

[REDACTED]

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

**PETITIONER'S OPPOSITION TO
PATENT OWNER'S DISCRETIONARY DENIAL BRIEF [REDACTED]**

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Ex-1003	Curriculum Vitae of Dr. Dennis Kasper
Ex-1004	Prosecution History of U.S. Patent No. 11,058,757
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Ex-1006	International Publication No. WO 2017/011338 (“Mekalanos”)
Ex-1007	U.S. Patent No. 8,808,707 (“Siber”)
Ex-1008	International Publication No. WO 2016/149771 (“Babb”)
Ex-1009	International Publication No. WO 2016/207905 (“Matur”)
Ex-1010	International Publication No. WO 2015/121783 (“Gu”)
Ex-1011	Keith P. Klugman et al., <i>Pneumococcal Conjugate Vaccine and Pneumococcal Common Protein Vaccines</i> , in <i>Vaccines</i> 504 (Stanley A. Plotkin, Walter A. Orenstein & Paul A. Offit eds., 6th ed. 2013); Lisa A. Jackson, <i>Pneumococcal Polysaccharide Vaccines</i> , in <i>Vaccines</i> 542 (Stanley A. Plotkin, Walter A. Orenstein & Paul A. Offit eds., 6th ed. 2013) (“Plotkin”)
Ex-1012	K. Aaron Geno et al., <i>Pneumococcal Capsules and Their Types: Past, Present, and Future</i> , 28 <i>Clin. Microbiol. Rev.</i> 871, 871–899 (2015) (“Nahm”)
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Ex-1018	Mark T. Dransfield et al., <i>Superior Immune Response to Protein-Conjugate Versus Free Pneumococcal Polysaccharide Vaccine in Chronic Obstructive Pulmonary Disease</i> , 180 <i>Am. J. Respir. Crit. Care Med.</i> 499–505 (2009) (“Dransfield”)
Ex-1019	Marta Domenech et al., <i>Emerging, Non-PCV13 Serotypes 11A and 35B of Streptococcus pneumoniae Show High Potential for Biofilm Formation In Vitro</i> , 10 <i>PLoS One</i> e0125636 (2015) (“Domenech”)
Ex-1020	Sandra S. Richter et al., <i>Changes in Pneumococcal Serotypes and Antimicrobial Resistance After Introduction of the 13-Valent Conjugate Vaccine in the United States</i> , 58 <i>Antimicrob., Agents Chemother.</i> 6484, 6484–6493 (2014) (“Richter 2014”)
Ex-1021	International Publication No. WO 2007/034280 (“Blay”)
Ex-1022	International Publication No. WO 2006/065137 (“Nierop”)
Ex-1023	Matthias 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> , 15 <i>BMC Infect. Dis.</i> 61 (2015) (“Imöhl”)
Ex-1024	Stefan Flasche et al., <i>Effect of Pneumococcal Conjugate Vaccination on Serotype Specific Carriage and Invasive Disease in England: A Cross Sectional Study</i> , 8 <i>PLoS Med.</i> e1001017 (2011) (“Flasche”)
Ex-1025	Sarkis K. Mazmanian & Dennis L. Kasper, <i>The Love–Hate Relationship Between Bacterial Polysaccharides and the Host Immune System</i> , 6 <i>Nat. Rev. Immunol.</i> 849 (2006) (“Mazmanian and Kasper 2006”)
Ex-1026	Stephen D. Bentley et al., <i>Genetic Analysis of the Capsular Biosynthetic Locus from All 90 Pneumococcal Serotypes</i> , 2 <i>PLoS Genet.</i> e31 (2006) (“Bentley”)

