

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**AdvanCell Pty Ltd.**  
Petitioner

v.

**Sciencons AS**  
Patent Owner

Post Grant Review No.: PGR2025-00029

**PETITION FOR POST GRANT REVIEW OF  
U.S. PATENT NO. 12,125,603**

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| 1002        | Declaration of Saed Mirzadeh.                                                                                                                                                                                                                                                                                                      |
| 1003        | Hassfjell, Sindre P. and Hoff, Per, “A Generator for Production of $^{212}\text{Pb}$ and $^{212}\text{Bi}$ ”, Appl. Radiat. Isot., vol. 45, no. 10, pp 6-25 (1994) (“ <b>Hassfjell-Hoff</b> ”).                                                                                                                                    |
| 1004        | WorldCat Index for <b>Hassfjell-Hoff</b> .                                                                                                                                                                                                                                                                                         |
| 1005        | International Publication Number WO 01/60417.                                                                                                                                                                                                                                                                                      |
| 1006        | File History of U.S. Patent No. 12,125,603.                                                                                                                                                                                                                                                                                        |
| 1007        | US Patent Application Publication No. 2018/0047474 A1 (“ <b>O’Hara</b> ”).                                                                                                                                                                                                                                                         |
| 1008        | Hassan, Ahmed and Alnaser, Ibrahim Abdullah, “A Review of Different Manufacturing Methods of Metallic Foams” ACS Omega 2024 9 (6), 6280-6295 DOI: 10.1021/acsomega.3c08613 (“ <b>Hassan</b> ”).                                                                                                                                    |
| 1009        | Lefebvre, Louis-Philippe, Banhart, John, and Dunand, David C., “Porous Metals and Metallic Foams: Current Status and Recent Developments,” Advanced Engineering Materials, 10, September 9, pp. 775-787, 2008 <a href="https://doi.org/10.1002/adem.200800241">https://doi.org/10.1002/adem.200800241</a> , (“ <b>Lefebvre</b> ”). |
| 1010        | U.S. Patent Number 3,087,807.                                                                                                                                                                                                                                                                                                      |
| 1011        | “Radioisotopes,” International Atomic Energy Agency, <a href="https://www.iaea.org/topics/nuclear-science/isotopes/radioisotopes">https://www.iaea.org/topics/nuclear-science/isotopes/radioisotopes</a> (last accessed February 11, 2025).                                                                                        |
| 1012        | File History of U.S. Patent Application Serial No. 18/680,605.                                                                                                                                                                                                                                                                     |
| 1013        | File History of U.S. Patent Application Serial No. 18/680,372.                                                                                                                                                                                                                                                                     |
| 1014        | Hassfjell, Sindre, “A $^{212}\text{Pb}$ generator based on a $^{228}\text{Th}$ source”, Appl. Radiat. Isot., vol. 55, no. 4, pp 433-439 (2001) (“ <b>Hassfjell-2001</b> ”).                                                                                                                                                        |
| 1015        | U.S. Patent Number 6,592,843.                                                                                                                                                                                                                                                                                                      |
| 1016        | “O-Ring Handbook,” Parker Hannifin Corporation, <a href="https://www.hdslippers.com/cgi-bin/pdf/Catalogues/05-O-Ring-Handbook_ODE5705-EN%20Luglio%202015.pdf">https://www.hdslippers.com/cgi-bin/pdf/Catalogues/05-O-Ring-Handbook_ODE5705-EN%20Luglio%202015.pdf</a> (last accessed March 7, 2025).                               |
| 1017        | Declaration of Per Hoff.                                                                                                                                                                                                                                                                                                           |

| CHART OF CLAIMS                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| [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, wherein the precursor isotope source is disposed on the rod;                             |
| [1b] 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                                                                                                                                                                                                                                             |
| [1c] isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position.                                                                                                                                                                                                                                                                                              |
| [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 ( $^{228}\text{Th}$ ) and/or a radium 224 isotope ( $^{224}\text{Ra}$ ), the method further comprising allowing the $^{228}\text{Th}$ to decay into at least one of a radon 220 isotope ( $^{220}\text{Rn}$ ) and a lead 212 isotope ( $^{212}\text{Pb}$ ). |
| [3] The method of claim 2, the method further comprising allowing the $^{212}\text{Pb}$ to deposit on the interior surface of the container.                                                                                                                                                                                                                                                                                  |
| [4] The method of claim 1, wherein isolating the precursor isotope source from the container further comprises withdrawing the precursor isotope source into a chamber having a gas tight seal.                                                                                                                                                                                                                               |
| [5] The method of claim 4, wherein 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.                                                                                                                                                                                                            |
| [6] The method of claim 1, the method further comprising turning the container before exposing the interior surface to the precursor isotope.                                                                                                                                                                                                                                                                                 |
| [7] The method of claim 1, wherein exposing the interior surface of the container to the precursor isotope source exposing the interior surface of the container to the precursor isotope source without having the precursor isotope source touch the interior surface.                                                                                                                                                      |
| [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.                                                                                                                                         |
| [9] The method of claim 1, 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                                                                                                                                                                                 |

| CHART OF CLAIMS                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| 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.                                                                                                                                                                                           |
| [10] 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.                                                                                                                                                                                                                                                                      |
| [11] The method of claim 1, the method further comprising changing an orientation of the container before exposing the interior surface to the precursor isotope.                                                                                                                                                                                                                                                                                                      |
| [12] A system for generating radioisotopes, the system comprising:                                                                                                                                                                                                                                                                                                                                                                                                     |
| [12a] 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. |
| [13] The system of claim 12, wherein the precursor isotope source comprises a thorium 228 isotope ( $^{228}\text{Th}$ ) and/or a radium 224 isotope ( $^{224}\text{Ra}$ ), the one or more progeny isotopes comprising at least one of a radon 220 isotope ( $^{220}\text{Rn}$ ) and a lead 212 isotope ( $^{212}\text{Pb}$ ).                                                                                                                                         |
| [14] The system of claim 12, wherein, 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.                                                                                                                                                                                                                                                                    |
| [15] The system of claim 14, wherein the rod includes at least one O-ring to form the gas tight seal with the tube in the closed position.                                                                                                                                                                                                                                                                                                                             |
| [16] The system of claim 12, wherein the rod holds the precursor isotope source without having the precursor isotope source touch the interior surface.                                                                                                                                                                                                                                                                                                                |
| [17] The system of claim 12, wherein the precursor isotope source is encapsulated in a gas permeable barrier.                                                                                                                                                                                                                                                                                                                                                          |
| [18] The system of claim 12, wherein the precursor isotope source is disposed on a sponge, a wool, a strip, or a sphere comprising at least one material selected from the list consisting of: quartz, glass, mineral, paper, plastic, metal, ceramic, natural fibers, and synthetic fibers.                                                                                                                                                                           |
| [19] The system of claim 13, further comprising the container, wherein the interior surface of the container is configured to allow the $^{212}\text{Pb}$ to deposit on the interior surface.                                                                                                                                                                                                                                                                          |

| <b>CHART OF CLAIMS</b> |
|------------------------|
|------------------------|

|                                                                                                                                                                                                                                      |
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| [20] The system of claim 12, 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. |
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## I. INTRODUCTION

AdvanCell Pty Ltd. (“Petitioner”) hereby petitions for post-grant review of claims 1-20 (“Challenged Claims”) of U.S. Patent No. 12,125,603 (EX1001, “the 603 patent”).

Petitioner certifies that the 603 patent is available for post-grant review and that Petitioner is not barred or estopped from requesting a post-grant review (“PGR”) challenging the patent claims on the grounds identified in this Petition. *See* 37 C.F.R. §42.201.

Petitioner is filing this Petition within nine months of the 603 patent’s issue date (October 22, 2024), and this Petition is therefore timely. *See* 37 C.F.R. §42.202.

The 603 patent is eligible for PGR because its earliest priority date claimed is December 5, 2019. *See* AIA §3(n)(1).

