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IP Update

The Federal Circuit's En Banc *Therasense* Decision Tightens the Standard for Inequitable Conduct

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On May 25, 2011, the en banc Federal Circuit heightened the test for inequitable conduct, changing the standard for materiality and clarifying the requirements for finding intent to deceive.

Writing for a six-judge majority and joined by Judges Newman, Lourie, Linn, Moore, and Reyna, Chief Judge Rader explained that inequitable conduct is an equitable defense that developed from a trio of Supreme Court cases applying the doctrine of unclean hands to patent cases. Citing fluctuating standards and “evolution of the doctrine” over time, the majority stated that “the inequitable conduct doctrine has plagued not only the courts but also the entire patent system.” Slip op. at 23. Thus, the majority set out to “tighten [] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public” with this en banc decision. *Id.* at 24. The Court explained that if an accused infringer proves both the intent and materiality elements by clear and convincing evidence, the district court must then weigh the equities to determine whether the applicant’s conduct warrants rendering the entire patent unenforceable.

Turning to the standard, the majority first addressed the requisite intent for finding inequitable conduct. The Court clarified two issues regarding intent to deceive. First, the Court reaffirmed its prior decisions that require the party challenging the patent to prove a specific intent to deceive the U.S. Patent and Trademark Office (“PTO”) by clear and convincing evidence. A knowing and deliberate decision to deceive the PTO is required to establish deceptive intent. Second, the Court made clear that a district court may not use a “sliding scale” to find intent. That is, a weak showing of intent may not be found sufficient based on a strong showing of materiality, or vice versa. While a district court may infer intent from indirect and circumstantial evidence, to meet the clear and convincing evidence standard, the Court reiterated that specific intent to deceive must be “the single most reasonable inference able to be drawn from the evidence.” *Id.* at 25 (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)). The Court reaffirmed that intent may not be inferred solely from materiality of the allegedly false or withheld information.

For the materiality aspect of the inequitable conduct inquiry, the Court held that, as a general matter, the requisite materiality required to establish inequitable conduct is now “but-for materiality.” *Id.* at 27. That is, the district court must find that clear and convincing evidence establishes that but-for the deception, the PTO would not have allowed a claim. “In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.” *Id.* at 28. Furthermore, the Court held that an exception to the but-for general rule of materiality would arise in cases of affirmative egregious misconduct, such as the filing of an unmistakably false affidavit.

Accordingly, because the district court did not apply the new but-for test for materiality, the Court vacated the district court’s findings of materiality and remanded for determination consistent with the Court’s but-for test. Furthermore, because the district court did not apply the knowing and deliberate standard for

proof of intent to deceive, the Court vacated and remanded the district court's findings of intent, as well.

In a separate opinion, Judge O'Malley dissented from the majority's opinion regarding the test for materiality and decision to vacate and remand for reassessment of that factor, but concurred with the rest of the majority's decision and judgment. Specifically, Judge O'Malley joined the portion of the majority opinion that set forth the standard for specific intent to deceive. Regarding materiality, Judge O'Malley stated that she believes that both the majority and the dissent "strain too hard to impose hard and fast rules." Slip op. at 3 (O'Malley, J., concurring-in-part, dissenting-in-part). Judge O'Malley would adopt a test similar to the majority's materiality test, but would also allow the district court flexibility to find materiality if the district court found the behavior to be "so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined." *Id.* at 9. Moreover, Judge O'Malley would confirm that the test was for guidance purposes only and that the district courts should be allowed to exercise discretion with respect to inequitable conduct claims.

Writing in dissent and joined by Judges Gajarsa, Dyk, and Prost, Judge Bryson would have affirmed the district court's judgment of inequitable conduct. The dissent first noted its agreement that proof of inequitable conduct requires a showing of specific intent to deceive the PTO and that there should be no "sliding scale" of proving intent or materiality. The dissent then stated that the area of "sharp disagreement" was regarding the proper standard for determining materiality. Slip op. at 3 (Bryson, J., dissenting). The dissent stated that it would adhere to the PTO's materiality standard for two reasons. First, the PTO is in the best position to know what information examiners need to examine applications. Second, the dissent believes the majority's higher standard would not provide appropriate incentives for applicants to comply with the PTO's disclosure obligations. The dissent believes that the majority's but-for test "is not a tweak to the doctrine of inequitable conduct; it is a fundamental change." *Id.* at 8.

Evaluating the district court's decision in light of what it believed to be the proper test for materiality, the dissent did not consider the district court's findings to be clearly erroneous.

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