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# Patent Law's Falstaff: Inequitable Conduct, the Federal Circuit, and *Therasense*

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PATENT LAW'S FALSTAFF: INEQUITABLE CONDUCT, THE  
FEDERAL CIRCUIT, AND *THERASENSE*

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ABSTRACT

*For decades, the relationship between the U.S. Court of Appeals for the Federal Circuit and patent law's doctrine of inequitable conduct has resembled that between Shakespeare's Prince Hal and John Falstaff. The former recognizes the excess, the deservedly ill repute, even the at least occasional wickedness of the latter, but cannot tear away from his close companion. Likewise, for decades, Federal Circuit judges have criticized the excesses of the defense of inequitable conduct, which can render a patent unenforceable as a result of misrepresentation or nondisclosure to the U.S. Patent and Trademark Office. Nevertheless, U.S. patent law remains wedded to the defense's existence. Without a real option of repudiating the defense, the Federal Circuit has instead sought to guide and confine the defense's application in hopes of advancing legitimate aims at acceptable social cost. In this effort, the opinion for the en banc Federal Circuit written by Chief Judge Randall Rader in *Therasense, Inc. v. Becton, Dickinson & Co.* figures prominently. The background, content, and prospects for the Federal Circuit's legal rulings in *Therasense* are the focus of this Article.*

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INTRODUCTION

Why dost thou converse with that trunk of humours,  
that bolting hutch of beastliness, that swollen parcel  
of dropsies, that huge bombard of sack, that stuffed  
cloak-bag of guts, . . . that grey Iniquity . . . ?

—Prince Hal in *Henry IV, Part 1*<sup>1</sup>

For decades, the relationship between the U.S. Court of Appeals for the Federal Circuit and patent law’s doctrine of inequitable conduct has resembled that between Shakespeare’s Prince Hal and John Falstaff. The former recognizes the excess, the deservedly ill repute, even the at least occasional wickedness of the latter, but cannot tear away from his close companion. Likewise, for decades, Federal Circuit judges have criticized the excesses of the defense of inequitable conduct,<sup>2</sup> a defense that can render a patent unenforceable when, in applying for the patent, the prospective patentee made a material misrepresentation or nondisclosure to the U.S. Patent and Trademark Office with specific intent to deceive.<sup>3</sup> In language resonant of Hal’s fusillade

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<sup>1</sup> WILLIAM SHAKESPEARE, 1 HENRY IV 2.5, ll. 409-414, in NORTON SHAKESPEARE 1187 (S. Greenblatt et al. eds., 1997).

<sup>2</sup> See David McGowan, *Inequitable Conduct*, 43 LOY. L.A. L. REV. 945, 946 & n.6 (2010) (“The Federal Circuit’s recent opinions cast the doctrine [of inequitable conduct] as a noxious weed”).

<sup>3</sup> See *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense)*, 649 F.3d 1276, 1285, 1288 (Fed. Cir. 2011) (en banc) (“Inequitable conduct is an

of insults to Falstaff, Federal Circuit judges have variously characterized the inequitable conduct defense or its attendants as “an absolute plague,”<sup>4</sup> “the ‘atomic bomb’ of patent law,”<sup>5</sup> and a potential cause of inequity itself.<sup>6</sup> Nevertheless, U.S. patent law remains wedded to the defense’s existence despite other countries’ demonstrated capacity to do without it.<sup>7</sup>

What can the Federal Circuit do about this unhappy marriage? King Henry V (formerly Prince Hal) ultimately repudiated Falstaff.<sup>8</sup> But absent some sort of miraculous enhancement of the Federal Circuit’s authority, that court is essentially powerless to repudiate the defense of inequitable conduct. At least some version of the defense is enshrined in Supreme Court precedent.<sup>9</sup>

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equitable defense to patent infringement that, if proved, bars enforcement of a patent.”); JANICE MUELLER, *PATENT LAW* 348, 431 (3d ed. 2009) (“The defense of inequitable conduct asserts that a court should refuse to enforce a patent if it was procured through improper conduct before the USPTO.”); *cf.* *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995) (“[C]lear and convincing evidence must prove that an applicant had the specific intent to . . . mislea[d] or deceiv[e] the PTO.”).

<sup>4</sup> *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“[T]he habit of charging inequitable conduct . . . has become an absolute plague.”); *cf.* *Therasense*, 649 F.3d at 1293 (speaking of “the way inequitable conduct has metastasized”).

<sup>5</sup> *Therasense*, 649 F.3d at 1288 (“[T]he remedy for inequitable conduct is the ‘atomic bomb’ of patent law.”) (quoting *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting)).

<sup>6</sup> *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007) (Newman, J., dissenting) (“To avoid the inequity resulting from litigation-driven distortion of the complex procedures of patent prosecution, precedent firmly requires that the intent element of inequitable conduct must be established by clear and convincing evidence of deceptive intent . . .”).

<sup>7</sup> MARTIN J. ADELMAN, RANDALL R. RADER & JOHN R. THOMAS, *CASES AND MATERIALS ON PATENT LAW* 586 (3d ed. 2009) (observing that a charge of inequitable conduct “is generally unavailable as an infringement defense” in other countries).

<sup>8</sup> WILLIAM SHAKESPEARE, 2 *HENRY IV* 5.5, ll. 61-62, *in* NORTON SHAKESPEARE, *supra* note 1, at 1374 (“I banish thee, on pain of death, [a]s I have done the rest of my misleaders. . .”).

<sup>9</sup> *See* *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 819 (1945) (concluding that “inequitable conduct impregnated Automotive’s entire cause of action and justified dismissal”); *see also* *Therasense*, 649 F.3d at 1285 (“This judge-made doctrine evolved from a trio of

Arguably, the defense is implicit in statutory law.<sup>10</sup>

Without a real option of repudiation, the Federal Circuit has instead sought to guide and confine the defense's application in hopes of advancing legitimate aims at acceptable social cost. In this effort, the opinion for the en banc Federal Circuit written by Chief Judge Randall Rader in *Therasense, Inc. v. Becton, Dickinson & Co.*<sup>11</sup> figures prominently. The background, content, and prospects for the Federal Circuit's legal rulings in *Therasense* are the focus of this Article.

## I. BACKGROUND TO *THERASENSE*

### A. *Reasons for a Limited Inequitable Conduct Defense*

It is not hard to understand why the defense of inequitable conduct has been characterized as “the ‘atomic bomb’ of patent law.”<sup>12</sup> Nor is it hard to understand why it is a difficult defense for

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Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct.”); 6 DONALD S. CHISUM, CHISUM ON PATENTS § 19.03[1] (2011) (discussing cases in which the U.S. Supreme Court “held that fraud and inequitable conduct was a defense under the general equitable doctrine of clean hands.”).

