



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. IPR2026-00374
U.S. Patent No. 11,058,757

**PETITIONER'S OPPOSITION TO
PATENT OWNER'S DISCRETIONARY DENIAL BRIEF**

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EXHIBIT LIST

Exhibit	Short Name	Document
EX1001	'757 patent	U.S. Patent No. 11,058,757
EX1002	Musey Dec.	Declaration of Luwy Musey, M.D.
EX1003		Curriculum Vitae of Luwy Musey, M.D.
EX1004	Goldblatt	Goldblatt, <i>Conjugate Vaccines</i> , CLIN. EXP. IMMUNOL. Vol. 119, pp. 1-3 (2000)
EX1005	Veeramachineni	Veeramachineni et al., <i>Bacterial Capsular Polysaccharides of Pathogens – A Toolbox for Vaccines and Therapeutics</i> , IN: GLYCOME: THE HIDDEN CODE OF BIOLOGY, ed. Dipak K. Banerjee (Nova Science Publishers, Inc., 2021)
EX1006	Ravenscroft	Ravenscroft et al., <i>Genetic and Structural Elucidation of Capsular Polysaccharides from Streptococcus Pneumoniae Serotypes 23A and 23B, and Comparison to Serotype 23F</i> , 450 CARBOHYDRATE RES. 19-29 (October 2017)
EX1007	Deng	Deng et al., <i>Antibody Enhanced HPLC for Serotype-Specific Quantitation of Polysaccharides in Pneumococcal Conjugate Vaccine</i> , NPJ VACCINES (2023)
EX1008	Alexander	International Patent Application WO 2005/120563
EX1009	Gu	International Patent Application WO 2015/121783
EX1010	Porro	International Patent Application WO 2014/118201

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EX1011	Al-Sherikh	Al-Sherikh et al., <i>Distribution of Serotypes and Antibiotic Susceptibility Patterns Among Invasive Pneumococcal Diseases in Saudi Arabia</i> , ANNALS OF LABORATORY MEDICINE, Vol. 34, 210-15 (2014)
EX1012	<i>Reserved</i>	<i>Reserved</i>
EX1013	Richter	Richter et al., <i>Changes in Pneumococcal Serotypes and Antimicrobial Resistance after Introduction of the 13-Valent Conjugate Vaccine in the United States</i> , ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, Vol. 58, No. 7, 6486-89 (2014)
EX1014	Wagenvoort	Wagenvoort et al., <i>Risk and Outcomes of Invasive Pneumococcal Disease in Adults with Underlying Conditions in the Post-PCV7 Era, The Netherlands</i> , VACCINE, Vol. 34, 334-40 (2016)
EX1015	Kaplan	Kaplan et al., <i>Multicenter Surveillance of Streptococcus pneumoniae Isolates from Middle Ear and Mastoid Cultures in the 13-Valent Pneumococcal Conjugate Vaccine Era</i> , CLINICAL INFECTIOUS DISEASES 60:1339-1345 (2015)
EX1016	Pilishvili	Pilishvili et al., <i>Sustained Reductions in Invasive Pneumococcal Disease in the Era of Conjugate Vaccine</i> , JOURNAL OF INFECTIOUS DISEASE, No. 201, 32-41 (2010)
EX1017	Waight	Waight et al., <i>Effect of the 13-valent Pneumococcal Conjugate Vaccine on Invasive Pneumococcal Disease in England and Wales 4 Years After Its Introduction: An Observational Cohort Study</i> , LANCET

