

Filed: March 30, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner,

v.

POGONA, LLC
Patent Owner.

Case IPR2026-00221
Patent 11,058,757

**DECLARATION OF BRUCE D. FORREST IN SUPPORT OF
PATENT OWNER'S DISCRETIONARY DENIAL BRIEF**

I, Bruce D. Forrest, hereby declare as follows:

1. My name is Bruce D. Forrest. I am over the age of eighteen (18) and competent to make this Declaration. I have personal knowledge of the facts set forth below and could testify competently to them if asked to do so. I make this Declaration in support of Patent Owner Pogona, LLC's ("Patent Owner") Request for Discretionary Denial.

2. I am the CSO and manager of Patent Owner and the co-inventor of U.S. Patent No. 11,058,757 ("the '757 Patent), the patent at issue in the above-captioned proceeding.

3. In reliance on the '757 Patent, the Patent Owner (or affiliate) has expended an extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval, including:

- 1) Formed Corporate Entities to Develop a Product from the '757 Patent:
 - Liffey Biotech Ltd., Dublin, Ireland
 - Pogona, LLC, Delaware (now wholly owned subsidiary of Aeolian Biotech, LLC)
 - Aeolian Biotech Corp. (now LLC), Delaware
- 2) Hired two Chief Executive Officers:
 - Geno Germano (Liffey Biotech Ltd.)
 - J. Tyler Martin, MD (Aeolian Biotech Corp.)

- 3) License of Serotype 6C Patent from University of Alabama, Birmingham to include in vaccine composition. Fees: \$269,138.92:
- U.S. Patent No. 8,481,054 entitled “Pneumococcal Serotypes,” filed on June 17, 2008, and issued on July 9, 2013.
 - U.S. Patent No. 9,778,266 entitled “Pneumococcal Serotypes,” filed on May 9, 2013, and issued on October 3, 2017.
 - U.S. Patent Application No. 15/723,136 entitled “Pneumococcal Serotypes,” filed on October 2, 2017.
 - Australian Patent No. 2006336520 entitled “Pneumococcal Serotypes,” filed on June 17, 2008, and issued on January 5, 2012.
 - European Patent No. 1976974 entitled “Pneumococcal Serotypes,” filed on June 17, 2008, issued on July 2, 2014, and validated in Denmark, Italy, Sweden, Switzerland, France, Germany, and United Kingdom.
 - Japanese Patent No. 5285431 entitled “Pneumococcal Serotypes,” filed on June 30, 2008, and issued on June 7, 2013.
 - Canadian Patent Application No. 2,635,208 entitled “Pneumococcal Serotypes,” filed on June 25, 2008.
- 4) Legal Fees (Wilson Sonsini Goodrich & Rosati):
- Patent Licensing of UAB Patents: \$101,851.00

- Equity Financing: \$292,270.41
 - General Patent Matters: \$211,324.50
- 5) Legal Fees (Wolf, Greenfield & Sacks, P.C.):
- General Patent Matters: \$209,177.32
- 6) Legal Fees (DLA Piper):
- Review and Negotiation of Financing Proposal: \$33,992.57
- 7) Legal Fees (Strain, PLLC):
- Intellectual Property Strategy: \$25,729.39
- 8) Legal Fees (Cooley, LP):
- General Corporate Legal: \$275,015.46
- 9) Accounting Fees (Moss Adams):
- Accounting: \$26,000.00
- 10) Licensing Meetings, Negotiations, Due Diligence re:
- Sanofi Pasteur, Swiftwater, PA
 - Pfizer, Inc., New York, NY
 - The BIKEN Group (The Research Foundation for Microbial Diseases of Osaka University), Osaka, Japan
 - Daiichi Sankyo Co. Ltd., Tokyo, Japan
 - Takeda, Inc., Tokyo, Japan
 - GlaxoSmithKline Biologicals S.A., Rixensart, Belgium

- Mitsubishi Tanabe Pharma Corporation, Osaka, Japan
- Medicago, Inc., Laval, Quebec, Canada
- Merck & Co., Inc., Rahway, NJ

