

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

ALLERGAN USA, INC., ALLERGAN  
HOLDINGS UNLIMITED COMPANY, and  
EDEN BIODESIGN, LLC,

Plaintiffs,

v.

MSN LABORATORIES PRIVATE  
LIMITED, MSN PHARMACEUTICALS,  
INC., and SUN PHARMACEUTICAL  
INDUSTRIES LIMITED,

Defendants.

C.A. No. 19-1727-RGA

**MEMORANDUM ORDER**

Before me is Defendants' motion to strike portions of Dr. Berkland's testimony at trial. (D.I. 463). Defendants objected to Dr. Berkland's testimony at the bench trial, and I reserved judgment on the issue. (Tr. 380:19-381:10).<sup>1</sup> I have considered the parties' briefing. (D.I. 463, 467, 470). For the reasons set forth below, Defendants' motion is granted in part and denied in part.

**I. BACKGROUND**

The disputed expert testimony concerns one paragraph in the patent specification. The patent specification recites,

For preparing formulations of the present disclosure, such as tablets, [eluxadoline] is mixed with one or more pharmaceutical excipients to form a solid preformulation composition containing, in preferred embodiments, a homogeneous mixture of the excipient(s) with the active ingredient. When referring to these preformulation compositions as "homogeneous," it is meant that the active ingredient are [sic] dispersed evenly throughout the composition so that the composition may be readily subdivided into equally effective unit dosage forms such as tablets or capsules. This solid preformulation is then subdivided into unit dosage forms of the

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<sup>1</sup> The transcript is at D.I. 458.

type described above containing from, for example, about 10 to about 200 milligrams of the active ingredient.

(D.I. 467-1, Ex. A at col. 12:52-68).

At trial, Plaintiffs' expert Dr. Berkland offered testimony regarding how a POSA would understand this paragraph. (*See, e.g.*, Tr. 379:10-380:12). Defendants objected to Dr. Berkland's testimony. Defendants assert, "There is no disclosure of any opinion regarding preformulation processes in Dr. Berkland's report." (Tr. 380:19-21).

I allowed Dr. Berkland to testify and advised Defendants to move to strike in post-trial briefing. Defendants now move to strike various portions of Dr. Berkland's testimony, to wit, Tr. 378:9-16; 379:24-380:12; 382:4-383:6; 412:13-413:6; 428:25-429:3; 429:8-431:12.

## II. LEGAL STANDARD

Federal Rule of Civil Procedure "26(a)(2)(B) requires that a testifying expert witness provide a written report containing, among other things, 'a complete statement of all opinions the witness will express' and 'the facts or data considered by the witness in forming them.'" *Ansell Healthcare Prod. LLC v. Reckitt Benckiser LLC*, 2017 WL 6328149, at \*1 (D. Del. Dec. 11, 2017) (quoting Fed. R. Civ. P. 26(a)(2)(B)(i)-(ii)). "In determining whether an expert's testimony has exceeded the scope of his or her report, the Court has not required verbatim consistency with the report, but has allowed testimony which is consistent with the report and is a reasonable synthesis and/or elaboration of the opinions contained in the expert's report." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 585 F. Supp. 2d 568, 581 (D. Del. 2008).<sup>2</sup>

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<sup>2</sup> Rule 26(a)(2)(B) was amended in 2010. Rule 26(a)(2)(B)(ii) was changed from "data or other information" to "facts or data considered by the witness in forming" an opinion. This change was made "to limit disclosure to material of a factual nature by excluding theories or mental impressions of counsel." Fed. R. Civ. P. 26 advisory committee notes to 2010 amendments. I do not consider the 2010 amendment to Rule 26(a)(2)(B)(ii) to alter the validity of the Court's analysis in *Power Integrations*.

### III. DISCUSSION

Defendants argue that Dr. Berkland offered an undisclosed opinion regarding the portion of the patent specification that discusses a “preformulation composition.” (D.I. 470 at 1). Defendants contend that Dr. Berkland for the first time at trial “testified that the meaning of the term ‘preformulation,’ in the context of the patent specification, is ‘a completely different definition’ from how a POSA would understand it.” (*Id.* at 1-2 (citing Tr. 429:11-16)). Defendants argue that Dr. Berkland’s expert report only uses the term “preformulation” once, and it does not provide a definition for that term. (*Id.* at 4 (citing D.I. 467-1, Ex. C, ¶ 200)). Defendants clarify that they are not seeking to strike Dr. Berkland’s opinions on “the mixing process,” just the “opinion that the term ‘preformulation’ has a different meaning in the context of the specification than what a POSA would understand it to mean based on the literature.” (*Id.*).

Plaintiffs raise two arguments in response. First, they argue that Dr. Berkland’s testimony should be permitted because it was offered in response to Dr. Gemeinhart’s testimony regarding the meaning of “preformulation” and “preformulation composition” as described in the patent specification, which was not disclosed in Dr. Gemeinhart’s opening report. (D.I. 467 at 2-3). In other words, Defendants’ presentation of non-disclosed expert testimony justifies Plaintiffs’ subsequent presentation of non-disclosed expert testimony. Second, Plaintiffs argue that Dr. Berkland’s opinions were disclosed in his expert report. (*Id.* at 3-4).

I agree with Defendants that Dr. Berkland’s opinion regarding the meaning of the term “preformulation” was not previously disclosed in his expert report. His testimony regarding the meaning of the term should therefore be stricken. The single paragraph of Dr. Berkland’s report that Plaintiffs cite (D.I. 467-1, Ex. C, ¶ 200) does not say anything about what a POSA would

understand the terms “preformulation” or “preformulation composition” to mean, let alone that a POSA would understand the terms to deviate from their normal meanings.

I disagree with Plaintiffs that Dr. Berkland’s testimony is proper because it was in response to a new opinion from Dr. Gemeinhart. Dr. Gemeinhart’s expert report recites, “The first step in dosage for[m] design is the completion [of] preformulation research where the stability and physico-chemical properties of the active pharmaceutical ingredient (‘API’) are measured.” (D.I. 467-1, Ex. B, ¶ 22). Dr. Gemeinhart’s testimony at trial (Tr. 309:19-21) is entirely consistent with his expert report.

Therefore, I believe that Dr. Berkland’s testimony regarding the meaning of “preformulation” should be struck from record. Berkland’s testimony at Tr. 383:1-6; 412:22-413:6; 428:25-429:3; 429:8-20 is struck as these portions of his testimony provide an undisclosed opinion regarding the meaning of the terms “preformulation” and “preformulation composition.”

I, however, disagree with Defendants that the other cited portions should be stricken. While Dr. Berkland’s testimony regarding the meaning of “preformulation” was not disclosed in his expert report, Dr. Berkland’s opinion about the mixing step was. Defendants concede that; they “are not moving to strike Dr. Berkland’s opinion on the mixing process.” (D.I. 470 at 4). I think these portions of Dr. Berkland’s testimony are proper because Dr. Berkland is merely elaborating on his expert report. *See Power Integrations*, 585 F. Supp. 2d at 581. To put it another way, I think Defendants are overreaching when it comes to the amount of Dr. Berkland’s testimony that they want to strike.

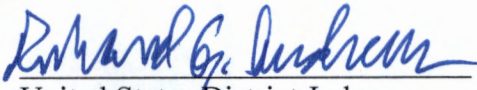
I think Dr. Berkland’s testimony at Tr. 378:9-16; 379:24-380:12, 382:4-25; 412:13-22; and 429:21-431:12, does not need to be stricken. While Dr Berkland may use the word “preformulation” in this testimony, he is not testifying about the meaning of the term. Rather, he

is testifying about what the relevant part of the patent specification says or what a POSA would understand the specification to be teaching. Just because he did not offer a definition of the word “preformulation” in his expert report does not prevent him from using the word.

#### IV. CONCLUSION

For the reasons stated above, Defendants motion is granted-in-part and denied-in-part. Dr. Berkland’s testimony at Tr. 383:1-6; 412:22-413:6; 428:25-429:3; 429:8-20 is struck from the record.

IT IS SO ORDERED this 4<sup>th</sup> day of August 2023.

  
United States District Judge