IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Plaintiffs, vs. HOSPIRA, INC., Defendant.	**C.A. NO. 17-944-JFB-SRF** **MEMORANDUM AND ORDER**

This matter is before the Court on the defendant's Motion to exclude the testimony of Karen M. Becker, Ph.D., under Federal Rule of Evidence 702 and the principles set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 597 (1993) (D.I. 149).[1] This is a patent infringement case arising under the Hatch-Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 271(e).

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Plaintiffs" or "Par") manufactures and sells Adrenalin® brand epinephrine injection, which is used for emergency treatment of allergic reactions, including anaphylaxis. Hospira, Inc., is seeking FDA approval to market a generic version of Par's Adrenalin® product ("Hospira's ANDA Product") prior to the expiration of Par's patents covering Adrenalin®, U.S. Patent Nos. 9,119,876 ("the '876 patent") and 9,295,657 ("the '657 patent") (together, "the Patents-in-Suit") (D.I. 1, Exs. 1-2). Par alleges that Hospira's ANDA Product infringes the Patents-in-Suit under 35

[1] Also pending is a request for oral argument (D.I. 174). The Court finds oral argument is unnecessary and the request will be denied.

U.S.C. § 271(e)(2), and that the manufacture, use, offer for sale, sale, or importation of Hospira's ANDA Product will infringe the Patents-in-Suit under 35 U.S.C. §§ 271(a), (b), and/or (c). D.I. 1. A four-day bench trial is scheduled to begin on June 28, 2019 (D.I. 153).

By way of background, in 2012, the Food and Drug Administration ("FDA") approved the Adrenalin® epinephrine injection formulation of Par's predecessor, JHP Pharmaceuticals ("JHP"). However, the FDA asked JHP to investigate improvements to the formulation and process to reduce the levels of impurities in the Adrenalin® product. Subsequent testing revealed the presence of Impurity A, Impurity B, and Unknown C. The inventors developed a procedure using gradient Hydrophobic Interaction Liquid Chromatography ("HILIC")2 to isolate Impurity A, Impurity B, and Unknown C ('876 patent, col. 16:38-20:61, Figs. 1-4).

Hospira moves to preclude the testimony of Dr. Karen Becker, Par's regulatory expert. She is expected to testify concerning the regulatory framework in the context of Hospira's statements and actions before FDA. Hospira contends her testimony is speculative and irrelevant. It also challenges Dr. Becker's qualifications, contending she is unqualified as an expert in the case because she has never been employed by the FDA or a pharmaceutical company, and because she has advised on medical devices or combination drug/device products rather than drug products. In response, Par argues that Dr. Becker's testimony will assist the Court in evaluating the weight, credibility, and meaning that should be accorded to Hospira's statements and actions before FDA.

Dr. Becker has a Bachelor of Science degree in Biological Chemistry with High Honors from the University of Maryland; a National Institutes of Health Graduate

Research Fellowship; and a Ph.D. in Pharmacology from the University of North Carolina School of Medicine. Dr. Becker is an FDA regulatory consultant. Her clients have included pharmaceutical, medical device, and multi-national healthcare companies, Dr. Becker has held positions in a series of successful scientific and FDA regulatory consulting firms over the course of 25 years.

I. LAW

In *Daubert,* the Supreme Court explained that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. The rule requires that expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Expert testimony is admissible only if "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d); *see generally Elcock v. Kmart Corp.*, 233 F.3d 734, 741–46 (3d Cir. 2000) (noting the requirements of Rule 702 embody "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability and fit").

"[T]he language of Rule 702 requiring the expert to testify to scientific knowledge means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3rd Cir. 1994) (quoting *Daubert*, 509 U.S. at 590). The proponent of the expert testimony has the burden of establishing its admissibility by a

preponderance of the evidence. *Padillas v. Stork–Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999).

The Third Circuit recognizes a "liberal policy of admissibility" regarding Rule 702. *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); *see also United States v. Schiff*, 602 F.3d 152, 173 (3d Cir. 2010). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. "Rule 702 and Daubert put their faith in an adversary system designed to expose flawed expertise." *U.S. v. Mitchell*, 365 F.3d 215, 244-45 (3d Cir. 2004) (citations omitted).

An expert's opinion on a legal conclusion "'is neither necessary nor controlling.'" *See High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1313 (Fed. Cir. 2013) (quoting *Avia Grp. Int'l, Inc. v. L.A. Gear Cal., Inc*., 853 F.2d 1557, 1564 (Fed. Cir. 1988), *abrogated on other grounds by Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008) (*en banc*)). An expert cannot usurp the role of the judge or jury. *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). That said, an expert's opinion may be relevant to the factual aspects of the analysis leading to that legal conclusion. *Id*. When an expert's methodology is sound, and the evidence relied upon is sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011).

Moreover, trial courts should be more reluctant to exclude evidence in a bench trial than a jury trial. *See First Am. State Bank v. Cont'l Ins. Co.*, 897 F.2d 319, 328 (8th Cir. 1990); *Builders Steel Co. v. Comm'r*, 179 F.2d 377, 379 (8th Cir. 1950). In bench trials, evidence should be admitted and then sifted when the district court makes its findings of fact and conclusions of law. *Fields Eng'g & Equip., Inc. v. Cargill, Inc.*, 651 F.2d 589, 594 (8th Cir. 1981). In a nonjury case, the trial court is presumed to consider only the competent evidence. *First Am. State Bank*, 897 F.2d at 328. Where the court has assumed the role of fact-finder in a bench trial, "the better course 'is to hear the testimony, and continue to sustain objections when appropriate.'" *Easley v. Anheuser-Busch, Inc.*, 758 F.2d 251, 258 (8th Cir. 1985).

II. DISCUSSION

The Court finds Hospira's motion should be denied. Hospira's contentions that the opinions are speculative and/or irrelevant lose force because this is a bench trial. The Court can disregard any such speculative or irrelevant testimony.

The Court rejects Hospira's challenge to Dr. Becker's qualifications and methods. Dr. Becker's testimony, based on her education and experience, is reliable. Dr. Becker has a doctorate in pharmacology and is familiar with the topics addressed in her expert report. She is a regulatory consultant and appears to have the education and experience necessary to aid the Court in its understanding of FDA approval processes. She draws on over twenty-five years of training, knowledge and utilization of FDA regulations, policies, procedures and practices. The totality of her knowledge and experience provides a reliable basis for her opinions. Providing the context for FDA regulations governing drug approval can be relevant and proper expert testimony. *See, e.g.*, *Reece*

v. Astrazeneca Pharm., LP, 500 F. Supp. 2d 736, 744 (S.D. Ohio 2007); *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig*., No. CIV. 05-2596DWFAJB, 2007 WL 1964337, at *7 (D. Minn. June 29, 2007); *Lillebo v. Zimmer, Inc.*, No. 03-2919 (JRT/FLN), 2005 WL 388598, at *5 (D. Minn. Feb. 16, 2005). The Court finds that Dr. Becker's testimony may be helpful to the Court in some respects and she should be permitted to testify as to the FDA regulations and procedures. To the extent that Dr. Becker's narrative summary of actions before the FDA may be duplicative of record evidence, that objection may be interposed at trial. Accordingly,

IT IS ORDERED:

1. Hospira's Motion to exclude the testimony of Karen Becker, Ph.D., (D.I. 149) is denied.

2. Hospira's request for oral argument (D.I. 174) is denied.

Dated this 6th day of June 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge