1.] Defendants contend that the '805 patent is invalid on several grounds, and they also contend that the '805 patent is unenforceable because it was obtained fraudulently and through inequitable conduct.

The privileged document at issue, Exhibit 71, is a "Publications/Presentations Release Form" for the publication entitled "The *in vitro* and *in vivo* Ocular Pharmacology of AL-4943A,

an Effective Anti-allergic/Anti-histaminic Agent." [Docket No. 91, Ex. O.] Exhibit 71 has attorney handwritten notes in the middle and at the top of the document. It was produced to Defendants as part of a group of electronically stored documents.

On January 29, 2008, Stella Robertson was deposed by counsel for Defendants on Exhibit 71. [Docket No. 91, Ex. P at 122:20 – 123:12.] After marking the document Exhibit 71, defense counsel asked Robertson if she recognized the document. She said she did not. Defense counsel asked if she recognized the handwriting at the top of the page. She said she did not. Defense counsel then marked Exhibit 72. During this twelve-line discussion pertaining to Exhibit 71, Plaintiffs' counsel did not object to the introduction of this document nor indicate that it had been inadvertently produced.

On February 6, 2008, defense counsel deposed Patrick Ryan, in-house counsel for Plaintiff Alcon. Defense counsel again introduced Exhibit 71 and asked Ryan about the handwritten notations at the top of the document. Ryan identified the handwriting as that of Jim Arno, Alcon's Vice President and intellectual property counsel, and the recipient as in-house counsel Julie Cheng (but later determined to be Dr. John Michael Yanni). [*See* Docket No. 91 at 21.] After an eight-minute break, defense counsel asked Ryan about the handwritten note in the middle of the page, which was signed by Ryan. At this point, Plaintiffs' counsel indicated that this writing may be privileged and moved to strike this notation. Plaintiffs' counsel did not at that time specifically identify the handwriting at the top of the document as being privileged.

Plaintiffs determined that the document was included on the privilege log as having notes written by Ryan (but not Arno), but the document had been inadvertently produced because of an electronic document break error. On February 11, 2008, Plaintiffs provided Defendants with a redacted version of the document, in which the handwritten notes by both Ryan and Arno were

omitted, and asked Defendants to destroy all copies of the document with the notations pursuant to the protective order signed by the parties. Defendants did not return or destroy the copies of the document with the notation, but instead provided copies of the document to its expert witnesses, one of whom relied upon it in his expert report.

2. Applicable Law.

For matters of procedural law not unique to the areas of law exclusive to Federal Circuit jurisdiction, the law of the regional circuit in which the case is filed applies. *Cygnus Telcoms. Tech., LLC v. Totalaxcess*, 345 F.3d 1372, 1375 n.3 (Fed. Cir. 2003). On the other hand, Federal Circuit law is applied where a determination regarding an attorney-client privilege issue implicates substantive issues of patent law. *See, e.g., In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 803-04 (Fed. Cir. 2000).

Defendants raise three arguments regarding Plaintiffs' assertion of attorney-client privilege over Exhibit 71: inapplicability of the protective order, waiver, and the crime fraud exception. In *In re Spalding Sports* the parties disputed production of the invention record. *Id*. at 804. The Court determined that "whether the invention record is protected by the attorney-client privilege [] is unique to patent law because the invention record relates to an invention submitted for consideration for possible patent protection." *Id*. at 804. The document disputed in the case at bar—a "Publications/Presentations Release Form" on which two attorneys made notes—does not so obviously involve substantive patent law, and the applicability of the protective order to and waiver of the document do not raise any issues "unique to patent law." Rather, these two arguments pertaining to privilege are more akin to the issues addressed in *In re Regents of the University of California*, 101 F.3d 1386 (Fed. Cir. 1996), where the Federal Circuit Court applied Seventh Circuit law because "whether a licensor and a licensee are joint

clients for purposes of privilege under the community of interest doctrine, was not unique to patent law." *In re Spalding*, 203 F.3d at 804. Therefore, Seventh Circuit law shall govern the issues of applicability of the protective order to and waiver of the document in question.

