

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOEHRINGER INGELHEIM ANIMAL HEALTH USA INC.,
Petitioner,

v.

KANSAS STATE UNIVERSITY RESEARCH FOUNDATION,
Patent Owner.

PGR2022-00021
Patent 10,954,274 B2

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Denying Institution of Post Grant Review
35 U.S.C. § 324, 37 C.F.R. § 42.4

I. INTRODUCTION

A. Background and Summary

Boehringer Ingelheim Animal Health USA Inc. (“Petitioner”) filed a Petition requesting a post-grant review of claims 1–27 of U.S. Patent No. 10,954,274 B2 (Ex. 1001, “the ’274 patent”). Paper 2 (“Pet.”). Kansas State University Research Foundation (“Patent Owner”) did not file a Preliminary Response.

We may institute a post-grant review if the information presented in the Petition and the Preliminary Response shows that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable. 35 U.S.C. § 324. However, the Board has discretion to deny a petition even if a petitioner meets that threshold. *See, e.g.*, 35 U.S.C. § 325(d); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”).

For the reasons set forth below, we exercise our discretion, on behalf of the Director, and deny institution of a post-grant review for Petitioner’s Grounds 1–5 because the same or substantially the same prior art or arguments previously were presented to the Office. 35 U.S.C. § 325(d). Furthermore, upon consideration of the Petition, as well as all supporting evidence, we determine that the Petition fails to demonstrate that it is more likely than not that at least 1 of the claims challenged in the Petition is unpatentable based on Petitioner’s Ground 6. Accordingly, we deny the Petition

B. Real Parties in Interest

In the Petition, Petitioner identifies itself as a real party-in-interest and additionally lists the following entities as real party-in-interest: Boehringer Ingelheim USA Corporation, Boehringer Ingelheim Vetmedica GmbH, Boehringer Ingelheim Corporate Center GmbH, and Boehringer Ingelheim International GmbH. Pet. 4. Patent Owner identifies itself and Merck & Co., Inc., Merck Sharp & Dohme Corp., Intervet, Inc., and Intervet International BV as the real parties-in-interest. Paper 4, 1.

C. Related Proceedings

The parties identify PGR2020-00076, in which Petitioner challenged related U.S. Patent No. 10,450,351 B1 (“the ’351 patent”), as a related matter. Pet. 4; Paper 4, 1. The ’351 patent is also the subject of a stayed litigation before the District of Kansas, *Boehringer Ingelheim Animal Health USA Inc. v. Intervet Inc. et al.*, No. 20-cv-2378. Pet. 4; Paper 4, 1.

D. The Asserted Grounds of Unpatentability

Petitioner challenges claims 1–27 of the ’274 patent based on the grounds set forth in the table below.

Ground	Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–27	112(a)	Lack of written description
2	1–27	112(a)	Lack of enablement
3	1–3, 5–8, 12–13, 24–25	103	Palinski, ¹

¹ Ex. 1019, Palinski, et al., *A Novel Porcine Circovirus Distantly Related to Known Circoviruses Is Associated with Porcine Dermatitis and Nephropathy Syndrome and Reproductive Failure*, 91 J. VIROL. 1–13 (2016) (“Palinski”).

Ground	Claims Challenged	35 U.S.C. §	Reference(s)/Basis
			Genbank Deposit KT869077, ² Genbank Deposit KX458235 ³
4	1–16, 24–25	103	Palinksi, Genbank Deposit KT869077, Genbank Deposit KX458235, Eichmeyer ⁴
5	1–3, 5–8, 12– 13, 17–20, 24–25	103	Palinksi, Genbank Deposit KT869077, Genbank Deposit KX458235, Feneaux ⁵

² Ex. 1032, Printout of National Center for Biotechnology Information entry for GenBank Accession No. KT869077.1, available at <https://www.ncbi.nlm.nih.gov/nucleotide/KT869077> (“Genbank Deposit KT869077”).

³ Ex. 1033, Printout of National Center for Biotechnology Information entry for GenBank Accession No. KX458235.1, available at <https://www.ncbi.nlm.nih.gov/nucleotide/KX458235> (“Genbank Deposit KX458235”).

⁴ Ex. 1034, Eichmeyer et al., U.S. Patent No. 7,829,101, issued November 9, 2010 (“Eichmeyer”).

⁵ Ex. 1021, Feneaux, et al., *A Chimeric Porcine Circovirus (PCV) with the Immunogenic Capsid Gene of the Pathogenic PCV Type 2 (PCV2) Cloned into the Genomic Backbone of the Nonpathogenic PCV1 Induces Protective Immunity against PCV2 Infection in Pigs*, 78 J. VIROL 6297–6303 (2004) (“Feneaux”).

