

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.
Petitioner

v.

POGONA, LLC
Patent Owner

Case IPR2026-00189
U.S. Patent No. 11,058,757

**PETITIONER PFIZER INC.'S OBJECTIONS TO
PATENT OWNER'S EVIDENCE**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Pfizer Inc. (“Pfizer”) objects as follows to the admissibility of evidence filed and served by Patent Owner Pogona, LLC with its Patent Owner Response.

Pfizer maintains its original objection that Exhibits 2001 through 2005 cited in Patent Owner’s Updated Exhibit List (Paper 25) do not correspond to Exhibits 2001 through 2005 cited in Patent Owner’s Discretionary Denial Brief (Paper 9). *See* Paper 17 (Petitioner Pfizer Inc.’s Objections To Patent Owner’s Preliminary Evidence). The documents identified as Exhibits 2001 through 2005 in the Updated Exhibit List were never filed with or submitted to the Board and are therefore not part of the evidentiary record in this proceeding. Because these documents were never served on Pfizer or made of record before the Board, they cannot properly be considered evidence in this proceeding and are irrelevant for all purposes. *See* 37 C.F.R. 42.63(a), (e).

Exhibit	Objections
Ex. 2018 – Declaration of Dr. George G. Zhanel, Ph.D. in Support of Patent Owner's Response	Federal Rules of Evidence (“FRE”) 106, 402, and 403: The testimony offered in at least paragraphs 52-55, 59-64, 66-69, 72-73, 77, 79, 81-86, 90-92, 139-40, and 150 is misleading, incomplete, and irrelevant, including because the testimony offered lacks support. Therefore, the proffered testimony’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

	FRE 402: For each paragraph not cited in Patent Owner’s Response, the exhibit is not relevant to any ground upon which trial was instituted. FRE 702 and 703: The testimony offered in at least paragraphs 52-55, 59-64, 66-69, 72-73, 77, 79, 81-86, 90-92, 139-40, and 150 is not based on sufficient facts or data. FRE 802: To the extent any paragraph relies on any exhibit that contains impermissible hearsay and it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay. Right to Cross-Examine: Petitioner reserves the right to cross-examine the declarant under 37 CFR § 42.53 or else move to exclude the exhibit as hearsay.
Ex. 2020 – Declaration of Dr. Louis J. Defilippi, Ph.D. in Support of Patent Owner's Response	FRE 106, 402, and 403: The testimony offered in at least paragraphs 51, 58, 68, 76, and 84 is misleading, incomplete, and irrelevant, including because the testimony offered lacks support. Therefore, the proffered testimony’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 402: For each paragraph not cited in Patent Owner’s Response, the exhibit is not relevant to any ground upon which trial was instituted.

	FRE 702 and 703: The testimony offered in at least paragraphs 51, 58, 68, 76, and 84 is not based on sufficient facts or data. FRE 802: To the extent any paragraph relies on any exhibit that contains impermissible hearsay and it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay. Right to Cross-Examine: Petitioner reserves the right to cross-examine the declarant under 37 CFR § 42.53 or else move to exclude the exhibit as hearsay.
Ex. 2022 – Deposition Transcript of Luwy K. Musey, M.D., taken July 23, 2026	FRE 106: The exhibit is an incomplete and/or inaccurate transcript because the transcript does not include any forthcoming errata sheet. To the extent the witness submits an errata sheet, it must in fairness be considered at the same time as the exhibit.
Ex. 2023 – Feikin et al., <i>Serotype-Specific Changes in Invasive Pneumococcal Disease after Pneumococcal Conjugate Vaccine Introduction: A Pooled Analysis of Multiple Surveillance Sites</i> , PLOS Medicine (2013)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2024 – Supporting Information for Feikin et al., <i>Serotype-Specific Changes in Invasive Pneumococcal Disease after Pneumococcal Conjugate Vaccine Introduction: A Pooled</i>	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

