

[D.I. 146]

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

BAYER CROPSCIENCE AG,

Plaintiff,

v.

DOW AGROSCIENCES LLC,

Defendants.

Civil No. 10-1045 (RMB/JS)

OPINION AND ORDER

This matter is before the Court on defendant Dow Agrosciences LLC's ("DAS") "Motion for Leave to File an Amended Answer." [D.I. 146]. DAS seeks to amend its answer to assert an inequitable conduct counterclaim and related affirmative defenses. The Court received the response of plaintiff Bayer Cropscience AG ("Bayer"), DAS's reply, and held oral argument. For the reasons to be discussed, DAS's motion is DENIED.

Background

By way of brief background, Bayer filed this patent infringement lawsuit regarding its '401 patent on December 3, 2010, and DAS filed its answer with counterclaim on May 6, 2011. On December 30, 2011, the Honorable Renée Marie Bumb granted in part and denied in part Bayer's motion to strike DAS's fifth and seventh affirmative defenses and third counterclaim. See December 30, 2011 Opinion and Order, D.I. 127, 128, 2011 WL 6934557. As to DAS's

fifth affirmative defense raising equitable estoppel, the motion was granted. Judge Bumb ruled that the defense was not pleaded with particularity as required pursuant to Fed. R. Civ P. 9(b). As to DAS's seventh affirmative defense alleging patent misuse, Bayer's motion was denied. However, Judge Bumb held that if DAS intended to rely on a patent misuse claim that implicates fraud, it needed to re-plead the defense with particularity. DAS's third counterclaim for a declaratory judgment of unenforceability was premised on the claim that the '401 patent was invalid due to equitable estoppel, patent misuse and prosecution history estoppel. To the extent the counterclaim was based on equitable estoppel, it was dismissed without prejudice because of DAS's failure to offer the particularity required by Fed. R. Civ. P. 9(b) for claims sounding in fraud. Bayer's request to dismiss the patent misuse and prosecution history estoppel claims was denied.

DAS's motion seeks to add the affirmative defense of inequitable conduct, to re-plead the affirmative defense of equitable estoppel, to amend the existing patent misuse affirmative defense, and to amend the existing counterclaim for a declaratory judgment of unenforceability. DAS Opening Brief ("Brief") at 1. At oral argument the parties agreed that these amendments rely on the same core set of facts and the claims and defenses rise or fall

together.¹

DAS's proposed amendment is based on the conduct of Dr. Kenneth N. Timmis, a named inventor of the '401 patent. The sum and substance of DAS's claim is that Timmis failed to disclose to the PTO relevant information in his possession before the '401 patent issued. DAS avers that "but for" Timmis's failure to disclose this material information, the claims of the '401 patent as written would not have issued. Proposed Amended Answer ("PAA") ¶¶44, 48.d.

The withheld information at issue relates to claim 1 of the '401 patent that recites the term "biological activity of 2, 4-D monooxygenase." DAS avers that the remaining claims of the '401 patent depend from claim 1 and, therefore, also include the

¹ As will be discussed in more detail herein, the reason DAS's amendments rise or fall together is because they are all premised on the allegation that Bayer committed fraud, e.g., it acted with the specific intent to deceive the United States Patent and Trademark Office ("PTO"). If the fraud allegation is not properly pled pursuant to applicable Federal Circuit precedent, DAS's amendment must be denied as futile. See Delano Farms Co. v. California Table Grape Com'n., 655 F.3d 1337, 1350 (Fed. Cir. 2011). ("A charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if the plaintiff's complaint recites facts from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO.") Notably, Delano Farms does not distinguish between a counterclaim and affirmative defense raising inequitable conduct. This Opinion does not take issue with Judge Bumb's ruling that "this Court does not apply Twombly/Iqbal to affirmative defenses." 2011 WL 6934557, at *4. The same is true for the ruling that there is no "enhanced pleading requirement applicable to patent misuse claims." Id.

limitation of "biological activity of 2, 4-D monooxygenase." Id. ¶37. DAS also avers that the written description of the '401 patent describes only the disclosed gene--the *tfdA* gene--as a monooxygenase. Id. ¶38. However, DAS avers that while the '401 patent application was pending, Timmis was one of the authors of a June 1995 published paper revealing that the *tfdA* gene encoded a dioxygenase, not a monooxygenase. According to DAS, Timmis "deliberately withheld this information with a specific intent to deceive the PTO." Id. ¶¶45, 48.b.

