AN ECONOMIC ANALYSIS OF PATENT LAW'S INEQUITABLE CONDUCT DOCTRINE

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In recent years, patent law's inequitable conduct doctrine has attracted considerable attention from judges, legislators, patent lawyers, and commentators. This trend culminated most recently in Therasense, Inc. v. Becton, Dickinson & Co., an en banc decision from the Federal Circuit that revised certain aspects of the doctrine. Building on the work of other scholars, this Article proposes an instrumental view of the doctrine as, ideally, a tool for inducing patent applicants to disclose the optimal quantity of information relating to the patentability of their inventions; it then presents a formal model of the applicant's choices in deciding how much information to reveal. The model suggests, among other things, that even after Therasense, the conditions that trigger a finding of inequitable conduct are at best only a rough proxy for the conditions defining optimal disclosure. The model also illuminates how, both pre- and post-Therasense, the doctrine poorly defines many of the variables affecting a rational applicant's decisionmaking process and thus potentially encourages risk-averse agents to overdisclose. Although the model neither confirms nor refutes critics' claims that the doctrine routinely induces overdisclosure and excessive administrative costs, the model demonstrates how various reforms including but not limited to those adopted in Therasense, can be expected to reduce these reputed consequences. The model also suggests, however, that the need for some type of inequitable conduct doctrine may be greater in a regime like the United States, which lacks an effective system for post-grant oppositions. Conversely, if the United States adopted a post-grant opposition system, the need for a robust inequitable conduct doctrine would decline.

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INTRODUCTION

In patent litigation, the defense of inequitable conduct to a claim of patent infringement authorizes a court to render an otherwise valid patent unenforceable if the accused infringer can prove that, during the course of applying for ("prosecuting") the patent before the U.S. Patent and Trademark Office ("USPTO"), the inventor or her associates either intentionally submitted materially false information relating to the invention at issue or intentionally failed to disclose information that was material to the examination of the patent application. Although courts did not clearly recognize (and litigants rarely invoked) the inequitable conduct doctrine until the middle to later part of the twentieth century, the doctrine has emerged from obscurity over the past 30 years to become one of the most frequently raised defenses—and most hotly debated topics—in contemporary patent law. The doctrine nevertheless often has been surprisingly

^{1.} See infra Part I.

^{2.} Estimates of how often the defense is asserted vary somewhat. See Christopher A. Cotropia, Modernizing Patent Law's Inequitable Conduct Doctrine, 24 BERKELEY TECH. L.J. 723, 739 (2009) (stating that the defense is asserted in about 25% of all patent cases filed); Christian E. Mammen, Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct, 24 Berkeley Tech. L.J. 1329, 1358 tbl.2 (2009) (presenting an empirical study concluding that the defense was raised in about 40% of all patent cases filed since 2007); Benjamin Brown, Comment, Inequitable Conduct: A Standard in Motion, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 593, 605-15 (2009) (reporting that from 2000 to 2007 "courts addressed, on average, inequitable conduct in less than 20% of all reported patent cases," but that "it is almost impossible to ascertain the number of times inequitable conduct was pled"); Kevin Mack, Note, Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands, 21 BERKELEY TECH. L.J. 147, 155-56 & tbl.1 (2006) (reporting that "from 2000 to 2004... an inequitable conduct adjudication appeared in 16% to 35% of all reported patent opinions," and that "it can be inferred that the percent of patent cases in which a litigant ple[d] inequitable conduct is substantially higher than these figures"). In its recent decision in Therasense, Inc. v. Becton,

Dickinson & Co., the Federal Circuit noted that "[o]ne study estimated that eighty percent of patent infringement cases included allegations of inequitable conduct." Nos. 2008-1511, -1512, -1513, -1514, -1595, 2011 WL 2028255, at *8 (Fed. Cir. May 25, 2011) (en banc). The position paper referenced by the court for this proposition, however, is over 20 years old and cites no supporting data for its estimate. Ad Hoc Comm. on Rule 56 and Inequitable Conduct, Am. Intellectual Prop. Law Ass'n, The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Procurement: Its Current Adverse Impact on the Operation of the United States Patent System, 16 AIPLA O.J. 74, 75 (1988). Similarly, some Federal Circuit judges have referred to the "habit of charging inequitable conduct in almost every major patent case" as "an absolute plague," see Larson Mfg. Co. v. Aluminart Prods. Ltd., 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., concurring) (quoting Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 n.15 (Fed. Cir. 1988)), a charge that is repeated in Therasense, see 2011 WL 2028255, at *9, but the reference to the doctrine being raised in "almost every major patent case" appears to be something of an overstatement, see Mammen, *supra*, at 1331 (citations omitted); Brown, *supra*, at 626.

The following examples illustrate the ongoing debate involving the doctrine: S. REP. No. 110-259, at 31-33 (2008) (discussing proposed changes to the doctrine, including permitting courts to consider sanctions other than unenforceability of the patent in its entirety); id. at 59-62 (providing additional views of Senators Specter and Hatch on the inequitable conduct doctrine, who argue that courts need more guidance concerning when to impose "more severe or less severe penalties"); FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 5, at 11–13 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf (recommending expanded use of relevance statements); NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 121-23 (Stephen A. Merrill et al. eds., 2004) (proposing abolition of the doctrine, or in the alternative various reforms); SECTION OF INTELLECTUAL PROP. LAW, AM. RECOMMENDATION 107B (2009),Ass'n, available www.abanow.org/wordpress/wp-content/themes/ABANow/wp-content/uploads/resolutionpdfs/107B.pdf (recommending that the doctrine be limited to situations in which fraud results in the granting of one or more invalid claims); Robert A. Armitage, Inequitable Conduct and Post-Grant Review: Why the Imperative to Eliminate the "Inequitable Conduct" Defense? What Relates Eliminating the Defense to Expanding Post-Grant Review?, Am. INTELL. PROP. L. ASS'N, Jan. 2009, at 1–5 (arguing in favor of abolition); Cotropia, supra, at 737-46, 773-83 (reviewing critiques of current doctrine and proposing reforms); Lisa A. Dolak, Inequitable Conduct: A Flawed Doctrine Worth Saving, in 4th ANNUAL PATENT LAW INSTITUTE, at 877, 879, 881–92 (PLI Patents, Copyrights, Trademarks & Literary Prop., Course Handbook Series No. 997, 2010), available at http://ssrn.com/abstract=1588916 (reviewing critiques of current doctrine and proposing reforms); Robin Feldman, The Role of the Subconscious in Intellectual Property Law, 2 HASTINGS SCI. & TECH. L.J. 1, 14-23 (2010) (arguing that current doctrine "requires inventors to act against their own interests and in a manner that contradicts their instincts, and then charges them with immoral behavior for an inability to consciously override those instincts"); Senator Orrin G. Hatch, Keynote Address at the National Press Club in Washington, D.C. (Mar. 18, 2009), in 78 GEO. WASH. L. REV. 513, 517 (2010) (arguing for a narrower definition of materiality); Mammen, supra, at 1390-94 (presenting reform proposals); Kate McElhone, Inequitable Conduct: Shifting Standards for Patent Applicants, Prosecutors, and Litigators, 17 Tex. INTELL. PROP. L.J. 385, 405-12 (2009) (proposing various reforms and discussing other proposals); David McGowan, Inequitable Conduct, 43 Loy. L.A. L. Rev. 945 (2010) (arguing for a reformed version of the doctrine); Lee Petherbridge et al., The Federal Circuit and Inequitable Conduct: An Empirical Assessment, 84 S. CAL. L. REV. (forthcoming 2011) (presenting an empirical study of the courts' application of the doctrine and concluding that the doctrine rarely succeeds in practice);

uncertain both in its application and efficacy in promoting the goals of the patent system.

Conventionally, the law of inequitable conduct (like its cousin, patent misuse) can be viewed as an outgrowth of the equitable doctrine of unclean hands-in the present context, as a means of preventing patent owners from profiting through fraud on the USPTO.³ Courts have expanded the doctrine's reach so that in its present incarnation, inequitable conduct encompasses not only misrepresentations and omissions amounting to outright fraud but also to an amorphous category of somewhat lesser sins. The Federal Circuit has made clear, for example, that conduct need not rise to the level of fraud that would sustain a Walker Process antitrust claim in order to be characterized as inequitable conduct.⁴ Nevertheless, defining exactly what inequitable conduct is has sometimes proven elusive: as discussed below, case law has often defined the doctrine's key elements of "intent" and "materiality" in ways that seem both imprecise and inconsistent.⁵ For practical purposes, the significance of the doctrine resides in the fact that a finding of inequitable conduct results in the unenforceability of all of the claims of the patent at issue and sometimes even of related patents.⁶ Alarmed at these potential consequences, critics charge that the doctrine has become a death sentence for minor offenses, while defenders counter that the doctrine deters

Randall R. Rader, Always at the Margin: Inequitable Conduct in Flux, 59 Am. U. L. REV. 777, 785 (2010) (arguing in favor of clearer standards); David O. Taylor, *Patent Fraud*, 83 TEMP. L. REV. 49, 72–73, 77–98 (2010) (arguing that inequitable conduct should be limited to the fraudulent procurement of patents, and that other penalties should be imposed for lesser misconduct, and proposing other possible reforms); Melissa Feeney Wasserman, Limiting the Inequitable Conduct Defense, 13 VA. J.L. & TECH. 7, 16-22 (2008) (arguing for limiting the doctrine to common law fraud and for a range of penalties); Brown, supra, at 616-20 (reviewing testimony presented at Patent Reform Act hearings); Mack, supra, at 166-75 (proposing various reforms); Nicole M. Murphy, Note, Inequitable-Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?, 93 MINN. L. REV. 2274, 2274–75, 2296–2302 (2009) (reviewing critiques of current doctrine and proposing guidelines for a range of sanctions); Katherine Nolan-Stevaux, Note, Inequitable Conduct Claims in the 21st Century: Combating the Plague, 20 Berkeley Tech. L.J. 147, 164-72 (2005) (discussing and proposing various reforms); The Patent Reform Act Will Hurt, Not Help, the U.S. Patent System, PATENT OFFICE PROF'L ASS'N (Sept. 2007), http://www.popa.org/pdf/misc/reform-popa-04sep2007.pdf (arguing that proposed Patent Reform Act changes to the doctrine would reduce applicant candor and render the doctrine moot).

- 3. *See* Cotropia, *supra* note 2, at 728 (noting the conventional understanding of inequitable conduct as a doctrine rooted in equity rather than in utilitarian considerations).
- 4. See Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1346–48 (Fed. Cir. 2007). A Walker Process claim is an antitrust claim premised on the theory that the antitrust defendant's enforcement of a fraudulently procured patent constitutes an act of monopolization or attempted monopolization in violation of Sherman Act § 2. See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965); Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998).
 - 5. See infra Part I.
 - 6. See id.
- 7. See Murphy, supra note 2, at 2274 (quoting Robert Armitage as likening the penalty to "imposing the death penalty for relatively minor acts of misconduct"); see also

misconduct and thus contributes to the integrity of patent prosecution and enforcement. And, although the Federal Circuit's recent en banc decision in *Therasense, Inc. v. Becton, Dickinson & Co.* has recast the doctrine in ways that likely will pacify some of the critics, the question still remains whether *Therasense* succeeds in stemming further reforms or doctrinal adjustments. Congress has long considered changes to the inequitable conduct doctrine as part of a comprehensive system of patent reform, and, as of this writing, a certiorari petition in *Therasense* seems likely.

Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting) (referring to the "'atomic bomb' remedy of unenforceability").

- 8. See Dolak, supra note 2, at 881–86 (advocating reforms but ultimately arguing in favor of retaining the doctrine because "inequitable conduct happens!"); Brown, supra note 2, at 616–17 (reviewing congressional testimony in favor of retaining the doctrine).
- 9. Nos. 2008-1511, -1512, -1513, -1514, -1595, 2011 WL 2028255 (Fed. Cir. May 25, 2011) (en banc). The conduct at issue in *Therasense* consisted of representations made to the USPTO by Abbott Laboratories' patent attorney and an Abbott executive during the course of prosecuting what came to be the patent in suit—the '551 Patent. *Id.* at *1–2. Specifically, these individuals had represented that a person of skill in the relevant art would have understood the phrase "optionally, but preferably" as used in a prior art patent (the '382 Patent) to mean "necessarily." *Id.* On the basis of these representations, the examiner allowed the '551 Patent. *Id.* at *2–3. It later came to light, however, that Abbott's European patent counsel had made conflicting representations about the meaning of the same claim term in an earlier proceeding before the European Patent Office involving the European counterpart of the '382 Patent. *See id.* The legal issues surrounding application of the inequitable conduct doctrine are discussed in Part I below.
- The most recent actions in Congress were the approvals by the Senate of the Patent Reform Act of 2011 and by the House Judiciary Committee of the American Invents Act of 2011. Using identical language, both bills would modify the inequitable conduct doctrine by allowing patent owners to request supplemental examinations "to consider, reconsider, or correct information believed to be relevant to the patent' and providing that "a patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination" concluded before the date on which the patentee files suit for infringement. See S. 23, 112th Cong., § 10(a) (2011), available at http://www.govtrack.us/congress/billtext.xpd?bill=s112-23; HR 1249, 112th Cong., § 11(a) (2011), available at http://www.govtrack.us/congress/bill.xpd?bill=h112-1249. Some previous patent reform bills introduced in recent years would have reformed the doctrine in other ways. See Patent Reform Act of 2009, S. 610, 111th Cong., § 11 (2009), available at http://www.govtrack.us/congress/billtext.xpd?bill=s111-610 (providing for administrative proceedings and civil sanctions for misconduct before the USPTO, and otherwise stating that "a patent shall not be held invalid or unenforceable on the basis of misconduct before the Office"); Patent Reform Act of 2007, S. 1145, 110th Cong., § 12 (2008) (codifying the reasonable examiner standard, among other things, and enabling courts to hold the entire patent unenforceable; only some claims unenforceable; or to allow the patentee to recover reasonable royalties only); Patent Reform Act of 2007, HR 1908, 110th Cong., § 12(b) (2007) (codifying a materiality standard similar to the 1992 version of Rule 56 to allow courts to consider a range of penalties); Patent Reform Act of 2006, S. 3818, 109th Cong., § 5(c) (2006) (providing that a court may not hold a patent unenforceable by reason of inequitable conduct unless one or more claims are invalid; and that a defendant may not

Some recent scholarship has begun to cast the inequitable conduct doctrine in a more instrumental vein by focusing on the doctrine as, ideally, a tool for encouraging patent applicants to engage in the optimal disclosure of information relevant to their applications. 12 This Article builds upon this body of work by modeling the variables a rational applicant would consider in deciding how much information to reveal to the USPTO. The model suggests, among other things, that the conditions that trigger a finding of inequitable conduct, both in the doctrine's current and previous versions—as well as in various proposed reformulations—are at best only a rough proxy for the conditions that define the optimal disclosure of information relating to patentability. The model also illuminates how poorly the doctrine has traditionally defined many of the factors affecting a rational applicant's decisionmaking process and has potentially encouraged risk-averse agents to overdisclose. Put another way, the model is intended primarily to clarify what various factors the courts have identified as relevant to the analysis might mean, how these factors relate to one another, and how, depending on their meanings and interrelationships, they would be expected to affect the behavior of both risk-neutral and, subsequently, risk-averse patent applicants and their agents. Thus, although the model neither confirms nor refutes critics' claims that the doctrine has routinely induced overdisclosure and excessive

plead the defense until there has been a judgment that the patent is "not invalid in whole and has been infringed"); Patent Reform Act of 2005, HR 2795, 109th Cong., § 5 (2005) (providing that a court must refer possible misconduct to the USPTO for investigation, but only if one or more claims have been held invalid; and that it may declare a patent unenforceable only if the USPTO concludes that inequitable conduct occurred).

- 11. See Kevin Noonan, Therasense, Inc. v. Becton, Dickinson & Co. (Fed. Cir. 2011) (en banc): Judge O'Malley's Opinion, PAT. DOCS: BIOTECH & PHARMA PAT. L. & NEWS BLOG (May 30, 2011), http://www.patentdocs.org/2011/05/therasense-inc-v-becton-dickinson-co-fed-cir-2011-en-banc-judge-omalleys-opinion.html; Harold C. Wegner, A Post-Therasense Rule 56 Duty of Disclosure, IP FRONTLINE (May 30, 2011), http://www.ipfrontline.com/depts/article.aspx?id=25337&deptid=7.
- See Cotropia, supra note 2, at 746–62 (characterizing the doctrine as a tool for attaining optimal patent quality); Clarisa Long, Patent Signals, 69 U. CHI. L. REV. 625, 668-71 (2002) ("By imposing higher costs on patentees who would attempt to take advantage of high observer verification costs by making false statements in the patent, penalties for inequitable conduct make it more costly for dishonest firms to mimic the behavior of honest firms."); McGowan, supra note 2, at 974 (arguing that the doctrine should reflect "the instrumental concern that examiners have the information they need to decide whether an application satisfies the statutory criteria"); Taylor, supra note 2, at 63-64 (discussing the costs of overdisclosure). The goals of attaining optimal patent quality, or of preserving a patent's function as a signal of firm value, can be subsumed within the broader utilitarian concept of optimal disclosure. As discussed in Part II of this Article, the concept of optimal disclosure assumes that the patent applicant's disclosure of relevant information, properly defined, promotes social welfare when (1) the applicant enjoys a cost advantage over the examiner in discovering and disclosing the information, and (2) the social benefits of additional disclosure outweigh the social costs of information overload. When these conditions are not present, patent quality and signaling may suffer. See Cotropia, *supra* note 2, at 770–73. This instrumental explanation for the doctrine attempts to conform the doctrine to the utilitarian thrust of patent law generally, though it contrasts with the more conventional understanding of the doctrine as promoting the integrity of the patent system as a deontological end in itself. See id. at 746-47.

administrative costs—again, the model is intended principally as positive or explanatory, not normative—it demonstrates some ways in which various doctrinal changes, either by themselves or in combination, might be expected to reduce the negative consequences that critics claim the doctrine has generated. Finally, the model suggests that the social value of an inequitable conduct doctrine may be greater in a regime like that of the United States, which lacks an effective system for post-grant oppositions. Conversely, if the United States adopted a post-grant opposition system, the need for a robust inequitable conduct doctrine would decline.

I. DOCTRINAL CONTOURS

By many accounts, the inequitable conduct doctrine has its origins in three mid-twentieth century U.S. Supreme Court decisions in which the Court held that the patents at issue were unenforceable because the patent owners had engaged in some sort of fraudulent conduct in the course of procuring or litigating their patents.¹³ Lower courts thereafter developed different tests for determining whether the patent owner or applicant had engaged in inequitable conduct, thus rendering the patent unenforceable.¹⁴ Independent from these developments, the USPTO in 1977 promulgated Patent Rule 56, which imposed on patent applicants and persons associated with them a duty to disclose "information they are aware of which is material to the examination of the application." Rule 56 defined

^{13.} See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 819 (1945) (holding that, where patent owner had every reason to believe that purported inventor had submitted false testimony during the course of an interference proceeding relating to his dates of invention and conception, the resulting patent was rendered unenforceable); Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 250 (1944) (setting aside a judgment of patent infringement, where patent owner had caused the publication of a trade journal article authored by its patent attorney but attributed to a 'disinterested expert" that falsely touted the subject invention's advances over the prior art, and had used that article to deceive both the Patent Office and the district court on the issue of patentability); Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 245, 246–47 (1933) (affirming dismissal of complaint for patent infringement, where patent owner had corrupted a witness and suppressed evidence of another's prior use in order to defend against patent invalidity in a prior infringement action involving related patents). As in the patent misuse cases, which the Court was deciding during roughly the same time period, in these three cases the Court drew an analogy to the equitable doctrine of unclean hands. Earlier patent law had recognized limited rights to cancel patents that were procured by fraud. See Robert J. Goldman, Evolution of the Inequitable Conduct Defense in Patent Litigation, 7 HARV. J.L. & TECH. 37, 39-45 (1993); McGowan, supra note 2, at 948-56; Sean M. O'Connor, Defusing the "Atomic Bomb" of Patent Litigation: Avoiding and Defending Against Allegations of Inequitable Conduct After McKesson et al., 9 J. MARSHALL REV. INTELL. PROP. L. 330, 331-33 (2010).

^{14.} See, e.g., Plastic Container Corp. v. Cont'l Plastics, Inc., 607 F.2d 885, 899–901 (10th Cir. 1979); Norton v. Curtiss, 433 F.2d 779, 791–97 (C.C.P.A. 1970). For discussion of post-Precision Instrument, pre-Federal Circuit case law, see Goldman, supra note 13, at 56–57; O'Connor, supra note 13, at 340–44, 352; Gerald Sobel, Reconsidering the Scope of the Inequitable Conduct Doctrine in View of Supreme Court Precedent and Patent Policy, 18 FED. CIR. B.J. 169, 172–74 (2009).

^{15. 37} C.F.R. § 1.56 (1977). An earlier version of Rule 56 merely authorized the USPTO to strike an application that was "fraudulently filed or in connection with which any

information as material if "there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." The USPTO's amended version of Rule 56, which went into effect in 1992, similarly imposes on "[e]ach individual associated with the filing and prosecution of a patent application . . . a duty to disclose to the Office all information known to that individual to be material to patentability," 17 while also providing a more detailed definition of materiality. Specifically, the current version of Rule 56 states that information is material if "it is not cumulative to information already of record or being made of record in the application," and it either "establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim" or "refutes, or is inconsistent with, a position the applicant takes in . . . [o]pposing an argument of unpatentability relied on by the Office, or . . . [a]sserting an argument of patentability." Rule 56 further specifies that "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."19

Since its formation in the early 1980s, the Federal Circuit has drawn on these various sources to fashion its own version of an inequitable conduct defense that sometimes applies to conduct significantly less egregious than the misconduct that was at issue in the Supreme Court trilogy. Illustrating how the doctrine operates under current law requires a short foray into the workings of patent prosecution and litigation. Briefly stated, to begin the process of obtaining a patent, the inventor files a patent application with the USPTO. The USPTO then assigns an examiner to determine whether the application meets the statutory requirements for patentability—among them, whether the application recites patentable subject matter, the relevant prior art, and whether the application

fraud [was] practiced or attempted on the Patent Office." O'Connor, *supra* note 13, at 338 (quoting 37 C.F.R. § 1.56 (1949)).

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

Id. § 1.56(b)(2)(ii).

- 19. *Id.* § 1.56(a).
- 20. See 35 U.S.C. § 111(a) (2006).
- 21. See 35 U.S.C. § 101 (2006); Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010).
- 22. See 35 U.S.C. §§ 102, 103 (2006).

^{16. 37} C.F.R. § 1.56 (1977).

^{17. 37} C.F.R. § 1.56(a) (2009). In the wake of the recent en banc *Therasense* decision, discussed below, the USPTO has proposed a revision to the Rule 56 materiality standard that tracks *Therasense*. *See* Revision to the Materiality Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43631 (July 21, 2011).

^{18. 37} C.F.R. § 1.56(b) (2009). The rule goes on to state:

conforms to Patent Act § 112.²³ Ostensibly, to assist the examiner in making this determination, Rule 56 (as noted above) requires the inventor to disclose material information, either in the body of the patent application or in a document known as an "Information Disclosure Statement" or "IDS."²⁴ If the inventor is successful in obtaining a patent, she is then free to file suit against anyone she has reason to believe is making, using, or selling the invention without authorization.²⁵

Suppose, then, that inventor P files suit against defendant D for infringement. In defense, D typically will first assert that he is not infringing; for example, D may contend that, contrary to P's allegations, D's products or services do not fall within the scope of any of the patent's claims. Second, D is likely to assert that, even if his products fall within the scope of one or more of the patent's claims, D's conduct is lawful because the claims themselves are invalid. D may contend, among other things, that during the course of patent prosecution the examiner overlooked or failed to appreciate the significance of certain prior art references demonstrating that the invention lacked novelty or was obvious; or that the claims do not recite patentable subject matter; or that the specification fails to conform to § 112. ²⁶ A third possible defense is that, even if the patent is both valid and infringed, it remains unenforceable by reason of inequitable conduct. ²⁷ To understand how this defense differs from invalidity requires an exploration of a fairly complex body of Federal Circuit case law.

According to the Federal Circuit, inequitable conduct encompasses both the intentional submission of materially false information and the failure to disclose material information. More precisely, the substantive elements of inequitable conduct are: "(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the

^{23.} As interpreted by the courts, § 112 requires the applicant to provide a written description demonstrating that the inventor is in possession of the claimed subject matter, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); to enable a person of skill in the art to make and use the invention, *id.* at 1343 (quoting 35 U.S.C. § 112 (2006)); to reveal the inventor's best mode, if any, of carrying out the invention, *id.*; and to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," 35 U.S.C. § 112, para. 2. The claims therefore define the boundaries of the invention; the typical patent contains multiple claims relating to various aspects of the invention.

^{24.} See 37 C.F.R. §§ 1.97, 1.98 (2009).

^{25.} See 35 U.S.C. § 271(a) (2006).

^{26.} Patents are presumed valid, 35 U.S.C. § 282 (2006), and the defendant has the burden of proving invalidity by clear and convincing evidence, Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2242 (2011). Nevertheless, statistics show that defendants are successful in proving invalidity—essentially, that the USPTO made a mistake in issuing one or more claims of the patent—almost 50% of the time. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205–07 (1998).

^{27.} Other possible defenses not relevant to the present discussion include patent misuse, laches, and implied license.

PTO."²⁸ Difficulties arise, however, in trying to define these elements of materiality and intent with any degree of precision.

As for materiality, prior to *Therasense* the Federal Circuit had retained *all five* of the standards reflected in pre-Federal Circuit case law, the 1977 version of Rule 56, and the 1992 version of Rule 56. These five standards included: (1) an objective but-for test (i.e., the patent *should not* have issued absent the fraud); (2) a subjective but-for standard (i.e., the patent *would not* have issued absent the fraud); (3) a but-it-may-have standard (i.e., the fraud *may have affected* the issuance of the patent); (4) the reasonable examiner standard as set forth in original Rule 56 (i.e., there is a substantial likelihood that a reasonable examiner would have considered the omitted reference important in deciding patentability); and (5) the current Rule 56 standard (i.e., the information is material in the sense of establishing a prima facie case of unpatentability, or refuting or being inconsistent with a position the applicant takes regarding patentability before the USPTO).²⁹ According to one panel, however, because the "reasonable examiner" standard is the broadest of these standards, it gradually had become "the sole standard invoked by this court," though "in no way did it supplant or replace the case law precedent."³⁰

The Federal Circuit's *Therasense* decision, handed down in May 2011, revised the court's governing standards on materiality by holding that "as a general matter, the materiality required to establish inequitable conduct is but-for materiality." More specifically:

^{28.} Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009) (citing Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008)). The Federal Circuit reaffirmed this definition of inequitable conduct in *Therasense. See* Therasense, Inc. v. Becton, Dickinson & Co., Nos. 2008-1511, -1512, -1513, -1514, -1595, 2011 WL 2028255, at *6 (Fed. Cir. May 25, 2011) (en banc). The defendant must plead the defense with particularity pursuant to Federal Rule of Civil Procedure 9(b), *see Exergen*, 575 F.3d at 1318, and must prove the two elements of intent and materiality by clear and convincing evidence, *see Therasense*, 2011 WL 2028255, at *6; Larson Mfg. Co. v. Aluminart Prods. Ltd., 559 F.3d 1317, 1344 (Fed. Cir. 2009).

^{29.} See Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314–16 (Fed. Cir. 2006).

^{30.} *Id.* at 1316.

^{31.} Therasense, 2011 WL 2028255, at *11. Chief Judge Rader's majority opinion was joined by Judges Newman, Lourie, Linn, Moore, and Reyna. Judge O'Malley filed a separate opinion concurring in the majority's resolution of the "intent" issue but dissenting from its resolution of "materiality." Under Judge O'Malley's proposed standard, conduct would be material where:

⁽¹⁾ but for the conduct (whether it be in the form of an affirmative act or intentional non-disclosure), the patent would not have issued . . . ; (2) the conduct constitutes a false or misleading representation of fact (rendered so either because the statement made is false on its face or information is omitted which, if known, would render the representation false or misleading); 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.

Id. at *20 (O'Malley, J., concurring in part and dissenting in part). In dissent, Judge Bryson, joined by Judges Gajarsa, Dyk, and Prost, argued for adoption of the USPTO's 1992

When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction. . . . Often the patentability of a claim will be congruent with the validity determination—if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires clear and convincing evidence, a higher evidentiary burden than that used in prosecution at the PTO. However, even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards.³²

Two ambiguities nevertheless remain. First, it is not entirely clear from the opinion whether the majority intended to adopt the "objective" or the "subjective" but-for test as the governing standard for materiality. On the one hand, the majority's frequent use of the word "would" (as opposed to "should") might suggest that it was opting for the subjective test. On the other hand, the majority's further statement that a reference is "necessarily" material "if a claim is properly invalidated in district court based on the ... reference" would seem more consistent with the objective test; the mere fact that a court properly found the reference to be invalidating does not "necessarily" indicate that the actual examiner, as opposed to a hypothetical ideal examiner, would have made the same finding.³⁴ Second, the majority recognized an exception to the but-for rule "in cases of affirmative egregious misconduct" such as "the filing of an unmistakably false affidavit."35 Because the exception applies only to affirmative misrepresentations and not omissions, 36 it may have relatively infrequent application³⁷—though for now that conclusion is far from certain. In dissent, Judge Bryson cited the example of "a submission to the PTO that purports to describe the

materiality standard. See id. at *22 (Bryson, J., dissenting).

^{32.} *Id.* at *11 (majority opinion) (citations omitted).

^{33.} *Id*

^{34.} For defense of my pairing of the terms "subjective but-for" with the actual examiner, and of "objective but-for" with a hypothetical ideal examiner, see *infra* text accompanying note 92.

^{35.} *Therasense*, 2011 WL 2028255, at *12. The majority appears to see such conduct as implicating the traditional equitable doctrine of unclean hands. *See id.* at *6, *12–13.

^{36.} See id. at *12 ("Because neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct, claims of inequitable conduct that are based on such omissions require proof of but-for materiality.").

^{37.} See Petherbridge et al., supra note 2, at 34 ("[O]mission . . . is far and away the most common form of material conduct described in Federal Circuit opinions.").

state of the prior art but knowingly omits the closest prior art" as evidence that "it is often difficult to draw a line between nondisclosure and affirmative misrepresentation" and predicted that "[t]he distinction between 'affirmative acts' and 'nondisclosure' is thus apt to become fertile ground for litigation in the future, not to mention the distinction between 'egregious' misconduct and misconduct that is assuredly less than 'egregious."³⁸

As for the intent element, over 20 years ago in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*,³⁹ the Federal Circuit held en banc that a defendant asserting inequitable conduct must prove intent to deceive and not merely gross negligence on the part of the patent applicant.⁴⁰ Subsequent case law nevertheless muddied the waters by adopting conflicting views on the precise meaning of "intent to deceive." One line of Federal Circuit cases interpreted *Kingsdown* to mean that, while intent could be inferred from circumstantial evidence, neither gross negligence nor the materiality of the information withheld was, by itself, sufficient evidence of intent.⁴¹ A competing line of cases held that the trier of fact could infer intent to deceive where the omitted information was highly material, the party who failed to disclose the information knew or should have known of its materiality, and that party offered no credible explanation for failing to disclose it.⁴² Critics argued that this latter line of authority could not be reconciled with *Kingsdown*, because a "knew or should have known" standard would allow the trier of fact to infer intent to deceive on the basis of mere negligence (not even amounting to gross negligence).⁴³ Further compounding the

^{38.} Therasense, 2011 WL 2028255, at *33 n.3 (Bryson, J., dissenting); see also id. at *18 n.3 (O'Malley, J., concurring in part and dissenting in part) ("If 'unclean hands' remains available in cases of PTO misconduct, charges of unclean hands could simply supplant the very allegations of inequitable conduct the majority seeks to curb.").