<i>Analysis of Multiple Surveillance Sites</i>, PLOS Medicine (2013)	FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay. FRE 901: Patent Owner has not produced evidence sufficient to support a finding that the exhibit is what Patent Owner claims it is. Patent Owner has not established when, where, and how the exhibit was published.
Ex. 2025 – Imöhl et al., <i>Pneumococcal Meningitis and Vaccine Effects in the Era of Conjugate Vaccination: Results of 20 Years of Nationwide Surveillance in Germany</i>, BMC Infectious Diseases (2015)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2026 – Chiang et al., <i>National Surveillance of Invasive Pneumococcal Diseases in Taiwan, 2008- 2012: Differential Temporal Emergence of Serotype 19A</i>, Vaccine 32 (2014)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2027 – Olarte et al., <i>Impact of the 13-Valent Pneumococcal Conjugate Vaccine on Pneumococcal Meningitis in US Children</i>, Clinical Infectious Diseases (2015)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

	FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2028 – Jin et al., <i>Using a Practical Molecular Capsular Serotype Prediction Strategy to Investigate Streptococcus pneumoniae Serotype Distribution and Antimicrobial Resistance in Chinese Local Hospitalized Children</i> , BMC Pediatrics (2016)	FRE 401 and 402: The exhibit is not relevant to any ground upon which trial was instituted because it post-dates the priority date of U.S. Patent No. 11,058,757. FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2029 – Steens et al., <i>A Review of the Evidence to Inform Pneumococcal Vaccine Recommendations for Risk Groups Aged 2 Years and Older</i> , Epidemiol. Infect. (2014)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2030 – Centers for Disease Control & Prevention, <i>Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)</i> , Morbidity and Mortality Weekly Report (2010)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

	FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2031 – Tomczyk et al., <i>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Recommendations of the Advisory Committee on Immunization Practices (ACIP)</i> , Morbidity and Mortality Weekly Report (2014)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2032 – Marsh et al., <i>Molecular Characterisation of Pneumococcal Serotype 16F: Established Predominant Carriage and Otitis Media Serotype in the 7vPCV Era</i> , Vaccine 25 (2007)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2033 – Andrews et al., <i>Serotype-Specific Effectiveness and Correlates of Protection for the 13-Valent Pneumococcal Conjugate Vaccine: A Postlicensure Indirect Cohort Study</i> , Lancet Infectious Diseases (2014)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2034 – Rajam et al., <i>Functional Antibodies to the O-Acetylated Pneumococcal</i>	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the

<i>Serotype 15B Capsular Polysaccharide Have Low Cross-Reactivities with Serotype 15C, Clinical and Vaccine Immunology</i> (Sept. 2007)	danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2035 – H. Findlow & R. Borrow, <i>Interactions of Conjugate Vaccines and Co-Administered Vaccines, Human Vaccines & Immunotherapeutics</i> (2016)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2036 – Park et al., <i>Discovery of a New Capsular Serotype (6C) within Serogroup 6 of Streptococcus pneumoniae</i>, <i>Journal of Clinical Microbiology</i> (2007)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2037 – Cooper et al., <i>The 13-Valent Pneumococcal Conjugate Vaccine (PCV13) Elicits Cross-Functional Opsonophagocytic Killing Responses in Humans to Streptococcus pneumoniae Serotypes 6C and 7A</i>, <i>Vaccine</i> 29 (2011)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.