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		INFECTIOUS DISEASES, Vol. 15, 535-43 (2015)
EX1018	ECDC	<i>European Centre for Disease Control and Prevention, Surveillance of Invasive Bacterial Diseases in Europe, 2012 (Stockholm: ECDC, 2015)</i>
EX1019	PHAC	<i>Public Health Agency of Canada, Streptococcus and STI Unit, National Laboratory Surveillance of Invasive Streptococcal Disease in Canada: Annual Summary 2013 (Winnipeg, Manitoba: PHAC, 2014)</i>
EX1020	Lee	Lee et al., <i>Immune Response in Infants to the Heptavalent Pneumococcal Conjugate Vaccine Against Vaccine-Related Serotypes 6A and 19A</i> , CLINICAL AND VACCINE IMMUNOLOGY, Vol. 16, No. 3, 376-81 (2009)
EX1021	Anttila	Anttila et al., <i>Contribution of Serotype-Specific IgG Concentration, IgG Subclasses, and Relative Antibody Avidity to Opsonophagocytic Activity Against Streptococcus Pneumoniae</i> , CLINICAL AND EXPERIMENTAL IMMUNOLOGY, Vol. 118, 402-07 (1999)
EX1022	PFL	<i>Prevnar® FDA Label</i>
EX1023	Vesikari	Vesikari et al., <i>Immunogenicity of the 10-Valent Pneumococcal Non-Typeable Haemophilus Influenzae Protein D Conjugate Vaccine (PHiD-CV) Compared to the Licensed 7vCRM Vaccine</i> , THE PEDIATRIC INFECTIOUS DISEASE JOURNAL, Vol. 28, No. 4, S66-S76 (2009)
EX1024	Yeh	Yeh et al., <i>Immunogenicity and Safety of 13-Valent Pneumococcal Conjugate Vaccine in Infants and Toddlers</i> , PEDIATRICS, Vol. 126, No. 3, e493–e505 (2010)
EX1025	Myers	Myers, <i>Wyeth's 7-valent Vaccine for Pneumococcal Disease Registered In Russia</i> ,

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		FIERCE BIOTECH, March 5, 2009, https://www.fiercebiotech.com/biotech/wyeth-s-7-valent-vaccine-for-pneumococcal-disease-registered-russia
EX1026	Pichichero	<i>Pichichero, Protein Carriers of Conjugate Vaccines, HUMAN VACCINES & IMMUNOTHERAPEUTICS, 2505-23 (2013)</i>
EX1027	WHO	World Health Organization, <i>Pneumococcal Conjugate Vaccine for Childhood Immunization</i> , WEEKLY EPIDEMOL. REC. 82(12) 93, 94 (2007)
EX1028	Hu	Hu et al., <i>Approach to Validating an Opsonophagocytic Assay for Streptococcus Pneumoniae</i> , CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY, Vol. 12, No. 2, 287-95 (2005)
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EX1030	Costantino	Costantino et al., <i>The Design of Semi-Synthetic and Synthetic Glycoconjugate Vaccines</i> , EXPERT OPINIONS IN DRUG DISCOVERY, Vol. 6, No. 10, 1045-66 (2011)
EX1031	Wessels	Wessels et al., <i>Structural Properties of Group B Streptococcal Type III Polysaccharide Conjugate Vaccines that Influence Immunogenicity and Efficacy</i> , INFECTION AND IMMUNITY, Vol. 66, No. 5, 2186-92 (1998)
EX1032	Baker	Baker et al., <i>Safety and Immunogenicity of Capsular Polysaccharide-Tetanus Toxoid Conjugate Vaccines for Group B Streptococcal Types Ia and Ib</i> , JOURNAL OF

