

Federal Circuit Patent Bulletin: *Takeda Pharm. Co. v. Zydus Pharms. USA Inc.*

February 20, 2014

"[For purposes of 35 U.S.C. § 112,] the mere possibility of different results from different measurement techniques [regarding the claimed composition does not render the claim] indefinite."

On February 20, 2014, in *Takeda Pharm. Co. v. Zydus Pharms. USA Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost,* Plager, Chen) reversed-in-part, affirmed-in-part and remanded the district court's judgment that Zydus infringed U.S. Patent No. 6,328,994, which related to the proton pump inhibitor drug lansoprazole used to treat gastroesophageal reflux disease or acid reflux and marketed by Takeda as Prevacid® SoluTab™, and that the '994 patent was not invalid. The Federal Circuit stated:

[T]here is no indication in the claim that 400 μm was intended to mean anything other than exactly 400 μm . To the contrary, the phrase "400 μm or less" is not qualified by the word "about" or any other indicator of imprecision. Moreover, the specification confirms that the inventors did not intend to deviate from that clear and unambiguous plain meaning. . . . The word "about" is used to modify the phrase "400 μm or less" only three times in the specification. [H]ad the inventors desired the average particle diameter to include a margin of error, they could easily have included the word "about" in the claim language. In the absence of their decision to do so, however, we will not take it upon ourselves to rewrite the claim in that way. . . . We long ago established that "[w]here there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning." Thus, even if the two proposed constructions before us presented an "equal choice"—and they do not—the narrower construction would be more appropriate. We therefore reverse the district court's claim construction and conclude that the proper construction of the disputed claim term is "fine granules having an average particle diameter of precisely 400 μm or less." . . . Thus, there can be no dispute that Zydus's ANDA product does not literally infringe claim 1 of the '994 patent. . . .

“Whether a claim is invalid for indefiniteness requires a determination whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.” [T]here was evidence from both parties’ experts that there are several possible ways to measure average particle diameter. Indeed, the patent specification itself identifies laser diffraction as just one “example” of such a measurement technique, and the experts agreed that optical microscopy is another equally viable method. . . . Because the two methods use different means of approximating average particle diameter, they can produce different results even for the same sample. However, we do not believe that the mere possibility of different results from different measurement techniques renders claim 1 indefinite. Rather, the evidence established that both methods of measurement accurately report average particle diameter; the experts agreed that “the correct but differing particle size results obtained using various instruments are all equally correct, but each simply may be expressing its correct results in different terms.” [T]here was no evidence in this case that different measurement techniques in fact produced significantly different results for the same sample. . . . Therefore, we conclude that Zydus has not met its burden of establishing by clear and convincing evidence that claim 1 of the ‘994 patent is invalid for indefiniteness.

The test for written description is “whether the disclosure of the application . . . reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” . . . Zydus argues that claim 1 addresses average particle size in the finished tablet, while the specification only teaches how to measure particle size pre-tableting with no discussion of how to ensure particle size is not altered by that process. . . . However, Zydus’s argument depends on there actually being an impact on particle size from the tableting process, and the evidence showed the opposite. [N]o extensive manipulation of the samples is required prior to measurement, [and] Zydus did not present clear and convincing evidence that the method of measurement is in fact outcome-determinative in the infringement analysis. . . .

Under the enablement requirement of 35 U.S.C. § 112, “the specification must enable one of ordinary skill in the art to practice the claimed invention without undue experimentation.” . . . It is well established that the “enablement requirement is met if the description enables any mode of making and using the invention.” Thus, because the patent identifies laser diffraction as a viable measurement technique, and there is no dispute that a skilled artisan would know how to use laser diffraction to measure particle diameter, Zydus has not established that the patent is invalid for lack of enablement on this basis.

However, we note for the record that if the district court had been correct that the patent requires deagglomeration prior to particle size measurement, we would be forced to reach a different conclusion regarding enablement. Specifically, nothing in the written description directs a skilled artisan to evaluate whether a sample contains “more than nominal” hard agglomerates prior to measurement, such that optical

microscopy should be used, nor does it explain how one would make that determination. Similarly, it does not explain how to conduct virtual dissection of deagglomerates using optical microscopy. Thus, if the patent required deagglomeration prior to measurement in certain circumstances, as the district court found that it did, it could not be said that the written description informed a skilled artisan how to make and use the claimed invention. . . . We cannot conclude that the patent affirmatively requires a step that was entirely absent from (and even precluded by) the procedure described in the specification.