<sup>10</sup> See generally 35 U.S.C. § 282 (2000) (mandating the availability of a defense of unenforceability “in any action involving the validity or infringement of a patent”). While reforming the U.S. Patent Act in 2011, Congress declined to abrogate the doctrine and instead limited the range of situations in which it may apply. See Leahy-Smith America Invents Act, H.R. 1249, 112th Cong. § 12(a) (2011) (to be codified at 35 U.S.C. § 257) (enabling a patent owner to “request supplemental examination . . . to consider, reconsider, or correct information believed to be relevant to [a] patent” and thereby to inoculate a prior disclosure failure against a later charge of inequitable conduct); *id.* at § 15(a) (to be codified at 35 U.S.C. § 282(3)) (providing that “failure to disclose the best mode [of practicing a claimed invention] shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable”); *cf.* *Bilski v. Kappos*, 130 S. Ct. 3218, 3228 (2010) (observing that the existence of a statutory provision providing a special defense to infringement of a business method patent “further undermine[s]” an “argument that business methods are categorically outside of . . . [the U.S. Patent Act’s] scope”).

<sup>11</sup> 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

<sup>12</sup> *Id.* at 1288 (quoting *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir.2008) (Rader, J., dissenting)).

an accused infringer to resist asserting. Even when unsuccessful, an assertion of inequitable conduct can inflict substantial discovery and other litigation costs on a patentee, thereby raising the cost of seeking to enforce patent rights.<sup>13</sup> The assertion can also help shift the moral undercurrents often implicit in litigation posturing and argument, with the accused infringer no longer being solely in the position of denying wrongdoing but also in position to accuse the patentee of being a wrongdoer.<sup>14</sup> Moreover, when successful, the inequitable conduct defense enables an accused infringer to render an entire patent—perhaps even an entire set of related patents—permanently and entirely unenforceable.<sup>15</sup> The accused infringer

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<sup>13</sup> See Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 740 (2009) (observing that “litigation of inequitable conduct claims is particularly costly,” in part because “deposition of the prosecuting attorney who handled the application is almost always necessary,” and such a deposition implicates “complex attorney-client privilege issues”); see also Randall R. Rader, *A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Foreward: Always at the Margin: Inequitable Conduct in Flux*, 59 AM. U. L. REV. 777, 783 (2010) (“An allegation of inequitable conduct open[s] the door to vast discovery into the circumstances of the patent prosecution . . .”).

<sup>14</sup> See Christian Mammen, *Revisiting the Doctrine of Inequitable Conduct Before the Patent and Trademark Office*, 21 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1007, 1009 (2011) (“Inequitable conduct is also a popular defense because of the litigation narrative it provides.”); cf. David O. Taylor, *Patent Fraud*, 83 TEMPLE L. REV. 49, 65 (2010) (stating that “[a]llegations of inequitable conduct also may affect juries’ and courts’ views of the merits of other issues in patent infringement lawsuits, primarily infringement and validity” and allegations “have a negative impact on the reputations of inventors and patent attorneys accused of wrongdoing”). See generally CHISUM, *supra* note 9, at § 19.03[6] (listing, as potential consequences of “proof of fraud or inequitable conduct,” “liability for damages under the antitrust laws,” “liability under the Federal Trade Commission Act,” “liability under the federal securities laws,” and “disciplinary action against an attorney or agent who is registered to practice before the Patent and Trademark Office”).

<sup>15</sup> *Therasense*, 649 F.3d at 1288 (“Unlike validity defenses, which are claim specific, inequitable conduct regarding any single claim renders the entire patent unenforceable . . . . Moreover, the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family.”) (citations omitted). In contrast, an invalidity defense, such as an assertion that patent claims are invalid for lack of novelty, ordinarily proceeds on a comparatively plodding claim-by-claim basis.

might also be able to recover attorney fees<sup>16</sup> or to pursue an antitrust claim against the patentee.<sup>17</sup> Thus, in multiple ways, the inequitable conduct defense is a way of turning the tables and taking the “offensive” against a patentee.

Should U.S. patent law rid itself of an infringement defense based on inequitable conduct? Should concerns with inequitable conduct instead be addressed separately through professional discipline or regulation of future relations between a patentee and the USPTO? These points can be argued,<sup>18</sup> but as Part I suggests, even aside from Federal Circuit precedent, both Supreme Court precedent and congressional action or inaction indicate that the United States will have a substantial inequitable conduct defense

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*See* 35 U.S.C. § 282 (“Each claim of a patent . . . shall be presumed valid independently of the validity of other claims . . . .”); 800 Adept, Inc. v. Murex Sec., Ltd., 539 F.3d 1354, 1368 (Fed. Cir. 2008) (“Under the patent statute, the validity of each claim must be considered separately.”). Hence, just because one claim is invalid does not necessarily imply that another claim is, but if a patent applicant has committed inequitable conduct in relation to even just one claim in a patent application, the entire patent might be rendered unenforceable.

<sup>16</sup> *Therasense*, 649 F.3d at 1289 (“[P]revailing on a claim of inequitable conduct often makes a case ‘exceptional,’ leading potentially to an award of attorneys’ fees . . . .”); CHISUM, *supra* note 9, at § 19.03[6] (listing “an award of attorney’s fees” as a potential consequence of “proof of fraud or inequitable conduct”).

<sup>17</sup> *Id.* (“A finding of inequitable conduct may also spawn antitrust and unfair competition claims.”); CHISUM, *supra* note 9, at § 19.03[6] (listing “liability for damages under the antitrust laws” as a potential consequence of “proof of fraud or inequitable conduct”).

<sup>18</sup> *See, e.g.*, NATIONAL RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 123 (2004) (“In view of its cost and limited deterrent value the committee recommends the elimination of the inequitable conduct doctrine or changes in its implementation.”); Cotropia, *supra* note 13, at 728 (“This Article’s main finding is that the inequitable conduct doctrine has the ability to improve patent quality as long as the inherent tendency to overcomply with the doctrine by overloading the USPTO with information is kept in check.”); *cf.* Lisa A. Dolak, *The Inequitable Conduct Gyre Widens*, 50 IDEA 215, 215 (2010) (“On several occasions of late, I have been unable to resist the temptation to introduce my remarks relating to . . . the doctrine of inequitable conduct with a warning to the patent practitioners in the audience: ‘Get out! Get out while you still can!’”).

for the foreseeable future and thus that the debate is largely academic.<sup>19</sup>

In any event, retention of even a flawed inequitable conduct defense is not necessarily a bad thing. Reliance on inequitable conduct as a potentially powerful counterpunch to a suit of infringement might plausibly be viewed as an important and even critical part of the complicated system of checks and balances that constitutes U.S. patent law. There is reasonable cause to believe that an inequitable conduct defense can help correct for a combination of limitations of that system, including:

- (1) The USPTO's limited ability to check for deception or, more generally, to conduct thorough reviews of all material potentially relevant to a particular patent application's allowability;<sup>20</sup>
- (2) The substantial incentive for deception that an issued patent's strong presumption of validity in litigation<sup>21</sup> might provide;<sup>22</sup> and
- (3) The likely lack, even after relevant aspects of the recent patent reform act become effective, of administrative procedures to challenge the validity of another's issued or contemplated patent rights that are as robust as those found in other leading

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<sup>19</sup> See *supra* text accompanying notes 9-11.

