

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
Patent 9,517,219

PATENT OWNER'S OBJECTIONS TO REPLY EVIDENCE

Pursuant to 37 C.F.R. § 42.64, Patent Owner Almirall, LLC ("Almirall") hereby objects to the admissibility of evidence Petitioners Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal") submitted with their Reply to Patent Owner's Response (Paper 28):

Exhibit 1045: Almirall objects to Exhibit 1045 as lacking authentication under FRE 901. Exhibit 1045 appears to be a portion of a printout of a webpage. There is no evidence establishing that it contains true and correct content. Accordingly, Amneal has not provided evidence sufficient to support a finding that Exhibit 1045 "is what [Amneal] claims it is. *See* FRE 901. Almirall further objects to Exhibit 1045 as irrelevant under FRE 401 and 402. If the content is taken as true, the information on the printout relates to 2019. Petitioner has not established that Exhibit 1045 is a prior art publication that was available to the public. Exhibit 1045 has no tendency to make any fact of consequence in determining this action more or less probable than it would be without this exhibit. Therefore, Exhibit 1045 is inadmissible as not relevant.

Exhibit 1046: Almirall objects to Exhibit 1046 as lacking authentication under FRE 901. Exhibit 1046 appears to be a proprietary technical data sheet from Lubrizol. There is no evidence establishing that it contains true and correct content. Accordingly, Amneal has not provided evidence sufficient to support a

finding that Exhibit 1045 “is what [Amneal] claims it is.” *See* FRE 901. Almirall further objects to Exhibit 1046 as inadmissible hearsay under FRE 801 and 802. Amneal relies on Exhibit 1046 for the truth of the matter asserted, but has provided no evidence of the truth of the assertions in Exhibit 1046. To the contrary, the exhibit states on its face that “no representations... of any kind are made as to [the] accuracy” of the information contained therein. Ex. 1046 at 1. Further, Petitioner has not established that Exhibit 1046 is a prior art publication that was available to the public. Exhibit 1046 has no tendency to make any fact of consequence in determining this action more or less probable than it would be without this exhibit. Therefore, Exhibit 1046 is further inadmissible under FRE 401 and 402 as not relevant.

Exhibit 1047: Almirall objects to Exhibit 1047 as irrelevant under FRE 401 and 402. Exhibit 1047 purports to have a publication date of February 2016, and is therefore not a prior art publication, and has no tendency to make any fact of consequence in determining this action more or less probable than it would be without this exhibit.

Exhibit 1048: Almirall objects to Exhibit 1048 as irrelevant under FRE 401 and 402. Exhibit 1048 purports to have a publication date of December 2012, and is therefore not a prior art publication, and has no tendency to make any fact of

consequence in determining this action more or less probable than it would be without this exhibit.

Exhibit 1050: Almirall objects to Exhibit 1050 as irrelevant under FRE 401 and 402 because Amneal did not rely upon or discuss this exhibit in its Reply. The only citation in its Reply to Exhibit 1050 is clearly an error: the pincite is to “¶36”, but Exhibit 1050 has no paragraph numbers (nor is there any way to count the handful of paragraphs in the document to arrive at thirty-six); nor does the content of the document correspond in any way to the content of the paragraph in which it is cited. Paper 28 at 15–16. The only other citation to this exhibit is in the Second Declaration of Dr. Michniak-Kohn. Ex. 1043 ¶ 63. Any use of this exhibit would be improper incorporation by reference under 37 C.F.R. § 42.6(a)(3).

Almirall also objects to Exhibit 1050 as lacking authentication under FRE 901. Exhibit 1050 appears to be a proprietary technical data sheet from Noveon. There is no evidence establishing that it contains true and correct content. Accordingly, Amneal has not provided evidence sufficient to support a finding that Exhibit 1050 “is what [Amneal] claims it is.” *See* FRE 901. Almirall further objects to Exhibit 1046 as inadmissible hearsay under FRE 801 and 802. Amneal relies on Exhibit 1046 for the truth of the matter asserted, but has provided no evidence of the truth of the assertions in Exhibit 1050. To the contrary, the exhibit

states on its face that “no representations... of any kind are made as to [the] accuracy” of the information contained therein. Ex. 1050 at 1. Further, Petitioner has not established that Exhibit 1050 is a prior art publication that was available to the public. Exhibit 1050 has no tendency to make any fact of consequence in determining this action more or less probable than it would be without this exhibit. Therefore, Exhibit 1050 is further inadmissible under FRE 401 and 402 as not relevant.

Exhibit 1052: Almirall objects to Exhibit 1052 as irrelevant under FRE 401 and 402 because Amneal did not substantively discuss this exhibit in its Reply. Any use of this exhibit would be improper incorporation by reference under 37 C.F.R. § 42.6(a)(3). Almirall further objects to Exhibit 1052 as lacking authentication under FRE 901. Exhibit 1052 appears to be a printout of a portion of a spreadsheet titled “3Q2018EXCEL,” and Amneal’s expert Dr. Michniak-Kohn describes it as “the FDA DMF database that [she] downloaded” from a particular weblink. *See* Ex. 1043 ¶ 66 n.6. There is no evidence establishing that it contains true and correct content, nor does the content at the provided web address match that of Exhibit 1052. Accordingly, Amneal has not provided evidence sufficient to support a finding that Exhibit 1052 “is what [Amneal] claims it is.” *See* FRE 901. Almirall further objects to Exhibit 1052 as inadmissible hearsay under FRE 801

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.