## II. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner requests cancellation of claims 1-20 of the 603 patent in view of the following grounds:

| Ground | Claims                | Stat. Basis | Prior Art                 |
|--------|-----------------------|-------------|---------------------------|
| 1      | 1-8, 11-17, 19        | 102         | Hassfjell-Hoff            |
| 2      | 5-7, 10-11, 15-16, 20 | 103         | Hassfjell-Hoff            |
| 3      | 9-10, 18, 20          | 103         | Hassfjell-Hoff and O’Hara |

| Ground | Claims               | Stat. Basis | Prior Art |
|--------|----------------------|-------------|-----------|
| 4      | 1-3, 7-10,<br>12, 20 | 112         |           |

### III. THE 603 PATENT

#### A. Overview of the 603 patent

The 603 patent describes a method and a system for producing highly purified  $^{212}\text{Pb}$ , a radioactive isotope utilized in targeted alpha therapy for cancer treatment. EX1001, cls. 1, 12, 9:64-67. The process involves isolating and purifying  $^{212}\text{Pb}$  from mixtures containing other isotopes through a specific decay chain that begins with  $^{228}\text{Th}$ . EX1001, FIG. 1. The resulting  $^{212}\text{Pb}$  is intended for use in producing radiopharmaceuticals, enhancing the effectiveness of cancer therapies. EX1001, 17:18-21. The earliest claimed priority date for this patent is December 5, 2019. EX1001, cover. EX1002, ¶¶29-30.

#### B. Overview of the 603 patent's File History

The examiner never issued a rejection based on the prior art in this Petition. EX1006. EX1002, ¶¶31-32.

#### C. Person of Ordinary Skill in the Art

A person of ordinary skill in the art at the time of the alleged invention of the 603 patent (December 5, 2019) (“POSITA”) 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. Additional graduate education could substitute for professional experience, and significant experience in the field could substitute for formal education. EX1002, ¶33. EX1017, ¶27.

**D. Claim Construction**

The Challenged Claims are interpreted using the same claim construction standard that is used to construe the claims in a civil action in federal district court. 37 C.F.R. §42.100(b). Petitioner does not contend that its proposed constructions are complete constructions of these limitations or the claims for any other purpose, including for issues that may be raised in a future litigation. Because the prior art asserted herein discloses the preferred embodiment within the indisputable scope of the claims, the Board need not construe the outer bounds of the claims as part of these proceedings. Any claim terms not listed below should be construed according to their plain and ordinary meaning to a POSITA at the time of the 603 patent. EX1002, ¶34.

**1. “disposed on the rod” (claim 1)**

This limitation should be construed to include directly or indirectly attaching to the rod. The 603 patent specification describes attaching the isotopes indirectly to the rod using a strip or sphere:

In one or more embodiments of the invention a strip or sphere is attached to the second part, which comprises means for holding the strip or sphere, such as a rod.

In one or more embodiments of the invention the second part comprises a syringe, or wherein the rod is the syringe.

....

The  $^{212}\text{Pb}$  isotope source can be deposited on a strip, sphere or a rod which is made of material that is selected from the group consisting of paper, plastic, metal, ceramic, and natural or synthetic fibers. The strip or sphere can be attached to the second part or be contained or comprised in the second parts, which comprises means for holding the strip or sphere. Such means can for example be a rod.

EX1001, 3:54-58, 8:58-65. EX1002, ¶35.

2. **“wherein exposing the interior surface of the container to the precursor isotope source exposing the interior surface of the container to the precursor isotope source without having the precursor isotope source touch the interior surface.”** (claim 7)

As explained in §VII(D), the words of this claim are nonsensical. Petitioner anticipates Patent Owner proposes that this claim should be re-written as:

wherein exposing the interior surface of the container to the precursor isotope source [**comprises**] exposing the interior surface of the container to the precursor isotope source without having the precursor isotope source touch the interior surface.”

EX1002, ¶¶36-37.

3. **“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)

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. EX1002, ¶38.

4. **“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)

The plain language requires the precursor isotope source must be configured such that it decays and emanates the one or more progeny isotopes for exactly 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours. *See Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) (“in accord with our settled practice we construe the claim as written, not as the patentees wish they had written it.”). Alternatively, 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. EX1002, ¶39.

#### **IV. GROUND 1: CLAIMS 1-8, 11-17, 19 ARE ANTICIPATED BY HASSFJELL-HOFF**

##### **A. Hassfjell-Hoff**

Hassfjell-Hoff is a journal article published in 1994 and entitled “A Generator for Production of  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ .” EX1003, 1-6. Hassfjell-Hoff was

included in volume 45, number 10, of the “Applied Radiation and Isotopes” Journal (EX1003, 5 (Contents)), which was published in October 1994. EX1003, 1 (cover page); EX1004. Volume 45, number 10, of the “Applied Radiation and Isotopes” Journal was assigned ISSN 0969-8043 (EX1003, 5) and was received by the University of Wisconsin’s Health Sciences Library on November 11, 1994. EX1003, 1 (cover page). As such, Hassfjell-Hoff was published and available to the public no later than November 11, 1994. EX1003, 1. EX1002, ¶¶40. EX1017, ¶¶29-31.

Hassfjell-Hoff was publicly accessible and indexed as a publication in public catalogs such as *e.g.*, the WorldCat index. EX1004. As further evidence of its public accessibility, Hassfjell-Hoff was cited in an International Patent Application including inventor Roy Larsen (same inventor as the 603 patent) directed to analogous art that published on August 23, 2001, which proves both that (i) Hassfjell-Hoff was published to those of skill in the art at least as early as that date, and (ii) which itself serves as an index for Hassfjell-Hoff. EX1005, 10:17-18; *see also* EX1015, 7:67-8:1, 13:39-41. A POSITA would have understood that journals (*e.g.*, EX1003) and published patent applications (*e.g.*, EX1005) are reliable sources for information and would have been capable of accessing them well before the alleged filing date of the 603 patent. Accordingly, Hassfjell-Hoff

qualifies as prior art under 35 U.S.C. §102(a) (post-AIA). There is no evidence that any of the 35 U.S.C. §102(b) exceptions apply. EX1002, ¶41.

Hassfjell-Hoff discloses a radioisotope generator for the production of  $\alpha$ -emitting radionuclides. EX1003, 6. Figures 2 and 3 show the disclosed generator:

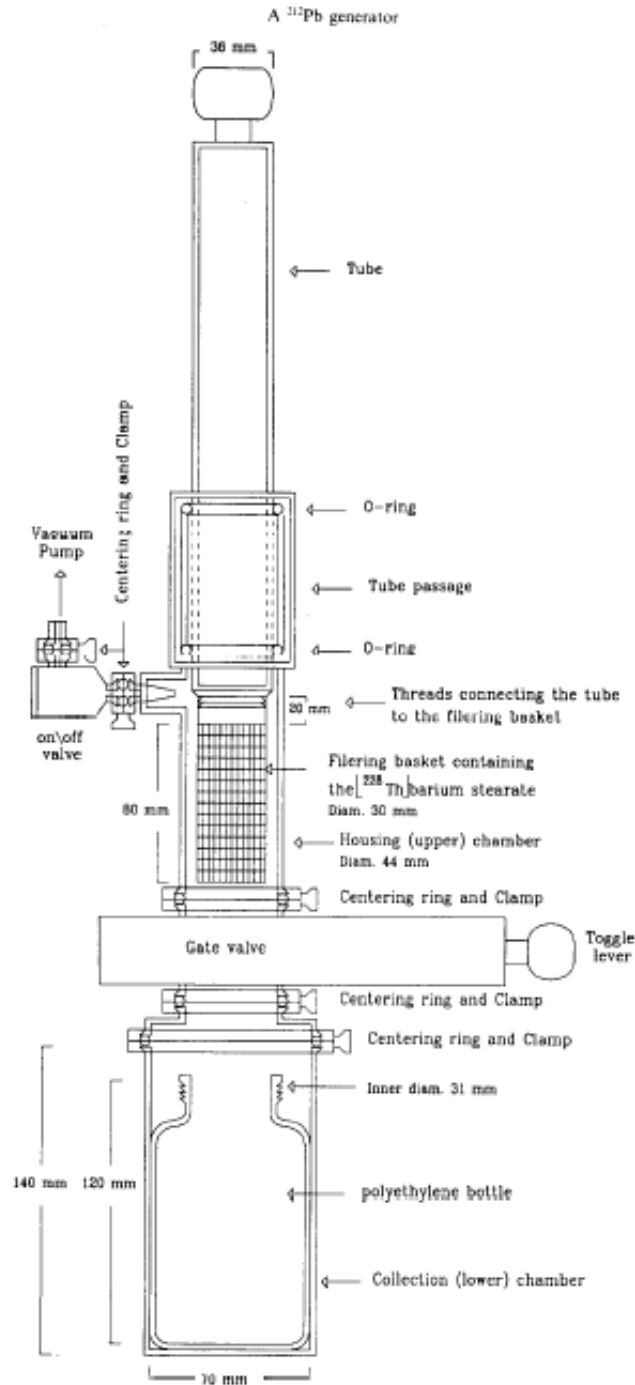


Fig. 2. The design of the generator showing functional details and operating mechanism.

