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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

POGONA, LLC, Plaintiff, v. MERCK SHARP & DOHME LLC, Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **DEMAND FOR JURY TRIAL**

Plaintiff Pogona, LLC ("Pogona" or "Plaintiff"), having an address at 135 Piermont Avenue, Nyack, New York 10960, by its attorneys, complains against Defendant Merck Sharp & Dohme LLC ("Merck" or "Defendant"), having an address at 126 East Lincoln Avenue, Rahway, New Jersey 07065, and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to the infringement of U.S. Patent No. 11,058,757 ("the '757 patent" or "Asserted Patent") by Merck through its

manufacture, use, offer for sale, and sale of its Capvaxive Vaccine ("Capvaxive") within the United States.

2. The Asserted Patent arises out of Pogona's extensive research into improved pneumococcal conjugate vaccines ("PCV"). In the course of Pogona's study of PCVs, Pogona's inventors identified that the marketed and investigational PCVs at the time were likely to provide inadequate coverage against invasive pneumococcal disease ("IPD"), and identified a novel composition of pneumococcal serotypes that were currently causing IPD and that had not previously been included in any pneumococcal vaccine—whether polysaccharide or conjugate. The Asserted Patent embodies these discoveries and covers the novel composition of pneumococcal serotypes that the '757 patent's inventors discovered.

3. This action arises out of Merck's current manufacture, use, sale, offer to sell within the United States and/or importation into the United States, of Merck's new Capvaxive PCV.

4. Merck's Capvaxive Vaccine infringes one or more claims of the Asserted Patent. For example, Merck's Capvaxive Vaccine includes each of serotypes 23A, 23B, and 35B—which are each recited in the '757 patent's claim 1. Merck's Capvaxive Vaccine also includes each of serotypes 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 20A, and 22F, which are additionally recited in the '757 patent's claim 12.

5. Merck is aware of Pogona's patent claiming Pogona's PCV invention, including a novel composition of serotypes. Yet Merck intentionally proceeded to launch its infringing product without the right to practice Pogona's PCV invention or include Pogona's novel composition of serotypes.

6. On information and belief, Merck chose to infringe Pogona's '757 patent with Capvaxive because of the importance to its business of pneumococcal conjugate vaccines.

7. Without the use of the PCV invention claimed in the Asserted Patent, Merck has no way to bring Capvaxive to market.

8. Merck's infringement is and has been knowing, reckless, and willful, and has resulted in and will continue to result in significant damage to Pogona.

9. Pogona brings this action to hold Merck accountable for its willful disregard of Pogona's patent rights.

THE PARTIES

A. Plaintiff

10. Plaintiff Pogona, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business located at 135 Piermont Avenue, Nyack, New York 10960.

11. Pogona is a biotechnology company advancing innovative discoveries and biotechnology that improves PCVs.

12. Pogona and its predecessor entities were established to create and bring to market an improved, next-generation pneumococcal conjugate vaccine ("iPCV") utilizing a novel composition of serotypes, as claimed in the '757 patent.

13. The majority of Pogona's management team comprises members who have previously held senior-level roles at Pfizer/Wyeth for Prevnar and/or Prevnar 13, and thus have tremendous experience in the development, approval, manufacturing, and commercialization of PCVs.

B. Defendant

14. Upon information and belief, Defendant Merck is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 126 East Lincoln Avenue, Rahway, New Jersey 07065.

15. Merck is one of the largest pharmaceutical companies in the world and ranked among the top five global pharmaceutical companies by revenue in 2024.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

17. This Court has personal jurisdiction over Merck because, *inter alia*, Merck is incorporated in and maintains its principal place of business in the State of New Jersey. Upon information and belief, Merck has availed itself of this forum by filing suit in the United States for the District of New Jersey, including, for example, *Merck Sharp & Dohme LLC v. Hetero USA Inc. et al*., 2-23-cv-02364 (DNJ); *Merck Sharp & Dohme LLC v. Lupin Limited et al*., 2-23-cv-00094 (DNJ); *Merck Sharp & Dohme LLC v. Hetero USA, Inc. et al*., 2-22-cv06820 (DNJ); *Merck Sharp & Dohme LLC v. Gland Pharma Limited*, 2-22-cv-05461 (DNJ); *BioMarin Pharmaceutical Inc. et al v. Aurobindo Pharmaceuticals Limited et al*., 3-22-cv02345 (DNJ).

