

# COMMENT

## THE *EXERGEN* AND *THERASENSE* EFFECTS

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*This Comment empirically investigates the doctrine of inequitable conduct in patent law. Inequitable conduct is a defense to patent infringement that accuses the patent holder of committing fraud on the U.S. Patent and Trademark Office to secure the patent. Before the Federal Circuit's recent Exergen and Therasense decisions, the defense was seen as chronically overused. As a result, patent applicants cited more prior art in their applications to avoid later being charged, during litigation with fraudulent omissions. The Federal Circuit responded with Exergen and Therasense, which heightened the pleading standard and raised the legal proof required for inequitable conduct, respectively.*

*Many commentators, and especially members of the patent defense bar, now feel that the Federal Circuit has gone too far in restricting the inequitable conduct defense, to the point that it is essentially a dead doctrine. This Comment informs the debate by adding comprehensive data. To better comprehend the effects of the Exergen and Therasense cases, this Comment calculates the rates at which accused infringers plead and prove inequitable conduct—for every patent case over the periods in question. The results show that the inequitable conduct defense is used significantly less often than many assume, contradicting assertions by the Federal Circuit's Therasense majority. Moreover, the data indicate that Exergen and Therasense have both contributed to an even further decline in accused infringers' use of the inequitable conduct defense. Based on a full exploration of the data, the Comment concludes that the Federal Circuit went too far in Therasense (but not in Exergen). A better formulation of inequitable conduct doctrine would be the test advocated by the dissent in Therasense, which embraced the U.S. Patent and Trademark Office's lower standard of materiality.*

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## INTRODUCTION

In patent law, a finding that inequitable conduct occurred during the prosecution of a patent application renders the whole patent unenforceable. Because the remedy for inequitable conduct is so drastic, an inequitable conduct charge—even one without merit—hangs like a specter over patentees in litigation.<sup>1</sup> According to the Federal Circuit, inequitable conduct claims force patentees to refuse settlement and defend themselves against accusations of bad faith.<sup>2</sup> Further, the reputational consequences for the patent attorney who prosecuted the patent application are disastrous.<sup>3</sup> In response to increased use of this defense, patent prosecutors began citing more prior art in patent applications,<sup>4</sup> burying examiners in references.<sup>5</sup>

To cure this “plague,”<sup>6</sup> the Federal Circuit tightened the pleading standard in *Exergen Corp. v. Wal-Mart Stores, Inc.*<sup>7</sup> and raised the legal standard required to establish inequitable conduct in *Therasense, Inc. v. Becton, Dickinson & Co.* to require separate showings of but-for materiality and specific intent to

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1. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc).

2. *Id.*

3. *Id.*

4. In general, prior art is information available to the public before a patent application’s filing date. For the precise definition, see 35 U.S.C. § 102 (2011). Such information must be disclosed to the U.S. Patent and Trademark Office in the patent application.

5. *Therasense*, 649 F.3d at 1289.

6. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client’s interests adequately, perhaps.”).

7. 575 F.3d 1312 (Fed. Cir. 2009).

deceive the U.S. Patent and Trademark Office (PTO).<sup>8</sup> But has the Federal Circuit gone too far? Many now believe that inequitable conduct is essentially a dead doctrine in patent law.<sup>9</sup>

This Comment argues that the Federal Circuit has gone too far. Although it was right to restrict access to the doctrine, it ultimately has made inequitable conduct too difficult to prove. To quantify the *Exergen* and *Therasense* effects, this Comment considers the prevalence of inequitable conduct charges over several time periods. The comprehensive data indicate that the *Therasense* decision was likely unnecessary to further suppress unmeritorious inequitable conduct claims. Moreover, this research reveals that the two studies on which the Federal Circuit relied to justify the major legal shift in *Therasense* are both deeply flawed, thus causing the Federal Circuit to exaggerate the overuse of inequitable conduct claims as a litigation tactic.

Once again, the Federal Circuit must realign inequitable conduct doctrine with its original purpose: to deter fraud before the PTO. Part I provides some background on the inequitable conduct doctrine, beginning with its origins and continuing through the “plague” years and the recent “cure.” Next, in Part II, I present my empirical methodology to test the effects *Exergen* and *Therasense* have had on pleading and finding inequitable conduct, and I discuss my results. Part III surveys the policies underlying inequitable conduct and the *Therasense* decision, suggesting, based on my empirical and analytical findings, that the Federal Circuit should adopt the PTO’s lower, Rule 56 materiality standard.<sup>10</sup>

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8. *Therasense*, 649 F.3d 1276.

9. See, e.g., Dennis Crouch, *Inequitable Conduct: Federal Circuit Places Another Nail in the Coffin*, PATENTLY-O (Sept. 14, 2012, 11:06 AM), <http://www.patentlyo.com/patent/2012/09/inequitable-conduct-federal-circuit-places-another-nail-in-the-coffin.html>; Frederick Frei & Sean Wooden, *Inequitable Conduct Claims One Year After Therasense*, MANAGING INTELL. PROP. (July 18, 2012), [http://www.andrewskurth.com/media/article/1620\\_Managing%20IP%20Article.pdf](http://www.andrewskurth.com/media/article/1620_Managing%20IP%20Article.pdf) (“After the holding in *Therasense*, it was widely believed that the court had sounded the death knell to the inequitable conduct defence by imposing evidentiary requirements that could rarely be met.”). For a view that inequitable conduct is still available in Abbreviated New Drug Application (ANDA) cases, see *Inequitable Conduct Defenses Still Alive in ANDA Cases*, ANDA ADVISORS (Feb. 8, 2013), <http://andaadvisors.com/inequitable-conduct-defenses-still-alive-in-anda-cases>.

10. See 37 C.F.R. § 1.56 (2013). The PTO promulgates regulations pursuant to statutory authority. 35 U.S.C. § 2 (2011). These regulations govern proceedings before the PTO. Section 1.56 (also called Rule 56) defines parties’ duty of candor to the PTO in administrative filings and proceedings. Rule 56 therefore outlines the information the PTO itself considers material in arriving at administrative decisions.

## I. BACKGROUND ON INEQUITABLE CONDUCT

A. *The Patent Prosecution Process*

Before outlining the origins of the inequitable conduct doctrine, a short introduction to patent prosecution is in order for those unfamiliar with the process. To obtain a patent, an applicant must submit a patent application to the PTO, and the application must successfully pass through the PTO's prosecution process. During this process, a patent examiner reviews the patent to ensure that the patent claims patent-eligible subject matter,<sup>11</sup> that the invention is novel<sup>12</sup> and non-obvious,<sup>13</sup> and that the patent contains a sufficient written description of the invention.<sup>14</sup> In the patent application, the applicant makes numerous representations, such as certifying that she is the true inventor of the claimed invention. The applicant also cites prior art—or previous inventions in the field—to aid the examiner in determining whether the patent is novel and non-obvious. Misrepresentations or omissions in the patent application or in statements to a patent examiner during prosecution can be the basis of an inequitable conduct claim when the patent is later the subject of litigation.

B. *Origins*

Inequitable conduct is a judge-made doctrine that derives from the equitable unclean hands doctrine, which generally requires that a party seeking equitable relief come to the court with clean hands. Patentees who defraud the PTO ask an equity court to enforce an unclean patent. Over a period of twelve years, the Supreme Court decided three cases involving unclean hands in patent law, forming the backbone for modern inequitable conduct doctrine: *Keystone Driller Co. v. General Excavator Co.*,<sup>15</sup> *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*,<sup>16</sup> and *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*<sup>17</sup> Briefly reviewing these cases will aid us in understanding the type of behavior that the Supreme Court originally intended the inequitable conduct doctrine to deter.

In *Keystone Driller*, the patentee failed to disclose a potentially invalidating prior use to the PTO during the prosecution process.<sup>18</sup> The patentee later

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11. 35 U.S.C. § 101 (2011).

12. *Id.* § 102.

13. *Id.* § 103.

14. *Id.* § 112.

15. 290 U.S. 240 (1933).

16. 322 U.S. 238 (1944), *abrogated on other grounds by* *Standard Oil Co. v. United States*, 429 U.S. 17 (1976).

17. 324 U.S. 806 (1945).

