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Amicus Briefs: Sounding Off on Reforming Inequitable Conduct

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**AMICUS BRIEFS:
SOUNDING OFF ON REFORMING
INEQUITABLE CONDUCT**

*Joy Lynn Bala**

*Inequitable conduct, which has been characterized as an “absolute plague” and an “atomic bomb,” allows an accused infringer to assert an affirmative defense against a patentee for violating the duty of candor and good faith in acquiring a patent. The consequences of this “atomic bomb” extend well beyond the litigation context and significantly impact the U.S. Patent and Trademark Office (PTO), patent agents, and patent attorneys. Such consequences include exorbitant litigation costs, overdisclosure to the PTO and thus decreased efficiency by PTO examiners, disciplinary action and potential disbarment of patent agents and attorneys, and even decreased innovation. The Federal Circuit’s recent en banc, 6–1–4 decision in *Therasense, Inc. v. Becton, Dickinson & Co.* attempted to reshape the doctrine. However, the decision also highlighted the court’s varying viewpoints, and the optimistic majority may not have cured the doctrine’s problems. Courts are responsive to the differing roles of patents in the myriad industries that patent law affects, and courts often turn to amicus briefs, which provide an important source of information regarding the role of patents within varying innovation contexts. Amicus briefs thus constitute key sources of empirical data that can be used in studying the patent system. As a result, these briefs can be particularly influential. Therefore, this Note’s analysis of the thirty-four amicus briefs in *Therasense* sheds light on the various commercial and societal concerns of patent law and, most importantly, on the impact*

* J.D. Candidate, May 2012, Loyola Law School Los Angeles; Ph.D. Chemistry, 2009, University of Southern California; B.S. Chemistry, 2004, Creighton University. I would like to thank Professor Lee Petherbridge for his valuable guidance and insight throughout the writing process. I would also like to thank the exceptional work and dedication of all the editors and staffers of Volume 44 and Volume 45 of *Loyola of Los Angeles Law Review*, particularly Milena Shtelmakher, Edith Nazarian, Anne Hopkins, Blythe Golay, Alicia Bower, and Joshua Rich. Finally, I am thankful for my family and friends, especially Christopher Nemirow, David Agler, and Larryn Peterson, for their endless support.

that inequitable conduct has on these myriad interests. This Note discusses data that were gathered from the briefs and that center on the three doctrinal components of inequitable conduct: materiality, intent, and the balancing step. Furthermore, this Note proposes a solution that focuses on the three prongs in light of the different arguments that the amici proposed: (1) courts should adopt Rule 1.56 as the materiality standard, which the Federal Circuit can further clarify by establishing factors for lower courts to consider in evaluating this prong; (2) courts should require a specific intent to deceive to satisfy the intent prong; and (3) courts should eliminate a sliding scale approach to the balancing step and maintain the harsh penalty of unenforceability.

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I. INTRODUCTION

In patent law, commentators have extensively criticized and characterized inequitable conduct as an “absolute plague”¹ and an “atomic bomb.”² The doctrine of inequitable conduct allows an accused infringer to assert an affirmative defense against a patentee for violating the duty of candor and good faith during the patentee’s acquisition of the patent. The consequences of this “atomic bomb” extend well beyond the litigation context and significantly impact the U.S. Patent and Trademark Office (PTO), patent agents, and patent attorneys. Such consequences include exorbitant litigation costs, disciplinary actions against and potential disbarment of patent agents and attorneys, and even decreased innovation; moreover, the doctrine incentivizes patent applicants to overdisclose information to the PTO, thereby decreasing the efficiency of PTO examiners.³ Scholars and practitioners have extensively discussed these problems and have called for reform.⁴

In *Therasense, Inc. v. Becton, Dickinson & Co.*,⁵ the Federal Circuit granted a request for an en banc hearing regarding inequitable conduct,⁶ signaling the court’s recognition of the need to resolve issues surrounding the doctrine. Although the court appears to have

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

2. Randall R. Rader, *A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Foreword: Always at the Margin: Inequitable Conduct in Flux*, 59 AM. U. L. REV. 777, 782 (2010).

3. See *infra* Part II.

4. See, e.g., David McGowan, *Inequitable Conduct*, 43 LOY. L.A. L. REV. 945, 946 (2010); Benjamin Brown, Comment, *Inequitable Conduct: A Standard in Motion*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 593, 593–94 (2009).

5. 374 F. App’x 35 (Fed. Cir. 2010) (per curium), *opinion reinstated in part*, 649 F.3d 1276 (Fed. Cir. 2011).

6. *Id.* Abbott Diabetes Care, Inc. (“Abbott”), the successor to Therasense, Inc. and a subsidiary of Abbott Laboratories, brought a patent infringement suit against defendants Becton, Dickinson and Co., its supplier Nova Biomedical Corp., and Bayer HealthCare LLC, for Abbott’s U.S. Patent No. 5,820, 551 (the “’551 patent”). *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1293 (Fed. Cir.), *vacated*, 374 F. App’x 35 (Fed. Cir. 2010) (per curium), *opinion reinstated in part*, 649 F.3d 1276 (Fed. Cir. 2011). The defendants then asserted that their products did not infringe Abbott’s patents and that the patents were invalid. *Id.* Subsequently, the District Court held the ’551 patent unenforceable due to inequitable conduct. *Id.* On appeal, the Federal Circuit affirmed the district court’s holding. *Id.* at 1311. However, the majority and dissent viewed materiality and intent differently. *Id.* at 1312 (Linn, J., concurring in part and dissenting in part).

reshaped the doctrine,⁷ its 6–1–4 decision also shows how the Federal Circuit features many varying viewpoints. Moreover, some scholars have already suggested that the optimistic majority may not have fashioned a test to cure all of the doctrine’s problems.⁸ Thus, the story surrounding inequitable conduct may not be over.⁹

Prior to the en banc hearing, the Federal Circuit not only asked the parties to file briefs addressing the current standards of the doctrine but also called for amici to voice their concerns on the matter.¹⁰ More than thirty amicus briefs, each articulating its own viewpoint on inequitable conduct, were filed.

Amici importantly represent patentees, the “fourth pillar” of the patent system.¹¹ The courts are responsive to the differing roles of patents in the myriad industries affected by patent law,¹² and the courts often turn to amicus briefs, which provide an important source of information regarding the role of patents within varying innovation contexts.¹³ The Federal Circuit has stated that the number and diversity of the briefs “reflect the complexity of these [commercial and societal] concerns,” which lies “not in the fate of these litigants and these long-expired patents” but “in the way this judge made law affects technologic innovation and competition.”¹⁴ Furthermore, amicus briefs can influence the courts—including the Federal Circuit and the Supreme Court—and appear to be more cost-

7. See *infra* Part II.C.

8. Jason Rantanen & Lee Petherbridge, *Therasense v. Becton Dickinson: A First Impression*, (Aug. 5, 2011) (unpublished essay), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1859764.

9. In July 2011, the PTO proposed “to revise the materiality standard for the duty to disclose information to the [PTO] in patent applications and reexamination proceedings set forth in §§ 1.56(b) and 1.555(b) in light of the Federal Circuit’s decision in *Therasense*.” Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43631, 43632 (proposed July 21, 2011) (to be codified as amended at 37 C.F.R. pt. 1). The PTO even sought comments concerning the proposed rule change. *Id.*

10. *Therasense*, 374 F. App’x at 35. For a discussion of the en banc holding, see *infra* Part II.

11. The three other pillars are represented by Congress, the courts, and the PTO. Colleen V. Chien, *Patent Amicus Briefs: What the Courts’ Friends Can Teach Us About the Patent System 5* (Santa Clara Univ. Legal Studies Research, Paper No. 10–05, 2010), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1608111&rec=1&srcabs=1656568.

12. *Id.* at 6 (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006); *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627 (1999)).

13. *Id.* at 3.

14. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1379 (Fed. Cir. 2003).

effective than lobbying Congress is; thus, because of their effectiveness, the briefs are an attractive means for commentators to voice concerns.¹⁵ Because of these advantages, amicus interest is at an all-time high.¹⁶

Amicus briefs constitute a key source of empirical data for studying the patent system.¹⁷ For example, Colleen V. Chien found that patentees and their lawyers, “creators” of the patents, composed 75 percent of briefs that were filed in the Supreme Court and Federal Circuit from 1989 to 2009.¹⁸ The remaining 25 percent were filed by public interest advocates and “consumers” of patented goods, such as citizen groups, governments, and academics.¹⁹ Moreover, Chien determined that the Supreme Court ruled in alliance with the position that the United States advocated in every instance but one.²⁰ According to Chien’s findings, amicus briefs that the United States and PTO filed predicted the prevailing party in 90 percent of Supreme Court cases and in 80 percent of Federal Circuit cases.²¹ Additionally, Chien found that a company’s business model can predict the position that it would take in any amicus brief.²² For example, patent holding companies and universities—which often have limited exposure as patent defendants yet often have significant opportunities as patent licensors or plaintiffs—heavily favor strong patent rights for the patentee, while public companies often oppose the patentee.²³

Analysis of the thirty-four briefs that were filed in *Therasense* can shed light on the various commercial and societal concerns of patent law and, most importantly, on the impact of inequitable conduct on these myriad interests. Moreover, because amicus briefs significantly influence the Federal Circuit, these briefs can also provide insight into how inequitable conduct should be changed.

15. Chien, *supra* note 11, at 6.

16. For example, more than sixty-five non-party amicus briefs were filed in the recent Supreme Court case *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). *Id.* at 4.

17. *Id.* at 5–6.

18. *Id.* at 13, 15–16.

19. *Id.* at 16–17.

20. *Id.* at 31.

21. *Id.*

22. *Id.* at 34.

23. *Id.* at 25.

Part II.A discusses the historical development of inequitable conduct, and Part II.B presents the numerous drawbacks of the doctrine that caught the attention of an en banc panel of the Federal Circuit. Part II.C discusses the recent en banc *Therasense* decision and suggests that the test may not be a cure-all for the doctrine. Part III briefly describes the design and methodology that this Note employs in analyzing these amicus briefs, including an explanation of why this Note's study is important. Part IV presents a summary and analysis of data that are gathered from the briefs; it focuses particularly on the doctrinal components of materiality, intent, and the balancing step. Part IV also includes a comparison to Chien's findings in an attempt to highlight any revelations that are unique to inequitable conduct. Part V proposes a solution that differs slightly from that in the recent *Therasense* decision and that focuses on the three main prongs of inequitable conduct in light of the different arguments that the amici proposed: (1) the maintenance of specific intent to deceive as the standard for intent; (2) the elimination of sliding scale formulations of the balancing step, and the maintenance of the harsh penalty of unenforceability; and (3) the use of 37 C.F.R. § 1.56 ("Rule 1.56") as the standard for materiality with delineated factors for courts to use in determining if information is material.

II. INEQUITABLE CONDUCT: PRE- AND POST-*THERASENSE*

A. *Historical Development*

Inequitable conduct is a judicially created doctrine that originated from a trilogy of Supreme Court cases.²⁴ In each of these cases, the entire patent acquisition and enforcement process had been tainted with egregious fraud, perjury, and extortion; without such fraudulent conduct, the patent right would not have been enforceable.²⁵ The only remaining question for the Supreme Court was how the fraudulent conduct should affect the patentee's case.²⁶

24. Rader, *supra* note 2, at 779–80; see *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by* *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933).

25. Rader, *supra* note 2, at 779, 781.

26. *Id.* at 779–80.

The trilogy culminated in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*,²⁷ where the Supreme Court fashioned an inequitable conduct defense from the equitable doctrine of unclean hands.²⁸ Although the Supreme Court did not articulate a specific test or provide detailed guidance on inequitable conduct, the doctrine developed over the next few decades with influences from the courts and the PTO.²⁹

An alleged patent infringer may assert inequitable conduct as an affirmative defense to patent infringement when an applicant violates the duty of candor and good faith.³⁰ As the doctrine stood prior to the en banc holding in *Therasense*, inequitable conduct was composed of (1) materiality; (2) intent; and (3) an equitable balancing step.³¹ A finding of inequitable conduct rendered the entire patent unenforceable and could even have adversely affected other related patents.³² Because of its harsh penalties, inequitable conduct satisfied two important goals: (1) enforcing the “duty of good faith and fair dealing that binds patent applicants in dealing with the public”; and (2) protecting the “social utility of the patent system, i.e., it attempts to diminish the probability that unscrupulous individuals wrongfully obtain undeserved rents.”³³

Materiality, the first element, focused on whether affirmative misrepresentations or omissions of information were material;³⁴ this element also still applies post-*Therasense*. During the ex parte

27. 324 U.S. 806 (1945).

28. *Id.* at 815–16, 819–20.

29. *See, e.g.*, Brown, *supra* note 4, at 597. In fact, the PTO created Rule 1.56 in response to the *Precision* Court’s decision; Rule 1.56 was subsequently amended over the following decades, and it reached its present form in 1992. *Id.* at 597, 600. For a discussion of Rule 1.56, see *infra* notes 35–39 and accompanying text.

30. *See, e.g.*, Kevin Mack, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 147–48 (2006) (citing DONALD S. CHISUM, CHISUM ON PATENTS § 19.03[6][b][ii] (2004)).

31. *See, e.g.*, Lee Petherbridge et al., *The Federal Circuit and Inequitable Conduct: An Empirical Assessment*, 84 S. CAL. L. REV. (forthcoming 2011) (manuscript at 6), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1686102.

32. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (“When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is unenforceable.”); *see also* *Lummus Indus., Inc. v. D.M. & E. Corp.*, 862 F.2d 267 (Fed. Cir. 1988) (holding several patents unenforceable after determining that inequitable conduct occurred).

33. Petherbridge et al., *supra* note 31, at 3 n.2.

34. *See* *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998).

process of obtaining a patent, patent applicants had to abide by Rule 1.56 while they dealt with the PTO,³⁵ as they still must do today. The rule imposes a “duty of candor and good faith” on “[e]ach individual associated with the filing and prosecution of a patent application.”³⁶ This includes a “duty to disclose to the Office all information known to that individual to be material to patentability” that extends to all pending claims.³⁷ According to subsection (b) of Rule 1.56:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office or (ii) Asserting an argument of patentability.³⁸

The rule additionally states that a prima facie case of unpatentability is established “when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence.”³⁹ Thus, the PTO explicitly defined a materiality standard and the appropriate level of disclosure necessary for a patentee to satisfy the PTO’s regulations. Although several standards existed for finding information as material,⁴⁰ courts typically used the “reasonable examiner” test, which evaluates if a reasonable examiner would have considered the information “important in deciding whether to allow the application to issue as a patent.”⁴¹

35. 37 C.F.R. § 1.56(a) (2010); Petherbridge, *supra* note 31, at 4.

36. 37 C.F.R. § 1.56(a).

37. *Id.*

38. *Id.* § 1.56(b).

39. *Id.*

40. *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315–16 (Fed. Cir. 2006) (“[T]he objective ‘but for’ standard, where the misrepresentation was so material that the patent should not have issued; the subjective ‘but for’ test, where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; the ‘but it may have’ standard, where the misrepresentation may have influenced the patent examiner in the course of prosecution. . . . [; and Rule 1.56,] yet a fourth ‘official standard.’” (citations omitted)).

41. *Id.* at 1315 (quoting 37 C.F.R. § 1.56).

The second element of inequitable conduct required the court to determine whether the patent applicant intended to deceive or mislead the PTO;⁴² this prong remains a key component of the doctrine today. Intent to deceive did not need to be proven by direct evidence, but could have been inferred from the surrounding circumstances of the applicant's alleged conduct.⁴³ Prior to *Therasense*, the only clear doctrinal constraint on intent to deceive was that it had to be greater than gross negligence.⁴⁴

Both materiality and intent had to be proven by clear and convincing evidence.⁴⁵ Once threshold levels of both elements were satisfied, courts balanced all of the evidence to determine whether the applicant behaved inequitably, and courts ultimately concluded whether the conduct was sufficiently culpable to warrant a finding of unenforceability.⁴⁶ During the balancing step, some courts considered a "sliding scale," where a higher level of materiality allowed a court to accept a lower level of intent as sufficient for a finding of inequitable conduct.⁴⁷

Because materiality and intent to deceive were conclusions of ultimate fact based on broad factual inquiries, these elements were only "reviewed for clear error or substantial evidence" on appeal.⁴⁸ Moreover, appellate courts reviewed the balancing step by applying an abuse of discretion standard, an even more deferential form of review.⁴⁹ Thus, alleged infringers who were victorious at the trial level in demonstrating a patentee's inequitable conduct secured judgments that received some insulation from appellate courts due to the deferential standard of review.⁵⁰

42. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 873 (Fed. Cir. 1988).

43. *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1329 (Fed. Cir. 1998).

44. Petherbridge et al., *supra* note 31, at 6.

45. *E.g.*, *Digital Control*, 437 F.3d at 1313.

46. *Id.*

47. *E.g.*, *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 716 (1st Cir. 1981) ("Questions of 'materiality' and 'culpability' are often interrelated and intertwined, so that a lesser showing of the materiality of withheld information may suffice when an intentional scheme to defraud is established, whereas a greater showing of the materiality of withheld information would necessarily create an inference that its nondisclosure was 'wrongful.'").

48. Petherbridge et al., *supra* note 31, at 7 (citations omitted).

49. *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693–94 (Fed. Cir. 2001).

50. Petherbridge et al., *supra* note 31, at 7.

*B. Inequitable Conduct's
Shortcomings*

Although the three elements of inequitable conduct were well known, the test remained vague, causing some scholars to complain of pervasive confusion and varying applications by the courts. The unclear standards and harsh punishment associated with the doctrine yielded several drastic consequences, impacting the patentees and their industries, the court system, the PTO, and patent agents and attorneys.

A scholar even described the remedy for inequitable conduct as “death-penalty-like.”⁵¹ Denial of patent protection for the entire length of the patent term could result from a patent applicant’s failure to disclose information to the PTO without regard to any inherent traits of the patented invention itself. Thus, a finding of inequitable conduct rendered the entire patent unenforceable and prevented the patentee from asserting the patent’s claims against other infringers.⁵² This harsh penalty could even extend to related patents, rendering those unenforceable as well.⁵³ Furthermore, a finding of inequitable conduct may make a case “exceptional” and thus entitle the accused infringer to attorney fees, which can easily reach into the seven-figure range.⁵⁴ The patentee may even be exposed to antitrust liability.⁵⁵

Inequitable conduct has been viewed as a “plague” on the court system.⁵⁶ Because of the vagueness of the doctrine and the complete unenforceability of the patent upon a finding of inequitable conduct, the defense has become too attractive an advantage for an accused patent infringer to ignore.⁵⁷ Consequently, the accused infringers are incentivized to assert the defense whenever possible, including asserting the defense to infringement claims relating to patents that the defendants have not even been accused of infringing; moreover,

51. Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 725 (2009).

52. *Id.* at 764.

53. *See* *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 809 (Fed. Cir. 1990) (holding several patents unenforceable after finding inequitable conduct).

54. Cotropia, *supra* note 51, at 764 (citing 35 U.S.C. § 285 (2006)).

55. *Id.*

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

57. *E.g.*, Christian E. Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1329, 1346 (2009).

accused infringers take advantage of the vague standards of the doctrine by strategically choosing particular articulations of the test that are most favorable to their cases.⁵⁸ Alleged infringers have asserted the defense in approximately 25 percent of all patent cases that have been filed, a number that even judges view as inappropriately high.⁵⁹

Asserting the defense of inequitable conduct also creates exorbitant litigation costs.⁶⁰ Considering that the subjective element of intent often involves circumstantial evidence, summary judgment is particularly difficult, and thus litigation becomes costly.⁶¹ Additionally, deposing the prosecuting attorney who handled the application is almost always necessary in these cases, but such depositions often involve complex attorney-client privilege issues, requiring their own additional attorneys and judicial resources to resolve.⁶² The actual validity of the patent becomes irrelevant to the doctrine as determinations of inequitable conduct turn into “satellite litigations where the effort expended has little spillover benefits for other parts of the litigation.”⁶³ Unfortunately, the amount of time and effort spent on the defense tends to turn attention away from the actual core issues of a case—the validity and infringement of the patent at issue—and “hamper their complete and correct resolution.”⁶⁴

The doctrine also adversely impacts the PTO. Inequitable conduct requires only material information to be submitted, places no weight on the quantity of information that is submitted, and urges the patent applicant to avoid the submission of cumulative information.⁶⁵ However, because of the doctrine’s harsh penalty of unenforceability and the excessive litigation costs compared to the low cost of simply submitting all information in one’s possession to the PTO, the

58. *Id.* at 1346.

59. Cotropia, *supra* note 51, at 739–40 (citing *Burlington Indus.*, 849 F.2d at 1422; *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1454 (Fed. Cir. 1984); FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 156 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>).

60. *Id.*

61. *Id.* at 740.

62. *Id.*

63. *Id.*

64. *Id.*

65. See 37 C.F.R. § 1.98 (2008); Cotropia, *supra* note 51, at 763, 770.

doctrine actually incentivizes patent applicants to err on the side of quantity.⁶⁶ Thus, as applicants disclose information that was only remotely relevant to the claimed subject matter, PTO examiners receive loads of information that are increasingly immaterial to the determination of patentability.⁶⁷ Moreover, PTO examiners are already overworked as they face an increasing number of applications with a decreasing amount of time.⁶⁸ Considering the highly technical information (the patent application and prior art) that the examiners must already process, abundant information that the applicant submits significantly overloads the examiner.⁶⁹ Similarly, overdisclosure may lead an examiner to waste time on immaterial information or even cause the examiner to become so overwhelmed that the examiner will ignore the applicant's submission completely.⁷⁰ Thus, "[t]he bigger the haystack, the more lost a needle becomes," and the harm of the overload can negatively impact the examiner's ability to reach a proper conclusion on the application's patentability.⁷¹

A finding of inequitable conduct may also affect patent agents or attorneys. A failure on behalf of the agents and attorneys to comply with the doctrine can become the basis of malpractice suits and lead to disciplinary action before the PTO.⁷² Agents and attorneys may even lose their licenses to practice before the PTO.⁷³ Attorneys' conduct may be referred to their state bar, which can also impose discipline or revoke attorneys' general licenses to practice law.⁷⁴ Furthermore, personal costs may also be at stake, including one's reputation within the patent community and with the PTO.⁷⁵

66. Cotropia, *supra* note 51, at 763, 770.

67. *Id.* at 770.

68. *Id.* at 771.

69. *Id.*

70. *Id.*

71. *Id.* at 771–72.

72. See Edwin S. Flores & Sanford E. Warren, Jr., *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent and Trademark Office*, 8 TEX. INTELL. PROP. L.J. 299, 314–15 (2000); David Hricik, *How Things Snowball: The Ethical Responsibilities and Liability Risks Arising from Representing a Single Client in Multiple Patent-Related Representations*, 18 GEO. J. LEGAL ETHICS 421, 459 (2005).

73. Flores & Warren, *supra* note 72, at 314–15.

74. Cotropia, *supra* note 51, at 766 (citing Flores & Warren, *supra* note 72, at 314–15).

75. *Id.* at 763 (citing Kelly Merkel, *How to Stump a Corporate Lawyer: Means of Effective Legal Risk Management for IP Counsel*, 1 J. LEGAL TECH. RISK MGMT. 1, 3 (2006)).

Inequitable conduct may also undermine innovation, which would be directly contrary to the patent system's goals of fostering discovery, development, and investment of innovations.⁷⁶ Small companies without experience or the resources that they need to prosecute their patent applications may not be able to minimize their vulnerability to allegations of inequitable conduct. For example, scientists and managers at these companies may act in good faith by undertaking a commonsense approach to disclosing information and yet will fail to realize that infringers may later turn their actions into material and intentional omissions.⁷⁷ Fearing the threat of the consequences of inequitable conduct, investors in small companies may never spend the money that the companies need to turn innovative ideas into commercial products.⁷⁸

Yet, despite these shortcomings, some proponents of inequitable conduct argue that the doctrine polices conduct during the *ex parte* patent-application process before the PTO and thus remains useful.⁷⁹ The PTO issues an estimated 85 percent to 97 percent of filed patents, and thus, due to this high rate of issuance, it is quite likely that improperly granted patents do exist.⁸⁰ Such patents can incur significant social and economic costs, but the doctrine can remedy these problems by preventing undeserving patentees from asserting infringement.⁸¹

C. *Post-Therasense* *Inequitable Conduct*

The 6–1–4 en banc decision attempted to cure the ills of the doctrine and “tighten[] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to

76. *See* *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (stating that the patent system “promotes disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires”).

77. Brief of Amici Curiae Johnson & Johnson and the Procter & Gamble Co. in Support of Neither Party at 3, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390238.

78. *See id.* at 4.

79. *See, e.g.*, Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 147 (2005).

80. NAT'L RESEARCH COUNCIL, *A PATENT SYSTEM FOR THE 21ST CENTURY* 53 (Stephen A. Merrill et al. eds., 2004).

81. Nolan-Stevaux, *supra* note 79, at 148.

the detriment of the public.”⁸² The majority held that “but for” materiality is required for a finding of inequitable conduct; in making such a patentability determination, courts should apply the preponderance of the evidence standard.⁸³ However, the majority also delineated a critical exception: “When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.”⁸⁴ The majority also clarified that “neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct.”⁸⁵

To satisfy the intent element, the court held that an accused infringer “must prove that the [applicant misrepresented or omitted material information] with the specific intent to deceive the PTO.”⁸⁶ Simply showing that an applicant “knew of a reference, should have known of its materiality, and decided not to submit it to the PTO” does not satisfy this standard.⁸⁷

The court also demolished sliding scale formulations of the balancing step.⁸⁸ Once materiality and intent are separately proven by clear and convincing evidence,⁸⁹ a patent is only rendered unenforceable “where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”⁹⁰

Both the dissent and Judge O’Malley, who wrote an opinion concurring in part and dissenting in part, agreed with the majority’s standard for intent and its requirement that intent and materiality be separately proven by clear and convincing evidence.⁹¹ However, the dissent argued that “[s]ince its first days, this court has looked to the PTO’s disclosure rule, Rule 56 . . . as the standard for defining materiality.”⁹² The dissent believed that “the PTO is in the best

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

83. *Id.* at 1291–92.

84. *Id.* at 1292.

85. *Id.* at 1292–93.

86. *Id.* at 1290.

87. *Id.*

88. *Id.*

89. *Id.* at 1290, 1292.

90. *Id.* at 1292.

91. *Id.* at 1302 (Bryson, J., dissenting); *id.* at 1297 (O’Malley, J., concurring in part and dissenting in part).

92. *Id.* at 1303 (Bryson, J., dissenting) (citation omitted).

position to know what information examiners need to conduct effective and efficient examinations”; moreover, the dissent argued that the majority’s “higher standard of materiality . . . will not provide appropriate incentives for patent applicants to comply with the disclosure obligations the PTO places upon them.”⁹³

However, O’Malley believed that both the majority and the dissent “eschew flexibility in favor of rigidity,” and she disagreed with both approaches to materiality, finding that both “fail to provide district courts with flexibility to find inequitable conduct in an extraordinary case where the conduct in question would not be defined as such under either test.”⁹⁴ O’Malley structured a test that she believed would allow district courts to exercise their discretion in inequitable inquiries, thereby respecting Supreme Court precedent that reflected the Court’s recognition of courts of equity.⁹⁵ She argued that conduct should be deemed material where:

(1) but for the conduct . . . , the patent would not have issued . . . ; (2) the conduct constitutes a false or misleading representation of fact . . . ; or (3) the district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined.⁹⁶

The en banc panel’s disagreement over materiality indicates that the doctrine’s reformation may not necessarily be complete. Moreover, scholars are already questioning the majority’s optimistic proclamations that the doctrine has been fixed for the better.⁹⁷ Thus, the story of the doctrine’s development likely continues.

III. DESIGN AND METHODOLOGY

The Federal Circuit recognized the need to reform the doctrine of inequitable conduct and sought the insight from amicus briefs on how the doctrine should be reformed. Amicus briefs generally represent a useful source of information that can shed insight into the

93. *Id.*

94. *Id.* at 1298 (O’Malley, J., concurring in part and dissenting in part).

95. *Id.* at 1298–99.

96. *Id.* at 1300.

97. *See* Rantanen & Petherbridge, *supra* note 8.

many aspects of patent law and can even impact a court's decision. The briefs filed in *Therasense* particularly highlighted the need to address the issues of inequitable conduct, and they illustrated the varying opinions—emanating from various facets of patent law—on how to alleviate the doctrine's problems.

The diversity of interests within patent law can be better understood by analyzing how patent stakeholders cluster in their amicus briefs.⁹⁸ Colleen V. Chien previously undertook a large empirical study of amicus briefs that were filed in Supreme Court and Federal Circuit patent cases for the last twenty years in an attempt to better understand the patent system.⁹⁹ Comparing the stance of the amici in *Therasense* with the stances of amici in Chien's findings can further validate her results. Additionally, any differences with Chien's findings may reveal aspects that are unique to inequitable conduct. For example, would patent practitioners with more at stake when they are faced with this affirmative defense argue differently than they would in other contexts of patent law? Such insight can prove useful in considering how inequitable conduct should be reformed.

The author collected the *Therasense* amicus briefs¹⁰⁰ and categorized them into the following groups: (1) the PTO; (2) bar associations and intellectual property associations; (3) intellectual property professors and intellectual property centers in academia; (4) public interest groups; and (5) industry, which is further subdivided into bio/pharma companies, high-tech companies, non-practicing entities (NPEs), and trade associations. Each brief was specifically analyzed for its arguments on materiality, intent, and the balancing step.

After considering the standards for each of these three prongs and the corresponding levels of stringency that are required for application of the standards, the author drew conclusions on whether the amici favored patentee or non-patentee standards for inequitable conduct. For this discussion, the author assumed that a pro-patentee stance favors stringent standards for inequitable conduct, making it

98. Chien, *supra* note 11, at 6.

99. *Id.*

100. The briefs were collected either through Westlaw or by accessing PDF files from Tony Dutra, *Therasense Briefs Ask Federal Circuit to Fix Inconsistency in Inequitable Conduct Rulings*, 80 PAT. TRADEMARK & COPYRIGHT J. 814 (2010).

difficult for an alleged infringer to successfully assert the defense.¹⁰¹ For arguments of materiality, the author considered that the “reasonable examiner” test is the weakest and most in favor of non-patentees. The author also concluded that an “objective but for” test is the most stringent standard and strongly favors patentees while Rule 1.56 falls in between these two extremes. For intent, the author considered “specific intent to deceive” to be a stringent standard that highly favors patentees; on the other hand, a “should have known” standard would highly favor non-patentees.

Lastly, an unclear framework for the balancing step, when it is combined with heightened standards for materiality and intent, may adversely affect patentees by allowing for findings of inequitable conduct where there may not be any if a court had considered only the first two prongs. On the other hand, a carefully delineated standard for the balancing step and its strict application serves as an additional requirement that must be met to support a finding of inequitable conduct and thus likely favors patentees. Therefore, the author considered that the elimination of a balancing step without specific guideposts, such as a sliding scale formulation, and the clarification of an appropriate standard of this prong are pro-patentee; those who argue for the test’s continuance in its vague state favor non-patentees. Moreover, arguments for matching the penalty to the conduct, and thus implementing less harsh remedies as opposed to only applying unenforceability in all instances, are also viewed as pro-patentee.