18. Defendant has committed acts of infringement of the ’757 patent in this judicial District by making, using, offering to sell, and/or selling Capvaxive throughout the United States, including in this judicial District, since its launch in June of 2024.

19. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) because Merck resides in this District and because Merck is subject to personal jurisdiction in this District.

THE ASSERTED PATENT

20. On July 13, 2021, the U.S. Patent and Trademark Office duly and legally issued the ’757 patent, entitled “Saccharide-Polypeptide Conjugate Compositions and Methods of Use Thereof,” to Pogona, LLC as assignee of the named inventors Bruce D. Forrest and Jack D. Love. A true and correct copy of the ’757 patent is attached hereto as Exhibit A.

21. The ’757 patent was invented by Bruce D. Forrest—Pogona’s CSO and Manager—and Jack D. Love—Pogona’s Head of Regulatory. Dr. Forrest was formerly the global clinical team leader for Prevnar® and as SVP, Late Phase Programs, Vaccines Research & Development at Wyeth /Pfizer led the organization responsible for the development of Prevnar 13®. Dr. Love was formerly the head of global regulatory affairs for Wyeth/Pfizer Vaccines Research & Development, and oversaw Prevnar and Prevnar 13 regulatory submissions.

22. The claims of the ’757 patent are valid and enforceable. The ’757 patent is wholly owned by Pogona, who therefore has the right to sue for and obtain damages for infringement of the ’757 patent.

23. The ’757 patent claims priority to a provisional filed on March 31, 2016, and issued on July 13, 2021.

24. The ’757 patent will expire on July 13, 2037.

BACKGROUND

25. *Streptococcus pneumoniae* (pneumococcus) can cause serious illness, including sepsis, meningitis, and pneumonia with bacteremia (invasive) or without bacteremia (noninvasive). (https://www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm#:~:text=Background,the%20utility%20of%20this%20recommendation).

26. As of the priority date of the '757 patent, there were two pneumococcal vaccines licensed for use in the United States. (https://www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm#:~:text=Background,the%20utility%20of%20this%20recommendation). The first is Merck's Pneumovax 23 pneumococcal polysaccharide vaccine ("PPSV23"), for which the serotype composition was determined from epidemiology dated in the 1970s. PPSV23 is directed to serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F.

27. Since the early 1980s, PPSV23 has been recommended for individuals aged two and older who have certain medical conditions, as well as for all adults aged sixty-five and older. Pneumococcal polysaccharide vaccines are not immunogenic in children under the age of two.

28. The second is Wyeth/Pfizer's Prevnar 13 PCV ("PCV13"), which replaced the 7-valent PCV, Prevnar.

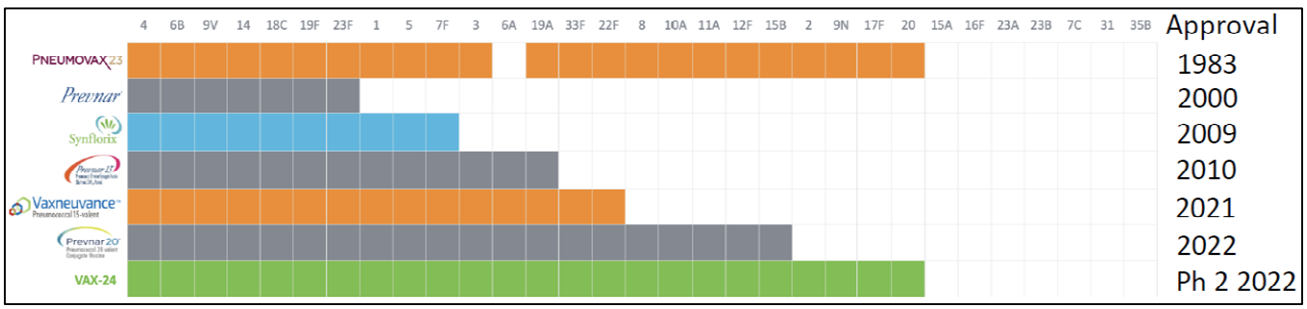
29. Prevnar was approved in 2000 and developed by conjugating CRM197 to polysaccharide for what were—at one time—the seven most important serotypes from PPSV23. Prevnar is directed to serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F—all of which are a subset of the serotypes in PPSV23. When Prevnar was launched, pneumococcus remained the most common cause of severe pneumonia and bacterial meningitis, leading to a global estimate at that time of 735,000 deaths among children under 5 years old per year.