18. 290 U.S. at 243.

sued Byers Machine Co., obtaining an injunction.<sup>19</sup> Keystone Driller then proceeded to assert the patent against several other entities. However, this time, the defendants discovered that the patentee had attempted to cover up the prior use by paying the prior user to state that he had abandoned his use.<sup>20</sup> The district court, sitting in equity, found the unclean hands doctrine inapplicable. The circuit court, however, reversed, dismissing the case for lack of standing on grounds of unclean hands, and the Supreme Court affirmed the circuit court's dismissal. Because Keystone Driller asked the equity court for relief based upon the injunction obtained in the Byers Machine Co. case, which had resulted from its misconduct, it came to the court with unclean hands, and the action was dismissed for lack of standing.<sup>21</sup>

The *Hazel-Atlas Glass* case also involved significant, affirmative misconduct. The patent applicants were "confronted with apparently insurmountable Patent Office opposition."<sup>22</sup> To overcome the opposition, the prosecuting attorneys decided to write an article on the device, describing it as "revolutionary."<sup>23</sup> They subsequently had this article signed by an expert in the field, who published it in a trade journal. When the attorneys provided the PTO with the article, the patent was allowed.<sup>24</sup> The Supreme Court held that this was a clear case of unclean hands, and it dismissed the lawsuit.<sup>25</sup>

In the third case, *Precision Instrument Manufacturing*, the patentee plainly committed fraud before the PTO. Automotive Maintenance Machinery Co. and Precision Instrument Manufacturing Co. were engaged in an interference proceeding in the PTO.<sup>26</sup> During discovery, the parties learned that Larson, a Precision employee, was not the inventor as claimed, and that he had also submitted affidavits to the PTO with "false dates as to the conception, disclosure, drawing, description and reduction to practice of his claimed invention."<sup>27</sup> Larson testified in the interference proceedings to these false facts.<sup>28</sup> After Auto-

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19. *Id.* at 242.

20. *Id.* at 243. Note that a patent is invalid for lack of novelty under 35 U.S.C. § 102(a) if the invention was in public use prior to the patent's filing date. At the time *Keystone Driller* was decided, a patent lacked novelty if, inter alia, the invention was in public use before the date of invention. See 35 U.S.C. § 102(a) (1952) (codifying prior case law on novelty). With respect to the abandonment argument, the patentee in *Keystone Driller* would have been entitled to the patent had the prior user truthfully abandoned his use of the invention. See 35 U.S.C. § 102(g) (1952); *Peeler v. Miller*, 535 F.2d 647, 653-55 (C.C.P.A. 1976).

21. *Keystone Driller*, 290 U.S. at 247.

22. 322 U.S. 238, 240 (1944) (internal quotation mark omitted), *abrogated on other grounds* by *Standard Oil Co. v. United States*, 429 U.S. 17 (1976).

23. *Id.* (internal quotation mark omitted).

24. *Id.* at 240-41.

25. *Id.* at 250.

26. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 809 (1945).

27. *Id.*

28. *Id.* at 810.

motive discovered these facts, it decided to cover them up—even though it was not a guilty party—by entering into a settlement with Larson and Precision through which it was given the application, along with the other advantages derived from Larson’s false testimony.<sup>29</sup> The patent eventually issued. Later, someone at Automotive brilliantly decided to assert the obviously inequitably procured patent against Precision, the company that knew its true history. Of course, this strategy was not successful, and the Supreme Court concluded that “[s]uch inequitable conduct impregnated Automotive’s entire cause of action and justified dismissal by resort to the unclean hands doctrine.”<sup>30</sup>

Inequitable conduct doctrine thus arose from three instances of egregious conduct by patentees. Because the conduct in those cases was so extreme, and because the Court was making equitable rulings, the Supreme Court did not articulate clear legal standards to guide lower courts. As the Supreme Court withdrew from intervening in inequitable conduct cases, the regional circuit courts were left to explore the limits of what initially seemed to be a narrow subset of unclean hands doctrine.

### C. *The “Plague”*

Over the next four decades prior to the creation of the Federal Circuit, the inequitable conduct doctrine slowly evolved in the regional circuits, without any definitive standard emerging.<sup>31</sup> One important development was the change in remedy from dismissal of the suit for lack of standing to unenforceability of the entire patent. Given that the doctrine of unclean hands signified that no person could come before an equity court in bad faith, the proper remedy was dismissal for lack of standing.<sup>32</sup> However, in *Hazel-Atlas Glass*, the Supreme Court observed that the true remedy for such fraud on the PTO would be to vacate the patent (which has the same consequences as rendering a patent unenforceable).<sup>33</sup> But the Supreme Court did not have this power at the time, as this remedy was only available in direct proceedings brought by the United States government.<sup>34</sup> The enactment of the Patent Act of 1952, however, gave courts the power to render patents unenforceable in private infringement ac-

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29. *Id.* at 813-14.

30. *Id.* at 819.

31. Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37, 52-67 (1993).

32. Damages were usually unavailable to the defendant in unclean hands cases because courts of equity generally did not have jurisdiction to order legal remedies. DOUGLAS LAYCOCK, MODERN AMERICAN REMEDIES 5-6 (Vicki Been et al. eds., 4th ed. 2010).

33. *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 251 (1944), *abrogated on other grounds by Standard Oil Co. v. United States*, 429 U.S. 17 (1976).

34. *United States v. Am. Bell Tel. Co.*, 128 U.S. 315, 373 (1888).

tions brought under 35 U.S.C. § 282.<sup>35</sup> Thereafter, courts gradually adopted unenforceability as the remedy for inequitable conduct.

With the creation of the Federal Circuit came uniformity with respect to inequitable conduct doctrine. Unfortunately, despite such uniformity, the elements needed to prove inequitable conduct were often vague and shifting.

For the entire duration of the Federal Circuit's existence, it has been clear that inequitable conduct has two elements: materiality and intent.<sup>36</sup> Materiality was typically based on the standard described in Rule 56. Between 1977 and 1992, Rule 56 described information as material "where 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."<sup>37</sup> This was a very low bar for accused infringers to clear—a reference merely had to be "important," a standard that easily devolved into requiring simple relevance.<sup>38</sup>

The intent standard was also quite minimal, especially given that a finding of inequitable conduct renders the entire patent unenforceable. Although the Federal Circuit insisted that mere negligence was not enough,<sup>39</sup> district courts sometimes found inequitable conduct "based on actions that may fairly be characterized as sloppy or imprecise work by the patent lawyer during prosecution."<sup>40</sup>

Unjustified claims of inequitable conduct became so common that a Federal Circuit panel in 1988 described them as an "absolute plague."<sup>41</sup> Later that year, in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, a more diplomatic en banc court acknowledged a "present proliferation of inequitable con-

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35. 35 U.S.C. § 282(b)(1) (2011); Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1-376 (2011)).

36. *See Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1383 (Fed. Cir. 1983) ("Establishing that a patent was procured by fraud or with such egregious conduct as to render it unenforceable requires clear, unequivocal, and convincing evidence of an intentional misrepresentation or withholding of a material fact from the PTO."); *see also Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc) ("[I]nequitable conduct came to require a finding of both intent to deceive and materiality.").

37. 37 C.F.R. § 1.56 (1977).

38. Harry F. Manbeck, Jr., *The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 140 (1992) ("I concluded that existing Rule 56 was indeed too imprecise, and could, and probably was, leading to unjustifiable charges of inequitable conduct in litigation. It should be changed.").

39. *Orthopedic Equip.*, 707 F.2d at 1383 ("[M]ere evidence of simple negligence, oversight, or an erroneous judgment made in good faith not to disclose prior art is not sufficient to render a patent unenforceable.").

40. Christian E. Mammen, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1329, 1338 (2009).

41. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.").

duct charges.”<sup>42</sup> This outcry from the Federal Circuit led to reform efforts, and Rule 56 was rewritten. Under the new Rule 56, information was material only if it was not cumulative to information already in the application and either established a prima facie case of unpatentability of a claim or was inconsistent with a position the applicant took in arguing for the invention’s patentability.<sup>43</sup> Rule 56 also clarified that

[a] prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, 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.<sup>44</sup>

Therefore, the 1992 version of Rule 56 fell short of requiring but-for materiality—meaning that a claim would not have been allowed had the information been known to the PTO—but it came close with its requirement that an omitted reference establish a prima facie case of unpatentability. The Federal Circuit also tightened the intent standard, holding that gross negligence alone cannot support a finding of intent.<sup>45</sup> Instead, inequitable conduct required the intent to deceive.<sup>46</sup>

Despite the changes to Rule 56, the next two decades saw the Federal Circuit slowly unravel its stricter intent element. In 1996, the panel in *Nordberg, Inc. v. Telsmith, Inc.* quoted a 1987 case that *Kingsdown* criticized, adopting in the process a “should have known” intent standard.<sup>47</sup> Further baby steps toward gross negligence were made following *Nordberg*,<sup>48</sup> and in 2006, *Ferring B.V. v. Barr Laboratories, Inc.* not only brought back the gross negligence standard, but also presumed intent to deceive absent an innocent explanation from the patentee.<sup>49</sup> Naturally, litigants began regularly asserting inequitable conduct, and the “plague” returned.

42. 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc).

43. 37 C.F.R. § 1.56 (1992).

44. *Id.*

45. *See Hoffman-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 688 (Fed. Cir. 1990); *Kingsdown*, 863 F.2d at 876.

46. *Hoffman-La Roche*, 906 F.2d at 688; *Kingsdown*, 863 F.2d at 876.

47. 82 F.3d 394, 397 (Fed. Cir. 1996) (“Applicant must be chargeable with knowledge of the existence of the prior art or information, for it is impossible to disclose the unknown. Similarly, an applicant must be chargeable with knowledge of the materiality of the art or information; yet an applicant who knew of the art or information cannot intentionally avoid learning of its materiality through gross negligence, i.e., it may be found that the applicant ‘should have known’ of that materiality.” (quoting *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987))).

48. *See, e.g., Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001).

49. 437 F.3d 1181, 1191 (Fed. Cir. 2006) (“[S]ummary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the



#### D. The “Cure”

The Federal Circuit’s attempt to cure the plague arguably began with *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*<sup>50</sup> In *Star Scientific*, the panel warned courts against “permitting the defense to be applied too lightly”<sup>51</sup> and reformed the law concerning the balancing of materiality and intent. Prior to *Star Scientific*, courts would consider evidence of materiality and intent, and then balance the two to determine whether inequitable conduct had or had not occurred.<sup>52</sup> This procedure compelled an inequitable conduct finding when a highly material reference was omitted from the patent application, but there was little evidence of intent, even under a “should have known” standard. In all likelihood, courts rendered some patents unenforceable for inequitable conduct when the patentee had behaved entirely honestly. With a “gross negligence” intent standard, it is quite possible that a diligent prior art search—but one that simply missed a highly relevant reference—would in hindsight look like inequitable conduct.

*Star Scientific* gave the balancing step much more structure. Both intent and materiality must be separately found by clear and convincing evidence. These are basic threshold requirements that the accused infringer must meet before reaching the balancing step. Significantly, “materiality does not presume intent,”<sup>53</sup> and “the fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element.”<sup>54</sup> *Star Scientific* further held that “[i]f a threshold level of intent to deceive or materiality is not established by clear and convincing evidence, the district court does not have any discretion to exercise and cannot hold the patent unenforceable regardless of the relative equities or how it might balance them.”<sup>55</sup> Rather, as a second stage of the inquiry, after materiality and intent have each been proved by clear and convincing evidence, “the district court must balance the *substance* of those now-proven facts and all the equities of the case to determine whether the severe penalty of unenforceability should be imposed.”<sup>56</sup> Whereas the balancing step before *Star Scientific* often made it easier to prove inequitable conduct by allowing lesser showings of either materiality or intent, *Star Scientific* reframed

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applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.”). This intent standard was later replaced by a stricter one in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc).

50. 537 F.3d 1357 (Fed. Cir. 2008).

51. *Id.* at 1366.

52. *See, e.g., Ferring*, 437 F.3d at 1194.

53. *Star Scientific*, 537 F.3d at 1366 (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001)) (internal quotation mark omitted).

54. *Id.*

55. *Id.* at 1367.

56. *Id.*

the balancing step as another hurdle that must be overcome by the accused infringer after proving materiality and intent separately.

The Federal Circuit next tackled the requirements for pleading inequitable conduct in *Exergen Corp. v. Wal-Mart Stores, Inc.*<sup>57</sup> According to the Federal Circuit, inequitable conduct is a type of fraud,<sup>58</sup> so the *Exergen* court held that it must be pleaded with particularity under Federal Rule of Civil Procedure 9(b).<sup>59</sup> The court then proceeded to significantly raise the level of pleading necessary to survive a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss: “[T]he pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission . . .”<sup>60</sup> “What” and “where” require pleadings “to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found.”<sup>61</sup> To sufficiently state “why” and “how” a withheld reference is not cumulative, pleadings must explain which claim limitations are absent from the record, including why material information is not cumulative and how an examiner would have used the information in assessing the invention’s patentability.<sup>62</sup> Although Rule 9(b) allows intent to be averred generally, *Exergen* requires pleadings to “include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.”<sup>63</sup>

Clearly, the *Exergen* decision has not only made inequitable conduct arduous to plead, but has also sent a strong signal to district courts that inequitable conduct should not be found nearly as frequently as it was when the Federal Circuit declared it a “plague” in 1988. Moreover, by requiring accused infringers to plead certain facts—for example, that a specific individual knew of the withheld reference—the *Exergen* court underlined several doctrinal points that may have been loosely enforced prior to the decision. As the next Part will demonstrate, *Exergen* had a strong effect on accused infringers’ ability to prove inequitable conduct, even though the decision was only addressed to the pleading requirements.

Not yet finished restricting the scope of inequitable conduct, the Federal Circuit sitting en banc decided *Therasense, Inc. v. Becton, Dickinson & Co.* in

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57. 575 F.3d 1312 (Fed. Cir. 2009).

58. For an argument that Rule 9(b) should not apply to inequitable conduct, see David Hricik, *Wrong About Everything: The Application by the District Courts of Rule 9(b) to Inequitable Conduct*, 86 MARQ. L. REV. 895, 913-20 (2003).

59. *Exergen*, 575 F.3d at 1326.

60. *Id.* at 1328.

61. *Id.* at 1329.

62. *Id.* at 1329-30.

63. *Id.* at 1328-29.

2011.<sup>64</sup> Under *Therasense*, accused infringers must prove that the patent applicants' specific intent to deceive the PTO is the single most reasonable inference to be drawn from the evidence.<sup>65</sup> Arguably going even further, the court stated that "when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found."<sup>66</sup> The court also increased the materiality standard to require but-for materiality, holding 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."<sup>67</sup> Besides a difference in the standard of proof (preponderance of the evidence versus clear and convincing evidence),<sup>68</sup> this but-for materiality is equivalent to the test for invalidating a claim: the claim is unpatentable over the prior art.

Accounting for the Supreme Court decisions in *Keystone Driller*, *Hazel-Atlas*, and *Precision* mentioned earlier, the Federal Circuit created an exception for affirmative egregious misconduct. If the accused infringer proves that the patent applicant committed affirmative egregious misconduct, such as the filing of an unmistakably false affidavit, materiality is presumed.<sup>69</sup> Finally, the court eliminated the balancing requirement that was reformed in *Star Scientific*, holding that intent and materiality are completely independent from each other.<sup>70</sup>

The current state of the law now makes inequitable conduct extraordinarily difficult to plead and prove. *Exergen* requires a party pleading inequitable conduct to closely inspect the patent and prior art to plead complex theories of reference non-cumulativeness, along with having at least some factual basis for pleading the specific intent to deceive—all before discovery opens. *Therasense* restricts inequitable conduct to only omissions or misrepresentations that would have prevented the patent from issuing. Moreover, there must be no other reasonable inference to be drawn from the evidence other than the specific intent to deceive the PTO—an extraordinarily high bar given the rarity of direct evidence of intent to deceive. And, even if a district court is still inclined to find inequitable conduct under the new doctrine in an individual case, the strong language in *Star Scientific*, *Exergen*, and *Therasense* will surely make the court think twice before rendering a patent unenforceable.<sup>71</sup>

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64. 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

65. *Id.* at 1290.

66. *Id.* at 1290-91.

67. *Id.* at 1291.

68. *Id.* at 1291-92; *see also infra* note 117.

69. *Therasense*, 649 F.3d at 1292.

70. *Id.* at 1290.

71. In fact, in the short time since *Therasense*, the Federal Circuit has already reversed or vacated at least three findings of inequitable conduct by district courts. *See* *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285 (Fed. Cir. 2012) (reversing the district court's finding of inequitable conduct); *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367 (Fed. Cir. 2012) (same); *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318 (Fed. Cir. 2011) (vacating district court's finding of inequitable conduct and remanding).

## II. THE *EXERGEN* AND *THERASENSE* EFFECTS

Have *Exergen* and *Therasense* reduced inequitable conduct's prevalence in patent litigation, as intended by the Federal Circuit? This Part attempts to answer that question. In particular, data were collected on the frequency with which parties plead and prove inequitable conduct to answer two questions: (1) do parties successfully prove inequitable conduct less frequently after *Exergen* and *Therasense*? and (2) do parties plead inequitable conduct less frequently after *Exergen* and *Therasense*?

### A. *Proving Inequitable Conduct*

#### 1. *Methodology*

To determine the rates at which litigants prove inequitable conduct, every final disposition of inequitable conduct on the merits at the district court level between January 1, 2008, and April 10, 2013, was read. This includes any time a district judge considered the factual merits of an inequitable conduct claim, which occurred most commonly at summary judgment and after bench trials. Dismissals at the pleading stage under Rule 12(b)(6) were not considered determinations on the merits and were therefore not included.<sup>72</sup> Similarly, district court decisions to deny summary judgment were also not included.<sup>73</sup>

Cases were located primarily by searching "inequitable conduct" in the Westlaw "Federal District Court Cases" database. This search returns a very large number of cases, which were each read individually to compile final merits decisions into a case list.<sup>74</sup> The case lists created in this manner were cross-checked with Lex Machina searches and the University of Houston Law Center's Patstats.org. Only one case was added through this cross-checking, so the final dataset of cases is likely highly, if not completely, comprehensive.

