UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

MERCK SHARP & DOHME LLC,
Petitioner,

v.

SURROZEN OPERATING, INC.,
Patent Owner.

---

Case No. PGR2026-00027

**U.S. PATENT NO. 12,297,278**

---

# PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

## TABLE OF ABBREVIATIONS

| Abbreviation | Term |
|---|---|
| "'278 patent" | U.S. Patent No. 12,297,278 |
| "Garcia" | International Patent Publication No. WO 2016/040895 |
| "Garcia US" | U.S. Patent Publication No. 2017/0306029 |
| "MPEP" | Manual of Patent Examining Procedure |
| "Patent Owner" or "Surrozen" | Surrozen Operating, Inc. |
| "Petitioner" or "Merck" | Merck Sharp & Dohme LLC |
| "Wu" | Wu et al., *Simultaneous Targeting of Multiple Disease Mediators by a Dual-Variable-Domain Immunoglobulin*, 25 Nature Biotech. 1290 (2007) |

## TABLE OF CONTENTS


**I. INTRODUCTION ..... 1**

**II. OVERVIEW OF THE '278 PATENT AND THE PRIOR ART ..... 2**

**A. The '278 Patent (Ex. 1001) ..... 2**

**B. Garcia (Ex. 1004) ..... 4**

**III. PROSECUTION HISTORY ..... 4**

**IV. THE DIRECTOR SHOULD DENY INSTITUTION UNDER § 325(D) . 6**

**A. Ground 4 Relies on Substantially the Same Art and Arguments That Were Considered by the Office Without Error ..... 7**

1. *Advanced Bionics* Step 1 (*Becton* Factors (a), (b), and (d)): Substantially the Same Art and Arguments Were Previously Presented to the Patent Office ..... 8

2. *Advanced Bionics* Step 2 (*Becton* Factors (c), (e), and (f)): Petitioner Has Failed to Identify Any Material Error ..... 9

**B. Grounds 1–3 Rely on the Same or Substantially the Same Arguments That Were Considered by the Office Without Error 13**

1. *Advanced Bionics* Step 1 (*Becton* Factors (a), (b), and (d)): Substantially the Same Arguments Were Previously Presented to the Patent Office ..... 13

2. *Advanced Bionics* Step 2 (*Becton* Factors (c), (e), and (f)): Petitioner Has Failed to Identify Any Material Error ..... 17

**V. PETITIONER RELIES EXTENSIVELY ON EXPERTS ..... 20**

**VI. CONCLUSION ..... 20**

## TABLE OF AUTHORITIES

**Cases** Page(s)

*AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*,
759 F.3d 1285 (Fed. Cir. 2014) .....19

*Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*,
IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) .....*passim*

*Amgen Inc.* v. *Sanofi,*
143 S. Ct. 1243 (2023).....18, 19, 23

*Apple Inc. v. Wi-LAN Inc*,
25 F.4th 960 (Fed. Cir. 2022) .....23

*AscentCare Dental Prods., Inc. v. Solmetex*,
IPR2025-01065, Paper 11 (P.T.A.B. Oct. 17, 2025).....9

*Baxalta Inc. v. Genentech, Inc.*,
81 F.4th 1362 (Fed. Cir. 2023) .....19, 23

*Becton, Dickinson & Co. v. B. Braun Melsungen AG*,
IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) .....6

*Ecto World, LLC v. RAI Strategic Holdings, Inc.*,
IPR2024-01280, Paper 13 (P.T.A.B. May 19, 2025) .....6, 9, 11, 16

*FMC Corp. v. Sharda USA, LLC*,
145 F.4th 1326 (Fed. Cir. 2025) .....22

*Fujirebio Diagnostics, Inc. v. Quanterix Corp.*,
IPR2025-01060, Paper 13 (P.T.A.B. Oct. 17, 2025).....19

*Juno Therapeutics, Inc. v. Kite Pharma, Inc.*,
10 F.4th 1330 (Fed. Cir. 2021) .....19

*Sandoz Inc. v. Acerta Pharma B.V.*,
IPR2023-00478, Paper 17 (P.T.A.B. Aug. 7, 2023).....8

*Stone Basket Innovations, LLC v. Cook Med. LLC*,
892 F.3d 1175 (Fed. Cir. 2018) .....11

*TankLogix, LLC v. SitePro, Inc.*,
PGR2025-00060, Paper 6 (P.T.A.B. Sept. 17, 2025).....16

*TankLogix, LLC v. SitePro, Inc.*,
PGR2025-00060, Paper 9 (P.T.A.B. Nov. 20, 2025).....16

*Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*,
--F.4th--, 2026 WL 1025802 (Fed. Cir. Apr. 16, 2026).....7, 18, 19

*Unified Patents Inc. v. Berman*,
IPR2016-01571, Paper 12 (P.T.A.B. Jan. 31, 2017).....16