<sup>20</sup> See *Cotropia*, *supra* note 13, at 753-54 (observing that patent examiners generally "do not have ready access to all technical literature" or other forms of prior art such as "offers to s[ell], conference presentations, test data, and product brochures"); *id.* at 756 (observing that "examiners do not have the time[, resources, or training] to independently verify all of an applicant's statements and claims").

<sup>21</sup> *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2244 (2011) (rejecting contentions that proof of patent claim invalidity requires only "a preponderance of the evidence").

<sup>22</sup> See *Taylor*, *supra* note 14, at 86 ("Reducing the standard of proving invalidity for undisclosed or unconsidered material prior art would encourage compliance with the duty of disclosure . . .").



patent jurisdictions, such as Japan and the European Union.<sup>23</sup>

As long as these three features of the U.S. patent system remain, courts and policymakers might correctly believe that an inequitable conduct defense able to be asserted by private parties is a necessary measure to curtail opportunistic or abusive behavior in dealings with the USPTO.<sup>24</sup>

In short, the existence of an inequitable conduct defense can generate significant systemic benefits, but the defense has proven to be difficult to manage and also to generate significant systemic costs. How then should the Federal Circuit seek to regulate the defense's use? In principle, the court could take a relatively hands-off approach, leaving the doctrine's application as a matter of minimally guided equitable discretion, and giving district court judges relatively free rein to apply the doctrine in individual cases. But given the severe sanction of unenforceability currently associated with inequitable conduct as a matter of course, such an approach would seem to leave the defense's application intolerably unpredictable, raising the resulting systemic costs and defeating part of Congress's apparent purpose in promoting national uniformity and predictability in patent litigation through creation of a centralized court of appeals for patent infringement suits.<sup>25</sup> The Federal Circuit thus seems properly charged with trying to

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<sup>23</sup> See Thomas F. Cotter, *An Economic Analysis of Patent Law's Inequitable Conduct Doctrine*, 53 ARIZ. L. REV. 735, 778 (2011) (suggesting 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").

<sup>24</sup> See Jason Rantanen & Lee Petherbridge, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24, 30 (2011) (describing the inequitable conduct defense as "[t]he clearest tool of pre-[America Invents Act] patent law to discourage" a strategy of nondisclosure of relevant information to the USPTO).

<sup>25</sup> Daniel J. Meador, *Retrospective on the Federal Circuit: The First 20 Years—A Historical View*, 11 FED. CIR. B.J. 557, 558 (2002) (discussing how interest in "enhanc[ing] national uniformity in federal decisional law" helped lead to creation of the Federal Circuit); Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 7 (1989) (observing how substantial divergence in how regional circuits applied federal patent law became a justification for creation of the Federal Circuit).

hammer out doctrinal contours for an inequitable conduct defense that is both substantial and limited, an effective deterrent for prospective patentees and remedy for accused infringers that avoids becoming too much of a vehicle for opportunistic and abusive behavior itself.

This last task of confining the inequitable conduct doctrine within sensible bounds is perhaps particularly hard because the United States' federal courts, by constitutional command, do not work in a vacuum; they cannot focus on defining Platonic ideals or even tracing shadows on walls. The meaning and application of judge-made law is hammered out in adversarial litigation, in which each side can be expected to seek to push—indeed to distend—favorable doctrines as far as possible and necessary to suit their clients' ends. As a result, as Chief Judge Rader himself has observed, a doctrine like that of inequitable conduct has a natural tendency to become bloated as one and then another defendant tries to establish this most desirable defense under questionably clear sets of facts.<sup>26</sup> The courts might succeed in filtering out most improper claims of inequitable conduct, but the fallibility or different perspectives of Article III judges<sup>27</sup> mean that, at some point, one or another of the weaker claims for inequitable conduct is likely to have its day.<sup>28</sup> The success of this claim will then become a precedent that later accused infringers will cite, and there is potential for an amplified unraveling of the doctrinal constraints that are meant to keep both the doctrine's application and its invocation within reasonable bounds. The resulting bloat of patent law's Falstaff will have again overcome any pretense of restraint.

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<sup>26</sup> See Rader, *supra* note 13, at 780 (2010) (“A cursory examination of the development of inequitable conduct law . . . lends support to the notion that this doctrine is constantly overflowing its banks.”).

<sup>27</sup> Cf. Lee Petherbridge, Jason Rantanen & Ali Mojibi, *The Federal Circuit and Inequitable Conduct: An Empirical Assessment*, 84 S. CAL. L. REV. 1293, 1351 (2011) (suggesting that Federal Circuit standards for inequitable conduct might be difficult to enforce because “judges’ decisions on inequitable conduct are impacted by their moral views of right and wrong”).

<sup>28</sup> Cf. Rader, *supra* note 13, at 785 (observing that “litigants continually solicit courts to rewrite or modify the law to suit their particular needs” and courts “sometimes oblige without adequate attention to the full consequences”).

What can the Federal Circuit do about the inequitable conduct defense's seemingly natural tendency toward bloat? One can imagine at least two nonexclusive responses: (1) limiting the defense's application by, for example, tightening the requirements for pleading the defense or for proving its elements; (2) limiting or diluting the defense's effects by, for example, enabling district courts to provide remedies other than complete patent unenforceability.<sup>29</sup> The Federal Circuit has pursued the first course.<sup>30</sup> The remainder of this Article will explore how this pursuit has led up to and been embodied in the opinion for the en banc court in *Therasense*.

### B. Precursors to *Therasense*

Whatever the validity of concerns that Federal Circuit judges lack sufficient exposure to economics or non-patent-based thinking to have substantial responsibility for the development of innovation-oriented law or policy,<sup>31</sup> among members of the federal

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<sup>29</sup> See Cotropia, *supra* note 13, at 774-75 (proposing various ways to mollify the consequences of an inequitable conduct finding); Taylor, *supra* note 14, at 85 (“One possible reform is to return judicial discretion to the application of remedies for findings of inequitable conduct.”).

<sup>30</sup> The opinion for the en banc Federal Circuit in *Therasense* contains at least a hint at the possibility of pursuing the second course in its statement that “the unclean hands doctrine remains available to supply a remedy for egregious misconduct.” 649 F.3d at 1287. Consistent with this statement, “egregious misconduct” might provide a basis for equitable relief distinct from complete patent unenforceability in situations where the “egregious misconduct” does not fit the category of “affirmative egregious misconduct” that constitutes inequitable conduct. *Id.* at 1292.

