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The Federal Circuit to Address the Inequitable Conduct Doctrine En Banc for the First Time in Over 20 Years

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Proponents of inequitable conduct reform have heavily petitioned Congress for change. The Federal Circuit, however, is poised to be the first to take action as a result of yesterday's grant of a request for *en banc* rehearing on the issue of inequitable conduct in *Therasense, Inc. v. Becton, Dickinson & Co*. 2008-1511 (Fed. Cir. 2010) (available here).

Over 20 years ago, in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, the Federal Circuit issued an *en banc* opinion in which it held that inequitable conduct requires that both materiality and deceptive intent be separately proven by clear and convincing evidence. 863 F.2d 867 (Fed. Cir. 1988). Many district courts, and even the Federal Circuit, however, have been criticized for inconsistently applying *Kingsdown* and its progeny, turning the application and value of the inequitable conduct doctrine into hotly-debated issues.

The inequitable conduct issue in *Therasense* concerned the district court's finding that the patentee made statements to the United States Patent and Trademark Office ("PTO") regarding certain prior art that were inconsistent with statements made to the European Patent Office ("EPO").[1] *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088 (N.D. Cal. 2008). Specifically, the patent at issue was directed to a glucose test strip for diabetics designed to function without a membrane over the strip's sensor. A prior art reference disclosed a similar test strip, but referred to the use of a membrane as "optionally, but preferably when being used on live blood." The district court found that, in an attempt to distinguish its invention, the patentee told the PTO, in both a declaration and amendment, that the prior art would be understood by a person of ordinary skill in the art as ***requiring*** a membrane for use with whole blood. *See* 565 F. Supp. 2d at 1107. Prior to this representation, however, the district court found the patentee argued to the EPO that the same prior art was "unequivocally clear" in disclosing that the membrane is ***optional***, and merely preferred for live blood. *Id.* at 1109. Significantly, the district court found the patentee never disclosed to the PTO the statements it had previously made to the EPO. The district court held that the statements made to the EPO were material, and that both the prosecuting attorney and the individual who made the declaration before the PTO had the intent to deceive the PTO. *Id.* at 1112-17.

On January 25, 2010, the Federal Circuit affirmed the district court's holding of inequitable conduct. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289 (Fed. Cir. 2010). The Federal Circuit found that the district court's findings regarding materiality were not clearly erroneous, and were indeed manifestly correct: the EPO statements were highly material because they contradicted a position taken before the PTO. 593 F.3d at 1303, 1305. The Federal Circuit also found no clear error in the

district court's finding on intent, reasoning that the patentee came forward with no plausible rationale for the nondisclosure, and relying on the district court's assessment of witness credibility. *Id.* at 1306, 1308.

In a lengthy dissenting opinion, Judge Richard Linn stated that the district court and the majority erred on both the materiality and intent prongs. As to materiality, he found the majority erred because they adopted an unfavorable inference of materiality when there was an equally reasonable favorable inference that the EPO submission was immaterial; in his opinion, this is inappropriate under *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365 (Fed. Cir. 2008), when submissions are open to multiple reasonable interpretations, as were the EPO submissions in this case. *Therasense*, 593 F.3d at 1312-13. As for intent, Judge Linn stated that the majority erred by failing to recognize that the required intent to deceive is measured by a subjective standard rather than an objective standard, explaining that the question is not whether it is plausible that the statement was immaterial, but whether it is plausible that the patentee *subjectively believed* the statement was immaterial. *Id.* at 1312, 1320.

In petitioning the Federal Circuit for rehearing *en banc*, Therasense argued that: (1) the inequitable conduct doctrine needs reform; (2) the majority's decision deepens persistent confusion about inferring deceptive intent and significantly lowers the standard for proving it; (3) the panel opinion creates intra-circuit conflict by permitting intent to be inferred from a reasonable dispute over materiality; and (4) the majority undermines the rule that arguments about prior art are not material when the PTO has the underlying prior art.

Yesterday's *en banc* order vacated the January 25, 2010 panel decision, and specifically requested that the following six questions be addressed in new briefing:

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 Precison 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.

Pursuant to the Order granting *en banc* rehearing, Appellants' *en banc* brief is due 45 days from April 26, 2010. The response brief is due within 30 days of service of the appellants' *en banc* brief, and the

reply brief within 10 days of service of the response brief. In addition, briefs of *amici curiae* will be entertained, and the USPTO has been invited to participate as *amicus curiae*.

The ruling by the Federal Circuit in *Therasense* will be a significant event in the development of patent law. Whether the Federal Circuit will finally succeed in curbing the "plague" of inequitable conduct allegations, *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988), will likely depend on the clarity and strength of the opinion ultimately issued.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following New York Paul Hastings lawyers:

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[1] There were three patents in suit in *Therasense*. The district court found that certain claims of U.S. Patent No. 5,820,551 ("the '551 patent") were obvious, and the entire '551 patent was unenforceable due to inequitable conduct. The district court also found that U.S. Patent Nos. 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent") were not infringed, and the '745 patent was invalid due to anticipation. Therasense appealed all determinations from the district court, and the Federal Circuit affirmed on all counts. This Alert only addresses the district court's and Federal Circuit's decisions relating to inequitable conduct.