Filed on behalf of: Janssen Biotech, Inc.

Entered: September 23, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JANSSEN BIOTECH, INC.,
Patent Owner.

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IPR2026-00258
Patent No. 12,122,824

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**PATENT OWNER'S UPDATED EXHIBIT LIST**

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner respectfully submits the following updated Exhibit List:

| Exhibit | Description |
|---|---|
| 2001 | Prosecution History for U.S. Patent No. 11,041,020 B2 ("'020 Patent PH") (EXCERPT) |
| 2002 | Prosecution History for U.S. Patent No. 12,122,824 B2 ("'824 Patent PH") (EXCERPT) |
| 2003 | U.S. Patent Application Publication No. US 2021/0277104 A1 ("104 Publication") |
| 2004 | RESERVED |
| 2005 | Proposed Protective Order |
| 2006 | Proposed Protective Order Redline |
| 2007–2011 | RESERVED |
| 2012 | Press Release, Johnson & Johnson, Johnson & Johnson to Break Ground on New State-of-The-Art Biologics Facility in North Carolina to Deliver Market-Leading Portfolio of Transformational Therapies (Mar. 21, 2025), https://www.jnj.com/media-center/press-releases/johnson-johnson-to-break-ground-on-new-state-of-the-art-biologics-facility-in-north-carolina-to-deliver-market-leading-portfolio-of-transformational-therapies ("J&J 3/21/2025 Press Release") |

| Exhibit | Description |
|---|---|
| 2013 | Press Release, Johnson & Johnson, Johnson & Johnson Reaches Agreement with U.S. Government to Improve Access to Medicines and Lower Costs for Millions of Americans; Delivers on U.S. Manufacturing and Innovation Investments (Jan. 8, 2026), https://www.jnj.com/media-center/press-releases/johnson-johnson-reaches-agreement-with-u-s-government-to-improve-access-to-medicines-and-lower-costs-for-millions-of-americans-delivers-on-u-s-manufacturing-and-innovation-investments ("J&J 1/8/2026 Press Release") |
| 2014 | FDA, SIMPONI ARIA® (Golimumab) Prescribing Information (revised Apr. 2025), https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI+ARIA-pi.pdf ("SIMPONI ARIA® FDA Label") |
| 2015 | Bio-Thera Solutions, Ltd., 2019 Annual Report (Chinese) |
| 2016 | English Translation and Certificate of Translation of an excerpt of Exhibit 2015 (Bio-Thera Solutions, Ltd., 2019 Annual Report) ("Bio-Thera 2019 Ann. Rep.") |
| 2017 | Bio-Thera Solutions, Ltd., 2020 Annual Report (Chinese) |
| 2018 | English Translation and Certificate of Translation of an excerpt of Exhibit 2017 (Bio-Thera Solutions, Ltd., 2020 Annual Report) ("Bio-Thera 2020 Ann. Rep.") |
| 2019 | Bio-Thera Solutions, Ltd., 2021 Annual Report (Chinese) |
| 2020 | English Translation and Certificate of Translation of an excerpt of Exhibit 2019 (Bio-Thera Solutions, Ltd., 2021 Annual Report) ("Bio-Thera 2021 Ann. Rep.") |
| 2021 | Bio-Thera Solutions, Ltd., 2024 Annual Report (Chinese) |
| 2022 | English Translation and Certificate of Translation of an excerpt of Exhibit 2021 (Bio-Thera Solutions, Ltd., 2024 Annual Report) ("Bio-Thera 2024 Ann. Rep.") |

