UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL CO, LIMITED, et al. Plaintiffs, v. ZYDUS PHARMACEUTICALS USA INC., et al. Defendants.	Civil Action No. 10-1723 (JAP) **OPINION**

PISANO, District Judge.

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc., (collectively, "Takeda") and Ethypharm, S.A. ("Ethypharm," together with Takeda, "Plaintiffs") bring this Hatch-Waxman patent infringement action against defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Defendants") claiming infringement of the following patents alleged to cover Takeda's Prevacid SoluTab product ("SoluTab"): U.S. Patent Nos. 6,328,994 (the " '994 patent"), 7,431,942 (the " '942 patent"), 7,875,292 (the " '292 patent) and 5,464,632 (the " '632 patent"). Trial is scheduled to begin on March 26, 2013. Presently before the Court are the parties' motions *in limine*.

1. Plaintiff's Motion to Preclude Expert James Morrison

Plaintiffs move to preclude the testimony of Defendants' expert witness James Morrison, a former employee of the United States Food and Drug Administration ("FDA") who was

employed with the agency for nearly 40 years. Federal Rule of Evidence 702 governs the admissibility of expert testimony and states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. "Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable.'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589-92 (1993)). In making this determination, the Court undertakes a three-pronged inquiry: (1) the witness is qualified as an expert in a particular field; (2) the methodology applied by the witness is sufficiently reliable; and (3) the witness's testimony "fits" the facts of the case in dispute—that is, the proffered testimony would assist the trier of fact. *Pineda*, 520 F.3d at 244. The burden of meeting these elements, and of showing that "good grounds" exist for the expert's opinion, lies with the proponent. *U.S. v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004).

Plaintiffs' argument in support of its motion centers on its assertions that Morrison is not qualified to testify because he is not one skilled in the relevant art and, therefore, cannot opine on infringement and invalidity. However, as Defendants state, they are not proffering Morrison to testify or opine "on the intricacies of the chemistry underlying the claims at issue, or even patent invalidity." Def. Br. at 10. Rather, Defendants state that they intend to proffer Morrison to testify about the "expectations of the [FDA] vis-á-vis [certain] representations made by Zydus …, and whether the FDA would accept certain conclusions reached by Plaintiffs' infringement

expert…" Def. Br. at 2. In this light, the Court has reviewed the materials submitted by Defendants and finds that Defendants have shown that Morrison satisfies the three requirements noted above. As such, the Court shall deny Plaintiffs' motion.[1]

2. Plaintiffs' Motion to Preclude Evidence of Prior Art References

Plaintiffs move pursuant to Federal Rule of Civil Procedure 37(c)(1) to preclude all testimony and other evidence relating to six particular prior art references (the "New References") that Plaintiffs allege were improperly introduced for the first time at the September 24, 2012 deposition of Plaintiffs' expert Dr. Fennerty and the February 20, 2013 deposition of Plaintiffs' expert Dr. Byrn. Plaintiffs claim that Zydus never cited any of the New References in any of its required contentions or in any of its expert reports, and further state that Defendants "[u]ndoubtedly … will try to use the New References accompanying new invalidity theories to bolster its case that the asserted '632 patent is purportedly invalid." Pl. Br. at 2.

Rule 37 provides that "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Under Rule 26(a), however, evidence that is to be used solely for impeachment purposes is not required to be produced as the rule's required disclosures.

In response to Plaintiffs' motion, Defendants state that their intent is only to offer the New References at trial with Dr. Byrn for impeachment and/or to refresh recollection. In such a situation, it is not required that the references be previously disclosed as part of Defendants'

[1] In permitting Morrison to testify, the Court makes no determination at this time regarding this witnesses' credibility. If the Court, as factfinder, does not find Morrison's testimony to be convincing, or if the basis for any of his conclusions is lacking, then his testimony can be found to be not credible.

earlier-served invalidity contentions. Being that it is not Defendants' intent to offer the New References as invalidating prior art, the Court finds Plaintiffs' motion to be without basis and the motion shall be denied.

3. Defendants' Motion to Preclude Evidence of Particle Size Diameter

Defendants have moved *in limine* to preclude certain evidence of average particle diameter. Defendants rely primarily upon *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000) in arguing that the Court need not look beyond the ANDA to resolve the infringement issues in this case. Plaintiffs oppose the motion, and argue that Defendants' motion, although styled as one *in limine*, is actually more properly a motion for summary judgment.

The focus of the infringement inquiry in this case, like a typical ANDA case, is on what the ANDA applicant will likely market if the application is approved. *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1330 (Fed. Cir. 2012). The question to be answered is whether, if Defendants' drug were put on the market, it would infringe the relevant patents. *See id.* Such a question should not be resolved by way of a motion *in limine*, but rather, given the stage of this litigation, should be determined at trial. The Court, therefore, denies Defendants' motion.

4. Defendants' Motion to Preclude Evidence of Instrument Testing

During *Markman* proceedings in this case the parties sought construction of a number of claim terms, including the following: "fine granules having an average particle diameter of 400 μm or less" ('994 Patent, Claim 1); "fine granules having an average particle diameter of 300 to 400 μm" ('942 Patent, Claim 1); and "wherein the average particle diameter of the fine granules is 300 to 400 μm" ('994 Patent, Claim 2). Plaintiffs' proposed constructions for these terms,

ultimately adopted by the Court, incorporated a ± 10% deviation into the average particle diameter measurement. This was based upon the accepted standard of error for a method of measurement called laser diffraction.

Defendants are seeking to prevent Plaintiffs from introducing evidence of the average particle diameter of the granular distribution of fine granules in Zydus's exhibit batch tablets measured by any method other than laser diffraction. Defendants now assert that the Court's claim constructions that incorporate the ± 10% deviation apply only to laser diffraction and only to batch/bulk sample measurements. However, the Court did not construe the abovementioned terms to include any such limitations. Indeed, Defendants did not even advance such a position during the claim construction process. The Court having not previously construed the above terms to include the limitations now advanced by Defendants, the Court will not preclude Plaintiffs from introducing evidence of particle sized measured by a method other than laser diffraction. Defendants' motion is denied.

For the reasons above, the parties' motions *in limine* are denied. An appropriate Order accompanies this Opinion.

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