

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.
Petitioner

v.

POGONA, LLC
Patent Owner

Case IPR2026-00189
U.S. Patent No. 11,058,757

**PETITIONER PFIZER INC.'S OPPOSITION TO
PATENT OWNER'S DISCRETIONARY DENIAL BRIEF**

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LIST OF EXHIBITS

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
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 INFECTIOUS DISEASES, Vol. 15, 535-43 (2015)
EX1018	ECDC	European Centre for Disease Control and Prevention, <i>Surveillance of Invasive Bacterial Diseases in Europe, 2012</i> (Stockholm: ECDC, 2015)
EX1019	PHAC	Public Health Agency of Canada, Streptococcus and STI Unit, <i>National Laboratory Surveillance of Invasive Streptococcal Disease in Canada: Annual</i>

		Summary 2013 (Winnipeg, Manitoba: PHAC, 2014)
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	Prevnam® FDA Label
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> , FIERCE BIOTECH, March 5, 2009, https://www.fiercebiotech.com/biotech/wyeth-s-7-valent-vaccine-for-pneumococcal-disease-registered-russia
EX1026	Pichichero	Pichichero, <i>Protein Carriers of Conjugate Vaccines</i> , HUMAN VACCINES & IMMUNOTHERAPEUTICS, 2505-23 (2013)

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)
EX1029	Romero-Steiner	Romero-Steiner et al., <i>Use of Opsonophagocytosis for Serological Evaluation of Pneumococcal Vaccines</i> , CLINICAL AND VACCINE IMMUNOLOGY, Vol. 13, No. 2, 165-69 (2006)
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 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 Coinjugate 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)
EX1040	Jefferies	Jefferies et al., <i>13-Valent Pneumococcal Conjugate Vaccine (PCV13)</i> , HUMAN VACCINES 1012-1018 (2011)
EX1041	Reserved	Reserved
EX1042	Malley	U.S. Patent Application Publication No. 2015/0374811

EX1043		File History of U.S. Patent No. 11,058,757 - Application 16/089040 File History (Excerpts)
EX1044		File History of U.S. Provisional Application 62/316555
EX1045	Daniels	Daniels et al., <i>A Review of Pneumococcal Vaccines: Current Polysaccharide Vaccine Recommendations and Future Protein Antigens</i> , J. PEDIATRIC PHARMACOLOGY AND THERAPEUTICS, Vol. 21, No. 1, 27-35 (2016)
EX1046	<i>Reserved</i>	<i>Reserved</i>
EX1047	Pogona Complaint	<i>Pogona, LLC v. Merck Sharp & Dohme LLC</i> , 2-25-cv-15294 (D.N.J. September 5, 2025) (D.I. 1, Complaint)
EX1048	CDC	Centers for Disease Control and Prevention, <i>Invasive Pneumococcal Disease in Children 5 Years After Conjugate Vaccine Introduction – Eight States, 1998-2005</i> , MORBIDITY AND MORTALITY WEEKLY REPORT, Vol. 57, No.6, 144-48 (2008)
EX1049	SDD	Pfizer's Search Disclosure Declaration (Protective Order Material – Filing Party & Board Only)
EX1050	Merck Study	A Study to Evaluate the Safety, Tolerability and Immunogenicity of V114 in Healthy Adults and Infants (V114-005) (Version 5, 2015-11-03)
EX1051	Forrest	International Patent Application WO 2017/173415
EX1052	'060 patent	U.S. Patent No. 9,399,060

I. INTRODUCTION

Patent Owner Pogona’s discretionary denial request (Paper 9, “DD Br.”) illustrates why the Director should decline to deny institution. To start, the Examiner of U.S. Patent No. 11,058,757 (“the ’757 patent,” EX1001) never issued a single prior-art rejection and stated that the *Streptococcus pneumoniae* (*S. pneumoniae*) serotypes recited in the claims were “free of prior art,” Pet. at 10–12, even though multiple prior-art references—some in Pogona’s own submissions—expressly disclosed them. Tellingly, Pogona makes no argument under 35 U.S.C. § 325(d). Discretionary denial is inappropriate where the Examiner materially erred in evaluating relevant prior art—and the prosecution here involved just such error.

Instead, Pogona asks the Director to deny review based on other grounds, including (1) purported “settled expectations”; (2) alleged weakness on the merits; and (3) a flawed application of other *Fintiv* factors. None of these arguments has merit. First, the ’757 patent had been in force for fewer than 4.5 years when Pfizer filed its Petition; Pfizer promptly sought review after Pogona asserted the patent against Merck in the district court. That Pogona and Pfizer had interacted *before the U.S. application leading to the ’757 patent had even been filed* is no basis to shorten the customary window before which “settled expectations” bar institution.

Second, the merits are strong, not weak. The Petition asserts multiple, independent anticipation and obviousness grounds, supported by prior art not before

the Examiner—including Alexander and Gu—that expressly discloses the claimed serotypes and their use in multivalent pneumococcal conjugate vaccines (“PCVs”). The ’757 patent claims no new technology, no new conjugation method, and no new carrier protein. It claims only a selection of known serotypes that the prior art and public health agencies had already identified as important serotypes for future PCVs.

Third, the remaining *Fintiv* factors provide no basis for denial. Pfizer is not a party to Pogona’s district court litigation against Merck, and no trial date has been set in that litigation. Thus, the most important *Fintiv* factor is wholly absent.

Where a petition presents a clear material examination error and a strong case that a patent’s claims are anticipated and obvious, the Director’s discretion is best exercised by reviewing the patent. No other factors overcome that strong reason for institution. The Director should therefore refer Pfizer’s Petition to the Board and allow it to adjudicate the substantial invalidity challenges Pfizer has asserted.

II. POGONA’S OMISSION OF 35 U.S.C § 325(d) FAVORS INSTITUTION

Conspicuously absent from Pogona’s brief is any argument under 35 U.S.C. § 325(d). That omission is not an oversight. It is a concession. Section 325(d) gives the Director discretion to deny institution where “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). Under the Board’s two-part *Advanced Bionics* framework, the analysis asks: (1) whether the same or substantially the same art or arguments were previously

presented to the Examiner; and (2) if so, whether the Examiner materially erred in evaluating that art. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential). Here, the Examiner materially erred *and* Pfizer presents additional, dispositive art.

As to the first part of the framework, Pfizer’s Petition presents both new prior art references and new arguments. The Examiner failed to cite or apply a single prior art reference during prosecution of the ’757 patent. Pet. at 10–11. The references asserted in the Petition, including Alexander and Gu, were not listed in an IDS by Pogona and are not substantially the same or cumulative of the IDS references considered by the Examiner. Pet. at 13–21. And the novelty and obviousness arguments presented in this Petition are new and are supported by the newly asserted prior art. These facts strongly favor referral and institution.

Further, the Examiner materially erred in evaluating—or failed to evaluate—even that prior art that was before the Office; this favors referral and institution under the second part of the framework. The Board has consistently held that an examiner’s failure to meaningfully consider prior art that was before the Office, as opposed to a considered judgment that the art did not anticipate or render obvious the claims, weighs in favor of institution. *See Samsung Electronics Co., Ltd. v. Evolved Wireless LLC*, IPR2021-00943, Paper 9 at 10–12 (PTAB Dec. 1, 2021) (declining to issue discretionary denial where “the references were not used in a

rejection or discussed by the Examiner in any Office Action”); *see also 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,’ . . .”). Here, by erroneously stating in the Notice of Allowance that the claimed serotypes are “free of prior art,” Pet. at 10, while overlooking prior art references in the IDS that disclosed those very serotypes, Pet. at 11–12—and, presumably because of these errors, never issuing any prior art rejections during examination, the Examiner committed precisely the kind of material error that the second part of the *Advanced Bionics* framework is intended to correct through IPR.

