

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC,  
Petitioner,

v.

HOSPIRA, INC.,  
Patent Owner.

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

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**PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64 TO  
PETITIONER'S EVIDENCE SUBMITTED WITH  
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,338,470**

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

Patent Owner, Hospira, Inc., respectfully submits the following objections to exhibits filed by Petitioner on August 10, 2016, in conjunction with its Petition for *Inter Partes* Review of U.S. Patent No. 8,338,470 ("the Petition"). These objections are made within ten business days from the institution of the trial on February 9, 2017 (*see* Paper No. 11).

The following chart lists Patent Owner's objections to the admissibility of certain documents (identified below) that accompany the Petition, and the basis for those objections:

Objected to Exhibit	Basis for Objection
<b>Exhibit 1015</b>	<p><b>FRE 901:</b> This exhibit has not been authenticated. Petitioner has not provided evidence regarding the origin of the document or whether the document is a true and correct copy.</p> <p><b>FRE 802:</b> This evidence cites to and incorporates hearsay. Because no hearsay exception applies, the identified exhibit is inadmissible in this proceeding.</p> <p><b>35 U.S.C. § 311(b):</b> Petitioner has not provided evidence that the exhibit is a prior art publication</p>

	<p>because Petitioner has not authenticated the exhibit or provided admissible evidence regarding the date upon which it became publicly available.</p> <p><b>FRE 401-403:</b> This exhibit is irrelevant because it has not been authenticated and proven as a prior art reference. Moreover, the exhibit and the statements therein are irrelevant and therefore inadmissible, and/or their 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> <p>For example, Exhibit 1015 describes the benefits of centralized preparation of drugs in “ready to use syringes” to reduce contamination in pediatric and neonatal intensive care units. Centralized preparation of drugs in syringes is irrelevant to drug compositions that are manufactured in “ready to use” form. Such disclosure, therefore, is irrelevant and of little probative value in light of the confusion</p>
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	that would be introduced by this exhibit.
<b>Exhibit 1016</b>	<p><b>FRE 901:</b> This exhibit has not been authenticated. Petitioner has not provided evidence regarding the origin of the document or whether the document is a true and correct copy.</p> <p><b>FRE 802:</b> This evidence cites to and incorporates hearsay. Because no hearsay exception applies, the exhibit is inadmissible in this proceeding.</p> <p><b>35 U.S.C. § 311(b):</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><b>FRE 401-403:</b> This exhibit is irrelevant because it has not been authenticated and proven as a prior art reference. Moreover, the exhibit and the statements therein are irrelevant and therefore inadmissible, and/or their probative value, if any, is substantially</p>

	<p>outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, and/or wasting time.</p> <p>For example, Exhibit 1016 discusses a variety of strategies for reducing medication error that are irrelevant to ready to use compositions, focusing primarily on centralized preparation of drug dilutions in syringes. Such disclosure is, therefore, irrelevant and of little probative value in light of the confusion and waste of time that would be introduced by this exhibit.</p>
<b>Exhibit 1017</b>	<p><b>FRE 901:</b> This exhibit has not been authenticated. Petitioner has not provided evidence regarding the origin of the document or whether the document is a true and correct copy.</p> <p><b>FRE 802:</b> This evidence cites to and incorporates hearsay. Because no hearsay exception applies, the exhibit is inadmissible in this proceeding.</p>

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