| Exhibit | Description |
|---|---|
| 2023 | Bio-Thera Solutions, Ltd., 2025 Semi-Annual Report (Chinese) |
| 2024 | English Translation and Certificate of Translation of an excerpt of Exhibit 2023 (Bio-Thera Solutions, Ltd., 2025 Semi-Annual Report) ("Bio-Thera 2025 Semi-Ann. Rep.") |
| 2025 | RESERVED |
| 2026 | Factset Research Systems Inc., FactSet Entity Data Management: Accord BioPharma, Inc. (0TBGSZ-E) - Subsidiary (Apr. 2, 2026) ("Accord Entity Data") |
| 2027 | PitchBook Data, Inc., Intas Pharmaceuticals \| Private Company Profile (Mar. 16, 2026) ("Intas Pharms. Profile") |
| 2028 | Company News, Bio-Thera Solutions, Ltd., Bio-Thera Solutions Announces Further Expansion of Partnership with Intas Pharmaceuticals for BAT2506, a Proposed Biosimilar Referencing Simponi® (Golimumab), Through Exclusive Commercialization and License Agreement in India (Mar. 23, 2026), https://www.bio-thera.com/col_62/1390.html ("Bio-Thera 3/23/2026 News") |
| 2029–2030 | RESERVED |
| 2031 | *The Chinese Government's Evolving Control of The Nonstate Sector: Rep. to Cong. of the U.S.-China Econ. & Sec. Rev. Comm'n*, 117th Cong. 214–239 (Nov. 2021), https://www.uscc.gov/sites/default/files/2021-11/Chapter_2_Section_3--Chinese_Governments_Evolving_Control_of_the_Nonstate_Sector.pdf ("2021 Cong. Rep.") |
| 2032 | RESERVED |

| Exhibit | Description |
|---|---|
| 2033 | Memorandum from the Acting Under Sec'y of Com. for Intell. Prop. & Acting Dir. of the USPTO to Members of the P.T.A.B. (July 31, 2025), https://www.uspto.gov/sites/default/files/documents/aapa_memo_final__signed.pdf ("7/31/2025 Acting Dir. Mem.") |
| 2034 | Memorandum from the Under Sec'y of Com. for Intell. Prop. & Dir. of the USPTO to All P.T.A.B. Users (Mar. 11, 2026), https://www.uspto.gov/sites/default/files/documents/Additional_Discretionary_Institution_Considerations_US_Manufacturing_and_Small_Business_Use_of_AIA_Proceedings.pdf ("3/11/2026 Dir. Mem.") |
| 2035 | RESERVED |
| 2036 | Tomas Gabriel Bas, *Innovative Formulation Strategies for Biosimilars: Trends Focused on Buffer-Free Systems, Safety, Regulatory Alignment, and Intellectual Property Challenges*, 18 PHARMS. 908 (2025) ("Bas (2025)") |
| 2037 | Max Beauroyre, *Clinical-Trial Costing 101: Building a Phase-by-Phase Budget Your Board Will Trust*, ABACUM (June 25, 2025), https://www.abacum.ai/blog/clinical-trial-costing ("Beauroyre (2025)") |
| 2038 | Marc D. Cohen & Edward C. Keystone, *Intravenous Golimumab in Rheumatoid Arthritis*, EXPERT REV. CLINICAL IMMUNOLOGY 1–8 (2014) ("Cohen (2014)") |
| 2039 | RESERVED |
| 2040 | Hirotaka Nonaka, FTO (FREEDOM TO OPERATE) IN THE PHARMACEUTICAL INDUSTRY 16–33 (MIPLC Studies Vol. 34, 1st ed. 2018), https://www.jstor.org/content/oa_chapter_monograph/j.ctv941tn6.5?seq=1 ("Nonaka (2018)") (EXCERPT) |
| 2041–2042 | RESERVED |

