

**LITIGATION ISSUES RELEVANT TO PATENT
PROSECUTION —
THE DEFENSE OF INEQUITABLE CONDUCT**

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I.	INTRODUCTION	1
II.	BURDEN OF PROOF AND STANDARD OF REVIEW ...	4
III.	INFORMATION MATERIAL TO PATENTABILITY	5
A.	Origin Of The Materiality Standard	5
B.	The 1977 Enactment of 37 C.F.R. § 1.56	6
C.	The 1992 Amendment To 37 C.F.R. § 1.56	6
D.	Limitations On The Applicant’s Duty	9
E.	Applying The Materiality Standard	10
1.	The Continued Application Of Both Pre- and Post- 1992 Standards.....	11
2.	Categories Of Disclosures And Omissions	16
(a)	Proceedings Before The FDA.....	16
(b)	Proceedings Before the EPO	17
(c)	Inventorship	18
(d)	Other Types Of Information	20
3.	Information Need Not Be Invalidating To Be Material	21
4.	Attorney Arguments Are Not Material	23
IV.	INTENT TO DECEIVE OR MISLEAD THE PTO	25
A.	The Intent Standard	25
B.	Applying The Intent Standard	26
1.	Representative Case Law Finding Deceptive Intent	26
2.	Representative Case Law Finding Insufficient Evidence of Deceptive Intent	29
3.	Credibility Determinations.....	32
C.	Merging of Materiality and Intent	34
D.	Considerations of Good Faith.....	36

V.	THE PLEADING REQUIREMENTS FOR INEQUITABLE CONDUCT	37
VI.	THE CONTINUED EVOLUTION OF INEQUITABLE CONDUCT	39
VII.	THE EXCEPTIONAL CASE	47
VIII.	CONCLUSION.....	50

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I. INTRODUCTION

All patent applicants have a duty to prosecute their applications with “candor and good faith.”¹ This duty of candor also extends beyond mere applicants, further covering individuals who are “substantively involved in preparation or prosecution of the application,” including named inventors and attorneys or agents who help prepare or prosecute the application.² The duty does not, however, apply to corporations or institutions unless an individual within the corporation or institution was substantively involved in prosecuting the application.³

Compliance with the duty of candor is of paramount importance during prosecution of an application. Any failure to comply with the duty exposes an applicant to a potential finding of

¹ 37 C.F.R. § 1.56(a) (2008) (“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

² 37 C.F.R. § 1.56(c)(3) (2008).

³ *Id.*; M.P.E.P. § 2001.01 (8th ed. 2001, rev. July 2008) (*hereinafter* “M.P.E.P.”); *see also Therasense, Inc. v. Becton, Dickinson & Co. (Therasense I)*, 593 F.3d 1289 (Fed. Cir. 2010) (scientific advisor of the patentee found to have a duty of disclosure where he submitted information to the USPTO on behalf of the applicant in a declaration used to overcome the prior art, but did not disclose contradictory representations made to the European Patent Office, of which he was aware).

inequitable conduct, which carries with it a host of undesirable and potentially expensive consequences. The Federal Circuit has articulated that “[a] patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution.”⁴ The finding of unenforceability is not necessarily limited to the particular patent at issue, and can be extended to other related patents and applications.⁵ Additionally, a patent attorney or agent may be sanctioned by the Patent Office, including suspension, for violating his/her duty of candor and good faith. The consequences may also extend to prospective plaintiffs in patent infringement actions, who, in the event that a patent in suit is found unenforceable for inequitable conduct, can be ordered to pay the attorney fees of the opposing party.⁶

⁴ *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007) (quoting *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006)); *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330-31 (Fed. Cir. 2004); *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1288 (Fed. Cir. 2002).

⁵ *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933); *Molins*, 48 F.3d at 1178; *Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804 (Fed. Cir. 1990) (holding that inequitable conduct resulting from concealment of the best mode of a first patent rendered a second unrelated patent and continuation-in-part patents of the second patent unenforceable because concealment of information regarding the first patent allowed disclosure of that same information during prosecution of the other patents); see also *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373-75 (Fed. Cir. 2005) (holding that inequitable conduct as to the prosecution of one patent will not affect an earlier related patent that is tied to the later patent by a terminal disclaimer, if the earlier patent was “not acquired through culpable conduct”).

⁶ *Evident Corp. v. Church & Dwight Co.*, 399 F.3d 1310, 1315 (Fed. Cir. 2005); *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001); see also *Therasense, Inc. v. Becton, Dickinson and Company*, No. C 04-02123, U.S. Dist LEXIS at *8 (N.D. Cal. Aug. 21, 2008).

An inequitable conduct analysis requires a court to weigh two separate elements in determining whether an applicant breached his duty of candor and good faith: (1) materiality of the information omitted or falsified; and (2) intent to deceive on the part of the applicant.^{7,8} After a court finds sufficient evidence of materiality and intent, “the court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, ‘with a greater showing of one factor allowing a lesser showing of the other.’”⁹ Further, materiality and intent must be weighed “in light of all the circumstances to determine whether the applicant’s conduct is *so culpable* that the patent should be held unenforceable.”¹⁰ Where an allegation of inequitable conduct is tied to a particular claim of a patent, a court performing a full analysis must not limit its analysis only to that claim, but must also look at other claims, the specification and drawings, the prior art, attorney remarks during prosecution (both before the USPTO as well as in connection with foreign counterparts), co-pending and continuing applications, and invalidity, “[w]hen a court has finally determined that inequitable conduct occurred in relation to one or more claims during

Deleted: earlier and later versions of the claim in question.

Deleted: ¹¹ Distinct from

⁷ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006); *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439 (Fed. Cir. 1991).

⁸ At the time of printing, the *Therasense en banc* Federal Circuit decision (*Therasense II*) had not yet been issued. The materiality and intent standards described herein are reflective of Federal Circuit jurisprudence at the time of the *Therasense II* decision.

⁹ *McKesson Info Solutions.*, 487 F.3d at 913 (internal quotations omitted); *Ferring*, 437 F.3d at 1186; *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

¹⁰ *Ferring*, 437 F.3d at 1186 (quoting *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362-63 (Fed. Cir. 2003) (additional citation omitted)).

prosecution of the patent application, the entire patent is rendered unenforceable.”¹²

II. BURDEN OF PROOF AND STANDARD OF REVIEW

The defendant that charges a patentee with inequitable conduct before the PTO must prove it by clear and convincing evidence.¹³ The “clear and convincing” standard applies equally to the elements of materiality and intent.¹⁴ With respect to the intent element, the Federal Circuit has stated that this stringent burden of proof is necessary because of “the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive.”¹⁵ Despite this high standard, intent is often inferred from circumstantial evidence. Recently however, some members of the Federal Circuit have stated their belief that there exists a need for more stringent application of the deceptive intent standard.¹⁶ Senator Orrin Hatch, who has been active over the years in promoting new patent legislation, has also expressed a similar view.¹⁷

¹² *Kingsdown*, 863 F.2d at 877; *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1560-62 (Fed. Cir. 1984), overruled on other grounds.

¹³ *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006); *see also FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 525 (Fed. Cir. 1987).

¹⁴ *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362 (Fed. Cir. 2003).

¹⁵ *Molins*, 48 F.3d at 1181 (citation omitted).

¹⁶ *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343-44 (Fed. Cir. 2009) (Linn, J., *concurring*); *Aventis Pharma S.A. v. Amphastar Pharms. Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., *dissenting*); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008).

¹⁷ Senator Orrin G. Hatch, Address at the U.S. Court of Appeals for the Federal Circuit Symposium (Mar. 18, 2009).

On appeal, the ultimate conclusion of inequitable conduct is reviewed for an abuse of discretion.¹⁸ The standard of review for the underlying factual findings of materiality and intent depends, however, on whether those findings were made at trial or on summary judgment disposition. If the underlying findings of fact are made at trial by the judge or the jury, the Federal Circuit reviews them for clear error.¹⁹ On the other hand, if those findings are made in the context of summary judgment, they are reviewed *de novo*.²⁰

III. INFORMATION MATERIAL TO PATENTABILITY

A. Origin Of The Materiality Standard

“The inequitable conduct doctrine, a judicially created doctrine, was borne out of a series of Supreme Court cases in which the Court refused to enforce patents whereby the patentees had engaged in fraud in order to procure those patents.”²¹ Originally, courts applied one of four separate standards in making a materiality determination: (1) the objective “but for” standard, wherein the patent actually should not have issued; (2) the subjective “but for” standard, wherein the misrepresentation caused the Examiner to approve the patent when he otherwise would not have; (3) a “but it may have” standard, wherein a misrepresentation may have influenced the decisions of the Examiner; and (4) a “reasonable examiner” standard, requiring a

¹⁸ *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1343 (Fed. Cir. 2005); *Ferring*, 437 F.3d at 1194; *Kingsdown*, 863 F.2d at 876 (“To overturn a discretionary ruling of a district court, the appellant must establish that the ruling is based upon clearly erroneous findings of fact or a misapplication or misinterpretation of applicable law or that the ruling evidences a clear error of judgment on the part of the district court.”) (citations omitted).

¹⁹ *Warner-Lambert*, 418 F.3d at 1343; *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1378 (Fed. Cir. 2005).

²⁰ *Ferring*, 437 F.3d at 1187.

²¹ *Digital Control*, 437 F.3d at 1315.

showing that “a reasonable examiner” would have considered such prior art or information important in deciding whether to allow the application to issue as a patent.²²

B. The 1977 Enactment of 37 C.F.R. § 1.56

The “reasonable examiner” standard, already considered the broadest of the four materiality standards, was codified in 1977 in 37 C.F.R. § 1.56. It essentially encompassed the others and eventually became the primary standard invoked by the Federal Circuit, yet “in no way did it supplant or replace the case law precedent.”²³ As such, even after the 1977 amendment to 37 C.F.R. § 1.56, the other three previously articulated standards remained equally appropriate.²⁴

C. The 1992 Amendment To 37 C.F.R. § 1.56

In 1992, the PTO again revised its rules regarding the definition of materiality, adding yet another option to the list of materiality standards. In its amended version, compliance with the duty of candor and good faith of 37 C.F.R. § 1.56 requires disclosure of information that establishes “a *prima facie* case of unpatentability of a claim; or [that] refutes, or is inconsistent with, a position the applicant takes in (i) [o]pposing an argument of unpatentability relied on by the [PTO], or (ii) [a]sserting an

²² *Digital Control*, 437 F.3d at 1315; *Ferring*, 437 F.3d at 1187 n.6; *Dayco Prods.*, 329 F.3d at 1363; *see also, e.g.*, 37 C.F.R. § 1.56 (1984); *J.P. Stevens & Co.*, 747 F.2d at 1562 (discussing the standard for determining materiality in 1963); *Kingsdown*, 863 F.2d at 876 (holding that gross negligence alone does not result in a finding of intent to deceive).

