UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

Marine Polymer Technologies, Inc.

v.

Civil No. 06-cv-100-JD Opinion No. 2010 DNH 133

HemCon, Inc.

ORDER

Marine Polymer Technologies, Inc. accused HemCon, Inc. of infringing United States Patent 6,864,245 ("the '245 patent"), and summary judgment was entered in Marine Polymer's favor on infringement. A bifurcated trial was held in late April of 2010, which resulted in a verdict in Marine Polymer's favor on HemCon's invalidity defenses of anticipation and obviousness and an award of \$29,410,246 as a reasonable royalty for infringement damages. HemCon's inequitable conduct defense and counterclaim were reserved for consideration by the court. Marine Polymer moves for summary judgment that no inequitable conduct occurred, and HemCon objects.

Standard of Review

Summary judgment is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party is entitled to summary judgment when "the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." <u>Celotex Corp. v.</u> <u>Catrett</u>, 477 U.S. 317, 323 (1986). All reasonable inferences are taken in the light most favorable to the nonmoving party. <u>Anderson v. Liberty Lobby, Inc.</u>, 477 U.S. 242, 255 (1986).

"Inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to mislead or deceive the examiner, and those two elements, materiality and intent, must be proven by clear and convincing evidence." <u>Optium Corp. v. Emcore Corp.</u>, 603 F.3d 1313, 1320 (Fed. Cir. 2010). "[S]ummary judgment may be granted [on inequitable conduct] when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the nonmovant cannot prevail."¹ <u>Id.</u> at 1319; <u>Astrazeneca Pharms.</u>

¹HemCon relies on <u>Mack v. Cape Elizabeth Sch. Bd.</u>, 553 F.2d 720, 722 (1st Cir. 1977), for the proposition that Marine Polymer has an affirmative duty to show an absence of disputed material facts to succeed on its motion. Since <u>Mack</u>, the Supreme Court has explained that "a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." <u>Celotex</u>, 477 U.S. at 323; <u>see also Sensing v. Outback Steakhouse of Fla.</u>, LLC, 575 F.3d 145, 152-53 (1st Cir. 2009). Therefore, a moving party can meet its burden under Rule 56(c) if the nonmoving party is unable to

<u>LP v. Teva Pharms. USA, Inc.</u>, 583 F.3d 766, 770 (Fed. Cir. 2009) (same).

<u>Discussion</u>

Marine Polymer seeks summary judgment in its favor on HemCon's defense and counterclaim that the '245 patent is invalid due to inequitable conduct that occurred during the patent prosecution. HemCon contends that Marine Polymer withheld material information from the Patent and Trademark Office ("PTO"), withheld prior inconsistent statements made during the prosecution of United States Patent No. 6,743,783 (the '783 patent), misrepresented to the PTO that no new matter was added in an amendment to the application that became the '245 patent, and withheld communications with the FDA. HemCon also contends that Marine Polymer intended to deceive the PTO patent examiners. Marine Polymer asserts that HemCon cannot prove inequitable conduct.²

provide proof of an essential element of its claim. <u>Celotex</u>, 477 U.S. at 323.

²Marine Polymer also argues that HemCon failed to plead inequitable conduct with particularity as required by Federal Rule of Civil Procedure 9(b). To the extent that Marine Polymer asserts a pleading deficiency as a ground for summary judgment, that theory is too late. Marine Polymer filed an answer to HemCon's counterclaims on May 15, 2006, but failed to challenge the sufficiency of HemCon's pleadings until the current motion "To successfully prove inequitable conduct, the accused infringer must present evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the PTO." <u>Pressure</u> <u>Prods. Med. Supplies, Inc. v. Greatbatch, Ltd.</u>, 599 F.3d 1308, 1320 (Fed. Cir. 2010) (internal quotation marks omitted). Both materiality and intent to deceive must be proven by clear and convincing evidence. <u>Orion IP, LLC v. Hyundai Motor Am.</u>, 605 F.3d 967, 978 (Fed. Cir. 2010). "If the materiality and intent requirements are met, the court must then determine whether the cited conduct amounts to inequitable conduct by balancing the levels of materiality and intent; a greater showing of one allows a lesser showing of the other." <u>Taltech Ltd. v. Esquel Enters.</u> Ltd., 604 F.3d 1324, 1328 (Fed. Cir. 2010).