Ground	Claims Challenged	35 U.S.C. §	Reference(s)/Basis
6	1–27	103	Genbank Deposit ADU77001, ⁶ Genbank Deposit ADU77002, ⁷ Genbank Deposit KM111537.1, ⁸ Genbank Deposit AIR09408, ⁹ WO 2011/091389 A2 ¹⁰

The '274 patent resulted from a division of the application that led to the '351 patent (Ex. 1020). Pet. 1. The '351 patent, and the subsequent '274 patent, both claim priority to an earlier provisional application (“the '866

⁶ National Center for Biotechnology Information entry for GenBank Accession No. ADU77001.1, available at <https://www.ncbi.nlm.nih.gov/protein/ADU77001.1> (“Genbank Deposit ADU77001”).

⁷ National Center for Biotechnology Information entry for GenBank Accession No. ADU77002.1, available at <https://www.ncbi.nlm.nih.gov/protein/ADU77002.1> (“Genbank Deposit ADU77002”).

⁸ Ex. 1038, Printout of National Center for Biotechnology Information entry for GenBank Accession No. KM111537.1, available at <https://www.ncbi.nlm.nih.gov/nucleotide/KM111537> (“Genbank Deposit KM111537.1”).

⁹ Ex. 1039, Printout of National Center for Biotechnology Information entry for GenBank Accession No. AIR09408.1, available at <https://www.ncbi.nlm.nih.gov/protein/689594715> (“Genbank Deposit AIR09408”). Petitioner represents that “AIR09408 is the protein sequence that corresponds to the KM111537 nucleic acid sequence.” Pet. 78 n.11.

¹⁰ Ex. 1036, Delwert et al., PCT Application No. WO 2011/091389 A2, published July 28, 2011. Petitioner cites this reference as WO 2011091389 A1 which we presume is a typo.

provisional”), filed on October 16, 2015. *Id.* at 14. Without priority, the ’274 patent would have a filing date of October 11, 2019. *Id.* at 15.

Petitioner asserts Grounds 3–5 conditionally, based on a determination that “the earliest priority date available to the ’274 Patent is October 2019.” *See, e.g.*, Pet. 7–8, 67. Thus, Petitioner’s Grounds 3–5 require Petitioner to first establish that the Specification does not provide sufficient written description support for the challenged claims to support its argument that the ’274 patent is not entitled to the priority date of the earlier filed applications to which the ’274 patent claims the benefit of priority. *Id.* at 14–15. Specifically, Petitioner contends that

intervening prior art published between the filing date of the ’274 Patent and those earlier applications invalidate the Challenged Claims of the ’274 Patent under 35 U.S.C. §103 (Grounds 3–5).

Id. at 15.

Petitioner also relies on the Declaration of Robert M. Nordgren, Ph.D. (Ex. 1026).

E. Illustrative Claim

Petitioner challenges claims 1–27 of the ’274 patent, of which claim 1 is the only independent claim. Claim 1 is illustrative and is reproduced below:

1. A vector comprising:

at least one heterologous nucleic acid sequence encoding a first porcine circovirus type 3 (PCV3) protein selected from the group consisting of ORF1, ORF2, ORF3, and any combination thereof, wherein the PCV3 protein has at least 90% sequence homology with a sequence selected from the group consisting of SEQ ID NO. 4, SEQ ID NO. 6, or SEQ ID NO. 8, and any combination thereof.

Ex. 1001, 71:24–32.

F. The '274 Patent

The '274 patent was issued on March 23, 2021, and is titled “Porcine Circovirus Type 3 Immunogenic Compositions and Methods of Making and Using the Same.” *Id.* The '274 patent is directed to porcine circovirus type 3 (“PCV3”) immunogenic compositions and methods of making and using such compositions. *Id.* at Abstract.

PCV3 is a new species of circovirus that has been identified in sows having clinical symptoms normally associated with PCV2 infection. *Id.* at 1:31–35. DNA from four sows exhibiting those symptoms was subjected to amplification, inverse PCR gel electrophoresis, and Sanger sequencing of overlapping amplicons spanning the complete genome. *Id.* at 1:39–2:7. As a result, a 2,000 base pair PCV3 genome (SEQ ID NO. 1) was determined. *Id.* at 2:5.

PCV3 has three major open reading frames (ORFs), named ORF1, ORF2, and ORF3, that each code for a different viral protein. *Id.* at 2:8–35. Genetic analysis identified an open reading frame (ORF1; SEQ ID NO. 3) encoding a predicted 296 amino acid (“aa”) protein (SEQ ID NO. 4). *Id.* at 2:8–10. A second ORF (ORF2; SEQ ID NO. 5) in the opposite orientation encoded a predicted 214 aa protein (SEQ ID NO. 6). *Id.* at 2:19–21. ORF2 is the immunogenic capsid protein of PCV3. *Id.* at 16:30–31. A third ORF (ORF3; SEQ ID NO. 7) encodes a predicted 233 aa protein (SEQ ID NO. 8). *Id.* at 2:26–28.

The Specification states that “[the ORF2] sequence, as well as those for ORF1 and ORF3 could vary by as much as 10% in sequence homology and still retain the antigenic characteristics that render it useful in immunogenic compositions.” *Id.* at 8:49–56. It also discloses two PCV3 genome sequences having a 99% nucleotide identity. *Id.* at 48:20–25.

The Specification describes, in one aspect, a method of producing and/or recovering recombinant PCV3 ORF2 protein, by “1) infecting a number of susceptible cells in culture with a recombinant viral vector encoding a PCV3 protein, 2) expressing PCV3 protein by the recombinant viral vector, 3) recovering the PCV3 protein, and 4) separating cell debris from the expressed PCV3 protein via a separation step.” *Id.* at 4:1–9. Preferably, an inactivation step is included to inactivate the viral vector prior to recovery of PCV3 protein that will be used in an immunogenic or immunological composition such as a vaccine. *Id.* at 4:10–14. The inactivation step “can be performed as step 5) in addition to steps 1-4 described above . . . just before or just after the filtration or separation step.” *Id.* at 4:14–17. A neutralization step may also be included after step 5. *Id.* at 4:23–24. Example 3 of the ’274 patent demonstrates the cloning, expression and purification of the PCV3 capsid protein. *Id.* at 44:30–31. Example 4 describes the production and in vitro characterization of an anti-PCV3 capsid monoclonal antibody by inoculating mice with a mixture of purified, truncated capsid protein (35–214 aa) and Freund’s incomplete adjuvant biweekly for eight weeks. *Id.* at 44:57–64. The Specification states “[i]t will be found that the immunogenic compositions comprising recombinant PCV3 ORF protein as provided herewith are very effective in reducing the severity of or incidence of clinical signs associated with PCV3 infections up to and including the prevention of such signs.” *Id.* at 12:12–16.

The Specification explains that another infectious agent, porcine circovirus type 2 (“PCV2”), was previously identified in pigs with postweaning multisystemic wasting syndrome (“PMWS”). *Id.* at 1:19–21. PCV2-associated disease in pigs included PMWS, pneumonia, porcine

dermatitis and nephropathy syndrome (“PDNS”), and reproductive failure. *Id.* at 1:24–28. Commercial vaccines have effectively controlled PCV2-associated disease. *Id.*

G. Prosecution History of the '274 Patent

On March 31, 2020, the Examiner made a non-final rejection based on, *inter alia*, 35 U.S.C. § 112(a). Ex. 1002, 124. For that written description rejection of claims 1, 2, and 5–25, Examiner cited to prior art reference “Gagnon,” stating “[t]he instant claims lack written description distinguishing the instant PCV3 proteins and PCV3 ORF1, ORF2, and/or ORF3 from the PCV3 ORF1 and ORF2 proteins of Gagnon et al.” *Id.* at 126. Examiner emphasized that a specification must provide sufficient distinguishing identifying characteristics of a genus to satisfy adequate written description for that claimed genus; important factors include complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and methods of making the claimed product. *Id.* at 127. While sequence identifiers were disclosed for PCV3 proteins, sufficient characteristics were not disclosed for the PCV3 proteins and/or ORF1–3 as recited in original claims 1, 2, and 5–25. *Id.* In addition, claim 3 was one of several claims rejected over the '351 patent for double patenting. *Id.* at 129.

