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LITIGATING INEQUITABLE CONDUCT AFTER *THERASENSE, EXERGEN, AND THE AIA:* LESSONS FOR LITIGANTS, OPTIONS FOR OWNERS

*Lisa A. Dolak**

INTRODUCTION

In April 2010, the Federal Circuit undertook to reconsider, en banc, the standards governing the judicially-created defense of inequitable conduct.¹ The level of amici participation in the case, *Therasense, Inc. v. Becton Dickinson & Co.*, reflected the importance to the patent and business communities of the issues considered. The United States, companies, intellectual property organizations, bar associations, industry organizations, law professors, practitioners and others weighed in on issues including the definition of materiality, what evidence should (and should not) suffice to establish deceptive intent, and appropriate inequitable conduct remedies.²

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¹ *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511, 2008-1512, 2008-1514, 2008-1595, 2010 WL 1655391 (Fed. Cir. Apr. 26, 2010) (ordering en banc review).

² See, e.g., Brief of Amici Curiae Teva Pharm. USA, Inc. et al. in Support of Appellees and in Favor of Affirmance, *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (Nos. 2008–1511, 2008–1512, 2008–1513, 2008–1514, 2008–1595) (“There is no need and no justification for changing the current definition of materiality . . . or for modifying the current principles by which deceptive intent may be inferred from circumstantial evidence”); Brief of Amici Curiae Acacia Research Corp. and 1st Media, LLC in Support of Neither Party and in Support of Returning the “Unenforceability” Defense to Its Traditional Scope of “Unclean Hands”, *Therasense*, 649 F.3d 1276 (recommending the Court return to the unclean hands standard set out in Supreme Court cases); Brief for Amici Curiae 22 Patent Prosecution Firms and Practitioners Supporting Neither Party, *Therasense*, 649 F.3d 1276 (“A return to the doctrine’s roots in common law fraud as articulated in the *Keystone* trilogy . . . would provide a more equitable analytical framework to decide questions of misconduct.”); Brief and Appendix of the American Bar Association as Amicus Curiae, *Therasense*, 649 F.3d 1276 (recommending that the court adopt a “but for” standard of materiality); Brief of Amicus Curiae the American Intellectual Property Law Assoc. in Support of Neither Party, *Therasense*, 649 F.3d 1276 (recommending that the court adopt a “but for” standard for materiality); Brief of Eisai Co., Ltd. and Eisai Inc. as Amici Curiae on Rehearing En Banc in Support of Neither Party, *Therasense*, 649 F.3d 1276 (recommending a “but for” materiality standard and flexibility to district courts in crafting equitable remedies for inequitable conduct); Brief of Intellectual Property Owners Assoc. in Support of Neither Party, *Therasense*, 649 F.3d 1276 (encouraging the

On May 25, 2011, a divided court re-defined and limited the defense.³ In the two years since then, the Federal Circuit and the district courts have had the opportunity to apply the new standards in various procedural contexts.⁴ Their decisions reflect the impact of *Therasense* on litigating inequitable conduct.⁵ Furthermore, *Therasense* has altered the potential utility of post-grant examination to thwart or undermine inequitable conduct challenges.⁶ But *Therasense* is not the only significant recent development affecting inequitable conduct litigation.

Before *Therasense*, the Federal Circuit had issued an important ruling relating to pleading inequitable conduct. The court's decision in *Exergen Corp. v. Wal-Mart Stores, Inc.*,⁷ has itself had a significant impact on litigating inequitable conduct.⁸ Moreover, since *Therasense*, Congress has given patent owners an opportunity to take anticipated inequitable conduct issues off the table for litigation.⁹

Without a doubt, the inequitable conduct litigation landscape has changed. A careful, thorough consideration of all of these developments and

court to adopt a “but for” standard of materiality and eliminating the sliding scale for inferring intent from materiality); Brief of the Biotechnology Industry Organization as Amicus Curiae in Support of Neither Party, *Therasense*, 649 F.3d 1276 (recommending the addition of a third element to the inequitable conduct framework which requires a showing of “reasonable reliance” by the USPTO on the misrepresentation or omission); Brief of Amicus Curiae the Assoc. of Citizens for Patent Protection in the Public Interest in Support of Defendants-Appellees and Affirmance, *Therasense*, 649 F.3d 1276 (advocating for rejecting the “but for” standard of materiality and abandoning the “should have known” and “most reasonable inference” standards for intent to deceive); Brief of Amicus Curiae Intellectual Property Law Professors Concerning En Banc Review of Inequitable Conduct and in Support of Neither Party, *Therasense*, 649 F.3d 1276 (encouraging the court to adopt 37 C.F.R. § 1.56 as the standard for materiality in inequitable conduct); Brief of Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Neither Party, *Therasense*, 649 F.3d 1276 (encouraging the court to limit inequitable conduct to claims asserted in the litigation and to abandon the sliding scale test for proving intent from materiality); Brief for the United States as Amicus Curiae on Rehearing En Banc in Support of Neither Party, *Therasense*, 649 F.3d 1276 (encouraging the court to adopt 37 C.F.R. § 1.56(b) as the standard for materiality); Brief of Amicus Curiae the University of Akron School of Law, Center for Intellectual Property Law & Technology, in Support of Affirmance on En Banc Review, *Therasense*, 649 F.3d 1276 (encouraging the court to adopt 37 C.F.R. § 1.56 as the sole standard for materiality in the inequitable conduct doctrine).

³ *Therasense*, 649 F.3d at 1297.

⁴ See *infra* Parts I.A.2 and I.B.2.c.

⁵ See *id.*

⁶ See *infra* Part III.A.

⁷ 575 F.3d 1312 (Fed. Cir. 2009).

⁸ See *infra* Part I.B.2.

⁹ See *infra* Part II.

their implications is a must for any litigant or counsel faced with or considering asserting a charge of inequitable conduct. This Article discusses these significant recent inequitable conduct-related developments and their combined impact on litigating the defense. Part I of this Article reviews the new judicial standards for pleading and proving inequitable conduct, illustrates their application in recent Federal Circuit and district court decisions, and summarizes lessons for litigators from recent cases. Part II discusses the legislature's recent contribution to the inequitable conduct landscape: the supplemental examination proceeding created by the Leahy-Smith America Invents Act (AIA).¹⁰ Part III considers the options, post-*Therasense* and the AIA, for patent owners faced with a potential inequitable conduct challenge. Following Part III is a conclusion of the discussion.

I. JUDICIAL DEVELOPMENTS

A. *Therasense, Inc. v. Becton, Dickinson & Co.*

1. New Substantive Standards

Citing concerns regarding the frequency with which inequitable conduct was being alleged in patent cases, and the consequences of those allegations for the courts, patent prosecutors, and the United States Patent & Trademark Office (USPTO), the en banc Federal Circuit in *Therasense* announced stricter standards for proving the defense of inequitable conduct.¹¹ After *Therasense*, a challenger must still “prove that the applicant misrepresented or omitted material information with the specific intent to deceive the [USPTO]”¹² by clear and convincing evidence.¹³ However, a new, narrower definition of materiality now governs inequitable conduct determinations post-*Therasense*. The general rule is that the misrepresented or omitted information must be “but-for material”—the challenger must prove that “the [USPTO] would not have allowed a claim had it been aware of the undisclosed” or correct information.¹⁴ The court made an exception to this requirement for “cases of affirmative

¹⁰ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 35 U.S.C.).

¹¹ *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290–93 (Fed. Cir. 2011) (en banc).

¹² *Id.* at 1287. The court had previously announced the “specific intent to deceive” standard in *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

¹³ *Id.* at 1287.

¹⁴ *Id.* at 1291. In making such a determination, a court is to “apply the preponderance of the evidence standard and give claims their broadest reasonable construction,” in accordance with USPTO practice. *Id.* at 1291–92 (citing Manual of Patent Examining Procedure (MPEP) §§ 706, 2111 (8th ed. Rev. 8, July 2010)).

egregious misconduct.”¹⁵ Specifically, “[w]hen the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.”¹⁶

Regarding intent, “[a] finding that [a] misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known’ standard does not satisfy th[e] intent requirement.”¹⁷ The *Therasense* majority gave an example:

“In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.” In other words, the accused infringer 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.¹⁸

The third significant holding of *Therasense* concerned the “‘sliding scale,’ where a weak showing of intent [could] be found sufficient based on a strong showing of materiality, and vice versa.”¹⁹ The majority declared that “[i]ntent and materiality are separate requirements.”²⁰ It instructed the district courts not to use a “sliding scale,” and specifically directed that “a district court may not infer intent solely from materiality.”²¹ Again, giving an example, the court stated that “[p]roving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the [USPTO] does not prove specific intent to deceive.”²²

The court acknowledged that “a district court may infer intent from indirect and circumstantial evidence.”²³ But it reiterated that such an inference should be drawn only if it is “the single most reasonable inference able to be drawn from the evidence.”²⁴ “Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.”²⁵

¹⁵ *Id.* at 1292.

¹⁶ *Id.*

¹⁷ *Id.* at 1290.

¹⁸ *Id.* (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.* (citing *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

²³ *Id.* at 1290.

²⁴ *Id.*

²⁵ *Id.* at 1290–91.

2. The New Standards in Operation

a. Materiality After *Therasense*

The Federal Circuit had occasion to apply the new *Therasense* standards shortly after they were announced. On June 27, 2011, in *American Calcar, Inc. v. American Honda Motor Co.*,²⁶ the court applied the “but-for materiality” standard to distinguish between prior art information that had been found to anticipate the claims at issue—inherently a finding that the USPTO would not have issued those claims²⁷—and other information as to which no such specific finding had been made.²⁸ As to the latter information, the Federal Circuit vacated the district court’s findings of materiality and remanded for consideration of the issue under the standard set forth in the interim in *Therasense*.²⁹ *American Calcar* illustrates how the Federal Circuit has upheld materiality findings where the undisclosed prior art was found to invalidate the claims at issue.³⁰

In the two years since the Federal Circuit decided *Therasense*, the court has had limited opportunity to apply the *Therasense* materiality standards to information other than undisclosed prior art. A fulsome understanding of the new boundaries of material information must await the development of the case law, but the court has begun to lay down some markers. For example, the court considered an applicant’s failure to update a Petition to Make Special in *Powell*

²⁶ 651 F.3d 1318 (Fed. Cir. 2011).

²⁷ A district court evaluates anticipation and obviousness under a “clear and convincing” standard of proof. *See, e.g., ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1322 (Fed. Cir. 2012) (citing *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238 (2011)) (“Anticipation must be proven by clear and convincing evidence.”); *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 517–18 (Fed. Cir. 2012) (citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359–60 (Fed. Cir. 2007)) (“The district court applied the correct standard, that the challenger must demonstrate by clear and convincing evidence that the invention would have been obvious to a person of ordinary skill in the field of the invention at the time the invention was made.”). Accordingly, a district court’s finding of invalidity reflects a level of proof beyond what would be required to establish that the USPTO would not have issued the claims at issue applying its “preponderance of the evidence” standard.

²⁸ *See Am. Calcar*, 651 F.3d at 1335.

²⁹ *Id.*

³⁰ *See id. Compare* *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1334 (Fed. Cir. 2012) (affirming a district court’s finding of materiality, having affirmed the district court’s finding that the withheld references rendered obvious the claims at issue), *with* *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (affirming the district court’s dismissal of the accused infringer’s inequitable conduct counterclaim where the undisclosed product, even if on sale prior art, “would not render the asserted claims obvious in view of the other cited prior art”).

v. *Home Depot U.S.A., Inc.*³¹ There, the applicant had failed to alert the USPTO that he was no longer under an obligation to manufacture, as he had asserted in his previously-filed petition.³² According to the court, the applicant's failure-to-update "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.'"³³

The Federal Circuit also applied the *Therasense* materiality standard in *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*³⁴ Without specifically applying the "but-for" standard, the court held that the existence of litigation regarding a parent patent was not material to the prosecution of a continuation where, during the pendency of the continuation, the litigation (a declaratory judgment action relating only to non-infringement) did not involve allegations of invalidity or unenforceability.³⁵

The court, however, declined to decide whether a false declaration of small entity status qualifies as "an unmistakably false affidavit" for purposes of the *Therasense* "affirmative egregious misconduct" exception to the "but-for materiality" requirement.³⁶ Acknowledging that "on its face, it appears that a false small entity declaration would fall within the definition of an 'unmistakably false affidavit,' particularly since a party that claims entitlement to small entity status does so in a sworn written declaration," the court held that it "need not decide that question," because "there was no evidence that anyone involved in the patent prosecution knew that a patent license had been granted to a large entity and deliberately withheld that information in order to pay small entity fees."³⁷ This case illustrates how the Federal Circuit, in particular, may increasingly rely on insufficient record evidence of deceptive intent to decide appeals relating to inequitable conduct.³⁸ Thus, the intent prong of the analysis (discussed below) may come to dominate the inequitable conduct inquiry post-*Therasense*, and the development of the law concerning the new materiality standards may proceed at a slower pace. In contrast, the less exacting materiality

³¹ 663 F.3d 1221, 1234 (Fed. Cir. 2011).

