

Clarity: A First Look at *Therasense, Inc. v. Beckton Dickinson and Co.*

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Bryan C. Diner
202.408.4116



Daniel Cooley
202.408.4386

I. Introduction

The U.S. Court of Appeals for the Federal Circuit has called rampant allegations of inequitable conduct an "absolute plague."¹ When successful, an allegation of inequitable conduct can unleash the "atomic bomb"² of patent law. Specifically, a finding of inequitable conduct can render an entire patent unenforceable and create additional collateral damage. Applicants and prosecuting attorneys often feel compelled to engage in counterproductive activities to buttress against inequitable conduct allegations. These activities may include swamping the U.S. Patent and Trademark Office ("PTO") with marginally relevant or irrelevant prior art.

In *Therasense, Inc. v. Beckton Dickson and Co.* ("*Therasense*"), sitting en banc the U.S. Court of Appeals for the Federal Circuit addresses the difficult issue of inequitable conduct. In the opinion, the Federal Circuit "tightens" its standards for establishing the intent and materiality necessary for a finding of inequitable conduct. Importantly, the court outlines a new "but-for" test for determining materiality. By recalibrating the inequitable conduct standard, the Federal Circuit clarifies the expectations for attorneys and applicants and raises the bar for establishing this equitable defense.

This paper reviews the Federal Circuit's *Therasense* decision and discusses questions raised by the decision. These questions include the practical impact of *Therasense* on prosecuting attorneys, inventors, and anyone else owing a duty of candor to the PTO.

II. The Legal Doctrine of Inequitable Conduct

The legal doctrine of inequitable conduct seeks to remedy the harm caused by unfair practices in securing patent protection from the PTO. A finding of inequitable conduct requires a showing that a patentee or related party intentionally deceived the PTO by submitting false information or withholding material information during prosecution of a patent application.³ Therefore, proving inequitable conduct requires a showing of both 1) intent and 2) materiality.⁴ If both intent and materiality are found, a court can hold the relevant patent unenforceable.⁵

Prior to *Therasense*, courts often looked to 37 CFR 1.56 ("Rule 56") as a starting point for determining the materiality of a given piece of information (e.g., a prior art reference).⁶ The most recent version of Rule 56 provides that information is material if it establishes a prima facie case of unpatentability of a claim or is inconsistent with a position that an applicant takes during prosecution.⁷ Courts have also used the "reasonable examiner" standard for materiality. This standard states that information is material if a reasonable examiner would consider it important in determining whether to allow an application to issue as a patent.⁸

To establish intent, courts prior to *Therasense* sought to determine if the evidence clearly and convincingly established that an applicant had the intent to mislead or deceive the PTO.⁹ In some cases, courts used a "sliding scale" to allow a strong showing of materiality to make up for a lesser showing of intent, and vice versa.¹⁰ After finding both materiality and intent with respect to the non-disclosure of information or submission of false information, a court could hold the relevant patent unenforceable due to inequitable conduct.

The remedy for inequitable conduct has been called the "atomic bomb" of U.S. patent law.¹¹ Inequitable conduct destroys the patent monopoly for every single claim in the patent.¹² A finding of inequitable conduct can also generate significant collateral damage, such as rendering related patents unenforceable,¹³ putting the prosecuting attorney at risk of having his/her USPTO registration revoked,¹⁴ and creating potential anti-trust liability for the patentee.¹⁵

Despite the weighty remedy for inequitable conduct, the vague standards associated with intent and materiality prior to *Therasense* led to unpredictable outcomes. In some cases, courts found inequitable conduct based on conduct that appeared merely negligent or would not impact the patentability of the claims. As a result, the Federal Circuit has sought to clarify the standards for establishing inequitable conduct.

