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CAFC Rules on Anticipation under 35 U.S.C. §102(b)

The United States Court of Appeals for the Federal Circuit affirmed a district court's ruling that omission during prosecution of "comparative data" that is not at issue in a prior art does not constitute inequitable conduct. However, the court reversed the lower court's ruling that found the patent to be invalid as anticipated. *Impax Laboratories Inc. v. Aventis Pharmaceuticals Inc.* Case No. 05-1313 (Fed. Cir., Nov. 20, 2006)

Riluzole is the chemical compound 6-trifluoromethoxy-2-benzothiazolamine used to treat ALS. ALS is a disease of the central nervous system that involves progressive degeneration of the nerves that control motor function and carry impulses to muscles. Riluzole is effective in treating ALS by 1) increase the number of neurons in the cells, 2) increase the number of neuritis per neuron, and 3) increase neuronal diameter.

Aventis owns the rights to patent number 5,527,814 ('814 patent) which involves the use of riluzole to treat Amyotrophic Lateral Sclerosis (ALS) – also known as Lou Gehrig's disease. Aventis sells riluzole under the trade name Rilutek.

Impax filed an ANDA to market a generic version of Rilutek, and subsequently sought declaratory judgment action that 1) the '814 patent is invalid based on inequitable conduct, and 2) '814 patent is invalid because it was anticipated by patent number 8,236,940 ('940 patent).

With respect to the inequitable conduct issue, Impax's main assertion was that, during the prosecution of the '814 patent, Aventis presented comparative data relating to certain compounds while withholding results from other compounds. Aventis argued that their omission of the rest results from other compounds were omitted because those tests results, although conducted, were not relevant to the '814 patent. The court in *Digital Control Inc. v. Charles Machine Works* 437 F.3d 1309 ruled that the basis for inequitable conduct requires intent to deceive, and that was absent in this case. Consequently the CAFC agreed with the lower court that there is insufficient evidence to establish such intent, thus no inequitable conduct.

With respect to the anticipation issue under 35 U.S.C. §102(b), Impax alleged that claims 1 through 5 of the '814 patent were anticipated by Aventis' own '940 patent. The district court agreed with Impax that formula I disclosed in the '940 patent included riluzole. However, formula I disclosed in the '940 patent is so broad and encompasses such a large number of compounds, it is highly unlikely that a person of ordinary skill in the art would of recognized that riluzole was effective in treating ALS. Citing *Rasmusson v. SmithKline Beecham Corp.* 413 F.3d 1318, the CAFC concluded that the court erred in its determination that one of the alleged two items of invalidating prior art did not enable a method of using riluzole to treat ALS and, therefore could not serve as an anticipatory reference under 25 U.S.C. §102(b).

The court affirmed the district court's decision with respect to the inequitable conduct issue, and remanded the case back to the district court to determine whether the '940 patent is enabling based on the proper legal standard established in Rasmusson.

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