²³ *Digital Control*, 437 F.3d at 1316.

²⁴ The “reasonable examiner” standard was not considered to be a replacement of the existing standard, but rather a codification of the existing standard. The “reasonable examiner” standard thus was intended simply to be sufficiently broad as to encompass the other three existing common law standards. *See Digital Control*, 437 F.3d at 1314-15.

argument of patentability.”²⁵ The Federal Circuit has held that this additional standard should only apply to applications and reexamination proceedings pending or filed after the March 16, 1992 effective date of the amendment.²⁶

Nothing precludes, however, the application of earlier standards to such activities. The 1992 amendment to 37 C.F.R. § 1.56, like the 1977 amendment, does not replace the existing materiality standards, but merely offers an additional possibility.²⁷ In the Federal Circuit’s 2006 decision in *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129 n.6 (Fed. Cir. 2006) (citing the Federal Circuit’s 2003 decision in *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003)), the Court stated that the 1992 amendment “was not intended to constitute a significant substantive break with the pre-1992 standard.” And in the Federal Circuit’s 2006 decision in *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309 (Fed. Cir. 2006), the Court went as far as saying that the 1992 amended definition of “materiality” was not meant to replace the older “reasonable examiner” standard, but instead, provides an *additional* test of materiality: “[I]f a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the ‘reasonable examiner’ standard or under the older three tests, it is also material.”²⁸

In this regard, patent applicants must remember that a *prima facie* case of unpatentability, as articulated in the 1992 amendment, is established when the information compels the

²⁵ 37 C.F.R. § 1.56(b) (2008); *Dayco Prods.*, 329 F.3d at 1363-64.

²⁶ *Molins*, 48 F.3d at 1179 n.8 (citing 57 Fed. Reg. 2021 (Jan. 17, 1992)).

²⁷ *Dayco Prods.*, 329 F.3d at 1363-64.

²⁸ *Digital Control*, 437 F.3d at 1316 (noting further that this interpretation of the 1992 amendment is supported by the PTO’s own comments during the amendment process); *see also Cargill Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007).

conclusion that a claim is unpatentable (applying the preponderance of evidence standard). This determination is made “before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.”²⁹ Thus, patent applicants should be aware that they cannot avoid disclosing information to the patent office that could compel a finding of non-patentability simply because they have evidence sufficient to rebut the information, as the rebuttal information will not be considered in determining the materiality of the information.

Under any definition of materiality, “[a]ffirmative misrepresentations . . . in contrast to misleading omissions, are more likely to be regarded as material.”³⁰ For instance, affirmatively false statements made in declarations or affidavits submitted to the PTO have been described as “inherently material.”³¹

Likewise, under any definition of materiality, an applicant does not have the duty to submit information, even that which is potentially material to patentability, if that information is cumulative to other information already before the Examiner.³² However, applicants should be cautioned to tread lightly where non-disclosure of information is concerned. Tempering any

²⁹ 37 C.F.R. § 1.56 (2008).

³⁰ *Digital Control*, 437 F.3d at 1318 (quoting *Hoffmann-La Roche*, 323 F.3d at 1367).

³¹ *Digital Control*, 437 F.3d at 1318 (citing *Refac Int’l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996) and *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983)); see also *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1188 n.9 (Fed. Cir. 2006); *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 480 F.3d 1129, 1136 (Fed. Cir. Mar. 2007).

³² See 37 C.F.R. § 1.56 (2008); *Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000); cf. *Tap Pharm. Prods., Inc. v. Owl Pharms., L.L.C.*, 419 F.3d 1346, 1351-52 (Fed. Cir. 2005) (addressing cumulative references that are not material).

motivation for applicants to keep information from the PTO, the Federal Circuit has stated that “[c]lose cases should be resolved by disclosure [of the information in question], not unilaterally by the applicant.”³³ And, “where the materiality of the information is uncertain, disclosure is required.”³⁴

D. Limitations On The Applicant’s Duty

While patent applicants have an affirmative duty to disclose information in their possession which they know (or suspect) to be material, there is no corresponding duty for applicants to educate themselves. For example, patent applicants have no duty to conduct a prior art search of their own.³⁵ Nor must they disclose prior art of which they are not aware.³⁶

Conversely, applicants may not cultivate ignorance by “disregard[ing] numerous warnings that material information or prior art may exist merely to avoid actual knowledge of that information or prior art.”³⁷ Likewise, an applicant who is aware of prior art or information cannot intentionally avoid learning of its materiality through gross negligence. In such instances, courts have applied a “should have known” standard with respect to the

³³ *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992); *Brasseler*, 267 F.3d at 1386.

³⁴ *Id.*

³⁵ *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996) (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984)).

³⁶ *Id.*

³⁷ *FMC Corp.*, 836 F.2d at 526 n.6; *see also Brasseler*, 267 F.3d at 1374, 1376 (inequitable conduct found due to, *inter alia*, failure by prosecuting attorneys to investigate a potential on-sale bar of which they were aware); *Nordberg*, 82 F.3d at 396-97 (no inequitable conduct in part because, even though the patentee also owned prior art, there was no evidence that the patentee’s employees who were subject to the duty of disclosure were aware of the existence of the prior art in the patentee’s files).

material information in question.³⁸ Further explanation of the patent applicant's state of mind in conjunction with non-disclosure of information is contained in the discussion of the intent element, *infra*.

The application process has a built-in method of ensuring compliance with the duty of disclosure. By timely filing an information disclosure statement (IDS), an applicant can fulfill the disclosure duties of 37 C.F.R. § 1.56.³⁹ However, consistent with the limitations on the duty of disclosure, the Manual of Patent Examining Procedure ("MPEP") states that "[t]he filing of an information disclosure statement shall not be construed as a representation that a search has been made," or even that the information disclosed in the statement is material to patentability.⁴⁰

Compliance with the MPEP guidelines however, should not be viewed as a safe harbor from inequitable conduct.⁴¹ Ultimately, applicants must comply with their duty of candor under § 1.56(a). The MPEP and 37 C.F.R. §§ 1.97-1.98 do no more than articulate a baseline level of disclosure that is expected of all applicants.⁴²

E. Applying The Materiality Standard

Determining whether information is material is not necessarily straightforward. This is largely due to courts'

³⁸ *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411 (Fed. Cir. 1987). The use of a "should have known" intent standard has recently come under criticism as being too lenient and as potentially contradictory to the stringent standard espoused by *Kingsdown*. This is discussed further at *infra* pp. 38.

³⁹ 37 C.F.R. § 1.56(a) (2008); 37 C.F.R. §§ 1.97-1.98 (2008).

⁴⁰ M.P.E.P. § 609.

⁴¹ *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368 (Fed. Cir. 2000)

⁴² *Id.*

continued use of multiple materiality standards. While a clear roadmap for when disclosure is required thus does not exist, past application of the different standards at least provides some guidance.

1. The Continued Application Of Both Pre- and Post- 1992 Standards

The Federal Circuit continues to apply both the new standard in 37 C.F.R. § 1.56 and the older “reasonable examiner” standard when determining materiality. In *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1239 (Fed. Cir. 2008), the Court held that certain omitted notes were material because the notes refuted and/or were inconsistent with “a position the applicant took in opposing the Examiner’s argument of unpatentability” under 37 C.F.R. 1.56.⁴³ On the other hand, in *Digital Control*, the Court applied the “reasonable examiner” standard when it reviewed the District Court’s findings on materiality.⁴⁴ In the March 2009 decision in *Larson Mfg. Co. of S.D. v. Aluminart Prods.*, 559 F.3d 1317, 1326 (Fed. Cir. 2009), the Federal Circuit reiterated its long-standing precedent that “information is material when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” As these cases demonstrate, a finding of materiality under any of the Court’s standards will be sufficient. Notably, courts often mention both standards in their analyses, noting that the codified, post-1992 standard was never meant as a replacement for the “reasonable examiner” standard.⁴⁵

In *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 70 U.S.P.Q.2d 1185 (S.D.N.Y. 2004), the District Court addressed the

⁴³ The Court also noted “a substantial likelihood that a reasonable examiner would have considered . . . the notes important in deciding whether to allow the application to issue.” *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1240 (Fed. Cir. 2008).

⁴⁴ *Digital Control*, 437 F.3d at 1316.

⁴⁵ *Digital Control*, 437 F.3d at 1309; *Dayco Prods.*, 329 F.3d at 1363-64, *Hoffmann-La Roche.*, 323 F.3d at 1368 n.2.

patentee's assertions (both in the specification and during prosecution) that it had discovered that the claimed pharmaceutical formulation could provide adequate pain relief in 90% of patients at a reduced dosage range. This discovery was based on insight rather than scientific proof. The District Court, applying the "reasonable examiner" standard, held that the patentee's lack of scientific proof of the discovery was material because it would have been viewed by the examiner as important to the ultimate decision on patentability.⁴⁶

In the first appeal (*Purdue I*) and on reconsideration (*Purdue II*), the Federal Circuit agreed with the District Court's basic finding that the information was material.⁴⁷ In *Purdue II*, however, the Federal Circuit looked to the current version of Rule 56 rather than the pre-1992 version of the Rule to find that Purdue's omissions were material.⁴⁸ However, the Court held that "the level of materiality [wa]s not especially high" and that "[t]his omission of information was material, but not as material as an affirmative misrepresentation would have been."⁴⁹ Finding that the District Court primarily inferred deceptive intent based on what it viewed to be a high level of materiality, the inequitable conduct judgment was vacated and the case was remanded to the District Court.⁵⁰ Because the action settled after remand and before further review by the District Court, there were no further findings or conclusions on the issue of inequitable conduct in this action. However, in a subsequent proceeding, when addressing substantially similar allegations of inequitable conduct in the context of antitrust claims, the District Court adopted the Federal

⁴⁶ *Purdue Pharma*, 70 U.S.P.Q.2d 1185.

⁴⁷ *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 410 F.3d 690, 697 (Fed. Cir. 2005); *Purdue Pharma*, 438 F.3d at 1133 (Fed. Cir. 2006).

⁴⁸ Compare *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006), with *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 70 U.S.P.Q.2d 1185 (S.D.N.Y. 2004).

⁴⁹ *Id.* at 1133.

⁵⁰ *Id.* at 1134.

Circuit's determination based on the post-1992 standard regarding materiality, ultimately resulting in a finding of no inequitable conduct.⁵¹ (The intent aspect of the Federal Circuit decisions, as well as its application in the subsequent antitrust District Court case, is further discussed *infra*).

