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 IPR2019-00207[1]
Patent 9,517,219

PATENT OWNER'S RESPONSE TO PETITIONER'S SUPPLEMENTAL BRIEF

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

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I. INTRODUCTION

Petitioners' supplemental brief does nothing to challenge or in any way undermine the credibility of Dr. Warner's declaration submitted during prosecution of the '219 patent. Petitioners were granted additional discovery to seek information regarding the reliability of and "explore the factual underpinnings" of the experiments reported in Dr. Warner's declaration. *See* Paper 39 at 6. Unable to discredit the reported experiments in his declaration, Petitioners took the 10-page opportunity to rehash its arguments already of record, misrepresenting Dr. Warner's testimony in the process.

What matters here is whether *Dr. Osborne's reliance* on the Warner Declaration is reasonable, and nothing in Petitioners' supplemental brief shows that it is not. Dr. Osborne took from the Warner Declaration what POSA reading the file history of the '219 patent would—and what the Examiner did. Petitioners' arguments that Dr. Osborne lacked personal knowledge of the actual experiments performed and described in the Warner Declaration are irrelevant, a fact posturing him no differently than the same POSA, and the same Examiner.

As for the so-called "critical admissions" Dr. Warner allegedly made in his deposition in the *Taro* action, these fall into two categories. Either they are legally irrelevant to the question of obviousness, prohibitively focused on the path the

inventor himself followed in arriving at the claimed invention, or they are grossly mischaracterized. Read in context, and thus fairly, the prior deposition testimony confirms that Dr. Warner performed (or directed) the experiments just as described in his declaration. And so it remains that the credibility of the parties' experts in opining as to the import a POSA would ascribe to the Warner Declaration is to be considered and weighed by the Board.

II. DR. WARNER'S INVENTOR TESTIMONY DOES NOT SHOW *PRIMA FACIE* OBVIOUSNESS

Petitioners' attempts to use Dr. Warner's testimony as to why and how he came to the inventions claimed in his patent are legally irrelevant. "Patentability shall not be negated by the manner in which the invention was made." 35 U.S.C. § 103. And as the Federal Circuit has explained, "[t]he inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art." *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012). Petitioners are required to show obviousness in respect of the *prior art*. The inventor's actions in arriving at the invention are not prior art. Petitioners' attempts to rely on the inventor's own steps and reasoning to show *prima facie* obviousness indeed is hindsight in its purest form. *Id.*

Proceeding as unaware of this well-settled law, Petitioners nonetheless serially misrepresent Dr. Warner's deposition testimony in attempting to use his own steps to show obviousness. Rather than testifying, as Petitioners represent, that steps he took were generally "routine," Dr. Warner took care to testify that increasing solubilized dapsone and increasing DGME was the formulation strategy *of his particular team*. Ex. 1078 at 51:21–53:7. On its face, the remaining testimony cited by Petitioners on this point—that additional safety studies would need to be done if using more than the maximum amount of DGME listed in the IIG at the time of development of the 7.5% dapsone gel (*id.* at 58:6–59:20); and that during his experiments in developing the invention he "observed [Carbopol] crashing out at 40 percent and at 35 percent," so was concerned about "potential incompatibility" at 30% DGME (*id.* at 185:1–16)—hardly speaks to any "routineness" of increasing DGME concentration.

Petitioners' representations that Dr. Warner testified that Sepineo "*was known in the art to have* 'better aesthetics,' 'improvements on particle size,' 'good suspension for stability of dapsone,' as well as 'ease in manufacturing'" are simply not borne out by the transcript. Paper 49 at 3 (emphasis added). Dr. Warner testified *not to what the prior art disclosed or taught*, but instead to what *he*, *the*

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