Bayer opposes DAS's amendment on futility grounds and asserts two main arguments. Bayer first argues the withheld information was not material to the patent examiner during the prosecution of the '401 patent. Bayer contends the patentability of the claims did not depend on the distinction between a "monooxygenase" and a "dioxygenase." Bayer argues this is true because the patent defines "the biological activity of 2, 4-D monooxygenase" as the ability to "cleave the side chain" of the herbicide 2, 4-D. Answering Brief ("AB") at 2. Bayer further argues the exact mechanism of action of the enzyme (how it cleaves the side chain of 2,4-D) or the name given to the enzyme is not relevant to the patentability of the invention. Id. Bayer also argues its nomenclature is not wrong. Bayer alleges DAS's argument is based on a misreading of the prosecution history "that cannot possibly be accepted." Id. at 3. Bayer argues that since DAS's arguments are

futile, DAS cannot show that "but for" the fact Timmis withheld the referenced information the '401 patent would not have issued.

Bayer's second main argument is that DAS's defense is futile because it does not adequately allege a specific intent to deceive the PTO. Bayer argued in its Brief that its alleged specific intent to deceive the PTO is not the single most reasonable inference to draw from the evidence. AB at 18-19. Bayer did not pursue this defense at oral argument. Albeit, Bayer still argues DAS did not sufficiently plead that it intended to deceive the PTO.

Also relevant to this background discussion is the fact that Bayer recently filed a Motion for Partial Summary Judgment on DAS's Infringement of Claims 1-3 and 8 of the '401 Patent [D.I. 111] and DAS filed a Motion for Summary Judgment of Non-Infringement [D.I. 218].² Oral argument on the motions as well as the Markman hearing will be held in June 2012.

Discussion

As noted, Bayer argues DAS's amendment should be denied as futile. In determining futility the Court applies the same standard of legal sufficiency as applies under Rule 12(b)(6). In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997). The Court must accept as true all well pleaded allegations in the proposed amendment and reasonable inferences to

² DAS also filed a Motion for Partial Summary Judgment that Claims 4 and 5 are Invalid Because they are Indefinite [D.I. 220] and a Motion for Summary Judgment of Invalidity for Failure to Satisfy the Written Description Requirement of 35 U.S.C. §112, Paragraph 1 [D.I. 241].

be drawn from them. Brown v. Phillip Morris Inc., 250 F.3d 789, 796 (3d Cir. 2001). The factual allegations must be enough when taken as true to state a claim for relief plausible on its face. Bell Atlantic Corp. v. Twombly, 550 U.S. 554, 570 (2007). Determining whether a claim is plausible is "context specific, requiring the reviewing court to draw on its experience and common sense." Ashcroft v. Iqbal, 556 U.S. 662, 663-64 (2009).

Although decisions related to a motion to amend are reviewed pursuant to regional law, the sufficiency of a pleading of inequitable conduct is a question unique to patent law and is therefore governed by Federal Circuit law. Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1318 (Fed. Cir. 2009). The standard for pleading a sufficient inequitable conduct defense was addressed in Exergen.³ To successfully plead inequitable conduct the accused infringer must include sufficient allegations of underlying facts from which a court may reasonably infer the applicant (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO. Id. at 1328-29. Subsequent to Exergen the Federal Circuit issued its opinion in Therasense, Inc. v. Becton, Dickinson

³ Generally, "[a] patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006).

and Co., 649 F.3d 1276 (Fed. Cir. 2011). Although the Therasense decision did not squarely address the pleading requirements for an inequitable conduct defense, but instead involved the review of a district court's opinion after a bench trial, the decision is still relevant to the pleading issues involved herein. While Therasense held that a showing of materiality and intent is necessary for inequitable conduct, it ruled that courts should not apply a "sliding scale" analysis where a weak showing of intent could be found sufficient with a strong showing of materiality, or vice versa. Id. at 1290-91. Therasense also held that a party making an inequitable conduct claim must show "but for" an omission or misrepresentation of the patent applicant, the PTO would not have allowed a patent to issue. Id. at 1291-92.

Bayer's first main argument is that DAS failed to plead sufficient facts to show that it omitted to disclose a material fact to the PTO. Bayer argues, therefore, that DAS's amendment is futile because it does not show that "but for" Timmis's omission the '401 patent would not have issued. The Court disagrees. The PAA alleges: (1) the written description of the '401 patent describes the only disclosed gene--the tfdA gene--as a monooxygenase (¶38); (2) while the application was pending before the PTO, the named inventor, Timmis, learned that the tfdA gene was a dioxygenase, not a monooxygenase (¶39); (3) this fact was material to the patentability of the application that issued as the '401 patent (¶41); (4) Timmis had a duty to disclose this

information to the PTO but breached the duty by not disclosing the information (§§42-43), and; (5) “[b]ut for at least Timmis’ failure to disclose this material information to the PTO, the claims of the ‘401 patent as written would not have issued” (§44). These averments satisfy the requirements set forth in Exergen and sufficiently allege “materiality” and “but for” causation.

