

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.

IPR2026-00221
Patent 11,058,757

PATENT OWNER'S DISCRETIONARY DENIAL BRIEF

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EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Bruce D. Forrest in Support of Patent Owner's Discretionary Denial Brief, dated March 27, 2026.
2002	Email correspondence between Bruce D. Forrest and Julie M. Skinner.
2003	Email correspondence from Bruce D. Forrest to Stephen E de Laszlo.
2004	U.S. Patent No. 11,395,849 to Richard J. Porambo, et al.
2005	U.S. Patent and Trademark Office, Information Disclosure Statement for Application No. 16645023.
2006	Court's Order, <i>Pogona, LLC v. Merck Sharp & Dohme LLC</i> , No. 2:25-cv-15294-BRM-JBC (D.N.J.), dated March 2, 2026.
2007	Matanock, M.D., Almea, et al., <i>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Updated Recommendations of the Advisory Committee on Immunization Practices</i> , Morbidity and Mortality Weekly Report, Vol. 68 No. 46 (2019).
2008	Cynthia Whitney, M.D., MPH, Pneumococcal Vaccines for Older Adults: What is the right approach?
2009	Almea Matanock, M.D., <i>Invasive Pneumococcal Disease in the U.S. – 2008-2016</i> , National Center for Immunization & Respiratory Diseases, October 26, 2017.

I. INTRODUCTION

On January 26, 2026, Merck Sharp & Dohme LLC (“Petitioner” or “Merck”) filed its Petition for *inter partes* review directed to U.S. Patent No. 11,058,757 (“the ’757 patent”) (Ex. 1001) challenging claims 1–19 as anticipated and/or obvious. This was over a month after Pfizer filed a similar IPR against the same patent. Pursuant to the Director’s March 26, 2025, memorandum regarding Interim Processes for PTAB Workload Management (“PTAB Memo”), Patent Owner Pogona, LLC (“Patent Owner” or “Pogona”) requests that the Director exercise his discretion and deny institution of the Petition filed by Petitioner.

Specifically, discretionary denial is warranted here where, despite knowing of the ’757 patent application for nearly nine years following meetings between Petitioner and Patent Owner’s predecessor, Petitioner did nothing until the ’757 patent claims had been in force for approximately five years, creating settled expectations for Patent Owner. During that time, in reliance on its ’757 patent, Patent Owner expended significant amounts of time, money, and energy into developing a vaccine utilizing the novel composition of serotypes claimed in the ’757 patent.

In addition, the Petition’s merits are particularly weak, suffering from the same flaw that resulted in denial of institution of a prior IPR directed to a different pneumococcal conjugate vaccine (“PCV”) serotype patent.

Finally, because the ’757 patent is the subject of parallel district court

litigation, and because a part not involved in the district court litigation has already filed an IPR against the '757 patent, institution of this IPR could potentially result in three different validity adjudications for the '757 patent—an inefficient use of the Board's resources and a recipe for inconsistent results.

For all these reasons, and as explained more fully below, the Director should exercise his discretion to deny institution.

II. FACTUAL BACKGROUND

Patent Owner Pogona is a biotechnology company advancing innovative discoveries and biotechnology that improves PCVs. Pogona and its predecessor entities were established to create and bring to market an improved, next-generation PCV utilizing a novel composition of serotypes, as claimed in the '757 patent.

On July 13, 2021, the U.S. Patent and Trademark Office issued the '757 patent, which claims priority to a provisional filed on March 31, 2016, and is entitled “Saccharide-Polypeptide Conjugate Compositions and Methods of Use Thereof,” to Pogona, LLC as assignee of the named inventors 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.

“*Streptococcus pneumoniae* (pneumococcus) can cause serious illness, including sepsis, meningitis, and pneumonia with bacteremia (invasive) or without bacteremia (noninvasive).” (Ex. 2007 at 1.) As of the priority date of the ’757 patent, there were two pneumococcal vaccines licensed for use in the United States. (*Id.*) The first is Merck’s Pneumovax 23 pneumococcal polysaccharide vaccine (“PPSV23”), for which the serotype composition was determined from epidemiology developed 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. 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—unlike PCVs—are not immunogenic in children under the age of two.

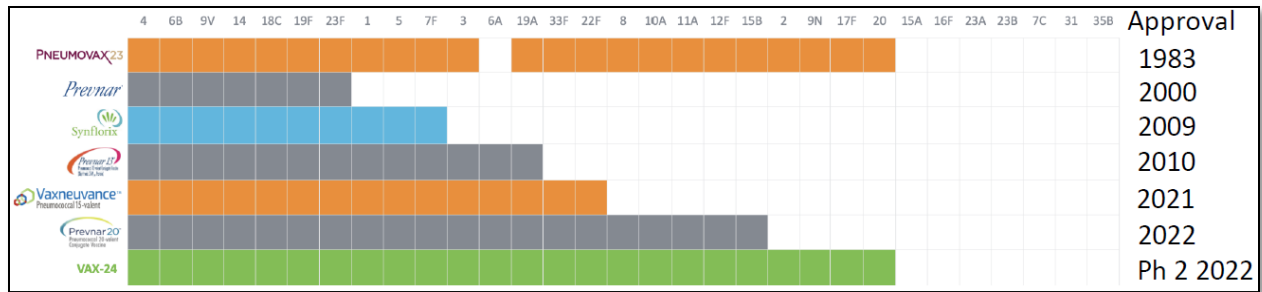
The second is Wyeth/Pfizer’s Prevnar 13 PCV (“PCV13”), which replaced the 7-valent PCV, Prevnar. Prevnar was approved in 2000 and developed by conjugating CRM197 to polysaccharide for what were—at one time—the seven most important serotypes from PPSV23. Prevnar is directed to serotypes 4, 6B, 9V, 14, 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.

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.

Prevnar 13 (“PCV13”), 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. 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.

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



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

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 currently causing IPD that had not previously been included in any pneumococcal vaccine—whether polysaccharide or conjugate. The '757 patent embodies these discoveries and covers the novel composition of pneumococcal serotypes that the '757 patent's inventors discovered.

Pogona's team worked for years on an improved PCV for the prevention of pneumococcal disease not currently covered by Prevnar 13. Specifically, 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

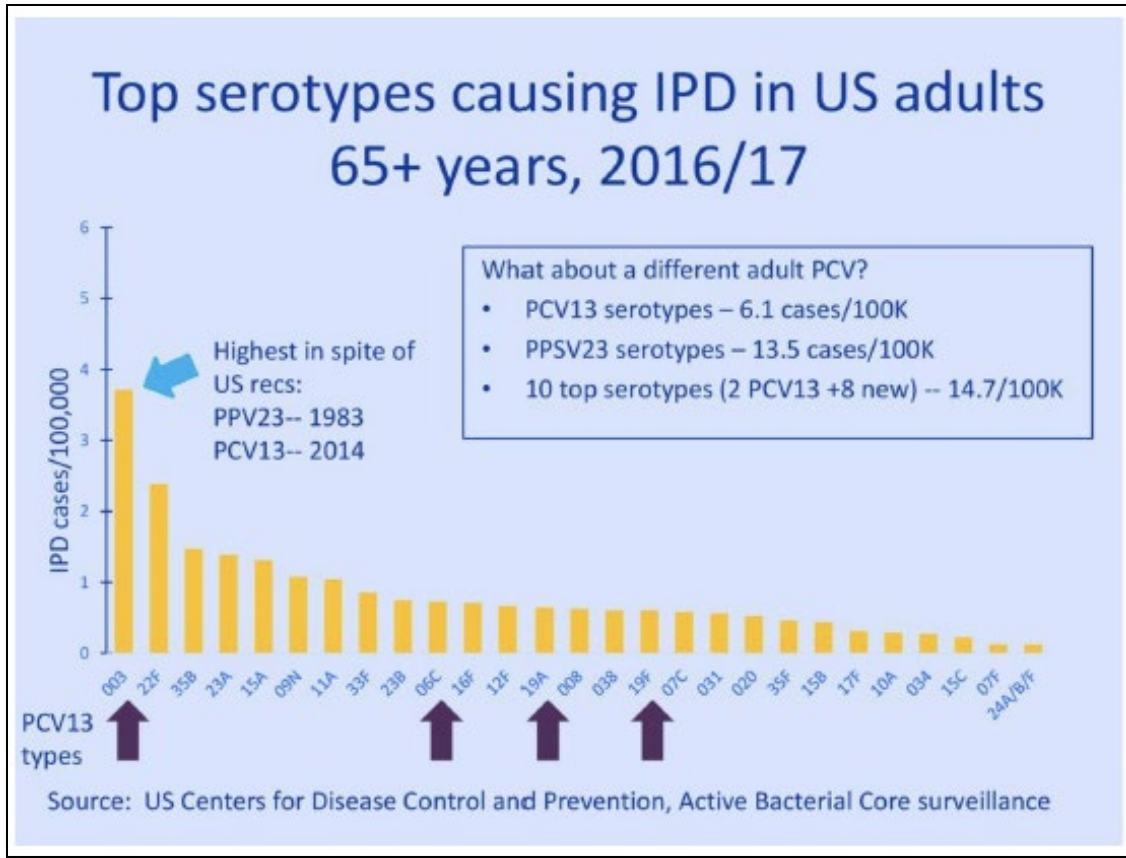
surveillance, are the serotypes causing most invasive pneumococcal disease in adults, and which is a combination of serotypes different than those in Prevnar 13. Through this approach, Pogona developed the novel composition of serotypes described and claimed in the '757 patent, including, for example:

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.

Claims 13/14: depending from claim 1, wherein the selected serotypes comprise/consist of 6C, 9N, 15A, 15C, 16F, 23A, 23B, and 35B.

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



(Ex. 2008 at 28.)

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

(Ex. 2009 at 9.)

This is what the '757 patent's inventors understood—over a year earlier—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). 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.

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.

III. THE DIRECTOR SHOULD DENY INSTITUTION UNDER 35 U.S.C. § 314(a)

The PTAB Memo and 35 U.S.C. § 314(a) gives the Director discretion to deny institution of an IPR. The PTAB Memo also includes a non-exhaustive list of factors that may be raised in discretionary briefing. (PTAB Memo at 2–3.) In evaluating these factors, the Director’s decision should be based on “a holistic review of the facts and circumstances.” *See* USPTO, *Interim Directory Discretionary Process*, <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process> (last visited Mar. 29, 2026). The factors shown below favor denial of the Petition.

A. Settled Expectations in the ’757 Patent Warrant Discretionary Denial

Due to the early priority date of the ’757 patent, it served as prior art to many other patent applications in the industry, including Petitioner’s own patents. (*See, e.g.,* Ex. 2004 at 2; Ex. 2005 at 2.) Despite knowing of the ’757 patent application for nearly nine years following meetings between Petitioner and Patent Owner’s predecessor entity, Petitioner did nothing until the ’757 patent claims had been in force for approximately five years, creating settled expectations for Patent Owner.

The Director has repeatedly held that “Petitioner’s awareness of Patent

Owner’s applications and failure to seek early review of the patents favors denial” of the Petition. *iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, -374, -376, -377, -378, Paper 10 at 3 (Acting Dir. June 6, 2025); *see Murata Mfg. Co. LTD v. Georgia Tech Rsch. Corp.*, IPR2025-00383, -384, Paper 14 at 2–3 (Acting Dir. July 29, 2025) (denying Petition under 35 U.S.C. § 314(a) and holding that where Petitioner was aware of Patent Owner’s involvement in the space and/or patent “for a significant amount of time before filing its Petition challenging Patent Owner’s patent[, a] failure to seek early review of the patent favors denial.”)

Petitioner has been aware of the ’757 patent—in the form of its PCT application—for nearly nine years. Specifically, on October 25, 2017, individuals representing Liffey/Vax Ltd. (“Liffey”)—a precursor to Pogona—met with Merck to discuss Liffey’s development progress and IP related to their expanded coverage PCV. During this meeting, Liffey informed Merck of its Patent Application number PCT/US2017/025621—which later issued as the ’757 patent—and that its patent application covers 1) major contributing serotypes to antimicrobial resistance; (2) serotype 20B vaccine composition; and 3) polysaccharide structures for serotypes 23A and 23B. (Ex. 2001, ¶ 3.) Merck did not choose to license Liffey’s IP or partner with Liffey following this meeting. Liffey, and its subsequent entities, continued to develop its improved PCV and prosecute the ’757 patent.

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." (Ex. 2002 at 4.) Dr. Forrest participated with Dr. Skinner and others on Merck's advisory panel for their next-generation pneumococcal vaccine program, V116.

On July 13, 2021, U.S. Patent Number 11,058,757 was granted. After this grant, 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. (Ex. 2001, ¶ 3.)

On October 10, 2021, after participating with Dr. Skinner on Merck's advisory panel for their next gen. 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....I have attached the issued patent, and additional patent application numbers....US Patent Grant: US11058757 Priority Date: 03/31/2016.

(Ex. 2002 at 1–2.)

On October 11, 2021, Dr. Forrest also wrote a similar message to Merck’s Stephen de Laszlo, Executive Director Strategic Licensing and Acquisition. (Ex. 2003 at 1.) 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.” (Ex. 2002 at 1.)

These facts weigh in favor of denial. *See JinkoSolar Co. v. LONGi Green Energy Tech. Co.*, IPR2025-00859, Paper 10 at 3 (Acting Dir. Sept. 3, 2025) (denying Petition under 35 U.S.C. § 314(a) where “Petitioner has been aware of the published application for the challenged patent since at least 2016, when the application was listed on a search report during prosecution of one of Petitioner’s Chinese patent applications.”); *Belden Inc. & PPC Broadband, Inc. v. CommScope, Inc. of N. Carolina*, IPR2025-00833, Paper 13 at 2 (Acting Dir. Sept. 12, 2025) (denying Petition under 35 U.S.C. § 314(a) where “Petitioner has been aware of the challenged patent since at least 2022”); *Google LLC v. SoundClear Techs. LLC*,

IPR2025-00344, -345, Paper 15 at 2–3 (Acting Dir. Aug. 4, 2025) (denying Petition under 35 U.S.C. § 314(a) where Petitioner’s knowledge of the challenged patents since 2019 creates strong settled expectations); *Amazon.com, Inc. v. SoundClear Techs. LLC*, IPR2025-01067, -1080, -1096, Paper 15 at 2 (Director Oct. 17, 2025) (denying Petition under 35 U.S.C. § 314(a) as Petitioner’s knowledge of the challenged patent since 2018 creates strong settled expectations).

Additionally, the ’757 patent claims have been in force for nearly five years—since July 2021. “Although there is no bright-line rule on when expectations become settled, in general, the longer the patent has been in force, the more settled expectations should be.” *Dabico Airport Sols. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 at 3 (Acting Dir. June 18, 2025) (informative). Indeed, the Director has found settled expectations in patents in force for as little as three years when the IPR Petition was filed. *See Samsung Elecs. Co. & Samsung Elecs. Am., Inc. v. GenghisComm Holdings, LLC*, IPR2025-00780, -781, Paper 11 at 2 (Acting Dir. Aug. 22, 2025) and *Samsung Elecs. Co. & Samsung Elecs. Am., Inc. v. GenghisComm Holdings, LLC*, IPR2025-00792, -793, Paper 12 at 2 (Acting Dir. Aug. 22, 2025) (holding that there were “strong settled expectations for Patent Owner” and that “essentially the same discretionary considerations” that existed for patents “in force for approximately eight and six years,” existed with respect to patents that issued in July and August of 2022, such that the Petitions for these

patents was denied under 35 U.S.C. § 314(a)). By the time a patent has been in force for six years, the Director has repeatedly found “strong settled expectations” for Patent Owner. *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, -602, -603, Paper 9 at 3 (Acting Dir. July 24, 2025) (informative) (denying Petitions under 35 U.S.C. § 314(a) for patents in force for six years, “creating strong settled expectations for Patent Owner”); *Kahoot! AS v. Interstellar Inc.*, IPR2025-00696, Paper 12 (Acting Dir. July 31, 2025) (similar); *Samsung*, IPR2025-00780, -781, Paper 11 at 2 (similar); *Yangtze Memory Techs. Co. v. Micron Tech., Inc.*, IPR2025-00498, -499, -500, -501, Paper 11 (Acting Dir. Aug. 14, 2025) (similar); *HS Hyosung Adv. Materials Corp. v. Kolon Indus., Inc.*, IPR2025-00662, -663, -664, Paper 12 (Acting Dir. Aug. 14, 2025) (similar); *Adv. Micro Devices, Inc. v. Adv. Cluster Sys., Inc.*, IPR2025-00862, -863, Paper 14 (Acting Dir. Sept. 3, 2025) (similar); *Intel Corp. v. Adv. Cluster Sys., Inc.*, IPR2025-00794, -795, Paper 13 (Acting Dir. Aug. 14, 2025) (similar).