The analysis that is presented in Part IV will include a comparison to Chien’s conclusions within each category based on her studies and a discussion of whether the briefs confirm perceptions of patent interests within particular categories.¹⁰²

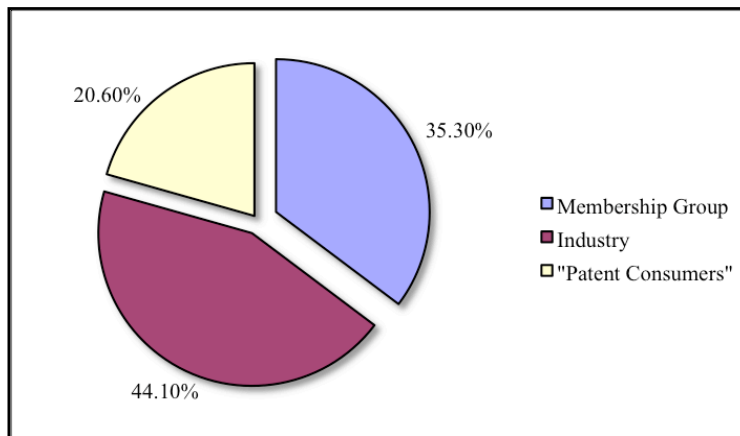
101. However, exceedingly difficult standards may also inadvertently lead to other consequences that may be harmful to patentees. Such high standards would likely make a finding of inequitable conduct exceptionally rare, allowing bad actors to obtain and enforce patents on innovations that likely do not deserve protection and would impute significant costs onto others within the system who act in good faith. See David Hricik, *Aerial Boundaries: The Duty of Candor as a Limitation on the Duty of Patent Practitioners to Advocate for Maximum Patent Coverage*, 44 S. TEX. L. REV. 205, 222 (2002) (“Large numbers of improvidently granted patents may create *in terrorem* effects on entrepreneurship, ranging from holdup licensing to patent thickets.”). Thus, stringent standards for inequitable conduct may not necessarily form a pro-patent system.

102. The Author acknowledges that some results discussed below may be the result of a small sample size.

IV. RESULTS:
ANALYZING AMICI'S
ARGUMENTS

In *Therasense*, various amici, ranging from the PTO to an intellectual property association composed of law students, filed a total of thirty-four amicus briefs. Here, industry groups (including companies and trade associations) and membership groups composed of intellectual property attorneys and agents, represented 44.1 percent and 35.3 percent of the total briefs, respectively. Together, these two groups accounted for nearly 80 percent of the amicus briefs that were filed in this case. "Patent consumers" (including the government), public interest groups, and academics (including professors and a university's center for intellectual property law) represented the remaining 20.6 percent of the briefs.

FIGURE 1. The *Therasense* Amici



These results confirm the trend identified by Chien, who also found that IP lawyers and industries ("patent creators") represented 75 percent of the briefs that she studied, while citizen groups, governments, and academics ("patent consumers") filed the remaining briefs.¹⁰³ This trend demonstrates that the patent system is primarily focused on private interests; however, this is unsurprising considering the low number of consumer groups that are focused on

103. Chien, *supra* note 11, at 16.

patent issues, especially compared to the large number of groups that are focused on the interests of patent owners and attorneys.¹⁰⁴

A. *The PTO*

The PTO unsurprisingly asserted that its own standard of materiality, Rule 1.56, should be adopted for three main reasons: (1) the agency is in the best position to know what information is essential for determining patentability; (2) the rule presents clear guidance for applicants; and (3) the rule is consistent with Supreme Court precedent.¹⁰⁵ By contrast, a narrow “but for” standard, where the patent would not have issued “but for” the misconduct, would allow applicants to freely “engage in a wide-variety of misconduct . . . so long as it cannot be proven later that the patent would not have issued ‘but for’ the misconduct.”¹⁰⁶ According to the PTO, a “reasonable examiner” standard is simply too ambiguous and fails to provide meaningful guidance.¹⁰⁷

The PTO further argued that the proper standard for intent should be a specific intent to deceive, which would calm the fears of patent applicants and attorneys that drive them to overdisclose information to the PTO.¹⁰⁸ A court may not infer intent solely from materiality, but the accused infringer must prove both elements separately by clear and convincing evidence.¹⁰⁹

According to the PTO, given the doctrine’s equitable nature, it would be inappropriate for a court to automatically hold a patent unenforceable after the court finds that both the materiality and intent prongs have been satisfied; therefore, the last element of the test should not be abolished.¹¹⁰ Instead, the PTO urged the court to clarify that the balancing step consists of neither a sliding scale nor a rigid rule but rather requires a court to consider all of the evidence to determine whether an unenforceability penalty is warranted only

104. *Id.* at 17.

105. Brief for the United States as Amicus Curiae on Rehearing En Banc in Support of Neither Party at 8–12, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390234, at *8–12.

106. *Id.* at 12–13.

107. *Id.* at 16–17.

108. *Id.* at 17, 18–22.

109. *Id.* at 25–26.

110. *Id.* at 25.

after the accused infringer successfully establishes materiality and intent by clear and convincing evidence.¹¹¹

The PTO's stance for the application of Rule 1.56 did not entirely favor patentees. However, the PTO's support for a specific intent to deceive test indicated its pro-patentee viewpoint. Yet, the PTO's call for clarification of the balancing test may tend to favor patentees; additionally, its argument that courts should apply the harsh penalty only under limited circumstances indicated more of a preference for patentees. Thus, the PTO's proposed standards for reforming inequitable conduct may lean toward a pro-patentee stance. This result tends to conflict with that in Chien's study, which found that the government often tended to favor non-patentees.¹¹² Perhaps the PTO's unexpected stance here signals its concern with the impact of inequitable conduct on the PTO, including such adverse consequences as overdisclosure and decreased efficiency by the PTO examiners. Thus, the PTO's argument should carry significant weight.¹¹³

*B. Bar Associations
and Intellectual
Property Associations*

Patent attorneys and agents, who are represented by bar and intellectual property associations, are typical amicus filers. In fact, in the briefs that Chien analyzed, six such associations reached her list of the "Top Ten" of all patent amici for their prolific brief filings;¹¹⁴ four of these six filed briefs in *Therasense*. A total of twelve different membership groups—composed of patent attorneys, patent agents, and even intellectual property law students¹¹⁵—accounted for

111. *Id.* at 25–26.

112. Chien, *supra* note 11, at 26.

113. Notably, Chien also points out that federal government amici accurately predicted the winner in 90 percent of Supreme Court cases and in 80 percent of Federal Circuit cases. *Id.* at 31. However, the en banc panel disagreed with the PTO's materiality view. *Compare* *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1293 (Fed. Cir. 2011) ("This court does not adopt the definition of materiality in PTO Rule 56."), *with* Brief for the United States as Amicus Curiae on Rehearing En Banc in Support of Neither Party at 13, *supra* note 105 (criticizing the "but for" standard). Perhaps, considering Chien's findings, the Supreme Court's holding may side with the PTO if questions regarding inequitable conduct are ever raised before the Court and the Court considers them.

114. Chien, *supra* note 11, at 20.

115. These include: Twenty-two patent prosecution firms and practitioners, American Bar Association (ABA), American Intellectual Property Law Association (AIPLA), Boston Patent

35 percent of the total number of amicus briefs that were filed in *Therasense*. In Chien's findings, membership groups only accounted for 17 percent of the amici that she studied.¹¹⁶ Although the sample sizes may account for this difference in percentages, it is possible that these findings illustrate a heightened interest of attorneys and agents because of the potential personal consequences that they face with inequitable conduct.

Four associations (AIPA, IPO, BPLA, and SDIPLA) and Patterson vouched for an objective "but for" materiality standard while WSPLA and FCBA supported the PTO's Rule 1.56(b)(1) and (b)(1-2), respectively. Interestingly, WSPLA also recommended that common-law fraud should serve as the basis for inequitable conduct's standards, where a misrepresentation or omission would be material only when at least one claim would not have issued; however, WSPLA also posited that this standard remains consistent with Rule 1.56(b)(1) since the failure of the prima facie test would correlate with the failure of the "but for" standard.¹¹⁷ Also of note, HIPLA advocated for a "middle ground" approach that falls between a reasonable examiner standard and a "but for"-type test: "information is 'material' if it was material under the PTO rules applicable at the time of the examination of the patent at issue."¹¹⁸

In considering intent, these amici appeared to agree that intent is a separate element from materiality and cannot be inferred from a high level of materiality alone. Such an inference would only be appropriate where it is the "single most reasonable inference" to be drawn from the evidence. Gross negligence would not be sufficient.¹¹⁹

Law Association (BPLA), Conejo Valley Bar Association (CVBA), Federal Circuit Bar Association (FCBA), Houston Intellectual Property Law Association (HIPLA), Intellectual Property Owners Association (IPO), Intellectual Property Law Association of Chicago (IPLAC), Patterson Thunte Christensen Pedersen, P.A. (Patterson), San Diego Intellectual Property Law Association (SDIPA), University of Kentucky Intellectual Property Law Association (UKIPLA), and Washington State Patent Law Association (WSPLA). Patterson is a mid-size intellectual property firm, but is placed in this category for simplicity and on the assumption that the firm's concerns mirrors those of the other groups.

116. Chien, *supra* note 11, at 16.

117. Amicus Curiae Brief by Washington State Patent Law Ass'n Supporting Neither Party at 10, 15, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595).

118. Brief of the Houston Intellectual Property Law Ass'n as Amicus Curiae in Support of No Party at 8, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390231, at *8; *see infra* Table 1.

119. *See infra* Table 1.

Several amici in this category argued for the removal of the balancing step and a return to the principles of common-law fraud.¹²⁰ Although SDIPLA also argued for the balancing framework to be removed, it also advocated a slightly different proposition: find inequitable conduct when information that the patentee intentionally withheld or misrepresented meets or exceeds Rule 1.56 and tailor an appropriate remedy where unenforceability is imposed only if the nature of the withheld or misrepresented information exceeds an objective “but for” standard.¹²¹ On the other hand, three amici (FCBA, IPO, and HIPLA) actually supported the balancing step; however, FCBA and IPO also argued that the court must clarify the importance of this step, which the court should only use as an exercise of its equitable discretion and where it weighs materiality and intent to determine if unenforceability is warranted.¹²² Other amici, such as CVBA and WSPLA, also echoed the argument that the penalty should be based on the degree of the inequitable conduct.¹²³

Within this category, several amici appeared to support a “but for” materiality standard that strongly favors patentees; others who addressed the prong argued for standards that clearly favor neither pro- nor anti-patentees. A stable consensus could be found within intent, where a significant majority of this category of amici supported a stringent intent standard. Moreover, several of these amici supported the removal of the balancing step or a return to common-law fraud principles, standards that would likely increase a

120. See, e.g., Brief and Appendix of the American Bar Ass’n as Amicus Curiae at 19–20, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 2751537, at *16 (“[A] better standard for determining inequitable conduct is one where the following elements have been shown, each by clear and convincing evidence: (1) a person having a duty of candor and good faith to the PTO misrepresented or omitted material information from the PTO; (2) in the absence of such misrepresentation or omission, the PTO, acting reasonably, would not have granted or maintained in force at least one patent claim; and (3) the misrepresentation or omission was made with a specific intent to deceive the PTO, which intent cannot be established by the mere materiality of the misrepresentation or omission.”).

