

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

ALMIRALL, LLC,  
Patent Owner.

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Case IPR2019-00207<sup>1</sup>  
U.S. Patent No. 9,517,219 B2

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**PETITIONERS' OPPOSITION TO MOTION TO EXCLUDE EVIDENCE**

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<sup>1</sup> Cases IPR2019-00207 and IPR2019-01095 have been joined in this proceeding.

## **I. Introduction**

On October 4, 2019 and October 18, 2019, Almirall's declarants, Dr. Osborne and Dr. Kircik, respectively made critical admissions during cross-examination that undermined Almirall's case and supported Amneal's declarant's (Drs. Michniak-Kohn and Gilmore) opinions. Thereafter, Dr. Michniak-Kohn and Dr. Gilmore, in their Reply declarations, included *facts* about Almirall's declarants' admissions *via* information from counsel, as opposed to combing through the voluminous transcripts themselves. When questioned by Almirall's counsel on cross-examination about the genesis of their understanding about these *facts*, both of Amneal's experts testified truthfully that they obtained the understanding from counsel. But, relying on information from counsel does not render an expert's opinions unreliable so long as the expert: disclosed the information relied upon, based their opinions on reliable principles and methods, and reliably applied those principles and methods to the facts of the case.

Almirall, concerned about and desperate to escape the adverse consequences likely to stem from the admissions its declarants made, now seeks to exclude the opinions of Drs. Michniak-Kohn and Gilmore without factual or legal support. The Board should deny Almirall's motion for at least two reasons. *First*, Almirall did not timely raise the evidentiary basis on which it now moves. Not only does this mean that Almirall did not satisfy its threshold obligation, but failing to timely

object deprived Amneal an opportunity to cure any issue. *Second*, the challenged testimony is not unreliable, as Almirall contends. The challenged testimony was based on the experts' view of the published literature and prior art, their own experience, and their understanding of the technical field. The information supplied by counsel to Amneal's experts are undisputed facts extracted from the deposition transcripts of Almirall's declarations—it is the undisputed record, and nothing more. Almirall has not shown that any fact supplied by Amneal's counsel was incorrect or not in the record. And, Almirall has not articulated any cognizable reason why Amneal's expert's opinions are unreliable because some facts were supplied by counsel.

## **II. Argument**

### **A. Almirall did not timely raise its objection to the now-challenged testimony.**

For the first time during the deposition of Amneal's declarants, Dr. Michniak-Kohn and Dr. Gilmore, Almirall raised objection to *declaration testimony* (not deposition testimony) of those experts because each had relied upon factual information supplied by counsel about deposition admissions of Almirall's declarants. 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, thereby depriving Amneal the opportunity to potentially cure any objection.

Rule 42.64(b)(1) states that “[o]nce a trial has been instituted, any objection must be filed within five business days of service of evidence to which the objection is directed. The objection must identify the grounds for the objection with sufficient particularity to allow correction in the form of supplemental evidence.” *See* 37 CFR § 42.64(b)(1). Almirall never filed its current objection to Dr. Michniak-Kohn’s or Dr. Gilmore’s testimony within five business days of those declaration being filed. Without timely raising its objection, Almirall effectively deprived Amneal of an opportunity to potentially cure any objection by having Dr. Michniak-Kohn and Dr. Gilmore review the deposition transcripts of Almirall’s declarants and state whether they agreed with the information supplied by counsel. That is, following the scriptures of Rule 42.64 would have mooted Almirall’s entire motion to exclude.

Recognizing that its failure to timely object is fatal to its motion, Almirall tries to fix the problem by claiming that during these depositions “it became clear that [Almirall’s declarants] had come to [their] understanding of Almirall’s experts’ deposition testimony via counsel rather by relying on the deposition transcripts themselves.” *See* Paper 43, 5-6, n2. Almirall’s excuse is unavailing. Almirall acts as if it seeks to exclude *deposition evidence* under Rule 42.64(a) rather than *declaration evidence* under Rule 42.64(b). Since Almirall is seeking to exclude *declaration evidence*, any objection to that evidence at the depositions was

untimely because those depositions occurred more than five business days from filing. In fact, Dr. Michniak-Kohn and Dr. Gilmore were deposed on December 6 and December 12, respectively, which were more than five business days after November 1 when Amneal's Reply declarations were filed. Paper 32; Paper 33.

Moreover, it is illogical that Almirall somehow needed to wait until the depositions of Drs. Michniak-Kohn and Gilmore, as the context of the information supplied by counsel was clear. As Almirall's motion highlights, each time Dr. Michniak-Kohn and Dr. Gilmore relied upon information from counsel they started the sentence with "I understand." Paper 43, 2-5, 7-9. Even if Almirall needed deposition testimony, it should have objected within the time allotted and then obtained any clarification at the deposition. Because Almirall failed to diligently review the declarations of Dr. Michniak-Kohn and Dr. Gilmore and file any objections within five business days, Almirall's motion to exclude should be denied on this basis alone.

**B. The now-challenged testimony is not inadmissible under Fed. R. Evid. 702.**

In a cursory one-paragraph argument for each declarant, Almirall argues that certain paragraphs from Dr. Michniak-Kohn's and Dr. Gilmore's declarations should be excluded as unreliable because Dr. Michniak-Kohn and Dr. Gilmore did not themselves comb through the transcripts of Almirall's declarants to determine the veracity of those statements. But, that is irrelevant, particularly where Almirall

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