New York Law Journal

A NEW YORK LAW JOURNAL SPECIAL SECTION

An ALM Publication

Litigation

WWW.NYLJ.COM

MONDAY, AUGUST 16, 2010

Federal Circuit Considers 'Inequitable Conduct' En Banc

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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 would be unenforceable if there were proof that the patent applicant made material misrepresentations or omissions with specific intent to deceive the PTO, and that the PTO relied on 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 Court of Appeals for the Federal Circuit now applies an inequitable conduct standard, known as the materiality-intent-balancing test, in determining whether a patent is unenforceable.[5]

The evolution of the inequitable conduct standard, along with varying definitions of materiality, has now prompted the Federal Circuit to grant a request for en banc review of the inequitable conduct standard as a whole.[6] This article will consider the current state of this standard and particular issues being addressed by the Federal Circuit in the *TheraSense* case.

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]

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 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."[19] 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.[20]

Because direct evidence of an intent to deceive is rare,[21] "intent to deceive" is often based on the totality of the circumstances, including circumstantial evidence.[22] "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."[23] 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."[24]

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'TheraSense' Raises the Issue

In a current case, *TheraSense Inc. v. Becton, Dickinson & Co.*,[25] the patent-at-issue was originally filed by Medisense Inc., but during its 14 year examination, responsibility transferred to Abbott upon acquisition of Medisense (operating as TheraSense, a subsidiary of Abbott).

Abbott asserted that Becton, Dickinson & Co., et al., sold glucose sensors that infringed the claims of Abbott's resulting U.S. patent number 5,820,551 ("the '551 patent"), directed to a membrane-less electrochemical sensor for measuring glucose levels in human blood. The inequitable conduct charge alleged that Abbott knew about statements made to the European Patent Office (EPO) that directly contradicted statements made to the PTO regarding a prior art reference but failed to disclose this information to the PTO.[26]

The prior art reference in the '551 patent prosecution, U.S. patent number 4,545,382 ("the '382 patent"), had a European counterpart, "the EP'636 patent," with which it shared a common specification. During examination of the EP'636 patent in Europe, Medisense distinguished its EP'636 application from the prior art on the basis that the '382/EP'636 patent "unequivocally" describes a sensor without a membrane, as opposed to the prior art reference which necessitated a membrane.

To make the point, Medisense cited a portion of the common specification which stated, "[o]ptionally, but preferably when being used on live blood, a protective membrane" is used, arguing that this passage supported that the membrane was not needed.[27]

When Medisense was acquired, its technical director relayed the arguments made during the EP'636 patent examination to Abbott's in-house counsel now in charge of the '551 patent's examination in the United States. The '551 application was facing consistent rejection on the basis of the '382 patent, and the very same language regarding an "optional[], but preferabl[e]" membrane was at issue in the United States.[28]

At this time, the technical director and attorney made a conscious decision to not disclose the EPO statements and instead take the position that the sensors of the '382/EP'636 patents do require a protective membrane, in contrast to Medisense's statements to the EPO. The technical director filed a declaration and the attorney filed further supportive statements with the PTO, attesting to Abbott's new position. Neither individual disclosed Medisense's EPO statements to the PTO.[29] At trial, both testified that they believed the EPO statements were irrelevant.[30]

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 preferabl[e]" 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 unpatentability 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.

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.[34] 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.[35]

The Pending Rehearing En Banc

Abbott moved for a rehearing en banc, which the Federal Circuit granted.[36] The Circuit's affirmance 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.[37]

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.[38] Abbott argues the current standard needs 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.[44]

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.[46]

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 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.

1. See *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244-45, 246-47 (1933).
2. See *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250, n.5 (1944); see also *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006).
3. See, e.g., *Hazel-Atlas*, 322 U.S. at 241-244, 250.
4. See *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1375 n.3 (Fed. Cir. 2006).
5. *McKesson Info. Solutions Inc. v. Bridge Med. Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007).
6. *TheraSense Inc. v. Becton, Dickinson & Co.*, 2010 U.S. App. LEXIS 9549 (Fed. Cir. April 26, 2010).
7. *Hazel-Atlas*, 322 U.S. at 240-41 (1944), *Precision Instr. Mfg. v. Auto Maint. Mach. Co.*, 324 U.S. 806, 818-20 (1945), and *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 243 (1933). See also *Digital Control*, 437 F.3d at 1315.
8. Compare *Hazel-Atlas*, 322 U.S. at 241-244, 250, with *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 373-374, 385 (1928).
9. *Keystone*, 290 U.S. at 243-244.
10. Id. at 243.
11. Id. at 245-247.
12. See *Hazel-Atlas*, 322 U.S. at 241-244, 250; *Precision*, 324 U.S. at 818-20.
13. See *Agfa*, 451 F.3d at 1375 n.3.
14. See *McKesson*, 487 F.3d at 913 (quotations omitted).
15. Id. (quotations omitted).
16. *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008).
17. *Digital Control*, 473 F.3d at 1315.
18. *Digital Control*, 437 F.3d at 1316.
19. *Star Scientific*, 537 F.3d at 1366.
20. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).
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).
25. *TheraSense*, 2010 U.S. App. LEXIS 9549.
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*, 593 F.2d at 1300.
36. *TheraSense*, 2010 U.S. App. LEXIS 9549 at *5-6.
37. Id.
38. *TheraSense*, Petition for Rehearing En Banc of Plaintiff-Appellants Abbott Diabetes Care Inc. and Abbott Laboratories, pp. 3, 5-8 (Feb. 24, 2010) (citing *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)).
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. 4-9 (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 Plaintiffs-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.
55. *TheraSense*, Brief of Amici Curiae Nine Intellectual Property Law Professors in Support of En Banc Review of Inequitable Conduct, pp. 5-6 (March 8, 2010).
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 Plaintiffs-Appellants' petition for Rehearing En Banc, pp. 5-6 (March 10, 2010).
58. See id. at pp. 4-7.
59. Id. at pp. 3, 3-4, 6, 7-8.