IN THE 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

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW PURSUANT TO *ARTHREX*

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I. REQUEST FOR DIRECTOR REVIEW

Pursuant to 37 C.F.R. § 42.71(d), Patent Owner Almirall, LLC ("Patent Owner" or "Almirall") respectfully requests review of the Patent Trial and Appeal Board's (the "Board") Final Written Decision dated May 29, 2020 (*see* Paper 58) by a Director of the United States Patent and Trademark Office ("Director") that was appointed by the President and confirmed by the Senate as required by *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (June 21, 2021). Almirall requests that the Director finds that Petitioners have not met their burden to show that Claims 1-8 of U.S. Patent No. 9,517,219 (the "'219 Patent") are unpatentable.

II. LEGAL STANDARD

The Director reviews Final Written Decisions *de novo*.[1]

III. ARGUMENT

A. The Board Erred in Finding a Presumption of Obviousness Based on Overlapping Ranges in Garrett

Compromising its entire analysis, the Board improperly found a presumption of obviousness based on overlapping ranges despite acknowledging that no reference disclosed a formulation with every element of those claimed in the '219 patent. The

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[1] https://www.uspto.gov/patents/patent-trial-and-appeal-board/procedures/arthrex-qas (A1. Q: "…The Director's review may address any issue, including issues of fact and issues of law, and will be *de novo*.").

Board first held that the claims of the '219 patent were presumptively invalid because Garrett disclosed overlapping or abutting ranges for the values of each component in the claimed formulations, even though Garrett does not disclose an A/SA gelling agent as required by the '219 patent. But, for the A/SA-based thickener, the Board looked to Nadau-Fourcade or Bonacucina, both of which disclosed "Sepineo" as an A/SA gelling agent. Then, apparently relying on Carbopol and Sepineo's supposed interchangeability, the Board swapped Sepineo for Carbopol in the Garrett formulation, using Garrett's Carbopol ranges, creating a fictional prior art formulation that, in the Board's view, a POSA could routinely optimize to arrive at the compositions recited in the '219 patent.

An overlapping range-based presumption of obviousness applies, if at all, only when a single reference discloses the same process or formulation as claimed, with ranges for certain variables that a POSA would have reason to optimize. With no formulation in the prior art to optimize, there can be no ranges-based presumption of obviousness. *See, e.g., Galderma Laboratories, LP v. Tolmar, Inc.*, 737 F.3d 731, 736-38 (Fed. Cir. 2013); *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1304-05 (Fed. Cir. 2015). If the prior art's formulation differs from the claimed composition – as it does here, significantly – then a POSA cannot possibly optimize it to arrive at the claimed composition: a POSA could not optimize a range of a carbomer-based thickener to arrive at a range or amount of an A/SA-based thickener.

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