*Weatherford U.S., L.P. v. Enventure Glob. Tech., Inc.*,
IPR2020-01661, Paper 19 (P.T.A.B. Apr. 15, 2021).....9, 13

**Statutes**

35 U.S.C. § 325(d).....6, 7

**Rules**

37 C.F.R. § 42.4(a).....7

**Other Authorities**

MPEP § 2103(I).....14

MPEP § 2163(I)(3)(a)(ii) (2023).....15

MPEP § 2173.02.....15

## TABLE OF EXHIBITS

| Exhibit No. | Description |
|---|---|
| 2001 | Declaration of Jeanna Wacker in Support of Motion for Admission *Pro Hac Vice* |
| 2002 | Declaration of Ashley Ross in Support of Motion for Admission *Pro Hac Vice* |
| 2003 | Chen Xue et al., *Wnt Signaling Pathways in Biology and Disease: Mechanisms and Therapeutic Advances*, 2025 NATURE 1–44 (2025) |
| 2004 | Univ. of Wis. Madison Dep't of Biochemistry, *Biochemistry News* (2003), https://biochem.wisc.edu/wp-content/uploads/sites/1394/2023/02/2003BiochemNewsletter.pdf |
| 2005 | Anand Desai, LinkedIn, https://www.linkedin.com/in/anand-desai-b698b09/ |
| 2006 | *Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in* Amgen Inc. et al. v. Sanofi et al., 89 Fed. Reg. 1563 (2024) |
| 2007 | Sept. 12, 2022 Office Action, App. No. 16/954,484 |
| 2008 | Memorandum from Coke Morgan Stewart, Acting Under Sec'y of Com. for Intell. Prop. & Acting Dir. of the U.S. Pat. & Trademark Off. to All PTAB Judges (Mar. 26, 2025), https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf |
| 2009 | FAQs for Interim Processes for PTAB Workload Management, USPTO, https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management (last updated Aug. 15, 2025) |

****All emphasis added unless otherwise noted****

## I. INTRODUCTION

Surrozen respectfully requests that the Director exercise his discretion to deny the Petition for post-grant review filed by Merck challenging the '278 patent. Surrozen, a 40-person public company founded in 2015 and based out of California, is focused on developing medications to preserve and restore vision in patients with ophthalmic diseases. Surrozen is a pioneer in harnessing the power of the Wingless-related integration site ("Wnt") signaling pathway—an intercellular communication system that plays a central role in tissue repair and regeneration. At the heart of this project are Surrozen's Wnt proteins designed to engage two types of cell-surface molecules: Frizzled receptors ("Fzd") and low-density lipoprotein receptor-related proteins ("LRP") 5/6 in a novel tetravalent format. These tetravalent proteins act as surrogate molecules that agonize Wnt signaling in a controlled and reproducible manner, representing a significant advance over prior approaches. On May 13, 2025, the Patent Office issued the '278 patent, which reflects the inventors' work.

Merck now seeks to invoke the Patent Office's post-grant review procedures, advancing a host of invalidity arguments premised on strained interpretations of the claims and prior art. But Merck's grounds for invalidity and its referenced prior art were already considered by the Examiners during prosecution, and Merck failed to show any error, let alone material error, requiring the Patent Office to expend its limited resources and undertake a cumulative rerun of those issues. Moreover,

Merck's Petition relies on 225 pages of expert testimony that will mire the Board in a protracted dispute over the technical principles of cellular signaling and protein engineering. This is better suited for a jury to decide: the Petition reflects, at most, disputes between experts on dispositive issues. The Director should deny institution.

## II. OVERVIEW OF THE '278 PATENT AND THE PRIOR ART

### A. The '278 Patent (Ex. 1001)

The '278 patent, titled "Wnt Surrogate Molecules and Uses Thereof," discloses "Wnt pathway agonists." Ex. 1001 at Title, Abstract. Wnt ligands and their downstream signaling pathways play key roles in the control of development, homeostasis, and regeneration of essential organs and tissues in the human body. *Id.* at 1:41–48. Because of their central role in tissue regeneration and repair, Wnt signaling pathways have potential for novel treatment approaches to degenerative diseases and tissue injuries. *Id.* at 1:48–50.