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		INFECTIOUS DISEASES, Vol. 179, 142-50 (1999)
EX1033	Whitney 2003	Whitney et al., <i>Decline in Invasive Pneumococcal Disease after the Introduction of Protein-Polysaccharide Conjugate Vaccine</i> , N. ENGL. J. MED. 1737-1746 (2003)
EX1034	Jakobsen	Jakobsen et al., <i>Intranasal Immunization with Pneumococcal Conjugate Vaccines with LT-K63, a Nontoxic Mutant of Heat-Labile Enterotoxin, as Adjuvant Rapidly Induces Protective Immunity Against Lethal Pneumococcal Infections in Neonatal Mice</i> , INFECTION AND IMMUNITY, Vol. 70, No. 3, 1443-52 (2002)
EX1035	Sogaard	Søgaard, <i>The Clinical Use of Adjuvants in Pneumococcal Vaccination</i> , HUMAN VACCINES, Vol. 7, No. 2, 276-80 (2011)
EX1036	Giudice	Giudice and Rappuoli, <i>Genetically Derived Toxoids for use as Vaccines and Adjuvants</i> , VACCINE, Vol. 17, S44-S52 (1999)
EX1037	Lees	Lees et al., <i>Versatile and Efficient Synthesis of Protein-Polysaccharide Conjugate Vaccines Using Aminooxy Reagents and Oxime Chemistry</i> , VACCINE 716-729 (2006)
EX1038	Whitney 2014	Whitney et al., <i>Dosing Schedules for Pneumococcal Conjugate Vaccine Considerations</i> , THE PEDIATRIC INFECTIOUS DISEASE JOURNAL, S172-S181 (2014)
EX1039	Nunes	Nunes et al., <i>The Impact of Private Use of PCV7 in 2009 and 2010 on Serotypes and Antimicrobial Resistance of Streptococcus Pneumoniae Carried by Young Children in Portugal: Comparison with Data Obtained Since 1996 Generating a 15-year Study Prior to PCV13 Introduction</i> , VACCINE 1648-1656 (2016)

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EX1040	Jefferies	<i>Jefferies et al., 13-Valent Pneumococcal Conjugate Vaccine (PCV13), HUMAN VACCINES 1012-1018 (2011)</i>
EX1041	<i>Reserved</i>	<i>Reserved</i>
EX1042	Malley	<i>U.S. Patent Application Publication No. 2015/0374811</i>
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EX1044		<i>File History of U.S. Provisional Application 62/316555</i>
EX1045	Daniels	<i>Daniels et al., A Review of Pneumococcal Vaccines: Current Polysaccharide Vaccine Recommendations and Future Protein Antigens, J. PEDIATRIC PHARMACOLOGY AND THERAPEUTICS, Vol. 21, No. 1, 27-35 (2016)</i>
EX1046	<i>Reserved</i>	<i>Reserved</i>
EX1047	Pogona Complaint	<i>Pogona, LLC v. Merck Sharp & Dohme LLC, 2-25-cv-15294 (D.N.J. September 5, 2025) (D.I. 1, Complaint)</i>
EX1048	CDC	<i>Centers for Disease Control and Prevention, Invasive Pneumococcal Disease in Children 5 Years After Conjugate Vaccine Introduction – Eight States, 1998-2005, MORBIDITY AND MORTALITY WEEKLY REPORT, Vol. 57, No.6, 144-48 (2008)</i>
EX1049	<i>Reserved</i>	<i>Reserved</i>
EX1050	Merck Study	<i>A Study to Evaluate the Safety, Tolerability and Immunogenicity of V114 in Healthy Adults and Infants (V114-005) (Version 5, 2015-11-03)</i>
EX1051	Sotera Stipulation	<i>Sotera Stipulation Letter Regarding IPR Invalidity Grounds, Pogona, LLC v. Merck</i>

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		<i>Sharp & Dohme LLC</i> , No. 25-cv-15294 (D.N.J.) / IPR2026-00374
EX1052	Stay Order	February 25, 2026 Letter Order Staying Discovery for <i>Pogona, LLC v. Merck Sharp & Dohme, LLC</i> , No. 25-15294 (D.N.J.)
EX1053	Continued Stay Order	February 25, 2026 Letter Order Staying Discovery for <i>Pogona, LLC v. Merck Sharp & Dohme, LLC</i> , No. 25-15294 (D.N.J.)
EX1054	NJ Local Patent Rules	District of New Jersey Local Patent Rules
EX1055	Platt Decl.	Declaration of Heather Platt [[UNDER SEAL]]
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EX1057	Merck Internal Presentation	Merck Internal PowerPoint Presentation (Excerpt) [[UNDER SEAL]]
EX1058	Court Statistics	Federal Courts Management Statistics (December 31, 2025), https://www.uscourts.gov/data-news/data-tables/2025/12/31/federal-courtmanagement-statistics/n-a .
EX1059	June 2024 Capvaxive Press Release	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-diseaseand-pneumococcal-pneumonia-in-adults/ .