<sup>31</sup> See Rochelle Cooper Dreyfuss, *The Federal Circuit: A Continuing Experiment in Specialization*, 54 CASE W. RES. L. REV. 769, 782 (2004) (noting critics' contention that Federal Circuit suffers from “a failure to properly consider the interaction between the rules the court articulates and innovation policy”); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1106-07 (2003) (criticizing a Federal Circuit decision for “ignor[ing] the economic reality . . . that patents are not generally necessary as a mechanism for promoting innovation in the area of business methods”); cf. Paul R. Gugliuzza, *Patent Law's Uniformity Principle and the Consequences of Judicial Specialization*, 100 GEO. L.J. (forthcoming 2012) (suggesting that Federal Circuit adjudication

judiciary they are unusually well placed to understand how patent law's various constituencies are affected by the defense of inequitable conduct, a defense that focuses peculiarly on details of patent law practice. Concentration of patent appeals in the Federal Circuit ensures that each Federal Circuit judge consumes a steady diet of patent cases each year.<sup>32</sup> If there is a "plague" of difficult-to-resolve charges of inequitable conduct, Federal Circuit judges are, *ex officio*, likely to know about it.

Moreover, Federal Circuit judges gather information about problems with the practice of patent law through other channels. As part of an apparent effort to stay in touch with relevant patent communities, Federal Circuit judges regularly participate in patent-law-related conferences, speak at events organized by law schools or bar associations, compare notes with U.S. trial judges and judges from other jurisdictions, and make written contributions to law reviews or bar journals. Indeed, the Federal Circuit's Chief Judge Randall Rader—a casebook co-author,<sup>33</sup> regular teacher at law schools,<sup>34</sup> occasional trial judge,<sup>35</sup> and seemingly tireless traveler to conferences, both domestic and foreign—embodies this dedication to engagement with relevant patent communities at a level of intensity that is virtually exhausting to describe.

One can debate whether, generally speaking, Federal Circuit

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could improve if the court had a broader docket of economically oriented cases).

<sup>32</sup> Cf. John M. Golden, *The Supreme Court as "Prime Percolator": A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. REV. 657, 667 (2009) (observing in 2009 that "the typical Federal Circuit judge has participated in deciding several hundred patent cases on the merits").

<sup>33</sup> See ADELMAN, *supra* note 7.

<sup>34</sup> *GW Law – Faculty Directory*, THE GEORGE WASHINGTON UNIVERSITY (last visited May 15, 2012), <http://www.law.gwu.edu/Faculty/profile.aspx?id=3258> (describing "Professorial Lecturer in Law" Randall R. Rader as having "taught courses . . . at The George Washington University Law School, University of Virginia School of Law, Georgetown University Law Center, the Munich Intellectual Property Law Center, and other university programs in Tokyo, Taipei, New Delhi, and Beijing").

<sup>35</sup> See, e.g., *PA Advisors, LLC v. Google, Inc.*, 706 F. Supp. 2d 739 (E.D. Tex. 2010) (Rader, J.); *IP Innovation L.L.C. v. Red Hat, Inc.*, 705 F. Supp. 2d 692 (E.D. Tex. 2010) (Rader, J.); *Performance Pricing, Inc. v. Google Inc.*, 704 F. Supp. 2d 577 (E.D. Tex. 2010) (Rader, J.); *Cornell Univ. v. Hewlett-Packard Co.*, 654 F. Supp. 2d 119 (N.D.N.Y. 2009) (Rader, J.).

judges succeed through their extra-judicial activities in exposing themselves to the “right” cross section of persons interested in how the U.S. patent system or, more generally, the U.S. innovation ecosystem operates. There has long been concern that the benefits of engagement-based expertise such as that indicated above can be counterbalanced by the detriments of engagement-based “capture.”<sup>36</sup> But such concern seems substantially less salient with respect to inequitable conduct, an issue that parties regularly and heatedly contest before the Federal Circuit and within the communities with which Federal Circuit judges otherwise regularly interact.<sup>37</sup>

Of course, merely being in position to recognize problems with the inequitable conduct defense does not ensure success in shaping the defense’s doctrinal development. In light of the defense’s tendency toward bloat, such success likely requires constant work. Often, this work will occur through majority opinions, as was ultimately the case in the 2011 opinion by Chief Judge Rader for the en banc court in *Therasense*. Even before *Therasense*, however, the 2008 opinion for a Federal Circuit panel in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,<sup>38</sup> with then-Chief Judge Michel writing, emphasized “[t]he need to strictly enforce the burden of proof and elevated standard of proof” for inequitable conduct and articulated the requirement that an inference of deceptive intent must “be the single most reasonable inference able to be drawn from the evidence.”<sup>39</sup> Likewise, the 2009 opinion for a Federal Circuit panel in *Exergen Corp. v. Wal-Mart Stores, Inc.*,<sup>40</sup>

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<sup>36</sup> See John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1099 (2011) (observing that “concerns of capture and bias are normal in administrative law,” but that “[a] number of commentators suggest that such concerns have been systematically exaggerated”); cf. Rai, *supra* note 31, at 1110 (“Because capture is an obvious alternate explanation for the [Federal Circuit]’s jurisprudence, it is important to evaluate carefully . . . this hypothesis.”).

<sup>37</sup> Cf. Golden, *supra* note 32, at 683 (observing that, in circumstances involving “relative balance in advocacy,” “there seems, at first blush at least, little basis for picking out a single systematic direction for capture to take”).

<sup>38</sup> 537 F.3d 1357 (Fed. Cir. 2008).

<sup>39</sup> *Id.* at 1365-66.

<sup>40</sup> 575 F.3d 1312 (Fed. Cir. 2009).

penned by Judge Linn, operated to limit application of the defense by embracing a relatively demanding view of pleading requirements under Federal Rule of Civil Procedure 9(b).<sup>41</sup>

But significant groundwork for the Federal Circuit's retuning of inequitable conduct doctrine in *Therasense* was also laid through a series of separate, non-majority opinions.<sup>42</sup> In a 2007 dissent in *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,<sup>43</sup> Judge Pauline Newman complained that standards for what constituted inequitable conduct had slipped to the point of encouraging a new "plague" of . . . unwarranted charges,<sup>44</sup> and she warned that the majority's approach risked making routine "the inequity [of patent unenforceability] resulting from litigation-driven distortion of the complex procedures of patent prosecution."<sup>45</sup> Almost exactly one year later, then-Judge Rader added a dissent of his own, arguing that holdings of inequitable conduct should be restricted to "extreme cases of fraud and deception"<sup>46</sup> and echoing Judge Newman's concerns about

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<sup>41</sup> *Id.* at 1328-29 ("[A]lthough 'knowledge' and 'intent' may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO."); see also Taylor, *supra* note 14, at 72 ("*Exergen* may represent the first foray into the adoption of principles from the law of fraud into the law of inequitable conduct.").

