

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC AND  
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,  
Petitioners,

v.

ALMIRALL, LLC  
Patent Owner.

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Case IPR2018-00608  
Patent No. 9,161,926 B2

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**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 29):

1. Almirall objects to Exhibit 1035 as lacking authentication under FRE 901. Exhibit 1035 purports to be a publication from 2012 but 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 1035 “is what [Amneal] claims it is.” *See* FRE 901. Almirall further objects to Exhibit 1035 as irrelevant under FRE 401 and 402. Exhibit 1035 purports to be a publication from December 2012. There is no evidence that Exhibit 2012 is a prior art publication available to the public before *November 20, 2012*, the earliest date to which U.S. patent No. 9,161,926 claims priority. *See* Ex. 1001 at cover, 1:8–12. Almirall further objects to Exhibit 1035 as inadmissible hearsay under FRE 801 and 802. Amneal failed to examine Dr. Harper, a purported author of this document, regarding Exhibit 1035. *See generally* Ex. 1049 (transcript of March 11, 2019 deposition of Dr. Harper).

2. Almirall objects to Exhibit 1036 as irrelevant under FRE 401 and 402 because Amneal did not rely upon or discuss this exhibit in its Reply. This exhibit

is only cited in the Second Declaration of Dr. Gilmore. Ex. 1034 ¶ 21. Any use of this exhibit would be improper incorporation by reference under 37 C.F.R.

§ 42.6(a)(3).

3. Almirall objects to Exhibit 1037 as irrelevant under FRE 401 and 402 because Amneal did not rely upon or discuss this exhibit in its Reply. This exhibit is only cited in the Second Declaration of Dr. Gilmore. Ex. 1034 ¶ 20. Any use of this exhibit would be improper incorporation by reference under 37 C.F.R.

§ 42.6(a)(3).

4. Almirall objects to Exhibit 1038 as irrelevant under FRE 401 and 402 because Amneal did not rely upon or discuss this exhibit in its Reply. This exhibit is only cited in the Second Declaration of Dr. Gilmore. Ex. 1034 ¶ 20. Any use of this exhibit would be improper incorporation by reference under 37 C.F.R.

§ 42.6(a)(3).

5. Almirall objects to Exhibit 1039 as irrelevant under FRE 401 and 402 because Amneal did not rely upon or discuss this exhibit in its Reply. This exhibit is only cited in the Second Declaration of Dr. Gilmore. Ex. 1034 ¶ 20. Any use of this exhibit would be improper incorporation by reference under 37 C.F.R.

§ 42.6(a)(3).

6. Almirall objects to Exhibit 1040 as irrelevant under FRE 401 and 402 because Amneal did not rely upon or discuss this exhibit in its Reply. This exhibit

is only cited in the Second Declaration of Dr. Gilmore. Ex. 1034 ¶ 20. Any use of this exhibit would be improper incorporation by reference under 37 C.F.R.

§ 42.6(a)(3).

7. Almirall objects to Exhibit 1041 as irrelevant under FRE 401 and 402 because it has no tendency to make any fact of consequence in determining this action more or less probable than it would be without this exhibit. Almirall further objects to Exhibit 1041 as lacking authentication under FRE 901. Exhibit 1041 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, Amneal has not provided evidence sufficient to support a finding that Exhibit 1041 “is what [Amneal] claims it is.” *See* FRE 901. Almirall further objects to Exhibit 1041 as inadmissible hearsay under FRE 801 and 802. Amneal has provided no evidence of the truth of the assertions in Exhibit 1041.

8. Almirall objects to Exhibit 1042 as irrelevant under FRE 401 and 402 because it has no tendency to make any fact of consequence in determining this action more or less probable than it would be without this exhibit. Almirall further objects to Exhibit 1042 as lacking authentication under FRE 901. Exhibit 1042 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, Amneal has not provided evidence sufficient to support a finding that Exhibit 1042 “is what

[Amneal] claims it is.” *See* FRE 901. Almirall further objects to Exhibit 1042 as inadmissible hearsay under FRE 801 and 802. Amneal has provided no evidence of the truth of the assertions in Exhibit 1042.

9. Almirall objects to Exhibit 1043 as irrelevant under FRE 401 and 402 because it has no tendency to make any fact of consequence in determining this action more or less probable than it would be without this exhibit. Almirall further objects to Exhibit 1043 as lacking authentication under FRE 901. Exhibit 1043 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, Amneal has not provided evidence sufficient to support a finding that Exhibit 1043 “is what [Amneal] claims it is.” *See* FRE 901. Almirall further objects to Exhibit 1043 as inadmissible hearsay under FRE 801 and 802. Amneal has provided no evidence of the truth of the assertions in Exhibit 1043.

10. Almirall objects to Exhibit 1044 as irrelevant under FRE 401 and 402 because it has no tendency to make any fact of consequence in determining this action more or less probable than it would be without this exhibit. Almirall further objects to Exhibit 1044 as lacking authentication under FRE 901. Exhibit 1044 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, Amneal has not provided evidence sufficient to support a finding that Exhibit 1044 “is what

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