121. Brief of Amicus Curiae San Diego Intellectual Property Law Ass’n in Support of Neither Party at 5, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390230, at *5.

122. Brief of the Federal Circuit Bar Ass’n as Amici Curiae in Support of No Party at 3, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390230, at *3; Brief of Intellectual Property Owners Ass’n in Support of Neither Party at 14, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595).

123. Brief of Amicus Curiae Conejo Valley Bar Ass’n at 6, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595); see *infra* Table 1.

court's difficulty in finding inequitable conduct and therefore favor a patentee. Arguments ensuring that the penalty matches the conduct also illustrated these amici's concerns for patentees. Thus, overall, this category appeared to somewhat favor patentees.¹²⁴

Chien found that, although bar associations and intellectual property associations are generally perceived as pro-patentee, they only filed briefs on behalf of patentees 55 percent of the time.¹²⁵ But, considering that patent attorneys and agents face personal consequences that are as harsh as disbarment due to a finding of inequitable conduct, it seems unsurprising that the associations representing them would argue for stringent standards and that the *Therasense* case would be a predictable opportunity for these groups to file briefs on behalf of the patentees.

124. See *infra* Table 1. One amicus even argued that the conduct be based entirely on "objectively lawful standards," which would serve the public interest. Brief of Amicus Curiae University of Kentucky Intellectual Property Law Society in Support of Neither Party at 17, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595).

125. Chien, *supra* note 11, at 26 n.162.

TABLE 1. Summary of Arguments by Bar Associations
and Intellectual Property Associations
That Demonstrate Their Pro-Patentee Stance¹²⁶

Bar/IP Association	Standard of Materiality	Intent	Balancing	Other
ABA	“But for”	Intent may be proven by direct and circumstantial evidence, but not by mere materiality	Replace and follow common-law fraud principles	—
AIPLA	“But for”	Gross negligence is insufficient; inference of intent may not be based on a finding that applicant should have known of materiality; cannot infer from materiality alone, but applicant’s “knowledge of materiality” may be considered in the totality of circumstances	Replace and follow a standard for finding fraud on PTO based on the totality of the circumstances	—
IPO	Objective “but for”	Cannot infer intent solely from materiality; clear and convincing evidence of specific intent to deceive is required	Maintain balancing as an exercise of the court’s equitable discretion in finding a remedy after intent and materiality are affirmatively determined	—
22 Patent Prosecution Firms/ Practitioners	—	Clear evidence of deceptive intent is required	Abandon	—
BPLA	Objective “but for”	Separate from materiality	—	—
IPLAC	—	—	—	Return doctrine to common-law roots of fraud; patent unenforceability should only apply for the most egregious cases
SDIPLA	Meets or exceeds Rule 1.56 and objective “but for” standard	Intent cannot be inferred solely from materiality	If information meets or exceeds Rule 1.56, the court may fashion a remedy based on the level of materiality; if materiality meets the objective “but for” standard, the patent is held unenforceable	—

126. *Supra* Part IV.B; see Brief for Amici Curiae 22 Patent Prosecution Firms & Practitioners Supporting Neither Party, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390223; Brief of Amicus Curiae the Intellectual Property Law Ass’n of Chicago Supporting Neither Affirmance nor Reversal, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390227; Brief of Amicus Curiae University of Kentucky Intellectual Property Law Society in Support of Neither Party, *supra* note 124; Brief for Amicus Curiae Patterson Thunte Christensen Pedersen, P.A., in Support of Neither Party, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595).

Bar/IP Association	Standard of Materiality	Intent	Balancing	Other
HIPLA	PTO rules applicable at time of examination of the patent at issue	Requires clear and convincing evidence; inference should only be made where it is the single most reasonable inference	Modify with heightened standards	—
CVBA	—	—	—	A finding of inequitable conduct is only for exceptional cases; judges should decide; the penalty should be based on the degree of inequitable conduct
FCBA	Current Rule 1.56(b)	Gross negligence, knew, and should have known are insufficient to prove intent; may not be inferred from materiality only, but the degree of materiality should determine the type or quality of the evidence needed to prove by clear and convincing evidence; courts must find intent to deceive PTO is the single most reasonable inference	If the first two prongs are established by clear and convincing evidence, then courts must determine in equity whether the patent is unenforceable	—
UKIPLA	—	—	—	Replace current framework and at a minimum modify the test to emphasize the public interest in patents
WSPLA	Common-law fraud standards	A specific, fraudulent intent to deceive is required	Court has the discretion to craft an equitable remedy	—
Patterson	Objective “but for”; materiality can be considered a factor in whether or not an action or omission amounts to a breach of the duty of candor	Separate frameworks would remove the need for inferring intent from materiality	Abandon	Use two separate legal frameworks: (1) for fraud in patent procurement, the remedy should be patent unenforceability; and (2) for failure of fairness during patent prosecution, courts should fashion a remedy

C. Academics

Professor Christian Mammen, Professor David Hricik, and the Center for Intellectual Property Law and Technology at the University of Akron filed amicus briefs representing the interests of academics. These three briefs represented nearly 9 percent of the total number of briefs that were filed in *Therasense*.

Mammen argued for a clear separation between the elements of materiality and intent, the application of Rule 1.56, the emphasis on the necessity for clear and convincing evidence of intent with gross negligence being insufficient for a finding of intent, and the abandonment of the balancing step.¹²⁷ These high standards tended to favor patentees.¹²⁸

By contrast, Hricik argued for the abolishment of the doctrine unless the court felt compelled to continue the inequitable conduct because of stare decisis, in which case the reasonable examiner standard should apply for materiality.¹²⁹ Hricik suggested that courts can further clarify this standard by requesting that the PTO provide evidence of its practices and regulations.¹³⁰ Hricik also appeared to advocate a high intent standard, arguing that it is insufficient to infer intent when, for example, highly material information is intentionally withheld.¹³¹ Just as Mammen did, Hricik disapproved of the balancing step but further argued that a range of equitable remedies should be available.¹³²

Perhaps the complete abolishment of the doctrine may seem pro-patentee since it would remove any patentee's fear of facing an allegation of the defense during litigation. But this type of scenario may amplify the possibility that the entire patent system would become anti-patent, allowing bad actors to remain unpunished for obtaining and maintaining undeserving patents.¹³³ Therefore, considering the potential consequences of eliminating the doctrine, perhaps Hricik's main viewpoint can be considered at least anti-patent system. But, putting these concerns aside, Hricik's proposed standard for materiality was less stringent compared to that which Mammen advocated, signaling an anti-patentee stance; however,

127. Brief of Amici Curiae Intellectual Property Law Professors Concerning En Banc Review of Inequitable Conduct and in Support of Neither Party at 4–6, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390222, at *4–6.

128. *See infra* Table 2.

129. Amicus Brief of Professor David Hricik in Support of Neither Party at 14–15, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390229, at *11–14.

130. *Id.* at 8–9.

131. *See id.* at 14–15.

132. *See id.* at 19; *infra* Table 2.

133. *See* Brief of Amici Curiae Johnson & Johnson and the Proctor & Gamble Co. in Support of Neither Party, *supra* note 77, at 4–5.

Hricik also advocated standards for intent and materiality that would likely favor patentees.

The Center for Intellectual Property Law and Technology at the University of Akron advocated a position between Mammen's and Hricik's extremes. The brief argued: (1) Rule 56, as promulgated by the PTO in 1992, should be used as the materiality standard; (2) intent cannot be inferred from materiality alone; and (3) if the remedy is applied to only the affected claims and not to the entire patent, the court should eliminate the balancing test.¹³⁴ Although this materiality standard does not clearly favor patentees, the arguments concerning intent and balancing tended to show a preference for patentees.¹³⁵

Chien's study, despite a widespread assumption that professors are anti-patent, revealed that these amici actually supported patentees nearly 40 percent of the time.¹³⁶ All three of the *Therasense* amici from academia supported standards for inequitable conduct that would likely favor patentees. Thus, this result corroborates Chien's rebuttal against the assumption that academia has an anti-patent stance.

TABLE 2. Summary of Academics' Arguments That Demonstrate Their Pro-Patentee Stance¹³⁷

Academia	Materiality	Intent	Balancing	Other
Professor Mammen	Rule 1.56	Separate from materiality; prove by clear and convincing evidence; gross negligence is insufficient	Abandon	—
Professor Hricik	Reasonable examiner	Insufficient to infer intent when highly material information is intentionally withheld	Disapproved, but range of remedies should be available	Abolish doctrine
Center of Law and Technology, University of Akron	Rule 1.56 promulgated by PTO in 1992	Cannot be inferred from materiality alone	If remedy is applied only to affected claims, eliminate	—

134. Brief of Amicus Curiae the University of Akron School of Law, Center for Intellectual Property Law & Technology, in Support of Affirmance on En Banc Review at 2–3, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595).

135. See *infra* Table 2.

136. Chien, *supra* note 11, at 26–27.

137. See *supra* Part IV.C.

*D. Public Interest and
Public Policy Groups*

Three public interest groups filed amicus briefs in *Therasense*, accounting for nearly 9 percent of the total number of briefs that were filed in the case: International Intellectual Property Institute (IIPI, a not-for-profit organization); Washington Legal Foundation (WLF, a public interest law and policy center); and Association of Citizens for Patent Protection in the Public Interest (ACPPPI, a not-for-profit organization whose mission includes ensuring that patent protection laws serve the public interest). While IIPI primarily focused its argument on an objective “but for” test for determining materiality,¹³⁸ WLF argued that Rule 1.56(b)(1) should serve as the materiality standard and that intent should be established by clear and convincing evidence.¹³⁹ Moreover, WLF focused on the balancing test, arguing that “district courts should examine all of the equities in determining whether inequitable conduct occurred—including examining whether the patent holder’s misconduct bears *an immediate and necessary relation* to the relief it seeks from the court.”¹⁴⁰ Moreover, WLF even suggested that the court withdraw from holding the entire patent unenforceable after finding inequitable conduct, arguing that this blanket rule fails to affect claims that bear “immediate and necessary relation” to the conduct and can only be described as punishment—which is improper in equity.¹⁴¹

ACPPPI had an interesting take on the materiality standard: “information is material when it has a natural tendency to influence, or is capable of influencing, the PTO’s decision to grant a patent.”¹⁴² ACPPPI argued that the materiality standard in other contexts is not so high as to require a “but for” test; such a high standard would undermine the public interest in ensuring that relevant information

138. Brief of Amicus Curiae International Intellectual Property Institute in Support of Plaintiffs-Appellants at 3, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3481627, at *3.