30. PCVs overcame the challenge of poor immunogenicity in infants and young children through the use of conjugation technology. In PCVs, polysaccharides (or their derivatives) are covalently linked to carrier proteins. However, due to the complexity of the conjugation process, PCVs have contained fewer serotypes than the 23 included in PPSV23.

31. Prevnar 13, which was approved in 2010, was developed by conjugating CRM197 to polysaccharide for what were—at one time—the thirteen most important serotypes from PPSV23. PCV13 is directed to serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F—all of which are a subset of the serotypes in PPSV23, minus serotype 6A. Serotype 6A is the only serotype to be added to PCVs beyond the serotypes included in the original PPSV23 before the '757 patent's priority date.

32. PCV13 has been included in the routine pediatric immunization schedule since 2010 and, since 2014, has been recommended for all adults aged 65 and over in combination with PPSV23.

33. Since PPSV23 was approved in 1983, pharmaceutical companies have ignored most of the over 100 immunologically distinct serotypes of pneumococcus that have been described, and have almost exclusively developed new pneumococcal vaccines by conjugating additional serotypes from the original PPSV23 composition backbone, as shown in the graphic below:



34. Pogona, by contrast, took a different approach, focusing not on the PPSV23 composition serotypes, but on aligning vaccine coverage with emerging invasive disease serotypes.

35. Pogona took this approach based on the hypothesis of the ’757 patent inventors that the effectiveness of PCV13 and its inclusion in routine immunization schedules would result in the increased importance of non-PPSV23 serotypes.

36. Pogona’s team worked for years on an improved PCV for the prevention of pneumococcal disease not currently covered by Prevnar 13. Before Merck’s infringement, Pogona’s team was working toward FDA approval of a vaccine containing a combination of serotypes claimed in the ’757 patent, which, based on current epidemiological surveillance, are the serotypes causing most invasive pneumococcal disease in adults, and which is a combination of serotypes different than those in Prevnar 13.

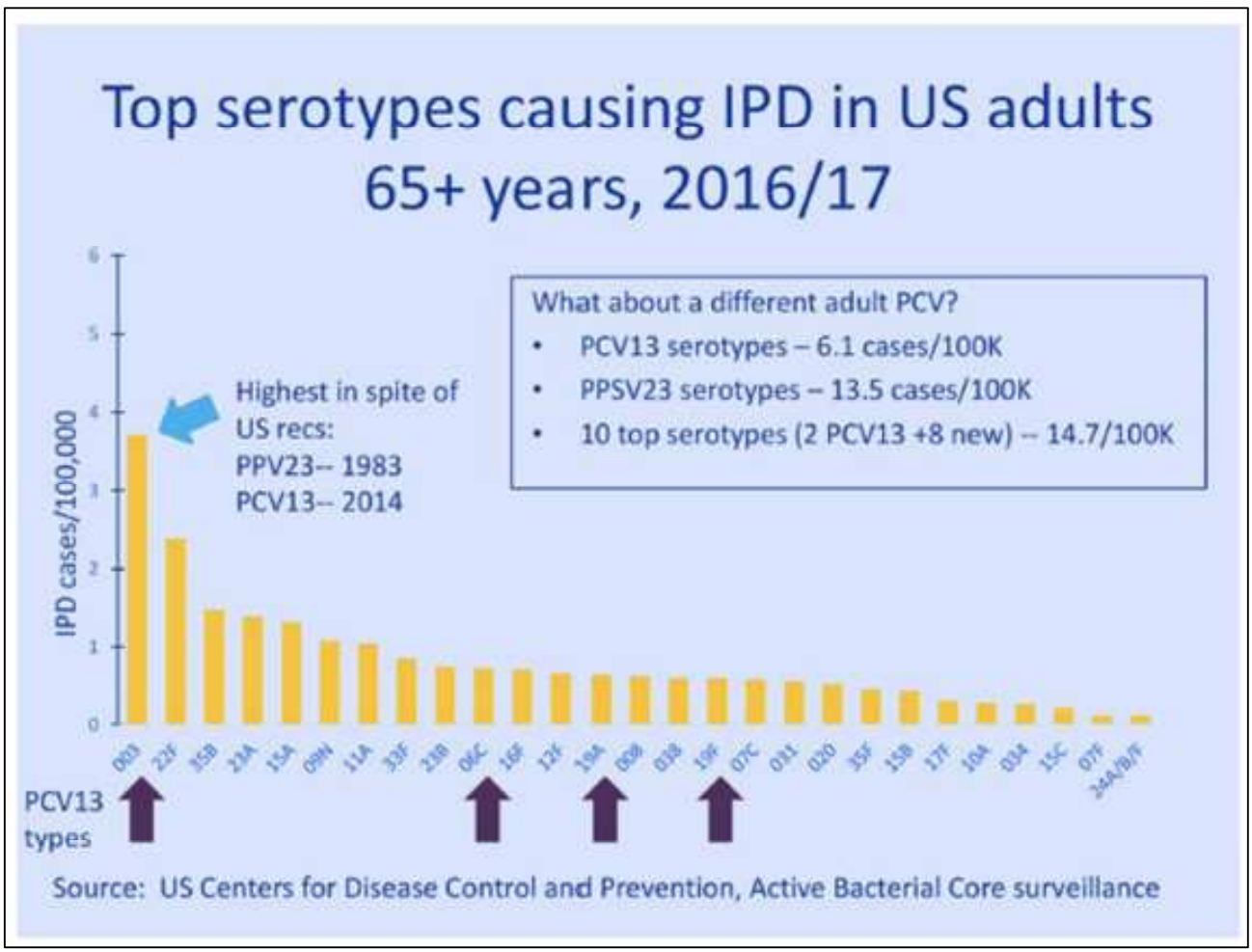
37. Through this novel approach, Pogona developed the novel composition of serotypes described and claimed in the ’757 patent, including, for example:

- Claim 1: reciting selecting at least two unique serotypes from the group of serotypes 23A, 23B, and 35B—none of which are serotypes included in PPSV23.
- Claim 12: depending from claim 1 and reciting further selecting at least one additional serotype from the group of serotypes 6C, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 20A, 20B, 22F, and 34—of which 6C, 15A, 15F, 20A, 20B, and 34 are serotypes not included in PPSV23.

38. Pogona’s approach proved to be correct. Initially, the serotypes included in PCV13 accounted for approximately 85% of the PPSV23 serotypes that cause disease.

39. As Pogona's inventors predicted, the effectiveness of PCV13 resulted in a decrease in disease caused by the 13 PCV13 serotypes, from 75% in the late 1990s to 25% by 2016.

40. Consequently, this decrease in the percentage of disease caused by PCV13 serotypes resulted in an increased rate of disease being caused by non-PCV and non-PPSV23 serotypes, as shown in the graphic below:



(https://www.advac.org/images/alumni-meetings/files/ADVAC_at_IDWeek_2018_final-1.pdf).

41. Over a year after the '757 patent's priority date—on October 26, 2017—the Center for Disease Control and Prevention's ("CDC") National Center for Immunization &

Respiratory Diseases ranked the non-PCV13 serotypes causing invasive pneumococcal disease, as shown in the graphic below:

Rank order of non-PCV13 serotypes causing IPD, 2015-2016

Children < 5 years

TYPE	Cases/100,000
23B	0.62
22F	0.62
33F	0.57
15C	0.52
15A	0.48
35B	0.43
10A	0.33
12F	0.29
15B	0.29
38	0.19
other	1.67

Adults ≥ 65 years

TYPE	Cases/100,000
22F	2.57
23A	1.33
35B	1.31
15A	1.16
33F	0.97
16F	0.88
11A	0.82
9N	0.72
23B	0.67
12F	0.61
other	4.66

Green denotes serotypes common to both age groups

(https://stacks.cdc.gov/view/cdc/57593).

42. This is what the '757 patent's inventors understood when they described and recited in claim 1 a vaccine reciting selecting at least two unique serotypes from the group of serotypes 23A, 35 B (top two non-PPSV23 serotypes causing IPD in adults sixty-five and older), and 23B (top non-PPSV23 serotype causing IPD in children under five years).

43. Additionally, claim 12, which depends from claim 1, recites further selecting at least one additional serotype from a group that includes the following additional serotypes from the CDC's list: serotypes 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, and 22F.

44. Based on the CDC's data, in a marked departure from decades of pharmaceutical companies developing new pneumococcal vaccines by conjugating additional serotypes from the original PPSV23 composition backbone, CDC advised the pharmaceutical industry in 2018 to update pneumococcal vaccine coverage in adults to include circulating serotypes.

