



ARE Patent Law Alert: Federal Circuit Finds Patents Unenforceable Under Therasense Standard

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(May 11, 2012) On April 9, 2012, the Federal Circuit affirmed the U.S. District Court for the District of Delaware's holding that Aventis Pharma's patent claims were unenforceable on inequitable conduct grounds under the higher standard for unenforceability set forth in *Therasense*. See *Aventis Pharma S.A. v. Hospira*, 2012 U.S. App. LEXIS 7095, at *20 (Fed. Cir. Apr. 9, 2012) ("*Aventis II*"). Notably, the district court had found inequitable conduct under standards that were in effect prior to the Federal Circuit's *en banc* decision in *Therasense*.

In affirming the district court's findings that the inventor of the patents at issue engaged in inequitable conduct by failing to disclose two prior art references, the Federal Circuit relied on its holding in *Therasense* which had rejected a "sliding scale" approach to proving inequitable conduct, finding instead that the two elements of the inequitable conduct defense - materiality and intent - are "separate requirements" Under *Therasense*, "but-for materiality is the standard for evaluating the materiality prong of the analysis unless there is affirmative egregious misconduct." *Aventis II*, 2012 U.S. App. LEXIS 7095, at *20. *Therasense* further requires clear and convincing proof that "the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." Moreover, a finding of specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." *Id.* The Federal Circuit agreed with the district court's finding of intent and materiality were sufficient to find inequitable conduct under the heightened *Therasense* standards. *Id.* at *19.

As to materiality, the Federal Circuit agreed that the but-for materiality standard was met because, *inter alia*, the district court had found these references sufficient to render the asserted claims of the patents-in-suit obvious and the references were inconsistent with the positions that patentee took in arguing for the patentability of the claims. *Id.* at *21.

As to the intent prong, the district court had found intent to deceive based on the evidence and its assessment of the inventor's testimony, and determined that the inventor knew that the reference was relevant to the patentability of his alleged invention, but chose not to disclose it. Although the inventor attempted to raise certain excuse-arguments, the district court found and Federal Circuit agreed that such excuses were not credible and were inconsistent with other aspects of his testimony. For example, the inventor argued that he did not disclose one of the references, because tests based on using the solution disclosed



therein had failed. However, this was contradicted by other evidence and testimony which highlighted the importance of the solution to the patented invention. Deferring to the district court's credibility determinations in light of the evidence, the Federal Circuit did not disturb the district court's finding of specific intent to deceive the PTO. *Id.* at *26.

Aventis II is significant in that it marks the first the time that the Federal Circuit has upheld a finding of inequitable conduct since the *Therasense* decision and demonstrates that failure to cite prior art can still raise issues of inequitable conduct in the face of the higher standard articulated in *Therasense*.

We will continue to monitor and report on inequitable conduct cases, and encourage you to review the publications and events page of our firm website (www.arelaw.com) for more information. Please feel free to contact one of our firm's attorneys to learn more.

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