

Counsel's Actions Support Inference of Intent to Deceive PTO: Regeneron Pharmaceuticals v. Merus N.V.

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In a decision clarifying the analysis for inequitable conduct, a split panel of the US Court of Appeals for the Federal Circuit affirmed a district court finding of specific intent to deceive the US Patent and Trademark Office (PTO) during prosecution of an asserted patent, based largely on misconduct by litigation counsel during the district court action. *Regeneron Pharmaceuticals, Inc. v. Merus N.V.*, Case No. 16-1346 (Fed. Cir., July 27, 2017) (Prost, CJ) (Newman, J, dissenting). The dissent argued that the decision ignored the Court's own requirement that intent to deceive must be proved and not merely inferred.

Regeneron filed suit alleging that Merus infringed its patent directed to using large DNA vectors to target and modify endogenous genes and chromosomal loci in eukaryotic cells. The patented technology allows users to target and modify specific genes in mice so that the mice develop antibodies that can be used by humans.

Days before the PTO issued a notice of allowance for the application that would mature into the asserted patent, a third party filed a submission in the parent application, disclosing three prior art references. Regeneron's in-house patent prosecution counsel, who was prosecuting the application, knew of the references submitted in the parent application but failed to cite them to the examiner.

Merus contended that Regeneron's failure to cite those references constituted inequitable conduct. Regeneron argued that the in-house counsel did not have an obligation to disclose the references to the examiner because they were cumulative of other cited art and therefore not "but-for" material. Merus argued, however, that the withheld prior art taught the very thing that Regeneron's counsel claimed was missing from the prior art: insertion of human variable region gene segments into mouse immunoglobulin loci.

The district court scheduled a bench trial on Regeneron's inequitable conduct, bifurcating the trial based on the two elements of inequitable conduct: a first bench trial on the materiality of the withheld references and a second to consider specific intent to deceive the PTO. Following the first part of the bench trial, the district issued an opinion explaining why the withheld references were material. The district court never concluded the second part of the bench trial, however. Instead, the district court pointed to Regeneron's discovery misconduct, sanctioned Regeneron by drawing an adverse inference of specific intent to deceive the PTO, and held the patent unenforceable. Regeneron

appealed.

The Federal Circuit panel majority concluded that under the broadest reasonable construction of the claims (the construction applicable to the PTO examinations), the district court properly found that the withheld references were material. As for specific intent to deceive the PTO, the majority accepted the district court's sanctions, underscoring the extent and seriousness of Regeneron's litigation misconduct, in particular its "sword/shield" discovery tactics regarding the attorney-client privilege. The panel cited to the 2011 Federal Circuit *Therasense* decision for the proposition that "in a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference," but explained that "direct evidence of intent is not, however, required." Rather, a "court may infer intent from circumstantial evidence." The Court went on to note that Regeneron's behavior in district court was "beset with troubling misconduct." This misconduct included withholding as privileged a memo by an outside counsel regarding whether the prior art should be presented to the PTO, only to produce the memo at the last moment, at the start of deposition of the memo's writer.

In dissent Judge Newman argued that, under Supreme Court of the United States and Federal Circuit precedent, "deliberate withholding of but-for invalidating prior art, with the intent to deceive the examiner, must be established by clear and convincing evidence." Newman relied on *Apptix* for the proposition that "the remedies for litigation misconduct bar the malfeasant who committed the misconduct. The property right itself remains independent of the conduct of a litigant." In Newman's view, "intent to deceive the Examiner cannot be inferred from purported litigation misconduct several years later." Addressing the dissent, the panel majority took the position that *Apptix* was inapposite, that prosecution misconduct had occurred, and that Regeneron's litigation misconduct "obfuscated its prosecution misconduct."

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