Pogona’s strategic decision to avoid § 325(d) altogether speaks volumes. It confirms that even Pogona recognizes the Examiner’s error is indefensible under the *Advanced Bionics* standard. Where the Examiner materially erred by overlooking relevant prior art, including art that a reasonable search would have uncovered and art submitted in applicants’ own IDS, institution is the appropriate remedy—not discretionary denial.

III. NO SETTLED EXPECTATIONS EXIST

Contrary to Pogona’s arguments, settled expectations do not warrant discretionary denial of review of the ’757 patent. The patent had been in force for

fewer than 4.5 years when Pfizer’s Petition was filed—far from a long-standing patent with wide market reliance. Pfizer’s alleged “knowledge” of the patent was knowledge only of a *PCT application* that neither included the ultimately-issued claims nor disclosed claims reciting known serotypes that the Examiner later—erroneously—deemed “free of prior art.” This “knowledge” did not enable nor oblige Pfizer to challenge the patent earlier. Pfizer acted promptly, filing its petition just about three months after Pogona’s assertion of the ’757 patent against Merck in district court. *Pogona, LLC v. Merck Sharp & Dohme LLC*, 2-25-cv-15294 (D.N.J.).

A. Timing Does Not Warrant Denial Based on “Settled Expectations”

The fact that the ’757 patent had been in force for only about 4.5 years weighs *against* discretionary denial, not in favor of it. The Board has repeatedly and routinely granted review where the challenged patent had been in force for fewer than six years—as is the case here. *Samsung Elecs. Co. v. Wilus Inst. of Standards & Tech. Inc.*, IPR2025-00935, Paper 12 at 2 (PTAB Sep. 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 at 2–3 (Acting Director June 26, 2025) (granting review for patents that had been in force since 2019 and 2020); *Berkshire Hathaway Energy Co. v. Birchtech Corp.*, IPR2025-00274, Paper 23 at 3 (Acting Director July 2, 2025)

(“[T]he challenged patents issued in 2019 and 2020, such that Patent Owner has not developed strong settled expectations that favor discretionary denial.”).

Ignoring this precedent, Pogona argues that the time since issuance counsels for denial. However, the only settled-expectations denial it cites as to a patent that had been in force for fewer than six years reflected a particular factual situation not presented here. DD Br. at 13. In *Samsung*, the Director denied review of three-year-old patents because they were part of large family involved in ongoing parallel litigation, presenting “essentially the same discretionary considerations” as those from related patents that had already been before the Board and had been in force for six and eight years. *Samsung Elecs. Co., Ltd. & Samsung Elecs. Am., Inc. v. GenghisComm Holdings, LLC*, IPR2025-00792, -793, Paper 12 (PTAB Aug. 22, 2025). In other words, having denied institution as to other, nearly identical patents and circumstances, it made no sense to grant review of a later-filed family member. No such considerations apply to the ’757 patent.

Confronted with the wealth of authorities against its position, Pogona resorts to listing the investments it purportedly made in reliance on the ’757 patent to claim that it has, “through its actions, further demonstrated strong settled expectations.” DD Br. at 15. Specifically, Pogona cites *Amgen* to argue that “extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval” could correlate to settled expectations. *Amgen Inc. v. Bristol-*

Myers Squibb Co., IPR2025-00603, Paper 8 at 2 (Acting Director July 24, 2025)

(informative). But *Amgen* actually supports institution here: the Director there found discretionary denial of a young patent improper because the patentee failed to “sufficiently articulate” the “extraordinary circumstances” required to justify it. *Id.* at 2–3 (instituting review). The same is true here; the investments Pogona identifies are hardly extraordinary. Pogona’s cited investments (personnel hiring, meetings, and legal/accounting fees) are routine, baseline business expenses, not the “extraordinary” expenditures required to create settled expectations.