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Ex-1027	<i>Explaining How Vaccines Work</i> , CDC, https://www.cdc.gov/vaccines/basics/explaining-how-vaccines-work.html (last visited Jan. 9, 2026) (“CDC”)
Ex-1028	S.K. Obaro, <i>The New Pneumococcal Vaccine</i> , 8 <i>Clin. Microbiol. Infect.</i> 623–33 (2002) (“Obaro”)
Ex-1029	P.H. Mäkelä, <i>Capsular Polysaccharide Vaccines Today</i> , 12 <i>Infection</i> S72 (1984) (“Mäkelä”)
Ex-1030	Rino Rappuoli et al., <i>On the Mechanisms of Conjugate Vaccines</i> , 116 <i>Proc. Nat’l Acad. Sci. U.S.</i> 14, 14–16 (2019) (“Rappuoli”)
Ex-1031	Oswald T. Avery & Walther F. Goebel, <i>Chemo Immunological Studies on Conjugated Carbohydrate Proteins: II. Immunological Specificity of Synthetic Sugar Protein Antigens</i> , 50 <i>J. Exp. Med.</i> 533 (1929) (“Avery”)
Ex-1032	Porter Anderson et al., <i>Priming and Induction of Haemophilus influenzae Type b Capsular Antibodies in Early Infancy by Dpo20, an Oligosaccharide-Protein Conjugate Vaccine</i> , 111 <i>J. Pediatr.</i> 644, 644–650 (1987) (“Anderson 1987”)
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Ex-1036	U.S. Patent No. 5,360,897 (“Anderson 1994”)
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Ex-1038	Nicole M. Payton et al., <i>Lyophilized Vaccine Development, in Practical Aspects of Vaccine Development</i> 297 (Parag Kolhe & Satoshi Ohtake eds., Academic Press 2022) (“Payton”)

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Ex-1039	Gregory B. Lesinski & M.A.J. Westerink, <i>Novel Vaccine Strategies to T-Independent Antigens</i> , 47 <i>J. Microbiol. Methods</i> 135 (2001) ("Lesinski")
Ex-1040	Mekalanos Claim Comparison with Provisional
Ex-1041	Adam Finn, <i>Bacterial Polysaccharide-Protein Conjugate Vaccines</i> , 70 <i>Br. Med. Bull.</i> 1 (2004) ("Finn")
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Ex-1043	Henry Shinefield et al., <i>Use of a Staphylococcus aureus Conjugate Vaccine in Patients Receiving Hemodialysis</i> , 346 <i>N. Engl. J. Med.</i> 491 (2002) ("Shinefield")
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Ex-1045	Victor Morais et al., <i>Conjugation Mechanism for Pneumococcal Glycoconjugate Vaccines: Classic and Emerging Methods</i> , 9 <i>Bioengineering</i> 774 (2022) ("Morais")
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Ex-1047	Lawrence C. Paoletti et al., <i>Neonatal Mouse Protection against Infection with Multiple Group B Streptococcal (GBS) Serotypes by Maternal Immunization with a Tetravalent GBS Polysaccharide-Tetanus Toxoid Conjugate Vaccine</i> , 62 <i>Infect. Immun.</i> 3236 (1994) ("Paoletti")
Ex-1048	Scott E. Johnson et al., <i>Correlation of Opsonophagocytosis and Passive Protection Assays Using Human Anticapsular Antibodies in an Infant Mouse Model of Bacteremia for Streptococcus pneumoniae</i> , 180 <i>J. Infect. Dis.</i> 133, 133-40 (1999) ("Johnson")
Ex-1049	Robert L. Burton et al., <i>Development and Validation of a Fourfold Multiplexed Opsonization Assay (MOPA4) for Pneumococcal Antibodies</i> , 13 <i>Clin. Vaccine Immunol.</i> 1004 (2006) ("Burton")