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EX1060	Refiled Motion to Stay Order	July 23, 2026 Letter Order Requiring Refiling of Motion to Stay Briefs in <i>Pogona, LLC v. Merck Sharp & Dohme, LLC</i> , No. 25-15294 (D.N.J.)
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TABLE OF AUTHORITIES

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<i>Amgen Inc. v. Bristol-Myers Squibb Co.</i> , IPR2025-00601, Paper 9 (Acting Dir. July 24, 2025).....	8
<i>Anthony Inc. v. ControlTec, LLC</i> , IPR2025-00636, Paper 9 at 2 (Acting Dir. July 16, 2025).....	3
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I. INTRODUCTION

Merck's petition presents the same grounds and evidence as Pfizer's petition in IPR2026-00189 ("Pfizer IPR") challenging U.S. Patent No. 11,058,757 ("the '757 patent"). That posture supports institution, not denial: the Director has already rejected many of Pogona, LLC's ("PO" or "Pogona") similar discretionary denial arguments in the Pfizer IPR, and the Board has instituted review based on the merits. The Director should likewise conclude here that Petitioner Merck Sharp & Dohme LLC's ("Merck") Petition challenging the '757 patent is an appropriate and efficient use of Office resources.

First, Merck commits to an understudy role that avoids additional burden on the Board and PO while allowing the Office to correct the material error that led to issuance of the challenged claims should the Pfizer IPR settle. PO has made no effort to rebut Merck's and Pfizer's showing that the Examiner materially erred during prosecution of the '757 patent. Pet. at 24–25. And the Board has now found Pfizer reasonably likely to prevail on the merits with respect to its challenge. IPR2026-00189, Paper 16 at 2. It is an appropriate use of Office resources to review potential error.

Second, there are no "settled expectations." The '757 patent is young (less than five years old at the time of the petition) and Pogona's argument that awareness

of an application can trigger settled expectations before the relevant claims issue is unsupported by the Interim Process Memo and undermined by the Board's institution of the Pfizer IPR. DD Br. at 9–16. Pogona's prior-interaction and investment evidence likewise does not rise to the level required to deny review or create settled expectations.

Third, the *Fintiv* factors favor institution. The parallel district court case is in its earliest stages—no discovery has occurred, no scheduling conference has been scheduled, and no meaningful resources have been invested by the parties. Moreover, the district court has directed the parties to file a renewed motion to stay the case pending IPR. Ex-1052, -1053, -1060. A final written decision in this case will also issue well before any anticipated trial would occur. And Merck has filed a revised *Sotera* stipulation, eliminating the risk of relitigating in the district court any ground raised or that reasonably could have been raised in this or its original IPR.

The Director's non-merits denial of Merck's previous IPR does not support discretionary denial here. Neither that prior denial nor *Magnolia* supports foreclosing Merck's understudy Petition before any tribunal has adjudicated the merits of the instituted grounds. Moreover, countervailing public health interests favor institution.

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

As described in the Petition, the '757 patent issued without any meaningful examination of the prior art. Pet. at 24–25. 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.” *Id.* That conclusion was wrong—multiple prior-art references, *including references in Pogona's own submissions*, expressly disclosed the same serotypes that the Examiner deemed novel. Pet. at 25 (citing Ex-1042 and Ex-1043). That is the kind of material error that the Director¹ has acknowledged as an “appropriate use of Office resources” to correct. *Anthony Inc. v. ControlTec, LLC*, IPR2025-00636, Paper 9 at 2 (Dir. July 16, 2025) (declining discretionary denial where “Petitioner persuasively explains that the patent examiner erred by overlooking the teachings of [a prior-art reference]”).²

