IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ALMIRALL, LLC,
Patent Owner

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

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**PETITIONERS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE**

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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

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The Board should grant Petitioners' Motion to Exclude Evidence.

## I. The Warner Declaration is hearsay and should be excluded.

Almirall first argues that the Warner Declaration is an "opposing party's statement" under Federal Rules of Evidence 801(d)(2)(A), (C), and (D). This is illogical. The Warner Declaration is not a statement offered against Almirall or Dr. Warner. Rather, the Warner Declaration was offered *by Almirall* against the patent examiner during prosecution and again *by Almirall* against Amneal here. POR, 60-62; AMN1017, 282-285, 289-293. Therefore, FRE 801(d)(2) is inapplicable.

Second, Almirall argues that they and their expert declarant Dr. Osborne take the Warner Declaration at face value, rather than rely on it for its truth. This makes no sense. As Patent Owner, Almirall and Dr. Osborne need to meet their burden of production of secondary considerations by relying on Dr. Warner's Declaration for its truth. They both do exactly that. EX2057, ¶¶173-181 ("*the statements and evidence in Dr. Kevin Warner's Declaration* show unexpected results of the claimed formulation.") (emphasis added); POR, 60 ("*the Warner Declaration showed* that the topical pharmaceutical compositions as claimed had improved properties ….") (emphasis added). Almirall cannot have it both ways—either the Warner Declaration is used for its truth, in which case it is hearsay, or it is not used for its truth, in which case there is no actual evidence of unexpected results.

Almirall's last argument is that Petitioners' objection was untimely because the declaration was filed as part of the prosecution history of the '219 patent with the Petition. Petitioners submitted the declaration "solely for rebuttal purpose" only, as they are required to do. *Actelion Pharms Ltd. v. Icos Corp.*, IPR2015-00561, Paper 50 at 40 (PTAB Aug. 3, 2016). Petitioners timely objected to the Warner Declaration once Almirall used its contents for their truth. Paper 21, 14-16.

## II. No hearsay exception applies to the Warner Declaration.

Almirall first argues that the public records exception applies because the declaration was part of the prosecution history. Unlike an Office Action or some other document representing the duties of the Patent Office, the Warner Declaration is not "a record or statement of a public office" and does not "set out the [examiner's] activities." *See* FRE 803(8)(a). The document was created by a third party, and the Board already agreed that significant questions are unanswered about its contents, so it also lacks trustworthiness. *See* FRE 803(8)(b); Paper 39, 5-6.

Second, the declaration does not qualify as former testimony of an unavailable witness exception under FRE 804(b)(1). Dr. Warner is not unavailable under FRE 804(a)(5)(A). As the statement's proponent, Almirall failed to show that it was unable to procure Dr. Warner "by process or other reasonable means." Rather, Almirall was in contact with the witness but simply failed to comply with

the Board's order to produce Dr. Warner for deposition. Paper 44, 2-3; EX2070, 8:20-13:8. Next, the declaration is not "former testimony" as it was not given at a witness at a trial, hearing, or deposition. *See* FRE 804(b)(1)(A). Nor is Amneal a party who had "an opportunity and similar motive to develop it by direct, cross-, or redirect examination" (*see* FRE 804(b)(1)(B)) because Amneal did not have a meaningful opportunity to develop it. Therefore, this exception does not apply.

Third, the declaration is not a statement offered against a party (i.e., Amneal) that wrongfully caused Dr. Warner's unavailability under FRE 804(b)(6). Dr. Warner's unavailability had nothing to do with Amneal and everything to do with Almirall's lack of diligence. Almirall knew since September 2019 that a deposition of Dr. Warner was possible but now faults the Board for failing to issue an order for "two and a half months." Paper 50, 8; AMN1036, 4. Almirall had ample time to secure Dr. Warner's availability. Nor did Amneal fail to cooperate, as Almirall suggests. Almirall even admitted that the modified schedule it proposed to accommodate Dr. Warner's deposition on Jan. 30 was "suicidal" and "chaotic." EX2070, 14:3-12, 26:23-27:6. Therefore, Amneal did not "wrongfully cause" Dr. Warner's unavailability.

Last, the residual hearsay exception does not apply. The residual exception is not "a broad license on trial judges to admit hearsay statements that do not fall within one of the other exceptions." *Conoco Inc. v. Dep't of Energy*, 99 F.3d 387,

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