

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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TAKEDA PHARMACEUTICAL CO,  
LIMITED, et al.

Plaintiff,

v.

ZYDUS PHARMACEUTICALS  
USA INC., et al.

Defendant.

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Civil Action No. 10-1723 (JAP)

**OPINION**

On February 20, 2014, the Court of Appeals for the Federal Circuit entered judgment reversing-in-part and affirming-in-part this Court’s entry of final judgment in this matter. Specifically, the Federal Circuit reversed this Court’s claim construction ruling with respect to Claim 1 of the ‘994 patent as well as its finding of literal infringement by Zydus. The Federal Circuit affirmed the Court's judgment of no invalidity with respect to the ‘994 patent. The matter was remanded for further proceedings, and jurisdiction returned to this Court on June 9, 2014, when the Federal Circuit entered its mandate.

By way of two status conferences and thorough letter briefing, the Court has heard the parties on the question of which issues remain to be addressed on remand. Plaintiff argues that there remains a single issue to be addressed, namely, “whether Zydus’ proposed ANDA product meets the “fine granules having an average particle diameter of 400  $\mu$  or less” limitation in claim 1 of the ‘994 patent under the doctrine of equivalents. Plaintiff has asked the Court to allow

additional expert discovery in connection with the filing of dispositive motions on this issue by the parties. Defendant objects to any further discovery. Zydus argues that there is no issue remaining in the case to be decided, noting that Plaintiff did not raise a doctrine of equivalents claim at trial and, therefore, Plaintiff has waived any such claim. However, Defendant has stated that if the Court were inclined to hear from the parties on the doctrine of equivalents, it requests the chance to show by way of dispositive motion that Plaintiff cannot rely upon the doctrine of equivalents at this procedural stage of this litigation.

The Court agrees that the additional discovery requested by Plaintiff should not be permitted. Plaintiff had every opportunity prior to trial to take discovery on the equivalents issue. Plaintiff chose not to, and, further, chose not to raise the doctrine of equivalents at trial.

Furthermore, the Court rejects Plaintiff's argument that because the Court had adopted Plaintiff's proffered construction of the term "fine granules having an average particle diameter of 400  $\mu$  or less," the doctrine-of-equivalents issue was rendered moot after the claim construction phase of this case and did not become live again until after the Federal Circuit's decision. The question during claim construction was whether the particle size limitation in the relevant claim was a hard cutoff (*i.e.*, precisely 400  $\mu$ ) or whether there was room for error (*e.g.*, 400  $\mu \pm 10\%$ ). At trial, the dispute as literal infringement of this claim turned on how average particle diameter was determined, specifically, whether multiple particles that were fused together should be treated separately or as a single particle for measurement purposes. Given the question presented at trial, the Court cannot see how the adoption of one or the other of the proffered claim constructions would have mooted a claim under the doctrine of equivalents had Plaintiff not prevailed on its claim for literal infringement.

Having not pursued an infringement claim under the doctrine of equivalents at trial, Plaintiff cannot do so now. The Court finds Plaintiff has waived the claim.<sup>1</sup> *C.f. Chainey v. Street*, 523 F.3d 200, 209 (3d Cir. 2008) (party waived defense by not raising it until after trial; rule requiring earlier notice is meant “to avoid surprise and undue prejudice” by providing adversary with notice and the opportunity to demonstrate why the opponent should not succeed.). To find otherwise would not further the interests of finality, judicial economy and fundamental fairness to the Defendant. Plaintiff could have pursued an equivalents claim but did not, and it will not be permitted to relitigate this matter to take a second bite at the proverbial apple. In so ruling, this case and the parties are in the same position they would have been in had the Court ruled in Defendant’s favor on literal infringement at trial.

There is no dispute that under the claim construction directed by the Federal Circuit, Defendant’s ANDA product does not literally infringe the claim at issue. *Takeda Pharm. v. Zydus Pharm. USA*, No. 2013-1406 (Fed. Cir. February 20, 2014). Accordingly, Judgment will be entered in favor of defendant. An appropriate Order and Judgment accompanies this Opinion.

/s/ Joel A. Pisano  
JOEL A. PISANO, U.S.D.J.

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<sup>1</sup> The parties have thoroughly briefed this issue by letter and, therefore, the Court does not require motions on the question.