UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ALCON RESEARCH, LTD., ALCON LABORATORIES, INC., ALCON PHARMACEUTICALS, LTD., and KYOWA HAKKO KIRIN CO., LTD. Plaintiffs,	)	1:09-cv-102-RLY-TAB
vs.	)	
APOTEX, INC. and APOTEX CORP. Defendants.	)	

ENTRY ON PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON DEFENDANTS' AFFIRMATIVE DEFENSES AND COUNTERCLAIMS ALLEGING INEQUITABLE CONDUCT

This case arises out of the Abbreviated New Drug Application ("ANDA") filed by Apotex, Inc., and Apotex Corp. (collectively "Defendants"), with the United States Food and Drug Administration. Apotex seeks approval to manufacture and sell a generic version of Alcon's[1] Pataday™ ophthalmic solution, a prescription eye drop for the treatment of allergic eye disease. Use of the Pataday product, whose active ingredient is olopatadine, is protected by, *inter alia*, U.S. Patent No. 6,995,186 (the "'186 patent") and United States Patent No. 7,402,609 (the "'609 patent"). After receiving notice of

[1] Alcon Pharmaceuticals, Ltd. is the assignee of the '186 and '609 patents, Alcon Research is the exclusive licensee of the asserted patents, and Alcon Laboratories, Inc., sells drug products covered by these patents. (Complaint ¶¶ 30-33, 50-53). The court will refer to the Alcon plaintiffs collectively as "Plaintiffs" or "Alcon."

Apotex's ANDA, Alcon filed the present lawsuit[2] on February 2, 2009, alleging infringement of the '186 and '609 patents.

On September 22, 2010, Apotex filed an Amended Answer, Defenses and Counterclaims. Apotex's Fifth affirmative defense and Count V of its Counterclaim allege that the '186 and '609 patents are unenforceable because the patents were procured through inequitable conduct. Plaintiffs now move for summary judgment with respect to Defendants' inequitable conduct affirmative defenses and counterclaims. For the reasons set forth below, Plaintiffs' motion is **DENIED**.

I. Factual Background

A. Pataday

Pataday™ is an ophthalmic solution developed and sold by Alcon for the treatment of allergic eye disease. Pataday, which contains olopatadine at a concentration of 0.2%, is protected by the '186 and '609 patents.

Before the development of Pataday, Alcon developed and manufactured Patanol®, a drug remarkably similar to Pataday. Patanol, with an olopatadine concentration of 0.1%, is protected by the '805 patent, noted in footnote 1. The primary difference between these two pharmaceutical drugs is this: Patanol, with a 0.1% concentration of olopatadine, must be administered to the affected eye at least twice a day; Pataday, with

[2] As originally filed, this case included United States Patent No. 5,641,805 (the "'805 patent"). Kyowa Hakko Kirin Co. Ltd. is a co-owner of the '805 patent, and on that basis, was a plaintiff in this case. The claims of the '805 patent asserted in this litigation have been recently invalidated by the Federal Circuit. *Alcon Research, Ltd., et al. v. Apotex, Inc., et al.*, 687 F.3d 1362, 1369-70 (Fed. Cir. 2012), *cert. denied*, 569 U.S. __ (2013). Thus, the patents in dispute here are the '186 and '609 patents, and Kyowa Hakko Kirin no longer has an interest in this case.

twice the concentration of olopatadine, may be administered just once per day.

Olopatadine at 0.2% is not physically stable, meaning that it will not remain dissolved in solution. Over time, precipitants such as crystals or other particles will form in the solution. (Expert Report of Harry Brittain ¶¶ 32-33). The '186 and '609 patents claim the use of either of two polymers — polyvinylpyrrolidone ("PVP") or polystyrene sulfonic acid ("PSSA") — to enhance the physical stability of low viscosity[3] solution compositions containing olopatadine. ('186 patent, col. 16-18; '609 patent, col. 16).

B. The '186 Patent Prosecution History

Attorney Patrick Ryan filed United States Patent Application No. 10/175,106 ("the '106 application"), entitled Olopatadine Formulations for Topical Administration, which led to the '186 and '609 patents. The inventors listed on the application include, *inter alia*, Dr. Ernesto J. Castillo, Dr. Huixian Zhang, Haresh G. Bhagat, and Joseph Bullock.

