BY DOROTHY AUTH AND JASON M. ROCKMAN

AS EARLY AS the 1930s, the U.S. Supreme Court recognized that there must be some severe consequence where a patent applicant deliberately violated its duty of candor and good faith to the U.S. Patent and Trademark Office (PTO) in submitting information to gain allowance of a patent.1

The Supreme Court borrowed principles from common law fraud in deciding how to deal with such conduct,2 specifically, ruling that the resulting patent was unenforceable if there were proof that the patent applicant made material misrepresentations or omissions with specific intent to deceive the patent examiner; and the PTO relied upon those actions in determining to allow the patent application.3

Over the years, this standard has evolved to the point where common law fraud need no longer be proved to establish patent unenforceability.4

The Supreme Court officially accepted a “gross negligence” standard, the concept of misleading statements/conduct, detriment of reliance, injury and intent were critical elements.7 The Court did not define “material misrepresentation,” but did recognize the difference between a misrepresentation that had an “immediate and necessary relation to the equity” of patent unenforceability, as opposed to one where the conduct did not relate to allowability of a patent.8

For example, in Keystone, a party was given “valuable consideration” by a patent owner in exchange for suppressing evidence of prior use that potentially invalidated the patent.9 The party misrepresented, e.g., that the prior use was an “abandoned experiment.”10

The Court held that the patent owner’s conduct amounted to “unclean hands” and therefore the patent owner could not seek relief at equity for patent infringement.11 The other two early Supreme Court cases similarly emphasize that a party who has committed a fraud on the Patent Office, which the PTO has relied upon, can not come to the court seeking enforcement of its patent.12

The current Federal Circuit materiality-intent-balancing test for inequitable conduct allows for a lessened showing of either materiality or intent based on a stronger showing of the other, the court has consistently held that “materiality does not presume intent, which is a separate and essential component of inequitable conduct.”13 Nor does the Federal Circuit accept a “gross negligence” approach, whereby an applicant should have known from the materiality of a reference that it required disclosure.14

Because direct evidence of an intent to deceive is rare,15 “intent to deceive” is often based on the totality of the circumstances, including circumstantial evidence.16 “Further, 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 to meet the clear and convincing standard.”17 Thus, “[o]nly after adequate showings are made as to both materiality and deceptive intent may the district court look to the equities by weighing the facts underlying those showings.”18

The Supreme Court first approached inequitable conduct in a trilogy of cases, using principles borrowed from common law fraud where the concepts of misleading statements/conduct, detrimental reliance, injury and intent were critical elements.7 The Court did not define “material misrepresentation,” but did recognize the difference between a misrepresentation that had an “immediate and necessary relation to the equity” of patent unenforceability, as opposed to one where the conduct did not relate to allowability of a patent.8

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The current Federal Circuit materiality-intent-balancing test for inequitable conduct does not expressly include elements of reliance or specific intent.13 The current standard requires that 1) a patentee misrepresented or withheld “material” information known to the applicant; and 2) the misrepresentation/omission was the result of an “intent to deceive” the PTO.14 “The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent.”15

The “materiality” prong of the test is currently judged, inter alia, under the “[what would be] important to a reasonable examiner” standard.16

The Federal Circuit has indicated that several other standards for judging materiality may be applied, including the 37 C.F.R. §1.56(b) (“Rule 56”) definition of materiality, and:

...[1] the objective “but for” standard, where the misrepresentation was so material that the patent should not have issued; [2] the subjective “but for” test, where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; and [3] the “but it may have” standard, where the misrepresentation may have influenced the patent examiner in the course of prosecution.17

The Federal Circuit has repeatedly held that in each case where a new criterion of materiality is expressed, it “does not supplant or replace [Federal Circuit] case law. Rather, it merely provides an additional test of materiality.”18

Although the current Federal Circuit “balancing test” for inequitable conduct allows for a lessened showing of either materiality or intent based on a stronger showing of the other, the court has consistently held that “materiality does not presume intent, which is a separate and essential component of inequitable conduct.”13 Nor does the Federal Circuit officially accept a “gross negligence” approach, whereby an applicant should have known from the materiality of a reference that it required disclosure.14

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The district court found inequitable conduct based on its determination that the EPO statements were material, because:
1) the statements were directed to the same portion of the '382/EP'636 patents, i.e., the "optional[, but preferable]" language;  
2) in both cases patentability depended on proper interpretation of that language; and,  
3) the statements made to the PTO directly contradicted the applicant’s statements to the EPO.31

In reaching this holding, the district court relied on the Rule 56 definition of material information, requiring disclosure of information that "refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of patentability relied on by the Office, or (ii) Asserting an argument of patentability."32 An intent to deceive was found based on evidence that: (1) Abbott authorities discussed the statements, and (2) affirmatively decided not to disclose the statements, knowing that the same issue with a contrary interpretation was being debated in the '551 patent’s examination.33

As early as the 1930s, the U.S. Supreme Court recognized that there must be some severe consequence where a patent applicant deliberately violated its duty of candor and good faith to the patent office in submitting information to gain allowance of a patent.34

The district court concluded, “[i]f concealment of extrinsic information as close to the heart of the prosecution as was involved here is allowed to pass, then we would in effect be issuing licenses to deceive patent examiners in virtually all cases,” suggesting that the weight of the balancing test here was on materiality.35 The Federal Circuit affirmed the district court’s decision, stating that “[t]his is one of those rare cases in which a finding of inequitable conduct is appropriate, particularly in light of the critical nature of the representations to the PTO,” again focusing on materiality.36

The Pending Rehearing En Banc

Abbott moved for a rehearing en banc, which the Federal Circuit granted.37 The Circuit’s affirmation was vacated and the parties have been asked to brief the following questions:
1) whether the materiality-intent-balancing framework should be modified/replaced;  
2) whether the replacement standard should be tied to fraud/unclean hands;  
3) whether materiality of a reference should be judged by PTO standards or whether the proper standard for materiality requires that one or more claims of the patent would not have issued but for the alleged misconduct;  
4) whether intent may be inferred from materiality and when;  
5) whether the balancing inquiry should be abandoned; and  
6) whether standards in other areas of law inform the materiality/intent standard.38

In its brief, plaintiff-appellant Abbott argues the district court’s finding of inequitable conduct in TheraSense is a resurrection of the “gross-negligence” test for determining intent, which the Federal Circuit previously rejected, because the holding allegedly infers intent based on a standard whereby Abbott “should have known” that such material comments required disclosure.39 Abbott argues the current standard is clarification, because a “should have known” standard conflicts with Star Scientific’s holding that requires an “intent to deceive” to be shown to be the most reasonable inference under the circumstances.39

Abbott cites Judge Richard Linn’s “vigorous dissent,” particularly with respect to the intent prong, as illustrative of the plausible good-faith inferences that existed and demonstrated that Abbott did not intend to deceive the PTO.40

Defendants/Appellees Becton, Dickinson, et al., on the other hand, argue that the current standard is clear, citing the district court’s opinion as proof that clear and convincing findings on the issue of intent can be articulated.41 BD argues that “[i]f ever a case clearly and convincingly compelled a finding of inequitable conduct under the highest standard dictated by this Court, it would be this one,”42 and concludes that there is no reason to revisit inequitable conduct standards under the facts of TheraSense.43

Amici Argue for Some Reform

Several amici curiae have filed briefs in this case, all of which advocate some reform to the standard for determining inequitable conduct. Interestingly, the amicus brief submitted by the American Bar Association proposes a modified standard for determining inequitable conduct.

Under the ABA’s approach, parties alleging inequitable conduct would need to show (1) a person having a duty of candor and good faith misrepresented or omitted material information
from the PTO; (2) in the absence of such misrepresentations or omissions the PTO would not have granted at least one patent claim; and, (3) the misrepresentation was made with specific intent to deceive the PTO.54

The ABA proposal emphasizes that intent cannot be based on materiality, so that materiality and reliance proceed under a “but for” standard.45 The ABA’s proposal also ties materiality and reliance to the patentability of specific claims.56

The ABA asserts that the benefit achieved from requiring a showing that the PTO relied on an applicant’s misrepresentations to issue specific claims is that it avoids rendering a patent unenforceable where a “patentee only committed minor missteps” that may not directly correlate to the patentability of any claims at issue.47 Further, the ABA’s approach would realign the intent element with the more stringent fraud standard originally structured by the U.S. Supreme Court.48

According to the ABA, its approach will stop “the circular overemphasis on materiality that has expanded inequitable conduct doctrine far beyond those instances where the applicant truly acted with fraudulent intent.”49 This theme is also found in the amicus brief of the Washington Legal Foundation (WLF), which advocates clarification of the materiality prong of the current inequitable conduct standard.50

In the WLF’s view, the current materiality standards are mere generalized statements, i.e., little more than an ‘I know it when I see it’ rule.51 To make its point, the WLF highlights the apparent disparity between the TheraSense decision and precedent in Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1378-79 (Fed. Cir. 2008), where the Federal Circuit held that foreign arguments regarding patentability were not material to U.S. examination.52 In contrast, the opinion in TheraSense held that the EPO statements were material to the ’551 patent examination.53 The WLF recommends a bright-line rule that only factual information, as opposed to lawyer argument, be considered “material” information for purposes of inequitable conduct.54

Other briefs discuss the current inconsistency in the standards for materiality and intent. For example, Nine Law Professors filed an amicus brief advocating reform to the standard as it relates to intent. They argue that two inconsistent lines of precedent exist on the intent issue: one holding that “gross negligence” cannot prove intent, the other holding that intent can be established where the applicant “should have known” of the materiality of withheld information.55 The Nine Law Professors assert that the court in TheraSense applied the gross negligence standard and clarification is needed as to which standard is proper.56

Another brief, filed by the International Intellectual Property Institute and its chairman and president, Bruce A. Lehman, explains how the current inequitable conduct standard compels practitioners to disclose voluminous amounts of information that they may truly feel is irrelevant or cumulative to the information already before the examiner, just to safeguard against a future judge who may disagree with their determination regarding materiality.57 Practitioners are worried, according to the Lehman brief, that despite their good faith efforts, intent to deceive may be found in later litigation, potentially leading to malpractice claims.58

The Lehman brief posits that this results in a “dump” of information on the PTO, exacerbating the existing problems of understaffing and application backlogs.59 Practitioners are closely watching TheraSense, particularly because the inequitable conduct defense is currently widely applied in patent infringement litigation, to see how the Federal Circuit will respond. If the amicus briefs are indicative, changes to the standard are likely, and such changes will surely affect both how patents are procured as well as how they are litigated. Patent practitioners are well advised to keep an eye out for the Federal Circuit’s en banc decision in the TheraSense case.

3. See, e.g., Hazel-Atlas, 322 U.S. at 241-244, 250.
10. Id. at 243.
11. Id. at 245-247.
13. See Agfa, 451 F.3d at 1375 n.3.
14. See McKesson, 487 F.3d at 913 (quotations omitted).
15. Id. (quotations omitted).
17. Digital Control, 437 F.3d at 1315.
18. Digital Control, 437 F.3d at 1316.
21. Digital Control, 437 F.3d at 1317.
22. See Star Scientific, 537 F.3d at 1366.
23. Id.
24. Id. at 1367 (emphasis supplied).
26. See id. at 1105.
27. Id. at 1105.
28. Id.
29. See id.
30. Id. at 1116.
31. Id. at 1112-13 (citing 37 C.F.R. §1.56(b)(2)).
32. Id. at 1111, 1113.
33. See id. at 1113.
34. Id. at 1114-15.
35. TheraSense, 993 F.2d at 1300.
37. Id.
39. Id. at pp. 7-8.
40. Id. at p. 2.
41. TheraSense, Becton, Dickinson and Company and Nova Biomedical Corp.’s Response to Abbott’s Petition for Rehearing En Banc, pp. 6-11 (Mar. 18, 2010); TheraSense, Bayer’s Response to Abbott’s Petition for Rehearing En Banc, pp. 49 (March 19, 2010).
42. TheraSense, BD Response Brief, p. 1 (March 18, 2010).
43. Id. at pp. 14-15.
44. TheraSense, Brief and Appendix of the American Bar Association as Amicus Curiae, p. 1 (June 17, 2010) at pp. 16-18.
45. Id.
46. Id. at p. 16, fn.5.
47. Id. at pp. 16-17.
48. Id. at pp. 18-19.
49. Id. at p. 8.
50. See TheraSense, Brief of Washington Legal Foundation as Amicus Curiae in Support of Plaintiff-Appellants’ Petition for Rehearing En Banc, p. 7 (March 10, 2010).
51. Id. at pp. 8-9.
52. Id. at p. 6.
53. Id. at pp. 6-7.
54. Id. at p. 10.
56. See id. at pp. 6-7.
57. TheraSense, Brief of Amici Curiae Bruce A. Lehman and the International Intellectual Property Institute in Support of Plaintiff-Appellants’ petition for Rehearing En Banc, pp. 5-6 (March 10, 2010).
58. See id. at pp. 4-7.
59. Id. at pp. 3, 4, 6, 7-8.

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