

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

HOSPIRA, INC.,
Patent Owner.

Case No. IPR2016-01578
Patent 8,338,470

**PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64 TO
PETITIONER'S SUPPLEMENTAL EVIDENCE SUBMITTED WITH
PETITIONER'S RESPONSE TO PATENT OWNER OBJECTIONS**

Patent Owner's Objections to Supplemental Evidence for IPR2016-01578

Patent Owner, Hospira, Inc., respectfully submits the following objections to exhibits filed by Petitioner on March 8, 2017, in conjunction with its Response to Patent Owner Objections ("Response to Objections"). These objections are made within five business days of the date upon which the evidence was served.

The following chart lists Patent Owner's objections to the admissibility of the supplemental evidence served on March 8, 2017, and the basis for those objections:

Objected to Exhibit	Basis for Objection
Exhibit 1064, ¶ 4	FRE 702: Dr. Yaman is not qualified to testify as an expert witness under FRE 702 with respect to issues concerning the technology involved in this IPR proceeding, including stereochemistry and dexmedetomidine. Moreover, Dr. Yaman's opinion is not based on sufficient facts or data. Therefore, Dr. Yaman's expert declaration is inadmissible expert testimony under FRE 702.
Exhibit 1064, ¶ 6	FRE 901: Dr. Yaman testifies to the authenticity and publication date of Exhibit 1066. However, Dr.

Patent Owner's Objections to Supplemental Evidence for IPR2016-01578

	<p>Yaman has presented no evidence that he has personal knowledge regarding the date upon which the cited reference was made publicly available, or whether the document is a true and correct copy of the reference published on the specified date.</p>
<p>Exhibit 1064, ¶ 7</p>	<p>FRE 602/901: Dr. Yaman incorporates by reference Mr. Tully's testimony regarding the authenticity and publication dates of several exhibits. However, Dr. Yaman has presented no evidence that he has personal knowledge regarding the dates upon which the cited references were made publicly available, or whether the documents are true and correct copies of references published on the specified dates.</p>
<p>Exhibit 1065</p>	<p>37 CFR §11.307: Mr. Tully is counsel of record for Petitioner in this proceeding. In submitting a declaration testifying to the authenticity and publication dates of exhibits submitted by the Petitioner, Mr. Tully has made himself a witness in this proceeding as well. This conduct is in violation</p>

Patent Owner's Objections to Supplemental Evidence for IPR2016-01578

	<p>of 37 CFR §11.307, which precludes a practitioner from acting as both an advocate and necessary witness in the proceeding.</p>
<p>Exhibit 1065, ¶¶ 5-8, 10-22, 24-29, 31</p>	<p>FRE 602/901: Mr. Tully testifies to the authenticity and publication dates of several exhibits. Mr. Tully has presented no evidence that he has personal knowledge regarding the dates upon which the cited references were made publicly available, or whether the documents are true and correct copies of references published on the specified dates.</p>
<p>Exhibit 1065, ¶ 9</p>	<p>37 CFR §42.65(a): The cited paragraph includes testimony regarding United States patent law and patent examination practice, which is inadmissible under 37 CFR §42.65(a).</p>
<p>Exhibit 1066</p>	<p>FRE 901: This exhibit has not been authenticated. Petitioner has not provided admissible evidence regarding the origin of the document or whether the document is a true and correct copy.</p>

	<p>FRE 802: This exhibit cites to and incorporates hearsay. Because no hearsay exception applies, the exhibit is inadmissible in this proceeding.</p> <p>35 U.S.C. § 311(b): Petitioner has not provided evidence that the exhibit is a prior art publication because Petitioner has not authenticated the exhibit or provided admissible evidence regarding the date upon which it became publicly available.</p> <p>FRE 401-403: At least because this exhibit has not been authenticated and proven to have been publicly available prior to January 4, 2012, the exhibit is irrelevant to this proceeding and therefore inadmissible, and/or its probative value, if any, is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, and/or wasting time.</p>
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