In a telephone interview on May 29, 2020, Examiner noted that Patent Owner would distinguish the claimed PCV3 over Gagnon in the next reply. *Id.* at 142. Patent Owner filed a Response and Amendment on July 16, 2020, asserting that the written description rejection was overcome—without amendment—because the PCV3 virus was not a combination of PCV1 or PCV2 which were identified in the Gagnon reference. *Id.* at 152. Patent

Owner asserted that supporting evidence included the low degree of sequence homology between PCV3 and PCV1 and PCV2. *Id.*

Next, Examiner issued a final rejection on August 3, 2020, stating that “[s]tructural differences between the instant PCV3 virus and the virus of Gagnon, or any other porcine circovirus is not claimed or readily apparent.” *Id.* at 158. Examiner repeated her prior statement on disclosing distinguishing identifying characteristics of the claimed genus. *Id.* at 159. Patent owner then requested reconsideration and filed a Response and Amendment on October 2, 2020. *Id.* at 170, 176–182. Patent Owner amended claims 1, 3, 19, and 21, and asserted that the amendments overcame the rejection without further explanation, aside from a statement that the limitations of original claim 3 were amended into claim 1. *Id.* at 181.

On November 03, 2020, Patent Owner further amended claim 1 and included in its remarks definitions of “sequence homology” and “sequence identity”—from the Specification—to overcome a rejection based on substantial duplication of claims. *Id.* at 330–337. Claim 1 was amended to include the words, “and any combination thereof” at the end of the claim language. *Id.* at 332. Examiner then issued a Notice of Allowance on November 12, 2020. *Id.* at 338.

H. Person of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in a patentability analysis. *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner describes a person having ordinary skill in the art as follows:

A person of ordinary skill in the art (or “POSITA”) in the field of the ’274 Patent in the October 2015 to October 2019 timeframe would have held a Doctorate in Veterinary Medicine (D.V.M.) or equivalent, or a Ph.D. or equivalent in immunology, vaccinology, virology, molecular biology, animal science, and/or husbandry, or a closely related field. A POSITA would also have practical knowledge of immunology, including how vaccine candidates are first identified and then subsequently developed. The knowledge may come from the POSITA’s own experience, or it may come through research or work collaborations with other experienced individuals in the medical, pharmaceutical, or biotech industry, *e.g.*, as members of a research team or group.

Pet. 16 (citing Ex. 1026 ¶ 34).

Absent opposition from Patent Owner, we adopt Petitioner’s definition because it is consistent with the level of ordinary skill in the art reflected by the prior art in this proceeding. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

I. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.200(b) (2019). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner contends that it “does not believe any term of the ’274 Patent needs to be construed in this proceeding.” Pet. 29. We agree and independently determine that it is unnecessary to expressly construe any claim term for purposes of rendering this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

II. POST-GRANT ELIGIBILITY

As a threshold matter, we must determine whether the ’274 patent is eligible for post-grant review. The post-grant review provisions set forth in section 6(d) of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (September 16, 2011) (“AIA”), apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (stating that the provisions of section 6(d) “shall apply only to patents described in section 3(n)(1)”). Patents subject to the first-inventor-to-file provisions are those that issue from applications that contain or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after [March 16, 2013]; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA § 3(n)(1).

Our rules require that each petitioner for post-grant review certify that the challenged patent is available for post-grant review. 37 C.F.R. § 42.204(a) (“The petitioner must certify that the patent for which review is

sought is available for post-grant review . . .”). In addition, “[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be).” 35 U.S.C. § 321(c).

Petitioner asserts that the ’274 patent is eligible for post-grant review because (i) it has an effective filing date of no earlier than October 16, 2015; and (ii) this petition is being filed within nine months of its March 23, 2021 issue date. Pet. 6.

Because the ’274 patent claims have an effective filing date after March 16, 2013, and because the Petition was filed within nine months of the ’274 patent’s issue date on March 23, 2021, we find that the ’274 patent is eligible for post-grant review. *See id.* at 6; *see also* Ex. 1001, codes (45), (60).

III. ANALYSIS

A. Petitioner’s Grounds 1 and 2: Exercise of Discretion Under 35 U.S.C. § 325(d)

1. Legal Principles

The Patent Office may deny institution under 35 U.S.C. § 325(d), which provides, in pertinent part, that “[i]n determining whether to institute or order a proceeding under this chapter, . . . the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” In evaluating whether the same or substantially the same prior art or arguments were previously presented to the Office, the Board has identified several non-exclusive factors that may be considered. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at

17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“the *Becton, Dickinson* factors”). Those factors are as follows:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Id.; see also The Patent Trial and Appeal Board Consolidated Trial Practice Guide (“Trial Practice Guide”) (Nov. 2019) at 62–63 (citing the *Becton, Dickinson* factors).¹¹

As more recently explained in *Advanced Bionics, LLC v. MED-EL Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8–10 (Feb. 13, 2020) (“*Advanced Bionics*”) (precedential), the Board addresses § 325(d) applying a “two-part framework.” In the first part of the framework, we ask 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. *Advanced Bionics* at 8. Factors (a), (b), and (d) of *Becton, Dickinson* come into play under this first part of the framework. *Id.* at 8–10. If either condition of the framework’s first part is

¹¹ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

met (*e.g.*, substantially the same art is presented), we move to part two of the framework, asking “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims.” *Id.* at 8. Factors (c), (e), and (f) of *Becton, Dickinson* fall within part two of the framework. *Id.* at 10 (“[F]actors (c), (e), and (f) relate to whether the petitioner has demonstrated material error by the Office.”).