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Ex-1050	Robert Malley et al., <i>Serotype-Independent Pneumococcal Experimental Vaccines That Induce Cellular as Well as Humoral Immunity</i> , 109 <i>Proc. Nat'l Acad. Sci. U.S.</i> 3623 (2012) ("Malley")
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Ex-1056	S.T. Sigurdardottir et al., <i>Safety and Immunogenicity of CRM197-Conjugated Pneumococcal–Meningococcal C Combination Vaccine (9vPnC-MnCC) Whether Given in Two or Three Primary Doses</i> , 26 <i>Vaccine</i> 4178, 4178–4186 (2008) ("Sigurdardottir")
Ex-1057	Catherine Satzke et al., <i>Molecular Epidemiology of Streptococcus pneumoniae Serogroup 6 Isolates from Fijian Children, Including Newly Identified Serotypes 6C and 6D</i> , 48 <i>J. Clin. Microbiol.</i> 4298, 4298–4300 (2010) ("Satzke")
Ex-1058	Sandra S. Richter et al., <i>Changing Epidemiology of Antimicrobial-Resistant Streptococcus pneumoniae in the United States, 2004–2005</i> , 48 <i>Clin. Infect. Dis.</i> e23 (2009) ("Richter 2009")
Ex-1059	Yao KH et al., <i>Type distribution of serogroup 6 Streptococcus pneumoniae and molecular epidemiology of newly identified serotypes 6C and 6D in China</i> , 70 <i>Diag. Microbiol. Infect. Dis.</i> 291, 291–98 (2011) ("Yao")

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Ex-1060	James J. Calix et al., <i>Elucidation of structural and antigenic properties of pneumococcal serotype 11A, 11B, 11C, and 11F polysaccharide capsules</i> , 193 <i>J. Bacteriol.</i> 5271, 5271–5278 (2011) (“Calix”)
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Ex-1062	Sotera Stipulation Letter Regarding IPR Invalidity Grounds, <i>Pogona, LLC v. Merck Sharp & Dohme LLC</i> , No. 25-cv-15294 (D.N.J.) / IPR2026-00221
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Ex-1070	Press Release, Merck, U.S. FDA Approves CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine) for Prevention of Invasive Pneumococcal Disease and Pneumococcal Pneumonia in Adults (June 17, 2024), 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/ .
Ex-1071	U.S. Patent No. 9,399,060

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<i>Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020)	2, 4
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I. INTRODUCTION

U.S. Patent No. 11,058,757 (“the ’757 Patent”) issued without any meaningful examination of the prior art. During prosecution, the Examiner failed to issue a single prior art rejection and concluded that the claimed serotypes “appear to be free of prior art.” As explained in the Petition, that conclusion was wrong—multiple prior art references of record expressly disclosed the same serotypes that the Examiner deemed novel. Recent activity at the Patent Office confirms the occurrence of this material error. During prosecution of U.S. Application No. 17/347,435 (“the ’435 Application”)—a continuation of the ’757 Patent—a different Examiner found claims similar to those of the ’757 Patent anticipated and/or obvious in light of one of the *same references* used in Merck’s petition. That ’435 Application remains rejected.

Rather than addressing material error, Patent Owner Pogona, LLC (“PO”)¹ requests that the Director deny institution based on: (1) settled expectations; (2) alleged substantive weaknesses in Merck’s petition; and (3) *Fintiv*. None of these three bases withstand scrutiny. First, PO’s settled expectations arguments ignore the reality that the ’757 Patent has been in force for less than five years. PO also conflates routine business communications with acquiescence to patent validity.

¹ Unless otherwise stated, PO includes PO’s predecessor entities.

Second, PO's merits arguments misread not only the prior art but also an unrelated, non-precedential, and factually inapposite PTAB case. Finally, the weight of the *Fintiv* factors—properly applied—strongly favors institution.

Most significantly, PO does not attempt to rebut the objective fact of the Office's error—confirmed by the Office's continued rejection of the '435 Application. Accordingly, the Director should refer Merck's petition to the Board for institution.

II. THE EXAMINER'S MATERIAL ERROR REQUIRES CORRECTION BY THE BOARD

A. PO Does Not Attempt to Rebut Merck's Showing of Material Examination Error

In its discretionary denial brief, PO said nothing to rebut Merck's showing that the Examiner materially erred in the prosecution of the '757 Patent. Pet. at 11–12. PO's brief does not grapple with the objective prosecution facts demonstrating that error. As an initial matter, PO does not contend that the Petition should be denied under § 325(d), and nothing in the record supports denial. Under the Board's two-part *Advanced Bionics* framework, the Director considers: (1) whether substantially the same art or arguments were previously before the Examiner; and (2) whether the Examiner materially erred. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential). Neither *Advanced Bionics* prong is satisfied here. Merck's petition presents new

art—Porro and Mekalanos—and new arguments, and the prosecution record reveals clear evidence of material error.

1. The '757 Patent Prosecution Record Demonstrates Material Examiner Error

The Examiner allowed the '757 Patent claims without a single prior art rejection. Allowance turned instead on an Examiner-initiated interview during which the only independent claim—originally a Markush listing of thirty-eight serotypes—was amended by the Examiner to recite just three: 23A, 23B, and 35B. Ex-1004, 1239–40, 1244.² The Examiner then stated that those serotypes appeared “to be free of prior art.” Ex-1004, 1244. That statement was wrong. The Board has consistently distinguished between an Examiner's considered judgment and a failure to meaningfully engage with prior art. *See Carrier Fire & Security America's Corp. v. Sentrilock, LLC*, IPR2021-00664, Paper 12 at 21–23 (PTAB Sept. 16, 2021) (“The prosecution history provides little insight into the Examiner's evaluation of the prior art. As Patent Owner acknowledges, the Examiner ‘issued no rejections,’ . . .”). That distinction applies here. References in PO's IDSs disclosed the claimed serotypes, yet the Examiner never addressed them. Pet. at 11–12 (“References of record such as Matur (Ex-1009) and Babb (Ex-1008) disclosed *S. pneumoniae* serotypes 23A,

² Citations to exhibits refer to original pagination or paragraph numbers except for Ex-1004 and Ex-1066.

23B, and/or 35B.” (citing Ex-1002 ¶¶ 70–72)). Additionally, due to the lack of a sufficient search, multiple references never before the Examiner, including Porro, Mekalanos, Gu, Blay, and Nierop disclosed conjugate vaccines including the claimed serotypes. Pet. at 9–10, 12 (citing Exs-1005–06, 1010, 1021–22). That is the kind of material error that the second part of *Advanced Bionics* exists to correct.

2. The '435 Continuation Application Confirms Material Examiner Error

More significantly, the Patent Office's ongoing examination of PO's related '435 Application confirms the material error in the '757 Patent prosecution. Pet. at 17–24. The '435 Application is a continuation of the '757 Patent and recites serotype combinations overlapping with those claimed in the '757 Patent. *See* Ex-1015, 179, 1487; Ex-1067 (comparison of Claim 1 of the '757 Patent and examined claims of the '435 Application).

During prosecution of the '435 Application, a different Examiner: (1) relied on the *same prior art reference* relied upon in Grounds 1 and 4 of Merck's Petition (Porro); (2) rejected PO's claims under 35 U.S.C. §§ 102 and 103 based on the same or similar arguments; and (3) rejected PO's arguments supporting those claims. Pet. at 19–24. The Petition explains how the Examiner in the '435 Application found that Porro disclosed each of the claim limitations of claims 1, 3, and 12. Pet. at 19–24 (providing citations to '435 Application prosecution history (Ex-1015) for claim

elements). PO then amended the claims in response to renewed Porro anticipation rejections, and ultimately added limitations not contained in the challenged claims of the '757 Patent. *See, e.g.*, Ex-1015, 1468, 1493–94, 1504–06, 1817–18, 1880–82. Even now, the amended claims of the '435 Application remain rejected as obvious in view of references including Porro. *See* Ex-1066, 2, 7–9, 28–31.

The prosecution history of the '435 Application is clear, objective evidence from a neutral fact finder that the original Examiner's allowance of the '757 Patent was erroneous. The same Office that issued the '757 Patent without a single prior art rejection is now—upon more careful examination of PO's related claims—relying on Porro to reject narrower claims reciting overlapping serotypes as anticipated and/or obvious. Porro's disclosures of the claimed serotypes and conjugate vaccine formats would have been central to patentability of the '757 Patent and underscores the Examiner's failure to conduct a sufficient search. Pet. at 17. PO's narrowing amendments—prompted specifically by Porro and not present in the currently challenged claims—confirm that, when Porro is applied, broader serotype-combination claims in the same family face serious patentability problems—problems not addressed during the '757 Patent's examination. Accordingly, the prosecution of the '435 Application provides contemporaneous, objective confirmation that applying Porro leads to findings that PO's claims directed to these

broad serotype combinations without structural or additional other limitations are unpatentable.

III. NONE OF PO'S DISCRETIONARY ARGUMENTS ARE VALID

The Director's March 26, 2025 memorandum regarding Interim Processes for PTAB Workload Management ("Interim Process Memo") identifies a non-exhaustive list of "considerations" or bases that may be considered in discretionary denial briefing. PO addresses three of these bases, but they all favor Merck: (1) there are no settled expectations for a patent in force less than five years, and which was not asserted until more than a year after Capvaxive[®] was approved and launched; (2) the unpatentability challenge is compelling; and (3) *Fintiv* does not warrant discretionary denial on this record. These discretionary denial factors are addressed in more detail below.

A. There Are No Settled Expectations

PO's settled expectations argument rests on two theories: the duration the patent has been in force and Merck's alleged awareness of the patent and its application based on PO's interactions with Merck. Neither theory supports discretionary denial. At the time of Merck's petition, the '757 Patent was less than five years old. And the facts surrounding PO's interactions with Merck support Merck more than PO. As Dr. Heather Platt explains, Merck independently made its serotype selection for Capvaxive[®] beginning in 2015, nearly a full year before the

'757 Patent's earliest priority date. Ex-1063, Platt Decl. ¶¶ 5–8. PO's cited interactions do not support discretionary denial.

1. The Age of the '757 Patent Does Not Support Denial

The '757 Patent issued on July 13, 2021, meaning the claims had been in force for approximately 4.5 years when Merck filed its Petition. “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 Solns. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 at 3 (Acting Dir. June 18, 2025) (informative). The Director³ has repeatedly declined to exercise discretion based on settled expectations where the challenged patent had been in force for fewer than six years. *Samsung Elecs. Co. v. Wilus Inst. of Standards & Tech. Inc.*, IPR2025-00935, Paper 12 at 2 (Acting Chief APJ Sept. 26, 2025) (finding that a patent that issued in 2021 had “not been in force for a significant period of time” and Patent Owner had “not developed strong settled expectations that favor discretionary denial”); *Cambridge Indus. USA, Inc. v. Applied Optoelects., Inc.*, IPR2025-00434, Paper 11 (Acting Dir. June 26, 2025) (similar); *Berkshire Hathaway Energy Co. v. Birchtech Corp.*, IPR2025-00274, Paper 23 (Acting Dir. July 2, 2025) (similar).

³ Discretionary decisions cited herein refer to decisions by the Director, which includes the then-Acting Director or delegate of the Director or Acting Director.

2. Merck's Prior Interactions With PO Are Irrelevant

PO points to three interactions between Merck and PO: (1) an October 2017 meeting at which PO disclosed the existence of a PCT application; (2) PO's declarant's participation in Merck's V116 advisory panel in 2021; and (3) PO's October 2021 licensing overture. DD Br. at 10–13. None of these interactions justify any settled expectations.

As to PO's first interaction, "settled expectations" do not attach to patent applications—they attach to issued claims. *See* Interim Process Memo at 2 ("Settled expectations of the parties, *such as the length of time the claims have been in force.*"). The October 2017 meeting involved disclosure of PO's PCT application, not the '757 Patent. As noted above, this was after Merck had already begun development of its own pneumococcal vaccine and chosen its serotypes. Ex-1063, Platt Decl. ¶¶ 5–6. Regardless, PO's PCT application—WO 2017/173415—had not entered the U.S. national stage, contained no working examples, and, most significantly, did not include claims directed to the serotype combinations that ultimately issued in the claims of the '757 Patent.⁴ It was not until March 2021—

⁴ Moreover, Pogona's and Dr. Forrest's characterization of the PCT application was false. For example, Pogona alleges "Liffey informed Merck that its ['757 Patent] application covers ... polysaccharide structures for 23A and 23B" DD Br. at 10 (citing Ex-2001, ¶ 3). The '757 Patent, however, does not disclose the structures of 23A and 23B. Ex-1001, Table 1 (providing "polysaccharide structures of various *S. pneumoniae* serotypes" but not including 23A and 23B).

