

DISMANTLING THE ATOMIC BOMB OF PATENT DEFENSES

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On May 25, 2011, the Court of Appeals for the Federal Circuit (CAFC) issued a long-awaited en banc decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 2011 U.S. App. LEXIS 10590 (Fed. Cir. 2011). The decision raises the standard for proving inequitable conduct and presumably will make it much more difficult for defendants to succeed on the inequitable conduct defense, which has often been referred to as the “atomic bomb” of patent defenses due to its immensely destructive effects on patent rights.

In a 6-1-4 decision, the court held: (1) the sliding scale test for materiality and intent no longer applies, (2) materiality and intent must be separately proven by clear and convincing evidence, (3) specific intent to deceive the United States Patent & Trademark Office (hereinafter PTO) cannot be inferred unless such inference is the only reasonable inference that can be drawn from the evidence, (4) materiality requires a finding that, but for the information not being disclosed to the PTO, the claim at issue would not have been allowed, and (5) even if materiality and intent are proven by clear and convincing evidence, the patent will only be held to be unenforceable if the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim. The court carved out an exception to the but-for materiality requirement for cases where egregious affirmative misconduct on the part of the patentee is proven.

Background

At the core of the decision were claims in U.S. Patent No. 5,820,551 (hereinafter the ‘551 patent) issued to Therasense, Inc. (now Abbott Diabetes Care, Inc.). The claims at issue were

directed to disposable blood glucose test strips for diabetes management. Among other elements of the claims, the claims recite an active electrode “configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member....” The claims had been repeatedly rejected by the examiner over another patent owned by Abbott, U.S. Patent No. 4,545,382 (hereinafter the ‘382 patent). In discussing protective membranes, the disclosure of the ‘382 patent reads, “[o]ptionally, 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.” The examiner found that this language taught exposing an active electrode to a whole blood sample without an intervening membrane or other whole blood filtering member, as recited in the claims of the ‘551 patent.

In order to overcome the examiner’s rejection, the prosecuting attorney submitted a declaration by Abbott’s Director of Research and Development stating that “one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample.” Concurrently with the submission of the declaration, the prosecuting attorney submitted arguments that one skilled in the art would not have read this portion of the ‘382 patent as teaching that a protective membrane is optional when used with whole blood samples.

Many years earlier, during the prosecution of a counterpart application to the ‘382 patent in the European Patent Office (EPO), the European patent counsel for Abbott had argued in briefs submitted to the EPO that it was “unequivocally clear” from the disclosure that the protective membrane was optional, but preferred, when being used on live blood.

Subsequently, during the litigation in the district court, the court held that the ‘551 patent was unenforceable on grounds that the failure of Abbott to disclose the EPO briefs to the EPO constituted inequitable conduct. *Therasense, Inc. v. Becton, Dickinson & Co.*, 560 F. Supp. 2d 835 (N.D. Cal. 2008). On the first appeal, the CAFC affirmed the district court’s findings of invalidity, noninfringement and unenforceability. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289 (Fed. Cir. 2010). Abbott petitioned the court for an en banc rehearing. Recognizing that there were problems associated with the overuse and expansion of the inequitable conduct doctrine, the court granted the petition and vacated its prior affirmation of the district court’s findings of invalidity, noninfringement and unenforceability. *Therasense, Inc. v. Becton, Dickinson & Co.*, 374 Fed. Appx. 35 (Fed. Cir. 2010).

Majority Opinion

1. Origin of the Inequitable Conduct Doctrine

The majority opinion was written by Chief Judge Rader and joined in full by Judges Newman, Lourie, Linn, Moore and Reyna. In the en banc *Therasense* decision, the court discussed the evolution of the judicially-created doctrine of inequitable conduct from a trio of U.S. Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct: *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), *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), and *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). All of

these cases involved affirmative acts of deception on the part of the patentee before the PTO and/or the courts. *Keystone* involved suppression of evidence. *Hazel-Atlas* involved both the manufacture and suppression of evidence. *Precision* involved perjury before the PTO and suppression of the perjury before the court.

