

PATENT UNENFORCEABILITY AND STAR SCIENTIFIC'S IMPACT

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In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Company et ano (Star Scientific)*, on August 25, 2008, the US Court of Appeals for the Federal Circuit (Federal Circuit) clarified and set more difficult requirements for rendering a patent unenforceable based upon the defence of inequitable conduct. Patent litigators dealing with patent unenforceability issues will be wise to tailor their strategies to the reasoning of the Federal Circuit's ruling in *Star Scientific*. It is to this court, which specialises in patent law, that all patent appeals are taken. Given that the US Supreme Court does not accept many patent appeals, Federal Circuit decisions such as *Star Scientific* are that much more significant.

Inventors and others substantially involved in the preparation of patent applications and their prosecution owe a duty of candour to the US Patent and Trademark Office (USPTO). They must disclose to the USPTO all known information that is material to its examination of an application. Inequitable conduct normally arises as a result of one or more misrepresentations or omissions of material fact, coupled with an intent to mislead or deceive the USPTO. The most common allegation involves the withholding of material prior art from the USPTO. However, inequitable conduct may also arise from a failure to disclose the best mode of the claimed invention at the time of filing the application. Other examples of misconduct that are potentially fatal to a patent application include submitting a misleading declaration, failing to name a co-inventor and including false statements in petitions.

It is District Court judges, not juries, who at their sole discretion decide whether patents should be rendered unenforceable. Where a court determines that there has been a breach of this duty of candour with respect to some of the patent claims, the court can use its discretion to render the entire patent unenforceable.

Courts have expanded the scope of this doctrine to encompass conduct that is far less egregious than fraud. Some have applied this doctrine to relatively minor patent prosecution missteps involving minimal culpability. Where allegations are misused, inequitable conduct has been referred to as a "scourge" on patent litigation by the Federal Circuit for causing ballooning litigation costs and adding uncertainty to the outcome of disputes.

The unanimous decision in *Star Scientific* changes this landscape and offers welcome predictability. The court reaffirmed the importance of intent to deceive the USPTO as an essential component of inequitable conduct. It is an element distinct from the issue of materiality. The Federal Circuit makes it clear that intent will not be presumed from mere evidence of the materiality of information having been withheld from the USPTO. An accused infringer will now be required to present clear and convincing evidence of specific intent to mislead or deceive the USPTO. He will be required to prove that

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the applicant made a deliberate decision to withhold a known reference. Inferences drawn from lesser types of evidence, such as from indirect and circumstantial evidence, will not satisfy the Federal Circuit's predicate for deceptive intent. District Courts will be constrained to ensure that, for an inference of deceptive intent to be properly drawn, it must be the single most reasonable inference able to be drawn from the evidence, in order to meet the clear and convincing evidence standard.

If a threshold level of intent to deceive is not established by clear and convincing evidence, or if materiality is not established by applying the same evidentiary standard, *Star Scientific* removes from the District Court's exercise of discretion the right to render a patent unenforceable, regardless of the relative equities or how it might balance them. Only after adequate showings of both intent to deceive and materiality will District Courts be entitled to weigh the equities. The absence of a good faith explanation, absent other clear and convincing evidence showing intent to mislead or deceive, will not alone warrant a finding of an inference of intent. There must be evidence to support the inference.

Star Scientific makes it far tougher for an accused infringer to convince a court to render a patent unenforceable.

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