Since its discovery in the 1980s, scientists have extensively studied Wnt signaling and identified three different signaling pathways. Ex. 2003 at 9–10. One of them—the "canonical" pathway—is particularly relevant here. *See id.* at 1. In the canonical pathway, a Wnt agonist binds two cell-surface molecules: an Fzd receptor and an LRP5 or LRP6 coreceptor. *Id.* at 2–3. This triggers a series of downstream effects in the cell that modulate gene expression. *Id.* Prior work in the field suggested that canonical Wnt signaling pathways could be activated using molecules that

consisted of a ***single*** region that bound to an Fzd receptor and another that bound an LRP5/6 coreceptor—a "1:1 stoichiometry." *See infra* § II.B. But Surrozen's scientists discovered that molecules with this 1:1 stoichiometry did not often work as signal-modulating agents. *See* Ex. 1001 at 157:52–158:47; Ex. 1008 at 4168–70. To solve this problem, the inventors developed the molecular architecture claimed in the '278 patent—a ***tetravalent***, multispecific structure comprising two Fzd binding regions and two LRP5/6 binding regions that reliably activates Wnt signaling pathways. Ex. 1001 at 1:59–62, 155:11–157:50, 158:48–161:34.

The '278 patent discloses Surrozen's invention in detail. The specification begins by identifying 13 illustrative tetravalent molecular structures. *Id.* at Figs. 1A–D. The specification then discloses detailed information outlining the Fzd and LRP5/6 binding components of the structure, namely: (1) the complementarity-determining region ("CDR") sequences for 448 Fzd binding regions that each showed preliminary binding activity with one or more of the ten known Fzd receptors (*see id.* at Table 1A), and testing results showing confirmed binding for 91 of these binding regions across all ten receptors (*id.* at Table 1B); and (2) the CDR sequences for 211 binding regions that showed binding with LRP5/6 (*see id.* at Tables 2A–B). The inventors used these sequences in 90 varied tetravalent molecules, and ***every*** disclosed tetravalent molecule activated Wnt signaling. *See id.* at 155:11–157:50, 158:48–161:34.

### B. Garcia (Ex. 1004)

Garcia is disclosed in the '278 patent's specification. Ex. 1001 at 162:27–32. The publication of its United States stage entry—Garcia US, which Petitioner admits is "substantively identical" to Garcia, *see* Pet. at 15 n.2—is cited on the face of the '278 patent and was extensively considered by the Examiners during prosecution. *See* Ex. 1001 at References Cited; Ex. 1008 at 2972–75, 3982–86. Garcia is titled "Wnt Signaling Agonist Molecules" and discloses "Wnt signaling agonists . . . compris[ing] a frizzled binding moiety, which is fused or conjugated to an LRP5 or LRP6 binding moiety." Ex. 1004 at Title, Abstract. Garcia does not disclose the claimed tetravalent molecules, which consist of ***two*** Fzd binding regions and ***two*** LRP5/6 binding regions. Instead, Garcia's Wnt agonist molecules combine ***one*** Fzd binding region with ***one*** LRP5/6 binding region. *See id.* at [00197].

## III. PROSECUTION HISTORY

During prosecution of the '278 patent, the Patent Office published guidelines providing direction for examiners to evaluate an application's compliance with § 112 in view of recent Federal Circuit and Supreme Court precedent on claims to antibodies. *See infra* § IV.B.2. Thereafter, the Examiners twice rejected the claims as obvious over Garcia US. *See* Ex. 1008 at 2973, 3982. On June 13, 2024, the Examiners rejected the application's claims as obvious over Garcia US in combination with Wu. *Id.* at 2973. They expressly stated that "Garcia [US] does not

teach dual variable domain (DVD) format of bispecific antibody"—an antibody format consisting of ***two*** binding regions for each target antigen as claimed in the application—but nonetheless asserted that such a format would have been obvious in view of Wu. *Id.* Applicant responded by explaining that Garcia US describes Wnt agonists "which are ***bi***valent and ***bi***specific" and does not suggest the claimed ***tetra***valent molecules. *See id.* at 3956. Applicant further explained that the claims would not have been obvious over Garcia US and Wu, including because Wu would have supplied no reason for a POSA to modify Garcia US's disclosures to make the claimed tetravalent molecules. *See id.* at 3956–57.

On December 27, 2024, the Examiners rejected the claims over Garcia US again. *Id.* at 3982–86. The Examiners noted that "Garcia [US] does not teach dual variable domain (DVD) format of bispecific antibody," but nonetheless maintained obviousness in combination with Wu. *Id.* at 3982–83. In their response to the second Office Action, Applicant noted again that "Garcia [US] does not disclose or contemplate any other stoichiometry between Fzd binding regions and LRP5/6 binding regions" apart from 1:1. *Id.* at 4005. Applicant submitted the declaration of Dr. Li—a named inventor with over 26 years of experience in the biopharmaceutical industry—who explained that Garcia US "only described Wnt surrogate molecules having 1:1 Fzd binder:Lrp5/6 binder stoichiometry, and did not suggest or provide any motivation for a person skilled in the art to design a tetravalent molecule as

claimed." *Id.* at 4168. The Examiners allowed the claims. *See id.* at 4207.

## IV. THE DIRECTOR SHOULD DENY INSTITUTION UNDER § 325(D)

The Director should decline to institute the Petition under 35 U.S.C. § 325(d) because the Petition raises "substantially the same prior art or arguments previously" presented to the Office. The Director applies a two-part framework to analyze discretionary denial under § 325(d): (1) "whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office;" and (2) "if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, at 8 (P.T.A.B. Feb. 13, 2020) (precedential; footnote omitted). The Director also considers the six non-exclusive factors set forth in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, at 17–18 (P.T.A.B. Dec. 15, 2017) (precedential). "If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute" review. *Advanced Bionics*, Paper 6, at 8–9; *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13, at 5 (P.T.A.B. May 19, 2025) (precedential) (petitioner cannot "simply rely on its unpatentability contentions to imply that an error occurred").

Discretionary denial is appropriate here because Petitioner raises arguments and prior art that were considered and overcome during examination. For its anticipation assertions, the Petition raises the very same art that the Examiners considered and ultimately rejected. And for its § 112 arguments, the Petition (1) parrots an assortment of caselaw that (a) the MPEP and Patent Office guidelines expressly direct all examiners to consider and (b) pre-dates prosecution of the '278 patent, and (2) does not address the recent Federal Circuit decision in *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*, --F.4th--, 2026 WL 1025802 (Fed. Cir. Apr. 16, 2026). The Petition offers no reason for this wasteful exercise, nor any material error on the Examiners' part. The Director should thus exercise discretion and deny institution under § 325(d).

### A. Ground 4 Relies on Substantially the Same Art and Arguments That Were Considered by the Office Without Error

Ground 4 challenges claims 1 and 4 of the '278 patent as anticipated by Garcia. Though Petitioner attempts to bury this ground at the end of its Petition, Petitioner cannot hide from the fact that the Examiners already considered and rejected the same art. They expressly considered Garcia's disclosures via the "substantively identical" Garcia US (Pet. at 15 n.2), issued two obviousness rejections before allowing the claims, and in each rejection found that Garcia US ***does not*** disclose every limitation. *See* Ex. 1008 at 2973, 3983; *supra* § III. Petitioner's attempt to seek yet another review of Garcia US by chalking up the

Examiners' allowance to baseless accusations that Patent Owner "mischaracterized" the reference should not be condoned, and instead warrants discretionary denial.

**1. *Advanced Bionics* Step 1 (*Becton* Factors (a), (b), and (d)): Substantially the Same Art and Arguments Were Previously Presented to the Patent Office**

Discretionary denial is appropriate because Petitioner's arguments based on Garcia are wholly cumulative of the Examiners' evaluation of Garcia US's disclosures on the record. Indeed, Petitioner itself admits that Garcia US—listed in Information Disclosure Statements, *see* Ex. 1008 at 2929, and the basis for the Examiners' § 103 rejections—is "substantively identical" to the Garcia reference Petitioner now asserts. Pet. at 15 n.2. Garcia is thus "substantially the same" to Garcia US, which was previously presented to the Examiners. *See Sandoz Inc. v. Acerta Pharma B.V.*, IPR2023-00478, Paper 17, at 15 (P.T.A.B. Aug. 7, 2023) (finding U.S. patent was "substantially the same art" as PCT counterpart considered by the Office because it was "nearly identical . . . in its disclosure").

The Petition not only raises the same prior art, but it raises arguments about Garcia US's teachings that the Examiners ***expressly considered***. For example, the Petition argues that "Garcia discloses 'a soluble, tetravalent, multispecific, Wnt surrogate molecule' comprising 'two Fzd binding regions' and 'two LRP5/6 binding regions.'" *See* Pet. at 88. The Examiners—both doctorate holders, Ex. 2004 at 20; Ex. 2005 at 1—stated twice that "***Garcia [US] does not teach dual variable domain***

***(DVD) format of bispecific antibody***," and looked to Wu for the missing tetravalence limitation. Ex. 1008 at 2973, 3983. Because Garcia's "substantively identical" counterpart (1) was "submitted on one or more Information Disclosure Statements during prosecution of" the '278 patent and (2) "formed … the basis for multiple prior art rejections," the first part of the *Advanced Bionics* framework is satisfied. *Weatherford U.S., L.P. v. Enventure Glob. Tech., Inc.*, IPR2020-01661, Paper 19, at 16 (P.T.A.B. Apr. 15, 2021).

**2. *Advanced Bionics* Step 2 (*Becton* Factors (c), (e), and (f)): Petitioner Has Failed to Identify Any Material Error**

Petitioner also has not met its burden of showing the Office erred in a manner material to the patentability of the claims. Instead, the Petition invites the Director to second-guess the Examiners' decision on patentability, without showing any error. But the Patent Office is "a qualified government agency presumed to have properly done its job," and its examiners "are assumed to have some expertise in interpreting the references." *Stone Basket Innovations, LLC v. Cook Med. LLC*, 892 F.3d 1175, 1179–80 (Fed. Cir. 2018). For this reason, Petitioner ***must*** offer a particularized explanation of ***how*** the Office erred. *See Ecto World*, Paper 13, at 5–6. Petitioners must show, for example, that "previously presented art teaches the limitations of the challenged claims, and that no reasonable examiner could have found otherwise." *Id.* at 6. Mere disagreement "with the Examiner's treatment of the art without showing ***material*** error" is not enough. *AscentCare Dental Prods., Inc.*

*v. Solmetex, LLC*, IPR2025-01065, Paper 11, at 3 (P.T.A.B. Oct. 17, 2025). Importantly, "[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability." *Advanced Bionics*, Paper 6, at 8–9.

Petitioner's "material error" argument boils down to unfounded accusations that Applicant "mischaracterized" Garcia's disclosures and pulled a fast one over the Examiners, who are both highly credentialed. *See* Pet. at 87; *supra* § IV.A.1. Petitioner argues that Applicant's prosecution statements and Dr. Li's declaration, submitted ***after*** the second Office Action, "mischaracterized" Garcia because they explained that Garcia disclosed only "bivalent, bispecific molecules comprised of a single polypeptide and having a stoichiometry of 1:1 Fzd binder:LRP5/6 binder." *Id.* at 88 (original emphasis). Petitioner's only cited support in Garcia is a single sentence that states that a "polypeptide wnt surrogate may be a single chain, dimer, or higher order multimer." Ex. 1004 at [0056]. It argues that this disclosure of a "dimer" or "multimer" necessarily means that Garcia discloses a ***tetravalent*** molecule with ***two*** Fzd and ***two*** LRP5/6 binders, the implication being that the Examiners' failure to reject the claims in view of this sentence means they "materially erred." *See* Pet. at 87–88. Petitioner is wrong.

***First***, there is no indication that the Examiners were somehow unaware of this statement in Garcia US, and indeed Petitioner does not accuse the Examiners of

misapprehending the reference. That should end the inquiry, as "a [P]etitioner must explain . . . how ***the Examiner*** erred in overlooking the prior art." *See Ecto World*, Paper 13, at 5. Petitioner's allegation that Garcia US was "erroneously dismissed by the Examiner as a result" of Applicant's purported "mischaracteriz[ation]," Pet. at 87, is simply false. The Examiners themselves—before Applicant submitted its first Office Action response or Dr. Li's declaration—noted on the record that "***Garcia does not teach dual variable domain (DVD) format of bispecific antibody,***" and looked to Wu to supply the missing tetravalence limitation. Ex. 1008 at 2973, 3983.

***Second***, the Examiners and Applicant correctly construed Garcia/Garcia US; ***Petitioner*** conflates two distinct biochemical properties: a molecule's valency and the number of polypeptide chains in its structure. Petitioner's quoted sentence from Garcia says its molecules may consist of a single polypeptide chain, or two or more such chains (*i.e.,* a dimer or higher-order multimer), but says nothing about their valency—the number of ***binding domains*** the molecule contains. For example, as Garcia explains, "[i]ntact antibody ***tetramers*** are comprised of two heavy chain-light chain ***dimers."*** Ex. 1004 at [0096]. Yet, "[w]hen natural antibodies fold …, the heavy and light chains are brought together in three-dimensional space so that they create a ***single*** hypervariable antigen binding site." *Id*. In other words, Garcia itself describes a ***di***mer structure that is ***mono***valent, dispelling any notion that its mention of dimers and multimers somehow discloses a tetravalent molecular structure.

Regardless, even if one could read Garcia's dimer disclosure as somehow disclosing a tetravalent molecule, Garcia still fails to disclose Wnt molecules with ***two*** Fzd and ***two*** LRP5/6 binding domains. Garcia expressly states that "[a] wnt surrogate can be a polypeptide, where ***a*** binding domain for Fzd is joined to ***a*** binding domain for Lrp5/6." *Id.* at [0056]. Garcia's claims further recite "[a] water soluble canonical Wnt signaling agonist that ***dimerizes a*** Frizzled (Fzd) receptor with Lrp5/6," *see id.* at 49, and Garcia's two disclosed working examples each comprise a single Fzd domain and a single LRP5/6 domain, *see id.* at [00196]–[00197]. Applicant, Dr. Li, and the Examiners all understood, correctly, that Garcia US does not disclose the claimed tetravalent molecular structure.

***Third*****,** the Petition incorrectly argues that "Dr. Li's declaration" somehow "confirms that the 'dimer' described in Garcia includes two Fzd binding regions specifically binding to two Fzd receptors," *see* Pet. at 90—his declaration refutes that. He unequivocally states that "Garcia et al. ***only*** described Wnt surrogate molecules having 1:1 Fzd binder:Lrp5/6 binder stoichiometry, and did not suggest or provide any motivation for a person skilled in the art to design a tetravalent molecule as claimed." Ex. 1008 at 4168. Dr. Li's declaration confirms Petitioner's interpretation of Garcia is incorrect.

Because Petitioner has failed to provide "persuasive evidence or reasoning" to show the Examiner materially erred in considering the same prior art and

arguments the Petition now raises, both *Advanced Bionics* steps weigh in favor of denying institution of Ground 4. *See Weatherford*, Paper 19, at 16–19 (denying institution where petitioner alleged anticipation by a prior-art reference the examiner previously used for multiple obviousness rejections). Institution should be denied.

### B. Grounds 1–3 Rely on the Same or Substantially the Same Arguments That Were Considered by the Office Without Error

Grounds 1–3 allege the '278 patent claims fail § 112's written description (Ground 1), enablement (Ground 2), and definiteness (Ground 3) requirements, but they retread familiar ground. The Examiners already evaluated the '278 patent in light of § 112's requirements, as required under the MPEP and specific guidance issued by the Patent Office. And as with Ground 4, Petitioner fails to identify any material error in the Examiners' analysis, warranting discretionary denial.

#### 1. *Advanced Bionics* Step 1 (*Becton* Factors (a), (b), and (d)): Substantially the Same Arguments Were Previously Presented to the Patent Office

During prosecution of the '278 patent, the Examiners evaluated the patent claims for conformance with § 112 in light of specialized guidance addressing the same case law that Petitioner now sets forth, and concluded the claims as written met the requirements for patentability. As the MPEP dictates, "[u]nder the principles of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory

requirement." MPEP § 2103(I) (2023). The examiner must therefore determine, *inter alia*, whether (1) under § 112(b), "the claim(s) particularly point out and distinctly claim the invention," (2) under the written description requirement, the specification "reasonably convey[s] to those skilled in the art that the inventor was in possession of the claimed invention as of the date of invention," and (3) under the enablement requirement, the specification "enable[s] a person skilled in the art to make and use the claimed invention without undue experimentation." *Id.* § 2103(IV)(A)–(B).

The Examiners had before them the same specification, disclosures, and claims that Petitioner now presents the Board, and had specific Patent Office guidance on the very same Federal Circuit and Supreme Court precedent Petitioner now cites as allegedly supporting its arguments. As to enablement, the Office published guidelines in January 2024—six months before the first Office Action, *supra* § III—that were "intended to inform USPTO personnel and the public on the USPTO's implementation of the Supreme Court decision in *Amgen Inc. et al.* v. *Sanofi et al.,* 143 S. Ct. 1243 (2023)" (cited in Pet. at 3, 62, 64–65, 68, 72–73). Ex. 2006 at 1. That guidance provided an in-depth overview of the claims at issue not just in *Amgen*, but also in subsequent Federal Circuit decisions, including *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362 (Fed. Cir. 2023) (cited in Pet. at 72–73). *See* Ex. 2006 at 2–4. The Examiners thus had detailed guidance regarding the very cases Petitioner claims are "indistinguishable" from this one. *See* Pet. at 72.

The Examiners were also instructed on the same written description cases on which Petitioner relies. The MPEP, which cites *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021) (cited in Pet. at 2, 55–57), explains that "[t]he written description requirement for a claimed genus may be satisfied through sufficient description … to show the inventor was in possession of the claimed genus." MPEP § 2163(I)(3)(a)(ii) (2023). And, with reference to *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014)—which Petitioner cites as "instructive," Pet. at 57; *id.* at 32, 38—the MPEP says: "when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus." MPEP § 2163(I)(3)(a)(ii) (2023).

Finally, with respect to indefiniteness, the MPEP explains that "[i]n reviewing a claim for compliance with 35 U.S.C. 112(b) … the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope." *Id.* § 2173.02. Indeed, with respect to the '278 Patent's parent application, one of the Examiners issued an indefiniteness rejection that Applicant later overcame. *See* Ex. 2007 at 5. The Examiners could have done the same here if they believed the '278 patent claims and disclosures necessitated a § 112 rejection. Instead, and in full view of the relevant case law and examining guidance on enablement, written description, and indefiniteness, the Examiners issued the claims.

To the extent Petitioner argues that the absence of a § 112 rejection means the

Examiners did not ***properly*** consider the questions raised in the Petition, that argument is foreclosed by Board precedent. For example, the Director recently issued guidance making clear that "[c]hallenging the claims using the same prior art that was previously presented on an IDS is sufficient to satisfy the first part of the *Advanced Bionics* framework," and a petitioner must show error even if the examiner did not apply the reference in a rejection. *See Ecto World*, Paper 13, at 4; *see also Unified Patents Inc. v. Berman*, IPR2016-01571, Paper 12, at 3 (P.T.A.B. Jan. 31, 2017) (rejecting assertion that examiner considered prior art for anticipation and not obviousness as "speculative and … premised on the assumption that the Examiner blindly analyzed the reference for compliance with" § 102 "while ignoring other statutory requirements"). The Board has applied this reasoning outside the prior-art context. In *TankLogix, LLC v. SitePro, Inc.*, for example, the Director denied institution where the patent owner argued that "[t]he Examiner understood the claims were not abstract, as ***a § 101 rejection was never raised*** during prosecution of the '184 Patent," PGR2025-00060, Paper 6, at 10 (P.T.A.B. Sept. 17, 2025), even though a final written decision would have issued prior to a district court trial date and there were no settled expectations, *id.* at 12; *TankLogix*, Paper 9, at 1 (P.T.A.B. Nov. 20, 2025). Likewise, here, the Examiners understood the claims were sufficiently supported such that no § 112 rejection was warranted. Step 1 thus favors discretionary denial.

### 2. *Advanced Bionics* Step 2 (*Becton* Factors (c), (e), and (f)): Petitioner Has Failed to Identify Any Material Error

Petitioner also has not met its burden of showing the Office erred in a manner material to the patentability of the claims. *See Advanced Bionics*, Paper 6, at 8. ***First***, Petitioner's invalidity arguments rest on claim constructions that are tenuous at best. Petitioner contends that the Examiners should have (1) construed the preamble "Wnt surrogate molecule" as limiting; (2) found that Patent Owner engaged as lexicographer in defining the preamble term as a "molecule that is biologically active in binding to one or more Fzd receptor and to one or more LRP5 and LRP6, and in activation of Wnt signaling, *i.e.*, the molecule is a Wnt agonist"; and (3) based on those two claim constructions, invalidated every claim as indefinite, lacking adequate written description, and non-enabled. Pet. at 17, 23.

That position is untenable. Petitioner would have the Board depart twice from the axiom that "[a] claim term is generally given its plain and ordinary meaning," *see Apple Inc. v. Wi-LAN Inc*, 25 F.4th 960, 967 (Fed. Cir. 2022), only to hold that under that contorted construction, all claims are invalid. Petitioner's multi-layer approach can hardly show material error, particularly considering the high burden Petitioner faces to show not only that the preamble is ***limiting***, *FMC Corp. v. Sharda USA, LLC*, 145 F.4th 1326, 1334 (Fed. Cir. 2025) ("Preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim."), but also that the Patent Owner acted as a ***lexicographer***,

*Apple*, 25 F.4th at 967 ("To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term."). No error occurred.

***Second***, Petitioner points to no material error on patentability for these claims. None of Petitioner's cited cases "presented the circumstances of … this case—i.e., a well-known genus used as part of a different invention." *Teva*, 2026 WL 1025802, at *8. *Teva* is instructive on this point. There, the Federal Circuit upheld method of treatment antibody claims as enabled and adequately described after the district court found otherwise despite a jury verdict finding enablement and adequate written description under § 112. The Federal Circuit reasoned:

> Although the specification disclosed just one humanized anti-CGRP antagonist antibody, it also disclosed several murine versions and prior-art methods of humanization—against a backdrop of anti-CGRP antagonist antibodies (and methods of making them) being well known and humanization being routine. And, critically, a skilled artisan would have understood from the specification that ***all*** humanized anti-CGRP antagonist antibodies treat headache.

*Id.* at *6. That was not the case in Petitioner's cited authorities, which held invalid claims that broadly recited—in purely functional terms—antibodies that were not known in the art, and in which the specification had insufficient disclosure of those

antibodies. *See, e.g., Juno*, 10 F.4th at 1339; *Amgen*, 143 S. Ct. at 1256.

Like the patent specification at issue in *Teva*, the '278 patent specification says that anti-Fzd and anti-LRP5/6 antibodies and fragments thereof were "known in the art and [we]re commercially available," Ex. 1001 at 79:63–80:15, 115:25–39; it lists ***hundreds*** of examples of such antibodies and fragments thereof, *see id.* at tbls. 1A–1B, 2A–B; and it provides POSAs with several methods known in the art to make such antibodies, *see id.* at 13:37–16:16. The inventors took these known antibodies, and methods of making them, and combined them in a novel, tetravalent structure. *See, e.g., id.* 151:29–152:45, tbl. 3. And, critically, ***all*** of the '278 patent's working examples of that structure—every one of the 90 exemplary tetravalent molecules the inventors tested—successfully agonized the Wnt pathway. *See id.* at 155:11–157:50, 158:48–161:34. The Examiners did not err in allowing these claims.

