



JONES DAY
COMMENTARY

***THERASENSE v. BECTON, DICKINSON*: THE FEDERAL CIRCUIT HEIGHTENS THE STANDARD FOR PROVING INEQUITABLE CONDUCT IN PATENT LITIGATION**

On May 25, 2011, the Federal Circuit issued its much-anticipated *en banc* opinion in *Therasense, Inc. v. Becton, Dickinson & Co.* In that opinion, the Federal Circuit “tighten[ed]” the standards for proving inequitable conduct in patent litigation, requiring heightened showings of both intent and materiality before inequitable conduct will be found, and rejecting a “sliding scale” approach that had been endorsed by previous decisions. The court also held that the traditional remedy for inequitable conduct—a finding that the entire patent is unenforceable—should be limited to circumstances when “the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”

The *en banc* court was divided 6-1-4 (four judges dissented, and one dissented-in-part). But there is little question that the court’s new, “tighten[ed]” approach will, if it is not reviewed and altered by the U.S. Supreme Court, make it harder to prove inequitable conduct in patent litigation.

The opinion will also likely have broad implications for patent prosecution before the United States Patent and Trademark Office (“PTO”). Only a day after the *Therasense* decision, the PTO issued a press release announcing that it expects to soon issue guidance to patent applicants related to the prior art and information they must disclose to the Office in view of *Therasense*.

Below, we briefly trace the path to the *Therasense* decision.

INEQUITABLE CONDUCT BEFORE *THERASENSE*

The defense of inequitable conduct is a judge-made doctrine borne out of a series of Supreme Court cases utilizing the equitable doctrine of unclean hands to dismiss patent cases involving egregious misconduct by the patentee. Inequitable conduct

typically occurs when a patent applicant breaches the duty of candor it owes to the PTO, and does so with deceptive intent. It can arise from either an affirmative misrepresentation, or failure to disclose certain information, to the PTO.

To prove inequitable conduct, the accused infringer must show by clear and convincing evidence that: (1) the patent owner withheld material information from, or provided false material information to, the PTO; and (2) did so with an intent to deceive the PTO. Before *Therasense*, courts commonly followed PTO Rule 56 (37 C.F.R. § 1.56) in determining whether information or prior art was material, a standard that has changed over time as the regulation itself has changed. The intent element was shown by direct evidence, or inferred in light of the surrounding circumstances.

Until *Therasense*, courts also utilized a “sliding scale” approach when analyzing materiality and intent, such that a greater level of materiality required a lower level of intent, and vice versa, before inequitable conduct could be found. If the accused infringer proved materiality and intent, the judge was then required to exercise his or her discretion to determine whether the equities warranted a conclusion that inequitable conduct occurred, and that the entire patent should be adjudged unenforceable. This “atomic bomb” remedy—as described by Chief Judge Rader in his opinion for the *Therasense* court—made the inequitable conduct defense an all-too-often-used litigation tactic for accused infringers. On the other hand, patent applicants, to be safe, would overload the PTO with prior-art references, many of which had marginal relevance. These negative, unintended consequences of the inequitable-conduct doctrine led to it being described as an “absolute plague” on the patent system and gave rise to the Federal Circuit’s desire to revisit the contours of the doctrine *en banc*.

***TERASENSE’S* FACTUAL AND PROCEDURAL BACKGROUND**

The Federal Circuit’s opinion sets forth this background of the case:

Therasense, Inc. owned U.S. Patent No. 5,820,551 (“the ‘551 patent”), which involves disposable blood-glucose test

strips for diabetes management. These strips are used in glucose meters and employ electrochemical biosensors to measure the level of glucose in a sample of blood. The ‘551 patent claims a test strip with an electrochemical sensor for testing whole blood without a protective membrane over the electrode.

Therasense filed the original application leading to the ‘551 patent in 1984. The application remained in prosecution for more than 13 years, during which time it was repeatedly rejected over U.S. Patent No. 4,545,382 (“the ‘382 patent”), also owned by Therasense. Eventually, Therasense submitted amended claims based on a sensor that did not require a protective membrane for whole blood, and argued that this distinction would overcome the prior art ‘382 patent, whose electrodes allegedly required a protective membrane. The specification of the ‘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.” This “optionally but preferably” language became the single roadblock to allowance, as the examiner focused on whether the ‘382 patent indeed disclosed membraneless devices for use with whole blood. Therasense submitted a declaration stating that one skilled in the art would not have read the above-quoted language of the ‘382 patent to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred in view of the teaching of the rest of the patent. Therasense also argued to the PTO that the “optionally but preferably” language was mere patent phraseology, and that the ‘382 patent did not teach or suggest unprotected active electrodes for use with whole blood. Based on the claim amendments, the declaration, and the accompanying arguments, the examiner finally allowed the ‘551 patent to issue.