Defendants' crime fraud argument, however, does require considerations of the substantive merits of patent law. The crime fraud argument is premised on past representations to the PTO, the significance of those representations in the realm of patent law, and how the document in question relates to those representations. Because answering these questions involves considerations of substantive patent law and processes, Federal Circuit law governs Defendants' crime fraud argument.

3. Discussion.

(a) Applicability of the protective order.

Defendants first argue that the May 18, 2007, protective order issued by this Court does not apply to Exhibit 71, and that seeking removal of Exhibit 71 from the evidentiary record is misplaced. More specifically, Defendants argue that ¶ 20 of the protective order only requires "the return of inadvertently produced attorney-client communications . . . [not] for removal of deposition exhibits from the record." [Docket No. 91 at 16.] They argue that because "Exhibit 71 is now part of the deposition record and potentially the trial record," [Docket No. 91 at 16], Plaintiffs' recourse is to file a motion in limine, not enforcement of the protective order.[1]

[1] Ironically, Defendants also argue that "Plaintiffs complain about the disclosure of Exhibit 71 to [Defendants'] experts" but that "the document was marked confidential under the Protective Order" and therefore "[Defendants'] experts have and will continue to keep all contents of the document confidential" and "Alcon has suffered no prejudice or harm by the disclosure." [Docket No. 91.] If the Court accepts Defendants' argument that this document no longer falls under the protective order, then it is unclear why Defendants would need to continue to maintain confidentiality of the document. Furthermore, this argument fails to acknowledge the difference between documents marked confidential to be used only by certain persons and

Defendants' argument is without merit. The protective order governs "the pretrial disclosure and/or production of information, documents and tangible things in connection with the Action." [Docket No. 44 at ¶ 1.] Marking a document as an exhibit for purposes of a deposition does not make the document part of the trial record, as Defendants implicitly acknowledge by stating that Exhibit 71 is only *potentially* part of the trial record. Thus, the document is still only a "pretrial disclosure," and the protective order governs the inadvertent disclosure of this document.

(b) Waiver.

Defendants do not contest that the unredacted version of Exhibit 71 is privileged.[2] However, Defendants argue that Plaintiffs waived their right to assert privilege "by allowing the privileged handwriting at the top of the document to be used without objection at two separation depositions . . . ." [Docket No. 91 at 18.]

The law upon which Defendants rely seems to assume the success of their argument that the protective order does not govern this issue. For example, Defendants cite several cases to support the proposition that "[i]t is well-established that by permitting a document to be used and marked as an exhibit at a deposition, the disclosing party can waive all potential claims of privilege relating to that document." [Docket No. 91 at 18.] Of the five cases Defendants cite to

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documents that are privileged and therefore not to be used at all in litigation.

[2] The following exchange occurred at the September 26 hearing:

> The Court: . . . But there's no dispute, though, absent waiver, it's privileged a communication?
> Mr. Cwik: We're not disputing that.

[Docket No. 87 at 32:19-22.]

support this point, four either had no protective order or the protective order did not have a provision similar to ¶ 20 of this Court's May 18, 2007, order. *See FDIC v. Ernst & Whinney*, 137 F.R.D. 14, 19 (E.D. Tenn. 1991) (protective order addressed only confidential documents, not privileged documents); *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co.*, 132 F.R.D. 204, 209 (N.D. Ind. 1990) (no mention of a claw back provision as part of the protective order); *Edwards v. Whitaker*, 868 F. Supp. 226, 229 (M.D. Tenn. 1994) (no mention of a protective order); *Crossroads Sys. (Texas), Inc. v. Dot Hill Sys. Corp.*, 2006 WL 1544621, at *1-2 (W.D. Tex. May 31, 2006) (no mention of a protective order with a clawback provision).

Furthermore, the relevance of this case law may be questioned given the new Federal Rule of Evidence 502, which was enacted and became effective on September 19, 2008. Both parties rely on Rule 502(b), which provides the standard to be used to determine whether disclosure of a privileged document waives the privilege. However, this standard provides limited guidance given the language of Rule 502(d), which provides:

> A federal court order that the attorney-client privilege or work product protection is not waived as a result of disclosure in connection with the litigation pending before the court governs all persons or entities in all state or federal proceedings, whether or not they were parties to the matter before the court, if the order incorporates the agreement of the parties before the court.

The May 18, 2007, protective order has a provision that expressly addresses inadvertent disclosures of privileged documents. [Docket No. 44 ¶ 20.] The May 18, 2007, protective order provides:

> If a producing party inadvertently or mistakenly produces information, documents or tangible items in this Action that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice such claim or otherwise constitute a waiver of any claim of attorney-client privilege or work product immunity for such information, provided that the producing party promptly makes a good-faith representation that such production was inadvertent or mistaken and takes prompt remedial action to withdraw the

> disclosure upon its discovery. Within three (3) business days of receiving a written request to do so from the producing party, the receiving party shall return to the producing party any documents or tangible items that the producing party represents are covered by a claim of attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The receiving party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information; provided, however, that this Order shall not preclude the party returning such information from making a motion to compel production of the returned information on a basis other than a waiver because of its inadvertent production as part of a discovery production under this protective order. The producing party shall retain copies of all returned documents and tangible items for further disposition.

[Docket No. 44 at ¶ 20.]

Defendants cite *Golden Valley Microwave Foods*, 132 F.R.D. at 207, to support placing the burden on Plaintiffs to prove that their disclosure was truly inadvertent. However, the May 18 protective order requires only that the producing party "promptly [made] a good-faith representation that such production was inadvertent or mistaken." [See Docket No. 44 at ¶ 20.] Plaintiffs have provided the required good-faith representation. Plaintiffs told Defendants at the second deposition that the disclosure was inadvertent and provided Defendants with a letter on February 11, 2008, stating that it was inadvertent. Plaintiffs also previously included Exhibit 71 in the privilege log, and have explained that an electronic break error was the cause of the inadvertent production.

The Robertson deposition does not undermine Plaintiffs' good-faith representation that production of Exhibit 71 was inadvertent. At that deposition, Exhibit 71 was discussed for only a moment, and Robertson did not recognize the document or handwriting. Nothing further was mentioned about Exhibit 71 at that time. Fairness demands that this brief exchange cannot rise to the level necessary to call into question Plaintiffs' good-faith representation that they did not know about the inadvertent disclosure until the Ryan deposition. Furthermore, Defendants

admitted at the hearing that they have no evidence to dispute that the disclosure was inadvertent. [Docket No. 87 at 32:23 – 33:1.] Thus, Plaintiffs have—at the very least—established good faith as to their representation that the production was inadvertent and was not discovered until the Ryan deposition.

However, according to ¶ 20 of the protective order, before the receiving party is obligated to either return or destroy the privileged information, the producer also must have taken "prompt remedial action to withdraw the disclosure upon its discovery." In this regard, Defendants' citation to *Baxter Travenol Labs, Inc. v. Abbott Labs.*, 117 F.R.D. 119, 121 (N.D. Ill. 1987) is on point, but is distinguishable. In *Baxter*, there was a protective order in place stating that inadvertent disclosure of documents does not waive the privilege of those documents. The document in question in that case was first produced inadvertently amidst eight boxes of documents. It was thereafter specifically requested and produced without objection. The document was relied upon by the receiving party and attached to several legal memoranda submitted to the court before the producing party asserted privilege several months later. Thus, the court determined that the plaintiffs had waived the attorney-client privilege.

Defendants in the case at bar likewise argue that Plaintiffs cannot show that they promptly took remedial action to withdraw the disclosure. They note that Plaintiffs allowed Exhibit 71 to be marked and Robertson to be questioned without objection, and that Exhibit 71 was used again for several questions at Ryan's deposition before an objection was raised. Defendants also point out that they seek to use the handwritten note at the top of Exhibit 71 made by in-house attorney James Arno, which was not noted on the privilege log and was not specifically objected to until the February 11, 2008, letter.

This situation is distinguishable from *Baxter*. As compared with several months,

Plaintiffs in the case at bar asserted privilege of the document immediately upon discovering the inadvertent disclosure of the document. Within days of discovering the inadvertent disclosure, they more specifically asserted privilege over the handwriting at the top of the document. Also, Defendants did not rely on this document in any filings before the Court. In fact, it is reasonable to conclude that Defendants did not rely on Exhibit 71 at all until after Plaintiffs asserted privilege, when they distributed the document to their experts apparently without regard to the possible consequences.

It is true that Plaintiffs' counsel did not *immediately* assert privilege for every reason available. Significantly, counsel did not specifically object to the handwriting at the top of the page until several days after the second deposition. However, the handwriting on the privileged document—particularly the notation at the top of the sheet including the signature—is difficult to read. The handwriting at the top of the page is also rather similar to the handwriting in the center of the page, so on first glance both writings could easily be attributed to the same author. Failure by the attorney creating the privilege log to immediately recognize the handwriting at the top of the page as that of a different attorney is understandable. Likewise, the several-day delay Plaintiffs took after the Ryan deposition to review the document against its records, decipher the handwriting, and ascertain all communicators involved does not indicate a lack of prompt remedial action by Plaintiffs.

Concluding otherwise would undermine one of the main purposes of new Evidence Rule 502, which codifies the primary purpose of provisions such as ¶ 20 of the protective order in this case: to address the "widespread complaint that litigation costs necessary to protect against waiver of attorney-client privilege or work product have become prohibitive due to the concern that any disclosure (however innocent or minimal) will operate as a subject matter waiver of all

protected communications or information" which is "especially troubling in electronic discovery." Fed. R. Evid. 502 advisory committee's note. Perhaps the situation at hand could have been avoided had Plaintiffs' counsel meticulously double or triple-checked all disclosures against the privilege log prior to any disclosures. However, this type of expensive, painstaking review is precisely what new Evidence Rule 502 and the protective order in this case were designed to avoid.

Therefore, because Plaintiffs have complied with ¶ 20 of the protective order by making a good-faith representation that the disclosure was inadvertent and by taking prompt remedial action when they discovered the disclosure, Plaintiffs have not waived their privilege as to Exhibit 71.

(c) Crime Fraud Exception.

Defendants also argue that the privilege does not apply to the handwritten notations at the top of Exhibit 71 because the note indicates that Plaintiffs committed fraud on the PTO during the prosecution of the '805 patent. Defendants claim Plaintiffs improperly represented "that the compound claimed in their application possessed superior mast cell stabilizing activity as compared with the structurally similar compounds disclosed in U.S. Patent No. 4,923,892 ('the Lever patent')." [Docket No. 91 at 21.] Thus, Defendants argue that Plaintiffs committed fraud by claiming to the PTO that their compound had superior mast cell stabilizing activity, and that the handwriting at the top of Exhibit 71 demonstrates that Plaintiffs knew that the claim was false and made the misrepresentation intentionally.

The Federal Circuit Court requires that the following factors are generally necessary to a finding of fraud:

> (1) a 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, 203 F.3d at 807. Furthermore, "to invoke the crime-fraud exception, a party challenging the attorney-client privilege must make a *prima facie* showing that the communication was made 'in furtherance of' a crime or fraud." *Id*.

The writing at the top of the page is not excepted from privilege based on the crime fraud exception because Defendants cannot show that the representation of fact derived from the note at the top of Exhibit 71 is material or false. This note merely asks a question. The question seems to be directed toward the relationship between the products of Plaintiffs and Defendants, but the question does not clearly contain any assumptions or provide any answers. Defendants ignore this fundamental shortcoming and instead use select portions of the note to infer a definitive statement of knowledge that they claim is false based on other supporting documentation. However, the most accurate inference from a fair reading of the entire note is that the note's author contemplated whether a question being raised in this lawsuit might be an issue. Defendants have no reason to claim falsity regarding the fact that Plaintiffs knew there might be an issue regarding the '508 patent. Nor is the fact that Plaintiffs knew this possibility particularly material to ascertaining a resolution to this issue. Thus, Defendants fail to demonstrate that the privileged notations meet the first two requirements of the crime fraud exception so the crime fraud exception does not apply.

Accordingly, privilege applies to Exhibit 71. Defendants shall delete or return to Plaintiffs all copies of the unredacted version of Exhibit 71 and shall verify in writing to Plaintiffs such actions taken. Furthermore, the portion of Defendants' expert witness report

relying on these notes is hereby stricken. Defendants' shall have 30 days to serve an updated expert report consistent with this order.

