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Federal Circuit Restricts the Doctrine of Inequitable Conduct in *Therasense v. Becton Dickinson*

The Federal Circuit has significantly raised the bar for proving inequitable conduct. *Therasense v. Becton Dickinson*, No. 2008-1511 (Fed. Cir., May 25, 2011) (en banc). The test for inequitable conduct now requires proving by clear and convincing evidence:

1. But-for materiality: the PTO would not have allowed the patent based on the non-disclosed reference;
2. Specific intent to deceive the PTO separate from materiality (a deliberate decision to withhold a known material reference).

Despite raising the bar for inequitable conduct, we do not expect a significant change in patent prosecution practice, specifically in IDS preparation, as submitting prior art before the USPTO also provides the benefit of consideration by the Examiner. However, the USPTO is preparing new guidance under the *Therasense* decision. We will keep you updated as to these developments.

Majority Opinion (Rader, C.J.)

In their decision in *Therasense*, the Federal Circuit has tightened the standards for proving inequitable conduct in order to redirect a doctrine that has been overused to the detriment of the public. *Id.* at 24. The concept of a “sliding scale” is explicitly abandoned, “[a] district court should not use a sliding scale, where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.” *Id.* at 25. This aspect of the holding restates the holding of *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988). Specifically, *Therasense* restates that intent and materiality are separate requirements and then goes further to meaningfully redefine both elements.

For purposes of inequitable conduct, materiality is no longer defined as whether a reference “refutes or is inconsistent with any position the applicant took regarding patentability,” as stated by the current version of PTO Rule 56, 37 C.F.R. § 1.56 (1992). *Id.* at 32. A reference is now “material”, as the term applies to inequitable conduct, if the PTO would not have allowed a claim had it been aware of the reference, imposing a but-for standard for materiality. *Id.* at 27. The court based this holding on the premise that it is unfair to render a patent unenforceable if the PTO would have granted the patent notwithstanding the undisclosed reference. *Id.* To support this aspect of its holding, the Federal Circuit turned to the Supreme Court’s ruling in *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 373-74 (1928), which demonstrated the court’s general unwillingness to extinguish a patent in the face of a misrepresentation that did not affect issuance of the patent itself. The exception to this general rule is egregious affirmative misconduct on the part of the patentee. *Id.* at 29. In extreme cases, such as the filing of demonstrably false affidavits, the misconduct is material even if it cannot be proven that the PTO would not have issued the patent over the undisclosed reference. *Id.* As an example, the court cited facts similar to those in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 245 (1944) (“deliberately planned and carefully executed schemes”).

Under *Therasense* “intent” is now defined as the specific intent to defraud the PTO. *Id.* at 24. Neither negligence nor gross negligence suffices to meet this intent requirement. *Id.* citing *Kingsdown* at 876. In order to successfully employ this defense the accused infringer must prove by clear and convincing evidence that 1) the applicant knew of the reference, 2) knew that it was material and 3) deliberately withheld it. *Id.* Direct evidence is not necessary but in order to meet the clear and convincing standard the specific intent to deceive must be the most reasonable inference that can be drawn from the evidence. *Id.* at 25. “(T)he evidence must be sufficient to require a finding of deceitful intent in the light of all the circumstances.” *Id.* at 25-26 citing *Kingsdown* at 873.

The opinion in Therasense reinforces and expands the court's holding in Kingsdown at the expense of a range of cases, notably Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc., 525 F.3d 1334 (Fed. Cir. 2008) and Critikon v. Becton Dickson Vascular Access, 120 F.3d 1253 (Fed. Cir. 1997). Fewer than ten years after Kingsdown, the Critikon court ignored Kingsdown and instead cited earlier cases when using a strong showing of materiality to find inequitable conduct in the absence of any showing of intent. In Aventis, the court found inequitable conduct on facts that would satisfy neither the intent nor materiality prongs as they are to be applied under Therasense, prompting an impassioned dissent from now Chief Judge Rader.