In March 2004, Therasense filed a lawsuit in the Northern District of California against several defendants, including Becton, Dickinson & Company (“BD”), alleging infringement of the ‘551 patent. Following trial, the district court held, among other things, that the ‘551 patent was unenforceable due to inequitable conduct because Therasense did not disclose to the PTO allegedly inconsistent statements that had previously been made to the European Patent Office regarding the same “optionally but preferably” language in

the European counterpart to the '382 patent. Therasense appealed to the Federal Circuit, where a three-judge panel initially affirmed the holding of unenforceability. Therasense then petitioned for rehearing *en banc*. The Federal Circuit, recognizing the problems inherent in the inequitable conduct doctrine as it stood, granted the petition in an April 26, 2010, order vacating the judgment of the panel. Oral argument took place on November 9, 2010.

THE FEDERAL CIRCUIT'S *EN BANC* DECISION

Eleven Federal Circuit judges participated in the *en banc* Therasense decision. (The court normally consists of 12 judges, but there is presently one seat open.) The court divided 6-1-4. The majority opinion, written by Chief Judge Rader, was joined by Judges Newman, Lourie, Linn, Moore, and Reyna. Judge O'Malley issued her own opinion, partially concurring with the majority opinion and partially dissenting. Judge Bryson authored a dissenting opinion, which was joined by Judges Gajarsa, Dyk, and Prost. (Interestingly, Judges O'Malley and Reyna were not members of the court at the time of oral arguments in November 2010; they were confirmed to the Federal Circuit in December 2010 and April 2011, respectively.)

The Majority Raises the Bar for Proving Inequitable Conduct. The Federal Circuit's majority opinion vacated the district court's inequitable conduct judgment and remanded for further proceedings consistent with the opinion. Agreeing with the sentiment that "[l]eft unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system," the majority "tighten[ed] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." In particular, the following six highlights emerge from the majority's opinion:

1. To prevail on a claim of inequitable conduct, an accused infringer must prove that the patentee acted with specific intent to deceive the PTO. A finding that a misrepresentation or omission amounts to gross negligence or negligence under a "should have known" standard does not satisfy this intent requirement. In a case that involves nondisclosure of information, the accused infringer must prove by clear and

convincing evidence that the applicant: (a) knew of the reference, (b) knew that it was material, and (c) made a deliberate decision to withhold it. Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. However, to meet the clear and convincing evidence standard, the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." Thus, when multiple reasonable inferences may be drawn, intent to deceive cannot be found. Moreover, the absence of a good-faith explanation from the patentee for withholding a material reference does not, by itself, prove intent to deceive. Indeed, a patentee need not provide a good faith explanation unless and until the accused infringer establishes "a threshold level of intent to deceive by clear and convincing evidence."

2. As a general matter, the materiality required to establish inequitable conduct is "but-for" materiality. With regard to undisclosed prior art, but-for materiality is present only if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction. The majority tied its but-for standard to the basic fairness that underlies all doctrines of equity, noting that if a patent would have issued regardless of a patentee's misconduct, the patentee has gained no advantage from the misconduct, nor is the public harmed by the enforcement of an otherwise valid patent. Notably, the majority declined to adopt the definition of materiality in PTO Rule 56, finding that Rule 56 sets such a low bar for materiality that adopting this standard would "inevitably result in patent prosecutors continuing the existing practice of disclosing too much prior art of marginal relevance and patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy."

3. There is an exception to but-for materiality in cases of affirmative egregious misconduct. When a patentee engages in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material regardless of the effect the misconduct had on the patent issuing. However, because neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious

misconduct, claims of inequitable conduct based on such omissions require proof of but-for materiality.

4. Intent and materiality are separate requirements. A district court should not use a “sliding scale,” where intent may be found sufficient based on a strong showing of materiality, and vice versa, nor may a district court infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality.

5. As an equitable doctrine, inequitable conduct hinges on basic fairness. Because the remedy for inequitable conduct is akin to an “atomic bomb” rendering an entire patent (or even a patent family) unenforceable, the doctrine should be applied only in instances where the patentee’s misconduct actually resulted in the unfair benefit of receiving an unwarranted claim. In other words, even after finding the materiality and intent prongs to be satisfied by clear and convincing evidence, a court still must weigh the equities to determine whether the remedy of inequitable conduct is warranted.

6. The unclean hands doctrine remains an available remedy, separate from inequitable conduct, for egregious misconduct. This is so even though Supreme Court unclean hands cases formed the basis of the inequitable conduct doctrine. The majority stressed that these early unclean hands cases did not contain any materiality standard and that the Federal Circuit’s development of such a standard with respect to inequitable conduct “does not (and cannot) supplant Supreme Court precedent.”

