Clarifying the Doctrine of Inequitable Conduct

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Recommended Citation
CLARIFYING THE DOCTRINE OF INEQUITABLE CONDUCT

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A. Introduction

During Judge Michel’s first year on the bench, Judge Nichols wrote that “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”43 Cognizant of the importance of this issue, Judge Michel, the author of more than twenty opinions addressing inequitable conduct,44 told the American Intellectual Property Law Association that:

[H]e felt a “burden of responsibility” to [clarify the doctrine of inequitable conduct] particularly . . . the interpretation of materiality and intent-to-deceive. “There are four different standards of materiality. That’s a terrible train wreck right there and makes the problem four times harder,” he said.45

With a month left in Chief Judge Michel’s tenure on the United States Court of Appeals for the Federal Circuit, the Court took, perhaps, a big step towards ending the plague by granting en banc review in Therasense v. Becton Dickinson.46 Addressing squarely the issue of the multiple standards of materiality in inequitable conduct litigation, Therasense raises many difficult issues that could be clarified through the lens of the analogous concept of fraud on the Trademark Office. The standards for finding fraud on the Trademark Office lack the ambiguity found in the

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*Associate Professor of Law, Catholic University of America. The author was privileged to clerk for the Honorable Paul R. Michel on the Court of Appeals for the Federal Circuit, to whom this article is dedicated. His leadership and guidance has been invaluable over the years, and is deeply appreciated.

43 Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).
46 Therasense, Inc. v. Becton-Dickinson & Co., 374 F. App’x. 35 (Fed. Cir. 2010).
doctrine of inequitable conduct, despite the parallel penalties of unenforceability and requirements of proof of materiality and intent.

Judge Michel’s jurisprudence is tremendous in its depth and breadth. The author of more than 800 opinions during his twenty-two years on the bench, Judge Michel brought clarity to the law through his opinions, his public speaking, and his engagement with the bench and bar. Informed by the many decisions of Judge Michel, the essay below touches on inequitable conduct, Judge Michel’s contribution to “law, equity and ethics—a pretty heady mix,” and concludes that the standards for finding fraud before the Trademark Office, as set forth in In re Bose, light the path the United States Court of Appeals for the Federal Circuit should follow in Therasense, setting workable standards for finding inequitable conduct before the United States Patent and Trademark Office.

B. Multiple Inequitable Conduct Tests

A patent is an exclusive right conferred by the United States government to promote the progress of science and the useful arts. When that right is procured through fraud, the patent may be held unenforceable. An applicant has a duty to disclose to the Patent Office “all information known to that individual to be material to patentability,” pursuant to 37 C.F.R. § 1.56 (“Rule 56”). Intentional failure to do so can result in a finding of inequitable conduct “the penalty for [which] is so severe, [resulting in] the loss of the entire patent even where every claim clearly meets every requirement of patentability.”

If a patent is procured through inequitable conduct, it is unenforceable. To prevail on inequitable conduct, a party must show that the applicant for patent: “(1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the PTO.”

The inequitable conduct doctrine, a judicially created doctrine, was borne out of a series of Supreme Court cases in which the Court refused to enforce patents where the patentees had engaged in fraud in order to procure those patents. Although the Supreme Court did not articulate precisely what rendered a patent unenforceable, the courts generally tended to apply a doctrine somewhat akin to that of common law fraud, albeit broader. That is, the courts required a showing that the information which was misrepresented to or withheld from the PTO was material as well as a showing of wrongfulness, such as deceptive intent, willful misconduct, or gross negligence. In 1949, the PTO created its first version of Rule 56, prohibiting fraud

48 In re Bose Corp., 580 F.3d 1240 (Fed. Cir. 2009).
49 Therasense, Inc. v. Becton-Dickinson & Co., 374 F. App'x. 35 (Fed. Cir. 2010).
Before the PTO. Neither the Supreme Court nor the PTO, however, articulated exactly what constituted a material misrepresentation.

There is no one standard for what is "material" or what it means to intend to deceive the Patent Office. This "train wreck" has led to great confusion among the bar as to the appropriate standard to apply to determine materiality, a question squarely before the full Federal Circuit, which heard *Therasense v. Becton Dickinson* en banc on November 9, 2010. Reflecting on these difficult issues, the parties were asked to argue the following questions:

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?

