

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANCECELL PTY LTD.,
Petitioner,

v.

SCIENCONS AS and ARTBIO, INC.,¹
Patent Owner.

PGR2025-00040
Patent 12,249,437 B2

Before GRACE KARAFFA OBERMANN, JO-ANNE M. KOKOSKI, and
KIMBERLY MCGRAW, *Administrative Patent Judges*.

McGRAW, *Administrative Patent Judge*.

DECISION
Granting Institution of Post-Grant Review
35 U.S.C. § 324

¹ Patent Owner Sciencons AS requested that “the caption of this proceeding be amended to include ARTBIO, Inc. as the current exclusive licensee,” who is responsible for defending the challenged patent in this proceeding. *See* Paper 4, 1; Prelim. Resp. 1. As explained, *infra*, we grant Sciencons AS’s request and amend the caption to include both Sciencons AS and ARTBIO, Inc. To the extent any party disputes ARTBIO, Inc.’s right to participate in this proceeding or be included in the caption, the party shall request authorization to brief the issue within 10 business days of this Decision.

I. INTRODUCTION

A. Background and Summary

AdvanCell Pty Ltd. (“Petitioner”) filed a Petition requesting post-grant review of claims 1–38 of U.S. Patent No. 12,249,437 B2 (Ex. 1001, “the ’437 patent”). Paper 1 (“Pet.”). After the Director referred the Petition to the Board (Paper 6), Sciencons AS filed a Preliminary Response (Paper 7 “Prelim. Resp.”). Thereafter, Petitioner filed an authorized Reply (Paper 12, “Reply”) and PAT filed a Sur-reply (Paper 13, “PO Sur-reply”). As discussed in further detail below, Sciencons, AS disclaimed claims 10 and 34. Therefore, claims 1–9, 11–33, and 35–38 (“the challenged claims”) remain before us.

Under 35 U.S.C. § 324(a), a post-grant review may be instituted only if “the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” Post-grant review is available for patents that issue from applications that at one point contained at least one claim with an effective filing date on or after March 16, 2013. *See Leahy-Smith America Invents Act*, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), §§ 3(n)(1), 6(f)(2)(A).

After considering the briefing and the evidence of record, for the reasons set forth below, we determine that Petitioner has shown that the ’437 patent is eligible for post-grant review and that it is more likely than not that at least one challenged claim of the ’437 patent is unpatentable under § 324(a). Accordingly, we institute a post-grant review of all challenged claims of the ’437 patent.

B. Real Parties in Interest and Request to Amend Caption

Petitioner identifies itself, AdvanCell Pty Ltd., as the real party-in-interest. Pet. 98. Patent Owner Sciencons AS states that itself, as well as ArtBio AS and ARTBIO, Inc. are the real parties-in-interest. Paper 4, 1. Patent Owner explains that Sciencons AS granted ArtBio AS an exclusive license, with the right to grant sublicenses, to the '437 patent and that ArtBio AS later granted ARTBIO, Inc. an exclusive license to the '437 patent. *Id.*

Sciencons AS also states that ARTBIO, Inc. is responsible for defending the '437 patent in this proceeding and requests that ARTBIO, Inc. be included in the caption for this proceeding.² Paper 4, 1. ARTBIO, Inc. has signed powers of attorney appointing the same practitioners that were appointed by Sciencons AS to transact all business associated with the instant post-grant review review of the '437 patent. *See* Paper 3. To date, no objection has been raised to Patent Owner's request.

Given Sciencons AS's representation that ARTBIO, Inc. is currently the exclusive licensee of the '437 patent and is responsible for defending the '437 patent, we grant Sciencons AS's unopposed request that ARTBIO, Inc. be included in the caption. For convenience we refer to Sciencons AS and the purported exclusive licensee ARTBIO, Inc. collectively as "Patent Owner." As stated *supra*, to the extent any party disputes ARTBIO, Inc.'s right to participate in this proceeding or to be included in the caption, the party shall request authorization to brief the issue within 10 business days of this Decision.

² Patent Owner has not requested that ArtBio AS, the other entity identified as a real party in interest, be added to the caption.

C. Related Matters

The parties identify PGR2025-00029, which challenges US Patent No. 12,125,603 (“the ’603 patent”), as a related matter. Pet. 98; Paper 4, 1. The ’437 patent is a continuation of the ’603 patent. Ex. 1001, code (63).

D. Overview of the ’437 Patent

The ’437 patent, titled “Production of Highly Purified ^{212}Pb ,” is directed to a container comprising ^{212}Pb on the walls obtained from a ^{212}Pb precursor isotope source without the need for processing, with high yields, and which can be safely and efficiently transported to the locations where it is to be used. Ex. 1001, code (54), (57); *see also id.* at 1:20–27. The ’437 patent describes methods for obtaining a container having ^{212}Pb on its walls, by providing an assembly having first and second parts, wherein the first part comprises a container for collecting ^{212}Pb and the second part comprises a ^{212}Pb precursor isotope source. *Id.* at 2:27–33. The ’437 patent states that the ^{212}Pb precursor isotope source may be selected from ^{232}Th , ^{228}Ra , ^{228}Ac , ^{228}Th , and/or ^{224}Ra . *Id.* at 3:1–3. The method includes allowing the ^{212}Pb precursor isotope source sufficient time to decay to progenies ^{220}Rn , ^{216}Po , or ^{212}Pb and settle onto the inner wall of the container and then removing or isolating the precursor isotope from the assembly. *Id.* at 2:27–47. During the process, the precursor isotope does not come into contact with the inner wall of the container. *Id.*

E. Illustrative Claims

Claims 1 and 16 are the only independent challenged claims and are reproduced below.

Claim 1. [Preamble] A radioisotope generator comprising:

[1.A] a solid precursor isotope source configured to emanate one or more gaseous progeny isotopes,

[1.B] the solid precursor isotope source comprising a precursor isotope; and

[1.C] wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal, and

[1.D] wherein the solid precursor isotope source and the collector surface are configured such that the one or more gaseous progeny isotopes deposit one or more solid progeny isotopes on the collector surface.

Claim 16. [Preamble] A method of generating a progeny radioisotope, the method comprising:

[16.A] allowing one or more gaseous progeny isotopes to emanate from a solid precursor isotope source,

[16.B] the solid precursor isotope source comprising a precursor isotope;

[16.C] fluidly coupling a volume including a collector surface to the solid precursor isotope source using a gas tight seal; and

[16.D] allowing one or more solid progeny isotopes of the one or more gaseous progeny isotopes to deposit on the collector surface.

See Pet. xiv–xv, 15–22, 34–35; Ex. 1001, 21:40–51 (claim 1), 22:34–45 (claim 16) (with bracketing and formatting added).

F. Disclaimer of Claims 10 and 34

A “patent owner may file a statutory disclaimer under 35 U.S.C. [§] 253(a) in compliance with § 1.321(a) of this chapter, disclaiming one or more claims in the patent. No post-grant review will be instituted based on disclaimed claims.” 37 C.F.R. § 42.207(e).

A disclaimer under 35 U.S.C. § 253(a) is “considered as part of the original patent” as of the date on which it is “recorded” in the U.S. Patent

and Trademark Office (“Office”). 35 U.S.C. § 253(a). For a disclaimer to be “recorded” in the Office, the document filed by the patent owner must:

- (1) Be signed by the patentee, or an attorney or agent of record;
- (2) Identify the patent and complete claim or claims, or term being disclaimed. A disclaimer which is not a disclaimer of a complete claim or claims, or term will be refused recordation;
- (3) State the present extent of patentee’s ownership interest in the patent; and
- (4) Be accompanied by the fee set forth in [37 C.F.R.] § 1.20(d).

37 C.F.R. § 1.321(a); *see also Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1382 (Fed. Cir. 1998) (holding that a § 253 disclaimer is “recorded” on the date that the Office receives a disclaimer meeting the requirements of 37 C.F.R. § 1.321(a), and that no further action is required in the Office for a disclaimer to be “recorded”).

Here, Patentee Sciencons AS filed a statutory disclaimer of claims 10 and 34 of the ’437 patent. Ex. 2001; Prelim. Resp. 43. Based on our review of Exhibit 2001 and the Office’s public records, we find that the disclaimer of claims 10 and 34 complies with the above-listed requirements of 37 C.F.R. § 1.321(a). Accordingly, we treat claims 10 and 34 as having never been part of the ’437 patent. *See Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) (“This court has interpreted the term ‘considered as part of the original patent’ in [35 U.S.C.] § 253 to mean that the patent is treated as though the disclaimed claims never existed.”). Because post-grant review cannot be instituted based on disclaimed claims, claims 10 and 34 are outside the scope of this proceeding. 37 C.F.R. § 42.207(e) (“No post-grant review will be instituted based

on disclaimed claims.”); *General Elec. Co. v. United Techs. Corp.*, IPR2017-00491, Paper 9 (PTAB July 6, 2017) (precedential) (denying institution in view of a statutory disclaimer of all the challenged claims). Thus, we confine our analysis in this Decision to claims 1–9, 11–33, and 35–38, the remaining challenged claims that have not been disclaimed.

G. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–9, 11–33, and 35–38 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §³	Reference(s)/Basis
1, 3, 4, 7–9, 11, 12, 14–19, 22–26, 28, 29, 31, 32, 36, 38	102	Hassfjell-Hoff ⁴
1, 3, 4, 7–9, 11, 12, 14–19, 22–26, 28, 29, 31, 32, 36, 38	103	Hassfjell-Hoff
1, 3, 5–7, 15–16, 18, 20–22, 29–33, 35–37	103	Norman ⁵
1, 3, 5–7, 15–16, 18, 20–22, 29–33, 35–37	103	Norman
1, 3–9, 11, 12, 14–26, 28–33, 35–38		Hassfjell-Hoff, Norman
2	103	Hassfjell-Hoff, IAEA ⁶

³ The AIA amended 35 U.S.C. §§ 102, 103, and 112. Because the challenged claims of the ’437 patent have an effective filing date after the effective date of the applicable AIA amendment, we refer to the AIA version of 35 U.S.C. §§ 102, 103, and 112.

⁴ Hassfjell, Sindre P. and Hoff, Per, “A Generator for Production of ²¹²Pb and ²¹²Bi, Appl. Radiat. Isot., vol. 45, no. 10, pp 1021–1025 (1994) (Ex. 1003, “Hassfjell-Hoff”).

⁵ US 5,038,046, issued Aug. 6, 1991 (Ex. 1007, “Norman”).

⁶ International Atomic Energy Agency, “Radiotracer Generators for Industrial Applications”, IAEA Radiation Technology Series No. 5, IAEA, Vienna (2013) (Ex. 1008, “IAEA”)

Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
13, 27	103	Hassfjell-Hoff, Westrøm ⁷
8, 9, 11, 12, 14, 17, 23–26, 28, 38	103	Norman, Hassfjell-Hoff
13, 27	103	Norman, Hassfjell-Hoff, Westrøm
13, 27	103	Hassfjell-Hoff, Norman, Westrøm
1–9, 11–15, 35–38	112	Indefiniteness

Pet. 1–2. Petitioner relies on the Declaration of Saed Mirzadeh (Ex. 1002) and the Declaration of Per Hoff (Ex. 1019) in support of its contentions.

H. *Eligibility for Post-Grant Review*

The post-grant review (“PGR”) provisions of the AIA apply only to patents subject to the first inventor to file provisions of the AIA. AIA § 6(f)(2)(A). Specifically, the first inventor to file provisions apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time a claim to a claimed invention that has an effective filing date on or after March 16, 2013. *Id.* § 3(n)(1). Furthermore, “[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); *see also* 37 C.F.R. § 42.202(a) (setting forth the same). Petitioner has the burden of demonstrating eligibility for post-grant review. *See Mylan Pharms. Inc. v. Yeda Res. & Dev. Co.*, PGR2016-00010, Paper 9 at 10 (PTAB Aug. 15, 2016).

⁷ Westrøm, Sara; Generalov, Roman; Bønsdorff, Sara B.; and Larsen, Roy H., “Preparation of ²¹²Pb-labeled monoclonal antibody using a novel ²²⁴Ra-based generator solution”, *Nuclear Medicine and Biology*, vol. 51, pp 1–9 (August 2017) (Ex. 1009, “Westrøm”).

The effective filing date of an application for a patent on an invention is “the filing date of the earliest application for which the . . . application is entitled, as to such invention, to a right of priority under section 119, 365(a), 365(b), 386(a), or 386(b) or to the benefit of an earlier filing date under section 120, 121, 365(c), or 386(c).” 35 U.S.C. § 100(i)(1)(B). In the event that the application is not entitled to any earlier filing date or right of priority, the effective filing date is “the actual filing date of . . . the application for the patent containing a claim to the invention.” 35 U.S.C. § 100(i)(1)(A).

The ’437 patent issued on March 11, 2025, from U.S. Application No. 18/680,605, filed on May 31, 2024 (“the ’605 application”), which is a continuation of U.S. Application No. 17/756,805, filed as PCT/EP2020/084701 on December 4, 2020 (now U.S. Patent No. 12,125,603) under 35 U.S.C. § 365(c), which claims priority to European application 19213759, filed December 5, 2019, and European application 20172038, filed April 29, 2020. Ex. 1001, codes (21), (22), (30), (63), (86). Thus, the ’437 patent contains a claim that has an effective filing date on or after March 16, 2013, and the Petition was filed within nine months of ’437 patent’s issue date. *See* Paper 5 (showing a filing date of April 8, 2025).

Petitioner certifies that the ’437 patent is available for post-grant review. Pet. 1. On this record, we agree with the Petitioner and determine that the ’437 patent is eligible for post-grant review.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art “would have had a bachelor’s degree in chemistry, chemical engineering, physics,

nuclear chemistry, radiochemistry, or materials science, or a comparable field of study, plus approximately two to three years of professional experience with radioisotope generators, radiopharmaceutical chemistry, nuclear medicine, or other relevant industry experience” and that “[a]dditional graduate education could substitute for professional experience, and significant experience in the field could substitute for formal education.” Pet. 2–3 (citing Ex. 1002 ¶ 33; Ex. 1019 ¶ 27). At this stage of the proceeding, Patent Owner does not dispute Petitioner’s proposed definition nor provide a proposed definition of its own. *See generally* Prelim. Resp.

For the purposes of this Decision, we adopt Petitioner’s undisputed proposed definition of a POSITA.

B. Claim Construction

The Board construes claims at issue in a post-grant review proceeding using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.200(b). This includes applying the claim construction standard articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Under this standard, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips*, 415 F.3d at 1313. Only those terms in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Realtime Data LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019).

The parties provide arguments about the claim term “fluidly coupled” and the phrase “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal.” *See, e.g.*, Pet. 3–4; Prelim. Resp. 6–11; Pet. Reply 1–5; PO Sur-reply 1–5. Petitioner also provides constructions for “gas tight seal,” “valve associated with the solid precursor isotope,” “connected to an opening of the container,” “removeably connect,” and “with.” Pet. 5–10. We address the construction of “fluidly coupled” and “wherein the solid precursor isotope source is configured to be coupled to a volume including a collector surface with a gas tight seal” below, and determine that, at this stage of the proceeding, no additional express claim constructions are required to resolve any issues in dispute.

1. Fluidly coupled

Petitioner asserts that “fluidly coupled” is recited in claims 1, 16, 18, 29, and 38 and means “capable of being connected or linked together using a gas.” Pet. 4 (citing Ex. 1002 ¶ 35).

Patent Owner responds that Petitioner improperly argues that “fluidly coupled” means “capable of being connected or linked together using a gas” or “*selectively* fluidly coupled.” Prelim. Resp. 7 (citing Pet. 4, 19) (emphasis added). Patent Owner contends that Petitioner attempts “to rewrite the claim and effectively render existing language superfluous invites legal error and should be rejected.” *Id.* at 7–8.

We agree with the parties that two structures that have gas flow therebetween are fluidly coupled to each other. *See, e.g.*, Pet. 21; Prelim. Resp. 16. We also agree with Patent Owner that the term “fluidly coupled”

itself does not mean “*capable of* being connected or linked together using a gas.” Prelim. Resp. 7 (emphasis added).

Claim 1, however, “recites a generator having a “solid precursor isotope source [that] *is configured to be fluidly coupled . . .*” Ex. 1001, 21:40–47. Thus, at this stage of the proceeding, we do not construe claim 1 to require that the isotope source *is fluidly coupled* to a volume, but rather that the isotope source is *configured to be fluidly coupled* to the volume.

Independent claim 16 does not recite “configured to be” or “fluidly coupled.” Rather, claim 16 recites a method comprising “fluidly coupling a volume including a collector surface to the solid precursor isotope source using a gas tight seal.” In accordance with the plain and ordinary meaning of this phrase, we understand method claim 16 to require fluidly coupling a volume, which includes a collector surface, to an isotope source and that the fluidly coupling step requires use of a gas tight seal. As shown in Figure 4, the gas tight seal can be a valve. At this stage of the proceeding, we understand that a gas tight valve is a gas tight seal regardless of whether the valve is closed (preventing gas flow) or open (allowing gas flow) position. This understanding is supported by Figure 4B which identifies the lid/valve as a “Gas and liquid tight lid/valve” even when the lid/valve is in the open (allowing gas flow) position.

2. “*wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal*”

Claim 1 recites “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface *with a gas tight seal.*” Ex. 1001, 21:45–47 (emphasis added). Petitioner asserts that the phrase “with a gas tight seal” renders the limitation

ambiguous because it is not clear what has to be “with a gas tight seal.”

Pet. 5. Petitioner asserts that there are three possible constructions for what has to be “with a gas tight seal”, namely:

(1) the volume (“wherein the solid precursor isotope source is configured to be fluidly coupled to a **volume** including a collector surface ***with a gas tight seal***”);

(2) the collector surface (“wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including ***a collector surface with a gas tight seal***”); or

(3) the fluidly coupling (“wherein the solid precursor isotope ***source is configured to be fluidly coupled*** to a volume including a collector surface ***with a gas tight seal***”).

