

MERCK & CO. v. TEVA PHARMACEUTICALS USA, INC.

395 F.3d 1364 (Fed. Cir. 2005)

The Federal Circuit ruled that the application of the patentee-as-lexicographer rule is only appropriate where the patentee clearly expresses his intent to redefine a term with sufficient clarity to put a person of ordinary skill in the art on notice about the redefinition.

Merck owns U.S. Patent No. 5,994,329, which details a method of treating and preventing osteoporosis through less-than-daily administration of biphosphonate compounds. The described method decreases the adverse side effects associated with the standard practice of daily doses of biphosphonates by employing a once-weekly dosing. Importantly, the claims refer to the use of *about* 35 (or 70) mg of alendronic acid. Teva sought FDA approval to market generic versions of Merck's patented compound, and Merck filed suit alleging infringement. The controversy centered on the meaning of the term "about" used in the claim—specifically, whether Merck intended to define "about" as meaning "exactly," or whether the term should be given its ordinary meaning of "approximately." The district court concluded that Merck acted as its own lexicographer and, through the specification, redefined the ordinary meaning of "about" to mean "exactly." Relying on this construction of "about," the district court dismissed Teva's allegations that the claims were anticipated or rendered obvious by a prior publication.

Teva appealed. The Federal Circuit reversed the district court's claim construction and held that the word "about" should be given its ordinary meaning of "approximately." Accordingly, the patent was held invalid as obvious. The court reasoned that when a patentee acts as his own lexicographer he must clearly express the intent with sufficient clarity in the written description to put a person having ordinary skill in the art on notice that the inventor intended to redefine the term. The court found the definition of "about" in the specification to be ambiguous, and that Merck failed to redefine "about" to mean "exactly" in clear enough terms to justify a counterintuitive definition of "about." Because the passage that Merck relied upon to define "about" was amenable to a second, more reasonable, interpretation, the court held that Merck did not set out its own definition of "about" with sufficiently reasonable clarity, deliberateness, and precision and thus failed to act as its own lexicographer. Additionally, the specification suggested that Merck contemplated a range of dosages, and the range of doses further indicated that Merck did not intend for "about"

to mean “exactly.” In light of the correctly constructed claims, the court invalidated the patent as obvious in view of a prior publication.

Judge Rader wrote a scathing dissent arguing the need to respect the role of patentee-as-lexicographer and urging the Federal Circuit to adopt a rule to observe some deference to the trial court’s construction of a patent claim.