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# Managing Inequitable Conduct by Legislation and/or Regulation

Alan J. Kasper

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**MANAGING INEQUITABLE CONDUCT BY LEGISLATION  
AND/OR REGULATION\***

*Alan J. Kasper\*\**

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I. INTRODUCTION

The defense of “inequitable conduct” in patent litigation is rooted in equity and derives, not from any legislative formulation or regulatory construct, but instead from the principles of “unclean hands.” In *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, the United States Supreme Court dismissed a case brought by a patent owner because the patent in suit and certain related contracts were “perjury tainted” and “inequitable conduct impregnated Automotive’s entire cause of action.”<sup>1</sup> The *Precision Instrument* case and the only two

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1. 324 U.S. 806, 819 (1945).

other earlier decisions<sup>2</sup> by the Supreme Court to consider an unclean hands defense, “involved overt fraud, not equivocal acts of omission.”<sup>3</sup>

#### A. *Development of Inequitable Conduct in the Federal Circuit*

Notwithstanding the Supreme Court’s originally narrow focus on fraudulent conduct, in the three decades prior to the establishment of the U.S. Court of Appeals for the Federal Circuit (CAFC) in 1982, the defense of inequitable conduct grew, but with inconsistent underlying principles.<sup>4</sup> However, shortly after its creation, the CAFC articulated the test for inequitable conduct in *J.P. Stevens & Co. v. Lex Tex Ltd.* and identified two basic criteria: (1) a threshold level of materiality of omitted or false information; and (2) a threshold level of intent to deceive the Patent and Trademark Office (PTO), both of which must be proven by clear and convincing evidence.<sup>5</sup> If the thresholds of intent and materiality are met, “the court must balance them and determine as a matter of law whether the scales tilt to a conclusion that inequitable conduct occurred.”<sup>6</sup>

In an era when patent litigation accelerated at a historic pace, the defense of inequitable conduct was pled with such frequency that the CAFC in 1988 characterized the defense as a “plague” on the patent system.<sup>7</sup> In order to confine this growing trend, the court clarified the requirements for inequitable conduct in *Kingsdown Medical Consultants Ltd. v. Hollister, Inc.*, by holding that an omission or misrepresentation must be material to patentability and must be made with an intent to deceive the Patent Office.<sup>8</sup> *Kingsdown* also required materiality and intent to be proven separately by “clear and convincing evidence,” and rejected proof of intent based on even “gross negligence.”<sup>9</sup>

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2. *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944).

3. *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Products Ltd.*, 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring).

4. See Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 *Harvard J.L. & Tech.* 37, 68 (1993) (“[I]t is only a slight exaggeration to say that one could find pre-1982 decisions going both ways (i.e., finding or not finding inequitable conduct) on almost any set of facts.”).

5. 747 F.2d 1553, 1559-60 (Fed. Cir. 1984), *overruled by* *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 945 F.2d 1546 (Fed. Cir. 1991).

6. *Id.* at 1560 (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1367 (Fed. Cir. 1984)).

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

8. 863 F.2d 867, 872 (Fed. Cir. 1988).

9. *Id.*

Notwithstanding this attempt to tighten the requirements for proving inequitable conduct, the Federal Circuit in the ensuing years has not held to a consistent standard or otherwise issued decisions that would reduce the perceived “plague.” Starting with the early decision in *Critikon v. Becton Dickinson*<sup>10</sup> and continuing with *Novo Nordisk v. Bio-Tech General*,<sup>11</sup> *Ferring v. Barr Labs*,<sup>12</sup> and *Aventis v. Amphastar*,<sup>13</sup> the Federal Circuit has relaxed the requirement for proving intent. In these cases, the basis for proving an “intent to deceive” has been extended to embrace a pure negligence standard (“should have known”) and to impute intent solely on the basis of the materiality of the information involved.<sup>14</sup> Moreover, as to materiality, even though the PTO established a narrow materiality standard in 1992, the Federal Circuit held in *Digital Control Inc. v. Charles Machine Works* that the agency rule cannot “supplant” the judicially developed standard.<sup>15</sup>

Because inequitable conduct serves as an “atomic bomb remedy” in patent litigation,<sup>16</sup> the trend towards pleading inequitable conduct in a majority of patent cases has led judges on the Federal Circuit to call for a reevaluation of the current standards en banc and a return to the principles in *Kingsdown*, previously clarified en banc.<sup>17</sup> It has been noted that the recent requirement for a “credible explanation” of conduct by the patentee

effectively shifts the burden to the patentee to prove a negative: that it did not intend to deceive the PTO. This shift is viewed as contrary to the basic principle that it is the ‘accused infringer’—not the patentee—who ‘must prove by clear and convincing evidence that the material

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10. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (drawing an inference of intent based on what a person “should have known”).