³² *Id.* at 1235.

³³ *Id.* The court did not elaborate.

³⁴ 695 F.3d 1285, 1294 (Fed. Cir. 2012).

³⁵ *Id.* at 1290–91.

³⁶ *Id.* at 1294.

³⁷ *Id.* at 1294–95 (noting that the applicable regulation allows for the correction of good faith mistakes in small entity claims).

³⁸ See also *infra* notes 39–43 and accompanying text.

standards in force prior to *Therasense* led to an expanding list of potentially material information.³⁹

b. Deceptive Intent After *Therasense*

The Federal Circuit has thus far rigorously enforced its “most reasonable inference” requirement for evidence of deceptive intent. For example, in *Cordis Corp. v. Boston Scientific Corp.*,⁴⁰ the court affirmed a district court’s holding that the patents at issue were not unenforceable for inequitable conduct because the district court had concluded that “the inferences argued by [the patentee] are supported by evidence of record and are as reasonable as those inferences argued by [the challengers].”⁴¹ Similarly, in *In re Rosuvastatin Calcium Patent Litigation*,⁴² the court affirmed “that unenforceability based on inequitable conduct was not established,” despite affirming the district court’s determination that the undisclosed references at issue were material, because “deceptive intent was not the single most reasonable inference” based on the evidence.⁴³

Further, in accordance with its *Therasense* directive regarding the need to assess evidence of deceptive intent “independent of its analysis of materiality,”⁴⁴ the court has also vacated or reversed (pre-*Therasense*) findings of intent that were predicated significantly on findings of materiality. For example, in *1st Media, LLC v. Electronic Arts, Inc.*,⁴⁵ the court reversed a judgment of unenforceability without evaluating but-for materiality where the evidence supported only that the inventor and his lawyer “(1) knew of the references, (2) may have known they were material . . . , and (3) did not inform the [USPTO] of them” and thus failed to establish that they “made a *deliberate decision* to withhold [them].”⁴⁶ And in *American Calcar*, discussed above, the court

³⁹ See Lisa A. Dolak, *Inequitable Conduct: A Flawed Doctrine Worth Saving*, 11 WAKE FOREST J. BUS. & INTELL. PROP. L. 1, 11 (2010) (discussing how “recent Federal Circuit decisions have expanded the categories of potentially material information”); see also Thomas F. Cotter, *An Economic Analysis of Patent Law’s Inequitable Conduct Doctrine*, 53 ARIZ. L. REV. 735, 738 (2011) (“Courts have expanded the doctrine’s reach so that in its present incarnation, inequitable conduct encompasses not only misrepresentations and omissions amounting to outright fraud but also to an amorphous category of somewhat lesser sins.”).

⁴⁰ 658 F.3d 1347, 1360 (Fed. Cir. 2011).

⁴¹ *Id.* at 1360–61 (quoting *Cordis Corp. v. Boston Scientific Corp.*, 641 F. Supp. 2d 353, 359 (D. Del. 2009)).

⁴² 703 F.3d 511 (Fed. Cir. 2012).

⁴³ *Id.* at 521–22 (“The district court found that the evidence as a whole ‘paints a more innocent explanation of Mr. Shibata as a new and inexperienced manager attempting to handle an understaffed and overworked Patent Department.’”).

⁴⁴ *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

⁴⁵ 694 F.3d 1367 (Fed. Cir. 2012).

⁴⁶ *Id.* at 1376–77 (quoting *Therasense*, 649 F.3d at 1290) (emphasis added).

vacated a “finding” of inequitable conduct where the district court “made no holding that any of the inventors . . . made a deliberate decision to withhold it” but “[i]nstead . . . bas[ed] its finding of intent significantly on the materiality of the [withheld information] to the claimed invention.”⁴⁷

However, in *Aventis Pharma S.A. v. Hospira, Inc.*,⁴⁸ the court upheld a pre-*Therasense* finding of deceptive intent “[b]ased on the district court’s thorough discussion of its factual findings and its well-reasoned analysis that [was] consistent with *Therasense*.”⁴⁹ The Federal Circuit pointed to the district court’s specific findings that the witness’s explanations for withholding the references at issue lacked credibility, and “other evidence,” such as the witness’s knowledge of the relevant prior art, his selective citation of information to the USPTO, and inconsistencies between the witness’s testimony and corporate documents regarding relevant experiments.⁵⁰ This case shows that the exacting post-*Therasense* intent standard can be met, with appropriate evidence and detailed, specific judicial findings.

B. *Exergen Corp. v. Wal-Mart Stores, Inc.*

1. New Pleading Standards

Exergen was aimed at curbing inequitable conduct allegations at their source—the pleadings. In this 2009 panel decision, the Federal Circuit affirmed a district court decision denying an infringement defendant’s motion to amend its answer to allege inequitable conduct on the ground that the allegations of the amendment were insufficiently particular under Federal Rule of Civil Procedure 9(b).⁵¹ The court held that “simply aver[ring] the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).”⁵²

Standing alone, this holding is not particularly remarkable, given that in several cases preceding *Exergen* the Federal Circuit had expressly enforced a requirement for specificity in inequitable conduct pleadings.⁵³ What is

⁴⁷ *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1335 (Fed. Cir. 2011).

⁴⁸ 675 F.3d 1324 (Fed. Cir. 2012).

⁴⁹ *Id.* at 1337.

⁵⁰ *Id.* at 1335–37.

⁵¹ 575 F.3d 1312, 1331 (Fed. Cir. 2009).

⁵² *Id.* at 1326–27.

⁵³ *See, e.g.*, *Cent. Admixture Pharmacy Serv., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007) (holding insufficient a charge that “during prosecution . . . the patentee failed to disclose all the relevant prior art known to it” and “by manipulation of various measurements and units, the patentee sought to mislead the [USPTO] regarding the relationship between the claimed invention and the prior art”); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006) (rejecting as insufficiently particular an allegation that a patentee “was motivated to extend its patent

noteworthy about the panel ruling in *Exergen* is the degree and nature of the specificity it demands. According to the court, “in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [USPTO].”⁵⁴ Applying this standard, the court held that a recitation that “Exergen, its agent and/or attorneys” failed to identify the “who,” and the pleading inadequately set forth the “‘what’ and ‘where’ of the material omissions” by “fail[ing] to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found.”⁵⁵ It similarly held that generally stating that the withheld references “are ‘material’ and ‘not cumulative to the information already of record’” fails to “explain both ‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.”⁵⁶ The court indicated that “identify[ing] the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record” would be necessary in this regard.⁵⁷

As to intent, the Federal Circuit held that:

although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under [Fed. R. Civ. Proc.] Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the [USPTO].⁵⁸

Applying this standard, the court held that the defendant’s allegations regarding the patentee’s deceptive intent, in failing to disclose the references at issue, were insufficient.⁵⁹ Furthermore, the court held that merely alleging awareness of a reference does not allege knowledge of the supposedly material information contained in the reference.⁶⁰ Moreover, the court also stated that an allegation “that an applicant disclosed a reference during prosecution of one application,

monopoly beyond the [patent] term by patenting [a structurally-similar compound], and it needed to conjure up ‘unexpected’ results”); *Ferguson Beauregard/Logic Controls, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (upholding the district court’s dismissal of an accused infringer’s inequitable conduct charge for lacking particularity because the accused infringer merely asserted that a patent revival was “improper”).

⁵⁴ *Exergen*, 575 F.3d at 1327.

⁵⁵ *Id.* at 1329.

⁵⁶ *Id.* at 1329–30.

⁵⁷ *Id.* at 1329.

⁵⁸ *Id.* at 1328–29.

⁵⁹ *Id.* at 1331.

⁶⁰ *See id.* at 1330.

but did not disclose it during prosecution of a related application, is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct.”⁶¹

2. The New Standards in Operation

a. Pleading the “Who”

The recent decision of the United States District Court for the District of Delaware in *Senju Pharm. Co., v. Apotex, Inc.*⁶² provides a good illustration of what *Exergen* requires as to the particularity of the facts alleged. According to the court:

Apotex alleges that “but for” material omissions and misrepresentations made by “Senju [Pharma], Kyorin, the inventors, and/or those acting on their behalf” with an intent to deceive the [USPTO], the reexamined claims of the ‘045 patent would not have issued. Specifically, the pleadings allege that the following materials were withheld: (1) portions of the trial record and expert reports from the prior litigation disclosing that Kyorin’s researchers had been the first to make and test gatifloxacin ophthalmic formulations covered by the ‘045 patent claims; (2) evidence showing that the formulations as claimed by the ‘045 patent did not exhibit unexpected results; and (3) deposition testimony of Senju’s expert from the prior litigation allegedly conceding the obviousness of preparing aqueous liquid compositions containing 0.3 w/v% gatifloxacin and 0.01 w/v% of disodium edetate, based on the well-known use of disodium edetate to prevent coloration.⁶³

The court compared these allegations against the required “who, what, when, where, and how of the material misrepresentation or omission committed before the [USPTO].”⁶⁴ The court held that the “pleadings at issue sufficiently plead the ‘how’ . . . and ‘where’ standards” (by alleging that the patentee misled the USPTO regarding “evidence of obviousness, secondary considerations, and the scope of the patent’s written description”).⁶⁵ Furthermore, the court held that the pleadings met “the ‘what’ . . . and ‘when’ . . . standards and plead the requisite state of mind.”⁶⁶ The “what” was satisfied by the allegation that “material evidence and testimony” was omitted, and the “when” was met by the allegation that the patentee’s actions occurred “during reexamination of the ‘045 patent.”⁶⁷ As for the “requisite state of mind,” “[t]he

⁶¹ *Id.* at 1331.

⁶² 921 F. Supp. 2d 297 (D. Del. 2013).

⁶³ *Id.* at 300–01 (citations and footnotes omitted).

⁶⁴ *See id.* at 306 (applying *Exergen*, 575 F.3d at 1329–30).

⁶⁵ *See id.* at 306–07.

⁶⁶ *Id.* at 307.

⁶⁷ *See id.*

court can reasonably infer, given the volume of materials from the prior litigation that was submitted during reexamination, that the materials that were withheld were done so with knowledge and intent to deceive the [USPTO].”⁶⁸

However, the court found that the challenger’s allegations did not meet the *Exergen* pleading standard with respect to the “who” (deceived the USPTO) requirement.⁶⁹ Starting from the premise that “[t]he duty of candor and good faith in dealing with the [USPTO] applies to individuals, not organizations,” the court noted that the challenger alleged “that ‘Senju [Pharma], Kyorin, the inventors and/or those acting on their behalf made the alleged misrepresentations and omissions before the [USPTO].’”⁷⁰ It compared the reference to “Senju [Pharma], Kyorin, the inventors and/or those acting on their behalf” to the “similarly-worded allegation—only naming ‘Exergen, its agents and/or attorneys’”—found lacking in *Exergen* “because it failed to identify the specific individual or individuals who deceived the [USPTO],”⁷¹ and those held insufficient by the Delaware district court in *XpertUniverse, Inc. v. Cisco Sys., Inc.*,⁷²—allegations of inequitable conduct against “Abraham Zelkin or one or more of the other individuals listed as an inventor.”⁷³

The problems in *Senju* were the challenger’s references to entities and its “broadly cast net around the inventors and those acting on their behalf.”⁷⁴ Similar insufficiencies resulted in the dismissal of inequitable conduct allegations in *Everlight Electronics Co., Ltd. v. Nichia Corp.*,⁷⁵ where the pleading accused “‘Yoshinori Shimzu, Kensho Sakano, Yasunobu Noguchi, Toshio Moriguchi, and/or other persons who were substantially involved in the preparation or prosecution of the application that led to the [patent at issue].’”⁷⁶ Similarly, in *Mitsubishi Heavy Indus., Ltd. v. GE*,⁷⁷ the inequitable conduct allegations were dismissed where the pleading attributed the alleged inequitable conduct to “‘the named inventors Kazunari Ide, Yoshoyuki Hayashi, and Masaaki Shibata, and/or the attorneys and agents substantively involved in the preparation or prosecution of the [patent at issue]’” and to “‘applicants.’”⁷⁸

⁶⁸ *Id.*

⁶⁹ *See id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² 868 F. Supp. 2d 376 (D. Del. 2012).

⁷³ *Senju*, 921 F. Supp. 2d at 307 (quoting *XpertUniverse*, 868 F. Supp. 2d at 381). According to the court in *XpertUniverse*, by using “the qualifiers that either Zelkin, or ‘one or more’ of the other inventors, knew about the [withheld information] and [its] materiality—[the pleader in *XpertUniverse*] afford[ed] the possibility that Zelkin, the only specific individual named, did not know about them at all.” 868 F. Supp. 2d at 381.

⁷⁴ *See Senju*, 921 F. Supp. 2d at 307.

⁷⁵ 907 F. Supp. 2d 866 (E.D. Mich. 2012).

⁷⁶ *Id.* at 871 (emphasis added).

⁷⁷ No. 6:10-cv-812-ORL-28, 2012 WL 831525 (M.D. Fla. Mar. 12, 2012).

⁷⁸ *Id.* at *2.

According to the *Mitsubishi* court, the problem was the use of the “and/or” conjunction:

The double “and/or” conjunction is too often used by lawyers trying to cover all bases. Its use often has unintended consequences. Through the “and” part of the conjunction, GE has managed to lump the named inventors, attorneys, and agents together under the title “Applicants,” and through the “or” portion GE has disjoined them; the result is that GE has failed to specifically identify who is guilty of misconduct . . . Moreover, a strict application of the “or” alternative of the double conjunction in this case results in an allegation that either the named inventors or some other individual or individuals engaged in deceptive conduct. The other individual or individuals, who remain unnamed, are perhaps the only ones to have engaged in the suspect behavior. Under this construction, GE certainly cannot be said to have made an allegation against a particular person.⁷⁹

This type of searching analysis is typical of district court decisions regarding the sufficiency of inequitable conduct allegations post-*Exergen*.⁸⁰ The district court’s decision in *Oracle Corp. v. DrugLogic, Inc.*⁸¹ is particularly illuminating, as the court carefully distinguished among various allegations regarding the persons alleged to have engaged in inequitable conduct. The defendants’ pleading identified the following persons who allegedly “knowingly failed to disclose material information to the [USPTO]”:⁸²

- Oracle International;
- Kim Rejndrup, the ‘221 patent inventor;
- “Each attorney or agent who prepared or prosecuted the application”;
- “Every other person who was substantively involved in the preparation or prosecution of the application that became the ‘221 patent and who was associated with the inventor, with the assignee, or with anyone to whom there was an obligation to assign the application”;
- “Every individual having a duty of disclosure under 37 C.F.R. § 1.56”⁸³

⁷⁹ *Id.*

⁸⁰ *See, e.g.,* W.L. Gore & Assoc., Inc. v. Medtronic, Inc., 850 F. Supp. 2d 630, 637 (E.D. Va. 2012) (denying the patentee’s motion to dismiss the defendant’s inequitable conduct counterclaim); Oracle Corp. v. DrugLogic, Inc., 807 F. Supp. 2d 885, 900 (N.D. Cal. 2011) (granting leave to amend to supplement inequitable conduct allegations with additional facts).

⁸¹ *Oracle*, 807 F. Supp. 2d 885.

⁸² *Id.* at 897.

⁸³ *Id.* at 897–98.

According to the court:

All but one of these categories are quite general and will not suffice on their own under *Exergen* . . . DrugLogic has adequately pled the “who” of the alleged material omission with respect to Mr. Rejndrup, but not with respect to any other person. In any amended complaint, DrugLogic may only name specific, identified individuals, including Mr. Rejndrup.⁸⁴

The *Oracle* decision clearly illustrates a significant *Exergen* impact: pleadings alleging inequitable conduct will generally be required to “name names.”⁸⁵

b. Pleading the “What” and “Where”

How to satisfactorily plead the “what” and “where” of the alleged inequitable conduct depends on the type of conduct at issue. In *Exergen*, for example, where the inequitable conduct challenge was based (in part) on an alleged withholding of material prior art,⁸⁶ the Federal Circuit held that in “fail[ing] to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found” the pleading failed to sufficiently allege “the ‘what’ and

⁸⁴ *Id.* at 898.

⁸⁵ See also Bruce D. DeRenzi & Sean E. Jackson, *A Procedural Remedy for the “Plague”? Pleading Inequitable Conduct After Exergen Corp. v. Wal-Mart Stores, Inc.*, N.Y. INTELL. PROP. ASSOC. BULLETIN 10 (Aug./Sept. 2010), available at <http://www.crowell.com/documents/A-Procedural-Remedy-for-the-Plague-Pleading-Inequitable-Conduct-After-Exergen-Corp-v-Wal-Mart.pdf> (“The ‘who’ requirement is straightforward. A pleading must identify the specific individual(s) alleged to have engaged in inequitable conduct.”); Gary Fischman, *Inequitable Conduct Pleadings, Post-Exergen*, LAW360 (Aug. 18, 2010), available at <http://www.law360.com/articles/184527/inequitable-conduct-pleadings-post-exergen> (“While in the past some courts would allow pleadings to merely allege ‘an inventor’ or ‘a prosecuting attorney,’ under *Exergen* litigants must specifically identify the person who committed the inequitable conduct.”); Salvatore B. Tamburo & Daniel P. Archibald, *Inequitable Conduct—Alive and Well Post-Exergen . . . At Least for Now*, INTELL. PROP. TODAY (Aug. 2010), available at <http://www.iptoday.com/issues/2010/08/inequitable-conduct-alive-and-well-post-exergen-iat-least-for-now.asp> (noting that “most district courts appear to require that the allegations name the specific individual(s) accused of the inequitable conduct,” but citing *Cal. Inst. of Tech. v. Canon U.S.A.*, 2009 U.S. Dist. LEXIS 126174, at *7–10 (C.D. Cal. Oct. 26, 2009), as an example of a post-*Exergen* decision holding that “the pleadings may generally name the inventor(s), the prosecuting attorney(s), and/or other individual(s) who have a duty of disclosure under 37 C.F.R. § 1.56 where at least one person is specifically named and adequate additional facts are pleaded so as to allow the court to ‘reasonably infer deceptive intent’”).

⁸⁶ See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1325–26 (Fed. Cir. 2009).

‘where’ of the material omission.”⁸⁷ Obviously, in undisclosed-reference-type situations, specific identification (e.g., by page and/or line numbers) to the precise location of the allegedly material information in the reference and a corresponding identification of the claim limitation(s) allegedly undermined by the undisclosed reference should suffice.⁸⁸ However, what should matter is that the pleading somehow identifies the specific information that was (allegedly) withheld or misrepresented and connect it to the claim coverage or other benefit the patent owner obtained as a result.

The recent decision of the United States District Court for the Northern District of Illinois in *CoStar Realty Info., Inc. v. CIVIX-DDI, LLC*⁸⁹ illustrates this pragmatic application of the “what” and “where” requirements of *Exergen*. The challenger, CoStar, identified particular references that were omitted from a declaration the patent owner had submitted in response to a USPTO request (during prosecution) that the patent owner identify the most relevant among hundreds of disclosed references.⁹⁰ It alleged “that the omitted references disclose the use of the Internet or ‘internet-like networking systems generally’ to communicate between a user and a remote database from which the user seeks information.”⁹¹ It further alleged “that the references are relevant ‘to all the asserted claims of the ‘335 Patent, as claim 1, the only independent claim, pertains to ‘advertising over the Internet’, and all other claims of the ‘335 Patent are dependent on claim 1.’”⁹²

In response to the patent owner’s *Exergen*-based challenge, the court held that the latter allegation “adequately identifies the claims the withheld references are relevant to.”⁹³ Regarding “where in the references the relevant information is found,” the court acknowledged that the pleading at issue did “not identify page

⁸⁷ *Id.* at 1329.

⁸⁸ The defendant’s use of a claim chart to illustrate the relevance of an allegedly withheld reference to particular claims of the patent at issue was cited as satisfying the “where” requirement in *BASF Catalysts LLC v. Aristo Inc.*, No. 2:07-cv-222-PPS-APR, 2010 WL 2952982, at *4 (N.D. Ill. July 23, 2010) (“The similarity between the processes the [withheld reference] seeks to protect and the claims levied against Aristo under the [challenged] patent is striking and satisfies the ‘where’ component.”). *See also* Konami Digital Entm’t Co. v. Harmonix Music Sys., Inc., No. 6:08cv286-JD, 2009 WL 5061812, at *2 (E.D. Tex. Dec. 14, 2009) (“The Court is similarly persuaded that Viacom has met the “what” and “where” requirements with pleadings that identify charts of potentially invalidating Konami prior art games—on a claim-by-claim and limitation-by-limitation basis.”).

⁸⁹ Nos. 12 C 4986, 12 C 7091, 12 C 8632, 2013 WL 2151548 (N.D. Ill. May 15, 2013).

⁹⁰ *Id.* at *10.

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

numbers to specifically pinpoint the relevant information.”⁹⁴ However, by “stating that the withheld references ‘disclose the use of CompuServe on the Internet’ and ‘were relevant in teaching the use of the Internet-like networking systems generally,’” the pleading (in the court’s view) “describe[d] what information in the references is relevant.”⁹⁵ The court continued:

Although a party alleging inequitable conduct would be well-advised to include page numbers, doing so is not absolutely necessary to meet *Exergen*’s requirements if the pleading adequately describes the relevant information. Indeed, if the relevant information is adequately described, filling in the page and line numbers is merely an academic, redundant exercise. This court will not require such technical pleading In the context of the patents-in-suit, CoStar’s descriptions plainly indicate that the relevant information in the withheld references is how to use the Internet to communicate between a user and a remote database from which the user seeks information.⁹⁶

A comparatively more strict interpretation of the “what” and “where” requirements in the context of allegedly withheld material prior art is illustrated by the *Oracle* decision. The inequitable conduct allegations at issue concerned the alleged nondisclosure of specified “hierarchical relational medical thesaurus dictionaries” during the prosecution of the asserted patent.⁹⁷ The patent owner summarized the invention as follows:

The presently claimed system is operable to store and classify a plurality of terms, such as clinical or scientific terms according to a hierarchy of relations. The relations define and organize the terms according to more general and more specific terms. In other words, the relations may indicate which terms may be subclasses[,] superclasses[,] or synonyms of other terms. Such organization is beneficial in scientific or medical studies where large quantities of data are processed and consistency among term usage may not be deterministic.⁹⁸

According to the challenger, “this statement also describes already-existing hierarchical relational medical thesaurus dictionaries such as” those alleged to have been withheld, and a subsequent claim amendment further limiting the relevant thesauruses to those “of clinical terms used in conjunction with a clinical study” also did not distinguish or diminish the relevance of the allegedly withheld prior art.⁹⁹ The level of specificity in these allegations appears on par

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.* at *10–11.

⁹⁷ See *Oracle Corp. v. DrugLogic, Inc.*, 807 F. Supp. 2d 885, 889–90 (N.D. Cal. 2011).

⁹⁸ *Id.* at 890.

⁹⁹ See *id.*

with those held adequate for “what” and “where” purposes in the *CoStar* decision discussed above.¹⁰⁰ But the *Oracle* court held them insufficient:

DrugLogic does not specifically identify any claims of the ‘221 patent or particular limitation in those claims to which the allegedly withheld references are relevant. DrugLogic only provides generalized descriptions of the claims of the ‘221 patent within block quotations of statements allegedly made by Oracle to the [USPTO] during the prosecution of the ‘221 patent. Although DrugLogic identifies potentially material information contained in the allegedly withheld references by noting that WHO-Drug, COSTART, Read Codes, CPT, Unified Medical Language System, Metathesaurus, MeSH, and PubMed are all “hierarchical relational medical thesauruses,” some of which contain “clinical terms used in conjunction with clinical studies,” DrugLogic fails to allege where specifically in those references that material could be found. Thus, the Court finds that DrugLogic has not properly pled the “what” and “where” of the alleged material omission.¹⁰¹

These two decisions—*Oracle* and *CoStar*—illustrate how the district courts may vary in their applications of the *Exergen* “what” and “where” standards.

As noted above, the required “what” and “where” allegations must necessarily be tailored to the nature and circumstances of the alleged improper conduct. The “what,” for example, might be facts relating to proper inventorship,¹⁰² or previous litigation,¹⁰³ or prior sales activity.¹⁰⁴ The alleged conduct might have occurred in or before the USPTO,¹⁰⁵ in a specific district

¹⁰⁰ See *supra* notes 89–96 and accompanying text.

¹⁰¹ *Oracle*, 807 F. Supp. 2d at 898 (citations omitted).

¹⁰² See, e.g., *Mycone Dental Supply Co. v. Creative Nail Design, Inc.*, No. 11-4380 JBS, 2013 WL 3216145, at *3 (D.N.J. June 24, 2013) (noting that the plaintiff-patentee’s challenge to the defendant’s inequitable allegations was based, in part, on the defendant’s failure to “identify the [defendant’s] employees that should have been named as inventors”).

¹⁰³ *Civix-DDI, LLC v. Hotels.com, L.P.*, 711 F. Supp. 2d 839, 845–46 (N.D. Ill. 2010) (applying *Exergen* and refusing to dismiss an inequitable conduct charge, concluding that “[d]efendants have alleged that the prosecuting attorneys, including Curtis Vock, along with Civix inventors—W. Lincoln Bouve, William T. Semple, and Steven Oxman—failed to disclose material information, namely, the existence of the Nav-Tech litigation, the interference application, the Nav-Tech settlement, and the conception documents, to the [USPTO] while Civix was prosecuting the ‘622, ‘307, and ‘291 patents during the time period of 1999 and 2000”).

¹⁰⁴ See, e.g., *Mycone*, 2013 WL 3216145, at *7 (holding that a pleading that “does not specify the commercial sales information that [the patentee] should have disclosed” does not satisfy the *Exergen* standard).

¹⁰⁵ See, e.g., *Senju Pharm. Co., v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306–07 (D. Del. 2013) (“The pleadings at issue sufficiently plead the . . . ‘where’ (materials omitted in submissions to the [USPTO] and teachings of the written description) standard[.]”).

court,¹⁰⁶ or out in the marketplace.¹⁰⁷ Whatever the relevant allegedly undisclosed or misrepresented information, and wherever it is found or occurred, a challenger seeking to plead inequitable conduct after *Exergen* is well-advised to be as specific as possible in setting forth facts corresponding to the “what” and “where” of the asserted improper conduct.

c. Pleading the “When” and “How”/“Why”

“When” the alleged inequitable conduct occurred depends on the nature of the alleged misconduct. For example, where the conduct at issue involves undisclosed information, some courts have found it sufficient for the challenger to allege that the misconduct occurred “during prosecution.”¹⁰⁸ Others have not.¹⁰⁹ However, allegations that the nondisclosure occurred during the pendency of the prosecution, with specific references to the filing dates of disclosure statements that did not include the allegedly withheld information, have been held sufficient. For example, according to the court in *BASF Catalysts LLC v. Aristo Inc.*:¹¹⁰

[T]he “when” component was identified by Aristo as occurring during the pending ‘210 patent application, from June 21, 1996 through February 2, 1999, and particularly in the disclosure statements filed by BASF on August 1, 1996, and February 3, 1998. Alleging the exact dates and

¹⁰⁶ See, e.g., *Civix-DDI*, 711 F. Supp. 2d at 848 (stating that regarding an alleged failure to disclose relevant litigation, the “where” requirement was met with allegations that the conduct at issue occurred in the “District Court in Colorado and at the [USPTO]”).

¹⁰⁷ See DeRenzi & Jackson, *supra* note 85, at 11 (“When the alleged inequitable conduct is based on a failure to disclose relevant activities, such as sales, offers for sale, or litigation, specific identification of the location of the activity is necessary.”).

¹⁰⁸ *Id.* (collecting cases holding “during prosecution”-style allegations sufficient).

¹⁰⁹ See, e.g., *Target Training Int’l, Ltd., v. Extended Disc N. Am., Inc.*, No. H-10-3350, 2011 WL 3235683, at *5 (S.D. Tex. July 27, 2011) (“The defendant admits to not pinpointing specific people responsible for its vague allegation of inequitable conduct, and only offers a six-year patent prosecution period as the time frame for the alleged wrongdoing.”); *Halo Elecs. v. Bel Fuse, Inc.*, No. C-07-06222 RMW, 2010 WL 2464811, at *2 (N.D. Cal. June 14, 2010) (holding the defendant’s inequitable conduct allegations, including assertions that the conduct at issue occurred during prosecution, insufficient for “fail[ing] to specify the who, what, when, where, and how of the material misrepresentations or omissions, as required by [Fed. R. Civ. P.] 9(b).”).

¹¹⁰ No. 2:07-cv-222-PPS-APR, 2010 WL 2952982 (N.D. Ill. July 23, 2010).

documents containing the inequitable conduct satisfies the “when” portion of the *Exergen* standard.¹¹¹

Other types of inequitable conduct defenses (or counterclaims) may necessitate allegations regarding when particular events occurred (for example, pre-critical date sales or uses),¹¹² or when specified persons became aware of particular information.¹¹³

The “how” aspect of the *Exergen* standard has been called “[t]he most difficult step in the *Exergen* analysis[, requiring] the causal link between the activity alleged and the granting of the patents in suit.”¹¹⁴ The Federal Circuit held that the pleading at issue in *Exergen* failed the “how” inquiry because although it “state[d] generally that the withheld references are ‘material’ and ‘not cumulative to the information already of record,’” it did “not identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record.”¹¹⁵ According to the court, “[s]uch allegations are necessary to explain both ‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.”¹¹⁶

The Federal Circuit’s language in this regard has spawned some disagreement among the district courts as to whether there is a “why”

¹¹¹ *Id.* at *4; *see also* *McKechnie Vehicle Components USA, Inc. v. Lacks Indus., Inc.*, No. 09-cv-11594, 2010 WL 4643081, at *4 (E.D. Mich. Nov. 9, 2010) (approving as satisfying the *Exergen* “when” requirements allegations relating to conduct during the pendency of the patents at issue, which allegations stated “[t]hat information should have been given in information disclosure statements the inventors and [the attorney] filed with the USPTO on November 7, 2003, and July 8, 2004”).

¹¹² *See, e.g., Somanetics Corp. v. CAS Med. Sys., Inc.*, No. 09-13110, 2010 WL 2178836, at *6 (E.D. Mich. May 26, 2010) (applying the *Exergen* standard to a pleading alleging an intentional withholding of an “on sale” event, holding that the “when” was satisfied by “identif[y]ing the execution date of the [sales] Agreement [at issue], and the issue date of two relevant press releases related to the Agreement”).

¹¹³ *See, e.g., Aerocrine AB v. Apieron Inc.*, No. 08-787-LPS, 2010 WL 1225090, at *9 (D. Del. Mar. 30, 2010) (“The ‘when’—describing when the inventors became aware of the allegedly material prior art—is either during the 1993 Cologne Conference, or, at the latest, by the 1998 Toronto Workshop; in either case the art was not disclosed to the [USPTO] during prosecution of the ‘610 patent.’”).

¹¹⁴ *McKechnie*, 2010 WL 4643081, at *5.

¹¹⁵ *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009).

¹¹⁶ *Id.* at 1329–30.

requirement distinct from the “how.”¹¹⁷ The district court in *Johnson Outdoors Inc. v. Navico, Inc.*¹¹⁸ described the debate (and its and another court’s resolution) as follows:

For a “withholding” claim, the party alleging inequitable conduct must explain “‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.” In *Lincoln National Life v. Jackson National Life Insurance Company*, the district court noted that “a plain reading of the *Exergen* opinion strongly suggests there is no independent ‘why’ requirement Rather, the ‘how’ and ‘why’ factors . . . both refer to the broader requirement of materiality.” The Northern District of Indiana arrived at this conclusion for several reasons. First, the court noted that the Federal Circuit in *Exergen* explicitly adopted the who, what, where, when, and how requirements from the Seventh Circuit opinion in *DiLeo* [*v. Ernst & Young*], 901 F.2d [624,] 627 [7th Cir. 1990]. *DiLeo* made no mention of an independent “why” requirement, or a “why” requirement at all. Second, as observed in *Lincoln National Life*, the *Exergen* court itself did not mention a “why” requirement when it first adopted the Seventh Circuit’s standard. Rather, *Exergen* held “that in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [USPTO].” Nor did it later when the *Exergen* court elaborated the standard for a second time. The “why” was elevated to the status of a pleading requirement based on the parentless “scare quotes” escorting the word later in the *Exergen* opinion.

This court agrees with the reasons elaborated by the Northern District of Indiana, and adds one of its own. The so-called “why” requirement, as the *Exergen* court has spelled it out, requires the court to examine both the withheld information in order to determine its actual materiality, and the information actually presented to the [USPTO] to determine whether the withheld information is cumulative. This is not an appropriate examination to conduct at the pleading stage.¹¹⁹

In holding that there is no separate “why” requirement, the *Lincoln National* court concluded that “the ‘how’ and ‘why’ factors described by the Federal Circuit both refer to the broader requirement of materiality.”¹²⁰ More

¹¹⁷ “Litigants defending against a motion to amend, including Lincoln in the present case, have seized on this apparent addition and attempted to write a distinct ‘why’ requirement into the Federal Circuit’s holding.” *Lincoln Nat. Life v. Jackson Nat. Life Ins. Co.*, No. 1:07–CV–265, 2010 WL 1781013, at *6 (N.D. Ind. May 3, 2010) (citing *Kinetic Concepts, Inc. v. Convatec Inc.*, No. 1:08–cv–918, 2010 WL 1427592, at *7–8 (M.D.N.C. Apr. 8, 2010)).

¹¹⁸ 774 F. Supp. 2d 1191 (M.D. Ala. 2011).

¹¹⁹ *Id.* at 1198 (citations omitted).

¹²⁰ *Lincoln Nat.*, 2010 WL 1781013, at *7.

specifically, “the party seeking leave to amend must show *how* the patent examiner would have used the withheld reference in evaluating the patent application; that is to say, *why* the withheld information is material and not cumulative to the information already disclosed.”¹²¹

Another debate concerning the “how” factor relates to whether an inequitable conduct challenger must expressly (and separately) allege that the (undisclosed or allegedly misrepresented) information at issue was not cumulative.¹²² As noted above, the Federal Circuit held that the pleading at issue in *Exergen* failed the “how” inquiry because although it “state[d] generally that the withheld references are ‘material’ and ‘not cumulative to the information already of record,’” it did “not identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record.”¹²³ The court continued: “[s]uch allegations are necessary to explain both ‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.”¹²⁴ It is this language in *Exergen* that has given rise to the debate regarding whether a pleader must expressly allege that the allegedly withheld or misrepresented information at issue was not cumulative of the other information before the USPTO examiner.¹²⁵

As the district court in *Aerocrine AB v. Apieron Inc.*¹²⁶ recognized, however, the problem in *Exergen* was not a failure to expressly alleged non-cumulativeness, but rather the bald (unexplained) allegation to that effect.¹²⁷ Thus, the *Aerocrine* court found allegations identifying particular claim limitations that were asserted to be missing from the information of record before the USPTO, and “explaining that a reasonable examiner would have found this art to be material to at least [specified claims], because it represents the prior invention, anticipates, and/or renders obvious at least those claims” sufficient to “*explain* the ‘why’ and ‘how.’”¹²⁸ The court noted, however, the existence of “disagreement in the reported case law on this point.”¹²⁹

That disagreement among the district courts as to whether *Exergen* treats non-cumulativeness as an aspect of the defense that must be pled in addition to (sufficient allegations of) materiality continues. Some courts, for example, have

¹²¹ *Id.*

¹²² *See, e.g., Aerocrine AB v. Apieron Inc.*, No. 08-787-LPS, 2010 WL 1225090, at *9 (D. Del. Mar. 30, 2010).

