

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANCELL PTY LTD.,
Petitioner,

v.

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

Case No. PGR2025-00029
Patent 12,125,603

**PATENT OWNER'S RESPONSE
PURSUANT TO 37 C.F.R. § 42.220**

TABLE OF CONTENTS

I. Introduction.....	1
II. Summary of '603 Patent.....	3
III. Hassfjell-Hoff.....	7
IV. Claim Construction.....	9
A. “precursor isotope source” (Claims 1 and 12).....	10
B. “disposed on the rod” (Claims 1 and 12).....	14
C. “allowing sufficient time for the precursor isotope source to decay comprises allowing 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours” (claim 10).....	16
D. “the precursor isotope source is configured to decay and emanate the one or more progeny isotopes into the container for 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours” (claim 20).....	17
V. The Petition Fails to Meet Its Burden to Show the Unpatentability of Any Challenged Claim	18
A. Ground 1 Fails to Demonstrate Hassfjell-Hoff Anticipates Claims 1-6, 8, 11-17, and 19.....	18
1. Petitioner fails to show that Hassfjell-Hoff discloses “isolating the precursor isotope source” by sliding a rod or exposing the precursor isotope source by sliding a rod as recited in the independent claims	19
2. Petitioner fails to show that Hassfjell-Hoff discloses a precursor isotope source “disposed on [a/the] rod” as recited in independent claims 1 and 12	24
3. Petitioner fails to show that Hassfjell-Hoff discloses the limitations of dependent claims 5, 14, and 15.....	31
4. Petitioner fails to show that Hassfjell-Hoff discloses the limitations of dependent claims 8 and 17.....	34
B. Grounds 2 and 3 Fail.....	35
1. Grounds 2 and 3 fail to remedy ground 1’s independent-claim deficiencies	35
2. Ground 2 fails to remedy the deficiencies of dependent claims 5 and 15	36
3. Ground 3’s combination fails to meet the limitations of claims 9 and 18	37
C. Ground 4 Fails to Demonstrate Unpatentability Under §112.....	38
1. Claim 1.....	39

2. Claim 2.....	42
3. Claim 3.....	45
4. Claims 8-9.....	46
5. Claim 10.....	49
6. Claim 12.....	51
7. Claim 20.....	51
VI.Petitioner’s Expert Testimony Deserves No Weight.....	54
VII.Conclusion.....	56
VIII.Exhibit List.....	58

AdvanCell Pty Ltd. (“Petitioner”) filed a petition for post grant review of various claims of U.S. Patent No. 12,125,603 (the “’603 patent”, EX1001).

Sciencons, AS and ARTBIO, Inc. (“Patent Owner” or “PO”) hereby requests that the Board now issue a final written decision confirming that claims 1-6 and 8-20 are not unpatentable.

I. INTRODUCTION

As is well-known, Petitioner in a Post-Grant Review challenge bears the unshifting burden of proving unpatentability of the challenged claims. *In re Magnum Oil Tools Int’l*, 829 F.3d 1364, 1375 (Fed. Cir. 2016). Here, Petitioner simply fails to meet that burden. The only prior art ground applied against the independent claims alleges anticipation over Hassfjell-Hoff. To anticipate a claim, a reference “must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). The petition fails to satisfy the exacting standard for anticipation and fails to show that Hassfjell-Hoff anticipates any claim.

Each independent claim is directed to radioisotope generation, and each recites isolating and exposing a precursor isotope source (disposed on a rod) to a container’s interior surface specifically by sliding a rod between an open position

for exposure and a closed position in which the precursor isotope source is sealed off from the container's interior surface. As Petitioner's own expert confirmed during cross-examination, Hassfjell-Hoff's generator lacks this feature. While Hassfjell-Hoff's generator has a tube, sliding that tube does not isolate the precursor isotope source in the manner recited in the challenged claims. Isolation or exposure in Hassfjell-Hoff is controlled separately and entirely by a gate valve operated by a "toggle lever," not "by sliding the rod" as the claims explicitly require. Because these limitations are not found in Hassfjell-Hoff, it fails to anticipate either independent claim.

Each independent claim also recites a precursor isotope source that decays into progeny isotopes and is disposed on a rod. Both experts now agree there is no precursor isotope source in Hassfjell-Hoff other than [^{228}Th]barium stearate found in packets. There is no dispute—nor could there be—that those [^{228}Th]barium stearate packets are not attached, directly or indirectly, to anything in Hassfjell-Hoff's generator. As stated plainly in the prior art reference, the [^{228}Th]barium stearate packets are placed loosely in a lace basket that Petitioner's own expert confirmed would not be considered a "source" by any POSITA. As both experts agree, Hassfjell-Hoff lacks any "precursor isotope source [that] is disposed on the rod," and the petition fails to demonstrate otherwise. The anticipation challenge should be rejected for at least this reason alone.

The petition's arguments regarding dependent claims are also defective. In addition to failing to cure the defects in the petition's independent claim arguments, multiple arguments raised in grounds 1-3 regarding dependent claim limitations are also inconsistent with Petitioner's independent claim arguments or the prior art. Accordingly, each of grounds 1-3 fail.

Ground 4 raises various challenges under §112 for written description, enablement, and indefiniteness. However, as the institution decision (DI, Paper 11) correctly observed, the arguments raised in ground 4 are not well founded. Not only are the ground 4 arguments premised misinterpretation of the claims, but the expert testimony Petitioner relies on fails to identify, much less apply, the appropriate legal standards. Petitioner's §112 grounds should thus be rejected.

Accordingly, Patent Owner respectfully submits that the Board should issue a final written decision upholding the patentability of each challenged claim.

II. SUMMARY OF '603 PATENT

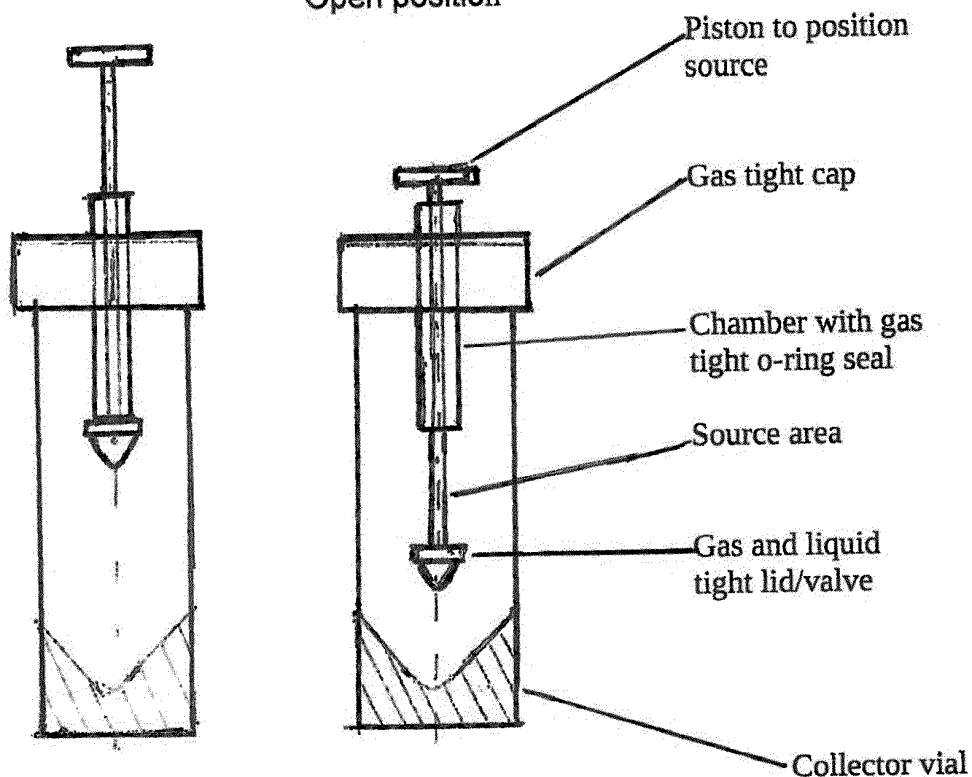
The '603 patent discloses methods and systems for producing highly purified radioisotopes, such as ^{212}Pb . As the '603 patent explains, such isotopes have important medical applications. See EX1001, 7:23-26 (use in radiopharmaceuticals), 9:58-67 (use in cancer therapy). For example, the 10.6-hour half-life of ^{212}Pb makes it a useful radioisotope for anti-cancer treatment, as it can act rapidly on its target, delivering a large dose of radiation, but it will also decay

quickly enough such that it substantially stops acting as a radioactive source in the body shortly after treatment. EX1001, 1:63-2:3. However, the short half-life also impedes centralized production, storage, and distribution (since the isotope will decay during storage and shipment), raising the need for methods of production that may be performed easily in the location where the radioisotopes are needed, such as a hospital. EX1001, 1:63-2:3, 6:1-14; EX2002, ¶¶27-28.

The '603 patent provides solutions to these problems, disclosing devices and methods allowing the on-location generation of radioisotopes like ^{212}Pb safely, efficiently, and in high purity. EX1001, Abstract. For example, Fig. 4 (below) is shown on the face of the '603 patent and depicts a device configured to generate radioisotopes and deposit them on the interior surface of a collector vial.

Closed position

Open position



EX1001, Fig. 4; *see also id.* 14:39-45, 18:19-35. The collector vial (container) is connected to a cap, and together, they define a gas-tight volume in which a rod or piston, with a radioisotope source disposed thereon, is movably located. EX1001, 14:39-45, 18:19-35, 13:64-14:26, Figs. 2, 4. The rod moves between an open or closed position by moving it up or down. *Id.* When the rod is moved to the open position as shown on the right, the radioisotope source is exposed to the volume, including the vial's interior collector surface, allowing decay products to emanate into the collector vial and collect on the walls. *Id.* By moving the rod to the closed position as shown on the left, the radioisotope source is isolated from the

remaining volume of the collector vial, preventing gaseous decay products from emanating from the radioisotope source to the container walls. *See id.*; EX2002, ¶¶29-30.

The radioisotope source (e.g., ^{228}Th , ^{224}Ra , or a combination) produces ^{220}Rn gas via radioactive decay. EX1001, 3:1-8, 4:52-5:8, 20:16-31, Fig. 1. In the closed position, the gas is isolated from the collector vial's interior surface until the device is moved into the open position by sliding the rod downward. *See* EX1001, 13:64-14:26, 18:25-19:35, Figs. 2, 4. In the open position, the ^{220}Rn emanates throughout the collector vial container, the ^{220}Rn gas decays into ^{216}Po and ^{212}Pb , and the emanation process completes by depositing these decay products on the container's interior surface. *See id.*; *see also id.*, 2:27-47, 13:64-14:25. After sufficient ^{212}Pb is deposited on the collector surface, the rod is moved into the closed position, isolating the radioisotope source and allowing the ^{212}Pb to be extracted. *See* EX1001, 11:7-25. The device disclosed in the specification allows for efficient, safe production of ^{212}Pb . EX1001, 1:20-27; EX2002, ¶29.

These features are reflected in the claims of the '603 patent. EX2002, ¶31. Applying the element numbering from the petition, claim 1 recites:

[1pre] A method of generating radioisotopes, the method comprising:

[1a] exposing an interior surface of a container to a precursor isotope source by sliding a rod from a closed position in which the precursor isotope source is sealed off from the interior surface of the

container to an open position in which the precursor isotope source is exposed to the interior surface of the container,

[1b] wherein the precursor isotope source is disposed on the rod;

[1c] allowing sufficient time for the precursor isotope source to decay into one or more progeny isotopes and to emanate the one or more progeny isotopes into the container; and

[1d] isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position.

Independent claim 12 recites similar limitations directed to a system for generating radioisotopes.

III. HASSEFJELL-HOFF

The only prior art challenge to independent claims 1 and 12 in the petition (Ground 1) is alleged anticipation by Hassfjell-Hoff. Pet. 12-18, 31-32. As discussed in greater detail herein, the petition fails to establish anticipation. The challenges to the dependent claims, including Grounds 2-3, fail at least for depending on the unsubstantiated challenges to independent claims 1 and 12.

Hassfjell-Hoff describes a device for generating ^{212}Pb as a decay product from [^{228}Th]barium stearate, which is a barium stearate salt into which ^{228}Th is incorporated. EX1003, 6-7, Fig. 2; EX2002, ¶53. As depicted in Fig. 2 (below), the device includes a lower collection chamber containing a polyethylene bottle and an upper housing chamber separated from the lower chamber by a gate valve.

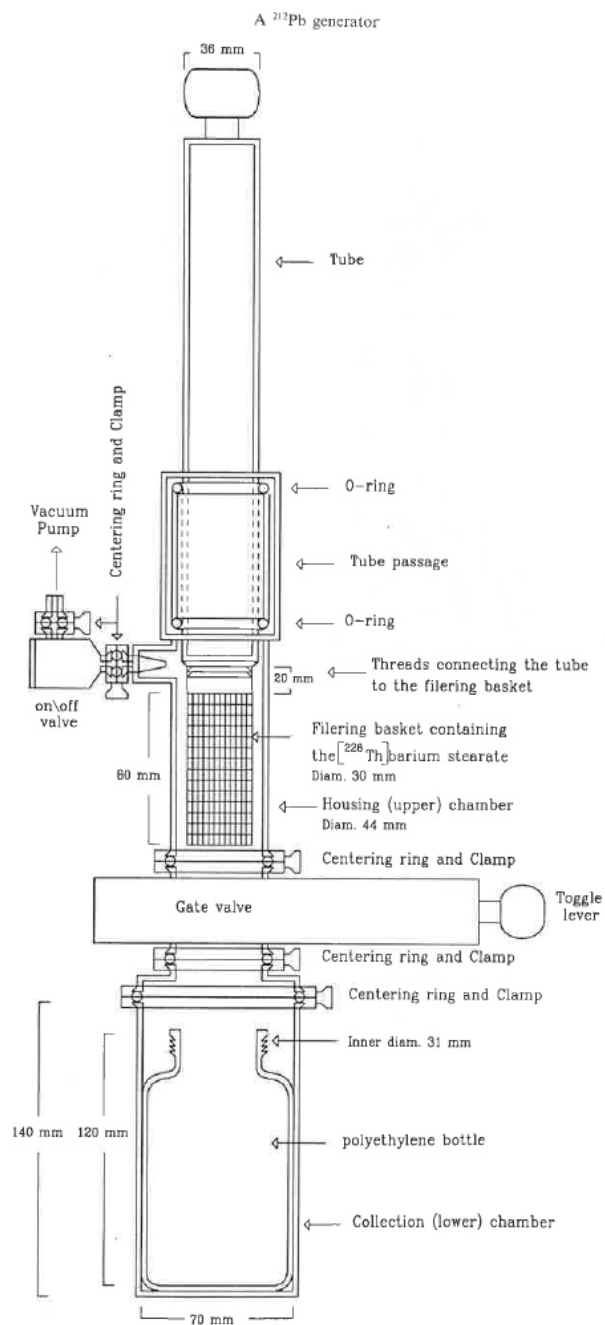


Fig. 2. The design of the generator showing functional details and operating mechanism.

EX1003, Fig. 2 (annotated). $[^{228}\text{Th}]$ barium stearate is placed inside membrane packets, and the packets are placed into a “filing basket”—a basket made of a fabric similar to lace. EX1003, 7; see Pet., 10 n.1. The packets rest loosely at the

bottom of the basket; thus, none of the [^{228}Th]barium stearate, the packets, and the filtering basket are attached to anything. EX2002, ¶65.

The [^{228}Th]barium stearate in the packets decays to produce ^{220}Rn gas, which emanates from the [^{228}Th]barium stearate and which decays into ^{216}Po and ^{212}Pb , which can deposit on walls. EX1003, 6. To allow these emanating atoms to pass out of the upper housing chamber and reach the walls of the polyethylene bottle in the lower chamber, the gate valve is opened, exposing the [^{228}Th]barium stearate and its emanated decay products to the bottle—whereas isolation occurs only by closing the gate valve. EX1003, 7; EX2002, ¶¶54-56.

In mapping to the independent claims of the '603 patent, the petition maps the claimed “rod” to Hassfjell-Hoff’s “tube,” it maps the claimed “container” to Hassfjell-Hoff’s polyethylene bottle, and it repeatedly maps the claimed “precursor isotope source” to the [^{228}Th]barium stearate. *See* Pet., 14, 15, 16, 18, 31-32. There is no dispute that the [^{228}Th]barium stearate is the only precursor isotope source in Hassfjell-Hoff’s generator. EX2002, ¶63.

IV. CLAIM CONSTRUCTION

In a post grant review, a claim is given its ordinary and customary meaning. 37 C.F.R. §42.200(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). Petitioner advances constructions for several terms. Pet., 3-5. Below, these terms are addressed, as well as a term (“precursor isotope source”)

for which the petition offered no construction. EX2002, ¶35; *see also id.*, ¶¶32-34 (applying Petitioner’s definition of level of skill in the art).

A. “precursor isotope source” (Claims 1 and 12)

Each independent claim recites the term “precursor isotope source” in multiple claim limitations. Additionally, each claim further limits “the precursor isotope source” to one that “decay[s] into one or more progeny isotopes” that emanate into the chamber. *See, e.g.*, EX1001, claims 1, 12. The petition does not propose a construction of the term “precursor isotope source” and no construction is believed necessary. EX2002, ¶¶36-37. Any prior art analysis, however, must give effect to the plain language recited in the claims.

With regard to the asserted art, both experts now agree there is no other precursor isotope source in Hassfjell-Hoff other than [²²⁸Th]barium stearate found in packets. EX2004, 61:7-10; EX2002, ¶63; *see also id.*, ¶¶1-10; EX2003. Indeed, the petition primarily relies on the [²²⁸Th]barium stearate in its mapping to the “precursor isotope source” recited in the claims. *See, e.g.*, Pet. 15, 17, 18, 31-32. The petition, however, provides one conclusory sentence asserting that, alternatively, “the combination of the [²²⁸Th]barium stearate packets and [filering]

basket is the source of the precursor isotope in Hassfjell-Hoff.” Pet. 17.¹ To the extent this “alternative” argument is not deemed conceded and considered further here, it fails to give effect to the plain language of the challenged claims.

It is well-established that claim analysis “starts with the language of the claim itself.” *CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1316 (Fed. Cir. 2000); *see, e.g., Phillips*, 415 F.3d at 1312 (“[T]he claims are ‘of primary importance....’” (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876))); *Sumitomo Dainippon Pharma Co. v. Emcure Pharms. Ltd.*, 887 F.3d 1153, 1157 (Fed. Cir. 2018) (“The plain claim language marks the starting point for our analysis”). Rather than looking at a claim term in isolation, “the context of the surrounding words of the claim also must be considered.” *Phillips*, 415 F.3d at 1314 (quoting *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003)). Here, the claims plainly state the precursory isotope source “decay[s] into one or more progeny isotopes.” Petitioner’s own expert agrees, under the plain language of the claims only Hassfjell-Hoff’s [²²⁸Th]barium stearate qualifies—there is no other “source,” including the lace basket or any other component of the “combination.” EX2004, 59:9-22, 61:7-16.

¹ Petitioner is careful in its wording and does not assert that the combination actually qualifies as a “precursor isotope source” as claimed (it does not).

The Institution Decision *sua sponte* stated that in some embodiments of the specification “the ’603 patent does not limit the precursor isotope source to only the radioactive material but can also comprise a ‘holder’ as well as other structures, such as a ‘grid or ring’ that surround the ‘holder’ of the radioactive material.” DI at 17 (citing EX1001, 10:1-7 (“The source may or may not contain a holder....”)). This does not, however, support including the lace (filtering) basket of Hassfjell-Hoff as the claimed “precursor isotope source” for at least several reasons.

First, it is the claim that defines the scope of the invention, not provisions from the specification. *Phillips*, 415 F.3d at 1323 (the “claims themselves set forth the limits of the patent grant.”). It is well-established that claims need not and generally do not encompass all aspects discussed in the specification, and it is improper to interpret claim terms to encompass embodiments when doing so would contradict the language of the claims. *E.g.*, *TIP Sys. LLC v. Phillips & Brooks Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008). Here, each independent claim expressly identifies the precursor isotope source as one that “decay[s] into one or more progeny isotopes.” EX2002, ¶37. The claims also distinguish between the precursor isotope source and the rod (e.g., “holder”) on which it is disposed. *See also* EX2002, ¶¶38-40 (citing EX1001, 1:46-53, 3:1-8, 3:34-39, 8:12-13, claims 1, 9) (distinction consistent with disclosure in specification).

Second, both experts agree that other than [²²⁸Th]barium stearate, there is no “precursor isotope source” in Hassfjell-Hoff’s generator—certainly not the lace basket. The institution decision cites to a sentence in the specification which states “[t]he source may or may not contain a holder for the radioactive part and a grid or ring or similar surrounding the source to prevent cross contamination when the ²¹²Pb precursor isotope source is withdrawn from the container.” EX1001, 10:3-7. As explained in the Conroy declaration, the cited passage never states the source “comprise[s] a ‘holder’” and expressly distinguishes between the “holder” and “the radioactive part.” The cited passage also distinguishes between the “source” and another structure (the grid or ring) that is described as “*surrounding* the source” to prevent cross contamination. EX2002, ¶¶41-43.

As explained in the Conroy declaration, the remaining citations in the institution decision (p. 17) do not support reading the claimed “precursor isotope source” as including the lace basket of Hassfjell-Hoff. EX2002, ¶40. For example, the institution decision cites to the ’603 patent at 21:50-51² (claim 1) as “stating the precursor isotope source is disposed on the rod.” DI at 17. As discussed above, this confirms the claim language distinguishes between the precursor isotope source and the rod (e.g., holder) on which it is disposed. Likewise, the language cited in

² The citation to “1:50-51” (DI at 17) is believed a typographical error.

claim 9 that the precursor isotope source is “disposed in a sponge, a wool, a strip, or a sphere” again differentiates the precursor isotope source from materials on which it is disposed.

Accordingly, there is no dispute—nor could there be—that there is no other “precursor isotope source” in Hassfjell-Hoff besides [²²⁸Th]barium stearate found in packets.

B. “disposed on the rod” (Claims 1 and 12)

Claim 1 recites “wherein the precursor isotope source is disposed on the rod” and claim 12 recites “a precursor isotope source disposed on a rod.” With virtually no analysis, the petition proposes substituting the term “disposed on the rod” in claim 1 with “directly or indirectly attaching to the rod.” Pet., 3-4³. The petition challenge fails whether the Board applies the plain meaning of the term or Petitioner’s proposed construction. In this sense, no construction is necessary to find the petition challenge fails.

As addressed in the POPR, and not rebutted, a petitioner may not substitute claim terms with different terminology. *See, e.g., Chef Am., Inc. v. Lamb-Weston,*

³ As discussed in section VI, Petitioner cites to a declaration paragraph which repeats the petition’s words essentially verbatim. The petition provides no basis to attribute any special meaning to this term based on the understanding of persons of ordinary skill.

Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004) (“This court, however, repeatedly and consistently has recognized that courts may not redraft claims....”); *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008) (“Courts cannot rewrite claim language.”); *Taurus IP, LLC v. DaimlerChrysler Corp.*, 726 F.3d 1306, 1321 (Fed. Cir. 2013) (“Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.” (quoting *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1365 (Fed. Cir. 1999))); *K-2 Corp.*, 191 F.3d at 1365 (Fed. Cir. 1999) (“[C]ourts can neither broaden nor narrow claims to give the patentee something different than what he has set forth.” (quoting *Texas Instruments Inc. v. International Trade Comm’n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993))).

There is also no dispute the petition fails to address the plain meaning of “disposed on the rod.” Conversely, numerous courts have reviewed the term “disposed on” as common patent claim verbiage and concluded the plain meaning refers to being located on something. For example, the court in *Astra Aktiebolag v. Andrx Pharms., Inc.*, explained that “the phrase ‘disposed on’ as used in its conventional patent law sense...refer[s] to the position or location of an element in a structure.” 222 F. Supp. 2d 423, 470 (S.D.N.Y. 2002), *aff’d* 84 F. App’x 76, 80 (Fed. Cir. 2003) (“The district court correctly construed ‘disposed on’....”); *see also, e.g., Junk Food Custom Arcades, LLC v. Hit Box, LLC*, No. 2:21-CV-262-RWS, 2023 U.S. Dist. LEXIS 240434, at *22 (N.D. Ga. Apr. 11, 2023) (construing

“‘disposed on’ to mean ‘located or positioned’ [on]”); *360Heros, Inc. v. GoPro, Inc.*, No. 17-1302-LPS-CJB, 2019 U.S. Dist. LEXIS 173093, at *19 (D. Del. Oct. 4, 2019) (“[T]he Court recommends that ‘disposed thereon’/’disposed on’ be construed to mean ‘located thereon’/’located on.’”), *report and recommendation adopted*, 2019 U.S. Dist. LEXIS 234420 (D. Del. Nov. 4, 2019). The petition even states the plain meaning applies to the claims here. *See* Pet., 3 (no dispute plain and ordinary meaning applies); EX2002, ¶¶44-47.

However, Petitioner’s prior art challenge fails regardless of whether the Board applies the plain meaning or Petitioner’s proposed language. As discussed in detail below with respect to ground 1, the petition relies on, for the claimed precursor isotope source, Hassfjell-Hoff’s [²²⁸Th]barium stearate found in packets that are “placed in a filtering basket.” EX1003 at 7. As the reference itself indicates, neither the [²²⁸Th]barium stearate nor the packets are attached, directly or indirectly, to the identified tube. The [²²⁸Th]barium stearate is certainly not “disposed on [a] rod.”

C. “allowing sufficient time for the precursor isotope source to decay comprises allowing 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours” (claim 10)

The petition proposes that this limitation means that “allowing decay...occurs for at least...one of the listed times.” Pet., 5. For Ground 4, however, the petition departs from this plain meaning to suggest the claim may be

“construed to require exactly one of the listed times.” Pet., 61. No construction is necessary, but the Ground 4 challenge of claim 10 can be rejected at least on the basis that the petition fails to address its own proposed understanding of the claim. EX2002, ¶48-49.

D. “the precursor isotope source is configured to decay and emanate the one or more progeny isotopes into the container for 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours” (claim 20)

Petitioner first proposes rewriting claim 20 to insert the word “exactly” before the recited list of times. Pet. 5. Curiously, the petition cites as support case law forbidding precisely what the petition proposes—i.e., rewrite a claim rather than address the claim as written. *See* Pet., 5 (citing *Chef. Am.*, 358 F.3d at 1374). In the next sentence, Petitioner suggests an “alternative” construction paralleling the construction of claim 10. Putting aside any potential confusion with this approach, Ground 4 depends on the adopting the first construction (inserting the word “exactly”). Pet. 61-62. The first construction should be rejected as legally erroneous (as the petition’s own argument dictates), thereby rendering the Ground 4 challenge of claim 20 moot. EX2002, ¶50.

V. THE PETITION FAILS TO MEET ITS BURDEN TO SHOW THE UNPATENTABILITY OF ANY CHALLENGED CLAIM

A. Ground 1 Fails to Demonstrate Hassfjell-Hoff Anticipates Claims 1-6, 8, 11-17, and 19

The petition fails to show that Hassfjell-Hoff anticipates claims 1-6, 8, 11-17 and 19. To begin with, the petition fails to show that Hassfjell-Hoff discloses the step of isolating “isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position” as recited in element 1d, the step of exposing the precursor isotope source by sliding the rod from the open position to the closed position as recited in element 1a, or the corresponding features recited in independent claim 12. Petitioner’s own expert testified in both related PGR2025-00040 and during cross examination here that it is the closing of the gate valve in Hassfjell-Hoff that isolates the polyethylene container from the [²²⁸Th]barium stearate source—not movement of Hassfjell-Hoff’s tube.

The petition also fails to show that Hassfjell-Hoff discloses a “precursor isotope source [that] is disposed on the rod” as recited in each independent claim. Both experts agree, there is no precursor isotope source in Hassfjell-Hoff other than [²²⁸Th]barium stearate found in packets. As Hassfjell-Hoff states plainly, the [²²⁸Th]barium stearate packets are placed loosely in a basket and displaced from the tube.

Moreover, the petition fails to show that Hassfjell-Hoff teaches dependent claim limitations, including the limitations of claims 5, 8, 14, 15, and 17. As the petition fails to show anticipation of either independent claim, Petitioner fails to meet its burden in ground 1 with respect to any of claims 1-6, 8, 11-17, and 19. EX2002, ¶51.

1. Petitioner fails to show that Hassfjell-Hoff discloses “isolating the precursor isotope source” by sliding a rod or exposing the precursor isotope source by sliding a rod as recited in the independent claims

Claim element 1d recites “isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position,” and claim 1a similarly recites exposing the precursor isotope source by sliding the rod from closed to open. Similarly, claim 12 recites a “rod configured to slide between an open position in which the precursor isotope is exposed...” and “a closed position in which the precursor isotope source is sealed off from the container to isolate the precursor isotope source from the interior surface.” The petition fails to show that Hassfjell-Hoff discloses these elements. EX2002, ¶52.

The petition identifies Hassfjell-Hoff’s tube as the “rod,” and indicates that the tube can be “pushed down” when gate valve is in an “open” position and the

tube “pulled up” when in a “closed” position. Pet., 15, 18.⁴ However, claim 1 requires “isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position.” Claim 12 similarly recites the rod slides between the same open and closed positions for exposure (when the rod is in the open position) and isolation (when the rod is in the closed position).

Petitioner’s expert, Dr. Mirzadeh, testified repeatedly that it is the closing of Hassfjell-Hoff’s gate valve that isolates the [²²⁸Th]barium stearate source from the polyethylene collection bottle—not movement of tube (identified as the rod). Dr. Mirzadeh offered testimony in related PGR2025-00040 inconsistent with Petitioner’s anticipation theory here, explaining “Hassfjell-Hoff’s system includes a gate valve that is used to selectively fluidly couple or isolate the source (when it is retracted into the upper chamber) and the lower volume (i.e., lower collection chamber).” PGR2025-00040, EX1002, ¶¶56-57. Dr. Mirzadeh confirmed this repeatedly during cross-examination, stating plainly that isolating the [²²⁸Th]barium stearate is controlled solely by the gate valve:

⁴ Petitioner relies on essentially identical arguments for the similar elements of claim 12. See Pet., 31-32.