B. Pfizer’s 2018 Discussions with Pogona Are Irrelevant

Pogona’s settled-expectations argument rests largely on Pfizer’s supposed awareness of a published PCT application from a meeting between Pfizer and Pogona’s predecessor entity (Liffey) in 2018, before the U.S. application leading to the ’757 patent was even filed. EX1051. Pogona argues that this warrants denial under cases noting that “Petitioner’s awareness of Patent Owner’s applications and failure to seek early review of the patents favors denial.” DD Br. at 10 (citing *iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, -374, -376, -377, -378, Paper 10 at 3 (Acting Director June 6, 2025)). This argument fails for two reasons: first, Pogona’s argument gets the law wrong, and second, the PCT application of which Pfizer supposedly was aware predated the Examiner’s material error (and

indeed any U.S. prosecution) and bore little resemblance to the claims that ultimately issued in the ’757 patent.

**1. A Petitioner’s Awareness of a Patent Does Not Create
“Settled Expectations”**

First, Pogona cites no authority for the proposition that “awareness” of a patent (let alone an application) can alter the period of time over which “settled expectations” emerge, thereby warranting denial for a patent issued fewer than six years previously. On the contrary, the weight of authority is clear that the amount of time a patent has been *in force* is central in discretionary denial proceedings. The Director’s March 26, 2025, memorandum regarding Interim Processes for PTAB Workload Management (“Interim Processes Memo”) confirms this point, explaining that “relevant considerations . . . may include . . . [s]ettled expectations of the parties, such as the length of time the claims have been in force[.]” Consistent with that guidance, while “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 Director June 18, 2025) (informative) (emphasis added). This approach makes sense: only once a patent *has issued* does a patentee possess a property right in which, over time, it might come to enjoy a “settled expectation.”

Critically, of the decisions Pogona cites as factoring in a Petitioners’ knowledge of a patent, *none* grants discretionary denial where the challenged patents

had been in force for fewer than six years. A Petitioner’s awareness is only an “[a]dditional[]” factor that may be considered once a patent has been in force for a lengthy period, rather than a factor that is independently sufficient to warrant a discretionary denial. *Murata Mfg. Co. Ltd. v. Ga. Tech Rsch. Corp.*, IPR2025-00383, -384, Paper 14 at 2–3 (Acting Director July 29, 2025); *Jinkosolar Co., Ltd. v. Longi Green Energy Tech. Co. Ltd.*, IPR2025-00859, Paper 10 at 3 (Acting Director Sept. 3, 2025).¹

Moreover, even in the cases Pogona cites where the Director has referred to knowledge of an application rather than an issued patent, the cases have generally involved knowledge of *U.S.* patent applications—not, as here, a PCT application that

¹ In other decisions cited by Pogona, Director has similarly denied review of petitions where the challenged patents were in force for *more* than six years. *See iRhythm Techs.*, Paper 10 at 3 (“ . . . in force since as early as 2012”); *Belden Inc. and PPC Broadband, Inc. v. CommScope, Inc. of N. Carolina*, IPR2025-00833, Paper 13 at 2 (Acting Director Sept. 12, 2025) (“ . . . in force for nine years”); *Google LLC v. SoundClear Techs. LLC*, IPR2025-00344, -345, Paper 15 at 2-3 (Acting Director Aug. 4, 2025) (“ . . . in force for approximately ten years”); *Amazon.com, Inc. et al. v. SoundClear Techs. LLC*, IPR2025-01067, -1080, -1096, Paper 15 at 2 (Director Oct. 17, 2025) (“ . . . in force for ten, eight, and ten years”).

had not been nationalized in the U.S. *See* Patent Owner’s (“PO’s”) DD Br., *Jinkosolar*, Paper 6 at 21 (PTAB July 18, 2025) (“The first search report during prosecution of that application, dated May 4, 2016, cited to US 2013/098423, the publication number of the ’214 Patent.”); PO’s DD Br., *Amazon.com*, Paper 6 at 14 (PTAB Aug. 25, 2025) (“In fact, two different Examiners notified Amazon of U.S. Publication No. 2013/0073283”); PO’s DD Br., *Belden Inc.*, Paper 7 at 4 (PTAB July 23, 2025) (“[I]n April 2022, Petitioner PPC Broadband filed an IPR discussing the publication of the ’697 patent application (US Pub No. 2010/0314484)”).