EX1003, Fig. 2.

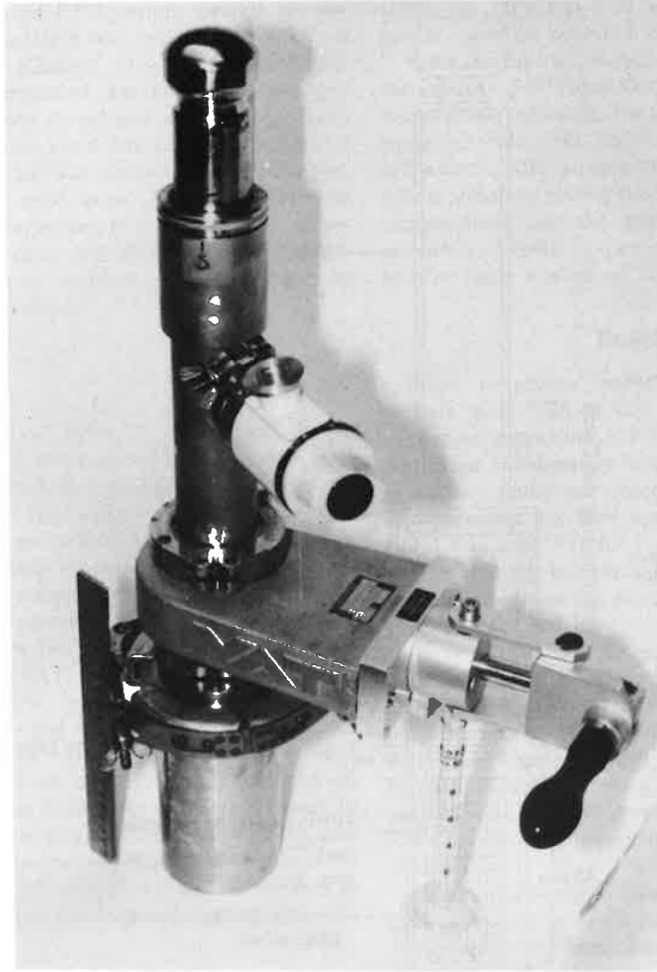


Fig. 3. A picture of the generator.

EX1003, Fig. 3. “The generator is based on the emanation of  $^{220}\text{Rn}$  from  $[\text{}^{228}\text{Th}]$ barium stearate.” EX1003, 6. The decay product of  $^{220}\text{Rn}$ , which is  $^{212}\text{Pb}$ , is deposited on the walls of a polyethylene bottle and can be washed off with distilled water. EX1003, 6. Hassfjell-Hoff discloses the construction of the generator shown in figures 2 and 3:

All generator parts were made of stainless steel, and connected to standard high vacuum equipment to avoid leakage of radioactivity to the surroundings. 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 [ $^{228}\text{Th}$ ]barium stearate are placed in a filering basket<sup>1</sup> mounted by threads to the end of a long tube closed in both ends.... The tube can slide on two O-rings, thus facilitating the filering basket to move between the two chambers, through the gate valve.

EX1003, 7. “[A] polyethylene bottle is placed inside the collection chamber” to collect the emanated  $^{212}\text{Pb}$ . EX1003, 7. Hassfjell-Hoff discloses how the generator was operated:

When the tube is lowered, the filering basket with the emanating [ $^{228}\text{Th}$ ]barium stearate becomes positioned inside the bottle. The decay products from the emanated  $^{220}\text{Rn}$ ,  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ , deposit on the walls of the bottle. After an appropriate collection time, the tube is pulled up, placing the  $^{228}\text{Th}$  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.

EX1003, 7. EX1002, ¶42. EX1017, ¶32.

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<sup>1</sup> Throughout Hassfjell-Hoff, the document refers to a “filering basket.” A “filering” is a Norwegian word that means a lace-like material. EX1002, ¶fn. 1; EX1017, fn. 1.

The [ $^{228}\text{Th}$ ]barium stearate packets are made using conventional means by taking [ $^{228}\text{Th}$ ]barium stearate precipitated from a solution, filtering it onto a filter membrane and washing it with methanol. EX1003, 6-7. The filter membrane with the precipitate is then folded and wrapped up into two additional filters to avoid any loss of [ $^{228}\text{Th}$ ]barium stearate. EX1003, 7. The packets are then secured with plastic strips. EX1003, 7. EX1002, ¶43. EX1017, ¶33.

Hassfjell-Hoff is analogous art to the 603 patent and was not considered during prosecution of the 603 patent. EX1001; EX1006. Hassfjell-Hoff is not cumulative of the other prior art considered during prosecution of the 603 patent. EX1006. Though Hassfjell-2001, a different article by the same author, was cited during prosecution, it is materially different from Hassfjell-Hoff. *Compare* EX1014 *with* EX1003. Hassfjell-2001 discloses a radioisotope generator that includes a bubbler where  $^{220}\text{Rn}$  is collected by passing dry air continuously through a cage, carrying emanated  $^{220}\text{Rn}$  out of the cage and into a glass bubbler. EX1014, 3, Fig. 1. In contrast, Hassfjell-Hoff discloses that 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. EX1003, 7. Though Hassfjell-Hoff was cited during the prosecution of related patents, the pending claims in the related patents are materially different from the 603 patent claims. EX1012; EX1013. Moreover, as

shown below, it was material error for the 603 patent claims to issue over Hassfjell-Hoff. EX1002, ¶¶44-47.

**B. Claim 1**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. EX1002, ¶¶48-57. EX1017, ¶¶29-38.

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

Hassfjell-Hoff discloses a method of generating radioisotopes. EX1003, 6-7 (“Materials and Methods”).

A generator has been developed for the production of the  $\alpha$ -emitting radionuclide  $^{212}\text{Bi}$  and its parent nuclide  $^{212}\text{Pb}$ . The generator is based on the emanation of  $^{220}\text{Rn}$  from [ $^{228}\text{Th}$ ]barium stearate. The decay product of  $^{220}\text{Rn}$ ,  $^{212}\text{Pb}$  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.

EX1003, Abstract.

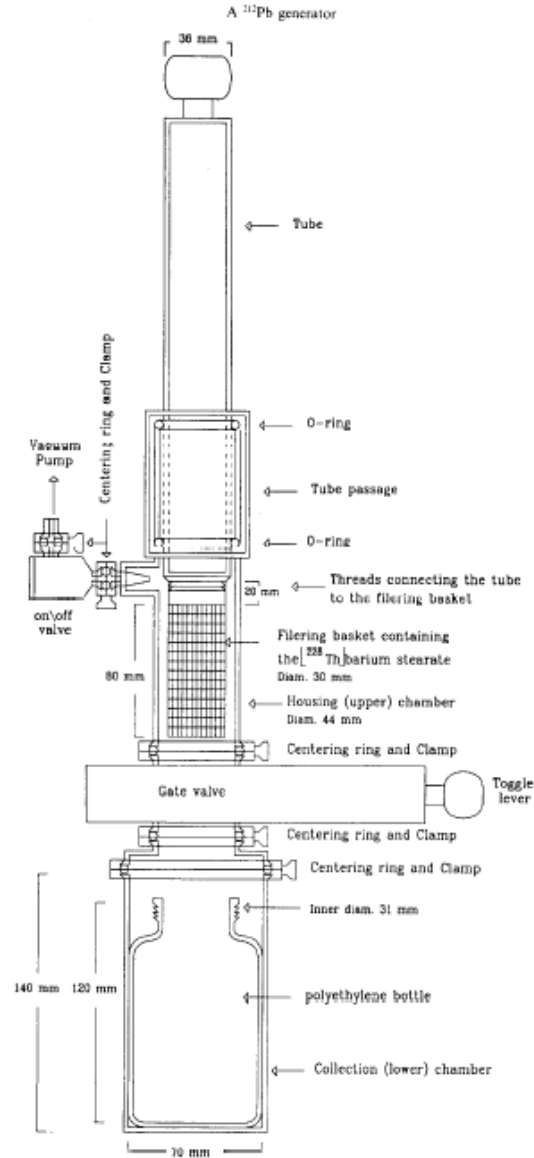


Fig. 2. The design of the generator showing functional details and operating mechanism.

