

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.

PGR2025-00029
Patent 12,125,603 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 has 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; Paper 7, 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 1–20 of U.S. Patent No. 12,125,603 B2 (Ex. 1001, “the ’603 patent”). Paper 1 (“Pet.”). Sciencons AS filed a Preliminary Response. Paper 10. As discussed in further detail below, Sciencons, AS disclaimed claim 7. Therefore, claims 1–6 and 8–20 (“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 ’603 patent is eligible for post-grant review and that it is more likely than not that at least one challenged claim of the ’603 patent is unpatentable under § 324(a). Accordingly, we institute a post-grant review of all challenged claims of the ’603 patent.

B. Real Parties in Interest and Request to Amend Caption

Petitioner identifies itself, AdvanCell Pty Ltd., as the real party-in-interest. Pet. 63. Patent Owner Sciencons AS states that itself, as well as ArtBio AS and ARTBIO, Inc. are the real parties-in-interest. Paper 4, 1;

Paper 7, 1. Patent Owner explains that Sciencons AS granted ArtBio AS an exclusive license, with the right to grant sublicenses, to the '603 patent and that ArtBio AS later granted ARTBIO, Inc. an exclusive license to the '603 patent. Paper 4, 1; Paper 7, 1.

Sciencons AS also states that ARTBIO, Inc. is responsible for defending the '603 patent in this proceeding and requests that ARTBIO, Inc. be included in the caption for this proceeding.² Paper 4, 1; Paper 7, 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 proceeding of the '603 patent. *See* Papers 3, 4, 7, 8. 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 '603 patent and is responsible for defending the '603 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.

C. Related Matters

Petitioner does not identify any related matters. Pet. 64. Patent Owner identifies *AdvanCell Pty. Ltd. v. Sciencons AS*, PGR2025-00040 as a

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

related matter. *See, e.g.*, Paper 7, 1. PGR20205-00040 challenges US Patent No. 12,249,437, which claims priority to the '603 patent.

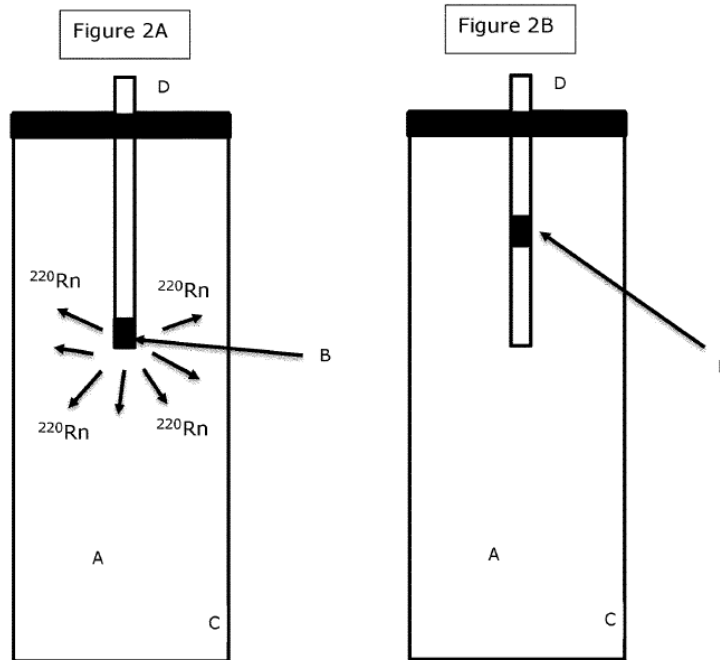
D. Overview of the '603 Patent

The '603 patent, titled “Production of Highly Purified ^{212}Pb ,” is directed to devices and methods allowing the on-location generation of radioisotopes such as ^{212}Pb . Ex. 1001, code (54), (57). The '603 patent “relates to a single chamber diffusion generator (assembly), assemblies and method for obtaining a container comprising ^{212}Pb on the walls obtained from a ^{212}Pb precursor isotope source.” *Id.* at 1:20–23. The '603 patent states that its process produces ^{212}Pb in high purity without a need for processing, with high yields, and provides a product that can be transported to locations for its use. *Id.* at 1:23–27.

The '603 patent describes a method for obtaining a container having ^{212}Pb on its walls, the method including 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 '603 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. Ex. 1001, 2:27–47. During the process, the precursor isotope does not come into contact with the inner wall of the container. *Id.*

The '603 patent's Figures 2A and 2B are reproduced below.



Figures 2A and 2B depict a single chamber container assembly for the generation of ^{220}Rn gas comprising a first part, i.e., container (A) and a second part, i.e., upper part (D). *Id.* at 2:27–30, 13:64–14:21. Upper part (D) comprises a cover/cap with a rod attached pointing towards the center of the container and ^{212}Pb precursor isotope source (B). *Id.* at 13:64–14:21. The ^{212}Pb precursor isotope source generates ^{220}Rn gas that is released into container (A) and, after decay, settles as ^{212}Pb “onto the inner walls of the container (C).” *Id.* at 13:64–14:16.

Figure 2B depicts “a situation where the ^{212}Pb precursor isotope source (B) has been withdrawn into a gas tight seal that ensures that no ^{220}Rn is released into the container.” *Id.* at 14:21–25. The ^{212}Pb precursor isotope source can also be removed entirely from the assembly. *Id.* at 14:25–26.

E. Illustrative Claim

Claims 1 and 12 are the only independent challenged claims. Claim 1 is illustrative of the challenged subject matter and is reproduced below.

1. [preamble] 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.

Ex. 1001, 21:43–58 (with bracketed material used by Petitioner added); Pet. 12–18.

F. Disclaimer of Claim 7

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 claim 7 of the '603 patent. Ex. 2001. Based on our review of Exhibit 2001 and U.S. Patent and Trademark Office public records, we find that the disclaimer of claim 7 complies with the above-listed requirements of 37 C.F.R. § 1.321(a). Accordingly, we treat claim 7 as having never been part of the '603 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, claim 7 is 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 1–6 and 8–20, the remaining challenged claims that have not been disclaimed.

G. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–6 and 8–20 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §³	Reference(s)/Basis
1–6, 8, 11–17, 19	102	Hassfjell-Hoff ⁴
5, 6, 10, 11, 15, 16, 20	103	Hassfjell-Hoff
9, 10, 18, 20	103	Hassfjell-Hoff, O’Hara ⁵
1–3, 8–10, 12, 20	112	Indefiniteness, Enablement, Written Description

Pet. 1–2. Petitioner relies on the Declaration of Saed Mirzadeh (Ex. 1002) and the Declaration of Per Hoff (Ex. 1017) 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. AIA § 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.

³ The AIA amended 35 U.S.C. §§ 102, 103, and 112. Because the challenged claims of the ’603 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 6-25 (1994) (Ex. 1003, “Hassfjell-Hoff”).

⁵ US 2018/0047474 A1, pub. Feb. 15, 2018 (Ex. 1007, “O’Hara”)

§ 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).

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 ’603 patent issued on October 22, 2024, from U.S. Application No. 17/756,802, filed on December 4, 2020 (“the ’802 application”), which claims priority to PCT/EP2020/084701 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, (21), (22), (30), (86). Thus, the ’603 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 ’603 patent’s issue date. *See* Paper 5 (showing a filing date of March 10, 2025).

Petitioner certifies that the ’603 patent is available for post-grant review. Pet. 1. On this record, we agree with the Petitioner and determine that the ’603 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, 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. 1017 ¶ 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.

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).

Under *Phillips*, claim terms are afforded “their ordinary and customary meaning,” which is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention in the context of the specification and prosecution history. *See Phillips*, 415 F.3d at 1312–1313; *see also id.* at 1317 (stating like the specification, “the

prosecution history provides evidence of how the PTO and the inventor understood the patent”).

The parties provide arguments about claim terms including “*the precursor isotope source is disposed on the rod*” recited in claim 1; “*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*” recited in claim 10; and “*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*” recited in claim 20.

Because the arguments regarding these terms are entwined with the parties’ unpatentability arguments, we address claim construction in connection with the unpatentability analysis below.

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

Petitioner argues that claims 1–6, 8, 11–17, and 19 are anticipated by Hassfjell-Hoff. Pet. 5–39.

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.