In discussing this trio of cases and the evolution of the inequitable conduct doctrine, the CAFC explained how the inequitable conduct doctrine had diverged from the unclean hands doctrine and had come to encompass, in addition to affirmative acts of misconduct, mere nondisclosure of information before the USPTO. The court discussed how the potency of the remedy for inequitable conduct had increased to include unenforceability of the entire patent rather than mere dismissal of the instant suit. The court discussed how the increased potency of the remedy for inequitable conduct had led the court in prior decisions to require findings of both intent to deceive and materiality in order to find inequitable conduct. The court acknowledged that the standards of materiality and intent applied by the court had fluctuated over time from standards for intent that could be met by showing negligence or gross negligence (should have known that the withheld reference was material) to the sliding scale test where inequitable conduct could be proved by a high showing of materiality combined with a low showing of intent, and vice versa.

The court also discussed at length the detrimental effects that overuse of the inequitable conduct defense has had on the PTO, the courts, patentees, and attorneys, including, for example, discouraging settlement, deflecting attention from the merits of invalidity and infringement issues, increasing the complexity, duration and cost of litigation, attacking the reputation of the prosecuting attorney, and increasing the number of references of only marginal value that are

disclosed to the PTO. The court referred to its previous decision in *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting) characterizing the inequitable conduct defense as the “atomic bomb” of patent law in that, unlike invalidity defenses that are directed to individual claims, inequitable conduct regarding any single claim can render the entire patent unenforceable, cannot be cured by reissue, can spread from a single patent to render unenforceable related applications and patents, can lead to awards of attorneys fees, and can give rise to antitrust and unfair competition claims.

2. Raising the Intent Standard

After discussing the origins of the inequitable conduct doctrine and public policy arguments that justify raising the standard for inequitable conduct, the court set forth a higher standard for inequitable conduct that purportedly will realign it with the unclean hands doctrine and reduce its overuse. In doing so, the court relied heavily on its holdings in *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008) and *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988). In particular, the court held that in order to prove intent, the defendant must prove by clear and convincing evidence that the applicant knew of a reference, knew that it was material, and made a deliberate decision to withhold it. The court explained that the requirement of knowledge and deliberate action had its origin in the trio of U.S. Supreme Court unclean hands cases, *Keystone, Hazel-Atlas and Precision*. The court also held that the sliding scale test, which has been applied in cases such as *Digital Equipment Corp. v. Diamond*, 653 F.2d 701 (1st Cir. 1981), *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984), *Union Pac. Res. Co. v. Chesapeake Energy*

Corp., 236 F.3d 684 (Fed. Cir. 2001), and *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309 (Fed. Cir. 2006), should not be used by district courts.

In addition, the court held that while specific intent to deceive may be inferred from the evidence, specific intent to deceive must be “the single most reasonable inference able to be drawn from the evidence,” quoting *Star Scientific*, 537 F.3d at 1366. The court held that the evidence “must be sufficient to require a finding of deceitful intent in the light of all the circumstances,” quoting *Kingsdown*, 863 F.2d at 873. The court further held that because the party alleging inequitable conduct bears the burden of proof, the “patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence,” quoting *Star Scientific*, 537 F.3d at 1368.

3. Raising the Materiality Standard

After setting forth the higher standard for proving intent, the court noted that the higher intent standard alone would not be sufficient to curb overuse of the inequitable conduct defense and would not cure the problem of over-disclosure of marginally relevant prior art to the PTO. For these reasons, the court also raised the materiality standard. The court found support for raising the standard in *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928). That case involved submission by the patentee of two affidavits to the PTO that falsely claimed that the invention had been used in the production of rubber goods when in fact only test slabs of rubber had been produced. The Court held that because the misrepresentations were not the but-

for cause of the patent's issuance, they were immaterial and refused to extinguish the patent's presumption of validity.

After laying the ground work for raising the materiality standard based on the holding set forth in *Corona Cord*, the CAFC went on to hold:

as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.

Thus, under the but-for materiality standard adopted by the court, a reference is not material unless the reference taken alone or in combination with other references would have rendered the claim unpatentable by a preponderance of the evidence.

The court explained that it is possible for a reference to be material under the higher but-for standard even if a court would not have rendered the claim at issue invalid because courts must find invalidity by the higher standard of clear and convincing evidence rather than by the lower, preponderance of the evidence standard. Conversely, the court also noted that if a claim is found by a court to be invalid over the reference taken alone or in combination with other references by clear and convincing evidence, the reference necessarily meets the but-for materiality standard adopted by the court. In the latter case, therefore, knowledge of the

reference coupled with deliberate failure to disclose the reference to the PTO could lead to a finding of inequitable conduct.