| Exhibit | Description |
|---|---|
| 2043 | Qichacha (QCC), Bio-Thera Solutions, Ltd. Enterprise Credit Report (Chinese) |
| 2044 | English Translation and Certificate of Translation of an excerpt of Exhibit 2043 (Qichacha (QCC) Report, Bio-Thera Solutions, Ltd. Enterprise Credit Report Professional Edition, Report No. 1775619203666287 \| Report Verification No.: sq0MJfAi (Apr. 8, 2026, 11:33:51 a.m.)) ("Bio-Thera Credit Rep.") |
| 2045 | Qichacha (QCC), Bio-Thera Solutions, Ltd. Partnership Chart (Chinese) |
| 2046 | English Translation and Certificate of Translation of an excerpt of Exhibit 2045 (Qichacha (QCC) Report, Bio-Thera Solutions Ltd. w-Guangzhou Zhongke Yuechuang No. 3 Venture Capital Partnership (Apr. 8, 2026)) ("Bio-Thera Partnership Rep.") |
| 2047 | Press Release, N.C. Off. of Governor Josh Stein, Governor Stein Announces Johnson & Johnson Will Build Second Major Facility in Wilson County (Jan. 9, 2026), https://governor.nc.gov/news/press-releases/2026/01/09/governor-stein-announcesjohnson-johnson-will-build-second-major-facility-wilson-county ("N.C. Gov. Press Release") |
| 2048 | RESERVED |
| 2049 | Nat'l Inst. of Health, Nat'l Lib. of Med., *History of Changes for Study: NCT02181673, A Study of Golimumab in Participants With Active Psoriatic Arthritis*, ClinicalTrials.gov archive (latest version submitted Dec. 20, 2017), https:/clinicaltrials.gov/ct2/history/NCT02181673?V_30=View#StudyPageTop (last visited Feb. 12, 2020, 15:27) ("NCT02181673 Study History") |

| Exhibit | Description |
|---|---|
| 2050 | Press Release, Accord BioPharma, FDA Approves IMMGOLIS™ (golimumab-sldi) and IMMGOLIS INTRI™ (golimumab-sldi), First Biosimilars to Simponi® (golimumab) and Simponi Aria® (golimumab); Accord BioPharma to Lead U.S. Commercialization (5/18/2026, 12:05 ET), https://www.accordbiopharma.com/news/fda-approves-immgolis-golimumab-sldi-and-immgolis-intri-golimumab-sldi-first-biosimilars-to-simponi-golimumab-and-simponi-aria-golimumab-accord-biopharma-to-lea/ ("Accord 5/18/2026 Press Release") |
| 2051 | Memorandum from the Under Sec'y of Com. for Intell. Prop. & Dir. of the USPTO to All P.T.A.B. Judges (Oct. 28, 2025), https://www.uspto.gov/sites/default/files/documents/Precedential_designation_of_Corning_Optical_Communications_RF_LLC_v._PPC_Broadband_Inc_Memo_-_Dated_10_28_25.pdf ("10/28/2025 Dir. Mem.") |
| 2052 | Eur. Meds. Agency (EMA), Sci. Meds. Health, Comm. for Med. Prods. for Hum. Use (Day 120 Assessment Report, EMA/416184/2014), *Withdrawal Assessment Report: Simponi (golimumab)*, EMEA/H/C/000992/X/0047 (Janssen Biologics B.V., Applicant) (Oct. 24, 2013) |
| 2053 | Ctr. for Drug Evaluation & Rsch., Clinical Pharm. & Biopharmaceutics Rev., Simponi (Golimumab), BLA Appl. No. 125289 (submitted June 24, 2008) (EXCERPTS) |
| 2054 | Declaration of Dr. Nigil Haroon, M.D., Ph.D., M.B.A. in Support of Patent Owner's Preliminary Response ("Haroon") |
| 2055 | *Curriculum Vitae* of Dr. Nigil Haroon |
| 2056 | Press Release, Johnson & Johnson, Janssen Receives Two U.S. FDA Approvals for Simponi Aria® (Golimumab) for the Treatment of Adults With Active Psoriatic Arthritis or Active Ankylosing Spondylitis (Oct. 20, 2017), https://www.jnj.com/media-center/press-releases/janssen-receives-two-us-fda-approvals-for-simponi-aria-golimumab-for-the-treatment-of-adults-with-active-psoriatic-arthritis-or-active-ankylosing-spondylitis |

