

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

Case IPR2024-00648
Patent 11,643,462 B2

**PATENT OWNER'S MOTION TO SEAL AND
FOR ENTRY OF A MODIFIED PROTECTIVE ORDER**

Pursuant to 37 C.F.R. § 42.54 and the Board’s Scheduling Order (Paper 13), Patent Owner Johns Hopkins University (“JHU”) submits this Motion to Seal and for entry of a Modified Protective Order (“Motion”) concurrent with the filing of its Patent Owner’s Response (“POR”).

As described in further detail below, the documents that JHU moves to seal include information that JHU and Petitioner Merck Sharp & Dohme LLC (“Merck”) (collectively, the “Parties”) have designated as Highly Confidential. Merck has confirmed to JHU that it does not oppose this Motion.

The Parties have negotiated terms of a modified protective order (“MPO”) for the protection of Highly Confidential Information in this proceeding. The Parties have agreed that these terms are appropriate and jointly request entry of the MPO. A clean version of the MPO is attached as Appendix A. A redlined comparison between the MPO and the Board’s default protective order is attached as Appendix B.

I. BACKGROUND

On August 29, 2024, the Board granted with modifications JHU’s request for additional discovery in related IPR2024-00240. *See* IPR2024-00240, Paper 32. Following the Board’s Order, the Parties negotiated and JHU served alternative document requests. Pursuant to the Parties’ negotiations, Merck produced documents responsive to JHU’s alternative discovery requests. The produced

documents include certain documents that were also produced in the related district court litigation: *Merck Sharp & Dohme LLC v. The Johns Hopkins University*, 1-22-cv-03059 (D. Md.). The Parties agreed that the produced documents could be submitted in IPR2024-00240, IPR2024-00622, IPR2024-00623, IPR2024-00624, IPR2024-00625, IPR2024-00647, IPR2024-00648, IPR2024-00649, and IPR2024-00650 under an appropriate protective order, and accordingly, negotiated the terms of the MPO to govern access to and use of Highly Confidential Information in this proceeding. The changes to the default protective order proposed in the MPO would provide similar protections to Highly Confidential Information in this proceeding commensurate with the protections afforded by the protective order in the related district court litigation.

JHU is filing documents with its POR containing Highly Confidential Information belonging to both JHU and Merck. The motion, if granted, would ensure that these documents are maintained in confidence in accordance with the terms of the MPO.

II. REQUEST TO SEAL MERCK'S HIGHLY CONFIDENTIAL INFORMATION

In an *inter partes* review ("IPR"), the party moving to seal information must demonstrate "good cause." 37 C.F.R. § 42.20(c). The Board has explained that "a movant to seal must demonstrate adequately 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.”

Argentum Pharmaceuticals LLC v. Alcon Research, Ltd., IPR2017-01053, Paper 27 at 4 (PTAB Jan. 19, 2018) (informative).

A. Documents Requested to be Sealed

JHU respectfully moves to seal the following documents:

- **Exhibits 2167-2174 and 2181-2182** – Merck produced these documents to JHU pursuant to the Board’s Order authorizing JHU’s motion for additional discovery in IPR2024-00240. *See* IPR2024-00240, Paper 32. Merck has indicated that these documents contain Highly Confidential Information under the MPO.
- **Exhibits 2273-2275** – These documents are respective submissions made by JHU to the Food and Drug Administration (FDA) pursuant to JHU’s investigational new drug (IND) application related to a Phase 2 study of MK-3475 in patients with microsatellite unstable (MSI-H) tumors. The IND submissions contain highly sensitive and Highly Confidential Information concerning JHU’s clinical trial and Highly Confidential communications between JHU and FDA, and

highly sensitive, Highly Confidential Information regarding Merck's drug pembrolizumab.

- **Patent Owner's Response** – JHU's POR contains arguments that refer to Highly Confidential Information contained in Exhibits 2167-2174, 2181-2182, and 2273-2275.

Based on the Board's instruction in IPR2024-00240, the Parties will file public versions of relevant documents with redactions within ten business days of the filing of this Motion.¹ *See* Exhibit 2403.

¹ Substantially the entirety of JHU's IND submissions (Exhibits 2273-2275) are directed to Highly Confidential Information. JHU therefore requests that Exhibits 2273-2275 remain sealed in their entirety. JHU does not intend to file public versions of these highly sensitive documents that would leave any portions of the documents unredacted. Merck similarly did not submit public versions of its own FDA filings where it requested the documents remain sealed in their entirety (e.g., Exhibits 2167-2174) in IPR2024-00240.

B. *Argentum* Factors

Regarding *Argentum* factors (1), (2), and (4), Merck provided the following explanation in support of this Motion with respect to Exhibits 2167-2174 and 2181-2182²:

“Merck’s Highly Confidential Attorney Eyes Only Documents 1-10 consist of PDFs of Merck’s non-public, highly sensitive filings with the FDA regarding Merck’s proprietary drug, Keytruda®. Public disclosure of these documents, and the information contained within, would cause competitive harm to Merck by revealing Merck’s confidential research, technical, and commercial information regarding its drug, as well as Merck’s competitive regulatory strategies.

