

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HYPERION THERAPEUTICS, INC.,
Patent Owner.

Case IPR2015-01117
Patent 8,642,012

**PETITIONER'S OBJECTIONS UNDER 37 C.F.R. § 42.62
TO EVIDENCE SUBMITTED BY PATENT OWNER**

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IPR2015-01117
Patent No. 8,642,012
Par's Objections to Evidence

Pursuant to 37 C.F.R. §42.64(b)(1), Petitioner Par Pharmaceutical, Inc. objects as follows to the admissibility of evidence submitted by the Patent Owner on March 28, 2016.

In this paper, a reference to "FRE" means the Federal Rules of Evidence, a reference to "CFR" means the Code of Federal Regulations, and "'012 patent" means U.S. Patent No. 8,642,012. 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 Patent Owner's exhibit list 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
2012	Transcript of Deposition of Dr. Neal Sondheimer, March 10-11, 2016	A, G, H, K, L ¹
2013	Gerard Berry & Robert Steiner, "Long-term management of patients with urea cycle disorders," J. Ped., 138(1):S56-61 (2001)	A, B, K, L, N, O

¹ Par also maintains each of its objections as stated in the March 10-11, 2016 Deposition of Dr. Neal Sondheimer.

IPR2015-01117
Patent No. 8,642,012
Par's Objections to Evidence

2014	Summar et al., "Unmasked Adult-Onset Urea Cycle Disorders in the Critical Care Setting," Crit. Care Clin., S1-S8 (2005)	A, B, K, L, N, O
2015	Geraghty, M.T. and Brusilow, S.W., "Disorders of the Urea Cycle," in Liver Disease in Children, 827-842 (2001)	A, B, G, K, L, N, O
2016	Endo, F. et al., "Clinical Manifestations of Inborn Errors of the Urea Cycle and Related Metabolic Disorders During Childhood," J. Nutrition, 134, 1605S-1069S (2004)	A, B, K, L, N, O
2017	Maestri et al., "Long-term survival of patients with argininosuccinate synthetase deficiency," J. Ped., 929-35 (1995)	A, B, K, L, N, O
2018	Lichter-Konecki et al., "Ammonia control in children with urea cycle disorders (UCDs): Phase 2 comparison of sodium phenylbutyrate and glycerol phenylbutyrate," Mol. Gen. & Metab., 103:323-29 (2011)	A, B, C, D, E, F, K, L, N, O
2020	Singh et al., "Nutritional Management of Urea Cycle Disorders," in Presentation and Management of Urea Cycle Disorders Outside the Newborn Period, Critical Care Clinics, 21:S27-35 (2005)	A, B, K, L, N, O
2023	The Urea Cycle Disorders Conference Group, Consensus Statement from a Conference for the Management of Patients with Urea Cycle Disorders, J. Ped. (Supplement) S1-S5 (2001)	A, B, G, K, L, N, O
2025	BUPHENYL® Prescribing Information (2003)	A, B, K, L, N, O
2026	James et al., "The Conjugation of phenylacetic acid in man, subhuman primates and some non-primate species," Proc. R. Soc. Lond., 182, 25-35 (1972)	A, B, K, L, N, O

IPR2015-01117
Patent No. 8,642,012
Par's Objections to Evidence

2027	Ambrose, Power & Sherwin, "Further Studies on the Detoxication of Phenylacetic Acid," J. Biol. Chem., 101, 669-675 (1933)	A, B, K, L, N, O
2028	Horizon Therapeutics, Inc. v. Par Pharma., Inc., 14-cv-384 (E.D. Tex.), Joint Claim Construction Charts, D.I. 80	A, K, L, 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 '012 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 '012 patent or the prior art status is not clear.

IPR2015-01117
Patent No. 8,642,012
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- 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 the IPR proceeding.
- L: FRE 403 (confusing, waste of time) the document is not relevant to any issue in the IPR proceeding.
- M: No exhibit filed.
- N: FRE 602 (lack of personal knowledge).
- 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

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