



24 May 2004

TECHNOLOGY LAW UPDATE

A report of the latest Federal Circuit updates brought to you by Preston Gates.

Merck & Co. v. Teva Pharms. USA, Inc.

No. 03-1168 (Fed. Cir. Oct. 30, 2003)

“In [patent claim interpretation], the court must apply the same understanding as that of persons knowledgeable in the field of the invention. ‘Patents are written not for laymen, but for and by persons experienced in the field of the invention.’”

On October 30, 2003, the Federal Circuit affirmed the district court’s judgment following a bench trial that Teva infringed U.S. Patent No. 4,621,077, which related to alendronate salt that Merck markets as Fosamax®, and that the patent was not invalid as anticipated by the prior art. The Federal Circuit stated:

The claim herein is directed to a method of treatment of urolithiasis and inhibiting bone reabsorption, by administering an effective amount of the specified biphosphonic acid. The evidence of all the qualified witnesses was that persons in this field would understand that the acid is the active agent and that the acid is administered when it is in the form of the salt. There was no evidence that the claimed method of treatment is not achieved by the acid salt. The record shows that Teva and Zenith, as well as Merck, label their products with the “free acid equivalent.”

The record contains extensive evidence that persons experienced in this field use the same lexicography as did the inventors in referring to the active ingredient “in the form of” the salt. Dr. Recker, an expert on behalf of Merck, testified that the ‘ 077 patent uses the word “acid” to encompass the sodium salt, and that to a pharmacologist this usage is well understood. The cited articles match this usage. The Director of the Patent and Trademark Office also so recognized, in informing the Food and Drug Administration that the patent covers the federally registered product.

The only contrary evidence was provided by a Teva witness who was a chemist and who conceded that he was not qualified in pharmacology. He testified that an acid is not a salt. The district court discounted this testimony, recognizing the absence of qualification of the witness in the field of the invention. The specification shows that the inventors knew the chemical difference between an acid and a salt, for they described the pharmacologic use of the acid “as the salt,” and referred to the “biphosphonic acid, sodium salt.” The district court placed weight on the evidence of persons qualified in the field of the invention, as against the simplified answer of a witness who, although qualified as a chemist, was notable for his distance from the field of pharmacology.

[I]t is not whether a general chemist would know the difference between an acid and a salt [but] whether [one] experienced in the field of the invention and familiar with the usages of pharmacology and the prior art, reading the patent specification, would know that for the treatment of urolithiasis and to inhibit bone reabsorption, the statement that [alendronate salt] is administered to treat these diseases, encompasses administration as the acid salt. [T]he pharmacologist witnesses agreed that this was the correct reading. [E]vidence extrinsic to the patent documents cannot change the meaning of a term as used in the claim from the meaning with which it is used in the specification. [But] the opinions and advice of experts [may be provided] to explain the meaning of terms as they are used in patents and as they would be perceived and understood in the field of an invention. [T]here was not reversible error in the court’s crediting of the pharmacologists’ testimony, buttressed by publications, the usages in the specification, and the [PTO] view, as against the testimony of a chemist without experience in the specific field of the invention.

The prosecution history is not contrary to this conclusion [and the] specification shows that the active ingredient in the claimed method is the biphosphonic acid; there was no rejection of the method claim during prosecution, and no departure from the meaning of the terms as used in the specification.