EX1003, Fig. 2. EX1002, ¶¶49. EX1017, ¶¶29-38.

2. [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

Hassfjell-Hoff discloses this limitation. EX1002, ¶¶50-53. EX1017, ¶¶29-38.

Hassfjell-Hoff discloses that the system for producing radioisotopes includes a *precursor isotope source* (i.e., packet of [ $^{228}\text{Th}$ ]barium stearate). See EX1003, Abstract, 7, Fig. 2. Figure 1 of Hassfjell-Hoff also discloses the decay mode of the  $^{228}\text{Th}$  to the therapeutically-desired  $^{212}\text{Pb}$ , including intermediate and subsequent isotopes.

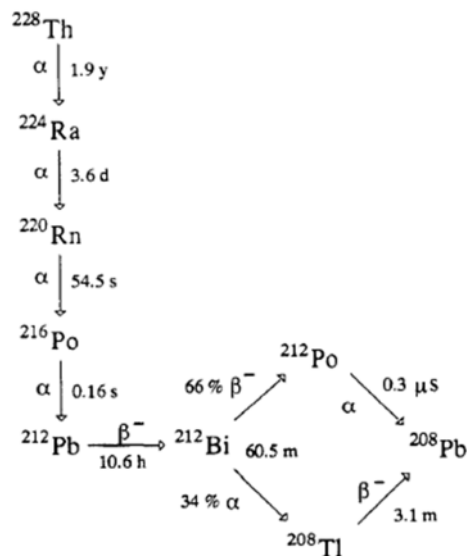


Fig. 1. The decay mode of  $^{228}\text{Th}$  to stable  $^{208}\text{Pb}$ .

EX1003, Fig. 1. EX1002, ¶51. EX1017, ¶¶29-38.

Hassfjell-Hoff discloses the operation of *exposing an interior surface of a container* (i.e., the inside of the “polyethylene bottle”) *to a precursor isotope source* (i.e., packet of [ $^{228}\text{Th}$ ]barium stearate) *by sliding a rod* (i.e., tube slidably coupled to a collection chamber and a housing) *from a closed position in which the precursor isotope source 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 source is exposed to the interior surface of the container* (i.e., when the gate valve is open and the tube is pushed down):

The generator was made with two compartments, a lower compartment which is a collection chamber and an upper compartment which is a housing for the source when the collection chamber is removed. These two compartments are connected via a gate valve (VAT). The packets of [ $^{228}\text{Th}$ ]barium stearate are placed in a filering basket mounted by threads to the end of a long tube closed in both ends. The filering basket has a capacity of 3-4 [ $^{228}\text{Th}$ ]barium stearate packets. The tube can slide on two O-rings, thus facilitating the filering 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  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ , a polyethylene bottle is placed inside the collection chamber.

When the tube is lowered, the filering basket with the emanating [ $^{228}\text{Th}$ ]barium stearate becomes positioned inside the bottle. The decay products from the emanated  $^{220}\text{Rn}$ ,  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ , deposit on

the walls of the bottle. After an appropriate collection time, the tube is pulled up, placing the  $^{228}\text{Th}$  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.

EX1003, 7. Hassfjell-Hoff discloses exposing an interior surface of the polyethylene bottle to a precursor isotope source of [ $^{228}\text{Th}$ ]barium stearate when the tube is lowered so that the filtering basket becomes positioned inside the bottle.

EX1003, 7. The tube/basket is lowered from a *closed position* where the  $^{228}\text{Th}$  is not positioned inside the bottle to an *open position* where the  $^{228}\text{Th}$  is positioned inside the bottle and exposed to the *interior surface of a container*. There 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. Instead, claim 1 is silent as to the step in which the precursor isotope source is “*sealed off*”—it is a *comprising* claim that does not preclude additional actions being required to create the seal. Thus, a POSITA would have understood that Hassfjell-Hoff discloses that its rod is moved from a *closed position* where the  $^{228}\text{Th}$  is *sealed off* to an open position by *sliding a rod*. EX1002, ¶¶52-53. EX1017, ¶¶29-38.

**3. [1b] wherein the precursor isotope source is disposed on the rod**

Hassfjell-Hoff discloses this limitation. See §III(D)(1) (construction).

Hassfjell-Hoff states “[t]he packets of [ $^{228}\text{Th}$ ]barium stearate are placed in a filtering basket mounted by threads to the end of a long tube closed in both ends.

The filering basket has a capacity of 3-4 [ $^{228}\text{Th}$ ]barium stearate packets.” EX1003, 7. Thus, the packets of [ $^{228}\text{Th}$ ]barium stearate, which comprise the [ $^{228}\text{Th}$ ]barium stearate precipitate (*i.e.*, *precursor isotope source*) in the Hassfjell-Hoff isotope generator, are attached (*i.e.*, *disposed*) to the long tube (*i.e.*, *rod*). See EX1003, 7, Fig. 2. As such, Hassfjell-Hoff teaches that the *precursor isotope source is disposed on the rod*. Alternatively, and additionally, the combination of the [ $^{228}\text{Th}$ ]barium stearate packets and basket is the *source* of the precursor isotope in Hassfjell-Hoff, and those are directly connected to the rod. See EX1003, 7, Fig. 2. EX1002, ¶54. EX1017, ¶¶29-38.

**4. [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**

Hassfjell-Hoff discloses this limitation. Hassfjell-Hoff states:

When the tube is lowered, the filering basket with the emanating [ $^{228}\text{Th}$ ]barium stearate becomes positioned inside the bottle. The decay products from the emanated  $^{220}\text{Rn}$ ,  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ , deposit on the walls of the bottle. After an appropriate collection time, the tube is pulled up, placing the  $^{228}\text{Th}$  source in the upper compartment, and the gate valve is closed.

EX1003, 7. Hassfjell-Hoff thus references a *sufficient time* (*i.e.*, an appropriate collection time) *for the precursor isotope source* (*i.e.*, the [ $^{228}\text{Th}$ ]barium stearate) *to decay into one or more progeny isotopes and to emanate the one or more progeny isotopes* (*i.e.*,  $^{220}\text{Rn}$ ) *into the container* (*i.e.*, the decay products from the

emanated  $^{220}\text{Rn}$ , which are  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ , deposit on the walls of the bottle).

EX1003, 7. As such, Hassfjell-Hoff teaches 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. EX1002, ¶¶55-56. EX1017, ¶¶29-38.

**5. [1d] isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position.**

Hassfjell-Hoff discloses this limitation. Hassfjell-Hoff teaches that *the precursor isotope source (i.e., packet of [ $^{228}\text{Th}$ ]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., tube is pulled up and gate valve is closed)*. EX1003, 7 (“After an appropriate collection time, the tube is pulled up, placing the  $^{228}\text{Th}$  source in the upper compartment, and the gate valve is closed.”), (“The generator was made with two compartments, a lower compartment which is a collection chamber and an upper compartment which is a housing for the source when the collection chamber is removed.”), Fig. 2. EX1002, ¶57. EX1017, ¶¶29-38.

- C. Claim 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 ( $^{228}\text{Th}$ ) and/or a radium 224 isotope ( $^{224}\text{Ra}$ ), the method further comprising allowing the  $^{228}\text{Th}$  to decay into at least one of a radon 220 isotope ( $^{220}\text{Rn}$ ) and a lead 212 isotope ( $^{212}\text{Pb}$ ).”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §IV(B) (claim 1). Hassfjell-Hoff discloses:

When the tube is lowered, the filtering basket with the emanating [ $^{228}\text{Th}$ ]barium stearate becomes positioned inside the bottle. The decay products from the emanated  $^{220}\text{Rn}$ ,  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ , deposit on the walls of the bottle.

EX1003, 7. Hassfjell-Hoff also discloses the overall decay chain from  $^{228}\text{Th}$  to  $^{224}\text{Ra}$  to  $^{220}\text{Rn}$  to  $^{216}\text{Po}$  to  $^{212}\text{Pb}$ . EX1003, 7, Fig. 1. Thus, the *interior surface* of the container is exposed to  $^{228}\text{Th}$ , which is allowed to decay into gaseous  $^{220}\text{Rn}$  and thereafter solid  $^{212}\text{Pb}$ . EX1002, ¶¶58-60. EX1017, ¶¶29-39.