Pogona says nothing to rebut Merck's showing that the Examiner materially erred during prosecution of the '757 patent. And the Board has now instituted Pfizer's petition. IPR2026-00189, Paper 16 at 2. Given Merck's understudy role,

¹ 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 Moreover, due to the lack of a sufficient search, multiple references never before the Examiner, including the lead prior-art references asserted in the Petition (Alexander and Gu), disclose pharmaceutical compositions comprising conjugates of *S. pneumoniae* serotypes 23A, 23B, and 35B.

which avoids any additional burden on the Board or PO, institution is an appropriate use of the Board's resources because it preserves the Office's ability to correct this material error if the Pfizer IPR settles.

III. THERE ARE NO SETTLED EXPECTATIONS

PO's settled expectations argument rests on two theories: the length of time the patent has been in force and Merck's alleged awareness of the patent or its application based on PO's interactions with Merck. Neither theory supports discretionary denial. At the time Merck filed its Petition, the '757 patent had been in force for less than five years. And the facts surrounding PO's interactions with Merck support Merck, not 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-1055 Platt Decl. ¶¶ 5–8. PO's cited interactions do not support discretionary denial.

A. 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 less than five 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 Director 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 Optoelecs., Inc.*, IPR2025-00434, Paper 11 at 2–3 (Acting Dir. June 26, 2025) (similar); *Berkshire Hathaway Energy Co. v. Birchtech Corp.*, IPR2025-00274, Paper 23 at 3 (Acting Dir. July 2, 2025) (similar).

B. 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 justifies discretionary denial or creates settled expectations.

As to PO's first interaction, “settled expectations” do not attach to patent applications; they attach, if at all, 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 occurred after Merck had already begun development of its own pneumococcal vaccine and chosen its serotypes. Ex-1055,

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 '757 patent.³ It was not until March 2021—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 Techs. 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) (referring 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

³ 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 10–11 (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).

justify creating settled expectations in whatever a participating panelist 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, it would also 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, which again predated PO's earliest application. Merck's decision not to take a license cannot reasonably be viewed as acknowledging the '757 patent's validity or patentability. Indeed, it appears that PO reached out to at least eight pharmaceutical companies (not including Merck) and was unsuccessful in licensing the '757 patent to any of them. Ex-2001 at 4–5. After Merck promptly declined a license in October 2021, PO did not reach out again and did not bring suit until more than a year after Capvaxive[®] was approved in June 2024. Ex-1059. PO waited until September 2025 to assert the '757 patent against Merck. That silence cuts against any claim of settled expectations. If anything, Merck, not PO, had 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. DD Br. at 9–10. 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.

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

PO cites *Amgen* for the proposition that an "extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval" can correlate to settled expectations. DD Br. at 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, legal fees, and accounting fees—are routine activities of any early-stage biotechnology company attempting to develop a product. DD Br. at 15–16 (citing Ex-2001, ¶¶ 3–18). And even despite these routine investments, PO has no commercial product. They are not the "extraordinary" expenditures required to create settled expectations sufficient to override the public interest in correcting a materially erroneous patent. Nor can they outweigh Merck's

orders-of-magnitude greater investment in its own independently developed commercial product. Ex-1055, Platt Decl. ¶ 7.

IV. 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 case is in its infancy: no discovery has occurred, no schedule has yet issued, and Merck has filed a *Sotera* stipulation. Ex-1051. 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*): PO argues that Factor 1 is neutral and that Factors 2 and 3 favor denial because the '757 patent is subject to two IPR challenges in addition to district court litigation. DD Br. at 17. The record shows otherwise: no discovery has occurred, there has been no scheduling conference, and nothing is currently calendared in the district court litigation. *Id.* The district court has also ordered Merck to refile its motion to stay the case by August 14, 2026, and to include an update on the status of the IPRs and the effects of estoppel in district court, which is addressed by Merck's revised *Sotera* stipulation. Ex-1060. Additionally, because this case will follow the same schedule as the Pfizer IPR, a final written decision is expected by May 26, 2027. IPR2026-00189, Paper 16; 35