A co-pending patent application in a similar art area may also be material to patentability.⁵² “For example, if a particular inventor has different applications pending in which similar subject matter but patentably indistinct claims are present, that fact should be disclosed to the Examiner of each of the involved applications.”⁵³ In *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003), the Federal Circuit found that the failure by the applicants to disclose a co-pending application met the threshold level of materiality, as the co-pending application could result in a double patenting rejection and preclude patentability. The Court, using the pre-1992 standard, further held that a “contrary decision of another Examiner reviewing a substantially similar claim” meets the threshold materiality requirement of “*any* information that a reasonable examiner would substantially likely consider important.”⁵⁴ Applicants should therefore disclose any known treatment of similar subject matter by another Examiner in a co-pending or related application.

In *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354 (Fed. Cir. 2003), the Federal Circuit applied the older “reasonable examiner” standard, and found that the patentee had made a material misrepresentation to the PTO during prosecution by describing an example of the specification in the past tense (including results) although the experiment had not actually been

⁵¹ *In re OxyContin Antitrust Litigation*, 530 F. Supp. 2d 554 (S.D.N.Y. 2008).

⁵² M.P.E.P. § 2001.06(b).

⁵³ *Id.*

⁵⁴ *Dayco Prods.*, 329 F.3d at 1368.

performed.⁵⁵ This misrepresentation was held to constitute fraud and inequitable conduct.

In *Therasense, Inc. v. Becton, Dickinson & Co.* (*Therasense I*), 593 F.3d 1289 (Fed. Cir. 2010),⁵⁶ an applicant withheld from the USPTO prior statements made during prosecution of a related foreign application before the European Patent Office (“EPO”). The district court, applying the post-1992 standard, found the statements to be “highly material” because they not only related to the application pending before the USPTO, but were also directly contradictory to positions being put forth by the applicant in that application.⁵⁷ Using the same standard, the Federal Circuit affirmed the finding of materiality, explaining that “[a]n applicant’s earlier statements about prior art, especially one’s own prior art, are material to the PTO when those statements directly contradict the applicant’s position regarding that prior art in the PTO.”⁵⁸

Some commentators have expressed concern regarding the confusion stemming from the use of both pre-and post-1992 materiality standards. For example, an *Amicus Curiae* brief supporting a request for rehearing of the Federal Circuit’s decision in *Therasense I* noted the “lack of uniformity in the Court’s decisions concerning which standard applies to patents prosecuted after 1992.”⁵⁹ The *Amici* noted that since *Digital Control*, the Federal Circuit fairly consistently applied the “reasonable

⁵⁵ *Hoffmann-La Roche*, 323 F.3d at 1364-66.

⁵⁶ During the pendency of *Therasense I*, Therasense, Inc. merged with Abbott Diabetes Care, Inc., also a party to that action. For simplicity, we will refer to the *Therasense* plaintiffs collectively as “Therasense”.

⁵⁷ *Id.* at 1301.

⁵⁸ *Id.* at 1305

⁵⁹ Brief of *Amicus Curiae* Intellectual Property Law Professors Concerning *En Banc* Review of Inequitable Conduct at 9, *Therasense II*, No. 2008-1511 (Fed. Cir. July 30, 2010).

examiner” standard, but in *Therasense*, the Federal Circuit cited to the post-1992 standard.⁶⁰ Moreover, the commentators believe that “[i]t is not accurate to postulate . . . that the two standards are substantively nearly the same” because the PTO clearly rejected the “reasonable examiner” standard for a more objective test.⁶¹ The parties in *Therasense*, who each proposed more formulaic tests of materiality (either a strict “but-for” test, requiring that the patent would not have issued ‘but for’ the omission or representation, or a statutory test invoking whatever form of 37 C.F.R. § 1.56 is in effect at the time of prosecution), also echoed this complaint.⁶² Although these arguments may merit consideration from the Federal Circuit in the future, it appears from past and recent case law that in general, no matter which standard is applied, the materiality outcome will likely remain the same.⁶³

Certain *Amici* filing opinions with regard to the *Therasense* rehearing, as well as the *Therasense* parties and the USPTO itself, have also expressed a more general complaint that in the absence of clarity in the materiality standard, applicants will likely inundate the PTO with extraneous material to avoid a later finding of inequitable conduct.⁶⁴ Although it remains to be seen

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *See supra* at § VI.A

⁶³ *See PerSeptive Biosystems Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321, 1322 n.2 (Fed. Cir. 2000) (finding inequitable conduct using the pre-1992 standard); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003) (finding materiality using the reasonable examiner standard, but not ultimately finding inequitable conduct); *Dayco Prods.*, 329 F.3d at 1363-64 (declining to decide which standard to use where materiality would be found under either one); *Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000); *see also Digital Control*, 437 F.3d at 1316; *Hoffmann-La Roche.*, 323 F.3d at 1368 n.2

⁶⁴ Brief of Washington Legal Foundation as *Amicus Curiae* in Support of Petition for Rehearing *En Banc* at 4, *Therasense II* No. 2008-

(Continued...)

whether fears of “overloading” examiners with irrelevant prior art will ring true, in the meantime, applicants can make thoughtful and well-reasoned decisions regarding disclosure based on existing case law, both from the district courts and the Federal Circuit.

2. Categories Of Disclosures And Omissions

(a) Proceedings Before The FDA

Applicants should be mindful of any information that has been submitted to the Food and Drug Administration (“FDA”). This information may or may not be material to patentability, as the PTO and the FDA have different disclosure requirements. For instance, the standard of proof necessary for a proposed labeling claim is substantially higher than that required by the PTO for allowance of claims.⁶⁵ In *Purdue II* (discussed *infra*), this fact was recognized by the Federal Circuit and used, among other things, to criticize the District Court’s analysis of the intent prong of the inequitable conduct analysis.

In *Bruno Indep. Living Aids v. Acorn Mobility Servs.*, 394 F.3d 1348 (Fed. Cir. 2005), the Federal Circuit affirmed the District Court’s holding that the applicant engaged in inequitable conduct for failure to disclose to the PTO invalidating prior art. There, the applicant’s employer had previously been involved in making submissions to the FDA seeking regulatory approval, identifying its stairlift product as substantially equivalent to another, pre-existing product.⁶⁶ Later, during prosecution of a patent covering its stairlift, the employer failed to disclose the pre-

(...Continued)

1511 (Fed. Cir. Aug. 2, 2010); Brief of *Amici Curiae* The Honorable Bruce A. Lehman and the International Intellectual Property Institute in Support of Petition for Rehearing *En Banc* at 5, *Therasense II* (Fed. Cir. Aug 16, 2010).

⁶⁵ *Purdue Pharma*, 438 F.3d at 1134-35.

⁶⁶ *Bruno*, 394 F.3d at 1352.

existing product, which had been instrumental in gaining FDA approval, to the PTO.⁶⁷ Although disclosure to the FDA does not, by itself, establish the materiality of information, patent applicants should carefully consider the nature of such information before making a decision not to disclose it.

(b) Proceedings Before the EPO

Applicants should also be aware that information disclosed or statements made during proceedings before the EPO may be relevant to a determination of inequitable conduct. For example, in *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995), the applicant failed to disclose material prior art to the PTO. During foreign prosecution, however, the applicant disclosed the prior art to the EPO and further indicated that the reference “was the most relevant prior art.”⁶⁸ In affirming the district court’s findings of both materiality and intent, the Federal Circuit noted that “[f]ailure to cite to the PTO a material reference cited elsewhere in the world justifies a strong inference that the withholding was intentional.”⁶⁹

Similarly, in *Therasense*, the trial found that the applicant made directly contradictory representations to the EPO regarding the teaching of a prior art reference,⁷⁰ but did not disclose those contradictory representations to the PTO during prosecution of a related patent.⁷¹ The Federal Circuit stated that “[t]o deprive an examiner of the EPO statements— statements directly contrary to [the applicant’s] representations to the PTO — on the grounds that

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at 1182.

⁷⁰ *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088, 1113 (N.D. Cal. 2008).

⁷¹ *Therasense I*, 593 F.3d 1289, 1302 (Fed. Cir. 2010).

they were not material would be to eviscerate the duty of disclosure.”⁷²

Not all statements made to the EPO that are withheld from the PTO will result in a finding of inequitable conduct, however. For example, in *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378-79 (Fed. Cir. 2008), the prosecuting attorney identified a prior art reference as the “closest prior art” during foreign prosecution and subsequently amended claims in the foreign application to disclaim the teachings of the prior art reference.⁷³ Although the applicant submitted the same prior art reference to the PTO, the patent attorney additionally stated that the reference “did not relate” to the invention.⁷⁴ The District Court concluded, and the Federal Circuit agreed, that the applicant’s contradictory representation of the prior art reference to the PTO amounted to “mere attorney argument.”⁷⁵ Because the Examiner had the prior art reference in front of her, she was “free to accept or reject” the patentee’s arguments distinguishing its invention from the prior art.⁷⁶

(c) Inventorship

Information relating to inventorship can also meet the threshold level of materiality. For example, in *PerSeptive Biosystems Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000), the Federal Circuit held that a patent was unenforceable for inequitable conduct where the applicant failed to disclose the nature of the working relationship between the listed inventors and the other scientists who were the source of certain starting materials used to make the claimed invention.⁷⁷ The Court

⁷² *Id.* at 1304-05.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *PerSeptive Biosystems*, 225 F.3d at 1321.

stated that a full and accurate disclosure of the true nature of the relationship between the inventors and the collaborating scientists would have been important to a reasonable examiner's consideration of whether the correct inventors were listed on the application.⁷⁸

Likewise, in *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006), the Federal Circuit held that the applicant, ConAgra, intended to deceive the PTO by filing a patent application misrepresenting the material facts of inventorship. Prior to the critical date of the patent, Unitherm demonstrated its meat browning technology to ConAgra, which subsequently filed and obtained a patent with claims covering Unitherm's browning methods. The Court found it reasonable for a jury to conclude that ConAgra was fully aware that its patented invention was the same process Unitherm had been demonstrating and trying to sell to ConAgra prior to the critical date. The Court determined that ConAgra's filing of the required oath of inventorship, and its declaration that the named inventor was "the original and first inventor," was a material misrepresentation; thus, the Court held the patent unenforceable.⁷⁹

While withholding or providing misleading information on inventorship meets the present standard for materiality, this is an area that may be subject to change depending on the outcome of the *en banc* rehearing in *Therasense*. Under a "but-for" materiality standard, such as the one proposed by the Appellants, it appears likely that withholding of such information may not be material since disclosure of the information would be unlikely to prevent issuance of the patent.

⁷⁸ *Id.* at 1322.

⁷⁹ 375 F.3d at 1360-61 (citation omitted).

(d) Other Types Of Information

Patent applicants should be cautioned against believing that there is a bright line rule for materiality. The inquiry is particularly fact specific. One court may conclude that an omission of a specific type of information is not material, while another, addressing similar facts, may conclude that the disclosure or omission is material.