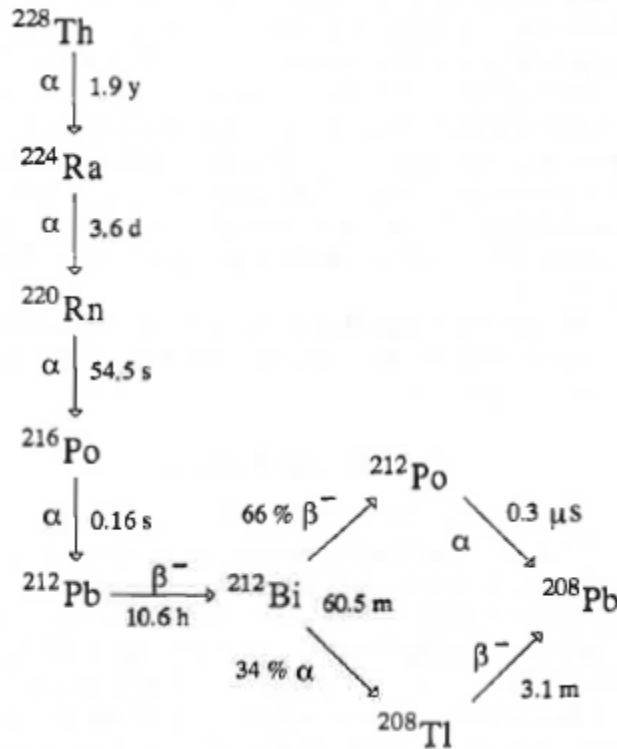


Figure 1 shows the decay mode of ^{228}Th to ^{212}Pb and then to stable ^{208}Pb . *Id.* at 7.

Hassfjell-Hoff's Figure 2 is reproduced below.

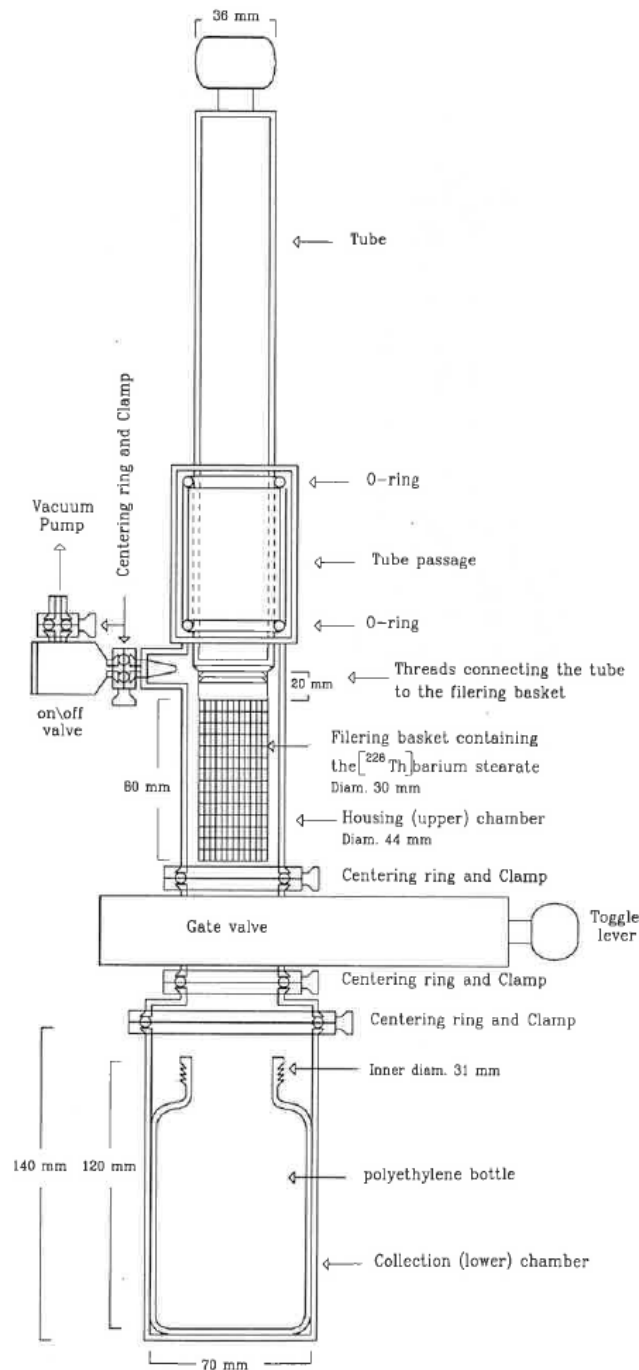


Figure 2 depicts the design of a generator. *Id.* at 8. Hassfjell-Hoff states:

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. Analysis for Claim 1

Petitioner asserts that Hassfjell-Hoff discloses a generator for producing radioisotopes (e.g., ^{212}Bi and its parent nuclide ^{212}Pb) by exposing the interior of a container (the inside of a polyethylene bottle) to a precursor isotope (packet of [^{228}Th]barium stearate) by sliding a rod (a tube slidably coupled to a collection chamber and a housing) from a closed position in which the precursor isotope is sealed off from the interior surface of the container (i.e., when the tube is pulled up and the gate valve is closed) to an open position in which the precursor isotope is exposed to the interior surface of the container (i.e., when the gate valve is open and the tube is pushed down) as recited in the preamble and claim element [1.A]. Pet. 12–

16 (citing *inter alia* Ex. 1003, Fig. 2; Ex. 1002 ¶¶ 49–53; Ex. 1017 ¶¶ 29–38).

Claim element [1.B] recites “wherein the precursor isotope source is disposed on the rod.” Petitioner asserts that “disposed on the rod” should be construed “to include directly or indirectly attaching to the rod.” Pet. 3–4 (citing Ex. 1001, 3:54–58, 8:58–65; Ex. 1002 ¶ 35). Petitioner asserts that Hassfjell-Hoff discloses a precursor isotope source disposed on the rod, by disclosing that the packets of [²²⁸Th]barium stearate are placed in a filtering basket mounted by threads to the end of a long tube closed in both ends. Pet. 16–17 (citing Ex. 1003, 7, Fig. 2). Petitioner alternatively argues that the combination of the packets and the basket is the source of the precursor isotope in Hassfjell-Hoff and that those are directly connected to the rod. *Id.* at 17 (citing Ex. 1003, 7, Fig. 2; Ex. 1002 ¶ 54; Ex. 1017 ¶¶ 29–38).

Claim step [1.C] 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.” Petitioner asserts Hassfjell-Hoff discloses this limitation by referencing “sufficient time” (i.e., an appropriate collection time) “for the precursor isotope source” (i.e., the [²²⁸Th]barium stearate) “to decay into one or more progeny isotopes and to emanate the one or more progeny isotopes” (i.e., ²²⁰Rb) “into the container” (the decay products from the emanated ²²⁰Rb, which are ²¹²Pb and ²¹²Bi, deposit on the walls of the bottle). Pet. 17–18 (citing Ex. 1003, 7; Ex. 1002 ¶¶ 55–56; Ex. 1017 ¶¶ 29–38).

With respect to claim step [1.D], Petitioner asserts Hassfjell-Hoff discloses that “the precursor isotope source” (i.e., the packet of [²²⁸Th]barium stearate) is isolated from the container by sliding the rod (i.e.,

sliding the tube slidably coupled to collection chamber) from the open position (i.e., gate valve is open and tube is down) to the closed position (i.e., the tube is pulled up and the gate valve is closed). Pet. 18 (citing Ex. 1003, 7, Fig. 2; Ex. 1002 ¶ 57; Ex. 1017 ¶¶ 29–38).

After reviewing the parties’ briefs and supporting evidence, we determine that Petitioner has sufficiently shown that Hassfjell-Hoff discloses each element of claim 1. As such, Petitioner’s argument and evidence as set forth above and further discussed below, sufficiently shows that it is more likely than not that claim 1 is anticipated by Hassfjell-Hoff, notwithstanding Patent Owner’s arguments, also addressed below.

Patent Owner argues that Petitioner has not sufficiently explained or established how Hassfjell-Hoff’s [²²⁸Th]barium stearate packets (the asserted precursor isotope source) are “disposed on” the rod as required by claim element [1.B]. Prelim. Resp. 18–19. Patent Owner asserts that the packets are not “disposed on the rod” under Petitioner’s construction—i.e., “attached directly or indirectly attached to the rod”—because the packets are merely placed in a basket and are not attached anything. *Id.* (citing Pet. 3, 17; Ex. 1003, 7, Fig. 2). Patent Owner further argues that Petitioner may not rely upon Hassfjell-Hoff’s basket as constituting part of the precursor isotope source because the rest of the Petition maps only the packets, but not the basket, to the precursor isotope source. Prelim. Resp. 19–20 (citing Pet. 14–16, 18, 31, 32). Patent Owner further asserts that the basket cannot be a source because the basket is a lace net, does not decay into anything, and does not emanate progeny isotopes. *Id.* at 20.