B. Consent forms used in clinical trials.

Defendants contend that Plaintiffs should provide them with informed consent documents relating to clinical trials conducted in 1994. Plaintiffs argue that it need not produce these consent documents for several reasons. First, Plaintiffs argue that the public use defense was not properly pleaded so they were not given sufficient notice of the defense. One of Defendants' affirmative defenses is: "The '805 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112." [Docket No. 1 at ¶ 28.] Plaintiffs cite several cases from other jurisdictions to support the proposition that this affirmative defense is an insufficient "pleading of the statute." [Docket No.92.] These cases argue that, like in a complaint, simply citing to a statute provides insufficient notice. *See Sprint Commc'ns Co. v. Theglobe.com, Inc.*, 233 F.R.D. 615, 618 (D. Kan. 2006)*; PB Farradyne, Inc. v. Peterson*, 2006 WL 132182 at *2 (N.D. Cal. Jan. 17, 2006); *Qarbon.com Inc. v. eHelp Corp.*, 315 F. Supp. 2d 1046, 1049 (N.D. Cal. 2004).

These cases' reasoning is compelling, but the question of pleading is not before the Court. Plaintiffs have not moved to strike the affirmative defenses. Furthermore, there is no indication that Plaintiffs objected to Defendants Document Request No. 5 for "[a]ll documents concerning any use of the subject matter claimed in the '805 patent on or before the priority date" on the grounds that they did not receive fair notice of the public use defense. [*See* Docket No. 91 at 3-4.] Rather, Plaintiffs provided Defendants with consent forms for at least five other clinical trials relating to the '805 patent. [*See* Docket No. 91 at 4.] Thus, Plaintiffs cannot avoid

supplementing their response to these documents on the basis of lack of notice.

Plaintiffs also argue that these consent forms are not relevant to the issue of the public use affirmative defense. They argue that because the '805 patent used in these clinical studies was not used to treat allergic eye disease, but rather was used on asymptomatic individuals, these studies are not relevant as a matter of law to the public use exception. Plaintiffs cite *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 364 F. Supp. 2d 820, 913 (S.D. Ind. 2005), which states as a conclusion of law:

> The subjects of the Phase I clinical trials were normal volunteers who were not suffering from any disorder of the central nervous system and who were not receiving olanzapine for any pharmaceutical or medicinal purpose whatsoever. These were safety experiments. They were not "public uses" of the pharmaceutical invention claimed in the 382 patent.

The problem with relying on this conclusion of law is that the requisite finding of fact—whether these protocals were safety experiments only—has not yet been conclusively determined in the case at bar. Plaintiffs represent to the Court that these studies do not purport to treat allergic eye diseases, but Plaintiffs do not cite to the Court evidence necessary to justify this claim, and Defendants question the claim. [*See* Docket No. 92 at 34-36; Docket No. 91 at 6-7.] The Court cannot—based on Plaintiffs' representation only and without other evidence and argumentation—rule out that these tests are relevant or may lead to relevant evidence, particularly where other similar tests were produced by Plaintiffs. Therefore, denial on the basis of relevance is not justified.

Plaintiffs' argument that the requests for these studies are new requests rather than supplements to requests already made is tied to Plaintiffs' relevance argument. The initial request was made for "non-privileged documents *sufficient to show* any use by individuals not

employed by Alcon or Kyowa of the subject matter claimed in the '805 patent." [Docket No. 92 at 33.] Because Plaintiffs contend that these studies were conducted for safety only and do not demonstrate a use of the '805 patent, Plaintiffs contend that these documents do not fall within the category requested. As the Court already noted, it is not persuaded that the purpose and results of the tests in question are based on safety only. Therefore, the Court rejects this premise as the basis for determining that the request made by Defendants for these studies is new.

Finally, Plaintiffs argue that these studies were conducted by third-party investigators and that if the consent forms still exist, they are held by the third-party investigators. Defendants correctly point out that copies of the informed consent forms were supposed to be provided to the patients and to Plaintiffs, [*see* Docket No. 91, Ex. A], so even if Plaintiffs did not receive these forms, they are entitled to them.

