

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
Patent No. 9,161,926 B2

**PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE UNDER
37 C.F.R §42.64**

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c), Patent Owner Almirall, LLC (“Almirall”) moves to exclude from evidence, in their entirety, Exhibits 1041, 1042, 1043, 1044, 1045, 1046, 1047, and 1048, which were submitted by Petitioners Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (together, “Amneal”) with its Reply (Paper 29). This motion is timely pursuant to the Scheduling Order dated August 29, 2018 (Paper 11).

II. STATEMENT OF MATERIAL FACTS

In its Reply, Amneal cited Exhibits 1041–1047 in a single footnote as purported evidence of “pay or benefits” Almirall’s expert Dr. Julie Harper received for “promotional activities for ACZONE® Gel 5%.” Paper 29 at 5 n.3. Exhibit 1048 is not cited in Amneal’s Reply. These exhibits all appear to be printouts from webpages of which Dr. Harper has no personal knowledge. Amneal has submitted no evidence or testimony regarding the authenticity of these documents.

Following service of Amneal’s Reply, Almirall timely objected to Exhibits 1041–1048 by filing objections pursuant to 37 C.F.R. § 42.64(b)(1) on March 25, 2019. Paper 32. Amneal did not serve Supplemental Evidence in response to Almirall’s objections to these exhibits.

III. LEGAL STANDARDS

The Federal Rules of Evidence govern the admissibility of evidence and expert testimony in an *inter partes* review. 37 C.F.R. § 42.62(a). Evidence is relevant if: (1) it has any tendency to make a fact more or less probable than it would be without the evidence; and (2) the fact is of consequence in determining the action. Fed. R. Evid. 401. Irrelevant evidence is not admissible. Fed. R. Evid. 402. Moreover, “the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is.” Fed. R. Evid. 901.

IV. ARGUMENT

A. Exhibits 1041, 1042, 1043, 1044, 1045, 1046, and 1047 and Related Argument Should Be Excluded as Unauthenticated and Irrelevant

Exhibits 1041 and 1042 appear to be webpage printouts or partial printouts titled “Dollars for Docs. Exhibits 1043, 1044, 1045, 1046, and 1047 appear to be webpage printouts or partial printouts titled “Open Payments Data.” All of these exhibits purport to show compensation that Dr. Harper, a practicing dermatologist, received from various pharmaceutical companies, including Allergan, in various years. *See, e.g.*, Ex. 1043 at 3 (listing items including “Food and Beverage” or “Consulting Fee” from Abbvie, Inc. and Allergan Inc.). Amneal presented no evidence establishing that the content of these printouts is true and correct. Accordingly, Amneal has not met its burden to provide evidence sufficient to

support a finding that these exhibits are admissible under Federal Rule of Evidence 901.

Nor are these exhibits relevant to whether the challenged claims of U.S. Patent No. 9,161,926 (Ex. 1001) are unpatentable as obvious over the prior art asserted by Amneal. That a leading dermatologist has received lunches and consulting fees from pharmaceutical companies is not surprising, but has no bearing whatsoever on the patentability of the challenged claims under 35 U.S.C. § 103. As these exhibits are not relevant, they and any related argument should be excluded as inadmissible under Federal Rules of Evidence 401 and 402.

B. Exhibit 1048 Should Be Excluded as Unauthenticated and Irrelevant

Exhibit 1048 appears to be a further webpage printout or partial printout titled "Dollars for Docs." It purports to show compensation that various doctors have received related to Aczone from August 2013 to December 2016. Ex. 1048 at 1. Amneal presented no evidence establishing that the content of this printout is true and correct. Accordingly, Amneal has not met its burden to provide evidence sufficient to support a finding that this exhibit is admissible under Federal Rule of Evidence 901.

Nor is this exhibit relevant to whether the challenged claims of U.S. Patent No. 9,161,926 (Ex. 1001) are unpatentable as obvious over the prior art asserted by

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Patent Owner's Motion to Exclude

Amneal. That a leading dermatologist has received lunches and consulting fees from pharmaceutical companies is not surprising, but has no bearing whatsoever on the patentability of the challenged claims under 35 U.S.C. § 103. Amneal did not even bother to cite this exhibit in its Reply. As Exhibit 1048 is not relevant, it should be excluded as inadmissible under Federal Rules of Evidence 401 and 402.

V. CONCLUSION

Given the lack of evidence that these unauthenticated webpage printouts are what they purport to be, and moreover their utter lack of relevance, Almirall requests that Exhibits 1041–1048, and all argument related thereto, be excluded from evidence in their entirety and expunged from the record.

Dated: May 1, 2019

Respectfully submitted,

FENWICK & WEST LLP

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