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## Fed. Circ. Reins In Inequitable Conduct Doctrine

*Law360, New York (September 09, 2008)* -- Recently, the Federal Circuit in *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 2007-1524, articulated perhaps its most conservative approach yet concerning the deceptive intent element of the inequitable conduct defense, ruling that deceptive intent drawn from indirect evidence must be the single most reasonable inference able to be drawn from the evidence.

Inequitable conduct requires a material act or omission coupled with an intent to deceive. While that standard may seem clear enough, the doctrine of inequitable conduct evolved with wavering guidelines concerning the quantum of evidence necessary to prove the defense, particularly with respect to the intent element.

The *Star Scientific* decision may signal an effort by the Federal Circuit to halt the swinging pendulum that has plagued the inequitable conduct doctrine since its inception.

### *The Swinging Pendulum Of Inequitable Conduct Law*

Originally, loss of a patent for inequitable conduct was applied in cases of “technical fraud” on the Patent Office. Early notions of fraud included false representations of material fact coupled with an intent to deceive the Patent Office for purposes of obtaining a patent.

In *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), for example, the fraud included a submission of a falsified article describing the inventor’s work as “a remarkable advance” over the prior art.

While the Supreme Court recognized that not all types of fraud demand “equitable intervention,” the Court nevertheless found the conduct so egregious as to justify denying the patentee any relief sought through a patent infringement action.

Subsequent evolution of the doctrine provided that a more liberal standard of gross negligence could evidence intent to deceive for purposes of inequitable conduct.

In *In re Jerabek*, 789 F.2d 886 (Fed. Cir. 1986), for example, the Federal Circuit held that “one may properly infer an intent to mislead the PTO from counsel’s failure to disclose [a material prior art] reference.” That inference can be drawn from “clear and convincing evidence” that counsel was “grossly negligent in failing to disclose the reference” to the PTO.

In *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1998) (en banc), the Federal Circuit rejected the gross negligence standard, and the pendulum swung back to a more conservative approach.

In *Kingsdown*, the patent applicant erroneously represented to the PTO that the claim in the application corresponded to a claim previously allowed by the examiner in the parent application. The Federal Circuit stated that “*Kingsdown*’s counsel may have been careless, but it was clearly erroneous to base a finding of intent to deceive on that fact alone.”

While the Federal Circuit appeared to settle on a more conservative approach in *Kingsdown*, the pendulum swung back to more liberal approaches in subsequent cases. For example, in *Bristol-Meyers Squibb Co. v. Rhone-Poulenc Rorer Inc.*, 326 F.3d 1226 (Fed. Cir. 2003), the Federal Circuit affirmed inequitable conduct because a foreign patent agent failed to inform U.S. patent counsel of the existence of certain prior art.

Despite the fact that the examiner found the missing prior art and identified it in a search report, there was no indication that the examiner appreciated the importance of the prior art. The Federal Circuit upheld the district court’s conclusion that counsels’ knowledge of the article and of their duty to disclose material information was “sufficient to establish intent.”

The pendulum swung even further in the liberal direction in *Novo Nordisk Pharmaceuticals Inc. v. Bio-Technology General Corp.*, 424 F.3d 1347 (Fed. Cir. 2005), where the Federal Circuit upheld a finding of inequitable conduct because the prophetic examples contained in the patent were written in past tense.

Despite evidence that the Danish inventor did not understand that verb tense could change the meaning of an example for purposes of U.S. patent law, the Federal Circuit upheld the lower court’s inference of deceptive intent based on the presumption that the inventor “knew or should have known that the PTO and the Board would have considered the information” material.

### *The Federal Circuit In Star Scientific Swings The Pendulum Again*

This week, the Federal Circuit swung the pendulum back in the conservative direction in *Star Scientific*, ruling that to prevail on the defense of inequitable conduct, “the accused infringer must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO.”

Writing for the panel, Chief Judge Michel stated that “materiality does not presume intent,” rather “the accused infringer must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO.”

Despite the high professional reputations of those involved, the district court concluded that counsel engaged in inequitable conduct by not disclosing prior art to the PTO that they knew or should have known to be material.

The Federal Circuit reversed this finding, concluding that the alleged infringer failed to elicit any evidence that counsel had knowledge of the non-disclosed prior art during prosecution of the patent application.

The panel stated that “[n]o inference can be drawn if there is no evidence, direct or indirect, that can support the inference. [Defendants’] lack of any evidence at all on the crux of its theory, let alone clear and convincing evidence, demonstrates that it failed to carry its burden.”

While purporting to uphold the Federal Circuit’s guidance that “intent can be inferred from indirect and circumstantial evidence,” the panel limited that proposition by stating that inferences drawn from “lesser evidence,” i.e., less than clear and convincing, “cannot satisfy the deceptive intent requirement.”

In other words, the predicate facts upon which a court may draw an inference of deceptive intent must be proven by clear and convincing evidence.

The panel further ruled that “the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.”

The Federal Circuit also held that the patentee need not offer a good faith explanation for the misconduct absent clear and convincing evidence of intent to deceive. “Only when the accused infringer has met this burden is it incumbent upon the patentee to rebut the evidence of deceptive intent with a good faith explanation for the alleged misconduct.”

Interestingly, the panel stated in dicta that “even if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant’s conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable.”

While the exercise of “equitable intervention” has always been part of the inequitable conduct doctrine, Chief Judge Michel might be laying the groundwork for adding more hoops to the inequitable conduct defense.

The pendulum thus appears to be heading away from the liberal approaches articulated in cases such as *Novo Nordisk* to the more conservative approaches advanced in cases such as *Kingsdown*.

*Where Do We Go From Here?*

Whereas the courts have been liberalizing the inequitable conduct standards in recent years, the Federal Circuit in *Star Scientific* appears to have swung the pendulum back to a more conservative approach.

In asserting a defense of inequitable conduct, an accused infringer may now have to jump through more hoops in order to satisfy its burdens under the clear and convincing evidence standards.

Even if the accused infringer is successful in proving an inequitable conduct defense, the district court may not be required to hold the patent unenforceable.

While *Star Scientific* may signal yet another shift in the pendulum of inequitable conduct law, this will certainly be an area worth watching for both patent holders and potential infringers.

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