Patent Law Update: Federal Circuit Signals Big Changes on Inequitable Conduct Likely By Year End 2010

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Federal Circuit Signals Big Changes on Inequitable Conduct Likely By Year End 2010

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On April 26, 2010 the Federal Circuit Court of Appeals signaled that big changes are likely to come soon to the law of inequitable conduct, as related to patent procurement and enforcement. The Court granted a petition to take a case en banc, posing questions to the parties that foreshadow potential for a substantial narrowing of the doctrine of inequitable conduct. In that case, *Therasense, Inc. v. Becton Dickinson & Co.*, No. 2008-1511, a three judge panel affirmed a district court conclusion of inequitable conduct. The conclusion was specifically that a patent related to disposable diabetes blood test strips was unenforceable because statements made in international patent prosecution were not disclosed to the US PTO in the corresponding US case.

The district court found no evidence of good faith. The majority of the Federal Circuit panel agreed. Judge Linn, however, dissented as to this conclusion in a lengthy opinion that discerned many reasonable patent-owner-favorable interpretations of the statements made, and discerned plausible, specific, and detailed reasons for an alleged belief that the information was not material. Judge Linn also asserted that the rule of law was that inequitable conduct required any adverse inference drawn from the evidence had to be the single most reasonable inference, and that the rule of law was violated in the case.

In the Federal Circuit decision today, the Court accepted the case en banc, and listed the following questions for the parties (the court's references to specific cases are omitted):

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 US PTO'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.

As apparent from the number and range of these questions, the whole of the framework of law for inequitable conduct is now in question at the Federal Circuit. The Court is asking whether to modify, replace or abandon the balancing of materiality and intent. It is asking for a potential new standard for materiality. It is asking for potential new law on inferring intent from materiality. It is asking if definitions of materiality and intent from other bodies of law should cause it to change the standards of materiality and intent for patent law. Given the Court's willingness to replace older Federal Circuit law as expressed for example by *In re Seagate* as to willfulness of infringement, the Federal Circuit is expressing the potential for the whole of inequitable conduct law to change.

The Court invites an amicus brief from the US PTO, and states it will entertain other amicus briefs. It also puts the case on a briefing schedule such that briefing should be complete in about 3 or more months. Assuming as much interest as in *Seagate*, many local and national patent bar associations, and many individual corporations along with foundations and industry advocacy groups will weight in with amicus briefs. Assuming about 5 months to decision after briefing as in *Seagate*, the patent law is likely to have a new law of inequitable conduct by year end 2010. Note that by then, Chief Judge Michel will be retired, and 2 of the Court's 12 judges will likely be new to the Court's bench.

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