Filed on behalf of: Janssen Biotech, Inc.

Entered: May 27, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACCORD BIOPHARMA, INC., INTAS PHARMACEUTICALS LTD., AND BIO-THERA SOLUTIONS, LTD.,
Petitioner,

v.

JANSSEN BIOTECH, INC.,
Patent Owner.

IPR2026-00259
Patent No. 12,291,566

PATENT OWNER JANSSEN BIOTECH, INC.'S MOTION TO FILE DOCUMENTS UNDER SEAL AND FOR A PROTECTIVE ORDER

I. INTRODUCTION

Pursuant to 37 C.F.R. §§ 42.14 and 42.54, Patent Owner Janssen Biotech, Inc. ("Janssen") respectfully requests the Board authorize the filing under seal of the Patent Owner Discretionary Denial Brief and Exhibits 2500, 2501, and 2502 (collectively, the "Confidential Exhibits"). In addition, Janssen respectfully requests the Board enter the Proposed Protective Order, a copy of which is filed herewith as Exhibit 2005.

A redline comparison of the Proposed Protective Order and the Default Protective Order is also filed concurrently as Exhibit 2006. *See* U.S. Pat. & Trademark Off., Patent Trial and Appeal Board Consolidated Trial Practice Guide 91 (Nov. 2019) ("Consolidated Trial Practice Guide") ("If the parties choose to propose a protective order deviating from the default protective order, they must submit the proposed protective order jointly along with a marked-up comparison of the proposed and default protective orders showing the differences between the two and explain why good cause exists to deviate from the default protective order.").

The Patent Owner Discretionary Denial Brief and Confidential Exhibits contain Janssen's confidential information that Janssen designates as HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL under the Proposed Protective Order. *See* Ex. 2005 (Proposed Protective Order). The Patent Owner Discretionary Denial Brief and Confidential Exhibits Janssen seeks to seal include

confidential technical and financial information, including financial data, manufacturing data, business strategy, and business plans. This information relates to the core of Janssen's business. Public disclosure of this information would significantly harm Janssen's competitive positions because it would allow competitors to access sensitive technical and business information.

Janssen respectfully submits that the status of the parties as competitors; the wide acceptance of the fact that highly sensitive and confidential technical information should be afforded protections from disclosure; and the confidential nature of the information that is the subject of the Proposed Protective Order all weigh strongly in favor of granting this motion.

As shown below, good cause supports this motion.

II. GOOD CAUSE SUPPORTS ENTRY OF THE PROTECTIVE ORDER

Good cause supports entry of the Proposed Protective Order. The Patent Owner Discretionary Denial Brief relies on information that Janssen treats as highly sensitive, including trade secrets and other confidential research, development, and business information. Janssen has designated this and similar information as "HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL" in a related district court case.

There is good cause to deviate from the Default Protective Order. As shown in Exhibit 2006, the proposed deviations from the Default Protective Order:

1) identify two levels of protective order information, including PROTECTIVE ORDER MATERIAL and HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL; 2) provide requirements for designating categories of discovery material as PROTECTIVE ORDER MATERIAL or HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL; 3) establish that information revealed during a deposition must be treated as HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL for at least 30 days; 4) specify the individuals that may access HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL including limiting access by in-house counsel to two designated in-house counsel; 5) provide a procedure for identifying designated in-house counsel; 6) specify expert disclosure requirements regarding access to HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL; 7) require that outside counsel must maintain Acknowledgments for a year after termination of this proceeding; 8) limit use of PROTECTIVE ORDER MATERIAL and HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL to this proceeding; 9) specify conditions for using artificial intelligence ("AI"); 10) provide a procedure in the event of inadvertent disclosure of protective order material; and 11) specify the scope of documents that must be returned or destroyed after termination of the proceeding. These changes are intended to match the already-entered protective order between the parties in the district court case.

A. Good cause exists to include two levels of protective order material

The Default Protective Order allows all in-house counsel of a party to access protective order material from the other party. In the related district court case, HIGHLY CONFIDENTIAL – ATTORNEY EYES ONLY MATERIAL information may only be accessed by two designated in-house counsel for each party. Good cause supports continuing this restriction in this IPR proceeding because the confidential information filed or likely to be filed in this proceeding is, at least in part, information previously produced in the district court case and/or relates to company financials and other sensitive business information. The parties, which are competitors represented by qualified outside counsel, do not significantly benefit in this proceeding from allowing more than two in-house counsel access to such information.

Additional deviations in the Proposed Protective Order related to facilitating two levels of protective order material guarantee efficient discovery in this proceeding. Such deviations include requirements for marking confidential information, automatic treatment of confidential information disclosed during deposition, identification of designated in-house counsel, expert disclosure requirements, a requirement to maintain a record of all Acknowledgments, and use of such materials. Currently, the parties are conducting discovery in the district court

case under these terms. A departure from these terms in this proceeding would disturb the parties' norms and expectations established in the district court case.