At this stage of the proceeding, we agree with Petitioner that Hassfjell-Hoff’s asserted precursor isotope source may include the basket in

which the [²²⁸Th]barium stearate packets are placed. *See, e.g.*, Pet. 17. The '603 patent states that the precursor isotope source “can be in different forms, sizes and shapes depending on the application type” (Ex. 1001, 7:59–60) and that “[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 precursor isotope source is withdrawn from the container (*id.* at 10:3–7). Thus, 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. *See id.* at 10:1–7; *see also id.* at 1:50–51 (stating the precursor isotope source is disposed on the rod), 22:22–33 (stating that the precursor isotope source is disposed in a sponge, a wool, a strip, or a sphere).

Given that the '603 patent refers to the precursor isotope source as including items that are not radioactive and do not decay, Patent Owner’s argument (i.e., that the precursor claimed isotope source cannot include Hassfjell-Hoff’s basket, because the basket does not decay) is not persuasive on the present record. Indeed, Hassfjell-Hoff’s packets themselves, which Patent Owner does not appear to dispute could constitute a source, are made of 0.8µm filter membrane, a material that also does not appear to decay. Ex. 1003, 7. The parties are invited to further address these issues at trial if they so choose.

Patent Owner also argues that Hassfjell-Hoff’s filter basket is not “directly attached to the rod” as the basket is “at best indirectly coupled via threads and displaced by at least 20mm.” Prelim. Resp. 21–22. We disagree

with this argument on the present record as we understand the threads to directly attach the basket to the rod. *See* Ex. 1007, Fig. 2.

Patent Owner also asserts that because it is Hassfjell-Hoff's *gate valve* and not the position of its tube that determines whether or not the [²²⁸Th]barium stearate is sealed off or isolated from the container's inner surface, Hassfjell-Hoff does not disclose either claim step [1.A] or [1.D]. Prelim. Resp. 22–27.

Based on the present record, we disagree with Patent Owner's argument. Claim step [1.A] recites “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.” Claim step [1.D] recites “isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position.” Hassfjell-Hoff states that when its tube (rod) is lowered from the upper chamber to the lower chamber, the [²²⁸Th]barium stearate is positioned inside the polyethylene bottle (container) and decay products deposit on the walls of the bottle. *See* Ex. 1003, 7; Pet. 15–16. Hassfjell-Hoff further states that the tube can be pulled up, placing the ²²⁸Th back in the upper compartment. Ex. 1003, 7; Pet. 15–16. We understand this disclosure to meet the steps of [1.A] and [1.D]. The parties are invited to address this issue at trial if they chose.

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. 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. *Remaining Claims*

a) *Independent Claim 12*

Citing to, *inter alia*, its arguments for claim 1, Petitioner provides argument and evidence that claim 12 is anticipated by Hassfjell-Hoff. Pet. 31–32 (citing Pet. §§ IV(B)(2)–(5); Ex. 1003, 7, Fig. 2; Ex. 1002 ¶¶ 90–93; Ex. 1017 ¶¶ 29–37, 56).

Patent Owner argues that claim 12 is patentable for reasons similar to those asserted for claim 1. *See* Prelim. Resp. 22–27. We disagree with these arguments for the reasons stated above.

Patent Owner also asserts that the Petition’s more limited discussion of claim 12 is defective because Petitioner’s analysis of claim 12 does not identify the combination of [²²⁸Th]barium stearate and the filtering basket as the precursor isotope source. Prelim. Resp. 22. We disagree with Patent Owner on this issue because Petitioner cites to its discussion of claim 1 when setting forth its claim 12 arguments. *See, e.g.*, Pet. 31 (citing Pet. § IV(B)(2)(4)). Thus, at this stage of the proceeding, we understand Petitioner’s arguments mapping Hassfjell-Hoff’s filtering basket to the precursor isotope source set forth for claim 1 also apply to Petitioner’s arguments relating to claim 12. The parties are free to address this issue at trial.

b) Dependent Claims 2–6, 8, 11, 13–17, and 19

Petitioner provides argument and evidence that claims 2–6, 8, 11, 13–17, and 19 are anticipated by Hassfjell-Hoff. Pet. 19–31, 33–39. Other than the arguments presented above, Patent Owner does not present any particularized argument directed to the challenged dependent claims. *See generally* Prelim. Resp.

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 Petitioner’s arguments that claims 2–6, 8, 11, 13–17, and 19 are unpatentable over Hassfjell-Hoff. *See* 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”).

D. Asserted Obviousness over Hassfjell-Hoff (Ground 2) and over Hassfjell-Hoff and O’Hara (Ground 3)

Petitioner argues that claims 5, 6, 10, 11, 15, 16, and 20 would have been obvious over Hassfjell-Hoff (Pet. 39–50) and that claims 9, 10, 18, and 20 would have been obvious over Hassfjell-Hoff and O’Hara (Pet. 50–56).

Other than the arguments presented above, Patent Owner does not present any particularized argument directed to the claims challenged in these grounds. *See* Prelim. Resp. 27 (asserting that Petitioner’s grounds 2 and 3 do not remedy the deficiencies identified 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 grounds 2 and 3. *See* 37 C.F.R. § 42.208.

E. Asserted Grounds for Claims 1–3, 8–10, 12, and 20 under 35 U.S.C. § 112

Petitioner argues that claims 1–3, 8–10, 12, and 20 are unpatentable under 35 U.S.C. § 112. Pet. 57–62. In particular, Petitioner argues that claims 1 and 12 are not enabled and lack written description (Pet. 57–58, 61), claims 2 and 3 are indefinite and not enabled (Pet. 58–59), claims 8 and 9 are indefinite for lack of antecedent basis (Pet. 60–61), claim 10 is indefinite and lacks written description (Pet. 61), and claim 20 is indefinite, non-enabled, and lacks written description. (Pet. 61–62). 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. We provide the following comments for guidance to the parties.

1. Claims 1 and 12

Claim 1 recites, *inter alia*,

exposing an interior surface of a container to a precursor isotope source by sliding a rod . . . 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.*

Ex. 1001, 21:45–55 (emphasis added). Claim 12 similarly recites, *inter alia*,

a precursor isotope source disposed on a rod, the rod configured to slide between an open position in which the precursor isotope is exposed to an interior surface of a container *to allow the precursor isotope source to decay into one or more*

progeny isotopes emanated into the container, 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.

Id. at 22:40–48.

Petitioner asserts that because the '603 patent discloses only one progeny isotope (^{220}Rn) in a gaseous form, the '603 patent only identifies *one* progeny isotope that both decays and *emanates* into the container. Pet. 57–58 (citing Ex. 1001, 18:25–27, 19:30–33, Fig. 1). Petitioner asserts that, as a result, the '603 patent does not enable or provide written description support for this feature of claim 1. *Id.*; *see also id.* at 61 (stating claim 12 is non-enabled and lacks written description support for the same reasons as claim 1).

Patent Owner responds that the diffusion of gaseous ^{220}Rn from the source to the walls of the container is *part* of the emanation of progeny isotopes to the walls of the container, but it is not the end of the process as ^{220}Rn decays into ^{216}Po , which decays into ^{212}Pb , and that this decay is also part of the emanation process. Prelim. Resp. 28–29. Patent Owner further notes that the '603 patent describes allowing time for ^{20}Rn , ^{216}Po , and/or ^{212}Pb to settle onto the inner walls of the container. *Id.* at 29–30 (citing, *inter alia*, Ex. 1001, 2:27–47, 13:64–14:25, 18:25–29; Ex. 1002 ¶¶ 82, 103).

At this stage of the proceeding, Patent Owner appears to have the better argument. Patent Owner's explanation that a POSITA would understand that the decay products of ^{220}Rn (e.g., ^{216}Po , ^{212}Pb) further emanate to the walls of the container and settle as ^{212}Pb appear to have merit. This issue, however, is best resolved on a full record.