Information is material "if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent," although information may be material even if it would not invalidate the patent. <u>Leviton Mfg. Co., Inc. v. Universal</u> <u>Sec. Instruments, Inc.</u>, 606 F.3d 1353, 1359 (Fed. Cir. 2010)

for summary judgment, more than four years later.

(internal quotation marks omitted). An intent to deceive is rarely proven by direct evidence and instead is "generally inferred from the facts and circumstances surrounding the applicant's overall conduct." <u>Id.</u> at 1362 (internal quotation marks omitted). Even when the nondisclosed material is highly material, intent to deceive cannot be inferred if the applicant provides a "plausible, good faith explanation" for not disclosing the material, although the absence of an explanation does not prove intent. <u>Id.</u> at 1362-63.

I. <u>Nondisclosure</u>

HemCon contends that Marine Polymer engaged in inequitable conduct by failing to disclose certain materials and information to the PTO. In particular, HemCon argues that Marine Polymer should have, but did not, disclose an article written by Paul Sandford that was published in a book in 1989, the Sandford Article. <u>See</u> Paul A. Sandford, "Chitosan: Commercial Uses and Potential Applications," published in <u>Chitin and Chitosan:</u> <u>Sources, Chemistry, Biochemistry, Physical Properties and</u> <u>Applications</u>, 51 - 59 (1989). HemCon also argues that certain statements Marine Polymer made during the prosecution of the '783 patent were inconsistent with statements made to the PTO examiner during the prosecution of the '245 patent and should have been

disclosed. In addition, HemCon lists in its statement of facts that Marine Polymer's communications with the FDA, including Marine Polymer's § 510 submissions, were withheld from the PTO.

A. <u>Sandford Article</u>

The Sandford Article discusses chitin and chitosan derived from crustacean shells. The Article explained the manufacturing process, noted the biological and chemical properties, and addressed its commercial uses. The Article suggests uses of chitin and chitosan in the clarification and purification of water, pharmacology, wound healing, cosmetics and personal care, agriculture, and biotechnology.

1. <u>Materiality</u>

In its motion, Marine Polymer contends that the Sandford Article was not material to the '245 patent application. Marine Polymer cites the opinion and testimony of its expert witness, Dr. Langer, that the Sandford Article does not meet the limitations of the '245 patent as the claims were construed by the court in this case. In addition, Marine Polymer cites Dr. Langer's opinion that the Sandford Article was no more material than other prior art that was cited during prosecution of the '245 patent and the opinion of another expert, Stephen Kunin,

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that the Sandford Article was merely cumulative of other cited references. Marine Polymer also notes that the jury found that the Sandford Article did not disclose the elements of the asserted claims of the '245 patent for purposes of anticipation and obviousness.

HemCon asserts that the Sandford Article was highly material based on the PTO's communication in the reexamination proceeding and Sergio Finkielsztein's testimony at trial. In March of this year, the PTO examiner issued a nonfinal communication, rejecting all of the claims of the '245 patent as obvious in light of the Sandford Article.³ HemCon also cites Sergio Finkielsztein's trial testimony that he would have disclosed the Sandford Article if he had been aware of it during patent prosecution.

