IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UPSHER-SMITH LABORATORIES, LLC,

Plaintiff,

v.

Civil Action No. 21-1132-GBW

ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LIMITED,

Defendants.

MEMORANDUM ORDER

Pending before the Court are Plaintiff Upsher-Smith Laboratories, LLC's ("USL") Motions to Exclude the Expert Testimony of certain witnesses of Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus"). Specifically, USL moves the Court to exclude the opinions of Michael A. Carrier, Jennifer A. Davidson, and Paul J. Jarosz. D.I. 242; D.I. 243; D.I. 244.

I. LEGAL STANDARD

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The Third Circuit has explained:

> [T]he district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury.

> *See Daubert* ("Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) [of the Federal Rules of Evidence] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.").

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404–05 (3d Cir. 2003) (footnote and internal citations omitted). Qualification examines the expert's specialized knowledge, reliability examines the grounds for the expert's opinion, and fit examines whether the testimony is relevant and will "assist the trier of fact." *Id.* at 404.

When, however, a "case will be tried to the court rather than to a jury, there is less need for the court to police the admission of expert testimony than would be the case if this case were being tried to a jury." *APEX Fin. Options, LLC v. Gilbertson*, No. 19-0046-WCB-SRF, 2022 WL 613347, at *3 (D. Del. Mar. 1, 2022). Rather than "pre-screen expert testimony," the Court "can simply disregard expert evidence that it regards as unreliable, irrelevant, or unhelpful." *Wright v. Elton Corp.*, No. 17-286-JFB, 2022 WL 1091280, at *1 (D. Del. Apr. 12, 2022). Therefore, "in bench trials evidence should be admitted and then sifted when the district court makes its findings of fact and conclusions of law." *Id.*

II. DISCUSSION

A. Michael Carrier

USL moves to exclude the testimony of Michael Carrier on the grounds that it consists of improper legal opinions and that it is unreliable. D.I. 245 at 4-5. Mr. Carrier, a professor of law at Rutgers University, notes that his area of expertise encompasses the intersection of antitrust and intellectual property laws. D.I. 246, Ex. 1 at 1-2. In his expert report, Mr. Carrier explains that he was retained by Zydus to describe the public policy considerations that may be implicated by no-relinquishment provisions, including their effects on competition. *Id.*

There is a "well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances because it is the Court's function to determine the applicable legal standards." *PureWick Corp. v. Sage Prods., LLC*, No. 19-1508, 2021 WL 2593338, at *1 (D. Del. June 24, 2021). An expert opinion that "really reads like an attorney's argument or brief" should be excluded. *Id.* at *2.

Having reviewed Mr. Carrier's report, the Court recognizes that certain portions of Mr. Carrier's report constitute legal opinions. *See, e.g.*, D.I. 245, Ex. 2 ("Carrier Reply") at 2 (arguing that USL's expert "fails to respond to my arguments regarding how a court would treat the no-relinquishment clause"), 9 ("[A] court applying antitrust law should, in my opinion, find an antitrust violation."); Ex. 3 ("Carrier Dep.") at 233:23-235:21 ("It is my opinion that the license and settlement agreement as interpreted by USL presents significant antitrust concerns that I underscored in my analysis of a per se analysis, a quick look, and rule of reason."). However, his report also discusses the history and competitive effects of no-relinquishment provisions, and other aspects of these provisions that, while implicating legal regulations, may ultimately provide helpful context to the Court in analyzing USL's contract claim and Zydus's public policy affirmative defense. *See SourceOne Dental, Inc. v. Patterson Companies, Inc.*, No. 15-5440 (BMC), 2018 WL 2172667, at *1 (E.D.N.Y. May 10, 2018) (Explaining that antitrust experts may "testify about factors that would tend to show anticompetitive conduct in a market and describe why, in the expert's opinion, those factors are present in the case at hand"). Thus, the Court is not prepared at this time to find Mr. Carrier's testimony inadmissible or unnecessary.

This is particularly the case given that this matter is scheduled for a bench trial. Indeed, the Court is certain that "[t]he able attorneys on both sides of this case can articulate the law in their arguments and post-trial briefing." *PureWick*, 2021 WL 2593338, at *2. To the extent that

Mr. Carrier's testimony is duplicative of those arguments, it "risks wasting a substantial amount of time." *Dille Family Trust v. Nowlan Family Trust*, 276 F. Supp. 3d 412, 426 (E.D. Pa. 2017). Ultimately, however, any time wasted redounds to Zydus. The Court will not wholesale exclude Mr. Carrier's testimony, but Zydus should carefully consider whether it is the best use of time.

USL also moves to exclude Mr. Carrier's testimony for various purported methodological flaws. D.I. 245 at 7-14. USL's arguments on this point go to the weight of Mr. Carrier's testimony, not its admissibility. Given this is a bench trial, the Court will not exclude Mr. Carrier from taking the stand. Should the Court, at the bench trial, find Mr. Carrier's testimony to be unreliable, it will simply disregard that testimony.

B. Jennifer Davidson

USL moves to exclude the testimony of Jennifer Davidson for improperly offering an opinion on a legal conclusion. Ms. Davidson is a lawyer and intends to testify on the FDA regulatory regime. Opinion testimony that "draws a legal conclusion by applying law to the facts is generally inadmissible." *Dille Family*, 276 F. Supp. 3d at 426. Courts sometimes permit experts to testify as to FDA regulations and procedures, "because of the complex nature of the process and procedures." *In re Yasmin & YAZ (Dropsirenone) Mktg., Sales PRacs. & Prod. Liab. Litig.*, No. 09-MD-0211-DRH, 2011 WL 6302287, at *25; *see also Par Pharmaceutical, Inc. v. Hospira Inc.*, No. CV 17-944-JFB-SRF, 2019 WL 2396748 at * 3 (D. Del. June 6, 2019); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009).

USL seeks to exclude a portion of Ms. Davidson's testimony in which she opines that "Dr. Weiseman's opinion that companies do not relinquish exclusivity does not support his conclusion that it was unreasonable for Zydus to support its exclusivity." D.I. 245 at 16-17 (citing Ex. 4 ¶ 84). In support of this opinion, Ms. Davidson conducted an analysis of specific instances in which

companies relinquished exclusivity but continued to seek FDA approval of their own ANDAs. D.I. 245, Ex. 4 ¶¶ 16, 31-80. The Court finds that Ms. Davidson's testimony on this issue situates real world examples of relinquishment in the context of FDA regulations and is permissible expert testimony. Other portions of Ms. Davidson's testimony may consist of impermissible legal conclusions but, for the reasons discussed regarding the testimony of Mr. Carrier, the Court is not prepared at this time to exclude all of her testimony.

C. Paul Jarosz

USL moves to exclude portions of the testimony of Dr. Paul Jarosz, an industrial scientist and former pharmaceutical executive, on grounds that Dr. Jarosz is not qualified to opine on the current FDA ANDA review process, especially the modern Complete Response Letter ("CRL") approach that the FDA uses to respond to ANDAs. D.I. 245 at 18-20.

Dr. Jarosz's opinions on the likelihood of Zydus obtaining ANDA approval based on Zydus's CRLs are based on his experience with the ANDA system. D.I. 245, Ex. 8, 32:8-12. Dr. Jarosz's experience predates the modern CRL system, and he testified that he has no experience responding to CRLs. *Id.* 34:15-22. However, Dr. Jarosz contends that he has "plenty of experience with deficiency letters, which are the same as CRLs, just in a different era." *Id.* at 35:21-36:1. The Court understands that USL contends that CRLs and deficiency letters are quite different, while Zydus contends that they are nearly the same. However, the alleged difference between CRLs and deficiency letters goes to the weight and credibility of Dr. Jarosz's opinions, not its admissibility. Also, given that his testimony will be provided to the Court during a bench trial, the Court finds no reason to exclude Dr. Jarosz's testimony based on the alleged difference between CRLs and deficiency letters.

WHEREFORE, at Wilmington this 16th day of July, 2024, **IT IS HEREBY ORDERED** that USL's Motions to Exclude the Opinions of Michael A. Carrier (D.I. 424), Jennifer A. Davidson (D.I. 243) and Paul J. Jarosz (D.I. 244) are **DENIED**. The Court is filing this opinion under seal because the briefing was filed under seal. **IT IS FURTHER ORDERED** that, by August 5, 2024, the parties shall file a proposed redacted version of this opinion, along with a motion supported by a declaration that contains a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotations omitted). If the parties do not file a proposed redacted version and corresponding motion by the deadline, or if the Court determines the motion lacks a meritorious basis, the opinion will be unsealed in whole or in part.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE