

Federal Circuit Tightens Inequitable Conduct Standards

In *Therasense, Inc. v. Becton, Dickinson & Co.*,¹ the United States Court of Appeals for the Federal Circuit, sitting *en banc*, clarified and tightened the standards for establishing the “inequitable conduct” defense in patent infringement proceedings. In a split decision² intended to make more difficult the invocation of the defense of inequitable conduct, the court held that defendants seeking to assert the inequitable conduct defense in a patent infringement suit must prove that (1) the patentee acted with specific intent to deceive the Patent and Trademark Office (“PTO”) when applying for the patent; and (2) but for the patentee’s deception, the PTO would not have issued the relevant patent.³ In doing so, the court rejected looser approaches employed by previous courts. Additionally, the court instructed that even when specific intent and but-for materiality are proven, courts should apply principles of equity and only rule a patent unenforceable due to inequitable conduct “where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”⁴

I. Background and Procedural History

Plaintiffs Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) and Abbott Laboratories (collectively “Abbott”) hold a series of patents for strips used to test blood glucose levels in diabetics, including U.S. Patent No. 5,820,551 (the “ ’551 patent”), a strip that employs electrochemical sensors to measure the level of glucose in a blood sample. Initially, Abbott encountered difficulty in obtaining the ’551 patent. Between 1984 and 1997, the PTO repeatedly denied Abbott’s patent applications on grounds of anticipation and obviousness, determining that the product was too similar to another patent already held by Abbott, U.S. Patent No. 4,545,382 (the “ ’382 patent”). In its 1997 reapplication, Abbott devised a new strategy to differentiate its product from the ’382 patent. Abbott argued that, unlike previous test strips, its product did not require a protective membrane to prevent red blood cells from sticking to the electrode and interfering with electron transfer. Although the ’382 patent specification discussed that the protective membrane was “optional[, but preferable when being used with live blood,” Abbott submitted an affidavit from its research and development director testifying that a skilled person would have believed the membrane in the ’382 patent was necessary, rather than merely optional. Abbott, however, failed to note that when applying for the European version of its ’382 patent, Abbott had argued to the European Patent Office that the membrane was optional. Unaware of the European application, the PTO granted Abbott the ’551 patent.

In 2004, Abbott became involved in litigation with Defendant Becton, Dickinson and Co. (“Becton”) over multiple intellectual property issues.⁵ Within this litigation, Abbott claimed that Becton infringed upon its ’551

¹ 2011 WL 2028255 (Fed. Cir. May 25, 2011) (en banc).

² In this case, six judges voted with the majority, one judge filed an opinion concurring in part and dissenting in part, and the remaining four judges joined in the dissenting opinion.

³ *Id.* at *9, *11. As will be discussed in Part II of this memorandum, the court did carve out an exception to the but-for materiality requirement in cases of “affirmative egregious misconduct.” *Id.* at *12.

⁴ *Id.*

⁵ Defendant Becton actually initiated the court battle in March 2004 in the District of Massachusetts by seeking a declaratory judgment of noninfringement of two of Abbott’s patents. Abbott countersued in the Northern District of California alleging that Becton’s test strip infringed the two patents for which Becton sought a declaratory judgment, as well as a third patent, which became the subject of the inequitable conduct allegation. The District of Massachusetts then transferred its case to the Northern District of California, where the cases were consolidated. *Id.* at *3.

patent. In response, Becton asserted the “inequitable conduct” defense, arguing that the ’551 patent was unenforceable, since Abbott did not disclose its filings in Europe.

The inequitable conduct doctrine is a judge-made equitable defense to patent infringement that, when proven, bars enforcement of a patent. The defense evolved from three Supreme Court cases in which the Court applied the unclean hands doctrine, denying the patentees the right to enforce their patents because they engaged in egregious misconduct.⁶ The remedy has been characterized as the “atomic bomb” of patent law, as a finding of inequitable conduct regarding any single claim renders the entire patent, and any related patents, unenforceable.⁷ Inequitable conduct cannot even be cured by reissuing the patent. Moreover, a finding of inequitable conduct “may spawn antitrust and unfair competition claims” and/or lead to an award of attorneys’ fees under 3 U.S.C. § 285.⁸ The inequitable conduct defense has become an attractive proposition for patent infringement defendants, as approximately eighty percent of patent infringement cases include inequitable conduct allegations.⁹

Following a bench trial in the Northern District of California, the district court held, *inter alia*, that Abbott could not enforce the ’551 patent because it engaged in inequitable conduct when it failed to disclose its position to the European Patent Office. The United States Court of Appeals for the Federal Circuit affirmed the district court’s decision, but one judge dissented on the inequitable conduct issue. The Federal Circuit, however, granted Abbott’s petition for rehearing *en banc*. In a 6-1-4 decision, the Federal Circuit *en banc* vacated the district court’s finding of inequitable conduct and remanded the case.

II. The Federal Circuit’s En Banc Decision

Chief Judge Rader, writing for the majority, began his inquiry by reviewing the evolution of the inequitable conduct defense. As the inequitable conduct defense evolved from the unclean hands doctrine, it grew to encompass “not only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts but also the mere nondisclosure of information to the PTO.”¹⁰ The defense also diverged from the doctrine of unclean hands by adopting a different and more potent remedy--unenforceability of the entire patent, rather than mere dismissal of the instant lawsuit.

The courts have recognized that a successful inequitable conduct defense must prove two elements: (1) that the patentee misrepresented or omitted material information to the PTO; and (2) that the patentee acted with the specific intent to deceive the PTO. As time passed, however, the courts have conflated and diluted the standards for inequitable conduct. In some cases, courts allowed findings of gross negligence, or even ordinary negligence, to satisfy the intent element. The courts also recognized low standards for materiality, requiring only “a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the

⁶ *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery 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. General Excavator Co.*, 290 U.S. 240 (1933).

⁷ *Therasense*, 2011 WL 2028255, at *8.

⁸ *Id.*

⁹ *See id.* (citing Ad Hoc Committee on Rule 56 and Inequitable Conduct, American Intellectual Property Law Association, Position Paper, *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1988); Christian Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329, 1358 (2009)).

¹⁰ *Therasense*, 2011 WL 2028255, at *6.

application to issue as a patent.”¹¹ Further weakening the standards were some courts’ use of a “sliding scale,” in which courts held patents unenforceable based on a reduced showing of intent if the record contained a strong showing of materiality, or vice-versa.

Although formulated for the purpose of encouraging disclosure to the PTO, the broad interpretation of inequitable conduct “has had numerous unforeseen and unintended consequences.”¹² In particular, loose standards for proving the defense have led to “increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality.”¹³

Recognizing scholarship and case law that derided the proliferation of inequitable conduct allegations as a “plague,” the majority chose to tighten and clarify the standards for proving the elements of intent and materiality.¹⁴ The court also rejected the use of a sliding scale for these requirements, emphasizing that intent and materiality are separate elements. Finally, the court provided guidance regarding the appropriateness of unenforceability as a remedy.

A. *Intent.* The *Therasense* court held that, “[t]o prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.”¹⁵ Findings of gross negligence or ordinary negligence under a “should have known” standard are not sufficient to establish the element of intent. Rather, the accused infringer must prove by clear and convincing evidence that the applicant “made a deliberate decision to withhold a known material reference.”¹⁶

Recognizing that direct evidence of deceptive intent is rare, the court held that the clear and convincing burden can be met by inference based upon indirect and circumstantial evidence. An inference of deceptive intent, though, must be the “single most reasonable inference” and “when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.”¹⁷ A district court’s factual findings on such should be reviewed for clear error.

Finally, the court clarified that the accused infringer bears the burden of proof for inequitable conduct. Consequently, the patentee need offer a good faith explanation for a misrepresentation or omission only if the accuser satisfies “a threshold level of intent to deceive by clear and convincing evidence[,]” and “[t]he absence of a good faith explanation . . . does not, by itself, prove intent to deceive.”¹⁸

B. *Materiality.* In addition to adjusting the standard for finding intent, the court tightened the requirements for materiality. Specifically, the court enunciated an objective standard of but-for materiality.¹⁹

¹¹ *Id.* at *7 (quoting PTO Rule, 37 C.F.R. § 1.56 (1977) (commonly referred to as “PTO Rule 56”).

¹² *Id.*

¹³ *Id.* at *9. For a more detailed discussion of the unforeseen and unintended consequences of the doctrine, see *id.* at *7-*9.

¹⁴ *Id.* at *8-*9.

¹⁵ *Id.* at *9.

¹⁶ *Id.* The court drew upon the trio of Supreme Court cases noted *supra* to support restricting the defense to instances involving deliberate intent. *Id.* at *10.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.* at *11.

Under this standard, the accused infringer must prove by preponderance of the evidence²⁰ that “the PTO would not have allowed a claim [by the patentee] had it been aware of the undisclosed prior art.”²¹ The Federal Circuit instructed district courts to “give claims their broadest reasonable construction.”²²

The court, however, set forth an exception to but-for materiality in cases of affirmative egregious misconduct. In such instances, the misconduct itself is deemed material since a patentee is unlikely to engage in deceptive behavior unless “it believes that the falsehood will affect issuance of the patent.”²³ Despite this exception, the court characterized the “mere nondisclosure of prior art references to the PTO” or the “failure to mention prior art references in an affidavit” as not constituting affirmative acts of egregious misconduct and directed that inequitable conduct claims based upon such omissions meet the standard of but-for materiality.²⁴

C. *Equitable Considerations.* Noting that the inequitable conduct doctrine is equitable in nature and therefore governed by principles of basic fairness, the court recognized that the doctrine only should be enforced “where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”²⁵ Where the patentee only has committed minor missteps or acted with minimal culpability, the court should avoid ruling an entire patent unenforceable.²⁶

²⁰ Unlike the element of intent, which requires clear and convincing evidence, materiality need only be proven by preponderance of the evidence.

²¹ *Id.* Such a standard is distinguishable from the PTO’s definition of materiality under PTO Rule 56. *Id.* at *14. As discussed *infra*, the dissent advocates adoption of Rule 56 as the appropriate standard. The majority opinion, however, responds to the dissent and justifies diverging from the PTO definition by arguing that prior instances of “[t]ying the materiality standard for inequitable conduct to PTO rules . . . has led to uncertainty and inconsistency in the development of the inequitable conducts doctrine.” *Id.*

Although the *Therasense* court did not extensively discuss specific fact patterns that would satisfy the materiality element, it offered one example for guidance. According to the court, an accused infringer satisfies the materiality element if it also successfully establishes the “invalidity defense” based upon withheld references to prior art. The invalidity defense, which is wholly separate from the inequitable conduct defense, asserts that the PTO never should have issued the patent. One way of proving invalidity is by showing that the patentee withheld references to prior art that would have otherwise resulted in the PTO denying the patent application. Unlike the inequitable conduct defense, the invalidity defense does not require intent to deceive. In *Microsoft Corp. v. i4i Limited Partnership*, the Supreme Court recently held that the invalidity defense must be proven by clear and convincing evidence. No. 10-290, slip op. at 1 (U.S. June 9, 2011). Both the invalidity defense and the materiality element of the inequitable conduct defense focus on whether the PTO would have issued a patent had it been aware of certain information regarding prior art. As the standard for the invalidity defense is “clear and convincing evidence,” it logically follows that by proving invalidity based upon withheld references to prior art, the accused infringer also has satisfied the lower standard of “preponderance of the evidence” that governs the materiality element of the inequitable conduct defense. However, even if an accused infringer seeking to establish the inequitable conduct defense satisfies the materiality element by proving invalidity, the accused infringer still must establish by clear and convincing evidence that the patentee intended to deceive the PTO.

²² *Id.* at *11 (citing Manual of Patent Examining Procedure §§ 706, 2111 (8th ed. Rev. 8, July 2010)).

²³ *Id.* at *12.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.* (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

D. *The Federal Circuit’s Remand for Further Proceedings.* After tightening the standards for intent and materiality and offering guidance on the rendering of unenforceability judgments, the court noted that the district court had reached its decision using standards inconsistent with the Federal Circuit’s majority opinion in *Therasense*. Consequently, the court vacated the district court’s finding of inequitable conduct and remanded the case for further proceedings.²⁷

III. Concurring Opinion

Judge O’Malley concurred with the majority’s decision on the intent requirement²⁸ but rejected both the majority’s adoption of the but-for materiality test and the dissent’s advocacy for a standard according to PTO Rule 56 as too strict. According to Judge O’Malley, neither test retains sufficient flexibility for an equitable doctrine. Instead, the O’Malley opinion advocates the adoption of a test that provides guidance to district courts while allowing the courts sufficient discretion in circumstances that may arise under equity jurisdiction but are difficult to predict in advance.

Under Judge O’Malley’s standard, materiality should be found where: “(1) but for the conduct (whether it be in the form of an affirmative act or intentional non-disclosure), the patent would not have [been] issued . . . ; (2) the conduct constitutes a false or misleading representation of fact (rendered so either because the statement made is false on its face or information is omitted which, if known, would render the representation false or misleading); or (3) the district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined.”²⁹ After applying the facts of *Therasense*, O’Malley concluded that Abbott’s omissions were material under the but-for prong and that the district court’s findings on materiality should be affirmed both under her standard and the majority’s.

