SANOFI-AVENTIS v. PFIZER INC., Appeal No. 2012-1345 (Fed. Cir. November 5, 2013). Before Newman, Lourie, and Davis (E.D. Tex., by designation). Appealed from the Board of Patent Appeals and Interferences.

Background:

Pfizer and Sanofi-Aventis ("Sanofi") each filed a patent application relating to a DNA polynucleotide that encodes a protein binding chain of the interleukin-13 receptor. Pfizer, as the junior party, had the burden of proof and presented evidence and testimony during the interference proceeding that it had a date of conception earlier than Sanofi's priority date. Sanofi argued that Pfizer cannot be credited with the earlier conception date because Pfizer's initial work included 8 nucleotide sequencing errors. As such, Sanofi argued that the conception date did not occur until Pfizer had the "fully correct nucleotide sequence," which occurred after Sanofi's priority date.

The BPAI disagreed and found that, despite the minor sequencing errors, Pfizer was the first to possess and appreciate the actual isolated DNA, and awarded priority of invention to Pfizer. Sanofi appealed.

Issue/Holding:

Did the BPAI err in holding that Pfizer had achieved conception before Sanofi's priority date? No, affirmed.

Discussion:

Sanofi relied on *Amgen Inc. v. Chugai Pharmaceutical Co.* and argued that Pfizer did not have a complete conception as a matter of law until Pfizer had the full correct nucleotide sequence. The Federal Circuit explained that the holding of *Amgen* does not support Sanofi's position. In particular, the Federal Circuit indicated that *Amgen* held that conception and reduction to practice can be established "'after the gene has been isolated,' accompanied by knowledge of 'other characteristics sufficient to distinguish it from other genes.'" The Federal Circuit agreed with the BPAI's finding that Pfizer was able to define the claimed invention so as "to distinguish it from other materials," and was also able "to define how to obtain it."

Sanofi next argued that the holding in *Fiers v. Revel* established a *per se* rule that conception of an isolated DNA requires the full and correct nucleotide sequence. Sanofi emphasized that conception of DNA, like conception of a chemical substance, requires a definition of that substance other than by its functionality. The Federal Circuit disagreed with Sanofi's assertions and agreed with BPAI that *Fiers* is distinguishable because no structure or definitive properties had been established for the isolated gene in that case.

Accordingly, the Federal Circuit concluded that the BPAI correctly based conception on possession and appreciation of the claimed invention, and affirmed the BPAI's decision to award priority of invention to Pfizer.