2. Claim 2

Claim 2 recites:

2. The method of claim 1, 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).

Ex. 1001, 21:59–64. Petitioner argues that the wherein clause of claim 2 sets forth three alternative precursor isotopes to which the interior surface is exposed: (i) ^{228}Th , (ii) ^{224}Ra , and (iii) a combination of ^{228}Th and ^{224}Ra . Pet. 58–59. Petitioner asserts that the full scope of claim 2 is not enabled and is indefinite because “of these possibilities, (i) is not possible, because the radioactive decay of ^{228}Th into ^{224}Ra cannot be stopped or even slowed down, and therefore any ^{228}Th source must inherently include some portion of ^{224}Ra as would be apparent to a POSITA.” *Id.* at 59 (citing Ex. 1002 ¶ 153). Petitioner further contends that “the ‘further comprising’ portion of claim 2 renders the claim indefinite because under alternative (ii) there is no ^{228}Th , so it is not reasonably certain to a POSITA whether this claim requires allowing the (nonexistent) ^{228}Th to decay” and, “[u]nder alternative (ii), if the claim does require allowing ^{228}Th to decay, then it is not enabled.” *Id.* (citing Ex. 1002 ¶ 154).

At this stage of the proceeding, we have concerns about Petitioner’s argument. First, the claim recites a step that “comprises” exposing the interior of the container to certain isotopes. As Patent Owner notes, “comprising” is an open-ended term and the “exposing” limitation “is satisfied if any of the listed isotopes, including ^{228}Th are exposed to the container, regardless of what other isotopes (such as ^{224}Ra) might or might

not be present. Prelim. Resp. 32. Moreover, as Petitioner admits, a POSITA would understand that any ^{228}Th source inherently must include some portion of ^{224}Ra . Pet. 59. The parties are invited to address this issue during trial if they choose.

3. Claim 3

Claim 3 recites “[t]he method of claim 2, the method further comprising allowing the ^{212}Pb to deposit on the interior surface of the container.” Ex. 1001, 21:65–67. Petitioner argues that “the literal scope” of claim 2, which claim 3 depends from, “covers allowing ^{228}Th to decay into ^{220}Rn only, which is not possible.” Pet. 59. Petitioner further contends that, even “if it were possible, then no ^{212}Pb is present to be deposited on the interior surface of a container” and thus claim 3 is indefinite and non-enabled for reasons similar to those for claim 2. *Id.* (citing Ex. 1002 ¶¶ 155–156).

We have concerns about Petitioner’s argument for reasons similar to those for claim 2. The parties are invited to address this issue during trial if they choose.

4. Claims 8 and 9

Claims 8 and 9 both depend from claim 1. Claim 1 recites “allowing sufficient time for the precursor isotope to decay *into one or more progeny isotopes* and to emanate the one or more progeny isotopes into the container;” claim 8 recites “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;” and claim 9 recites “wherein allowing sufficient time for *the at least one*

progeny isotopes to emanate into the container from the precursor isotope source comprises allowing sufficient time for *the at least one progeny isotopes* to emanate into the container from 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.” Ex. 1001, 21:52–55, 22:17–30 (emphasis added).

Petitioner argues that there is no antecedent basis for *the at least one progeny isotopes* that emanate into a container recited in claims 8 and 9 and that it is not apparent “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.” *Id.* at 60–61 (citing Ex. 1002 ¶ 160).

Patent Owner responds that the antecedent basis for “the at least one progeny isotopes” of claims 8 and 9 is the “one or more progeny isotopes” recited in claim 1. *See, e.g.,* Prelim. Resp. 36–37; *see also id.* at 37 (noting that Petitioner’s own expert demonstrates a lack of ambiguity for these terms and citing Ex. 1002 ¶¶ 85–86, 138–140).

Based on the present record, we understand Petitioner’s argument to be that claims 8 and 9 are unpatentable under § 112 because these claims recite “the at least one progeny isotopes” as opposed to “at least one of the one or more progeny isotopes” and thus 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. *See* Pet. 60–61. Whether claims 8 and 9 are

indefinite for improper antecedent basis is best addressed on a full trial record.

5. *Claim 10*

Claim 10 depends from claim 1 and further requires that the “allowing sufficient time for the precursor isotope source to decay” recited in claim 1 “comprises allowing 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours.” Ex. 1001, 22:31–34.

