

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner.

Case IPR2017-01767
Patent 9,254,278

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

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Pursuant to 37 C.F.R. §42.64(b)(1), Petitioner Par Pharmaceutical, Inc. (“Petitioner”) objects as follows to the admissibility of supplemental evidence submitted by Patent Owner Horizon Therapeutics, LLC (“Patent Owner”) on May 31, 2018. Petitioner maintains each of its objections to Exhibits 2002-2046 as stated in Petitioner’s Objections Under 37 C.F.R. § 42.64 to Evidence Submitted by Patent Owner, dated May 16, 2018 (Paper No. 24).

In this paper, a reference to “FRE” means the Federal Rules of Evidence, a reference to “CFR” means the Code of Federal Regulations, and “’278 patent” means U.S. Patent No. 9,254,278. All objections under FRE 802 (hearsay) apply to the extent Patent Owner relies on the exhibits identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are as listed in Patent Owner’s Updated Exhibit List, dated May 31, 2018 and are used for identification purposes only. The use of the description does not indicate that Petitioner agrees with the descriptions or characterizations of the documents.

Exhibit	Description	Objection
2047	<i>RESERVED for Alexander Broomfield & Stephanie Grunewald, “How to use Serum Ammonia,” Archives of Disease in Childhood—Education and Practice 97:72–77 (2012), with reference list included. (“Broomfield with references”).</i>	A, B, C, E, K, L, N, O
2048	<i>RESERVED for Guoyao Wu, “Amino Acids: Metabolism, Functions, and Nutrition,” Amino Acids</i>	A, B, C, E, K, L, M, N,

IPR2017-01767
Patent No. 9,254,278
Par's Objections to Evidence

	37:1–17 (2009), print version. (“Wu Print”).	O
2049	<i>RESERVED</i> for Alexander Broomfield & Stephanie Grunewald, “How to use Serum Ammonia,” <i>Archives of Disease in Childhood—Education and Practice</i> 97:72–77 (2012), print version. (“Broomfield Print”).	A, B, C, E, K, L, N, O
2050	<i>RESERVED</i> for Gregory M. Enns, “Nitrogen Sparing Therapy Revisited 2009,” <i>Molecular Genetics and Metabolism</i> 100:S65–S71 (2010), print version. (“Enns 2010 Print”).	A, B, C, E, K, L, N, O
2051	<i>RESERVED</i> for Johannes Häberle, “Clinical Practice: The Management of Hyperammonemia,” <i>Eur. J. of Pediatrics</i> 170:21–34 (2011), print version. (“Häberle Clinical Print”).	A, B, C, E, K, L, N, O
2052	<i>RESERVED</i> for Marshall L. Summar, <i>et al.</i> , “Diagnosis, Symptoms, Frequency and Mortality of 260 Patients with Urea Cycle Disorders from a 21-Year, Multicentre Study of Acute Hyperammonaemic Episodes,” <i>Acta Paediatrica</i> 97:1420–25 (2008), print version. (“Summar 2008 Print”).	A, B, C, E, K, L, N, O
2053	<i>RESERVED</i> for Gregory M. Enns, “Neurologic Damage and Neurocognitive Dysfunction in Urea Cycle Disorders,” <i>Seminars in Pediatric Neurology</i> , 15:132-139 (2008), print version. (“Enns 2008 Print”).	A, B, C, E, K, L, N, O
2054	<i>RESERVED</i> for Declaration of Ann K. Kotze In Response to Petitioner’s Objections to Evidence.	A, B, K, L, N
2055	<i>RESERVED</i> for Declaration of Dr. Gregory Enns In Response to Petitioner’s Objections to Evidence.	A, B, K, L, N
2056	<i>RESERVED</i> for Marshall L. Summar, <i>et al.</i> , “The Incidence of Urea Cycle Disorders,” <i>Molecular Genetics and Metabolism</i> , 110:179–180 (2013), print version. (“Summar 2013 Print”).	A, B, C, E, K, L, N, O
2057	<i>RESERVED</i> for Saul W. Brusilow & Arthur L. Horwich, “Urea Cycle Enzymes,” in <i>The Metabolic and Molecular Bases of Inherited Disease</i> , ch. 85, 1909-1963 (Charles R. Scriver <i>et al.</i> , eds., 8 th ed. 2001). (“Brusilow Print”).	A, B, C, E, K, L, M, N, O


Objection Key:

- A: FRE 802 (hearsay).
- B: FRE 901 (lacking authentication).
- C: FRE 402 (relevance) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '278 patent or the prior art status is not clear.
- D: FRE 402 (relevance) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods.
- E: FRE 403 (confusing, waste of time) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '278 patent or the prior art status is not clear.
- F: FRE 403 (confusing, waste of time) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods.
- G: FRE 106 (completeness) the document is incomplete and includes only a select portion of a larger document that in fairness should be considered along with this document.
- H: FRE 1001-1003 (best evidence).
- I: FRE 403, 901 (improper compilation).
- J: FRE 403 (cumulative).
- K: FRE 402 (relevance) the document is not relevant to any issue in this IPR proceeding.
- L: FRE 403 (confusing, waste of time) the document is not relevant to any issue in this IPR proceeding.
- M: Exhibit not cited in Patent Owner's Response.
- N: FRE 602 (lack of personal knowledge).

IPR2017-01767
Patent No. 9,254,278
Par's Objections to Evidence

- O: FRE 702/703 to the extent that the patent owner seeks to rely on statements made in an exhibit as improper expert opinion, the exhibit is objected to on the grounds that it: (i) is not based on sufficient facts or data; and/or (ii) is not the product of reliable principles and methods; and/or (iii) is unreliable because the exhibit is not of a type reasonably relied upon by experts in the field.
- P: FRE 1006 (improper summary).

Dated: June 7, 2018


David H. Silverstein (Reg. No. 61,948)
AXINN, VELTROP & HARKRIDER LLP
114 West 47th Street, 22nd Floor
New York, NY 10036
(212) 261-5651

Attorney for Petitioner
Par Pharmaceutical, Inc.

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