Only if the same or substantially the same art or arguments were previously presented to the Office do we then consider whether petitioner has demonstrated error. *Id.* at 8–10. “If the petitioner fails to show that the Office erred, the Director may exercise his discretion not to institute.” *Id.* at 8–9. “At bottom, this [§ 325(d)] framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9 (“If 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.”).

2. § 325(d) Framework: Part One

The first part of the *Advanced Bionics* framework requires us to determine whether the Petition advances the same or substantially the same art or arguments previously presented to the Office. *See Advanced Bionics* at 8. For the reasons set forth below, we determine that the same or substantially the same art was previously presented to the Office, such that part one of the framework is satisfied.

Under step one of the *Advanced Bionics* framework, Petitioner argues that “[t]he prosecution of the ’274 Patent raised written description, but did not resolve the same issue presented by this Petition.” Pet. 26. More specifically, Petitioner contends that the Examiner did not resolve the

question of whether “a POSITA would be unable to identify a protein as derived from PCV3 without requisite structures or identifying characteristics.” *Id.* at 28.

We do not find Petitioner’s argument persuasive. As Petitioner correctly notes, the Examiner rejected all but original claims 3¹² and 4¹³ of the then-pending 25 claims under written description. *Id.* (citing Ex. 1002, 126). In doing so, the Examiner emphasized that “[t]o provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus.” *Id.* (citing Ex. 1002, 127) (emphasis omitted). According to the Examiner, those identifying characteristics included “disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, [and] methods of making the claimed product” *Id.* However, with the omission of claims 3 and 4 from that written description rejection, the Examiner indicated that she considered and understood that the language of claims 3 and 4, reciting at least 90% sequence homology, met those stated requirements under 35 U.S.C. § 112. In its Petition, Petitioner now asks us to consider its argument asserting that the ’274 patent lacks adequate written

¹² Original claim 3 provides as follows: The vector of claim 2, wherein the PCV3 protein has at least 90% sequence homology with a sequence selection from the group consisting of SEQ ID NO. 4, SEQ ID NO. 6, or SEQ ID NO. 8. Ex. 1002, 149.

¹³ Original claim 4 provides as follows: The vector of claim 1, wherein the heterologous nucleic acid sequence has at least 90% sequence homology with a sequence selection from the group consisting of SEQ ID NO. 3, SEQ ID NO. 5, or SEQ ID NO. 7. Ex. 1002, 149.

description support for the claimed genus—“the 10% homology range genera.” *Id.* at 31.

Part one of the *Advanced Bionics* framework requires only that the same or substantially the same art *or* substantially the same arguments were previously presented to the Office. *See Advanced Bionics* at 8. Because we determine that the record shows that the Examiner considered the recited 90% sequence homology limitation under 35 U.S.C. § 112, we conclude that the arguments asserted in this proceeding are substantially the same arguments previously presented to the Office. Accordingly, we proceed to part two.

3. § 325(d) Framework: Part Two

In part two of the framework, we consider “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims.” *Advanced Bionics* at 8. We determine that Petitioner has failed to meet its burden in demonstrating that the Office materially erred.

Under step two of the *Advanced Bionics* framework, Petitioner argues that

the Examiner permitted the Applicant to amend rejected claims to add limitations from other, unrelated claims that she found allowable, but mistakenly did not appear to assess whether Applicant set forth sufficient common characteristics among the claimed genus.

Pet. 80 (citing Ex. 1002 at 157–159, 177, 181, 330–337, 365–366). But, as discussed above, the Examiner did assess whether Patent Owner disclosed sufficient common characteristics among the claimed genus. In the event that Petitioner is arguing that the Examiner materially erred in her

determination that claims reciting at least 90% sequence homology met the requirements under 35 U.S.C. § 112, we address that argument below.

