

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

**PETITIONERS' OBJECTIONS TO EVIDENCE AS OF
AUGUST 16, 2019**

Pursuant to 37 C.F.R. § 42.64(b)(1), Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, “Petitioners”) timely objects under the Federal Rules of Evidence (FRE) to the admissibility of Exhibits 2010-2011, 2013, 2017-2018, 2021, 2024, 2026-2027, 2029, 2032, 2038-2040, 2041-2052, and 2054. In addition, Petitioners object to the admissibility of paragraphs 1-19, 21-22, 57, 60-62, 65, 76-79, 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. Collectively, these exhibits (“Challenged Evidence”) were served by Patent Owner, Almirall, LLC, with its Patent Owner’s Response filed on August 9, 2019. Petitioners file these objections to provide notice to Patent Owner that Petitioners may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c), unless timely cured by Patent Owner.

**IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS
FOR OBJECTIONS**

A. Numerous exhibits and declaration paragraphs should be excluded as irrelevant.

Petitioners object to the use of Exhibits 2010-2011, 2013, 2017-2018, 2021, 2024, 2026-2027, 2029, 2032, 2038-2040, and 2050-2052 under FRE 401 and 403. These exhibits are not substantively relied on, or even cited, in Patent Owner’s Response. Consequently, these exhibits do not appear to make any fact of consequence more or less probable than it would be without them.

Petitioners also object to paragraphs 1-19, 21-22, 57, 60-62, 65, 76-79, 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 under FRE 401 and 403. These declaration paragraphs are not substantively relied on, or even cited, in Patent Owner's Response. Consequently, these declaration paragraphs do not appear to make any fact of consequence more or less probable than the fact would be without these paragraphs. Alternatively, if Patent Owner asserts that the aforementioned paragraphs are relevant, then Patent Owner must incorporate by reference into its Response these declaration paragraphs. Doing so, however, would add far more than the 525 words left to spare in Patent Owner's Response, thereby violating the word count limit set forth in 37 C.F.R. § 42.24(b).

B. Multiple exhibits are inadmissible as not relevant, not authenticated, and/or contain hearsay, and are therefore more prejudicial than probative as to any fact of consequence.

Exhibits 2013, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2048, 2049, 2050, and 2054 are inadmissible for at least the following reasons:

Exhibit 2013: This exhibit lacks authentication, and is inadmissible under FRE 901. Exhibit 2013 purports to be an article from Drug Therapy Topics, but there is no evidence establishing that it contains true and correct content. A table on page 7 and a figure on page 9 are not available in this exhibit and cannot be seen in the document. Accordingly, Patent Owner has not provided evidence

sufficient to support a finding that Exhibit 2013 “is what [Patent Owner] claims it is.” *See* FRE 901.

Exhibit 2013 is also inadmissible under FRE 401 and 403. Exhibit 2013 purports to be an article from Drug Therapy Topics, but is missing a table on page 7 and a figure on page 9. There is no evidence that Exhibit 2013 is a prior-art publication that was fully available to the public. Therefore, Exhibit 2013 is inadmissible as not relevant.

To the extent that the Patent Owner relies on the contents of this document to prove the content of the original document, Petitioners object to this document as not being an original document under FRE 1002, an authentic duplicate under FRE 1003, or a document that falls under any exception to the original-document requirement, including those of FRE 1004. Petitioners also object to Exhibit 2013 to the extent it violates the Best Evidence Rule under FRE 1002, which provides that the original of a “writing, recording, or photograph” is required to prove the contents thereof.

Exhibit 2040: Exhibit 2040 is inadmissible under FRE 401 and 403. Exhibit 2040 purports to be an excerpt from the Physicians’ Desk Reference 66th Ed. from 2012. But there is no evidence that Exhibit 2040 is a prior-art publication that was available to the public. Therefore, Exhibit 2040 is inadmissible as not relevant.

Exhibit 2040 is inadmissible as hearsay under FRE 801 and 802. Patent

Owner relies on the “2012” date in Exhibit 2040 for the truth of the matter asserted. Patent Owner cannot rely on the “2012” date shown in Exhibit 2040 because there is no evidence that the reference was a printed publication as of a particular date. No exception applies.

To the extent that the Patent Owner relies on the contents of this document to prove the content of the original document, Petitioners object to this document as not being an original document under FRE 1002, an authentic duplicate under FRE 1003, or a document that falls under any exception to the original-document requirement, including those of FRE 1004.

Exhibit 2041: This exhibit lacks authentication, and is inadmissible under FRE 901. Exhibit 2041 purports to be a printout or partial printout of a webpage but there is no evidence establishing that it contains true and correct content. Accordingly, Patent Owner has not provided evidence sufficient to support a finding that Exhibit 2041 “is what [Patent Owner] claims it is.” *See* FRE 901.

Exhibit 2041 is also inadmissible under FRE 401 and 403. Exhibit 2041 is a web article from Galderma US purportedly dated “December 15, 2011.” There is no evidence that Exhibit 2041 is a prior-art publication that was available to the public. Therefore, Exhibit 2041 is inadmissible as not relevant.

Exhibit 2041 is inadmissible as hearsay under FRE 801 and 802. Patent Owner relies on the “December 15, 2011” date in Exhibit 2041 for the truth of the

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