

TAKEDA PHARMACEUTICAL CO. LTD. v. ZYDUS PHARMACEUTICALS USA, INC.,  
Appeal No. 2013-1406 (Fed. Cir. February 20, 2014). Before Prost, Plager and Chen. Appealed  
from D.N.J. (Judge Pisano).

Background:

Plaintiff owns a patent directed to orally disintegrable tablet for treating acid reflux. Defendant filed an abbreviated new drug application (“ANDA”) for a generic version of the drug. Plaintiff sued for patent infringement, claiming that Defendant's ANDA product infringed an independent claim of Plaintiff's patent. Defendant counterclaimed that the disputed claim was invalid under various requirements of §112.

The disputed claim of Plaintiff's patent requires "fine granules having an average particle diameter of 400  $\mu\text{m}$  or less." The district court construed the recited average particle diameter to include a deviation of  $\pm 10\%$  because it was universally accepted that there is a 10% standard of error for particle size measurements. Under this claim construction, the district court found that Defendant's product literally infringed the disputed claim. The district court also concluded that Defendant had not established that the disputed claim was invalid under §112. Accordingly, the district court entered an injunction preventing Defendant from selling its product until expiration of Plaintiff's patent. Defendant appealed all of the district court's rulings.

Issues/Holdings:

(1) Did the district court err in its construction of the disputed claim term and its resulting finding of literal infringement? Yes, reversed. (2) Did the district court err in its ruling that the disputed claim was not invalid under §112? No, affirmed.

Discussion:

The Federal Circuit determined that the district court erred in reading a margin of error into the disputed claim term. The Federal Circuit found that (1) there was no indication in the disputed claim language that 400  $\mu\text{m}$  was intended to mean anything other than exactly 400  $\mu\text{m}$ , and (2) the mere presence of the word “about” at three points in the specification did not justify a 10% expansion of claim scope because the rest of the specification and prosecution history confirmed that the inventors did not intend to deviate from that clear and unambiguous plain meaning. Under the Federal Circuit's construction of the disputed claim term, there was no dispute that Defendant's product did not literally infringe the disputed claim. Thus, the district court's finding of literal infringement was reversed.

With respect to indefiniteness, the Federal Circuit found that the mere fact that there happens to be more than one way of determining the average particle diameter of particles of a particular sample does not render the disputed claim indefinite. Furthermore, there was no evidence that different measurement techniques in fact produced significantly different results for the same sample. To the contrary, the submitted measurements of Defendant's product, acquired using different techniques, though not exactly the same, were substantially similar and thus any theoretical minor differences between the different measurement techniques were insufficient to render the patent invalid. Thus, the Federal Circuit affirmed the district court's ruling on indefiniteness because the mere possibility of different results from different measurement techniques was insufficient to establish that the disputed claim was invalid.