

The Federal Circuit Agrees to Rehear Inequitable Conduct Case En Banc

MAY 1, 2010

Last week, the Court of Appeals for the Federal Circuit (“CAFC”) granted a petition requesting that it rehear *en banc* its January 25, 2010 decision in *Therasense, Inc. v. Becton, Dickinson & Co.* The previous *Therasense* panel decision (Judges Linn, Friedman and Dyk) affirmed a district court’s ruling that one of the three patents-in-suit (owned by Abbott Diabetes Care, Inc.) was unenforceable due to inequitable conduct. The inequitable conduct finding was based upon the patentee’s failure to disclose to the U.S. Patent & Trademark Office certain statements made by the patentee’s attorneys to the European Patent Office. Those statements occurred during the patentee’s prosecution of a European patent application that was a counterpart to a patent asserted during the litigation to be invalidating prior art to one of the three patents-in-suit in the litigation.

In the order, the CAFC identified the issues that will now be reconsidered and ruled upon by all of the CAFC justices. These issues include:

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 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?
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?

All of these issues are ones that have been identified as having unclear answers due to conflicting panel decisions of the CAFC over its almost 30 years of existence.

The CAFC’s decision to address inequitable conduct *en banc* should come as no surprise to those who have been following the Court’s inequitable conduct decisions over the last few years as several of those decisions have included detailed and vigorous concurrences and dissents by various justices. Judge Linn, in fact, explicitly identified the need for the CAFC to address at least “the test for inferring deceptive intent” in his concurring opinion in *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317 (Fed. Cir. 2009). Similarly, Judge Rader in *Aventis Pharma S.A. v. Amphastar Pharmas., Inc.* 525 F.3d 1134 (Fed. Cir. 2008) referred to inequitable conduct as having “taken on a new life as a litigation tactic” and suggested that the CAFC “ought to revisit occasionally its *Kingsdown*

opinion” where the Court had concluded inequitable conduct was a “plague” and took steps to reduce abusive allegations of the defense.

Hearing of the *Therasense* case *en banc* and a decision on all of the issues identified for rehearing should result in the CAFC clarifying the legal standards for proving inequitable conduct and, thus, provide greater guidance on what conduct will lead to a patent being declared unenforceable. Opening briefs are due in June and all briefing will be completed before the end of July, followed by oral arguments at a date to be determined (possibly September or October). The decision by the *en banc* CAFC may not be issued until the end of 2010 or the beginning of 2011.

Additional Information

For more information, please contact:

Jenny Sheaffer at 216.363.4453 or jsheaffer@beneschlaw.com.