^{39. 863} F.2d 867 (Fed. Cir. 1988) (en banc).

^{40.} *Id.* at 876.

^{41.} *See*, *e.g.*, Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1355–56 (Fed. Cir. 2008).

^{42.} See, e.g., Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1313–14 (Fed. Cir. 2008); Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006); cf. Cancer Research Tech. Ltd. v. Barr Labs., Inc., 625 F.3d 724, 733–34 (Fed. Cir. 2010) ("A court cannot simply infer that an applicant 'should have known' the materiality of withheld information and thus intended to deceive the PTO because the applicant knew of the information and the information is material. A district court must find some other evidence that indicates that the applicant appreciated the information's materiality." (citation omitted)); Optium Corp. v. Emcore Corp., 603 F.3d 1313, 1321 (Fed. Cir. 2010) ("[C]onsistent precedent has rejected the notion that the materiality of a reference alone can suffice to prove deceptive intent." (citations omitted)).

^{43.} See, e.g., Larson Mfg. Co. v. Aluminart Prods. Ltd., 559 F.3d 1317, 1343–44 (Fed. Cir. 2009) (Linn, J., concurring); Mammen, supra note 2, at 1391–92. Arguably, the "knew or should have known" standard was an inadvertent throwback to pre-Kingsdown law. See Erik R. Puknys & Jared D. Schuettenhelm, Application of the Inequitable Conduct Doctrine After Kingsdown, 25 Santa Clara Computer & High Tech. L.J. 839, 850–51 (2009) (noting that the Federal Circuit in Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997), cited a pre-Kingsdown case, Driscoll v. Cebalo, 731 F.2d 878 (Fed. Cir. 1984), for the "knew or should have known" standard);

confusion, some decisions referred to the intent and materiality standards as involving a "sliding scale," in the sense that a stronger showing of intent would allow a finding of inequitable conduct on a somewhat lower showing of materiality, and vice versa. 44

Therasense has now clarified the intent to deceive element by expressly holding that the appropriate standard is "specific intent to deceive," not negligence or gross negligence, 45 and by rejecting the "sliding scale." Recognizing that "direct evidence of deceptive intent is rare," however, the Therasense majority conceded that "a district court may infer intent from indirect and circumstantial evidence" while also citing with approval prior case law holding that "to meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence"—indeed, the evidence must "require a finding of deceitful intent in the light of all the circumstances."47 Some ambiguity in the application of the new standard nevertheless may remain at the margin. In her concurring opinion, for example, Judge O'Malley stated her understanding that a court may still "consider the level of materiality as circumstantial evidence in its intent analysis," even though it must "reach separate conclusions of intent and materiality and may not base a finding of specific intent to deceive on materiality alone, regardless of the level of materiality."48 In a similar vein, Judge Bryson suggested that it remains appropriate to "consider[] the degree of materiality as relevant to the issue of intent . . . particularly given that direct evidence of intent, such as an admission of deceptive purpose, is seldom available." The majority did not respond directly to the concurring or dissenting opinion on this particular issue; thus, the question of the precise relationship between materiality and intent remains to be determined.

Therasense appears to leave the inequitable conduct doctrine unchanged in all other respects. First, nothing in *Therasense* reverses prior case law holding that, if the defendant makes the requisite showing of both intent and materiality, the district court should engage in a balancing test to determine whether the

Brett J. Thompsen, Note, *Resolving Inequitable Conduct Claims According to* Kingsdown, 18 Tex. INTELL. PROP. L.J. 269, 275–76 (2010) (same).

^{44.} *See, e.g.*, Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1380 (Fed. Cir. 2002); *Critikon*, 120 F.3d at 1256. Nevertheless, the defendant was supposed to prove by clear and convincing evidence that each element met the minimum threshold of both intent and materiality. *See* AstraZeneca Pharm. LP v. Teva Pharm. USA, Inc., 583 F.3d 766, 776 (Fed. Cir. 2009). For a helpful visual depiction, see Mammen, *supra* note 2, at 1344.

^{45.} Therasense, Inc. v. Becton, Dickinson & Co., Nos. 2008-1511, -1512, -1513, -1514, -1595, 2011 WL 2028255, at *9 (Fed. Cir. May 25, 2011) (en banc). All eleven active members of the court agreed on this holding. *Id.* at *17 (O'Malley, J., concurring in part and dissenting in part); *id.* at *22 (Bryson, J., dissenting).

^{46.} *Id.* at *10 (majority opinion). All eleven judges agreed on this point as well. *Id.* at *17 (O'Malley, J., concurring in part and dissenting in part); *id.* at *22 (Bryson, J., dissenting).

^{47.} *Id.* at *10 (majority opinion) (quoting Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 873 (Fed. Cir. 1988) (en banc)).

^{48.} See id. at *17 n.1 (O'Malley, J., concurring in part and dissenting in part).

^{49.} *Id.* at *24 n.1 (Bryson, J., dissenting).

applicant committed inequitable conduct.⁵⁰ Second, *Therasense* reaffirms that a district court's factual findings on intent and materiality are subject to appellate review only for clear error.⁵¹ Third, *Therasense* appears to leave intact the rule that whether conduct meeting the minimal thresholds of materiality and intent should be characterized as "inequitable" is a matter entrusted to the district court's equitable discretion, reviewable on appeal for abuse of discretion.⁵²

Fourth, and most importantly, the practical significance of the doctrine continues to reside in the penalty that follows from a finding of inequitable conduct. Even after *Therasense*, a finding of inequitable conduct renders the *entire* patent ⁵³—and sometimes even related patents ⁵⁴—unenforceable. As a consequence, even when the plaintiff fails to prove infringement or the defendant succeeds in proving the invalidity of some or all of the claims at issue, a court will typically go on to consider the merits of a properly raised inequitable conduct defense. If successful, this challenge will render *all* of the claims of the patent unenforceable—not only against the defendant who raised the defense, but also against any other potential infringer. At least in this respect, the inequitable conduct doctrine remains, in Chief Judge Rader's words, the "atomic bomb" of patent litigation. ⁵⁵

See AstraZeneca Pharm. LP v. Teva Pharm. USA, Inc., 583 F.3d 766, 776
 (Fed. Cir. 2009).

^{51. 2011} WL 2028255, at *10.

^{52.} See id. at *24 (Bryson, J., dissenting); see also id. at *10 (majority opinion) (indicating that courts retain discretion not to find inequitable conduct, even when the threshold showings of materiality and intent are present); Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1353 (Fed. Cir. 2008) (quoting *Kingsdown*, 863 F.2d at 876).

^{53. 2011} WL 2028255, at *12. In addition, a finding of inequitable conduct can result in a finding that a case is exceptional and, therefore, that the defendant is entitled to attorney's fees. *See id.* at *8; Aspex Eyewear Inc. v. Clariti Eyewear, Inc., 605 F.3d 1305, 1315 (Fed. Cir. 2010); Taltech Ltd. v. Esquel Enters. Ltd., 604 F.3d 1324, 1328 (Fed. Cir. 2010); Wedgetail, Ltd. v. Huddleston Deluxe, Inc., 576 F.3d 1302, 1304–05 (Fed. Cir. 2009). In contrast to the misuse doctrine, the inequitable conduct doctrine does not envision any way for the patentee to purge its misconduct and thus restore the patent's enforceability.

^{54.} On the doctrine of "infectious unenforceability," compare *Fox Industries v. Structural Preservation Systems, Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990) ("[A] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application."), with *Baxter International, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1332 (Fed. Cir. 1998) ("[W]here the claims are subsequently separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to inequitable conduct committed in the parent application.").

^{55.} Therasense, 2011 WL 2028255, at *8. Adoption of the objective but-for standard, however—assuming that this is the standard the court has adopted, and ignoring for now the exception for affirmative misrepresentations—will obviate one consequence associated with the other four materiality standards, namely the possibility of rendering a patent unenforceable by reason of the applicant's failure to disclose references that would have had no effect on validity. To illustrate, suppose that a court finds that P intentionally failed to disclose a prior art reference that, on its face, suggests that her invention may have been obvious at the time of invention to a person of ordinary skill in the art, see 35 U.S.C. §

Prior to *Therasense*, the complexity and operation of the inequitable conduct doctrine had generated intense criticism from some members of the patent community. Critics argued that the multiplicity of possible standards, as well as the corresponding inconsistencies in the case law, often made it irresistible for defendants to avoid raising the defense.⁵⁶ In addition, some critics noted a risk of

103(a) (2006), but that P would have been able to "traverse" (distinguish) the reference through persuasive argument or other evidence of patentability. In such a case, under preTherasense law the patent may well have been valid but unenforceable as a result of P's failure to disclose the suggestive, though ultimately non-invalidating, reference.

Alternatively, P may have failed to disclose information that a reasonable examiner might have considered relevant, though ultimately non-invalidating, to various other patentability requirements such as subject matter, enablement, or best mode. See infra note 63 and accompanying text.

Yet another example would be information that has no bearing at all on patentability as such, but that relates instead to the inventor's entitlement to various prosecution-related benefits. Pre-Therasense, the Federal Circuit had held that misrepresentations relating to socalled "petitions to make special," otherwise known as petitions for expedited examination, U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 708.02 (Magdalen Greenlief ed., 8th ed., rev. July 2010), or to a patent owner's small entity status (rendering the applicant eligible to pay lower examination fees), could be the basis of a finding of inequitable conduct, see Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V., 528 F.3d 1365, 1375 (Fed. Cir. 2008) ("When the setting involves a petition to make special...a false statement that succeeds in expediting the application is, as a matter of law, material for purposes of assessing the issue of inequitable conduct." (footnote omitted)); Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1231-32 (Fed. Cir. 2007) ("While a misrepresentation of small entity status is not strictly speaking inequitable conduct in the prosecution of a patent, as the patent has already issued if maintenance fees are payable (excepting an issue fee), it is not beyond the authority of a district court to hold a patent unenforceable for inequitable conduct in misrepresenting one's status as justifying small entity maintenance payments." (citation omitted)); see also Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139, 1144 (Fed. Cir. 2003) ("Historically issues of unenforceability have arisen in cases involving inequitable conduct occurring in the prosecution of patents. But, we see no reason why the doctrine should not extend into other contexts, like the present one, where the allegation is that inequitable conduct has occurred after the patent has issued and during the course of establishing and paying the appropriate maintenance fee. In this context, it is equally important that the PTO receive accurate information from those who practice before it." (citation omitted)). The court had also held that failure to disclose related litigation involving a parent patent, as required under § 2001.06(c) of the Manual of Patent Examining Procedure, was material even if the patentee prevailed in that litigation. Leviton Mfg. Co. v. Universal Sec. Instruments, Inc., 606 F.3d 1353, 1362 (Fed. Cir. 2010); see also McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 919-26 (Fed. Cir. 2007) (affirming findings of materiality and intent with respect to failures to disclose rejections in co-pending application, and examiner's own prior allowance of claims in a related application). Presumably the holdings in the cases cited in this paragraph survive *Therasense* where the applicant has engaged in affirmative misrepresentations, but not where the applicant merely fails to disclose.

56. See Larson Mfg. Co. v. Aluminart Prods. Ltd., 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., concurring); see also NAT'L RESEARCH COUNCIL, supra note 2, at 122; Cotropia, supra note 2, at 739–41; Wasserman, supra note 2, at 14–15. While few observers would defend an inventor's right to make affirmative misrepresentations to the patent office, as noted above, the vast majority of inequitable conduct allegations related to the broader,

"hindsight bias" in determining, at the time of trial, whether the applicant knew at the time of prosecution that information she chose to withhold was material; attempts to explain, during the course of litigation many years later, why the information did not appear material at the time of prosecution may sound unconvincing.⁵⁷ Others contended that the doctrine induced patent applicants to disclose far *more* information than was necessary—indeed, more than a patent examiner could be expected to review and comprehend—simply to reduce the probability of a subsequent finding of inequitable conduct.⁵⁸ As a consequence, the doctrine may have raised the cost of litigation by encouraging accused infringers to conduct fishing expeditions to determine whether the patentee failed to call some arguably relevant piece of information to the attention of the patent examiner.⁵⁹ At the very least, if the critics were right, an overly expansive inequitable conduct doctrine raised the cost of patent prosecution to some degree, often with very little corresponding social benefit.

There are other criticisms related to the all-or-nothing nature of the penalty for inequitable conduct. Several observers have argued that rendering *all* claims of the affected patent unenforceable—including claims that themselves were unrelated to the alleged fraud, and potentially even claims of other, related

and less easily containable, category of failures to disclose material information. *See supra* note 37 and accompanying text.

^{57.} See Feldman, supra note 2, at 17, 20–22; Murphy, supra note 2, at 2274.

^{58.} See, e.g., S. Rep. No. 110-259, at 32 n.152 (2008); Fed. Trade Comm'n, supra note 2, at 11-12; SECTION OF INTELLECTUAL PROP. LAW, AM. BAR ASS'N, supra note 2, at 2; Armitage, supra note 2, at 2-3; Cotropia, supra note 2, at 770-73 (discussing information overload); Hatch, supra note 2, at 516 (referring to the production of boxes of documents); Brown, supra note 2, at 618-20 (describing testimony presented at Patent Reform Act hearings); Murphy, supra note 2, at 2293. The majority in Therasense accorded this purported overdisclosure phenomenon considerable weight in its decision to alter the materiality standard. 2011 WL 2028255, at *9. But see McGowan, supra note 2, at 979 (questioning the information overload argument); Petherbridge et al., supra note 2, at 41, 54-55 (noting reasons applicants may choose not to disclose, notwithstanding the risk of unenforceability, and questioning whether burdensome disclosure obligations provide a compelling reason for substantially modifying the doctrine); Christopher A. Cotropia et al., Do Applicant Patent Citations Matter? Implications for the Presumption of Validity 15–16, 19-25 (Stanford Law & Econ., Working Paper No. 401, 2010), available at http://ssrn.com/abstract=1656568 (presenting empirical evidence that examiners tend to ignore applicant-submitted art, even when it is likely to be relevant to patentability).

^{59.} See Section of Intellectual Prop. Law, Am. Bar Ass'n, supra note 2, at 2; Armitage, supra note 2, at 2. A more subtle consequence is that fears of incurring a charge of inequitable conduct may discourage some patent applicants from filing so-called Rule 131 affidavits. See Dennis D. Crouch, Is Novelty Obsolete? Chronicling the Irrelevance of the Invention Date in U.S. Patent Law, 16 Mich. Telecomm. & Tech. L. Rev. 53, 97–98 (2009). Patent Rule 131 allows the applicant to "swear behind" a prior art reference—that is, to assert a date of invention prior to a reference that otherwise may anticipate or render obvious the applicant's invention—and thus helps to promote the U.S. policy of awarding patents to the first to invent (as opposed to the "first to file" rule the rest of the world follows). In this respect, an expansive or uncertain inequitable conduct doctrine would tend to undermine one aspect of U.S. patent policy. I thank Rebecca Eisenberg for bringing this point to my attention.

patents—is often disproportionate to the magnitude of the offense, ⁶⁰ and that a more sensible approach would permit courts to select from a range of penalties (e.g., partial enforceability, temporary enforceability, awarding damages only, or assessing attorney sanctions only). ⁶¹ In her concurring opinion in *Therasense*, Judge O'Malley argues in favor of this option, ⁶² though perhaps the definitions of materiality and intent adopted in the majority opinion will reduce this reform's perceived urgency. ⁶³ As suggested above, however, even after *Therasense* several

^{60.} See New Medium LLC v. Barco N.V., 582 F. Supp. 2d 991, 999 (N.D. Ill. 2008) (Posner, J., sitting by designation), vacated by agreement of parties, No. 05 C 5620, 2009 WL 2385890 (N.D. Ill. May 15, 2009); Armitage, supra note 2, at 1; Wasserman, supra note 2, at 17–18; Murphy, supra note 2, at 2274.

^{61.} See, e.g., S. REP. No. 110-259, at 33 (2008); McElhone, supra note 2, at 408–09; McGowan, supra note 2, at 979–80; Murphy, supra note 2, at 2296–2302; see also Wasserman, supra note 2, at 18–22 (proposing a "second tier of remedies for less offensive behavior").

^{62. 2011} WL 2028255, at *19 (O'Malley, J., concurring in part and dissenting in part) ("We should recognize that determining the proper remedy for a given instance of inequitable conduct is within the discretion of district courts . . . [A] district court may choose to render fewer than all claims unenforceable . . . simply dismiss the action before it, or . . . fashion some other reasonable remedy, so long as the remedy imposed by the court is 'commensurate with the violation.'" (citation omitted)).

Under pre-Therasense doctrine, a finding of inequitable conduct could 63. sometimes result from what might be termed "near-misses," that is, from the applicant's failure to disclose information that almost would have had a bearing on patentability. To illustrate, suppose that an applicant intentionally failed to disclose some piece of information that arguably could be deemed relevant to carrying out her best mode of practicing the invention, but ultimately the defendant was unable to prove a best mode violation by the requisite clear and convincing evidence. Because compliance with the best mode requirement is a necessary precondition to a valid patent, intentionally withholding one's best mode *can* constitute a material omission and thus qualify as inequitable conduct. See Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 808-09 (Fed. Cir. 1990). And, while the applicant's failure to disclose in this hypothetical would not be deemed material under an objective but-for test or, most likely, under the 1992 version of Rule 56, the question could be close enough that the examiner would have rejected the application, had she known the facts (materiality standard 2); failure to disclose may have affected issuance of the patent (materiality standard 3); and a reasonable examiner might have considered the omitted information "important" (materiality standard 4). Thus, it is possible that the omission might have constituted inequitable conduct, even if there is no actual best mode violation (and even though questions of compliance with the best mode requirement rarely arise during patent prosecution). See U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, supra note 55, § 2165.03 ("It is extremely rare that a best mode rejection properly would be made in ex parte prosecution. The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during discovery procedures in interference, litigation, or other *inter partes* proceedings."). Given the criticism that some observers have leveled against the best mode doctrine generally, see NAT'L RESEARCH COUNCIL, supra note 2, at 120–21 (suggesting that that the penalty of invalidity is often disproportionate to the value of the withheld information, given that the inventor's best mode as of the date of filing may have little relevance to the practice of the invention many years later, and the absence of a best mode doctrine in any other country's patent system), one might question

issues surrounding the definitions of materiality and intent remain undetermined; nor is it clear that *Therasense* itself will be the last word on materiality and intent. The need for a clearer analytical framework remains.

II. A FORMAL MODEL OF THE INEQUITABLE CONDUCT DOCTRINE

Although a more traditional view would locate the inequitable conduct doctrine in considerations of ethics and—as the name of the doctrine implies—equity, from an economic perspective the doctrine can be thought of as a tool for encouraging patent applicants and their agents to disclose information to the USPTO.⁶⁴ More precisely, in theory, the doctrine could serve the purpose of inducing the efficient disclosure of information that is relevant to patentability (and perhaps other information as well, as discussed below). In this Part, I first present a model of a socially optimal inequitable conduct doctrine. I then model the applicant's incentive to disclose material information, as well as various possible definitions of materiality, intent, and "balancing."

A. A Socially Optimal Inequitable Conduct Doctrine

To model a socially optimal inequitable conduct doctrine requires consideration of two key points. First, the doctrine should induce the applicant to disclose a preexisting, 65 relevant 66 unit 67 of information I—a potential prior art

whether it would ever make sense to allow accused infringers to leverage unsuccessful best mode defenses into successful inequitable conduct defenses.

- 64. See Cotropia, supra note 2, at 754; McGowan, supra note 2, at 974.
- 65. In other words, the model above focuses on the more common situation of alleged inequitable conduct arising from an applicant's failure to disclose existing information, rather than from her affirmative misrepresentation or fabrication of evidence. Penalizing the latter species of inequitable conduct poses fewer problems from a utilitarian perspective, insofar as there is, presumably, no social benefit (and potentially considerable private and social costs) from manufacturing evidence—though whether unenforceability is always the appropriate penalty even in this instance, particularly given the risk of judicial error, is a difficult question. Not every misrepresentation relates to patentability after all. *See supra* note 55 (discussing misrepresentations as to small entity status and petitions to make special). Of course, an applicant who misrepresents some material fact is also, by necessity, failing to disclose relevant information of which she is aware (i.e., the true state of the world as she understands it to be). In this sense, every misrepresentation also involves a nondisclosure.
- 66. As the discussion below indicates, deciding what type of information should be deemed "relevant" for purposes of the inequitable conduct doctrine—formally, what information comprises the set *S* discussed in the text above—is not easy. The 1992 version of Patent Rule 56 adopts a fairly narrow definition of relevance, for example, whereas the "reasonable examiner" standard adopts a much broader one. *Cf.* FED. R. CIV. P. 26(b)(1) (generally authorizing the discovery of relevant evidence, even if not admissible at trial, if its "discovery appears reasonably calculated to lead to the discovery of admissible evidence"); FED. R. EVID. 401 (defining relevant evidence as "having any tendency to make the existence of any fact that is of consequence . . . more probable or less probable than it would be without the evidence"); FED. R. EVID. 403 (authorizing courts to exclude relevant evidence "if its probative value is substantially outweighed by . . . considerations of undue delay, waste of time, or needless presentation of cumulative evidence"). Analogously, one could define the universe of information within set *S* as including, for example, all

reference, for example, or information that could assist in enabling a person of skill in the art to make or use the invention or to practice the inventor's best mode—only if it is less costly for the applicant to disclose the information than it would be for the examiner to find it herself.⁶⁸ Second, on the assumption that the applicant does enjoy a cost advantage over the examiner with respect to some set of information *I*, the doctrine should induce disclosure only if, in addition, the social benefit of disclosure (in terms of reducing the risk of issuing an invalid patent) outweighs the social cost (in terms of processing information of only marginal relevance).

As for the first point, formally the goal would be to design a standard that would induce Applicant to reveal information I at time t_I whenever

$$P_{Exam}\left[I \in S\right] \ge x,\tag{1}$$

and

$$C_{App} < C_{Exam},$$
 (2)

where t_I is the date of filing; P_{Exam} $[I \in S]$ is the probability the examiner would conclude that I falls into set S; C_{App} is Applicant's cost of disclosing I; and C_{Exam} is the examiner's cost of discovering I.⁶⁹ Three obvious questions—which I will merely note for now, but which will also be relevant to the inequitable conduct doctrine's definition of materiality, as presented below —are (1) whether P_{Exam} should refer to the probability assigned by the actual examiner or by some hypothetical examiner; (2) what sort of information comprises set S; and (3) the value of x.

One matter to consider at this stage is whether the law would be improved if the standard for inequitable conduct simply mirrored these criteria, properly

information that renders the patentability of the invention even slightly more or less probable, or only information that is likely to affect patentability; one could include information that reasonably could lead to the discovery of such information, or exclude information that is cumulative; and so on.

- 67. The model proposes focusing on units of information such as individual prior art references, rather than on larger aggregation of information (the proverbial boxloads of documents that applicants sometimes submit in connection with IDSs, *see* Hatch, *supra* note 2, at 516). One reason to focus on individual documents is that this is what the courts do in deciding whether a failure to disclose a specific reference constitutes inequitable conduct. To be sure, individual applicants and their agents may not always have a specific probability estimate as to the materiality of each such item of information; perhaps their probability assessments operate at a rougher level of, say, classes or types of information. If so, one might think of the probability corresponding to a given unit of information *I* as applying to all such information within a given class of similar information. *See infra* note 84.
 - 68. *See* Cotropia, *supra* note 2, at 754, 756.
- 69. As noted in Part I, disclosure may take the form of inclusion of I in the application's written description (e.g., an enabling or best mode disclosure) or in an IDS. The latter may include information on possibly relevant prior art, inventorship, or other matters affecting patentability. Finally, as the term is used above, disclosure may mean not misrepresenting or concealing facts relating to one's entitlement to certain privileges such as small entity status or expedited examination (a petition to make special).
 - 70. See infra Part II.C.

defined.⁷¹ Some version of Expression (1), as discussed below, already constitutes part of the materiality inquiry under current law. ⁷² Incorporating Expression (2) as a doctrinal requirement, however, seems impracticable. Taken literally, Expression (2) would require the applicant to disclose I whenever it would be cheaper for the applicant to disclose I than for the examiner to discover I; presumably this would include some instances in which the applicant was not initially aware of I but, through the exercise of reasonable effort, could have discovered (and disclosed) I more cheaply than the examiner could have discovered it on his own. As such, Expression (2) would contravene patent law's traditional reluctance to impose upon applicants a duty to search for prior art of which they are not aware. Whether imposing a duty to search would be desirable is debatable;⁷³ but for the foreseeable future, the creation of such a duty would seem to be an unlikely development in patent law.⁷⁴ Second, even if it were possible to implement a duty to search, determining whether the applicant or the examiner was the lower-cost discoverer of information of which the applicant was not initially aware would surely be difficult to determine in many cases. From a practical standpoint, such a standard may not be much of an improvement over existing doctrine, at least as far as certainty and predictability are concerned.

To overcome these problems, one might instead define C_{App} as the cost to the applicant of disclosing relevant information *of which she is aware*; in such a case, one would expect the applicant to be the lower-cost information provider. Invoking the inequitable conduct doctrine whenever Expression (1) and (as reinterpreted) Expression (2) are satisfied, therefore, might be viewed as the best *attainable* means of inducing the lower-cost party to disclose relevant information, even if such a standard falls short of the ideal. This standard would likely fall even shorter of the ideal, however, given the difficulty and ambiguity (in some cases) of determining whether the applicant *was* aware of information *I*. Depending on how the term "knowledge" is defined, such a standard could generate substantial

^{71.} That is, one would still need to specify from whose point of view, and at what time, P_E would be determined; the content of S; and the value of x.

^{72.} See infra Part II.C.

^{73.} See, e.g., FED. TRADE COMM'N, supra note 2, ch. 5, at 11 (reviewing competing views, and deciding not to recommend such a duty); Cotropia, supra note 2, at 779–81 (arguing against imposing such a duty).

^{74.} See FED. TRADE COMM'N, supra note 2, ch. 5, at 11 (noting commentators' skepticism over proposals to impose a duty to search). Although the 2007 Patent Reform bills would have authorized the USPTO to impose a duty to search, the more recent bills would not create such a duty; and to my knowledge no foreign patent system imposes such a duty on applicants either. Moreover, as Christopher Cotropia notes, the imposition of a duty to search is hard to reconcile with other proposals designed to make the inequitable conduct doctrine less costly in its implementation. See Cotropia, supra note 2, at 744–46.

^{75.} See Cotropia, supra note 2, at 754. But see Feldman, supra note 2, at 23 ("Perhaps the burden of providing extensive prior art information rests too heavily on the shoulders of the patent applicant, who is not in the best position psychologically to bear that burden. . . . The solution may lie in finding others in the system who are better situated to provide that perspective, either by allowing earlier intervention from adversaries or beefing up the resources of the administrative experts.").

administrative costs and thus undermine its proposed cost-saving rationale. Perhaps more problematically, a requirement that applicants disclose any relevant information of which they are aware could discourage some applicants from exposing themselves to potential prior art. Analogous problems once arose in connection with the law of enhanced damages, where, until recently, an accused infringer's mere pre-infringement exposure to the patent at issue potentially rendered the defendant liable for treble damages. Partly in response to criticism that this standard discouraged firms from reading patents, the Federal Circuit in 2007 held that patentees must prove both objective and subjective recklessness as a precondition to a damages enhancement. In the present context, requiring the defendant to prove more than mere knowledge on the part of the patentee as a precondition to a finding of inequitable conduct similarly might be viewed as a means for reducing the risk of abuse (in this case, on the part of defendants and not patentees), though at the cost of moving yet further away from any clear relationship to the policy of inducing the lower-cost party to disclose.

As for the second key point—maximizing the social benefit of the applicant's disclosure over the social cost—the relevant inquiry can be illustrated graphically. Figure 1 illustrates the difference between the privately and socially optimal levels of disclosure in a system that induces some degree of overdisclosure. (As noted above, critics argued that pre-*Therasense* doctrine had precisely this effect. Figure 1 therefore should be viewed as a reflection of reality, only if the doctrine's critics were right.) The *x*-axis denotes the quantity of relevant⁷⁹ information of which the applicant is aware and which she discloses, ⁸⁰

^{76.} For example, would knowledge on the part of a low-ranking corporate employee constitute knowledge on the part of the corporate assignee? Would an employee's mere exposure to an existing patent impute constructive knowledge, on the part of the employer, of the patent as prior art? In practice, the Rule 56 duty of candor extends only to "[i]ndividuals associated with the filing and prosecution of a patent application," 37 C.F.R. § 1.56(c) (2009) (emphasis added); even so, questions do arise from time to time concerning whether the duty of disclosure extended to the person who allegedly violated it, see, e.g., Avid Identification Sys., Inc. v. Crystal Imp. Corp., 603 F.3d 967, 973-77 (Fed. Cir. 2010) (affirming finding that company president was "substantively involved" in prosecution and therefore subject to the duty of candor). For somewhat differing perspectives on the question of who should be subject to the duty, compare Mack, supra note 2, at 160-61, 173–74 (arguing in favor of retaining rule under which knowledge on the part of the patent owner's representatives is imputed to the patent owner), with Armitage, supra note 2, at 2–3 (lamenting that, under current doctrine, innocent patent assignees sometimes wind up suffering for applicants' misdeeds).

^{77.} See Thomas F. Cotter, An Economic Analysis of Enhanced Damages and Attorney's Fees for Willful Patent Infringement, 14 FED. CIR. B.J. 291, 299–300 (2004) (noting that "some commentators have suggested that the [then-existing] rules might make some companies reluctant to permit their employees to review patents").

^{78.} See In re Seagate Tech., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). But see Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2069 (2011) (holding that "willful blindness" to the existence of a patent can satisfy the state of mind requirement for inducement liability under 35 U.S.C. § 271(b) (2006)).

^{79.} More precisely, as one moves along the *x*-axis, the information remains relevant in the Federal Rules of Evidence context, *see supra* note 66, but its relevance diminishes or the information becomes increasingly cumulative.

and with respect to which she has a cost advantage over the examiner; the *y*-axis denotes some unit of value. Curve U_S illustrates the social utility of disclosure. Initially, the disclosure of additional units of relevant information increases U_S , but the marginal social benefits of disclosure outpace the marginal social costs only up to Q^* ; as additional units of information are disclosed, social utility declines as the marginal costs begin to outweigh the benefits. From the applicant's private perspective, however, disclosure makes sense as long as the marginal benefits to the applicant outweigh the applicant's marginal costs. The applicant therefore will disclose up to Q^{**} , the point at which the applicant's utility from disclosure (U_{App}) is at a maximum (i.e., the surplus of private benefits over private costs is at a maximum). The region in between Q^* and Q^{**} denotes information the disclosure of which maximizes the applicant's expected private utility but detracts from social utility; its disclosure, in other words, is socially inefficient. Ideally, the inequitable conduct doctrine would reduce the difference between Q^* and Q^{**} to zero by aligning the private and social costs and benefits of disclosure. Put another way, the goal of the inequitable conduct doctrine would be to ensure that

$$dU_{S}/dQ = 0. (3)$$

As with the cost comparison approach above, however, it is probably not feasible to attempt to estimate the relevant variable (here, dU_S/dQ). The analysis nevertheless suggests a way of thinking about the relevant policy issue that underlies the inequitable conduct doctrine; it also further illustrates the gap between the policy ideal and what may be practically attainable.

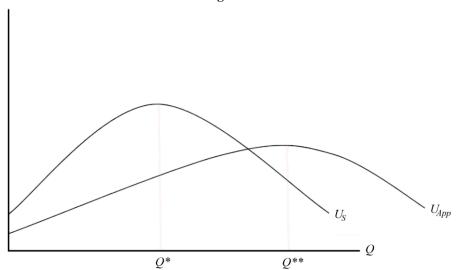
^{80.} Alternatively, one could consider the social utility attributable to the disclosure of information whether the applicant is initially aware of the information or not; this would enable modeling of a duty to search. As discussed above, however, the imposition of such a duty appears to me to be an unlikely development. *But see* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 61–62 (2007) (proposing a voluntary, supplementary review process that would allow applicants to submit their own prior art searches in return for a stronger presumption of validity).

^{81.} These costs include both the private cost to the applicant and any cost incurred by the examiner or third parties in processing the additional information. As noted above, however, one recent study casts doubt on the proposition that examiners are suffering from the effects of "information overload"; on average, they appear not to devote substantial attention to applicant-submitted prior art even when there is reason to believe it may be relevant. *See* Cotropia et al., *supra* note 58.

^{82.} These marginal benefits include whatever additional revenue the applicant is likely to derive from disclosure, as modeled in the text above.

^{83.} Much of the criticism of pre-*Therasense* inequitable conduct doctrine was premised on the belief that this difference was often substantial. *See supra* notes 58–59 and accompanying text.

Figure 1



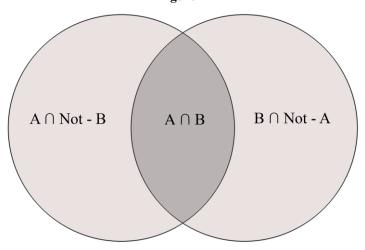
B. Modeling an Applicant's Incentive to Disclose

From a more pragmatic perspective, in deciding whether to reveal a discrete unit of information I at t_I , Applicant will consider her expected return from patenting if she discloses I versus her expected return if she does not. A rational applicant's decisionmaking process will depend on several considerations. One set of factors to consider is Applicant's subjective probability that the existence of I affects the validity of one or more of Applicant's desired claims, as well as the probability that Applicant's nondisclosure of I amounts to inequitable conduct under the governing legal standard. More precisely, we can define P(A) as Applicant's subjective probability that I, if disclosed or discovered, would affect the validity of one or more of her desired claims (and thus P(Not-A) = 1 - P(A) = Applicant's subjective probability that I would not affect the validity of any of her desired claims), and P(B) as Applicant's subjective probability that her failure to disclose I, if such failure were discovered, would constitute inequitable conduct (and thus P(Not-B) = 1 - P(B) = Applicant's subjective probability that the failure to disclose I would not constitute inequitable

^{84.} In reality, the lawyers and agents that draft patent applications may not consciously take all of the variables discussed above into account in deciding whether to disclose a given piece of information to the USPTO; they may rely on "best practices" concerning *types* of information to disclose rather than making individualized judgments about each and every *I* (though individual judgment may be brought to bear with respect to whether to provide less commonly encountered types of references). Nevertheless, one would expect agents' decisions at least implicitly to reflect their understanding of the consequences, as modeled above, of disclosing or not disclosing certain individual references or categories of references, and to adjust over time with changes in the governing case law. I thank Dennis Crouch and John Golden for bringing this point to my attention.

conduct). Recall from Part I above that, both pre- and post-*Therasense*, information sometimes may be material but non-invalidating.) Figure 2 illustrates the relationships between these variables—though not necessarily the relative size of each set, which can vary depending on the applicable legal standards.

Figure 2



$$\sum [(A \cap B) + (A \cap Not - B) + (B \cap Not - A) + (Not - A \cap Not - B)] = 1$$

Applicant's decisionmaking process also must take into account, however, the probabilities that, if she does not disclose I, a third party (the examiner, an accused infringer, a potential licensee, or some other interested third party) subsequently will discover (1) I's existence, and (2) Applicant's intentional nondisclosure of I. Formally, we can define $P(d_E)$ as Applicant's subjective probability that a third party will subsequently (i.e., at time t_{I+n}) discover I's existence, and $P(d_{ND})$ as Applicant's subjective probability that a third party subsequently will discover that Applicant intentionally failed to disclose I. Applicant then can estimate the present value of revenue I0, net of costs, to be gained under each possible combination of I1, I2, I3, I3, I4, I5, I5, I5, I5, I5, I6, I6, I7, I7, I8, I9, I9,

^{85.} $P(Not-A \cap Not-B) = P(Not-A) \times P(Not-B/Not-A)$ therefore is Applicant's subjective probability that I does not affect validity and that the failure to disclose I does not constitute inequitable conduct. $P(Not-A \cap B) = P(Not-A) \times P(B/Not-A)$ is Applicant's subjective probability that I does not affect validity but that the failure to disclose I constitutes inequitable conduct. $P(A \cap Not-B) = P(A) \times P(Not-B/A)$ is Applicant's subjective probability that I affects validity but that failure to disclose I does not constitute inequitable conduct.

^{86.} Conceivably, $P(d_E)$ could be related to the amount of information disclosed. That is, if Q^{**} in Figure 1 exceeds some critical value, perhaps $P(d_E)$ goes down due to some sort of "needle in a haystack" effect. *See infra* note 91. If examiners typically pay little attention to applicant-submitted prior art, however, regardless of its quantity or quality, this effect may be minimal.

^{87.} With four variables to consider, the various combinations cannot be illustrated in a two-dimensional Venn diagram as in Figure 2 above.

present purposes, let us assume that Applicant expects to earn R_I if either of the following two conditions is satisfied:

- (1) I ultimately has no impact on the validity of any of Applicant's desired claims, and either
 - (a) Applicant discloses *I*, or
 - (b) Applicant intentionally does not disclose *I*, but this does not result in a finding of unenforceability because
 - (i) the failure to disclose I is held not to constitute inequitable conduct, or
 - (ii) Applicant's intentional nondisclosure of I is not discovered.
- (2) *I* ultimately would have affected the validity of one or more of Applicant's desired claims, but Applicant intentionally does not disclose *I* and no third party ever discovers *I*'s existence (or, *a fortiori*, Applicant's intentional nondisclosure of *I*).

Assume further that Applicant expects to earn R_2 ($< R_1$) if either of the following two conditions is satisfied:

- (1) Applicant voluntarily discloses I and I ultimately does affect the validity of one or more of her desired claims; or
- (2) Applicant intentionally fails to disclose *I*; a third party subsequently discovers *I*'s existence, and *I* ultimately affects the validity of one or more of Applicant's desired claims; but Applicant's failure to disclose *I* does not result in a finding of inequitable conduct, either because the third party does not discover that Applicant intentionally failed to disclose *I* or because a court concludes that Applicant's conduct did not qualify as such.

Note that R_2 may be zero if the patent is wholly invalid, ⁸⁸ but it may be greater than zero if I does not affect all of Applicant's claims.

Finally, assume that Applicant expects to earn R_3 if she intentionally fails to disclose I; a third party subsequently discovers I's existence and Applicant's intentional failure to disclose; and the failure to disclose I ultimately results in a finding of inequitable conduct. Although $R_3 = 0$ under current law, ⁸⁹ it could be greater than zero under some of the proposed reforms. The universe of possible outcomes can then be summarized as follows:

^{88.} Strictly speaking, R_2 can be greater than zero even if the patent is wholly invalid, if Applicant earns some revenue from its exploitation prior to its being declared invalid.

^{89.} As with invalidity, R_3 could be greater than zero if Applicant earns some revenue from the patent's exploitation prior to the patent's being declared unenforceable.

Table 1 Universe of Possible Outcomes

Validity	(A = at least one desired claim would be invalid if third party discovered Ps existence)	A	A	A	A	A	A	A	A Not-A Not-A	Not-	Vot-A	Not-A	Not-A	Not-A	Not-A Not-A	Not-A	Not-A
Enforceability	(B = patent would be unenforceable if third party discovered that Applicant intentionally failed to disclose I)	В	Not-B	В	В	Not-B	Not-B	Not-B	В	B 1	B Not-B	В	В	Not-B	Not-B Not-B	В	Not-B
Discovery of I's existence absent voluntary disclosure	$(d_E = \text{third party would discover } I$'s existence)	d_E	^{3}p	$Not ext{-}d_E$	d_E Not- d_E	$Not ext{-}d_E$	d_E	$Not\text{-}d_E$ $Not\text{-}d_E$ d_E $Not\text{-}d_E$ d_E $Not\text{-}d_E$ $Not\text{-}d_E$ $Not\text{-}d_E$	$Not ext{-}d_E$	d_E	d_E	Not- d _E	d_E	Not- d_E	d_E	Not- d _E	Not- d_E
Discovery of Applicant's intentional nondisclosure	$(d_{ND}$ = third party would discover that Applicant intentionally failed to disclose I)	d_{ND}	$d_{N\!D}$	$d_{_{ND}}$	Not-d _{ND}	d_{ND}	Not-d _{ND}	Not- d_{ND} Not- d_{ND} d_{ND} d_{ND}	Not-d _{ND}	d_{ND}	$d_{\scriptscriptstyle ND}$	$d_{\scriptscriptstyle ND}$	$Not ext{-}d_{\scriptscriptstyle ND}$	d_{ND}	Not-d _{ND} Not-d _{ND} Not-d _{ND}	Not-d _{ND}	Not-d _{ND}
Applicant's expected 1 voluntarily discloses I	Applicant's expected revenue if Applicant voluntarily discloses ${\cal I}$	R_2	R_2		R_2		R_2	R_2	R_2	R_I	R_I	1	R_I	,	R_I	R_I	R_I
Applicant's expdisclose I	Applicant's expected revenue if Applicant does not disclose I	R_3	R_2	1	R_2		R_2	R_I	R_I	R_3	R_I	ı	R_I	1	R_I	R_I	R_I

Note that Applicant's intentional failure to disclose I cannot be discovered unless I's existence is discovered (d_{ND} is a subset of d_E , in other words), so (Not- d_E) \cap d_{ND} is an empty set.

Next, let us define F_D as the cost (legal fees) of prosecution and enforcement, net of the cost of disclosure (C_{App}), if Applicant discloses I; and F_{ND} as Applicant's expected cost of prosecuting and enforcing the patent if she does not disclose. One would expect F_D to correlate positively with P(A), reflecting an increased cost of prosecution and enforcement the greater the likelihood that I raises questions about the patentability of one or more claims. Similarly, one would expect F_{ND} to correlate positively with P(A), P(B), d_E , and d_{ND} , reflecting an increased cost of prosecution and enforcement the greater (1) Applicant's subjective probability that I will be detected and will raise problems with respect to validity; and (2) Applicant's failure to disclose I will be detected and will raise problems with respect to enforceability.

We are now ready to state Applicant's expected revenue if she discloses and if she does not. If Applicant discloses, her expected revenue $E(R)_D$ is

$$E(R)_{D} = R_{1}P(Not-A) + R_{2}P(A) - C_{App} - F_{D}.$$
 (4)

The intuition is straightforward. Applicant expects to receive R_I if I does not invalidate any claims and R_2 if it does. The direct cost of disclosure (e.g., drafting an IDS) is C_{App} , and Applicant's expected legal fees (not including the direct costs of disclosure) are F_D .

If Applicant does not disclose, then (simplifying terms) Applicant's expected revenue $E(R)_{ND}$ is

$$E(R)_{ND} = R_1 P(Not-A \cap Not-B \cap d_E) + R_1 P(Not-A \cap B \cap d_E \cap Not-d_{ND}) + R_1 P(Not-d_E) + R_2 P(A \cap Not-B \cap d_E) + R_2 P(A \cap B \cap d_E \cap Not-d_{ND}) + R_3 P(B \cap d_E \cap d_{ND}) - F_{ND}.$$

$$(5)$$

A rational, risk-neutral Applicant therefore will choose disclosure over nondisclosure whenever Expression (4) is greater than Expression (5), that is, whenever (after combining terms)

^{90.} To the extent a finding of inequitable conduct risks rendering other, related patents unenforceable, *see supra* note 54, and puts the patentee at some risk of having to pay the defendant's attorney's fees, *see supra* note 53, these potential costs would be subsumed within F_{ND} .

^{91.} The analysis therefore elides the possibility that Applicant could disclose *I* in such a manner that would still leave open the possibility of a finding of inequitable conduct by, for example, indiscriminately disclosing *I* among thousands of other pieces of information. The trend in the case law has been away from holding indiscriminate disclosure to constitute inequitable conduct. *See* Molins PLC v. Textron, Inc., 48 F.3d 1172, 1182–84 (Fed. Cir. 1995). *But see* Feldman, *supra* note 2, at 15 & n.55 (noting the possibility that excessive disclosure could subject the patent attorney "to discipline for breach of ethics" under 37 C.F.R. § 11.18(b)). To the extent this remains a possibility, however, the analysis above should be understood as assuming that Applicant has engaged in *meaningful* disclosure.

$$R_{I}P(Not-A \cap B \cap d_{E} \cap d_{ND}) + R_{2}P(A \cap B \cap d_{E} \cap d_{ND}) + (F_{ND} - C_{App} - F_{D})$$

$$> (R_{I} - R_{2})P(A \cap Not-d_{E}) + R_{3}P(B \cap d_{E} \cap d_{ND}).$$
(6)
and

$$E(R)_D = R_1 P(Not-A) + R_2 P(A) - C_{App} - F_D > 0.$$
(7)

This last condition is necessary because if the cost of proceeding with the application is too high, Applicant's preferred strategy is to abandon the application (and not reveal I) even if $E(R)_D > E(R)_{ND}$. Note that, in Expression (6), $(F_{ND} - C_{App} - F_D)$ is Applicant's net expected cost saving attributable to disclosure. It could be either positive or negative, depending on the magnitude of C_{App} and the difference between Applicant's expected legal fees net of C_{App} when she discloses versus when she does not. In the limiting case in which $P(d_E) = 0$ (that is, Applicant believes that I would never be discovered unless she disclosed it), the first two terms on the left-hand side are zero and the third term is negative because $F_{ND} \le F_D$. Because $R_I \ge R_2$, the right-hand term $(R_I - R_2)P(A \cap Not-d_E)$ must be ≥ 0 , and thus a purely self-interested applicant would never voluntarily disclose under these circumstances.

C. Modeling Materiality, Intent, and Balancing

The values of P(B) and P(Not-B) in the expressions above will depend on Applicant's understanding of the standard for a finding of inequitable conduct. Under current law, as noted above, a finding of inequitable conduct depends on three factors—materiality, intent, and balancing—which can be modeled as follows. First, using Expression (1) above, we can define I as material if

$$P_{Exam}[I \in S] \ge x. \tag{1}$$

In other words, I is material if the probability that the relevant examiner would conclude that I falls within set S is greater than or equal to some value x. As suggested above, however, the meaning of this expression will vary depending on the identity of the relevant examiner, the content of set S, and the value of x. In theory, P_{Exam} could stand for the probability from the standpoint of the actual examiner assigned to the application, or from the standpoint of a hypothetical "reasonable" examiner, or from the standpoint of an ideal examiner who perfectly applies the law to the facts. ⁹² Moreover, in theory P_E could be determined at different time periods, including not only t_I (the date of application) but alternatively t_2 (the date of issuance) or t_3 (the date of judgment)—or perhaps even some other time, such as the date Applicant offers a license or the date on which infringement begins. ⁹³ In addition, S can be defined to include any or all of the following subsets of information:

^{92.} As noted above, the *Therasense* opinion does not clearly indicate whether the new materiality standard defines the relevant examiner as the actual examiner or the ideal examiner. *Therasense* does clearly reject prior case law's focus on the hypothetical reasonable examiner, however. *See supra* notes 33–34 and accompanying text.

^{93.} Some of the reforms proposed prior to *Therasense* would have conditioned a finding of inequitable conduct upon at least one claim being held invalid in litigation, on the basis of information the applicant intentionally withheld from the USPTO. *See supra* note 10 (discussing Patent Reform Act proposals); *see also* McElhone, *supra* note 2, at

Subset 1. Information of such a nature that, if Applicant did not disclose it and the patent nevertheless issued at t_2 , one or more claims would be invalid; but if Applicant did disclose the information, Applicant would still obtain ⁹⁴ a patent of the desired claim scope at t_2 . Examples would be disclosures necessary to satisfy Patent Act § 112 and disclosures of the names of co-inventors.

Subset 2. Information that would preclude Applicant from obtaining a patent of the desired claim scope, but not necessarily from obtaining a patent of narrower scope. Examples would be information that either solely or in combination with other information demonstrates (at least until rebutted) that one or more of the Applicant's desired claims lack novelty or are obvious.

Subset 3. Information that some other rule of patent law requires the Applicant to disclose truthfully, but that is not of a type that would lead to invalidation if not disclosed. Examples would include information relating to small entity status or to the Applicant's entitlement to a petition to make special.

Subset 4. Information the disclosure of which might lead to the discovery of information falling into one of the other categories. Subset 4 could be further broken down into smaller subsets—for example, information that would necessarily lead to the discovery of information falling into Subset 1 only, or information that would not necessarily lead to the discovery of information falling into one of the other subsets but rather would only increase the probability of the discovery of such information by some amount q.

Finally, the value of x in Expression (1) depends on how strict the materiality requirement is. In theory, x could fall anywhere along the spectrum of

407–08; Brown, *supra* note 2, at 618 (discussing testimony presented at Patent Reform Act hearings in support of such a but-for rule). This proposal in effect would adopt the relevant time period as t_3 . The proposal differs from the standard adopted in *Therasense*, in which the majority posited the possibility that information the applicant withheld could have made a difference to the examiner under the preponderance of the evidence standard or under the "broadest reasonable construction" canon that applies to the construction of patent claims during examination—and thus would be material—but would not lead to patent invalidation under the corresponding evidentiary standards that apply during litigation. *See* Therasense, Inc. v. Becton, Dickinson & Co., Nos. 2008-1511, -1512, -1513, -1514, -1595, 2011 WL 2028255, at *11 (Fed. Cir. May 25, 2011) (en banc).

- 94. Depending on the identity of the relevant examiner, "would still obtain" could mean that Applicant would be entitled to a patent of the desired claim scope at t_2 , or that Applicant would, in fact, obtain a patent of the desired claim scope at t_2 . Note that the actual examiner is not allowed to testify on these matters. U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, *supra* note 55, § 1701.01.
- 95. In the wake of *Therasense*, current law would now appear to include at least Subsets 1 and 2 within *S*, insofar as this type of information affects patent validity. *Therasense* would appear to exclude Subset 3, however, unless the applicant has made affirmative misrepresentations concerning this sort of information. *See supra* note 55. *Therasense* does not clearly indicate whether or to what extent information falling within Subset 4 is material under the new standard, though a strict but-for standard might suggest that information is material only if it necessarily would have led to the discovery of information falling into Subsets 1 or 2.

 $0 < x \le 1$, though the closer x is to 1 the more likely a consensus would exist that the information is material.

The differences among the various past, present, and proposed standards of materiality therefore can be compared as follows:

Table 2
Past, Present, and Proposed Standards of Materiality

Standard	Relevant examiner	Time when P_E is determined	Contents of S	<i>x</i> =
Objective but-for	Ideal	t_I	Subsets 1, 2; 4?	1
Subjective but-for	Actual	t_I	Subsets 1, 2; 4?	1
"But it may have"	Actual? Reasonable?	t_{I}	1, 2, 4	?
Rule 56, 1977 version	Reasonable	t_I	1, 2, 3, 4	?
Rule 56, 1992 version	Ideal?	t_I	1, 2	1?
Proposed standard under which no inequitable conduct unless at least one claim is rendered invalid as a result	Ideal	t_3	1, 2	1

Viewed in this format, the differences among the standards—and the areas with respect to which the value of the relevant variables is uncertain or ambiguous, as denoted by the question marks in Table 2—become apparent. First, the identity of the relevant examiner varies, not surprisingly, depending on the standard used. (Indeed, with respect to two of the standards, the case law did not clearly identify the relevant examiner.) Second, the relevant time frame for all five of the pre-Therasense standards would appear to be t_l . By contrast, with respect to a proposed standard under which a finding of inequitable conduct is contingent on the invalidity of at least one claim, the relevant time frame is arguably t_3 , the date of judgment. Third, the content of the relevant information set varies depending on the test employed, though once again the precise content is unclear with respect to at least two of the standards. Fourth, and perhaps most significantly, x is presumably some amount less than 1 under the but-it-may-have and reasonable examiner standards (and maybe under the 1992 version of Rule 56); just how much less, however, is unclear. Given these uncertainties, the fact that the decisions on inequitable conduct struck many observers as inconsistent is not surprising.

As for the second relevant factor, we can define Applicant as having the requisite deceptive intent if

$$P_{App} \left[I \in S \right] \ge y. \tag{8}$$

that is, if Applicant's subjective probability at t_I that the information falls within set S is greater than some value y. Put another way, does Applicant believe at t_I that I may be material, and if so, how strongly does Applicant believe this? ⁹⁶

On this analysis, an applicant who is not aware of the information would (as under current law) lack deceptive intent altogether. Similarly, an applicant who is aware of the information but who does not grasp its significance also would (as under current law) lack deceptive intent, even if the applicant's failure to grasp its significance can be characterized as simple or gross negligence. Presumably, then, y must be substantially higher than zero. How high it must be nevertheless remains unclear, even post-*Therasense*. Must it be close to 1? Only greater than 0.5? Further compounding this uncertainty is the question of how an accused infringer may go about proving that y exceeds the relevant threshold. As noted in Part I, the extent to which materiality can serve as circumstantial evidence of intent remains somewhat unclear post-Therasense; further, pre-Therasense, some cases held that an inference of deceptive intent was appropriate if I was highly material, the applicant knew or should have known of its materiality, and the applicant could not offer a convincing explanation for withholding the information.⁹⁷ From a purely evidentiary standpoint, using materiality as an indicium of intent might not seem problematic; all other things being equal, the information's actual materiality is likely to correlate to some degree greater than zero with the applicant's subjective belief as to its materiality. As discussed above, however, critics contended that the now-discarded "should have known" standard tended to conflate intent with materiality and permitted an inference of intent on the basis of

^{96.} By focusing on the applicant's state of mind, rather than on the state of mind of the examiner or some hypothetical entity, Expression (8) distinguishes deceptive intent from materiality as modeled in Expression (1). Perhaps a more complete definition of deceptive intent would be $P_{App}[P_{Exam}[I \in S] \ge x] \ge y$, meaning that Applicant has deceptive intent if she believes that the probability is greater than or equal to y that the probability the relevant examiner would find I to fall within S is greater than or equal to x. This would reflect a possible feedback effect between materiality and intent, but it would also make an already complex analysis yet more complex without necessarily adding much to the model's predictive value. Note also that, if S is defined to include, say, only Subsets 1 and 2, an intent to deceive as to one's small entity status (for example), though deceptive, would not count as deceptive intent for purposes of the inequitable conduct doctrine.

At least one commentator has argued that deceptive intent should incorporate another factor—specifically, that no deceptive intent should be found where the examiner should have discovered the information at issue by following the examination protocols set forth in the *Manual of Patent Examining Procedure*. See Brief of Amicus Curiae Dolby Labs., Inc. in Support of Neither Party at 6, Therasense, 2011 WL 2028255 (Nos. 2008-1511, -1512, -1513, -1514, -1595), 2010 WL 2861896, at *6. The analysis above avoids this additional complicating factor; if added, however, Expression (10) could be revised to state $(P_{App}|I \in SJ) \ge y \cap (P_{App}(d_E) \ge y'))$, where y' presumably would be at or near 1. See also Petherbridge et al., supra note 2, at 47–48, 53–54 (discussing various ways of characterizing intent, and suggesting that, pre-Therasense, what counted as deceptive intent for purposes of the inequitable conduct doctrine might be a more fluid concept).

^{97.} *See supra* text accompanying note 42.

mere negligence. The analysis above arguably provides some support for this view. One way of thinking about the "should have known" standard is that it substituted a hypothetical, reasonable applicant's estimate of the probability of materiality—in much the same way that the reasonable examiner standard substituted a hypothetical reasonable examiner's probability estimate for the actual examiner's estimate. To the extent a hypothetical reasonable examiner and a hypothetical reasonable applicant are likely to have similar probability estimates, therefore, critics may have been right in arguing that the "should have known" standard conflated intent with (a high degree of) materiality, at least where materiality was determined under the reasonable examiner standard.

The third relevant factor—balancing—means that even if the threshold levels of materiality and intent are present, the court must balance the equities to determine if a finding of inequitable conduct is appropriate. ⁹⁹ Mathematically, then, one might represent the three requirements for inequitable conduct in the following manner. Inequitable conduct is present if:

$$P_{Exam} \left[I \in S \right] \ge x, \tag{1}$$

$$P_{App} \left[I \in S \right] \ge y, \tag{8}$$

and

$$\alpha(\mathbf{x}, \mathbf{y}) \ge z,\tag{9}$$

where α is an operator applied to x and y. Even after *Therasense*, however, it remains unclear exactly what that operator is (addition? multiplication? something more complex?); similarly unspecified is the requisite value of z.

On the basis of this analysis, we may define P(B) in the following manner:

$$P(B) = P^*[(P_{Exam}[I \in S] \ge x) \cap (P_{App}[I \in S] \ge y) \cap (\alpha(x, y) \ge z)],$$
(10)

where P^* equals Applicant's subjective probability at time t_1 that a court at time t_3 would view the three conditions set forth in Expressions (1), (8), and (9) as satisfied.

III. IMPLICATIONS OF THE PRECEDING ANALYSIS

Scholarly discussion of the inequitable conduct doctrine to date has centered on aspects of the doctrine that critics viewed as dysfunctional—among them, the multiplicity and inconsistency of the relevant standards for determining materiality and intent; the resulting compliance and adjudication costs; and the

^{98.} *See supra* text accompanying note 43. Another related critique might be that the focus on the applicant's inability to offer a convincing explanation conflicted with the requirement that intent (and materiality) be proven by clear and convincing evidence.

^{99.} See supra text accompanying note 50. Furthermore, as noted above, prior to *Therasense*, the Federal Circuit had approved the use of a sliding scale under which a higher degree of materiality could compensate for a lesser, but still above-the-threshold, degree of intent and vice versa. See supra text accompanying note 44.

perceived disconnect, in some cases, between the gravity of the offense and resulting penalty. 100 As noted above, *Therasense* resolves some but not all of these issues (and may not, in any event, be the last word on the contours of the doctrine, given the possibility of further refinements on the part of Congress or the Supreme Court). The debate is therefore likely to continue, and it would benefit from additional efforts, both to ground the doctrine in a deeper theoretical framework and to subject its real-world impact to rigorous empirical analysis. 101 This Article has attempted to advance matters on the theoretical front by restating, with as much precision as possible, both the conditions under which the doctrine would promote the public interest and the factors that would influence a rational applicant in deciding how much information to disclose. This Part discusses the implications of the theoretical analysis presented above. In particular, it highlights the imperfect nature of the inequitable conduct doctrine as a means for inducing optimal disclosure, and it provides some basis for predicting the effects (alone or in combination) of various actual or proposed reforms. Although some of the predictions are obvious (e.g., narrowing the definitions of materiality or intent will reduce disclosure), the interactions among the relevant variables are not. By disaggregating the forces that lead to the predicted results, future policymakers may consider the impacts of modifying one or more of the relevant policy levers, as well as the ways in which other possible reforms may increase or decrease the effect of, or need for, a robust inequitable conduct doctrine.

A. The Gap Between Theory and Practice

Perhaps the most striking implication of the theoretical analysis presented above is the gap between the inequitable conduct doctrine (even post-*Therasense*) and the proposed underlying purpose of inducing optimal disclosure. Part II proposed that the ideal inequitable conduct standard would induce disclosure when:

$$P_{Exam}[I \in S] \ge x,\tag{1}$$

$$C_{App} < C_{Exam},$$
 (2)

and

$$dU_{S}/dQ = 0. (3)$$

As suggested, however, while it might be tempting to consider simply adopting these criteria themselves as the conditions under which a failure to disclose constitutes inequitable conduct, attempts to measure dU_S/dQ or to compare C_{App} with C_{Exam} are probably impracticable. At best, then, the inequitable conduct doctrine can provide only a rough proxy for these ideal conditions; although Expression (1) embodies some version of a materiality standard, neither of the other conditions shares any obvious connection with the deceptive intent element or with balancing.

^{100.} See supra notes 56–63 and accompanying text.

^{101.} Two recent empirical studies of note are Cotropia et al., *supra* note 58 (examining examiner behavior), and Petherbridge et al., *supra* note 2 (examining courts' application of the doctrine).

A second implication arises from Part II's analysis of the factors that would induce a rational, risk-neutral applicant to choose disclosure over nondisclosure. As above, those conditions are:

$$R_{1}P(Not-A \cap B \cap d_{E} \cap d_{ND}) + R_{2}P(A \cap B \cap d_{E} \cap d_{ND}) + (F_{ND} - C_{A} - F_{D}) > (R_{1} - R_{2})P(A \cap Not-d_{E}) + R_{3}P(B \cap d_{E} \cap d_{ND})$$
(6)

and

$$E(R)_D = R_1 P(Not-A) + R_2 P(A) - C_A - F_D > 0,$$
(7)

where

$$P(B) = P^*[(P_{Exam}[I \in S] \ge x) \cap (P_{App}[I \in S] \ge y) \cap (\alpha(x, y) \ge z)].$$
(10)

As we have seen, many of these variables are either inherently difficult to estimate (for example, F_{ND}) or poorly defined (for example, just about everything that goes into P(B)). Whether current law comes close to inducing disclosure to the extent that it would occur under ideal conditions (1), (2), and (3) is, therefore, doubly indeterminate. Conceivably, the existing standards could induce departures from the ideal in either direction (i.e., too much or too little disclosure, in comparison with the ideal), depending on the case. In some other areas of the law, such as antitrust, a method of dealing with analogous risks of error involves crafting standards that attempt to minimize the total cost of "false positives" (wrongly finding violations where none exist), "false negatives" (wrongly exonerating violative conduct), and enforcement and other administrative costs. ¹⁰³ The cost of false positives and false negatives, in turn, is a function of both their frequency and magnitude. How might such an approach play out in the context of the inequitable conduct doctrine?

On the one hand, one might argue that the cost of false negatives should be of greater concern than the cost of false positives, on the theory that more information is generally better than less. All other things being equal, a broad (that is, relatively defendant-friendly) standard of inequitable conduct should induce more disclosure of information that might relate to patentability (or otherwise implicate the integrity of the patent system); in turn, the disclosure of such information may help to weed out invalid claims that otherwise would have evaded successful challenge. Moreover, one might argue, applicants can avoid the cost of false positives simply by following a policy of "when in doubt, disclose." ¹⁰⁵ On

^{102.} *Therasense* resolves some, but not all, of the ambiguity with respect to these variables. *See supra* notes 32–49 and accompanying text.

^{103.} See, e.g., Thomas F. Cotter, The Procompetitive Interest in Intellectual Property Law, 48 WM. & MARY L. REV. 483, 490–91 & n.17 (2006) (discussing the use of error-costs analysis in antitrust and intellectual property law).

^{104.} See id. at 493 n.24, 526.

^{105.} See Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289, 1305 (Fed. Cir. 2010) ("[I]f this could be regarded as a close case, which it is not, we have repeatedly emphasized that the duty of disclosure requires that the material in question be submitted to the examiner rather than withheld by the applicant."), vacated and reh'g en banc granted, 374 F. App'x 35 (Fed. Cir. 2010) (per curiam). Further, the consequences of a false negative surely could be present in some cases—for example, when the misconduct would not come

this view, efforts to weaken the inequitable conduct doctrine will lead to less disclosure and more fraud, to the detriment of the public. (Note, however, that the magnitude of the harm resulting from a false negative will be mitigated if $P(d_E)$ and $P(d_{ND})$ are sufficiently high or C_{Exam} is sufficiently low. If, on the other hand, $P(d_E)$ and $P(d_{ND})$ are low $P(d_E)$ or $P(d_E)$ are low $P(d_E)$ or $P(d_E)$ or $P(d_E)$ or $P(d_E)$ are low $P(d_E)$ or $P(d_E)$ or P

The problem with this view is that it ignores the cost of both false positives and enforcement. As for false positives, it may be true that the private cost of disclosing one additional piece of information in an IDS is small; but the cost of disclosing hundreds of references in order to avoid a false positive may add up significantly. To be sure, the disclosure burden that the inequitable conduct doctrine imposes may not price many applicants out of the market, but at the margin there is some risk that, in terms of Expression (6), if C_{App} is too high $E(R)_D < 0$ and the applicant's better strategy is abandoning the application. ¹⁰⁷ More is not always better, particularly if the disclosed information is of little social value. ¹⁰⁸ In short, the threat of false positives encourages over-compliance with patent law's disclosure requirements, in ways that may (at times) be at best pointless and at worse counterproductive—though whether, either pre- or post-Therasense, those costs generally outweigh the costs of false negatives cannot be determined by theory alone.