With these changes to the inequitable-conduct doctrine, the majority sought to remedy what it noted to be the many unforeseen and unintended consequences resulting from the previous low standards for intent and materiality, including increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, and impaired patent quality. While the majority recognized that equitable doctrines require some measure of flexibility, it rejected the notion—advanced by Judge O’Malley in her separate opinion—that the use of rules and tests for determining inequitable conduct is inappropriate in view of the way in which the doctrine has “metastasized.”

Judge O’Malley’s Separate Opinion. Judge O’Malley concurred-in-part and dissented-in-part. Within her opinion, Judge O’Malley agreed with the majority’s decision relating to the intent element for inequitable conduct and the majority’s abolition of the sliding-scale approach to materiality and intent. Judge O’Malley also agreed that the case should be remanded so that the district court could properly consider whether there was intent to deceive.

Judge O’Malley parted company with the majority, however, by urging that district courts should be afforded significant flexibility when deciding both whether inequitable conduct occurred, and, if so, what the appropriate remedy should be. Judge O’Malley based her position on the premise that inequitable conduct is an equitable doctrine that judges should have great discretion in applying. To this end, Judge O’Malley argued that both the majority and dissenting positions in *Therasense* wrongly seek to impose hard-and-fast rules for district courts to apply when deciding inequitable conduct. The approaches of the majority and dissent fail to appreciate that there will undoubtedly be circumstances, not envisioned here, where inequitable conduct should be found even though the circumstances are not encompassed by rigid tests. Moreover, assuming inequitable conduct is found, the district court should not be limited to choosing only one remedy—total unenforceability—but rather should have the discretion to select other remedies as appropriate (e.g., finding only certain claims unenforceable, dismissing the action, etc.), subject to statutory constraints.

Judge Bryson’s Dissenting Opinion. Writing for himself and three other judges, Judge Bryson agreed with the majority opinion on the subject of intent and its rejection of the sliding scale approach. Judge Bryson, however, vehemently disagreed with the majority on the proper standard for materiality. On this point, Judge Bryson argued that the majority’s “but-for” standard is too radical a change to the test for inequitable conduct and that it marks an “unwise departure from this court’s precedents.” Indeed, Judge Bryson describes the majority’s new test as not “merely reform[ing] the doctrine of inequitable conduct, but com[ing] close to abolishing it altogether.”

Instead of the “but-for” standard, the dissenting opinion advocates following the PTO’s present standard for materiality set forth in 37 C.F.R. § 1.56: that information is material if it establishes a *prima facie* case of unpatentability, or if it refutes or is inconsistent with a position the patent applicant takes before the PTO with respect to patentability. Such a standard, the dissent argued, is consistent with Federal Circuit and Supreme Court precedent. Moreover, “the PTO is in the best position to know what information examiners need to conduct effective and efficient examinations, *i.e.*, what information is material to the examination process.” Citing the PTO’s *amicus* brief, the dissent further argued that the “but-for” standard actually entices an applicant not to disclose a potentially invalidating prior art reference to the PTO, since later discovery of that reference, and presumed finding of inequitable conduct, would essentially apply to claims that would be invalid anyway. Put simply, the dissent argued that the “but-for” test for materiality is too restrictive and swings the pendulum too far in the other direction, making inequitable conduct nothing more than a paper tiger.

CONCLUSION

While the majority opinion in *Therasense* unquestionably makes it more difficult to prove inequitable conduct in patent litigation, it remains to be seen what real effects this will have in patent litigation, and whether it will truly result in the diminished use of inequitable conduct as a defense in patent cases. Indeed, as the majority notes, the Federal Circuit attempted to curtail the inequitable conduct doctrine by raising the intent standard in its 1988 *Kingsdown* decision, without any real success. Moreover, it is too early to know exactly how *Therasense* will affect the behaviors of patent applicants, and their counsel, engaged in prosecution before the PTO. On that latter point, the PTO’s forthcoming guidance on the subject of inequitable conduct may provide clues to what the future might bring.

Most significantly, however, is the possibility of Supreme Court review of the *Therasense* decision. The Supreme Court has shown a greater interest in reviewing Federal Circuit patent decisions over the last eight years, and it has not treated the Federal Circuit’s decisions particularly kindly in those cases, oftentimes replacing rigid rules announced by the Federal Circuit with more flexible, case-by-case standards. On June 1, 2011, BD filed a motion with the Federal Circuit to stay the issuance of the mandate in the *Therasense* case pending the filing of a petition for writ of certiorari to the Supreme Court. In this motion, BD asserted that the Federal Circuit’s decision in *Therasense* “constitutes a dramatic change from established precedent,” and that the Supreme Court “likely will also want to consider the impact of the new materiality standard on the integrity of the U.S. patent system and on the public interest in the PTO’s ability to issue strong patents.” It remains to be seen whether the Court will take up the issue of inequitable conduct in its next Term.

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