In its reply, Marine Polymer does not pursue the issue of the materiality of the Sandford Article. Instead, Marine Polymer focuses on the intent requirement. For purposes of summary

³The PTO examiner agreed with the court's claim construction except to further define "biocompatibility tests" as "cytotoxicity elution assays having a test score of 0, 1, or 2." The court construed "biocompatible poly- β -1-4-N-acetylglucosamine or biocompatible poly- β -1-4-glucosamine" to mean:

polymers with their stated compositions (poly- β -1-4-N-acetylglucosamine and poly- β -1-4-glucosamine) and with low variability, high purity, and no detectable biological reactivity as determined by biocompatibility tests.

judgment, therefore, it appears that there is at least a factual dispute as to whether the Sandford Article was material.

2. <u>Intent to Deceive</u>

"[T]he 'intent' element of inequitable conduct is not simply intent to take the action or omission complained of, but intent to deceive or mislead the patent examiner into granting the patent." <u>Optium</u>, 603 F.3d at 1320. When a charge of inequitable conduct is based on the applicant's "nondisclosure of information rather than affirmative misrepresentation, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference." <u>Id.</u> (internal quotation marks omitted). In addition, deceptive intent cannot be inferred merely because the nondisclosed information was highly material. <u>Id.</u> at 1321-22.

HemCon argues that intent to deceive can be inferred from the materiality of the Sandford Article and because one of the `245 patent inventors, Dr. Ernest Pariser, had the <u>Chitin and</u> <u>Chitosan</u> book, where the Sandford Article is published, and because other articles from the book were cited to the PTO. Because Dr. Pariser had the book in his possession, HemCon surmises that Dr. Pariser reviewed the book to choose the other

cited articles. HemCon further surmises that to choose the other cited articles, Dr. Pariser necessarily saw the Sandford Article and decided not to cite it either because he thought it was not material, due to the crustacean source, or because he did not want the PTO examiner to consider the Sandford Article.

In its reply, Marine Polymer responds that it is not reasonable to infer that Dr. Pariser intentionally withheld the Sandford Article or even knew that the article existed. Marine Polymer points out that the <u>Chitin and Chitosan</u> book includes eighty-seven articles and that the articles Dr. Pariser cited to the PTO pertained to "derivatization".⁴ Marine Polymer also contends that HemCon cannot show that Dr. Pariser thought the Sandford Article was material.

An infringer "must prove by clear and convincing evidence a specific intent to deceive the PTO." <u>Larson Mft. Co. of S.D. v.</u> <u>Aluminart Prods. Ltd.</u>, 559 F.3d 1317, 1340 (Fed. Cir. 2009). The absence of an explanation for failing to disclose a reference, by

⁴The parties did not identify which articles from the <u>Chitin</u> <u>and Chitosan</u> book were cited to the PTO, referring only to "two articles." The '245 patent, however, lists three articles from <u>Chitin and Chitosan</u> as references cited: "Production and application of chitin and chitosan in Japan," by S. Hirano; "Preparation of iodo-chitins and graft copolymerization onto the derivatives," by K. Kurita and S. Inoue; and "Hydroxypropylation of chitosan," by G. Maresch, T. Clausen, and G. Lang. Sergio Finkielsztein testified in his deposition that two or three references from the book were cited to the PTO examiner.

itself, does not prove an intent to deceive. <u>Id.</u> at 1341. An inference of "deceptive intent [may be] based on a showing that a patentee withheld references with which it was intimately familiar and which were inconsistent with its own patentability arguments to the PTO." <u>Aqfa Corp. v. Creo Prods. Inc.</u>, 451 F.3d 1366, 1378 (Fed. Cir. 2006). In addition, deceptive intent may be inferred if the applicant knew of withheld material information, knew or should have known that the information was material, and failed to provide a credible explanation for failing to cite the information. <u>Ferring B.V. v. Barr Labs.</u>, <u>Inc.</u>, 437 F.3d 1181, 1191 (Fed. Cir. 2006).

Neither party has presented evidence from Dr. Pariser.⁵ HemCon urges the court to infer intent to deceive. HemCon's inferential theory, however, is missing several links.