<sup>42</sup> The sequence of separate opinions and suggestive panel opinions leading up to the en banc court's decision in *Therasense* illustrates how even this single appellate court can act as a "percolator" for new ideas and approaches despite the normally ossifying effect of circuit precedent. See Lee Petherbridge, *Patent Law Uniformity?*, 22 HARV. J.L. & TECH. 421, 428 (2009) ("The presence of large numbers of written opinions with significantly different outcomes suggests that Federal Circuit decisions in the area of law studied are not characterized by irretrievably entrenched broad-rule precedents."). *But cf.* Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1646 (2007) (observing that "intracircuit percolation does not escape the constraining force of precedent").

<sup>43</sup> 487 F.3d 897 (Fed. Cir. 2007).

<sup>44</sup> *Id.* at 926 (Newman, J., dissenting).

<sup>45</sup> *Id.*

<sup>46</sup> *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349

inequitable abuse of this equitable defense by observing that the defense had “taken on a new life as a litigation tactic.”<sup>47</sup> Judge Richard Linn added his own significant separate opinions on inequitable conduct both before and after his opinion for a Federal Circuit panel in *Exergen*. In a 2009 concurring opinion, he lamented that Federal Circuit precedent had come to “perpetuat[e] what was once referred to as a ‘plague.’”<sup>48</sup> In 2010, Judge Linn wrote a lengthy dissent from a decision by a three-judge panel in the *Therasense* case itself.<sup>49</sup>

Such majority and non-majority opinions are only a sampling of the pushing and pulling, the expressions of dissatisfaction, and the implicit invitations of attorney challenges to the status quo that led up to the en banc court’s holdings in *Therasense*. After the Federal Circuit signaled interest in a wholesale reevaluation of the inequitable conduct doctrine in its grant of en banc review,<sup>50</sup> Chief Judge Rader used a concurring opinion to deliver a further shot across the bow by describing *Therasense* as intended “to address the transformation of inequitable conduct from the rare exceptional cases of egregious fraud that results in the grant of a patent . . . to a rather automatic assertion in every infringement case.”<sup>51</sup>

Moreover, communications by Federal Circuit judges came through mechanisms other than judicial opinions. Earlier in the same month in which the Federal Circuit granted en banc review in *Therasense*,<sup>52</sup> an issue of the *American University Law Review* featured a foreword by Chief Judge Rader suggesting that “the

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(Fed. Cir. 2008) (Rader, J., dissenting).

<sup>47</sup> *Id.*

<sup>48</sup> *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., concurring).

<sup>49</sup> *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense III)*, 593 F.3d 1289, 1312-25 (Fed. Cir. 2010) (Linn, J., dissenting), *vacated*, 374 Fed. Appx. 35 (Fed. Cir. 2010).

<sup>50</sup> *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense IV)*, 374 Fed. Appx. 35, 35-36 (Fed. Cir. 2010) (en banc) (listing various questions to be addressed in “new briefs”).

<sup>51</sup> *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 835 (Fed. Cir. 2010) (Rader, J., concurring).

<sup>52</sup> *Therasense IV*, 374 Fed. Appx. at 35 (granting en banc review on April 26, 2010).

Federal Circuit's inequitable conduct jurisprudence might profit from a renewed focus on propounding clear standards that can be easily applied by lower courts and the public."<sup>53</sup>

Thus, the Federal Circuit made its way to the threshold of reformulation of inequitable conduct doctrine in *Therasense*. Part II looks at what the court did upon crossing.

## II. DOCTRINAL RETRENCHMENT IN *THERASENSE*

### A. *Therasense Facts*

The basic facts relevant to the inequitable conduct charge in *Therasense* help to put the Federal Circuit's rulings in context and can be described as follows. Abbott Laboratories and its subsidiary Therasense, Inc. (hereinafter collectively referred to as "Abbott") sued Becton, Dickinson & Co. for infringement of U.S. Patent No. 5,820,551 ("the '551 patent").<sup>54</sup> The '551 patent contains claims directed to "disposable blood glucose test strips for diabetes management."<sup>55</sup> The '551 patent specifically claims a form of test strip that tests the glucose concentration level in "whole blood"—i.e., "blood that contains all of its components, including red blood cells."<sup>56</sup> As described in the patent's sole independent claim, the form of test strip claimed uses an "active electrode . . . configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member."<sup>57</sup>

The '551 patent issued after a contentious, more than fourteen-year prosecution history that featured no fewer than six continuations or continuations-in-part of abandoned applications.<sup>58</sup>

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<sup>53</sup> Rader, *supra* note 13, at 785.

<sup>54</sup> *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense II)*, 565 F. Supp. 2d 1088, 1091 (N.D. Cal. 2008) (describing procedural history), *aff'd in part and vacated in part*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

<sup>55</sup> *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense)*, 649 F.3d 1276, 1282 (Fed. Cir. 2011) (en banc).

<sup>56</sup> *Id.* at 1283.

<sup>57</sup> U.S. Patent No. 5,820,551 col.14 ll. 1-3 (issued Oct. 13, 1998).

<sup>58</sup> *See id.* (showing "Related U.S. Application Data" on patent's cover page); *see also Therasense*, 649 F.3d at 1283 ("Over thirteen years, that original



Abbott was not the original owner of rights in what ultimately became the '551 patent. About a dozen years into the '551 patent's prosecution history, Abbott acquired Medisense, Inc., the company owning rights in the '551-related applications.<sup>59</sup> A patent attorney at Abbott, Lawrence Pope, then took over prosecution of the '551 application and submitted new claim language that included the requirement for a sensor “that did not require a protective membrane for whole blood.”<sup>60</sup> With a supporting affidavit from Abbott's Director of Research and Development, Dr. Gordon Sanghera, Pope argued that this claim limitation distinguished the claimed invention from disclosures in a prior-art patent also acquired from Medisense, U.S. Patent No. 4,545,382 (“the '382 patent”).<sup>61</sup>

The tricky point in Abbott's argument was that the '382 patent describes “a protective membrane” for a glucose sensor that is present “[o]ptionally, but preferably when being used on live blood.”<sup>62</sup> At least to a layperson, the plain language of this statement might suggest that the '382 patent discloses that use of a “protective membrane” for purposes like that associated with the claims of the '551 patent was already recognized as merely “optiona[l]” and therefore not required. But Dr. Sanghera's affidavit contended that, upon reading the '382 patent, a person skilled in the relevant technological art—the relevant person for legal purposes—“would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample.”<sup>63</sup> Consistent with this understanding, the skilled artisan “would not read [the '382 patent's 'optionally, but preferably' language] to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.”<sup>64</sup> Attorney Pope

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application saw multiple rejections for anticipation and obviousness, including repeated rejections over . . . another patent owned by Abbott.”).

<sup>59</sup> *Therasense II*, 565 F. Supp. 2d at 1093.

<sup>60</sup> *Therasense*, 649 F.3d at 1283.