III. Background of the *Therasense* Case

The *Therasense* case came to the Federal Circuit on Appeal from the United States District Court for the Northern District of California ("the Trial Court").¹⁶ Following a bench trial, the Trial Court found that U.S. Patent No. 5,820,551 ("the '551 patent") was unenforceable due to inequitable conduct.¹⁷ Specifically, the Trial Court found that Therasense Inc., now Abbott Diabetes Care, Inc. ("Abbott"), intentionally failed to disclose material information to the PTO during prosecution of the '551 patent.¹⁸

The '551 patent is directed to an electrode strip for detecting the concentration of a compound in whole blood.¹⁹ The '551 patent claimed, amongst other features, "an active electrode on said strip . . . wherein said active electrode is configured to be exposed to said whole blood sample *without an intervening membrane or other whole blood filtering member.*"²⁰ During prosecution, the '551 patent was repeatedly rejected over U.S. Patent No. 4,545,382 ("the '382 patent"), which was also owned by Abbott.²¹ The '382 patent disclosed that "[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."²²

To overcome the rejections based on the '382 patent, Abbott submitted a declaration and accompanying arguments to the PTO.²³ These documents stated that those of skill in the art would *not* have read the '382 patent as teaching that the protective membrane was optional when the device was in contact with the whole blood.²⁴ Rather, Abbott argued that those of skill in the art believed that a protective membrane for such use was required. Abbott's submissions to the PTO stated that the "optionally, but preferably" language of the '382 patent would have been understood by skilled artisans as "patent phraseology."²⁵ In sum, Abbott contended that the '382 patent did not teach or suggest unprotected active electrodes for use with whole blood specimens.²⁶

Several years prior, Abbott made arguments in a foreign counterpart of the '382 patent that the Trial Court found to be inconsistent with Abbott's position that the protective membrane of the '382 patent was thought to be required by those of skill in the art. In an effort to distinguish over a foreign reference, Abbott's foreign counsel argued that the protective membrane disclosed in the '382 foreign counterpart was "optional."²⁷ Abbott did not disclose the briefs from this foreign prosecution to the PTO during the prosecution of the '551 patent.²⁸

As a result of Abbott's nondisclosure of the foreign briefs to the PTO, the Trial Court held that the '551 patent was unenforceable due

to inequitable conduct.²⁹ Abbott appealed the Trial Court's finding of inequitable conduct.³⁰ Abbott's appeal ultimately resulted in the Federal Circuit reviewing, en banc, the Trial Court's inequitable conduct finding.

IV. The Intent and Materiality Standards Established by *Therasense*

In tightening the inequitable conduct standard in *Therasense*, the Federal Circuit addressed both the intent and the materiality prongs of the standard. First, the Federal Circuit revisited its previous holdings to clarify the law with respect to intent. The Federal Circuit also established a new, tighter "but-for" standard for finding materiality. By doing so, the court struck what it called "a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct."³¹

A. Intent to Deceive the PTO

The Federal Circuit first revisited the standard for establishing intent to deceive the PTO. The Court clarified and reemphasized that: 1) the party alleging inequitable conduct must prove both knowledge *and* deliberate action; 2) courts must make a finding of intent separate from a finding of materiality; and 3) that the party alleging inequitable conduct bears the burden of establishing intent to deceive by clear and convincing evidence.

The Court clarified the need for proving both knowledge and deliberate action. A party alleging inequitable conduct "must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it."³² Negligence or even gross negligence does not satisfy the intent prong of the inequitable conduct inquiry (e.g., it is not sufficient that a party knows of a reference and *should have known* that the reference was material).³³ The alleged wrongdoing party must know that the reference in question is material.

The Court also reemphasized that intent and materiality are separate inquiries, rejecting the "sliding scale" theory.³⁴ The Court stated that "a district court may not infer intent solely from materiality."³⁵ In other words, there must be separate evidence of a party's intent to deceive, although intent to deceive can be established by either direct or circumstantial evidence. When circumstantial evidence is used to infer intent, the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence,"³⁶ and "when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found."³⁷

Finally, the Court held that the party alleging inequitable conduct bears the burden of establishing intent to deceive by clear and convincing evidence.³⁸ The Court noted that the "absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive."³⁹

B. "But for" Materiality

The Federal Circuit next established a groundbreaking "but-for" test for materiality. To give courts flexibility under this equitable inquiry, the Court also carved out an important exception to the but-for test for especially egregious conduct.