The language of the holding in Therasense is much more forthright than that found in Kingsdown and redefining materiality as but-for materiality should significantly diminish the frequency with which inequitable conduct is found. However, Therasense is not the first case which purports to diminish the doctrine of inequitable conduct, it may or may not be the last. The Therasense decision was decided 6-1-4, meaning that there are a significant number of dissenters, more than enough to form an entire panel. It would not be surprising to see another decision in the vein of Critikon or Aventis in coming years. It remains an open question as to whether the doctrine of inequitable conduct will come to be reserved exclusively for extreme situations or if Therasense, like Kingsdown, will be intermittently ignored.

Concurrence (O'Malley)

In her concurring opinion, Judge O'Malley agreed with the majority's opinion that intent to deceive and materiality must be found separately. Therasense concurrence at 3. However, the concurrence dissents from those portions of the majority opinion which apply a rigid but-for test in assessing materiality. Id. Rather, the concurrence would leave to district courts the discretion to apply the equitable conduct doctrine to unique circumstances and to impose a proper remedy for a given instance of inequitable conduct. Id. at 6. In excising its discretion, the district court should find materiality where: (1) but for the conduct, the patent would not have issued; (2) the conduct constitutes a false or misleading representation of fact; 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. Id. at 9. Applying this test to the case, the concurrence affirms the district court's finding that the nondisclosure of information was material. Id. at 10.

Dissent (Bryson)

Judge Bryson agrees with the majority that the standard of intent for assessing whether an applicant has made false accusations should go beyond gross negligence. Therasense dissent at 2-3. He also joins the majority in rejecting the idea of a sliding-scale whereby a strong showing of intent can overcome materiality and vice-versa. Id. at 6.

The dissent's disagreement with the majority stems from the definition of materiality, arguing for a return to Rule 56. Id. at 3. Materiality here however should not be the majority's 'but for' test, it should be defined using the PTO's Rule 56. Id. Under the Rule 56 standard, materiality of information is shown if a disclosure would establish a prima facie case for unpatentability or if it is inconsistent with a prior position taken by the applicant before the PTO. Id.

The dissenters argue that under the 'but for' test there is no incentive for an applicant to disclose information. See id. at 9. Inequitable conduct is a redundancy under the 'but for' test, only claims that are inherently invalid would be unenforceable due to inequitable conduct. Id. The applicant can hide information and later litigate whether that information would have rendered the claims invalid. Id. The dissent argues that Rule 56 is the embodiment of what the PTO thinks works best for the purposes of examination and should be followed without judicial intervention. See id. at 8.

The 'but for' test for materiality is a departure from precedent both in the PTO and in other areas of law. See id. at 3, 27. The 1977 revision of Rule 56 defined a 'reasonable examiner' standard, where

information was material if there was a substantial likelihood an examiner would find it important. See Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991) (affirming the 1977 revision). The PTO later considered adopting a 'but for' test but rejected it, saying it would not give examiners enough information, and therefore meaningful examination of applications would first take place through litigation. Therasense, No. 2008-1511 at 23. Other bodies of law have for similar reasons rejected a 'but for' test for materiality. Id at 23 (citing Matrixx Initiatives, Inc. v. Siracusano, No. 09-1156 (U.S.) which adopted a 'reasonable investor' standard in relation to disclosure of information by companies; Restatement of Torts which holds that to prove fraud a 'reasonable man' standard is used for materiality.) Judge Bryson therefore comes to the conclusion that the 'but for' test, having been rejected by the Supreme Court, PTO and Federal Circuit, is not a proper standard of materiality.

Inequitable conduct is seen by the dissent as being in an unsatisfactory state, however they would correct it through means other than changing the standard for materiality. See id. at 7. Strict pleading requirements of the Fed. R. Civ. P. 9(b) apply to claims of inequitable conduct, thus some claims could be thrown out under pleading standards. See Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1326-1329 (Fed. Cir. 2009). Sanctions under Fed. R. Civ. P. 11 could act as a deterrent to the filing of claims that lack factual and legal support. Therasense, No. 2008-1511 at 7. Lastly, inequitable conduct is inherently an equitable doctrine and therefore controllable by the courts to limit its perceived abuse. Id.