<sup>61</sup> *Id.* (describing the affidavit and accompanying attorney argument).

<sup>62</sup> U.S. Patent No. 4,545,382 col.4 ll. 63-65 (issued Oct. 8, 1985).

<sup>63</sup> *Therasense*, 649 F.3d at 1283 (internal quotation marks omitted).

<sup>64</sup> *Id.* (internal quotation marks omitted).

similarly argued that the “optionally, but preferably” language was “mere patent phraseology” and that a skilled artisan “would not have read [the ’382 patent] as teaching that the use of a protective membrane with whole blood samples was optional.”<sup>65</sup> Despite the ’382 patent’s plain language, the contentions of Pope and Sanghera were apparently convincing. In the wake of these representations, the USPTO examiner “finally approved the proposed claims.”<sup>66</sup>

Something the examiner was not told was that, in appealing revocation of the European counterpart of the ’382 patent in 1995, Medisense had argued to the European Patent Office (EPO) that the sentence featuring the “[o]ptionally, but preferably” language was “unequivocally clear”: “The protective membrane is optional[;] however, it is preferred when used on live blood . . . . [T]he sensor electrode as claimed does not have (and must not have) a semipermeable membrane in the sense of [another prior-art reference].”<sup>67</sup> Given that Pope and Sanghera had needed to counter the ’382 patent’s plain language with an affidavit about the particular meaning that an ordinary artisan would attach to that language, one might have expected them to recognize that an examiner or, perhaps more to the point, a court would be interested in prior statements asserting that the language was “unequivocally clear.” As a matter of best practice, one might have thought they should disclose those statements to the USPTO even if they believed them reconcilable with their current contentions because of differences in context, etc. But, although both attorney Pope and Dr. Sanghera knew of these prior statements by Abbott’s predecessor in interest, they concededly “made a conscious and deliberate decision to withhold disclosure” of them to the USPTO.<sup>68</sup>

At trial, Abbott argued that the nondisclosure was immaterial,<sup>69</sup> and attorney Pope and Dr. Sanghera testified that they lacked

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<sup>65</sup> *Id.* (internal quotation marks omitted).

<sup>66</sup> *Therasense II*, 565 F. Supp. 2d at 1094.

<sup>67</sup> *Therasense*, 649 F.3d at 1284 (emphasis omitted).

<sup>68</sup> *Therasense II*, 565 F. Supp. 2d at 1107-08.

<sup>69</sup> *See id.* at 1112 (discussing arguments that the nondisclosure was immaterial).

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deceptive intent.<sup>70</sup> A key assertion was that the statements from the EPO prosecution focused on distinguishing a “diffusion-limiting membrane” and thus were properly viewed as irrelevant to distinction of “blood separation membranes and filters”—“completely separate pieces of technology” according to Dr. Sanghera.<sup>71</sup> The district court disagreed and held that the nondisclosure was “highly material,”<sup>72</sup> that neither attorney Pope nor Dr. Sanghera had any “plausible reason” for their nondisclosure, and that both acted with intent to deceive.<sup>73</sup> Before the Federal Circuit’s review of the case en banc, a divided Federal Circuit panel affirmed the district court, holding that the district court did not clearly err in its factual findings of materiality<sup>74</sup> and intent,<sup>75</sup> and “did not abuse its discretion in holding the ’551 patent unenforceable due to inequitable conduct.”<sup>76</sup>

### B. New Rules for Intent and Materiality

If the en banc Federal Circuit had focused on resolving whether inequitable conduct had occurred under the particular facts of *Therasense*, there seems a good chance that the division of opinion

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<sup>70</sup> *Id.* at 1113-16 (discussing contentions of lack of deceptive intent).

<sup>71</sup> *Id.* at 1116 (quoting Dr. Sanghera’s testimony) (internal quotation marks omitted).

<sup>72</sup> *Id.* at 1110.

<sup>73</sup> *See id.* at 1113 (“Sadly, this order must find that Attorney Pope had no plausible reason for consciously withholding the EPO submissions and that he acted with specific intent to deceive Examiner Shay and the PTO.”); *id.* at 1116 (“Taking into account all possible inferences of good faith, this order concludes that Dr. Gordon Sanghera had no plausible reason for concealing the inconsistent EPO submissions and that he consciously made sworn statements to the [USPTO] that were deliberately misleading . . .”).

<sup>74</sup> *Therasense III*, 593 F.3d at 1305 (“The district court’s finding that the EPO statements were highly material because they contradicted the position taken before the PTO was not clearly erroneous and was strongly supported by the uncontradicted record.”).

<sup>75</sup> *Id.* at 1308 (concluding that “the district court was clearly correct in concluding that the explanations offered by Pope and Dr. Sanghera were not plausible” and that, “[a]ccordingly, the district court did not clearly err in finding that Pope and Dr. Sanghera both intended to deceive the PTO by withholding the EPO documents”).

<sup>76</sup> *Id.*

evident at the panel stage might have dominated the opinions issued after the rehearing en banc. As in many cases where inequitable conduct is charged, there was a nondisclosure that reasonable people might view as, at the very least, suspiciously contrary to principles of best practice, most specifically the norm of erring on the side of disclosure to the USPTO.<sup>77</sup> Add to the violation of such norms the possibility of different understandings of the context-specific significance of the nondisclosure and the likelihood of decision-makers having different priors about the probability of deceptive intent when nondisclosure or misrepresentation occurs.<sup>78</sup> The result is a situation in which outcomes of the adjudication of inequitable conduct charges is likely to be highly unpredictable, thus raising various concerns about arbitrariness and unfairness in adjudication, potential litigation abuse, and incentives for wasteful and possibly distracting overdisclosure to the USPTO.

In this context, the en banc Federal Circuit appears properly to have focused on providing general prescriptions for adjudication of inequitable conduct charges while leaving for the district court the task of reconsidering the specific question of how the defense should apply to *Therasense's* particular facts.<sup>79</sup> The general prescriptions provided give the law a significant, non-fact-specific

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<sup>77</sup> See *Therasense III*, 593 F.3d at 1305 (“[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.”). See generally U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2004, at 2000-10 (rev. 8th ed. 2010) (“When in doubt, it is desirable and safest to submit information. . . . [T]he question of relevancy in close cases[] should be left to the examiner and not the applicant.” (internal quotation marks omitted)); *Therasense III*, 593 F.3d at 1319 (Linn, J., dissenting) (describing “the familiar adage that ‘[c]lose cases should be resolved by disclosure’” as “sage advice” that “practitioners should take . . . to heart” (citation and emphasis omitted)).

<sup>78</sup> Such priors might be personalized because they reflect personal experience, relatively individualized understandings of human nature, or relatively individualized understandings of the care and precision with respect to which people can be expected to act during patent prosecution.