One such type of information is a reference cited in a foreign search report of a foreign counterpart application. These references are not *necessarily* material, both because the claims may differ, and because foreign countries employ different patentability standards.⁸⁰ Nevertheless, where there is doubt about the materiality of information, the most prudent course of action for an applicant is to disclose the information, allowing the PTO to decide the question of materiality and patentability for itself.⁸¹

However, patent applicants must be sure that prior art references are disclosed in their entirety. Recently, in *Golden Hour Data Sys., Inc. v. emsCharts, Inc.*, 2009 U.S. Dist. LEXIS 24225 (E.D. Tex. Mar. 23, 2009), a patent was found unenforceable for inequitable conduct where only a portion of a prior art reference was disclosed and distinguished before the PTO. The applicants selectively disclosed certain portions of a prior art product brochure, but failed to disclose those portions that would have been an obstacle to patentability. In distinguishing their invention from the prior art brochure, the applicants were thus able to avoid any patentability issues that the Examiner may have raised relating to the undisclosed portion of the brochure. The Court found material both the applicants' omission of relevant portions of the brochure, as well the applicants' misleading statements regarding the effect of the brochure on the patentability of their

⁸⁰ *Molins*, 48 F.3d at 1180.

⁸¹ *Brasseler*, 267 F.3d at 1380 (“To avoid a finding of inequitable conduct, doubts concerning whether information is material should be resolved in favor of disclosure.”).

invention.⁸² Thus, while a mere statement that attempts to distinguish an invention from disclosed prior art may not be material information, such arguments must not obscure potentially material information elsewhere in the prior art reference.

Other information that may be considered material includes the best mode of practicing the invention,⁸³ evidence relating to prior sales,⁸⁴ testing and other data submitted in support of patentability,⁸⁵ and information relating to claims copied from a patent.⁸⁶

3. Information Need Not Be Invalidating To Be Material

While an invalidating prior art reference will always be considered material, information that would not invalidate the patent may also possess the requisite materiality. “[U]nder the ‘reasonable examiner’ standard, a misstatement or omission may be material even if disclosure of that misstatement or omission

⁸² *Id.* at *14-18.

⁸³ *Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1322 (Fed. Cir. 2006) (holding that, although a failure to disclose the best mode is “‘inherently material,’” such a failure “‘will not constitute inequitable conduct in every case’”) (*quoting Consol. Aluminum Corp.*, 910 F.2d at 808); *see generally In re Hayes Microcomputer Prods., Inc. Patent Litig.*, 982 F.2d 1527, 1546 (Fed. Cir. 1992).

⁸⁴ *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1263-64 (Fed. Cir. 2001) (no inequitable conduct found); *Brasseler*, 267 F.3d at 1376 (inequitable conduct found due to failure to disclose on-sale event); *but see Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 31 Fed. Appx. 727, 733 (Fed. Cir. 2002) (affirming finding of no inequitable conduct where record did not contain “any evidence of a formal offer, acceptance, contract, or bill of sale,” or other evidence of a commercial offer).

⁸⁵ *Hoffmann-La Roche*, 323 F.3d at 1368 n.2; *Rohm & Haas Co.*, 722 F.2d at 1570-71 (inequitable conduct found).

⁸⁶ M.P.E.P. § 2001.06(d).

would not have rendered the invention unpatentable.”⁸⁷ In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003), the Federal Circuit found a journal article material, even though the article did not render the invention unpatentable.⁸⁸

In *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139 (Fed. Cir. 2003), the Federal Circuit held that improperly claiming small entity status with respect to payment of maintenance fees also could constitute fraud and inequitable conduct. The Court reasoned that the payment of maintenance fees was necessary for survival of a patent and, as such, established a threshold level of materiality.⁸⁹

Likewise, in *In re Klein*, 6 U.S.P.Q.2d 1528 (U.S. Dep’t Commerce. 1986), a practitioner was sanctioned for falsely representing in a certificate of mailing that the responses were mailed on certain dates when the practitioner knew or should have known that each response would be mailed after the respective dates in the certificates.⁹⁰

Materiality can also arise out of an attempt to affect the treatment of a pending application in the PTO. For example, false statements made in affidavits submitted to the PTO, including those not specifically directed to patentability arguments, such as petitions to make special, can be material as a matter of law if they

⁸⁷ *Digital Control*, 437 F.3d at 1318.

⁸⁸ 326 F.3d at 1242; *see also PerSeptive Biosystems*, 225 F.3d 1315.

⁸⁹ *Ulead Sys.*, 351 F.3d at 1146.

⁹⁰ *In re Klein*, 6 U.S.P.Q.2d 1528 (U.S. Dep’t Commerce. 1986), *adopted & modified*, 6 U.S.P.Q.2d 1547 (Comm’r Pats. 1987), *aff’d sub nom. Klein v. Peterson*, 696 F. Supp. 695 (D.D.C. 1988), *aff’d*, 866 F.2d 412 (Fed. Cir. 1989).

“succeed[] in prompting expedited consideration of the application.”⁹¹

Here too, applicants and litigators are cautioned to keep an eye out for the *Therasense II* decision. Although non-invalidating information remains potentially material, if the Federal Circuit, *en banc*, adopts a “but-for” standard for materiality, withholding of non-invalidating information will not likely continue to be viewed as material.

4. Non-Misleading Attorney Arguments Distinguishing Prior Art Are Not Material

As stated above, attempts by applicants to distinguish prior art from the claimed invention, to the extent they are not misleading, should not form the basis of a finding of inequitable conduct.⁹² This is because the Examiner has access to the prior art and is therefore free to make “his [or] her own conclusions regarding the prior art.”⁹³ Examiners are taught not to rely on arguments made by applicants about cited references, but to consider independently any cited information. “[M]ateriality is determined from the viewpoint of a reasonable patent examiner, and not the subjective beliefs of the patentee.”⁹⁴

⁹¹ *Digital Control*, 437 F.3d at 1318 (quoting *Gen. Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994)).

⁹² *Innogenetics*, 512 F. 3d at 1378-79. While arguments made to distinguish applications from the prior art that are not misleading generally do not form the basis of inequitable conduct findings, such statements may nonetheless expose the applicant to infringement defenses under the Doctrine of Equivalents during a prospective patent litigation.

⁹³ *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000) (citing *Akzo N.V. v. U.S. Int’l Trade Comm’n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986)).

⁹⁴ *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1238 (Fed. Cir. 2003) (citing *Molins*, 48 F.3d at 1179).

However, if the applicant goes beyond merely submitting a legal argument regarding the prior art, and instead submits *extrinsic* evidence in the form of an affidavit from a person of skill in the art, arguments in the affidavit regarding the prior art will likely be material.⁹⁵ In *Therasense*, an affidavit was submitted to the PTO containing instructions as to how a skilled person would interpret a prior art reference. This affidavit was critical to the allowance of the claims of the patent. However, the affiant, a scientific advisor, failed to disclose his own prior inconsistent statements to the EPO. Because the affidavit itself is inherently material,⁹⁶ all of the information contained in the affidavit, including the withheld information, was also found to be material.⁹⁷ Unlike the situation in *Innogenetics*, where the Examiner was in possession of the *intrinsic* evidence — the prior art — the Examiner in *Therasense* had no basis to test the veracity of the statements in the affidavit. As the District Court explained, the applicant “was duty-bound to present any inconsistent extrinsic information known to him” because “[i]n the arena of *extrinsic* evidence, the examiner was unable to fend for himself.”⁹⁸

The Federal Circuit agreed, finding that an affiant’s earlier statements about prior art are “material to the PTO when those arguments directly contradict the applicant’s position regarding the prior art in the PTO.”⁹⁹ Moreover, the Court expressly rejected any suggestion that an affidavit submitted by a scientific advisor could be considered “attorney argument.”¹⁰⁰

⁹⁵ *Therasense I*, 593 F.3d 1289, 1301-05 (Fed. Cir. 2010).

⁹⁶ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1188 n.9 (Fed. Cir. 2006).

⁹⁷ *Therasense I*, 593 F.3d at 1305.

⁹⁸ *Therasense*, 565 F. Supp. 2d 1088, 1112 (N.D. Cal. 2008).

⁹⁹ *Therasense I*, 593 F.3d at 1305.

¹⁰⁰ *Id.* (“[F]actual assertions as to the views of those skilled in the art, provided in affidavit form” are not merely lawyer arguments.”).

IV. INTENT TO DECEIVE OR MISLEAD THE PTO

A. The Intent Standard

A finding of materiality does not end the inequitable conduct inquiry. The party alleging inequitable conduct must also separately prove, by clear and convincing evidence, a specific intent to deceive the PTO.¹⁰¹ Intent to deceive will rarely be established by direct evidence; instead, it will typically be inferred from circumstantial or indirect evidence.¹⁰² Such evidence must still be clear and convincing.¹⁰³ Moreover, while the standard is not consistently articulated, “the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.”¹⁰⁴ The “most reasonable inference” standard was also advanced by both parties in *Therasense II*.¹⁰⁵ Therefore, barring an different, independent determination of a different standard by the Federal Circuit, the “most reasonable inference” standard is likely to survive in the wake of *Therasense II*.

In cases involving an omission or misrepresentation of a material reference to the PTO, the party alleging inequitable conduct must prove by clear and convincing evidence that the applicant: (1) made a deliberate decision to withhold or misrepresent a known material reference; *and* (2) withheld or

¹⁰¹ *Larson*, 559 F.3d 1317, 1340-41 (Fed. Cir. 2009).

¹⁰² *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006).

¹⁰³ *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008).

¹⁰⁴ *Id.*

¹⁰⁵ Reply Brief of Plaintiff-Appellant Abbott at 4, *Therasense v. Becton, Dickinson & Co (Therasense II)*, No. 2008-1511 (Fed. Cir. Oct. 21, 2010); *En Banc* Brief of Defendants-Appellees Becton, Dickinson & Co. & Nova Pharm. at 32-33, *Therasense II*, No. 2008-1511 (Fed. Cir. Oct. 8, 2010).

misrepresented the material subject matter with the intent to deceive.¹⁰⁶ The applicant's state of mind and the deliberate nature of the omission or misrepresentation are thus critical to the consideration, as courts have more recently held that an intent to deceive cannot be inferred from gross negligence alone: "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive."¹⁰⁷

B. Applying The Intent Standard

1. Representative Case Law Finding Deceptive Intent

Intent to deceive can not be inferred solely from the fact that information was misrepresented or not disclosed. Instead, there must be a factual basis for a finding of deceptive intent.¹⁰⁸ In *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370 (Fed. Cir. 2001), the Court found a factual basis to infer intent. The applicant had knowledge that an on-sale event had occurred more than one year prior to the filing date of the patent. The applicant's attorney was instructed by the applicant to file a patent application "within three days," in order to avoid the on-sale bar that would have arisen out of that event.¹⁰⁹ Upon hearing the testimony of the parties, the District Court found that the prosecuting attorney was likely aware of the potential on-sale bar problem. This was evidenced by his evasive testimony at trial, the

¹⁰⁶ *Eli Lilly v. Zenith Goldline Pharma.*, 471 F.3d 1369, 1382 (Fed. Cir. 2006); *Digital Control*, 437 F.3d at 1313; *Therasense*, 565 F. Supp. 2d 1088, 1111 (N.D. Cal. 2008).