19 Q. Okay. And it is the closing of the gate
20 valve that isolates the polyethylene bottle from the
21 source, correct?
22 A. Correct.

EX2004, 65:19-22.

Even with Hassfjell-Hoff's tube in the upward position, the polyethylene bottle is exposed (not isolated) to radon gas if the gate valve is open and isolated only by closing the gate valve. EX2004, 60:20-23; 64:15-65:1 ("You can leave it open and still you have a communication between the source and the collection vessel"). As Dr. Mirzadeh explained, only closing of the gate valve isolates the bottle from the source, and closing of the gate valve is accomplished only by actuating the "toggle lever." EX2004, 64:5-13. In other words, there is no dispute that sliding the tube of Hassfjell-Hoff up and down does not isolate the polyethylene bottle—that is solely accomplished by closing the gate valve.

Dr. Mirzadeh's testimony is confirmed by the Hassfjell-Hoff reference and agreed upon in the Conroy declaration. As plainly illustrated in Hassfjell-Hoff, the position of its tube does not determine whether the [²²⁸Th]barium stearate is exposed to the container's interior surface (mapped to the inside of the polyethylene bottle) or isolated (sealed off) from it. Rather, it is the gate valve that determines whether the polyethylene bottle is exposed to or isolated from the "emanating [²²⁸Th]barium stearate." EX1003, 7 ("These two compartments are

connected via a gate valve (VAT)”), Fig. 2 (reproduced in part herein). For example, when the gate valve is open, the polyethylene bottle is exposed to the emanating $[^{228}\text{Th}]$ barium stearate regardless of whether the tube is in an up or down position. Similarly, the $[^{228}\text{Th}]$ barium stearate is not isolated or sealed off by sliding the tube; only when the gate valve is closed does such isolation or sealing off occur. Both experts agree.

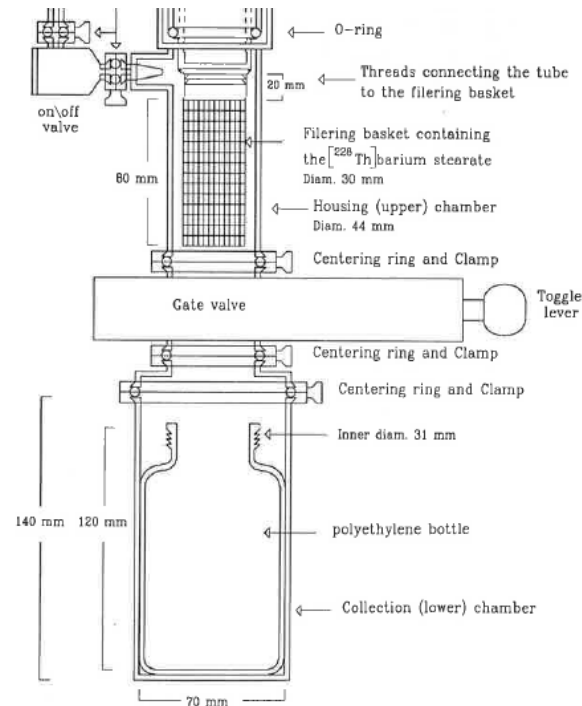


Fig. 2. The design of the generator showing functional details and operating mechanism.

EX2004, 65:19-22; EX2002, ¶¶53-57. Accordingly, Hassfjell-Hoff’s exposure and sealing off (isolating) is controlled by the opening or closing of the gate valve, not by sliding the tube.

Petitioner’s argument to reach the independent claim elements contradicts its own expert and the prior art reference itself, as well as the claim language. For example, Petitioner asserts that “[t]here is nothing in the claim or specification of the 603 patent that requires the movement of the rod to the closed position to result in a seal.” Pet., 16. This assertion is plainly wrong, as explained in the Conroy declaration and evident from the claims themselves. Claim element 1 expressly

recites “isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position,” with the closed position of the rod defined as a position of the rod “in which the precursor isotope source is sealed off from the interior surface of the container.” Thus, claim 1 does expressly recite a step of isolating the container’s interior surface—that is, sealing off the container from the precursor isotope source by sliding the rod from an open position to a closed position. EX2002, ¶58; *see also id.*, ¶59 (understanding consistent with specification examples).

Claim 12 parallels claim 1 in also requiring that the open and closed positions *of the rod* are positions that the rod slides between to determine whether the rod is exposed or sealed off. The same feature was noted by the Examiner as a feature of the claims during prosecution, as he indicated that the claims were allowable due to “inventive features of including said precursor on *a rod that can operate the exposure* in an open or closed configuration.” EX1006, 264, 280. Thus, the claim language itself ties the movement of the rod to the recited exposure/sealing off, with the prosecution history confirming that the claimed rod position imparts the exposure or sealing respectively. The petition addresses none of this. EX2002, ¶58.

As described above, Hassfjell-Hoff lacks these aspects recited in the independent claims. The [²²⁸Th]barium stearate is exposed if the gate valve is open

or sealed off when the gate valve is closed, this is indisputably true regardless of the position of the tube. Moreover, Hassfjell-Hoff's tube is only movable when the gate valve is open and the bottle already exposed, the tube does not slide down when the gate valve is closed. Similarly, when its gate valve is open, moving Hassfjell-Hoff's tube up into the upper chamber does not "isolate the precursor isotope source from the container"—the tube (and the packets in the bag hanging from the tube) remains exposed to the container due to an open gate valve.

2. Petitioner fails to show that Hassfjell-Hoff discloses a precursor isotope source “disposed on [a/the] rod” as recited in independent claims 1 and 12

The petition fails to show Hassfjell-Hoff discloses a “precursor isotope source disposed on a rod” (or “on the rod”) as recited in independent claims 1 and 12. The petition presented two theories, neither of which supports a finding of anticipation. EX2002, ¶¶60-61.

a. Failed Theory 1: Hassfjell-Hoff's [^{228}Th]barium stearate is undeniably not attached to anything

Throughout its ground 1 discussion for both independent claims, the petition repeatedly maps the recited “precursor isotope source” to Hassfjell-Hoff's [^{228}Th]barium stearate, which is contained in packets. *E.g.*, Pet., 14 (“a precursor isotope source (i.e., packet of [^{228}Th]barium stearate)” for element 1a), 15 (same), 16 (“a precursor isotope source of [^{228}Th]barium stearate”), 17 (“the packets of

[²²⁸Th]barium stearate, which comprise the [²²⁸Th]barium stearate precipitate (i.e., *precursor isotope source*)” for element 1b), 17-18 “*the precursor isotope source* (i.e., the [²²⁸Th]barium stearate)” for element 1c), 18 (“*the precursor isotope source* (i.e., the [²²⁸Th]barium stearate)” for element 1d), 31 (“*the precursor isotope source* (i.e., packet of [²²⁸Th]barium stearate)” for element 12a), 32 (“*the precursor isotope source* (i.e., packet of [²²⁸Th]barium stearate)” for element 12b) (emphases original). The petition further identifies Hassfjell-Hoff’s “tube” as the purported rod. *E.g.*, Pet., 15, 17, 31-32; EX2002, ¶62.

Hassfjell-Hoff’s [²²⁸Th]barium stearate, unquestionably, is not “disposed on the rod.” The petition’s construction equates “disposed on the rod” to “attached directly or indirectly to the rod.” See Pet., 3, 17. However, as stated plainly in Hassfjell-Hoff the [²²⁸Th]barium stearate is located in a membrane packet that is placed in a lace (“filering”) basket. See EX1003, 7 (“The packets of [²²⁸Th]barium stearate are placed in a filering basket....”), Fig. 2 (showing “Filering basket containing the [²²⁸Th]barium stearate” hanging by threads off of the end of a tube). Not only is the [²²⁸Th]barium stearate not attached to the tube, but even the packets containing the [²²⁸Th]barium stearate are not attached to it, directly or indirectly. They are not even attached to the *basket*, which merely holds the packets (in which the [²²⁸Th]barium stearate is found) loosely like a net. See *id.*, Fig. 2; EX2002, ¶65.

Nor is the location of the [²²⁸Th]barium stearate located on the tube, as the packets containing it are located at the bottom of the filering basket, far below the end of the tube that Petitioner identifies as a rod. *See* EX1003, Fig. 2; EX2002, ¶64. Thus, regardless of whether the term “disposed on the rod” is construed to mean located on the rod or attached to the rod (whether directly or indirectly), Hassfjell-Hoff’s [²²⁸Th]barium stearate is not disposed on a rod.

b. Failed Theory 2: [²²⁸Th]barium stearate is undisputedly the only “source” in Hassfjell-Hoff

As an “alternative,” the petition devotes a single conclusory sentence in suggesting that “the combination of the [²²⁸Th]barium stearate packets and basket is the source.” Pet., 17. This “alternative” theory is undeveloped and unsupported attorney argument lacking the support of any expert and should be rejected as such. Both experts here agree, there is no precursor isotope source in Hassfjell-Hoff other than [²²⁸Th]barium stearate found in packets. EX2002, ¶63. Petitioner’s own expert, Dr. Mirzadeh, confirmed this repeatedly during cross-examination:

7	Q. Okay. And there are no other sources
8	shown here, other than the 228 Thorium, barium
9	stearate, right?
10	A. Correct.

EX2004, 61:7-10; *see id.*, 59:19-22 (Thorium 228 is the only source in Hassfjell-Hoff's generator); *see also id.*, 42:11-14 (identifying "the source Thorium-228, in this case, has been precipitated as a barium stearate"), 53:18-25 (distinguishing the "Thorium-228 source" from the "filtering basket" and the "membrane-type material"), 56:13-17 (confirming only "[i]t is the precipitate that is the source"), 58:19-23 (confirming that "radon gas produced from the 228 barium stearate" is "the only Radon that we are discussing here"), 61:7-15 (confirming the "lace basket" not considered a "source"). This is, of course, corroborated by the Hassfjell-Hoff reference itself, which identifies the [²²⁸Th]barium stearate precipitate as the source. EX1003, 6-7 ("Materials and Methods"), 7 ("packets of [²²⁸Th]barium stearate"), Fig. 2; *see also* EX2002, ¶63.

Accordingly, there is no dispute—nor could there be—there is no other "precursor isotope source" in Hassfjell-Hoff other than [²²⁸Th]barium stearate found in packets. Petitioner's drive-by statement regarding an "alternative" is wholly unsupported and contradicted both by its own witness and the plain disclosure in the prior art, and it should be rejected for at least these reasons alone.

The institution decision *sua sponte* questioned whether the term "precursor isotope source" might be viewed so broadly so as to "comprise a 'holder' as well as other structures, such as a 'grid or ring' that surround the 'holder' of the radioactive material." DI, 16-17 citing EX1001, 10:1-7 ("[t]he source may or may

not contain a holder...”). No such argument is found in the petition, and no expert has testified as such. Just the opposite, both experts agree that other than [²²⁸Th]barium stearate precipitate, there is no other “precursor isotope source” in Hassfjell-Hoff as would be plainly understood by a POSITA.

Moreover, as explained above in §IV.A, any mapping of the “alternative” combination of components is inconsistent with both the petition itself and the language of the challenged claims. Each of independent claims 1 and 12 recites a “precursor isotope source,” which the claims further limit to “decay[ing] into one or more progeny isotopes.”

As Dr. Mirzadeh concedes, the filering basket is not a “source” and does not decay into progeny isotopes, nor does the membrane material of the packets. There is no dispute that the only component of Hassfjell-Hoff’s generator that decays is the [²²⁸Th]barium stearate. Indeed, when discussing element 1c, the petition identifies *only* the [²²⁸Th]barium stearate as the precursor isotope source. See Pet., 17 (“*the precursor isotope source (i.e., the [228Th]barium stearate)*”) (emphases original). It does not include the filering basket or the packet membrane in the precursor isotope source for this limitation, as Petitioner’s own expert acknowledges. Furthermore, the claims also distinguish between the precursor isotope source and the rod (e.g., “holder”) on which it is disposed. The cited passage also distinguishes between the “source” and “surrounding” structure (the

grid or ring) that is described as “*surrounding* the source” to prevent cross contamination. As such, any argument the claimed “precursor isotope source” would “comprise” a holder (e.g., rod or filering basket)—besides lacking the support of petition argument or expert testimony—conflicts with the language of the claims themselves.

The petition’s discussion of claim 12, at best, shares the defects of its claim 1 discussion. The claim 12 discussion in the petition identifies the precursor isotope source as a packet of [²²⁸Th]barium stearate,⁵ not a combination of [²²⁸Th]barium stearate and the filering basket. *See* Pet., 31 (“*the precursor isotope source* (i.e., packet of [²²⁸Th]barium stearate)” for element 12a), 32 (“*the precursor*

⁵ As noted above, the petition identifies Hassfjell-Hoff’s source as the [²²⁸Th]barium stearate, but in some instances it cites generally to the packet of [²²⁸Th]barium stearate. To be clear, both experts agree that other than [²²⁸Th]barium stearate precipitate, there is no other “precursor isotope source” in Hassfjell-Hoff. Petitioner’s anticipation theory fails at least because neither the [²²⁸Th]barium stearate precipitate nor the packets in which they are contained are attached to anything, as Petitioner’s anticipation theory requires. There is no “precursor isotope source” of Hassfjell-Hoff that is “disposed on the rod” as recited in the challenged claims.

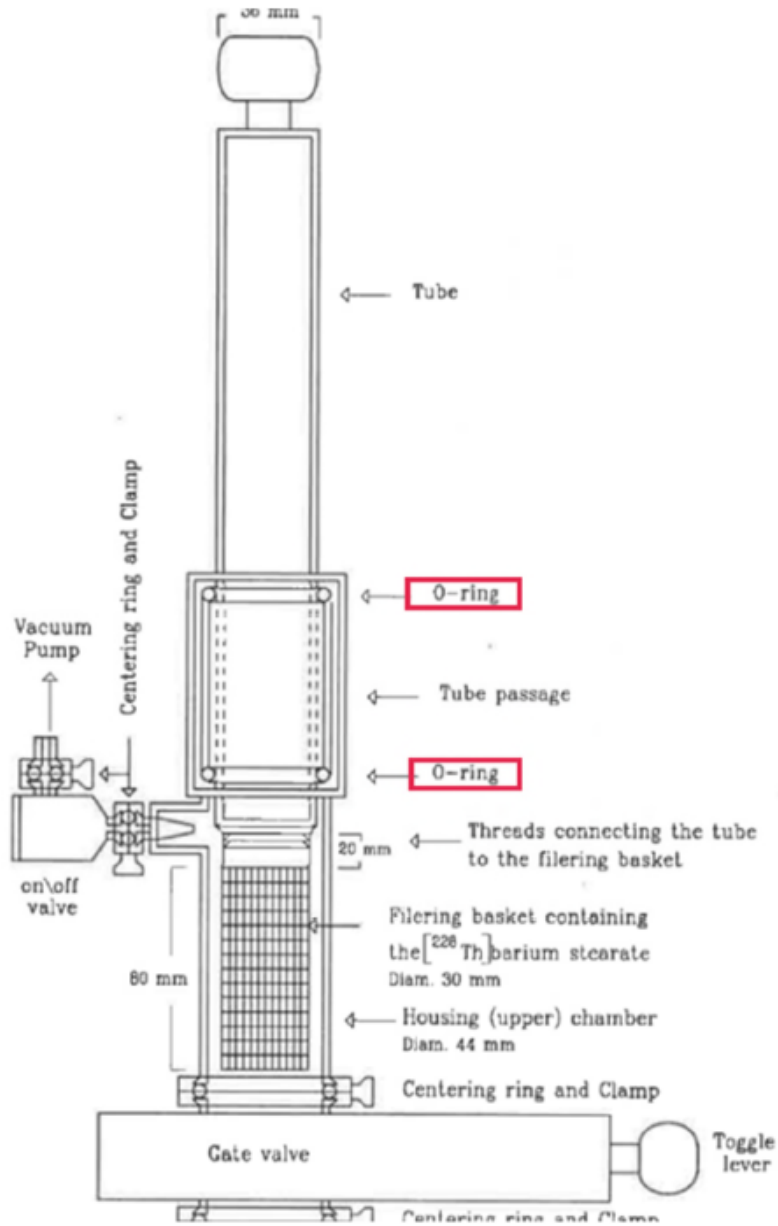
isotope source (i.e., packet of [²²⁸Th]barium stearate)” for element 12b). Patent Owner does not agree that the “alternative” argument in claim 1 was ever clearly made in the context of claim 12—clearly it was not. Neither Patent Owner nor the Board should be asked to play archeologist with the record on Petitioner’s behalf. 37 C.F.R. §42.6(a)(3) (“Arguments must not be incorporated by reference....”); see *Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1371-72 (Fed. Cir. 2023) (“A brief must make all arguments accessible to the judges, rather than ask them to play archaeologist with the record.” (quoting *DeSilva v. DiLeonardi*, 181 F.3d 865, 866-67 (7th Cir. 1999))). Here, the petition argument for claim 12 refers back to claim 1 but only identifies the [²²⁸Th]barium stearate as the claimed “precursor isotope source.” As discussed, Dr. Mirzadeh confirmed there is no other “precursor isotope source” in Hassfjell-Hoff other than [²²⁸Th]barium stearate found in packets. The petition thus fails to advance its “alternative” mapping for claim 12. Even if considered, the “alternative” argument fails for claim 12 for at least the same reasons it fails for claim 1.

Accordingly, the petition fails to show that Hassfjell-Hoff discloses a “precursor isotope source disposed on [a] rod,” as required by each independent claim.

3. Petitioner fails to show that Hassfjell-Hoff discloses the limitations of dependent claims 5, 14, and 15

Claim 5 depends from claim 4, which depends in turn from claim 1. Claim 5 recites “withdrawing the precursor isotope source into a gas tight seal comprises sealing the rod within a tube using an O-ring to form the gas tight seal between the rod and the tube.” Claim 14 depends from claim 12, reciting “in the closed position, the rod forms a gas tight seal with a tube in which the rod slides to isolate the precursor isotope source from the interior surface.” Claim 15 depends from claim 14, reciting that “the rod includes at least one O-ring to form the gas tight seal with the tube in the closed position.” Petitioner fails to show that Hassfjell-Hoff discloses any of these limitations. EX2002, ¶¶68-70.

Regarding claim 5, petitioner identifies the recited “tube” as a “tube passage” extending between the two O-rings in the marked-up figure reproduced below.



Pet., 21-23 (marking up EX1003, Fig. 2). However, while the “tube” identified by Petitioner as the recited rod passes through the identified tube passage, it is not *sealed within the tube* passage as required by claim 5. As the figure plainly shows, Hassfjell-Hoff’s tube extends below (as well as above) the identified tube passage,

so it is not sealed *within* it. Dr. Mirzadeh confirmed as much in cross-examination. See EX2004, 69:15-17; *see also* EX2002, ¶71.

Petitioner relies on its analysis of claim 5 to meet the similar limitations of claims 14-15. See Pet., 33-34. The petition's showing is similarly defective for these claims; indeed, the mappings of these claims include further defects. EX2002, ¶72.

For example, claim 14 requires that the “rod forms a gas tight seal with a tube in which the rod slides to isolate the precursor isotope source from the interior surface.” But the seal petitioner points to in Hassfjell-Hoff is not formed to isolate the precursor isotope source from the interior surface; rather, it is a seal that remains present at all times and serves merely to prevent gas from escaping to the environment, not to isolate the precursor isotope source from the interior surface. EX2002, ¶73.

As to claim 15, this claim further recites that “the rod includes at least one O-ring to form the gas tight seal with the tube in the closed position.” However, Hassfjell-Hoff's tube (mapped to the “rod”) does not “include” the O-ring; rather, the O-ring is affixed to the tube passage (mapped to the “tube”), with the rod sliding through it. EX2002, ¶74.

Thus, the petition's arguments regarding dependent claims 5, 14, and 15 fail to show the added limitations of these claims as well as the limitations of the independent claims. EX2002, ¶75.

4. Petitioner fails to show that Hassfjell-Hoff discloses the limitations of dependent claims 8 and 17

Dependent claims 8 and 17 recite as follows:

8. The method of claim 1, wherein allowing sufficient time for the at least one progeny isotopes to emanate into the container comprises allowing the at least one progeny isotopes to emanate into the container from the precursor isotope source through a gas permeable barrier.

17. The system of claim 12, wherein the precursor isotope source is encapsulated in a gas permeable barrier.

Hassfjell-Hoff has not been shown to disclose the elements of these claims.

EX2002, ¶76.

The petition identifies the gas permeable barrier recited in claims 8 and 17 as one or both of “the filtering basket and the packet filter material.” Pet., 30, 38. For example, for claim 17, Petitioner asserts that “[e]ach of the filtering basket and the packet encapsulates the precursor isotope source.” Pet., 38. Thus, for claims 8 and 17, Petitioner relies on the [²²⁸Th]barium stearate precipitate as the precursor isotope source (i.e., no “alternative” theory is presented here).

As discussed above, however, the [²²⁸Th]barium stearate is unquestionably not disposed on the rod as both independent claims 1 and 12 require. *Supra* §V.A.2. Petitioner’s arguments for dependent claims 8 and 17 fail to cure this deficiency. Thus, the anticipation challenge to claims 8 and 17 fails at least because those claims depend from claims 1 and 12, respectively, on which Petitioner’s anticipation challenge falls short.

As is readily apparent, the petition’s identification of the “gas permeable barrier” recited in claims 8 and 17 is not compatible with its “alternative” argument for independent claims 1 and 12. Each of claims 8 and 17 recites a “gas permeable barrier” as a separate element from the precursor isotope source, so if the precursor isotope source included the filtering basket and packet material, neither of them can be the gas permeable barrier. EX2002, ¶¶77-79.

Accordingly, the petition fails to meet its burden to show that Hassfjell-Hoff anticipates any of claims 1-6, 8, 11-17, and 19 under §102(a)(1). EX2002, ¶80.

B. Grounds 2 and 3 Fail

1. Grounds 2 and 3 fail to remedy ground 1’s independent-claim deficiencies

Ground 2 asserts that dependent claims 5-6, 10-11, 15-16, and 20 were obvious over Hassfjell-Hoff; and ground 3 asserts that dependent claims 9-10, 18, and 20 were obvious over Hassfjell-Hoff and O’Hara. However, neither ground addresses any element in independent claims 1 and 12, and in particular, neither

ground remedies the deficiencies of Hassfjell-Hoff as explained above for ground 1. Accordingly, the petition fails to meet its burden with regard to any claim challenged in grounds 2 or 3 for similar reasons to those described above for ground 1. *Supra* §V.A; EX2002, ¶¶81, 85.

2. Ground 2 fails to remedy the deficiencies of dependent claims 5 and 15

Ground 2's arguments do not remedy the independent deficiencies of claims 5 and 15.

Regarding claim 5, Petitioner argues that it would have been obvious to prevent escape of radioisotopes from the generator (Pet., 39-40); however, that does not address the deficiencies discussed above regarding claim 5's limitations. For example, Petitioner's proposed modification does not change the fact that that the purported rod (Hassfjell-Hoff's tube) is not sealed within the purported tube (Hassfjell-Hoff's tube passage). *Supra* §V.A.3; EX2002, ¶83.

Claim 15 depends from claim 14, and ground 2 addresses neither the deficiencies of claim 14 nor those of independent claim 12. *Supra* §V.A.3. Moreover, ground 2 argues with respect to claim 15 that it would be obvious for Hassfjell-Hoff's tube to *touch* an O-ring; however, claim 15 recites that the rod *includes* an O-ring, not merely that it touches one. Petitioner identifies no basis to

reinterpret the word “include” to encompass merely touching an object. EX2002, ¶84.

3. Ground 3’s combination fails to meet the limitations of claims 9 and 18

The petition’s ground 3 arguments with respect to dependent claims 9 and 18 also fail due to inconsistencies with the arguments in the independent claims.

Claim 18 recites that “the precursor isotope source is disposed on a sponge, a wool, a strip, or a sphere comprising at least one material selected from the group consisting of: quartz, glass, mineral, paper, plastic, metal, ceramic, natural fibers, and synthetic fibers,” and claim 9 recites a similar limitation: “the precursor isotope source disposed in a sponge, a wool, a strip, or a sphere comprising at least one selected from the group consisting of: quartz, glass, mineral, paper, plastic, metal, ceramic, natural fibers, and synthetic fibers.” EX2002, ¶¶85-87.

For claim 9, the petition asserts that a “POSITA would have been motivated to combine Hassfjell-Hoff and O’Hara to implement the filter membrane packets and surrounding filtering basket disclosed by Hassfjell-Hoff with the O’Hara gas permeable metal or mineral membrane, screen, filter, or porous disc (each are a sponge) containing the precursor isotope source.” Pet., 53; *see id.*, 56 (same argument for claim 18). Petitioner characterizes O’Hara as teaching “various examples of the precursor isotope source disposed on a mineral sorbent that is on a

‘permeable metal membrane, screen, [] filter’ or ‘porous disc,’” which Petitioner asserts each constitutes a “sponge.” Pet., 52 (quoting EX1007, [0020]-[0022]); EX2002, ¶88.

However, each of these examples involves depositing *source isotopes*—that is, radioactive material that decays into decay products—in these various materials. See EX1006, [0020]-[0022]. Indeed, Petitioner relies specifically on the [228Th]barium stearate as the precursor isotope source for these claims. As discussed above, the [²²⁸Th]barium stearate is unquestionably not disposed on the rod as both independent claims 1 and 12 require. *Supra* §V.A.2; EX2002, ¶90.

Petitioner’s alternative argument is not advanced here, nor could it be. It makes little sense to dispose *the filtering basket and its contents* in or on a sponge or other material recited in claims 9 or 18, and the petition does not explain how it could be in such a hypothetical combination. O’Hara at best supports disposing *radioactive isotopes* in various materials. EX2002, ¶¶88-89. The petition thus fails to show that either of claims 9 and 18 were obvious over Hassfjell-Hoff and O’Hara.

C. Ground 4 Fails to Demonstrate Unpatentability Under §112

The petition argues the unpatentability of claims 1-3, 8-10, 12, and 20 under 35 U.S.C. §112 for various combinations of enablement, written description, and indefiniteness. None of these challenges withstands scrutiny. EX2002, ¶91.

At institution, the Board expressed doubt as to each argument raised by Petitioner. DI, 21-29. The record after institution has only further undermined these arguments. Dr. Mirzadeh's declaration never provided legal standards for enablement, written description, and indefiniteness. *See generally* EX1003. Petitioner's own expert, Dr. Mirzadeh, admitted during cross-examination that his declaration was the only source of legal standards he applied, yet it only identified standards for anticipation and obviousness. EX2004, 35:17-19, 36:6-11, 37:4-39:9; *see* EX1002, ¶¶8-28. The petition's arguments are thus supported only by attorney argument. Yet petitioner's arguments are inconsistent with the plain language of the claims, petitioner's own claim construction arguments, and the understanding of a POSITA. EX2002, ¶¶91-108.

1. Claim 1

Petitioner asserts that claim 1 is non-enabled and lacks written description, but its challenge is based on misunderstanding of both the claim and the specification.

Petitioner specifically takes issue with claim 1's requirement of the "precursor isotope source to decay into one or more progeny isotopes and to emanate the one or more progeny isotopes into the container." Pet., 57. Petitioner interprets "one or more progeny isotopes" to mean at least two different isotope species, and Petitioner concedes that, as shown in Fig. 1, precursor isotopes such as

^{228}Th decay into various progeny isotopes including ^{220}Rn . Pet., 57-58. The petition further concedes that there is written description support for one progeny isotope (^{220}Rn) that “both decays from the precursor isotope source and emanates into the container.” Pet. 57. But Petitioner asserts that the open-ended nature of the term “one or more isotopes” lacks support because although the specification discloses decay into further progeny isotopes, it purportedly fails to disclose any emanation of these isotopes. Pet., 57-58. In particular, Petitioner presumes that because the specification notes that ^{220}Rn is a gas but does not include this label on the other isotopes, it must be “impossible” for any other isotopes to emanate to the walls of the container. EX2002, ¶92.

Petitioner’s argument fails. The specification describes emanation of other progeny isotopes beyond ^{220}Rn . The process of emanation into the container can begin with decay from (for example) ^{228}Th into ^{224}Ra , and then ^{220}Rn . See EX1001, Fig. 1. Since ^{220}Rn is naturally gaseous, it “will diffuse from the source.” EX1001, 6:28-38. This diffusion is part of the emanation of progeny isotopes to the walls of the container, but it is not the end of the process. The specification further indicates that ^{220}Rn decays with a 55.6 s half-life into ^{216}Po , which quickly decays (half-life of 145 ms) into ^{212}Pb . See EX1001, 2:27-47, Fig. 1, Table 1. The specification thus describes that the ^{220}Rn “after decay settle[s] as ^{212}Pb onto the inner walls of the container.” EX1001, 13:64-14:25; *see also id.*, 2:27-47 (describing allowing time

for “ ^{220}Rn , ^{216}Po , and/or ^{212}Pb to settle onto the inner walls of the single chamber container assembly”), 18:25-29 (deposition of ^{212}Pb onto surface). EX2002, ¶¶93-94.

In other words, the ^{220}Rn decays *while emanating as a gas*, and the emanation to the walls of the container completes when it settles as ^{212}Pb after decay. The emanation process can thus involve multiple progeny isotopes— ^{220}Rn emanates as a gas, and while emanating as a gas decays into ^{216}Po , which continues emanating briefly before decaying into ^{212}Pb , which completes the emanation by converting from gaseous form into a coating on the container surface. EX2002, ¶94. In cross-examination, Dr. Mirzadeh conceded that this was the case. EX2004, 31:25-32:15. At institution, the Board agreed, noting that “Patent Owner appears to have the better argument.” DI, 22.

The specification confirms that decay of ^{220}Rn was known to occur, and in fact was a challenge for prior “emanation and diffusion systems” whose long transport distances lost efficiency “due to decay of ^{220}Rn before reaching the collection vessels,” as the resulting ^{212}Pb would deposit away from the target container surfaces. EX1001, 2:4-12; *see also* EX1002, ¶¶103 (characterizing process in which “‘decay products from the emanated ^{220}Rn ,’ namely ‘ ^{212}Pb and ^{212}Bi , deposit on the walls’” as involving “*emanated* ^{212}Pb ” (quoting EX1003, 7)), 82 (“POSITA would have understood that the purity of the *emanated* ^{212}Pb is

ensured....”); EX2002, ¶95. Thus, contrary to the petition’s assertions, the specification provides written description and enablement for precursor isotopes not only decaying into one or more progeny isotopes (e.g., ^{220}Rn , ^{216}Po , and/or ^{212}Pb) but also those same one or more progeny isotopes emanating into the container, as recited in claim 1.

2. Claim 2

Claim 2 recites “wherein exposing the interior surface to the precursor isotope source comprises exposing the interior surface to a thorium 228 isotope (^{228}Th) and/or a radium 224 isotope (^{224}Ra), the method further comprising allowing the ^{228}Th to decay into at least one of a radon 220 isotope (^{220}Rn) and a lead 212 isotope (^{212}Pb).” Analyzing the first part of this claim in isolation, Petitioner asserts that it encompasses exposing the interior surface to ^{228}Th , ^{224}Ra , or a combination of the two. Pet., 58-59. Petitioner does not dispute that the specification enables exposing the interior surface to ^{224}Ra or to a combination of ^{224}Ra and ^{228}Th . The petition asserts that the claim is not enabled because it is “not possible” to expose a surface to ^{228}Th because ^{228}Th decays into ^{224}Ra , and thus, according to Petitioner, “any ^{228}Th source must inherently include some portion of ^{224}Ra as would be apparent to a POSITA.” Pet., 59; EX2002, ¶96.

This argument fails for multiple reasons, including for concerns regarding Petitioner’s arguments raised by the Board at institution. DI, 23-24.

First, the claim is open ended—the requirement that the exposing step “comprises exposing the interior surface to a thorium 228 isotope” is satisfied regardless of what other isotopes (including ^{224}Ra) might or might not be present. Petitioner is essentially using open-ended language to read in an allegedly non-enabled negative limitation by requiring support for a source that contains ^{228}Th and contains no ^{224}Ra whatsoever, whereas in fact this limitation is simply satisfied regardless of whether or not each isotope is present, so long as ^{228}Th is exposed to the interior surface. EX2002, ¶97.

Second, Petitioner’s assertion that it is impossible to have ^{228}Th without also including some portion of ^{224}Ra is conclusory and illogical. Even if some ^{228}Th eventually decays into ^{224}Ra , that does not prevent a source from initially containing pure ^{228}Th , nor does it preclude an open-ended claim from referring only to the ^{228}Th found in the source without speaking to the presence or absence of ^{224}Ra . Dr. Mirzadeh adds nothing, merely repeating the petition argument word-for-word (with the only differences being omitting the word “inherently” and adding “Therefore, in my opinion”). *Compare* Pet., 58-59, *with* EX1002, ¶153. And as discussed above, Dr. Mirzadeh never applied the appropriate legal standards in providing his opinions. *See* EX2004, 35:17-19, 36:6-11, 37:4-39:9; EX1002, ¶¶8-28; EX2002, ¶98.

Third, Petitioner undermines its own enablement argument, asserting that it “would be apparent to a POSITA” that “any ^{228}Th source must include some portion of ^{224}Ra .” Pet., 59. Claims are interpreted as understood by the person of ordinary skill in the art. *E.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). If Petitioner’s assertion is true, then a POSITA would have understood the claim’s reference to a source containing ^{228}Th and/or ^{224}Ra as consistent with this purportedly understood inherent property, rather than understanding the claim to require enablement of an impossible embodiment. *See also, e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 894 F.3d 1258, 1265 (Fed. Cir. 2018) (“[W]here claim language permits an operable construction, the inoperable construction is wrong.” (citing *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1345 (Fed. Cir. 2009))).

Petitioner’s indefiniteness argument fares no better. Petitioner asserts that the second half of claim 2 requires that there be some ^{228}Th in the source, so that it may decay, which Petitioner asserts is inconsistent with the source containing only ^{224}Ra , an alternative Petitioner identifies reading the first half of claim 2 in isolation. However, Petitioner fails to appreciate that limitations narrow the scope of a claim—even if the first half of claim 2 leaves open the option of there being no ^{228}Th , the second half may narrow the claim by requiring its presence. In fact, a

POSITA would understand and be enabled to practice claim 2 as written, contrary to Petitioner's unreasonable and unsupported arguments. EX2002, ¶99.

3. Claim 3

Petitioner advances a similar indefiniteness argument against claim 3 as claim 2, which fails for similar reasons. Indeed, the Board at institution correctly expressed the same concerns regarding claim 3 as claim 2. DI, 24.

Petitioner asserts that the phrase “allowing the ^{212}Pb to deposit on the interior surface of the container” is indefinite or non-enabled because the second half of claim 2 recites “allowing the ^{228}Th to decay into at least one of a radon 220 isotope (^{220}Rn) and a lead 212 isotope (^{212}Pb).” *See* Pet., 59. Petitioner does not dispute that claim 3 is definite and enabled for circumstances where the ^{228}Th decay produces at least some ^{212}Pb . However, Petitioner asserts that claim 2 can encompass other circumstances where ^{228}Th had only decayed into ^{220}Rn , which it says is inconsistent with claim 3's recitation of depositing ^{212}Pb .

Petitioner again misunderstands that a function of a claim limitation is to limit the scope of a claim, such that some embodiments may fail to satisfy the limitation despite meeting *other* limitations. Indeed, this is precisely what is required of claim 3 by 35 U.S.C. §112(d): it depends from claim 2, so it limits claim 2 by excluding some embodiments that might otherwise have fallen within its scope. Here, even if claim 2 might encompass circumstances where ^{228}Th

decayed into ^{220}Rn but not into ^{212}Pb , claim 3 need not encompass those embodiments—there is nothing inconsistent, indefinite, or non-enabled in claim 3 limiting itself to circumstances where some ^{212}Pb is produced and allowed to deposit on the container’s interior surface and excluding circumstances where the ^{228}Th decay had only produced ^{220}Rn but had not yet produced any ^{212}Pb to be deposited. EX2002, ¶¶100-01.

4. Claims 8-9

Petitioner asserts that the term “the at least one progeny isotopes” lacks antecedent basis in claims 8 and 9 because a POSITA allegedly would not know “which progeny isotopes would be allowed to emanate into the container as opposed to the one or more progeny isotopes that are emanated as disclosed in claim 1.” Pet., 60-61. Petitioner’s argument fails.

The Board at institution noted it understood Petitioner to assert that “it is not clear whether all of the ‘one or more emanating progeny isotopes,’ or only at least one of the one of the emanating progeny isotopes, and if only at least one, then which one of the emanating progeny isotopes must meet the additional claim limitations recited in claims 8 and 9.” DI, 25. However, this concern by Petitioner is misplaced, as the claims would not be misunderstood by a POSITA on this issue. EX2002, ¶¶102-03.

Claims need only “inform, with reasonable certainty, those skilled in the art about the scope of the invention” to avoid indefiniteness. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). It is a “well-settled rule that claims are not necessarily invalid for a lack of antecedent basis.” *Microprocessor Enhancement Corp. v. Tex. Instruments Inc.*, 520 F.3d 1367, 1376 (Fed. Cir. 2008); *see also, e.g., Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006) (“[T]he failure to provide explicit antecedent basis for terms does not always render a claim indefinite.” (quoting M.P.E.P. §2173.05(e))).

Here, the antecedent basis of “the at least one progeny isotopes” meets the standard of informing the POSITA with reasonable certainty of claim scope. Petitioner does not dispute that the word “the” indicates that this phrase refers to an antecedent earlier in the claims, and the only earlier reference to “progeny isotopes” in claim 1 or its dependent claims 8 and 9 is claim 1’s “one or more progeny isotopes.” Petitioner suggests that a POSITA might be confused, thinking “one or more” meant something different than “at least one.” This is not reasonable. “Anyone with even the most rudimentary understanding of the English language understands ‘at least one...’ to mean one or more....” *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999) (quoting *Kistler Instrumente Ag v. United States*, 628 F.2d 1303, 1311 (Ct. Cl. 1980)).

The surrounding claim language confirms the antecedent basis for this claim term, as claims 8 and 9 use this term in the phrase “wherein allowing sufficient time for the at least one progeny isotopes to emanate into the container from the precursor isotope source comprises....” This language parallels claim 1’s language in element 1b, which recites “allowing sufficient time for the precursor isotope source to decay into one or more progeny isotopes and to emanate the one or more progeny isotopes into the container.” The recited emanation in claims 8 and 9 corresponds to the emanation recited in claim 1, confirming that “the at least one progeny isotopes” refers to claim 1’s “one or more progeny isotopes,” at least because they are the only things that claim 1 describes as emanating. The lack of ambiguity in these terms is confirmed by Petitioner’s expert, who had no difficulty understanding the antecedent basis of “the at least one progeny isotopes” when addressing it in grounds 1 and 3, and failed to apply the legal standard for indefiniteness in his declaration. *See* EX1002, ¶¶85-86, 138-40; EX2004, 35:17-19, 36:6-11, 37:4-39:9.

Contrary to Petitioner’s arguments, POSITA would have understood that the antecedent of “the at least one progeny isotopes” in claims 8 and 9 is the “one or more progeny isotopes” of claim 1. EX2002, ¶103. Regarding the Board’s phrasing of Petitioner’s argument as asking “which one of the emanating progeny isotopes must meet the additional claim limitations” (DI, 25), the answer is all of them.

Yet even if there were any doubt, there would be no change to the claim scope regardless of whether claims 8 and 9 only required one progeny isotope to emanate. The relevant limitations of claim 1 are satisfied so long as one progeny isotope emanates. Under either interpretation, the relevant limitations of claims 8 and 9 are satisfied so long as one progeny isotope emanates *through a gas permeable barrier* as recited in claim 8 or *from the precursor isotope source disposed* in any of the materials recited in claim 9. In other words, Petitioner's imagined interpretation leads to the same conclusion as the interpretation a POSITA would arrive at: claims 8 or 9 are satisfied so long as the emanation limitations recited in claim 1 and claim 8 or 9 are met by an isotope.

Accordingly, Petitioner has failed to show that either of claims 8 or 9 is indefinite.

5. Claim 10

Petitioner asserts that claim 10 lacks written description “[t]o the extent that claim 10 is construed to require exactly one of the listed times”; however, the petition itself indicates that this is not the construction a POSITA would give this claim. See Pet., 5 (“This limitation should be construed to mean that allowing decay is inclusive and occurs for at least...one of the listed times.”); *see also* EX1002, ¶¶38 (same), ¶34 (each constructions given is “ordinary and customary meaning according to a POSITA”); *see also* EX2004, 35:17-19, 36:6-11, 37:4-39:9

(legal standards not applied). As the petition concedes that the alternative construction contemplated for this ground is not how a POSITA would understand it, and indeed asserts that the specification does not support such a construction (as it claims there is no written description for it), Petitioner advances no basis to conclude that claim 10 lacks written description as properly construed. *See also* EX1001, 12:16-24 (expressly disclosing production periods of “5 hours, 10[] hours, 20 hours or more”), Tables 3-4 (further disclosing periods of 24, 48, 72, and 96 hours); *infra* §V.C.7 (discussing parallel limitation in claim 20); EX2002, ¶¶104-05 (POSITA would not understand claim to be limited to exact times).

Petitioner also asserts that claim 10 is indefinite because a POSITA “would not know whether ‘allowing’ refers to the time the source decays or the time the bottle is left in the apparatus.” Pet., 61. Claim 10 recites “The method of claim 1, wherein allowing sufficient time for the precursor isotope source to decay comprises allowing 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours.” If Petitioner had read claim 1 when addressing claim 10, it would know that claim 1 recites “allowing sufficient time for the precursor isotope source to decay into one or more progeny isotopes and to emanate the one or more progeny isotopes into the container.” Thus, the *allowing* in claim 10 refers to claim 1’s step of “allowing sufficient time” for the source “to decay...and to emanate.” So neither of the petition’s alternative referents is correct—neither claim refers to *the time the*

bottle is left in the apparatus—and *time to decay* is underinclusive, as the recited time must be time to both *decay and emanate*. Accordingly, Petitioner has failed to support its assertion that claim 10 is indefinite.

6. Claim 12

Petitioner challenges claim 12 as lacking written description and enablement relying solely on its arguments for claim 1. Pet., 61. Its challenge to claim 12 fails for similar reasons as its challenge to claim 1. *See supra* §V.C.1.

7. Claim 20

Petitioner asserts that claim 20 is amenable to two alternative constructions, construing it to require the precursor isotope source to be configured either (1) to decay and emanate for exactly one of the recited times; or (2) decay and emanate for at least one of the recited times (or longer). Pet., 5, 40-41. At institution, the Board correctly adopted this second construction. DI, 28. Because Petitioner's indefiniteness arguments are tied to the first construction, they fail.

Petitioner asserts that under the first construction, the claims are unpatentable under §112, yet it fails to support this construction. *See* Pet., 5, 40-41. Petitioner's declarant provides no insight at all, repeating Petitioner's assertion

regarding this first construction without further comment.⁶ *See also* EX2004, 35:17-19, 36:6-11, 37:4-39:9 (failed to apply legal standards). Petitioner further argues that the first construction (though not the second) is inoperable, as ‘is impossible to “configure’ a precursor isotype source to decay” in the way required under the first construction.

Petitioner’s indefiniteness argument also runs afoul of the Federal Circuit’s admonition that “where claim language permits an operable construction, the inoperable construction is wrong.” *Power Integrations*, 894 F.3d at 1265. Petitioner’s own argument that its first proposed construction is inoperable, in combination with its argument that a POSITA would view both of its proposed constructions as permissible interpretations of the claim language, squarely confirms both that the claim is not indefinite (as only one of Petitioner’s proposed constructions is operable under the petition’s own arguments) and that it is both enabled and has adequate written description (as the petition does not dispute that its second construction satisfies these requirements).

⁶ Indeed, as noted below, the declaration itself makes it clear that the paragraph addressing this limitation was copied uncritically from the petition. *See infra* §VI (discussing EX1002, ¶39).

Moreover, even considered in isolation, Petitioner’s argument against written description and enablement fails. Petitioner’s constructions map the recited times to how long the precursor isotope source *decays and emanates*, yet in its §112 arguments, the petition asserts only that “is impossible to ‘configure’ a precursor isotope source to *decay* for an exact amount of time.” Pet., 61. Contrary to petitioner’s §112 arguments, what must satisfy the claimed time interval is the time that the source is allowed “to decay and emanate the one or more progeny isotopes into the container.” Using devices like those disclosed in the specification, stopping emanation after any recited amount of time is simple—it merely requires moving the rod to the closed position and sealing off the precursor isotope source at the appropriate time. EX2002, ¶¶106-08. Indeed, the specification expressly teaches performing such a decay-and-emanation process for various intervals each falling within the scope of claim 20. See EX1001, 12:16-24 (“5 hours, 10[] hours, 20 hours or more”), Tables 2-4 (24, 48, 72, and 96 hours). Nor are the recited time intervals exclusive—there is nothing inconsistent with a source being configured, for example, to decay and emanate for 96 hours being also configured to decay and emanate for 5 hours, or any other interval in between.

Accordingly, Petitioner fails to satisfy its burden in any of its §112 challenges to claims 1-3, 8-10, 12, and 20. EX2002, ¶¶91-108.

VI. PETITIONER’S EXPERT TESTIMONY DESERVES NO WEIGHT

The petition materials include declarations by two declarants, Per Hoff (EX1017) and Saed Mirzadeh (EX1002). These declarations fail to provide the meaningful analysis and explanation necessary to entitle them to weight. *See* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000) (lack of factual support can render expert testimony “of little probative value in a validity determination”); *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15-16 (precedential) (testimony merely repeating petition arguments without providing additional “supporting evidence or technical reasoning” is “conclusory and unsupported ... and is entitled to little weight”).

The declaration of Dr. Hoff, for example, is entirely conclusory. A representative page of his declaration is reproduced below, showing the entirety of his analysis of independent claim 1 in ground 1.

V. GROUND 1: CLAIMS 1-8, 11-17, AND 19 ARE ANTICIPATED BY HASSFJELL-HOFF

A. Claim 1

A method of generating radioisotopes, the method comprising:

exposing an interior surface of a container to a precursor isotope source by sliding a rod from a closed position in which the precursor isotope source is sealed off from the interior surface of the container to an open position in which the precursor isotope source is exposed to the interior surface of the container wherein the precursor isotope source is disposed on the rod;

allowing sufficient time for the precursor isotope source to decay into one or more progeny isotopes and to emanate the one or more progeny isotopes into the container; and

isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position.

38. In my opinion, Hassfjell-Hoff discloses this claim.

As illustrated, Dr. Hoff merely repeats the text of the claim and then asserts that Hassfjell-Hoff discloses it. This is the epitome of conclusory testimony and entitled to no weight.

The declaration of Saed Mirzadeh provides scant improvement. The Mirzadeh declaration copies the petition's attorney arguments verbatim (or nearly verbatim) without providing independent analysis. This is illustrated in his discussion for the construction of claim 20. Despite admitting he has no legal training, Dr. Mirzadeh not only duplicates the petition's text, he even includes the same case citation and quotation as the petition, illustrating that text was copied uncritically from the petition into the declaration. *See* EX1002, ¶39. This pattern of uncritically parroting content from the petition is illustrated throughout the Mirzadeh declaration. Moreover, as noted above, Dr. Mirzadeh was not provided, and thus failed to apply, any legal standards covering §112, confirming that his

conclusions were simply attorney argument dressed up as expert opinion. *See* EX2004, 35:17-19, 36:6-11, 37:4-39:9. Accordingly, as Dr. Mirzadeh merely copies the petition arguments without providing any new factual support or technical analysis, his declaration is also entitled to little or no weight. *See Xerox*, Paper 9 at 15-16.

VII. CONCLUSION

Accordingly, for at least the reasons set forth above, the Board should find that Petitioner has failed to show the unpatentability of any of claims 1-6 and 8-20.

Respectfully submitted,

Date: February 04, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

CERTIFICATE OF COMPLIANCE

Pursuant to §42.24(d), the undersigned certifies that this paper contains no more than 18,700 words, not including the portions of the paper exempted by §42.24(b). According to the word-processing system used to prepare this paper, the paper contains 11,495 words.

Respectfully submitted,

Date: February 04, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

VIII. EXHIBIT LIST

EXHIBIT NO.	DESCRIPTION
2001	Disclaimer of Claim 7 in U.S. Patent 12,125,603
2002	Declaration of Charles Conroy
2003	<i>Curriculum vitae</i> of Charles Conroy
2004	Mirzadeh Deposition Transcript
2005	Mirzadeh Deposition Errata

CERTIFICATE OF SERVICE

I certify that the foregoing Patent Owner's Response Pursuant to 37 C.F.R. § 42.220 and accompanying Exhibits 2002-2005 were served on this 4th day of February, 2026, on the Petitioner at the following electronic service addresses:

Jennifer Librach Nall
James M. Heintz
Gianni Minutoli
Joseph Helmsen
Nicholas Kokkinos
DLA PIPER LLP (US)
Jennifer.nall.ptab@us.dlapiper.com
jim.heintz@us.dlapiper.com
Gianni.Minutoli@us.dlapiper.com
Joseph.Helmsen@us.dlapiper.com
nicholas.kokkinos@us.dlapiper.com
Sciencons-AIP-IPR@us.dlapiper.com

Date: February 04, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182