B. Good cause exists for the other proposed deviations to the Default Protective Order

Janssen seeks to establish requirements to use AI without inadvertently disclosing confidential information. Ex 2005 ¶¶ 11-13. Good cause supports this addition because the provisions will enable the parties to benefit from the efficiencies associated with AI without risking disclosure of confidential information.

Janssen further seeks to make explicit the procedure for recovering inadvertently disclosed material subject to attorney-client privilege or the work-product immunity, or any other privilege or immunity. Ex. 2005 ¶ 16. Good cause supports this addition because inadvertent disclosure of privileged materials in this proceeding may cause the producing party to waive privilege to those materials in all other proceedings. The provision will help to avoid disputes among the parties in this proceeding because the parties previously agreed to the provision in the district court case.

Janssen also seeks to make explicit the documents that must be returned or destroyed after termination of this proceeding. Ex. 2005 ¶ 17. Good cause supports this addition because it will reduce the burden on the parties post-proceeding and reduce expenses associated with document return or destruction.

C. Petitioners' position regarding the Proposed Protective Order

Janssen certifies that it has conferred with Petitioners regarding the Proposed Protective Order. Petitioners have stated that they oppose the Proposed Protective Order (Ex. 2005), but consent to the Board's Default Protective Order. Janssen reserves the right to file a reply in response to any opposition Petitioners may file to the instant Motion.

III. GOOD CAUSE EXISTS TO SEAL THE CONFIDENTIAL EXHIBITS

The Trial Practice Guide provides that "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." Consolidated Trial Practice Guide 19. Further, the rules "identify confidential information in a manner consistent with Fed. R. Civ. P. 26(c)(1)(G), which provides for protective orders for trade secret or other confidential research, development, or commercial information." *Id.* (citing 37 C.F.R. § 42.54).

Here, good cause exists to allow Janssen to file the Patent Owner Discretionary Denial Brief and Confidential Exhibits under seal. As described in more detail below, the information in these materials that Janssen seeks to seal falls into two general categories: 1) non-public financial and business information related to clinical trials and patient support programs for Simponi and Simponi Aria; and 2) non-public financial and business information related to Janssen's manufacturing of

Simponi and Simponi Aria. As explained in detail for each exhibit below, good cause exists to seal the Confidential Exhibits, as each contains highly sensitive, non-public, commercial information, disclosure of which would create an elevated risk of commercial harm to Janssen and cause a chilling effect on biologics innovation.

In order to strike the appropriate balance and ensure that only truly confidential information is being sealed, Janssen provides the following detailed descriptions of the information in the Patent Owner Discretionary Denial Brief and the Confidential Exhibits that it seeks to seal; identifies the portions of each that it seeks to seal; and explains why the Board should seal these specific portions.

A. Patent Owner Discretionary Denial Brief and the Confidential Exhibits

Janssen requests that the Board seal the Patent Owner Discretionary Denial Brief and Exhibits 2500, 2501, and 2502 which contain references to Janssen's confidential, non-public business information. The Patent Owner Discretionary Denial Brief provides an analysis of Janssen's strong settled expectations in the '566 patent and its investment into U.S. biologic research and development, technology, and manufacturing. Exhibit 2500 is a declaration of Janssen's employee that similarly provides a description of Janssen's U.S. biologic manufacturing research and development, technology, and manufacturing. Exhibit 2501 is a declaration of Janssen's employee that describes Janssen's investment into the development of Simponi and Simponi Aria including clinical trials and regulatory approvals. Exhibit

2502 is a declaration of Janssen's employee that describes Janssen's investment into the marketing and commercialization of Simponi and Simponi Aria including patient support programs.

The Board should seal the information in the Patent Owner Discretionary Denial Brief and Exhibits 2500, 2501, and 2502 for several reasons. First, these materials include non-public, confidential information that is highly sensitive to Janssen. For example, the financial information contained in these materials includes Janssen's development, manufacturing, marketing, and commercialization of Simponi and Simponi Aria and other biologics. Public disclosure of the financial information contained in these materials would cause Janssen serious competitive harm by, for example, providing competitors with a strategic and unfair advantage. Additionally, these materials contain business information, including business plans and strategy related to manufacturing from which Janssen derives value, in part, because such information is not publicly available. Public disclosure of Janssen's business plans and strategy could cause serious competitive harm, jeopardize on-going negotiations, and derail transactions.

IV. CONCLUSION

For the foregoing reasons, Janssen respectfully requests the Board grant this motion, seal the Patent Owner Discretionary Denial Brief and Confidential Exhibits, and enter the Proposed Protective Order filed as Exhibit 2005.

Respectfully submitted,

Dated: May 27, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 27th day of May 2026, a copy of **Patent Owner Janssen Biotech, Inc.'s Motion To File Documents Under Seal And For A Protective Order** was served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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