

REGENERON PHARMACEUTICALS, INC., v. MERUS N.V., Appeal No. 2016-1346 (Fed. Cir. July 27, 2017). Before Prost, Newman, and Wallach. Appealed from S.D.N.Y. (Judge Forrest).

Background:

Regeneron sued Merus for patent infringement. Merus asserted a counterclaim of unenforceability due to inequitable conduct. Merus argued that Regeneron withheld four references from the PTO during prosecution that were but-for material, and were withheld by Regeneron with the specific intent to deceive the PTO. Regeneron argued that the references were not but-for material, but instead cumulative of references the PTO actually relied on during prosecution, and that Regeneron did not have any specific intent to deceive the PTO.

The district court bifurcated the trial based on the two elements of inequitable conduct (i.e., one for materiality, and another for intent). The district court found that the withheld references were but-for material, but never held the scheduled second trial on specific intent. Instead, the district court detailed Regeneron's discovery misconduct and sanctioned Regeneron by drawing an adverse inference of specific intent to deceive the PTO. The district court found that Regeneron failed to produce, *inter alia*, a number of documents on its privilege log relevant to topics in which privilege had been waived, such as its patent prosecutors' mental impressions of the withheld references (waived by Regeneron when they filed trial declarations by the patent prosecutors). Regeneron appealed.

Issues/Holdings:

Did the district court (i) err in finding the withheld references but-for material, and (ii) abuse its discretion by drawing an adverse inference of Regeneron's specific intent to deceive the PTO? No, affirmed.

Discussion:

The majority concluded that the district court properly found that the withheld references were but-for material and were not cumulative of references that the examiner considered during prosecution of the patent. With respect to intent, the majority stated that a district court has broad discretion to fashion an appropriate sanction for violating discovery obligations, including the discretion to proceed with a trial and give an adverse inference instruction. The majority held that the district court did not abuse its discretion by drawing an adverse inference of specific intent to deceive the PTO because Regeneron's widespread litigation misconduct obscured its prosecution misconduct, including the use of sword and shield tactics to protect thoughts and impressions on the withheld references. The majority commented that the district court did not punish Regeneron's litigation misconduct by holding the patent unenforceable, but rather only inferred intent after Merus proved the other elements of inequitable conduct.

Judge Newman dissented, stating that case law (*Aptix*) establishes that in order to invalidate the patent, the inequitable conduct must have occurred in patent prosecution, and therefore invalidation of the patent is not an available remedy for litigation misconduct. Accordingly, Judge Newman stated that a trial should be required for the question of intent as intent to deceive the examiner cannot be inferred from purported litigation misconduct several years later.