IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

DEY, L. P. and DEY, INC.,

Plaintiff,

v. // CIVIL ACTION NO. 1:09CV87
(Judge Keeley)

TEVA PARENTERAL MEDICINES, INC.,
TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Defendant.

MEMORANDUM OPINION AND ORDER

This memorandum opinion memorializes the ruling of the Court on April 17, 2012, **DENYING** the defendants' motion to exclude the expert testimony of Dr. Stephen R. Byrn.

I.

This patent infringement case involves four United States Patents issued to the plaintiffs, Dey L.P. and Dey, Inc. ("Dey"), including Patent Nos. 6,667,344 ("the '344 patent"), 6,814,953 ("the '953 patent"), 7,348,362 ("the '362 patent"), and 7,462,645 ("the '645 patent") (collectively, the "patents-in-suit"). The patents-in-suit cover aqueous compositions of formoterol that remain stable and, thus, suitable for direct administration during long-term storage. They also cover methods for using these compositions to treat broncho-constrictive disorders. Dey uses the

formulations and methods described in these patents in a commercial product known as Perforomist®.

The defendants, Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, LTD. (collectively, "Teva"), have filed an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration ("FDA") approval to market a generic formoterol fumarate inhalation solution 0.02 mg/2mL ("Teva's formoterol solution"). Teva also filed a certification with the FDA alleging certain claims of the four patents-in-suit are invalid, unenforceable, and not infringed by Teva's manufacture or sale of its generic formoterol fumarate product. In response, Dey filed this patent infringement action against Teva pursuant the Hatch-Waxman Act (the "Hatch-Waxman Act"). See 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271.

On March 22, 2012, Teva filed a motion to exclude the report and testimony of Dey's expert, Dr. Stephen R. Byrn ("Dr. Byrn"), who is expected to testify about the photostability of Teva's formoterol solution. Teva argues that the photostability required by Dey's patent claims distinguishes Dey's patent-in-suit from Teva's formoterol solution, which, Teva asserts, degrades when exposed to light. Dey intends to rebut Teva's assertion through the

testimony of Dr. Byrn, who opines that Teva's formoterol solution is photostable, based on two laboratory tests: a "window test" and a "light box test." (Dkt. No. 137-15). Teva argues these tests are unreliable, and, therefore, Dr. Byrn's testimony is inadmissible.

II.

The admissibility of expert testimony is governed by Fed. R. Evid. 702, which provides:

> 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.

Stated another way, expert testimony is admissible under Rule 702 if (1) it concerns "scientific, technical, or other specialized knowledge" that (2) will "aid the jury or other trier of fact to understand or resolve a fact at issue." Westberry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999) (citing Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592 (1993)). The first prong requires that the Court examine whether the reasoning or methodology underlying the expert's proffered opinion is reliable, and the second prong requires the Court to evaluate whether the

proffered testimony is relevant to the issues in controversy. Daubert, 509 U.S. at 590-92, 597.

In assessing whether an expert's opinion is sufficiently reliable and relevant, the Court operates as a gatekeeper and conducts a flexible inquiry focusing on the principles and methodology employed by the expert rather than the conclusions reached. Id. at 594-95. The Court may consider, but is not limited to, the following factors:

> (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community.

United States v. Crisp, 324 F.3d 261, 266 (4th Cir. 2003) (quoting Daubert, 509 U.S. at 593-94).

The proponent of expert testimony "must come forward with evidence from which the court can determine that the proffered testimony is properly admissible." Maryland Cas. Co. v. Therm-O-Disc, Inc., 137 F.3d 780, 783 (4th Cir. 1998); see also Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) ("The proponent of the testimony must establish its admissibility by a preponderance of proof.") (citing Daubert, 509 U.S. at 592 n.10).

Importantly, although the Fourth Circuit has not addressed the issue, other circuit courts have held that courts should "relax Daubert's application for bench trials." Watson v. United States, 668 F.3d 1008, 1015 (8th Cir. 2012). Daubert is meant to "protect juries from being swayed by dubious scientific testimony," In re Zurn Pex Plumbing Prods. Liab. Litig., 644 F.3d 604, 613 (8th Cir. 2011) (emphasis added), a concern that does not apply where the district court sits as the finder of fact. "'There is less need for the gatekeeper to keep the gate when the gatekeeper is keeping the gate only for himself.'" Id. (quoting United States v. Brown, 415 F.3d 1257, 1269 (11th Cir. 2005)).

III.

Teva does not dispute the relevance of Dr. Byrn's testimony about photostability, but argues that it is inadmissible because it is based on the results of two unreliable tests. The "window test," designed and conducted by the drug development laboratory Solid State Chemical Information, Inc. ("SSCI"), assessed the stability of Teva's formoterol solution when exposed to sunlight through a window. SSCI exposed vials of Dey's Performomist to sunlight filtered through a double-paned window with two sets of blinds for five days.