As for enforcement costs, it seems clear that the easier it is to plead inequitable conduct, and the more complex the legal standards themselves are, the higher these costs will be. These costs may be borne in a number of ways. To the extent the examiner must wade through numerous references of marginal relevance, the already-backlogged patent examination system risks incurring additional delays. To the extent the examiner ignores all or most of the references, the cost of processing them is merely deferred to the time, if any, at which the patent is litigated. At that point, an expansive inequitable conduct doctrine raises the (already quite high) costs of patent litigation, not only because of the doctrine's

to light otherwise because the defendant would not have had an incentive to raise the issue otherwise. Moreover, patentees who have failed to disclose may be able to extract unwarranted rents from risk-averse licensees. *See* Cotropia, *supra* note 2, at 751–52.

106. See Long, supra note 12, at 669 (suggesting that applicants may choose to conceal information they do not expect others to uncover).

107. Moreover, too much indiscriminate disclosure may actually impede others' ability to process the disclosed information in any meaningful way, *see* Cotropia, *supra* note 2, at 773, though the empirical evidence on this point is not strong, *see* Cotropia et al., *supra* note 58.

To be sure, the fewer patents there are, the smaller the risk of the associated social costs of patenting, including occasional monopolistic pricing. The same could be said for the inequitable conduct doctrine as applied in litigation. Even when a court incorrectly determines that a patentee engaged in inequitable conduct, the social cost of the false positive is not entirely a "cost" because the public gains free access to the invention. Taken to its logical conclusion, however, this reasoning would undermine the whole point of having a patent system. Put another way, this reasoning ignores the potential dynamic efficiency costs from arbitrarily undercutting the patent incentive, encouraging inventors to rely more heavily on trade secret protection over patent protection, and so on.

108. See Cotropia, supra note 2, at 770–73.

complexity but also because of the additional discovery burden imposed on the patentee. ¹⁰⁹ The system therefore risks imposing a vicious circle. Insofar as the higher F_{ND} is in Expression (6) above, the more the prudent applicant will choose to disclose, all other things being equal, and the more she discloses, the higher the ensuing litigation costs. At the margin, a feedback loop ¹¹⁰ may come into existence as more and more disclosure is seen as routine, thus influencing courts' and parties' expectations of the data that reasonably should be viewed as falling within S. Whether *Therasense* adequately addresses this problem, by virtue of its adoption of some version of a but-for standard of materiality, remains to be seen.

B. Predicting the Effects of Various Proposed Reforms

Many of the reform proposals put forward in recent years rest upon the premise that pre-*Therasense* law generally induced applicants to overdisclose information of only marginal relevance. The analysis presented in Part II provides a tool for predicting the effects of various reform proposals in countering this purported effect. It also may assist in imagining other possible reforms, and in predicting the effects on disclosure of proposals intended to reform other aspects of the patent system.

1. Some Commonly Suggested Reforms

As stated above, a rational, risk-neutral applicant would prefer disclosure to nondisclosure if disclosure promises a positive return, and if

$$R_1P(Not-A \cap B \cap d_E \cap d_{ND}) + R_2P(A \cap B \cap d_E \cap d_{ND}) + (F_{ND} - C_{App} - F_D) > (R_1 - R_2)P(A \cap Not-d_E) + R_3P(B \cap d_E \cap d_{ND}).$$
 (6)

We can also use Expression (6) to consider some of the reforms that critics of existing doctrine have proposed. One set of reform proposals would aim

Attorney—client privilege issues often arise. Satellite litigation over inequitable conduct can become a serious problem. *See* Cotropia, *supra* note 2, at 740. *But see* Jason Rantanen & Lee Petherbridge, *Therasense v. Becton Dickinson*: A First Impression 18 n.29 (June 17, 2011) (unpublished manuscript) (on file with *Arizona Law Review*) (questioning the impact of the doctrine on discovery costs). As for the expense of patent litigation, see AM. INTELLECTUAL PROP. LAW ASS'N, 2009 REPORT OF THE ECONOMIC SURVEY 29 (2009) (reporting median litigation costs of \$650,000 to \$5.5 million, depending on the amount at risk). Rantanen and Petherbridge also argue that, post-*Therasense*, the but-for standard could prove more costly than the reasonable examiner standard, due both to possible complexities in the but-for standard's application, and to a potential *increase* in defendant's proclivity to resist assertions of patent rights if the new standard results in the issuance of more patents of dubious value and/or an increase in unacceptable conduct on the part of patent owners. *See* Rantanen & Petherbridge, *supra*, at 15–19. Time will tell.

^{110.} *Cf.* James Gibson, *Risk Aversion and Rights Accretion in Intellectual Property Law*, 116 Yale L.J. 882, 898–900 (2007) (arguing that risk-averse users' decisions to license rather than to assert fair use rights creates a similar sort of feedback effect). In the case of inequitable conduct, a feedback loop might result from courts coming to expect more disclosure, and hence being more apt to find omissions both material and intentionally deceptive.

^{111.} See supra notes 58–59 and accompanying text.

to reduce P(B) by, for example, adopting a relatively narrow definition of materiality 112 or deceptive intent; 113 or by clarifying (or eliminating) the balancing inquiry modeled above in Expression (9). 114 (Therasense succeeds in narrowing the definitions of materiality and deceptive intent, though as noted above several ambiguities remain; and the opinion does not eliminate the balancing inquiry.) All other things being equal, a reduction in P(B) reduces the three terms on the lefthand side of Expression (6) while leaving the first term on the right-hand side unchanged. A predictable and intended result of reducing P(B), therefore, would be to reduce disclosure on the part of the applicant. To illustrate, consider the proposal to condition a finding of inequitable conduct upon a finding at t_3 that I renders one or more claims invalid. Pre-Therasense, the case law disclosed several instances in which information that the patentee withheld did not affect patentability but nevertheless did result in a finding of inequitable conduct. 116 In terms of the analysis above, this reform (as row 6 of Table 2 indicates) would, in effect, adopt an "ideal examiner" standard of materiality (because the court would be asking whether I should have affected claim validity from the court's own perspective as of t_3); would limit S to Subsets 1 and 2;¹¹⁷ and would equate x with 1. As a result, P(B) would be on average lower than under pre-Therasense law, where S may have included all four subsets and the value of x was indeterminate; and F_{ND} would be lower as well, reflecting a smaller expected litigation cost from nondisclosure. (The marginal decrease in uncertainty would also ameliorate risk aversion to some extent, as discussed in Part III.B.2 below.) In addition, because $P(Not-A \cap B)$ would be zero, the R_1 term on the left-hand side would equal zero

^{112.} See Dolak, supra note 2, at 887–88 (arguing that material misconduct should be defined as acts that "undermine the substantive examination function of the USPTO"); Mammen, supra note 2, at 1391 (arguing for adoption of the 1992 materiality standard).

^{113.} See Cotropia, supra note 2, at 775–77 (arguing in favor of "a specific, independent standard for intent"); Dolak, supra note 2, at 888–90 (arguing that courts should apply a more rigorous definition of intent); Mammen, supra note 2, at 1391–92 (similar).

^{114.} See Dolak, supra note 2, at 890–91 (arguing that courts should abandon the balancing inquiry because "it exacerbates the problem of lax application of the intent standard"); Mammen, supra note 2, at 1391 (arguing for clarifying and codifying the balancing requirement).

^{115.} *See supra* note 93 (discussing how this proposal differs from the rule adopted in *Therasense*).

^{116.} See, e.g., Avid Identification Sys., Inc. v. Crystal Imp. Corp., 603 F.3d 967, 973 (Fed. Cir. 2010) (affirming judgment of unenforceability due to inequitable conduct, where company president failed to disclose a trade show demonstration that, "while not invalidating, reflected the closest prior art, and thus was highly material to patentability"); Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1235 (Fed. Cir. 2007) (affirming judgment of unenforceability due to inequitable conduct; district court and court of appeals did not address validity); McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 926 (Fed. Cir. 2007) (affirming judgment of unenforceability of the '716 patent due to inequitable conduct; district court and court of appeals did not address validity); Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1371–72 (Fed. Cir. 2007) (affirming judgment of unenforceability of the '169 and '145 patents due to inequitable conduct; district court and court of appeals did not address the validity of these two patents).

^{117.} And, possibly, some portion of Subset 4. *See supra* note 95.

and the left-hand R_2 term also would decrease. As expected, then, the proposal would reduce the amount of disclosure—perhaps significantly, because of the multiple consequences for the left-hand side.

To be sure, the model cannot predict the amount by which a reduction in P(B) would decrease aggregate disclosure. Moreover, even if pre-*Therasense* law resulted in systematic overdisclosure, at some point further reductions in P(B) (for example, eliminating the doctrine altogether, such that P(B) = 0) risk overshooting the mark (in terms of Figure 1, of moving Q^{**} to the left of Q^{*}). In the example above, if the set S were defined too narrowly, applicants might choose to conceal information falling within Subsets 3 or 4 above, or information the truth that might have led the examiner to consider the evidence in a different light. It is at least arguable, however, that the inequitable conduct doctrine need not be invoked in such circumstances. Opposing counsel who uncovers evidence that, for example, the applicant misrepresented its small inventor status could instigate disciplinary proceedings against the offending attorney. Alternatively, one could retain a

118. More precisely, eliminating the inequitable conduct doctrine altogether would mean, *ceteris paribus*, that disclosure would occur only when:

$$(F_{ND} - C_{App} - F_D) > (R_I - R_2)P(A \cap Not - d_E).$$
 (11)

Given that $R_I \ge R_2$, the right-hand term is positive and applicants would disclose only for sufficiently high values of $(F_{ND} - C_{App} - F_D)$. This is not an impossible condition; if $P(d_E)$ is sufficiently high, Applicant might conclude that her revenue would be higher if she disclosed, accepted the resulting consequences, if any, and reduced to some extent the risk of a potentially costly validity challenge thereafter. For low values of $P(d_E)$, however, Applicant may choose not to disclose I. (Recall that as $P(d_E) \to 0$, $(F_{ND} - C_{App} - F_D)$ can become negative. See supra p. 762.) In such a case, the existence of some form of inequitable conduct doctrine may make the difference between applicant disclosure and nondisclosure.

119. An example can be drawn from the facts of *New Medium*, where Judge Posner concluded that the applicant intentionally failed to disclose an expert's previous connections with—and thus possible bias in favor of—the applicant. *See* New Medium LLC v. Barco N.V., 582 F. Supp. 2d 991, 998 (N.D. III. 2008) (Posner, J., sitting by designation), *vacated by agreement of parties*, No. 05 C 5620, 2009 WL 2385890 (N.D. III. May 15, 2009); *see also* Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1188 (Fed. Cir. 2006) ("[A] declarant's past relationships with the applicant are material if (1) the declarant's views on the underlying issue are material and (2) the past relationship to the applicant was a significant one."). Whether the truth would have made a difference or not is hard to tell. In terms of Table 2 above, a materiality standard that requires proof that x = 1 might eliminate the incentive to disclose information of this type.

120. See Brief & Appendix of the American Bar Ass'n as Amicus Curiae at 17 & n.6, Therasense, Inc. v. Becton, Dickinson & Co., Nos. 2008-1511, -1512, -1513, -1514, -1595, 2011 WL 2028255 (Fed. Cir. May 25, 2011) (en banc) (discussing USPTO's power to sanction patent attorneys); cf. Cotropia, supra note 2, at 766 (noting the various ways in which the failure to comply with the inequitable conduct doctrine can result in disciplinary action against the offending attorney). One piece of anecdotal evidence suggesting that opposing counsel would still be motivated to bring such lesser misconduct to the attention of a court, the USPTO, or another disciplinary authority, as appropriate, can be found in the context of Rule 11 sanctions. Rule 11 sanctions are generally less consequential than the penalties for inequitable conduct. See FED. R. CIV. P. 11(c)(4). Under this rule, for example, sanctions "must be limited to what suffices to deter repetition of the conduct or comparable conduct by others similarly situated," and "may include nonmonetary directives; an order to

broad definition of S while reforming the doctrine in other ways—for instance, by instituting a more nuanced system of penalties as discussed below, or by defining other P(B)-related variables such as α and x with more precision.

A second set of reform proposals involves modifying the penalty for inequitable conduct in some manner. Under current law, a finding of inequitable conduct results in the patent being rendered unenforceable in its entirety; as noted above, however, some reformers have suggested an administrative penalty alone, or a range of penalties from which a court could select, based on the seriousness of the offense. ¹²¹ In terms of Expression (6), any increase in the value of R_3 would increase the right-hand side of the Expression and thus make disclosure somewhat less likely, all other considerations being equal; it would also tend to mitigate, to some extent, any risk aversion 122 arising from uncertainty over the values of B, d_E , and d_{ND} . Moreover, to the extent R_3 is tailored to the egregiousness of the offense—that is, $R_3 = f(P(B))$ and $dR_3/d(P(B)) < 0$ —disclosure will decrease further as P(B) decreases. How much less disclosure will occur depends on the magnitude of R_3 , holding everything else constant. At the same time, any such reform could marginally increase F_{ND} and C_{Exam} by adding yet another layer of complexity (selecting the right penalty) to the inequitable conduct doctrine, though this additional complexity could be mitigated by adopting guidelines along the lines that some commentators have advocated. 123

A related reform would be to render unenforceable only those claims that are directly affected by the inequitable conduct. ¹²⁴ In theory, this reform could still

pay a penalty into court; or . . . an order directing payment to the movant of part or all of the reasonable attorney's fees and other expenses directly resulting from the violation." *Id.* As noted above, inequitable conduct results in unenforceability of the patent, and sometimes payment of attorney's fees as well. *See supra* note 53 and accompanying text. Nevertheless, it appears that attorneys still file Rule 11 motions when the evidence so warrants. While hardly dispositive, a Westlaw search of (motion /s ("frcp" "fed. r. civ. p." "fed. r. civ. proc." "federal rule of civil procedure" "federal civil procedure rule") +1 11) & da(aft 12-31-2008)) in the allfeds database yields 247 cites at the time of this writing. *See also* Charles Yablon, *Hindsight, Regret, and Safe Harbors in Rule 11 Litigation*, 37 Loy. L.A. L. Rev. 599, 614–15 (2004) (presenting results of "quick and dirty empirical research" to the effect that motions for Rule 11 sanctions decreased, as intended, after the 1993 amendment to the rule, but still appear to number in the hundreds every year).

- 121. See supra text accompanying notes 60–63.
- 122. See infra Part III.B.2.

123. See Murphy, supra note 2, at 2296–2302. Both Cotropia and Mammen argue against allowing courts discretion to choose among a range of penalties, however, on the ground that such discretion would increase uncertainty, see Cotropia, supra note 2, at 775, or encourage weak assertions of the defense, see Mammen, supra note 2, at 1392–93.

124. See Cotropia, supra note 2, at 775; Mammen, supra note 2, at 1392. If information is material only if it would have affected patent validity at t_3 this rule would render the inequitable conduct doctrine moot. See Patent Office Prof'l Ass'n, supra note 2, at 1. If information can be material even though it does not affect validity at t_3 —for example, because a reasonable examiner would have considered it important—inequitable conduct would still have an independent, though limited, role to play even if only some of the patent's claims are unenforceable. See Cotropia, supra note 2, at 779; Mammen, supra note 2, at 1392.

allow inequitable conduct to play a role independent of invalidity; 125 a claim might not be rendered invalid by virtue of I, for example, but if I posed a sufficiently serious risk of invalidating a particular claim, the applicant's failure to disclose I could be grounds for rendering that claim (but not the entire patent) unenforceable. In addition to the reduction in effects resulting from risk aversion that this latter change would entail, the proposal would increase R_3 and decrease F_{ND} ; in combination, these effects would reduce disclosure to some extent, though perhaps less so than would a substantial reduction in P(B).

