

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 IPR2024-00240
Patent 11,591,393 B2

**PATENT OWNER'S MOTION TO SEAL SUR-REPLY AND
ACCOMPANYING EXHIBITS**

Pursuant to 37 C.F.R. § 42.54 and the Board’s Scheduling Order (Paper 11), Patent Owner Johns Hopkins University (“JHU”) submits this Motion to Seal concurrent its Patent Owner’s Sur-Reply (“Sur-Reply”) and Exhibits 2404, 2410, and 2411, submitted concurrently with this Motion. Good cause exists for granting this Motion because the Sur-Reply and Exhibits 2404, 2410, and 2411 contain information that either Patent Owner JHU’s and/or Petitioner Merck’s Sharp & Dohme LLC (“Merck’s”) has designated as highly confidential. Merck has informed JHU that it does not oppose this Motion to Seal.

The Parties have agreed to, and previously filed, a proposed modified protective order. *See* Paper 37 at 7-9, Appx A. The Parties respectfully request entry of the modified protective order for the reasons previously explained. *Id.*

**I. GOOD CAUSE EXISTS FOR SEALING JHU’S AND 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:

- **Exhibit 2404** – This document is a deposition transcript from the deposition of Merck’s declarant Paul E. Oberstein, M.D., which includes discussion of documents that JHU marked as Highly Confidential during his deposition, one of which is Exhibit 2410 that is subject to this Motion.
- **Exhibit 2410** – This document is the Third Amendment to the Investigator Initiated Clinical Trial Research Agreement between JHU and Merck signed in July-August 2016 that contains Highly Confidential information, including financial information relating to Merck’s payments to JHU.
- **Exhibit 2411** – This document is a deposition transcript of from the deposition of Merck’s declarant Sean D. Sheridan, Ph.D., which includes discussion of Dr. Sheridan’s opinions that rely on Merck’s and third-party IQVIA’s Highly Confidential Information contained in Exhibits 2187 and 2188 discussed in JHU’s October 4, 2024 Motion to Seal. Paper 37 at 3-5.
- **Patent Owner’s Sur-Reply** – JHU’s Sur-Reply contains arguments that reference and cite to Highly Confidential Information contained in various

exhibits of record, including Exhibits 2167-2174, 2181-2182, 2187-2188, 2191, 2404, 2410, and 2411.

Pursuant to the Board's October 4, 2024 email, the Parties will file redacted documents within ten business days of the filing of this motion.¹ See Exhibit 3005.

B. *Argentum* Factors

Regarding *Argentum* factors (1), (2), and (4), Merck provided the following explanation in support of this motion to seal:²

“Dr. Oberstein’s Deposition Transcript: This document is a deposition transcript from the deposition of Merck declarant, Dr. Paul

¹ EX2410 is a five page amendment to an agreement between the Parties.

Substantially the entirety of EX2410 is directed to Highly Confidential Information. JHU therefore requests that Exhibit 2410 remain sealed in its entirety. JHU does not intend to file a public version of this highly sensitive document that would leave any portions of the document unredacted.

² JHU notes that it has offered Merck’s explanation only for the purpose of complying with the requirement for filing a motion to seal. JHU does not concede agreement with the assertions in Merck’s explanations.

Oberstein, which includes the discussion of non-public agreements between Merck and JHU, which JHU indicated should be designated as highly confidential under the protective order during Dr. Oberstein's deposition. The information reflects highly confidential sensitive business information. As such, good cause exists for sealing portions of Dr. Oberstein's deposition transcript."

"Dr. Sheridan's Deposition Transcript: This document is a deposition transcript from the deposition of Merck declarant, Dr. Sean Sheridan, which includes the discussion of Merck's highly confidential sensitive financial information and highly confidential third-party IQVIA data. As such, good cause exists for sealing portions of Dr. Sheridan's deposition transcript.

Argentum factors (1), (2), and (4) also support JHU's Motion to seal Exhibit 2410.³ As noted above, this document contains JHU's Highly Confidential Information and it should be sealed because it reflects Merck and JHU's sensitive financial information regarding funding information and terms regarding Merck's payments to JHU to fund a portion of JHU's clinical trial identified in EX1005, the MSI-H Study Record ("MSR") that is a document that forms the basis for all of the anticipation and obviousness grounds identified in Merck's Petition. 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 confidential and sensitive financial information. The public's interest in maintaining a complete and understandable record is balanced by the forthcoming submission of a redacted version of JHU's Sur-Reply.

³ Merck provided the following statement: "Merck does not oppose this motion, but maintains that JHU's submission of Exhibit 2410 with its sur-reply is improper." JHU disagrees with Merck's position regarding Exhibit 2410, but submits that the parties' dispute over Exhibit 2410 is not properly addressed in the context of this Motion to Seal.

Regarding *Argentum* factor (3)⁴, JHU has a genuine need to rely in this trial on the information sought to be sealed. JHU relies on this information in the Sur-Reply, 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, “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.” Paper 32, 5.

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

II. CONCLUSION

JHU respectfully requests that the Board seal and protect Exhibits 2404, 2410, 2411, and a confidential version of the Patent Owner’s Sur-Reply.

⁴ While Merck does not oppose this motion, Merck indicates that it disagrees with JHU’s arguments with respect to *Argentum* factor (3).

Respectfully submitted,

Dated: February 28, 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 February 28, 2025, a complete and entire copy of this Motion to Seal Sur-Reply and Accompanying Exhibits 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)
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