IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and MYLAN PHARMACEUTICALS INC., Petitioners

v.

ALMIRALL, LLC, Patent Owner

Case IPR2019-00207¹ Patent 9,517,219

PATENT OWNER'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE EVIDENCE UNDER 37 C.F.R. § 42.64

¹ Cases IPR2019-00207 and IPR2019-01095 have been joined in this proceeding.

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I. INTRODUCTION

Amneal's spoon-fed attorney argument served as the sole basis for certain paragraphs in Dr. Michniak-Kohn's and Dr. Gilmore's expert reports. Therasense, Inc. v. Becton, Dickinson & Co., 2008 WL 2323856, at *1 (N.D. Cal. May 22, 2008) ("One of the worst abuses in civil litigation is the attempted spoon-feeding of client-prepared and lawyer-orchestrated 'facts' to a hired expert who then "relies" on the information to express an opinion."). Patent Owner seeks to exclude paragraphs from Dr. Michniak-Kohn's or Dr. Gilmore's expert declarations that explicitly rely on Dr. Osborne's, Dr. Harper's, or Dr. Kircik's deposition testimony.² Both of Amneal's experts, Dr. Michniak-Kohn and Dr. Gilmore, admit that they did not review or possess Dr. Osborne's, Dr. Harper's, or Dr. Kircik's deposition testimony prior to submitting their respective expert declarations. Instead, Dr. Michniak-Kohn and Dr. Gilmore admit that the source of the paragraphs in question are Amneal's counsel.

The paragraphs in question directly concern issues central to this proceeding. But, Almirall was deprived of the opportunity to probe the bases of paragraphs in

² Patent Owner's motion seeks to exclude paragraphs 4, 15, 26, 35–37, 55, 59, 68, 70–73, 75, 78, 83, and 86 from Ex. 1043 and 8, 16, 17, 21, 26, 28, 37, 38, 40, and 46 from Ex. 1044 ("paragraphs in question").

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question. Instead, Amneal's counsel instructed Dr. Michniak and Dr. Gilmore not to answer, claiming that an expert's declaration "speaks for itself." Ex. 2069, 101:4-12 ("Well, the document says that she got that understanding from counsel in Paragraph 15. So it speaks for itself."). The right to explore and question the bases of an expert's opinion is fundamental to an *inter partes* review, as in any exercise of due process. Amneal's counsel blocked that fundamental right in the most basic of ways – employing attorney work product as both a sword and a shield. The Board should accordingly exclude Ex. 1043 at ¶¶ 4, 15, 26, 35-37, 55, 59, 68, 70-73, 75, 78, 83, and 86, as well as Ex. 1044 at ¶¶ 8, 16-17, 21, 26, 28, 37-38, 50 and 46.

II. ARGUMENT

A. Almirall could not have raised an objection before Amneal's expert testimony.

Almirall raised a timely objection at the first possible instance. All but conceding its counsel was the source of the "expert" testimony, Amneal resorts to a fragile argument on procedural grounds, stating: "Almirall's motion to exclude should be denied because Almirall did not timely raise any objection to the testimony of Dr. Michniak-Kohn and Dr. Gilmore." Paper 46 at 2. Amneal's argument resolves to this: because the paragraphs in question began with "I understand," Almirall should have instantly understood they were sourced from

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counsel and immediately objected to their admissibility. This shoot-before-youaim argument is unavailing on several scores.

First, Almirall could not assume what Amneal's experts relied upon in arriving at the paragraphs in question. That's the very purpose of cross-examination. Almirall required the expert's testimony to understand the bases of the paragraphs in question. It was only at the deposition that Almirall could confirm that Amneal's counsel was the sole basis for the paragraphs in question. *Second*, Almirall quite reasonably expected it could probe the bases of the paragraphs in question during the deposition, as a matter of proper course. It was not until Amneal's counsel instructed its experts to not answer that the paragraphs in question were revealed as sword and shield attorney work product. Simply put, Almirall could not have known that the paragraphs in question were inadmissible prior to the depositions of Drs. Michniak-Kohn and Gilmore. Almirall's objection to the evidence was timely, as such.

B. Evidence from Amneal's counsel is not admissible under F.R.E. 702.

The paragraphs in question amount to Amneal's counsel proffering expert opinions. Amneal mischaracterizes the paragraphs in question as "factual statements," but substantively the paragraphs in question are posited as expert opinions and expert interpretations of evidence. *See, e.g.,* Paper 41 at 5

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("I understand that Dr. Osborne conceded at his deposition that incompatibilities are either visibly present or they do not exist."); *see generally id.* at 2-5, 7-9. The paragraphs in question are nothing more than Amneal's attorneys argument masked as an expert opinion.

Amneal justifies the use of attorney argument as expert opinion by contending, "Almirall was also not deprived of the opportunity to cross-examine Dr. Michniak-Kohn or Dr. Gilmore about the 'veracity' of the information supplied by counsel." Paper 46 at 7. Amneal argues that Almirall had the opportunity to test the veracity of these statements by providing Dr. Osborne's, Dr. Harper's, or Dr. Kircik's testimony to Dr. Michniak-Kohn or Dr. Gilmore during their respective deposition. But, Amneal misses the point: Amneal's counsel is the sole basis of the "expert" opinion, not Dr. Michniak-Kohn or Dr. Gilmore.

Amneal's counsel interpreted the context of Dr. Osborne's, Dr. Harper's, or Dr. Kircik's testimony. Amneal's counsel interpreted that testimony in the context of the prior art as a whole, determined the weight of the evidence considered and discounted, and, ultimately, Amneal's counsel formed the expert opinion posited in the paragraphs in question. Dr. Michniak-Kohn and Dr. Gilmore have no firsthand knowledge of Amneal counsel's process. To test the veracity of the

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