¹⁰⁷ *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc*); see *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1329 (Fed. Cir. 1998).

¹⁰⁸ *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 1001-02 (Fed. Cir. 2006) (*citing Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996)).

¹⁰⁹ *Brasseler*, 267 F.3d at 1374, 1376.

“‘studied ignorance that he carefully cultivated’ and with which he prosecuted the application” and the deliberate and uncharacteristic failure to inquire into the circumstances surrounding the accelerated filing timeline. All of these facts led the District Court to conclude, and the Federal Circuit to agree, that there was deceptive intent.¹¹⁰

Similarly, in *Therasense*, an intent to deceive was found where the patent prosecution attorney “made a conscious decision to withhold . . . contradictory material from the USPTO.”¹¹¹ In addition to not finding any plausible excuse for the attorney’s failure to disclose material information, the District Court found him to be an unreliable trial witness and took his trial demeanor into account in making its intent finding.¹¹² The Federal Circuit affirmed, holding that the submission of an affidavit to the PTO suggesting how a person of skill in the art would interpret the prior art, coupled with the simultaneous withholding of prior inconsistent statements made to the EPO, showed the applicant’s deceptive intent.¹¹³ In so holding, the Federal Circuit applied the “most reasonable inference” standard, articulated in *Star Scientific*, relying in part on the district court’s credibility determinations.¹¹⁴

Other cases have similarly found sufficient evidence of deceptive intent where an applicant knowingly withheld material inconsistent statements from the PTO during prosecution. For example, in *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), a prosecutor made repeated representations to foreign patent offices, during prosecution of foreign counterpart applications, that a particular piece of prior art was the closest in existence.

¹¹⁰ *Id.* at 1376-77, 1383.

¹¹¹ *Therasense*, 565 F. Supp. 2d at 1113 (*aff’d* 593 F.3d 1289 (Fed. Cir. 2010)).

¹¹² *Id.*

¹¹³ *Therasense I*, 593 F.3d 1289, 1308 (Fed. Cir. 2010).

¹¹⁴ *Id.* at 1306.

However, the same prosecutor failed to disclose the same piece of prior art to the PTO during prosecution.¹¹⁵

Prosecuting attorneys are not the only ones subject to judicial scrutiny for their actions before the PTO. Also in *Therasense*, the Court reviewed the intent of the applicant's scientific advisor who had submitted the misleading affidavit. While he informed the prosecuting attorney of his prior inconsistent statements, neither of them informed the PTO. The District Court found his attempt to cure his misstatement by informing the prosecuting attorney unavailing. "A declarant who makes a materially false and misleading statement under oath to the PTO cannot escape a charge of inequitable conduct on the theory that he advised the lawyer that the statement was misleading and why."¹¹⁶ Here too, the Federal Circuit agreed with the District Court, noting that, "by submitting a declaration to the PTO, [an applicant] [is] obligated to avoid intentional deception."¹¹⁷ While an inventor or other declarant thus has no affirmative obligation to make any initial representations to the PTO regarding patentability, once such a representation is made, it cannot be misleading. Additionally, to the extent the same inventor or declarant has made statements before another tribunal that contradict those in a declaration provided to the PTO, such inconsistent statements must be disclosed to the Examiner.¹¹⁸

A similar situation occurred in *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348 (Fed. Cir. 2005). The *Bruno* Court held that, because the same individual had been involved in both the FDA and PTO submissions, he had both the

¹¹⁵ *Molins*, 48 F.3d at 1181.

¹¹⁶ *Therasense*, 565 F. Supp. 2d at 1115.

¹¹⁷ *Therasense I*, 593 F.3d at 1307.

¹¹⁸ *See supra* pp. 16-18.

requisite knowledge of the FDA submissions, and the clear intent to withhold the prior art from the PTO.¹¹⁹

2. Representative Case Law Finding Insufficient Evidence of Deceptive Intent

Inequitable conduct most often results either from a failure of a patent applicant to disclose material prior art, or from an applicant's affirmative misrepresentation to the PTO. On the other hand, if the applicant (or anyone with a duty to disclose) fails to "appreciate the materiality" of the prior art reference, then there is no inequitable conduct.¹²⁰ In *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326 (Fed. Cir. 2005), the Federal Circuit affirmed the District Court's determination that there was no inequitable conduct where the applicant failed to disclose material prior art to the PTO because he did not appreciate the materiality of another company's drug to his own invention.¹²¹ (The applicant and his team had had no clinical success with the other company's drug and so had abandoned their work with it). The credibility of the applicant as a trial witness was crucial to the District Court's findings – it believed the applicant's explanation as to why he failed to disclose the existence of a clearly material substance to the PTO. Because there was no intent to deceive the

¹¹⁹ *Id.* at 1354.

¹²⁰ See *Warner-Lambert*, 418 F.3d at 1347; see also *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1237-38 (Fed. Cir. 2005) (inequitable conduct not found with respect to a publication highlighting a potential prior art reference, when one of ordinary skill in the art would not be put on notice of the publication's materiality to a not-yet filed patent application).

¹²¹ However, an applicant cannot escape culpability for inequitable conduct by intentionally avoiding knowledge of the materiality of information. See *FMC Corp.*, 836 F.2d at 526 n.6; see also *Brasseler*, 267 F.3d at 1374, 1376 (inequitable conduct found where the applicant purposefully disregarded evidence that prior art existed).

PTO regarding the material reference, there was no inequitable conduct.¹²²

Where the only evidence of intent is the lack of a good faith explanation for nondisclosure, courts will generally not find inequitable conduct before the PTO. A “failure to disclose a prior art device to the PTO, where the *only evidence* of intent is a lack of a good faith explanation for the nondisclosure, cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent.”¹²³ In *M. Eagles*, the applicant did not disclose to the PTO a model die grinder that the applicant had made for several years and that bore some similarities to the claimed inventions. The Court found that, because “important differences” existed between the model grinder and the claimed invention, a conclusion that the patentee had an intent to deceive the PTO was not warranted.¹²⁴ Additionally, no other evidence existed to support a finding of culpable intent, nor was it clear that the applicant knew or should have known of the materiality of the earlier model die grinder produced by his employer.¹²⁵

An intent to deceive also cannot be inferred from a decision to withhold information, where the reasons given for the withholding are plausible.¹²⁶ In *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369 (Fed. Cir. 2006), the party alleging inequitable conduct argued that the applicant failed to mention to the PTO certain blood toxicity problems associated with its claimed drug, although these issues were discussed before the Swedish Board.¹²⁷ The Court found the applicant’s reasons for not disclosing this information to the PTO sufficiently credible. First,

¹²² *Warner-Lambert*, 418 F.3d at 1347-48.

¹²³ *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006) (emphasis added).

¹²⁴ *Id.*

¹²⁵ *Id.* at 1341-42.

¹²⁶ *Eli Lilly & Co.*, 471 F.3d at 1382.

¹²⁷ *Id.*

the PTO only questioned the applicant about blood cholesterol levels, not toxicity levels, during prosecution of the patent.¹²⁸ Second, the toxicity information was disclosed to the Swedish Board solely for the purpose of conducting human clinical studies in Scandinavia.¹²⁹ The applicant made no mention of cholesterol problems in front of the Swedish Board, nor was he questioned about issues relating to cholesterol. After considering the applicant's reasons for nondisclosure, the Federal Circuit held that he did not fail to disclose material information or contradict his later patentability arguments.¹³⁰

In *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 1001 (Fed. Cir. 2006), the Federal Circuit found no inequitable conduct where the applicant failed to disclose the full English translation of a Japanese publication.¹³¹ Because the material that the applicant did disclose to the PTO was consistent with what was contained in the undisclosed Japanese publication, there was no factual basis to infer intent.¹³²

Likewise, in *Seiko Epson Corp. v. Nu-Kote Int'l, Inc.*, 190 F.3d 1360 (Fed. Cir. 1999), the Court addressed whether the prosecuting attorney committed inequitable conduct for failing to file Japanese declarations with English translations when one of the inventors could not read or understand English.¹³³ 37 C.F.R. § 1.69, which relates to foreign language oaths and declarations, provides that an individual who cannot understand English must

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Atofina*, 441 F.3d at 1001-03; *see also* *Kao Corp. v. Unilever United States, Inc.*, 441 F.3d 963, 971-72 (Fed. Cir. 2006) (finding that a failure by the applicant to disclose material clinical data in the inventor's declaration until more than one year after the declaration was submitted was not sufficient evidence of intent to deceive the PTO).

¹³² *Id.* at 1002.

¹³³ *Seiko Epson*, 190 F.3d at 1366.

provide oaths or declarations to the PTO in a language that he or she can understand, along with a certified English translation. The District Court held that the failure to provide the declaration in the Japanese language constituted a *per se* violation of 37 C.F.R. § 1.69 that rendered the patents unenforceable due to inequitable conduct.¹³⁴ The Federal Circuit subsequently reversed the District Court's ruling, finding that, although the English translations were arguably material, there was no evidence that the submission was made with an intent to deceive the PTO. In addition, any technical violation of the rule was "cured" by the later filing of Supplemental Declarations of Inventorship, which were executed in accordance with § 1.69.¹³⁵

3. Credibility Determinations

Because applicants cannot generally be expected to admit to having possessed the intent to deceive the PTO during prosecution, a court's determinations as to witness credibility are often of great import in such findings.¹³⁶ For example, in *Therasense*, both the prosecuting attorney and a Therasense scientist who had submitted an affidavit to the PTO during prosecution offered testimony at trial regarding the reasons for their withholding of their material prior statements.¹³⁷ The District Court judge, observing their testimony, found their explanations neither plausible, nor credible.¹³⁸ The Federal Circuit, noting that "a [district court] judge's credibility determinations are 'virtually

¹³⁴ *Id.*

¹³⁵ *Id.* at 1367.

¹³⁶ See *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (deceptive intent must usually be inferred from circumstantial or indirect evidence because direct evidence is rarely available).

¹³⁷ *Therasense I*, 593 F.3d at 1306-07.

¹³⁸ *Id.* at 1306.

unreviewable,”¹³⁹ relied in part on these determinations in affirming the District Court’s finding of deceptive intent.¹⁴⁰

Similarly, in both *Molins* and *Bruno*, District Court determinations of the credibility of testifying witnesses played a role in the ultimate finding of deceptive intent. In *Molins*, the Federal Circuit “accord[ed] deference to the fact-finder’s assessment of [the] witness’ credibility and character,” ultimately finding that the applicant’s explanation of its good faith failure to provide known prior art to the PTO was unconvincing.¹⁴¹ In *Bruno*, the Court specifically called attention to the applicant’s failure to put forth any kind of credible explanation for its nondisclosure, drawing an inference of deceptive intent based in part on the absence of such an explanation.¹⁴²

However, a District Court’s credibility determinations alone, without more, are insufficient to show deceptive intent. In *Star Scientific*, an applicant’s testimony as to the reasons for a coincidentally-timed change of patent prosecution counsel was found to be not credible by the District Court. Importantly, the accused infringer had offered no evidence of its own in support of deceptive intent, and there had been no testimony on which to

¹³⁹ *Id.* at 1307 (quoting *Hambsch v. Dep’t of the Treasury*, 796 F.2d 430, 436 (Fed. Cir. 1986); see also *LNP Eng’g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1361 (Fed. Cir. 2001); *Griessenauer v. Dep’t of Energy*, 754 F.2d 361, 364 (Fed. Cir. 1985).

¹⁴⁰ *Id.* at 1308.

¹⁴¹ *Molins*, 48 F.3d at 1181.

¹⁴² *Bruno*, 394 F.3d at 1354. It has subsequently been held that a “patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.” *Star Scientific*, 537 F.3d at 1368. Though *Bruno* was decided before *Star Scientific*, this initial threshold burden had likely been carried by the accused infringer based on the same person having both made affirmative submissions to the FDA, and subsequently withheld the nature of those same submissions from the PTO.

make the threshold intent finding.¹⁴³ The Federal Circuit reversed the District Court, holding that “[o]nly when the accused infringer has met [its burden to prove a threshold level of intent by clear and convincing evidence] is it incumbent upon the patentee to rebut the evidence of deceptive intent with a good faith explanation for the alleged misconduct.”¹⁴⁴

C. Interplay of Materiality and Intent

While intent is often inferred from the circumstances surrounding the prosecution of a patent, “[i]t is improper . . . to infer intent *solely* from the fact that a material omission or misstatement was made.”¹⁴⁵ “[M]ateriality alone is never sufficient to establish intent because proof of intent ‘is a separate and essential component of inequitable conduct.’”¹⁴⁶ A determination of inequitable conduct that is “based *solely* on one part of the [two-part] test is legally erroneous.”¹⁴⁷

In *Purdue I*, the Court affirmed the District Court’s inference of intent from its findings on materiality. Purdue had “consistent and repetitive” communications with the PTO in which it failed to clarify that its “discovery” was based on insight rather than clinical data. To the Court, this indicated Purdue’s deliberate intent to misrepresent the nature of the “discovery” and thus to deceive the PTO.¹⁴⁸ In *Purdue II*, however, the Federal Circuit reexamined the evidence and determined that the materiality of the

¹⁴³ *Star Scientific*, 537 F.3d at 1367-68.

¹⁴⁴ *Id.*

¹⁴⁵ *In re OxyContin Antitrust Lit.*, 530 F. Supp. 2d 554, 560 (S.D.N.Y. 2008) (emphasis added) (citing *Purdue Pharma*, 438 F.3d at 1134) (addressing inequitable conduct in the context of antitrust litigation).

¹⁴⁶ *Id.* (quoting *Purdue Pharma*, 438 F.3d at 1134 and *Critikon*, 120 F.3d at 1257).

¹⁴⁷ *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1252 (Fed. Cir. 2008) (emphasis added).

¹⁴⁸ *Purdue Pharma*, 410 F.3d at 701.

omission was relatively low.¹⁴⁹ The District Court “erred to the extent it relied on a high level of materiality” in determining whether Purdue had an intent to deceive.¹⁵⁰ Because materiality does not presume intent, the Court vacated the inequitable conduct judgment and remanded the case to the District Court to review evidence of deceptive intent.¹⁵¹ As set forth, *supra*, no further proceedings occurred thereafter in the action due to settlement. However, in a subsequent related proceeding directed to antitrust claims, the District Court, applying the Federal Circuit’s finding from *Purdue II*, *supra*, found insufficient evidence of intent.¹⁵² The only additional evidence offered in the antitrust proceeding regarding intent was Purdue’s strong business incentive to obtain the patent. The District Court found that “[s]uch generalized allegations lack the particularity required to meet the threshold level of deceptive intent necessary for a finding of inequitable conduct.”¹⁵³

In *Research Corp. Techs, Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1252 (Fed. Cir. 2008), the District Court focused exclusively on the applicant’s intent to deceive and improperly excluded evidence of materiality of undisclosed experiments. The Federal Circuit reversed a finding of inequitable conduct and accordingly vacated an award of attorney fees.¹⁵⁴ Similarly, in *Larson*, the District Court largely inferred deceptive intent based on the applicant’s failure to disclose five items to the PTO.¹⁵⁵ On appeal, the Court determined that only two of the five items were material. Thus, the Court remanded the case to the District Court to

¹⁴⁹ *Purdue Pharma*, 438 F.3d at 1133.

¹⁵⁰ *Id.*

¹⁵¹ *Id.* at 1134-35 (citations omitted).

¹⁵² *In re OxyContin Antitrust Lit.*, 530 F. Supp. 2d at 562.

¹⁵³ *Id.* at 563 (citation omitted).

¹⁵⁴ *Id.* at 1249.

¹⁵⁵ *Larson*, 559 F.3d at 1327.

determine whether the party alleging inequitable conduct provided sufficient evidence of deceptive intent.¹⁵⁶

D. Considerations of Good Faith

The Federal Circuit in *Purdue II* also criticized the District Court for “discounting any evidence of good faith” in determining whether Purdue intended to deceive the PTO.¹⁵⁷ The District Court’s opinion focused on internal memoranda and trial testimony in which Purdue admitted that it was unable to prove, with experimental results, the drug efficacy required to obtain FDA approval.¹⁵⁸ The accused infringer argued that Purdue’s internal statements regarding the difficulty of obtaining FDA approval were inconsistent with Purdue’s assertions before the PTO that its drug was effective. The Court disagreed: “evidence that Purdue personnel believed it would be difficult to satisfy FDA requirements is at best marginally related to whether they intended to deceive the PTO.”¹⁵⁹ Moreover, “[w]hen determining whether intent has been shown, a court must weigh all evidence, including evidence of good faith.”¹⁶⁰ Thus, the District Court erred in giving significant weight to the FDA information while giving little weight to Purdue’s candor and good faith.

In *Bruno*, the Court focused on the applicant’s failure to offer a credible explanation for the nondisclosure: “an inference of deceptive intent may fairly be drawn in the absence of such an explanation.”¹⁶¹ The Court further explained that “[n]ormally, it can be expected that an innocent party will be motivated to try to present convincing reasons for its actions.”¹⁶² Based on this

¹⁵⁶ *Id.* at 1327-39.

¹⁵⁷ *Purdue Pharma*, 438 F.3d at 1134.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Bruno Indep. Living Aids*, 394 F.3d at 1354.

¹⁶² *Id.*

decision, it appeared that applicants had the affirmative obligation to offer evidence of good faith for omissions or nondisclosures of material prior art.

The Federal Circuit then provided further clarification of the applicant's burden in offering good faith explanations to rebut a showing of deceptive intent. In *Star Scientific*, the party alleging inequitable conduct argued that the applicant conspired to prevent his attorneys from disclosing a particular letter to the PTO by replacing them with another firm.¹⁶³ The applicant then allegedly "quarantined" the new firm by keeping them from learning about the letter.¹⁶⁴ The Court reversed a finding of inequitable conduct. In doing so, the Court explained that it was the burden of the party claiming inequitable conduct to prove intent to deceive based on the replacement of counsel.¹⁶⁵ Moreover, the "patentee need not offer any good faith explanation before the accused infringer first carried its burden of proving a threshold level of intent by clear and convincing evidence."¹⁶⁶ Only then must the applicant rebut the evidence of deceptive intent with a good faith explanation for the "alleged misconduct."¹⁶⁷ Therefore, an applicant's silence, such as in *Bruno*, may no longer be sufficient to prove an intent to deceive.

V. THE PLEADING REQUIREMENTS FOR INEQUITABLE CONDUCT

Under Federal Rule of Civil Procedure 9(b), "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be

¹⁶³ *Star Scientific*, 537 F.3d at 1367.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 1368.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

alleged generally.”¹⁶⁸ Thus, inequitable conduct “must be pled with particularity” under Rule 9(b).¹⁶⁹

In *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009), the Federal Circuit detailed the standard for pleading inequitable conduct with sufficient particularity. There, the Federal Circuit affirmed the District Court’s denial of the accused infringer’s motion to add inequitable conduct as an affirmative defense and counterclaim on the ground that the allegations failed to satisfy the pleading requirements of Rule 9(b).¹⁷⁰ The Federal Circuit explained that “to plead the ‘circumstances’ of inequitable conduct with the requisite ‘particularity’ under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.”¹⁷¹ Moreover, the pleading “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 PTO.”¹⁷²

The Court provided additional guidance on how to meet the “who, what, when, where, and how” prongs of the pleading standard. In order to satisfy the “who” prong, accused infringers must name “the specific individuals associated with the filing or prosecution of the application . . . who both knew of the material information and deliberately withheld or misrepresented it.”¹⁷³ In order to satisfy the “what” and “where” prongs, accused infringers

¹⁶⁸ Fed. R. Civ. R. 9(b).

¹⁶⁹ See *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003).

¹⁷⁰ *Id.* at 1326.

¹⁷¹ *Id.* at 1328.

¹⁷² *Id.* at 1328-29.

¹⁷³ *Id.* at 1329.

must “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.”¹⁷⁴ Finally, to satisfy the “why” and “how” prongs, an accused infringer must explain why the withheld information is material and not cumulative, and also explain how an Examiner would have used the information to determine the patentability of the claims.¹⁷⁵

VI. THE CONTINUED EVOLUTION OF INEQUITABLE CONDUCT

Even before the Federal Circuit agreed to hear argument *en banc* in *Therasense II*, some members of the Federal Circuit had expressed dissatisfaction with the Court’s treatment of inequitable conduct in recent years. For example, Judge Linn’s concurrence in the *Larson* decision discussed the Federal Circuit’s frequent use of a deceptive intent standard that he believes contradicts the stringent standard espoused by *Kingsdown*.¹⁷⁶ The more lenient standard “permits an inference of deceptive intent” when: (1) highly material information is withheld; (2) the applicant knew of the information and knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.¹⁷⁷ According to Judge Linn, this standard conflates the materiality and intent prongs of the inequitable conduct test, shifts the burden of proof to the patentee to prove that it did not intend to deceive the PTO, and is insufficient, as a matter of law, to establish the “clear and convincing” threshold required of deceptive intent.¹⁷⁸

Judge Linn reiterated his displeasure with the current application of the intent standard more recently in his dissent in

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 1330.