² Merck’s Highly Confidential Attorney Eyes Only Documents 1-10 correspond to Exhibits 2167-2174 and 2181-2182, respectively. JHU also notes that it has offered Merck’s explanation only for the purpose of complying with the requirements for filing a motion to seal set forth in *Argentum*. JHU does not concede agreement with the assertions in Merck’s explanations.

For the reasons stated with respect to Merck's Highly Confidential Attorney Eyes Only Documents 1-10, good cause exists to seal the confidential version of JHU's Patent Owner Response to prevent public disclosure of the competitively sensitive information reflected in Merck's Highly Confidential Attorney Eyes Only Documents 1-10. The public's interest in maintaining a complete and understandable record is balanced by the forthcoming submission of a redacted version of JHU's POR."

Argentum factors (1), (2), and (4) also support JHU's Motion to seal Exhibits 2273-2275. As noted above, these documents contain certain 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 risk harm to JHU and Merck through revelation of JHU's confidential research and regulatory strategies, and Merck's proprietary information regarding its drug. The public's interest in maintaining a complete and understandable

record is balanced by the forthcoming submission of a redacted version of JHU's POR.

Regarding *Argentum* factor (3)³, JHU has a genuine need to rely in this trial on the information sought to be sealed. JHU relies on this information in the POR, for example, to contest the obviousness grounds advanced in Merck's petition and to demonstrate objective indicia of non-obviousness. As the Board recognized in its order authorizing additional discovery in related IPR2024-00240, "Merck chose to include challenges based on obviousness in its Petition and JHU is entitled to present its own, full opposition to all of these challenges." IPR20240-00240, Paper 32 at p. 5.

For each of these reasons, the *Argentum* factors support this Motion to seal the above-identified documents.

III. REQUEST FOR ENTRY OF A MODIFIED PROTECTIVE ORDER

Good cause exists for modifying the Board's default protective order and for entry of the Parties' proposed MPO for the following reasons. An explanation of the proposed modifications and good cause for the modifications follows below.

³ While Merck does not oppose this Motion, Merck indicates that it disagrees with JHU's arguments with respect to *Argentum* factor (3).

Paragraphs 1–3, 5, and 9. The Parties have agreed to modify the default protective order to provide for a Highly Confidential tier of confidentiality, the only tier provided for in the MPO. This Highly Confidential tier is necessary to protect JHU’s and Merck’s highly sensitive filings with the FDA, competitively sensitive financial information, and third-party data. Further, by using a heightened tier of confidentiality, the Parties are able to ensure that the same documents produced under a highly confidential tier in the parallel district court litigation are afforded substantially the same protections in this IPR proceeding, and are affixed with the same confidentiality markings.⁴ Accordingly, the MPO provides definitions for “Highly Confidential Information,” “Producing Party,” and “Receiving Party” (paragraphs 1–3, respectively) that correspond to definitions provided in the district court protective order. The proposed modifications would limit access to Highly Confidential Information to outside counsel of record (paragraph 5(A)), experts (paragraph 5(B)) who execute a protective order

⁴ JHU notes that the MPO differs from the district court protective order in that the MPO does not provide a prosecution bar as the district court protective order does. The MPO proposed in this proceeding is identical to the MPO that the Parties earlier proposed in IPR2024-00240, which is pending the Board’s approval.

acknowledgement, up to four in-house counsel (paragraph 5(C)) who execute a protective order acknowledgement, contract attorneys (paragraph 5(D)), support personnel (paragraph 5(E)), and the Office (paragraph 5(F)). The MPO also defines limits to the use of the Highly Confidential Information, including that “Highly Confidential Information will be used solely for the purpose of the proceedings in IPR2024-00240, IPR2024-00622, IPR2024-00623, IPR2024-00624, IPR2024-00625, IPR2024-00647, IPR2024-00648, IPR2024-00649, and IPR2024-00650 (collectively, “the MSI-H IPR Proceedings”), but shall not be used in any other proceeding or for any other purpose unless otherwise agreed to by the Parties” (paragraph 9). Good cause exists for these modifications to protect Merck’s competitively sensitive information, as well as third-party data subject to confidentiality restrictions. Further, these modifications promote consistency in the treatment of Highly Confidential Information between this proceeding and the related district court litigation.

Paragraph 4. The MPO provides that Highly Confidential Information in this proceeding shall be clearly marked “HIGHLY CONFIDENTIAL – PROTECTIVE ORDER MATERIAL.” This provision will ensure that Highly Confidential Information in this proceeding can be marked with the same designation provided in the related district court proceeding, thereby promoting consistency with the related district court litigation and ensuring that documents

are marked in accordance with the Highly Confidential Information designation that was earlier defined in the MPO.

