

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC
Petitioner

v.

CIPLA LTD.
Patent Owner

Patent No. 8,168,620
Issue Date: May 1, 2012
Title: COMBINATION OF AZELASTINE AND STEROIDS

Inter Partes Review No. IPR2017-00807

**PETITIONER'S OBJECTIONS TO EVIDENCE PURSUANT TO
37 C.F.R. § 42.64(b)(1)**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Argentum Pharmaceuticals LLC (“Petitioner”) submits the following objections to the exhibit identified by Exhibit Number below, which were served by Patent Owner, Cipla Ltd. (“Patent Owner”), in conjunction with Patent Owner’s Preliminary Response (paper 7). These objections are timely, having been served within ten business days of the institution of trial (Paper 11). 37 C.F.R. § 42.64(b)(1).

Exhibit No.	Federal Rule(s) of Evidence	Objection
1002	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted (e.g., Ex. 2001 ¶¶27-29; Ex. 2005 ¶¶79, 112-113; Ex. 2007 ¶¶25, 31, 37, 42-47), and Petitioner has not had the opportunity to subject the declarant(s) to cross examination
1008	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted (e.g., Ex. 2001 ¶112) , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination
1034	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted (e.g., Ex. 2001 ¶82) , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination
1035	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted (e.g., Ex. 2001 ¶¶45, 49) , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination

1036	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted (e.g., Ex. 2001 ¶¶45, 49) , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination
1039	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted (e.g., Ex. 2001 ¶¶45, 49) , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination
1040	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted (e.g., Ex. 2001 ¶82) , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination
1045	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted (e.g., Ex. 2001 ¶108) , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination

2001 ¶¶15-17, 19, 27-29, 45, 46, 49, 61-64, 71, 73, 77, 82, 88-92, 94, 97, 99- 102, 105- 106, 108, 110, 112, 116, 118- 119, 121- 126, 128- 129, 131- 132, 135- 136, 138- 140, 142- 152	402/403; 802	<p>402/403: Petitioner objects to Patent Owner’s evidence regarding the alleged success, copying, and other alleged secondary considerations stemming from the Duonase product marketed and sold in India as being irrelevant, and having prejudicial value that outweighs any probative value.</p> <p>802: Inadmissible hearsay, as Dr. Carr relies on various cited documents and/or other “out-of-court” statements for the truth of the matter asserted therein; Petitioner was not a party to and did not participate in the trial referenced at paragraph 13 of Dr. Carr’s declaration, and therefore has not had any opportunity to cross examine any of the witnesses or declarants that provided evidence in that case.</p>
2003 ¶¶2, 11- 20, 22-27	802	Inadmissible hearsay, as Dr. D’Addio relies on various cited documents and/or other “out-of-court” statements for the truth of the matter asserted therein.

<p>2005 ¶¶3-4, 16-20, 22-35, 37-67, 69-71, 73-91, 93-101, 103-106, 112, 116; TABS 1-12 (pp. 54-70)</p>	<p>402/403; 702/703; 802</p>	<p>402/403: Petitioner objects to Patent Owner’s evidence regarding the alleged success, copying, and other alleged secondary considerations stemming from the Duonase product marketed and sold in India as being irrelevant, and having prejudicial value that outweighs any probative value.</p> <p>702/703/403: Inadequate showing of witness’ qualifications to opine on topics discussed in declaration; in addition, while expert testimony can rely on otherwise inadmissible evidence, Petitioner objects to the extent that it has not been provided sufficient access to such evidence, or discovery of other evidence in Patent Owner’s possession or control that may undercut or contradict the evidence relied upon by this witness, as Petitioner was not a party to the prior litigation involving Dymista; Petitioner further objects to Dr. Jarosz’s characterization of the cited exhibits being of the type normally relied upon by experts in this field.</p> <p>802: Inadmissible hearsay, as Dr. Jarosz relies on various cited documents and/or other “out-of-court” statements for the truth of the matter asserted therein; Petitioner was not a party to and did not participate in the trial involving Dymista, and therefore has not had any opportunity to cross examine any of the witnesses or declarants that provided evidence in that case</p>
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2007 ¶¶15, 17, 25, 31, 33, 36-37, 40-50, 55-56, 64-83	402/403; 702/703; 802	<p>402/403: Petitioner objects to Patent Owner’s evidence regarding the alleged success, copying, and other alleged secondary considerations stemming from the Duonase product marketed and sold in India as being irrelevant, and having prejudicial value that outweighs any probative value.</p> <p>702/703/403: Petitioner objects to Dr. Smyth’s testimony at ¶¶64-74 to the effect that Dymista and Duonase are embodiments of claims 4, 29, and 42-44 (and therefore the claims from which they depend), and regarding the alleged “imitator products,” because Petitioner was not a party to the referenced litigation, has not been provided sufficient access to such evidence or to cross examine the author(s) of Ex. 2028, or been afforded discovery of other evidence in Patent Owner’s possession or control that may undercut or contradict the evidence relied upon by this witness.</p> <p>802: Inadmissible hearsay, as Dr. Smyth relies on various cited documents and/or other “out-of-court” statements for the truth of the matter asserted therein; Petitioner was not a party to and did not participate in the trial referenced at paragraph 11 of Dr. Smyth’s declaration, and therefore has not had any opportunity to cross examine any of the witnesses or declarants that provided evidence in that case.</p>
2009	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination
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2017	802	Inadmissible hearsay, as the document appears to be relied upon by Patent Owner for the truth of the matter asserted , and Petitioner has not had the opportunity to subject the declarant(s) to cross examination
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These objections provide notice to Patent Owner that Petitioner may move under 37 C.F.R. § 42.64(c) to exclude these Exhibits or the cited portions thereof. Petitioner is available to meet-and-confer with Patent Owner to clarify/discuss any of the above objections should Patent Owner believe such discussions would be helpful to resolve Petitioner's objections.

Dated: September 5, 2017

By: /Michael R. Houston/

Reg. No. 58,486

Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing
PETITIONER'S OBJECTIONS TO EVIDENCE PURSUANT TO
37 C.F.R. § 42.64(b)(1) was served on September 5, 2017, on Counsel for Patent
Owner via electronic mail to the following:

dvarughe-PTAB@skgf.com
dsterlin-PTAB@skgf.com
alarock-PTAB@skgf.com
ueverett-PTAB@skgf.com

Dated: September 5, 2017

By: /Michael R. Houston/

Reg. No. 58,486

Counsel for Petitioner