Petitioner contends that the Specification fails to provide adequate written description for the claimed 90% homology range. Pet. 81 (citing Ex. 1026, §§V–VII), 32 (“Claim 1 covers a practically limitless number of amino acid sequences”) (citing Ex. 1026 ¶¶ 146–156). However, Petitioner does not dispute that the Specification adequately describes proteins comprising the amino acid sequence of SEQ ID NOs 4, 6, and 8. Indeed, the Specification provides an actual reduction to practice of 2,000 bp genome (SEQ ID NO: 1) and describes the complete structure (sequence) of proteins comprising SEQ ID NOs 4, 6, and 8. Ex. 1001, 2:5–30. The Specification also describes a method of making a protein comprising the claimed sequences. *Id.* at 44:30–53. The Specification further provides a definition of sequence homology such that those skilled in the art could recognize amino acid sequences that are 90% homologous to SEQ ID NO: 4 by comparing a given sequence to SEQ ID NO: 4. *Id.* at 10:46–65; *see also* Ex. 1002, 330–337 (Examiner considering this definition during prosecution). Thus, while Petitioner and its expert describe the genus as “large,” Petitioner fails to adequately explain why the size of the genus itself necessarily equates to an error made by the Examiner. Pet. 32; Ex. 1026 ¶¶ 146–156.

Petitioner additionally asserts that the “90% homology range—especially when applied to the less variable ORFs 1 and 3—covers proteins that are *not* PCV3 since PCV3 appears to be substantially less variable.” Pet. 33 (emphasis in original). Petitioner then cites to a panoply of exhibits which disclose varying degrees of sequence homology and sequence identity among PCV3 isolates. *Id.* at 33–35. However, Petitioner does not point to any reference disclosing a protein within the claimed 90% homology range

that is not a PCV3 protein—despite asserting “that a substantial amount of claim scope covers proteins that are not PCV3.” *Id.* at 34. Moreover, Petitioner does not address the fact that the Examiner’s prior art search did not identify any references that disclosed sequences within the claimed 90% sequence homology.

Furthermore, in contrast to the claims set forth in the related ’351 patent, this is not the case where the claims use functional language to define a composition. *See* PGR2020-00076. Specifically, the challenged claims are not directed to a subset of species with certain antigenic properties. The recited sequences share at least 90% of the structure of disclosed sequences while limiting the amount of variation to 10% sequence homology or sequence identity. *See, e.g.,* Ex. 1001, 71:24–36 (claims 1 and 2). Thus, unlike in the claims of the ’351 patent, the products claimed in the ’274 patent recite structural limitations—there is no requirement that the protein be capable of inducing an immunological response, for example. *See* Pet. 66 (Petitioner concluding that the Specification provides insufficient guidance to practice the full scope of the claims without undue experimentation because of the work “left to a POSITA, who would need to synthesize and screen numerous of candidate nucleic and amino acid sequences for immunological activity to identify operative embodiments of the claims.”).

In this regard, we are not persuaded that the Examiner erred by not additionally setting forth an enablement rejection. Petitioner’s enablement challenge is largely redundant to the Examiner’s rejection based on lack of adequate written description or otherwise focuses on certain functional characteristics disclosed in the Specification that are not recited in the challenged claims. Accordingly, Petitioner also does not present a

persuasive argument as to why it was a material error for the Examiner to omit an enablement rejection under 35 U.S.C. § 112.

In view of the above, we determine that part two of the *Advanced Bionics* framework is not satisfied with regard to Petitioner’s Grounds 1 and 2.

4. *Conclusion*

We exercise our discretion under § 325(d) and decline to institute post-grant review based on the two grounds presented in the Petition under 35 U.S.C. § 112.

B. *Petitioner’s Grounds 3–5*

As discussed above, Petitioner’s conditional assertion of Grounds 3–5 requires a determination that evidence and arguments presented in the Petition are sufficient to satisfy the “more likely than not” standard regarding the asserted unpatentability under 35 U.S.C. § 112. We exercise our discretion under § 325(d) and decline to institute post-grant review based on those § 112 grounds, for the reasons discussed above. Accordingly, we do not reach the merits of Petitioner’s Grounds 3–5, as they are premised upon the § 112 grounds.