Paragraphs 6-8. Paragraphs 6-8 have been revised to refer to “Highly Confidential Information,” “Producing Party,” and “Receiving Party” as defined in paragraphs 1–3, respectively. Good cause exists for these changes to ensure internal consistency of terms used in the MPO.

Paragraphs 10 and 11. Paragraphs 10 and 11 provide procedures for the inadvertent failure to designate and the inadvertent production of highly confidential or privileged documents. These paragraphs also provide a timeline and procedure for the Parties to correct inadvertent errors in production. Good cause exists because the protective order in the related proceeding has a similar provision and this change will help ensure consistency between forums.

Paragraph 12. The MPO modifies the time period for returning highly confidential information from 60 days (the Board’s default time) to 90 days. Good cause exists because the protective order in the related proceeding has a similar provision and this change will help ensure consistency between forums and will allow for sufficient time to return or destroy Highly Confidential Information..

IV. CONCLUSION

JHU respectfully requests that the Board seal and protect Exhibits 2167-2174, 2181-2182, 2273-2275, and a confidential version of the Patent Owner’s

Response. The Parties also respectfully request entry of the MPO as proposed and attached in Appendix A.

Respectfully submitted,

Dated: January 23, 2025

/Nicholas W. Stephens/
Nicholas Stephens, Reg. No. 74,320
Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4), the undersigned certifies that on January 23, 2025, a complete and entire copy of this JOINT MOTION FOR ENTRY OF MODIFIED PROTECTIVE ORDER was provided by email to the Petitioner by serving the correspondence address of record as follows:

Naveen Modi (Reg. No. 46,224)
Bruce M. Wexler (Reg. No. 35,409)
Preston K. Ratliff II (Reg. No. 43,034)
Daniel Zeilberger (Reg. No. 65,349)
Dana R. Weir (Reg. No. 55,865)
Jessica Stauring (*pro hac vice*)
Mark Stewart (Reg. No. 43,936)
Paul Hastings LLP
PH-MSD-JHU-IPR@paulhastings.com
mark.stewart@merck.com

/Crena Pacheco/
Crena Pacheco
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
pacheco@fr.com

Case No. IPR2024-00648

Patent No. 11,643,462

APPENDIX A – MODIFIED PROTECTIVE ORDER

Case No. IPR2024-00648

Patent No. 11,643,462

The following Protective Order will govern the filing and treatment of confidential information in this proceeding:

Protective Order

This protective order governs the treatment and filing of confidential information, including documents and testimony.

1. The term “Highly Confidential Information” shall include all information that the party producing such information believes in good faith constitutes, discloses or relates to proprietary business information, processes, operations, research, technical information, production, marketing and sales documents and things, and competitively sensitive financial and strategic information. The information contained in such documents and things and all copies, abstracts, excerpts, analyses thereof or other writings that contain, reflect, reveal, suggest or otherwise disclose such Highly Confidential Information shall also be deemed Highly Confidential Information. Each party shall act in good faith in designating information as Highly Confidential Information.

2. The term “Producing Party” shall include any producing person, entity, or third party, including a party’s counsel, retained experts, directors, officers, employees, or agents who produce any discovery material in this proceeding.

3. The term “Receiving Party” shall include any receiving person or entity, including a party’s counsel, retained experts, directors, officers, employees, or agents who receives any discovery material in this proceeding.

4. Highly Confidential Information shall be clearly marked “HIGHLY CONFIDENTIAL – PROTECTIVE ORDER MATERIAL.”

5. Access to Highly Confidential Information is limited to the following individuals who have executed the acknowledgment appended to this order as Exhibit A:

(A) Outside Counsel of Record. Outside Counsel of record for a party in this proceeding, including the secretarial, clerical, paralegal and other supporting personnel of said outside counsel.

(B) Experts. Retained experts of a party in the proceeding provided that disclosure of such Highly Confidential Information be made only after:

(i) Counsel desiring to disclose Highly Confidential Information to such an expert shall obtain a completed and signed Acknowledgement in the form of Exhibit A from the expert, certifying that the expert is not a competitor to any party, or a consultant for, or employed by, such a competitor with respect to the subject matter of the proceeding, and forward a copy of said completed and signed Acknowledgement and the person’s current curriculum vitae to counsel for the Producing Party,

wherein said current curriculum vitae includes information the expert would use in the ordinary course of business and the expert's business address, business telephone numbers, present employer and position (along with a job description), past or present relationship, if any, with the party receiving such Highly Confidential Information (including as a board member or advisor), and, for the past three (3) years, the expert's consulting activities, cases in which the expert has provided a written expert report or testified at trial or by deposition, and job history.