Petitioner argues that this limitation should be construed to mean that allowing decay is inclusive and occurs for at least (i.e., equal to or more than) one of the listed times. Pet. 5. Petitioner further contends, however, that, “[t]o the extent that claim 10 is construed to require exactly one of the listed times, there is no written description support regarding how a POSITA would perform the method for exactly the listed times.” Pet. 61.

Patent Owner responds that no construction of this term is necessary, but that Petitioner’s § 112 arguments can be rejected “at least on the basis that the petition fails to address its own proposed understanding.” Prelim. Resp. 16. Patent Owner further argues that Petitioner concedes that its alternative construction (i.e., that the claim requires exactly one of the listed times), is not how a POSITA would understand the claim and that the Specification does not support such a construction. *Id.* at 37–38 (citing, *inter alia*, Ex. 1001, 12:16–24, Tables 3–4).

Whether claim 10 should be construed as requiring that precursor isotopes must decay for exactly one of the listed times, and whether there is written description support under such a construction, are issues best resolved on a full record.

Petitioner also argues that “[c]laim 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 (citing Ex. 1002 ¶ 161). Patent Owner responds that “neither of the petition’s alternative referents is correct—neither claim 10 nor claim 1, from which it depends, “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*.” Prelim. Resp. 38. These arguments also raise issues that are best resolved on a full record.

6. Claim 20

Claim 20 depends from claim 12 and recites “wherein 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.” Ex. 1001, 23:8–11.

Petitioner provides two constructions for claim 10. First, Petitioner asserts that the plain language requires that the precursor isotope must be configured such that it decays and emanates the progeny isotope for “exactly” the hours listed in the claim. Pet. 5. Petitioner argues that under this construction requiring exactly one of the listed times, the claim lacks written description support and is not enabled because a POSITA would not understand how to configure the precursor isotope source to decay and emanate the one or more progeny isotopes into a container for an exact time (*e.g.*, 10 hours).” *Id.* at 61–62 (citing Ex. 1002 ¶ 163).

Patent Owner responds that Petitioner’s first proposed construction improperly rewrites claim 20 to insert the word “exactly” before the list of recited claims. Prelim. Resp. 16. Patent Owner further asserts that this

construction should be rejected (1) “as legally erroneous (as the petition concedes), thereby rendering [Petitioner’s § 112 arguments] moot” and also because (2) “where the claim permits an operable construction, the inoperable construction is wrong.” *Id.* at 17, 39–40.

Patent Owner also argues that “even considered in isolation,” Petitioner’s § 112 arguments fail because the claimed time interval merely requires that the source is allowed “to decay *and* emanate the one or more progeny isotopes into the container.” Prelim. Resp. 40 (emphasis added). Patent Owner asserts that the specification teaches stopping emanation after any amount of time by simply moving the rod to the closed position and sealing off the precursor isotope source at the appropriate time.” *Id.* Patent Owner further argues that the ’603 patent Specification teaches performing a decay-and-emanation process for various intervals falling within the scope of claim 20. *Id.* at 40 (citing Ex. 1001, 12:16–24 as disclosing 5, 10, 20 hours or more and Ex. 1001, Tables 2–4 as disclosing 24, 48, 72, and 96 hours).

Petitioner also proposes a second claim construction for claim 20 and asserts that “[a]lternatively, this limitation should be construed to include a precursor isotope source that is configured such that it decays and emanates the one or more progeny isotopes for at least (or more than) one of the listed times.” Pet. 5.

At this stage of the proceeding, we adopt Petitioner’s proposed second construction because it appears undisputed by Patent Owner. *See* Prelim. Resp. 16–17, 39–40. However, this construction is preliminary. Whether claim 20 should be construed as requiring that precursor isotopes must decay and emanate one or more progeny isotopes into a container for

exactly one of the times recited, and whether the claim would be unpatentable under § 112 under such a construction, is best resolved on a full record.

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

Patent Owner also asserts that neither Dr. Hoff's nor Dr. Mirzadeh's declarations should be entitled to any weight because the declarations are conclusory and fail to provide meaningful analysis or explanation. Prelim. Resp. 41–43 (citing Ex. 1002 ¶ 39; Ex. 1017 ¶ 38). How much weight to give Dr. Hoff's and Dr. Mirzadeh's testimony are issues that are best resolved upon a full 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 1–6 and 8–20 of the '603 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 '603 Patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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