11. *Novo Nordisk Pharms., Inc., v. Bio-Technology General Corp.*, 424 F.3d 1347 (Fed. Cir. 2005).

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

13. *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334 (Fed. Cir. 2008).

14. See Erik R. Puknys & Jared D. Schuettenhelm, *Application of the Inequitable Conduct Doctrine After Kingsdown*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 839, 870 (2008).

15. *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006).

16. *Aventis Pharma*, 525 F.3d at 1349 (Rader, J., dissenting).

17. *Larson Mfg.*, 559 F.3d at 1343 (Linn, J., concurring) (“But in seeming contradiction with *Kingsdown*, a standard even lower than ‘gross negligence’ has propagated through our case law. This standard permits an inference of deceptive intent when ‘(1) highly material information is withheld; (2) the applicant knew of the information [and] ... knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.’”).

information was withheld with the specific intent to deceive the PTO.<sup>18</sup>

Even if the Federal Circuit moves toward yet another en banc consideration of the inequitable conduct doctrine, it has been suggested that, absent clear legislative guidance for the courts, the issues may be best left for the administrative agency involved. Citing several U.S. Supreme Court decisions relevant to remedies for misconduct before a Federal agency,<sup>19</sup> including perjury and fraud, and highlighting the holding in *Vermont Yankee Nuclear Power Corp. v. NRDC*,<sup>20</sup> Professor John Duffy observed that the “Supreme Court unanimously emphasized that administrative process should ‘be left within the discretion of the agencies’, because ‘administrative agencies [are] in a better position than federal courts or Congress to design procedural rules adapted to the peculiarities of the industry and the tasks of the agency involved.’”<sup>21</sup> Professor Duffy identified the possible questions for Supreme Court review to include:

Whether a court may use its inherent powers to hold a patent unenforceable because of a failure to disclose information at the administrative level: That the PTO does not require to be disclosed. [Digital] That is “not indispensable to the granting of a patent” and “not the basis for [the patent] or essentially material to its issue.” [Corona Tire] Whether there are no allegations of perjury or attempts to conceal perjury. [Precision Instrument]<sup>22</sup>

### B. Consideration of Inequitable Conduct by the PTO

In 1977, the PTO promulgated a standard for a duty of disclosure of “material information” to the Office as being based on a reasonable examiner, that is, “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>23</sup> The PTO’s commentary to

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18. *Id.* at 1344, (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) (“This is in tension with the rule in *Star Scientific* that ‘the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the *single most reasonable* inference able to be drawn from the evidence.’” (emphasis in original))).

19. *ABF Freight System, Inc. v. N.L.R.B.*, 510 U.S. 317 (1994); *Buckman v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001).

20. 435 U.S. 519 (1978).

21. John Duffy, Hot Topics, The Coming End of Inequitable Conduct (As We Know It), presentation at the Association of Corporate Patent Counsel (ACPC) June 2008 Meeting (June 2008).

22. *Id.*

23. 37 C.F.R. 1.56 (1984).

the new Rule 56 stated that this standard “codifies the existing Office policy on fraud and inequitable conduct, which is believed consistent with the prevailing case law in the federal courts . . . [t]he section should have a stabilizing effect on future decisions in the Office and may afford guidance to courts as well.”<sup>24</sup>

With the increased volume of charges of inequitable conduct in the courts during the early 1980’s, the United States Patent and Trademark Office (USPTO) implemented a procedure for investigating charges of fraud in 1986.<sup>25</sup> However, that procedure was short lived and was abandoned in 1988 because “[t]he Office is not the best forum in which to determine whether there was an ‘intent to mislead’ and . . . [will not] investigate and reject original or reissue applications under 37 C.F.R. § 1.56.”<sup>26</sup>

In 1992, the Office adopted a new text for Rule 56 that abandoned the “reasonable examiner” standard<sup>27</sup> and defined information as being material if “(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.”<sup>28</sup>

Although the PTO established this standard to govern the scope of submissions by applicants, the courts have not embraced this definition as the basis for determining the materiality prong of inequitable conduct.<sup>29</sup> The failure to use the administrative agency test may raise issues that merit resolution by the Supreme Court.<sup>30</sup>

24. Rules of Practice in Patent Cases, 42 Fed. Reg. 5588, 5589 (January 28, 1977); *see also* Christian Mammen, *Controlling the ‘Plague’: Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1329 (2009).