(ii) The occurrence of the expiration of a period of five (5) calendar days, commencing with the receipt by counsel for the Producing Party of a copy of the expert's completed and signed Acknowledgement and current curriculum vitae. No disclosure of Highly Confidential Information shall be made to the proposed expert prior to the expiration of the five (5) day period. During this period, counsel for the Producing Party may request additional information or object in good faith to the disclosure of Highly Confidential Information to this expert or consultant for cause, identified in writing (e.g., an identified conflict of interest). If counsel for the Producing Party fails to object to such disclosure within the prescribed period, any objection to such shall be deemed waived, except as to a basis for objection that was not known and could not have been reasonably

discovered within the five-day period. In the event that a good faith objection is made within the prescribed period, there shall be no disclosure of Highly Confidential Information to the expert until there is an express written agreement of the Parties or Order from the Board resolving the dispute. Prior to seeking resolution by the Board of any disagreement as to the requested disclosure, the Parties shall meet and confer promptly and in good faith in an effort to resolve such disagreement. If the Parties are unable to reach agreement over the disclosure of material or information designated as Highly Confidential Information to the expert or consultant within seven (7) calendar days from when either party provides a written notification that an impasse has been reached subsequent to a good faith meet and confer, the Producing Party raising the objection shall have the obligation to seek relief from the Board preventing the disclosure.

(iii) In the event that a Receiving Party desires to provide access in good faith to Highly Confidential Information to any person not entitled to such access under this Paragraph 5, the Receiving Party shall first request in writing an agreement to do so from the Producing Party. If the Producing Party refuses to enter into such an agreement after the Parties have met and conferred, the Receiving Party shall have the obligation to seek relief from the Board by informal letter briefing, or some other method authorized or

permitted by the Board, within seven (7) calendar days. In the event that the motion is granted, such person may have access to Highly Confidential Information after first signing the Acknowledgement in the form of Exhibit A, a copy of which shall be forwarded promptly to counsel for the Producing Party, or under such other conditions as the Parties to this proceeding may agree or this Board may order.

(C) In-house counsel.

(i) When Merck is the Receiving Party, access to Highly Confidential Information shall be permitted to four in-house attorneys employed by Merck who are responsible for monitoring and/or supervising this proceeding, and their respective secretarial, clerical, paralegal and other supporting personnel. The four in-house Merck attorney designees shall be designated in writing at a later date. Merck's designated in-house attorneys shall complete and sign the Acknowledgement in the form of Exhibit A and Merck will forward a copy of the completed and signed Acknowledgement to JHU within three (3) calendar days of its execution.

(ii) When JHU is the Receiving Party, access to Highly Confidential Information shall be permitted to four in-house attorneys employed by JHU who are responsible for monitoring and/or supervising these actions, and their respective secretarial, clerical, paralegal and other supporting

personnel. The four in-house JHU attorney designees shall be designated in writing at a later date. JHU's designated in-house attorneys shall complete and sign the Acknowledgement in the form of Exhibit A and JHU will forward a copy of the completed and signed Acknowledgement to Merck within three (3) calendar days of its execution.

(D) Contract Attorneys. Contract attorneys retained by any party who are subject to the restrictions in Subparagraph 5(A).

(E) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

(F) The Office. Employees and representatives of the United States Patent and Trademark Office who have a need for access to the Highly Confidential Information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

6. Employees (e.g., corporate officers), consultants, or other persons performing work for a party, other than those persons identified above in Paragraph 5(A)–(E), shall be extended access to Highly Confidential Information only upon agreement of the Parties or by order of the Board upon a motion brought by the party seeking to disclose confidential information to that person and after signing the Acknowledgment. The party opposing disclosure to that person shall have the burden of proving that such person should be restricted from access to Highly Confidential Information.

7. The Receiving Party shall use reasonable efforts to maintain the confidentiality of the information, including:

(A) Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;

(B) Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the Receiving Party uses to maintain the confidentiality of information not received from the Producing Party;

(C) Ensuring that support personnel of the Receiving Party who have access to the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and

(D) Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

8. The Receiving Party shall use the following procedures to maintain the confidentiality of the information:

(A) Documents and Information Filed With the Board.

(i) A party may file documents or information with the Board along with a Motion to Seal. The Motion to Seal should provide a non-confidential description of the nature of the confidential information that is under seal, and set forth the reasons why the information is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The documents or information shall remain under seal unless the Board determines that some or all of it does not qualify for confidential treatment.

(ii) Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. A party may challenge the

confidentiality of the information by opposing the Motion to Seal. The non-confidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain under seal unless the Board determines that some or all of the redacted information does not qualify for confidential treatment.

(B) Documents and Information Exchanged Among the Parties. Documents (including deposition transcripts) and other information designated as confidential that are disclosed to the Receiving Party during discovery or in this proceeding before the Board shall be clearly marked as “HIGHLY CONFIDENTIAL - PROTECTIVE ORDER MATERIAL” and shall be produced in a manner that maintains its confidentiality.

