Filed: May 1, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner

v.

The Johns Hopkins University,
Patent Owner

IPR2024-00624
Patent No. 11,325,975

PETITIONER'S MOTION TO SEAL

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.54 and the Board's Scheduling Order (Paper 13), Petitioner Merck Sharp & Dohme LLC ("Merck") respectfully submits this Motion to Seal its Petitioner's Reply and Exhibits 1116, 1118, 1119, 1137, 1150, 1151, 1157, 1244, 1245, 1269, and 1270 submitted concurrently with this Motion. Good cause exists for granting this Motion because Petitioner's Reply and Exhibits 1116, 1118, 1119, 1150, 1245, 1269, and 1270 contain information that Patent Owner The Johns Hopkins University ("JHU") has designated as highly confidential and Exhibits 1137, 1151, 1157, and 1244, contain Merck's highly confidential information. JHU has informed Merck that it does not oppose this Motion to Seal.

The Parties have agreed to, and previously filed, a proposed modified protective order. (*See* Paper 32 at 8-11, Appx. A.) The Parties respectfully request entry of the modified protective order for the reasons previously explained. (*Id.*)

II. GOOD CAUSE EXISTS FOR SEALING CERTAIN INFORMATION DESIGNATED AS HIGHLY CONFIDENTIAL

To grant a Motion to Seal in an *inter partes* review ("IPR"), the Board must find "good cause" exists for sealing information. 37 C.F.R. § 42.54. "The rules aim to strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information." *See* Consolidated Trial Practice Guide at 19. Good cause may exist

where a movant establishes that "(1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, (3) there exists a genuine need to rely in the trial on the specific information sought to be sealed, and (4), on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record." *See Argentum Pharms. LLC v. Alcon Research, Ltd.*, IPR2017-01053, Paper 27 at 4 (P.T.A.B. Jan. 19, 2018).

A. Documents Requested to be Sealed

Merck respectfully moves to seal in its entirety the following document filed concurrent with this Motion:

- **Exhibit 1157:** This document reflects information contained in Merck's Highly Confidential Attorney Eyes Only Document 12, which reflects third-party IQVIA claims data.

Merck respectfully moves to seal the confidential versions of the following documents filed concurrent with this Motion:

- **Petitioner's Reply:** Merck's Reply refers to information that has been designated as Highly Confidential contained in Exhibits 1116, 1118-19, 1137, 1150, 1151, 1244, and 1245.
- **Exhibits 1116, 1118, 1119:** JHU produced these documents to Merck, and has indicated that these documents contain Highly Confidential Information.

- **Exhibit 1137:** This document is a deposition transcript from the deposition of JHU declarant Mr. Brian Segers, which includes discussion of Mr. Segers' opinions that rely on Merck's and third-party IQVIA's Highly Confidential Information contained in Exhibits 2187 and 2188 discussed in JHU's January 13, 2025 Motion to Seal (Paper 32). (IPR2024-00240 Paper 37 at 3, 5-8.)
- **Exhibit 1150:** This document is an expert declaration from Paul E. Oberstein, M.D., which contains Dr. Oberstein's analysis of information contained in documents that JHU produced and designated Highly Confidential (Exhibits 1116, 1118, and 1119).
- **Exhibit 1151:** This document is an expert declaration from Sean Sheridan, Ph.D., which contains Dr. Sheridan's analysis of Merck's and third-party IQVIA's Highly Confidential Information contained in Exhibits 1157 and 2187.
- **Exhibit 1244:** This document is a deposition transcript from the deposition of JHU declarant Mr. Brian Segers, which includes discussion of Mr. Segers' opinions that rely on Merck's and third-party IQVIA's Highly Confidential Information contained in Exhibits 2187 and 2188 discussed in JHU's January 13, 2025 Motion to Seal (Paper 32). (IPR2024-00240 Paper 37 at 3, 5-8.)

- **Exhibit 1245:** This document is a deposition transcript from the deposition of JHU declarant Dr. Nils Lonberg, which has been designated as Highly Confidential by JHU pursuant to the proposed protective order. (*See* Paper 32, Appx. A)
- **Exhibit 1269:** This document is a declaration from Mr. Brian Segers which has been designated as Highly Confidential by JHU pursuant to the proposed protective order. (*See* Paper 32, Appx. A).
- **Exhibit 1270:** This document is a declaration from Mr. Brian Segers which has been designated as Highly Confidential by JHU pursuant to the proposed protective order. (*See* Paper 32, Appx. A).