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72. Although *Exergen* surely had a significant impact on Rule 12(b)(6) dismissals, the purpose of this analysis was to understand how *Exergen* and *Therasense* affected litigants' attempts to plead inequitable conduct and their ability to prove inequitable conduct based on the evidence in the case. Including Rule 12(b)(6) dismissals would have negatively impacted the results in two principal ways: First, dismissals for failure to state a claim do not bear on the accused infringer's ability to prove inequitable conduct based on the evidence in the case. Second, the resulting data would have included a large number of pleadings based on the pre-*Exergen* legal regime that were dismissed under *Exergen*. This would overstate *Exergen*'s importance, and further, it only reveals that *Exergen* significantly raised the legal requirements for pleading inequitable conduct, which is readily apparent to anyone who reads the opinion.

73. Denials of summary judgment are not decisions on the merits because they do not definitively establish whether inequitable conduct did or did not occur. If summary judgment on inequitable conduct is denied, there is typically a later decision on the merits, absent the case settling or concluding on another dispositive issue.

74. The searches were run and the case list was compiled from April 20 to April 30, 2013.

The cases were divided into three datasets: (1) a “control” pre-*Exergen* group of cases decided between January 1, 2008, and August 3, 2009; (2) a group of cases decided between August 5, 2009, and May 24, 2011, and thus between *Exergen* and *Therasense*; and (3) a group of post-*Therasense* cases decided between May 26, 2011, and April 10, 2013.

Each case was read for three characteristics. First and most importantly, I noted whether inequitable conduct was found. That determination was then reduced into two further categories: (1) whether the patentee successfully refuted inequitable conduct on the intent element; and (2) whether the patentee successfully refuted inequitable conduct on the materiality element. A small handful of cases did not include detailed findings on inequitable conduct, therefore making it impossible to determine whether the patentee prevailed on materiality or intent. For the “materiality” and “intent” statistics, these cases were removed from the dataset. Relatedly, it was quite common for district courts to find that the accused infringer had failed to prove both materiality and intent. Those cases were counted under both materiality and intent. In other words, failing to prove materiality was not mutually exclusive of failing to prove intent, as there were two alternative grounds for the court’s finding of no inequitable conduct.

## 2. Results

Table 1 shows the basic statistics for the three time periods, including the proportions of cases finding inequitable conduct, a lack of materiality, and a lack of intent. Note that cases finding inequitable conduct were not included in the latter two proportions on materiality and intent—Table 1 shows the proportions of cases that found no inequitable conduct due to lack of materiality and intent. For example, 90% of pre-*Exergen* cases finding that the accused infringer failed to prove alleged inequitable conduct were due to the accused infringer’s failure to prove the intent element. Again, the lack of intent is not mutually exclusive with the lack of materiality, so many cases found that the accused infringer failed to prove both intent and materiality.

TABLE 1  
Proving Inequitable Conduct: Basic Statistics

	Pre- <i>Exergen</i>	Post- <i>Exergen</i> Pre- <i>Therasense</i>	Post- <i>Therasense</i>
Total Cases	56	65	64
Number of Cases with Inequitable Conduct Finding			
Yes	13 (23%)	8 (12%)	6 (9%)
No	43 (77%)	57 (88%)	58 (91%)
Reasons for Not Finding Inequitable Conduct*			
Intent	37 (90%)	49 (86%)	46 (87%)
Materiality	21 (51%)	30 (53%)	30 (57%)

\* Percentages exclude cases for which no opinion was available. Some cases failed to find either intent or materiality.

Somewhat surprisingly, the reasons that inequitable conduct defenses were rejected did not change substantially over the three periods. That is, courts found intent lacking in 90% of failed inequitable conduct defenses before *Exergen*, and that figure held at 86% in the next two periods. Similarly, accused infringers failed to prove materiality in 51% of cases before *Exergen*, with that figure increasing slightly after *Therasense*, up to 57%. These small changes were not statistically significant given the small number of cases in the dataset, but it is possible that the increase after *Therasense* correlates with *Therasense*'s higher materiality threshold.

The data also show that courts rejected inequitable conduct defenses for lack of intent much more often than for lack of materiality. This parallels Petherbridge et al.'s finding in their study of the Federal Circuit.<sup>75</sup> One possible reason for district courts to prefer intent over materiality—besides the simple explanation that specific intent to deceive the PTO is very difficult to prove—is that it is easier to decide the intent element than the materiality element.<sup>76</sup> To

75. Lee Petherbridge et al., *The Federal Circuit and Inequitable Conduct: An Empirical Assessment*, 84 S. CAL. L. REV. 1293, 1319-21 (2011) (“[W]hen the Federal Circuit gives a single reason for patentee success, that reason is nearly two and a half times more likely to be lack of intent to deceive than it is to be lack of materiality.”).

76. Of course, intent may depend on witness credibility, which cannot be decided at summary judgment, whereas materiality is a legal determination well suited for summary judgment. But many inequitable conduct claims do not depend on witness credibility. More commonly, a court is presented with evidence that a reference was material and possibly that an applicant knew of a reference, but little more. The accused infringer asks the court to infer intent based on those facts, and courts can often fairly easily find that such evidence is legally insufficient based on their experience in other areas of law. Of course, as noted above, litigants often ask courts to infer intent based on few facts simply because it is so difficult to find further evidence of specific intent to deceive the PTO.

understand whether an omitted reference is material, courts must delve deeply into the technology and prior art to determine cumulateness and other issues. By contrast, direct evidence of specific intent to deceive is difficult to find, so it is relatively simple for a judge to conclude that an accused infringer failed to prove intent. Moreover, judges often have to make similar intent determinations in other areas of law, so they may be more comfortable dealing with intent.

Although the number of inequitable conduct determinations remained relatively level throughout the three time periods, the accused infringer’s win rate decreased substantially after *Exergen*. Before *Exergen*, accused infringers succeeded with their inequitable conduct defenses 23% of the time. Between *Exergen* and *Therasense*, however, accused infringers won only 8 out of 65 cases, or 12%. This change was statistically significant at the 10% level as shown in Table 2 (p-value of 0.0571). The win rate decreased again after *Therasense*, but the change was relatively insubstantial, from 12% to 9%. This decrease, however, could have been due to random variation, as it was not statistically significant. As the drop from the pre-*Exergen* period to the post-*Exergen*, pre-*Therasense* period was significant, the further decline in win rates from before *Exergen* to after *Therasense* was significant at the 5% level (p-value of 0.0191).

In general, significance was difficult to determine because there were relatively few cases decided in each time period. As a result, the model was fairly underpowered. In this context, the finding that inequitable conduct win rates declined with nearly 5% confidence is fairly striking.

TABLE 2  
Success Rate of Inequitable Conduct: Z-Test Results

	Before	After	Z-Score	P-Value
<i>Exergen</i> Effect	23%	12%	1.5795	0.0571*
<i>Therasense</i> Effect	12%	9%	0.5354	0.2962
Combined Effect	23%	9%	2.0718	0.0191**

\* Indicates significance at the 10% level.

\*\* Indicates significance at the 5% level.

Note: A two-proportion z-test was used, with a null hypothesis of  $p_1 = p_2$ . The observations were all independent,  $n_1 p_1 > 5$ ,  $n_1(1 - p_1) > 5$ ,  $n_2 p_2 > 5$ , and  $n_2(1 - p_2) > 5$ , so this test was appropriate.

One possible alternative explanation for the decrease in inequitable conduct determinations around *Exergen* is the *Star Scientific* decision in August 2008. To test this explanation, I broke out the pre-*Exergen* data into cases decided before *Star Scientific* and cases determined after *Star Scientific* (but before *Exergen*). If *Star Scientific* was the driving factor behind the 12% win rate

between *Exergen* and *Therasense*, the win rate should decrease in the wake of *Star Scientific*.

The results of this additional test are displayed in Table 3. The win rate declined from 25% to 22%, a very minimal decrease. As only a handful of cases were decided in this time period, it is impossible to rule out random variation as being responsible for this decrease. More importantly, the post-*Star Scientific* proportion was 22%, still much higher than the 12% accused infringer win rate seen between *Exergen* and *Therasense*.

TABLE 3  
A *Star Scientific* Effect?

	Pre- <i>Star Scientific</i>	Post- <i>Star Scientific</i> Pre- <i>Exergen</i>
Total Cases	24	32
Number of Cases with Inequitable Conduct Finding		
Yes	6 (25%)	7 (22%)
No	18 (75%)	25 (78%)

Given the lack of other significant intervening changes in the law in this time period, it is reasonable to conclude that *Exergen*, despite being directed at the standards for pleading inequitable conduct, had a significant effect on litigants' ability to prove inequitable conduct. Most likely, *Exergen*'s effect was perceptual—the Federal Circuit had already signaled a renewed intent to restrict inequitable conduct in *Star Scientific*, but the major changes to the law in *Exergen* showed district judges that the Federal Circuit was serious about reducing accused infringers' access to the inequitable conduct defense.

Perhaps surprisingly, the data cannot confirm the existence of any *Therasense* effect on proving inequitable conduct. This could indicate that *Therasense* did not affect the use of the inequitable conduct defense by accused infringers. On the other hand, it is possible that it is too early to see *Therasense*'s effect, especially as the Federal Circuit continues to reverse district courts' rulings that patents are unenforceable for inequitable conduct.<sup>77</sup>

Another possibility is that the post-*Therasense* cases are the first set of cases to which *Exergen* applied at the pleading stage. This would indicate that only the more plausible inequitable conduct claims survived Rule 12(b)(6) motions and reached final determinations under *Therasense*. So while accused infringers won 12% of inequitable conduct claims between the decisions of *Exergen* and *Therasense*, these claims may have been relatively weaker on the whole than those that won only 9% of the time after *Therasense*.

77. See *supra* text accompanying note 71.



Fortunately, this theory could be tested empirically. Each of the post-*Exergen* cases was sorted based on whether the final inequitable conduct pleading—the last pleading in which the inequitable conduct allegations were amended—was filed before or after *Exergen*.<sup>78</sup> This sorting therefore captures cases in which the inequitable conduct allegations were amended in response to *Exergen*. The results, displayed below in Table 4, do not show that post-*Exergen* pleadings had significantly higher success rates when proving inequitable conduct. Cases with pre-*Exergen* pleadings succeeded in proving inequitable conduct 10% of the time, and cases with post-*Exergen* pleadings succeeded in proving inequitable conduct 12% of the time. It seems, then, that the explanation that post-*Therasense* cases generally dealt with better-developed inequitable conduct allegations is unsatisfactory. Rather, all accused infringers, no matter when they pleaded inequitable conduct, had a difficult time proving inequitable conduct under *Therasense*. The *Therasense* effect, at least in terms of success rates, may just truly be small—*Star Scientific* and *Exergen* may have effectively limited inequitable conduct to the core conduct the doctrine should deter.

One notable finding from the data in Table 4 is that post-*Exergen* pleadings had greater success if inequitable conduct was decided before *Therasense*. Indeed, inequitable conduct was proved in 11% (6 of 55) of pre-*Exergen*, pre-*Therasense* cases, compared to 20% (2 of 10) of post-*Exergen*, pre-*Therasense* cases. This suggests, as postulated above, that *Exergen* may have enjoyed some success in filtering out unmeritorious inequitable conduct defenses but that *Therasense* then made it so hard to prove inequitable conduct that nearly all inequitable conduct allegations were insufficient to establish inequitable conduct. Unfortunately, despite the comprehensiveness of the data, there were too few cases decided under these circumstances to draw any decisive conclusions. We are therefore left with some, but not conclusive, support for the idea that it was already so difficult to prove inequitable conduct after *Star Scientific* and *Exergen* that a strong *Therasense* effect would have essentially rendered the doctrine extinct.

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78. Another possible way to test this theory would be to only include cases with pleadings that survived a post-*Exergen* motion to dismiss. This dataset would potentially include a few cases in the “post-*Exergen*” category that were classified as “pre-*Exergen*” in the dataset actually compiled because they had filing dates that were pre-*Exergen* but were subjected to a later Rule 12(b)(6) motion. However, this methodology would exclude cases without Rule 12(b)(6) motions, which would likely bias the dataset because pleadings not challenged under Rule 12(b)(6) are more likely to be especially comprehensive. A slightly better version of this methodology would include all post-*Exergen* pleadings and pre-*Exergen* pleadings with a post-*Exergen* Rule 12(b)(6) motion in the “post-*Exergen*” category. But this methodology would suffer from the same problem, as it would exclude pre-*Exergen* pleadings that could have been subjected to a motion to dismiss based on *Exergen* but were not. The methodology actually used is, of course, imperfect as well, but it may be least likely to bias the results in either direction.

TABLE 4  
 Number and Proportion of Cases Finding  
 Inequitable Conduct by Timing of Pleading and Decision

		Pleading	
		Pre- <i>Exergen</i>	Post- <i>Exergen</i>
Decision	Pre- <i>Therasense</i>	6 / 55 (11%)	2 / 10 (20%)
	Post- <i>Therasense</i>	2 / 24 (8%)	4 / 40 (10%)
	Total	8 / 79 (10%)	6 / 50 (12%)

Each cell lists, for the respective time period, the number of cases with a finding of inequitable conduct, the total number of cases, and the proportion of the total cases finding inequitable conduct.

In sum, *Exergen* cut inequitable conduct win rates in half, and *Therasense* had a much smaller effect. These findings should raise the following question: was *Therasense* really necessary? Without examining the facts of every case in the dataset, it is impossible to determine whether seemingly meritorious cases are now losing. And besides, reasonable people can disagree over what a meritorious claim should be. At the very least, though, given that only 12% of inequitable conduct claims have succeeded after *Exergen*, we should ask whether *Therasense* really needed to go as far as it did. These questions will be explored in more detail later in this Comment.

### B. *Pleading Inequitable Conduct*

This Subpart examines the *Exergen* and *Therasense* effects on accused infringers' rates of pleading inequitable conduct.

#### 1. *Methodology*

Due to the large number of patent cases filed, it was impractical to read every pleading in every patent case to determine whether inequitable conduct was pleaded. Instead, Lex Machina was used to provide a reliable estimate. "Inequitable conduct" was searched in Lex Machina's database of patent pleadings.<sup>79</sup> The results were then sorted by case to extract the number of cases in which inequitable conduct was pleaded. To ensure that the search was not

79. Note that the same time periods that were used in Part II.A were used here. Additionally, for clarity, the time periods were applied to the date the pleading was filed, not the date the case was filed, as the case filing date would not always accurately reflect the law applied to the pleading. Finally, the search was conducted on May 3, 2013.

overinclusive, I sampled fifty of the search results in each time period.<sup>80</sup> The accused infringer pleaded inequitable conduct in every case checked in this manner. Assuming that Lex Machina's database is comprehensive, this search should not be underinclusive, as every pleading that seeks to plead inequitable conduct likely contains the term "inequitable conduct." Moreover, although there surely is some imprecision in this methodology, it likely is consistent across the three time periods, so it should be quite reliable for the purpose of deciphering trends over time. Therefore, while the exact numbers of cases that pleaded inequitable conduct are better seen as best estimates, the trends found in this data are less subject to scrutiny.

To measure the proportion of patent cases in which inequitable conduct was pleaded, Lex Machina's database of patent pleadings was searched for no keywords. When sorted for cases, this search returned the number of cases in which a pleading was filed.<sup>81</sup> Although this search necessarily includes cases that settled before an answer was filed and those in which there was an early default judgment, it is likely the most accurate denominator for the proportion of patent cases in which inequitable conduct was pleaded.<sup>82</sup>

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80. Various points in the search results order were sampled to ensure that any errors would be detected. More specifically, I surveyed the first hits and the last ones, along with some in the middle.

81. Lex Machina returns a maximum of 2000 cases when searched in this manner. Therefore, the three time periods were broken into smaller time periods when collecting data to avoid reaching this limit.

82. Previous studies have searched only the answers database to calculate pleading rates for inequitable conduct. *See, e.g.*, Mammen, *supra* note 40, at 1359; Jason Rantanen, *Recalibrating Our Empirical Understanding of Inequitable Conduct*, 3 IP THEORY 98, 101, 104 (2013). This has several disadvantages. First, it excludes declaratory judgment cases that pleaded inequitable conduct in the complaint rather than the answer. Second, it relies heavily on the accuracy of Lex Machina's labeling. While Lex Machina is generally a very reliable database, not all cases have pleadings labeled as "answers," and not all labels are correct. Therefore, to ensure that all pleadings with an inequitable conduct claim are identified, I chose to search the database of all pleadings, rather than restrict it to just answers. As a result, my methodology accurately calculates the percentage of all patent cases filed that involve an inequitable conduct claim, whereas the two studies above calculate—with some error—the percentage of answers in patent cases in which an inequitable conduct claim was pleaded. The raw numbers suggest that this error is not insubstantial, as the U.S. Courts Facts and Figures database reports that, in 2012 for example, there were 5163 patent cases filed, whereas Rantanen's methodology identifies only 3277 cases with an answer. *See* ADMIN. OFFICE OF THE U.S. COURTS, JUDICIAL FACTS AND FIGURES tbl.4.7 (2012), available at <http://www.uscourts.gov/Statistics/JudicialFactsAndFigures/judicial-facts-figures-2012.aspx>. Although it is possible that some 1900 cases in 2012 ended in settlement or default before an answer was filed, it is more likely that Mammen and Rantanen's chosen methodology skews upward the percentage of cases in which inequitable conduct was pleaded. Moreover, the denominator in my statistic includes default judgments and cases that settled before an answer was filed, so the resulting percentage of cases with inequitable conduct claims is necessarily smaller than that found in the other two studies. This key difference should be kept in mind when reading this Comment in the context of the Mammen and Rantanen articles.