In adopting the higher standard for materiality, the court refused to adopt the definition for materiality set forth in 37 CFR §1.56 (hereinafter PTO Rule 56). As discussed below, this was a major point of contention between the majority and the dissent, which argued that the definition of materiality applied by the courts should be the definition supplied in PTO Rule 56.

4. Raising the Overall Standard for Inequitable Conduct

In addition to raising the standards for materiality and intent, the CAFC further raised the overall standard for inequitable conduct. Relying again on *Star Scientific*, the court held that “[b]ecause inequitable conduct renders an entire patent (or even a patent family) unenforceable, as a general rule, this doctrine should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”

Therefore, even in cases where the higher standards of materiality and intent are met, the patent still may not be held to be unenforceable if the patent would have issued despite the deliberate failure of the patentee to disclose the reference. The court did, however, set forth an exception to the requirement of finding but-for materiality, holding that in cases of affirmative acts of egregious misconduct, the misconduct will be deemed material. In such cases, inequitable conduct may be found without proving that the undisclosed information meets the but-for materiality test.

After setting forth the higher standard for finding inequitable conduct, the court reversed the district court's findings of inequitable conduct and remanded with instructions to the district court to determine whether the EPO briefs are material under the but-for standard, whether the prosecuting attorney or Abbott's Director of R&D knew of the EPO briefs, and whether the prosecuting attorney or Abbott's Director of R&D made a conscious decision not to disclose the briefs to the PTO in order to deceive the PTO.

Concurring and Dissenting Opinions

1. Concurring In Part, Dissenting In Part

Judge O'Malley wrote a separate concurring-in-part, dissenting-in-part opinion. In the concurring portion of the opinion, she agreed with the majority that (1) intent to deceive and materiality are separate requirements, (2) that the sliding scale test may not be used, (3) that intent to deceive may not be inferred from materiality alone, and (4) that intent may be inferred from circumstantial and indirect evidence only where it is the single most reasonable inference able to be drawn from the evidence.

In the dissenting portion of the opinion written by Judge O'Malley, she disagreed with the majority on the but-for materiality standard and on the remedy for inequitable conduct. She essentially argued that the but-for materiality test and the remedy for inequitable conduct adopted by the majority are too inflexible to comport with principles of equity adopted by the U.S. Supreme Court. With respect to the but-for materiality standard, she argued that *conduct* should be deemed material 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 issued (as Chief Judge Rader explains that concept in the majority opinion); (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.

Thus, Judge O’Malley argued for a more flexible standard for materiality than that adopted by the majority.

With respect to the remedy for inequitable conduct, Judge O’Malley also argued for a more flexible approach, stating that a district court should be allowed to choose “to render fewer than all claims unenforceable, may simply dismiss the action before it, or may fashion some other reasonable remedy,” so long as the remedy imposed by the court is commensurate with the violation.

2. Dissenting Opinion

Judge Bryson wrote a separate dissenting opinion in which Judges Gajarsa, Dyk and Prost joined. The dissent substantially agreed with the majority’s higher standard for intent to deceive, i.e., that a showing of specific intent to deceive the PTO is required, that negligence or even gross negligence is not enough, that both specific intent and materiality must be separately shown by clear and convincing evidence, and that the sliding scale approach should not be used.

With respect to the but-for materiality standard adopted by the majority, the dissent sharply disagreed with the majority on the issue. The dissent argued that the court has always looked to PTO Rule 56 as the standard for defining materiality in cases involving failure to disclose information to the PTO. PTO Rule 56, in its current form, defines information as material if (1) it establishes a *prima facie* case of unpatentability, or (2) it refutes or is inconsistent with a position taken by the applicant in opposing an argument of unpatentability relied on by the PTO or in asserting an argument of patentability. The dissent argued that the materiality standard set forth in PTO Rule 56 should be the standard applied by the courts because (1) the PTO is in the best position to know what information examiners need to conduct effective and efficient examinations, and (2) the higher materiality standard adopted by the majority will not provide sufficient incentives for applicants to comply with disclosure obligations that are placed on them by the PTO.