¹²³ *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009).

¹²⁴ *Id.* at 1329–30.

¹²⁵ *See Aerocrine AB*, 2010 WL 1225090, at *9.

¹²⁶ No. 08-787-LPS, 2010 WL 1225090 (D. Del. Mar. 30, 2010).

¹²⁷ *Id.* at *9.

¹²⁸ *Id.* This case was decided before the Federal Circuit altered the materiality standard in *Therasense*. *See supra* notes 11–16 and accompanying text.

¹²⁹ *See Aerocrine AB*, 2010 WL 1225090, at *9 n.7 (collecting cases).

held that specific allegations that particular (undisclosed or misrepresented) information anticipates or renders obvious specific claims necessarily alleges that the information is not cumulative. For example, in *Cumberland Pharm., Inc., v. Mylan Institutional LLC*,¹³⁰ the court held:

By asserting that the withheld information would anticipate and/or render obvious each and every claim of the '356 patent, Mylan is clearly alleging that the patent application would not have been granted had the information been disclosed. Based on these allegations, the court can reasonably infer that the undisclosed information was not cumulative of the information before the [USPTO].¹³¹

The contrasting approach—interpreting the *Exergen* “how” factor as requiring an inequitable conduct pleading to specifically allege that (or even explain why) the information at issue is not cumulative *in addition to* specifically alleging and explaining how the information is material—is illustrated by the following excerpt from the recent decision of the district court in *Aevoe Corp. v. AE Tech. Co., LTD.*:¹³²

To fully plead that a specific person omitted material information, the Defendants’ pleading must also explain both “why” the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.”

Information that is withheld from the USPTO is but-for material only when “the [USPTO] would not have allowed a claim had it been aware of the undisclosed prior art.” Defendants’ counterclaim alleges that “[h]ad the USPTO been aware of a sale or any public disclosure made prior to June 14, 2010 of the Moshi iVisor AG or the Moshi iVisor Pro, the ‘942 Patent would not have issued.” Given the similarity between the laptop computer

¹³⁰ No. 12 C 3846, 2012 WL 6567922 (N.D. Ill. Dec. 14, 2012).

¹³¹ *Id.* at *6 (citing *Pollin Patent Licensing, LLC v. Capital One Auto Fin., Inc.*, No. 10 CV 07420, 2011 WL 5118891, at *3 (N.D. Ill. Oct. 25, 2011)). A similar analysis was undertaken by the court in *Bone Care Int’l v. Pentech Pharm.*, No. 08 CV 1083, 2010 WL 1655455 (N.D. Ill. Apr. 23, 2010):

In allegation D, Defendants allege that examiners relied on five of the omitted references in prior related patent applications to make rejections of substantially similar claims to those presented in the ‘488 application. Defendants also specify the claims of the ‘488 application to which each omitted reference is relevant. With respect to the five references, the clear implication is that if the references had been before the examiner on the ‘488 application, the substantially similar claims would have been rejected. That those claims were not rejected implies that no other information before the examiner compelled rejection, and thus that the five omitted references are not cumulative.

Id. at *6 (footnote omitted).

¹³² No. 2:12-cv-00053-GMN, 2013 WL 876036 (D. Nev. Mar. 7, 2013).

screen protectors and the products embodying the '942 Patent, the Court finds that Defendants have adequately pleaded that the patent examiner might not have allowed the unspecified claims if he/she had been aware of these undisclosed products.

The same cannot be said for Defendants' allegations that the two products were not cumulative of the information already disclosed during prosecution. "It is well-established . . . that information is not material if it is cumulative of other information already disclosed to the [USPTO]." Accordingly, to satisfy the "why" component, Defendants' counterclaim must also plead with particularity that the withheld information is not cumulative of the information actually disclosed during prosecution. Such facts are absent from Defendants' counterclaim. Therefore, the Court finds that Defendants' counterclaim fails to plead with particularity "why" the withheld information is material and not cumulative.¹³³

Clearly, until the Federal Circuit resolves these differing interpretations of the "how" requirement, a pleader would be well-advised to plead facts specifically (and perhaps separately) addressing "why" the information at issue was material, "why" it was non-cumulative, and "'how' an examiner would have used this information in assessing the patentability of the claims."¹³⁴

d. Pleading Deceptive Intent

As discussed above, in *Exergen*, the Federal Circuit held that "knowledge" and "intent" may be stated generally, but a pleading of inequitable conduct "must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the [USPTO]."¹³⁵ The district court in the *Lincoln National* case¹³⁶ applied this sufficient-facts-to-support-a-reasonable-inference-of-knowledge-and-specific-intent-to-deceive standard to an allegation of inequitable conduct based on an allegedly intentionally withheld reference.¹³⁷

[The defendant] has alleged that the named inventors knew of their duty to disclose relevant information and knew of the features of the withheld

¹³³ *Id.* at *7–8 (citations omitted). The *Aevoe Corp.* court also cited several other cases it regarded as supporting the notion of a separate requirement for allegations of non-cumulativeness. *See id.* at *8.

¹³⁴ *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329–30 (Fed. Cir. 2009).

¹³⁵ *Id.* at 1328–29.

¹³⁶ No. 1:07–CV–265, 2010 WL 1781013 (N.D. Ind. May 23, 2010), discussed *supra* notes 120–121 and accompanying text.

¹³⁷ *See id.* at *1.

Lincoln Reference that [the defendant] believes are relevant to the patentability of the '201 and '608 Patents. [The defendant] then argues that the Lincoln Reference was never cited as prior art during the prosecution of the '201 and '608 Patents and that it was withheld with intent to deceive the [USPTO]. Specifically, [the defendant] alleges that Lincoln submitted ten documents as part of a June 13, 2007, disclosure to the [USPTO] that the inventors believed were not relevant prior art. [The defendant] claims that Lincoln's failure to disclose the arguably relevant Lincoln Reference when it *did* disclose documents that it believed were *not* relevant prior art, creates a reasonable inference that the inventors acted to deceive the [USPTO].

These allegations are sufficient to create a reasonable inference that the Lincoln Reference was deliberately withheld from the [USPTO].¹³⁸

The court made clear that the defendant's ability to *prove* deceptive intent is a separate question from the adequacy of the pleading.¹³⁹

Lincoln National is an example of a pre-*Therasense* application of the *Exergen* intent pleading standard. Whether *Therasense* heightened the requirements for pleading deceptive intent beyond what *Exergen* required is another issue that has divided the district courts. Of course the pleading of a claim or defense must reflect changes in the relevant substantive definitions. Accordingly, a challenger "must plead a plausible claim for relief in accordance with *Therasense*."¹⁴⁰ But there is some disagreement among the district courts on

¹³⁸ *Id.* at *8–9 (citations omitted).

¹³⁹ *See id.* at *9 (quoting *Lincoln Nat. Life v. Transamerica Fin. Life Ins. Co.*, No. 1:08-cv-135, 2009 WL 4547131, at *2 (N.D. Ind. Nov. 25, 2009)) (stating "[t]he heightened pleading requirements of Rule 9(b) do not require that [the defendant] definitively prove the merits of its claim. What is determinative here is that [Lincoln] was given fair notice of the basis for [the defendant's] inequitable conduct defense."). The court also cited with approval *Nycomed U.S. Inc. v. Glenmark Generics Ltd.*, No. 08-cv-5023(CBA)(RLM), 2010 WL 1257803, at *18 (E.D.N.Y. Mar. 26, 2010) (quoting *Pall Corp. v. Cuno Inc.*, 681 F. Supp. 2d 258, 264 (E.D.N.Y. 2010)) ("In sum, '[t]he issue before the Court is not whether [the defendant] will ultimately prevail, but whether it is entitled to offer evidence' to support its allegations of inequitable conduct.").

¹⁴⁰ *See, e.g.*, *Mycone Dental Supply Co., v. Creative Nail Design, Inc.*, No. 11-4380 JBS, 2013 WL 3216145, at *6 (D.N.J. June 24, 2013) (citing *Bayer Cropscience AG v. Dow Agrosciences LLC*, No. 10-1045 RMB-JS, 2012 WL 1253047, at *2 (D. Del. Apr. 12, 2012)) ("Although the *Therasense* decision did not squarely address the pleading requirements for an inequitable conduct defense, but instead involved the review of a district court's opinion after a bench trial, the decision is still relevant to the pleading issues involved herein.").

the specific issue of how the Federal Circuit's substantive "single most reasonable inference" standard affects the pleading of deceptive intent.¹⁴¹

For example, the patentee in *Wyeth Holdings Corp. v. Sandoz, Inc.*¹⁴² initially argued that "unless the Court finds that intent to deceive is the 'single most reasonable inference' that can be drawn from the facts alleged in [the challenger's] pleading, *Therasense* compels dismissal of [the] inequitable conduct defense."¹⁴³ In his Report and Recommendation Regarding Plaintiffs' Motion to Dismiss Sandoz's Fourth Counterclaim and to Strike Sandoz's Fourth Affirmative Defense Directed to Inequitable Conduct, U. S. Magistrate Judge Christopher Burke rejected this argument, after discussing "how the 'single most reasonable inference' language from *Therasense* should be reconciled with the 'reasonable inference' directives from *Exergen*":¹⁴⁴

Several district courts have recently confronted this question and have reached different conclusions. On one end of the spectrum, the District of South Dakota [in *Hansen Mfg. Corp v. Enduro Sys., Inc.*, No. CIV. 114030, 2011 WL 5526627, at *4 (D.S.D. Nov. 14, 2011)] denied a motion for leave to file an amended answer alleging inequitable conduct because "there [were] multiple reasonable inferences that may be drawn" from the facts alleged in the proposed inequitable conduct pleading. This conclusion derives from the Hansen Court's determination that "*Therasense* tightened the *standard for pleading* so that specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." [See also *Quest Software, Inc. v. Centrifly Corp.*, No. 2:10—CV—859 TS, 2011 WL 5508820, at *2-3 (D. Utah Nov. 9, 2011) (denying defendant's motion for leave to file amended answer including inequitable conduct claim in part because "the allegations do not reveal that the intent to deceive is the most reasonable inference to be drawn from the evidence").

Other courts have held that the "single most reasonable inference" standard applies to at least some extent in the pleading context. For instance, the Eastern District of Virginia [in *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 803 F.Supp.2d 409 (E.D. Va. 2011)] determined that "*Exergen* still states the correct elements required for pleading inequitable conduct

¹⁴¹ See, e.g., *Cutsforth, Inc. v. Lemm Liquidating Co.*, No. 12-cv-1200 (SRN/JSM), 2013 WL 2455979, at *4 n.9 (D. Minn. June 6, 2013) (observing that "[d]istrict courts are currently conflicted on the effect of the Federal Circuit's holding in *Therasense* on the pleading requirements for the specific intent to deceive element" and citing decisions reaching different conclusions as to the significance of the "single most reasonable inference" requirement at the pleading stage).

¹⁴² No. 09-955-LPS, 2012 WL 600715 (D. Del. Feb. 3, 2012).