Pet. 5 (citing Ex. 1002 ¶ 36) (emphasis added).

a) Petitioner’s Contentions

(1) First construction

Petitioner further asserts that under ***the first construction (i.e., “the first ‘volume’ construction”)***, the “entire volume has a gas tight seal (with the precursor isotope source inside the volume).” Pet. 5. Petitioner states that under this first “volume” construction, the gas tight seal “include[s] a gas-tight seal that selectively fluidly couples the precursor isotope source to volume” as shown in Figure 4 of the ’437 patent. *Id.* at 5–6 (citing Ex. 1001, 14:21–25, 18:21–23, Fig. 4). In its Reply, Petitioner points to Figure 4B of the ’437 patent as an example to identify the “volume” that has a gas tight seal. Pet. Reply 4–5. Figures 4A and 4B with Petitioner’s color annotations added are reproduced below.

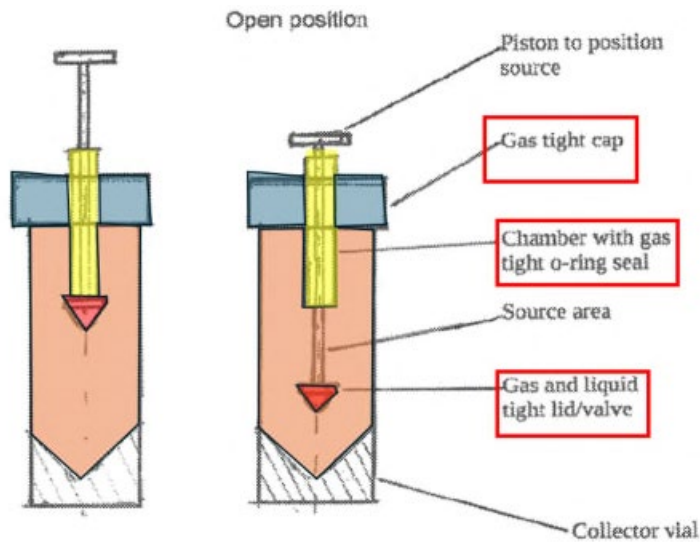


Fig. 4A

Fig. 4B

Figure 4 of the '437 patent, with Petitioner's color annotation added, depicts a single chamber diffusion generator with a retractable piston to position a source, a container (collector vial), a gas tight cap (blue), a chamber (yellow) with a gas tight o-ring seal, and a gas and liquid tight valve (red). Ex. 1001, 14:37–39, Fig. 4B; Pet. Reply 3–4 (citing Pet. 5–6).

Petitioner also explains that under its first “volume” construction (i.e., where the “gas tight seal” modifies “a volume”), the sealed volume includes both the volume where the source is located and the volume corresponding to the collector surface. Pet. Reply 4 (citing Pet. 5–6). Petitioner asserts that, as an example, the sealed volume in Figure 4B includes the yellow volume of the tube, the blue volume of the cap, and the beige volume of the container. *Id.* Petitioner further asserts that this “entire volume” includes a collector surface and has a gas tight seal provided by the combination of the both the “gas tight o-ring seal” as well as the “gas tight cap.” *Id.* at 4–5.

(2) *Second construction*

Petitioner asserts that under the ***second construction (i.e., “the second ‘collector surface’ construction”)*** “[j]ust the collector surface, not the entire volume, has a gas tight seal (when the precursor isotope source is inside the collector).” Pet. 5 (emphasis added); *see also* Pet. Reply 5 (stating a gas tight seal is required on “only the volume defined by the collector surface”). Petitioner states that the embodiments shown in Figures 3 and 5 of the ’437 patent meet this construction because, in these embodiments, “the precursor isotope source is fluidly coupled to a fully enclosed volume that has a gas-tight seal.” Pet. 6 (citing Ex. 1001, Figs. 3, 5). Figures 3A and 3B of the ’437 patent are reproduced below.

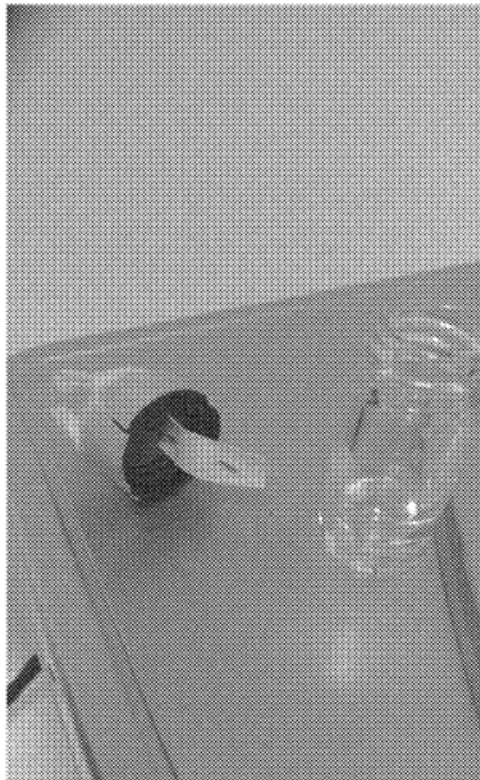


Fig. 3A



Fig. 3B

Figures 3A and 3B of the '437 patent “show pictures of a crude version of a generator system based on a 3 ml v-vial with a membrane inserted open top screw penetrated by a syringe tip.” Ex. 1001, 14:25–29. Precursor isotope source is placed onto a strip of paper attached to the syringe tip using a pipette before the screwcap with the source is attached to the vial. *Id.* at 14:29–36.

Figures 5A and 5B of the '437 patent are reproduced below.

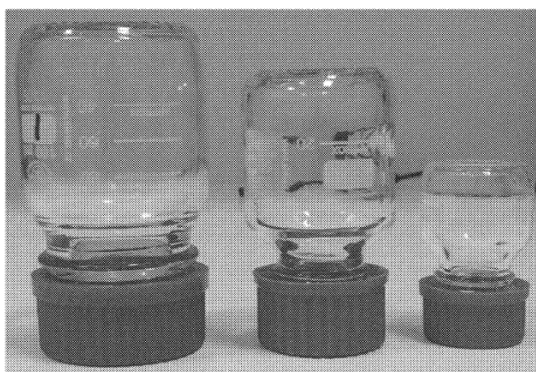


Fig. 5A

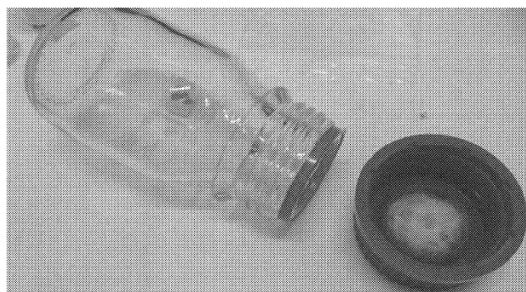
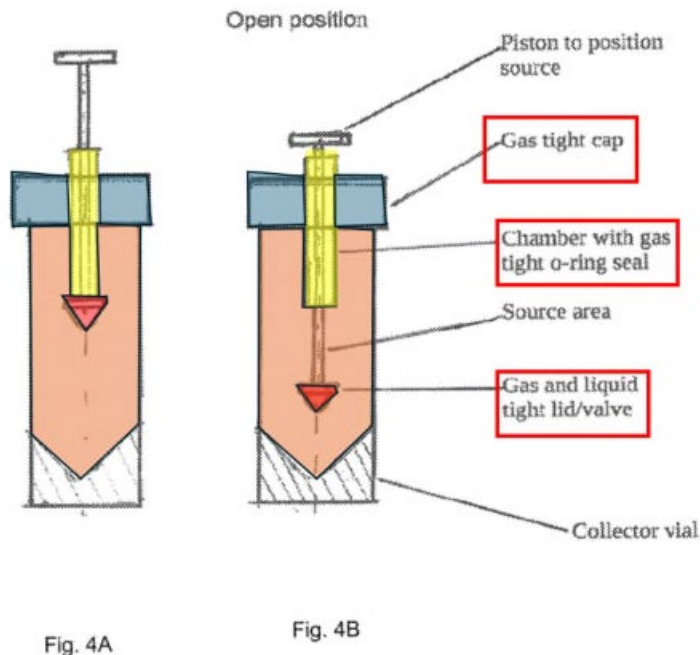


Fig. 5B

Figure 5A (left) shows 100, 50, and 10 ml generator units. Ex. 1001, 14:44–45. Figure 5B (right) shows the cap with quartz wool in the center of the inner surface. *Id.* at 14:56–46. The radioactive isotope precursor solution can be placed onto the quartz wool in the cap and the flask mounted for upside down storage to produce ^{212}Pb deposited on the flask's inner surface. *Id.* at 14:46–50.

In its Reply, Petitioner again asserts that this second “collector surface” construction reads upon the Figures 3A–B and 5A–B and further states that this construction does not read upon the Figure 4A–B embodiments, reproduced again below. Pet. Reply 5.



(3) *Third construction*

Petitioner asserts that under *the third construction* (“*the third ‘fluidly coupled’ limitation*”), the system is configured to selectively couple, using a gas tight seal, a volume with the solid precursor isotope source and a volume with a collector surface. Pet. 5; *see also id.* at 21–22 (identifying Hassfjell-Hoff’s gate valve as a gas tight seal that selectively fluidly couples the isotope source to the volume that has a collector surface).

