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Therasense Opinions And The Doctrine Of Inequitable Conduct

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I. BRIEF OVERVIEW OF THE DOCTRINE

Each person associated with the prosecution of a patent application has a duty of candor and good faith in dealing with the Patent and Trademark Office ("PTO"). Under the doctrine of inequitable conduct, a patent may be rendered unenforceable where that duty is breached, and the person intended to deceive or mislead the PTO.

In particular, one must disclose all material, non-cumulative information. Under the PTO's current rules, information is "material" if it satisfies either Rule 56(b)(1) or 56(b)(2). Information is material under Rule 56(b)(1) if it "establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim." Information is material under Rule 56(b)(2) if 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."

In litigation, a patent may be found unenforceable based on inequitable conduct where there is an intentional misrepresentation or failure to disclose material information during the prosecution of the patent. Under the current state of the law, information is material if it satisfies any one of a number of standards. Those standards include but are not limited to: (a) the PTO's Rule 56(b) standard; (b) the "reasonable examiner" standard, which asks whether there is a substantial likelihood that a reasonable PTO examiner would have considered the information "important" in deciding whether to allow a patent to issue; (c) the objective "but for" standard, whereby the misrepresentation was material if the patent should not have issued; and (d) the subjective "but for" standard, where the misrepresentation is material if it actually caused the examiner to approve the patent application when the examiner would not otherwise have done so.

If the accused infringer establishes materiality and intent to deceive by clear and convincing evidence, there is a sliding scale to determine if the patent should actually be held unenforceable, with the great showing of one element requiring a lesser showing of another.

II. UNDERLYING FACTS OF THE *THERASENSE* CASE

The Federal Circuit appeal is from a Northern District of California ruling by Judge William Alsup, following a bench trial, that United States Patent No. 5,820,551 (the "'551 patent") was unenforceable due to inequitable conduct. The '551 patent claims technology related to a disposable electrode strip whose electrodes can be covered by a single drop of solution. These strips could be inserted into a unit for digital readout of the target compound (like glucose) in a test liquid mixture (like blood).

The '551 patent was in prosecution for over fourteen years, twelve years of which by Fish & Richardson. While the patent was pending before the PTO, assignee Medisense was purchased by Abbott. One of Abbott's in-

house counsel, Lawrence Pope, took over the prosecution. During the prosecution, various claims were rejected over United States Patent No. 4,545,382 (the "'382 patent") and/or its related patent before the European Patent Office, No. 0078,636 B2 (the "'636 patent").

In an effort to overcome the PTO's rejections based on the '382 patent, Attorney Pope began working with Dr. Gordon Sanghera, Abbott's Director of Research and Development. They decided to espouse a new point of novelty – that the specification disclosed a sensor for use in whole blood *without* any protective membrane. However, a passage in the prior art '382 patent stated:

> **Optionally, but preferably when being used on live blood**, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules. [Note that all emphasis is added unless otherwise noted.]

Abbott thereafter asserted that one of skill in the art would have believed that a membrane was required, despite the above passage. Attorney Pope submitted a declaration by Dr. Sanghera in which Dr. Sanghera stated that "**one skilled in the art would not read [the '382 patent passage] to teach that the use of a protective membrane with a whole blood sample is optionally** [*sic*] **or merely preferred.**" Attorney Pope also submitted remarks that one of skill would have understood the "preferably" language as mere patent phraseology (essentially a weasel word for "required"), rather than a technical teaching. Based on those submissions, the Examiner finally approved the proposed claims.

However, several years prior, the '636 patent (the European counterpart to the '382 patent) was removed in an opposition proceeding based on a prior art reference called D1. The '636 patent specification also contained the pertinent sentence from the '382 patent. In an effort to protect the '636 patent, Medisense submitted a brief to the EPO, arguing:

> It is submitted that this disclosure is **unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood** in order to prevent the larger constituents of the blood, in particular erythrocytes, from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is "permeable" to glucose molecules.

Note that two functions of the membrane are disclosed in the passage above – protection and permeability. They play an important role in the Federal Circuit debate regarding materiality.

Dr. Sanghera had helped develop the arguments proffered by Medisense in the EPO appeal, and had attended the oral argument before the EPO. He disclosed the EPO submissions to Attorney Pope, who reviewed them at the time they made the pertinent submissions to the PTO in support of the '551 patent. They discussed the EPO statements, and determined not to disclose them to the PTO.

III. DISTRICT COURT DECISION HOLDING PATENT UNENFORCEABLE DUE TO INEQUITABLE CONDUCT

The district court found that the EPO submissions were "highly material" pursuant to Rule 56(b)(2) because they were "flatly inconsistent" with Attorney Pope and Dr. Sanghera's statements to the PTO that the '382 patent did not teach that a protective membrane was merely optional.

Judge Alsup rejected Abbott's position that the EPO submissions were cumulative, stating that Attorney Pope "knew or should have known" that they were highly material. The court further found that Attorney Pope's explanation for withholding that materials "was not plausible … and he was not credible," recounting that

Attorney Pope testified that he understood the "unequivocally clear" language to refer only to the concluding phrase "permeable to water and glucose molecules." In finding intent to deceive, Judge Alsup noted that he had "taken into account the demeanor of Attorney Pope during his trial testimony."