As originally filed, the claims in the '106 application did not contain a limitation regarding the viscosity of the claimed compositions. ('186 Patent File History ("PH") at ALPD0005352-55). On June 29, 2004, the PTO Examiner issued an Office Action rejecting all pending claims as either anticipated or obvious over the '805 patent. In particular, the Examiner noted that the '805 patent disclosed "the use of olopatadine in a pharmaceutical composition for the treatment of allergic disorders of the eye," and that "[t]he addition of [PVP] is also taught by the above reference ['805 patent]." (*Id*. at ALPD0005671).

[3] Viscosity is the resistance of a solution to flow, and is measured in centipoise ("cps"). (*Id*. ¶ 31).

In response to the Office Action, Ryan met with Bhagat, as well as co-inventors Dr. Castillo and Bullock, to discuss how to respond to the Examiner's determination. (Deposition of Patrick Ryan ("Ryan Dep.") at 168-70). Ryan needed to distinguish the use of PVP on the basis that PVP was able to stabilize olopatadine solutions while maintaining a low viscosity. (*Id*. at 178-79, 181). To support this argument, the applicants needed data comparing the viscosities of stable olopatadine formulations containing PVP with formulations using other polymers such as polyvinyl alcohol (or "PVA"). Ryan asked Bhagat to generate viscosity data for the three formulations listed in Tables 3 and 4 of the '106 patent application, listed as Formulation H (with HPMC), Formulation I (with Carbopol 974P), and Formulation J (with PVA). (*Id*. at 183). Bhagat, in turn, requested Dr. Zhang to conduct the testing for the three requested formulations because she was more familiar with viscosity measurements than he. (Deposition of Haresh Bhagat ("Bhagat Dep.") at 143, 145, 149; Deposition of Huixian Zhang ("Zhang Dep.") at 111).

On July 13, 2004, Ryan requested an interview with the Examiner. (PH at ALPD0005684). In the request form, Ryan noted that he planned to offer arguments of "superior results not disclosed or predicted by the prior art." (*Id*.).

On August 11, 2004, Dr. Zhang conducted the testing as requested by Bhagat for PVA. (*See* Zhang Laboratory Notebook at ALPD0079674 ("Zhang Lab. Ntbk.")). The results showed three different viscosity data points for Formulation J (polyvinyl alcohol or PVA), which was comprised of 0.2% olopatadine formulation containing 1.8% PVA. (*Id*.; Bhagat Dep. at 168-69). As specified in the examples of the '106 application, Dr.

Zhang measured the viscosity of Formulation J with a Brookfield DV-1+ Viscometer using a CP42 spindle. (Zhang Lab. Ntbk.). The Brookfield viscometer has a variation of experimental data, or error rate, of 5%. (Zhang Dep. at 83-84). Dr. Zhang conducted the test at three different rotation speeds: 12 rpm, 30 rpm, and 60 rpm, and recorded the results in her laboratory notebook.

Formulation J (PVA)

RPM	Viscosity	Torque
12	2.05 cps	4.0%
30	2.10 cps	10.5%
60	2.00 cps	20%

(Zhang Lab. Ntbk.). Dr. Zhang believed that the 2.10 cps measured at 30 rpm and the 2.00 cps measured at 60 rpm were scientifically valid measurements of the viscosity of Formulation J. (Zhang Dep. at 113-14).

Dr. Zhang noted in her laboratory notebook, without any explanation, that only the 2.10 cps measured at 30 rpm should be reported, marking that data point with an arrow and a note that stated, "Report data." (*See* Zhang Lab. Ntbk.). At her deposition, Dr. Zhang did not recall why she singled out the 2.10 cps measurement at the time, could not explain why she chose to report the 2.10 cps measurement over the 2.00 cps measurement, or why she did not report both "valid" values. (Zhang Dep. at 116-18).

The day after Dr. Zhang obtained the viscosity data for PVA, she sent an email with an attachment to Bhagat, replying to an email chain that included an email from Ryan to Bhagat discussing the prosecution of the '106 application. (*See* Pls.' Privilege Log at 26, Entry ALPD0102227-28, at 56, Entry ALPD0107973-74 at 56-57, Entry

ALPD0107975-76). Bhagat, in turn, forwarded Dr. Zhang's email with the attachment to Ryan. (*Id*.). Dr. Zhang postponed signing her laboratory notebook until the day after she emailed Bhagat. (*See* Zhang Lab. Ntbk.). The substance of these emails was ruled to be protected by the attorney-client privilege by order of Magistrate Judge Baker. (*See* Docket # 182).

Relying on the viscosity data Dr. Zhang collected for PVA, Ryan asked Bhagat to submit a declaration to the PTO. (Ryan Dep. at 179-80). Ryan prepared the initial draft of Bhagat's declaration "after talking with [Bhagat] . . . to understand what he did and what the results were." (*Id*. at 181). Ryan then provided Bhagat with the 2004 Office Action, which set forth the lack of unexpected results as a reason for the rejection, and the initial draft of his declaration "for him to review and mark up and edit." (*Id*. at 181, 183). Bhagat added his personal information to the declaration and the technical information regarding olopatadine formulations – including the viscosity data for Formulations H, I, and J — found in paragraphs 6-9 of his declaration. (Bhagat Dep. at 134-35; PH at ALPD0005696-97). Bhagat and Dr. Zhang then exchanged emails. (*See* Pls.' Privilege Log at 26, Entry ALPD0102227-28, Entry at ALPD0102233-36).

On September 8, 2004, Bhagat reviewed and verified Dr. Zhang's laboratory notebook that contained the viscosity data for Formulation J (PVA). (*See* Zhang Lab. Ntbk.; Bhagat Dep. at 155, 169). In paragraph 6 of his declaration submitted to the PTO, Bhagat included only the 2.10 cps measurement, and omitted the 2.0 cps measurement and information on the error rate associated with the Brookfield viscometer. (PH at ALPD0005695-97).

On September 9, 2004, Ryan met with the PTO to discuss responding to the 2004 Office Action. According to the Examiner's notes, Ryan agreed to consider "amending the claims to the Jepson format and inserting specific viscosity, and the Office will consider the amendments favorably." (*See* PH at ALPD0005685). Ryan interpreted the Examiner's remarks as "a nonbinding indication . . . that at least as of that moment, if you provided those things [listed in the Interview Summary], [the PTO] wouldn't have any other basis for rejecting the case and would likely to [*sic*] give you an allowance." (Ryan Dep. at 166-67). The day after meeting with the Examiner, he and Bhagat exchanged emails. (*See* Pls.' Privilege Log at 26-27, Entry ALPD0102237-38, at 57, Entry ALPD0107977).

On September 10, 2004, Ryan responded to the June 29, 2004 Office Action by submitting an amendment to the pending claims to specify a viscosity of 1-2 cps. The amendment to claim 1 reads as follows:

> In a topically administrable solution composition for treating allergic or inflammatory disorders of the eye and nose comprising olopatadine and a polymeric ingredient, the improvement wherein the amount of olopatadine in the solution is 0.17-0.62% (w/v), the polymeric ingredient is a polymeric physical stability-enhancing ingredient consisting essentially of polyvinylpyrrolidone [PVP] or polystyrene sulfonic acid [PSSA] in an amount sufficient to enhance the physical stability of the solution, and wherein the composition has a viscosity of 1-2 cps and *does not contain polyvinyl alcohol* [PVA] . . . .

(*See* PH at ALPD0005689) (emphasis added). Ryan distinguished the '106 application from the '805 patent by noting that the '805 patent "provides no basis for selecting polyvinylpyrrolidone [PVP] over the other named viscosity-enhancing agents." (*Id.* at ALPD0005692). Unlike the '805 patent, the '106 application "is based on the finding

that [PVP] . . ., unlike polyvinyl alcohol [PVA] and the polyacrylic acid carbomer 974P, enhance the physical stability of solutions containing 0.17-0.62% olopatadine when the solutions have a viscosity of 1-2 cps." (*Id*. at ALPD0005693). In addition, Bhagat signed a declaration reporting that Formulations H, I, and J [PVA] have viscosities *greater than* 1-2 cps. (*Id.* at ALPD0005695-97).

Ryan relied on Bhagat's declaration to overcome the PTO's rejection and to support the patentee's argument that PVP provided superior results over other polymers, such as PVA, in enhancing the physical stability of a 0.2% olopatadine solution while maintaining a low viscosity. (Ryan Dep. at 179). The declaration reported the following viscosity data as measured by the Brookfield DV-I+ Viscometer:

Formulation	**Viscosity**	**Spindle**	**RPM**
Formulation H (HPMC)	1502 cps	CP53	6 rpm
Formulation I (Carbolpol 974P)	45.4 cps	CP42	6 rpm
Formulation J (PVA)	2.1 cps	CP42	30 rpm

(PH at ALPD0005696).

Based on Plaintiffs' September 10, 2004 response to the 2004 Office Action, the PTO issued a Notice of Allowance on December 22, 2004, and the '186 patent issued from the '106 application on February 7, 2006. (*See* PH at ALPD0005700-03).

C. The '609 Patent Prosecution History

On March 15, 2005, Ryan filed United States Patent Application No. 11/079,996 ("the '996 application"), entitled "Olopatadine Formulations for Topical Administration," naming, *inter alia*, Dr. Castillo, Dr. Zhang, Bhagat, and Bullock, as the co-inventors.

('609 Patent File History at ALPD0005742-79). The '996 application is a continuation of the '106 application and, among other things, shares the same specification as the '106 application, which resulted in the '186 patent. (*See id.* at ALPD0005902). After several exchanges between the PTO and Ryan, on February 9, 2007, the PTO issued an Office Action rejecting the only pending claim ("2007 Office Action"). Citing Formulations H (HPMC) and J (PVA) in Table 3, the PTO found that although "Applicant alleges criticality of the advantages of adding [PVP] to olopatadine in comparison with the other polymers used with olopatadine . . . Applicant has presented no evidence that the addition of PVP is advantages [sic] over the other polymers used with olopatadine . . . ." (*See id.* at ALPD0006235-36).

In an effort to overcome the Examiner's rejection, Ryan submitted: (1) an amendment to the pending claims to recite a solution having "a viscosity of 1-2 cps"; (2) remarks representing that "[i]n contrast to the 1-2 cps solution compositions recited in Applicants' claims (as currently amended), none of the compositions shown in Table 3 [including Formulation J] has a viscosity of 1-2 cps"; and (3) Bhagat's declaration, previously submitted during the prosecution of the '106 application, reporting that Formulations H, I, and J have viscosities greater than 1-2 cps. (*See id.* at ALPD0006242-50). The PTO eventually issued a Notice of Allowance on July 2, 2008, and the '609 patent issued from the '996 application on July 22, 2008. (*See id*. at ALPD0006345-48).

All other facts necessary to a fair determination of this motion will be addressed in the Discussion Section.

II. Summary Judgment Standard

Summary judgment is appropriate if the record "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A factual dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is material if, under the substantive law, it could affect the outcome of the suit. *Id.*; *see also Payne v. Pauley*, 337 F.3d 767, 770 (7th Cir. 2003) (noting that summary judgment is not appropriate if a reasonable jury could return a verdict in favor of the nonmoving party).

In determining whether a genuine issue of material fact exists, the court construes the facts in the light most favorable to the non-moving party and draws all reasonable inferences in favor of that party. *Heft v. Moore*, 351 F.3d 278, 282 (7th Cir. 2003) (citing *Anderson*, 477 U.S. at 255). The moving party bears the burden of demonstrating the "absence of evidence on an essential element of the non-moving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If the moving party meets its burden, the non-moving party may not respond by simply resting on the pleadings, but must demonstrate by specific factual allegations that a genuine issue of material fact exists for trial. *Green v. Whiteco Industries, Inc.*, 17 F.3d 199, 201 (7th Cir. 1994) (citing *Celotex*, 477 U.S. at 322).

III. Inequitable Conduct Standard

"Patent Applicants are required to prosecute patent applications with candor, good faith, and honesty." *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d

1368, 1373 (Fed. Cir. 2000); *see also Molins PLC v. Textron, Inc*., 48 F.3d 1172, 1178 (Fed. Cir. 1995). Attorneys, agents, and applicants who have applications pending before the PTO have an uncompromising duty to report all facts concerning possible fraud or inequitable conduct underlying the application. *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 818 (1945); *see also* 37 C.F.R. § 1.56(a) (2012) (stating that the duty of candor extends to "[e]ach individual associated with the filing and prosecution of a patent application"). If a patent applicant violates these duties, the entire patent may be held unenforceable due to inequitable conduct. *Therasense, Inc. v . Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (characterizing the remedy for inequitable conduct as the "atomic bomb" of patent law).

"Inequitable conduct includes affirmative misrepresentations of material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1359 (Fed. Cir. 2005) (internal quotations and citations omitted). To prevail on a claim alleging the nondisclosure of information, as in this case, "the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Therasense*, 649 F.3d at 1290. Materiality and intent are separate elements that must be proven independently of the other. *Id*.

