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**DISARMING ‘ATOMIC BOMB’
FEDERAL CIRCUIT CLIPS INEQUITABLE CONDUCT**

Faced with the “absolute plague”¹ that the specter of inequitable conduct — the “atomic bomb”² of patent litigation — had become, the Federal Circuit has severely tightened its standards in *Therasense, Inc. v. Becton, Dickinson and Co.*³

Litigants and their counsel need to be on top of these new rules on finding inequitable conduct to avoid unpleasant surprises. In this edition of *IpQ: Enhancing your IP IQ*, we take a close look at the new standards and their context.⁴

Background

Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.⁵ Inequitable conduct in the procurement of a patent includes affirmative misrepresentation of a material fact, failure to disclose material information or submission of false material information during patent prosecution, combined with intent to deceive the U.S. Patent and Trademark Office (PTO).⁶

Thus, to establish inequitable conduct, the accused infringer must prove by *clear and convincing* evidence that (1) the patentee (applicant) made an affirmative misrepresentation of material fact, failed to disclose material information or submitted false material information; and (2) *intended* to deceive the PTO.⁷

U.S. Supreme Court Antecedents

Inequitable conduct originated in a trio of U.S. Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct.⁸

In *Keystone Driller Co. v. General Excavator Co.*,⁹ the patentee paid an invalidating prior user to keep quiet and sign a false affidavit stating that his use was an abandoned experiment. Thus armed, the patentee sought to enforce the patent. After initial litigation success, the fraud was discovered,

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1 *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc) (citing *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)).

2 *Id.* at 1288 (citing *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting)).

3 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

4 A detailed discussion of the facts can be found in the underlying district court opinion. *Therasense, Inc. v. Becton, Dickinson and Co.*, 565 F. Supp. 2d 1088, 1091-94 (N.D. Cal. 2008).

5 *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011).

6 *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1289, 1300 (Fed. Cir. 2010), *opinion vacated and rehearing en banc granted by Therasense, Inc. v. Becton, Dickinson and Co.*, 374 F.App’x 35 (Fed. Cir. 2010).

7 *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1334 (Fed. Cir. 2011) (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 1595 (2009)).

8 *Therasense, Inc.*, 649 F.3d at 1285.

9 290 U.S. 240 (1933).

and a subsequent patent infringement complaint was dismissed because of the patentee's unclean hands.¹⁰

Creative (but dishonest) patent counsel in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*¹¹ faced apparently insurmountable PTO opposition to their application. Undeterred, they wrote an article describing the invention as a remarkable advance in the art then had a well-known expert publish it as his own. Using the article to support the application, counsel obtained allowance. Continuing to rely on the article in litigation, the patentee went to great lengths to conceal the false authorship. Ultimately, the scam was uncovered, and the U.S. Supreme Court reinstated a judgment dismissing the patentee's case.¹²

In *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, the patentee suppressed evidence of perjury before the PTO then attempted to enforce the perjury-tainted patent. When the scheme was discovered, the Supreme Court held that dismissal of the complaint was warranted.¹³

Together, these three "unclean hands" cases of intentional fraud on the PTO formed the basis for the new doctrine of inequitable conduct.¹⁴

Inequitable Conduct Evolves

While the doctrine of unclean hands remains available,¹⁵ inequitable conduct has evolved and taken on a life of its own.¹⁶ Subsequent case law broadened the doctrine to encompass less egregious conduct,¹⁷ and inequitable conduct ultimately was expanded to include the mere *nondisclosure* of information to the PTO.¹⁸ The standards for intent and materiality also have varied over time, with some Federal Circuit opinions espousing relatively low standards for meeting the intent requirement.¹⁹

Importantly, the doctrine of inequitable conduct also diverged from its roots by adopting the "atomic bomb" remedy of unenforceability of the entire patent as opposed to mere dismissal of the instant case.²⁰

Immediately prior to *Therasense*, attributes of the inequitable conduct doctrine included:

- **Two-Prong Test** – A test requiring an intent to deceive and materiality.²¹
- **Burden** – Accused infringer required to provide clear and convincing evidence.²²
- **Sliding Scale** – A "sliding scale" for finding inequitable conduct, where both materiality and intent were evaluated and more of one would make up for less of the other.²³
- **Balance the Equities** – A requirement that the district court weigh the equities before invoking the remedy of unenforceability.²⁴

10 *Keystone Driller Co.*, 290 U.S. at 242–44; *Therasense, Inc.*, 649 F.3d at 1285-86.

