

Federal Circuit Raises the Bar for Inequitable Conduct

By Teige P. Sheehan

I. Introduction

In May 2011, the Federal Circuit issued a landmark en banc ruling in *Therasense, Inc. v. Becton, Dickinson & Co.* that redefined the doctrine of inequitable conduct.¹ A judge-made doctrine that evolved from the principle of unclean hands to deny patent rights to those who engaged in deceptive misconduct in obtaining patents,² the doctrine of inequitable conduct had become so commonly invoked as a defense in patent litigation that in 1988 the Federal Circuit famously stated that it had become “an absolute plague.”³

One benefit of succeeding on such a defense is that a finding of inequitable conduct as to even one claim renders an entire patent unenforceable, irrespective of its validity, a consequence that may also befall other members of the patent’s family within a portfolio,⁴ leading the Federal Circuit to note that “the remedy for inequitable conduct is the ‘atomic bomb’ of patent law.”⁵

Prior to its ruling in *Therasense*, not since its 1988 decision in *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.* had the Federal Circuit issued a decision en banc in an attempt to limit invocation of the doctrine to cases in which it was most appropriate.⁶ Nevertheless, the percentage of patent lawsuits in which inequitable conduct is pled has risen, particularly over the past decade, perhaps due to expansion of the doctrine’s scope in several post-*Kingsdown* Federal Circuit decisions.⁷

Finding that inequitable conduct had “metastasized” and had been “overused to the detriment of the public,”⁸ the Federal Circuit determined that the time was ripe to again address the issue en banc in order to stem the “resurgence of the plague that *Kingsdown* had intended to cure.”⁹

This article discusses the holding in *Therasense* in the context of other pertinent decisions and the effect the holding may have on patent practice. Part II is a general overview of the elements of inequitable conduct—i.e., materiality and intent. Parts III and IV discuss the Federal Circuit’s articulation in *Therasense* of the standards for materiality and intent, respectively, demonstrating how the decision is expected to engender a greater degree of stringency in subsequent analyses of inequitable conduct claims. Part V discusses the possible consequences of *Therasense*, with attention to issues that remain to be settled.

II. The Core Elements of Inequitable Conduct: Materiality and Intent

To successfully assert the defense of inequitable conduct, the alleged infringer “must present

‘evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive’” the USPTO during prosecution.¹⁰ The burden is on the party asserting the defense to demonstrate, by clear and convincing evidence, at least a threshold level of both an intent to deceive and the materiality of the deception.¹¹ If, but only if, these burdens are met, the trial court then performs an equitable balancing of the levels of materiality and intent to determine whether the patentee’s conduct was sufficiently egregious to warrant rendering the entire patent unenforceable.¹² In this regard, although “a greater showing of one factor allow[s] for] a lesser showing of the other,”¹³ materiality and intent are independent elements, both of which must be proved, and an insufficient showing of one cannot be overcome no matter how strong the evidentiary showing with regard to the other.¹⁴

Nevertheless, several Federal Circuit panel decisions had raised questions as to the limits of the inequitable conduct defense.¹⁵ For example, in *Ferring B.V. v. Barr Labs., Inc.*, the court held that a patentee’s failure to disclose his or her prior business relationships with declarants who, during prosecution, had provided affidavits in support of patentability constituted material misrepresentations, and a conclusion that the applicant “knew or should have known” that the undisclosed relationships were material satisfied the intent element.¹⁶ Notably, in *Kingsdown* the court had previously rejected the notion that intent could be established by a finding of “gross negligence,”¹⁷ such as where a patentee “should have known” of the materiality of undisclosed information.¹⁸

The same year *Ferring* was decided (2006), in *Digital Control, Inc. v. Charles Mach. Works*,¹⁹ the Federal Circuit reaffirmed the relevance of the broad scope of materiality embodied in prior Rule 56—which had provided that information is material “where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent”²⁰—even though Rule 56 had been modified following *Kingsdown* to replace the reasonable examiner standard with one that was more objective and specific.²¹ And, the year following the *Digital Control* and *Ferring* decisions, the Federal Circuit held in *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*²² that the rejection of claims during prosecution of one patent is information that is material to the prosecution of a related application, even if the pertinent claims of the copending applications are not “substantially similar,”²³ provided that “‘a reasonable examiner would substantially likely

consider [such information] important in deciding whether to allow an application to issue as a patent.”²⁴