more than three years *after* the 2017 meeting—that the Examiner issued a Notice of Allowance and entered an Examiner's amendment reciting serotypes 23A, 23B, and 35B in Claim 1. The claims in the PCT application did not focus on the recited serotypes. When claims of a parent application are materially different from the patent at issue, the Director has referred such petitions for consideration on the merits. *See, e.g., Solvatum Corp. v. Wound Healing Tech. Corp., LLC*, IPR2025-01042, Paper 11 at 7 (PTAB Oct. 3, 2025) (arguing petitioner could not have actual knowledge of claims based on earlier application to trigger settled expectations), Paper 12 (Dir. Nov. 20, 2025) (referred for institution).

As to the second interaction by PO's declarant, Dr. Forrest, his participation on Merck's V116 advisory panel in 2021 was a scientific engagement—a routine pharmaceutical industry practice that does not involve negotiating patent licenses or justify creating settled expectations in whatever a participant may be doing on their own. Nor does Dr. Forrest suggest otherwise. Treating advisory panel relationships as proof of settled expectations in the context of discretionary denial is not only without basis, but it would risk deterring a standard industry practice of engaging external scientists.

As to PO's licensing overture in October 2021, Merck made a business decision based on its own independent development of V116 that, again, predated PO's earliest application. Merck's decision not to take a license cannot be reasonably

seen as acknowledging the '757 Patent's validity. Indeed, it appears that PO reached out to at least eight pharmaceutical companies (not including Merck), and was still unsuccessful in licensing the '757 Patent. Ex-2001. After Merck promptly declined a license in October 2021, PO did not reach out again and did not bring suit until over a year after Capvaxive[®] was approved in June 2024. Ex-1070. PO waited until September 2025 to assert the '757 Patent against Merck. That silence cuts against any claim of settled expectations.

PO also relies on Merck's citation of the '757 Patent in an IDS for Merck's U.S. Patent No. 11,395,849. Such reliance is misplaced at best. Citing a prior art patent on an IDS, whether valid or not, reflects the obligation of candor to the Patent Office to disclose information material to an applicant's own submission. It is not proof of acquiescence to validity.

3. PO's Investment Evidence Does Not Establish "Extraordinary" Circumstances

PO cites the *Amgen* decision for the proposition that "extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval" can correlate to settled expectations. DD Br. at 14–15. Contrary to PO's argument, *Amgen* supports institution. In *Amgen*, the Director found discretionary denial *improper* because the patentee failed to "sufficiently articulate[]" the "extraordinary" circumstances required to justify denial of a young

patent. *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, -602, -603, Paper 9 at 2–3 (Acting Dir. July 24, 2025) (informative) (referring to PTAB for decision on institution). The same is true here. PO's cited investments—personnel hiring, (unsuccessful) licensing meetings, university IP acquisition, preclinical evaluation, investor meetings, FDA engagement, and legal fees—are routine activities of any early-stage biotechnology company attempting to develop a product. DD Br. at 15 (citing Ex-2001, ¶¶ 3–18). They are not the “extraordinary” expenditures required to create settled expectations sufficient to override the public interest in correcting a materially erroneous patent, or Merck's orders-of-magnitude greater investment in its own, independently developed product. Ex-1063, Platt Decl. ¶ 7. Indeed, PO has no commercial products at all.

B. Merck's Petition Presents a Strong Unpatentability Challenge

Merck presents a strong case on the merits. PO's merits argument rests heavily on the Board's decision in *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-01223, Paper 8 (PTAB Oct. 20, 2017), a decision based on a claim construction that is unrelated to the patent and prior art at issue here. *Wyeth* is non-precedential and factually inapposite.