HemCon provides no direct evidence that Dr. Pariser was aware of the Sandford Article when he cited other articles to the PTO examiner. Instead, HemCon speculates that Dr. Pariser would have read through <u>Chitin and Chitosan</u>, or at least through the article titles, to choose the cited articles. Based on that

⁵Marine Polymer faults HemCon for failing to depose Dr. Pariser on the question of intent to deceive, and HemCon faults Marine Polymer for failing to provide an affidavit from Dr. Pariser on the issue. Because HemCon bears the burden of proving inequitable conduct, Marine Polymer need not provide evidence negating intent to support its motion for summary judgment.

assumption, HemCon speculates that Dr. Pariser would have seen the Sandford Article during the selection process, would have known and appreciated the subject matter of the article, and chose not to cite the Sandford Article to the PTO.

HemCon's unsupported speculation cannot prove that Dr. Pariser withheld the Sandford Article for the purpose of deceiving the PTO examiner. Marine Polymer is not obligated to explain Dr. Pariser's choices. In the absence of evidence of intent to deceive, an essential element to prove inequitable conduct, HemCon cannot succeed on that claim based on Marine Polymer's failure to cite the Sandford Article to the PTO examiner.

B. Arguments Made During Prosecution of the '783 Patent

HemCon contends that Marine Polymer made statements during the prosecution of the '783 patent that were inconsistent with statements made during the '245 patent prosecution and failed to disclose the prior inconsistent statements. HemCon's inconsistent statements theory is difficult to understand.

The '245 patent and the '783 patent are part of a family of patents that shares a common specification and descends from United States Patent No. 6,610,668. HemCon contends that during prosecution of the '783 patent, Marine Polymer or its

representatives distinguished microalgal chitin from crustacean chitin. HemCon states: "The claims of the '245 patent were obvious in view of the claims of [the '783 patent], which means that the claims of the '245 patent had similar scope as the claims of [the '783 patent]." In support, HemCon cites an exhibit filed in support of a motion for summary judgment.⁶ The cited page merely shows approval of "Terminal Disclaimer" with a handwritten list of numbers. HemCon concludes: "As such, arguments made in the prosecution of [the '783 patent] are material to the prosecution of the '245 patent." Def. Mem. at 6, ¶ 10.

HemCon contends that the arguments made distinguishing the sources of chitin during prosecution of the '783 patent were inconsistent with Marine Polymer's arguments made in support of the '245 patent, which did not distinguish the invention based on the chitin source. HemCon states that Marine Polymer did not disclose the arguments made in support of the '783 patent application and withheld that information with the intent to deceive the PTO. Marine Polymer points out that the statements

⁶Specifically, HemCon cites "Dkt. 31, Exhibit 5D at 14." Document number 31 refers to HemCon's motion for summary judgment, filed on June 28, 2007, which was later terminated due to subsequent claim construction. Exhibit 5D is part of the prosecution history of the '245 patent submitted in support of the motion.

HemCon challenges are not inconsistent because the two patents claim different inventions.

The '783 patent is directed to microalgal p-GlcNAc while the '245 patent claims biocompatible p-GlcNAc without a source limitation. Marine Polymer cites its expert witness's opinion that the representative during the '783 patent prosecution did not argue patentability by distinguishing microalgal source chitin from animal source chitin but instead argued that prior art would not have provided motivation to make microalgal p-GlcNAc that was effective for hemostasis. HemCon has not provided sufficient evidence of materiality to raise even a disputed fact as to whether statements made during prosecution of the '783 patent should have been disclosed during the '245 patent prosecution.

Even if materiality were established, HemCon offers no evidence of intent to deceive. HemCon does not identify who on behalf of Marine Polymer withheld the allegedly inconsistent statements or any reason to suspect an intent to deceive. HemCon's inequitable conduct theory based on Marine Polymer's failure to disclose allegedly inconsistent statements during prosecution of the '245 patent is not based on sufficient evidence to raise a factual dispute.