C. *Petitioner’s Ground 6: Obviousness of Claims 1–27 over Genbank Deposit ADU77001 Genbank Deposit ADU77002, Genbank Deposit KM111537.1, Genbank Deposit AIR09408, and PCT WO 2011091389 A2*

Petitioner contends that claims 1–27 would have been obvious over Genbank Deposit ADU77001, Genbank Deposit ADU77002, Genbank Deposit KM111537.1, Genbank Deposit AIR09408, and PCT Application No. WO 2011091389 A2 (collectively referred to by Petitioner as the “PCV3 deposits”), in view of the state of the art, even if the ‘274 patent can

claim the benefit of a priority date. Pet. 76–80. For the reasons set forth below, we determine that Petitioner has not shown that it is more likely than not that it will prevail in establishing unpatentability with regard to Ground 6. In sum, the Petition is devoid of an adequate argument or sufficient evidence establishing how the prior art teaches or suggests the “PCV3 protein has at least 90% sequence homology” limitation.

1. Overview of Genbank Deposits ADU77001 and ADU77002

Genbank Deposits ADU77001 and ADU77002 are circovirus partial protein sequences cited in the '274 patent as having a publication date of January 31, 2011. Ex. 1001. Thus, on their face, ADU77001 and ADU77002 qualify as prior art under 35 U.S.C. § 102(a)(2).

ADU77001 and ADU77002 disclose partial protein sequences of 110 aa and 221 aa, respectively, from *Circoviridae PorkNW2/USA/2009*. *Id.* at 2:12–23.

2. Overview of Genbank Deposit KM111537.1 (Ex. 1038)

Genbank Deposit KM111537.1 is a circovirus genome sequence published on October 01, 2014. Ex. 1038. Thus, on its face, KM111537.1 qualifies as prior art under 35 U.S.C. § 102(a)(2).

KM111537.1 discloses an 859 bp DNA sequence from *Circoviridae SFBeef*. *Id.*

3. Overview of Genbank Deposit AIR09408 (Ex. 1039)

Genbank Deposit AIR09408 is a circovirus protein sequence cited in the '274 patent as having a publication date of October 01, 2014. Exs. 1001, 1039. Thus, on its face, AIR09408 qualifies as prior art under 35 U.S.C. § 102(a)(2).

AIR09408 discloses a 242 aa protein sequence from *Circoviridae* *SFBeef*. Ex. 1039.

4. *Overview of WO 2011/091389 A2 (Ex. 1036)*

WO 2011/091389 A2 is a PCT patent application that published on July 28, 2011. Ex. 1036. Thus, on its face, PCT WO 2011/091389 A2 qualifies as prior art under 35 U.S.C. § 102(a)(2). Pet. 78.

PCT WO 2011/091389 A2, titled “Cyclovirus and Method of Use,” discloses genetic and protein sequences of a novel cyclovirus, along with methods of detecting, diagnosing, preventing, and treating cyclovirus infection. Ex. 1036, Abstract. The specification discloses that “circoviruses include only two closely related species, PCV 1 and PCV2.” *Id.* at ¶ 4. From the sequence disclosures, SEQ ID No. 40 is a circovirus nucleic acid sequence, and SEQ ID No. 41 is a circovirus protein sequence from a putative replicase. *Id.* at FIG. 5N

5. *The Recited Element of At Least 90% Sequence Homology*

Claim 1 recites the element of a “PCV3 protein ha[ving] at least 90% sequence homology with a sequence selected from the group consisting of SEQ ID NO. 4, SEQ ID NO. 6, or SEQ ID NO. 8, and any combination thereof.” Ex. 1001, 71:24–32.

Petitioner contends that the disclosure by any of the above cited references “would be sufficient to disclose a genetic sequence within the claimed range” because “it would be obvious to a POSITA that there could be at least 3-4% natural variation in ORF2, which would also render obvious the 90% or greater sequence identity limitation for ORF2.” Pet. 77–79. Petitioner further argues that a person of ordinary skill in the art would have been motivated to combine the disclosed genetic sequences with vectors to

study protein expression. *Id.* at 79. To support its assertions, Petitioner cites to large portions of the Nordgren Declaration. *Id.* at 76, 79 (citing Ex. 1026).

We do not find Petitioner’s arguments persuasive. We address each argument, as it pertains to each cited reference, below.¹⁴

Petitioner contends that the ADU77001 and ADU77002 “deposited genome was 98% identical to SEQ ID No. 1 across the whole genome, 96% identical in ORF1 and 87% identical in ORF2.” *Id.* at 77 (citing Ex. 1001 (’274 patent) at 1:63–66, 2:8–13, 2:19–22). Because ADU77001 and ADU77002 disclose protein sequences, and not nucleic acid sequences, we do not reach Petitioner’s argument based on SEQ ID No. 1 in the ’274 patent—protein sequences cannot have sequence identity with nucleic acid sequences. *See* Ex. 1001, 2:5 (stating that SEQ ID No. 1 is a nucleic acid sequence).