III. *Therasense*: “But-for Materiality”

The patentee in *Therasense* brought a patent infringement suit against competitors, who responded with a defense of inequitable conduct pertaining to assertions made to the USPTO during prosecution of the patent in suit.²⁵ The patentee had argued that contested language of one of its prior patents did not disclose an essential limitation of the patent in suit.²⁶ However, during prosecution of the European counterpart of the prior patent, the patentee had submitted briefs that seemed to argue that it did teach such a limitation and did not disclose these briefs to the USPTO during examination of the patent in suit.²⁷ The trial court found that the nondisclosure amounted to inequitable conduct and held the patent unenforceable.²⁸ A panel of the Federal Circuit affirmed, and the patentee petitioned for rehearing en banc.²⁹

Recognizing the problems that unfettered inequitable conduct litigation imposes on the courts and patent practice and the failure of the *Kingsdown* decision to fully remedy the situation by addressing only the intent element, the en banc court in *Therasense* articulated a more stringent materiality standard.³⁰ By analogy to other areas of intellectual property law,³¹ the court held that an undisclosed prior art reference is material only if the USPTO “would not have allowed a claim had it been aware of the undisclosed prior art.”³² To conduct this analysis, a court is to give claims their broadest possible interpretation, and the alleged infringer must demonstrate “but-for materiality” by a preponderance of the evidence.³³ The Federal Circuit noted that because of the higher burden of proof required to invalidate claims, a district court’s invalidation of a claim on the basis of a deliberately withheld reference is sufficient, but not necessary, to demonstrate the reference’s but-for materiality.³⁴ The court also noted an exception to the requirement of but-for materiality, specifically for cases of “affirmative egregious misconduct.”³⁵ For example, as opposed to mere nondisclosure of a prior art reference,³⁶ “the filing of an unmistakably false affidavit” can constitute such egregious misconduct as to obviate a but-for materiality determination.³⁷

Furthermore, in declining to “abdicate[e] its responsibility to determine the boundaries of inequitable conduct” by deferring to the USPTO’s rules, the Federal Circuit explained that a definition of materiality as any violation of current Rule 56 would be too broad.³⁸ Rule 56 currently holds that noncumulative information is material if “[i]t establishes, by itself or in combination with other information, a prima facie case of unpatentability.”³⁹ Because this formulation encompasses even information the patentee might have been able to render irrelevant through subsequent argument or explanation, the Federal Circuit found it

to be too broad.⁴⁰ Rule 56 also holds that information is material if “[i]t refutes, or is inconsistent with, a position the applicant takes” in arguing for patentability or against unpatentability.⁴¹ The court rejected this formulation on the ground that it “broadly encompasses anything that could be marginally relevant to patentability.”⁴² Because the materiality element of the inequitable conduct holding under review in *Therasense* had been analyzed in accordance with current Rule 56, the Federal Circuit reversed the inequitable conduct holding and remanded the case to the district court for a determination of whether the nondisclosed material satisfied the new “but-for materiality” test.⁴³

IV. Intent to Deceive Must Be “Knowing and Deliberate”

The Federal Circuit emphasized in *Therasense* that sustaining the intent element of inequitable conduct requires the alleged infringer to “prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.”⁴⁴ In this regard, the court reiterated that a mere showing of gross negligence or that an applicant should have known of the materiality of undisclosed information does not establish that the patentee acted with the specific intent to deceive the USPTO.⁴⁵ Acknowledging that “direct evidence of deceptive intent is rare,” however, the court reaffirmed that “a district court may infer intent from indirect and circumstantial evidence.”⁴⁶

To meet the clear and convincing evidentiary standard in such a case, the court cautioned that “the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence,’”⁴⁷ and “the evidence ‘must be sufficient to require a finding of deceitful intent in the light of all the circumstances.’”⁴⁸ Finally, because the burden of proof lies on the party asserting inequitable conduct, the patentee must provide a good-faith explanation for withholding a material reference only in rebuttal, where an intent to deceive has first been demonstrated by clear and convincing evidence.⁴⁹ In that regard, because the district court’s finding of intent to deceive was premised on the “should have known” standard and “the absence of a good faith explanation for failing to disclose” the briefs in question, the Federal Circuit directed the trial court, on remand, to “determine whether there is clear and convincing evidence that [the patentees] knew of the [European Patent Office] Briefs, knew of their materiality, and made the conscious decision not to disclose them in order to deceive” the USPTO.⁵⁰

V. Conclusion

The Federal Circuit now requires a showing, by the preponderance of the evidence, that a claim would not have been allowed had undisclosed information been disclosed—i.e., a “but-for materiality” test—and, by

clear and convincing evidence, that such information was withheld with the specific intent of deceiving the USPTO—i.e., a “knowing and deliberate” test for intent.⁵¹ By “tighten[ing] the standards for both intent and materiality,”⁵² *Therasense*, together with another recent holding requiring that inequitable conduct be pled in accordance with the heightened particularity standards of FED. R. CIV. P. 9(b),⁵³ has the potential to stem the untoward tide of inequitable conduct litigation. Indeed, the Federal Circuit has already reversed a district court’s finding of inequitable conduct for failure to apply the “but-for materiality” and intent analyses articulated in *Therasense*.⁵⁴ Another consequence of the holding, which was alluded to in *Therasense*, may be a reduction in the prolixity of references with which applicants have felt compelled to “deluge” the USPTO during prosecution because of the “shadow of the hangman’s noose” cast by an overly broad inequitable conduct doctrine, with a potential to streamline the examination process.⁵⁵

However, the holding’s impact may well depend on whether the Supreme Court hears an appeal from the Federal Circuit’s decision, believed by many to be likely.⁵⁶ Another pending issue is whether, in light of the Federal Circuit’s expression in *Therasense* of an unfavorable view of Rule 56,⁵⁷ the USPTO will alter the rule so as to bring applicants’ duty to disclose information during examination in line with the but-for materiality standard. Indeed, the USPTO proposed an amendment to Rule 56 that would explicitly adopt the definition of materiality articulated in *Therasense*.⁵⁸ Another issue, faced by the applicants in *Therasense*⁵⁹ as well as in cases such as *McKesson*,⁶⁰ is what information pertaining to the examination of one application should be disclosed to the USPTO during examination of another. Although the holding in *Therasense* suggests that the substantive burden involved in making such decisions may now be less problematic, the corresponding procedural issues pertaining to application processing at the USPTO have yet to be fully settled.⁶¹

Endnotes

- 2011 WL 2028255 (Fed. Cir. 2011) (en banc).
- See *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933); *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds; *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); *Precision Instruments Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945).
- Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).
- See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (en banc); *Consol. Aluminum Corp. v. Fosco Int’l Ltd.*, 910 F.2d 804, 808-812 (Fed. Cir. 1990).
- Therasense*, 2011 WL 2028255, at *8 (quoting *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting)).
- 863 F.2d 867, 876 n.15 (Fed. Cir. 1988).
- See Christian E. Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1329, 1361-1375 (2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1339259#; Posting by Dennis Crouch to Patently-O, <http://www.patentlyo.com/patent/2010/06/measuring-the-plague-of-inequitable-conduct.html> (June 2, 2010).
- Therasense*, 2011 WL 2028255, at *9, *13.
- Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting).
- Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (quoting *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364-65 (Fed. Cir. 2007)).
- See *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006).
- See *Monsanto Co. v. Bayer BioScience N.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004).
- Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001).
- See *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003); *Star Scientific*, 537 F.3d at 1366.
- See Mammen, *supra* note 7, at 1361-75.
- 437 F.3d 1181, 1188, 1190-91 (Fed. Cir. 2006).
- 863 F.2d at 876.
- Hoffmann-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 687-688 (Fed. Cir. 1990); see also *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984) (a pre-*Kingsdown* decision holding that the element of intent can be sustained by a showing of gross negligence which, in turn, is demonstrated where an applicant should have known of information’s materiality); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008) (espousing a rule by which intent is established if an applicant should have known of the materiality of an undisclosed reference).
- 437 F.3d 1309 (Fed. Cir. 2006).
- 37 C.F.R. § 1.56 (1977).
- See *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d at 1202 n.3 (Fed. Cir. 2006) (Newman, J., dissenting); Mammen, *supra* note 7, at 1364-65. As discussed in Parts III and V, *infra*, current Rule 56 may be subject to further revision in light of *Therasense* (see Press Release, USPTO, Press Release 11-36, USPTO Studying *Therasense* v. Becton, Dickinson Decision to Assess Impacts on Agency Practice and Procedures; Expects to Issue Further Guidance to Applicants Soon (May 26, 2011), available at <http://www.uspto.gov/news/pr/2011/11-36.jsp>; Revision of the Materiality to Patentability Standard for the Duty To Disclose Information in Patent Applications, 76 Fed. Reg. 43,631, 43,632 (July 21, 2011) [hereinafter “Proposed Rule Amendment”]).
- 487 F.3d 897 (Fed. Cir. 2007). See *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1338 (Fed. Cir. 2009).
- McKesson*, 487 F.3d at 919. Thus, whereas the Federal Circuit had previously held that substantial similarity between the rejected claims of one application and the claims of a copending application is sufficient for the rejection to be material to the prosecution of the copending application, *McKesson* stood for the proposition that a finding of materiality did not require such substantial similarity (*id.*; see *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003)).
- McKesson*, 487 F.3d at 913 (quoting *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998) (quotation marks and citation omitted)).
- Therasense*, 2011 WL 2028255, at **1-3.
- Id.* at *2.
- Id.* at *3.
- Id.* at *3.
- Id.* at *3.
- Id.* at *4.
- Therasense*, 2011 WL 2028255, at *11.

