

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.
Petitioner

v.

RB PHARMACEUTICALS LIMITED
Patent Owner

Case No. IPR2014-00325
Patent 8,475,832

**PETITIONER'S OBJECTIONS UNDER 37 CFR § 42.64(b)(1)
TO EVIDENCE SUBMITTED IN CONNECTION WITH
PATENT OWNER RESPONSE**

Pursuant to 37 CFR § 42.64(b)(1), Petitioner BioDelivery Sciences International, Inc. (“BDSI”), objects to evidence submitted in connection with Patent Owner RB Pharmaceutical Limited’s (“Patent Owner”) Patent Owner Response filed on November 7, 2014 as follows:

Exhibit	Objection(s)
Ex. 2003	<ol style="list-style-type: none"> 1. Failure to comply with FRE 702. Dr. Johnston does not meet the definition of a person of ordinary skill in the art that he himself sets out in his declaration. 2. Failure to comply with FRE 702. Dr. Johnston’s declaration improperly relies on irrelevant or incomplete documents, unreliable evidence, and hearsay. See, e.g., objections to Exs. 2005, 2008, 2024, 2030, 2031, 2035, 2039, 2040, and 2051 below.
Ex. 2005	<ol style="list-style-type: none"> 3. Lack of relevance; Exhibit 2005 does not support the proposition for which it is cited. See Ex. 2003, Johnston Decl., at ¶42.
Ex. 2008	<ol style="list-style-type: none"> 1. Hearsay without exception under FRE 801-803. See also 77 Fed. Reg. 486121, 48645 (Aug. 14, 2012) (“United States patents present hearsay issues when offered to prove the truth of the matters they disclose.”)

Exhibit	Objection(s)
Ex. 2024	<ol style="list-style-type: none"> 1. Hearsay without exception under FRE 801-803. 2. Lack of authentication under FRE 901-902. 3. Lack of relevance. Exhibit 2024 is cited in the “Background Regarding Buprenorphine Dosages and Pharmacokinetics” section of the Johnston Declaration. However, on its face, Exhibit 2024 is dated 2011, after the asserted priority date of the ‘832 patent.
Ex. 2030	<ol style="list-style-type: none"> 1. Lack of relevance. Exhibit 2030 is cited in the Johnston Declaration for the proposition “[a]s of 2009, the POSITA would be informed” Ex. 2003, Johnston Decl., at ¶62. On its face, Exhibit 2030 purports to have been updated in 2013. <i>See</i> Ex. 2030 at 1. 2. Hearsay without exception under FRE 801-803. 3. Lack of authentication under FRE 901-902.

Exhibit	Objection(s)
Ex. 2031	<ol style="list-style-type: none"> 1. Lack of relevance; Exhibit 2031 does not support the proposition for which it is cited. With respect to Exhibit 2031, the Johnston Declaration states “as of 2009 (indeed, long before then), peroral administration of buprenorphine would have been regarded by the person of ordinary skill in the art as therapeutically inappropriate and unacceptable.” <i>See</i> Ex. 2003, Johnston Decl., at ¶63. On its face, Exhibit 2031 is dated 2013. 2. Hearsay without exception under FRE 801-803. 3. Lack of authentication under FRE 901-902.
Ex. 2035	<ol style="list-style-type: none"> 1. Hearsay without exception under FRE 801-803. 2. Lack of relevance under FRE 401-403. Ex. 2035 does not support the proposition for which it is cited in the Patent Owner Response. And on its face, Ex. 2035 is dated 2011.
Ex. 2039	<ol style="list-style-type: none"> 1. Hearsay without exception under FRE 801-803. 2. Lack of authentication under FRE 901-902.
Ex. 2040	<ol style="list-style-type: none"> 1. This document is heavily redacted and so is not the original document. <i>See</i> FRE 1001-1002. 2. Hearsay without exception under FRE 801-803. 3. Lack of authentication under FRE 901-902.

Exhibit	Objection(s)
Ex. 2042	1. Lack of relevance under FRE 401-403.
Ex. 2043	2. Lack of relevance under FRE 401-403. 3. Patent Owner mischaracterizes the contents of this document. <i>See, e.g.,</i> Patent Owner Response, at 50.
Ex. 2044	1. This document is incomplete.
Ex. 2045	2. Lack of relevance; Exhibit 2045 does not support the proposition for which it is cited. <i>See, e.g.,</i> Patent Owner Response, at 55 and 56.
Ex. 2046	1. Lack of relevance; Exhibit 2045 does not support the proposition for which it is cited. <i>See, e.g.,</i> Patent Owner Response, at 55-56.
Ex. 2047	1. Lack of relevance; Exhibit 2031 does not support the proposition for which it is cited. <i>See, e.g.,</i> Patent Owner Response, 55-56. 2. Lack of authentication under FRE 901-902. 3. Ex. 2047 contains highlighting, which is evidently not part of the original document, and accordingly this exhibit is not the original evidence per FRE 1001-1002.

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