



## Alerts

### Federal Circuit Reins in Patent Inequitable Conduct Law

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*Intellectual Property Update*

On May 25, 2011, the U.S. Court of Appeals for the Federal Circuit issued its long awaited *en banc* decision in *Therasense, Inc. v. Becton, Dickinson and Co.*, 2011 WL 2028255. The effect of the court's decision is a rewrite of the law of inequitable conduct in patent cases. Specifically, the Federal Circuit tightened the standards for proving both intent and materiality for inequitable conduct. An accused infringer must now prove that the patentee acted with the specific intent to deceive the U.S. Patent and Trademark Office (PTO) and that a withheld prior art reference meets a "but-for" standard of materiality to support an inequitable conduct claim. The appellate court also eliminated the so-called sliding scale that would allow a greater showing of materiality to compensate for a lesser showing of intent and vice versa.

Chief Judge Randall R. Rader, writing for the majority, stated that the accused infringer "must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." It is not enough to prove that the applicant knew of the reference, *should have known* of the reference's materiality and did not disclose the reference. While the requisite intent to deceive can be inferred, the specific intent to deceive must be the single most reasonable inference that can be drawn from the evidence.

The Federal Circuit emphasized that intent and materiality are separate requirements of inequitable conduct. Thus, courts should no longer use a sliding scale in determining the sufficiency of the materiality and intent evidence.

As to materiality, the Federal Circuit adopted a "but-for" standard requiring proof that the PTO would not have allowed the claim had it been aware of the reference. This determination is to be made using the preponderance of the evidence standard and the broadest reasonable claim construction supported by the specification—i.e., the standards used by the PTO during prosecution. The Federal Circuit did recognize an exception to the requirement of "but-for" materiality in the context of "affirmative egregious misconduct."

A four-judge dissent argued that the PTO's Rule 56, which imposes a duty of candor and good faith in dealing with the PTO, should be used as the standard for determining materiality because: (1) the PTO knows what level of disclosure

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is desirable during patent prosecution to allow examiners to do their jobs effectively without being buried in marginally relevant references; and (2) the majority's higher materiality standard will not provide any incremental incentive for applicants to disclose references because the only references required to be disclosed are those that would invalidate the claims anyway.

Most patent litigators accurately predicted the tightening of the intent standard and the demise of the sliding scale. But adoption of the but-for materiality standard came as a surprise to many. This materiality standard likely will require accused infringers to narrow the subject of their inequitable conduct allegations to undisclosed references that would have rendered a claim unallowable. Accused infringers would be wise to rely on those same references as part of their invalidity defense as well. Patent owners, meanwhile, should determine whether such undisclosed references can readily be proven to fall short of this mark. If so, they should consider early summary judgment motions to eliminate the specter of inequitable conduct, which, if proven, can lead to an exceptional case finding and award of attorney fees.

*This alert has been prepared by Hinshaw & Culbertson LLP to provide information on recent legal developments of interest to our readers. It is not intended to provide legal advice for a specific situation or to create an attorney-client relationship.*