<sup>79</sup> *Therasense*, 649 F.3d at 1296 (“[T]his court vacates the district court’s finding of inequitable conduct and remands for further proceedings consistent with this opinion.”).

shove toward a leaner doctrine of inequitable conduct. And interestingly, in light of criticism of the Federal Circuit for being overly formalist and inattentive to policy concerns,<sup>80</sup> the Federal Circuit explicitly tied this doctrinal shove to the court's assessment of the public interest. The majority opinion by Chief Judge Rader explained:

Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system. Because allegations of inequitable conduct are routinely brought on the slenderest grounds, patent prosecutors constantly confront the specter of inequitable conduct charges. With inequitable conduct casting the shadow of a hangman's noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value. . . .

While honesty at the PTO is essential, low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality. This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.<sup>81</sup>

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<sup>80</sup> See, e.g., Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 791 (2008) (discussing criticism of the Federal Circuit for “[f]ormalistic case-parsing, refusals to consider policy arguments, and reluctance to revise positions once taken”); Rai, *supra* note 31, at 1102-04 (arguing that “rule-formalism that is opaque to policy considerations . . . is a poor fit for [the U.S.] patent statute,” but that, “[i]n several major areas of patent law decisionmaking . . . the Federal Circuit’s approach . . . has been decidedly formalist”).

<sup>81</sup> *Therasense*, 649 F.3d at 1289-90 (internal quotation marks and citations omitted); *cf. id.* at 1302 (Bryson, J., dissenting) (“There is broad consensus that the law of inequitable conduct is in an unsatisfactory state and needs

Tightening of the law's intent requirement came about as follows. First, the court's eleven "active" judges<sup>82</sup> unanimously reaffirmed that proof of inequitable conduct requires clear and convincing evidence of "specific intent to deceive" and that "gross negligence or negligence under a 'should have known' standard does not satisfy this intent requirement."<sup>83</sup> Second, the Federal Circuit judges unanimously overruled circuit precedent<sup>84</sup> by holding that "court[s] should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa."<sup>85</sup> Finally, Chief Judge Rader's opinion for the court further clarified what is needed to prove specific intent by circumstantial evidence. The court reiterated the "single most reasonable inference" requirement implicit in any burden of proof requiring at least a preponderance of evidence<sup>86</sup> and previously articulated by a Federal Circuit panel

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adjustment.").

<sup>82</sup> The quotation marks around "active" reflect the fact that the Federal Circuit has a number of senior judges who are active in a less technical sense of the term in that they sit regularly on three-judge panels, helping to decide cases and to write opinions supporting the court's decisions.

<sup>83</sup> *Therasense*, 649 F.3d at 1290; *id.* at 1296-97 (O'Malley, J., concurring in part and dissenting in part) (indicating that she concurred with the majority on everything but the proper approach for "assessing materiality"); *id.* at 1302 (Bryson, J., dissenting) (observing that disagreement on the proper standard for materiality "is what divides the court in this case").

<sup>84</sup> *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002) ("While the intent to deceive may be inferred from the surrounding circumstances rather than by direct evidence, the intent necessary to establish inequitable conduct is based on a sliding scale related to materiality of the omission."), *overruled in part*, *Therasense*, 649 F.3d at 1276; *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) ("The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa."), *overruled in part*, *Therasense*, 649 F.3d at 1276.

<sup>85</sup> *Therasense*, 649 F.3d at 1290; *id.* at 1296-97 (O'Malley, J., concurring in part and dissenting in part) (indicating that she concurred with the majority on everything but the proper approach for "assessing materiality"); *id.* at 1302 (Bryson, J., dissenting) (observing that disagreement on the proper standard for materiality "is what divides the court in this case").

<sup>86</sup> *Id.* at 1290. The "single most reasonable inference" standard is implicit in burdens of proof requiring at least a preponderance of the evidence because, if

in *Star Scientific*.<sup>87</sup> The court added that “[t]he absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.”<sup>88</sup>

In contrast to the Federal Circuit judges’ basic unanimity on the proper approach to assessing intent, the eleven judges sharply split on the question of the proper standard for materiality.<sup>89</sup> A bare majority of six coalesced behind a new framework for assessing materiality.<sup>90</sup> The majority pointed to policy concerns to justify this “judicial reform,”<sup>91</sup> explaining that prior efforts to restrict inequitable conduct charges through a “higher intent standard” alone “did not reduce the number of inequitable conduct cases before the courts and did not cure the problem of overdisclosure of marginally relevant prior art to the PTO.”<sup>92</sup>

The majority’s answer to these continuing concerns was adoption of a general rule that “the materiality required to establish inequitable conduct is but-for materiality.”<sup>93</sup> In other words, alleged misconduct, such as nondisclosure of a prior-art reference, would, generally speaking, only be considered material for purposes of an inequitable conduct defense if the USPTO “would not have allowed a claim” in the issued patent if the misconduct

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the facts support a more probable or even just equally probable inference of a mental state more innocent than “specific intent to deceive,” then the existence of such specific intent is necessarily no more than fifty percent likely, a ceiling on the likelihood of specific intent presumably insufficient to support a finding of specific intent even under a mere preponderance-of-the-evidence standard.

<sup>87</sup> *Supra* text accompanying notes 38-39.

<sup>88</sup> *Therasense*, 649 F.3d at 1291.

<sup>89</sup> *See id.* at 1296 (O’Malley, J., concurring in part and dissenting in part) (reporting “respectfu[l] dissent” from the majority’s holdings on materiality); *id.* at 1302 (Bryson, J., dissenting) (contending that the majority’s approach “marks a significant and . . . unwise departure from [Federal Circuit] precedents”).

<sup>90</sup> *See id.* at 1291 (majority opinion) (“[T]his court adjusts as well the standard for materiality.”).

<sup>91</sup> Arti K. Rai, *Building a Better Innovation System: Combining Facially Neutral Patent Standards with Therapeutics Regulation*, 45 HOUS. L. REV. 1037, 1038 (2008) (noting in 2008 that, while “legislative reform ha[d] been thwarted,” “judicial reform” had proceeded).

<sup>92</sup> *Therasense*, 649 F.3d at 1291.

<sup>93</sup> *Id.*

had not occurred.<sup>94</sup>

Significantly, however, the majority did not stop with articulation of the new general requirement of but-for materiality. The majority qualified the general rule with an explicit exception. Specifically, the majority stated that “affirmative acts of egregious misconduct” are effectively material *per se*.<sup>95</sup> The majority emphasized that the purpose of this exceptional category was to give the new overall test for materiality “sufficient flexibility to capture extraordinary circumstances.”<sup>96</sup> Consistent with this aim, the majority declined to provide a complete definition of the category of “affirmative egregious acts.”<sup>97</sup> Instead, the majority gave an illustrative example of such an act—namely, “the filing of an unmistakably false affidavit.”<sup>98</sup>

### III. EPILOGUE

Is the Federal Circuit’s newly formulated approach to assessing inequitable conduct claims a good one? Of course, it is an empirical question whether that approach will succeed in substantially restraining a “plague” of inequitable conduct charges while maintaining a robust penalty that helps deter misconduct in dealings with the USPTO. For this empirical question, there is no

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<sup>94</sup> *Id.* The test for but-for materiality is apparently an objective one, not a subjective test tied to the individual idiosyncrasies of an actual, single examiner. The question appears to be whether a properly acting USPTO examiner, “giv[ing] claims their broadest reasonable construction” and “apply[ing] the preponderance of the evidence standard” for rejecting claims, would have allowed the claim to issue. *Id.* at 1291-92. Consistent with this objective understanding of materiality, the majority indicated that, because district courts use the best rather than the broadest reasonable construction for claims, and because invalidity of a patent claim must be proven by clear and convincing evidence in district courts, rather than a mere preponderance of the evidence, “if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material.” *Id.* at 1292.