U.S.C. § 316(a)(11). That timing would precede any reasonably anticipated district-court trial: under the New Jersey Local Patent Rules, even if discovery begins, by the time the Board's final written decision issues, the case likely would not have proceeded to a *Markman* hearing and fact discovery likely would remain open. Ex-1054 (Local Patent Rules). Indeed, the median time to trial in the District of New Jersey for a civil action is over four years. Ex-1058, Federal Courts Management Statistics at 15 (median time from filing to trial in civil cases for 2025 was 56.9 months). On this record—no discovery, no schedule, and no trial date—institution is likely to streamline the district court action rather than create parallel duplication. Pogona's assertion that the '757 patent is subject to "two separate IPR challenges" in addition to the district court litigation is belied by joinder and Merck's understudy role: Merck has accepted consolidated filings, no new arguments or grounds, and discovery limitations while Pfizer remains active.

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 district court any ground raised or that reasonably could have been raised in this Petition or its *original* IPR, mooted PO's estoppel arguments. Ex-1051. Merck's stipulation addresses PO's concerns based on *Network-1*. The IPR result will therefore be dispositive of the overlapping validity issues and directly

mitigate the “concerns of inefficiency and the possibility of conflicting decisions.”

Fintiv, Paper 11 at 12.

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. But party overlap is not independently dispositive. Here, the other *Fintiv* considerations either favor institution or are neutral. 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): The Board has already instituted Pfizer's petition, which presents the grounds Merck now seeks to join, after determining that Pfizer demonstrated a reasonable likelihood of prevailing on at least one challenged claim. Merck's Petition does not add new grounds; it proceeds on the same instituted grounds and evidence. That merits posture weighs strongly against discretionary denial, particularly where PO seeks to use discretionary arguments to prevent any merits review by Merck notwithstanding the already-instituted Pfizer IPR.

PO's reliance on the discretionary denial of Merck's earlier petition to argue that *Fintiv* Factor 6 favors denial is unsupported. That unexplained, non-merits denial did not adjudicate the patentability of the '757 patent and should not foreclose institution of a petition that proceeds on Pfizer's already-instituted grounds. Nor is

Magnolia analogous. DD Br. at 18 (citing *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17, 2 (Dir. May 14, 2026) (precedential)). *Magnolia* concerned abusive, repeated attacks after prior unsuccessful challenges; here, no tribunal has adjudicated the merits of Merck's or Pfizer's IPR grounds, and Merck seeks only an understudy role in an already-instituted proceeding.

V. PUBLIC HEALTH INTERESTS FAVOR INSTITUTION

The Director's 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-1055, Platt Decl. ¶¶ 2, 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 more than a decade of research, clinical development, and regulatory engagement—beginning with preclinical candidate documentation in April 2015, proceeding through Phase 1 and Phase 2 development, continuing through a comprehensive Phase 3 development program that included eight Phase 3 clinical trials enrolling thousands of participants, and culminating in FDA approval and

commercialization. Ex-1055, 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.

VI. CONCLUSION

PO's arguments for discretionary denial do not overcome the compelling case for institution. No settled expectations exist for a patent that had been in force for less than five years when Merck filed its Petition, was not asserted until September 2025, and was never acquiesced in by Merck. The prior non-merits denial of Merck's earlier petition does not bar institution here, and 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: July 29, 2026

Respectfully submitted,

/s/ Ben Haber

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. §42.24(d), Petitioner certifies that this Opposition includes 2,925 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 July 29, 2026, I caused a true and correct copy of the foregoing PETITIONER'S OPPOSITION TO PATENT OWNER'S DISCRETIONARY DENIAL BRIEF to be served in its entirety by filing these documents through the PTAB P-TACTS System, as well as by email, on counsel of record for Patent Owner:

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