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

PATENT OWNER'S OBJECTIONS PURSUANT TO 37 C.F.R. § 42.64(b)(1)

Pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence ("FRE"), Patent Owner objects to the following documents submitted by Petitioner Dr. Falk Pharma GMBH.

Nothing in this paper should be construed as an admission that any rights of Patent Owner would have been waived or forfeited had the paper or any objection herein not been filed, or that 37 C.F.R. § 42.64(b) applies to any of the objections herein if § 42.64(b) would not otherwise apply. The objections herein are premised upon § 42.64 potentially being determined to apply to the document in question and are submitted solely to preserve the rights of Patent Owner should § 42.64(b) be determined to apply.

I. Exhibit 1003

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it is not prior art, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

II. Exhibit 1004

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it is not prior art, it does not form a basis of the instituted

grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

III. Exhibit 1009

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

IV. Exhibit 1010

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

V. Exhibit 1011

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

VI. Exhibit 1012

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

VII. Exhibit 1013

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks

authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

VIII. Exhibit 1014

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

IX. Exhibit 1015

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

X. Exhibit 1017

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice,

confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XI. Exhibit 1018

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XII. Exhibit 1019

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XIII. Exhibit 1025

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its

probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XIV. Exhibit 1026

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XV. Exhibit 1027

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XVI. Exhibit 1028

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XVII. Exhibit 1029

Under FRE 401/402/403/702, this document has not shown that the purportedly expert declarant is qualified to testify competently regarding the matters that the expert's opinions are said to address. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XVIII. Exhibit 1031

Under FRE 106/1001, 35 U.S.C. § 312(a)(3) & (5), and 37 C.F.R. § 42.51(b)(1), these documents are incomplete and are not a copy which accurately reproduces the original.

XIX. Exhibit 1035

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its

probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XX. Exhibit 1036

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XXI. Exhibit 1039

Under FRE 106/1001, 35 U.S.C. § 312(a)(3) & (5), and 37 C.F.R. § 42.51(b)(1), these documents are incomplete and are not a copy which accurately reproduces the original.

XXII. Exhibit 1041

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks

authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XXIII. Exhibit 1042

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XXIV. Exhibit 1043

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XXV. Exhibit 1044

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice,

confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XXVI. Exhibit 1045

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XXVII. Exhibit 1047

Under FRE 401/402/403, this document is inadmissible as irrelevant because, among other things, it does not form a basis of the instituted grounds, and its probative value is outweighed by other considerations including prejudice, confusion and waste of time. Under FRE 901/902, this document lacks authentication and is not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

XXVIII. Exhibit 1048

Under FRE 106/1001, 35 U.S.C. § 312(a)(3) & (5), and 37 C.F.R. § 42.51(b)(1), these documents are incomplete and are not a copy which accurately reproduces the original.

XXIX. Exhibit 1049

Under FRE 106/1001, 35 U.S.C. § 312(a)(3) & (5), and 37 C.F.R. § 42.51(b)(1), these documents are incomplete and are not a copy which accurately reproduces the original.

XXX. Exhibit 1050

Under FRE 602/701/801/802 and 37 C.F.R. § 42.61, this document includes testimony that is not shown to be based on first-hand knowledge, is based on speculation, and constitutes and contains inadmissible hearsay. Under FRE and 37 C.F.R. § 42.65, this document, including for example and without limitation paragraphs 32-37, 44-49, 56-58, 60, 62-73, 79, 82, 87, 95, 96, 98-105, 112, 115-117, 119-122, 124-126, 129, 130, 133-139, 141, 144, 145, 151, 153-174, 181-185, 190, 195-199, 202-205, 210, 212, 213, 215-220, 222-224, 226, 227, 233-257, 264-270, 274-282, is inadmissible to the extent that it is conclusory and does not disclose bases for the opinions offered therein. Petitioner relies on this exhibit to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807. Under FRE 401/402/403/702,

this document, including for example and without limitation the paragraphs identified earlier in this objection, includes testimony that is not reliable and not relevant to the instituted review, because, among other things, it has not been shown that the purportedly expert declarant is qualified to testify competently regarding the matters the opinions are said to address, or that the declarant's testimony is based on sufficient facts or data or arrived at by reliable legal or art principles, procedures, or methods reliably applied to the facts of this case, or that the declarant's opinion will assist the trier of fact to understand the evidence or to determine any fact in issue and does not have a greater potential to confuse and/or mislead than to enlighten. Under FRE 401/705 and 37 C.F.R. § 42.65, this document does not disclose underlying facts and data. Under FRE 401/705 and 37 C.F.R. § 42.65, this document includes testimony on patent law and practice.

Date: June 17, 2025

Respectfully submitted,

BY: /Sanya Sukduang/

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CERTIFICATE OF SERVICE

I, Sanya Sukduang, hereby certify that on June 17, 2025, the foregoing **PATENT OWNER'S OBJECTIONS PURSUANT TO 37 C.F.R. § 42.64(b)(1)** were served electronically via email on the following counsel of record for Petitioner as follows:

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