

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 IPR2018-00608
U.S. Patent No. 9,161,926 B2

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 4 of the Scheduling Order (Paper 11). Amneal requests exclusion of Exhibits 2004, 2015, 2019, 2023, 2027, 2028, 2030-2035, 2038, 2040, 2041, and 2043-2047; paragraphs 1-40, 43, 61, 62, 64, 66-68, 71-80, 88-90, 92-98, 100, 104-112, 116-122, 125-143, 146-148, 152-158, 161-171, 173, 175-181, 183-192, 194-196, 200, and 202-218 of Exhibit 2003; and paragraphs 1-32, 35-39, 65, 78-80, 85-94, 96-112, 115, 132, 150, 163, and 173-200 of Exhibit 2022, 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. 37 C.F.R. § 42.62. As shown herein, the challenged exhibits contain irrelevant information under FRE 401, 402, and 403; hearsay under FRE 801 and 802; and are unauthenticated in violation of FRE 901. 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 HUNDREDS OF PARAGRAPHS OF EXPERT DECLARATIONS ARE NOT RELEVANT AND/OR ARE PREJUDICIAL.

Almirall submitted dozens of exhibits that it failed to cite in its Patent Owner's Response or Sur-Reply, rendering them irrelevant and/or prejudicial. Exhibits 2004, 2015, 2019, 2023, 2027, 2028, 2030-2035, 2038, 2040, 2041, and 2043-2047 appear nowhere in either Almirall's Response or Sur-reply and only appear buried in its expert declarations (Exhibits 2003 and 2022) submitted with the Response. Similarly, more than *250 paragraphs* out of a total of 418 paragraphs in Almirall's supporting expert declarations (Exhibits 2003 and 2022) were never cited in Almirall's Response or Sur-Reply.

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." FRE 401. Almirall's failure to cite Exhibits 2004, 2015, 2019, 2023, 2027, 2028, 2030-2035, 2038, 2040, 2041, and 2043-2047 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 2004, 2015, 2019, 2023, 2027, 2028, 2030-2035, 2038, 2040, 2041, and 2043-2047 were not cited or discussed in the Response or Sur-reply, so Almirall would have vastly 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.

Paragraphs 1-40, 43, 61, 62, 64, 66-68, 71-80, 88-90, 92-98, 100, 104-112, 116-122, 125-143, 146-148, 152-158, 161-171, 173, 175-181, 183-192, 194-196, 200, and 202-218 of Exhibit 2003, and paragraphs 1-32, 35-39, 65, 78-80, 85-94, 96-112, 115, 132, 150, 163, and 173-200 of Exhibit 2022¹ are likewise irrelevant

¹ These 263 paragraphs constitute an astounding 63% of Almirall’s 418 total paragraphs of expert testimony.

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. 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 263 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 2004, 2015, 2019, 2023, 2027, 2028, 2030-2035, 2038, 2040, 2041, and 2043-2047; paragraphs 1-40, 43, 61, 62, 64, 66-68, 71-80, 88-90, 92-98, 100, 104-112, 116-122, 125-143, 146-148, 152-158, 161-171, 173, 175-181, 183-192, 194-196, 200, and 202-218 of Exhibit 2003; and paragraphs 1-32, 35-39, 65, 78-80, 85-94, 96-112, 115, 132, 150, 163, and 173-200 of Exhibit 2022 should be excluded as irrelevant and/or prejudicial.

II. EXHIBITS 2043 AND 2044 SHOULD BE EXCLUDED AS INADMISSIBLE ON MULTIPLE GROUNDS.

A. Exhibit 2043 is irrelevant, unauthenticated hearsay.

Exhibit 2043 is document entitled "A Phase II, Randomized, Partial-Blind, Parallel-Group, Active and Vehicle-Controlled, Multicenter Study of the Safety and Efficacy of AczoneTM (Dapsone) Gel, 5% in Subjects With Papulopustular Rosacea." Ex. 2043, 1.

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