

FEDERAL CIRCUIT PATENT LAW CASE UPDATE

Merck & Co., Inc. v. Teva Pharms. USA, Inc., 04-1005 (Fed. Cir. Jan. 28, 2005) (Gajarsa, J.)

Disagreeing with the district court's claim construction for the term "about" in two claims of Merck's pharmaceutical patent for a method to treat osteoporosis, the court vacated the infringement judgment in this ANDA-based action. It also held the claims invalid for obviousness and therefore not infringed by Teva. Judge Rader dissented, arguing that the patentee acted as a lexicographer in defining the claim term, and arguing that the case called for greater deference to the trial court.

Merck owns U.S. Pat. No. 5,994,329, for "a method of treating and preventing osteoporosis through less-than-daily administration of bisphosphonate compounds," which include alendronate monosodium trihydrate. The method claimed a dosing schedule to reduce GI complications.

Merck has Food and Drug Administration ("FDA") approval to market both a once-weekly and a relatively diminished daily dose of alendronate monosodium trihydrate, which it does under the trade name Fosamax.

The district court concluded that Merck acted as its own lexicographer.

[It] concluded the terms "about 35 mg" in claim 37 and "about 70 mg" in claim 23 mean exactly 35 (or 70) mg of alendronic acid. . . .

According to the district court's opinion, the patentee uses the phrase "about 35 [or 70] mg" to account for variations in the molecular weight of the different derivatives of alendronic acid and to deliver exactly 35 (or 70) mg of alendronic acid.

Under this narrow construction, two 1996 articles in Lunar News did not anticipate nor render obvious the claims.

The court reversed the claim construction, holding that "about" should be given its plain meaning of "approximately." There was no clear intent to act as a lexicographer.

[T]he passage cited by the district court from the specification for Merck's definition of "about" is ambiguous. It fails to redefine "about" to mean "exactly" in clear enough terms to justify such a counterintuitive definition of "about."

This contributed to reversal of the district court's invalidity analysis.

In light of the corrected claim construction we find reversible error in the district court's obviousness analysis. . . .

These claims, and the July 1996 article, both teach administering alendronate once a week instead of once a day. These claims read in light of the specification, and the July 1996 article, both indicate – and it has been conceded as known in the art at the time – that for treating or preventing osteoporosis a once-weekly dosage at seven times the daily dose would be as effective as seven daily

doses. . . . There was no great leap required of those skilled in the art to go from 40 or 80 mg once a week . . . to a 35 or 70 mg pill once a week. . . .

The "specific combination" of elements in claims 23 and 37 differs from the disclosure in the Lunar News articles only in terms of a minor difference in the dosage; without this difference, the Lunar News articles would anticipate claims 23 and 37 under section 102. For the Lunar News articles to render claims 23 and 37 obvious, the district court need only have found a suggestion or motivation to modify the dosages from those in the articles to those in the claims. . . . But as noted above, Merck's own inventors admit the difference in dosing amount is obvious. If anything, concern over dosing amount suggests lowering the weekly dosage – from 80 to 70 mg, and from 40 to 35 mg, just as Merck did. . . .

The Lunar News articles had clearly suggested the once-weekly dosing. They did so, as noted above, and as described in the '329 patent, to avoid or minimize problems related to dosing frequency.

In addition, the court rejected the district court's reliance on secondary indicia of non-obviousness.

Although commercial success might generally support a conclusion that Merck's claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the Lunar News articles. Financial success is not significantly probative of that question in this case because others were legally barred [by Merck's other patents and FDA approval processes] from commercially testing the Lunar News ideas. Dr. Mazess, for example, could not put his ideas to practice in 1996 – he could only exhort Merck to try it. They did.

In dissent, Judge Rader argued that the majority only paid lip service to the patentee as lexicographer doctrine, and that there should be greater deference to the trial court.

The patentee's definition . . . fell five letters short of success because the phrase included the word "about." This court seized on that word, gave it an ordinary meaning, and cast aside the lexicographer rule without a convincing explanation.

