The Federal Circuit Decides to Reconsider Inequitable Conduct

Introduction

Two decades after the Federal Circuit termed the pleading of inequitable conduct a "plague,"[1] the problem of assertion of this affirmative defense has only metastasized. Today, it is pled not only in traditional situations, such as when a prior art reference has been intentionally withheld from the Patent Office, but also when prior art is actually before the Patent Office and expressly considered, but the applicants have made allegedly inconsistent arguments about it. A panel of the Federal Circuit faced one such non-traditional situation when rendering its decision in *TheraSense, Inc. v. Becton, Dickinson & Co*. In response to a petition for rehearing *en banc*, the entire Federal Circuit has decided to undertake a complete reconsideration of the doctrine of inequitable conduct. While briefing is not yet complete, many *amici* (both businesses and academics) have come forward to argue that the standard of proof of inequitable conduct should be raised, that the scope of the defense should be limited, or that the potential remedies for the defense should be broadened.

Existing Law on Inequitable Conduct

The doctrine of inequitable conduct arises indirectly from three Supreme Court cases involving actual "fraud on the Patent Office" – payoffs for witness silence to avoid detrimental testimony, fabrication of witness statements, and subornation of perjury.[2] The Federal Circuit translated those cases, and the 1952 amendments to the Patent Act (which categorized the pleading of "unenforceability" as a defense), into the modern doctrine of inequitable conduct.[3] Under this doctrine, more than just traditional fraud can render a patent unenforceable: a failure to disclose material information or a material misrepresentation can do so as well. The Patent Office then established regulations that set forth certain parameters for practitioners to comply with their duty of disclosure to the Patent Office and thereby avoid a finding of inequitable conduct.[4]

Under the original, and broadest, version of the Patent Office's regulations, an applicant is required to disclose any information that a "reasonable examiner" would consider material to the patentability of a claim.[5] Individuals, rather than companies, bear the burden of disclosure: any person "associated with the filing or prosecution of a patent application," which includes inventors, prosecuting patent attorneys and agents, and anyone else substantively involved in the prosecution of the patent, is required to disclose material information. Most commonly, inequitable conduct has been found when an inventor or prosecuting attorney has intentionally withheld material prior art from the Patent Office. Inequitable conduct requires "two elements, materiality and intent, [that] must be proven by clear and convincing evidence"; "'gross negligence' does not of itself justify an inference of intent to deceive."[6]

However, inequitable conduct has also been found in many non-traditional contexts, and with little or no showing of deceptive intent. Material information has been found to include non-prior art references, Patent Office decisions in applications prosecuted in parallel, and even

allowance of similar claims in related applications.[7] Federal Circuit decisions have been even looser with the required showing of intent. Indeed, the Federal Circuit has indicated that deceptive intent can be inferred – with no evidence of intentional deception – if (1) highly material information is withheld, (2) the applicant knew of the information and knew or should have known of the materiality, and (3) the applicant does not provide a credible explanation for the withholding.[8]

The *TheraSense* Panel Opinion

The *TheraSense* case presents one of the non-traditional situations in which the relevant prior art was before the Patent Office, yet the courts still found inequitable conduct because of the applicant's characterization of the art.[9] The material information that was withheld in that case was attorney argument regarding the scope of the claims of a foreign counterpart to a prior art reference that was before the Patent Office. The underlying prior art reference was unquestionably before the Patent Office, and even the Federal Circuit panel was split over the interpretation of the arguments in the foreign patent office; nonetheless, the majority of the panel found inequitable conduct in what is described as not a close case.

In *TheraSense*, Abbott's[10] patent application claimed a strip sensor system used to measure the amount of glucose in blood or interstitial fluids. The test strips used in the system did not require a membrane to slow the diffusion of glucose to the electrode or to prevent red blood cells from fouling the electrode. The Patent Office repeatedly rejected the claims of the application as either anticipated or obvious, including rejections based on another patent held by Abbott, U.S. Patent No. 4,545,382 ("the '382 patent"). The '382 patent claimed a test strip where a membrane was "optional, but preferable" when testing *live* blood (*i.e.*, *in vivo*). To argue over the '382 patent, Abbott asserted that a person having ordinary skill in the art at the time of the application would have understood the "optional, but preferable" language as still requiring a protective membrane when testing *whole* blood (*i.e.*, *in vitro*).

In support of its position, Abbott submitted a declaration from its Director of Research and Development asserting that the understanding in the field of the '382 patent was that a membrane was necessary for testing whole blood. Abbott's patent prosecution counsel relied on the declaration to argue that a person skilled in the art "would not, especially in view of the working examples, have read the 'optional, but preferable' language [in the '382 patent] as a technical teaching but rather as mere patent phraseology" in relation to whole blood. The patent examiner was convinced, and issued the patent-in-suit.

The Federal Circuit found that the statements characterizing the '382 patent were inconsistent with arguments made in briefs that were filed in revocation proceedings regarding the European counterpart to the '382 patent, but not provided to the U.S. Patent Office. Seeking to overcome a German reference cited in the European revocation proceedings, Abbott argued that "the purpose of the protective membrane [set forth in the claims of the foreign counterpart], preferably to be used with in vivo measurements, is a safety measurement to prevent any course [*sic*] particles coming off during use but is not a permeability control for the substrate."

Over a year later, in another brief in the European proceedings, Abbott "submitted that [the] disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor."

The *TheraSense* Federal Circuit panel majority concluded that the European briefs were highly material for two reasons. First, it found that the arguments made to the European Patent Office (EPO) clearly contradicted those made to the U.S. Patent Office in construing the prior art to the patent-in-suit. Second, the EPO briefs were directed toward explaining why a membrane was preferential when testing live blood, suggesting that the problems associated with testing blood *in vivo* (*i.e.*, live blood) were not present when testing blood *in vitro* (*e.g.*, whole blood). As a result, the majority concluded that it was known in the field that a membrane was not necessary to accurately measure glucose levels in some whole blood samples. Therefore, although the briefs included only attorney argument (that was interpreted as contrary to other attorney argument), the Federal Circuit found the briefs including those arguments represented material information that had to be disclosed to the Patent Office as contradictory to assertions made by Abbott in support of the patent-in-suit.

Regarding the element of intent, the majority focused on two findings made by the district court: that both Abbott's attorney and expert failed to provide a credible reason for not disclosing the EPO briefs, and their explanations for failing to disclose "were so incredible that they suggested intent to deceive." The majority found it unnecessary to disturb the lower court's conclusion that neither witness was credible in light of the standard of review. Additionally, an inventor of both the '382 patent and the patent-in-suit provided testimony that contradicted Abbott's position regarding the necessity of a membrane. The majority reasoned that the use of a different expert in making the declaration evinced an intent to deceive. Therefore, the majority concluded that both Abbott's expert and counsel intentionally withheld material information from the Patent Office and affirmed the district court's holding of unenforceability due to inequitable conduct.

Judge Linn dissented from the panel's inequitable conduct finding. In analyzing the materiality of the EPO briefs, he gave a more deferential reading to the explanation of the "optional, but preferable" language of the patent. Noting that the claim contested before the EPO was not directed exclusively to testing live blood, he reasoned that the briefs highlighted the need for membranes in certain situations, as in testing live blood, but not in others, such as when testing interstitial fluid. Therefore, he saw Abbott's position in prosecuting the patent-in-suit as being consistent with the representations made to the EPO. Judge Linn also concluded that the panel was incorrect in presuming intent to deceive because it was plausible that both the attorney and expert *subjectively* believed it was unnecessary to disclose the briefs to the Patent Office. He further discredited the majority's reliance on the inventor's testimony, as it was reasonable to believe that neither the attorney nor the expert was aware of the inventor's understanding of either the '382 patent or the level of skill in the art. Therefore, Judge Linn concluded neither witness had the requisite level of subjective intent necessary to support a finding of inequitable conduct.