¹⁷⁶ *Larson*, 559 F.3d at 1343-44.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

Therasense. There, Judge Linn again argued that the majority decision deviated from the *Kingsdown* standard.¹⁷⁹ While he looked favorably on other recent decisions such as *Star Scientific*, and *Dayco* that have articulated a “single most reasonable inference” standard, he viewed the majority’s opinion as an outlier.¹⁸⁰ Judge Linn argued that the prosecuting attorney and scientific advisor affiant had provided a *plausible* explanation for the withholding of information, and that the existence of any plausible explanation was enough to defeat a finding of deceptive intent.¹⁸¹ The majority disagreed, also relying on *Star Scientific*, which held only that where a finding of deceptive intent is inferred from circumstantial evidence, the inference of intent must be more reasonable than any other inferences that can be drawn.¹⁸²

Judge Linn is not alone in his opinion that the inequitable conduct doctrine is ripe for an overhaul. Judge Rader, in a dissent to the Court’s finding of inequitable conduct in *Aventis Pharma S.A. v. Amphastar Pharms. Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008), articulated similar concerns regarding the Federal Circuit’s inequitable conduct jurisprudence.¹⁸³ Judge Rader commented that “inequitable conduct has taken on a new life as a litigation tactic . . . [and] opens new avenues of discovery; impugns the integrity of patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors

¹⁷⁹ *Therasense I*, 593 F.3d at 1319-20 (Linn, J., dissenting).

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Star Scientific*, 537 F.3d at 1366 (citing *Scanner Techs.*, 528 F.3d at 1376) (“Whenever evidence proffered to show either materiality or intent is susceptible to multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable one.”).

¹⁸³ *Aventis Pharms. S.A. v. Amphastar Pharms. Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

of claim construction and other complex patent doctrines.”¹⁸⁴ He urged the Court to revisit the *Kingsdown* opinion, which “clearly conveyed that the inequitable conduct was not a remedy for every mistake, blunder, or fault in the patent procurement process . . . [and] properly made inequitable conduct a rare occurrence.”¹⁸⁵ He then discussed what he believed to be the problem areas in the Court’s inequitable conduct analyses: the emphasis on materiality almost to the exclusion of intent, the findings of inequitable conduct without clear and convincing evidence of intent, and the insufficient focus on the patentee’s good faith or candor.¹⁸⁶

Likewise, in *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008), the Court articulated the purpose of the doctrine of inequitable conduct as being to punish *fraudulent* practices.¹⁸⁷ By contrast “routine actions that do not affect patentability and that are devoid of fraudulent intent” should not be subject to the harsh consequences of an inequitable conduct finding.¹⁸⁸ Equally, “[t]echnical violations of PTO procedures, absent fraud or intentional deception, are not inequitable conduct as would invalidate the patent.”¹⁸⁹

**a. The Materiality Standards Proffered
By The Parties In Connection With The
Therasense En Banc Proceeding**

Therasense II was argued before an *en banc* panel of the Federal Circuit in November, 2010. In their respective briefing, the parties’ largest points of dispute centered on the standard for

¹⁸⁴ *Id.* at 1349-50.

¹⁸⁵ *Id.* at 1350.

¹⁸⁶ *Id.* at 1349-53.

¹⁸⁷ *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1357 (Fed. Cir. 2008).

¹⁸⁸ *Id.*

¹⁸⁹ *Seiko Epson*, 190 F.3d at 1367.

materiality, and whether the materiality-intent-balancing framework should remain.

i. The “But-For” Materiality Standard Proposed By Therasense

The most significant point of contention between the parties in *Therasense II* was the question of which standard courts should apply in deciding the materiality prong of inequitable conduct analysis. While the parties seemed to agree that there had not been a consistently-applied standard, there was disagreement as to how the inconsistency should be resolved. Therasense favored application of the “but-for” materiality test – the strictest of the commonly used tests. In support of this position, Therasense urged the Federal Circuit to view inequitable conduct from a historical perspective, highlighting that the doctrine arose from a line of cases based on fraudulent procurement of patents.¹⁹⁰ Because fraud requires “but-for” causation, it was reasoned, so too should inequitable conduct.¹⁹¹ Indeed, in *Precision Instrument* the court found that inequitable conduct was essentially “fraud-like”, and that the Supreme Court had “never rendered a patent unenforceable” based on conduct lesser than “perjury, fabricated evidence and bribery.”¹⁹² Further, even if inequitable conduct were to be construed more broadly, based on the “unclean hands” standard, Therasense suggested that the “unclean hands” doctrine also requires “but-for” causation in cases where there is a risk that

¹⁹⁰ *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944); *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

¹⁹¹ Reply Brief of Plaintiff-Appellant Therasense at 6-9, *Therasense II*, No. 2008-1511 (Fed. Cir. Oct. 21, 2010).

¹⁹² *Id.* at 9.

“property rights will be destroyed.”¹⁹³ The inequitable conduct doctrine was also compared to other areas of law in which “but-for” causation is required in support of the conclusion that mere misconduct is insufficient to eliminate rights.¹⁹⁴

However, as Appellees Becton Dickinson & Co. and Nova Biomedical, Inc. (“Becton”) (as well as the Patent Office) pointed out, the “but-for” standard is not without its problems. Indeed, Becton argued that the stringency of the “but for” standard created the risk that (a) a dishonest patentee might avoid sanction where the prosecution record lacks evidence of the reasons for allowance, and (b) honest patentees could trend toward a cautious surplus of disclosure, unnecessarily burdening the PTO.¹⁹⁵

**ii. The “Current Rule 56”
Standard Proposed By Becton**

As an alternative to the rigid “but-for” standard, Becton argued that the standard of materiality should differ from that applied in the context of fraud because the doctrine of inequitable conduct is distinct from fraud.¹⁹⁶ Particularly, the correct standard of materiality should be determined by reference to the version of Rule 1.56 “at the time of the conduct in question.”¹⁹⁷ This way, materiality would be tied to a single standard that reflects the duty of the patentee to the PTO and the disclosure standards of the PTO itself, and would effectively track any subsequent amendment to

¹⁹³ *Id.* at 10 (citing *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942); *Eckes v. Card Prices Update*, 736 F.2d 859, 861-62 (2d Cir. 1984)).

¹⁹⁴ Reply Brief of Plaintiff-Appellant, *supra* note 105 at 14

¹⁹⁵ *Id.* at 19.

¹⁹⁶ *En Banc* Brief of Defendants-Appellees, *supra* note 105 at 16-17 (noting a distinction between “fraud or inequitable conduct” (quoting *Precision*, 324 U.S. at 815-18)).

¹⁹⁷ *Id.* at 11.

the rule.¹⁹⁸ Otherwise, compliance with a standard in effect during prosecution might still fail to protect a patentee from a charge of inequitable conduct at trial.¹⁹⁹ This rule-based standard would provide a more flexible alternative to “but-for” materiality, allowing the PTO to continually reevaluate and update the standard in accordance with its Examination practices. Additionally, this standard would promote honesty and candor in dealings with the PTO by continuing to impose liability on applicants for any intentional misrepresentations made to the PTO, regardless of whether they affected the ultimate decision on patentability.

The adoption of a materiality standard based on Rule 1.56 was also supported by several *Amici*, including the USPTO itself, which was invited by the Federal Circuit to file an *Amicus* brief, and to be heard at oral argument.²⁰⁰

Therasense’s primary opposition to the adoption of this standard was procedural, highlighting that the PTO’s rule-making authority under the APA should not dictate (or replace) the legal standard that courts should apply.²⁰¹

iii. The Balancing Test

Both Becton and Therasense advocated for changes with respect to the current materiality-intent balancing test. One concern, articulated by Therasense, was that the balancing test has been improperly construed to dilute the degree of proof needed to find inequitable conduct, where “relatively weak evidence” of materiality or intent was allowed in the face of “strong evidence”

¹⁹⁸ *Id.* at 20.

¹⁹⁹ *En Banc* Brief of Defendants-Appellees, *supra* note 105 at 13-14.

²⁰⁰ *See* Brief for the United States as *Amicus Curiae* in Support of Neither Party at 17, *Therasense II*, No. 2008-1511 (Fed. Cir. Aug. 2, 2010); *see also* Court Order at 4, *Therasense II* (Fed. Cir. Apr. 26, 2010) (requesting *Amicus* participation by USPTO).

²⁰¹ *Id.* at 16.

of the other.²⁰² Indeed, neither party believed that the balancing test had been intended to operate in this way. The parties therefore proposed alternatively to do away with the balancing test completely (Therasense), or to recast the balancing test not as between materiality and intent, but instead as a balancing of the equities (Becton). Becton’s interpretation would allow courts, despite having made independent findings of both materiality and intent, to nonetheless avoid the “severe penalty of unenforceability” where the “patentee only committed minor missteps or acted with minimal culpability or in good faith.”²⁰³ In such cases, while the facts may support a finding of *prima facie* inequitable conduct, the equities given the totality of circumstances may compel a different result.

To address the potential risk that a conclusion of inequitable conduct could be found without the independent prongs having been met, Becton’s proposed modification to the balancing test provided that the balancing test would not be reached “absent proof of both materiality and intent”.²⁰⁴ The only possible results from the use of the balancing test would therefore be to either: (1) validate a finding of inequitable conduct where materiality and intent had been previously found; or (2) reject a finding of inequitable conduct in spite of a previous determination of materiality and intent. While the practical application of such a test is unclear, it might be expected that granting such discretion to the courts would decrease slightly the number and frequency of inequitable conduct findings.

b. Resolving Prior Inconsistency

As demonstrated by the many *Amici* who submitted papers in *Therasense II*, there is wide support for clarification. This stems primarily from a perceived inconsistency in the intent standard

²⁰² *Id.* at 23 (citing *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007)).

²⁰³ *Id.* at 52 (quoting *Star Scientific*, 537 F.3d at 1366).

²⁰⁴ *Id.* at 53.

being applied by the Federal Circuit since *Kingsdown*. The Court's *en banc* decision in *Kingsdown* purportedly put an end to the "gross negligence" standard of deceptive intent, holding that "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an intent to deceive."²⁰⁵ The holding appeared to remove from the intent determination whether or not the applicant "should have known" about the materiality of withheld information.²⁰⁶

Yet, the Federal Circuit's treatment of inequitable conduct since *Kingsdown* has not been universally interpreted as consistent. In *Brasseler*, the Court appeared willing to again accept gross negligence as a basis for finding deceptive intent, holding that "[w]here an applicant knows of information the materiality of which may so readily be determined, he or she cannot intentionally avoid learning of its materiality, even through gross negligence; in such cases the district court may find that the applicant should have known of the materiality of the information."²⁰⁷

In 2006, the Court's decision in *Ferring* demonstrated further acceptance of the "gross negligence" standard, affirming a finding of deceptive intent based in part on the conclusion that "the applicant knew or should have known of the materiality of the information,"²⁰⁸ a rationale that was also adhered to in *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008).