- D. Claim 3 “The method of claim 2, the method further comprising allowing the  $^{212}\text{Pb}$  to deposit on the interior surface of the container.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §§IV(B)-(C) (claims 1-2). Hassfjell-Hoff discloses “The decay products from the emanated  $^{220}\text{Rn}$ ,  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ , deposit on the walls of the bottle.” EX1003, 7. A POSITA would have understood that “the walls of the

bottle” correspond to the *interior surface of the container*. EX1002, ¶¶61-63.

EX1017, ¶¶29-40.

**E. Claim 4 “The method of claim 1, wherein isolating the precursor isotope source from the container further comprises withdrawing the precursor isotope source into a chamber having a gas tight seal.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §IV(B) (claim 1). Hassfjell-Hoff discloses:

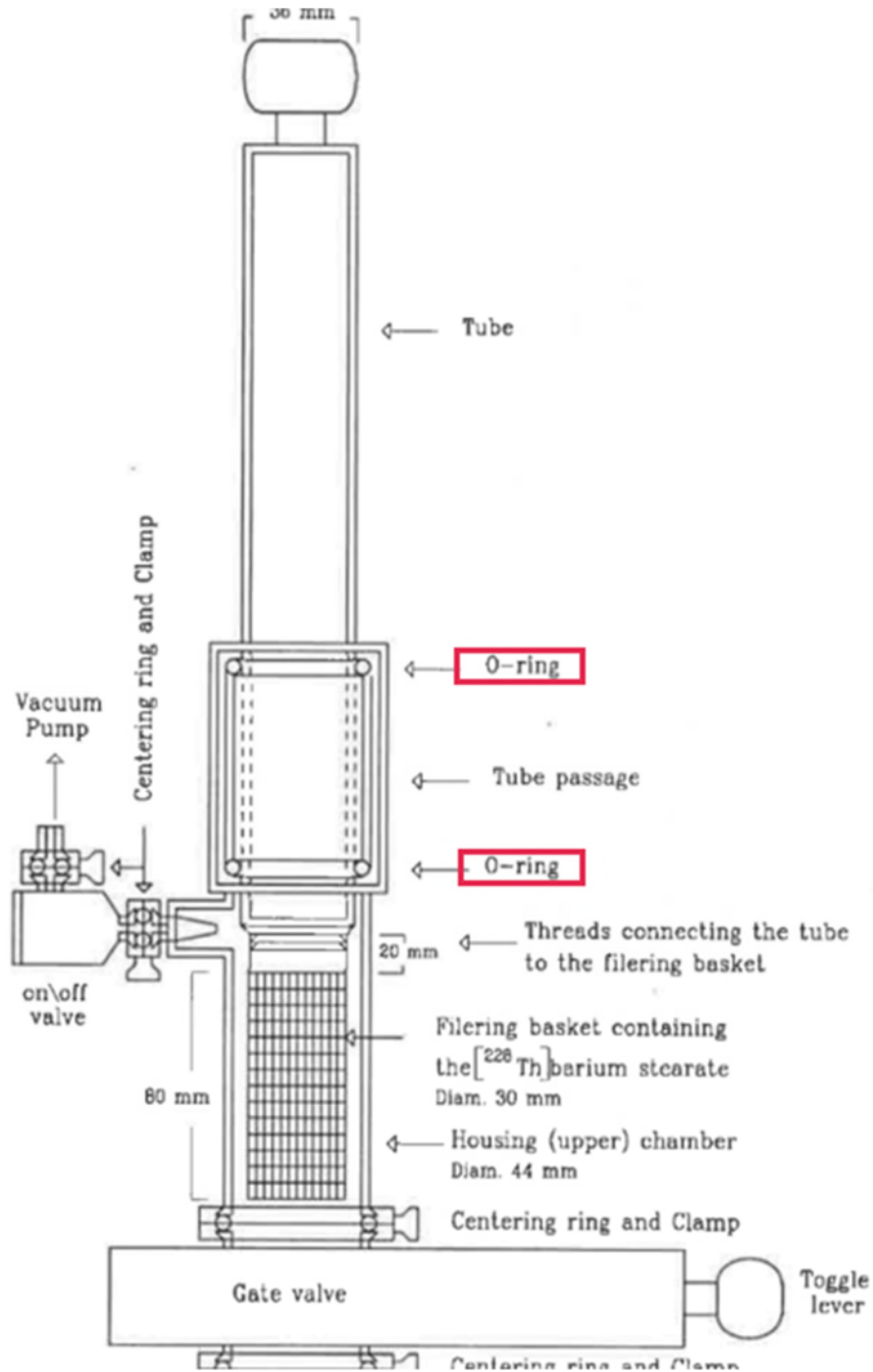
The generator was made with two compartments, a lower compartment which is a collection chamber and an upper compartment which is a housing for the source when the collection chamber is removed. These two compartments are connected via a gate valve (VAT).

EX1003, 7. The generator is “connected to standard high vacuum equipment to avoid leakage of radioactivity to the surroundings.” EX1003, 7. Hassfjell-Hoff further discloses “[a]fter an appropriate collection time, the tube is pulled up, placing the <sup>228</sup>Th source in the upper compartment, and the gate valve is closed.” EX1003, 7. Thus, the tube on which the precursor isotope is disposed is pulled up (*i.e.*, the precursor isotope source is withdrawn) into the upper compartment. Also, Hassfjell-Hoff discloses that “[d]espite the relatively strong <sup>228</sup>Th source, no detectable leakage of any kind of radioactivity out of the generator has been observed.” EX1003, 7. Because a radiation leak would occur via emanated gaseous <sup>220</sup>Rn, a POSITA would have understood that closing the gate valve forms a *gas*

*tight seal* between the upper compartment (*i.e.*, the housing *chamber*) and the lower compartment (*i.e.*, the collection *chamber*). EX1002, ¶¶64-67. EX1017, ¶¶29-38, 41-42.

**F. Claim 5 “The method of claim 4, wherein 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.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §§IV(B), (E) (claims 1, 4). As shown below in Figure 2, Hassfjell-Hoff’s tube extends through a larger-diameter tube passage that extends from the top end of the upper chamber. Hassfjell-Hoff discloses two O-rings interposed against the exterior surface of the tube and an interior surface of a larger-diameter tube passage. See EX1003, 7, Fig. 2. Hassfjell-Hoff’s O-rings permit the lower end of the tube to slide axially through the upper chamber and into the collection chamber, while sealing the space defined between the tube’s exterior surface and the larger-diameter tube passage’s interior surface. Being attached to the lower end of the tube, the filtering basket containing the [<sup>228</sup>Th]barium stearate moves with the tube from an “up” position to a “lowered” position. EX1003, 7.

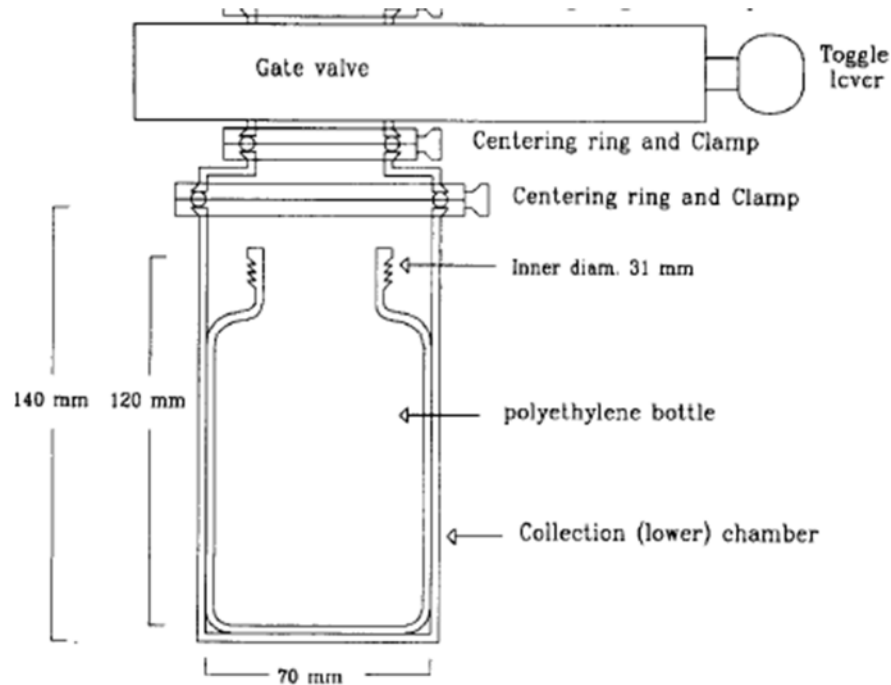


EX1003, Fig. 2. When Hassfjell-Hoff's tube is set in the "up" position, the filer basket containing the  $[^{228}\text{Th}]$ barium stearate is withdrawn inside the housing (upper) chamber. EX1003, Fig. 2. Hassfjell-Hoff discloses that the ring forms a

