

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
U.S. Patent No. 9,517,219

PETITIONERS' MOTION TO EXCLUDE EVIDENCE

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Petitioners Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (“Amneal”) file this motion pursuant to 37 C.F.R. §§ 42.62 and 42.64(c) and in accordance with Due Date 5 of the Scheduling Order (Paper 14). Amneal requests exclusion of Exhibits 2010-2011, 2013, 2017-2018, 2021, 2024, 2026-2027, 2029, 2032, 2038-2040, and 2050-2052; pages 289-293 of Exhibit 1017; paragraphs 1-19, 21-22, 83-93, 95, 98-100, 102-105, and 113-114 of Exhibit 2055; and paragraphs 1-37, 87-88, 109, 173-174, 165, 175-181, 190, 192-194 and 197 of Exhibit 2057, each of which it timely objected to through written Objections to Evidence.

The Federal Rules of Evidence (FRE) govern the admissibility of evidence in *inter partes* review proceedings. *See* 37 C.F.R. § 42.62. As shown herein, the challenged exhibits contain irrelevant information under FRE 401, 402, and 403, improper expert testimony under FRE 702 and 703, and hearsay under FRE 801 and 802. Accordingly, the Board should exclude the objected-to exhibits in their entirety for the reasons that follow.

It is not enough for the Board to find that this Motion is moot if the Board does not rely on the inadmissible evidence in reaching its Final Written Decision. If the exhibits and paragraphs identified herein remain in the record, Almirall could continue to rely upon them on appeal, and Amneal would be unfairly forced to address them again.

ARGUMENT

I. MULTIPLE EXHIBITS AND PARAGRAPHS OF EXPERT DECLARATIONS ARE NOT RELEVANT AND/OR ARE PREJUDICIAL.

Almirall submitted several exhibits that it failed to cite in its Patent Owner's Response or Sur-Reply, rendering them irrelevant and/or prejudicial. Exhibits 2010-2011, 2013, 2017-2018, 2021, 2024, 2026-2027, 2029, 2032, 2038-2040, and 2050-2052 appear nowhere in either Almirall's Response or Sur-reply and only appear buried in its expert declarations (Exhibits 2055 and 2057) submitted with the Response.

Evidence is relevant if it "has a tendency to make a fact more or less probable than it would be without the evidence" and "the fact is of consequence in determining the action." *See* FRE 401. Almirall's failure to cite Exhibits 2010-2011, 2013, 2017-2018, 2021, 2024, 2026-2027, 2029, 2032, 2038-2040, and 2050-2052 demonstrates that these exhibits do not have a tendency to make any fact of consequence more or less probable. If these exhibits were relevant to this proceeding, Almirall should have cited them in the Response or Sur-reply. This evidence is, therefore, inadmissible as irrelevant. *See* FRE 402 ("Irrelevant evidence is not admissible.").

If this evidence was actually submitted for the Board to consider, then this evidence should be excluded under FRE 403 as unfairly prejudicial. Exhibits 2010-

Case IPR2019-00207
Patent 9,517,219 B2

2011, 2013, 2017-2018, 2021, 2024, 2026-2027, 2029, 2032, 2038-2040, and 2050-2052 were not cited or discussed in the Response or Sur-reply, so Almirall would have overshot the word limits of its Patent Owner's Response and its Sur-reply had these exhibits been appropriately cited and discussed. Because "[a]rguments must not be incorporated by reference from one document into another document," 37 C.F.R. § 42.6(a)(3), any attempt by Almirall to reply upon these exhibits is prejudicial to Amneal. Amneal has followed the Board's rules throughout this proceeding, and would be prejudiced if Almirall is allowed to disregard those rules and incorporate this information by reference.

Additionally, paragraphs 1-19, 21-22, 83-93, 95, 98-100, 102-105, and 113-114 of Exhibit 2055, and paragraphs 1-37, 87-88, 109, 173-174, and 197 of Exhibit 2057 are likewise irrelevant and/or prejudicial. These paragraphs are not cited in either Almirall's Response or Sur-Reply. As with the improper exhibits, Almirall should have cited these paragraphs in its Response or Sur-reply if they were relevant. Almirall chose not to cite those paragraphs, so they must now be excluded from the record pursuant to FRE 401 and 402. Also of note, it is highly unlikely that Almirall could have properly discussed the omitted paragraphs in the space it had left in its Response or Sur-reply. If these paragraphs were relevant, Almirall's attempt to incorporate them into the Response or Sur-reply should be rejected as prejudicial under FRE 403.

Accordingly, Exhibits 2010-2011, 2013, 2017-2018, 2021, 2024, 2026-2027, 2029, 2032, 2038-2040, and 2050-2052; paragraphs 1-19, 21-22, 83-93, 95, 98-100, 102-105, and 113-114 of Exhibit 2055; and paragraphs 1-37, 87-88, 109, 173-174, and 197 of Exhibit 2057 should be excluded as irrelevant and/or prejudicial.

II. THE WARNER DECLARATION IN EXHIBIT 1017 AND DR. OSBORNE'S RELIANCE ON THE WARNER DECLARATION IN EXHIBIT 2057 ARE INADMISSIBLE HEARSAY.

Almirall's expert declarant, Dr. Osborne, relies on a declaration from co-inventor Kevin Warner (pages 289-293 of Exhibit 1017, herein "Warner Declaration") as the sole evidence of alleged unexpected results. Amneal had no opportunity to cross-examine Dr. Warner on his declaration because Almirall did not offer Dr. Warner for deposition in the first instance and Almirall then violated the Board's December 31, 2019 order by failing to provide Dr. Warner for deposition before January 17, 2020. Without the opportunity to cross-examine Dr. Warner, his declaration is inadmissible out-of-court testimony used for its truth and should be excluded.

The Warner Declaration (Exhibit 1017, 289-293) is inadmissible hearsay under FRE 801 and 802. The Warner Declaration contains out-of-court statements from Dr. Warner about his observations of dapstone compositions that were not under oath and were not subject to cross-examination. Ex. 1017, 289-293. Almirall relies upon this document for its truth—that one embodiment of the '219 patent's

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