As mentioned above, more recent opinions, such as *Star Scientific, Scanner Techs.*, *Dayco Prods.*, and *Therasense I*, have shifted the tide back towards the "single most reasonable

²⁰⁵ *Kingsdown*, 863 F.2d at 876.

²⁰⁶ See *Hoffman-La Roche, Inc. v. Lemmon Co.*, 906 F.2d 684, 687-88 (Fed. Cir. 1990).

²⁰⁷ *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001) (citing *Critikon, Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 1257 (Fed. Cir. 1997); *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996))

²⁰⁸ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).

inference” standard. And, in view of the parties’ agreement in *Therasense II* of the appropriateness of the “most reasonable inference” standard, clear guidance may accompany that decision. The articulation of a clear standard for both intent and materiality will hopefully curb the proliferation of inequitable conduct cases, and reduce what some members of the Court describe as “‘the plague’ whereby every patentee’s imperfections were promoted to ‘inequitable conduct.’”²⁰⁹

VII. THE EXCEPTIONAL CASE

Findings of inequitable conduct have far-reaching consequences for patentees.²¹⁰ Often, a finding of inequitable conduct will lead to the further finding of an “exceptional case,” which can form the basis of an award of attorney fees for a defendant.²¹¹ Under § 285 of the Patent Act, a district court may

²⁰⁹ *Abbott Labs.*, 544 F.3d at 1358 (internal quotations omitted); *see also Larson*, 559 F.3d at 1342 (Linn, J., concurring); *Aventis Pharms.*, 525 F.3d at 1350 (Rader, J., dissenting); *Ferring*, 437 F.3d at 1196; *Molins*, 48 F.3d at 1182.

²¹⁰ A finding of inequitable conduct can have a negative impact on the prosecuting attorneys as well. If associated with a finding of inequitable conduct, a prosecuting attorney may be exposed to disciplinary proceedings and reputational harm, which can further result in impairment of client relationships, and hindrance of future practice.

²¹¹ *Evident*, 399 F.3d at 1315 (“‘exceptional cases are normally those involving bad faith litigation or those involving inequitable conduct by the patentee in procuring the patent’”) (*quoting Brasseler*, 267 F.3d at 1380 (“[t]he prevailing party may prove the existence of an exceptional case by showing: inequitable conduct before the PTO”)); *Bruno Indep. Living Aids*, 394 F.3d at 1355; *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (“Among the types of conduct which can form a basis for finding a case exceptional are . . . inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit.”); *Rohm & Hass Co. v. Crystal Chem. Co.*, 736 F.2d 688, 691-92 (Fed. Cir. 1984) (“When prevailing alleged infringers are awarded attorney fees, ‘exceptional’ cases have involved litigation in bad faith by the patentee, or fraud or other inequitable conduct during prosecution before the PTO.”);

(Continued...)

award reasonable attorney fees to a prevailing party in a patent infringement case where the conduct of the losing party is deemed “exceptional.”²¹² Exceptional cases generally involve bad faith litigation or inequitable conduct by the patentee in procuring the patent.²¹³ However, “[a]lthough inequitable conduct may, by itself, justify a finding of an exceptional case, ‘there is no per se rule of exceptionality in cases involving inequitable conduct.’”²¹⁴ Similar to the findings of materiality and intent, clear and convincing evidence is required to establish an exceptional case.²¹⁵

As stated above, “inequitable conduct can be one of several bases sufficient to make a case exceptional for the purpose of awarding attorney fees under § 285.”²¹⁶ In *Therasense*, the Northern District of California found the case to be exceptional, and awarded attorney fees. The misleading information provided to the PTO was critical to allowance of the patent, which had previously been rejected twelve times.²¹⁷ Additionally, in that case, the applicant’s scientific advisor and attorney who provided

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Therasense, Inc. v. Becton, Dickinson and Company, No. C 04-02123, U.S. Dist LEXIS at *8 (N.D. Cal. Aug. 21, 2008) (“A case may be exceptional where there has been wrongful conduct such as willful infringement; fraud or inequitable conduct in procuring the patent; litigation misconduct; vexations or unjustified or otherwise bad faith pursuit of objectively baseless claims; violations of FRCP 11; or similarly unprofessional behavior.”) (citing *Brooks Furniture Mfg., Inc. v. Dutailier Int’l, Inc.*, 393 F.3d 1378, 1381 (Fed. Cir. 2005)).

²¹² 35 U.S.C. § 285.

²¹³ *Bruno Indep. Living Aids*, 394 F.3d at 1354; *Brasseler*, 267 F.3d at 1380.

²¹⁴ *Therasense, Inc. v. Becton, Dickinson and Company*, No. C 04-02123, U.S. Dist LEXIS at *8 (N.D. Cal. Aug. 21, 2008) (citing *Nilssen v. Osram Sylvania, Inc.*, 528 F.3d 1352, 1358 (Fed. Cir. 2008)).

²¹⁵ *Id.* at 1378-79.

²¹⁶ *Bruno Indep. Living Aids*, 394 F.3d at 1355.

²¹⁷ *Therasense*, No. C 04-02123, U.S. Dist. LEXIS at *9.

the misleading information were aware of the likelihood of success of the inequitable conduct defense at trial.²¹⁸

Although courts are more likely to find materiality in cases involving affirmative misrepresentations, courts will also award attorney fees in cases where an applicant makes a material omission. (*See supra*). For example, in both *Brasseler* and *Bruno*, the Federal Circuit affirmed the award of attorney fees based on the applicants' failure to disclose material information to the PTO.²¹⁹ Additionally, in *Special Devices, Inc. v. OEA, Inc.*, 117 F. Supp. 2d 989, 996 (C.D. Cal. 2000), *aff'd*, 270 F.3d 1353 (Fed. Cir. 2001), the patentee out-sourced production of the patented item and then bought units of that patented item from the out-sourcing entity prior to the critical date. The Court held that the patentee's failure to disclose these sales to the PTO constituted inequitable conduct that rendered the case exceptional and entitled the accused infringer to an award of attorney fees.²²⁰

The Federal Circuit will review both the district court's determination that a case is exceptional as well as the district court's decision to actually award attorney fees. Whether a case is exceptional is a question of fact.²²¹ Thus, the Federal Circuit will review a district court's findings of fact for clear error, although it will review *de novo* whether the district court correctly applied the law under § 285.²²² If the district court both "applied the correct legal standard and did not clearly err in its factual findings," the

²¹⁸ *Id.*

²¹⁹ *Brasseler*, 267 F.3d at 1376-77, 1383.

²²⁰ *Special Devices, Inc. v. OEA, Inc.*, 131 F. Supp. 2d 1171, 1177, 1180 (C.D. Cal. 2001) *appeal dismissed* 269 F.3d 1340 (Fed. Cir. 2001) (appeal dismissed for lack of jurisdiction due to unquantified award of attorney's fees).

²²¹ *Id.* at 1378.

²²² *Id.*

Federal Circuit will review the “[district] court’s decision whether or not to award attorney fees for abuse of discretion.”²²³

The Ninth Circuit has offered additional guidance as to when attorney fees are appropriate. In *Monolith Portland Midwest Co. v. Kaiser Aluminum & Chem. Corp.*, 407 F.2d 288 (9th Cir. 1969), the Court stated that inequitable conduct “is enough standing alone to convert [a] later infringement action into an exceptional case within the meaning of section 285.”²²⁴ In that case, the Court also provided a policy rationale for awarding fees, including “unduly prolong[ing] the litigation,” in the list of exceptional circumstances.²²⁵ The Court additionally stated that “[t]he party who succeeds in invalidating [an] unlawful patent performs a valuable public service,” and that “[i]t is appropriate under such circumstances to reward the prevailing party by giving him attorney fees for his efforts, and it is equally appropriate to penalize in the same measure the patentee who obtained the patent by his wrongdoing.”²²⁶

VIII. CONCLUSION

In dealing with the PTO during prosecution, and in submitting information disclosures, affidavits, or any other information, the inventor or his agent must be mindful of the “candor and good faith” requirement of 37 C.F.R. § 1.56. Maintaining a general awareness of this requirement and a broad understanding of the various standards of materiality and their application will allow the inventor to avoid subjecting himself to inequitable conduct defenses in any future litigations. The same is also true in the context of litigation. Effective arguments can be formed regarding the materiality of a misstatement or omission. As discussed above, materiality can be argued on the basis of up to

²²³ *Id.* at 1379.

²²⁴ *Monolith Portland*, 407 F.2d at 294.

²²⁵ *Id.*

²²⁶ *Id.*

five separately-intelligible standards: a *prima facie* showing, the “reasonable examiner” standard, “but may have” causation, and objective and subjective “but for” causation.²²⁷

Establishing the requisite threshold to satisfy the intent prong of the inequitable conduct analysis is less readily accomplished than establishing materiality. Not only does the necessary level of intent vary depending on the level of materiality, but intent is rarely established on the basis of direct evidence, circumstantial evidence being the more readily applicable means.²²⁸ Indeed, a prosecuting attorney can hardly be expected to freely admit to having had the intent to deceive the PTO. Although materiality and intent must ultimately be considered in concert, they are nonetheless distinct considerations. Thus, intent must not simply be inferred, or bootstrapped from an applicant’s material misstatement or omission. Further, though the issue remains somewhat unsettled, one should not presume that intent can be proven simply by showing that an applicant “should have known” about the materiality of withheld information.

Over the years, many courts have inferred deceptive intent whenever three elements (highly material information withheld, knowledge of the applicant, and lack of credible explanation for withholding) were satisfied. As discussed, *supra*, certain members of the Court believe that the intent prong may need to be applied in a more stringent manner, such that an inference of intent “must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence.”²²⁹ Similarly, Senator Orrin Hatch, speaking recently at the National Press Club Federal Circuit Symposium, suggested that “[r]eform to the inequitable conduct defense should focus on the nature of the

²²⁷ See *Digital Control*, 437 F.3d at 1315-16.

²²⁸ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006).

²²⁹ *Star Scientific*, 537 F.3d at 1366 (citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)).

misconduct and not permit the unenforceability of a perfectly valid patent on a meritorious invention.”²³⁰

It remains to be seen what effect the recent Federal Court holdings, and the *Therasense en banc* rehearing will have on the future of the inequitable conduct doctrine. Thus, until there has been further judicial treatment, patentees and potential litigants should keep abreast of the developments in the Federal Circuit. Nonetheless, patentees and applicants have reason for encouragement about the future of inequitable conduct, the predictability of the application of the materiality and intent standards, and with the heightened pleading requirements, the possibility of fewer challenges to the enforceability of patents.

²³⁰ Senator Orrin G. Hatch, Address at the U.S. Court of Appeals for the Federal Circuit Symposium (Mar. 18, 2009).