45. On April 14, 2022, Merck announced that its "investigational 21-valent pneumococcal conjugate vaccine, has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of invasive pneumococcal disease (IPD) and pneumococcal pneumonia caused by Streptococcus pneumoniae serotypes 3, 6A/C, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B/C, 16F, 17F, 19A, 20, 22F, 23A, 23B, 24F, 31, 33F, 35B in adults 18 years of age and older." (https://www.merck.com/news/merck-announces-u-s-fda-has-granted-breakthrough-therapy-designation-for-v116-the-companys-investigational-21-valent-pneumococcal-conjugate-vaccine-for-the-prevention-of-invasive-pneumococ/). Serotypes 23A, 23B, and 35B—included in Merck's investigational 21-valent PCV—are each non-PPSV23 serotypes recited in the '757 patent's claim 1. Serotypes 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, and 22F—included in Merck's investigational 21-valent PCV—are each serotypes additionally recited in the '757 patent's claim 12, and of these serotypes, 15A and 20A are also non-PPSV23 serotypes.

46. Merck stated that its investigational 21-valent PCV, which was later named Capvaxive, "is specifically designed to address strains of disease-causing pneumococcal bacteria that are most prevalent in adults, reflecting our population-specific approach to developing pneumococcal conjugate vaccines. V116 targets serotypes that account for 85% of all invasive pneumococcal disease in individuals aged 65 and over in the United States as of

2019 and it includes 8 serotypes not covered by currently licensed vaccines." (https://www.merck.com/news/merck-announces-u-s-fda-has-granted-breakthrough-therapy-designation-for-v116-the-companys-investigational-21-valent-pneumococcal-conjugate-vaccine-for-the-prevention-of-invasive-pneumococ/).

47. Once Merck's infringing Capvaxive Vaccine was announced, Pogona was no longer able to secure funding to continue its own development of its improved PCV.

MERCK'S KNOWLEDGE OF POGONA'S PATENTED PNEUMOCOCCAL CONJUGATE VACCINE INVENTION AND THE '757 PATENT

48. 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 ("ePCV").

49. 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.

50. Liffey also explained to Merck that CBER had approved of Liffey's early clinical development plan and proposed specifications.

51. Notably, 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, currently infringed by Merck's Capvaxive.

52. Specifically, 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 (current circulating strain); and 3) covers polysaccharide structures for serotypes 23A and 23B.

53. Merck did not choose to license Liffey's IP or partner with Liffey following this meeting.

54. Liffey, and its later entity Pogona, continued to develop its improved PCV and prosecute the '757 patent.

55. 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.

56. 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." (Exhibit B).

57. Dr. Forrest participated with Dr. Skinner and others on Merck's advisory panel for their next-generation pneumococcal vaccine program, V116.

58. On July 13, 2021, Pogona's U.S. Patent Number 11,058,757 was granted.

59. 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.

60. 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.

61. 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." (Exhibit B).

62. 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." (Exhibit C).

63. 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."

64. Despite having knowledge of Pogona's granted '757 patent since at least October 15, 2021, and of the '757 application since October 25, 2017, and having no authorization to use the invention claimed therein, Merck pursued development of and launched Capvaxive by using Pogona's patented PCV invention without Pogona's permission.

65. Despite Merck's knowledge of Pogona's '757 patent, on information and belief, Merck proceeded with its plans to launch its Capvaxive PCV, fully aware of its infringement and without having the right to practice the patent.

66. On June 17, 2024, the FDA approved Merck's Capvaxive, and on June 27, 2024, the CDC's Advisory Committee on Immunization Practices ("ACIP") recommended Merck's Capvaxive.

67. On information and belief, Merck was aware of its infringement of Pogona's '757 patent based at least on its October 2017 and October 2021 discussions, yet it still launched Capvaxive in June of 2024.

MERCK'S INFRINGEMENT IS WILLFUL

68. As set forth above, Merck is attempting to unfairly compete against Pogona by knowingly infringing Pogona's patented PCV invention to market and sell Merck's Capvaxive

Vaccine. Merck has knowledge of and is aware of the Asserted Patent, at least due to Pogona's precursor entity disclosing the '757 patent to Merck, as well as the previously filed application that issued as the '757 patent.

69. Merck knew about Pogona's patented PCV invention directed to a novel composition of serotypes, and knew that Pogona's patented composition of serotypes is included in Merck's Capvaxive Vaccine. Upon information and belief, despite knowing of the Asserted Patent, Merck developed its infringing Capvaxive Vaccine. Upon information and belief, Merck is knowingly infringing Pogona's PCV patent and flouting Pogona's right to exclude others from using its invention during the patent term of Pogona's '757 patent.