<sup>95</sup> *Id.* at 1292.

<sup>96</sup> *Id.* at 1293.

<sup>97</sup> *Id.*

<sup>98</sup> *Therasense*, 649 F.3d at 1293.



quick and easy answer.<sup>99</sup>

In the meantime, the new approach to assessing inequitable conduct outlined by *Therasense* appears at least to represent a reasonable and even laudable effort to improve the practical performance of a problematic body of law. Although commentators frequently criticize the Federal Circuit for excessive formalism, the *Therasense* court explicitly cites real-world policy concerns to support the change in course that it adopts.<sup>100</sup> Additionally, the court cites such policy concerns in an equitable context where consideration of policy concerns has traditionally been thought appropriate.<sup>101</sup> The court's tightening of the requirement of specific intent was relatively uncontroversial and, given concerns with uncertainty and overcompliance, quite defensible.<sup>102</sup> Further, the test for materiality adopted by the court seeks to strike a reasonable balance between clear guidance and reserved flexibility by employing a doctrinal arrangement common in equity: a strong default rule combined with a nontrivial allowance for exceptions.<sup>103</sup> The new materiality test's somewhat

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<sup>99</sup> See Petherbridge, Rantanen & Mojibi, *supra* note 27, at 1350 (concluding that “only time will tell whether the majority’s predictions [of positive effects] will come to pass”).

<sup>100</sup> See *supra* text accompanying notes 80-81.

<sup>101</sup> See, e.g., Zygmunt J.B. Plater, *Statutory Violations and Equitable Discretion*, 70 CAL. L. REV. 524, 538 (1982) (“In the field of nuisance law, equity invaded the common law by introducing a comparative weighing of public values in trespass actions.”); William Murray Tabb, *Reconsidering the Application of Laches in Environmental Litigation*, 14 HARV. ENVTL. L. REV. 377, 400 (1990) (“Public interest concerns traditionally have played a key role in affecting a court’s equitable discretion regarding entitlement and fashioning of equitable relief.”).

<sup>102</sup> See Cotropia, *supra* note 13, at 777 (arguing for a requirement of specific intent that is truly separate from that for materiality). *But see* McGowan, *supra* note 2, at 976 (arguing that “the court should reverse its course on scienter” and “return to a standard of recklessness”).

<sup>103</sup> See Mark Gergen, John M. Golden & Henry E. Smith, *The Supreme Court’s Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203, 206 (2012) (contending that, “[i]n deciding whether to issue injunctions, courts would generally do well by continuing to use the kinds of structured sets of presumptions and safety valves that have characterized traditional equitable practice”).

fuzzily defined exception for “affirmative egregious acts”<sup>104</sup> might help deter at least the worst forms of abuse not captured by the general requirement of but-for materiality.<sup>105</sup>

In at least one respect, we know that *Therasense* has been an almost immediate success. Within two months of the court’s decision, the USPTO, which had opposed a but-for materiality test in the en banc proceedings,<sup>106</sup> reversed course and proposed “to revise [its] materiality standard . . . to match the materiality standard, as defined in *Therasense*.”<sup>107</sup> The USPTO’s course change helps eliminate awkward incongruity between the USPTO’s definition of an applicant’s duty to disclose and the Federal Circuit’s definition of what constitutes inequitable conduct, and elimination of this incongruity has probably made intervention by the U.S. Supreme Court less likely.

Moreover, Congress has taken its own route to endorsing something like a but-for materiality test. The Leahy-Smith America Invents Act that became law in September 2011 provides for a process of “supplemental examination” by which a patentee can effectively inoculate a patent against charges of inequitable conduct by resubmitting the patent for reexamination based on corrected information.<sup>108</sup> Under the *Therasense* rubric, successful

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<sup>104</sup> As Judge Bryson’s dissent points out, “it is often difficult to draw a line between nondisclosure and affirmative misrepresentation,” “not to mention . . . between ‘egregious’ misconduct and misconduct that is assertedly less than ‘egregious.’” *Therasense*, 649 F.3d at 1313 n.3 (Bryson, J., dissenting).

<sup>105</sup> See Gergen, Golden & Smith, *supra* note 103, at 237-38 (“It is foundational that equity must be open textured in light of the ability of parties to opportunistically evade legal obligations.”).

<sup>106</sup> *Therasense*, 649 F.3d at 1305 (Bryson, J., dissenting) (describing the USPTO as “persuasively argu[ing] in its amicus brief [that] the ‘but for’ standard for materiality is too restrictive”).

<sup>107</sup> U.S. Patent & Trademark Office, Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43631, 43631 (proposed July 21, 2011).

<sup>108</sup> See Jason Rantanen & Lee Petherbridge, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24, 25 (2011) (describing the “supplemental examination” provision as “a patent amnesty program”). The act expressly provides 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

passage of a patent through such a supplemental examination might be viewed as effectively establishing that corrected errors in disclosure were not but-for material and thus not proper grounds for a holding of unenforceability due to inequitable conduct.

With such USPTO and congressional actions appearing effectively to bolster aspects of the *Therasense* approach, the Federal Circuit's new approach to determining whether there is inequitable conduct—including its relatively uncontroversial tightening of the specific intent requirement and its more controversial tightening of the materiality requirement—appears relatively secure. Will the Federal Circuit's *Therasense* prescription suffice to correct or, at least, substantially mitigate the inequitable conduct defense's faults? There seems at least a decent chance that it will. But patent law's Falstaff—the inequitable conduct defense—has proven irrepressible in the past. We will have to wait and see the outcome of the Federal Circuit's latest admonition that this Falstaff should “[m]ake less thy body . . . and more thy grace.”<sup>109</sup>

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incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.” Leahy-Smith America Invents Act, Pub. L. 112-29, § 12(a), 125 Stat. 284, 326 (2011) (to be codified at 35 U.S.C. § 257(c)(1)).

<sup>109</sup> WILLIAM SHAKESPEARE, 2 HENRY IV 5.5, l. 50, in NORTON SHAKESPEARE, *supra* note 1, at 1374 (Henry V's closing admonition to Falstaff).