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. IPR2025-00054
Patent No. 11,246,828

PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION FOR ADDITIONAL DISCOVERY

Petitioner Dr. Falk Pharma GmbH ("Petitioner") seeks additional discovery on Professor Lee (Paper 22), based on a report from Professor Lee that was submitted during European Patent Office ("EPO") proceedings and related litigation in the United Kingdom and Germany in 2019, and referenced in Patent Owner's Response. Paper 16; Ex. 2029. Petitioner cannot satisfy the *Garmin* factors, as the requested deposition and materials are not in the interest of justice. Petitioner does not demonstrate that anything useful will be uncovered through the additional discovery of Professor Lee, Petitioner is able to generate the relevant information by other means, and the requests are overly burdensome.

I. FACTUAL BACKGROUND

Professor Lee prepared a report measuring the disintegration rate of Petitioner's Jorveza tablets using the USP <701> Disintegration Test, and the report was submitted in the EPO proceedings, initiated by Petitioner, in 2019. The report is available publicly online at https://register.epo.org/application?number=EP10821232&lng=en&tab=doclist, submitted on July 23, 2020. Petitioner has known of this report since 2019 and had ample opportunity to request discovery and perform the same test. However, Petitioner did not challenge the report or seek discovery in the prior proceedings.

Patent Owner relies on the publicly available test results outlined in Professor Lee's report. As with all publicly available publications, Petitioner has the

opportunity to have its own expert opine on the veracity of Professor Lee's results, including running the USP <701> Disintegration Test.

Patent Owner did not retain or instruct Professor Lee to perform the test outlined in his report. Patent Owner does not have any materials Petitioner seeks and is unaware of whether Professor Lee maintained those records.

II. PETITIONER CANNOT SATISFY THE *GARMIN* FACTORS

The deposition and additional materials request of Professor Lee are not in the interest of justice. Petitioner failed to show that anything useful will be uncovered by the additional discovery requested and that discovery is unobtainable by other means. Further, Petitioner's requests are overly burdensome.

A. *Garmin* Factor 1: More Than a Possibility and Mere Allegation

Petitioner has failed to identify what useful information could be uncovered in Professor Lee's deposition or the requested materials. "[T]he requester of information should already be in possession of a threshold amount of evidence or reasoning tending to show beyond speculation that something useful will be uncovered." *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, No. IPR2012-00001, Paper 26 at 7-8 (P.T.A.B. March 5, 2013).

Petitioner asserts that Professor Lee's report "does not sufficiently describe how he conducted his testing[,]" and a deposition will give Petitioner the opportunity to gather missing information. Paper 22, 3. But Professor Lee's report outlines the

equipment used and the methodology followed. Ex. 2029, 2-4. Specifically, Professor Lee's report explains that the tablets were tested according to the USP <701> Disintegration Test using simulated saliva and the USP <701> Disintegration chapter was attached in Appendix C. Ex. 2029, 3-4, Appendix C. Petitioner has acknowledged the USP <701> Disintegration Test is a standardized test that a POSA would be aware of and understand. *See e.g.,* Paper 1, Section IV.D.

Petitioner fails to explain what additional information it will uncover, other than some nebulous "missing information." Petitioner *speculates* that there are "unreported test conditions and data[,]" but does not specify exactly what test conditions and data are missing. Paper 22, 3. Petitioner also contends that the deposition and additional materials are necessary to discover other disintegration tests. Paper 22, 3-4. Disintegration tests other than the USP <701> Disintegration Test are irrelevant to the claims at issue in this proceeding. Petitioner does not explain why discovery on other types of tests would be necessary or useful. Thus, *Garmin* Factor 1 weighs against additional discovery.

B. *Garmin* Factor 3: Ability to Generate Equivalent Information by Other Means

Petitioner has the ability to generate equivalent information in Professor Lee's report by other means. Specifically, Petitioner and its expert can test the reliability, accuracy, and veracity of the testing procedures and results described in Professor

Lee's report by running the equivalent test themselves (which Petitioner has likely already done as part of its regulatory package). Professor Lee's report offers ample information regarding the Jorveza tablets tested, the equipment, and the USP <701> Disintegration Test. Ex. 2029, 2-4. Thus, Petitioner is able to obtain the discovery it seeks by other means. Factor 3 therefore also weighs against additional discovery.

C. *Garmin* Factor 5: Petitioner's Requests are Overly Burdensome

As explained above, Patent Owner does not have contact with Professor Lee and does not possess any additional information or materials that Petitioner requests. Petitioner's requests for additional discovery are therefore overly burdensome and not in the interests of justice as Patent Owner cannot provide such discovery.

Further, to the extent the Petitioner seeks additional discovery on "any disintegration testing" conducted by Professor Lee or at his discretion, Petitioner's request is overly broad and burdensome. Paper 22, 4, 5 (seeking materials related to disintegration testing generally on Jorveza tablets). The claims at issue recite one particular disintegration test: the USP <701> Disintegration Test. Patent Owner relies on Professor Lee's report testing the Jorveza tablets under the USP <701> Disintegration Test to support secondary considerations of nonobviousness. No other disintegration tests are at issue. Petitioner does not explain why it requires additional discovery on any and all disintegration testing on Jorveza when only the USP <701> Disintegration Test is relevant.

Petitioner's request for a deposition with six hours on the record is also overly burdensome. Professor Lee's report is relevant to one limitation, the Disintegration Limitation, in the challenged claims. Petitioner does not and cannot justify why it requires six hours on the record for a discrete issue. Should the Board find that additional discovery is appropriate, and Patent Owner is able to make Professor Lee available for deposition, Patent Owner requests that any deposition of Professor Lee be limited in scope to only the USP <701> Disintegration Test and limited in time on the record to three hours.

III. CONCLUSION

For the reasons stated above, Petitioner has failed to demonstrate that additional discovery of Professor Lee is necessary for the interest of justice. Petitioner's motion for additional discovery should therefore be denied. If, however, the Board is inclined to allow additional discovery of Professory Lee, it should be limited to the disintegration testing done according to the USP <701> Disintegration Test, and should last no more than three hours on the record.

Date: November 3, 2025

Respectfully submitted,

BY: /Sanya Sukduang/

Sanya Sukduang
Reg. No. 46,390
Counsel for Patent Owner

Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Ave., NW
Suite 700
Washington D.C. 20004
Tel: (202) 776-2982
Fax: (202) 842-7887

CERTIFICATION OF SERVICE
UNDER 37 C.F.R. §§ 42.6(e), 42.105(a)

I hereby certify, pursuant to 37 C.F.R. Sections 42.6, that a complete copy of the attached **PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION FOR ADDITIONAL DISCOVERY** is being served via electronic mail on the 3rd day of November 2025, upon Petitioner's counsel as follows:

Nathanael Luman
Eric S. Furman
Philip J. Minnick
Jared C. Bunker
KNOBBE, MARTENS, OLSON, & BEAR, LLP
2nrl@knobbe.com
2esf@knobbe.com
2pjm@knobbe.com
2jcb@knobbe.com
BoxFalkPharma@knobbe.com

DATED: November 3, 2025

/Sanya Sukduang/
Sanya Sukduang
Reg. No. 46,390