Bayer’s argument as to “materiality” and “but for” causation does not appreciate the Court’s standard of review at this stage of the proceedings. As noted, in this context the Court must accept as true DAS’s well-pleaded facts. The Court may not weigh the facts and address the merits of Bayer’s averments. See In re Intel Corp. Microprocessor Antitrust Litig., 496 F. Supp. 2d 404, 407 (D. Del. 2007) (“The purpose of a motion to dismiss is to test the sufficiency of a complaint, not to resolve disputed facts or decide the merits of the case.”). See also Shionogi Pharma, Inc. v. Mylan, Inc., 2011 WL 3860680, at *3 (D. Del. Aug. 31, 2011). This is also not the appropriate time to rule on disputed issues of fact and claim construction. Nonetheless, Bayer asks the Court to do this very thing. One example is Bayer’s argument that “the patentability of the claims never depended on the distinction between a ‘monooxygenase’ and a ‘dioxygenase’.” AB at 2. Another example is Bayer’s argument that “[t]he change in nomenclature used to identify the enzyme is immaterial because it does not contradict the definition given in the ‘401 patent of the claimed ‘biological activity of 2,4-D monooxygenase,’ which the inventors defined as

the enzyme's ability to bring about the cleavage of the side chain of 2,4-D." Id. at 6. In addition, Bayer argues the "inventors' definition of the claimed 'biological activity' ... was defined in the patent as 'bringing about the cleavage of the side chain of 2,4-D'." Id. at 7. At this time there is no need to summarize DAS's responses to these arguments. Suffice it to say they are DAS vigorously contested. Thus, since Bayer's materiality argument is based upon disputed facts and a claim construction that has not yet been issued, the argument must be rejected at this time. Bayer's materiality argument goes to the heart of the case and will be addressed in the context of Judge Bumb's Markman and summary judgment rulings. If there are no genuine issues of material fact and Bayer is right as to claim construction, Bayer's motion for partial summary judgment will be granted. If that occurs, and if necessary, the Court can revisit Bayer's argument.⁴

Bayer also argues that DAS did not plead sufficient facts from

⁴ There are other examples of Bayer asking the Court to prematurely rule on claim construction and to weigh and decide disputed issues of fact. Bayer argues, "[t]he exact mechanism of action of the enzyme ... or the name given to the enzyme has never been relevant to the patentability of the invention." AB at 2. It also argues, "PTO's decision to issue the patent had nothing to do with how the enzyme performed its, biological function, i.e., what 'co-substrate' it used." Id. at 3. Bayer also argues, "[n]othing in the prosecution history indicates that patentability was based on the exact mechanism of action of the enzyme ... or what the enzyme is called." Id. at 6. In addition, Bayer argues "the inventors provided an explicit definition of 'biological activity of 2,4-D monooxygenase' in the patent specification" and its "use of the term '2,4-D monooxygenase' was consistent with the usage in the art at the time of the invention, ..., and consistent with usage today." Id. at 8. DAS contests all of these arguments.

which a reasonable inference may be drawn that it acted with the specific intent to deceive the PTO. The Court agrees. In Therasense the Federal Circuit wrote that the specific intent to deceive must be the single most reasonable inference to be drawn from the evidence. Id. at 1290. Some confusion has arisen as to whether this language applies to a party's pleading or whether the standard discussed in Exergen applies. Although there is a split of authority on the issue, the Court finds that Exergen sets forth the standard to be used to analyze whether DAS's inequitable conduct charge pleads sufficient facts to set forth a viable claim for relief. One reason is that Therasense discussed the evidentiary standard to be used at trial. The decision did not evaluate the sufficiency of the parties' pleadings. Second, in Exergen the Court distinguished between the Rule 9(b) pleading standard and the clear and convincing standard applicable to a review of the ultimate merits of the defense. Third, in a post-Therasense decision, Delano Farms Co., supra., the Federal Circuit appeared to endorse the Exergen standard when discussing whether a charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss. 655 F.3d at 1350. See generally Wyeth Holdings Corporation v. Sandoz, Inc., 2012 WL 600715 (D. Del. Feb. 3, 2012), adopted 2012 WL 749378 (D. Del. March 1, 2012). As a result, the Court will examine whether DAS pled sufficient facts from which a reasonable inference can be drawn that material information was not given to the PTO because it specifically

intended to deceive the PTO. The Court will not determine whether this is the single most reasonable inference to be drawn from the well pleaded facts.

The PAA pleads that Timmis deliberately withheld the alleged relevant information with the specific intent to deceive the PTO. PAA ¶50. However, the only relevant fact DAS pleads to support this allegation is that Timmis, a named inventor of the '401 patent, was a co-author of a June 1995 published paper disclosing that the tfdA gene was a dioxygenase. See PAA ¶40. For purposes of this analysis the Court assumes the truth of DAS's averments that (1) this fact was material, (2) Timmis had an ongoing duty to disclose the information to the PTO, and (3) Timmis failed to disclose the information. Nonetheless, the mere fact that Timmis had this knowledge is not in and of itself sufficient to justify the inference that "Timmis deliberately withheld this information with a specific intent to deceive the PTO." See PAA ¶45. "A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith." Exergen, 575 F.3d at 1329 n. 5. It is not reasonable to infer that Timmis had a specific intent to deceive the PTO simply because he did not reveal one aspect of the results published in his 1995 article. This is especially true since DAS does not allege that Timmis had any role or involvement in the prosecution of the '401 patent. Also, DAS does not even allege that Timmis had a direct personal stake in the outcome of the

prosecution.⁵ As Bayer notes, “[n]otably absent from DAS’s pleading is any allegation that Timmis was aware of the events that occurred during patent prosecution or had any reason to appreciate that his knowledge of the re-classification of the TfdA enzyme was material to those events.” AB at 17.

Furthermore, DAS’s averment that Timmis deliberately withheld information with the specific intent to deceive the PTO is at odds with the objective fact that Timmis published the allegedly incriminating information in June 1995. The Court agrees with Bayer’s argument that “DAS offers no reasonable explanation why Dr. Timmis would tell the whole world in a later publication something he didn’t want the PTO to know.” *Id.* at 19. Conversely, the Court disagrees with DAS that this was “unremarkable.” RB at 7. To the extent DAS argues that specific intent to deceive can be inferred from the fact that the discovery revealed in Timmis’s 1995 article was critically important, the argument is rejected. This argument resurrects the “sliding scale” analysis rejected in Therasense. As the Federal Circuit wrote:

[A] district court may not infer intent solely from materiality. Instead, a court must weight the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its

⁵ DAS argues, “[w]hether Timmis was intimately involved in patent prosecution is a red herring” because he acknowledged under section 1002 of Title 18 the duty to disclose material information. Reply Brief (“RB”) at 6. The Court finds the alleged breach of this duty does not create a reasonable inference that Timmis deliberately intended to deceive the PTO.

materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.

649 F.3d at 1290. Thus, materiality and intent are evaluated separately - intent may not be inferred solely from materiality. Id. Of course, since direct evidence of deceptive intent is rare, a court can infer intent from indirect and circumstantial evidence. Id. Here, however, insufficient averments have been pled from which the Court can make this inference. "Although 'knowledge' and 'intent' may be averred generally, our precedent like that of regional circuits, requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." Exeregn, 575 F.3d at 1327. The Court does not reasonably infer that Timmis had a specific intent to deceive the PTO simply because he failed to disclose the finding in his 1995 article.⁶

DAS argues all it seeks "is the chance to take discovery, and to try its allegations if warranted." RB at 3. However, before it proceeds down that road DAS must plead a proper charge of inequitable conduct. Accord Teva Neuroscience, Inc. V. Watson Laboratories, 2011 WL 741250 (D.N.J. Feb. 24, 2011); Teva Women's Health, Inc. V. Lupin, Ltd., 2010 WL 4392503 (D.N.J. Oct. 27, 2010); Recticel Automobilsysteme GmbH v. Automotive Components Holdings, LLC, 2011 WL 5307797 (E.D. Mich. Nov. 3, 2011); Abaxis,

⁶The Court gives no weight to DAS's pleading that persons other than Timmis may have had the same knowledge. DAS pleaded no facts to support this conclusory allegation.

Inc. V. Cepheid, 2011 WL 3741501 (N.D. Cal. Aug. 25, 2011).

Conclusion and Order

For all the foregoing reasons, DAS's motion will be DENIED. Accordingly, it is hereby ORDERED this 12th day of April, 2012, that DAS's Motion for Leave to File an Amended Answer is DENIED without prejudice. DAS is granted leave to re-file its motion within thirty (30) days of its receipt of this Order.⁷

s/Joel Schneider
JOEL SCHNEIDER
United States Magistrate Judge

⁷ Because the Court finds that amendment at this time is not futile, DAS will be given an opportunity to re-file its motion. See In re Burlington Coat Factory Securities Litig., supra, 114 F.3d at 1434.