The dissent argued that the higher standard adopted by the majority nearly abolishes, rather than reforms, the inequitable conduct doctrine:

[i]f 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. For example, under the “but for” test of materiality, an applicant considering whether to disclose facts about a possible prior use of the invention would have little reason to disclose those facts to the PTO. If the applicant remained silent about the prior use, the patent issued, and the prior use was never discovered, the applicant would benefit from the nondisclosure. But even if the prior use was discovered during litigation, the failure to disclose would be held to constitute inequitable conduct only if the prior use otherwise rendered the relevant claims invalid. The applicant would thus lose nothing by concealing the prior use from the PTO, because he would not be at risk of losing the right to enforce an otherwise valid patent.

As pointed out by the dissent, in many cases the majority's but-for materiality standard will only be met when the claim is invalid anyway in view of the prior art. This, however, is not necessarily the case. As indicated above, under the standard adopted by the majority, a reference is material if the reference taken alone or in combination with other prior art would render a claim invalid by a preponderance of the evidence. A court, however, determines invalidity based on the clear and convincing evidence standard. Therefore, there may very well be situations where the majority's but-for materiality standard is met even though a court would not find the claim to be invalid.

Effect of the En Banc *Therasense* Ruling

Because the district courts and the Federal Circuit are obliged to follow Federal Circuit precedent, the *Therasense* decision should make it much more difficult for defendants to succeed on the inequitable conduct defense and should result in fewer inequitable conduct defenses being asserted. In order to succeed on inequitable conduct defenses, defendants will be required to show by clear and convincing evidence that undisclosed information taken alone or in combination with other references would more likely than not have rendered a claim unpatentable, that the applicant knew of the information, and that the applicant deliberately failed to disclose the reference to the PTO in order to deceive the PTO. If the defendant is relying on circumstantial evidence to show intent, then the defendant will have to show that the single most reasonable inference to be drawn from the evidence is that the patentee intended to deceive the PTO by withholding the prior art.

In addition, even if the defendant can meet this heavy burden, the defendant will not succeed on the defense unless the misconduct resulted in the unfair benefit of receiving an unwarranted claim. Therefore, if the patent would have issued despite the misconduct, the patent will not be held to be unenforceable.

However, if a defendant can show that the patentee engaged in affirmative egregious acts of misconduct, then the defendant will not need to show that the information meets the but-for materiality standard. Therefore, in cases where the defendant can show that the patentee intentionally misled the PTO and that the deception resulted in the patentee receiving an unwarranted claim, the defendant should prevail on the inequitable conduct defense.

The decision should also have the effect of drastically reducing the amount of information that applicants are required to disclose to the PTO. Decisions by the CAFC in recent cases such as *McKesson Information Services, Inc. v Bridge Medical, Inc.* (Fed. Cir. 2007) have created incentives for applicants to over-disclose information to the PTO, even if the information is only of marginal value, if that. For example, many applicants, especially large corporations with large patent portfolios, err on the side of caution by cross-citing applications that arguably have some related subject matter, but that are not related as parent/child applications or as foreign counterparts. In addition to cross-citing the applications themselves, applicants have been faced with the daunting task of also cross-citing any prior art, office actions, search reports, responses, or other potentially relevant information cited in the cross-cited applications. This has resulted in exponential increases in the amounts and types of information that applicants cite to the PTO, even if the information is not known to be relevant to patentability. The decision in *Therasense* should greatly reduce this burden.

In addition, a few days after the *Therasense* decision was handed down, the PTO announced that it would be studying the decision and would soon issue guidance to applicants as to the prior art and information they must disclose to the PTO to meet information disclosure requirements. It seems likely that the PTO will revise PTO Rule 56 to comport with the decision, possibly by revising the definition of materiality in Rule 56 to be consistent with the but-for materiality standard adopted by the majority. If that happens, much of the disagreement between the dissent and the majority in *Therasense* would become moot.

Because the decision was split, however, many practitioners may be left wondering whether future CAFC panels will deviate from the majority decision in *Therasense*. I suppose only time will tell. It should be of some comfort to practitioners and to patentees that the dissent agreed with the majority on the higher standard for intent. Therefore, even if district courts and even the CAFC deviate in the manner in which they apply the materiality standard, there should at least be uniformity in applying the higher intent standard. Consequently, the decision should curb the overuse of the inequitable conduct defense and reduce the disclosure burdens experienced by practitioners and patentees.

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