25. MPEP §2004(18) (5th ed. Rev. 3, 1986).

26. Mammen, *supra* note 24, at 1341, *quoting* MPEP § 2010 (6th ed. Jan. 1995) (suggesting that the procedure was officially abandoned in 1995); *see also* Harry Manbeck, *The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 139-40 (1992).

27. Manbeck, *supra* note 26 (stating that the “reasonable examiner” standard was criticized as being “imprecise” and the goal of the new standard was to provide “a more objective set of guidelines”). *See also* Mammen, *supra* note 24, at 1337-38.

28. 37 C.F.R. § 1.56.

29. *See* Digital Control Inc. v. Charles Machine Works, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006) (adopting the 1984 test in *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984), and *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008)).

30. *See* Duffy, *supra* note 21, at footnote 23.

### C. Underlying Policy Considerations

Numerous policy considerations underlie any approach to inequitable conduct.

#### 1. Preventing Fraud

As often observed, the inequitable conduct defense is driven by the principle that “[t]he ‘far-reaching social and economic consequences of a patent’ give the public a strong incentive to ensure that patents come from ‘backgrounds free from fraud or other inequitable conduct.’”<sup>31</sup> Certainly, patentees should not be permitted to acquire patents or enforce them through common law fraud, as already acknowledged by the Supreme Court.<sup>32</sup> The penalties for inequitable conduct serve as a deterrent to dishonest conduct before the PTO,<sup>33</sup> as they currently include the risk that an entire patent, and even members of its family, may be held unenforceable.<sup>34</sup> However, there is an attendant risk that applicants and their counsel will be overly conservative and will flood the Examiner with prior art that is cumulative or marginally relevant.<sup>35</sup>

#### 2. Ensuring Quality Patents

The full and open disclosure of information to the PTO by applicants is essential to ensuring that the Examiner has all relevant information available at the time of examination,<sup>36</sup> and can enhance the quality of the granted patents.<sup>37</sup> A concern for the quality of issued

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31. Nicole M. Murphy, *Inequitable Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?*, 93 MINN. L. REV. 2274, 2285 (2010).

32. See *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 819 (1945); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944).

33. Melissa Wasserman, *Limiting the Inequitable Conduct Defense*, 13 VA. J.L. & TECH. 7, 9 (2008).

34. Mammen, *supra* note 24, at 1347-48.

35. Christopher Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 770-72 (2009).

36. Wasserman, *supra* note 33, at 10-11; see also the AMERICAN CHAMBER OF COMMERCE, RECOMMENDATIONS FOR CONSIDERATION BY THE INCOMING ADMINISTRATION REGARDING THE U.S. PATENT AND TRADEMARK OFFICE 6, (2009) (“The current duty to disclose material information to the PTO under 37 CFR 1.56 should be reemphasized without creating new requirements on applicants. The highest quality examination and the strongest patent protection occur when the PTO has all material information at the time patentability decisions are made. The applicant’s disclosure of known material information is critical to a high-quality examination process.”).

37. Cotropia, *supra* note 35, at 748-62.

patents comes from a broad spectrum of the public.<sup>38</sup> However, over-compliance by applicants and their attorneys, caused by the fear of violating the inequitable conduct doctrine, can result in reduced patent quality.<sup>39</sup>

### 3. Reducing Prosecution and Litigation Costs

The courts have recognized the continuing role of inequitable conduct as a “plague” on patent litigation, creating burdens for the parties and the judicial system, for more than two decades.<sup>40</sup> Moreover, a study by the National Academy of Sciences (NAS) in 2003 concluded that the then current rate for assertion of the inequitable conduct defense by defendants was excessive and resulted in high litigation costs and called for the removal of subjective elements in the patent law, for example, those related to inequitable conduct.<sup>41</sup> It was observed that the high cost to comply with enhanced disclosure requirements (e.g., the previously proposed disclosure requirements in the form of Examination Support Documents under the now withdrawn “claiming rules”) are likely to preclude independent inventors and SME’s from protecting their ideas.<sup>42</sup> A report of the Federal Trade Commission based on hearings held in the early part of the twenty-first century, observed that the “concern that mandatory statements of relevance could give rise to dubious allegations is well taken.”<sup>43</sup>

### 4. Avoiding Excessive Punishment, Particularly to Innocent Patent Owners

In contrast to concern for the public or potential competitors of the patentee who are disadvantaged by a patent that granted on the basis of

38. See Lisa Dolak, *Inequitable Conduct: A Flawed Doctrine worth Saving*, presented at panel *Inequitable Conduct: What Standard? What Evidence?* (Sept. 23, 2008) (unpublished manuscript), available at [http://works.bepress.com/lisa\\_dolak/5](http://works.bepress.com/lisa_dolak/5).