gas-tight seal. EX1003, Abstract (“The generator shows no leakage of any long-lived parent nuclides, is easy to operate and has a high degree of radiation safety.”), 6 (“enclosing the [ $^{228}\text{Th}$ ]barium stearate in a gas-tight collection chamber” was the known “simpler and better approach to collect[ion]”). A POSITA would have understood that *sealing the rod within a tube using an O-ring to form the gas tight seal between the rod and the tube* was necessary to prevent the escape of any gas from the chamber containing the filtering basket that contains  $^{228}\text{Th}$  and which emanates gaseous  $^{220}\text{Rn}$ . For example, Hassfjell-Hoff describes that it is known to enclose [ $^{228}\text{Th}$ ]barium stearate in a gas-tight collection chamber in order to collect  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ . EX1003, 6. A POSITA would have understood that if the O-ring of Hassfjell-Hoff did not form a gas-tight seal, then at least some gaseous  $^{220}\text{Rn}$  would diffuse past the space between the tube passage and the tube, creating unacceptable risks for any person in the vicinity of the radioisotope generator. EX1003, Fig. 2. A POSITA would have understood that the O-ring forms a gas tight seal because “[d]espite the relatively strong  $^{228}\text{Th}$  source, no detectable leakage of any kind of radioactivity out of the generator has been observed.” EX1003, 7. EX1002, ¶¶68-71. EX1017, ¶¶29-38, 41-44.

**G. Claim 6 “The method of claim 1, the method further comprising turning the container before exposing the interior surface to the precursor isotope.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. *See* §IV(B) (claim 1). Because this claim requires turning the container before exposing the interior surface, the 603 patent disclosure of picking up the bottle and turning it before putting on its cap corresponds to this claim. EX1001, 9:58-64, 10:7-19, 10:41-44. This claim limitation is so broad that it covers a technician at any time before placing Hassfjell-Hoff’s bottle in the collection chamber: removing the bottle’s lid (turning a bottle relative to a lid), rotating the bottle when placing it on a shelf, rotating the bottle when removing it from the box, or rotating the bottle during bottle manufacture. Hassfjell-Hoff does not explicitly disclose that the method further comprises the step of turning the container before exposing the interior surface (of the container) to the precursor isotope. However, Hassfjell-Hoff depicts that the container is a polyethylene bottle:



EX1003, Fig. 2. Figure 2 shows the bottle is a polyethylene bottle that has threads at the top and which has an inner diameter of 31 mm. EX1003, Fig. 2. A POSITA would have understood that the bottle is round (by virtue of it having a diameter) and is intended to be affixed to other articles (*e.g.*, a lid, etc.) by being *turned* and thereby screwed to whichever article is to be used. A POSITA would have understood that the polyethylene bottle would have had a lid on it before use to ensure that no contaminants are in the bottle before use. Because the container relative to its lid must be *turned* (for example, to remove the lid) *before* being placed within the collection (lower) chamber depicted by Hassfjell-Hoff, this limitation is disclosed. EX1002, ¶¶72-76. EX1017, ¶¶29-38, 45-47.

**H. Claim 7 “The method of claim 1, wherein exposing the interior surface of the container to the precursor isotope source exposing the interior surface of the container to the precursor isotope source without having the precursor isotope source touch the interior surface.”**

As explained in §VII(D), this claim is indefinite and nonsensical. In this section, Petitioner addresses this claim under an anticipated claim construction argument. *See* §III(D)(2) (construction). EX1002, ¶¶77-78.

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. *See* §IV(B) (claim 1). Figure 2 discloses that, based on the dimensions shown, the radioisotope generator is designed to prevent the precursor isotope source from touching the interior surface:

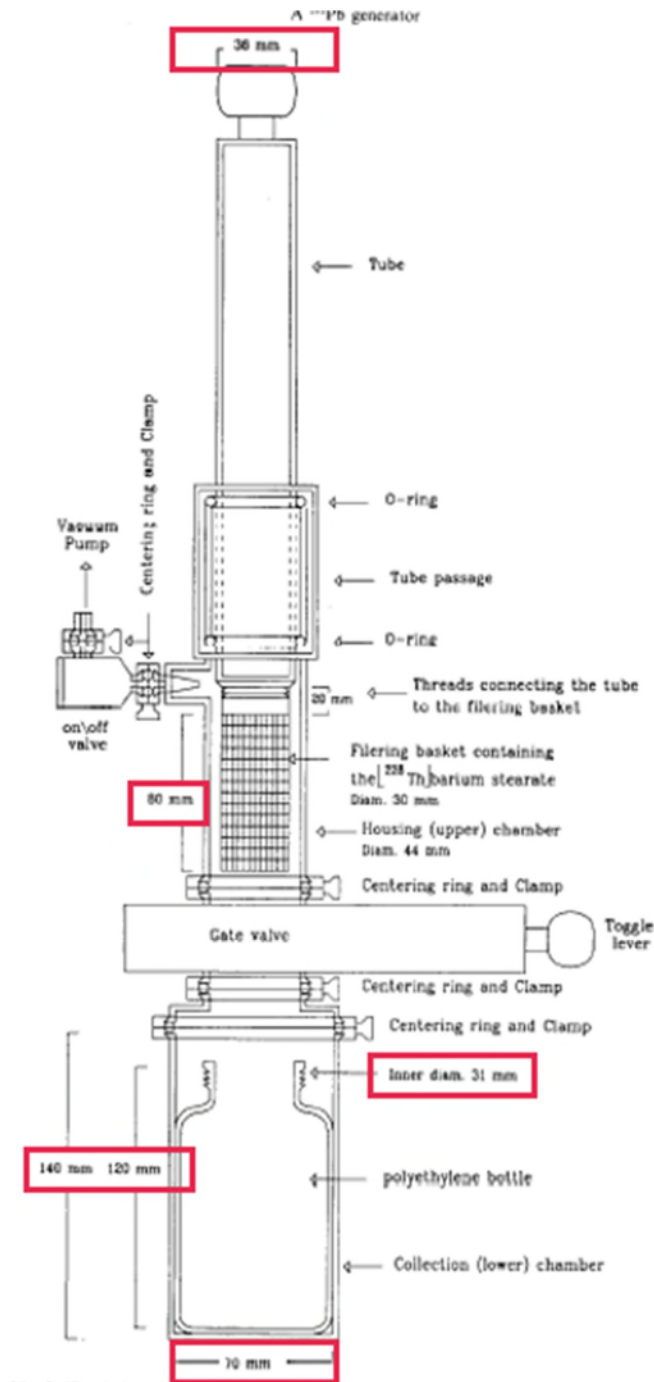


Fig. 2. The design of the generator showing functional details and operating mechanisms.

EX1003, Fig. 2. Figure 2 of Hassfjell-Hoff depicts that the filing basket is connected to the rod (*i.e.*, tube) by threads. EX1003, Fig. 2. The threads are positioned at the bottom end of the tube. EX1003, Fig. 2. The tube has a diameter

of 36 mm based on the label on the handle that is at the top of the tube. EX1003, Fig. 2. The inner diameter of the mouth of the polyethylene bottle is 31mm.

EX1003, Fig. 2. The filering basket containing the [<sup>228</sup>Th]barium stearate has a diameter of 30 mm and a height of 80 mm, and the polyethylene bottle has a height of 120 mm. EX1003, Fig. 2. Based on these dimensions, when the tube is pushed down to lower the filering basket the diameter of the filering basket (*i.e.*, 30mm) is smaller than the inner diameter of the neck of the polyethylene bottle (*i.e.*, 31mm).