The ’274 patent discloses an ORF1 with 296 aa and an ORF2 with 214 aa and discloses that ADU77001 and ADU77002 are partial protein sequences. *Id.* at 2:8–24. The Specification states that the disclosed ORF1 and ORF2 sequences have “genetic and structural similarities to members of the genus Circovirus.” *Id.* at 2:35–36. Petitioner does not identify, however, what portion of complete ORF protein sequences are represented by the partial sequences disclosed by ADU77001 and ADU77002. Nor does Petitioner attempt to demonstrate that ADU77001 and ADU77002 are PCV3 sequences by comparing the complete protein sequences associated with these references to those disclosed in the ’274 patent. Thus, on this record,

¹⁴ Because Petitioner makes only a passing mention to KM111537.1, with no argument pertaining to that reference, we do not include it in our analysis. *See* Pet. 78 n.11.

we determine that Petitioner has not demonstrated that ADU77001 and ADU77002 teach or suggest the 90% sequence homology limitation recited by Claim 1.

Moreover, Petitioner acknowledges that these references disclose “partial protein[s]” but asserts that “there were two ways to determine homology with a partial protein, one of which you would exclude the omitted amino acids.” Pet. 77 n.10 (citing Ex. 1024). We are not persuaded. To be sure, the Specification discloses that when determining the sequence homology of two sequences, “gaps are introduced if necessary.” Ex. 1001, 10:46–49. But Petitioner does not explain what portions of ADU77001 and ADU77002 would be omitted when determining sequence homology nor how the subsequent sequence homology determination would result in the claimed 90% sequence homology. Without more, this is merely a conclusory statement that does not support Petitioner’s assertion that ADU77001 and ADU77002 fall within the scope of Claim 1.

Next, Petitioner contends that “there was 94% sequence identity between [AIR09408] and the ’274 Patent’s ORF3 sequence.” Pet. 78 (citing Ex. 1001, 2:26–31). The ’274 patent discloses an ORF3 with 233 aa that “was 94% identical to one identified in a partial circovirus genome determined from ground beef.” Ex. 1001, 2:26–30. Again, Petitioner does not provide any information on the protein sequence disclosed by AIR09408, nor does it discuss whether the sequence is part of a complete or partial protein.

Finally, Petitioner contends that PCT WO 2011091389 A2 disclosed sequences that were “99% identical to ORF1 of the ’274 Patent.” Pet. 78 (citing Ex. 1036, SEQ ID Nos. 40–41). Beyond listing PCT WO 2011091389 A2 in the “References Cited,” the ’274 patent does not discuss

this reference. Ex. 1001. Petitioner does not explain how the sequences disclosed in PCT WO 2011091389 A2 relate, if at all, to the sequences disclosed in the '274 patent.

Moreover, notwithstanding the fact that Petitioner does not provide specific citations to evaluate its assertions, Petitioner does not direct our attention to any portion of the Nordgren Declaration providing information on why the partial sequences disclosed by the references teach or suggest the claimed 90% sequence homology. Pet. 76, 79 (citing Ex. 1026 at VII.C, ¶¶ 247–269). For example, Dr. Nordgren's assertion "a POSITA would anticipate natural genetic variation of PorkNW2/USA/2009 ORF2 would bring it within the scope of the Claim 1 genera" is not supported by substantial evidence. Ex. 1026 ¶ 256. Claim 1, for example, recites a PCV3 protein and does not recite partial proteins. Without knowing what portion of complete proteins are disclosed by the references, we are not persuaded that a person of ordinary skill in the art would have been able to predict the variation expected among a group of complete proteins to arrive at the claimed subject matter as is implied by Petitioner.

Petitioner's conclusory statements are insufficient to support a legal conclusion of obviousness. And while we agree with Petitioner that the protein sequences disclosed in the cited references do not necessarily have to be designated as PCV3 sequences, we determine that Petitioner has failed to meet its burden to demonstrate that any of the PCV3 deposit references teach or suggest the recited sequences within the claimed range. Pet. 79.

Therefore, Petitioner has not met its burden in showing that every claimed element is taught by its cited references, and we need not reach Petitioner's argument on motivation to combine.

Accordingly, we determine that Petitioner fails to carry its burden to show that it is more likely than not that at least 1 of the claims challenged in the Petition is unpatentable based on Petitioner's Ground 6.

IV. CONCLUSION

For the reasons provided above, we deny the Petition and decline to institute the requested post-grant review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the '274 patent and no trial is instituted.

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