Filed on behalf of: Janssen Biotech, Inc.

Entered: July 10, 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.

IPR2026-00256
Patent No. 11,014,982

PATENT OWNER'S REPLY TO PETITIONERS' OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

For the reasons set forth in Patent Owner's Brief on Discretionary Denial (Paper 10, "DD Br."), Patent Owner Janssen Biotech, Inc. ("Janssen") respectfully submits that there are ample reasons supporting denial of the Petition filed by Accord BioPharma, Inc. ("Accord"), Intas Pharmaceuticals Ltd. ("Intas"), and Bio-Thera Solutions, Ltd. ("Bio-Thera") (collectively, "Petitioners"). Petitioners' Opposition (Paper 13, "DD Opp.") does not change that conclusion. As relevant to the authorized Reply issues, two independent bases support denial. Ex. 3101.

First, Janssen's brief showed that the Chinese government controls, or at a minimum has the ability to control, this IPR. Petitioners' arguments to the contrary fall far short of meeting their burden to show a foreign government is not a real-party-in-interest ("RPI"). This alone compels denial under 35 U.S.C. § 311(a) and as a matter of discretion.

Second, Janssen's substantial investments in domestic manufacturing, including investments directly related to the relevant product SIMPONI ARIA®, are not outweighed by Accord's unrelated domestic investments. Petitioners do not deny their biosimilar product, BAT2506, will be exclusively manufactured overseas. Nor do Petitioners identify any BAT2506-related domestic manufacturing activity or investments. This consideration weighs strongly in favor of denial of institution.

I. PETITIONERS FAIL TO CARRY THEIR BURDEN ON RPI

The Petition should be denied because the Chinese government at a minimum

has the ability to control Bio-Thera and this IPR. This issue alone is dispositive.

Janssen's brief presented evidence and argument "sufficient to put into dispute whether the Petition identified all RPIs and whether there is an RPI who is not a person eligible to file an IPR." *Tianma Microelectronics Co. v. LG Display Co.*, IPR2025-01579, Paper 12 at 9 (P.T.A.B. Mar. 18, 2026) (precedential) (cleaned up). In particular, Janssen showed that the Chinese government is an RPI in this matter because it can control a major Bio-Thera shareholder and thus has the ability to control Bio-Thera. DD Br. 7-8. With the RPI identification in dispute, it is (and remains) Petitioners' burden to demonstrate all RPIs were named, and that the Chinese government does not have the ability to control the IPR. *Tianma,* IPR2025-01579, Paper 12 at 9-10. Petitioners failed to carry their burden.

First, Petitioners' self-serving declaration asserting that Accord "controls this IPR" (Ex. 1053 ¶5) cannot meet Petitioners' burden. *Id.* at 10 (conclusory, unsupported declaration "insufficient to rebut Patent Owner's credible arguments that Petitioner failed to name all RPIs."). No evidence from Bio-Thera or Intas supports this claim, and Accord does not address the critical question of a foreign sovereign's *ability* to control the IPR. *See Sun Pharms. Indus., Inc. v. Biofrontera Inc.*, PGR2026-00021, Paper 12 at 2 (P.T.A.B. May 19, 2026) ("RPIs … include entities that have the *ability* to control the proceeding.").

Second, Petitioners' argument that No. 3 Venture Capital Partnership ("No.

3") is not "state-owned" (DD Opp. 18) is irrelevant to the question of whether the Chinese government has the ability to control No. 3, and through No. 3, Bio-Thera and this IPR. *Tianma*, IPR2025-01579, Paper 12 at 7. On the pertinent question of ability to control, Petitioners do not dispute Janssen's argument that even a minority government stake affords the Chinese government the ability to control No. 3. DD Br. 7; Ex. 2031, -014. Instead, in a failed attempt to refute Janssen's evidence showing government ownership interest in No. 3—Bio-Thera's publicly available equity structure (which was taken from the same source as Petitioners' own Ex. 1104)—Petitioners' sole affirmative submission is a "confirmation letter from the No. 3 Venture Capital Partnership." DD Opp. 18. But the "confirmation letter" fails to qualify as admissible evidence under 37 C.F.R. § 42.63(a). At best, the "confirmation letter" is an affidavit or declaration, but utterly fails to conform with applicable rules: Ex. 1103 does not identify the affiant/declarant; it is unsigned; it is not sworn under penalty of perjury; and it is not dated. Ex. 1103; 28 U.S.C. § 1746; *see also* 37 C.F.R. §§ 1.68, 42.2; 42.53. Because it does not constitute evidence, Ex. 1103 is owed little or no weight, and cannot fulfill Petitioners' burden.