Judge Alsup found that Dr. Sanghera intended to deceive the PTO as well. Dr. Sanghera testified that he didn't think the EPO and PTO submissions were inconsistent, because they were directed to different types of membranes. However, Judge Alsup found that the EPO statements "plainly went beyond this point of distinction." Judge Alsup also noted that, "[a]s a trial witness, it must be said that Dr. Sanghera was impeached on substantive points with his prior inconsistent statements and exhibited an unconvincing demeanor."

IV. FEDERAL CIRCUIT AFFIRMANCE OF INEQUITABLE CONDUCT

A. Majority Opinion

The Federal Circuit (Judges Dyk and Friedman) affirmed all aspects of Judge Alsup's decision, finding the present case to be "one of those rare cases in which a finding of inequitable conduct is appropriate," and noting "the district court's careful and thorough findings as to materiality and intent."

1. Materiality of the EPO Submissions

As to materiality, the Federal Circuit found that Judge Alsup was "indeed clearly correct." Abbott contended that at the EPO, the focus was on distinguishing the semipermeable membrane of the D1 from the protective, permeable membrane of the '636 patent. However, the Court found that Abbott first explained that the optional but preferred language was "unequivocally clear," and then, using the transition, "furthermore," expressed its second point regarding permeability.

The Federal Circuit also rejected Abbott's argument that the submissions to the PTO were mere "lawyer argument," because there were contradictory arguments made in another forum, and because the representations were factual assertions as to the views of those skilled in the art, provided in affidavit form.

2. Attorney Pope – Intent to Deceive

As to intent, the Federal Circuit noted that Judge Alsup made five findings:

> (1) that the statements made to the PTO concerning the prior art '382 patent were absolutely critical in overcoming the examiner's earlier rejections to the claims of the '551 patent; (2) that the EPO statements would have been very important to an examiner because they contradicted the representations made to the PTO; (3) that Pope and Dr. Sanghera both knew of the EPO statements and consciously withheld them from the PTO; (4) that neither Pope nor Dr. Sanghera provided a credible explanation for failing to submit the EPO documents to the PTO; and (5) that Pope's and Dr. Sanghera's explanations for withholding the EPO documents were so incredible that they suggested intent to deceive.

The Federal Circuit specifically noted that the fourth and fifth findings were based on Judge Alsup's assessment of credibility, which were within his discretion and "amply supported." The Court further focused on the fact that Pope admitted that the "normal English construction" of the EPO statements contradicted his representations to the PTO.

3. **Dr. Sanghera – Intent to Deceive**

The Federal Circuit noted that Dr. Sanghera similarly testified that according to normal English construction, the EPO statement contradicted his representations to the PTO. Further, it noted that: (a) Dr. Sanghera was not a person of ordinary skill in the art at the time the application was filed; (b) an inventor on both the '551 and '382 patents, Dr. Higgins, testified that "preferably" meant the membrane was optional; and (c) that cases involving declarations are as a matter of law held to a higher standard of disclosure.

B. Dissent (Judge Linn)

There was a vigorous dissent by Judge Linn to the finding of inequitable conduct. He disagreed that the representations to the EPO were material. He found that the phrase "unequivocally clear" referred to "this disclosure," meaning the entire sentence. In his view, it would be reasonable to read the submission to say that what was "unambiguously clear" "is that the membrane serves the dual roles of preventing larger constituents in blood from interfering with the electrode sensor, while also allowing smaller water and glucose molecules to pass through." Thus, a finding of materiality was not proper because it was not the single most reasonable inference. (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) (which in turn cited *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)).

As to intent to deceive, Judge Linn emphasized that the correct inquiry was not whether it is plausible that the reference is immaterial, but whether the person in question "subjectively believed" that the reference was immaterial. He stated that Dr. Higgins (the inventor's) personal opinion was irrelevant as a matter of law, as was the fact that Dr. Sanghera was not one of skill in the art at the time the application for the '551 patent was filed.

Judge Linn further reasoned that District Judge Alsup's credibility determinations were improper because they: (1) were not factual findings, but instead reflected a disagreement with Attorney Pope and Dr. Sanghera's interpretations of the EPO submissions; (2) improperly anchored intent to the materiality determination; and (3) reflected the court's normative view of the law (that words are supposed to mean what they say).

V. THE FEDERAL CIRCUIT'S ORDER GRANTING ABBOTT'S PETITION FOR REHEARING *EN BANC*

Abbott petitioned for rehearing *en banc*, and the Federal Circuit granted rehearing on April 26, 2010, requesting briefing regarding the following issues:

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?

2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806 (1945); Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944), overruled on other grounds by Standard Oil Co. v. United States, 429 U.S. 17 (1976); Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240 (1933). If so, what is the applicable standard for fraud or unclean hands?

3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?

4. Under what circumstances is it proper to infer intent from materiality? See Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867 (Fed. Cir. 1988) (en banc).

5. Should the balancing inquiry (balancing materiality and intent) be abandoned?

6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

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