

INTELLECTUAL PROPERTY & *Life Sciences*

Overhauling the Inequitable Conduct Doctrine

By Angela Foster

It has been almost 25 years since the Federal Circuit sat en banc and rejected the prior inequitable conduct standard of gross negligence and held inequitable conduct requires that materiality and deceptive intent be *separately* proven under a clear and convincing standard. *Kingsdown v. Hollister*, 863 F.2d 867 (Fed. Cir. 1988). Inequitable conduct, a powerful and commonly pled defense to an allegation of patent infringement, if proven renders a patent unenforceable forever.

In *Kingsdown*, the attorney prosecuting a patent application incorrectly copied a rejected claim into the patent application which the Patent and Trademark Office (PTO) ultimately allowed as a patent. The district court held the patent unenforceable due to inequitable conduct because the attorney was grossly negligent in not noticing the mistake, or the attorney's actions were intended to deceive the PTO. Reversing the district court, the Federal Circuit held a mere mistake does not rise to the level of inequitable conduct, rather,

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a party must have intended to act inequitably in order to be guilty of committing inequitable conduct.

Despite the holding in *Kingsdown*, district courts have been criticized for inconsistently applying the inequitable conduct standard enunciated in *Kingsdown* by merging materiality and intent, thus lowering the bar. Sitting en banc, the Federal Circuit recently heard oral arguments in *Therasense, Inc. v. Becton*, regarding whether the inequitable conduct standard should be modified or replaced.

Background

Every person involved in the preparation of a patent application has a continued duty to disclose all information *material* to the patentability of the application. 37 C.F.R. § 1.56(a). Failure to disclose material information may render a patent unenforceable due to inequitable conduct if the person intended to deceive or mislead the PTO. Information is *material* if it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim, 37 C.F.R. § 1.56(b)(1), or if it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the PTO, or (ii) asserting

an argument of patentability. 37 C.F.R. § 1.56(b)(2) ("Rule 56(b)").

Several standards for materiality have been applied, including the "reasonable examiner" and "but for" standard. Under the reasonable examiner standard, information is deemed material to patentability when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008). The "but for" standard provides: (i) an objective test, where the misrepresentation was so material that the patent should not have issued; (ii) a subjective test, where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; and (iii) a "but it may have" standard, where the misrepresentation may have influenced the patent examiner in the course of prosecution. *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006).

In determining whether a failure to disclose material information was intentional, the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must show sufficient culpability to require a finding of specific intent to deceive.

Kingsdown, 863 F.2d at 876. However, because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence. *Star Scientific*, 537 F.3d at 1366. Some courts have held that intent to deceive the PTO was inferred from the materiality of an act or omission and other courts have held that intent may be established when an applicant knew, or should have known, of the materiality of an act or omission. See *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334 (Fed. Cir. 2008); *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008).

After establishing materiality and intent to deceive, the court determines whether the alleged conduct amounts to inequitable conduct by balancing the levels of materiality and intent. *Digital Control*, 437 F.3d at 1313.

Therasense v. Becton

Through mergers and acquisitions, Therasense (now “Abbott”) acquired U.S. Patent No. 4,545,382 (“’382 patent”) and its counterpart, European Patent No. 0078,636 B2 (“EPO ’636 patent”), which both shared the same specification that disclosed a test strip for measuring blood sugar from samples of whole blood. The specification stated that the test strip should “optionally, but preferably” contain a protective membrane when used on live blood.

The ’382 patent lived out its patent term; however EPO ’636 patent was initially revoked based on a German prior art reference labeled D1. The EPO argued that because D1 disclosed an electrode usable for glucose testing covered by a semipermeable membrane, the ’636 patent was obvious. Abbott argued that the ’636 phrase “optionally, but preferably” meant that a membrane was not absolutely required for whole blood testing while D1 required a membrane. As a result, the EPO ’636 patent was reissued.

Several years later, Abbott’s predecessors were granted U.S. Patent No. 6,820,551 (“’551 patent”), an advancement of the ’382 patent, which claimed a test strip with a membraneless electrochemical sensor for measuring glucose levels from whole blood. During prosecution,

several of the ’551 patent claims were rejected in light of the ’382 patent as being obvious. In an attempt to distinguish the ’382 patent, Abbott argued that the ’551 specification disclosed a sensor for use in whole blood without any protective membrane. Additionally, in contrast to the arguments made during the EPO ’636 patent revocation process, Abbott submitted a declaration by its scientist to the PTO stating one of ordinary skill in the art would have believed that the word “preferably” in the ’382 patent specification meant a membrane was required. Abbott did not disclose the prior statements made to the EPO regarding the ’636 patent and D1 reference to the PTO. Shortly thereafter, the PTO allowed the ’551 patent with claims for a membraneless sensor.

Subsequently, Abbott brought a patent infringement suit against Becton alleging that Becton sold glucose sensors that infringed the ’551 patent. The district court determined that claims 1-4 of the ’551 patent were invalid due to obviousness and that the entire ’551 patent was unenforceable due to inequitable conduct based on Abbott’s failure to disclose statements made to the EPO during the revocation proceeding of the EPO ’636 patent. *Therasense v. Becton*, 565 F.Supp.2d 1088 (N.D. Cal. 2008).

Addressing the inequitable conduct allegations, Abbott argued that lawyer arguments about prior art did not constitute information material to patentability and that since both the EPO and the PTO representations were merely arguments, any inconsistency between the two could not be material.

Applying the Rule 56(b) definition of materiality, the district court disagreed and held that the statements made to the EPO were material, and that both the attorney and the individual who made the declaration before the PTO had the intent to deceive the PTO. The court inferred intent because Abbott affirmatively decided not to disclose the EPO ’636 patent statements despite knowledge that the same issue with contrary interpretation was being debated in the ’551 patent examination.

Roads to Inequitable Conduct Doctrine II

Although the Federal Circuit initially affirmed the district court, the Federal Circuit granted a rehearing and directed the parties to brief whether the materiality-intent-balancing framework of the inequitable conduct standard should be modified or replaced. The court questioned whether a replacement standard should be tied directly to fraud or unclean hands. The parties were also asked to address the proper standard for materiality and under what circumstances intent should be inferred from materiality. The court also questioned whether balancing materiality and intent should be abandoned. *Therasense v. Becton*, 374 Fed. Appx. 35 (Fed. Cir. 2010).

During oral arguments, the court focused its questioning on the materiality and intent prongs of inequitable conduct. Addressing materiality, the parties agreed that the “reasonable examiner” standard is too vague and overly broad, resulting in a flood of documents on the PTO, and thus should be abandoned. Because of lack of precedent, the court appeared reluctant to adopt the “but for” standard.

The court expressed more concern with Rule 56(b) regarding the unpatentability standard. Under that standard, information should be deemed “material” and a claim found unpatentable if the information was known, and “material information” is defined as information that is inconsistent with an applicant’s position in support of patentability. Specifically, the court described these rules as broad, amorphous and effectively as problematic as the “reasonable examiner” standard. This suggests that a new rule may emerge somewhere between the “but for” and Rule 56(b) materiality standards.

Turning to intent, the court appeared eager to reaffirm *Kingsdown*, that the requisite level of intent is “specific intent” — not simple negligence, or even gross negligence. The parties agreed that intent should not be inferred from materiality but differed on whether intent should be determined independent of materiality. Although not siding either way, the court suggested a heightened standard for alleging inequitable conduct, including a requirement that intent be the single most reasonable inference; thus, suggesting inequitable conduct reform. ■