2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?

3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?

4. Under what circumstances is it proper to infer intent from materiality?

5. Should the balancing inquiry (balancing materiality and intent) be abandoned?

6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

As Judge Michel stated to the American Intellectual Property Law Association, there are multiple tests for what constitutes inequitable conduct. These standards included: the objective "but for" standard, where the misrepresentation was so material that the patent should not have issued; the subjective "but for" test, where the misrepresentation actually caused the examiner

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53 See 37 C.F.R. § 1.56 (1951).
54 Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1315 (Fed. Cir. 2006). This opinion was authored by Judge Clevenger and joined by Judge Michel.
55 Nurton, *supra* note 45.
56 374 F. App'x. 35 (Fed. Cir. 2010).
57 Id.
60 *Therasense*, 374 F. App'x. 35.
61 Nurton, *supra* note 45.
to approve the patent application when he would not otherwise have done so; and the "but it may have" standard, where the misrepresentation may have influenced the patent examiner in the course of prosecution. In addition, in 1977, the PTO amended Rule 56 to clarify the duty of candor and good faith before the PTO.62

Each of these standards is discussed further below.

The “But-For” Test

“A person attacking the validity of a patent for alleged fraudulent representations must prove that the representations were material— that the patent would not have issued but for the representations.”63 This test can be objective, “where the misrepresentation was so material that the patent should not have issued,” or subjective “where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so.”64 This is the most stringent of the tests for inequitable conduct, requiring knowledge of the examiner’s actual thinking process. If the misrepresentation is a failure to disclose prior art, inequitable conduct subject to the “but for” standard will be very difficult to prove. A recent law review article details empirical findings that “patent examiners effectively ignore almost all applicant-submitted art, relying almost exclusively on prior art they find themselves.”65 The “but for” standard makes it very difficult to prove that omission of a reference was the cause of the issuance of a patent, particularly in light of the findings that examiners find their own searches more reliable than submitted references. The impact of imposing such a stringent interpretation renders the inequitable conduct tool virtually useless.

The “Reasonable Examiner” Standard

[In 1977, the PTO amended Rule 56 to clarify the duty of candor and good faith before the PTO.66 That version of Rule 56 required applicants to disclose material information they are aware of, and stated 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.”67 In adopting this standard of materiality, the PTO did not claim to be replacing or supplanting the existing case law addressing materiality, but rather noted that it was “codifying] the existing Office policy on fraud and inequitable conduct, which is believed consistent with the prevailing case law in the federal courts.”68

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64 Digital Control, 437 F.3d at 1315.
66 Id.
Judge Michel wrote in 2008 "that information is material when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." Materiality was defined by the Patent Office as existing when there was "[1] a substantial likelihood that [2] a reasonable examiner [3] would consider it important [4] in deciding whether to allow the application to issue as a patent." This test is less stringent than the "but for" standard, which allows a lower burden of proof. If the reference is one the examiner would have considered important, but may not have been critical to the issuance, then the question becomes one of the level of intent of the patent applicant since "a finding of inequitable conduct requires a balancing of materiality and intent .... Thus, where "a reasonable examiner would merely have considered particular information to be important but not crucial to his decision' the requisite finding of intent must be high."

The "But it May Have" Standard

The least stringent test for materiality is the "but it may have" test where a "misrepresentation may have influenced the patent examiner in the course of prosecution." This standard asks whether the misrepresentation "might reasonably have affected the examiner's decision as to patentability." This standard is a more realistic standard than a strict "but for" analysis, but given the current balancing test maintained between materiality and intent, this standard requires a higher showing of intent. This test has been adopted by courts struggling with the difficulty of proving what the examiner was thinking during patent prosecution. As a result, under this test "even if the applicant misrepresents or withholding facts which are not material in a 'but for' sense, the Courts will refuse to enforce the patent if the applicant has misrepresented to the Patent Office facts which may be relevant to an issue of patentability." An early phrasing of this test stated that "Materiality... does not require that the patent would not have issued as a matter of law 'but for' the misrepresentation or concealment, but only that the misrepresentation or withholding be relevant to an issue of patentability."

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71 Duro-Last, Inc. v. Custom Seal, Inc., 321 F.3d 1098, 1107 (Fed. Cir. 2003) ("This court has long held that whether a prior reference is material, i.e., whether there is a substantial likelihood that a reasonable examiner would have considered the reference important in deciding whether to allow the application to issue as a patent, is not controlled by whether that reference actually anticipates the claimed invention or would have rendered it obvious.").
72 Digital Control, 437 F.3d at 1315–16 (quoting Am. Hoist & Derrick Co., 725 F.2d at 1362–63).
73 Id. at 1315.
75 Semiconductor Energy Lab. Co. v. Samsung Elec. Co., 204 F.3d 1368, 1373 (Fed. Cir. 2000) ("If these thresholds are satisfied, the trial court balances materiality and intent to determine whether the equities warrant the conclusion that inequitable conduct occurred.").
77 Id. at 940.
37 C.F.R. § 1.56(b) – the “Duty of Candor” test

“Patent applicants are required to prosecute patent applications with candor, good faith, and honesty.”78 This statement reflects the current Rule 56, as revised in 1992, to “present a clearer and more objective definition of what information the Office considers material to patentability”79 setting a standard of materiality based on what is cumulative. The current rule reads:

(a)... Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section . . . .

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (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.80

This test supplements the other standards, leaving it unclear whether applicants must abide by the strict “but for” standard, the more relaxed “reasonable examiner” standard, the lenient “but it may have” standard or some other test. As Judge Michel stated “patent applicants do have certain duties to the PTO, including duties of disclosure, beyond a certain point, how much more evidence to submit is in large part a determination for which a patentee and his agents must use good judgment. While there are certainly many factors which could go into such a decision, a duty to the PTO may not necessarily be one of them.”81

C. Trademark Law: In re Bose82

In 2009, Judge Michel authored In re Bose, setting forth the standard for finding fraud during the prosecution of a trademark application before the United States Patent and Trademark Office.83 Inequitable conduct requires defrauding the Patent Office during prosecution of a patent. Committing fraud on the Trademark Office parallels this doctrine.84 “Fraud in procuring a trademark registration or renewal

78 Semiconductor Energy Lab., 204 F.3d at 1373.
80 37 C.F.R. § 1.56 (2010).
81 Id.
82 580 F.3d 1240 (Fed. Cir. 2009).
83 Id.
84 15 U.S.C. § 1115(b) (2006) (If the right to “use the registered mark has become incontestable under section 1065 of this title, the registration shall be conclusive evidence of the registrant's
occurs when an applicant knowingly makes false, material representations of fact in connection with his application.\textsuperscript{85}

The Lanham Act imposes a duty on applicants that they cannot make "knowingly inaccurate or knowingly misleading statements" with no discussion of the materiality of these statements.\textsuperscript{86} Proof of fraud requires a showing of materiality, but unlike inequitable conduct, the question of materiality has not been one of debate in the trademark context. There are not multiple standards, and the prevailing jurisprudence applies a fairly lax standard, along the lines of the "but it may have" standard.

Intent is required in all claims of fraud under the Lanham Act. It does not matter how material the misleading statement is, "[t]here is no fraud if a false misrepresentation is occasioned by an honest misunderstanding or inadvertence without a willful intent to deceive."\textsuperscript{87} As Judge Michel wrote, "deception must be willful to constitute fraud."\textsuperscript{88} The high burden of proving intent can be met only when "the applicant or registrant knowingly makes a false, material representation with the intent to deceive the PTO."\textsuperscript{89} Such proof can be formed of "indirect and circumstantial evidence. But such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement."\textsuperscript{90}

\section*{D. The Parallel Paths of Fraud and Inequitable Conduct in Trademark and Patent Law}

The final question posed in the \textit{Therasense} en banc order asks whether "the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context."\textsuperscript{91} The answer must be yes, and we can look to practice before the Trademark Office, and Judge Michel's opinion in \textit{In re Bose}, for just such guidance. The standard for determining whether fraud has occurred in the prosecution of a trademark is analogous to the question of whether "patentees had engaged in fraud in order to procure those patents."\textsuperscript{92} If the en banc order in \textit{Therasense} is viewed in light of the standards articulated by Judge Michel in \textit{Bose} many of the questions raised in the inequitable conduct context are clarified.\textsuperscript{93}

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exclusive right to use the registered mark in commerce on or in connection with the goods or services specified in the affidavit filed under the provisions of said section 1065 subject to any conditions or limitations stated therein except when one of the following defenses or defects is established: (1) That the registration or the incontestable right to use the mark was obtained fraudulently . . .
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\textsuperscript{85} Torres v. Cantine Torresella, 808 F.2d 46, 48 (Fed. Cir. 1986).