1. On October 25, 2017, individuals representing Liffey/Vax Ltd. (“Liffey”)—a precursor entity to Pogona—including Geno Germano, Liffey’s CEO, met with individuals at Merck, to discuss Liffey’s development progress and intellectual property related to their expanded coverage PCV. During this meeting, Liffey explained to Merck that they had held a pre-IND meeting with the FDA’s Center for Biologics Evaluation and Research (“CBER”) to obtain feedback on Liffey’s clinical, toxicology, and manufacturing plan for a Phase 1/2 study of an expanded coverage PCV. Liffey explained to Merck that during this pre-IND meeting, CBER agreed with Liffey that there is an unmet medical need for a vaccine containing the most common pneumococcal serotypes causing disease in the U.S. today that are not in Prevnar 13. Liffey also explained to Merck that CBER had approved of Liffey’s early clinical development plan and proposed specifications.

2. During this meeting, Liffey informed Merck of Liffey's Patent Application number PCT/US2017/025621, with a priority date of March 31, 2016, which is the patent application that issued as the '757 patent. In addition to its patent application number, Liffey informed Merck that its patent application 1) covers major contributing serotypes to antimicrobial resistance; (2) covers serotype 20B vaccine composition; and 3) covers polysaccharide structures for serotypes 23A and 23B.
3. Merck did not choose to license Liffey's IP or partner with Liffey following this meeting.
4. Liffey, and its subsequent entities, continued to develop its improved PCV and prosecute the '757 patent.
5. Years later, in 2021, after hearing Dr. Bruce Forrest, inventor of the '757 patent, speak about PCV clinical trials, Merck's Senior Principal Scientist, Dr. Julie Skinner, extended an invitation to Dr. Forrest to participate in an event. In response to this invitation, on February 10, 2021, Dr. Forrest responded in part by stating: "Full disclosure ... I do hold patent applications in the field of expanded

coverage pneumococcal conjugate vaccines, and in a former existence Merck was involved in due diligence on that IP. These are owned in an entity with my business partner, Jack Love, who headed Wyeth's vaccines regulatory affairs organization and secured the regulatory approvals of Prevnar 13, Trumemba, etc. and worked with me previously when I was the global clinical team lead on Prevnar 13."

a. A true and correct copy of this exchange is provided as part of Ex. 2002.

6. Dr. Forrest participated with Dr. Skinner and others on Merck's advisory panel for their next-generation pneumococcal vaccine program, V116.
7. On July 13, 2021, Aeolian's U.S. Patent Number 11,058,757 was granted. After the granting of the '757 patent, Dr. Forrest's company began the process of raising funds to develop a next-generation PCV from his company's IP. Dr. Forrest's company had also been contacted by several firms interested in exploring the company's willingness to consider licensing its IP. As a

result, Dr. Forrest contacted Merck to explore whether Merck had an interest in developing a next-generation PCV composition based on the IP developed by Dr. Forrest and his colleagues.

8. On October 10, 2021, after participating with Dr. Skinner on Merck's advisory panel for their next generation pneumococcal vaccine program, V116, Dr. Forrest again discussed his IPR with Merck's Dr. Skinner, stating: "As I had declared before, I have been developing IP around next generation PCV compositions. ... As you might recall, Merck explored some of this IP back in 2018 where we were looking to [] develop it in Liffey Biotech Limited. ... Since then, the IP is now in Pogona, LLC, and we have one patent now granted in August, expecting the allowance of a second patent this year, and we are beginning the process of generating divisional filing etc. to expand on the original applications and PCT filings. ... My suspicion is that we have shared interests in a truly novel next generation PCV, and if that is so, we would prefer not to be a hindrance to seeing that come to fruition to our mutual benefit. My

preference is for this IP to be with a firm that I know has the wherewithal to see this developed successfully. ... I have attached the issued patent, and additional patent application numbers for the US, Europe and Japan where applicable. ... US Patent Grant: US11058757 Priority Date: 03/31/2016.”

a. A true and correct copy of this exchange is provided as part of Ex. 2002.