Questions for Rehearing *En Banc*

The Federal Circuit granted Abbott's petition for rehearing *en banc*, indicating that it intended to reconsider key issues related to inequitable conduct. The Court identified six questions of general importance:

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 Patent 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.[11]

Briefing of the Issues

To date, Abbott and a number of *amici* have filed briefs regarding the Court's six issues. Abbott argues that the Federal Circuit should return to a strict reading of the *Kingsdown* case and require a showing of specific intent to deceive. Abbott further argues that inequitable conduct should render a patent unenforceable only when the patent would not have issued absent any misconduct. Abbott also argues that the Federal Circuit should abandon the "sliding scale" that allows balancing of a strong showing of materiality against a weak showing of intent because it dilutes both the materiality and intent requirements.

The *amici* have also generally argued that the standards for a finding of inequitable conduct should be raised. The Patent Office suggests narrowing the standard for inequitable conduct to a violation of existing Rule 56, not a failure to comply with the "reasonable examiner" materiality standard. It also suggests that a specific intent to deceive should be required, and should be the single most reasonable inference from the facts. PhRMA (the Pharmaceutical Research and Manufacturers of America) suggests limiting inequitable conduct to acts that allow the issuance of at least one invalid claim and advocates for consideration of intent separately from the materiality of a reference. The American Bar Association and numerous other *amici* suggest that the standard be aligned with traditional fraud considerations and require that at least one

invalid claim have been issued due to the deceptive conduct. In the most extreme position, Acacia suggests abandoning the defense of inequitable conduct altogether. However, Apotex, a generic drug manufacturer, suggests retention of the current standards and tests for inequitable conduct.

Numerous *amici* have also suggested abandoning the all or nothing approach of unenforceability. Specifically, they argue that equity should allow a broad spectrum of remedies for inequitable conduct, including a reversal of the presumption of validity and other equitable remedies. These *amici* suggest that allowing the court to determine the remedy for inequitable conduct would allow it greater flexibility, which would not only be more consistent with other equitable remedies but also allow greater punishment for more culpable behavior.

Conclusion

In selecting the broad questions raised *en banc* in the *TheraSense* case, the Federal Circuit has indicated its intent to reconsider inequitable conduct at a fundamental level. The majority of the *amici* have suggested a heightened standard for inequitable conduct
– at least returning the standard of the last *en banc* Federal Circuit case on inequitable conduct, *Kingsdown* – that would narrow the defense to clear and convincing showings of both materiality and intent. Given that inequitable conduct itself is an extension of the Supreme Court's precedent, it would be sensible to follow the *amici*'s advice and narrow the application of the doctrine.

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Endnotes

1. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).
2. *Precision Instr. Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 807-08, 814-15 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250 (1944); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933).
3. 35 U.S.C. § 288; *J.P. Stevens Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984).
4. 37 C.F.R. § 1.56.
5. The Federal Circuit has continued to apply the "reasonable examiner" standard for disclosure even though the Patent Office has adopted a narrower standard which suggests that information is material only if "it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim" or "refutes, or is inconsistent with, a position the applicant takes in opposing an argument of unpatentability relied on by the Office, or [in] asserting an argument of

patentability." *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006)

6. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872, 876 (Fed. Cir. 1988) (*en banc*).
7. *See*, *e.g.*, *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-69 (Fed. Cir. 2003); *McKesson Info. Sol'ns, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 924 (Fed. Cir. 2007).
8. *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006).
9. *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1289 (Fed. Cir. 2010), *rehearing en banc granted, opinion vacated by* 2010 WL 1655391.
10. TheraSense became Abbott Diabetes Care, Inc. after the filing of the patent application. For simplicity's sake, TheraSense, its predecessors-ininterest, and its successors will all be referred to as "Abbott."
11. *Therasense rehearing en banc granted, opinion vacated by* 2010 WL 1655391.