C. Communications with the FDA

HemCon merely states that Marine Polymer withheld its communications with the FDA from the PTO. In the absence of any evidence that the communications were material and that Marine Polymer intended to deceive the PTO by withholding the communications, HemCon cannot prove inequitable conduct based on the FDA communications. HemCon has not shown a factual dispute sufficient to avoid summary judgment on its inequitable conduct defense and counterclaim, based on its claims that Marine Polymer failed to disclose material information to the PTO.

II. <u>Misrepresentations</u>

HemCon argues that Marine Polymer misled the PTO when Marine Polymer amended certain pending claims of the '245 patent, during patent prosecution, to eliminate the lower limit of a range of monosaccharides claimed. As amended, the claims retained the upper limit on the number of monosaccharides but lacked a lower limit. HemCon represents that Marine Polymer misled the PTO by stating to the PTO that support for the amendment could be found in certain cited parts of the specification and that no new matter had been introduced. HemCon contends that, contrary to Marine Polymer's statement, the amendment broadened the scope of the claims, by eliminating the lower limit on the number of

monosaccharides, and that the specification does not support a molecular weight below the limits originally included in the claims.

A patent examiner is free to accept or reject the applicant's arguments or interpretations provided in support of patentability of the invention. <u>Innoqenetics, N.V. v. Abbott</u> <u>Labs.</u>, 512 F.3d 1363, 1379 (Fed. Cir. 2008); <u>Life Techs., Inc. v.</u> <u>Clontech Labs., Inc.</u>, 224 F.3d 1320, 1326 (Fed. Cir. 2000). Therefore, an applicant's statements do not constitute a material misrepresentation when the patent examiner has the information before him to reach his own conclusion. <u>Akzo N.V. v. Int'l Trade</u> <u>Comm'n</u>, 808 F.2d 1471, 1482 (Fed. Cir. 1986).

HemCon does not dispute that the patent examiner had the specification to check Marine Polymer's argument that the specification supported the amendment. In addition, the examiner was free to decide for himself whether the elimination of the lower limit in the amendment broadened the amended claims. In these circumstances, any misrepresentation was not material. Further, HemCon offers no basis to infer that Marine Polymer intended to deceive the patent examiner in its representations about the amendment.

III. <u>Summary</u>

HemCon offered four bases for its defense and counterclaim of inequitable conduct: that Marine Polymer withheld the Sandford Article, that Marine Polymer made inconsistent statements during the '783 patent prosecution, that Marine Polymer failed to disclose its communications with the FDA, and that Marine Polymer misled the patent examiner with respect to amendment of claims. As is explained above, HemCon failed to provide clear and convincing evidence that the cited information was material, in some cases, and that Marine Polymer intended to deceive the PTO. In the absence of evidence sufficient to establish a triable issue on HemCon's inequitable conduct defense and counterclaim, Marine Polymer is entitled to summary judgment.

<u>Conclusion</u>

For the foregoing reasons, the plaintiff's motion for summary judgment (document no. 339) is granted. Summary judgment

in favor of the plaintiff is granted on the defendant's counterclaim and defense of inequitable conduct.

SO ORDERED.

Joseph A. DiClerico, Jı

United States District Judge

August 3, 2010

cc: Julie M. Baher, Esquire Celine Jimenez Crowson, Esquire Garet K. Galster, Esquire Daniel R. Johnson, Esquire Heather E. Krans, Esquire Joseph A. Kromholz, Esquire Raymond A. Kurz, Esquire Lynda Q. Nguyen, Esquire Keith B. O'Doherty, Esquire Rebekah L. Osborn, Esquire Brian M. Poissant, Esquire Daniel D. Ryan, Esquire Ognian V. Shentov, Esquire Jonathan M. Shirley, Esquire Daniel E. Will, Esquire Leigh S. Willey, Esquire