| Exhibit | Description |
|---|---|
| 2057 | NIH, Nat'l Lib. of Med., Nat'l Ctr. for Biotechnology Info., ClinicalTrials.gov: Search operation, https://clinicaltrials.gov/ (last visited May 3, 2026) |
| 2058 | NIH, Nat'l Lib. of Med., Nat'l Ctr. for Biotechnology Info., ClinicalTrials.gov, *An Efficacy and Safety Study of Golimumab in Participants With Ulcerative Colitis* (Janssen Rsch. & Dev., LLC, ClinicalTrials.gov ID NCT00488774) (updated June 14, 2013), https://clinicaltrials.gov/study/NCT00488774 |
| 2059 | Internet Archive Wayback Machine, Calendar of https:/clinicaltrials.gov/study/NCT02181673, https://web.archive.org/web/20230815000000*/https:/clinicaltrials.gov/study/NCT02181673 (last visited May 21, 2026) |
| 2060 | Internet Archive Wayback Machine, Search of ClinicalTrials.gov studies, https://web.archive.org/web/20151118232332/https://clinicaltrials.gov/ (last visited May 3, 2026) |
| 2061 | FDA, Actemra Prescribing Information (revised Oct. 2013) ("ACTEMRA® (tocilizumab) Label") |
| 2062 | FDA, Remicade Prescribing Information (revised Oct. 2015) ("REMICADE® (infliximab) Label") |
| 2063 | Anthony D. Bai et al., *Intention-To-Treat Analysis May Be More Conservative Than Per Protocol Analysis in Antibiotic Non-Inferiority Trials: A Systematic Review*, 21 BMC MED. RSCH. METHODOLOGY 1–10 (2021) |
| 2064 | B. Bruce & J.F. Fries, *The Health Assessment Questionnaire (HAQ)*, 23 CLINICAL EXPERIMENTAL RHEUMATOLOGY S14 (2005) |
| 2065 | L. Congi & E. Roussou, *Clinical Application of the CASPAR Criteria for Psoriatic Arthritis Compared to Other Existing Criteria*, 28 CLINICAL EXPERIMENTAL RHEUMATOLOGY 304 (2010) |

| Exhibit | Description |
|---|---|
| 2066 | A. Farid et al., *Narrow Band Ultraviolet B Therapy Deactivates Th1/Th17 Pathway and Activates Th2 Cytokines Secretion in Egyptian Psoriatic Arthritis Patients*, 13 J. RADIATION RSCH. APPLIED SCIS. 356 (2020) |
| 2067 | David T. Felson et al., *American College of Rheumatology Preliminary Definition of Improvement in Rheumatoid Arthritis*, 38 ARTHRITIS RHEUMATISM 727 (1995) |
| 2068 | Oliver FitzGerald et al., *Concepts of Pathogenesis in Psoriatic Arthritis: Genotype Determines Clinical Phenotype*, 17 ARTHRITIS RSCH. THERAPY 1–11 (2015) |
| 2069 | FITZPATRICK'S DERMATOLOGY IN GENERAL MEDICINE 427 (Irwin M. Freedberg eds., 6th ed. 2003) |
| 2070 | Mathurin Flamant et al., *Golimumab for the Treatment of Ulcerative Colitis*, 17 EXPERT OP. BIOLOGICAL THERAPY 879 (2017) |
| 2071 | Lars Fugger & Arne Svejgaard, *Association of MHC and Rheumatoid Arthritis HLA-DR4 and Rheumatoid Arthritis: Studies in Mice and Men*, 2 ARTHRITIS RSCH. 208 (2000) |
| 2072 | Dafna D. Gladman, *Effectiveness of Psoriatic Arthritis Therapies*, 33 SEMINARS ARTHRITIS RHEUMATISM 29 (2003) |
| 2073 | D.D. Gladman et al., *Psoriatic Arthritis: Epidemiology, Clinical Features, Course, and Outcome*, 64 ANNALS RHEUMATIC DISEASES ii14 (2005) |
| 2074 | Deepak R. Jadon et al., *Psoriatic Arthritis Mutilans: Characteristics and Natural Radiographic History*, 42 J. RHEUMATOLOGY 1–8 (2015) |
| 2075 | CHARLES A. JANEWAY, JR., ET AL., IMMUNOBIOLOGY-THE IMMUNE SYSTEM IN HEALTH & DISEASE ch. 3-6 (5th ed. 2001), https://www.ncbi.nlm.nih.gov/books/NBK27160/ (EXCERPT) |