Petitioner's extensive reliance on more than 220 pages of expert testimony setting forth various conflicting assertions about the state of the art, scope of the claims, and guidance in the specification does not change this outcome. *See* Ex. 1002; Ex. 1003. Board precedent is clear: "[i]f reasonable minds can disagree . . . , it cannot be said that the Office erred in a manner material to patentability." *Advanced Bionics*, IPR2019-01469, Paper 6, at 9; *Fujirebio Diagnostics, Inc. v. Quanterix Corp.*, IPR2025-01060, Paper 13, at 3 (P.T.A.B. Oct. 17, 2025) ("discretionary denial is appropriate" where petition shows "mere[] disagree[ment]

… without showing material error"). So too here. As Patent Owner's forthcoming Preliminary Response will explain, Petitioner's expert testimony is far from the consensus. Instead, Patent Owner's rebuttal expert testimony will demonstrate that Petitioner's experts considerably understate the import of the specification's disclosures, and draw questionable conclusions from the wealth of data disclosed in the patent to arrive at their opinions. At best, the Petition reflects disagreement between "reasonable minds," such that "it cannot be said that the Office erred in a manner material to patentability." *Advanced Bionics*, IPR2019-01469, Paper 6, at 9.

## V. PETITIONER RELIES EXTENSIVELY ON EXPERTS

Petitioner's "extensive reliance on expert testimony" also favors discretionary denial. Ex. 2008 at 2 (Workload Management Memo). Here, Petitioner pervasively relies on over 220 pages of testimony for several factually debatable assertions, including interpretations of the patent's technical terms and data, Pet. at 54, and to cast aspersions on the assays disclosed in the specification, *id.* at 76–83. These assertions will be the subject of Patent Owner's own rebuttal expert analysis in its forthcoming Preliminary Response, giving rise to a fact-intensive "battle of the experts." This is precisely the sort of contest the Director has recognized is "better resolved in an Article III court." Ex. 2009 at 7 (Board website's FAQs).

## VI. CONCLUSION

Surrozen respectfully requests the Director deny institution.

Date: April 23, 2026

Respectfully submitted,

*/s/ W. Todd Baker*

Gregg F. LoCascio, P.C.
Reg. No. 55,396
glocascio@kirkland.com
W. Todd Baker
Reg. No. 45,265
todd.baker@kirkland.com
Ashley Cade
Reg. No. 77,057
ashley.cade@kirkland.com
Postal and Hand-Delivery Address:
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Telephone: (202) 389-5000
Facsimile: (202) 389-5200

Jeanna M. Wacker, P.C.
(pro hac vice to be submitted)
jeanna.wacker@kirkland.com
Ashley Ross
(pro hac vice to be submitted)
ashley.ross@kirkland.com
Postal and Hand-Delivery Address:
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, N.Y. 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

Nicholas Groombridge
(pro hac vice to be submitted)
nick.groombridge@groombridgewu.com
Jennifer H. Wu
Reg. No. 75,232
jennifer.wu@groombridgewu.com
Postal and Hand-Delivery Address:

GROOMBRIDGE, WU, BAUGHMAN &
STONE LLP
555 Fifth Avenue
Suite 2900
New York, NY 10017
Telephone: (332) 269-0030
Facsimile: (332) 262-5334

*Attorneys for Patent Owner*

## CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that this Patent Owner's Brief on Discretionary Denial complies with the page count limitation outlined in § II.C.iii of the Interim Director Discretionary Process webpage (https://www.uspto.gov/patents/ptab/interim-director-discretionary-process), and consistent with 37 C.F.R. § 42.24 because the Patent Owner's Brief on discretionary Denial contains a total of 4,924 words and 20 pages, as calculated by Microsoft Word's word-count feature. This total excludes the cover page, signature block, and the parts of the Patent Owner's Brief on Discretionary Denial exempted by 37 C.F.R. § 42.24(a)(1).

Date: April 23, 2026

*/s/ W. Todd Baker*

W. Todd Baker
Reg. No. 45,265
todd.baker@kirkland.com
Postal and Hand-Delivery Address:
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Telephone: (202) 389-5000
Facsimile: (202) 389-5200

## CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing Patent Owner's Request for Discretionary Denial, together with all exhibits and other documents filed therewith, was served by email on the Petitioner's counsel of record at the United States Patent & Trademark Office having the following addresses:

| | |
|---|---|
| Mark J. Feldstein | mark.feldstein@finnegan.com |
| William B. Raich | william.raich@finnegan.com |
| Li Zhang | li.zhang@finnegan.com |
| Sarah Slone | sarah.slone@finnegan.com |
| | Finnegan-PGR2026-00027@finnegan.com |

Date: April 23, 2026

*/s/ W. Todd Baker*

W. Todd Baker
Reg. No. 45,265
todd.baker@kirkland.com
Postal and Hand-Delivery Address:
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Telephone: (202) 389-5000
Facsimile: (202) 389-5200