EX1003, Fig. 2. The tube slides on two O-rings, which are described in Figure 2 as “centering rings.” EX1003, Fig. 2, 7. As shown in Hassfjell-Hoff, the polyethylene bottle is held in the center of the collection (lower) chamber which prevents it from moving side to side. EX1003, Fig. 2. The tube passage and O-rings are aligned by the housing with the centering ring and clamp, gate valve, and the collection (lower) chamber. EX1003, Fig. 2. A POSITA would have understood that the disclosure of the “centering ring and clamp” and the inner diameter of the neck of the polyethylene bottle (31 mm) that is greater than the diameter of the filering basket (30 mm) signifies that the filering basket is able to enter the polyethylene bottle without touching the sides. Also, a POSITA would have understood that the filering basket will stop being lowered at the neck of the bottle before touching the bottom of the polyethylene bottle. The filering basket has a height of 80 mm which is shorter than the 120 mm height of the polyethylene bottle and a diameter of 30

mm which is smaller than the 70 mm diameter of the polyethylene bottle and the 31 mm inside diameter of the neck of the polyethylene bottle. EX1003, Fig. 2. In addition, a POSITA would have understood that the purity of the emanated  $^{212}\text{Pb}$  is ensured by preventing the precursor isotope source from touching the interior surface of the container. EX1003, 8, Fig. 2. Taken together, this discloses the claim feature where the precursor isotope source (*i.e.*, the [ $^{228}\text{Th}$ ]barium stearate contained in the filering basket) does not touch any interior surface of the container (*i.e.*, any interior wall or the bottom of the polyethylene bottle). EX1002, ¶¶79-82. EX1017, ¶¶29-38, 48-51.

**I. Claim 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.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §IV(B) (claim 1). Hassfjell-Hoff discloses *allowing sufficient time for the at least one progeny isotopes to emanate into the container*. See §IV(B)(4) (limitation 1c). Specifically, Hassfjell-Hoff discloses that this is accomplished by *allowing the at least one progeny isotopes to emanate into the container from the precursor isotope source through a gas permeable barrier*:

The packets of [ $^{228}\text{Th}$ ]barium stearate are placed in a filering basket mounted by threads to the end of a long tube closed in both ends. The filering basket has a capacity of 3-4

[<sup>228</sup>Th]barium stearate packets.... When the tube is lowered, the filtering basket with the emanating [<sup>228</sup>Th]barium stearate becomes positioned inside the bottle. The decay products from the emanated <sup>220</sup>Rn, <sup>212</sup>Pb and <sup>212</sup>Bi, deposit on the walls of the bottle.

EX1003, 7. The at least one progeny isotopes (*i.e.*, <sup>220</sup>Rn) are allowed to *emanate into the container* through the filtering basket and the packet filter material (either or both of which are *a gas permeable barrier*). According to Hassfjell-Hoff, Rn emanation is “well-known.” EX1003, 6. “<sup>220</sup>Rn has a relatively short diffusion distance at room temperature and atmospheric pressure,” and <sup>212</sup>Pb and <sup>212</sup>Bi can be collected “by enclosing the [<sup>228</sup>Th]barium stearate in a gas-tight collection chamber.” EX1003, 6. A POSITA would have understood Hassfjell-Hoff to disclose that the emanation happens for a *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*. EX1002, ¶¶83-86. EX1017, ¶¶29-38, 52.

**J. Claim 11 “The method of claim 1, the method further comprising changing an orientation of the container before exposing the interior surface to the precursor isotope.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §IV(B) (claim 1). The *interior surface* refers to the interior surface of the container. See §IV(B)(2) (limitation 1a); §IV(C) (claim 2). As explained in claim 6, this claim limitation is so broad that it covers a technician at any time

before placing the bottle in the collection chamber: removing the bottle's lid (turning a bottle relative to a lid), rotating the bottle when placing it on a shelf, rotating the bottle when removing it from the box, or rotating the bottle during bottle manufacture. §IV(G) (claim 6). A POSITA would have understood that turning the bottle constitutes *changing an orientation*, specifically the angular orientation. EX1002, ¶¶87-89. EX1017, ¶¶29-38, 53-55.

#### **K. Claim 12**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. EX1002, ¶¶90-93. EX1017, ¶¶29-37, 56.

##### **1. [12pre] A system for generating radioisotopes, the system comprising**

Hassfjell-Hoff discloses the preamble. See §IV(B)(1) (limitation 1pre). Hassfjell-Hoff discloses that radioisotope generation was performed using the depicted system. EX1003, 7. EX1002, ¶91. EX1017, ¶¶29-37, 56.

##### **2. [12a] 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**

Hassfjell-Hoff discloses this limitation. See §IV(B)(2) (limitation 1a). In Figure 2 of Hassfjell-Hoff, the *precursor isotope source* (i.e., packet of [<sup>228</sup>Th]barium stearate) is disposed on the end of a tube (i.e., *on a rod*) inside a basket (see §IV(B)(3) (limitation 1b)), and the tube (i.e., *rod*) is 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 (see §IV(B)(2) (limitation 1a)). EX1003, 6-7, Fig. 2. Hassfjell-Hoff also describes that the precursor isotope source decays into one or more progeny isotopes that emanate into the container (i.e., polyethylene bottle in Figure 2). See §IV(B)(4) (limitation 1c). EX1002, ¶¶92. EX1017, ¶¶29-37, 56.*

**3. [12b] 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.**

Hassfjell-Hoff discloses this limitation. Hassfjell-Hoff's tube is configured to slide to a closed position in which the *precursor isotope source* (i.e., packet of [<sup>228</sup>Th]barium stearate) is sealed off from the container to isolate the precursor isotope source from the interior surface. EX1003, 7; §IV(B)(5) (limitation 1d). Figure 2 shows that if the tube is pulled upwards and the gate valve is closed, the precursor isotope source is *sealed off from the* polyethylene bottle in the collection (lower) chamber. EX1003, 7, Fig. 2; §IV(B)(2) (limitation 1a). EX1002, ¶¶93. EX1017, ¶¶29-37, 56.

- L. Claim 13 “The system of claim 12, wherein the precursor isotope source comprises a thorium 228 isotope ( $^{228}\text{Th}$ ) and/or a radium 224 isotope ( $^{224}\text{Ra}$ ), the one or more progeny isotopes comprising at least one of a radon 220 isotope ( $^{220}\text{Rn}$ ) and a lead 212 isotope ( $^{212}\text{Pb}$ ).”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §IV(K) (claim 12). Hassfjell-Hoff discloses:

When the tube is lowered, the filering basket with the emanating [ $^{228}\text{Th}$ ]barium stearate becomes positioned inside the bottle. The decay products from the emanated  $^{220}\text{Rn}$ ,  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ , deposit on the walls of the bottle.

EX1003, 7. A POSITA would have understood that [ $^{228}\text{Th}$ ]barium stearate is the claimed thorium 228 isotope ( $^{228}\text{Th}$ ). Thus, the interior surface of the container is exposed to  $^{228}\text{Th}$  (*i.e.*, the *precursor isotope source*), which decays into (*i.e.*, becomes *progeny isotopes*)  $^{220}\text{Rn}$  and  $^{212}\text{Pb}$ . EX1003, 7. EX1002, ¶¶94-97.

EX1017, ¶¶29-37, 56-57.