31. See *id.* at *15.
32. *Id.* at *11.
33. *Id.*
34. See *id.* at *11.
35. *Id.* at *12.
36. See *id.* at *12 (holding that an entire patent should not be stricken down “where the patentee committed only minor missteps or acted with minimal culpability”). See also Posting by Kevin E. Noonan to Patent Docs, <http://www.patentdocs.org/2011/05/therasense-inc-v-becton-dickinson-co-fed-cir-2011.html> (May 25, 2010) (suggesting examples of prior, potentially “minor missteps” which had resulted in findings of inequitable conduct in previous cases).
37. *Therasense*, 2011 WL 2028255, at *12.
38. *Id.* at *14; see 37 C.F.R. § 1.56.
39. *Therasense*, 2011 WL 2028255, at *14 (quoting 37 C.F.R. § 1.56 (b) (1)).
40. See *Therasense*, 2011 WL 2028255, at *14; 37 C.F.R. § 1.56 (b).
41. *Therasense*, 2011 WL 2028255, at *14 (quoting 37 C.F.R. § 1.56 (b) (2)).
42. *Therasense*, 2011 WL 2028255, at *14.
43. See *id.* at *16.
44. *Id.* at *9. See *Mollins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995).
45. *Therasense*, 2011 WL 2028255, at *10 (“Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the [US]PTO does not prove specific intent to deceive.”).
46. *Id.* at *10. See *Larson Mfg. Co. of South Dakota, Inc. v. Aluminar Prods. Ltd.*, 559 F.3d at 1340.
47. *Therasense*, 2011 WL 2028255, at *10 (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d at 1366).
48. *Therasense*, 2011 WL 2028255, at *10 (quoting *Kingsdown*, 863 F.2d at 873 (emphasis added)).
49. See *Therasense*, 2011 WL 2028255, at *10.
50. *Id.* at *16.
51. *Id.* at *9, *11, *16.
52. *Id.* at *9.
53. See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).
54. See *American Calcar, Inc. v. American Honda Motor Co., Inc.*, 2011 WL 2519503, at *10-*11 (Fed. Cir. 2011).
55. See *Therasense*, 2011 WL 2519503, at *9; Posting by Dennis Crouch to Patently-O, <http://www.patentlyo.com/patent/2010/01/what-does-a-patent-examiner-do-with-900-references.html> (Jan. 28, 2010). See also *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 480 F.3d 1129, 1137 (Fed. Cir. 2007) (materiality established in part by an applicant’s submission of a 1139-page “blizzard of paper” to the USPTO and misrepresenting, as found by the Federal Circuit, that the submission did not contain prior art).
56. See Sheri Qualters, “*Therasense*” a Strong Candidate for High Court Review, *Patent Lawyers Say*, LAW.COM, May 26, 2011, <http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202495407647>.
57. See *Therasense*, 2011 WL 2519503, at *14.
58. See Qualters, *supra* note 56; Proposed Rule Amendment, *supra* note 21, at 43,632-43,633 (“While not as inclusive as current § 1.56 (b), the Office expects that the ‘but-for’...standard from *Therasense* will result in patent applicants providing the most relevant information and reduce the incentive for applicants to submit information disclosure statements containing only marginally relevant information out of an abundance of caution.”).
59. See *Therasense*, 2011 WL 2519503, at **1-3.
60. See *McKesson*, 487 F.3d at 919.
61. See Posting by Courtenay Brinckerhoff to PharmaPatents, <http://www.pharmapatentsblog.com/patent-office-practice/revisiting-ids-guidelines-while-youre-at-it/> (June 3, 2011); Posting by Nabeela Rasheed to Orange Book Blog, <http://www.orangebookblog.com/2011/05/therasense-in-this-case-the-court-unabashedly-states-that-it-is-reining-in-inequitable-conduct-because-to-do-so-is-in-the-i.html> (May 25, 2011).

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