As a general matter, the Federal Circuit held that 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.⁴⁰

The but-for materiality of a reference should be analyzed using the PTO's broadest reasonable interpretation and preponderance of the evidence standards.⁴¹ This new but-for standard is founded upon notions of basic fairness. In other words, inequitable conduct should only be found in instances where "the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted

claim."⁴²

To give trial courts flexibility for extraordinary circumstances, the Federal Circuit also carved out an important exception to the but-for test for affirmative and egregious misconduct.

When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material. . . . After all, a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent.⁴³

The Court stated that this exception gives the test "sufficient flexibility to capture extraordinary circumstances."⁴⁴ The Court clarified, however, that "mere nondisclosure," such as nondisclosure of prior art references to the PTO, does not constitute affirmative egregious misconduct, and therefore requires a showing of but-for materiality.⁴⁵

In establishing the new but for materiality standard, the Federal Circuit expressly rejected the materiality standard outlined by the PTO in Rule 56.⁴⁶ Therefore, the materiality standard of Rule 56 no longer controls inequitable conduct determinations. The PTO indicated in a press release that "it is carefully studying the important en banc decision by the U.S. Court of Appeals for the Federal Circuit in the case of *Therasense v. Becton*, Dickinson to assess how it may impact agency practices and procedures."⁴⁷

V. Practical Implications of *Therasense*

The Federal Circuit's *Therasense* decision will likely have an immediate impact on both applicants and prosecuting attorneys. Most importantly, the new standards clarify the expectations for attorneys and applicants and provide new tools to resolve challenging situations.

The but-for test provides attorneys and applicants guidance to draw on their existing understanding of patentability to determine what information is material and must be disclosed and what information is not material, as a matter of law, and need not be disclosed. Indeed, attorneys may use their existing understanding of 35 U.S.C § 102 (novelty), 35 U.S.C § 103 (obviousness), 35 U.S.C, § 112 (sufficiency of the specification), 35 U.S.C § 101 (double patenting), and nonstatutory double patenting,⁴⁸ to determine if information is material under these standards.⁴⁹

Due to improved clarity and practicality, *Therasense* should also help address common dilemmas facing applicants and prosecuting attorneys. Just by way of example, the but-for standard should help attorneys with the common dilemmas of: 1) determining if it is necessary to cross-cite materials in related applications and 2) determining if it is necessary to reopen prosecution in order to provide new information to the PTO.

Cross-citing information in related applications still presents a significant challenge. On the one hand, a decision *not* to cross-cite related applications could subject the attorney or applicant to allegations of inequitable conduct. On other hand, a decision *to* cross-cite often leads to an administrative nightmare for the attorney, undesired expenses for the applicant, and unwanted art for the examiner. And in either case, difficult line drawing is required. The new but-for standard provides attorneys an opportunity to apply a clearer standard and to utilize their knowledge of the patentability statutes and case law to decide what should and should not be cross-cited.

For example, if an office action from a related case is being assessed to determine if it constitutes material information to the issue of novelty or obviousness, one might question if non-prior art comments of another PTO examiner could destroy an invention's novelty or render it obvious under *Therasense*. The requirement to submit office actions from related cases has been an evolution of

the inequitable conduct jurisprudence. The *Therasense* case did not specifically address this relatively new category of material information. Nonetheless, since many recently litigated cases may contain inequitable conduct defenses premised on failure to submit an office action from a related case, courts will be assessing this defense in light of the new but-for standard of materiality. Practitioners will be carefully watching to determine how best to deal with this information going forward.