2. Pfizer’s Alleged 2018 “Knowledge” Was Not of the ’757 Claims

Second, the knowledge Pfizer supposedly gained in 2018 of Pogona’s predecessors’ patent portfolio was not of the patent now at issue, nor even of an application containing claims similar to the ’757 patent. Instead, it concerned a PCT application that (i) had not entered U.S. national stage, (ii) had no working examples, and (iii) included claims that did not focus on the ultimately recited pneumococcal serotypes. This application dated years before the Examiner’s material error, and years before the claims were amended to focus on the serotypes that ultimately issued as a result of this error. EX1051 at 88–116.

In fact, it was not until March 2021—years after the 2018 meeting—that the Examiner issued a Notice of Allowance incorrectly concluding that “polysaccharide conjugates 35B, 23A and 23B . . . appear to be free of prior art” and entered an

Examiner’s amendment following an interview focusing independent claim 1 to those serotypes. EX1043 at 24. Thus, even if pre-issuance “knowledge” properly factored into the settled-expectations inquiry (it does not), it is unrealistic to impute to Pfizer any knowledge that Pogona would ever seek or obtain claims narrowly focused to the handful of well-known serotypes that underpin the ’757 patent.

C. Pfizer Acted Promptly After Pogona Asserted the ’757 Patent Against Merck

The timing of Pfizer’s petition further underscores why discretionary denial would not be appropriate. Upon learning of Pogona’s first and only assertion of the ’757 patent against Merck on September 5, 2025, Pfizer promptly filed its petition just about three months later, on December 23, 2025—and without Pogona ever asserting the ’757 patent against Pfizer. In *Intel*, the Director explained that the Board may review challenged claims that are several years old, for example, when “a patent may have been in force for years but may not have been commercialized, asserted, marked, licensed, or otherwise applied in a petitioner’s particular technology space, if at all.” *Intel Corporation v. Proxense, LLC*, IPR2025-00327, Paper 12 at 2–3 (Acting Director June 26, 2025). Here, even though the ’757 patent is still new enough that settled expectations should not bar institution, similar policy considerations apply. This record thus reflects precisely the type of early challenge that the Director encourages, particularly for patents that have lain unasserted for a significant amount of the limited time that they have been in force.

IV. THE PETITION PRESENTS A STRONG UNPATENTABILITY CHALLENGE

Apart from settled expectations, the Interim Processes Memo identifies several other considerations relevant to the Director’s discretion, including “the strength of the unpatentability challenge.” Interim Processes Memo at 2–3. Here, this factor weighs decisively in favor of referral and institution.

The ’757 patent’s claims recite a pharmaceutical composition including immunogenic saccharide-polypeptide conjugates, generated using well-established conjugation technology, applied to known *S. pneumoniae* serotypes that several prior art references, including from public health agencies, had specifically recommended for inclusion in next-generation PCVs. Two independent lead references—Alexander and Gu—each disclose precisely the kind of pharmaceutical composition the claims recite, including the same serotypes Pogona asserts are novel and the Examiner erroneously concluded were absent from the prior art. Pet. at 22–49. Further, the “approach” that Pogona itself asserts as the novel aspect of its invention—“aligning vaccine coverage with emerging invasive disease serotypes,” DD Br. at 5—was well known and had been widely practiced in the field long before the alleged invention, EX1002 (Musey Dec.), ¶¶17–18, 27–30. In fact, this is precisely what many of Pfizer’s prior art references taught before the ’757 patent’s priority date. Pet. at 5–8, 15–19, 50–57; *see also* Serotype Prevalence References (EX1015–EX1019); Vaccine Recommendation References (EX1010–EX1011,

EX1013–EX1014). And contrary to Pogona’s aspersion that “Petitioner relies on laundry lists” of serotypes, DD Br. at 17, the serotypes Pogona recites are both expressly disclosed in the prior art (leading to anticipation) and expressly motivated by the prior art (leading to obviousness). *E.g.*, Pet. at 13–21, 24–27, 37, 50–54.