INFRINGEMENT BY DEFENDANT OF THE '757 PATENT UNDER 35 U.S.C. § 271 (A), (B), AND/OR (C)

70. Pogona incorporates each of the preceding paragraphs 70 as if fully set forth herein.

71. The '757 patent is valid and enforceable.

72. Merck's acts of making, using, offering for sale, selling, and/or importing Infringing Products, including but not limited to Merck's Capvaxive Vaccine ("the Infringing Products"), satisfy each and every claim limitation, including but not limited to the limitations of claims 1, 3, and 12.[1]

73. For example, the Infringing Products meet each and every limitation of claim 1.

74. Claim 1 of the '757 patent is reproduced below:

> 1. A pharmaceutical composition comprising a plurality of at least two unique immunogenic saccharide-polypeptide conjugates, each comprising individually a

[1] Pogona expressly reserves the right to identify additional asserted claims in its infringement contentions to be served in accordance with the Local Patent Rules or any scheduled set by the Court. Analysis of claims 1, 3, and 12 is provided for notice pleading only and is not presented as an "exemplary" claim of all other claims in the '757 patent.

capsular polysaccharides conjugated to a polypeptide, wherein each of the capsular polysaccharides is from a *Streptococcus pneumoniae* serotype selected from a group consisting of 23A, 23B, and 35B.

75. The Infringing Products are a pharmaceutical composition comprising a plurality of at least two unique immunogenic saccharide-polypeptide conjugates.

CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine)
Injection, for intramuscular use
Initial U.S. Approval: 2024

----------INDICATIONS AND USAGE----------

CAPVAXIVE™ is a vaccine indicated for:

- active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)
- active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)

See Capvaxive Physician Prescribing Information, Page 1, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

11 DESCRIPTION

CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine) is an injection for intramuscular use. CAPVAXIVE is a sterile solution of purified capsular polysaccharides from *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B (de-O-acetylated prior to conjugation), 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B individually conjugated to CRM197 carrier protein. CRM197 is a nontoxic mutant of diphtheria toxin (originating from *Corynebacterium diphtheriae* C7) expressed recombinantly in *Pseudomonas fluorescens*.

See Capvaxive Physician Prescribing Information, Page 8, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

76. Each unique immunogenic saccharide-polypeptide conjugate comprises an individually capsular polysaccharide conjugated to a polypeptide.

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- active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)

See Capvaxive Physician Prescribing Information, Page 1, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

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See Capvaxive Physician Prescribing Information, Page 8, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

77. Each of the capsular polysaccharides is from a *Streptococcus pneumoniae* serotype selected from a group consisting of 23A, 23B, and 35B.

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Injection, for intramuscular use
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----------INDICATIONS AND USAGE----------

CAPVAXIVE™ is a vaccine indicated for:

- active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)
- active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)

See Capvaxive Physician Prescribing Information, Page 1, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

> **11 DESCRIPTION**
>
> CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine) is an injection for intramuscular use. CAPVAXIVE is a sterile solution of purified capsular polysaccharides from *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B (de-O-acetylated prior to conjugation), 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B individually conjugated to CRM197 carrier protein. CRM197 is a nontoxic mutant of diphtheria toxin (originating from *Corynebacterium diphtheriae* C7) expressed recombinantly in *Pseudomonas fluorescens*.

See Capvaxive Physician Prescribing Information, Page 8, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

78. As another example, the Infringing Products also meet each and every limitation of claim 3.

79. Claim 3 of the '757 patent is reproduced below:

> 3. The pharmaceutical composition of claim 1, wherein at least one polypeptide of the plurality comprises CRM_{197}, tetanus toxoid, a diphtheria toxoid, cholera toxoid, pertussis toxoid, inactivated or mutant pneumococcal pneumolysin, pneumococcal surface protein A, pneumococcal adhesion protein A, pneumococcal lipoprotein PsaA, C5a peptidase group A or group B *Streptococcus*, a non-typable *H. influenzae* P4 protein, a non-typable *H. influenzae* P6 protein, *M. catarrhalis* uspA, keyhole limpet haemocyanin (KLH), OMPC from *N. meningitidis*, a purified protein derivative of tuberculin(PPD), protein D from *H. influenzae*, PspA, any fragment thereof, or any combination thereof.