The "light box test," designed and conducted by another laboratory, Aptuit, LLC ("Aptuit"), evaluated the stability of Teva's formoterol solution when exposed to visible light that a person of ordinary skill in the art would expect a pharmaceutical product to receive during manufacturing, distribution, storage, and patient use. Aptuit stored vials of Teva's formoterol solution, some wrapped in foil overwrap and some not, in a light box programmed to expose the samples to a target light intensity (525 lux) for twelve hours per day for thirty-one days. Based on the results of these two tests, Dr. Byrn opines that a person having ordinary skill in the art would understand that Teva's formoterol solution is photostable because it does not significantly degrade when exposed to "ambient" or "normal" visible or ultraviolet light conditions. (Dkt. No. 132-7 at ¶¶ 26, 38).

Teva contends that the results of these tests are unreliable because they are "custom studies" designed specifically for this litigation, never published or subjected to peer review, and not accepted within the scientific community. It argues that the tests deviated from the standards for evaluating photostability set forth in the FDA-approved International Conference on Harmonization Guidance for Industry ("ICH Guidance"), which require a "forced degradation" study. (Dkt. No. 137-10 at 8). In such a study,

product samples are placed less than 10 inches from an intense light source for 24 hours per day for 12 consecutive days. (Dkt. No. 137-11 at 3-4). Teva argues that Dr. Byrn's reliance on data from "ambient" light exposure in the window and light box tests is contrary to ICH Guidance and, thus, unreliable. Finally, it argues that inconsistencies in the testing procedures further undermined the reliability of their results.

IV.

In determining whether the window and light box tests are reliable, the Court is guided by the five Daubert factors. 509 U.S. at 593-94. These factors are not to be applied strictly; rather, "[t]he inquiry is a flexible one." Id. at 594. The Court must only ensure that the expert's testimony "both rests on a reliable foundation and is relevant to the task at hand." Id. at 597.

Although Teva asserts that the ICH Guidance establishes the only acceptable standards for evaluating photostability, the ICH Guidance Preamble makes clear that its standards are only intended to govern stress tests for new drug applications, and alternative methods may be used in other contexts:

> The guideline primarily addresses the generation of photostability information for submission in registration application for new molecular entities and associated drug products. The guideline does not cover the photostability of drugs after administration (i.e., under conditions of use) and those applications not covered by

> the parent guideline. Alternative approaches may be used if they are scientifically sound and justification is provided.

(Dkt. No. 137-10 at 1). Because Dr. Byrn was evaluating whether Teva's product is photostable during normal patient use, and not whether it meets new drug application standards, his reliance on alternative testing methods is approved by the ICH Guidance and does not undermine the reliability of his opinion.

Moreover, the fact that the window and light box tests were customized for this litigation does not imply that the tests were unreliable where they were "derived by the scientific method." Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony."). "[G]eneral acceptance" of a testing method may bolster its reliability, but it is "not a necessary precondition" to its admissibility. Daubert, 509 U.S. at 597.

Here, Dr. Byrn, a well-published solid-state chemist with more than forty years of experience in the field of photostability, based his opinions on two customized tests developed by reputable drug development laboratories. Dr. Byrn carefully reviewed both tests and, based on his knowledge and experience independent of this litigation, determined that they were well-designed to

approximate light exposure during manufacturing, distribution, storage, and patient use. (Dkt. No. 137-15 at ¶¶ 60, 65). That these tests were designed for such a narrow purpose does not undermine their reliability. Although the scientific community has not specifically endorsed the window and light box methods, it has embraced other similarly customized photostability tests, some of which have appeared in peer-reviewed publications, such as the Journal of Pharmaceutical and Biomedical Analysis. Pawel Grobelny, et al, Photostability of Pitavastatin - A Novel HMG-CoA Reductase Inhibitor, 50 J. Pharm. & Biomedical Anal 597 (2009) (approving of photostability test that did not reference ICH Guidance), available at (Dkt. No. 137-22).

To the extent Teva disputes Dr. Byrn's methodology and argues that the window and light box tests suffered from internal inconsistencies, these arguments go to the weight of Dr. Byrn's testimony, rather than its admissibility. Daubert instructs courts to allow such arguments to proceed to trial, where the conventional procedural devices ensure the reliability of expert testimony. 509 U.S. at 596. "Cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof, rather than wholesale exclusion under an uncompromising 'general acceptance' standard, is the appropriate means by which evidence based on valid

principles may be challenged." Id. at 580. This is especially true where, as here, there is no jury to protect because the Court is the finder of fact. Watson, 668 F.3d at 1015. Accordingly, because Dr. Byrn's opinion "both rests on a reliable foundation and is relevant to the task at hand," Daubert, 509 U.S. at 597, the Court **DENIES** Teva's motion to exclude his testimony (dkt. no. 132).

It is so **ORDERED.**

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: June 27, 2012

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE