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On behalf of **Dr. Falk Pharma GMBH**
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,

Petitioner

v.

ELLODI PHARMACEUTICALS, L.P.,

Patent Owner

Case No. IPR2025-00052
Patent No. 10,632,069

PETITIONER'S OBJECTIONS TO ADMISSIBILITY OF PATENT OWNER'S EVIDENCE

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner, Dr. Falk Pharma GmbH ("Dr. Falk") hereby timely files its objections to the admissibility of evidence submitted with the Patent Owner Response filed by Ellodi Pharmaceuticals, L.P. ("Ellodi") on September 9, 2025.

Exhibit Number and Description	Objections
EX2006 - Miehkle, Gut 0:1-10 (2015)	**Relevance (FRE 401, 403):** The date markings on this document are after the asserted priority date of Ellodi's patent. Ellodi's reliance on this document is misleading because the document does not represent the knowledge of a person of ordinary skill in the art at the time of Ellodi's alleged invention. **Hearsay (FRE 802):** The exhibit includes out-of-court statements offered for the truth of the matter asserted.
EX2007 - Declaration of M. C. Davies	**Relevance, Misleading (FRE 106, 401, 402, 403):** ¶¶ 48, 89, 92, 103, 108, 116, 139-141 are misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and do not represent the knowledge of a person of ordinary skill in the art at the time of Ellodi's alleged invention. **Improper Testimony by Expert Witness (FRE 702):** ¶¶ 48, 89, 92, 103, 108, 116, 139-141 are not based on sufficient facts and data, and do not reliably apply facts and data using scientific principles.

Exhibit Number and Description	Objections
EX2010 – EoE FLUTE Clinical Trials Study, Apr. 26, 2023	**Relevance (FRE 401, 403):** The date markings on this document are after the asserted priority date of Ellodi's patent. Ellodi's reliance on this document is misleading because the document does not represent the knowledge of a person of ordinary skill in the art at the time of Ellodi's alleged invention. **Hearsay (FRE 802):** The exhibit includes out-of-court statements offered for the truth of the matter asserted.
EX2016 Hahm, Ch. 9 Orally Disintegrating Tablets and Related Tablet Formulations	**Relevance (FRE 401, 403):** The date markings on this document are absent. Ellodi's reliance on this document is misleading because the document does not represent the knowledge of a person of ordinary skill in the art at the time of Ellodi's alleged invention. **Hearsay (FRE 802):** The exhibit includes out-of-court statements offered for the truth of the matter asserted.
EX2022 - Orange Book: N213976 (Eohilia™)	**Relevance (FRE 401, 403):** The date markings on this document are after the asserted priority date of Ellodi's patent. Ellodi's reliance on this document is misleading because the document does not represent the knowledge of a person of ordinary skill in the art at the time of Ellodi's alleged invention. **Hearsay (FRE 802):** The exhibit includes out-of-court statements offered for the truth of the matter asserted.

Exhibit Number and Description	Objections
EX2028 - U.S. Patent 9,867,780	**Relevance (FRE 401, 403):** The priority date for this patent is after the asserted priority date of Ellodi's patent. Ellodi's reliance on this patent is misleading because the patent does not represent the knowledge of a person of ordinary skill in the art at the time of Ellodi's alleged invention. **Hearsay (FRE 802):** The exhibit includes out-of-court statements offered for the truth of the matter asserted.
EX2029 - Geoffrey Lee Report	**Relevance, Misleading (FRE 106, 401, 402, 403):** Ellodi's reliance on this document is misleading, incomplete, and irrelevant because it lacks support for the contentions for which it is cited and does not represent the knowledge of a person of ordinary skill in the art at the time of Ellodi's alleged invention. **Improper Testimony by Expert Witness (FRE 702):** The content of this document is not based on sufficient facts and data and does not reliably apply facts and data using scientific principles.
EX2030 – Jorveza® label	**Relevance (FRE 401, 403):** The date markings on this document are after the asserted priority date of Ellodi's patent. Ellodi's reliance on this document is misleading because the document does not represent the knowledge of a person of ordinary skill in the art at the time of Ellodi's alleged invention. **Hearsay (FRE 802):** The exhibit includes out-of-court statements offered for the truth of the matter asserted.

Respectfully submitted,

Dated: September 16, 2025

By: */Nathanael R. Luman/*
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Attorney for Petitioner Dr. Falk Pharma GmbH

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this **PETITIONER'S OBJECTIONS TO ADMISSIBILITY OF PATENT OWNER'S EVIDENCE** was served by email to counsel for Ellodi at addresses below:

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