## 2. Results

Table 5 presents the basic statistics on the frequency with which accused infringers plead inequitable conduct. The number of cases in which inequitable conduct was pleaded remained nearly constant over the three periods. However, the proportion of cases in which inequitable conduct was pleaded fell substantially over the same periods, thanks to a sharp increase in the number of patent cases filed. Although there was only a modest increase in the number of cases filed from the pre-*Exergen* period to the period between *Exergen* and *Therasense*, the post-*Therasense* period saw many more patent cases filed, most likely due to the Leahy-Smith America Invents Act's new joinder rules.<sup>83</sup>

TABLE 5  
Pleading Inequitable Conduct: Basic Statistics

	Pre- <i>Exergen</i>	Post- <i>Exergen</i> Pre- <i>Therasense</i>	Post- <i>Therasense</i>
Cases Pleading Inequitable Conduct	1,349	1,346	1,329
Total Patent Cases Filed	7,978	9,570	17,561
Proportion Pleaded	17%	15%	8%

As Table 6 demonstrates, the reductions in inequitable conduct pleading rates after *Exergen* and *Therasense* were both highly significant. Beyond revealing that *Exergen* and *Therasense* had profound effects on inequitable conduct pleading rates, the p-values predominantly indicate that the test was overpowered due to the large number of data points. Here, the magnitude of the reductions themselves is most instructive. In the wake of *Exergen*, inequitable conduct was pleaded in 3% fewer cases, decreasing from 17% to 14%. A greater reduction occurred after *Therasense*, with the percentage declining from 14% to only 8%.

83. The rules prevent patentees from joining large numbers of defendants together in one case, which has resulted in some patentees filing many lawsuits, each against fewer defendants. See Tracie L. Bryant, *The America Invents Act: Slaying Trolls, Limiting Joinder*, 25 HARV. J.L. & TECH. 673, 689-90 (2012); Dennis Crouch, *Patent Infringement Litigation: Filings on the Rise*, PATENTLY-O (Mar. 13, 2012, 3:12 PM), <http://www.patentlyo.com/patent/2012/03/patent-infringement-litigation-complaints-on-the-rise.html>.

TABLE 6  
Pleading Inequitable Conduct: Z-Test Results

	Z-Score	P-Value
<i>Exergen</i> Effect	5.2035	0.0000***
<i>Therasense</i> Effect	17.1520	0.0000***

\*\*\*Indicates significance at the 1% level.

A two-proportion z-test was used, with a null hypothesis of  $p_1 = p_2$ . The observations were all independent,  $n_1 p_1 > 5$ ,  $n_1(1 - p_1) > 5$ ,  $n_2 p_2 > 5$ , and  $n_2(1 - p_2) > 5$ , so this test was appropriate.

At least one other author, Christian Mammen, has attempted to estimate the proportion of cases in which inequitable conduct was pleaded. The Federal Circuit cited the Mammen study in *Therasense* for the proposition that the inequitable conduct defense was overused, so the reliability of this research is especially crucial.<sup>84</sup> Mammen estimated that inequitable conduct was pleaded as a defense in approximately 30% of cases from 2002 to 2008.<sup>85</sup> His data also exhibited a strong upward trend, with the proportion increasing from only 4% of cases in 2002 to 40% of cases in 2008. Although Mammen reports counts using both the Westlaw database and the Stanford IP Litigation Clearinghouse (the predecessor to Lex Machina), he appears to rely on the Westlaw numbers—which were lower—for his 30% estimate.

This study found a lower rate of pleading inequitable conduct, 17%, over a period that overlaps somewhat with Mammen's data. (Inequitable conduct was pleaded in 40% of cases in 2008, according to Mammen). Repeating Mammen's methodology today—only four years later—returns different results than he reported, and today's results are consistent with the data reported in this Comment. Mammen indicates that he accessed the Stanford IP Litigation Clearinghouse, the predecessor to Lex Machina, in 2009 and searched answers in patent cases for “inequitable conduct.”<sup>86</sup> Repeating this search for 2008 on Lex Machina on May 8, 2013, returned 864 cases, nearly half the 1631 cases Mammen reports in his article.<sup>87</sup> The search returns 1928 different answers, which is closer to the statistic he provides but still is not identical.

Some follow-up research indicates that there are two reasons for the discrepancy between Mammen's data and that reported here. First, the number of cases Mammen reports is actually the number of answers with the term “inequi-

84. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc).

85. Mammen, *supra* note 40, at 1359 (“[Inequitable conduct] has been pled in about 3 of 10 cases during that same period, with a strong upward trend in the pleading frequency.”).

86. *Id.* at 1349 n.85.

87. *Id.* at 1351.

table conduct.” At the time Mammen conducted his research, Lex Machina did not provide a “sort results by case” option, meaning that Mammen’s search returned the number of answers pleading inequitable conduct without regard to later amended pleadings in the same case. The error introduced by Mammen’s inability to sort by case is significant: the raw search today returns 1928 answers, whereas the results sorted by case include only 864 cases to which those 1928 answers belong. Second, the Lex Machina database appears to still be growing. Four years later, the same Lex Machina search returned 1928 answers, 297 more than the 1631 answers found by Mammen.<sup>88</sup> This fact means that Mammen’s estimate is biased downward, although of course that bias has been outweighed by the first error.

Recently, Jason Rantanen identified several methodological problems in Mammen’s research design.<sup>89</sup> Acknowledging that Mammen’s study represents a groundbreaking contribution to the literature on the inequitable conduct doctrine—a sentiment shared here—Rantanen noted that “the size of Westlaw’s database has a direct, positive correlation with the year.”<sup>90</sup> This would explain the dramatic rise in inequitable conduct pleadings—it merely reflects the greater number of documents in Westlaw’s database. Rantanen also recognized that Mammen compares the number of pleadings mentioning inequitable conduct to the number of cases filed. Because many pleadings in a single case typically reiterate a single claim (amended counterclaims, answers to counterclaims, etc.), Mammen’s final statistic for pleadings mentioning inequitable conduct could easily overstate the number of individual cases involving an inequitable conduct claim.<sup>91</sup>

One further methodological flaw in Mammen’s study is the failure to account for declaratory judgment cases. Searching only answers ignores declaratory judgment cases that allege inequitable conduct in the complaint. This study broadens the search to include “any pleadings,” which accounts for all cases involving inequitable conduct claims. This improved search returns only 948 cases, still significantly fewer than Mammen reports.

Regardless, this Comment confidently reports counts of cases in which the accused infringer pleaded inequitable conduct. As discussed above, there are reasons to believe that the total number of patent cases identified by this Comment is slightly overstated, meaning that the true rate of pleading inequitable conduct is somewhat higher than the 17%, 14%, and 8% reported for the three time periods here. However, the true pleading rates are surely much closer to these numbers than to the 30%, or even 40%, estimated by Mammen.

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88. More evidence that the database is still growing is that Jason Rantanen’s repetition of the same search only three months earlier than the search in this Comment returned 863 cases, one fewer than found here.

89. Rantanen, *supra* note 82, at 104-05.

90. *Id.* at 104.

91. *Id.* at 104-05.

Returning to the decreased rate of inequitable conduct pleading post-*Therasense*, two principal explanations emerge. One is that *Therasense* had a signaling effect. The *Therasense* majority clearly manifested its intent to restrict the availability of the inequitable conduct defense. This may have signaled to attorneys that the Federal Circuit would strictly enforce *Exergen* as well. Patent lawyers may also have given up pleading inequitable conduct because *Therasense* made it so difficult to prove. Absent some relatively incriminating facts, inequitable conduct post-*Therasense* was simply not worth pleading any more.

Another explanation is that the drop in inequitable conduct pleading post-*Therasense* is actually a lagging *Exergen* effect. While judges must stay on top of new legal developments or risk appellate reversal, attorneys' habits may take longer to break. If pleading inequitable conduct was a matter of habit, as the *Therasense* majority suggests,<sup>92</sup> it may have taken some time for lawyers to react to the changed pleading standard. The smaller decrease in pleading rates seen in the year and a half immediately following *Exergen* could represent those attorneys who were most up to date, with the others falling in line with *Exergen* shortly thereafter during a time period that happened to coincide with *Therasense*.

### C. Summary of Findings

Based on the empirical analysis above, the *Exergen* effect is twofold. First, before *Exergen*, accused infringers successfully proved inequitable conduct at a rate of 23%. After *Exergen*, that percentage dropped to only 12%. This decline was statistically significant, and it was not a *Star Scientific* effect in disguise. Second, the rate at which accused infringers pleaded inequitable conduct dropped from 17% before *Exergen* to 14% after. This decrease was also statistically significant, although it was not nearly as large as the decline attributed to *Therasense*.

The *Therasense* effect also has two components. First, the decline in success rates continued through *Therasense*, dropping from 12% to 9%. Although this decrease was not statistically significant, the overall change from 23% before *Exergen* to 9% after *Therasense* was significant at the 5% level. Second, the pleading percentage declined substantially as a result of *Therasense*, from 14% to only 8%. This movement was statistically significant.