In sum, the documents Defendants request are either relevant or likely to lead to relevant evidence; any alleged failure to adequately provide notice regarding the public use defense is unavailing; these requests reasonably fall within the scope of documents requested by Defendants prior to the close of discovery; and these documents—if they still exist—are within the custody and control of Plaintiffs. Therefore, Plaintiffs shall make reasonable efforts to obtain these documents, and to the extent these documents exist, Plaintiffs shall produce them to Defendants within 30 days of the date of this order.

C. Documents related to the '863 patent.

Defendants seek thousands of documents related to Plaintiffs' '863 patent. Defendants previously sought these documents in the fall of 2007, and this Court determined that Defendants were not entitled to these documents because the burden to produce them outweighed any relevance they might have to the case. The '863 patent is being challenged in another litigation

in which Plaintiffs are required to produce these documents, so the burden associated with producing them no longer exists. Nonetheless, Plaintiffs argue they need not produce these documents because they are not relevant. Defendants contend that these documents are relevant to determining whether one of ordinary skill in the art knew or expected that olopatadine—the basic drug used for both the '805 and '863 patents—would effectively treat allergic diseases in the eye prior to Plaintiffs' alleged invention. The parties dispute whether it was obvious that because olopatadine was effective on human skin, nose, or lungs (the subject of the '863 patent), that it would also be effective on the eyes (the subject of the '805 patent).

Defendants argue the documents they seek may contain citations and discussions related to relevant prior art references that would aid in determining the scope and content of the prior art. Defendants also argue that the documents may contain admissions by the researchers that they knew at the time that olopatadine would be expected to treat human eyes.

Plaintiffs contend that to the extent these documents have information pertaining to defining the scope of the prior art in this case, such information has already been disclosed. In support of this point, Plaintiffs state that before this case was filed Defendants sent a notice letter to Plaintiffs with a detailed description of the prior art on which they intended to rely. Plaintiffs also argue that any statements made by researchers in these documents are not relevant to the obviousness argument because they do not constitute prior art and the test for obviousness entails comparing the invention to prior art. Plaintiffs also argue that "the prior art must be interpreted from the perspective of the hypothetical person of ordinary skill in the art" and that "the hypothetical person of ordinary skill for the '805 patent has different characteristics and qualifications than are relevant for the '863 patent." [Docket No. 92 at 30-31.]

"An invention is unpatentable as obvious if the differences between the patented subject matter and the prior art would have been obvious at the time of invention to a person of ordinary skill in the art." *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1258 (Fed. Cir. 2007); *accord* 35 U.S.C. § 103(a). Plaintiffs' argument that Defendants have available to them all prior art based on the fact that Defendants sent Plaintiffs a letter describing the prior art on which they intend to rely is unpersuasive. The Court has no way to ascertain, based on this assertion, whether Defendants have all or even close to all prior art necessary to make the inquiry of obviousness. Likewise, Plaintiffs' argument that because the documents Defendants seek have not been published they are not prior art and therefore have no relevance at all is unpersuasive. This argument assumes this unpublished information also bears no relevance on the question of obviousness to a person of ordinary skill in the art because the hypothetical person of ordinary skill is different for the '805 and '863 patents. While this premise may be true to some extent, the skill sets for these two hypothetical persons—who were both working with the effect of olopatadine on the human body—would seem to overlap quite a bit. To the extent that they do overlap, any admissions by these researchers of the '863 patent may be relevant to the obviousness from the perspective of the person of ordinary skill in the art as to the '805 patent. Accordingly, Plaintiffs' argument that this information is not relevant nor reasonably calculated to lead to the discovery of admissible evidence fails, and Defendants are entitled to the documents related to the '863 patent. Plaintiffs shall produce these documents within 30 days of the date of this order.

IV. Conclusion.

For the foregoing reasons, the Court determines that within 30 days of this order: (1)

Defendants shall delete or return to Plaintiffs all unredacted copies of Exhibit 71, and shall verify in writing to Plaintiffs such actions taken; (2) Defendants may serve an updated expert witness report consistent with this order, given that the portion of Defendants' expert report relying on the privileged notes is stricken; (3) Plaintiffs shall produce the consent forms used in the clinical trials; and (4) Plaintiffs shall produce documents relating to the '863 patent.

Dated: November 26, 2008

/s/ Tim A. Baker

Tim A. Baker
United States Magistrate Judge
Southern District of Indiana

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