B. *Argentum* Factors

The *Argentum* factors support maintaining Exhibit 1157 and the confidential versions of Exhibits 1137, 1151, 1244, 1269, and 1270 under seal.

Exhibit 1157 is an excerpt of Merck's Highly Confidential Attorney Eyes Only Document 12, which reflects third-party IQVIA claims data. While Merck maintains that JHU does not have "a genuine need to rely" on this information in this proceeding, JHU and its POR declarant Mr. Segers did so. Therefore, Dr. Sheridan cites and relies upon information from Merck's Highly Confidential Attorney Eyes Only Document 12 that is reflected in Exhibit 1157. The information contained in Exhibit 1157 is not public and is subject to restrictions by IQVIA that

require maintaining the information under the Highly Confidential designation of the Parties' proposed protective order (*See* Paper 32 at 8-11, Appx. A.), to limit the access of this information. Therefore, any public disclosure of the IQVIA claims data would cause competitive harm to both IQVA and Merck.

For the reasons stated with respect to Exhibit 1157 (and for the reasons previously stated with respect to Exhibits 2187 and 2188 in in JHU's January 13, 2025 Motion to Seal (Paper 32)), good cause exists to seal the confidential versions of Merck's Reply and Exhibits 1137, 1151, 1244, 1269, and 1270 to prevent public disclosure of IQVIA's and Merck's competitively sensitive information contained in Exhibits 1157, 2187, and 2188. (IPR2024-00240 Paper 37 at 3, 5-8.) The public's interest in maintaining a complete and understandable record is balanced by the forthcoming submission of redacted versions of Merck's Reply and Exhibits 1137, 1151, 1244, 1269, and 1270.

With respect to Exhibits 1116, 1118, and 1119, JHU provided the following explanations regarding the *Argentum* factors:

"Exhibits 1116, 1118, and 1119 are submissions from JHU to FDA pursuant to JHU's IND application related to a Phase 2 study of MK-3475 in patients with microsatellite unstable (MSI-H) tumors. The IND submissions contain sensitive and Highly Confidential Information concerning JHU's clinical trial and Highly Confidential communications between JHU and FDA. Public disclosure of these

documents, and the information contained therein, would harm JHU through revelation of JHU's confidential research and regulatory strategies. The public's interest in maintaining a complete and understandable record is balanced by the forthcoming submission of a redacted version of Merck's Reply."

With respect to *Argentum* factor (3), Merck has a genuine need to rely on the information contained in Exhibits 1116, 1118, and 1119 in this proceeding as the exhibits reflect submissions to the FDA regarding the Parties' clinical study that is disclosed in the prior art, (EX1005) and is the written description for the '975 patent claims.

For the reasons stated with respect to Exhibits 1116, 1118, and 1119, good cause also exists to seal the confidential versions of Merck's Reply and Exhibits 1150 and 1245 which cite to Exhibits 1116, 1118, and 1119.[1] The public's interest in maintaining a complete and understandable record is balanced by the forthcoming

[1] Merck does not concede that the information from Exhibits 1116, 1118, and 1119 cited in its Reply and Exhibits 1150 and 1245 requires sealing. The Parties will work together on appropriate redactions, if any, and file public versions of Merck's Reply and Exhibits 1150 and 1245 pursuant to the Board's IPR2024-00240 October 4, 2024 email (EX3005).

submission of sealed or redacted versions of Merck's Reply and Exhibits 1116, 1118, 1119, 1137, 1150, 1151, 1157, 1244, 1245, 1269, and 1270.

III. CONCLUSION

For the foregoing reasons, Merck respectfully requests that the Board seal Exhibit 1157 and protect the confidential versions of Petitioner's Reply and Exhibits 1116, 1118, 1119, 1137, 1150, 1151, 1244, 1245, 1269, and 1270. Further, the Parties respectfully request entry of the stipulated modified protective order. (*See* Paper 32, Appx. A).

Respectfully submitted,

Dated: May 1, 2025

By: /Preston K. Ratliff II/
Preston K. Ratliff II (Reg. No. 43,034)
Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that I caused to be served on the counsel identified below a true and correct copy of the foregoing Petitioner's Motion to Seal by electronic means on May 1, 2025:

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