9. Use of Highly Confidential Information. Highly Confidential Information will be used solely for the purpose of the proceedings in IPR2024-00240, IPR2024-00622, IPR2024-00623, IPR2024-00624, IPR2024-00625, IPR2024-00647, IPR2024-00648, IPR2024-00649, and IPR2024-00650 (collectively, “the MSI-H IPR Proceedings”), but shall not be used in any other proceeding or for any other purpose unless otherwise agreed to by the Parties. Highly Confidential Information that is subject to third-party approval prior to disclosure, however, shall not be used in any IPR proceeding other than IPR2024-

00240 until third-party approval is obtained on an individual basis for IPR2024-00622, IPR2024-00623, IPR2024-00624, IPR2024-00625, IPR2024-00647, IPR2024-00648, IPR2024-00649, and IPR2024-00650. The Parties agree to make good-faith efforts to obtain any necessary third-party approval for the use of Highly Confidential Information for each IPR proceeding included in the MSI-H IPR Proceedings, following a request to use such Highly Confidential Information in any of the MSI-H IPR Proceedings other than IPR2024-00240. This prohibition specifically covers any and all use in connection with any matter other than the MSI-H IPR Proceedings, including, but not limited to, research, development, manufacture, patent filing or prosecution, patent licensing (excluding any potential licenses between the Parties), business purpose, marketing purpose, regulatory purpose, any communications or any petitions submitted to the FDA, or any foreign governmental counterpart of these agencies, or for any other competitive purpose. Further, by way of another non-limiting example, this prohibition precludes searching and/or reviewing any Highly Confidential Information produced in this proceeding for possible use in a different proceeding that is not among the MSI-H IPR Proceedings. For avoidance of doubt, the MSI-H IPR Proceedings include any appeals of these proceedings to the United States Court of Appeals for the Federal Circuit. The Parties may use Highly Confidential Information from the MSI-H IPR Proceedings in any such appeals, provided that such use also complies with relevant

rules and requirements of the Federal Circuit. The use of any Highly Confidential Information that is subject to third-party approval, however, shall not be used in any appeals of the MSI-H IPR Proceedings until permission is provided by said third parties. For the avoidance of doubt, the Parties agree to make good-faith efforts to obtain any necessary third-party approval for the use of Highly Confidential Information for each IPR proceeding included in the MSI-H IPR Proceedings, or appeals therefrom.

10. Inadvertent Failure to Designate. The inadvertent disclosure or production of any information, document or tangible item without the designation provided by Paragraph 4 of this Protective Order shall not constitute a waiver of any claim of confidentiality. Where such undesigned disclosure or production resulted from inadvertence or mistake on the part of the Producing Party, such inadvertence or mistake shall be brought to the attention of the Receiving Party promptly after its discovery. Within five (5) business days of the notice of such inadvertent or mistaken undesigned disclosure or production, the Producing Party shall provide properly designated documents or tangible items, if applicable. Upon receipt of such notice and properly designated documents or tangible items, if applicable, the Receiving Party shall substitute properly designated copies for those previously received and treat the information contained in or derived from said replaced documents or tangible items as Highly Confidential Information.

11. Inadvertent Production of Highly Confidential or Privileged Documents. Should any Highly Confidential Information be inadvertently disclosed by the Receiving Party to any person not authorized to have access to such information under this Protective Order, the Receiving Party shall: (a) use its best efforts to obtain the prompt return of any such Highly Confidential Information and to bind such person to the terms of this Order; (b) within five (5) business days of the discovery of such disclosure, inform such person of the provisions of this Protective Order and identify such person to the Producing Party; and (c) request such person to sign an Acknowledgement in the form of Exhibit A. If executed, the Acknowledgement shall be served upon counsel of record for the Producing Party within five (5) business days of its receipt by the Receiving Party. The requirements set forth in this Paragraph 11 shall not prevent the Producing Party from applying to the Board for further or additional relief. The Parties shall exert their best efforts to identify documents or material protected by the attorney-client privilege, or work-product doctrine, or any other applicable privilege prior to the disclosure of any such documents or materials. If a Producing Party inadvertently or mistakenly produces information, documents or tangible items in this proceeding that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice such claim or otherwise constitute a waiver of any claim of attorney-client privilege or work product immunity for such

information, provided that the Producing Party promptly makes a good-faith representation in writing that such production was inadvertent or mistaken, requests the documents or materials be returned, and attaches a privilege log entry pertaining to the documents or materials that are privileged or otherwise immune from discovery. If that request is made and the privilege log provided, no party to this proceeding shall thereafter assert that the disclosure waived any privilege or immunity. Within seven (7) calendar days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The Receiving Party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information; provided, however, that this Protective Order shall not preclude the party returning such information from making a motion for additional discovery of the returned information within seven (7) calendar days of returning such information. For purposes of this Paragraph 11, “destroy” shall mean that the paper versions are shredded, that active electronic versions are deleted, and that no effort shall be made to recover versions that are not readily accessible such as those on backup media or only recoverable through forensic means. The Producing Party

shall retain copies of all returned documents and tangible items for further disposition.

12. Within 90 days after the final disposition of this action, including the exhaustion of all appeals and motions, the Receiving Party must return, or certify the destruction of, all copies of the Highly Confidential Information to the Producing Party.