139. Brief of Washington Legal Foundation as Amicus Curiae in Support of Plaintiffs-Appellants, Urging Reversal at 7, 11, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390237, at *7, *11.

140. *Id.* at 5.

141. *Id.* at 20–21; see *infra* Table 3.

142. Brief of Amicus Curiae the Ass’n of Citizens for Patent Protection in the Public Interest in Support of Defendants-Appellees and Affirmance at 4, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 4622533, at *4.

that is known to the patent applicant is brought to the PTO's examination process.¹⁴³ In fact, ACPPI's stance for materiality seemed to be reminiscent of a reasonable examiner standard (although it did not consider a hypothetical examiner).¹⁴⁴

Furthermore, unlike the majority of the amici across all categories, ACPPI argued that the "single most reasonable inference" standard is too high; thus, intent can be inferred when a person with a duty to disclose knowingly makes a material false statement or omission, misrepresents or withholds information despite an objectively high likelihood that the information is material, or misrepresents or withholds information despite knowing of and consciously disregarding a substantial risk that the information was material.¹⁴⁵

In Chien's study, public interest and public policy groups tended to favor non-patentees, supporting patentees less than 30 percent of the time.¹⁴⁶ Here, the ACPPI's low standards, as compared to those of other amici, for materiality and intent indicated a preference for non-patentees. Conversely, IPI appeared to support a pro-patentee standard yet only addressed one prong of the current inequitable conduct framework. Furthermore, although WLF's proposal for Rule 1.56(b)(1) likely did not clearly favor patentees, WLF's argument for a high standard for intent, for an "immediate and necessary relation" between the conduct and the relief, and for the removal of complete unenforceability may suggest some preference toward patentees. Thus, two-thirds of these amici appeared to favor patentees, which is somewhat contrary to Chien's findings. Perhaps these results highlight the presence of the amici's heightened interest in advancing the twin purposes of the doctrine: (1) enforcing the duty of good faith and fair dealing that binds patent applicants in dealing with the public; and (2) protecting the patent system's "social utility."

143. *Id.* at 5.

144. *See infra* Table 3.

145. Brief of Amicus Curiae the Ass'n of Citizens for Patent Protection in the Public Interest in Support of Defendants-Appellees and Affirmance, *supra* note 142, at 6-7; *see infra* Table 3.

146. Chien, *supra* note 11, at 26.

TABLE 3. Summary of Public Interest and Public Policy Groups' Arguments for Inequitable Conduct¹⁴⁷

Public Interest and Public Policy Groups	Materiality	Intent	Balancing	Other	Stance Toward Patentees
IPI	Objective "but for"	—	—	—	For
WLF	Rule 1.56(b)(1)	Establish by clear and convincing evidence	Examine all equities to find if inequitable conduct occurred, including whether misconduct bears an "immediate and necessary relation" to the relief sought	Remove unenforceability as a penalty	For
ACPPI	"Natural tendency to influence"	"Single most reasonable inference" is too high a standard	—	—	Against

E. Industry

Fifteen amicus briefs were filed by parties in several industries, ranging from flooring and lighting companies to biotechnology and pharmaceutical firms. These briefs represented the largest group of amici in *Therasense* (about 44 percent of the total number of briefs that were filed in the case).

Interestingly, the majority of the amici in this category agreed on a high standard for finding intent: gross negligence is insufficient, intent cannot be inferred from materiality alone, and specific or deceptive intent must be separately established from materiality by clear and convincing evidence.¹⁴⁸ Sap America even suggested factors that a court may invoke when analyzing whether a patent

147. See *supra* Part IV.D.

148. See, e.g., Brief of Amicus Curiae 43 Patent Practitioners Employed by Eli Lilly & Co., in Support of No Party, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390224; Brief of the Biotechnology Industry Organization as Amicus Curiae in Support of Neither Party, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390221; Brief of Amici Curiae Ole K. Nilssen & Geo Foundation, Ltd. in Support of Plaintiffs-Appellants Abbot Diabetes Care, Inc. & Abbot Laboratories' Brief on Rehearing En Banc Supporting Reversal, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390228; Corrected Brief of Amicus Curiae Sap America, Inc. in Support of Neither Party, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390216.

owner had the requisite intent during the alleged misconduct.¹⁴⁹ However, Apotex, a private pharmaceutical company, varied from other amici and argued that intent may be established by a “known or should have known” standard.¹⁵⁰ Moreover, materiality could be considered in determining whether an inference of deceptive intent is appropriate since materiality and culpability are often intertwined.¹⁵¹

Considering the large consensus for a high standard concerning intent (a pro-patentee stance), the following discussion will mostly focus on the materiality and balancing prongs, where the amici’s arguments varied significantly. Because of the diverse interests across the myriad technologies that the amici represented, the following discussion divides the amici into the following categories¹⁵²: (1) bio/pharma companies;¹⁵³ (2) high-tech companies;¹⁵⁴ (3) non-practicing entities (NPEs);¹⁵⁵ and (4) trade associations.¹⁵⁶

149. See, e.g., Corrected Brief of Amicus Curiae Sap America, Inc. in Support of Neither Party at 2–3, *supra* note 148.

150. Brief of Amicus Curiae Apotex, Inc. Not Supporting Any Party at 17–23, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 339024, at *17–23.

151. *Id.* at 18.

152. The following pairs of amici that fall within different categories but filed joint briefs are considered separately for this discussion: Microsoft Corporation (high-tech) and Sanofi-Aventis (pharma); and Teva Pharmaceuticals (pharma) and Cisco Systems, Inc. (high-tech).

153. These amici are: Apotex, Eisai, Eli Lilly, Johnson & Johnson, Procter & Gamble, Sanofi-Avenits, and Teva.

154. These amici are: Cisco Systems, Dolby, Ecore, Intel, Microsoft, Sap America, and Verizon.

155. A non-practicing entity is a “patent owner who does not manufacture or use the patented invention, but rather than abandoning the right to exclude, an NPE seeks to enforce its right through the negotiation of licenses and litigation.” Miranda Jones, Comment, *Permanent Injunction, A Remedy by Any Other Name Is Patently Not the Same: How Ebay v. Mercexchange Affects the Patent Right of Non-Practicing Entities*, 14 GEO. MASON L. REV. 1035, 1036 (2007). Amici Acacia and 1st Media (who jointly filed a brief in *Therasense*) have previously been considered NPEs and thus are categorized as such here. Sannu K. Shrestha, *Trolls or Market-Makers? An Empirical Analysis of Nonpracticing Entities*, 110 COLUM. L. REV. 114, 160 (2010). As Shrestha has noted, “the news media is the only means, in the public domain, of compiling a list of NPEs.” *Id.* at 159. A search of Ole K. Nilssen, an individual inventor of electric lighting, produced a recent commentary that described the inventor as an NPE. Peter Zura, *District Court Awards \$2.5M in Sanctions for NPE Asserting Unenforceable Patents*, THE 271 PATENT BLOG (July 20, 2009, 10:02 AM), <http://271patent.blogspot.com/2009/07/district-court-awards-almost-25m-in.html>. Thus, for simplicity here, Nilssen and his exclusive licensee, Geo Foundation, Ltd., are considered as part of this category.

156. These amici, representing the bio/pharma industry, are: Biotechnology Industry Organization (BIO), Generic Pharmaceutical Association (GPhA) who joined Teva Pharmaceuticals and Cisco in one brief, and Pharmaceutical Research and Manufacturers of America (PhRMA).

1. Bio/Pharma Companies

The bio/pharma amici did not reach a clear consensus on a standard for materiality. For example, one amici argued for a reasonable examiner standard,¹⁵⁷ on the other hand, another amici argued that the “but for” standard should not be used and even suggested that this occasion was an inappropriate time to differentiate between Rule 1.56 and a reasonable examiner test.¹⁵⁸ Eli Lilly advocated for an interesting take on the materiality standard: a “standard for materiality must require at least that a patent with an *illegitimate* scope of protection was issued.”¹⁵⁹ Additionally, Apotex argued that materiality could continue to be assessed by any prevailing standards, including Rule 1.56 and the “but for” standard.¹⁶⁰

Most of the bio/pharma amici argued for the elimination of the balancing step or at least for balancing the remedy against the harm (as opposed to comparing materiality and intent within a sliding scale approach). On the other hand, two amici (Apotex and Teva) argued for the maintenance of this step, which would allow more materiality to indicate intent.¹⁶¹

Notably, Johnson & Johnson and Procter & Gamble filed a joint amicus brief and took a different approach to answering the questions that the Federal Circuit posed. These amici argued that responsibility for policing misconduct before the PTO belongs to the PTO rather than to the courts.¹⁶² Thus, the federal courts must limit their considerations of patent applicant misconduct and only adjudicate allegations of misconduct when it is brought upon the

157. Brief of Eisai Co., Ltd. & Eisai Inc. as Amici Curiae on Rehearing En Banc in Support of Neither Party at 15, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (Nos., 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390220, at *15.

158. Brief of Amici Curiae Teva Pharmaceuticals USA, Inc., et al., in Support of Appellees and in Favor of Affirmance at 9–10 n.6, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 4622535, at *9–10 n.6.

159. Brief of Amicus Curiae 43 Patent Practitioners Employed by Eli Lilly & Co., in Support of No Party, *supra* note 148, at 4.

160. Brief of Amicus Curiae Apotex, Inc. Not Supporting Any Party, *supra* note 150, at 13–16; *see infra* Table 4.

161. *See infra* Table 4.

162. Brief of Amici Curiae Johnson & Johnson and the Procter & Gamble Co. in Support of Neither Party, *supra* note 77, at 17–18.

courts by the litigants' actions in the course of litigation.¹⁶³ With such a narrowed application of the doctrine, perhaps such a stance may be considered as pro-patentee since patentees may face fewer inequitable conduct allegations as a result of such an approach.¹⁶⁴

For those that discussed intent and balancing, the bio/pharma amici agreed on pro-patentee standards for these two prongs. However, the amici greatly differed in their views on materiality. Five amici could arguably be considered pro-patentee¹⁶⁵ while two amici tended to favor non-patentees.¹⁶⁶ Chien previously found that bio/pharma amici supported patentees 56 percent of the time, although the difference was not statistically significant.¹⁶⁷ However, the division between the bio/pharma amici in *Therasense* may confirm Chien's findings.

