

A Circuit Divided: Supreme Court Refuses Request to Reconcile Federal Circuit's Dissonant Inequitable Conduct Standards

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Last month's denial by the United States Supreme Court of a petition for certiorari filed by Aventis Pharma S.A. signals continued uncertainty regarding the state of the law of inequitable conduct. Aventis had petitioned the Supreme Court to review the Federal Circuit's decision affirming a district court finding of inequitable conduct in *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334 (Fed. Cir. May 14, 2008). Federal Circuit inequitable conduct cases decided since *Aventis*, such as *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. Aug. 25, 2008), have applied a restrictive view of the inequitable conduct defense that is inconsistent with the result in *Aventis*. The Supreme Court's refusal to intervene leaves practitioners wondering how to reconcile the Federal Circuit's divergent lines of authority.

In May of 2008, the Federal Circuit, by a panel majority consisting of Judges Prost and Moore, affirmed a district court's judgment that the patents asserted by Aventis are unenforceable. The patents in suit were directed to low molecular weight heparins used to prevent thromboses (blood clotting) while minimizing the possibility of hemorrhaging, especially during high risk surgery. *Aventis Pharma*, 525 F.3d at 1337-38.

During prosecution, Aventis had responded to the examiner's claim rejections by submitting a declaration stating that the half-life of the claimed formulation was distinguishable from the half-life of the prior art formulations on which the examiner relied. *Id.* at 1338-39. The examiner maintained his obviousness rejection stating that Aventis presented no evidence that the claimed compounds would have any properties or activities not necessarily inherent in the prior art compounds, the differences between the claimed compounds and the prior art compounds were minimal, and there were no unexpected results. *Id.* at 1339. Aventis submitted a second declaration

referencing and attaching tables showing half-life results to support a claim that the half-lives are different. Thereafter, the application was allowed. *Id.* at 1340.

During the infringement litigation, Defendant Amphastar asserted that the declaration Aventis submitted to overcome the examiner's claim rejection failed to disclose that the half-life studies comparing the patented composition to the prior art compound were done at different doses. Amphastar asserted that Aventis's misrepresentation of this material information constituted inequitable conduct. The district court agreed. *Id.* at 1341.

On a first appeal, the Federal Circuit held that the failure to disclose that the half-life studies were done at different doses constituted a material misrepresentation. The Federal Circuit remanded the case to the district court to determine the reasonableness of doing the comparison at difference doses, however, because reasonableness is relevant to intent to deceive. *Id.* at 1341-42.

On remand, Aventis asserted that doing the comparison at different doses was reasonable because (1) it was customary to compare half-lives at the "clinically relevant dose" and the comparisons were intended to show a difference in therapeutic properties, (2) half-lives are dose independent, and (3) the failure to disclose was mere inadvertence. *Id.* at 1342. The district court rejected these explanations and inferred that Aventis had intended to deceive the Patent Office. *Id.* at 1343.

The record contained no direct evidence of any intentional deception and Aventis provided multiple explanations for why the omission of the statement that the half-life comparison was done at different doses was not intended to deceive. Despite the multiple explanations proffered by Aventis, the Federal Circuit affirmed the district court explaining that "[t]he district court heard [the declarant's] testimony and considered it along with all other evidence relevant to deceptive intent, yet determined that it did not outweigh the cumulative evidence evincing an intent to deceive." *Id.* at 1348.

Judge Rader dissented stating that his "reading of [Federal Circuit] case law restricts a finding of inequitable conduct to only the most extreme cases of fraud and deception" and that because other reasonable explanations were given for the omission in this case a finding of deceptive intent cannot stand. *Id.* at 1349, 1351-52. Judge Rader lamented that "although designed to facilitate USPTO examination, inequitable

conduct has taken on a new life as a litigation tactic." *Id.* at 1349.

Later in 2008, in *Star Scientific*, the Federal Circuit sang a different tune when a panel consisting of Judges Michel and Dyk and Chief Judge Shalunna unanimously reversed a district court's finding that Star's patents were unenforceable due to inequitable conduct. The patents in suit were directed to a tobacco curing process aimed at lowering carcinogens. *Star Scientific*, 537 F.3d at 1361.

Defendant R.J. Reynolds asserted that Star committed inequitable conduct by withholding a letter written by a Star scientist raising concerns about some Chinese prior art. After a bench trial, the district court found the asserted Star patents unenforceable due to inequitable conduct. *Id.* at 1362, 1365.

In reversing the district court's finding of intentional deception, the Federal Circuit emphasized that "[t]he need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability." *Id.* at 1365.

Echoing the sentiment expressed in Judge Rader's dissent in *Aventis Pharma*, the Federal Circuit in *Star Scientific* warned that "courts must be vigilant in not permitting the defense [of inequitable conduct] to be applied too lightly" and that "[j]ust as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith." *Id.* at 1366.

The Federal Circuit held that to infer deceptive intent "the inference must not only be based on sufficient evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing evidence standard." *Id.* at 1366. The Federal Circuit thus held that because multiple inferences could be drawn from the facts, the district court clearly erred in finding deceptive intent. *Id.* at 1367-68.

Salient differences driving the distinct approaches to inequitable conduct in *Aventis Pharma* and *Star Scientific* are lacking. In both cases, the patent owner provided alternative explanations for the material omission or misrepresentation. In *Aventis Pharma*, the Federal Circuit gave the district court broad discretion to weigh the patentee's alternative explanation against the inference of deceptive intent. In *Star Scientific*, on the other hand, the Federal Circuit held that the existence of a reasonable alternative explanation completely precludes an inference of deceptive intent.

It remains to be seen how these divergent standards will be reconciled. Other recent Federal Circuit inequitable conduct reversals suggest that the trend may be leaning toward the standard applied in *Star Scientific*. But until the Federal Circuit takes the issue *en banc* or the Supreme Court intervenes, uncertainty remains. **(IPT)**