| Exhibit | Description |
|---|---|
| 2076 | Arthur Kavanaugh et al., *Treatment of Psoriatic Arthritis in a Phase 3 Randomised, Placebo-Controlled Trial with Apremilast, An Oral Phosphodiesterase 4 Inhibitor*, 73 ANNALS RHEUMATIC DISEASES 1020 (2014) |
| 2077 | Gabrielle H. Kingsley et al., *A Randomized Placebo-Controlled Trial of Methotrexate in Psoriatic Arthritis*, 51 RHEUMATOLOGY 1368 (2012) |
| 2078 | Mayke B.G. Koek et al., *Home Versus Outpatient Ultraviolet B Phototherapy for Mild to Severe Psoriasis: Pragmatic Multicentre Randomised Controlled Non-Inferiority Trial (PLUTO Study)*, 338 BRIT. MED. J. 1–11 (2009) |
| 2079 | Monalyn Labitigan et al., *Higher Rates and Clustering of Abnormal Lipids, Obesity, and Diabetes in Psoriatic Arthritis Compared with Rheumatoid Arthritis*, 66 ARTHRITIS CARE RSCH. 600 [1–16] (2014) |
| 2080 | R.J. Lories & D.L.P. Baeten, *Differences in Pathophysiology Between Rheumatoid Arthritis and Ankylosing Spondylitis*, 27 CLINICAL EXPERIMENTAL RHEUMATOLOGY S10 (2009) |
| 2081 | Iain B. McInnes et al., *Secukinumab, a Human Anti-Interleukin-17A Monoclonal Antibody, in Patients with Psoriatic Arthritis (FUTURE 2): A Randomised, Double-Blind, Placebo-Controlled, Phase 3 Trial*, S0140-6736(15)61134-5 LANCET 1–10 (2015) |
| 2082 | Philip J. Mease et al., *Etanercept Treatment of Psoriatic Arthritis – Safety, Efficacy, and Effect on Disease Progression*, 50 ARTHRITIS RHEUMATISM 2264 (2004) |
| 2083 | Philip J. Mease, *Is There a Role for Rituximab in the Treatment of Spondyloarthritis and Psoriatic Arthritis?*, 39 J. RHEUMATOLOGY 2235 (2012) |
| 2084 | D.R. Mould & R.N. Upton, *Basic Concepts in Population Modeling, Simulation, and Model-Based Drug Development—Part 2: Introduction to Pharmacokinetic Modeling Methods*, 2 CPT: PHARMACOMETRICS SYS. PHARMACOLOGY 1–14 (2013) |

| Exhibit | Description |
|---|---|
| 2085 | Philip Ian Murray & Saaeha Rauz, *The Eye and Inflammatory Rheumatic Diseases: The Eye and Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis*, 30 BEST PRAC. RSCH. CLINICAL RHEUMATOLOGY 802 (2016) |
| 2086 | Makoto Naganuma et al., *Recent Trends and Future Directions for the Medical Treatment of Ulcerative Colitis*, 9 CLINICAL J. GASTROENTEROLOGY 329 (2016) |
| 2087 | Masatsugu Ono et al., *Structural Basis for Tumor Necrosis Factor Blockade with the Therapeutic Antibody Golimumab*, 27 PROTEIN SCI. 1038 (2018) |
| 2088 | Eric M. Ruderman, *The Role of Concomitant Methotrexate in Biologic Therapy for Rheumatoid Arthritis*, 71 BULL. HOSP. JOINT DISEASES S29 (2013) |
| 2089 | P. Rutgeerts et al., *Randomised Clinical Trial: A Placebo-Controlled Study of Intravenous Golimumab Induction Therapy for Ulcerative Colitis*, 42 ALIMENTARY PHARMACOLOGY THERAPEUTICS 504 (2015) ("Rutgeerts 2015") |
| 2090 | P. Rutgeerts et al., *Supplemental Appendix* (2015) ("Rutgeerts App'x") |
| 2091 | Georg Schett et al., *Structural Damage in Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis: Traditional Views, Novel Insights Gained From TNF Blockade, and Concepts for the Future*, 13 ARTHRITIS RSCH. THERAPY S4 (2011) |
| 2092 | Georg Schett et al., *Oral Apremilast in the Treatment of Active Psoriatic Arthritis – Results of a Multicenter, Randomized, Double-Blind, Placebo-Controlled Study*, 64 ARTHRITIS RHEUMATISM 3156 (2012) |
| 2093 | Calen A. Steiner et al., *Anti-TNF Biologic Therapies Other Than Infliximab* in PEDIATRIC INFLAMMATORY BOWEL DISEASE 401 (P. Mamula et al. eds., 2017) |