Undisclosed information is material if "the PTO would not have allowed a claim had it been aware of the undisclosed [information]." *Id*. at 1291 (explaining that "the materiality required to establish inequitable conduct is "but-for" materiality). In addition,

the accused infringer must prove not only that the applicant knew of the material nature of the withheld information, but acted with the specific intent to deceive the PTO. *Id.* at 1290. "A finding that the misrepresentation or omission amounts to gross negligence or negligence under a 'should have known' standard does not satisfy [the] intent requirement." *Id*. (citing *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)). Instead, the specific intent to deceive "'must be the single most reasonable inference able to be drawn from the evidence.'" *Id*. (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)). Because evidence of intent to deceive is rarely available, such intent may be inferred from indirect and circumstantial evidence. *Id*. (citation omitted).

IV. Discussion

Although this motion was filed by the Plaintiffs, the court will begin its discussion with the theory underlying Defendants' inequitable conduct affirmative defenses and counterclaims, which the court will refer to, for simplicity's sake, as Defendants' inequitable conduct claims.

According to Defendants, the testing performed by Dr. Zhang reflected no significant difference between the viscosity of PVP as compared to PVA; therefore, PVP was not "unexpectedly superior" to PVA in stabilizing olopatadine in 0.17-0.62% solution. At this juncture, the language of claim 1 bears repeating:

> In a topically administrable solution composition for treating allergic or inflammatory disorders of the eye and nose comprising olopatadine and a polymeric ingredient, the improvement wherein the amount of olopatadine in the solution is 0.17-0.62% (w/v), the polymeric ingredient is a polymeric physical stability-enhancing ingredient consisting essentially of

> polyvinylpyrrolidone [PVP] or polystyrene sulfonic acid [PSSA] in an amount sufficient to enhance the physical stability of the solution, and wherein the composition has a viscosity of 1-2 cps and *does not contain polyvinyl alcohol* [PVA] . . . .
>
> (*See* PH at ALPD0005689)

Defendants' claims are premised on the omission of two key pieces of information during prosecution of the asserted patents. First, Defendants contend that the Applicants (Ryan, Dr. Zhang, and Bhagat) only reported the viscosity data for Formulation J (PVA) that was favorable to patentability (2.1 cps), and intentionally failed to disclose the viscosity data for Formulation J that was unfavorable to patentability (2.0 cps). Second, Defendants contend that the Applicants intentionally failed to disclose that the specific error rate for a Brookfield viscometer is 5%. Had the Applicants done so, say the Defendants, Formulation J (PVA at 2.0 cps) would have fallen within the statistically valid viscosity range of between 1.995 and 2.205 cps — overlapping with the claimed viscosity range in the asserted patents (between 1-2 cps). (*See* '186 patent, col. 16, ll:30-31; '609 patent, col. 16, ll:4-5).

For purposes of this motion, the parties agree that the viscosity value for Formulation J (PVA) at 2.1 cps was material to patentability. Thus, the merits of Defendants' inequitable conduct claims hinge on intent. On this point, Plaintiffs note that "a district court may not infer intent solely from materiality." *Therasense*, 649 F.3d at 1290.

In support of their motion, Plaintiffs argue the Applicants worked in isolation, unaware of what the other was doing or why. This is best exemplified by the following:

(1) Dr. Zhang, a named inventor of the ‘186 and ‘609 patents, claims she did not know why she was asked to conduct the viscosity test of Formulation J (PVA), (Zhang Dep. at 116); (2) Dr. Zhang claims she does not know why she provided the 2.1 cps data point for Formulation J to Bhagat, instead of the 2.0 data point, even though both values were scientifically valid, (*id*. at 116); (3) Bhagat, a named inventor of the ‘186 and ‘609 patents, who was also involved in prosecuting the patents, claims that the purpose of verifying Dr. Zhang’s test results was simply to verify that the experiments were conducted in the manner described in Dr. Zhang’s laboratory notebook page, (Bhagat Dep. at 165-66); (4) Ryan, who on behalf of Alcon was prosecuting the patent, claims the only data he received regarding the viscosity of Formulation J was the 2.10 cps data point provided by Bhagat, (Ryan Dep. at 190-92); (5) Plaintiffs claim there is no evidence that Bhagat and Dr. Zhang had knowledge that Ryan was adding the limitation “wherein the composition has a viscosity of 1-2cps” to the patent claims; and (6) Bhagat claims he did not mention the statistical error rate of 5% in his declaration to the PTO, because such information is “understood” by those “knowledgeable about using the instrument and dealing with viscosity measurements,” (Bhagat Dep. at 161). Relying principally on the Federal Circuit’s *en banc* decision in *Therasense*, Plaintiffs argue that the *only* reasonable inference to be gleaned from these facts is that the Applicants did not fail to disclose the viscosity data of Formulation J [PVA] with the specific intent to deceive.

