

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

REMBRANDT VISION TECHNOLOGIES §
Vs. § CIVIL ACTION NO. 2:05-CV-491
CIBA VISION CORPORATION §

MEMORANDUM OPINION AND ORDER

1. Introduction

After a jury trial, the jury found CIBA liable for infringement of claims 1, 2, and 6 of United States Patent No. 5,712,327 (“the ‘327 patent”). The jury rejected CIBA’s invalidity defenses, and awarded reasonable royalty damages in the amount of \$41,083,853. On March 27, 2008, the court held a bench trial on the issue of inequitable conduct. This memorandum opinion and order constitutes the court’s findings of fact and conclusions of law pursuant to Rule 52. The court has considered the admissible evidence and the parties’ briefing. For the following reasons, the court rejects the inequitable conduct defense and holds that the patent is enforceable.

2. Discussion

The ‘327 patent relates to a silicone hydrogel contact lens that has improved clinical performance and is suitable for extended wear. The ‘327 patent issued from Application No. 899,217 (“the ‘217 application”), which was filed on June 16, 1992. The ‘217 application is a continuation of Application No. 551,156 filed on July 11, 1990 (“the ‘156 application”). The ‘156 application claims priority to other applications, the earliest of which was filed on January 7, 1987.

As issued, claim 1 of the '327 patent claims a hydrophilic soft gas permeable contact lens made of a certain composition "characterized by high oxygen permeability, softness, rebound elasticity, and a high degree of clinical performance" '327 patent, claim 1. Other claims require "improved clinical performance." '327 patent, claims 7-14. The named inventors on the '327 patent are Dr. Sing-Hsiung Chang and his wife, Mei-Zyh Chang. The Changs, together with attorney William Speranza, were involved in the prosecution of the '327 patent. During the prosecution of the '327 patent, the Changs entered an agreement with Allergan, through which the parties attempted to commercialize the lenses invented by the Changs. At the time Dr. Chang first contacted Allergan in 1987, Allergan had little experience making contact lenses. Dr. Chang, however, had a great deal of experience designing contact lenses. During the agreement with Allergan, Allergan retained the Cornea & Contact Lens Research Unit ("CCLRU") in Australia to test the lens prototypes manufactured by Allergan. CCLRU issued various reports relating to testing conducted on the lenses. In addition, the Changs personally tested the contact lenses by wearing them in their own eyes.

CIBA contends that the Changs committed inequitable conduct by failing to disclose two of the CCLRU test reports to the United States Patent & Trademark Office ("PTO"). According to CIBA, two of the reports, issued in May 1989 and August 1989, contained findings that were material to patentability because the findings demonstrated that the lenses did not exhibit a high degree of clinical performance. CIBA also contends that the Changs should have disclosed to the PTO the fact that the Changs were the subjects of the studies sent to the PTO during the prosecution of the patent.

Patent applicants and attorneys representing them have a duty to prosecute patent applications

with candor, good faith, and honesty in their dealings with the PTO. 37 C.F.R. § 1.56; *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). To show that the '327 patent is unenforceable due to inequitable conduct, CIBA must show, by clear and convincing evidence: (1) that the applicants breached their duty either by making an affirmative misrepresentation of material fact, failing to disclose material information, or by submitting false material information, and (2) that the applicants intended to deceive the PTO. *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007). The proponent of the defense must prove materiality and intent by clear and convincing evidence. *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 971-72 (Fed. Cir. 2006). 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. 37 C.F.R. § 1.56(a)(1989)(current version at 37 C.F.R. § 1.56(a)(2000)). Information is also material if it satisfies the test of the current version of Rule 1.56. The current version of Rule 1.56 provides:

Information is material to patentability when it is not cumulative . . . , and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56.

The intent element requires that “the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988). If both materiality and intent are present, then the court must balance the equities to determine whether the patentee has committed inequitable conduct that warrants a holding of unenforceability. *Monsanto Co. v. Bayer Bioscience N.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004).

In the present case, the court assumes, *arguendo*, that the CCLRU reports are material. Nevertheless, the court finds that the defendant has not shown, by clear and convincing evidence, that the applicants intended to deceive the PTO by failing to disclose these reports. Although intent is often established by circumstantial evidence, the court must bear in mind that intent to deceive “cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.” *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1134 (Fed. Cir. 2006). Although certain portions of the CCLRU reports indicate adverse findings on clinical performance, Dr. Chang did not believe that these needed to be submitted to the PTO during prosecution of the ‘327 patent. The evidence is not clear, for instance, whether Allergan sent the entire reports to the Changs or whether Allergan merely sent summaries and reported the results to the Changs. The evidence found to be persuasive indicates that Dr. Chang had previously given Allergan information concerning proper lens design and formulations, including information about controlling the center thickness of the lenses to between 0.060-0.080 millimeters. The Allergan lenses tested in the May 1989 report had an average center thickness of 0.10 millimeters, which is well above Dr. Chang’s recommended thickness. Likewise, the Allergan lenses tested in the August 1989 report had an average center thickness of 0.12 millimeters and were also thicker than what Dr.

Chang had recommended. Dr. Chang complained to Allergan about the tests and believed in good faith that the test results were misleading. In addition, CCLRU issued several other reports that contained various findings, some of them favorable to the clinical performance of the lenses tested by that facility. The Changs also did not disclose those reports to the PTO.

In reaching this decision, the court has considered all of the evidence, including the court's observations of Dr. Chang's demeanor on the witness stand. Dr. Chang had a good faith belief that the adverse CCLRU findings were based on tests that were misleading. The court finds that his testimony is credible on the question of intent and further notes that he did not disclose other, more favorable reports from CCLRU to the PTO. In the court's view, the failure to disclose favorable CCLRU findings cuts strongly against a finding of deceptive intent.

Likewise, assuming the materiality of the fact that the Changs personally were the subjects of testing disclosed to the PTO, the court finds that CIBA has not met its burden of proof to show that Dr. Chang acted with the requisite intent when he failed to disclose this to the PTO. The evidence establishes that Dr. Chang had extensive experience in designing contact lenses. The court's observation of his demeanor on the witness stand, both in the jury phase of the case and during the bench trial, persuades the court that he did not intend to deceive the PTO during the prosecution of the '327 patent. Accordingly, the court rejects CIBA's inequitable conduct defense.

3. Conclusion

For these reasons, the court rejects the inequitable conduct defense asserted by CIBA and holds that the '327 patent is enforceable.

SIGNED this 26th day of September, 2008.


CHARLES EVERINGHAM IV
UNITED STATES MAGISTRATE JUDGE