| Exhibit | Description |
|---|---|
| 2094 | William Taylor et al., *Classification Criteria for Psoriatic Arthritis – Development of New Criteria From a Large International Study*, 54 ARTHRITIS RHEUMATISM 2665 (2006) |
| 2095 | Bella Ungar & Uri Kopylov, *Advances in the Development of New Biologics in Inflammatory Bowel Disease*, 29 ANNALS GASTROENTEROLOGY 243 (2016) |
| 2096 | R.N. Upton & D.R. Mould, *Basic Concepts in Population Modeling, Simulation, and Model-Based Drug Development: Part 3—Introduction to Pharmacodynamic Modeling Methods*, 3 CPT: PHARMACOMETRICS SYS. PHARMACOLOGY 1–16 (2014) |
| 2097 | Désirée van der Heijde et al., *Psoriatic Arthritis Imaging: A Review of Scoring Methods*, 64 ANNALS RHEUMATIC DISEASES ii61 (2005) |
| 2098 | Karin A. van Schie et al., *Therapeutic TNF Inhibitors Can Differentially Stabilize Trimeric TNF by Inhibiting Monomer Exchange*, 6 NATURE SCI. REPS. 1–10 (2016) |
| 2099 | Ronald F. van Vollenhoven, *Sex Differences in Rheumatoid Arthritis: More Than Meets the Eye...*, 7 BIOMED CENT. MED. 1–4 (2009) |
| 2100 | J.E. WARE & M. KOSINSKI, SF-36 PHYSICAL & MENTAL HEALTH SUMMARY SCALES: A MANUAL FOR USERS OF VERSION 1 (2d ed. 1994) (EXCERPTS) |
| 2101 | Michael E. Weinblatt, *Methotrexate in Rheumatoid Arthritis: A Quarter Century of Development*, 124 TRANSACTIONS AM. CLINICAL CLIMATOLOGICAL ASS'N 16 (2013) |
| 2102-2123 | RESERVED |
| 2124 | Declaration of Roger J. Chin Pursuant to 37 C.F.R. § 42.10(c)(2) |
| 2125 | Declaration of Kevin N. Zhang in Support of Patent Owner's Unopposed Motion for *Pro Hac Vice* Admission Under 37 C.F.R. § 42.10(c)(1) |

| Exhibit | Description |
|---|---|
| 2126–2499 | RESERVED |
| 2500 | Declaration of Ann Donlon ("Donlon Decl.") (HC-AEO MATERIAL AND REDACTED VERSIONS) |
| 2501 | Declaration of Luke Brennan ("Brennan Decl.") (HC-AEO MATERIAL AND REDACTED VERSIONS) |
| 2502 | Declaration of Thao Marzullo ("Marzullo Decl.") (HC-AEO MATERIAL AND REDACTED VERSIONS) |

Respectfully submitted,

Dated: September 23, 2026

By: / Raghav Bajaj /

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*Counsel for Patent Owner*
*Janssen Biotech, Inc.*

**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 23rd day of September, 2026, a true and correct copy of the foregoing **Patent Owner's Updated Exhibit List and Exhibit 2124-2125** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

Lora M. Green (Reg. No. 43,541)
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Keith A. Zullow (Reg. No. 37,975)
Michael Cottler (Reg. No. 79,455)
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