Determining whether to reopen prosecution after it has closed in order to cite new information to the PTO is another difficult situation. In today's world, large quantities of information flow across attorneys' and applicants' desks on a daily basis. This flow of information can result in an applicant or an attorney learning of new and potentially relevant art after prosecution has closed (e.g., an application has been allowed, has received a final office action, or is under appeal). In many circumstances, the applicant/attorney might file a request for continued examination (RCE) to reopen prosecution for the examiner to consider the new art. This can create expense and delay for the applicant and contributes to backlog at the PTO. Given these consequences, an attorney must determine if the new art necessitates consideration by the PTO. With the new but-for standard, attorneys will have better tools to decide if reopening of prosecution is truly necessary in a given case.

In sum, *Therasense* provides practical tools for addressing common problems faced by prosecuting attorneys and applicants and provides clearer guidance on how these parties should comport themselves during prosecution.

VI. Conclusion

With the *Therasense* decision, the U.S. Court of Appeals for the Federal Circuit has created a new, tightened standard for alleging inequitable conduct. *Therasense* has clarified the expectations for attorneys and applicants and provided them with more effective tools to address difficult situations. Only time will tell if the stated goals for the Federal Circuit are met.

You can find more information regarding the *Therasense* decision on Finnegan's [website](#). You can also find more information on Federal Circuit Court Decisions at <http://www.finnegan.com/publications/federalcircuit/>.

Endnotes

¹ *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

² *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

³ *Star Scientific, Inc. v. RJ Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

⁴ *Id.*

⁵ *Id.*

⁶ See, e.g., *AB Dick Co. v. Burroughs Corp.*, 798 F. 2d 1392, 1397 (Fed. Cir. 1986).

⁷ See 37 CFR 1.56(b).

⁸ See *Mckesson Info. Solutions v. Bridge Medical*, 487 F.3d 897, 913 (Fed. Cir. 2007).

⁹ *Digital Control, Inc. v. Charles Mach. Works*, 437 F. 3d 1309, 1318 (Fed. Cir. 2006).

¹⁰ *Am Hoist & Derrick Co. v. Sowa & Sons, Inc.* 725 F.2d 1350, 1363 (Fed. Cir. 1984).

¹¹ *Aventis Pharma S.A*, 525 F.3d at 1349 (Rader, J., dissenting).

¹² *Star Scientific, Inc.*, 537 F.3d at 1365.

¹³ See, e.g., *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 808-12 (Fed. Cir. 1990).

¹⁴ See 37 CFR § 11.22

¹⁵ *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965).

¹⁶ *Therasense, Inc. v. Becton, Dickinson and Co.*, 2008-1511, slip op. at 8 (Fed. Cir. 2011).

¹⁷ *Id.*

¹⁸ *Id.* at 14.

¹⁹ *Id.* at 9.

²⁰ *Id.* at 9-10 (emphasis added).

²¹ *Id.* at 10.

²² *Id.* (emphasis added).

²³ *Id.* at 11-12

²⁴ *Id.*

²⁵ *Id.* at 11.

²⁶ *Id.* at 11-12.

²⁷ *Id.* at 12-13.

²⁸ *Id.* at 14.

²⁹ *Id.*

³⁰ *Id.* at 8.

³¹ *Id.* at 30.

³² *Id.* at 24.

³³ *Id.*

³⁴ *Id.* at 25.

³⁵ *Id.*

³⁶ *Id.* at 25.

³⁷ *Id.* at 26.

³⁸ *Id.* at 26.

³⁹ *Id.*

⁴⁰ *Id.* at 27-28.

⁴¹ *Id.* at 28.

⁴² *Id.*

⁴³ *Id.* at 29.

⁴⁴ *Id.* at 30.

⁴⁵ *Id.* at 29-30.

⁴⁶ *Id.* at 32.

⁴⁷ USPTO Press Release, 11-36 (May 26, 2011), available at <http://www.uspto.gov/news/pr/2011/11-36.jsp>.

⁴⁸ See, e.g., *In re Vogel*, 422 F.2d 438 (CCPA 1970).

⁴⁹ As noted above, the question of what an examiner considers material under the new standard is assessed by applying the "broadest reasonable construction" and a preponderance of evidence standard.

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