Additionally, the Director has held that “there may be good reasons why a patent owner has strong settled expectations in a patent that has only been in force for [only] three years, for example an explanation of how an extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval correlates to settled expectations.” *Amgen*, IPR2025-00601, -602, -603, Paper 9 at 2 (informative). This is the case here, except the ’757 claims

have been in force for approximately five years, rather than three.

In reliance on the '757 patent application and later issued patent, the Patent Owner (or predecessor entities): (1) formed and consolidated corporate entities to develop a product from the '757 patented invention, including hiring two Chief Executive Officers and a Head of Technical Operations; (2) licensed the Serotype 6C patent family from the University of Alabama, Birmingham, in order to include this serotype in the claimed vaccine composition; (3) conducted licensing meetings, negotiations, and due diligence with numerous companies in the vaccine industry; (4) made and performed preclinical immunological evaluation of select pneumococcal serotype polysaccharide-conjugates; (4) partnered with numerous companies for vaccine development and manufacturing; (5) participated in numerous investor meetings to obtain funding for vaccine development; (6) conducted manufacturing facility acquisition due diligence; (7) held a Type B Pre-IND meeting with FDA concerning vaccine requirements for early clinical development and regulatory approval strategy; (8) incurred significant legal fees for patent prosecution, strategy, and licensing, and corporate work, and equity financing; and (9) incurred accounting fees. (Ex. 2001, ¶¶ 3–18.) Thus, Patent Owner has, through its actions, demonstrated strong settled expectations in its '757 patent.

By delaying nearly nine years from the date it first became aware of the '757 application through meetings with Patent Owner's predecessor, and approximately

five years since the '757 patent issued, Petitioner has created an implicit expectation between the parties, and an acquiescence as to the patentability of the claims of the '757 patent. These settled expectations favor exercising discretion and denying this Petition. *See Samsung Elecs., Co. v. W&Wsens Devices Inc.*, IPR2025-00995, -996, Paper 17 at 2 (Director Oct. 17, 2025) (denying Petition under 35 U.S.C. § 314(a) where “the challenged patents have been in force for approximately six years, creating settled expectations for Patent Owner[, and] Patent Owner provides evidence demonstrating Petitioner was aware of the challenged patents as early as 2020,” which “favors discretionary denial.”)

B. The Petition’s Challenge Is Weak

Discretionary denial is especially appropriate here, given the weakness of Petitioner’s challenge. As will be explained further in the Patent Owner Preliminary Response (“POPR”), the Petition fails to establish that the challenged claims are invalid over the asserted Grounds. Patent Owner asks the Director to consider the briefing presented in its POPR. *See Interim Process*, § II.C.i (patent owner may direct attention to an anticipated POPR and evidence for a discussion of the merits).

Independent claim 1 recites “a pharmaceutical composition comprising a plurality of at least two unique **immunogenic saccharide-polypeptide conjugates**, each comprising individually a 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.**” (Ex. 1001 at Claims (emphasis added).) Petitioner does not identify any reference disclosing **immunogenic** saccharide-polypeptide conjugates of any of serotypes 23A, 23B, and 35B. Instead, Petitioner relies on laundry lists of known *Streptococcus pneumoniae* serotypes, and argues that, because the references listing serotypes are directed to “immunogenic” conjugates, selecting two of serotypes 23A, 23B, and 35B from the laundry lists of known serotypes anticipates or renders obvious selecting two of serotypes 23A, 23B, and 35B, and conjugating them into immunogenic saccharide-polypeptide conjugates.” (Petition at 19–21, 26–27.)

However, in another PCV IPR filed by Petitioner, the Board denied institution because—just as Petitioner has done here—“Petitioner point[ed] to no evidence that the compositions relied upon by [their expert] were tested for the production of a functional antibody response.” *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-01223, Paper 8 at 16 (PTAB Oct. 20, 2017). There, the Board held that the use of those compositions, even in a vaccine trial, “do not provide evidence for Petitioner’s assertion that any serotype 3 conjugated to a protein carrier is immunogenic as claimed, i.e., showing higher serum IgG titers and overall greater functional antibody activity than seen with free polysaccharide alone or mixed with unconjugated CRM₁₉₇.” *Id.* at 16–17.

