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Client Alert

Intellectual Property Practice Group

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Federal Circuit Makes it More Difficult to Prove Inequitable Conduct During Patent Prosecution

Inequitable conduct is an equitable defense to a charge of patent infringement. It renders the entire patent unenforceable and leads to many other nefarious consequences, like having to pay an alleged infringer's attorneys fees, damaging the career of patent attorneys, and endangering a company's entire patent portfolio. Chief Judge Rader of the United States Court of Appeals for the Federal Circuit has called inequitable conduct the "atomic bomb" of patent law.[i]

Many practitioners and commentators have observed recently that inequitable conduct claims are too ubiquitous. One study reported that inequitable conduct is asserted in 80% of patent infringement cases.[ii] Several Federal Circuit judges have referred to inequitable conduct as a "plague."[iii] In view of these concerns, last year the Federal Circuit ordered a sweeping review of the inequitable conduct doctrine in *Therasense, Inc. v. Becton Dickinson and Co.*[iv]

On May 25, the Federal Circuit issued its decision in *Therasense* and significantly raised the legal standard required to prove inequitable conduct.[v] Before *Therasense*, an alleged infringer had to show that the patent applicant misrepresented or omitted material information with intent to deceive the PTO.[vi] Once that burden was met, the court performed a balancing test, weighing the equities and the showing of materiality and intent to determine whether the applicant's conduct warranted rendering the entire patent unenforceable. *Therasense* eliminates the balancing test and "tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public."[vii]

Intent to Deceive Tightened. *Therasense* tightens the standard for showing intent to deceive when information is not disclosed to the Patent Office by requiring proof that a patent applicant (1) knew of the prior art information, (2) knew that the information was material, and (3) made a deliberate decision to withhold it. Intent to deceive cannot be established by using a "sliding scale" to infer intent from a strong showing of materiality, or by proof that the applicant "should have known" about non-disclosed information or its materiality. *Id.* at 25-26. In addition, intent to deceive must be the "single most reasonable inference" from the evidence. If multiple reasonable inferences can be drawn, intent cannot be found. *Id.*

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Materiality Tightened. *Therasense* tightens the standard for establishing materiality by adopting a but-for test for materiality as the general rule. Slip Op. at 27-28. Under this test, "when an applicant fails to disclose prior art to the [Patent Office], that prior art is but-for material if the [Patent Office] would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* But-for materiality is assessed from the eyes of the patent examiner. The claim must be given its broadest reasonable construction rather than the court's claim construction in litigation, and a preponderance of the evidence standard applies rather than a clear and convincing standard. *Id.* *Therasense* recognizes an exception to the but-for standard for "cases of affirmative egregious misconduct" such as the filing of an unmistakably false affidavit. In such cases, the conduct is *per se* material. This exception is designed to incorporate elements of the Supreme Court cases that gave rise to inequitable conduct, where there were 'deliberately planned and carefully executed scheme[s] to defraud the PTO and the courts." *Id.* at 29.

What Therasense Means. At least three significant ramifications of *Therasense* are immediately apparent. First, inequitable conduct claims based on prior art or other information that is not disclosed to the Patent Office should become much more difficult to plead or establish. An accused infringer will need to plead facts sufficient to infer not only that someone involved in the patent prosecution knew of information that was not disclosed, but also knew of and appreciated facts that indicate a claim would not have been allowed if the information had been disclosed, and then made a deliberate decision to withhold that information from the Patent Office.

Second, patent applicants should be insulated from inequitable conduct when they document why information considered but not disclosed during prosecution was not cited to the Patent Office. *Therasense* requires intent to deceive to be the single most reasonable inference from the evidence, and precludes intent to deceive whenever multiple reasonable inferences can be drawn. Taken literally, any contemporaneous record evidence that shows a plausible reason for not disclosing information should establish that multiple reasonable inferences can be drawn and legally foreclose a finding of inequitable conduct.

Third, when the facts are sufficient to suggest that an inequitable conduct claim based on non-disclosure can be maintained, it will really be an "atomic bomb" because antitrust, unfair competition and tort counterclaims may often accompany such claims. Facts that are sufficient to establish inequitable conduct in many cases are also likely to meet the fraud standard required to assert these affirmative counterclaims.

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[i] *Aventis Pharma S.S. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. cir. 2008) (Rader, J. dissenting).

[ii] C. Mammen, *"Controlling the 'Plague': Reforming the Doctrine of Inequitable Conduct*," 24 Berkeley Tech. L.J. 1329, 1358 (2009)

[iii] *See, e.g., Ferring BV v. Barr Labs., Inc.*, 437 F.3d 1181, 1196 (Fed. Cir. 2006) (Newman, J. dissenting); *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342-43 (Fed. Cir. 2009) (Linn, J. concurring).

[iv] *Therasense, Inc. v. Becton, Dickinson and Co.*, Nos. 2008-1511, -1512, -1513, -1514, -1595 (Fed. Cir. Order Issued April 6, 2010).

[v] *Therasense, Inc. v. Becton, Dickinson and Co.*, Nos. 2008-1511, -1512, -1513, -1514, -1595 (Slip Op.) (Fed. Cir. May 25, 2011) available at http://www.cafc.uscourts.gov/opinions-orders/0/all.

[vi] *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

[vii] *Therasense*, Slip Op. at 24.