Even if Ex. 1103 were valid evidence, it does not carry Petitioners' burden. Ex. 1103 narrowly limits the term "state-owned shareholder" to only 50% or more government ownership (Ex. 1103, ¶ 6), which does nothing to disprove that the Chinese government has the ***ability*** to control No. 3, and therefore Bio-Thera and

this IPR. And Ex. 1103, like Bio-Thera's corporate annual reports, only states that No. 3 is not a "state-owned shareholder," without ever addressing whether the Chinese government has the *ability* to control No. 3 through its equity structure. Ex. 1103, ¶ 6; Ex. 2015, Ex. 2017, Ex. 2019, Ex. 2021, Ex. 2023. Indeed, Petitioners' briefing and evidence simply do not address the pertinent question of a foreign government's ability to control. *See* USPTO Trial Practice Guide § I.D.1. And while Petitioners argue that the equity structure in Ex. 1103 does not include Assets Supervision, the chart includes another Chinese government entity, Guangzhou Municipal Finance Bureau, in the same location as Assets Supervision on the equity structure from published reports (with an even greater ownership percentage). *Compare* Ex. 1103, -4 *with* Ex. 2046, -2. Petitioners never explain the discrepancy, nor do they deny that Finance Bureau is a government entity. At a minimum, Petitioners' new evidence demonstrates that there is "opacity in [the] chain of control," further supporting denial. *Tianma*, IPR2025-01579, Paper 12 at 7.

Petitioners have not carried their burden to show that the Chinese government does not have the ability to control the IPR, and institution should be denied.

II. ACCORD'S DOMESTIC INVESTMENT IS IRRELEVANT

Janssen's domestic manufacturing and investments related to Simponi Aria weigh in favor of denial. DD Br. 4-5. Petitioners' arguments focus largely on Accord only, claiming that Accord's "competing manufacturing" somehow

outweighs Janssen's domestic manufacturing, and fully satisfies a "preference for domestic operations." DD Opp. 14. But, as with the RPI issue, Petitioners' arguments are nothing more than a distraction and irrelevant to the issue at hand.

The relevant consideration, as Director Squires' memorandum explicitly set forth, is "the extent to which any products accused of infringement in a parallel proceeding are *manufactured* in the United States or are *related to* investments in American manufacturing operations." Ex. 2034 at 2. Petitioners do not contest BAT2506 is the "relevant product[] … for purposes of" Director Squires' memorandum (*id.* at 3), and do not contest that BAT2506 will be made in China.

Instead, Petitioners distract, and request consideration of Accord's "commercial distribution" and supply chain activities. DD Opp. 14. Distribution is not manufacturing, and it is axiomatic that a product sold in the U.S. will be distributed domestically, regardless of foreign manufacture (which Petitioners concede). Petitioners' arguments do not address the Director's inquiry.

Intas' Udenyca investments are likewise irrelevant. DD Opp. 16-17. Udenyca is a completely unrelated product, and Intas' Udenyca activities are unrelated to BAT2506; Petitioners do not even allege any relevance. Accord's other biosimilar approvals are likewise irrelevant. DD Opp. 17. Janssen is the only party domestically manufacturing the relevant product, and the only party investing billions in related manufacturing operations, which overwhelmingly supports denial.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 10th day of July, 2026, a true and correct copy of the foregoing **Patent Owner's Reply to Petitioners' Opposition to Patent Owner's Request for Discretionary Denial** was served by electronic mail on Petitioners' lead and backup counsel at the following email addresses:

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