

New Standards in Inequitable Conduct Post-*Therasense*

Ethical Considerations for Paragraph IV Cases

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Inequitable Conduct

To state a claim for inequitable conduct, the following two elements must be pleaded with the particularity required under Rule 9(b):

- (1) An individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and
- (2) the individual did so with a specific intent to deceive the PTO.

Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009)

Pleading Inequitable Conduct after *Therasense*

Human Genome Sciences, Inc. v. Genentech, Inc., 2011 WL 7461786, at *3-4 (C.D. Cal. Dec 09, 2011)

No Federal Circuit decision, before *Therasense* or after *Therasense*, has stated that the facts in a pleading for inequitable conduct must meet the clear and convincing standard...

* * *

To survive a motion to dismiss, the accused infringer must show that, in addition to the fact the contradiction occurred, the contradiction involved a false statement made with intent to deceive...

* * *

[T]he accused infringer must show facts indicating that the PTO was particularly concerned with a representation, or that the truth, if presented to the PTO, would have rendered the invention unpatentable.

Pleading Inequitable Conduct after *Therasense*

Delano Farms Co. v. Cal. Table Grape Comm'n, 655 F.3d 1337, 1350 (Fed. Cir. 2011)

- Post-*Therasense* opinion noting that, “[a] charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if the plaintiff’s complaint recites facts from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO”) (citing *Exergen*)

Sloan Valve Co. v. Zurn Industries, Inc., 2012 WL 1108129, at *4 (N.D. Ill. April 1, 2012)

- “*Therasense* did not address inequitable conduct claims at the pleading stage, nor did it override *Exergen*’s pleading requirements.”

Tessengerlo Kerley, Inc. v. Or-Cal, Inc., 2012 WL 1094324, at *2-3 (N.D. Cal. March 29, 2012)

- “*Therasense* did not address whether a more stringent standard should now be applied at the pleading stage... Nevertheless, the parties agree that the applicable pleading standard is set forth in *Exergen*...”

Pfizer Inc. v. Teva Pharms. USA, Inc., 803 F. Supp. 2d 409, 432 (E.D. Va. 2011)

- “*Exergen* still states the correct elements required for pleading inequitable conduct after *Therasense*.”

Finding Inequitable Conduct After *Therasense*

- *Therasense, Inc. v. Becton, Dickinson and Co.*, 2012 WL 1038715 (N.D. Cal. March 27, 2012)
 - On remand, affirmed finding of inequitable conduct in light of the more stringent requirements of proof of materiality and specific intent set forth by the Federal Circuit:
 - “In short, had the EPO briefs been before the examiner, he would have rejected the '551 patent application. This has been shown by clear and convincing evidence.” (*Id.*, at *6)
 - “The evidence is clear and convincing that Dr. Sanghera and Attorney Pope knew the content of the EPO briefs and knew that the EPO briefs, standing alone, would so seriously undermine their submission that the examiner would have reverted to unpatentability.” (*Id.*, at *8)
 - “The single most reasonable inference to be drawn from the trial record, including witness demeanor, and particularly the witness demeanor of Dr. Sanghera and Attorney Pope, is that they *did* believe that the omission was necessary to win an allowance and that they *did* deliberately elect to withhold the EPO briefs...” (*Id.*, at *11 (emphasis in original))

Finding Inequitable Conduct After *Therasense*

- ***Aventis Pharma S.A. v. Hospira, Inc.*, 2012 WL 1155716 (Fed. Cir. April 9, 2012)**
 - Upheld Delaware District Court finding that patents were unenforceable due to inequitable conduct
 - Federal Circuit noted that the District Court decision was rendered before *Therasense*, but still satisfied the stricter standards set forth in *Therasense*:
 - “Because such references are necessarily material to patentability, the district court did not err in finding that the materiality requirement was established.” (*Id.*, at *7)
 - “...concluding that Fabre acted with a specific intent to deceive the PTO, the district court did not rely solely on its finding that Fabre was not credible but instead viewed Fabre's testimony in light of the other evidence to reach its intent conclusion.” (*Id.*, at *9)

Finding Inequitable Conduct After *Therasense*

- *Apotex Inc. v. Cephalon, Inc.*, 2011 WL 6090696, at *26-28 (E.D. Pa. Nov. 7, 2011)
 - “[G]iven the unmistakable importance of the Lafon information, the inexplicable concealment of that information from the PTO, even after the examiner’s obviousness challenge unequivocally alerted Cephalon to its importance, as well as the direct misrepresentations made by Cephalon to the PTC, the only reasonable inference to be drawn is that Cephalon made a deliberate choice to deceive the PTO about the origin of its claimed invention. Such conduct warrants a finding of inequitable conduct and justifies rendering the patent unenforceable.”

No Finding of Inequitable Conduct After *Therasense*

- ***Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1235, 100 U.S.P.Q.2d 1742 (Fed. Cir. 2011)**
 - “Mr. Powell's conduct obviously fails the but-for materiality standard and is not the type of unequivocal act, ‘such as the filing of an unmistakably false affidavit,’ that would rise to the level of ‘affirmative egregious misconduct.’ “
- ***Cordis Corp. v. Boston Scientific Corp.*, 658 F.3d 1347, 1360-61, 100 U.S.P.Q.2d 1329 (Fed. Cir. 2011)**
 - Affirming finding that clear and convincing evidence of an intent to deceive was lacking where the inference of intent to deceive was not the only reasonable inference that could be drawn from the presented evidence
- ***August Technology Corp. v. Camtek Ltd.*, 655 F.3d 1278, 1290, 99 USPQ2d 1766 (Fed. Cir. 2011)**
 - Affirming the district court’s dismissal of inequitable conduct counterclaim after affirming that withheld evidence did not disclose all of the claim limitations and therefore did not render the asserted claim invalid for obviousness when combined with other prior art - affirming dismissal of inequitable conduct claim since the withheld information was not material.

