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To Have Committed Inequitable Conduct or Not? That is the Question—to be Answered

The U.S. Court of Appeals for the Federal Circuit, which hears all U.S. patent infringement appeals, issued an order on April 26, 2010 requesting briefs from the parties in *Therasense, Inc. v. Becton, Dickinson, and Co.* (appeal no. 2008-1511) to consider *en banc* the standards by which courts should find "inequitable conduct." The current standard to find inequitable conduct is that a: "patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." *Technologies Intl. v. Espeed,* 2008-1392, *34 (Fed. Cir. 2-25-2010) (citing *Digital Control Inc. v. Charles Mach. Works,* 437 F.3d 1309, 1313 (Fed. Cir. 2006)). This issue is typically decided by the trial court and not the jury. Where a judgment regarding inequitable conduct follows a bench trial...[the Federal Circuit] reviews the district court's findings of materiality and intent for clear error and its ultimate conclusion for an abuse of discretion. *See* 501 F.3d 1307, 1314 (Fed. Cir. 2007).

Significantly, the Federal Circuit has asked for briefing on all the major elements of the test for inequitable conduct as follows:

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? See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.,* 322 U.S. 238 (1944), overruled on other grounds by *Standard Oil Co. v. United States,* 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.,* 290 U.S. 240 (1933). 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? See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.,* 863 F.2d 867 (Fed. Cir. 1988) (en banc).
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.

Based on the tremendous significance of this issue, and the variety of cases impacted by the potential outcome, the Federal Circuit also requested amicus briefs (*i.e.,* "Friend of the Court" briefs) from interested stakeholders.

Courts disfavor this defense to patent infringement and at least some judges will be likely to limit the usage of inequitable conduct, in part because it has been pled in virtually every case by the accused infringer. At least some judges on the Federal Circuit have also recognized the law relating to inequitable conduct is not a model of clarity, which has led to practices disfavored by the U.S. PTO in prosecuting patent applications. As Judge Newman once complained:

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> Litigation-induced assaults on the conduct of science and scientists, by aggressive advocates intent on destruction of reputation and property for private gain, produced the past "plague" of charges of "inequitable conduct." A successful attack on the inventor or his lawyer will destroy the patent, no matter how valid the patent and how sound the invention. The uncertainties of the processes of scientific research, the vagaries of the inductive method, the complexities of patent procedures, and the twists of hindsight, all provided grist for this pernicious mill. Indeed, the prevalence of accusations of inequitable conduct in patent cases led judges to suspect that all scientists are knaves and all patent attorneys jackals.

Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1371 (Fed.Cir. 2003) (dissenting opinion). While the outcome of Therasense *en banc* cannot be determined with any certainty, the detailed questions to be briefed suggest that the Federal Circuit is about to take a hard look at the present loose standards applicable to allegations of inequitable conduct.

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