In short, the Petition’s challenges—spanning multiple anticipation and obviousness grounds—are legally sound, well supported, and compelling. The “strength of the unpatentability challenge” here counsels *for* institution. Interim Processes Memo at 2.

A. Pogona’s Immunogenicity Argument Fails for Both Anticipation and Obviousness

Pogona attempts to conjure a merits-based weakness where none exists by arguing that the Petition fails to identify references disclosing “saccharide-polypeptide conjugates” that are “immunogenic,” and that institution therefore should be denied, by analogy to the Board’s decision in *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-01223, Paper 8 (PTAB Oct. 20, 2017). Pogona misreads *Merck*, and its arguments fail for multiple reasons.

1. Merck Hinged on a Patent-Specific Claim Construction

First, the petitioner in *Merck* failed to demonstrate a reasonable expectation of success in making an “immunogenic composition” only according to a heightened immunogenicity standard that arose from a claim construction of “immunogenic” specific to the patent at issue there. *Merck*, Paper 8 at 11. The failure of proof in

Merck has no bearing here: There is no argument for applying that other patent’s claim construction to the phrase “immunogenic saccharide-polypeptide conjugate.” In fact, nothing in Pogona’s own specification suggests it contributed anything whatsoever to the art regarding immunogenicity, or even tested immunogenicity.

The Board in *Merck* concluded, on the basis of the relevant patent’s specification and prosecution history, that “immunogenic” referred in that patent to “eliciting higher serum IgG titers and overall greater functional antibody activity than seen with free polysaccharide alone.” *Id.* The Board came to this conclusion against a backdrop of failures relating to the specific serotype the patentee had added to the claims. The patent at issue in *Merck*, U.S. Patent No. 9,399,060 (the “’060 patent”, EX1052) expressly stated that “attempts to produce a multivalent pneumococcal conjugate vaccine that exhibits significant immunogenicity with respect to serotype 3 polysaccharides have been unsuccessful,” *id.* at 4:23–26, and the Board relied on those specific failures as to that serotype. *Merck*, Paper 8 at 16–17. The ’060 patent then disclosed how to solve that problem and included extensive experimental immunogenicity data—data that was necessary precisely because serotype 3 had a documented history of failures. EX1052 at Example 16.

Pogona’s ’757 patent at issue here contains nothing analogous. Neither the patent nor its prosecution history suggests any particular difficulty in making conjugate vaccines with the recited serotypes, 23A, 23B, or 35B. There is no

suggestion anywhere in the record that these serotypes presented immunogenicity challenges. And, unsurprisingly, the ’757 patent contains no immunogenicity data at all. Its disclosure is instead focused on selecting serotypes based on epidemiology data published prior to its priority date. EX1001, 3:35-4:9, 55:33-56:3. Tellingly, Pogona makes no mention of immunogenicity in the background of its brief, which describes its invention—consistent with the ’757 patent—as recognizing *which* serotypes to include in a vaccine, based on (supposed) insights about the prevalence of disease they caused. DD Br. at 5–9. Unlike in *Merck*, there is no indication in the record that once serotypes 23A, 23B, or 35B were selected, making an effective, immunogenic vaccine using known techniques would have required anything but ordinary skill. It would not have done so. *See* EX1002, ¶¶54–56, 78–80, 103–105.