¹⁴³ *Id.* at *6. The Magistrate Judge noted that Wyeth subsequently withdrew its contention that the *Therasense* standard should guide the determination of the sufficiency of the pleading. See *id.*

¹⁴⁴ *Id.*

after *Therasense*,” and that a party is not required at the pleading stage “to meet the clear and convincing evidence standard that applies on the merits.” However, the *Pfizer* Court concluded that in light of *Therasense*, “a party must make an initial showing from which it may be plausibly inferred that . . . the intent to deceive is the single most likely explanation for the non-disclosure [of but-for material information].” [A]ccord *VDF FutureCeuticals, Inc. v. Sandwich Isles Trading Co.*, Civ. No. 1100288 ACK_RLP, 2011 WL 6820122, at *6 (D. Haw. Dec. 27, 2011) (dismissing an inequitable conduct counterclaim where the allegations pled did not “give rise to a plausible inference that the intent to deceive was the single most likely explanation” for the alleged conduct). While the *Pfizer* and *VDF* Courts did not take as rigid a view as did *Hansen*, they nonetheless held that the “single most reasonable” rubric has been engrafted onto the inequitable conduct pleading standard from *Exergen*.¹⁴⁵

Magistrate Judge Burke cited three reasons for disagreeing with the *Pfizer* and *Hansen* courts, and holding that “to adequately plead the intent prong of an inequitable conduct defense, the claimant need only allege facts from which the Court could *reasonably infer* that the patent applicant made a deliberate decision to deceive the [USPTO].”¹⁴⁶ His analysis is thoughtful and thorough:

First, the Federal Circuit explains in *Therasense* that the “single most reasonable inference” requirement is an *evidentiary* standard that must be satisfied at the proof stage, not a pleading standard. The Federal Circuit notes that “to meet the clear and convincing *evidence* standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the *evidence* . . . Indeed, the *evidence* must be sufficient to require a finding of deceitful intent in light of all the circumstances.” This statement is couched strictly in terms of the ultimate evidentiary analysis, in which a district court determines whether under a heightened standard of proof (the clear and convincing evidence standard), deceptive intent is the single most reasonable inference to be drawn. This form of analysis clearly contrasts with the pleading stage analysis required by [*Ashcroft v. Iqbal*, 556 U.S. 662 (2009)] which asks whether, taking all of the alleged facts as true, the Court can draw the “reasonable inference” that a party is liable for the claimed misconduct, such that the claim is “plausible.” After all, courts “do not inquire whether a plaintiff will ultimately prevail when considering a motion to dismiss, only whether the plaintiff is *entitled to offer evidence to support his or her claims*.” Moreover, at the pleading stage, a court does not (and cannot) review “all of the circumstances” at play in a case, as the *Therasense* “single most reasonable inference” inquiry requires. Instead, a court assessing the sufficiency of a pleading looks only to a narrow category of materials (the pleading and any attached exhibits) provided only by one side (the party or parties asserting the inequitable conduct claim).

¹⁴⁵ *Id.* at *7 (citations and footnote omitted).

¹⁴⁶ *Id.*

Second, in *Exergen*, the Federal Circuit appeared to specifically indicate that the “single most reasonable inference” analysis was a separate inquiry from that used to examine whether inequitable conduct is well-pled. After holding that a party must plead facts from which a court can “reasonably infer” that material information was misrepresented or withheld with the specific intent to deceive the [USPTO], the *Exergen* Court noted how this pleading standard differs from the applicable standard of proof first articulated in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365–66 (Fed. Cir. 2008):

In contrast to the pleading stage, to prevail on the merits, the accused infringer must prove both materiality and intent by clear and convincing evidence. *See Star Scientific*, 537 F.3d at 1365. *Whereas an inference of deceptive intent must be reasonable and drawn from a pleading’s allegations of underlying fact to satisfy Rule 9(b), this inference must be the ‘single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.’* *Id.* at 1366.

Exergen, 575 F.3d at 1329 n. 5. To read *Therasense* as disturbing this well-established dichotomy would be to collapse inequitable conduct into a mini-trial on the pleadings, and to ignore the clear holdings from both *Star Scientific* and *Exergen*. The Court finds no language in *Therasense* to support such an outcome

Third, this reading is corroborated by the Federal Circuit’s own post-*Therasense* case law. In *Delano Farms Co. v. Cal. Table Grape Comm’n*, 655 F.3d 1337 (Fed. Cir. 2011), the Federal Circuit stated 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 [USPTO] and withheld that information with a specific intent to deceive the [USPTO].” Although this statement does not definitively resolve the issue . . . , it strongly suggests that [a pleader] need only set forth facts from which deceptive intent can be reasonably inferred. *Accord Human Genome Sciences, Inc. v. Genentech, Inc.*, Case No. 2:11-cv-6519-MRP (JEMx), slip op. at 6 (C.D.Cal. Dec. 9, 2011) (considering *Therasense* and *Exergen* and concluding that “[i]n order to survive dismissal [of an inequitable conduct claim], the accused infringer must allege facts from which it is plausible that the applicant had an intent to deceive,” and need not demonstrate that deceptive intent is “the most reasonable inference”).¹⁴⁷

¹⁴⁷ *Id.* at *7–8. *Accord* *W.L. Gore & Assoc., Inc. v. Medtronic, Inc.*, 850 F. Supp. 2d 630, 634 n.1 (E.D. Va. 2012), and *Cutsforth, Inc. v. Lemm Liquidating Co.*, No. 12-cv-1200 (SRN/JSM), 2013 WL 2455979, at *4 n.9 (D. Minn. June 6, 2013) (each citing the Federal Circuit’s decision in *Delano Farms*).

The issue of whether *Therasense* augmented the pleading requirements announced in *Exergen* awaits definitive resolution by the Federal Circuit.¹⁴⁸ Clearly, however, a requirement that patent challengers allege facts supporting deceptive intent as the most reasonable inference (as opposed to a plausible inference) would be difficult to satisfy in many cases at the pleading stage.

The recent decision of the district court in *Parkervision, Inc. v. Qualcomm Inc.*¹⁴⁹ dismissing an inequitable conduct allegation based on alleged “burying” of the assigned USPTO examiner ““with hundreds of references so as to distract his attention from highly relevant references”” illustrates how the combination of *Exergen* and *Therasense* may impact pleading standards.¹⁵⁰ Noting that *Exergen* requires ““sufficient allegations of underlying facts from which a court may reasonably infer”” that the patentee ““withheld or misrepresented [the] information with a specific intent to deceive the [USPTO],”” the district court held that “an equally if not more reasonable inference [to be drawn from the allegation that the patentee inundated the examiner] is that [the patentee] aimed to insulate itself from such claims by over-disclosing references.”¹⁵¹ *Parkervision* thus suggests that where a court can reasonably infer that deceptive intent is *not* the single most reasonable inference to be drawn from the alleged facts, dismissal of the subject allegations may be appropriate.

C. Lessons from Therasense and Exergen

To summarize, *Therasense*, *Exergen*, and the decisions applying them thus far suggest the following lessons for litigants and counsel:

- Withheld information that is found to anticipate or render obvious claims under a “clear and convincing evidence” standard necessarily satisfies the *Therasense* “but-for materiality” standard.
- Even where the USPTO requires disclosure of information, that information may not be regarded as material under *Therasense*.
- As compared with the pre-*Therasense* period, the development of Federal Circuit law relating materiality may be delayed to the extent the court declines to rule on materiality in cases where the deceptive intent standard is clearly not satisfied.

¹⁴⁸ The appellate briefs in *Delano Farms* were filed in early 2011 before *Therasense* was decided, and, accordingly, did not raise the issue of whether *Therasense* raised the bar for pleading deceptive intent beyond what *Exergen* requires.

¹⁴⁹ 924 F. Supp. 2d 1314 (M.D. Fla. 2013).

¹⁵⁰ *See id.* at 1318.

¹⁵¹ *Id.* (“Because specific intent to deceive is not the only or single most reasonable inference to be drawn from the disclosure of voluminous references to the [USPTO], Qualcomm’s pleading of the ‘burying’ theory fails as a matter of law.”).

- The Federal Circuit will closely scrutinize district court rulings and records regarding evidence of deceptive intent, which can be expected to influence district courts, in turn, to carefully consider such evidence. In particular, challengers will need to marshal evidence of a deliberate decision to deceive, or at least show that deceptive intent is the most reasonable inference to be drawn from the evidence.
- Deceptive intent findings that are based significantly on the materiality of the withheld or misrepresented information will be vulnerable on appeal.
- Allegations that inequitable conduct was committed by entities, “persons involved in the prosecution,” or “inventors and/or attorneys” are unlikely to be held sufficient. To satisfy *Exergen*’s “who” requirement, inequitable conduct pleadings must expressly (or effectively) “name names.”
- There is some disagreement among the district courts regarding inequitable conduct pleading requirements, including whether there is a “why” requirement distinct from the “how” requirement, whether an inequitable conduct challenger must expressly allege that the undisclosed or allegedly misrepresented information was not cumulative to other information before the examiner, and the impact the Federal Circuit’s substantive “single most reasonable inference” standard on the pleading of deceptive intent.
- The precise interplay between *Therasense* and *Exergen* on pleading allegations relating to deceptive intent is unresolved.

II. THE LEGISLATURE’S CONTRIBUTION: SUPPLEMENTAL EXAMINATION

The AIA created a new USPTO proceeding designated as a “supplemental examination.”¹⁵² The purpose is “to consider, reconsider, or correct information believed to be relevant to the patent” that is the subject of the request.¹⁵³ The USPTO is charged with evaluating the information presented in the request under the familiar reexamination standard: “whether [it] raises a

¹⁵² See 35 U.S.C. § 257 (West, Westlaw current through P.L. 113-57 (excluding P.L. 113-54 and 113-56) approved 12-9-13).

¹⁵³ See *id.* § 257(a).

substantial new question of patentability,”¹⁵⁴ and it will have three months to make that determination.¹⁵⁵ Only the patent owner can request a supplemental examination.¹⁵⁶

According to the new law, the consequence of a USPTO determination that any of the information in the request for supplemental examination raises a substantial new question of patentability is a reexamination proceeding¹⁵⁷ that differs from the usual *ex parte* reexamination in two principal respects. First, the patent owner (who filed the request for supplemental examination in the first place) is barred from submitting a statement.¹⁵⁸ Second, and significantly, the restriction limiting reexamination to consideration of “patents and printed publications”¹⁵⁹ does not apply,¹⁶⁰ and “information” is not otherwise limited or defined in the legislation.¹⁶¹ Accordingly, a patent owner can use supplemental examination not only to bring to the attention of the USPTO prior art patents and printed publications, but also non-print prior art (such as pre-critical date sales and public uses) and non-prior art information of the kind the Federal Circuit had held to be material for purposes of the inequitable conduct defense, prior to *Therasense*. Such non-prior art information includes:

¹⁵⁴ See *id.* “If . . . the Director finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for reexamination of the patent for resolution of the question.” *Id.* § 304; see, e.g., *In re Swanson*, 540 F.3d 1368, 1375 (Fed. Cir. 2008) (noting that “[t]he ‘substantial new question of patentability’ requirement prevents potential harassment of patentees by ‘act[ing] to bar reconsideration of any argument already decided by the [USPTO], whether during the original examination or an earlier reexamination.’” (quoting H.R. Rep. No. 96-1307(I) (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6462, 6466)).

¹⁵⁵ See 35 U.S.C. § 257(a) (West, Westlaw current through P.L. 113-57 (excluding P.L. 113-54 and 113-56) approved 12-9-13).

¹⁵⁶ See *id.*

¹⁵⁷ See *id.*

¹⁵⁸ See *id.* § 257(b).

¹⁵⁹ 35 U.S.C. § 302 authorizes “[a]ny person [to] file a request for reexamination . . . of any claim of a patent on the basis of any prior art cited under the provisions of section 301,” which authorizes the citation of “prior art consisting of patents or printed publications.” See 35 U.S.C. § 301 (current through P.L. 113-57 (excluding P.L. 113-54 and 113-56) approved 12-9-13).

¹⁶⁰ Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Review Reexamination Fees, 77 Fed. Reg. 48,828 (Aug. 14, 2012) (“Unlike a request for *ex parte* reexamination, the items of information presented in a request for supplemental examination are not limited to patents and printed publications.”).

¹⁶¹ See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, § 12 (2011).

- unpublished notes taken by a non-inventor, co-employee at a poster presentation,¹⁶²
- a non-prior art article relevant to whether the claims at issue were enabled,¹⁶³
- a third-party's patent application (in the inventor's possession) and information regarding the third-party's model of his own invention (which the inventor had seen),¹⁶⁴
- "intentional falsehoods, misrepresentations, and nondisclosures" relating to inventorship,¹⁶⁵
- a false statement in a Petition to Make Special,¹⁶⁶ and
- unjustified claims to small entity status.¹⁶⁷

Some of the non-prior art information listed above (without more) clearly will not raise a "substantial new question of patentability,"¹⁶⁸ and even more clearly

¹⁶² *Monsanto Co. v. Bayer Biosciences N.V.*, 514 F.3d 1229, 1235 (Fed. Cir. 2008).

¹⁶³ *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234–35 (Fed. Cir. 2003).

¹⁶⁴ *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274–75 (Fed. Cir. 2001).

¹⁶⁵ *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1317, 1320 (Fed. Cir. 2000).

¹⁶⁶ *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1375 (Fed. Cir. 2008); *Gen. Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994).

¹⁶⁷ *See Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1231 (Fed. Cir. 2007); *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003).

¹⁶⁸ "The presence or absence of a 'substantial new question of patentability' determines whether or not reexamination is ordered." Manual of Patent Examining Procedure (MPEP) § 2242 (8th ed. Rev. 8, July 2010). According to the USPTO's rules for implementing supplemental examination, "[t]he decision as to whether the information submitted in a request for supplemental examination raises a substantial new question of patentability is identical to the decision as to whether the information submitted in a request for ex parte reexamination raises a substantial new question of patentability, except that the information submitted in a request for supplemental examination is not limited to patents and publications and may be directed to issues of patentability in addition to those permitted in ex parte reexamination, such as issues under 35 U.S.C. 101 and 112." Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and to Review Reexamination Fees, 77 Fed. Reg. 48,828, 48,831 (Aug. 14, 2012). In ex parte reexamination, "[a] prior art patent or printed publication raises a substantial question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether or not the claim is patentable." Manual of Patent Examining Procedure (MPEP) § 2242. Accordingly, in supplemental examination, information will raise a substantial new question of patentability where there is a substantial likelihood that a reasonable examiner would consider the information important in deciding whether or not a claim is patentable.

will not satisfy the Federal Circuit’s new “but-for” materiality standard.¹⁶⁹ However, at least where there is doubt about how a court might regard information—prior art or otherwise—that was (or was arguably) not considered (or inadequately considered) by the USPTO during original (or a prior) prosecution, a patent owner could elect to pursue supplemental examination. New § 257(c) of the Patent Act sets forth the preemptive protection a patent owner can obtain via supplemental examination:

A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.¹⁷⁰

This is the key provision in the supplemental examination portion of the AIA. Unless certain exceptions relating to timing apply,¹⁷¹ the legislation strips the courts of the power to hold patents unenforceable for inequitable conduct in cases where the patentee has previously secured, via supplemental examination, USPTO consideration of the information the patent challenger alleges was withheld or misrepresented.¹⁷²

¹⁶⁹ See *supra* note 14 and accompanying text.

¹⁷⁰ 35 U.S.C. § 257(c)(1) (current through P.L. 113-57 (excluding P.L. 113-54 and 113-56) approved 12-9-13).

¹⁷¹ The injunction against a determination of unenforceability will not operate if either of two statutory exceptions applies. These exceptions relate to timing, and will be triggered by specified events. First, a patent owner contemplating an enforcement action (either in the district courts or in the International Trade Commission) and seeking to head off an anticipated inequitable conduct charge based on particular information will only obtain the benefit of the § 257(c)(1) protection if the USPTO has concluded its supplemental examination of that information (at the patent owner’s request) *and* any resulting reexamination *before* the patent owner files its enforcement action. See *id.* § 257(c)(2)(B). The second exception applies when the patent challenger (as opposed to the patent owner) makes the first move, e.g., by filing a declaratory judgment action or answer to complaint containing particularized allegations of inequitable conduct, or by sending the patent owner a Paragraph IV letter, see 21 U.S.C. § 355(j)(2)(A)(vii)(I–IV) (2006), before the patent owner files a supplemental examination request. See 35 U.S.C. § 257(c)(2)(A). In such a case, supplemental examination will not preclude litigation of the inequitable conduct defense at issue. These two exceptions operate to encourage patent owners to seek (and complete) supplemental examination (and any resulting reexamination) regarding any potentially problematic information before filing suit. A patent challenger who wants to press an inequitable conduct defense, on the other hand, will have to assert that defense—in a declaratory judgment complaint, an answer to an infringement complaint, or a Paragraph IV letter—before the patentee initiates a supplemental examination.

¹⁷² 35 U.S.C. § 257(c)(1).

The new § 257 took effect on September 16, 2012 and “appl[ies] to any patent issued before, on, or after that date.”¹⁷³ Thus, patent owners can use supplemental examination to anticipatorily defeat potential inequitable conduct charges relating to any of their issued, pending, or future patents.

III. OPTIONS FOR PATENT OWNERS AFTER *THERASENSE* AND THE AIA

A patent owner considering enforcement, but concerned about or aware of a potential inequitable conduct issue, should consider the implications of *Therasense* and the AIA. Thanks to these and other recent developments, the menu of potential options for such a patent owner has changed. This section discusses the options, post-*Therasense* and the AIA, for patent owners faced with a potential inequitable conduct challenge.

A. *Therasense’s Impact on the Evidentiary Significance of Reexamination and Reissue*

The first thing to consider is that as a result of *Therasense*, the evidentiary significance of reexamination and reissue has been altered. Prior to *Therasense*, a rejection of claims in reexamination or reissue over a previously undisclosed reference or references could serve as evidence of materiality. A claim rejection is an assertion by the USPTO that the reference(s) at issue *prima facie* anticipate or render obvious the claim(s) at issue.¹⁷⁴ A rejection thus represents the opinion of the USPTO—the expert agency—that more likely than not, the claims at issue are not patentable over the cited prior art. If the claims are (more likely than not) not patentable over a reference or references, then clearly a “reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”¹⁷⁵ And before *Therasense*, materiality could be established by satisfying the “reasonable examiner” standard.¹⁷⁶

¹⁷³ See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, § 12 (2011).

¹⁷⁴ *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). As the court in *In re Oetiker* explained:

The *prima facie* case is a procedural tool of patent examination, allocating the burdens of going forward as between examiner and applicant. The term “*prima facie* case” refers only to the initial examination step [T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.

Id.

¹⁷⁵ See *Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (quoting 37 C.F.R. § 1.56 (1977), the USPTO’s previous disclosure standard).

¹⁷⁶ See *id.* at 1316.

In fact, before *Therasense*, even the grant of a request for reexamination with respect to a particular reference or references was potential evidence of materiality,¹⁷⁷ because the “substantial new question of patentability” standard the USPTO applies to determine whether to grant a request for reexamination is the “reasonable examiner” standard.¹⁷⁸ Furthermore, a USPTO determination that a substantial new question of patentability exists is a determination that the subject patent or printed publication is not cumulative.¹⁷⁹ Thus, a determination that a patent or publication raises a substantial new question of patentability is a USPTO determination that the patent or publication is material to the claim(s) at issue under the pre-*Therasense* standard.¹⁸⁰ Of course, a *denial* of a reexamination request in light of a particular reference was (and continues to be) evidence of non-materiality.¹⁸¹ But the high reexamination grant rate,¹⁸² coupled

¹⁷⁷ See, e.g., Robert Greene Sterne et al., *Reexamination Practice with Concurrent District Court Litigation or Section 337 USITC Investigations*, 11 SEDONA CONF. J. 1, 24 (2010). Mr. Sterne and his co-authors note:

Parties may attempt to use a reexamination proceeding to buttress the materiality prong of the inequitable conduct analysis. To do so, the omitted prior art reference is used as the basis for a [substantial new question of patentability] in a reexamination request. If the examiner is persuaded that the omitted prior art reference forms a [substantial new question of patentability] and then orders a reexamination, this will be taken as further evidence as to the materiality of the reference.

Id.

¹⁷⁸ See Manual of Patent Examining Procedure (MPEP) § 2242 (8th ed. Rev. 8, July 2010) (“A prior art patent or printed publication raises a substantial question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether or not the claim is patentable.”).

¹⁷⁹ See *id.* § 2216 (instructing examiners that to find a substantial new question of patentability, “[i]t must first be demonstrated that a patent or printed publication that is relied upon in a proposed rejection presents a new, non-cumulative technological teaching that was not previously considered and discussed on the record during the prosecution of the application that resulted in the patent for which reexamination is requested, and during the prosecution of any other prior proceeding involving the patent for which reexamination is requested”); *id.* § 2242 (explaining that a substantial new question of patentability does not exist “where the examiner finds the additional (newly provided) prior art patents or printed publications are merely cumulative to similar prior art already fully considered by the Office in a previous examination of the claim”).

¹⁸⁰ MATTHEW A. SMITH, INTER PARTES REVOCATION PROCEEDINGS § 12:21 (2012) (“If a substantial new question is found, and especially if claims are rejected, this supports an argument that the reference is material.”).

¹⁸¹ See *id.* (“If an examiner finds no substantial new question of patentability, there is an argument that the reference was cumulative.”).

with the pre-*Therasense* “reasonable examiner” materiality standard, made reexamination more useful as a tool for generating evidence of materiality, rather than establishing non-materiality.

The extent to which the courts would accept as evidence of materiality either a claim rejection or a grant of reexamination varied.¹⁸³ But certainly, where a patent owner acquiesced to a rejection by amending claims in response to a rejection over a previously undisclosed reference, it was difficult for the patentee to convincingly contend that the reference was not material to patentability.¹⁸⁴

The situation has significantly changed post-*Therasense*. Now, where the USPTO confirms or issues claims over the references or information in question (in reexamination or reissue), such confirmation refutes the notion that “but-for” the USPTO’s inability to consider the reference, the claims in question would not have issued. That the reexamination request was granted in the first place, under the equivalent of the old “reasonable examiner” standard, is not enough to show materiality.

Accordingly, *Therasense* opens up a new frontier for a patent owner concerned about a potential inequitable conduct issue. If the previously undisclosed information is a patent or printed publication, the owner may be able to establish, by filing a request for reexamination and showing that its claims are patentable over the reference, that the reference is not “but-for” material. However, reexamination is not the only avenue. The Federal Circuit in *In re Tanaka*¹⁸⁵ held that reissue is available to add a dependent claim or

¹⁸² From July 1, 1981, when ex parte reexamination became available, through September 30, 2012, the USPTO granted ninety-two percent (92%) of such requests. See *Ex Parte Reexamination Filing Data - September 30, 2013*, UNITED STATES PATENT AND TRADEMARK OFFICE 3 (Sept. 30, 2013), available at http://www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2013.pdf.

¹⁸³ See SMITH, *supra* note 180, n.1 (collecting cases).

¹⁸⁴ See SMITH, *supra* note 180. The author notes:

The Federal Circuit has previously held that the “results” of reexamination can be of “strong probative value” to the question of materiality. It is not, however, dispositive. A rejection by the [USPTO] during reexamination over a reference that was previously not disclosed does not indicate materiality per se. The converse is also true: failure to reject claims in reexamination or the ultimate allowance of those claims does not indicate a lack of materiality per se. Neither does an amendment of claims over an omitted reference create a rule of materiality.

Id. (footnotes omitted).

¹⁸⁵ 640 F.3d 1246 (Fed. Cir. 2010).

claims.¹⁸⁶ Thus the addition of a dependent claim or claims provides an avenue into reissue that can then be used to “vet” a previously undisclosed reference or references—via an information disclosure statement¹⁸⁷—and obtain a USPTO determination that the reference does not anticipate or render obvious the claims of the patent and is, therefore, not “but-for” material. Furthermore, because the USPTO’s consideration of issues in reissue is not limited to prior art issues (let alone printed prior art issues),¹⁸⁸ information disclosure statements in reissue can be used to bring to the attention information beyond that which can properly be considered in reexamination. Thus, one potential option for patentees faced with a possible inequitable conduct problem is to obviate that problem by establishing, via reexamination or reissue, the immateriality of the information at issue.

Furthermore, although the Federal Circuit has recently reminded us that inequitable conduct cannot be “cured” via reexamination or reissue,¹⁸⁹ deceptive intent on the part of the patentee is no longer an impediment to the use of reissue to obtain USPTO consideration of previously withheld or misrepresented information. The AIA changed the reissue statute so that it no longer limits the availability of reissue to the correction of errors that occurred “without any deceptive intention.”¹⁹⁰ Thus, even where information was previously withheld

¹⁸⁶ *Id.* at 1251–52 (holding that allowing “the addition of dependent claims as a hedge against possible invalidity has been embraced as a reasonable interpretation of the reissue statute by [the Federal Circuit] and its predecessor for nearly fifty years without any obvious adverse consequences”).

¹⁸⁷ See Manual of Patent Examining Procedure (MPEP) § 1410 (8th ed. Rev.8, Aug. 2012) (authorizing the filing of information disclosure statements in reissue).

¹⁸⁸ See 37 C.F.R. § 1.176(a) (2013) (“A reissue application will be examined in the same manner as a non-reissue, non-provisional application, and will be subject to all the requirements of the rules related to non-reissue applications. Applications for reissue will be acted on by the examiner in advance of other applications.”); see also Kenie Ho, Esther H. Lim & Charles E. Van Horn, *Effective Uses of Reissues and Reexaminations in the United States*, CHINA IP NEWS (June 2009), available at <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=6424bc6c-0369-48a8-963d-014909818582> (“In reissue, patentability issues may be submitted based on any type of prior art, such as patents, printed publications, and prior knowledge, use, or sale of the claimed invention.”).

¹⁸⁹ See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc) (citing *Aventis Pharma S.A. v. Amphastar Pharm. Inc.*, 525 F.3d 1334, 1341 n.6 (Fed. Cir. 2008) and *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995)) (“Unlike other deficiencies, inequitable conduct cannot be cured by reissue, or reexamination.”).

¹⁹⁰ Compare 35 U.S.C. § 251 (2002) (“Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid”), with 35 U.S.C. § 251(a) (current through P.L. 113-57 (excluding P.L. 113-54 and 113-56) approved 12-9-13) (“Whenever any patent is, through error deemed wholly or partly inoperative or invalid”).

or misrepresented *with* deceptive intent, a patentee can now obtain consideration of the information in reissue, at least where the information substantively relates to patentability.¹⁹¹

Reissue would not be an appropriate choice where the information at issue does not bear on patentability. And although it appears that such information would not qualify as material under the *Therasense* “but-for” materiality standard,¹⁹² whether and under what circumstances misrepresentations regarding information unrelated to patentability could qualify as material under the alternative “affirmative egregious misconduct” standard is unclear.¹⁹³ Accordingly, depending on the nature of the conduct and information underlying the potential inequitable conduct issue, reexamination or even reissue may not provide an adequate venue for USPTO consideration of previously

¹⁹¹ See, e.g., Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 126–27 (2012) (“With the removal of the ‘deceptive intention’ provision, patent owners will be able to correct defects of any type in which reissue would otherwise have been proper.”); Naphtali Y. Matlis, *Reissue vs. Supplemental Examination, POST GRANT PROCEEDINGS*, available at http://www.postgrantproceedings.com/topics/Article-NYM_Reissue_v_Supplemental_Exam.html (last visited Dec. 27, 2013) (“By removing “without any deceptive intention” from § 251(a), the AIA, in conjunction with *Therasense*, arguably opens the door for patent owners to address questions of inequitable conduct via reissue. A patent owner may now admit to a defect in a patent, such a defect potentially including an omitted prior art reference.”).

¹⁹² But see *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1235 (Fed. Cir. 2011) (holding that an applicant’s failure to update facts in a Petition to Make Special “obviously fails the but-for materiality standard”).

¹⁹³ The Federal Circuit recently declined to decide whether a false declaration of small entity status qualifies as “affirmative egregious misconduct.” *Outside the Box Innovations, LLC v. Travel Caddy Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012). Prior to its en banc decision in *Therasense*, the Federal Circuit had on several occasions held that information unrelated to patentability could be material for purposes of the courts’ inequitable conduct analyses. In *General Electro Music Corp. v. Samick Music Corp.*, the Federal Circuit held “as a matter of law that a false statement in a Petition to Make Special is material if . . . it succeeds in prompting expedited consideration of the application.” 19 F.3d 1405, 1411 (Fed. Cir. 1994). The court reaffirmed this principle in *Scanner Technologies Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1375 (Fed. Cir. 2008). In two cases—*Nilssen v. Osram Sylvania, Inc.*, and *Ulead Systems, Inc. v. Lex Computer & Management Corp.*—the court held that unjustified claims to small entity status warranted the ultimate penalty of unenforceability if those statements were shown to have been made with deceptive intent. *Nilssen*, 504 F.3d 1223, 1231 (Fed. Cir. 2007) (affirming a district court decision holding all of the patents in suit unenforceable based on an improper assertion of entitlement to small entity status); *Ulead*, 351 F.3d 1139, 1146 (Fed. Cir. 2003) (upholding a finding that an unjustified declaration of small entity status in connection with a maintenance fee payment was material for inequitable conduct purposes).

undisclosed or misrepresented information, even after *Therasense*. This is certainly true pending further development of the law regarding materiality.¹⁹⁴

B. Resolving Anticipated Inequitable Conduct Issues: Considerations for the Patentee

So, given this change in the evidentiary significance of reexamination and reissue post-*Therasense*, and the availability of supplemental examination, what considerations should guide the patentee's choice of supplemental examination vs. the alternatives?

1. What Information Needs To Be Considered?

First, certain categories of information are not properly considered in reexamination or reissue, and, therefore, supplemental examination (in which any information can be considered¹⁹⁵) may be the only viable route for consideration of such information. Furthermore, it is only by proceeding through supplemental examination that true immunity from litigating inequitable conduct can be obtained.¹⁹⁶

Because reexamination is limited to patents and printed publications,¹⁹⁷ if the information concerns pre-critical date activities, or a previously-submitted misleading declaration, for example, reexamination will not offer the opportunity to have the information considered or corrected. Reissue, as noted above, is now available to add dependent claims,¹⁹⁸ and there is no longer a requirement to allege that the reissue error was made "without any deceptive intention."¹⁹⁹ However, the patentee must consider whether submission via an information disclosure statement in reissue will fairly and adequately present or explain the information at issue. For example, depending on the circumstances, neither reissue nor reexamination may provide a suitable avenue for consideration and correction of a prior misleading declaration (whether or not related to patentability) or other potential "affirmative egregious misconduct" situations.²⁰⁰

2. Is Litigating the Issue Under *Therasense* the Best Course?

Second, even where the information at issue *could* be considered in reexamination or reissue, in some cases a patentee may elect to bypass the

¹⁹⁴ See *supra* Part I.A.2(a).

¹⁹⁵ See *supra* notes 159–167 and accompanying text.

¹⁹⁶ See *supra* notes 170–172 and accompanying text.

¹⁹⁷ 35 U.S.C. §§ 301(a)(1), 302 (current through P.L. 113-57 (excluding P.L. 113-54 and 113-56) approved 12-9-13).

¹⁹⁸ See *supra* note 185 and accompanying text.

¹⁹⁹ See *supra* notes 190–191 and accompanying text.

²⁰⁰ See *supra* notes 193–194 and accompanying text.

USPTO and just litigate the issue of inequitable conduct under *Therasense* in the courts. As discussed above, the Federal Circuit has raised the bar for establishing materiality,²⁰¹ and where the patentee is confident that a court will not find the information at issue to be “but-for” material (and there is no potential issue of “affirmative egregious misconduct”), the patentee may be well-advised to simply litigate inequitable conduct.

3. Supplemental Examination as a Potential Fall-Back Strategy

Third, some have suggested the strategy of filing reissue first, then abandoning the reissue application and filing a request for supplemental examination if the claims are rejected in reissue based on the information in question.²⁰² Although such a rejection in reissue would tend to serve as evidence of materiality,²⁰³ if viable claims can be obtained in a reexamination resulting from a granted supplemental examination request, having proceeded through supplemental examination, the patent owner would be immune from inequitable conduct assertions based on the information in question.²⁰⁴

4. Is It Too Late to Obtain Immunity via Supplemental Examination?

As discussed above, the statutory immunity from an inequitable conduct challenge is available only to patent owners who file and complete supplemental examination (and any resulting reexamination) before initiating its enforcement action.²⁰⁵ And accused infringers can cut off the patentee’s opportunity to obtain immunity by asserting inequitable conduct in a declaratory judgment action or

²⁰¹ See *supra* notes 11–16 and accompanying text.

²⁰² See, e.g., Scott A. McKeown, *Is Supplemental Examination a Risk Worth Taking?* PATENTS POST-GRANT (Feb. 15, 2012), available at <http://www.patentspostgrant.com/lang/en/2012/02/supplemental-examination-or-patent-reissue>; Kevin B. Laurence & Matthew C. Philips, *Supplemental Examination and the Proposed Rules*, INTELL. PROP. TODAY (March 2012), available at <http://www.stoel.com/files/Supplemental%20Examination%20and%20the%20Proposed%20Rules%20-%20March%202012%20-%20IP%20Today.pdf>.

²⁰³ See *supra* note 174 and accompanying text.

²⁰⁴ See *supra* notes 170–172 and accompanying text. Robert Armitage has suggested the simultaneous use of supplemental examination and reissue:

The AIA appears to allow the USPTO to take coordinated action in situations where the patent owner is seeking both reissue and supplemental examination. Indeed, it is foreseeable that the USPTO, if it finds a substantial new question of patentability at the termination of the supplemental examination of a patent for which a reissue application is pending, would treat de facto the reissue and reexamination required as a single proceeding it could conduct concurrently.

Armitage, *supra* note 191, at 127.

²⁰⁵ See *supra* note 204 and accompanying text.

Paragraph IV letter before the patent owner initiates supplemental examination.²⁰⁶

However, particularly if supplemental examination is the only route through which consideration of the particular information at issue can be obtained,²⁰⁷ a patent owner who can use supplemental examination/reexamination to generate evidence of immateriality may benefit from proceeding through supplemental examination even if the statutory immunity is no longer available.

5. Applicable Standards and Procedures

A patent owner considering using a USPTO proceeding to preempt or blunt an anticipated inequitable conduct charge should note that a mere “substantial new question of patentability” will trigger reexamination²⁰⁸ (including via supplemental examination),²⁰⁹ whereas prima facie unpatentability is required for a rejection in reexamination.²¹⁰ Also, a patent owner who files a reissue application effectively re-opens prosecution, potentially inviting consideration of additional issues unrelated to the information it is trying to show is immaterial.²¹¹

Cost and the anticipated length of the various alternative proceedings should also be considered. Supplemental examination is expensive, even if no reexamination is ordered.²¹² On the other hand, the statute requires the USPTO to complete supplemental examination (and decide whether to order reexamination) within three months of the filing of the request.²¹³ Accordingly, a patent owner who has a high level of confidence that the USPTO will not find a substantial new question of patentability based on the information in question could make effective and efficient use of supplemental examination to preempt an inequitable conduct charge. On the other hand, if there is a reasonable possibility that the USPTO will find a substantial new question of patentability and order reexamination, the patent owner should consider whether they would prefer to proceed through reexamination, reissue or instead (where available), file a continuation application to have the information at issue considered.

²⁰⁶ *See id.*

²⁰⁷ *See supra* notes 191–194 and accompanying text.

²⁰⁸ *See supra* note 178 and accompanying text.

²⁰⁹ *See supra* note 157 and accompanying text.

²¹⁰ *See supra* note 174 and accompanying text.

²¹¹ *See* 37 C.F.R. § 1.176(a) (2013) (“A reissue application will be examined in the same manner as a non-reissue, non-provisional application, and will be subject to all the requirements of the rules related to non-reissue applications.”).

²¹² *See Fee Schedule*, UNITED STATES PATENT AND TRADEMARK OFFICE (Mar. 19, 2013), <http://www.uspto.gov/web/offices/ac/qs/ope/fee031913.htm>.

²¹³ 35 U.S.C. § 257(a) (West, Westlaw current through P.L. 113-57 (excluding P.L. 113-54 and 113-56) approved 12-9-13).

CONCLUSION

Significant recent judicial and legislative developments have changed the way litigants and counsel need to plan for and litigate inequitable conduct allegations. *Exergen* and *Therasense* have heightened the standards for pleading and proving inequitable conduct, respectively, and Congress has expanded the patentee's post-grant options for preempting or defeating inequitable conduct challenges. Litigants and counsel should holistically consider these developments and their implications for each particular potential inequitable conduct situation.