**1. The Prior Art Teaches the Claimed Serotypes and Provides
Appropriate Context**

PO characterizes Merck's prior art as "laundry lists." That is incorrect. Porro discusses claimed serotypes 23A and 35B as "[n]ew emerging serotypes of *S. pneumoniae*" and expressly teaches that they "might be likely included in a further up-dated broad-spectrum vaccine formulation." Ex-1005, 66:28–67:9. Porro also specifically recommends incorporating 23A and 35B in "preferred embodiments" of its immunogenic multivalent vaccines. Ex-1005, 14:26–15:3. Mekalanos likewise discloses that "[t]he *Streptococcus pneumoniae* polysaccharide of the **immunogenic** composition may be a capsular type ... 23B ... 35B" Ex-1006, 3:20–25. These are not generic lists of known serotypes; they are targeted recommendations to include the claimed serotypes in the same vaccine development context addressed by the challenged claims. As noted above in Section II.A.2, the Patent Office itself has now confirmed the strength of the Porro art.

PO's argument that its inventors identified a "novel composition of serotypes" based on emerging disease patterns also does not support discretionary denial. DD Br. at 2. Indeed, it was the Examiner and not PO that erroneously identified the serotypes as purportedly "novel." That the CDC later confirmed the trends that PO's inventors allegedly observed does not establish novelty—it confirms that a person

of ordinary skill in the art would have been aware of and motivated to address the emerging serotypes that PO claims to have discovered.

2. The Previous *Wyeth* IPR Is Inapposite

In *Wyeth*, an undesignated, non-precedential decision, the Board denied institution because the petitioner failed to show a reasonable expectation of success under a heightened immunogenicity standard specific to U.S. Patent No. 9,399,060 (“the ’060 Patent”). There, the Board construed “immunogenic” in that patent to mean “eliciting higher serum IgG titers and overall greater functional antibody activity than seen with free polysaccharide alone.” *Wyeth*, Paper 8 at 11. That construction arose against a backdrop specific to that patent: for example, the ’060 Patent’s specification expressly stated that “attempts to produce a multivalent pneumococcal conjugate vaccine that exhibits significant immunogenicity with respect to serotype 3 polysaccharides have been unsuccessful.” Ex. 1071, 4:23–26.

In sharp contrast, PO points to nothing in the ’757 Patent’s intrinsic record that supports reading “immunogenic saccharide-polypeptide conjugate” in the manner required by the specific situation of *Wyeth*. The ’757 Patent specification contains no immunogenicity data; documents no serotype-specific failures; and provides no basis for importing the claim construction of the unrelated ’060 Patent. PO does not even suggest that its alleged inventors tested immunogenicity for any serotype in the ’757 Patent, let alone that they overcame a known challenge. The

'757 Patent at issue here thus presents facts not analogous to the '060 Patent, and *Wyeth* should have no bearing on the merits, let alone the Director's decision on discretionary denial.

C. *Fintiv* Does Not Warrant Discretionary Denial on This Record

PO invokes *Fintiv* in support of discretionary denial. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020). Here, the district court has stayed all discovery pending disposition of a motion to stay the case; there is no schedule yet issued; and Merck has filed a *Sotera* stipulation as part of its strong merits challenge. Ex-1062. Properly analyzed, every *Fintiv* factor either favors institution or is neutral.

The District Court Litigation Is at Its Earliest Stage (*Factors 1–3: Stay, Trial Date, and Investment in Litigation*): The district court ordered a stay of all discovery in the parallel district court case pending resolution of Petitioner's motion to stay pending IPR. *See* Ex-1068, Stay Order. There has been no scheduling conference, and nothing is currently calendared. *Id.* Institution will not duplicate any substantial merits investment. Moreover, the median time to trial in the District of New Jersey for a civil action is over four years. Ex-1069, Federal Courts Management Statistics at 15 (median time from filing to trial in civil cases for 2025 was 56.9 months). On this record (discovery stay, no schedule, no trial date),

institution is likely to streamline the district court action rather than create parallel duplication.

Merck's *Sotera* Stipulation Eliminates the Risk of Inconsistent Outcomes

(Factor 4: *Overlap of Issues*): Merck has filed a *Sotera* stipulation, eliminating the risk of relitigating in the district court any ground raised or that reasonably could have been raised in the IPR. Ex-1062. The IPR result will therefore be dispositive of the overlapping validity issues—directly addressing the “concerns of inefficiency and the possibility of conflicting decisions.” *Fintiv*, Paper 11 at 12.