In *Therasense*, the Federal Circuit “tighten[ed] the standard for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.” *Id*. at 1288-90 (noting that, for example, “the inequitable conduct doctrine

has plagued not only the courts but also the entire patent system"). "Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive." *Id*. at 1290. Instead, to meeting the clear and convincing evidence standard, "the specific intent to deceive must be "'the *single most reasonable inference* able to be drawn from the evidence.'" *Id*. (quoting *Star Scientific*, 537 F.3d at 1366) (emphasis added). *Therasense*, however, was an appeal from a bench trial, and sets forth the standard for *proving* inequitable conduct at trial. Indeed, the opinion is replete with references to "the evidence," to "the burden of proof," and to what is necessary to "prevail on a claim." The court's function in that instance is to determine the facts and apply the law to those facts.

In marked contrast, this case is before the court on Plaintiffs' motion for summary judgment. To prevail, Plaintiffs have the burden of establishing the absence of an essential element of Defendants' case in accordance with the applicable standard of review. *Celotex Corp.*, 477 U.S. at 325; *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1319-20 (Fed. Cir. 2010). In other words, the inquiry is whether, viewing the evidence in the light most favorable to the Defendants, no reasonable trier of fact could find the Applicants acted with the specific intent to deceive the PTO. "'Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.'" *Astrazeneca Pharm. v. Teva Pharm.*, 583 F.3d 766, 777 (Fed. Cir. 2009) (granting summary judgment where threshold facts did not establish materiality and intent) (quoting *Dayco Products, Inc. v. Total Containment, Inc*., 329 F.3d 1358, 1367 (Fed. Cir. 2003)). *See also Morningware, Inc. v. Hearthware Home*

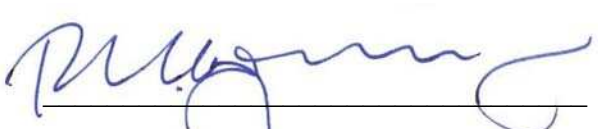
Products, Inc., 898 F.Supp.2d 1018, 1043 (finding disputed issue of fact existed "with respect to the intent prong of the *Therasense* analysis, which is a fact-sensitive inquiry"); *see also Mitsubishi Heavy Indus., Ltd. v. General Elec. Co.*, 2012 WL 4336208, at * 4 (M.D. Fla., Sept. 21, 2012) (finding disputed issue of fact on the issue of intent, and citing *Therasense*).

In light of the standard on summary judgment, the court finds a reasonable trier of fact could conclude the testimony of Ryan, Bhagat, and Dr. Zhang is not plausible in light of their roles in the prosecution of the patent, the email traffic amongst the three of them during the relevant time frame, and by the simple fact that neither Ryan, Dr. Zhang, nor Bhagat can explain why the 2.1 cps viscosity value for Formulation J was chosen over the 2.0 viscosity value, even though Dr. Zhang opined that both values were scientifically valid, nor why the Examiner was not informed of the potential error rate of 5%. Bhagat claims that the error rate was not reported because, to those knowledgeable and well-versed in the science of viscosity testing, it is just "understood" that there is an error rate. There is no evidence in this record, though, establishing that a PTO Examiner would be such a person well-versed in viscosity testing. A reasonable trier of fact could therefore conclude that in order to gain allowance of the asserted patents, Ryan, Dr. Zhang, and Bhagat, individually or in concert with one another, made a deliberate decision to withhold the 2.0 viscosity data of Formulation J from the Examiner, and/or made the deliberate decision to withhold the Brookfield viscometer error rate of 5%. Accordingly, Plaintiffs' motion for summary judgment is **DENIED**.

V. Conclusion

For the reasons set forth above, Plaintiffs' Motion for Summary Judgment (Docket # 162) is **DENIED**.

SO ORDERED this 21st day of May 2013.



RICHARD L. YOUNG, CHIEF JUDGE
United States District Court
Southern District of Indiana

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