No Finding of Inequitable Conduct After *Therasense*

- ***Metris U.S.A., Inc. v. Faro Tech., Inc.*, 2011 WL 4346852, at *2-4 (D. Mass. Sept. 19, 2011)**
 - Vacating a prior finding of inequitable conduct (from failing to disclose information regarding the contribution of a possible joint inventor and prior art created by that possible joint inventor); ruling that, in view of *Therasense*, “but for” materiality could not be proven: withheld information was “information that a reasonable patent officer would consider important in making a determination about who should be named as inventors” but did not satisfy but-for materiality standard.
- ***Joy MM Delaware Inc. v. Cincinnati Mine Machinery Co.*, 2011 WL 6046500 (W.D. Pa. Dec. 5, 2011)**
 - Entering judgment as a matter of law that the patent was not invalid as anticipated or unenforceable due to inequitable conduct where defendant “failed to satisfy its burden to come forth with sufficient evidence to prove both an intent to deceive and but-for materiality by clear and convincing evidence.”

No Finding of Inequitable Conduct After *Therasense*

- ***Duhn Oil Tool, Inc. v. Cooper Cameron Corp.*, 818 F. Supp. 2d 1193 (E.D. Cal. 2011)**
 - Finding no inequitable conduct where “Defendant did not establish by clear and convincing evidence that Robert Meek harbored intent to deceive the Patent Office” and where “Defendant did not establish by clear and convincing evidence that the '94 Catalogue would have been material prior art to the Examiner.”
- ***Seiko Epson Corp. v. E-Babylon, Inc.*, 2011 WL 5554447 (D. Or. Nov. 15, 2011)**
 - Granting partial summary judgment of no inequitable conduct: “the Court concludes no reasonable juror could find that Epson had ‘the specific intent to deceive’ the Patent Examiner regarding the prior art relating to the '917 Patent and the '902 Patent or that an intent to deceive was ‘the single most reasonable inference able to be drawn from the evidence.’” (citing *Therasense*)
 - (see also *Seiko Epson Corp. v. Inkjet Madness.com, Inc.*, 2011 WL 5588704 (D.O r. Nov 15, 2011); *Seiko Epson Corp. v. Glory South Software Mfg., Inc.*, 2011 WL 5570653 (D. Or. Nov 15, 2011); *Seiko Epson Corp. v. Abacus 24-7 LLC*, 2011 WL 5554524 (D. Or. Nov 15, 2011))

No Finding of Inequitable Conduct After *Therasense*

- ***Accentra Inc. v. Staples, Inc.*, 2011 WL 7563039 (C.D. Cal. Dec. 19, 2011)**
 - Finding no inequitable conduct where intent to deceive was not sufficiently proven: “Under *Therasense*, these facts do not come close to clear and convincing evidence “requiring” the “ ‘the single most reasonable inference’ “ of an intent to deceive ...”
- ***Carl Zeiss Vision Intern. GMBH v. Signet Armorlite, Inc.*, 2011 WL 6372785 (S.D. Cal. Dec. 19, 2011)**
 - Granting summary judgment of no inequitable conduct where evidence of withholding did not rise to the level of clear and convincing evidence of specific intent to deceive the PTO.

Sanctions in Light of *Therasense*

- 35 U.S.C. § 285: “The court in exceptional cases may award reasonable attorney fees to the prevailing party”
- Determining whether to award attorney fees under § 285 is a two-step process:
 - A district court must determine whether the prevailing party has proved by clear and convincing evidence that the case is exceptional;
 - Then court must determine whether an award of attorney fees is appropriate and, if fees are appropriate, the amount of the award.

(Eon–Net LP v. Flagstar Bancorp, 653 F.3d 1314, 1323-24 (Fed. Cir. 2011))

- “Absent misconduct in conduct of the litigation or in securing the patent, sanctions may be imposed ... only if both (1) the litigation is brought in subjective bad faith, and (2) the litigation is objectively baseless.”

(Old Reliable Wholesale, Inc. v. Cornell Corp., 635 F.3d 539, 543-44 (Fed. Cir. 2011) (citation omitted))

Sanctions in Light of *Therasense*

- ***Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 803 F. Supp. 2d 409 (E.D. Va. Aug. 12, 2011)**
 - No inequitable conduct where documents at issue were not material and there was no evidence of intent to deceive.
- ***Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 820 F. Supp. 2d 751 (E.D. Va. Oct. 17, 2011) awarded attorney fees to patentee:**
 - There was “utterly no evidence” of either materiality or specific intent in the allegations of inequitable conduct.
 - The material at issue “hardly approaches the but-for materiality required by *Therasense*.”
 - The inequitable conduct claim was “utterly baseless” because it was “far from being even remotely supported by clear and convincing evidence...”
 - Alleging “willful blindness” “provides no objective basis for a finding of materiality.
 - Mere nondisclosure, standing alone and without some affirmative action, does not itself constitute “affirmative egregious misconduct.”
 - “Given this court's finding that Teva presented no evidence of either the materiality or intent elements of a successful inequitable conduct claim, this case is properly termed ‘frivolous’ and ‘exceptional.’”