Here, just as in *Merck*, Petitioner has failed to provide any evidence

whatsoever that the claimed serotypes—assuming a POSA would have selected them among the 100+ serotypes available for selection—would have been immunogenic when conjugated to a polypeptide. In *Merck*, the Board declined institution where the prior art selected and tested the claimed serotypes in a conjugated vaccine, but had no evidence of immunogenicity (even though the goal, of course, was immunogenicity since the serotype was being tested in a vaccine). Here, Petitioner’s references do not even select the claimed serotypes among the laundry list of serotypes provided, much less conjugate and then test those serotype conjugates for immunogenicity in a vaccine.

Because neither Porro nor Mekalanos provide any evidence that the claimed serotypes, when conjugated, would be immunogenic, Petitioner’s anticipation theories for the immunogenicity limitation must rest on inherency: the assertion that any polysaccharide-protein conjugate made from these serotypes would necessarily be immunogenic. But inherency requires that the missing limitation be *necessarily present* in every embodiment of the prior art disclosure—not merely possibly or probably present. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010) (“The concept of ‘*inherent disclosure*’ *does not alter* the requirement that *all elements must be disclosed* in an anticipatory reference *in the same way as they are arranged or combined in the claim*. ‘Anticipation by *inherent disclosure* is appropriate only when the reference discloses prior art that *must*

necessarily include the unstated limitation.....Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” (cleaned up) (emphasis added).). And as the Board recognized in *Merck*, this is not the case here.

Petitioner’s obviousness challenges do not remedy the Petition’s lack of evidence that a POSA would have had a reasonable expectation of success at achieving immunogenicity when conjugating the claimed serotypes to a polypeptide. (See Petition at 39–41.) In addition, as discussed in Section II., above, Petitioner has not explained why a POSA would have been motivated to select the specific claimed serotypes when, since PPSV23 was approved in 1983, pharmaceutical companies have ignored most of the 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. Indeed, if the Board were to adopt Petitioner’s obviousness arguments, this would render obvious any serotype expansion of any PCV, ever. The weakness of the Petition’s merits further weights in favor of discretionary denial.

C. Other *Fintiv* Factors Weigh in Favor of Denial

Other *Fintiv* factors also favor denying institution. See *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).

Factor 1 is neutral, as Merck has moved for a stay, but the briefing on that

issue is ongoing and the Court has not yet ruled. (Ex. 2006.) With respect to factors 2 and 3, while the district court case does not yet have a trial date, this proceeding would still not be consistent with the AIA's objective to provide an effective and efficient alternative to litigation, as the '757 patent is now subject to two separate IPR challenges, *in addition to* district court litigation.

Factor 4 favors denial. Although Petitioner has filed a Sotera stipulation in the district court, because Petitioner filed its own IPR, rather than join the previously-filed Pfizer IPR that relies on art that overlaps with art in the instant Petition, there are still "concerns of inefficiency and the possibility of conflicting decisions." *Fintiv*, Paper 11 at 12. *See Pfizer Inc. v. Pogona, LLC*, IPR2026-00189, Paper 3 at 17–18, 50, 53, 56 (PTAB Dec. 23, 2025).

Factor 5 favors denial because Petitioner is the defendant in the district court litigation.

Factor 6 favors denial because, as explained above, the Petition fails to establish that the challenged claims are invalid over the asserted Grounds.

IV. CONCLUSION

For the reasons stated above, Patent Owner respectfully requests discretionary denial of the Petition.

Dated: March 30, 2026

Respectfully Submitted,

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CERTIFICATE UNDER 37 C.F.R. § 42.24

Under the provisions of 37 C.F.R. § 42.24, the undersigned hereby certifies that the foregoing **PATENT OWNER'S DISCRETIONARY DENIAL BRIEF** complies with the 20-page limit requirement allowed under the Interim Director Discretionary Process for discretionary denial briefs filed after September 1, 2025.

See Interim Director Discretionary Process (II)(C)(iii)
(<https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>).

Dated: March 30, 2026

/Sarah E. Spires/
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on March 30, 2026, a true and correct copy of the foregoing was served via electronic mail upon the attorneys of record for Petitioner at the following addresses:

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