Moreover, again unlike in *Merck*, the claims of the patent reinforce that “immunogenic” refers to a well-known property of saccharide-polypeptide conjugates used in vaccines, rather than a particular level of immunogenicity that might have been a challenge to meet. Claim 6 of the ’757 patent, which depends from independent claim 1, simply requires “an opsonophagocytic response.” EX1001, 70:65-67. As Pfizer’s Petition (and accompanying expert declaration) explained, that is simply the type of response that all PCVs elicit. Pet. at 30–31, 45–46, 58–59; *see also* EX1002, ¶¶20–23, 120–121, 170–173, 221–227. The language of claim 6 refutes any need for the specialized, comparative immunogenicity

standard applied in *Merck*.

2. Pogona’s Immunogenicity Argument Cannot Defeat Pfizer’s Anticipation Grounds

Second—and fatally for Pogona—even if the claims here did require some heightened level of immunogenicity (and they do not), this case differs from *Merck* in that it asserts two anticipation grounds, based on Alexander and Gu. Pet. at 22–36, 40–48. Each of those references expressly discloses immunogenic conjugates comprising the very serotypes recited in the ’757 patent claims and discloses that the peptides increase their immunogenicity, thus achieving the *Merck* standard. EX1008 (Alexander), ¶¶26, 34, 61, 105–06, 126; EX1009 (Gu), 30:32–31:2, 57:11–12; EX1002, ¶¶22–23. Alexander is directed to “vaccines which contain as an active ingredient an *immunogenically effective amount* of a composition comprising at least one conjugate of the present invention.” Pet. at 23 (emphasis added); see EX1008, ¶¶63 (disclosing Pogona’s claimed serotypes), 105. Gu, entitled “Immunogenic Glycoprotein Conjugates,” likewise teaches “[g]lycoconjugates of the invention comprising a bacterial capsular polysaccharide *can be used in the production of antibodies* against such a bacterial capsular polysaccharide.” Pet. at 41 (emphasis added); see EX1009, 22:31–23:1 (disclosing Pogona’s claimed serotypes), 30:32–31:2. A composition that induces antibody production is, by definition, immunogenic, and these references are presumed to be enabling. *Impax Lab’ys, Inc. v. Aventis Pharms., Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008). They

therefore amply satisfy Pfizer’s obligation to demonstrate a disclosure of “immunogenic” conjugates. There simply is no basis to suggest that Pfizer needed to “test th[e claimed] serotype conjugates for immunogenicity,” DD Br. 18, particularly given that Pogona itself did nothing of the kind.

3. The Record Shows Motivation and Reasonable Expectation of Success

Third, Pfizer’s obviousness grounds are supported by additional references, beyond Alexander and Gu, clearly showing that for the relevant date here and the serotypes Pogona claims, skilled artisans perceived no immunogenicity problem analogous to the one at issue in *Merck*. On the contrary, multiple references expressly recommend including *the very serotypes recited in the claims*—23A, 23B, and 35B—in future vaccines using conventional PCV technology, thus indicating that there would have been a reasonable expectation of success in practicing the claimed invention. Pet. 53–54; *see also* EX1010 (Porro) at 66:28–67:14; EX1011 at 210, 213–14 (Al-Sherikh); EX1014 at 334, 338–39 (Wagenvoort); *see* EX1002, ¶¶203–204. These are not the kinds of teachings one sees in the art when the POSA does not expect success. Rather, they reaffirm what the Petition explains: the POSA would have reasonably expected to create immunogenic saccharide-peptide conjugates of the claimed serotypes using routine, well-established vaccine technology. *Merck* is inapposite.

Finally, Pogona argues that Pfizer “has not explained why a POSA would

have been motivated to select the specific claimed serotypes,” DD Br. at 19. This argument fails in view of the very same obviousness references just discussed—which expressly recommended including serotypes 23A, 23B, and 35B in future vaccines. Pet. at 51–54. Far from presenting a POSA with a choice of “100+ immunologically distinct serotypes,” as Pogona wrongly suggests, DD Br. at 17–19, those references provide an express, clear, and precisely directed motivation—the paradigm of a finite number of identified, predictable solutions. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

V. THE *FINTIV* FACTORS DO NOT SUPPORT DENIAL

Pogona invokes the *Fintiv* framework to argue that institution would be inefficient given the parallel district court litigation. See *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential). On the facts presented, however, the majority of the *Fintiv* factors weigh strongly in favor of referral and institution—none support discretionary denial.

Pogona concedes that the district court case between Pogona and Merck, in which Pfizer is not a party, “does not yet have a trial date.” DD Br. at 20. Where no trial date has been set and the parallel proceeding is at a very early stage, there is no risk of duplicative proceedings or inconsistent outcomes (**Factor 2—Trial Date**); also, the district court and parties that are involved have invested very little time and resources into the parallel litigation (**Factor 3—Investment**). Again, Pfizer is not a

party in the parallel litigation between Pogona and Merck (**Factor 5—Party Overlap**). Thus, Factors 2, 3 and 5 weigh in favor of referral and institution. And while Pogona and Merck have both filed opposing briefs as to the motion to stay in the district court litigation, the pendency of an unresolved stay motion renders Factor 1 neutral at minimum (**Factor 1—Stay**).

Additionally, Pogona argues that Merck’s decision to file its own separate IPR rather than join this Petition creates inefficiency justifying denial. DD Br. at 20. The efficiency concern under Factor 4 is whether the same parties will relitigate the same issues in district court as those tried before the Board. *Fintiv*, Paper 11 at 12. Pfizer is not a party to the district court litigation, and thus, denial would simply strip Pfizer of its independent statutory right to challenge a patent. The Director should not use a third party’s procedural choices to foreclose Pfizer’s own IPR rights. To the extent the two petitions raise similar issues, the proper remedy is coordination or joinder—not denial. *See* 35 U.S.C. § 315(c) (**Factor 4—Issue Overlap**).

Factor 6 considers the merits of the unpatentability challenge. *Fintiv*, Paper 11 at 14–15. During prosecution, the Examiner stated that the recited serotypes “appear to be free of prior art.” That statement was incorrect. And as set forth in Section IV above, the Petition presents a strong case that the claims of the ’757 patent are anticipated and/or obvious over an abundance of prior art. Such a strong merits showing, particularly one grounded in prior art overlooked during

prosecution, counsels strongly in favor of referral and institution (**Factor 6—Other Considerations-Merits**).

Thus, when the *Fintiv* factors are properly applied—especially in light of the Petition's strong merits and the fact that Pfizer has nothing to do with the district court litigation—discretionary denial is unwarranted.

VI. PFIZER'S VOLUNTARY SEARCH DISCLOSURE DECLARATION

Finally, pursuant to the Director's November 17, 2025, memorandum *Voluntary Search Disclosure Declarations as a Favorable Factor in Institution Decisions*, Pfizer filed a Search Disclosure Declaration explaining its prior-art search techniques. EX1049. It is hoped that this declaration will assist the Office in improving its internal processes and, in future examinations, avoid the error that occurred here. Consistent with that Memorandum, Pfizer respectfully requests that its filing be weighed as an additional discretionary factor in favor of institution.

VII. CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that the Director decline to exercise discretion to deny institution and refer the Petition to the Board. The Board should institute *inter partes* review and cancel all challenged claims.

Dated: April 6, 2026

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that the foregoing Petitioner Pfizer Inc.'s Opposition to 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 (III)(C)(iii) (<https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>). The page count does not include the items excluded by 37 C.F.R. § 42.24 as not counting towards the page limit.

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CERTIFICATE OF SERVICE

I hereby certify that on April 6, 2026, I caused a true and correct copy of the foregoing

- Petitioner Pfizer Inc.'s Opposition to Patent Owner's Discretionary Denial Brief and supporting exhibits

to be served on Patent Owner by delivering a copy via electronic mail to the following individuals at the email address below:

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