In its Reply Brief, Petitioner asserts that this construction aligns particularly with Figures 4A and 4B of the '437 patent. Pet. Reply 2–3 (citing Ex. 1001, Fig. 4). Petitioner asserts that this embodiment has three gas tight seals (the vial cap, the o-rings, and the lid/valve) annotated in red and three distinct spaces, annotated in yellow, blue, and beige. *Id.* The vial cap and the o-rings provide the gas tight seal and the lid/valve fluidly couple the isotope source to the volume. *See id* at 3. Petitioner asserts that the precursor isotope located in the yellow volume is fluidly coupled to the beige and blue volumes, which include a collector surface vial, when the lid/valve is open as shown in Figure 4B. *Id.* The yellow volume is not fluidly coupled to the beige or blue volumes when the gas and liquid tight lid/valve is closed as depicted in Figure 4A.

b) Patent Owner's Contentions

Patent Owner does not state how the term should be construed. *See generally* Prelim. Resp.; PO Sur-reply. Instead, Patent Owner states that “[t]o the extent ambiguity is present, it lies with Petitioner’s various different constructions and its reasoning (or lack thereof) to get there.” Prelim. Resp. 8. Patent Owner states that each of Petitioner’s proposed constructions should be rejected together with the grounds relying thereon. *See, e.g., id.*

c) Analysis

We begin our analysis with the language of claims. *Phillips*, 415 F.3d at 1312; *see also SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 874–875 (Fed. Cir. 2004) (“There is a ‘heavy presumption’ that the terms used in the claims ‘mean what they say and have the ordinary

meaning that would be attributed to those words by persons skilled in the relevant art.”).

(1) Collector Surface (Second Construction)

On a first read, the phrase “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including **a collector surface with a gas tight seal**,” could be read to mean that only the collector surface has a gas tight seal as the “collector surface” immediately precedes “with a gas tight seal.” This construction corresponds to the Petitioner’s “second construction.” Under this second “collector surface” construction, (1) the collector surface itself must have a gas tight seal and (2) the isotope source is configured to be fluidly coupled to the volume that has a collector surface. We agree with Petitioner that the embodiments of Figures 3 and 5 of the ’437 patent meet this construction, because the interior surface of the vials (i.e., the collector surface of the volume) form a gas tight seal when the vial is sealed with a screw cap. Ex. 1001, Figs. 3, 5. The fact that this construction reads upon an embodiment in the ’437 patent tends to support that this construction may be correct.

(2) Volume (First construction)

Alternatively, the phrase “wherein the solid precursor isotope source is configured to be fluidly coupled to **a volume** including a collector surface **with a gas tight seal**,” could be read to mean a *volume*, which has a collector surface, *has a gas tight seal*. This construction corresponds to the Petitioner’s “first construction.” Under this first “volume” construction, the isotope source must be configured to be fluidly coupled to a volume that has a collector surface. Under this construction, the volume must have both a collector surface and a gas tight seal, but (unlike the second construction

above), this first construction also requires that the collector surface portion of the volume have the gas tight seal.

We agree with Petitioner that, *inter alia*, the embodiments described at 18:21–23 of the '437 patent, which are shown in Figures 2 and 4, read upon this first construction when the gas and liquid tight seal is in the open position. Pet. 5–6 (citing Ex. 1001, 14:21–25, 18:21–23, Fig. 4). In this embodiment, the o-rings in combination with the cap provide a gas tight seal of the “entire volume” (i.e., the volumes with a collector surface (e.g., the vial walls)) and the volume without a collector surface (e.g., the volume inside the piston) and when the gas and liquid tight lid/cap is open, that volume (e.g., the volume inside the piston and the volume inside the vial) has an isotope source that is in fluid communication with the collector surface.

Additionally, we understand that the embodiments of Figures 3 and 5 of the '437 patent also read upon this first “volume” construction. Figures 5A and 5B of the '437 patent are again reproduced below.

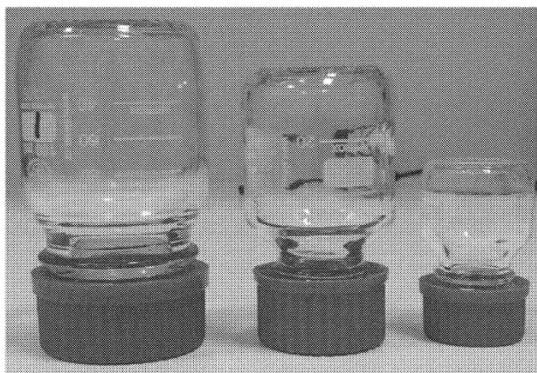


Fig. 5A

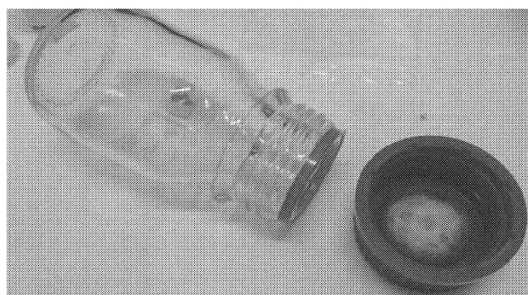


Fig. 5B

Figure 5A (left) shows 100, 50, and 10 ml generator units. Ex. 1001, 14:44–45. Figure 5B (right) shows the cap with quartz wool in the center of the inner surface. *Id.* at 14:56–46. In these embodiments, the interior surface of the vials (i.e., the collector surface of the volume) forms a gas

tight seal with the screw cap and the isotope source is fluidly coupled to the vials (a volume including a collector surface). *See id.* at 1, Figs. 3, 5. Here again, the fact that this construction reads upon embodiments in the '437 patent tends to support that this construction may also be correct.

(3) *Fluidly Coupled (Third Construction)*

Alternatively, the phrase “wherein the ***solid precursor isotope source is configured to be fluidly coupled*** to a volume including a collector surface ***with a gas tight seal***” could be read to mean that the *isotope source is configured to be fluidly coupled, with a gas tight seal*, to a volume that includes a collector surface. This construction corresponds to the Petitioner’s “third construction.” Under this third “fluidly coupled” limitation, the solid precursor isotope source is configured to be coupled to a volume that has a collector surface and the coupling between the two is done with a gas tight seal.

We agree with Petitioner that this construction reads upon Figures 4A and 4B of the '437 patent, which are reproduced again below. Pet. Reply 2–3 (citing Ex. 1001, Fig. 4).

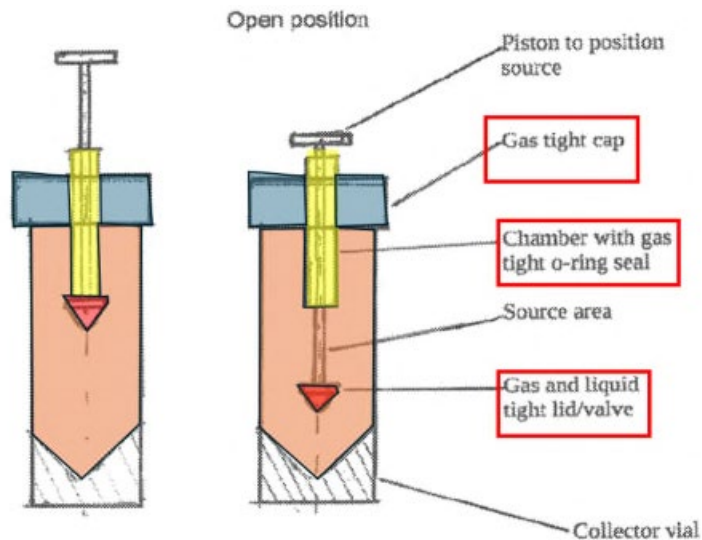


Fig. 4A

Fig. 4B

In this embodiment, when the piston is in the closed position as shown in Figure 4A, the isotope source is not fluidly coupled to the vial (depicted in beige) having interior wall surface. The “Gas and liquid tight lid/valve” (i.e. “valve”) prevents gas flow (fluid communication) between the isotope source and the volume that has a collector surface. Thus, in Figure 4A, the isotope source is not fluidly coupled to a volume including a collector surface.

In Figure 4B, however, when the piston is in the open position, the valve no longer prevents gas flow (fluid communication) between the isotope source and the vial walls. Rather, when the valve is open, there is fluid communication between the isotope source and the walls of the vial. Therefore, because opening the valve from the closed position (Figure 4A) to the open position (Figure 4B), allows for gas flow between the isotope source and the vial walls, we agree with Petitioner that in this embodiment reads upon the third construction. In particular, the isotope source is configured to be fluidly coupled to the vial (a volume including a collector

surface as shown in beige) and the fluid coupling occurs by moving the piston so that the valve is opened, thereby permitting gas flow between the isotope source and the vial walls. The fact that this construction reads upon an embodiment in the '437 patent tends to support that this construction may be correct.

We again note that, at this stage of the proceeding, we understand that a gas tight valve is a gas tight seal regardless of whether the valve is closed (preventing gas flow) or open (allowing gas flow) position. This understanding is supported by Figure 4B of the '437 patent, which identifies the lid/valve as a "Gas and liquid tight lid/valve" even when the lid/valve is in the open (allowing gas flow) position.

At this stage of the proceeding, we do not see any reason to limit claim 1 to any particular one of Petitioner's constructions. A claim may be broadly drafted so as to read upon multiple embodiments.⁸ Thus, at this stage of the proceeding, particularly because all three constructions read upon an embodiment set forth in the specification, we determine that claim 1 encompasses all three constructions as set forth above. This construction is preliminary and the parties are invited to address this issue during trial.

We determine that, at this stage of the proceeding, no additional express claim constructions are required to resolve any issues in dispute.