9. On October 11, 2021, Dr. Forrest also wrote to Merck’s Stephen de Laszlo, Executive Director Strategic Licensing and Acquisition, similarly stating that “I’d like to explore any interest that Merck might have in the IP that my team and I have developed in the field relating to serotype compositions of pneumococcal conjugate vaccines. As you might recall, Merck explored some of this IP back in 2018 where we were looking to develop it in Liffey Biotech Limited. ... The IP is now in Pogona, LLC, and we have one patent now granted in August, expecting the allowance of a second patent this year, and we are beginning the process of generating divisional filings etc. to expand on the original

applications and PCT filings. ... I have attached the issued patent, and additional patent application numbers for the US, Europe and Japan where applicable. ... US Patent Grant: US11058757 Priority Date: 03/31/2016.”

- a. A true and correct copy of this exchange is provided as Ex. 2003.

10. On October 15, 2021, Merck’s Dr. Skinner wrote that

“[w]e’ve reviewed the Pogona, LLC PCV IP with our IP counsel and do not have any interest in the IP at this time.”

- a. A true and correct copy of this exchange is provided as part of Ex. 2002.

11) Raised Capital Financing: \$2,660,713

12) Consolidated Corporate Entities

- Aeolian Biotech, LLC acquired Pogona, LLC: \$5,000,000 in all stock transaction

13) Hired a Head of Technical Operations: Paul Keith, PhD

14) Made and Performed Preclinical Immunological Evaluation of Select Pneumococcal Serotypes Polysaccharide-Conjugates: \$114,517.42

- Pearl River Laboratories, Pearl River, NY
- University of Nebraska, Nebraska

- Sunfire Biotechnologies, LLC, Birmingham, AL
- 15) Partnering on Vaccine Development and Manufacturing with:
- Inventprise, Inc., Redmond, WA
 - Biological, E Limited, Hyderabad, India
 - PnuVax, Inc., Kingston, ON, Canada
 - Fina Biosolutions, LLC, Rockville, MD
 - Integrated Biotherapeutics, Inc., Rockville, MD
 - EuBiologics Co., Ltd., Seoul, South Korea
 - Wacker Biosolutions, Ann Arbor, MI
- 16) Investor Meetings with:
- CTI Life Sciences, Montreal, Canada
 - Novartis Venture Fund, Basel, Switzerland
 - New Enterprise Associates, New York, NY
 - Fort Worth Investors, Fort Worth, TX
 - CARB-X Grant Funding Application, Boston, MA
 - Paragon Biosciences, LLC, Chicago, IL
 - SR One, Ltd., Redwood City, CA
 - Novo Ventures, Inc., San Francisco, CA
 - Curie.bio, Boston, MA
 - Fortress Biotech, Inc., Waltham, MA

- Baker Bros. Advisors, LP, New York, NY
- Deep Track Capital, Greenwich, CT
- Driehaus Capital Management, LLC, Chicago, IL
- Woodline Partners, San Francisco, CA
- Bioscience Equity Partners, New York, NY
- Cowen, Inc., New York, NY
- Meehan Family Investments Ltd., Vancouver, Canada
- Armastus, Toronto, Canada
- 5am Ventures, LLC, San Francisco, CA
- Samsung Venture Investment Corporation, Menlo Park, CA
- New Oak, New York, NY
- Commodore, New York, NY
- Vivo Capital, Palo Alto, CA

17) Manufacturing Facility Acquisition Due Diligence re:

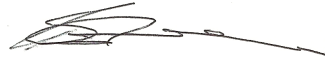
- JN-International Medical Corporation, Omaha, NB

18) FDA Pre-IND Meeting, June 7, 2017

- Successful Type B Pre-IND Meeting with the FDA concerning vaccine requirements for early clinical development and regulatory approval strategy (disclosed to Merck).

Under penalty of perjury, I declare the above statements as true and accurate to the best of my recollection. I further state that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the U.S. Code.

Executed this 27th day of March, 2026.



Bruce D. Forrest