

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC AND
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
Petitioners,

v.

ALMIRALL, LLC,
Patent Owner.

Case IPR2019-00207

Patent 9,517,219 B2

**PETITIONERS' MOTION FOR ADDITIONAL DISCOVERY PURSUANT
TO 37 C.F.R. § 42.51(b)(2)**

Pursuant to 37 C.F.R. § 42.51(b)(2) and the Board's October 11, 2019 Order (Paper 24) authorizing this motion, Amneal respectfully requests that the Board order Patent Owner Almirall LLC ("Almirall") to:

- Make co-inventor Dr. Kevin S. Warner, on whose declaration Almirall is relying in this proceeding, available for deposition; and
- Produce the transcripts of Dr. Warner's deposition from the district court litigation involving the same U.S. Patent No. 9,517,219 ("the '219 patent") that is challenged here.¹

Dr. David Osborne, one of Almirall's expert declarants in this case, relies on inventor Dr. Warner's declaration from prosecution, as the **sole** basis for alleged unexpected results. EX2057, ¶¶173-194 (citing AMN1017, 289-293). In his prosecution declaration, Dr. Warner compares a 7.5% dapstone formulation containing Carbopol to a 7.5% dapstone formulation containing Sepineo, and presents his observations as to the differences between those formulations.

Additional discovery in the form of Dr. Warner's deposition here and production of Dr. Warner's deposition transcript from the related litigation is necessary so that Amneal can fully prepare its Reply to Almirall's Response and to defend against Almirall's allegations of purported unexpected results. Dr. Warner's declaration omits many necessary details, so Dr. Warner's deposition testimony is

¹ *Almirall LLC v. Taro Pharms. Indus. Ltd.*, 17-663 (D. Del.).

needed to fill those gaps in his declaration. For example, Dr. Warner’s observation that the dapsone/carbopol formulation showed “undesired polymer aggregates” is purely subjective. Without an objective measure, this Board cannot determine what Dr. Warner viewed was “undesired” aggregates. Moreover, how Dr. Warner prepared the dapsone/carbopol and dapsone/Sepineo compositions—information not found in the declaration—is relevant to whether Dr. Warner’s observations are attributable to differences in the formulations or differences in the preparation process like the prior art teaches.

Only Dr. Warner knows this information. Dr. Osborne merely regurgitates what Dr. Warner said and Dr. Osborne otherwise has no personal knowledge of the information contained in Dr. Warner’s declaration. Dr. Osborne cannot fill the gaps in Dr. Warner’s declaration. Moreover, the requested additional discovery does not present any undue prejudice or burden to Almirall. Accordingly, in the interests of justice Amneal requires Dr. Warner’s deposition testimony to fill the gaps in his declaration.

As explained below, Amneal’s request meets the five factors set forth in *Garmin Int’l, Inc. v. Cuozzo Speed Tech. L.L.C.*, IPR2012-00001, Paper 26 (P.T.A.B. Mar. 5, 2013) for requesting additional discovery. *See* 37 C.F.R. § 42.51(b)(2). To the extent that the Board is disinclined to grant Amneal’s request, then Amneal submits that all statements in Dr. Warner’s declaration are relied

upon for their truth and are, therefore, inadmissible hearsay, or are otherwise entitled to little or no weight.

I. FACTUAL BACKGROUND

Almirall filed its Patent Owner Response (Paper 20) on August 9, 2019. On August 15, 2019, counsel for Almirall emailed counsel for Amneal, offering Dr. Leon Kircik for deposition. Ex. 1036, 7-8. On August 22, 2019, counsel for Almirall offered Dr. David Osborne for deposition. *Id.* at 7. Almirall only offered two of the three declarants Almirall relied upon. On September 13, counsel for Amneal requested dates to depose Almirall's third declarant, Dr. Warner, and requested that Almirall produce Dr. Warner's deposition transcript from the related district court action over the '219 patent. *See* Ex. 1036, 4; Paper 1, 64-65. Almirall responded by questioning why Dr. Warner's testimony was needed, to which Amneal immediately explained that the only evidence in support of Almirall's alleged unexpected results allegations came from Dr. Warner's declaration. *Id.* at 3-4.

Having heard nothing from Almirall for nearly three weeks, Amneal again followed up on October 2 regarding Dr. Warner's deposition and transcript. Ex. 1036, 2. Almirall waited two more days before informing counsel for Amneal that Almirall would refuse to make Dr. Warner available for deposition and would refuse to produce Dr. Warner's deposition transcript from the *Taro* action, but did

not explain any prejudice or burden supporting its refusal. *Id.* Within 4 days, counsel for Amneal emailed the Board requesting a call to obtain authorization to file this motion. Ex. 1037, 1. The Board authorized Amneal's motion on October 11, 2019.

II. THE INTERESTS OF JUSTICE SUPPORT GRANTING ADDITIONAL DISCOVERY BECAUSE AMNEAL'S REQUEST SATISFIES ALL FIVE GARMIN FACTORS.

A. Garmin Factor 1 favors Amneal: there is more than a mere possibility that Dr. Warner's prior testimony and any new testimony will provide useful information.

The first *Garmin* factor favors Amneal, which requires that there is more than a mere possibility that something useful will be discovered. Between his requested testimony in this case and his prior testimony in the related district court action, Amneal will obtain relevant and useful information. The Board has previously granted additional discovery when, as here, information necessary for a scientific analysis are absent. For example, in *Mylan Pharmas. Inc. v. Allergan, Inc.*, IPR2016-01127, Paper 28 (P.T.A.B. May 31, 2017), the Board found that "underlying data is necessary to evaluate" data relied on by patent owner and was appropriate additional discovery. *Id.*, 3.

Here, Dr. Warner was the sole observer of the information contained in his declaration. And his declaration forms the sole basis for Almirall's allegations of purported unexpected results. No other witness will be able to provide the

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