⁸ We acknowledge that here, the claim is read upon different embodiments by construing the claim differently, which may raise indefinite issues as discussed below when addressing Petitioner's indefiniteness argument.

C. Asserted Anticipation by Hassfjell-Hoff (Ground 1)

Petitioner argues that claims 1, 3, 4, 7–9, 11, 12, 14–19, 22–26, 28, 29, 31, 32, 35, 36, and 38 are anticipated by Hassfjell-Hoff. Pet. 10–44. Patent Owner opposes. Prelim. Resp. 13–21.

1. Hassfjell-Hoff

Hassfjell-Hoff is an article titled “A Generator for the Production of ^{212}Pb and ^{212}Bi ” included in the October 1994 volume of the monthly publication titled “Applied Radiation and Isotopes.” Ex. 1003, 1, 4, 6. At this stage of the proceeding, Patent Owner does not dispute that Hassfjell-Hoff qualifies as prior art.

Hassfjell-Hoff states:

A generator has been developed for the production of the α -emitting radionuclide ^{212}Bi and its parent nuclide ^{212}Pb . The generator is based on the emanation of ^{220}Rn from [^{228}Th]barium stearate. The decay product of ^{220}Rn , ^{212}Pb deposits on the walls of a polyethylene bottle, and can be washed off with distilled water. The generator shows no leakage of any long-lived parent nuclides, is easy to operate and has a high degree of radiation safety.

Id. at 6.

Hassfjell-Hoff describes the production of [^{228}Th]barium stearate by precipitating [^{228}Th]barium stearate from a solution, filtering the [^{228}Th]barium stearate onto a filter membrane that was washed, and folding and wrapping the precipitate with filters to create a packet of [^{228}Th]barium stearate. *Id.* at 6–7.

Hassfjell-Hoff’s Figure 1 is reproduced below.

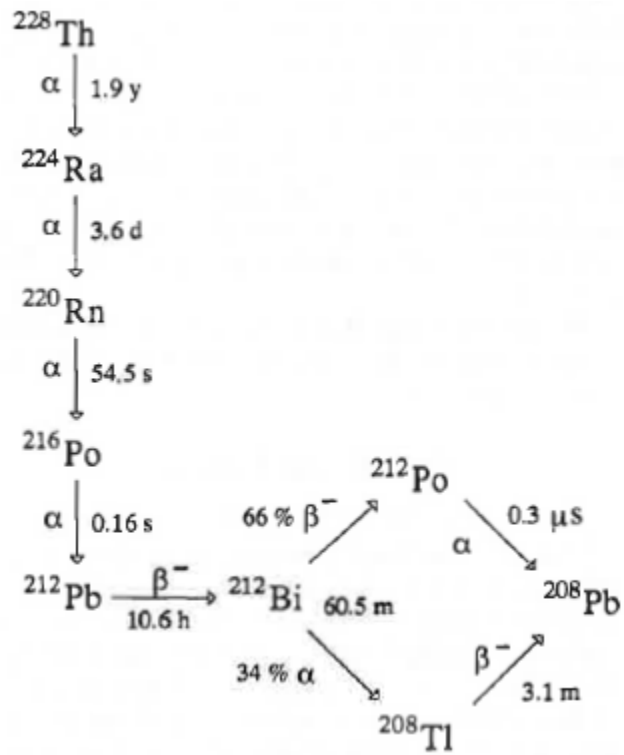


Figure 1 shows the decay mode of ^{228}Th to ^{212}Pb and then to stable ^{208}Pb . *Id.* at 7.

Hassfjell-Hoff's Figure 2 is reproduced below.

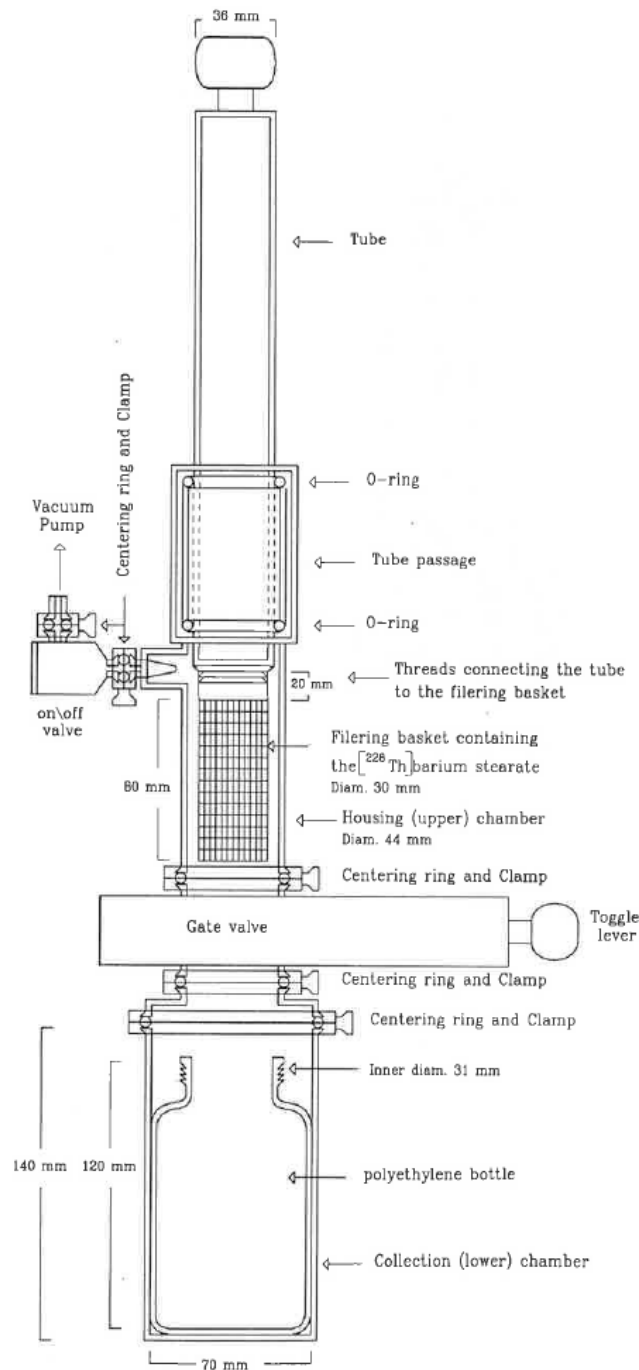


Figure 2 depicts the design of a generator. *Id.* at 8. Hassfjell-Hoff states:

The generator was made with two compartments, a lower compartment which is a collection chamber and an upper compartment which is a housing chamber for the source when the collection chamber is removed. These two compartments are

connected via a gate valve (VAT). The packets of [^{228}Th]barium stearate are placed in a [filtering] basket mounted by threads to the end of a long tube closed in both ends. The [filtering] basket has a capacity of 3–4 [^{228}Th]barium stearate packets. The tube can slide on two O-rings, thus facilitating the [filtering] basket to move between the two chambers, through the gate valve. To neutralize pressure differences when the tube is moved, an on-off valve (VAT) with connection to a filtered air outlet is placed in the upper chamber. To collect the ^{212}Pb and ^{212}Bi , a polyethylene bottle is placed inside the collection chamber.

When the tube is lowered, the [filtering] basket with the emanating [^{228}Th]barium stearate becomes positioned inside the bottle. The decay products from the emanated ^{220}Rn , ^{212}Pb and ^{212}Bi , deposit on the walls of the bottle. After an appropriate collection time, the tube is pulled up, placing the ^{228}Th source in the upper compartment, and the gate valve is closed. The polyethylene bottle is then removed and the radioactivity easily washed off with a suitable solution.

Id.

2. Claim 1

Petitioner asserts Hassfjell-Hoff discloses all elements of claim 1. Pet. 15–23. Patent Owner disagrees. Prelim. Resp. 13–21.

Petitioner asserts that Hassfjell-Hoff discloses a radioisotope generator for producing radioisotopes (e.g., ^{212}Bi and its parent nuclide ^{212}Pb) having a solid precursor isotope source (a packet of [^{228}Th]barium stearate) that is configured to emanate one or more gaseous progeny isotopes (including ^{220}Rn) as recited in the preamble and claim element [1.A]. Pet. 15–18 (citing, *inter alia*, Ex. 1003, 6–7, Fig. 1; Ex. 1012 ¶¶ 14, 41, 47–49; Ex. 1013, 6, 55–57; Ex. 1002 ¶ 52; Ex. 1019 ¶¶ 29–38). Petitioner also asserts that Hassfjell-Hoff discloses that the solid precursor isotope source (the packet of [^{228}Th]barium stearate) comprises a precursor isotope (^{228}Th)

as required in claim element [1.B]. Pet. 18 (citing Pet. § IV(B)(2); Ex. 1003, 7; Ex. 1002 ¶ 54; Ex. 1019 ¶¶ 29–38). Petitioner further asserts that Hassfjell-Hoff’s packet of [^{228}Th]barium stearate (the isotope source) and interior walls of the polyethylene bottle (the collector surface) are configured such that gaseous ^{220}Rn (gaseous progeny isotope) deposits ^{212}Pb and ^{212}Bi (solid progeny isotopes) on the interior walls of the polyethylene bottle (the collector surface). *Id.* at 22–23 (citing Ex. 1003, 7; Ex. 1002 ¶ 58; Ex. 1019 ¶¶ 29–38). At this stage of the proceeding, Patent Owner does not dispute these contentions. *See generally* Prelim. Resp.

Petitioner asserts that Hassfjell-Hoff discloses claim element [1.C] under both the first and third constructions. Pet. 19–22. We agree with Petitioner’s assertions at this stage of the proceeding. For both of these constructions, Petitioner relies upon Hassfjell-Hoff’s Figure 2 (reproduced above).

For both of these constructions, Petitioner sufficiently shows that Hassfjell-Hoff discloses the claimed “solid precursor isotope source” (the packet of [^{228}Th]barium stearate) and the “volume including a collector surface” (the volume that includes the collector surface (the interior walls of the polyethylene bottle) in the lower chamber). Pet. 19–22 (citing Ex. 1003, 7, Fig. 2). For both of these constructions, Petitioner also sufficiently shows that when the gas valve is open, the isotope source ([^{228}Th]barium stearate) is fluidly coupled to the lower chamber having the polyethylene bottle (a volume including a collector surface). *Id.* (citing Ex. 1003, 7, Fig. 2).

With respect to the first “volume” construction (“wherein the solid precursor isotope source is configured to be fluidly coupled to a *volume* including a collector surface *with a gas tight seal*”), Petitioner sufficiently

shows that when the packet of [^{228}Th]barium stearate (the isotope source) is in the upper chamber and the gate valve between the upper and lower chamber is opened, both the upper volume and lower volumes are enclosed in a gas tight seal formed by the o-rings between the tube and tube passage and the three sets of centering rings and clamps between the lower collection chamber and the tube passage. Pet. (citing Ex. 1003, 6–7); *see also* Pet. Reply 4–5. As noted above, under this construction, the volume that has a gas tight seal must *include*, but is not limited to, the volume that includes the collector surface. We agree with Petitioner, at this stage of the proceeding, that the combination of the upper chamber and the lower chamber (which has a volume including a collector surface) is a volume with a gas tight seal as required under the first “volume” construction. *See, e.g.*, Ex. 1003, 6 (discussing “a gas tight collection chamber”).

With respect to the third “fluidly coupled” construction (“wherein the solid precursor isotope *source is configured to be fluidly coupled to a volume* including a collector surface *with a gas tight seal*”), Petitioner sufficiently shows that the gate valve (a gas tight seal) is used to fluidly couple the upper chamber (the volume having the isotope source) to lower chamber with a polyethylene bottle having interior walls (a volume including a collector surface). Pet. 21–22; Ex. 1003, Fig. 2. Petitioner sufficiently shows that opening the gate valve permits gas flow between the upper and lower chambers, which results in the fluid coupling of the isotope source to a volume including a collector surface as required by the third “fluidly coupled” construction. *Id.*

We have considered, but disagree with, Patent Owner’s arguments at this stage of the proceeding. *See* Prelim. Resp. 13–21.

With respect to the first “volume” construction, Patent Owner asserts that when Hassfjell-Hoff’s gate valve is open, the gate valve does not provide a gas tight seal for the identified lower chamber. Prelim. Resp. at 17 (citing Ex. 1003, 7). We disagree with this argument, because, under the first construction the volume must have a gas tight seal that includes, but is not limited to, the volume having a collector surface. As noted above, Petitioner sufficiently shows that Hassfjell-Hoff provides a gas tight seal to a volume that includes both the lower chamber (which includes the volume having a collector surface) and the upper chamber. *See* Pet. 20–21 (asserting that the gas tight seal is provided using o-rings between the tube and tube passage and the three sets of centering rings and clamps between the lower collection chamber and the tube passage); Ex. 1003, 6–7, Fig. 2. Although Petitioner cites to Hassfjell-Hoff’s gas tight lid/valve as a gas tight seal that selectively fluidly couples the isotope source to a volume, we do not understand Petitioner to rely upon this gas tight seal as providing a gas tight seal for the volume as required by claim 1 under the first construction.

With respect to the Petitioner’s “third construction” theory, Patent Owner asserts that Petitioner fails to explain “how the challenged claims satisfy this construction” because the Petition recites two volumes when the claim only recites 1 volume, and the Petition does not specify which component of Hassfjell-Hoff it maps to “each of the two new volumes its construction introduces” or “the volume recited in claim 1.” Prelim. Resp. 18–19. We disagree with Patent Owner’s argument because we understand Petitioner to sufficiently map Hassfjell-Hoff to the claim element [1.C] as discussed above.

Patent Owner also appears to assert that Hassfjell-Hoff's gate valve is not a gas tight seal when it is open. Prelim. Resp. 19. We disagree with this argument, because, as noted above, under the present claim construction, a gas tight seal is a gas tight seal even in an open position. *See* Ex. 1001, Fig. 4B (identifying the lid/valve in the open position as a "Gas and liquid tight lid/valve").

Patent Owner also argues that it does not understand Petitioner's contentions. For example, Patent Owner asserts that it is unclear how the first and second constructions differ when the same argument is presented to satisfy two different constructions. Prelim. Resp. 19; *see also id.* (stating Petitioner's third construction theory should be rejected as cryptic). Patent Owner also argues that Petitioner uses different words than those recited in the claim to support its arguments. For example, Patent Owner asserts that Petitioner argues that "Hassfjell-Hoff meets the first construction because 'the gas-tight seal selectively fluidly couples the precursor isotope source to a volume,'" but the claims recite "fluidly coupled." Prelim. Resp. 18 (citing Pet. 19). Patent Owner also asserts that Petitioner uses "various new and different terms without explanation." *Id.*

We disagree with Patent Owner based on the present record. The issue is whether Petitioner sufficiently maps Hassfjell-Hoff to the claim language. We have set forth our understanding of Petitioner's arguments, and determine that, at this stage of the proceeding, Petitioner's contentions are sufficient to show Hassfjell-Hoff discloses the claimed limitations. To the extent the panel misunderstands the parties' arguments, the parties are invited to clarify any misunderstandings during trial.

Thus, for the foregoing reasons, based upon the present record, Petitioner sufficiently shows that Hassfjell-Hoff discloses the limitations of claim 1, including the claim element [1.C] under either of Petitioner's first or third constructions, Petitioner has sufficiently shown that it is more likely than not that Hassfjell-Hoff anticipates claim 1.

Therefore, because Petitioner has shown sufficiently that it is more likely than not that at least claim 1 is anticipated by Hassfjell-Hoff, we institute a post-grant review as to all of the challenged claims and grounds contained in the Petition. 37 C.F.R. § 42.208 ("When instituting post-grant review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim"); *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 371 (2018); USPTO, Guidance on the Impact of SAS on AIA Trial Proceedings (Apr. 26, 2018).

We offer the following views on the remaining claims and grounds for the parties' consideration.

3. *Independent Claim 16 and Dependent Claims 3, 4, 7–9, 11, 12, 14–15, 17–19, 22–26, 28, 29, 31, 32, 35, 36, and 38*

Petitioner asserts that Hassfjell-Hoff discloses all of the limitations of independent claim 16 and dependent claims 3, 4, 7–9, 11, 12, 14–15, 17–19, 22–26, 28, 29, 31, 32, 35, 36, and 38, which depend directly or indirectly from either claim 1 or claim 16. Pet. 10–44 (citing Ex. 1002 ¶¶ 80–86; Ex. 1019 ¶¶ 29–38, 49).

For example, with respect to independent method claim 16, Petitioner asserts that Hassfjell-Hoff discloses a method of generating a progeny isotope using the disclosed system as recited in the preamble. Pet. 34 (citing, *inter alia*, Ex. 1003, 7). The method allows one or more gaseous progeny isotopes (Rn gas) to emanate from a solid precursor isotope source

(i.e., a packet of [^{228}Th]barium stearate) that comprises a precursor isotope as recited in steps [16.A] and [16.B]. *Id.* at 34–35 (citing, *inter alia*, Ex. 1003, 7; Pet. § IV(B)(3)). Petitioner also asserts that Hassfjell-Hoff discloses “fluidly coupling a volume including a collector surface to the solid precursor isotope source using a gas tight seal” as recited in [16.C] because it discloses opening the gate valve to connect the upper volume to the lower volume. Pet 35 (citing, *inter alia*, Pet. § IV(B)(4)). Petitioner asserts that the gate valve is a gas tight seal that is selectively fluidly coupling the isotope source to the volume that includes the collector source (i.e., the lower volume). *Id.* Petitioner asserts that the fluid coupling occurs by opening the gate valve. *Id.*

Patent Owner responds that claim 16 recites similar limitations to those of claim 1 and that the Petition fails to show Hassfjell-Hoff satisfies the corresponding element recited in claim 16. Prelim. Resp. 6, 13. Patent Owner asserts that when Hassfjell-Hoff’s gate valve is open, the gate valve does not provide a gas tight seal. *Id.* at 16–17, 20 (citing Pet. 35).

Based on the present record, Petitioner sufficiently shows that Hassfjell-Hoff discloses the limitations of claim 16. Claim 16 requires “fluidly coupling a volume including a collector surface to the solid precursor isotope source using a gas tight seal.” We are persuaded that Hassfjell-Hoff discloses this limitation by moving (i.e., turning) the gate valve (a gas tight seal) to its open position to fluidly couple the isotope source with the polyethylene bottle (i.e., a volume including a collector surface). We disagree with Patent Owner’s contention that the precursor isotope source must be in fluid communication when the gate valve is closed in order to provide a gas tight seal separating the upper chamber, having the

isotope source, from the lower chamber. Patent Owner's argument relies upon a claim construction that we do not adopt at this stage of the proceeding.

Because Petitioner has shown sufficiently that at least one claim is unpatentable, we institute a post-grant review as to all of the challenged claims and grounds contained in the Petition, including all of the claims challenged in ground 1. *See* 37 C.F.R. § 42.208.

D. Asserted Obviousness Over Hassfjell-Hoff (Ground 2)

Petitioner asserts that claims 1, 3, 4, 7–9, 11, 12, 14–19, 22–26, 28, 29, 31, 32, 36, and 38 would have been obvious over Hassfjell-Hoff. Pet. 46. Petitioner asserts that to the extent Hassfjell-Hoff's gate valve does not form a gas tight seal under the first and third constructions, that it would have been obvious to use Hassfjell-Hoff's gate-valve to establish a gas tight seal between the upper and lower collection chambers to improve safety, and a POSITA would have had a reasonable expectation of success in doing so. *See id.*

Patent Owner argues that Petitioner's arguments regarding Ground 2 fail to remedy the deficiencies regarding Ground 1. Prelim. Resp. 21–22. This argument is not persuasive at this stage of the proceeding for the same reasons set forth above for ground 1.

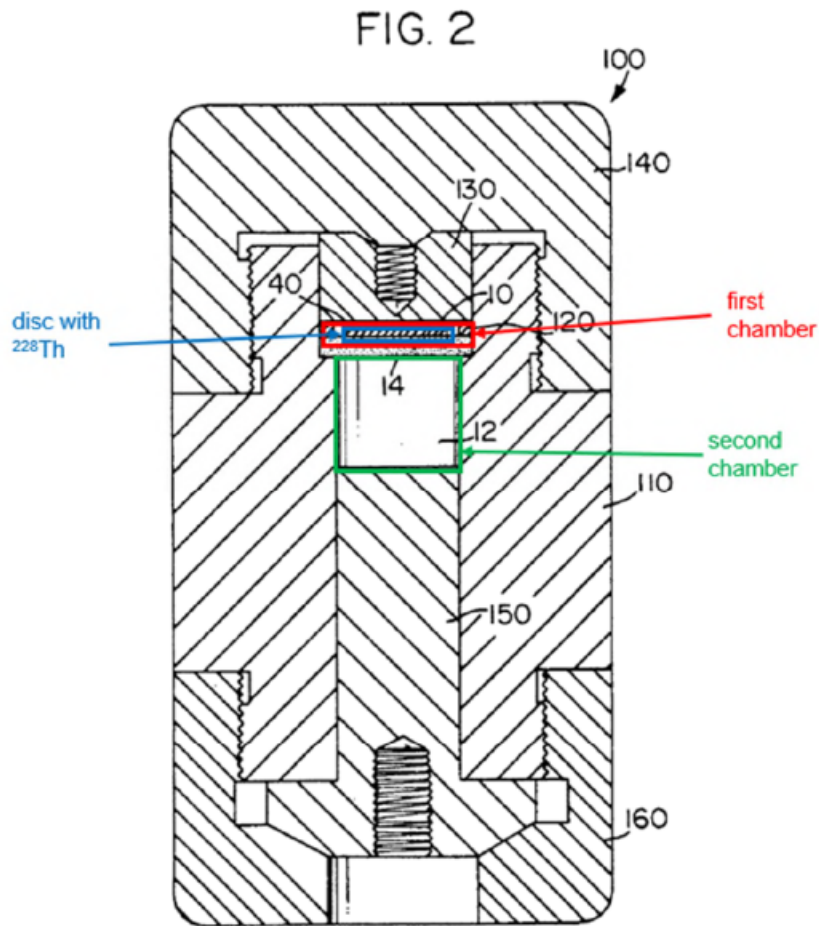
Because Petitioner has shown sufficiently that at least one claim is unpatentable, we institute a post-grant review as to all of the challenged claims and grounds contained in the Petition, including the claims challenged in ground 2. *See* 37 C.F.R. § 42.208.

E. Asserted Anticipation by Norman (Ground 3)

Petitioner asserts that Norman anticipates claims 1, 3, 5–7, 15, 16, 18, 20–22, 29–33, and 35–37. Pet. 46–63. Patent Owner opposes. Prelim. Resp. 22–32.

1. Norman

Norman is a US Patent titled “Method and Generator for Producing Radioactive Lead-212” that issued on August 6, 1991. Ex. 1007, codes (45), (54). Norman discloses a method and generator for preparing ^{212}Pb , “whereby ^{228}Th , in a closed first chamber [10], is allowed to decay to gaseous ^{220}Rn which is then readily separated from the thorium and other decay products by diffusing the ^{220}Rn gas into a second chamber [12], where it decays to ^{212}Pb which can then be collected from the second chamber. *See id.* at code (57). Figure 2 of Norman is reproduced below.



Norman Figure 2, with Petitioner's color annotations added is a sectional view of a generator, having reactor 100 having cylindrical body 110, gas permeable membrane 14, body 110, parental chamber 10, receiving chamber 12, seal ring 120, seal cap 140, plunger 150, plunger body 110, and plunger cap 160. Ex. 1007, 7:65–8:18.

2. Analysis

Petitioner asserts that Norman anticipates, *inter alia*, claim 1 and provides argument and evidence to support this contention. Pet. 46–55. Patent Owner disagrees. Prelim. Resp. 22–32. Based upon our review of the present record, we determine Petitioner sufficiently shows at this stage of

the proceeding that Norman anticipates claim 1 under Petitioner's first and third constructions. We provide the following comments to provide guidance to the parties. *See* 37 C.F.R. § 42.208

a) First "volume" construction

Based on the current record, we agree with Petitioner that each of Norman's Figures 1 and 2 sufficiently discloses limitation [1.C] under Petitioner's first construction. Under the first "volume" construction (i.e., "wherein the solid precursor isotope source is configured to be fluidly coupled to *a volume* including a collector surface *using a gas tight seal*"), Petitioner sufficiently shows that the asserted isotope source 40 is fluidly coupled to second chamber 12 (the asserted volume including a collector surface) through gas permeable membrane 14. Pet. 51. Petitioner also sufficiently shows that Norman's devices have a volume (chambers 10 and 12) that includes a collector surface (second chamber 12 has a collector surface), using a gas tight seal. *Id.* at 52. In particular, Petitioner asserts that the generator of Figure 1 has chambers 10 and 12 and that when plungers 22 and 30 are inserted and secured with end caps 24 and 32, the escape of radon from the generator is prevented from chamber 10 and 12 (collectively the volume with a gas tight seal). Pet. 52–53 (quoting Ex. 1007, 7:22–25).

At this stage of the proceeding, we disagree with Patent Owner's argument that Norman does not disclose claim element [1.C] under the first "volume" construction because Norman's second chamber does not have a gas tight seal. Prelim. Resp. 25. As explained above, under this construction the volume having a gas tight seal is not limited to chamber 12, but also includes chamber 10. Petitioner also sufficiently shows at this stage of the proceeding that a POSITA would have understood that the generator

of Norman's Figure 2 also has a volume (chambers 10 and 12) with a gas tight seal because we understand Norman's Figure 2 embodiment does not leak. *See* Pet. at 53–54 (citing Ex. 1007, 7:65–8:24, Fig. 2). Patent Owner's arguments that the cited material does not describe the asserted claim elements raise issues best resolved on a full trial record. *See* Prelim. Resp. 29.

At this stage of the proceeding, we disagree with Patent Owner's argument that the Petition fails to sufficiently map Norman to the claims and requires the Board and Patent Owner to play archeologist with the record. Prelim. Resp. 23. At this stage of the proceeding, the Board understands Petitioner's mapping, which is addressed by the Board above. To the extent the Board misunderstands the parties' arguments, the parties are invited to address any misunderstanding during trial.

At this stage of the proceeding, we disagree with Patent Owner's argument that Petitioner relies on two separate embodiments to support its anticipation arguments. Prelim. Resp. 24–25. As set forth above, we understand Petitioner to have asserted that each of Norman's embodiments separately anticipate the challenged claims.

b) Third “Fluidly Coupled” Construction

At this stage of the proceeding, Petitioner sufficiently shows that Norman's Figures 1 and 2 discloses limitation [1.C] under Petitioner's third construction. Under the third “fluidly coupled” construction (i.e., “wherein the solid precursor isotope source is configured to *be fluidly coupled* to a volume including a collector surface *using a gas tight seal*”), Petitioner sufficiently shows that the asserted isotope source located in chamber 10 is fluidly coupled to a volume including a collector surface (second chamber

12) using a stopcock(using a gas tight seal). Pet. 54–55 (citing Ex. 1007, 8:33–41). Patent Owner asserts that Petitioner refers to Norman’s stopcock as a valve, not as a gas tight seal. Prelim. Resp. 30. We disagree with this argument because we understand Petitioner to assert that Norman’s stopcock/valve is the recited gas tight seal. See Pet. 54–55.

Patent Owner also argues that, similar to its arguments regarding Hassfjell-Hoff in Ground 1, a no gas tight seal is used to provide fluid coupling required by claims 1 and 16 because any coupling requires that there be no gas tight seal. Prelim. Resp. 31–32. We disagree with this argument for the same reasons stated above in connection with Ground 1. As noted above, we understand that a gas tight valve is a gas tight seal regardless of whether the valve is in the closed (preventing gas flow) or open (allowing gas flow) position. See Ex. 1001, Fig. 4B (identifying a lid/valve as a “Gas and liquid tight lid/valve” even when the lid/valve is in the open (allowing gas flow) position).

c) Second “Collector Surface” Construction

At this stage of the proceeding, we have concerns about Petitioner’s argument that Norman’s Figures 1 and 2 sufficiently disclose limitation [1.C] under Petitioner’s second construction. Pet. 51–54. Under the second “collector surface” construction (i.e., “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a *collector surface using a gas tight seal*”), the collector surface (i.e., just the interior walls of Norman’s second chamber 12) must have a gas tight seal. We do not understand the Petition to provide sufficient evidence and argument explaining how just Norman’s second chamber 12 has a gas tight seal.

Because Petitioner has shown sufficiently that at least one claim is unpatentable, we institute a post-grant review as to all of the challenged claims and grounds contained in the Petition, including the claims challenged in ground 3. *See* 37 C.F.R. § 42.208

F. Asserted Obviousness over Norman (Ground 4)

Petitioner asserts, *inter alia*, that to the extent Norman does not disclose that Figure 2 has a gas tight seal, that it would have been obvious “to utilize the teaching of Norman regarding having a gas tight seal for Figure 1 in the Figure 2 embodiment.” Pet. 65–66. Patent Owner asserts that this argument is conclusory and insufficiently explained and that there is no explanation as to why the plungers and end caps would have been combined into the embodiment of Norman Figure 2. Prelim. Resp. 32–33. We disagree with Patent Owner’s argument at this stage of the proceeding because we understand Petitioner to argue that a POSITA would have made Norman’s Figure 2 embodiment gas tight to prevent escape of radioactive gas, just as the embodiment of Figure 1 is gas tight to prevent escape of radioactive gas. Whether a POSITA would have understood that the embodiment of Figure 2 could be gas tight is an issue best resolved on a full trial record.

Because Petitioner has shown sufficiently that at least one claim is unpatentable, we institute a post-grant review as to all of the challenged claims and grounds contained in the Petition, including the claims challenged in ground 4. *See* 37 C.F.R. § 42.208.

G. Asserted Obviousness over Hassfjell-Hoff and Norman (Ground 5)

Petitioner argues that claims 1, 3–9, 11, 12, 14–26, 28–33, and 35–38 would have been obvious over Hassfjell-Hoff and Norman. Pet. 66–72.

Petitioner asserts that, to the extent Hassfjell-Hoff does not teach claim element [1.C] under the second “collector surface” construction, it would have been obvious to implement Hassfjell-Hoff so that there is a gas tight seal around the collection container during collection as disclosed by Norman. *Id.* at 67. Petitioner asserts that it would have been obvious to configure the surface at the top of the inner neck of the polyethylene bottle to mate with the chamfered end of the tube to enhance the integrity with a gas tight seal between the end of the tube and the bottle. *Id.* Petitioner asserts that a POSITA would have made the modification because a gas tight seal on the collection chamber of Norman would reduce the possibility of escaping radioactivity. *Id.* at 68 (citing, *inter alia*, Ex. 1007, 2:49–52, 7:22–25). Petitioner further asserts that a POSITA would have understood that it was well within the skill of the art to use the well-known ways to create a gas tight seal on the collection chamber and that doing so would have led to predictable results, with a reasonable expectation of success, and was a mere design choice. *Id.* at 68–69.

Patent Owner argues that Ground 5 is only based on the unreasonable and unsubstantiated “second construction” and therefore “should be rejected as based on a faulty premise with no alternate theory presented.” Prelim. Resp. 34. As noted above, we construe claim 1 as including Petitioner’s second construction. Thus, we disagree with this argument by Patent Owner on the present record.

Patent Owner further asserts that the combination is “illogical and nonsensical” and driven by hindsight as Petitioner has not explained how Norman’s plungers/end caps would support the leap to providing a chamfered end of the tube in Hassfjell-Hoff. Prelim. Resp. 34–35. Patent

Owner also asserts that Petitioner has not shown sufficiently why a POSITA would have sought to provide a gas tight seal between the bottom end of Hassfjell-Hoff's tube and the neck of the polyethylene bottle when the filtering basket is lowered into the interior of the polyethylene bottle. *Id.* at 35–41.

Whether or not a POSITA would have been motivated to modify Hassfjell-Hoff to provide a gas tight seal on the collection chamber with a reasonable expectation of success is an issue that is best resolved on a full trial record.

Because Petitioner has shown sufficiently that at least one claim is unpatentable, we institute a post-grant review as to all of the challenged claims and grounds contained in the Petition, including the claims challenged in ground 5. *See* 37 C.F.R. § 42.208.

H. Asserted Obviousness over Hassfjell-Hoff and IAEA (Ground 6), over Hassfjell-Hoff and Westrøm (Ground 7), over Norman and Hassfjell-Hoff (Ground 8), over Norman, Hassfjell-Hoff, and Westrøm (Ground 9), and over Hassfjell-Hoff, Norman, and Westrøm (Ground 10)

Petitioner argues in each of grounds 6–10 that different sets of dependent claims would have been obvious over either Hassfjell-Hoff or Norman in combination with various secondary references. *See* Pet. 73–95.

Other than the arguments presented above, Patent Owner does not present any other argument specifically directed to the claims challenged in these grounds. *See, e.g.*, Prelim. Resp. 41–42 (asserting Petitioner's grounds 6–10 challenging dependent claims do not remedy the deficiencies regarding the independent claims). Because Petitioner has shown sufficiently that at least one claim is unpatentable, we institute a post-grant review as to all of

the challenged claims and grounds contained in the Petition, including the claims challenged in grounds 6–10. *See* 37 C.F.R. § 42.208.

I. Asserted Indefiniteness of Claims 1–9, 11–15, and 35–38 under 35 U.S.C. § 112 (Ground 11)

Petitioner argues that independent claim 1 and dependent claims 2–9, 11–15, and 35–38, which depend directly or indirectly from claim 1, are unpatentable under 35 U.S.C. § 112 as indefinite. Pet. 95–96. Petitioner contends that there are different possible constructions of claim element [1.C] and that a POSITA reading the '437 patent would not be able to determine the scope of the claims with reasonable certainty. Pet. 95 (citing Ex. 1002 ¶ 289); *see also* Pet. Reply 1–5.

Patent Owner responds that Petitioner fails to show the claims are indefinite because Petitioner fails to show its constructions are plausible and provides no basis that a POSITA would be unable to understand the plain and ordinary meaning of the claims. Prelim. Resp. 42–43 (citing 35 U.S.C. § 322(a)(3); 37 C.F.R. § 42.204(b)(3)–(4)).

At this stage of the proceeding, Patent Owner may have a persuasive argument. Although we preliminarily construe claim 1 as encompassing all three of Petitioner's proposed constructions, we have concerns as to whether it is appropriate to construe claim element [1.C] as having multiple constructions. We invite the parties to address the proper claim construction, and Petitioner's indefiniteness arguments, regarding claim element [1.C] at trial.

Because Petitioner has shown sufficiently that at least one claim is unpatentable, we institute a post-grant review as to all of the challenged claims and grounds contained in the Petition, including the claims challenged in ground 11. *See* 37 C.F.R. § 42.208.

J. Whether Petitioner's Declarants' Testimony is Entitled to Any Weight

Patent Owner also asserts that neither Dr. Hoff's nor Dr. Mirzadeh's declarations are entitled to any weight because the declarations are conclusory and fail to provide meaningful analysis or explanation. Prelim. Resp. 43–45 (citing Ex. 1002 ¶ 178; Ex. 1019 ¶ 38). How much weight to give Dr. Hoff's and Dr. Mirzadeh's testimony are issues that are best resolved upon a full trial record.

III. CONCLUSION

After considering the arguments presented in the Petition and the evidence of record, we determine that Petitioner has demonstrated that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable.

At this stage of the proceeding, the Board has not made a final determination as to the construction of any claim term or the patentability of any challenged claim.

Our determinations at this stage of the proceeding are based on the evidentiary record currently before us. We will base any final decision on the full record developed during trial.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 324(a), a post-grant review of claims 1–9, 11–33, and 35–38 of the '437 Patent is *instituted* with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4(b), post-grant review of the '437 Patent shall commence on

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the entry date of this Order, and notice is hereby given of the institution of a trial.

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FOR PETITIONER:

Jennifer Nall
James Heintz
Gianni Minutoli
Joseph Helmsen
Nicholas Kokkinos
DLA PIPER LLP (US)
jennifer.nall.ptab@us.dlapiper.com
jim.heintz@dlapiper.com
gianni.minutoli@dlapiper.com
joseph.helmsen@us.dlapiper.com
nicholas.kokkinos@us.dlapiper.com

FOR PATENT OWNER:

Michael Rosato
Patrick Medley
Michael Hostetler
WILSON SONSINI GOODRICH & ROSATI
mrosato@wsgr.com
pmedley@wsgr.com
mhostetler@wsgr.com