Exhibit A

Standard Acknowledgment for Access to Protective Order Material

I _____, affirm that I have read the Protective Order; that I will abide by its terms; that I will use the confidential information only in connection with this proceeding and for no other purpose; that I will only allow access to support staff who are reasonably necessary to assist me in this proceeding; that prior to any disclosure to such support staff I informed or will inform them of the requirements of the Protective Order; that I am personally responsible for the requirements of the terms of the Protective Order and I agree to submit to the jurisdiction of the Office and the United States District Court for the Eastern District of Virginia for purposes of enforcing the terms of the Protective Order and providing remedies for its breach.

Dated: _____

Signature: _____

Title: _____

Address: _____

Case No. IPR2024-00648

Patent No. 11,643,462

**APPENDIX B – MODIFIED PROTECTIVE ORDER
(SHOWING REDLINES TO DEFAULT PROTECTIVE ORDER)**

Case No. IPR2024-00648

Patent No. 11,643,462

The following ~~Default~~ Protective Order will govern the filing and treatment of confidential information in ~~the~~this proceeding:

~~Default~~ Protective Order

This protective order governs the treatment and filing of confidential information, including documents and testimony.

~~1. Confidential information shall be clearly marked “PROTECTIVE ORDER MATERIAL.”~~

1. The term “Highly Confidential Information” shall include all information that the party producing such information believes in good faith constitutes, discloses or relates to proprietary business information, processes, operations, research, technical information, production, marketing and sales documents and things, and competitively sensitive financial and strategic information. The information contained in such documents and things and all copies, abstracts, excerpts, analyses thereof or other writings that contain, reflect, reveal, suggest or otherwise disclose such Highly Confidential Information shall also be deemed Highly Confidential Information. Each party shall act in good faith in designating information as Highly Confidential Information.

2. The term “Producing Party” shall include any producing person, entity, or third party, including a party’s counsel, retained experts, directors, officers, employees, or agents who produce any discovery material in this proceeding.

3. The term “Receiving Party” shall include any receiving person or entity, including a party’s counsel, retained experts, directors, officers, employees, or agents who receives any discovery material in this proceeding.

4. Highly Confidential Information shall be clearly marked “HIGHLY CONFIDENTIAL – PROTECTIVE ORDER MATERIAL.”

2.5. Access to ~~confidential information~~ Highly Confidential Information is limited to the following individuals who have executed the acknowledgment appended to this order as Exhibit A:

(A) ~~Parties. Persons who are owners~~ Outside Counsel of a patent involved in the proceeding and other persons who are named parties to the proceeding.

(B) ~~Party Representatives. Representatives~~ Record. Outside Counsel of record for a party in ~~the proceeding~~ this proceeding, including the secretarial, clerical, paralegal and other supporting personnel of said outside counsel.

(~~C~~) Experts. Retained experts of a party in the proceeding ~~who further certify in the provided that disclosure of such Highly Confidential Information~~ be made only after:

(i) Counsel desiring to disclose Highly Confidential Information to such an expert shall obtain a completed and signed Acknowledgement ~~that they are~~ in the form of Exhibit A from the expert, certifying that the expert is not a competitor to any party, or a consultant for, or employed by, such a

competitor with respect to the subject matter of the proceeding, and forward a copy of said completed and signed Acknowledgement and the person's current curriculum vitae to counsel for the Producing Party, wherein said current curriculum vitae includes information the expert would use in the ordinary course of business and the expert's business address, business telephone numbers, present employer and position (along with a job description), past or present relationship, if any, with the party receiving such Highly Confidential Information (including as a board member or advisor), and, for the past three (3) years, the expert's consulting activities, cases in which the expert has provided a written expert report or testified at trial or by deposition, and job history.

(D)-(ii) The occurrence of the expiration of a period of five (5) calendar days, commencing with the receipt by counsel for the Producing Party of a copy of the expert's completed and signed Acknowledgement and current curriculum vitae. No disclosure of Highly Confidential Information shall be made to the proposed expert prior to the expiration of the five (5) day period. During this period, counsel for the Producing Party may request additional information or object in good faith to the disclosure of Highly Confidential Information to this expert or consultant for cause, identified in writing (e.g., an identified conflict of interest). If counsel for

the Producing Party fails to object to such disclosure within the prescribed period, any objection to such shall be deemed waived, except as to a basis for objection that was not known and could not have been reasonably discovered within the five-day period. In the event that a good faith objection is made within the prescribed period, there shall be no disclosure of Highly Confidential Information to the expert until there is an express written agreement of the Parties or Order from the Board resolving the dispute. Prior to seeking resolution by the Board of any disagreement as to the requested disclosure, the Parties shall meet and confer promptly and in good faith in an effort to resolve such disagreement. If the Parties are unable to reach agreement over the disclosure of material or information designated as Highly Confidential Information to the expert or consultant within seven (7) calendar days from when either party provides a written notification that an impasse has been reached subsequent to a good faith meet and confer, the Producing Party raising the objection shall have the obligation to seek relief from the Board preventing the disclosure.

