

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.  
Petitioner,

v.

HORIZON THERAPEUTICS, INC.  
Patent Owner

Case IPR2017-01159  
Patent 9,254,278

**PETITIONERS' OBJECTIONS TO EVIDENCE  
PURSUANT TO 37 C.F.R. § 42.64**

Petitioners Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin”) hereby object pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence (“FRE”) to the admissibility of certain exhibits served by Patent Owner Horizon Therapeutics, Inc. on July 24, 2017 in connection with its Preliminary Response to Lupin’s Petition for *Inter Partes* Review of U.S. Patent No. 9,254,278 (“the ’278 patent”). The exhibits objected to, and grounds for Lupin’s objections, are listed below. Lupin also objects to Patent Owner’s reliance on or citations to any objected evidence in its papers.

**I. IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS FOR OBJECTIONS**

**A. Exhibit 2001 (IPR2016-00829 Enns Declaration)**

Lupin objects to Exhibit 2001 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2001 is an expert declaration submitted by Patent Owner in a different proceeding on a different patent, *i.e.*, IPR2016-00829. Therefore, Exhibit 2001 should be excluded under FRE 402 and 403. Lupin further objects to Exhibit 2001 under FRE 802 because it is inadmissible hearsay, not within a hearsay exception.

**B. Exhibit 2006 (IPR2017-01159 Enns Declaration)**

Lupin objects to Exhibit 2006, the declaration of Dr. Gregory M. Enns, under FRE 402 to the extent that it includes or relies on irrelevant or inadmissible information and under FRE 403 to the extent that it includes or relies on information that probative value of which is substantially outweighed by the danger of unfair prejudice, wasting time, or needlessly presenting cumulative evidence as set forth herein. Lupin further objects to Exhibit 2006 under FRE 901 on the basis that it cites or relies on exhibits that have not been properly authenticated or lack foundation, as set forth herein.

**C. Exhibit 2012 ('157 Publication)**

Lupin objects to Exhibit 2012 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2012 was published in 2012 and, therefore, bears no relevance to what the person of ordinary skill in the art would have known by Sept. 30, 2011, the priority date used for the purposes of this proceeding. Therefore, Exhibit 2012 should be excluded under FRE 402 and 403. Lupin further objects to Exhibit 2012 under FRE 802 on the basis that it is inadmissible hearsay, not within a hearsay exception.

**D. Exhibit 2019 (Haberle)**

Lupin objects to Exhibit 2019 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2019 is dated after Sept. 30, 2011, and therefore bears no relevance to what the person of ordinary skill in the art would have known by the priority date used for the purposes of this proceeding. Therefore, Exhibit 2019 should be excluded under FRE 402 and 403. Lupin further objects to Exhibit 2019 under FRE 802 on the basis that it is inadmissible hearsay, not within a hearsay exception.

**E. Exhibit 2026 (ABMGG Webpage regarding Specialties of Genetics)**

Lupin objects to Exhibit 2026 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2026 is dated after Sept. 30, 2011, and therefore bears no relevance to what the person of ordinary skill in the art would have known by the priority date used for the purposes of this proceeding. Therefore, Exhibit 2026 should be excluded under FRE 402 and 403. Lupin further objects to Exhibit 2026 under FRE 802 on the basis that it is inadmissible hearsay, not within a hearsay exception. Lupin also objects to Exhibit 2026 under

FRE 901 on the basis that it has not been properly authenticated and lacks foundation.

**F. Exhibit 2027 (About Us Webpage for Urea Cycle Disorders Consortium)**

Lupin objects to Exhibit 2027 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2027 does not have a discernible publication date and Patent Owner has not established that it is prior art. Absent such a showing, it bears no relevance to what the person of ordinary skill in the art would have known by the priority date used for the purposes of this proceeding. Therefore, Exhibit 2027 should be excluded under FRE 402 and 403.

Lupin further objects to Exhibit 2027 under FRE 802 on the basis that it is inadmissible hearsay, not within a hearsay exception. Lupin also objects to Exhibit 2027 under FRE 901 on the basis that it has not been properly authenticated and lacks foundation.

**G. Exhibit 2029 (Enns Article on Hyperammonemia)**

Lupin objects to Exhibit 2029 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2029 is dated after September 30, 2011, and therefore bears no relevance to what the person of ordinary skill in

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