Nevertheless, Chien also found that the amici's business models were better predictors for whether the amici favored patentees or non-patentees: public companies, regardless of industry, favored the patentee only 32 percent of the time.¹⁶⁸ The bio/pharma amici in *Therasense* were nearly all public companies (only Apotex was private),¹⁶⁹ and 83 percent of these public companies appeared to be pro-patentee. Although the differences between the percentages in Chien's findings and in this Note's study may be attributed to a smaller sample size in *Therasense*, perhaps it is also indicative of the industry's strong interest in inequitable conduct. Bio/pharma companies are typically known for their preference for strong patents to protect their investments, yet Chien's study revealed only weak support for this expectation.¹⁷⁰ However, *Therasense* may uniquely reveal more pro-patentee support from this industry based on the consequences that are associated with inequitable conduct, such as the potential invalidation of long-standing and heavily-invested patents and of those that are related to the patent at issue.

163. *Id.* at 16–17.

164. *See infra* Table 4.

165. Eisai; Eli Lilly (although it is perhaps not entirely evident if an “illegitimate scope” standard for materiality can clearly favor patentees); Johnson & Johnson, Procter & Gamble; and Sanofi-Aventis.

166. Apotex and Teva; *see infra* Table 4.

167. Chien, *supra* note 11, at 24.

168. *Id.* at 24–25.

169. Eisai and Teva.

170. Chien, *supra* note 11, at 24–26.

TABLE 4. Summary of Arguments
by Amici from the
Biotech/Pharma Industry¹⁷¹

Biotech/Pharma Industry	Materiality	Balancing	Other	Stance Toward Patentee
Apotex (Private)	Rule 1.56 and “but for”	Maintain	—	Against
Eisai (Public)	Objective reasonable examiner	Fashion appropriate remedies	—	For
Eli Lilly (Public)	“Illegitimate scope”	Eliminate	—	For
Johnson & Johnson (Public)	—	—	PTO should police the misconduct	For
Procter & Gamble (Public)	—	—	PTO should police the misconduct	For
Sanofi-Aventis (Public)	Separate from intent	Sliding scale is wrong	—	For
Teva (Public)	Reject “but for”	Maintain	—	Against

2. High-Tech Companies

Turning to the amici within the high-tech industry, they argued for a variety of materiality standards, such as the “but for” standard,¹⁷² the reasonable examiner test,¹⁷³ or neither.¹⁷⁴ Additionally, for those that discussed the issue, some amici advocated for the elimination of the balancing step, although Intel urged the court to consider the misconduct to see if, in equity, a harsh unenforceability penalty was warranted.¹⁷⁵ Verizon echoed the remedy concern, suggesting that courts consider a range of remedies.¹⁷⁶ Because of their support for a high level of materiality,

171. *Supra* Part IV.E.1; see Brief for Sanofi-Aventis & Microsoft Corp. as Amici Curiae Supporting Appellants and Reversal at 11, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3229935, at *11.

172. Brief of Amicus Curiae Ecore International, Inc. in Support of Neither Party at 3, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390236, at *3.

173. Brief of Amicus Curiae Intel Corp. in Support of the Appellees at 8, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 4622534, at *8.

174. Brief of Amici Curiae Teva Pharmaceuticals USA, Inc., et al. in Support of Appellees and in Favor of Affirmance, *supra* note 158.

175. Brief of Amicus Curiae Intel Corp. in Support of the Appellees, *supra* note 173, at 3–4.

176. Brief for Verizon Communications Inc. as Amicus Curiae in Support of Neither Party on Rehearing En Banc at 4–8, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 2861897, at *4–8.

the elimination of the balancing step, and varying levels of remedy, only six amici¹⁷⁷ tended to favor the patentee. Only one amici¹⁷⁸ favored a non-patentee stance, arguing for weaker materiality standards and even for maintaining the current balancing step.¹⁷⁹

According to Chien, high-tech industries, where the cumulative nature of innovation creates liabilities for companies that introduce new technologies, unsurprisingly tended to oppose patentees;¹⁸⁰ in fact, her study revealed that high-tech companies supported patentees only 36 percent of the time.¹⁸¹ In *Therasense*, 86 percent of these companies supported patentees, perhaps showing this industry's increased concern for the doctrine's potentially harsh consequences.

However, Chien conceded that her finding was not statistically significant and turned her analysis to a company's business model, finding that public companies favored the patentee only 32 percent of the time.¹⁸² Of the seven high-tech amici in *Therasense*, six were public companies,¹⁸³ and 83 percent of those public companies appeared to favor the patentees. These results present an interesting contrast to Chien's conclusion that public companies, regardless of industry, more often favor an anti-patentee stance. Perhaps the industry's nature of innovation—which often creates liabilities and thus causes companies to possibly face increased litigation in which there exist significant chances that they will encounter inequitable conduct as an affirmative defense—causes the doctrine to raise enough concern within the bio/pharma industry, thereby leading to this reversal toward a preference for patentees.

177. Dolby, Ecore, Intel, Microsoft, Sap, and Verizon.

178. Cisco.

179. Brief of Amici Curiae Teva Pharmaceuticals USA, Inc., et al. in Support of Appellees and in Favor of Affirmance, *supra* note 158, at 3–4; *see infra* Table 5.

180. Chien, *supra* note 11, at 25.

181. *Id.* at 24.

182. *Id.* at 24–25.

183. Cisco, Dolby, Intel, Microsoft, Sap, and Verizon.

TABLE 5. Summary of Arguments
by Amici from the High-Tech Industry¹⁸⁴

High-tech Industry	Materiality	Balancing	Other	Stance Toward Patentee
Cisco (Public)	Reject “but for”	Maintain	—	Against
Dolby (Public)	—	Eliminate	—	For
Ecore (Private)	Objective “but for”	—	—	For
Intel (Public)	“Reasonable examiner”	Balance remedies with inequitable conduct	—	For
Microsoft (Public)	Separate from intent	Sliding scale is wrong	—	For
Sap (Public)	—	—	Employ factors to determine credibility of the applicant	For
Verizon (Public)	—	—	Consider availability of remedies less severe than unenforceability, particularly overriding the presumption of validity	For

3. NPEs

Because Chien found that a business model can predict an amici’s pro- or non-patentee stance, the author separately considered NPEs. Acacia Research Corp. and 1st Media, LLC argued that inequitable conduct should not exist since the defense lacks any statutory foundation.¹⁸⁵ Such a complete abolishment of the doctrine would allow patentees to avoid facing the defense and thus represents a pro-patentee stance.¹⁸⁶ Other NPEs, Ole K. Nilssen and Geo Foundation, argued that Rule 1.56 should serve as the

184. *Supra* Part IV.E.2; see Brief of Amicus Curiae Dolby Laboratories, Inc. in Support of Neither Party, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 2861896; Brief for Sanofi-Aventis & Microsoft Corp. as Amici Curiae Supporting Appellants and Reversal, *supra* note 171; Corrected Brief of Amicus Curiae Sap America, Inc. in Support of Neither Party, *supra* note 148; Brief of Amici Curiae Teva Pharmaceuticals USA, Inc. et al. in Support of Appellees and in Favor of Affirmance, *supra* note 158.

185. Brief of Amici Curiae Acacia Research Corp. & 1st Media, LLC in Support of Neither Party and in Support of Returning the “Unenforceability” Defense to Its Traditional Scope of “Unclean Hands” at 2, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 3390243, at *2.

186. However, this stance may also be considered anti-patent system. See Nolan-Stevaux, *supra* note 79, at 165.

materiality standard and that the courts should employ an “immediate and necessary relation” requirement between the asserted patent rights and misconduct.¹⁸⁷ Although the Rule 1.56 standard is weaker than a “but for” standard and may not necessarily favor non-patentees, the high level of intent and a close causal connection between the patent rights and misconduct likely protects a patentee; thus, Ole K. Nilssen and Geo Foundation’s stance may be considered pro-patentee.¹⁸⁸ These results confirm Chien’s findings that NPEs favor patentees nearly all of the time. Moreover, these results are unsurprising given that the often-litigious NPEs would likely prefer to avoid having inequitable conduct defenses asserted against them.

TABLE 6. Summary of Arguments by NPEs¹⁸⁹

NPEs	Materiality	Balancing	Other	Stance Toward Patentee
Acacia	—	—	Doctrine should not exist	For
1st Media	—	—	Doctrine should not exist	For
Ole K. Nilssen	Rule 1.56	“Immediate and necessary relation”	—	For
Geo Foundation	Rule 1.56	“Immediate and necessary relation”	—	For

4. Trade Associations

Three trade associations that represent the bio/pharma industry also filed amicus briefs: BIO, PhRMA, and GPhA. These amici varied in their arguments for a materiality standard: BIO argued for a “but for” standard that is considered at the time of trial,¹⁹⁰ while PhRMA argued that information is material “only if that information

187. Brief of Amici Curiae Ole K. Nilssen & Geo Foundation, Ltd. in Support of Plaintiffs-Appellants Abbott Diabetes Care, Inc. & Abbot Laboratories’ Brief on Rehearing En Banc Supporting Reversal, *supra* note 148, at 4–5.

188. *See infra* Table 6.

189. *See supra* Part IV.E.3.

190. Brief of the Biotechnology Industry Organization as Amicus Curiae in Support of Neither Party, *supra* note 148, at 21.

establishes that one or more of the claims asserted in the litigation is invalid.”¹⁹¹ However, in practice, the differences between these two standards may not be significant, and both appear to require a high level of materiality. Moreover, BIO and PhRMA agreed that the balancing step must be abandoned. Overall then, these two trade associations appeared to take a pro-patentee stance. On the other hand, GPhA argued against a “but for” standard and for maintenance of the current state of inequitable conduct, and thus GPhA seemingly favored a non-patentee stance.¹⁹²

Chien found that groups that represent bio/pharma/chem only supported patentees 59 percent of the time, and although the sample size was statistically insignificant, the result still confirmed the perceptions of the patent group.¹⁹³ Two-thirds of the trade associations’ briefs in *Therasense* favored patentees; although three amici may have been a statistically insignificant sample size, the trade associations’ arguments were still consistent with the expectation that their industries would favor strong patent protection.

TABLE 7. Summary of Arguments by Industrial Trade Associations¹⁹⁴

Industrial Trade Associations	Materiality	Balancing	Stance Toward Patentee
BIO	“But for”	Eliminate	For
PhRMA	“Asserted claims”	Eliminate	For
GPhA	Reject “but for”	Maintain	Against

F. Summary

The percentages of *Therasense* amici, by category, that favored pro-patentee standards for inequitable conduct are summarized in Table 8. Table 8 also provides Chien’s results for comparison. As shown in Table 8, three categories of amici (“Bar Associations and

191. Brief of Pharmaceutical Research & Manufacturers of America as Amicus Curiae in Support of Neither Party at 6, *Therasense*, 649 F.3d 1276 (Nos. 2008-1511, -1512, -1513, -1514, -1595).

192. *Infra* Table 7; see Brief of Amici Curiae Teva Pharmaceuticals USA, Inc., et al., in Support of Appellees and in Favor of Affirmance, *supra* note 158.

193. Chien, *supra* note 11, at 26.

194. See *supra* Part IV.E.4.

Intellectual Property Associations,” “Public Interest and Public Policy Groups,” and the “High-tech Industry”)¹⁹⁵ varied from those in Chien’s results. Moreover, public companies, regardless of industry, also contrasted with those in Chien’s findings.

TABLE 8. Percentages of *Therasense* Amici that Favor Patentees, by Category, as Compared to Chien’s Findings

Category	Percentage of <i>Therasense</i> Amici Favoring Patentee	Percentage of Time That Amici Favored Patentee According to Chien’s Findings
PTO	100 %	28 %
Bar/IP Associations	100 %	55 %
Academia	100 %	Nearly 40 %
Public Interest/ Policy Group	66 %	20 %
Bio/Pharma Industry	71 % (83 % of public, bio/pharma companies)	56 % (public companies, regardless of industry: 32 %)
High-Tech Industry	86 % (83 % of public, high-tech companies)	36 % (public companies, regardless of industry: 32 %)
NPEs	100 %	98 %
Trade Associations	66 %	59 %

V. PROPOSAL AND JUSTIFICATION

Amicus briefs “reflect the complexity of [major commercial and societal] concerns”¹⁹⁶ and, as such, represent an important source “for studying patent groups and their interests in the patent system.”¹⁹⁷ The thirty-four briefs that were filed in *Therasense* thus provide useful insight into how inequitable conduct affects the various contexts of patent law that each amici represents. The briefs also included proposals, some traditional and others unique, on how the

195. Chien’s findings rebutted the assumption that academia was anti-patentee. Although academics appear to favor patentees at a higher percentage rate than Chien’s findings indicate that it does, the percentage found in analyzing the *Therasense* academia amici further corroborates Chien’s rebuttal.

196. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1379 (Fed. Cir. 2003).

197. Chien, *supra* note 11, at 6.

doctrine should be modified. In light of these arguments, this Note's proposal seeks to synthesize the myriad views presented by the diverse amici into a workable test: (1) courts should adopt Rule 1.56 as the materiality standard, which the Federal Circuit can further clarify by establishing factors for lower courts to consider in evaluating this prong; (2) courts should reaffirm specific intent to deceive as the appropriate standard for intent; and (3) courts should eliminate a sliding scale approach to the balancing step and maintain the harsh penalty of unenforceability.

Moreover, the *Therasense* amici, both within each category and across categories, came to a consensus on certain viewpoints. The Federal Circuit should take particular note of that agreement. On the other hand, as Part IV revealed, certain amici's arguments appeared to be surprising based on expectations of their viewpoints according to Chien's findings. These contrasting results shed light on how inequitable conduct can particularly impact the contexts of patent law that these amici represent. Thus, this proposal merely suggests that the court should pay particular attention to certain amici that may face significant consequences from inequitable conduct in ways that may not be present in other doctrines of patent law.

A. *Listening to the Amici*

Amici often influence courts; the federal government and the PTO have been particularly successful in swaying the Federal Circuit and even the Supreme Court.¹⁹⁸ However, because of the doctrine's widespread ramifications—which extend beyond the litigants and impact the court system, patent practitioners, and the PTO—the Federal Circuit should have taken a closer look at arguments that the varied amici advanced instead of only considering those amici with a history of success with the courts.¹⁹⁹

Part V revealed that three categories of amici (Bar Associations and Intellectual Property Associations, Public Interest and Public Policy Groups, and the High-tech Industry) and public companies,

198. *Id.* at 28–29.

199. The Federal Circuit, in its en banc *Therasense* decision, appears to have at least acknowledged some amici. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1294 (Fed. Cir. 2011) (“Notably, both the American Bar Association and the American Intellectual Property Law Association, which represent a wide spectrum of interests, support requiring but-for materiality”); *id.* at 1305 (Bryson, J., dissenting) (“As the PTO persuasively argues in its amicus brief . . .”).

regardless of industry, surprisingly favored pro-patentee standards. Because of the potential adverse consequences on the careers of patent agents and attorneys, perhaps a court should give less credence to bar associations and intellectual property associations representing these practitioners here. A more significant preference for pro-patentee standards (as compared to the preference that is illustrated in Chien's results) by public interest and public policy groups may reveal their concerns with maintaining the integrity of the patent system, one of the key purposes of inequitable conduct. Moreover, high-tech industry and public companies' preferences for patentees likely reflect these amici's heightened concerns for having to potentially battle the defense and face the invalidation of their long-standing, heavily-invested patents, signaling their "commercial interest" at stake. Consequently, the Federal Circuit should particularly note briefs filed by public interest and public policy groups, high-tech industries, and public companies.

The PTO's amicus brief also should be carefully considered because of the close relationship between the *ex parte* process of patent prosecution in front of the PTO and the subsequent allegations of inequitable conduct. In fact, the government is often particularly persuasive and often predicts the accurate "winner" of a case.²⁰⁰ However, this proposal posits that the Federal Circuit should not only grant this amicus significant consideration but also equally consider other amici, especially those that are highlighted above.

B. Fashioning the Test

The amici varied significantly across all categories in their opinions on the materiality prong. Likewise, the *en banc* panel also disagreed as to the appropriate standard for this element,²⁰¹ and thus the standard for materiality may not necessarily be entirely settled law yet. On the one hand, a "but for" standard may not appropriately catch bad actors who affirmatively withhold or misrepresent material information to the PTO but whose misconduct did not affect the validity of the patent. On the other hand, a reasonable examiner

200. Chien, *supra* note 11, at 31. *Contra Therasense*, 649 F.3d at 1276, 1293–94 (disagreeing with the PTO's argument for Rule 1.56 as the standard for materiality).

201. *See supra* Part II.C.

standard also appears to be too amorphous and forces the court to consider the hypothetical examiner.

Therefore, Rule 1.56 may be an appropriate middle ground for the courts to adopt, but it may not set the bar high enough to warrant unenforceability as punishment. Some amici also argued that courts are not bound to follow regulations that the PTO sets. Moreover, oral arguments during the *Therasense* en banc hearing showed that the Federal Circuit exhibited some reluctance toward this standard, particularly with the potential breadth of Rule 1.56(b)(2).²⁰² The majority's opinion and adoption of the "but for" standard reflects these concerns.²⁰³ However, although the PTO's regulations would not be binding on the courts, the courts can still look to the PTO for useful guidance and choose to adopt the PTO's standard.

Then again, perhaps the materiality standard that the court ultimately adopts will have little impact,²⁰⁴ and the Federal Circuit's main concern over materiality is unfounded. The amici that are under examination here and other scholarly commentary have suggested that the Federal Circuit should simply articulate factors to aid courts in determining materiality.²⁰⁵ Even given the *Therasense* majority's "but for" standard, delineating specific factors as additional guidance for courts to look to would surely help, especially in light of the court's new "affirmative egregious misconduct" exception.

The vast majority of all amici tended to agree that the level of intent for a finding of inequitable conduct must be high. Under such a standard, gross negligence would not be enough to satisfy this prong; moreover, intent must be established independent of materiality and satisfy a clear and convincing evidence standard. This harmony across the diverse interests within the patent system should signal to the court that this standard is appropriate. However, if such a consensus exists, why is intent even at issue? Intent was shown to be the more critical factor as compared to materiality or the

202. Bruce M. Wexler, *Today's En Banc Oral Argument in Therasense: The Federal Circuit Wrestles with How Much to Reform Inequitable Conduct*, PAUL HASTINGS STAY CURRENT: A CLIENT ALERT FROM PAUL HASTINGS (Nov. 2010), http://www.paulhastings.com/assets/publications/1757.pdf?wt.mc_ID=1757.pdf.

203. *Therasense*, 649 F.3d at 1293–95.

204. Petherbridge et al., *supra* note 31, at 28 n.70.

205. *Id.* at 56–57; see Corrected Brief of Amicus Curiae Sap America, Inc. in Support of Neither Party, *supra* note 148, at 18.

balancing step.²⁰⁶ However, the Federal Circuit previously appeared to have a different understanding of intent than lower courts had,²⁰⁷ amplifying the confusion that surrounded the doctrine's framework. The Federal Circuit's reaffirmance of the requirement of a specific intent to deceive is in line with the majority of the amici's view, and perhaps the *Therasense* court even took this into account in reaching its holding for intent.

The amici in *Therasense* varied more in their opinions on the balancing step, with arguments for the maintenance, modification, or elimination of its current framework. However, as some amici argued, if the bar for the other two prongs of inequitable conduct is set sufficiently high, the balancing step is unnecessary.²⁰⁸ Moreover, in practice, this step appears to be a mere formality rather than a substantive part of the doctrine's framework.²⁰⁹ Regardless of its actual role in practice, this prong's articulation at least needed clarification. Moreover, as some notable amici argued,²¹⁰ any sliding scale approach should be eliminated.

Although other amici argued that the balancing step should entail an inquiry into whether unenforceability is a warranted penalty and whether the court should fashion remedies that are more appropriate to the conduct, these arguments seem unavailing. The other two prongs' standards are set sufficiently high such that a finding of inequitable conduct only arises for misconduct that warrants the harsh penalty of unenforceability. By maintaining such a harsh penalty, the courts may hopefully deter bad actors from adversely affecting the patent system. Thus, the societal interest in the patent system can be protected, thereby furthering a key purpose of inequitable conduct. Perhaps the Federal Circuit's grant of unenforceability "where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim"²¹¹ should be revised.

206. Petherbridge et al., *supra* note 31, at 29–39.

207. *Id.* at 43.

208. *See, e.g.*, Brief of Amici Curiae Intellectual Property Law Professors Concerning En Banc Review of Inequitable Conduct and in Support of Neither Party, *supra* note 127, at 6.

209. Petherbridge et al., *supra* note 31, at 33.

210. *See supra* Part III.

211. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011).

VI. CONCLUSION

The doctrine of inequitable conduct has led to several serious consequences that have impacted the court system, patentees and their industries, patent attorneys and agents, and the PTO. The plethora of amicus briefs that were filed in *Therasense*—which represent an important source of information that highlights the many contexts of patent law and that can even influence a court’s decision—demonstrates the widespread interest concerning the doctrine’s reform. Although the amici did not entirely agree on exactly how the doctrine should be reshaped, clarification of the exact standards for courts to use in finding inequitable conduct is necessary to alleviate the doctrine’s problems. Nonetheless, the *Therasense* majority’s new interpretation of the doctrine may need some additional reformation. A majority of the amici voiced that a finding of intent should require more than just gross negligence. Moreover, sliding scale formulations of the balancing step should be eliminated, and more specific guidance on performing materiality inquiries may be useful. However, the PTO’s Rule 1.56 should be the materiality standard that the court adopts. With clearly articulated standards for inequitable conduct, courts should be able to eliminate the “plague” on the patent system.