(iii) In the event that a Receiving Party desires to provide access in good faith to Highly Confidential Information to any person not entitled to such access under this Paragraph 5, the Receiving Party shall first request in writing an agreement to do so from the Producing Party. If the Producing

Party refuses to enter into such an agreement after the Parties have met and conferred, the Receiving Party shall have the obligation to seek relief from the Board by informal letter briefing, or some other method authorized or permitted by the Board, within seven (7) calendar days. In the event that the motion is granted, such person may have access to Highly Confidential Information after first signing the Acknowledgement in the form of Exhibit A, a copy of which shall be forwarded promptly to counsel for the Producing Party, or under such other conditions as the Parties to this proceeding may agree or this Board may order.

(C) In-house counsel. ~~In~~

(i) When Merck is the Receiving Party, access to Highly Confidential Information shall be permitted to four in-house counsel of a party: attorneys employed by Merck who are responsible for monitoring and/or supervising this proceeding, and their respective secretarial, clerical, paralegal and other supporting personnel. The four in-house Merck attorney designees shall be designated in writing at a later date. Merck's designated in-house attorneys shall complete and sign the Acknowledgement in the form of Exhibit A and Merck will forward a copy

of the completed and signed Acknowledgement to JHU within three (3) calendar days of its execution.

(ii) When JHU is the Receiving Party, access to Highly Confidential Information shall be permitted to four in-house attorneys employed by JHU who are responsible for monitoring and/or supervising these actions, and their respective secretarial, clerical, paralegal and other supporting personnel. The four in-house JHU attorney designees shall be designated in writing at a later date. JHU's designated in-house attorneys shall complete and sign the Acknowledgement in the form of Exhibit A and JHU will forward a copy of the completed and signed Acknowledgement to Merck within three (3) calendar days of its execution.

(D) Contract Attorneys. Contract attorneys retained by any party who are subject to the restrictions in Subparagraph 5(A).

(E) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

(F) The Office. Employees and representatives of the United States Patent and Trademark Office who have a need for access to the ~~confidential information~~Highly Confidential Information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

~~3.6.~~ Employees (e.g., corporate officers), consultants, or other persons performing work for a party, other than those persons identified above in ~~(d)(2)(Paragraph 5(A)–(E),~~ shall be extended access to ~~confidential information~~Highly Confidential Information only upon agreement of the ~~parties~~Parties or by order of the Board upon a motion brought by the party seeking to disclose confidential information to that person and after signing the Acknowledgment. The party opposing disclosure to that person shall have the burden of proving that such person should be restricted from access to ~~confidential information~~Highly Confidential Information.

~~4.7.~~ ~~Persons receiving confidential information~~The Receiving Party shall use reasonable efforts to maintain the confidentiality of the information, including:

(A) Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;

(B) Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the ~~recipient~~Receiving Party uses to maintain the confidentiality of information not received from the ~~disclosing party~~Producing Party;

(C) Ensuring that support personnel of the ~~recipient~~Receiving Party who have access to the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and

(D) Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

~~5.8. Persons receiving confidential information~~The Receiving Party shall use the following procedures to maintain the confidentiality of the information:

(A) Documents and Information Filed With the Board.

(i) A party may file documents or information with the Board along with a Motion to Seal. The Motion to Seal should provide a non-confidential description of the nature of the confidential information that is under seal, and set forth the reasons why the information is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The

documents or information shall remain under seal unless the Board determines that some or all of it does not qualify for confidential treatment.

(ii) Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The non-confidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain under seal unless the Board determines that some or all of the redacted information does not qualify for confidential treatment.

(B) Documents and Information Exchanged Among the Parties. Documents (including deposition transcripts) and other information designated as confidential that are disclosed to ~~another party~~ the Receiving Party during discovery or ~~other proceedings in this proceeding~~ before the Board shall be clearly marked as “HIGHLY CONFIDENTIAL - PROTECTIVE ORDER

MATERIAL” and shall be produced in a manner that maintains its confidentiality.

9. ~~Within 60~~ Use of Highly Confidential Information. Highly Confidential Information will be used solely for the purpose of the proceedings in IPR2024-00240, IPR2024-00622, IPR2024-00623, IPR2024-00624, IPR2024-00625, IPR2024-00647, IPR2024-00648, IPR2024-00649, and IPR2024-00650 (collectively, “the MSI-H IPR Proceedings”), but shall not be used in any other proceeding or for any other purpose unless otherwise agreed to by the Parties. Highly Confidential Information that is subject to third-party approval prior to disclosure, however, shall not be used in any IPR proceeding other than IPR2024-00240 until third-party approval is obtained on an individual basis for IPR2024-00622, IPR2024-00623, IPR2024-00624, IPR2024-00625, IPR2024-00647, IPR2024-00648, IPR2024-00649, and IPR2024-00650. The Parties agree to make good-faith efforts to obtain any necessary third-party approval for the use of Highly Confidential Information for each IPR proceeding included in the MSI-H IPR Proceedings, following a request to use such Highly Confidential Information in any of the MSI-H IPR Proceedings other than IPR2024-00240. This prohibition specifically covers any and all use in connection with any matter other than the MSI-H IPR Proceedings, including, but not limited to, research, development, manufacture, patent filing or prosecution, patent licensing (excluding any potential