2. The Effect of Risk Aversion

Thus far, the analysis has assumed a rational, risk-neutral applicant, but a more realistic assumption might be that the applicant (or her agent) is to some degree risk-averse. A risk-averse applicant, "when faced with a choice between two gambles with the same expected value, will usually choose the one with a smaller variability of return." In the present context, this means that a risk-averse applicant will sometimes choose disclosure over nondisclosure even when $E(R)_D < E(R)_{ND}$ —in effect, incurring the cost of a risk premium to avoid some degree of risk associated with nondisclosure. As a general matter, the greater the variance associated with $E(R)_{ND}$, the higher the risk premium a risk-averse applicant would be willing to incur. In the present context, the effect of risk aversion may be important for two reasons.

The first is that risk aversion could play a significant role in determining how much information applicants disclose. To be sure, the applicant may not be the individual inventor, but rather a corporate assignee and corporations may be less risk-averse than are individuals. But even if the assignee is not risk-averse,

^{125.} An objective but-for test would negate this possibility, but as noted above, it remains to be seen whether *Therasense* adopted such a test.

^{126.} Walter Nicholson, Microeconomic Theory: Basic Principles and Extensions 538 (9th ed. 2004); *see also* Robert S. Pindyck & Daniel L. Rubinfeld, Microeconomics 158 (5th ed. 2001).

^{127.} Suppose, for example, that $E(R)_D = \$100,000$ and $E(R)_{ND} = \$125,000$. Depending on her degree of risk aversion, a risk-averse applicant might prefer $E(R)_D$ to $E(R)_{ND}$ if the variance around the mean associated with nondisclosure is much larger than the variance associated with disclosure. To use the simplest possible example, if $E(R)_D$ were sure to equal \$100,000, whereas $E(R)_{ND}$ were sure to equal \$0,50% of the time, and \$250,000, 50% of the time, a moderately risk-averse applicant might choose the certain payoff associated with $E(R)_D$ to the less certain, though actuarially higher value, payoff associated with $E(R)_{ND}$.

^{128.} A common assumption among economists is that individuals tend to be risk-averse, while institutions tend to be risk-neutral. *See, e.g.*, PINDYCK & RUBINFELD, *supra* note 126, at 157; RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW § 1.2, at 11 (7th ed. 2007). Even so, corporate agents—like the patent attorneys discussed in the text above—may be risk-averse and, absent effective monitoring, act accordingly (thus imposing an agency cost on their corporate principals). Whether individual inventors are likely risk-averse is unclear. *See* F.M. Scherer, *The Innovation Lottery, in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 3, 19–21 (Rochelle C. Dreyfuss et al. eds., 2001) (discussing the possibility of a "lottery effect," whereby some inventors and creators are motivated by the small ex ante probability of

the individual patent attorney (like individuals generally) may exhibit some degree of risk aversion. As Professor Cotropia has noted, the consequences for an attorney accused of inequitable conduct can include reputational harm, disciplinary action, and opportunity costs associated with having to assist with discovery requests (including submitting to a deposition). As a result, patent applicants may incur an agency cost resulting from the disparity between the applicant's and the attorney's tolerance for risk. To the extent legal services exhibit credence characteristics, there may be no simple or direct way for applicants to constrain these costs.

The second is that, to the extent the applicant or her agent is risk-averse, the uncertainties inherent to the inequitable conduct doctrine may induce the applicant or her agent to disclose even when the left-hand side of Expression (6) is smaller than the right-hand side, that is, when

$$R_1P(Not-A\cap B\cap d_E\cap d_{ND})+R_2P(A\cap B\cap d_E\cap d_{ND})+(F_{ND}-C_{App}-F_D)<(R_1-R_2)P(A\cap Not-d_E)+R_3P(B\cap d_E\cap d_{ND}).$$

Under current law-arguably even post-Therasense-many of the considerations that a rational applicant would take into account in deciding whether to disclose are likely to exhibit high variability. In particular, the value of P(B), which in turn informs the value of $E(R)_{ND}$, is dependent on the values of S, x, y, α , and z, and on the identity of the relevant examiner. As we have seen, none of these variables was clearly defined pre-Therasense, and some of them remain hazy even in the wake of that decision. A legal standard that reduces the uncertainty surrounding P(B)—perhaps by clearly adopting some version of an objective butfor test and by further clarifying the meaning of the deceptive intent element and its relation to materiality—would alleviate this problem to some extent (although substantial uncertainty still might surround other variables such as d_E and d_{ND} , and because it is a function in part of these variables, F_{ND}). Of course, the effect of such a change might also be to reduce the value of P(B) as well, with the results as predicted in Part III.B.1 above. Further refining the standards for materiality or intent, in other words, would likely have a compound effect on the applicant's incentive to disclose by both decreasing the left-hand side of Expression (6) and by reducing the impact, if any, of applicant risk aversion.

3. Some Less Obvious Reforms

To the extent overdisclosure remains a problem under current law, a less obvious means for reducing that problem would be to raise C_{App} such that some amount of disclosure that Applicant would find cost-effective under current law

earning vast rewards from their creations); Cotter, *supra* note 103, at 529 n.192 ("In many institutional settings, however, managers may be more risk-averse than the risk-loving individuals considered by Scherer.").

^{129.} See Cotropia, supra note 2, at 765–66. But see Rantanen & Petherbridge, supra note 109, at 19 (arguing that, post-Therasense, applicants might be inclined to take too many risks).

^{130.} A credence good or service is one the quality of which the buyer has difficulty evaluating even after she has consumed it. *See* Michael R. Darby & Edi Karni, *Free Competition and the Optimal Amount of Fraud*, 16 J.L. & ECON. 67, 68–69 (1973).

would become cost-ineffective. The USPTO's proposed rule requiring applicants to explain the relevance of information disclosed in an IDS¹³¹ could have this effect, though it could have other consequences as well. In terms of Expression (7), raising C_{App} could result in more cases in which $E(R)_D = R_1 P(Not-A) + R_2 P(A) - C_{App} - F_D < 0$, with the result that the applicant might prefer abandoning the application to disclosing. On the other hand, to the extent an improved IDS would make it easier for the examiner to focus on relevant information, the number of erroneous grants should decrease, thus reducing the costs that invalid patents impose on potential licensees and accused infringers. In terms of the overall purpose of the inequitable conduct doctrine, however, requiring such disclosure makes sense only if (as Expression (2) proposes) $C_{App} < C_{Exam}$. In terms of Figure 1 above, the effect of such a move would be to shift U_{App} to the left; the disparity Figure 1 assumes between Q^* and Q^{**} would likely decrease.

Another possibility would be to raise the cost to defendants of asserting the defense. As noted above, defendants already must plead the defense with particularity and must prove materiality and intent by clear and convincing evidence. Some commentators nevertheless have argued that the defense is often raised for its nuisance value and have argued that courts or Congress should consider reforms that would target such abuses, such as more frequently awarding prevailing plaintiffs the attorney's fees they incur in responding to the defense. The model presented above does not directly capture the effects of the defense on defendant behavior; but reforms that would make the defense potentially more costly to assert presumably would reduce the frequency with which the defense is asserted, thus lowering F_{ND} and reducing the quantity of information applicants disclose purely for defensive purposes.

Another possible reform that, on its face, has nothing to do with the inequitable conduct doctrine would nevertheless likely impact the doctrine

^{131.} See Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808, 38,809 (July 10, 2006) (to be codified at 37 C.F.R. pt. 1); see also FED. TRADE COMM'N, supra note 2, ch. 5, at 12–13 (recommending greater use of relevance statements); Cotropia, supra note 2, at 777–78 (arguing in favor of prohibiting the submission of cumulative and nonmaterial prior art); Nolan-Stevaux, supra note 2, at 171–72 (arguing in favor of relevance statements). Alternatively, the USPTO or a court could impose a penalty of some sort for the disclosure of nonmaterial information, though I would worry that such a solution would aggravate the administrative costs of the current system absent a very clear definition of materiality.

^{132.} See supra note 28.

^{133.} See, e.g., NAT'L RESEARCH COUNCIL, supra note 2, at 123 (arguing in favor of fee shifting); Dolak, supra note 2, at 892 ("[I]t may make sense to implement a feeshifting provision in favor of patentees who prevail on the issue [of inequitable conduct], for example, an automatic award of inequitable-conduct-related attorney fees to a plaintiff who prevails on inequitable conduct, regardless of whether the patentee wins on infringement and validity."); McGowan, supra note 2, at 980 (arguing for "more liberal use of fee awards for meritless assertions of the defense"); Brown, supra note 2, at 627–28 (arguing for fee shifting when a court awards summary judgment to the patentee on the issue of inequitable conduct); Mack, supra note 2, at 172 (proposing fee shifting); Nolan-Stevaux, supra note 2, at 167–69 (arguing for fee shifting when a court awards summary judgment to the patentee on the issue of inequitable conduct).

indirectly. The reform at issue is the adoption of a post-grant opposition process similar to that which other nations have in place. 134 The purpose of introducing post-grant oppositions would be to provide a method, speedier and more effective than current reexamination procedures, for interested parties to challenge potentially invalid patents shortly after grant, before the issue is likely to arise in litigation. 135 Assuming the reform has the intended consequence of bringing more invalidating prior art to the attention of the USPTO, the reform would tend to increase d_E . The effect would likely be to increase disclosure, because an increase in d_E increases all three variables from the left-hand side of Expression (6) $(R_1P(Not-A\cap B\cap d_E\cap d_{ND}), R_2P(A\cap B\cap d_E\cap d_{ND}), \text{ and } F_{ND})$ and decreases the first term on the right. (Increasing d_E also increases the R_3 term on the right, but as long as this term remains at or near zero the effect will be minimal.) To the extent the current system already induces overdisclosure, introduction of an opposition system into U.S. law could aggravate the problem to some extent. The reform nevertheless might be desirable if it has the intended effect of weeding out invalid patents (and thus reducing their social costs) at a relatively early stage. Moreover, one might speculate that reform of the inequitable conduct doctrine, coupled with the adoption of an opposition system, would tend to cancel out any risk of encouraging yet more overdisclosure. The fact that other countries have oppositions and not an inequitable conduct doctrine, as such, 137 suggests the

^{134.} The various proposed Patent Reform Acts also have included provisions that would enable third parties to submit prior art to the USPTO before the issuance of the patent, though not to commence opposition proceedings at that time. See, e.g., S. 23, 112th Cong., §§ 5, 7 (2011), available at http://www.govtrack.us/congress/billtext.xpd?bill=s112-112th (2011),1249, Cong., §§ 5, 7 available http://www.govtrack.us/congress/bill.xpd?bill=h112-1249. Some other commentators have suggested a relationship between inequitable conduct and third-party submissions and oppositions. See NAT'L RESEARCH COUNCIL, supra note 2, at 123 (arguing that the doctrine would be unnecessary in light of such reforms); Armitage, supra note 2, at 6 (arguing that "commercially motivated competitors would likely assure that the information on which patent validity depends would be put before the Office" if Congress enacted legislation requiring publication of all applications at filing, permitting post-application submissions, and permitting post-grant oppositions); Wasserman, supra note 2, at 26; Harold C. Wegner, Inequitable Conduct and the Proper Roles of Patent Attorney and Examiner in an Era of International Patent Harmonization, 16 AIPLA Q.J. 38, 41, 73 (1988).

^{135.} See S. Rep. No. 110-259, at 18–23 (2008); see also Nat'l Research Council, supra note 2, at 95–103.

^{136.} To be sure, some such prior art would have been discovered later on, in litigation or elsewhere. But some of it might have escaped the attention of the infringement defendant.

^{137.} See Tatsuya Misawa, Decision Standards for Duty of Disclosure, 2004 INST. INTELL. PROP. BULL. 136, 140. This article notes:

The basis of the U.S. system for disclosure of information is compliance with the duty of candor. The U.S. system is a unique system in comparison to other countries' systems. Even in the United Kingdom which also uses common law as a base, inequitable conduct will not lead to the invalidation of a patent or the impossibility of exercise of the right.

Id. at 140. For example, "[i]n the U.K. Patents Act 1949, a false suggestion and representation were reasons for revocation." *Id.* at 140 n.24.

possibility that disclosure is adequate under such a combination, though, of course, no definitive inferences can be drawn merely from possibilities. Alternatively, the lack of an inequitable conduct doctrine in other countries may help to explain why oppositions are an important part of foreign patent systems. Either way, the analysis provides some reason for concern that eliminating the inequitable conduct doctrine altogether, without adopting oppositions or other measures designed to increase d_E , might be ill-advised.

CONCLUSION

At the end of the day, the formal analysis presented above leaves open many questions concerning the optimal contours of the doctrine of inequitable conduct. The analysis nevertheless does suggest several practical implications: among them that the doctrine is at best an imperfect means of inducing optimal disclosure; that, both pre- and post-Therasense, the doctrine leaves many key concepts without any precise definition; that the resulting uncertainties in the operation of existing doctrine may induce risk-averse agents to overdisclose; that, to the extent overdisclosure was or remains a pressing problem, any of a number of reforms would reduce the doctrine's significance, with the clear adoption of a single but-for standard of materiality probably having the greatest potential payoff; and that the social benefits of an inequitable conduct doctrine are likely to be greater in a system like the United States' in which opportunities for post-grant oppositions are constrained (conversely, the benefits of an expansive inequitable conduct doctrine may be small or negative in a system in which post-grant oppositions are common). Future work might fruitfully explore ways to test some of these conclusions empirically, for example, by investigating whether foreign patent regimes suffer from a greater incidence of fraud-related harms in the licensing and enforcement of patents. It also may be worth noting that, while the

"False suggestion" remains a ground for revocation in some countries. See, e.g., Ranbaxy Austl. Pty Ltd. v. Warner-Lambert Co., [2008] FCAFC 82, ¶¶ 135-40 (Austl.). In addition, some courts in Canada have held that misrepresentations made in response to a patent examiner's request for information violates a duty of candor and can result in a finding of patent abandonment. See BRADLEY LIMPERT, TECHNOLOGY CONTRACTING: LAW, PRECEDENTS AND COMMENTARY §§ 5.3(d)(iv), (e)(i) (2005) (reviewing Canadian case law). Cf. 37 C.F.R. § 1.105(a)(1) (2009) (authorizing examiners to "require the submission, from individuals identified under § 1.56(c), or any assignee, of such information as may be reasonably necessary to properly examine or treat the matter," and threatening a finding of abandonment in the event of a failure to reply); European Patent Convention art. 124(1)–(2) available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ ar124.html#conv.f134-note (authorizing the European Patent Office to "invite the applicant to provide information on prior art taken into consideration in national or regional patent proceedings and concerning an invention to which the European patent application relates," and providing that in the event of a failure "to reply in due time . . . the European patent application shall be deemed to be withdrawn"). As in Japan, however, there appears to be no close counterpart under European law to the United States' inequitable conduct doctrine. See Jan Krauss & Toshiko Takenaka, Neuere US-Entscheidungen betreffend "Inequitable Conduct" und ihre Effekte auf internationale Patent-Anmeldeverfahren, 2010 MITTEILUNGEN DER DEUTSCHEN PATENTANWÄLTE [MITT. HEFT] 569, 570–71 (Ger.).

optimal amount of fraud in the absence of error and enforcement costs may be zero, ¹³⁸ in the presence of such costs attempts to reduce false negatives to zero not only will be costly to enforce but may also dilute the value of truthful information to some degree. ¹³⁹ As courts and Congress struggle to develop a better framework, they would do well to consider the trade-offs and imperfections inherent in any system designed to reduce the incidence of fraud.

138. See Ackerman v. Schwartz, 947 F.2d 841, 847 (7th Cir. 1991).

^{139.} See Cotropia, supra note 2, at 770–73; see also Richard Craswell, Interpreting Deceptive Advertising, 65 B.U. L. Rev. 657, 688–92 (1985) (arguing that overregulation of false advertising can be counterproductive to the extent it chills advertisers from making truthful statements as well).