

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

POGONA, LLC,
Patent Owner.

Case No. IPR2026-00221
U.S. Patent No. 11,058,757

**DECLARATION OF HEATHER PLATT, M.D.
IN SUPPORT OF PETITIONER'S OPPOSITION TO PATENT OWNER'S
DISCRETIONARY DENIAL BRIEF**

LIST OF EXHIBITS

Ex. No.	Description
Ex-1064	Heather Platt <i>Curriculum Vitae</i>
Ex-1065	Merck Internal PowerPoint Presentation

I, Heather Platt, hereby declare as follows:

I. INTRODUCTION

1. My name is Heather Platt. I am over the age of eighteen and competent to make this Declaration. I have personal knowledge of the facts set forth below.

2. I have been employed by Merck since 2014. I currently serve as Scientific Associate Vice President of Merck Research Laboratories and Respiratory Vaccines Section Head, one of three sections, within the Division of Vaccines. I served as the Product Development Team Lead for V116, Merck's next-generation pneumococcal conjugate vaccine program, which was approved by the U.S. Food and Drug Administration under the brand name Capvaxive® in June 2024. My *curriculum vitae* is attached as Ex-1064.

3. I have been involved with pneumococcal vaccine development since May 2017 (as Clinical Representative), and when it proceeded from early-stage development to late-stage development in September 2021, I assumed the role of Product Development Team Lead. I have continued to work on the V116 program through regulatory approval, and continue to have responsibility over the program today. Prior to working on V116, I was involved in Merck's V114 program, which is Merck's 15-valent pneumococcal conjugate vaccine licensed under the brand name Vaxneuvance®. I was responsible for both pediatric and adult studies as part of the clinical development programs.

4. When I transitioned to my role in pneumococcal vaccine development, I reviewed documents outlining the history of the V116 program, including documents memorializing key milestones of the program. My Declaration is based on my review of these documents as well as my direct, firsthand involvement with Merck's pneumococcal conjugate vaccine development, including the V116 program.

II. MERCK'S INDEPENDENT DEVELOPMENT AND EARLY SEROTYPE SELECTION FOR V116

5. Merck's V116 program began early-stage development in 2015. The purpose of the program was to develop a next-generation pneumococcal conjugate vaccine ("PCV") that would provide coverage against pneumococcal disease associated with serotypes predominantly responsible for disease in adults that were not covered by existing pediatric-focused vaccines, including Pfizer's Prevnar® 13. The serotype selection for V116 was driven by Merck's internal analysis, including review of epidemiological data and technical feasibility.

6. Merck's serotype selection occurred nearly a full year before March 31, 2016. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

These are the same serotypes that are recited in Claim 1 of U.S. Patent No. 11,058,757

(“the ’757 patent”). [REDACTED]
[REDACTED]
[REDACTED]

Ex-1065, 20 (annotated)

7. The serotype composition of V116 evolved over the course of development [REDACTED]

[REDACTED] Merck independently invested extraordinary resources in V116. Merck’s investment of [REDACTED] in Capvaxive® spans over a decade of research, clinical development, and regulatory engagement—beginning with preclinical candidate documentation in 2015, proceeding through early development (Phase 1 and Phase 2), and continued investment in a comprehensive Phase 3

development program, including eight Phase 3 clinical trials enrolling thousands of participants, and culminating in FDA approval and commercialization.

8. In summary, Merck's development of V116, including the selection of serotypes 23A, 23B, and 35B, began in 2015 and was well established before March 31, 2016. Merck's serotype selection was conducted independent of Dr. Forrest, Pogona, or any affiliated entity.

Respectfully Submitted,

A handwritten signature in blue ink, consisting of a stylized 'H' and 'P' followed by a long horizontal line.

Heather Platt, M.D.