11 322 U.S. 238 (1944).

12 *Hazel-Atlas Glass Co.*, 322 U.S. at 240-50.

13 *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 809-10, 816-20 (1945).

14 *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011); see *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 1595 (2009).

15 *Therasense, Inc.*, 649 F.3d at 1287.

16 See *id.*

17 *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d at 1366.

18 *Therasense, Inc.*, 649 F.3d at 1287.

19 *Id.* at 1287-88.

20 *Id.* at 1287, 1288 (citing *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting)).

21 *Id.* at 1287 (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008)).

22 *Id.*

23 *Id.* at 1288 (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.* 725 F.2d 1350, 1362 (Fed. Cir. 1984)).

24 *Id.* at 1287 (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008)).

As 2011 draws to a close, I thank you for being a loyal reader of IpQ: Enhancing Your IP IQ. It has truly been my pleasure to research and write, and my privilege to send it to you. I look forward to more of your excellent comments and suggestions in 2012, and I wish you a most prosperous and happy New Year.

Peter

Unintended Consequences

The laudatory purpose of the doctrine of inequitable conduct was to foster full disclosure to the PTO. But as the doctrine evolved, numerous unanticipated consequences arose:²⁵

- **Litigation Staple and Increased Cost** – The doctrine became a staple of patent litigation strategy — disqualifying the prosecuting attorney from the litigation team, expanding discovery and ultimately driving up litigation costs.²⁶
- **Ruinous Effect** – The doctrine steered litigation strategy and deterred settlements because of the ruinous consequences for the reputation of the prosecuting attorney.²⁷
- **Other Claims** – A finding of inequitable conduct could spur antitrust and unfair competition claims.²⁸
- **Prior Art Inundation** – Faced with the “hangman’s noose” risk for failing to produce material art, patent prosecutors regularly deluged the PTO with prior art, most of which had marginal value. This ultimately bogged down the entire patent system.²⁹

Tightening the Standard

In *Therasense*, the Federal Circuit *en banc* “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.”³⁰ While addressing obvious weaknesses, the court retained the doctrine’s key features:

1. Intent

- **Specific Intent** – The accused infringer must *prove* the patentee acted with specific intent to deceive the PTO.³¹
- **Negligence Insufficient** – Negligence or even gross negligence under a “should have known” standard **does not** satisfy the intent requirement.³²
- **Clear and Convincing Proof** – In cases involving nondisclosure of information, clear and convincing evidence must show the patentee’s deliberate decision to withhold a known material reference.³³
- **No Overlap of Intent and Materiality** – Intent and materiality are separate requirements.³⁴ Evidence of intent must be weighed separately from evidence of materiality.³⁵ Thus, district courts **should not** use a “sliding scale” where a weak showing of intent may be found sufficient based on a strong showing of materiality.³⁶
- **Circumstantial Evidence Okay, But . . .** – Intent may be inferred from circumstantial and indirect evidence, because direct evidence is rare.³⁷ But specific intent to deceive must be

²⁵ See *id.* at 1288, 1290.

²⁶ *Id.* at 1288, 1289.

²⁷ *Id.* at 1288; see *Therasense, Inc. v. Becton, Dickinson and Co.*, 565 F. Supp. 2d 1088, 1092 (N.D. Cal. 2008) (recognizing the “seriousness of the accusation”).

²⁸ *Therasense, Inc.*, 649 F.3d at 1289.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.* at 1290 (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

³² *Id.*; *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

³³ *Therasense, Inc.*, 649 F.3d at 1290; *Star Scientific, Inc.*, 537 F.3d at 1366; *Kingsdown Med. Consultants, Ltd.*, 863 F.2d at 872.

³⁴ *Therasense, Inc.*, 649 F.3d at 1290; *Star Scientific, Inc.*, 537 F.3d at 1366.

³⁵ *Therasense, Inc.*, 649 F.3d at 1290.

