

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.

IPR2026-00258
Patent No. 12,122,824

DECLARATION OF LUKE BRENNAN

I, Luke Brennan hereby declare as follows.

1. I am the Finance Manager of Immunology Global R&D and Commercial Strategy, and I have personal knowledge of the facts set forth in this declaration. If called as a witness, I could and would testify competently thereto.

2. Janssen Biotech, Inc. (“Janssen”) is sponsor of the Biologics License Application No. 125289 for SIMPONI[®] and Biologics License Application No. 125433 for SIMPONI ARIA[®]. The active ingredient in both SIMPONI[®] and SIMPONI ARIA[®] is golimumab, an antibody that blocks the inflammatory molecule called tumor necrosis factor alpha (TNF α).

3. Janssen is a Pennsylvania corporation with its principal place of business in Horsham, Pennsylvania.

4. I understand that Accord BioPharma, Inc. and Bio-Thera Solutions, Ltd. (together, “Accord”) have submitted an abbreviated Biologics License Application for biosimilar versions of SIMPONI[®] and SIMPONI ARIA[®]. As biosimilars, Accord’s products will directly compete against SIMPONI[®] and SIMPONI ARIA[®].

5. In developing SIMPONI ARIA[®] to treat ankylosing spondylitis (AS), Janssen spent approximately [REDACTED] conducting the Phase III, GO-

ALIVE trial. The trial included 208 patients, for an approximate per patient investment of [REDACTED]

6. In developing SIMPONI ARIA® to treat active psoriatic arthritis (PsA), Janssen spent approximately [REDACTED] conducting the Phase III, GO-VIBRANT trial. The trial included 480 patients, for an approximate per patient investment of [REDACTED].

7. After approval, Janssen conducted the Phase III study for Pediatric SIMPONI ARIA® study for juvenile idiopathic arthritis, known as the GO-VIVA trial. The GO-VIVA trial supported FDA approval for the juvenile psoriatic arthritis indication of SIMPONI ARIA®. Janssen invested over [REDACTED] to conduct the study. The GO-VIVA trial included 130 patients, for an approximate per patient investment of [REDACTED].

8. Janssen spent approximately [REDACTED] to seek additional regulatory approvals for SIMPONI ARIA® based on the above studies.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Luke Brennan

Electronically signed by: Luke Brennan
Reason: I attest to the accuracy and integrity of this document
Date: May 26, 2026 10:31:09 EDT

Executed on May 26th, 2026, at 10:30AM EST.