PO also argues that Merck's decision to file its own IPR rather than join Pfizer's petition, IPR2026-00189, creates inefficiency. DD Br. at 2, 20. It does not. Merck's petition relies on different lead references—Porro and Mekalanos—compared to Pfizer's Alexander and Gu; Merck's petition also advances distinct invalidity theories that warrant independent consideration. Moreover, there was no proceeding that Merck could have joined. *See* 37 C.F.R. § 42.122 (permitting motion for joinder one month ***after institution*** of the proceeding to be joined). Merck's independent filing was the responsible course of action to ensure that all meritorious invalidity grounds are properly presented to the Director to decide the most efficient path forward for the Board to properly consider all the issues. To the extent Pfizer's and Merck's petitions raise similar issues, efficiencies could be addressed by consolidation or joinder. Pfizer appears to be in accord. *Pfizer Inc. v. Pogona, LLC*,

IPR2026-00189, Paper 14 at 19 (PTAB Apr. 6, 2026). In any event, how to proceed efficiently is best addressed at the merits stage or after institution—not now at the discretionary phase.

Party Overlap Does Not Outweigh the Factors Favoring Institution
(Factor 5: Overlap Between Petitioner and Defendant): Merck is the defendant in the parallel district court litigation. This factor is not independently dispositive. Here, every other *Fintiv* factor cuts the other way. Factor 5 cannot carry the weight that PO places on it against these countervailing considerations.

The Strength of the Challenge Favors Institution (Factor 6: Strength of the Merits): Merck's petition presents a compelling case that the claims of the '757 Patent are anticipated and/or obvious over prior art that teaches the relevant serotypes and their inclusion in pneumococcal vaccines. As explained in Sections II.A.2 and III.B above, the strength of the challenge is confirmed by the Patent Office's own contemporaneous treatment of Porro in PO's pending '435 Application. A strong merits showing grounded in prior art that the Examiner overlooked counsels strongly in favor of referral and institution.

IV. PUBLIC HEALTH INTERESTS FAVOR INSTITUTION

The Interim Process Memo identifies “[c]ompelling economic, public health, or national security interests” as a relevant consideration. *See* Interim Process Memo at 2. On June 17, 2024, the FDA approved Merck's Capvaxive® (also known as

“V116”)—a 21-valent pneumococcal conjugate vaccine for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults 18 years of age and older. Ex-1063, Platt Decl. ¶¶ 1, 5, 7. Capvaxive[®] serves a critical public health need and represents one of the most significant advances in adult pneumococcal disease prevention in decades. It is the first PCV specifically designed for the adult population. Merck's investment of [REDACTED] in Capvaxive[®] spans over a decade of research, clinical development, and regulatory engagement—beginning with preclinical candidate documentation in April 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. Ex-1063, Platt Decl. ¶ 7. Allowing a materially erroneous patent to stand unchallenged risks impeding further innovation by Merck (and others) in the vaccine space for American patients—precisely the outcome that the Memo's public health factor is designed to prevent.

V. CONCLUSION

The '757 Patent issued because the Examiner materially erred—and the Patent Office itself has confirmed it in a related prosecution. PO's arguments for discretionary denial cannot overcome that fact. No settled expectations exist for a patent in force fewer than five years that was never asserted until September 2025.

[REDACTED]

Petitioner's Opposition to Patent Owner's Discretionary Denial Brief
IPR2026-00221

The merits challenge is compelling, confirmed by the Patent Office's own rejection of PO's similar claims and arguments in the '435 Application. The *Fintiv* factors, properly applied, do not support denial. Compelling public health interests also independently favor institution. The Director should decline to exercise discretion to deny institution and should instead refer the Petition to the Board.

Dated: April 29, 2026

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. §42.24(d), Petitioner certifies that this Reply includes 3,857 words, as measured by Microsoft Word, exclusive of the table of contents, certificates of service, word count, and exhibits.

CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2026, I caused a true and correct copy of the foregoing PETITIONER'S OPPOSITION TO PATENT OWNER'S DISCRETIONARY DENIAL BRIEF was served in its entirety by filing these documents through the PTAB P-TACTS System, as well as by email, on the counsel of record for the Patent Owner:

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