80. At least one polypeptide of the plurality of at least two unique immunogenic saccharide-polypeptide conjugates in the Infringing Products comprises CRM197, tetanus toxoid, a diphtheria toxoid, cholera toxoid, pertussis toxoid, inactivated or mutant pneumococcal pneumolysin, pneumococcal surface protein A, pneumococcal adhesion protein A, pneumococcal lipoprotein PsaA, C5a peptidase group A or group B *Streptococcus*, a non-typable *H. influenzae* P4 protein, a non-typable H. influenzae P6 protein, *M. catarrhalis* uspA, keyhole limpet haemocyanin (KLH), OMPC from *N. meningitidis*, a purified protein derivative of tuberculin(PPD), protein D from *H. influenzae*, PspA, any fragment thereof, or any combination thereof. For example, at least one polypeptide of the plurality comprises CRM197.

11 DESCRIPTION

CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine) is an injection for intramuscular use. CAPVAXIVE is a sterile solution of purified capsular polysaccharides from *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B (de-O-acetylated prior to conjugation), 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B individually conjugated to CRM197 carrier protein. CRM197 is a nontoxic mutant of diphtheria toxin (originating from *Corynebacterium diphtheriae* C7) expressed recombinantly in *Pseudomonas fluorescens*.

See Capvaxive Physician Prescribing Information, Page 8, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

81. As another example, the Infringing Products also meet each and every limitation of claim 12.

82. Claim 12 of the '757 patent is reproduced below:

> 12. The pharmaceutical composition of claim 1, further comprising at least one additional immunogenic saccharide-polypeptide conjugate comprising a capsular polysaccharide from a unique *Streptococcus pneumoniae* serotype selected from the group consisting of 6C, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 20A, 20B, 22F, and 34.

83. The Infringing Products comprise at least one additional immunogenic saccharide-polypeptide conjugate comprising a capsular polysaccharide from a unique *Streptococcus pneumoniae* serotype selected from the group consisting of 6C, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 20A, 20B, 22F, and 34.

CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine)
Injection, for intramuscular use
Initial U.S. Approval: 2024

----------INDICATIONS AND USAGE----------

CAPVAXIVE™ is a vaccine indicated for:

- active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)
- active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)

See Capvaxive Physician Prescribing Information, Page 1, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

11 DESCRIPTION

CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine) is an injection for intramuscular use. CAPVAXIVE is a sterile solution of purified capsular polysaccharides from *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B (de-O-acetylated prior to conjugation), 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B individually conjugated to CRM197 carrier protein. CRM197 is a nontoxic mutant of diphtheria toxin (originating from *Corynebacterium diphtheriae* C7) expressed recombinantly in *Pseudomonas fluorescens*.

See Capvaxive Physician Prescribing Information, Page 8, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

84. Merck has also infringed indirectly and continues to infringe indirectly the '757 patent by active inducement under 35 U.S.C. § 271(b).

85. Merck has been aware of the '757 patent since no later than October 15, 2021, when, after Dr. Forrest wrote to Merck informing them of the grant of "US11058757," Merck's Dr. Julie Skinner wrote that Merck had "reviewed the Pogona, LLC PCV IP with our IP counsel and do not have any interest in the IP at this time." Because representatives from Pogona's precursor entity, Liffey, also provided Merck with detailed information about the '757 application on October 25, 2017, on information and belief, Merck has been aware of its infringement since it began work on its Capvaxive Vaccine.

86. On information and belief, Merck has intended, and continues to intend, to induce patent infringement by others, including prescribing physicians and other third parties, and has had knowledge that the inducing acts would cause infringement or has been willfully blind to the possibility that the inducing acts would cause infringement.

87. On information and belief, on or about June 2024, Defendant began importing, marketing, selling, offering for sale, and/or distributing Merck's Capvaxive Vaccine in the United States, including in this District. *See* U.S. FDA Approves CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine) for Prevention of Invasive Pneumococcal Disease and Pneumococcal Pneumonia in Adults, *available at* https://www.merck.com/news/u-

s-fda-approves-capvaxive-pneumococcal-21-valent-conjugate-vaccine-for-prevention-of-invasive-pneumococcal-disease-and-pneumococcal-pneumonia-in-adults/ (June 17, 2024).

88. For example, Merck provides prescribing information for the Infringing Products including indications and usage, dosage and administration, dosage forms and strengths, contraindications, warnings and precautions, adverse reactions, use in specific populations, and patient counseling information.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use CAPVAXIVE safely and effectively. See full prescribing information for CAPVAXIVE.

CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine)
Injection, for intramuscular use
Initial U.S. Approval: 2024

----------INDICATIONS AND USAGE----------
CAPVAXIVE™ is a vaccine indicated for:

- active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)
- active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. (1)

The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. (1)

----------DOSAGE AND ADMINISTRATION----------
For intramuscular use.

- Administer a single 0.5 mL dose. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------
CAPVAXIVE is an injection. A single dose is 0.5 mL. (3)

----------CONTRAINDICATIONS----------
Severe allergic reaction (e.g., anaphylaxis) to any component of CAPVAXIVE or to diphtheria toxoid. (4)

----------ADVERSE REACTIONS----------
The most commonly reported (>10%) solicited adverse reactions:

- in individuals 18 through 49 years of age were: injection-site pain (73.1%), fatigue (36.0%), headache (27.5%), myalgia (16.4%), injection-site erythema (13.8%), and injection-site swelling (13.3%). (6.1)
- in individuals 50 years of age and older were: injection-site pain (41.2%), fatigue (19.7%), and headache (11.0%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme LLC at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov .

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 06/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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See Capvaxive Physician Prescribing Information, Page 1, *available at* https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf.

89. Merck has also infringed indirectly and continues to infringe indirectly the ’757 patent by contributory infringement under 35 U.S.C. § 271(c).

90. Merck has and continues to intentionally commit contributory infringement by selling, offering to sell, or importing the Infringing Products, which have no substantial non-infringing use, including but not limited to their Capvaxive Vaccine, with the knowledge that

they will be used by others, including prescribing physicians and/or other third parties, to directly infringe claims of the ’757 patent.

91. Upon information and belief, Merck sold and distributed to customers in the United States $236 million in Merck’s Capvaxive Vaccine in the first two quarters of 2025.

92. Merck has had actual knowledge of the ’757 patent since no later than October 15, 2021, when, after Dr. Forrest wrote to Merck informing them of the grant of “US11058757,” Merck’s Dr. Julie Skinner wrote that Merck had “reviewed the Pogona, LLC PCV IP with our IP counsel and do not have any interest in the IP at this time.” Because representatives from Pogona’s precursor entity, Liffey, also provided Merck with detailed information about the ’757 application on October 25, 2017, on information and belief, Merck has been aware of its infringement since it began work on its Capvaxive Vaccine. On information and belief, despite having actual knowledge of their infringement of the ’757 patent, Merck has continued to willfully, wantonly, and deliberately infringe the ’757 patent. Merck has either failed to negotiate in good faith and/or refused to pay a reasonable license fee for the ’757 patent. Accordingly, Pogona seeks enhanced damages under 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Pogona to its attorneys’ fees and expenses.

93. Because representatives from Pogona’s precursor entity, Liffey, also provided Merck with detailed information about the ’757 application on October 25, 2017, on information and belief, Merck has been aware of its infringement since it began work on its Capvaxive Vaccine.

94. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met concerning the ’757 patent.

95. As a result of Merck's infringement of the '757 patent and refusal to take a license to it, Pogona has been injured by Merck's unauthorized use of Pogona's intellectual property.

96. Pogona seeks monetary damages in an amount adequate to compensate for Merck's infringement, but in no event less than a reasonable royalty for the use made of the invention by Merck, together with interest and costs as fixed by the Court.

97. The foregoing acts by Defendant constitutes induced infringement of at least claim 1 of the '757 patent under 35 U.S.C. § 271 (b).

98. Upon information and belief, Defendant acted without a reasonable basis for believing that it would not be liable for infringement of the '757 patent.

PRAYER FOR RELIEF

WHEREFORE, Pogona prays that this Court grant the following relief:

99. A judgment that one or more claims of the '757 patent are not invalid, are enforceable, and are infringed by Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States, of Merck's Capvaxive Vaccine.

100. Damages or other monetary relief to Pogona to compensate Pogona for its lost profits, but in no circumstance less than the value of a reasonable royalty, for Defendant's commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Merck's Capvaxive Vaccine before the expiration date of the '757 patent, including any extensions and/or additional periods of exclusivity to which Pogona is or becomes entitled.

101. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

JURY DEMAND

Pogona hereby demands a jury trial on all issues appropriately triable by a jury.

Dated: September 5, 2025

Respectfully submitted,

s/ Peter C. Urmston

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify to the best of my knowledge, information, and belief that the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

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

Dated: September 5, 2025

Respectfully submitted,

s/ Peter C. Urmston

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