\textsuperscript{86} \textit{In re Bose}, 580 F.3d at 1243 (quoting Bart Schwartz Int'l Textiles, Ltd. v. Fed. Trade Comm'n, 289 F.2d 665, 669 (C.C.P.A. 1961)).

\textsuperscript{87} Id. at 1246.

\textsuperscript{88} Id. at 1243.

\textsuperscript{89} Id. at 1245.

\textsuperscript{90} Id. (quoting Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

\textsuperscript{91} \textit{Therasense}, Inc. v. Becton-Dickinson & Co., 374 F. App'x. 35, 36 (Fed. Cir. 2010).

\textsuperscript{92} Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1315 (Fed. Cir. 2006).

\textsuperscript{93} \textit{See Therasense, Inc.}, 374 F. App'x at 35–36, \textit{In re Bose}, 580 F.3d at 1244–46.
The materiality-intent balancing inquiry should be abandoned. There is no balancing framework between materiality and intent present in trademark law—fraud requires proof of materiality and intent. Instead of balancing materiality and intent, a threshold requirement for inequitable conduct should be a showing of materiality and intent. Once that threshold has been met, even by a scintilla of evidence, then the overall conduct of the applicant during prosecution should be evaluated to see if it "warrant[s] holding the entire patent unenforceable." If that determination is made, then a finding of inequitable conduct may be justified.

A finding of fraud on the Trademark Office requires proof of materiality, but the level of materiality required is analogous to the "but it may have" standard. Inequitable conduct before the Patent Office should be analyzed under a similar standard, not as stringent a standard of materiality as high as the "but for" standard articulated. If the Examiner would profit from seeing the reference, then the public would benefit, and therefore the reference should be found material. The Manual of Patent Examining Procedure should inform what may have influenced the examiner.

Intent should never be inferred from materiality—the two doctrines are not dependent on each other. If a highly material document is withheld, then an inference of intent may be made, but it is only an inference, because "materiality does not presume intent, which is a separate and essential component of inequitable conduct." Again, the overall conduct of the applicant should be evaluated—and that evaluation should not be based solely on the level of materiality of the withheld document. Intent requires that "the involved conduct, viewed in light of all the evidence . . . indicate sufficient culpability to require a finding of intent to deceive."

E. Conclusion

Judge Michel wrote that "[t]o prevail on inequitable conduct, an accused infringer must show 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 [PTO].'" In his decision, Judge Michel referred to the Court's "scattered precedents" and the difficulty in determining what is material and what level of intent is required. In contrast, Judge Michel's decision in the determination of fraud on the trademark office sets forth a simple and workable test. There is no question in trademark of a balancing test between materiality and intent—if a misrepresentation is material — in that it may have impacted prosecution—and there was intent to defraud the Trademark Office, then the mark should not be enforceable.

In the patent context, the focus of inequitable conduct has been materiality, while the focus in litigating fraud before the Trademark Office, the focus has been on intent. The public would best be served by a focus on the overall behavior of the

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95 Id. at 1366 (quoting GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001)).
97 Leviton Mfg. Co. v. Universal Sec. Instruments, Inc., 606 F.3d 1353 (Fed. Cir. 2010).
98 Id.
99 Id.
applicant. When an applicant appears to have met the statutory requirements for a patent or a trademark but has done so by egregious behavior, the applicant deserves the ultimate sanction of losing the right to enforce their patent or trademark. The question should not be on whether the applicant withheld a sufficiently material reference with malice aforethought, but rather an overall analysis of the behavior of the prosecutor, after it has been proven that a material reference was knowingly withheld from the United States Patent and Trademark Office.