licenses between the Parties), business purpose, marketing purpose, regulatory purpose, any communications or any petitions submitted to the FDA, or any foreign governmental counterpart of these agencies, or for any other competitive purpose. Further, by way of another non-limiting example, this prohibition precludes searching and/or reviewing any Highly Confidential Information produced in this proceeding for possible use in a different proceeding that is not among the MSI-H IPR Proceedings. For avoidance of doubt, the MSI-H IPR Proceedings include any appeals of these proceedings to the United States Court of Appeals for the Federal Circuit. The Parties may use Highly Confidential Information from the MSI-H IPR Proceedings in any such appeals, provided that such use also complies with relevant rules and requirements of the Federal Circuit. The use of any Highly Confidential Information that is subject to third-party approval, however, shall not be used in any appeals of the MSI-H IPR Proceedings until permission is provided by said third parties. For the avoidance of doubt, the Parties agree to make good-faith efforts to obtain any necessary third-party approval for the use of Highly Confidential Information for each IPR proceeding included in the MSI-H IPR Proceedings, or appeals therefrom.

10. Inadvertent Failure to Designate. The inadvertent disclosure or production of any information, document or tangible item without the designation provided by Paragraph 4 of this Protective Order shall not constitute a waiver of any

claim of confidentiality. Where such undesigned disclosure or production resulted from inadvertence or mistake on the part of the Producing Party, such inadvertence or mistake shall be brought to the attention of the Receiving Party promptly after its discovery. Within five (5) business days of the notice of such inadvertent or mistaken undesigned disclosure or production, the Producing Party shall provide properly designated documents or tangible items, if applicable. Upon receipt of such notice and properly designated documents or tangible items, if applicable, the Receiving Party shall substitute properly designated copies for those previously received and treat the information contained in or derived from said replaced documents or tangible items as Highly Confidential Information.

11. Inadvertent Production of Highly Confidential or Privileged Documents. Should any Highly Confidential Information be inadvertently disclosed by the Receiving Party to any person not authorized to have access to such information under this Protective Order, the Receiving Party shall: (a) use its best efforts to obtain the prompt return of any such Highly Confidential Information and to bind such person to the terms of this Order; (b) within five (5) business days of the discovery of such disclosure, inform such person of the provisions of this Protective Order and identify such person to the Producing Party; and (c) request such person to sign an Acknowledgement in the form of Exhibit A. If executed, the Acknowledgement shall be served upon counsel of record for the Producing Party

within five (5) business days of its receipt by the Receiving Party. The requirements set forth in this Paragraph 11 shall not prevent the Producing Party from applying to the Board for further or additional relief. The Parties shall exert their best efforts to identify documents or material protected by the attorney-client privilege, or work-product doctrine, or any other applicable privilege prior to the disclosure of any such documents or materials. If a Producing Party inadvertently or mistakenly produces information, documents or tangible items in this proceeding that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice such claim or otherwise constitute a waiver of any claim of attorney-client privilege or work product immunity for such information, provided that the Producing Party promptly makes a good-faith representation in writing that such production was inadvertent or mistaken, requests the documents or materials be returned, and attaches a privilege log entry pertaining to the documents or materials that are privileged or otherwise immune from discovery. If that request is made and the privilege log provided, no party to this proceeding shall thereafter assert that the disclosure waived any privilege or immunity. Within seven (7) calendar days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client privilege or work product immunity and were

inadvertently or mistakenly produced. The Receiving Party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information; provided, however, that this Protective Order shall not preclude the party returning such information from making a motion for additional discovery of the returned information within seven (7) calendar days of returning such information. For purposes of this Paragraph 11, “destroy” shall mean that the paper versions are shredded, that active electronic versions are deleted, and that no effort shall be made to recover versions that are not readily accessible such as those on backup media or only recoverable through forensic means. The Producing Party shall retain copies of all returned documents and tangible items for further disposition.

6.12. Within 90 days after the final disposition of this action, including the exhaustion of all appeals and motions, ~~each party receiving confidential information~~the Receiving Party must return, or certify the destruction of, all copies of the ~~confidential information~~Highly Confidential Information to the ~~producing party~~Producing Party.

Exhibit A**Standard Acknowledgment for Access to Protective Order Material**

I _____, affirm that I have read the Protective Order; that I will abide by its terms; that I will use the confidential information only in connection with this proceeding and for no other purpose; that I will only allow access to support staff who are reasonably necessary to assist me in this proceeding; that prior to any disclosure to such support staff I informed or will inform them of the requirements of the Protective Order; that I am personally responsible for the requirements of the terms of the Protective Order and I agree to submit to the jurisdiction of the Office and the United States District Court for the Eastern District of Virginia for purposes of enforcing the terms of the Protective Order and providing remedies for its breach.

Dated: _____ Signature: _____

Title: _____

Address: _____