Ex. 2038 – Metcalf et al., <i>Strain Features and Distributions in Pneumococci from Children with Invasive Disease Before and After 13-Valent Conjugate Vaccine Implementation in the USA</i>, Clinical Microbiology and Infection (2016)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2039 – Diao et al., <i>Efficacy of 23-Valent Pneumococcal Polysaccharide Vaccine in Preventing Community-Acquired Pneumonia Among Immunocompetent Adults: A Systematic Review and Meta-Analysis of Randomized Trials</i>, Vaccine 34 (2016)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2040 – Lamontagne et al., <i>Pneumococcal Vaccination and Risk of Myocardial Infarction</i>, Canadian Medical Association Journal (2008)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2041 – Vila-Corcoles et al., <i>Clinical Effectiveness of Pneumococcal Vaccination Against Acute Myocardial Infarction and Stroke in People Over 60 Years: The CAPAMIS</i>	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

<i>Study, One-Year Follow-Up</i> , BMC Public Health (2012)	FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2042 – Choi et al., <i>Capsular Polysaccharide (CPS) Release by Serotype 3 Pneumococcal Strains Reduces the Protective Effect of Anti-Type 3 CPS Antibodies</i> , Clinical and Vaccine Immunology (2016)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2043 – Pichichero et al., <i>Next Generation Protein Based Streptococcus pneumoniae Vaccines</i> , Human Vaccines & Immunotherapeutics (2016)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2044 – Feldman & Anderson, <i>Review: Current and New Generation Pneumococcal Vaccines</i> , Journal of Infection (2014)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2045 – Jason W. Rosch, <i>Promises and Pitfalls of Live</i>	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was

<i>Attenuated Pneumococcal Vaccines</i>, Human Vaccines & Immunotherapeutics (2014)	instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2046 – Leroux-Roels et al., <i>Safety, Reactogenicity and Immunogenicity of a Novel Pneumococcal Protein-Based Vaccine in Adults: A Phase I/II Randomized Clinical Study</i>, Vaccine 32 (2014)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2047 – Rudolph et al., <i>Epidemiology of Pneumococcal Serotype 6A and 6C Among Invasive and Carriage Isolates from Alaska, 1986-2009</i>, Diagnostic Microbiology and Infectious Disease (2013)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.
Ex. 2048 – Jessie A. Key, <i>Factors that Affect the Rate of Reactions</i>, Introductory Chemistry - 1st Canadian Edition (2014)	FRE 106: The exhibit is an incomplete excerpt of a longer document. FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

	FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay. FRE 901: Patent Owner has not produced evidence sufficient to support a finding that the exhibit is what Patent Owner claims it is. Patent Owner has not established when, where, and how the exhibit was published.
Ex. 2049 – <i>Classification of Variables in Chemical Process Control</i> (CHEMICAL ADDA, Feb. 22, 2016)	FRE 403: The exhibit’s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. FRE 802: To the extent it is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay. FRE 901: Patent Owner has not produced evidence sufficient to support a finding that the exhibit is what Patent Owner claims it is. Patent Owner has not established when, where, and how the exhibit was published.

Dated: August 11, 2026

Respectfully submitted,
By: /David M. Krinsky/
David M. Krinsky (Reg. No. 72,339)
Williams & Connolly LLP
680 Maine Avenue, S.W.
Washington, D.C. 20024
Phone: 202-434-5338
Fax: 202-434-5029
Email: dkrinsky@wc.com
Counsel for Petitioner Pfizer Inc.

CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2026, I caused a true and correct copy of the foregoing

- Petitioner Pfizer Inc.'s Objections to Patent Owner's Evidence

to be served on Patent Owner by delivering a copy via electronic mail to the following individuals at the email address below:

Sarah E. Spires (Reg. No. 61,501)
Steven W. Hartsell (Reg. No. 58,788)
Ryan A. Hargrave (*Pro Hac Vice application to be submitted*)
SKIERMONT DERBY LLP
1601 Elm Street, Suite 4400
Dallas, TX 75201
Tel: (214) 978-6600
Fax: (214) 978-6601
Pogona_SDTeam@skiermontderby.com

Dated: August 11, 2026

Respectfully submitted,
By: /David M. Krinsky/
David M. Krinsky (Reg. No. 72,339)
Williams & Connolly LLP
680 Maine Avenue, S.W.
Washington, D.C. 20024
Phone: 202-434-5338
Fax: 202-434-5029
Email: dkrinsky@wc.com
Counsel for Petitioner Pfizer Inc.