Of the cases in which the accused infringer failed to prove inequitable conduct, the infringer fell short on proving intent between 85% and 90% of the time, whereas it only failed to prove materiality between 51% and 57% of the time. One possible explanation for this finding is that judges who are generally unfamiliar with patent law may be more comfortable deciding intent because a

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92. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc).

materiality determination often requires deep engagement with the technology and prior art. Another possible explanation is that the intent standard is simply very high and difficult to meet given that there is typically little to no direct evidence that the patentee intended to defraud the PTO.

Looking back at the pleading and success rates above, the *Exergen* and *Therasense* effects were somewhat reversed from what was expected. The rate at which accused infringers succeeded with inequitable conduct defenses dropped most significantly after *Exergen*, the case on pleading standards, and the rate at which accused infringers pleaded inequitable conduct declined most after *Therasense*, the case on proof standards. I suggest that *Exergen* served as a strong signal to district courts from the Federal Circuit that it was cracking down on the supposed “plague” of inequitable conduct, triggering the decline in proof rates. After *Exergen*, success rates were already so low that they could not drop much further without the defense becoming extinct, so *Therasense* was probably not necessary to restrict access to the inequitable conduct defense in practice, even though it tightened the legal standards for proving inequitable conduct and provided district courts with lots of rhetoric useful for rejecting inequitable conduct claims.

As for pleading inequitable conduct, the data show that rates decreased more substantially after *Therasense* than *Exergen*, as expected. I offer three explanations that are not mutually exclusive. First, the supposed *Therasense* effect could be a lagging *Exergen* effect, as practitioners are likely slower than district courts to react to changes in the law, especially given that pleading inequitable conduct was previously habitual practice. Second, *Therasense* could have underscored to patent litigators that the Federal Circuit meant what it said in *Exergen*. And third, the *Therasense* decision could have restricted access to inequitable conduct so much that patent litigators gave up on inequitable conduct as a possible defense. Support for this theory comes from the fact that so many in the patent bar considered inequitable conduct a “dead doctrine” after *Therasense*.<sup>93</sup>

Regardless, the data indicate that the *Therasense* decision may not have been entirely necessary to rein in the inequitable conduct doctrine, as *Exergen* had already substantially achieved that goal. As the next Part will demonstrate, *Therasense*’s legal changes separated the inequitable conduct doctrine from its policy anchors, risking the doctrine’s ability to deter fraudulent representations in patent prosecution. Instead, the Federal Circuit perhaps should have used similar rhetoric in *Therasense* but not made the same sweeping doctrinal changes. By preserving the perceptual shift against inequitable conduct’s overuse in litigation but refusing to go as far in changing the law, the data suggest that the Federal Circuit would likely have achieved its desired reduction in the purely strategic use of inequitable conduct without making the defense entirely inaccessible.

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93. See *supra* note 9 and accompanying text.



### III. REFORMULATING INEQUITABLE CONDUCT DOCTRINE AMID COMPETING POLICY CONCERNS

#### A. *The Policy Behind Exergen and Therasense*

Having seen that *Exergen*—and arguably *Therasense*—reduced the prevalence of the inequitable conduct defense in patent litigation, what were the concerns motivating those decisions? Thankfully, *Therasense* makes its policy rationales clear. Although inequitable conduct is intended to “foster full disclosure to the PTO,” “focus[ing] on encouraging disclosure has had numerous unforeseen and unintended consequences.”<sup>94</sup> These “numerous unforeseen and unintended consequences” can be sorted into two categories: litigation effects and PTO effects.

The Federal Circuit named five different reasons why lax inequitable conduct standards contribute to the doctrine being harmful to litigation. First, inequitable conduct “expands discovery into corporate practices before patent filing and disqualifies the prosecuting attorney from the patentee’s litigation team.”<sup>95</sup> This expanded discovery not only raises the cost of litigation, but also allows the accused infringer to put great additional burdens on the patentee. Second, inequitable conduct paints the patentee as a bad actor.<sup>96</sup> Accused infringers are likely to use this story to gain leverage in front of a jury. Third, because it paints the patentee as a bad actor, it discourages settlement because patentees must defend their behavior as ethical, and any settlement may look like a confession.<sup>97</sup> Fourth, it increases the cost and complexity of patent litigation, which is often already unwieldy.<sup>98</sup>

Finally, according to Chief Judge Rader, “the remedy for inequitable conduct is the ‘atomic bomb’ of patent law.”<sup>99</sup> A finding of inequitable conduct presents a laundry list of problems for the patentee. Most notably, the accused infringer automatically wins because the whole patent is rendered unenforceable.<sup>100</sup> Inequitable conduct committed in prosecuting one patent can also pollute other patents in the same family.<sup>101</sup> Moreover, inequitable conduct may even subject the patentee to antitrust claims.<sup>102</sup> Attorneys’ fees are available to

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94. *Therasense*, 649 F.3d at 1288.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.* (quoting *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting)).

100. *Id.*

101. *Id.* at 1288-89.

102. *Id.* at 1289; see also *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177-78 (1965) (antitrust action); *Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470, 1471 (Fed. Cir. 1998) (unfair competition claim).

the accused infringer, and privileged communications may be opened to discovery under the crime-fraud exception to attorney-client privilege.<sup>103</sup>

The Federal Circuit also explained why a broader inequitable conduct doctrine negatively impacts the PTO. Because patent prosecutors are worried that inequitable conduct may later render one of their patents unenforceable, they often cite overwhelming amounts of prior art in patent applications, burying PTO examiners in references.<sup>104</sup> As patent examiners sort through all the information, unnecessary disclosure increases the PTO prosecution backlog. And, because “[t]his tidal wave of disclosure makes identifying the most relevant prior art more difficult,” overdisclosure is unquestionably bad for patent quality.<sup>105</sup>

### B. *Questioning the Federal Circuit’s Rationale for Therasense*

Reading a list like the one above from the Federal Circuit makes it seem like inequitable conduct should be struck from patent law altogether. But inequitable conduct serves the important function of enforcing the duty of candor before the PTO.<sup>106</sup> And all of the negative effects on litigation strategy the Federal Circuit lists are not negative in the abstract—they are only detrimental if inequitable conduct is in fact asserted too often.

The data presented in this Comment indicate that inequitable conduct is used significantly less than the Federal Circuit suggests and that it has become even more rare in the wake of *Exergen* and *Therasense*. The Federal Circuit cited an extraordinary estimate that inequitable conduct was pleaded in 80% of patent cases,<sup>107</sup> when in fact the actual rate was likely closer to 17% before *Exergen* and 14% before *Therasense*. Success in proving inequitable conduct was halved to only 12% after *Exergen*, and that success rate now is under 10%.<sup>108</sup> Alarming, the American Intellectual Property Law Association (AIPLA) position paper underlying that 80% figure cited by the Federal Circuit in *Therasense* does not disclose its methodology, so it cannot be duplicated, critiqued, or revised by others. As the Federal Circuit heavily relied upon the

103. *Therasense*, 649 F.3d at 1289.

104. *Id.*

105. *Id.* at 1289-90.

106. *Id.* at 1288; see also ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 1103 (4th ed. 2007).

107. *Therasense*, 649 F.3d at 1289 (citing Ad Hoc Comm. on Rule 56 & Inequitable Conduct of the Am. Intellectual Prop. Law Ass’n, *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1988)).

108. One possible argument is that low success rates in proving inequitable conduct are strong evidence that the defense is pleaded too often. However, with the changes in the law that made it more difficult to prove inequitable conduct occurring in this time period, it is no surprise that success rates are low. With inequitable conduct now being pleaded in only 8% of patent cases, it appears that litigants are adjusting.

AIPLA position paper and the Mammen study—which have both been strongly called into question and replaced by updated statistics here and elsewhere<sup>109</sup>—as empirical support for its legal changes in *Therasense*, perhaps *Therasense* should be revisited.

The data also lead me to question whether *Therasense* was truly necessary. The Federal Circuit has reversed district courts' findings of inequitable conduct much more often than it has upheld them for quite some time.<sup>110</sup> With the Federal Circuit wavering for decades on the elements necessary to prove inequitable conduct, the *Exergen* decision may have been all the Federal Circuit needed to tell district courts to crack down on inequitable conduct once and for all. Even though *Exergen* did nothing to address the standard to prove inequitable conduct, accused infringer success rates declined substantially post-*Exergen*.

Further, *Therasense* strays too far from inequitable conduct's purpose in an attempt to quash the unintended consequences stemming from inequitable conduct's overuse. Requiring true but-for materiality to find inequitable conduct prevents patent examiners from doing their jobs: considering the most relevant prior art, even if it is not invalidating, in making a patentability decision. Using the Rule 56 standard, which was advocated by the dissent in *Therasense*, may be more appropriate. As discussed earlier, Rule 56 requires disclosure only when it can be the basis for a prima facie case of unpatentability. This is a high bar that is close to *Therasense*'s but-for materiality standard. The *Therasense* majority worried that Rule 56 is rather permissive because it allows a reference to be material based on any combination of it and other references.<sup>111</sup> But if warned about this by the Federal Circuit, courts can easily check arguments that stretch the imagination.

One may reasonably object that, should *Therasense* have changed anything, the materiality requirement should have been heightened, as the data in this paper demonstrate that courts have relied more often on intent than materiality to reject inequitable conduct allegations. However, as mentioned above, this is likely because it is much easier for a district judge to find intent lacking, not because materiality is unenforced. And besides, several references may truly be material to an application's patentability. The materiality standard exists principally to describe the realm of prior art that is essential to a patent examiner. The specific intent to deceive is really what inequitable conduct doctrine is designed to deter. Seen this way, with materiality defining the prior art that should be in front of an examiner and intent defining the exact type of conduct inequitable conduct should deter, it is logical to have a materiality standard that matches the PTO's own standard, coupled with a more rigorous intent requirement.

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109. Rantanen, *supra* note 82, at 101-09 (criticizing the Mammen study and replicating his work with a few methodological changes).

110. Mammen, *supra* note 40, at 1354.

111. *Therasense*, 649 F.3d at 1294-95.

Another important consideration, stressed by the majority in *Therasense* itself, is the need to prevent applicants from citing overwhelming numbers of references in their patent applications. Despite *Therasense*'s self-stated goal of limiting overdisclosure to the PTO, the statistics establish that the rise in citations has only continued in *Therasense*'s wake.<sup>112</sup> And, with research showing that examiners very rarely rely on prior art cited by applicants anyway,<sup>113</sup> there may be little harm in more overdisclosure.<sup>114</sup>

Further, the continued rise of prior art disclosure after *Therasense* demonstrates that it is not perfectly coupled with the inequitable conduct doctrine. Rather than perverting the inequitable conduct doctrine to reduce overdisclosure before the PTO, we might be better off if the PTO tackles overdisclosure. For example, the PTO could require applicants to describe the reason for including each piece of prior art in the application. Such a rule would significantly raise the costs to applicants of overdisclosing, and true compliance would provide examiners with vital information about which references are most important.

In sum, refocusing the inequitable conduct doctrine entails balancing several competing concerns. We must consider the doctrine's purpose of enforcing the duty of candor before the PTO. Recent empirical evidence suggests that the inequitable conduct doctrine has the potential to instill these valuable incentives in the patent system.<sup>115</sup> Some theories go further, however, holding that inequitable conduct doctrine should encourage the economically efficient level of dis-

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112. See Dennis Crouch, *Citing Patent References*, PATENTLY-O (Jan. 10, 2013, 7:24 AM), <http://www.patentlyo.com/patent/2013/01/citingreferences.html> (“[T]he percentage of patents citing more than 100 references has risen from 3% in 2005 to more than 8% today.”); Dennis Crouch & Jason Rantanen, *Citing References at the PTO*, PATENTLY-O (Oct. 23, 2012, 8:05 AM), <http://www.patentlyo.com/patent/2012/10/citing-references-at-the-pto.html> (showing that the average number of applicant-cited references per patent has risen from about seventeen in 2005 to thirty-six in 2012).

113. See Christopher A. Cotropia et al., *Do Applicant Patent Citations Matter?*, 42 RES. POL'Y 844, 847 (2013) (“[O]f the references examiners use to reject claims, only 12.7% come from the applicants, while 87.2% come from examiners.”); *id.* at 851 (“We find that examiners do not typically rely on an important source of art—that from patent applicants themselves—for their rejections. The explanation does not lie in the industry or the nature of the application. Nor can the tendency of applicants to tailor their claims to fit the art they know about explain the results.”).

114. It may at first seem that this criticism of *Therasense* also applies to *Exergen*. But *Exergen* is only minimally directed to the overdisclosure problem. Rather, *Exergen* attempts to better filter out unmeritorious inequitable conduct claims at the pleading stage. *Exergen* theoretically reduces overdisclosure only as a secondary consequence of decreasing patent prosecutors' fears of inequitable conduct. Because overdisclosure was not an explicit consideration in formulating *Exergen*'s doctrinal changes, inequitable conduct's pleading requirements were not unnecessarily perverted by overdisclosure concerns.

115. See Lee Petherbridge et al., *Unenforceability*, 70 WASH. & LEE L. REV. 1751, 1777-78 (2013) (suggesting that the doctrine of inequitable conduct discourages risky prosecution behavior, such as fewer citations to prior art and longer pendencies).

closure before the PTO.<sup>116</sup> But such theories do not account for the other side of the coin—the significant negative consequences of inequitable conduct as a litigation strategy. The costs of miscalibrating the doctrine are asymmetrical, with high costs to having too broad of a doctrine. While enforcing fraudulently procured patents has high costs as well, those isolated incidents are outweighed by the systemic costs of countless unmeritorious inequitable conduct claims, even if the “plague” is not as serious as the Federal Circuit has suggested.

Nevertheless, *Therasense*'s formulation of inequitable conduct surely underdeters. The specific intent to deceive is difficult to prove, and the later but-for materiality determination means there is little cost to withholding a key reference—claims must essentially be invalidated later in litigation for inequitable conduct to apply.<sup>117</sup>

### C. A Middle Path

What is needed is a middle path. The Federal Circuit should reform the materiality standard so that it matches Rule 56. Rule 56 describes the disclosures that the PTO itself considers essential. Given that inequitable conduct doctrine should encourage patent applicants to be forthcoming with the PTO, the scope of omissions and misrepresentations that falls within the inequitable conduct doctrine should be equivalent to the scope deemed material by the PTO.

However, because inequitable conduct is a serious charge prone to overuse, courts should strictly enforce *Therasense*'s intent requirement and *Exergen*'s pleading standards. As the empirics from this Comment demonstrate, this would likely keep litigants from pleading inequitable conduct as a matter of course. Aggressive attention to *Exergen* will remove many unmeritorious claims at the outset of litigation. But after *Exergen*, discovery is typically necessary to sufficiently plead inequitable conduct. Therefore, to ensure that strict adherence to *Exergen* does not also result in the dismissal of meritorious claims, courts must permissively grant leave to amend pleadings to add inequi-

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116. See Thomas F. Cotter, *An Economic Analysis of Patent Law's Inequitable Conduct Doctrine*, 53 ARIZ. L. REV. 735, 735 (2011).

117. Technically, a reference could be but-for material for inequitable conduct purposes but still not invalidating due to differences in the burden of proof. To prove inequitable conduct, the accused infringer must establish that a reference is but-for material by a preponderance of the evidence, but to invalidate a claim, the reference must be but-for material by clear and convincing evidence. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc). The principal cost to withholding a key reference in prosecution is the difference in remedy between invalidity and inequitable conduct. Winning an invalidity defense only invalidates a particular claim, whereas inequitable conduct renders the whole patent unenforceable. Perhaps, then, *Therasense* still deters patent prosecutors from withholding references that invalidate more auxiliary claims—patent prosecutors would prefer to forego those claims and not risk rendering the core claims unenforceable. But this means that *Therasense* fails to deter patent prosecutors from withholding key references that read onto the basic technology claimed in the patent application—the chief conduct that must be discouraged.

table conduct defenses. In fact, it is probably ideal for inequitable conduct defenses to be deferred until later in the litigation, as the basis for a meritorious inequitable conduct defense will usually not surface until after some discovery has been taken.<sup>118</sup> This combination of strict Rule 12(b)(6) enforcement and permissive amending rules would thus prevent accused infringers from gaining access to privileged discovery by merely pleading inequitable conduct, but it also would allow accused infringers to bring the defense into the litigation if they find evidence of inequitable conduct during discovery.

#### CONCLUSION

This Comment finds that *Exergen* and *Therasense* have had a substantial impact upon patent litigation. The prevalence of inequitable conduct claims has decreased from 17% to 8% of patent cases. Most of this drop occurred after *Therasense*, but it is likely that the decline is due to a combination of heightened pleading and proof standards. The data also establish a decrease in accused infringers' success in proving inequitable conduct when an ultimate determination is made. Before *Exergen*, accused infringers rendered a patent unenforceable in 23% of inequitable conduct decisions. After *Therasense*, the success rate was only 9%. Moreover, most of this drop (down to 12%) occurred before the *Therasense* decision. *Star Scientific* has been ruled out as an alternate cause, so it seems that *Exergen* discouraged district courts from holding patents unenforceable for inequitable conduct.

The data indicate that *Therasense* may have gone too far to quash inequitable conduct's overuse in patent litigation. Because the inequitable conduct doctrine is needed to enforce the duty of candor before the PTO, its materiality standard should be identical to Rule 56. By strictly enforcing pleading and intent requirements, the inequitable conduct doctrine should both deter undesirable behavior by patent applicants and be used properly by patent litigants.

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118. Of course, courts can and should be free to deny leave to amend if they feel that litigants are using permissive leave to amend as a judicial license to sandbag their best arguments, presenting them at the last possible minute.