

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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OTSUKA PHARMACEUTICAL CO., LTD.	:	
and H. LUNDBECK A/S,	:	
	:	
Plaintiffs,	:	
v.	:	C.A. No. 19-1938-LPS
	:	
ZENARA PHARMA PRIVATE LTD., et al.,	:	
	:	
Defendants.	:	

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**MEMORANDUM ORDER**

At Wilmington this **21st** day of **September, 2022**, having reviewed the parties’ briefing and other submissions (D.I. 554, 555, 565, 568) related to Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S’ (collectively, “Plaintiffs”) *Daubert* motion, directed at excluding the opinions and testimony of Defendants’ expert, Dr. Jeffrey Aubé,

**IT IS HEREBY ORDERED** that Plaintiffs’ motion (D.I. 554) is **DENIED**, for the reasons set out below.

1. Federal Rule of Evidence 702 creates a “gatekeeping role for the [trial] judge” to “ensur[e] that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). There are three distinct requirements for admissible expert testimony: (1) the expert must be qualified, (2) the opinion must be reliable, and (3) the opinion must relate to the facts. *See generally Elcock v. Kmart Corp.*, 233 F.3d 734, 741-46 (3d Cir. 2000). Hence, expert testimony is admissible if a qualified expert provides opinions “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). Rule 702 embodies a “liberal policy of admissibility.” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (internal citations omitted). Motions to exclude evidence are committed to the Court’s discretion. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994).

2. Plaintiffs contend that Dr. Aubé is not qualified to provide expert opinions with respect to the patents-in-suit (U.S. Patent Nos. RE48,059, 8,349,840, 8,618,109, and 9,839,637; hereinafter, the “Brexiprazole Patents”). (*See* D.I. 555 at 5) In their view, “a person of ordinary skill in the art seeking to develop an improved atypical antipsychotic drug must have had experience developing antipsychotic drug candidates, as well as a strong understanding of the complex pharmacology associated with them and the CNS.” (*Id.* at 6) (citing Pl. Ex. A (Ward Rebuttal Report) ¶ 17; Pl. Ex. G (Rothschild Opening Report) ¶ 75) Dr. Aubé “does not have experience in psychiatry” or “work[ing] at a pharmaceutical company to develop a drug candidate,” and “is not a medical doctor,” pharmacologist, or pharmacist; nor is he trained in pharmacology. (*Id.* at 3-4) (citations omitted) Plaintiffs also challenge Dr. Aubé’s reliance on the opinion of Defendants’ expert, Dr. Anthony Rothschild, “with respect to the psychiatry and pharmacology aspects of the art.” (*Id.* at 4) (citing Pl. Ex. B (Aubé Opening Report) ¶ 53) Plaintiffs further point out that Dr. Aubé’s pre-priority-date research did not relate to antipsychotics or their associated receptors, adding that they believe he has not gained sufficient experience since the priority date to qualify him to testify. (*Id.*) Therefore, according to Plaintiffs, “[b]efore the priority date of the Brexiprazole Patents, Dr. Aubé was not a person of ordinary skill, which is a requirement for a witness offering expert testimony concerning obviousness.” (*Id.*)

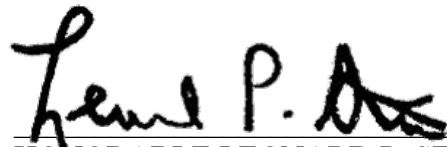
3. In response, Defendants contend that Dr. Aubé qualifies as a person of ordinary skill under Plaintiffs' experts' proffered definition. (*See* D.I. 565 at 9-10) (quoting Pl. Ex. A (Ward Rebuttal Report) ¶ 17) Defendants highlight Dr. Aubé's Ph.D. in organic chemistry and his years of postdoctoral research experience, as well as his expertise as a medicinal chemist who has worked on the development of drug candidates and whose experience is, at least according to his testimony, "reasonably portable across fields." (*E.g., id.* at 2-3, 9-10) (quoting Def. Ex. C (Aubé Dep. Tr.) at 156) Defendants also point to Dr. Aubé's 20 years of experience teaching pharmacy students about the medicinal chemistry of antipsychotics (*id.* at 10) (citing Def. Ex. B (Aubé Opening Report) ¶ 7), and his prior research on antipsychotic receptors (*id.* at 3) (citing Def. Ex. C (Aubé Dep. Tr.) at 43). Defendants also contend that, given the collaborative nature of drug development, it is proper for Dr. Aubé to rely Dr. Rothschild's pharmacology knowledge. (*Id.* at 11-12)

4. The Court is not persuaded that it should exclude Dr. Aubé's opinions and testimony. The Third Circuit has a "liberal standard[] for [the] qualifications of experts . . . ." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 754. "We have eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications." *Id.* at 741. Dr. Aubé's qualifications are sufficient for purposes of this case. Dr. Aubé has a Ph.D. in chemistry and postdoctoral research experience. (*See, e.g.,* Def. Ex. B (Aubé Opening Report) ¶ 5) He also has extensive experience teaching pharmacy students about antipsychotics (*id.* ¶ 7) and has done research on antipsychotic receptors (Def. Ex. C (Aubé Dep. Tr.) at 43), in addition to his medicinal-chemistry research experience (*see, e.g.,* D.I. 565 at 2-3). Dr. Aubé offers his testimony as an "expert in medicinal chemistry and drug discovery and design, with experience with the central nervous system." (Def. Ex. B (Aubé Opening Report) ¶ 16) Plaintiffs are free to

question Dr. Aubé about his qualifications, and may argue that they are not as good as others', but their challenges go to the weight that might be accorded to his opinions and not to their admissibility. *See generally Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997) (stating that where expert meets "liberal minimum qualifications, then the level of [his] expertise goes to credibility and weight, not admissibility").

5. The Court likewise finds no basis to preclude Dr. Aubé's reliance on Dr. Rothschild's opinion. Defendants will present evidence that drug development is conducted by a team and are free to argue that such a team might include members with qualifications like those of Dr. Aubé and Dr. Rothschild.

6. Finally, the trial will be a bench trial. Having reviewed the materials submitted in connection with Plaintiffs' motion, the Court is of the view that Dr. Aube's testimony will be helpful to it as the finder of fact.

  
HONORABLE LEONARD P. STARK  
UNITED STATES DISTRICT COURT