39. Cotropia, *supra* note 35, at 762-73.

40. *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting); see data published in Mammen, *supra* note 24, at 19-27.

41. NATIONAL ACADEMY OF SCIENCES, *A PATENT SYSTEM FOR THE 21ST CENTURY* 121-23 (Stephen A. Merrill et al. eds., 2004).

42. Cotropia, *supra* note 35, at 774 (“The duties under the doctrine should not be expanded to include a duty to search or provide relevancy statements. Such duties are likely to overload the examiner, price inventors out of the patent system, shift the burdens of examination away from a low cost provider, and destroy the benefits of independent review.”).

43. See FEDERAL TRADE COMMISSION, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY*, ch.5, p.13 (2003) available at [www.ftc.gov/os/2003/10/innovatorpt.pdf](http://www.ftc.gov/os/2003/10/innovatorpt.pdf).



some measure of inequitable conduct, there also is concern for the innocent or even negligent participant who makes a mistake in submitting misleading or incorrect information to the PTO. The concern is amplified in the case where the patent owner is a bona fide purchaser of the patent and had no knowledge of the alleged improper conduct.

## II. THE LEGISLATIVE AGENDA

Given the lack of consistency and clarity with which the doctrine of inequitable conduct has been addressed by the courts in the past twenty years and on the basis of the recommendations in the reports of the National Academy of Sciences and the Federal Trade Commission, the United States Congress has included inequitable conduct provisions in the several Patent Reform Bills that have been introduced during the past six Congressional sessions.<sup>44</sup> As noted by Christian Mammen in his recent article, the bills have provisions that fall into four broad categories:

- (1) specifying the prima facie elements of inequitable conduct, specifically materiality and intent; (2) specifying the standard of pleading or proof in litigation in the courts; (3) changing the range of remedies available in the courts; and (4) providing a forum within the PTO (rather than the courts) for adjudication of inequitable conduct allegations.<sup>45</sup>

The manner in which each of these categories of provisions would be implemented is discussed subsequently with reference to selected provisions of the introduced bills and proposed alternatives, which have been raised that had been raised.

Notably, in the 109th Congress, the Honorable Lamar Smith introduced H.R. 2795, which included in its section 5 a significant treatment of inequitable conduct issues, including: (1) referral of inequitable conduct investigations to the PTO; (2) codification of the duty of candor for applicants and attorneys; (3) establishment of civil sanctions for inequitable conduct; (4) the provision of a “but for” threshold before a patent can be held unenforceable; and (5) the

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44. American Intellectual Property Law Association Reports, Aug. 7, 2007 (reporting that “AIPLA was among the first to develop concrete patent reform proposals more than three years ago in responses to Federal Trade Commission and National Academies of Sciences reports on the patent system. Those proposals focused on . . . litigation reforms as to willful infringement and inequitable conduct”).

45. Mammen, *supra* note 24, at 1378.

application of the standard to parties adverse to a patent.<sup>46</sup> The corresponding Senate Bill S. 3818 simply proposed to amend current § 282 by adding unenforceability as a defense in patent litigation, establishing a statutory basis for a court finding a patent unenforceable if materiality and intent are proven by clear and convincing evidence, precluding unenforceability if at least one claim is not invalid, and provided for an exemption if there was a good faith employed.<sup>47</sup> The Senate Bill specifically provided that intent may not be based solely on gross negligence or on the materiality of the information misrepresented or not disclosed.<sup>48</sup> The original provisions regarding inequitable conduct in the House Bill were significantly altered during markup, primarily by deleting significant civil penalties. Both bills refer to intentional deception rather than relying on “knowing and willful deception.”<sup>49</sup> Nonetheless, despite the submission of various alternatives by stakeholders, neither bill was passed by the corresponding legislative body.<sup>50</sup>

In the 110th Congress, there was no treatment of inequitable conduct in the originally introduced House legislation (H.R. 1908),<sup>51</sup> but the bill as passed by the House did contain substantive provisions.<sup>52</sup> Similarly, the Senate Bill (S. 1145) originally did not contain any provisions for inequitable conduct,<sup>53</sup> but the bill as passed by the Judiciary Committee and reported to the Senate did include certain limited provision, including a provision that defined “materiality” on the basis of the “reasonable examiner” standard and precluded an “intent to deceive the Office” from being based solely on gross negligence or “the

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46. Patent Act of 2005, H.R. 2795, 109th Cong. § 5 (2005). As originally presented, H.R. 2795 would have changed the duty of candor and unenforceability; established a PTO group to determine inequitable conduct where there was no common law “fraud,” and take away most court jurisdiction over inequitable conduct but permit civil penalties up to \$5M for violations.

47. Patent Reform Act of 2006, S. 3818, 109th Cong. § 5(c) (2006).

48. *Id.*

49. H.R. 2795, § 5(a); S. 3818, § 5(c)(2); AIPLA Reports, *supra* note 44 (AIPLA advocated that, unlike the broader standard adopted in the drafts, unenforceability should depend on a court finding that at least one of the asserted claims should not have issued in view of the false or withheld information).

50. H.R. 2795, § 5, available at <http://www.govtrack.us/congress/bill.xpd?bill=h109-2795>; S. 3818, §5(c), available at <http://www.govtrack.us/congress/bill.xpd?bill=s109-3818>.

51. See Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 12 (as introduced in the House, Apr. 18, 2007).

52. *Id.* (as passed by the United States House of Representatives, Sept. 7, 2007).

53. See Patent Reform Act of 2007, S. 1145, 110th Congress (as introduced in the United States Senate, Apr. 18, 2007).

materiality of the information misrepresented or not disclosed.”<sup>54</sup> It also required that inequitable conduct be pled with particularity, but did not preclude such pleading until after a first judgment of invalidity of a claim is obtained.<sup>55</sup> Finally, it established specific remedies that a court could apply in its discretion.<sup>56</sup> Subsequently, additional proposed amendments to the Senate draft also provided for the elimination of inequitable conduct as a basis for invalidity or unenforceability and established a reissue process to purge the effects of any misconduct.<sup>57</sup> In addition, an alternative piece of legislation introduced by Senator Kyl (S. 3600) did address inequitable conduct and proposed shifting the issue from civil litigation to an administrative proceeding before the PTO, while also requiring patentees to go to the PTO: (1) to have the patent reissued in order to remove invalid claims; (2) assess the culpability of the applicant’s conduct; and (3) impose sanctions on any parties that have engaged in inequitable or fraudulent conduct.<sup>58</sup> However, in neither case did a bill get passed by the Senate before the 110th Congress ended.<sup>59</sup>

Now, in the 111th Congress, neither the original House Bill (H.R. 1260) nor the original Senate Bill (S. 515) contained any provisions dealing with inequitable conduct.<sup>60</sup> However, inequitable conduct

54. *Id.* § 12 (as passed by S. Comm. On the Judiciary, Jan. 24, 2008); Mammen, *supra* note 24, at 1379 (noting that three concerns prompted inclusion of provisions providing a clear standard of materiality, a separation of intent from materiality and the provision of discretion to a court to select a remedy).

55. S. 1145, § 12 (as reported by S. Comm. on the Judiciary, Jan. 24, 2008).

56. *Id.*

57. The proposal to limit inequitable conduct was accompanied by proposals to require the filing of an Applicant Quality Submission (AQS) that would identify material information and explain how the information is relevant to the claimed invention. S. 1145, § 11 (as reported by S. Comm. On the Judiciary, Jan. 24, 2008, proposing that patent applicants submit a search report and analysis to patentability); *see also* AMERICAN BAR ASSOCIATION SECTION OF INTELLECTUAL PROPERTY LAW, REPORT TO HOUSE DELEGATES RECOMMENDATION 107A, *available at* [http://www.abanet.org/leadership/2009/annual/summary\\_of\\_recommendations/One\\_Hundred\\_Seven\\_A.doc](http://www.abanet.org/leadership/2009/annual/summary_of_recommendations/One_Hundred_Seven_A.doc).

58. Patent Reform Act of 2008, S. 3600, 110th Cong. § 11 (2008).

59. Patent Reform Act of 2007, S. 1145, 110th Cong. (2007), *available at* <http://www.govtrack.us/congress/bill.xpd?bill=s110-1145>; Patent Reform Act of 2008, S. 3600, 110th Cong. § 11 (2008), <http://www.govtrack.us/congress/bill.xpd?bill=s110-3600>.

60. Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009); Patent Reform Act of 2009, S. 515, 111th Cong. (as introduced in the Senate, March 3, 2009). Interestingly, Senator Hatch’s press release of March 3, 2009, advising of the introduction of S. 515 as a jointly sponsored bill of Senator’s Hatch (R) and Leahy (D), acknowledging that “we cannot settle for mere codification of current practices,” and calling for a “more objective and clearer inequitable-conduct standard [that] will remove the uncertainty and confusion that defines current patent litigation” stated,

[I]f we are serious about enacting comprehensive patent law reform, then we must take steps to ensure that the inequitable-conduct doctrine is applied in a manner

remained a critical issue in the ongoing discussions of the Patent Reform Bills H.R. 1260 and S. 515, with Senator Orrin Hatch maintaining strong support for legislation focused on inequitable conduct issues. A separate bill (S. 610), introduced by Senator Kyl, included substantial provisions regarding inequitable conduct, although they differ somewhat from Senator Kyl's proposals in S. 3600 during the 110th Congress.<sup>61</sup> S. 610 precludes invalidity or unenforceability on the basis of misconduct before the Office (except for criminal or antitrust violations), and gives the PTO power to conduct investigations and levy civil sanctions for violations.<sup>62</sup>

A "Manager's Amendment" to S. 515<sup>63</sup> was released to the public on March 4, 2010 as a bill supported on both sides of the aisle and includes provisions regarding inequitable conduct<sup>64</sup> that are an amalgam of the recent proposals made in the Senate. If taken up and passed by the Senate, the inequitable conduct provisions in S. 515 still would face review and possible modification in the House of Representatives, particularly based on input by Judiciary Committee Chair John Conyers (D) and Representative Lamar Smith (R). Any resulting legislation could address one or more of the several issues relevant to inequitable conduct reform.

#### A. *Defining Materiality and Intent*

Motivated, at least by the constantly varying standards of intent and materiality in the courts, there have been various proposals in Congress to establish objective definitions of "materiality" and "intent." Congress

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consistent with its original purpose: to sanction true misconduct and to do so in a proportional and fair manner. Inequitable-conduct reform is core to this bill, as it dictates how patents are prosecuted years before litigation. The inequitable conduct defense is frequently pled, rarely proven, and always drives up the cost of litigation tremendously.

"Senators Hatch, Leahy Introduce Patent Reform Act of 2009," *available at* [http://hatch.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease\\_id=ce28c6f0-1b78-be3e-e028-418ea18126e5](http://hatch.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=ce28c6f0-1b78-be3e-e028-418ea18126e5). However, the Bill reported out by the Senate Judiciary Committee at that time had no provisions for inequitable conduct. Patent Reform Act of 2009, S. 515, 111th Congress (as reported by the S. Comm. on the Judiciary, Apr. 2, 2009). The recent Manager's Amendment to S. 515 filled that gap. *See* Patent Reform Act of 2010, S. 515, "Amendment in the Nature of a Substitute," 111th Cong. § 10 (2010), *available at* <http://judiciary.senate.gov/legislation/upload/PatentReformAmendment.pdf>.

61. Patent Reform Act of 2009, S. 610, 111th Cong. § 11 (2009).

62. *Id.*

63. Patent Reform Act of 2010, S. 515, "Amendment in the Nature of a Substitute," 111th Cong. (2010), *available at* <http://judiciary.senate.gov/legislation/upload/PatentReformAmendment.pdf>.

64. *See id.* § 10, "Supplemental Examination."

has the power to and certain members in both in the House and Senate appear to have the inclination to, statutorily define “materiality” and “intent.”

### 1. Materiality

The provision governing inequitable conduct in the recent Manager’s Amendment to S. 515 does not attempt to define “materiality,” perhaps because it is not relevant to the protocol established for “purging” most bases for inequitable conduct.<sup>65</sup> However, should such provision be added in the House, the Leahy approach to defining “materiality” of information on the basis of a “reasonable examiner” standard (important to a reasonable examiner in deciding whether to allow the patent application) or the House standard (reasonable examiner would have made a prima facie finding of unpatentability) may have the best chance of being adopted. A more objective standard that is based upon a patent claim actually being held invalid on the basis of the misrepresentation or non-disclosure of that information, as proposed in the Kyl draft of S. 3600, is less likely to be adopted.

### 2. Intent

As with materiality, the Manager’s Amendment does not include any provisions that legislatively define the “intent” factor of inequitable conduct because intent would not be relevant to the purging protocol that is established.<sup>66</sup> Nonetheless, should the House attempt to modify the Senate’s approach, the resulting provision may be based upon an intent that can be inferred, but cannot be based solely on the gross negligence of the patent owner or on the materiality of the information misrepresented or not disclosed. More than likely, any circumstantial evidence of intent would have to show a “conscious or deliberate behavior” in not disclosing material information or submitting false information.

### *B. Specifying Standard of Proof/Pleading*

The existing standard of “clear and convincing evidence” is not addressed in the Manager’s Amendment and is likely to be preserved in

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65. *See id.*

66. *See id.*

any legislation regarding the assertion of inequitable conduct as a defense under 35 U.S.C. § 282.<sup>67</sup>

In contrast to the Leahy bills from the 110th Congress, which provided that the defense or claim of inequitable conduct must be pled with particularity as required by Federal Rule of Civil Procedure (FRCP) 9(b), the Manager's Amendment does not address the requirements for pleading at all.<sup>68</sup> When considered by the House, it is possible that provisions could be added that restrict the time for pleading inequitable conduct to a period after a court has found one or more claims invalid, as previously provided in S. 3818 and H.R. 2795.<sup>69</sup> In any event, since a "but for" standard did not find universal support and was opposed based on it diluting the valuable role that inequitable conduct plays in discouraging fraud, it is not likely to be included in any final legislation.<sup>70</sup>

### C. *Changing the Range of Remedies*

H.R. 1908, as passed by the House in the 110th Congress, would have required a court to balance the equities and impose remedies including: (1) denying any equitable relief, limiting the remedy for infringement to a reasonable royalty; (2) holding the claims in suit or the claims affected by the inequitable conduct unenforceable; (3) holding the entire patent unenforceable, and/or holding the claims of a related patent unenforceable.<sup>71</sup>

However, even these remedies may be viewed as too harsh, especially for an innocent bona fide purchaser. Accordingly, the Manager's Amendment uses the ex parte reexamination process under 35 U.S.C. § 302 et seq. as a vehicle for purging or curing any improper conduct.<sup>72</sup> This approach, coupled with the possibility of intervening

67. *See id.*

68. *See id.*

69. *See* Patent Act of 2005, H.R. 2795, 109th Cong. § 5(a) (2005); *see also* Patent Reform Act of 2006, S. 3818, 109th Congress, § 5(c)(2) (2006).

70. *See* Letter from Harry Manbeck to Senators Leahy and Specter (Mar. 10, 2008), [http://www.patenthawk.com/blog\\_docs/080310\\_Manbeck\\_letter\\_re\\_inequitable\\_conduct.pdf](http://www.patenthawk.com/blog_docs/080310_Manbeck_letter_re_inequitable_conduct.pdf) ("I believe that the inequitable conduct doctrine should not be changed by legislation so that sanctions for misconduct are ruled out just because the patent claims in question are found to be valid.")

71. Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 12 (as passed by the House, Sept. 7, 2007).

72. Patent Reform Act of 2010, S. 515, "Amendment in the Nature of a Substitute," § 10; 111th Cong. (2010), *available at* <http://judiciary.senate.gov/legislation/upload/PatentReformAmendment.pdf>. Reissue under 35 USC § 251 had been considered as a candidate for a purging protocol; however, reissue requires a

rights under 35 U.S.C. § 252, appears to be preferred, although it still has limitations that may lead to inefficiencies and inequities and does not punish truly fraudulent behavior.

While the use of “minimum guidelines,” coupled with specified judicial discretion, has been proposed as a preferred approach that can consider the broad spectrum of conduct,<sup>73</sup> it has not been adopted in the Manager’s Amendment. It was rejected because the purging protocol would remove most bases for the inequitable conduct defense in court or before the International Trade Commission in a § 337 proceeding.

#### *D. Making the PTO the Forum for Investigation and/or Remedy*

Proposals to have the PTO conduct investigations of inequitable conduct have been met with skepticism, resulting from the financial, cultural and resource limitations in the PTO that previously led to the abandonment of the “fraud squad” in the late 1980’s.<sup>74</sup> Indeed, the use of the PTO to investigate inequitable conduct, as proposed in S. 3818, was quickly abandoned during the 109th Congress, and it appears that the proposals for USPTO investigations in the Kyl Bill (S. 610) were removed in the compromises that led to the Manager’s Amendment.<sup>75</sup>

Clearly, the Manager’s Amendment proposals to have the UPTO review the claims of a patent through reexamination, so that the withheld or correct information or prior art can be considered, has the most appeal, although in not all quarters.<sup>76</sup>

### III. FUTURE PROSPECTS

In legislatively addressing the “plague” of inequitable conduct charges routinely made in patent litigation and the perceived imbalance of extreme punishment to minor offense or honest mistake that often is alleged, while establishing incentives for full and honest communications with the PTO during the prosecution of patent applications, the Congress faces a broad spectrum of solutions.

At one end of the spectrum is the status quo, with the Congress doing nothing or, perhaps, simply legislating broad definitions of intent (negligence) and materiality (reasonable examiner) that reflect some

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showing of “error without deceptive intention,” and may have been viewed as too limited in scope for effectively purging inequitable conduct. 35 U.S.C. § 251 (1999) (discussing the reissue statute).

73. Murphy, *supra* note 31, at 2296-2302.

74. Manbeck, *supra* note 26, at 139-40.

75. See Patent Reform Act of 2009, S. 610, 111th Cong. § 11 (2009).

76. Murphy, *supra* note 31, at 2293-96.

recent judicial holdings. At the opposite end of the spectrum is the simple elimination of any punishment for inequitable conduct that is short of common law fraud.<sup>77</sup> A protocol for purging the basis for inequitable conduct, coupled with the elimination of most sanctions for inequitable conduct, appears to have the greatest support, despite a public policy in favor of some form of sanction as a deterrent.

#### A. *The Manager's Amendment*

The Manager's Amendment adds a new § 257 that provides for supplemental examinations, at the request of a patent owner, "to consider, reconsider or correct information believed to be relevant to the patent."<sup>78</sup> If information presented in the request raises "a substantial new question of patentability," the Director shall order *ex parte* reexamination of the patent under the existing provisions of 35 U.S.C. § 302 *et seq.* on "each substantial new question of patentability identified during the supplemental examination."<sup>79</sup> A key exception is that the reexamination will not be limited to patents and printed publications, thus permitting the examination of issues based on improper small entity claims and erroneous declarations.<sup>80</sup> Third parties would not be permitted to participate, but presumably could submit additional art or institute parallel *ex parte* or *inter partes* reexamination proceedings that could be merged.<sup>81</sup>

The effect of a completed reexamination, assuming that original or amended claims remain, is that the patent "shall not be held unenforceable under § 282 on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent."<sup>82</sup> In effect, this provision would permit a patent owner, whether or not involved in the original conduct that resulted submitted incomplete or erroneous information before the USPTO, to purge the basis for a claim of inequitable conduct. In fact, it

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77. See Wasserman, *supra* note 33, at 16 (advocating a two-tier system of remedies).

78. Patent Reform Act of 2010, S. 515, 111th Cong., § 10 (2010), *available at* <http://judiciary.senate.gov/legislation/upload/PatentReformAmendment.pdf>.

79. *Id.*

80. *Id.* Another exception is that the patent owner will not have the right to file a statement under § 304. *Id.*

81. *Id.*

82. *Id.* The statute would expressly provide that the making of the request or the absence of such request "shall not be relevant to enforceability of the patent under section 282." *Id.*



would preclude any defense of inequitable conduct should the purge occur.

There are exceptions to such preclusion where allegations of inequitable conduct are made in an answer to a complaint or in a complaint for declaratory judgment, prior to the request for supplemental examination.<sup>83</sup> In addition, sanctions based on criminal or antitrust laws are not precluded nor are investigations by the Director of the USPTO of misconduct in proceedings before the USPTO.<sup>84</sup>

The Manager's Amendment did not answer issues related to the effect of a purge where the resubmitted or newly submitted information is itself incomplete or allegedly erroneous.<sup>85</sup> Discovery, as to these issues, is certain to maintain a prominent role in the strategy for any accused infringer. Thus, the specter of the "plague" appears to remain, although, at a lower level. Further, the true effect of the purge protocol as a deterrent or as an invitation to dishonesty before the USPTO would require years to identify.

A more modest proposal that recognizes the complex factual situations that arise would grant the courts greater leeway in fashioning equitable relief, in such a manner that is appropriate for the proven degree of materiality and intent.<sup>86</sup> Such relief may be temporary or permanent. Also, it may reach one or more claims and one or more patents. Other proposals for reform also would take an equitable approach but would give greater weight to reducing over-compliance, and would tie the legal remedy with the harm that non-disclosure does to patent quality, thereby minimizing the remedies for failure to comply with the duty of disclosure.<sup>87</sup>

Whatever solution Congress fashions, the choice may not be driven solely by the desire for higher quality patents, but also may be shaped by broader public policies.

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83. *Id.*

84. *Id.*

85. *See id.*

86. *See* Murphy, *supra* note 31, at 2297 (advocating minimum guidelines coupled with judicial discretion for three categories of misconduct: (1) that related to patentability and unenforceable claims; (2) that unrelated to patentability; and (3) that demonstrating egregious intent to deceive); *see also* Dolak, *supra* note 38, at 11.

87. Cotropia, *supra* note 35, at 774-75.