³⁶ *Id.*; *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318 (Fed. Cir. 2011); *Star Scientific, Inc.*, 537 F.3d at 1367.

³⁷ *Therasense, Inc.*, 649 F.3d at 1290; *Star Scientific, Inc.*, 537 F.3d at 1366.

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ABOUT SHB

Shook, Hardy & Bacon offers expert, efficient and innovative representation to our clients. We know that the successful resolution of intellectual property issues requires a comprehensive strategy developed in partnership with our clients.



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"the single most reasonable inference to be drawn from the evidence."³⁸ Where multiple inferences are possible, the intent to deceive cannot be found.³⁹

- **No Explanation Required** – Finally, the patentee is under no obligation to provide a good-faith explanation unless or until the accused infringer proves a threshold level of intent. Logically, the absence of a good-faith explanation does not, by itself, prove the intent to deceive.⁴⁰

2. Materiality – Recognizing that attempts to curb misuse of the inequitable-conduct defense by raising the bar on proof of intent had proven ineffective, the *Therasense* opinion turned its attention to the materiality requirement.⁴¹ The court announced a new rule for determining materiality:

- **"But For" Materiality** – Relying on U.S. Supreme Court precedent, the Federal Circuit held that the standard for establishing inequitable conduct is but-for materiality.⁴² Prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.⁴³ Importantly, in making this determination, the district court should apply the preponderance-of-the-evidence standard and give claims their broadest reasonable construction as required by the Manual of Patent Examining Procedure.⁴⁴
- **Balancing the Equities** – In light of the severe penalty for inequitable conduct, district courts must maintain a high standard so that patents are not rendered unenforceable because of minor missteps. The remedy should be commensurate with the violation.⁴⁵ Thus, even when the high standard for inequitable conduct is met, district courts must balance the equities to determine if the applicant's conduct was bad enough to render the patent unenforceable.⁴⁶
- **Rule 56 Test Abandoned** – The *Therasense* opinion expressly abandoned the definition of materiality in PTO Rule 56.⁴⁷ Previously, Rule 56 served as a starting point for determining materiality, but that is no longer the case.⁴⁸
- **"Egregious Conduct" Exception** – The Federal Circuit recognized an exception to the materiality standard in cases of "affirmative egregious misconduct."⁴⁹ This gives the test sufficient flexibility to capture extraordinary circumstances.⁵⁰
- **Pleading Requirement** – The pre-*Therasense* rule for pleading inequitable conduct requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission.⁵¹ That rule remains in place.⁵²

Conclusions – The new "tightened standard" for inequitable conduct will make it harder than ever to prove this defense. Likely, only the most outrageous cases (likely qualifying for the exception) will lead to unenforceability. And the supplemental examination provision in the America Invents Act allowing disclosure of prior art after issuance,⁵³ may make this defense a dinosaur.

38 *Therasense, Inc.*, 649 F.3d at 1290; *Am. Calcar, Inc.*, 651 F.3d at 1334 (Fed. Cir. 2011).

39 *Therasense, Inc.*, 649 F.3d at 1290-91.

40 *Id.* at 1291, 1296; *Star Scientific, Inc.*, 537 F.3d at 1368.

41 *Therasense, Inc.*, 649 F.3d at 1291.

42 *Therasense, Inc.*, 649 F.3d at 1291, 1296; *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1334 (Fed. Cir. 2011); *Star Scientific, Inc.*, 537 F.3d at 1367.

43 *Therasense, Inc.*, 649 F.3d at 1291.

44 *Id.* at 1291-92; *Am. Calcar, Inc.*, 651 F.3d at 1334.

45 *Therasense, Inc.*, 649 F.3d at 1292.

46 *Star Scientific, Inc.*, 537 F.3d at 1365, 1367.

47 37 C.F.R. § 1.56; *Therasense, Inc.*, 649 F.3d at 1293, 1295.

48 *Therasense, Inc.*, 649 F.3d at 1294.

49 *Id.* at 1292.

50 *Id.* at 1293.

51 *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

52 *Pfizer Inc. v. Teva Pharms. USA, Inc.*, No. 2:10cv128, 2011 WL 3563112, at *16 (E.D. Va. Aug. 12, 2011).

53 35 U.S.C. § 257. (Sept. 16, 2011).