Judge O’Malley also argued for granting district courts flexibility in terms of the remedy they may fashion when inequitable conduct exists. Consistent with O’Malley’s advocacy for judicial discretion at the district level, she sets forth a standard under which “a district court may choose to render fewer than all claims unenforceable, may simply dismiss the action before it, or may fashion some other reasonable remedy . . . commensurate with the violation.”³⁰

IV. Dissenting Opinion

Judge Bryson, joined by three others, filed a dissenting opinion. The dissenters disagreed with the majority’s materiality standard³¹ and advocate adopting PTO Rule 56 as the appropriate test. PTO Rule 56 provides that

²⁷ *Id.* at *16.

²⁸ *Id.* at *17. Judge O’Malley offered a caveat to her joining the portion of the majority opinion setting forth the intent standard: “I do so with the understanding that the majority does not hold that it is impermissible for a court to consider the level of materiality as circumstantial evidence in its intent analysis.” *Id.* at *17 n.1.

²⁹ *Id.* at *20.

³⁰ *Id.* at *19.

³¹ The dissent expressed agreement with the majority’s requirement of specific intent and rejection of the sliding scale test. *Id.* at *22.

[I]nformation is material if it is not cumulative to information already of record or being made of record in the application and (1) [i]t establishes . . . a prima facie case of unpatentability of a claim; or (2) [i]t refutes, or is inconsistent with a position the applicant takes in: (i) [o]pposing an argument of unpatentability relied on by the [PTO], or (ii) [a]sserting an argument of patentability.³²

In addition to drawing upon cases in other area of the law that reject but-for standards of materiality, the dissent (which characterizes the majority approach as “far more radical”)³³ sets forth two reasons why adopting Rule 56 is proper. First, the dissent believes the PTO’s definition is entitled to deference because the PTO is in the best position to determine the type of information its examiners need to conduct effective investigations. Second, the dissent argues that the majority’s standard “will not provide appropriate incentives for patent applicants to comply with the disclosure obligations.”³⁴

V. Significance of the Decision

The Federal Circuit’s opinion in *Therasense* illustrates the concern that the inequitable conduct defense has expanded too far beyond its original conception, leading to unnecessary burden on the patent system and the courts. In an effort to rein in overuse of the inequitable conduct defense, the court issued a holding that has been described by some headlines as essentially “gutting” the inequitable conduct defense.

The defendants in *Therasense* have moved to stay the court’s decision pending review by the U.S. Supreme Court. Only a day after the court handed down its order, a federal magistrate in Marshall, Texas relied extensively on *Therasense*, denying an accused infringer’s motion for a finding of unenforceability due to inequitable conduct.³⁵ A few days later, Judge Wolfson of the District of New Jersey discussed *Therasense* as support for her holding in *Jersey Asparagus Farms, Inc. v. Rutgers University*.³⁶

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If you have any questions about the issues addressed in this memorandum or if you would like a copy of any of the materials mentioned, please do not hesitate to call or email Charles A. Gilman at 212.701.3403 or cgilman@cahill.com; Jon Mark at 212.701.3100 or jmark@cahill.com; John Schuster at 212.701.3323 or jschuster@cahill.com; or Mark Pincus at 212.701.3019 or mpincus@cahill.com.

³² *Id.* at *31 (quoting PTO Rule 56).

³³ *Id.* at *23.

³⁴ *Id.* at *22. The dissent offers the following rationale as support for its second reason: “If a failure to disclose constitutes inequitable conduct only when a proper disclosure would result in rejection of a claim, there will be little incentive for applicants to be candid with the PTO, because in most instances the sanction of inequitable conduct will apply only if the claims that issue are invalid anyway.” *Id.* at *25.

³⁵ Nate Raymond, *Citing Day-Old Federal Circuit Ruling in Therasense, Judge Rejects Inequitable Conduct Defense in Texas Infringement Suit*, The AmLaw Litigation Daily, May 26, 2011, http://www.law.com/jsp/tal/digestTAL.jsp?id=1202495380243&Citing_DayOld_Federal_Circuit_Ruling_in_Therasense_Judge_Rejects_Inequitable_Conduct_Defense_in_Texas_Infringement_Suit.

³⁶ 2011 WL 2148631, at *13-*15 (D.N.J. May 31, 2011).