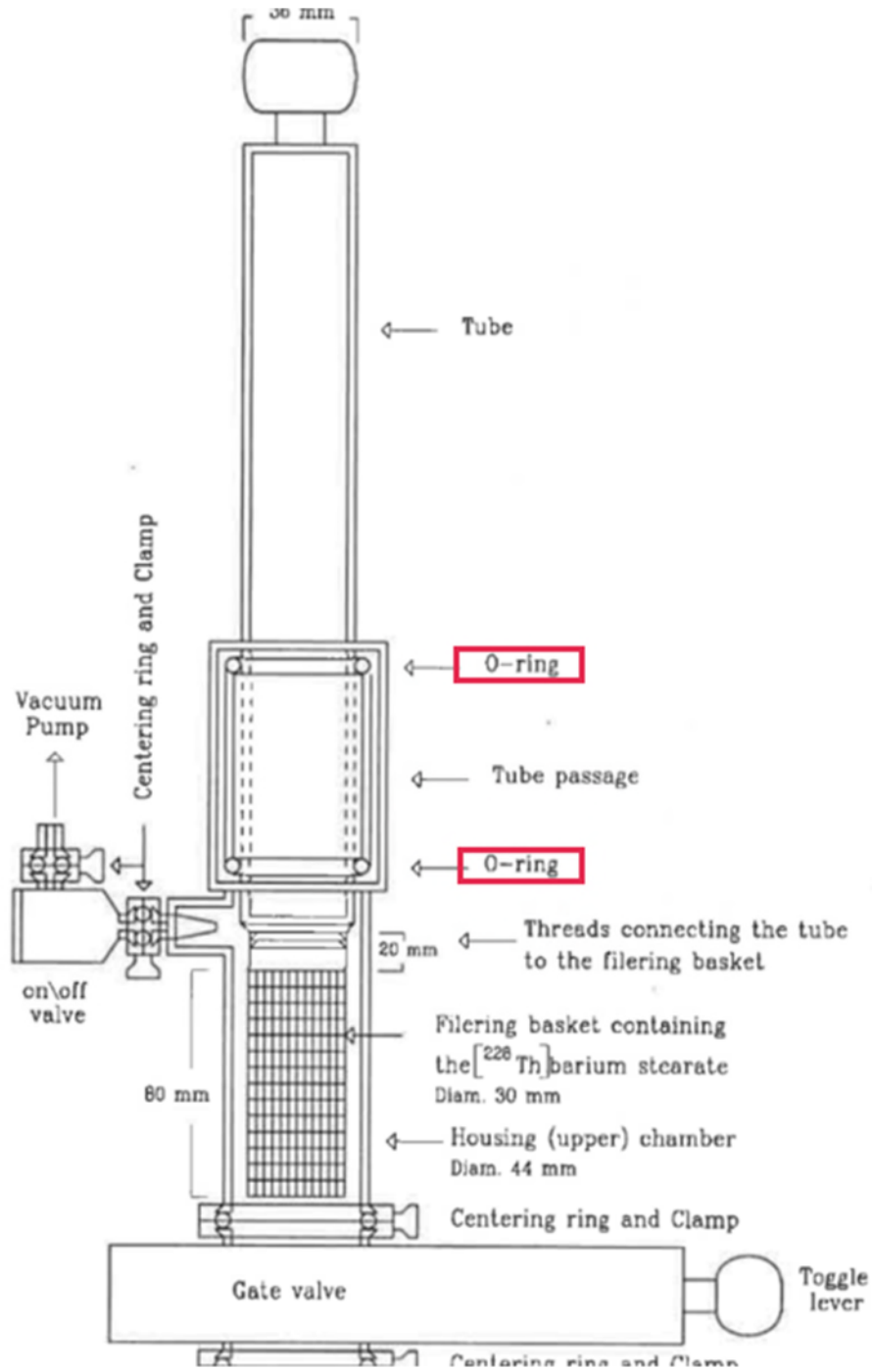
- M. Claim 14 “The system of claim 12, wherein, in the closed position, the rod forms a gas tight seal with a tube in which the rod slides to isolate the precursor isotope source from the interior surface.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §§IV(F), (K) (claims 5, 12). According to Hassfjell-Hoff, there is an O-ring that surrounds the tube (*i.e.*, *rod*) and is positioned between that tube and the surrounding tube passage (*i.e.*, *tube in which the rod slides*). EX1003, Fig. 2. Hassfjell-Hoff also discloses that “no detectable leakage of any kind of

radioactivity out of the generator has been observed.” EX1003, 7. EX1002, ¶¶98-100. EX1017, ¶¶29-37, 56, 58.

**N. Claim 15 “The system of claim 14, wherein the rod includes at least one O-ring to form the gas tight seal with the tube in the closed position.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §§IV(F), (K), (M) (claims 5, 12, 14). The top chamber has O-ring seals to keep the system gas tight. See EX1003, Fig. 2; §IV(F) (claim 5). As shown in Figure 2, at least two O-rings are present between the tube (the *rod*) and the tube passage (the *tube*). EX1003, Fig. 2. When in the closed position, no gas can escape through the O-ring. EX1003, 7 (there was “no detectable leakage of any kind of radioactivity out of the generator...”).



EX1003, Fig. 2. EX1002, ¶¶101-103. EX1017, ¶¶29-37, 56, 58-59.

**O. Claim 16 “The system of claim 12, wherein the rod holds the precursor isotope source without having the precursor isotope source touch the interior surface.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. See §IV(K) (claim 12). *The rod holds the precursor isotope source. See §IV(B)(3) (limitation 1b). The system operates without having the precursor isotope source touch the interior surface. See §IV(H) (claim 7).*

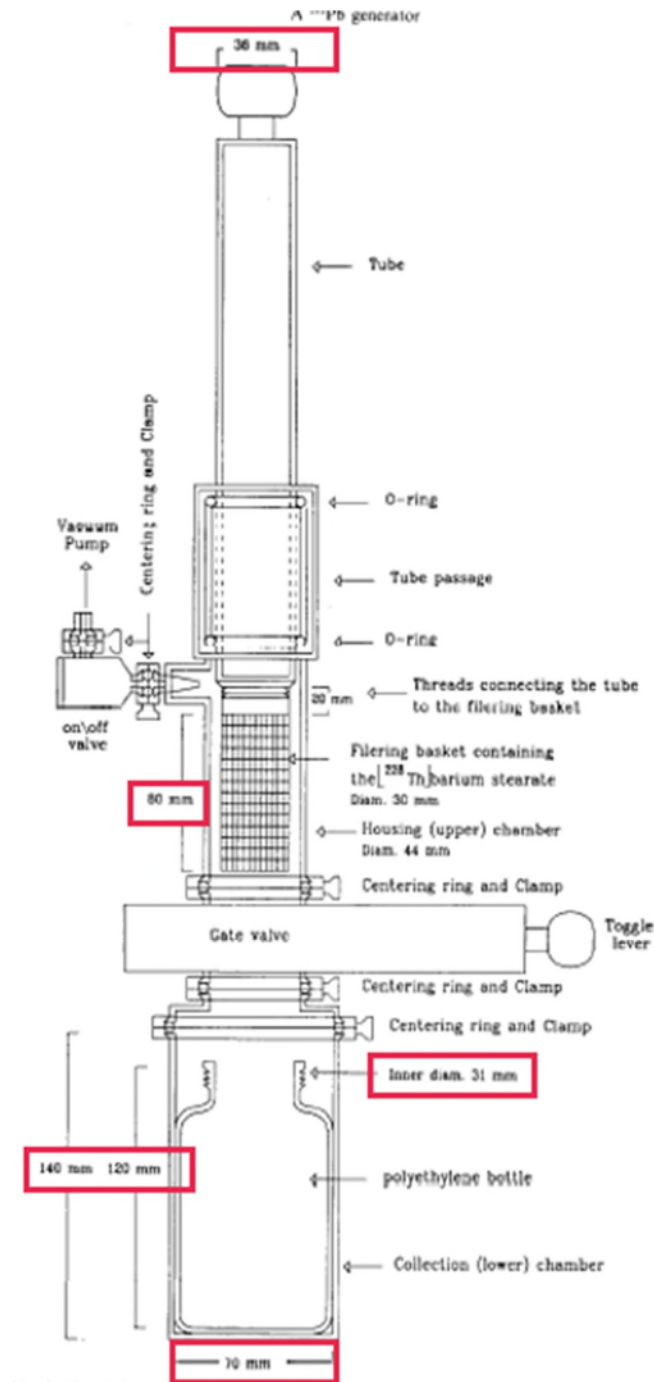


Fig. 2. The design of the generator showing functional details and operating mechanism.

EX1003, Fig. 2. As shown in Figure 2 of Hassfjell-Hoff, lowering the tube moves the filing basket through the gate valve and into the polyethylene bottle. EX1003, Fig. 2. When this occurs, the filing basket will be positioned in the center of the

polyethylene bottle. EX1003, Fig. 2 (showing multiple “centering ring and clamp”). *See also* §IV(H) (claim 7). A POSITA would have understood that the positioning of the filering basket, which contains the [<sup>228</sup>Th]barium stearate (*i.e.*, the precursor isotope source), at the center of the polyethylene bottle means that the rod holds the precursor isotope source without having the precursor isotope source touch the interior surface of the of the container. *See* EX1003, Fig. 2. EX1002, ¶¶104-106. EX1017, ¶¶29-37, 56, 60-62.

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

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. *See* §IV(K) (claim 12). The filering basket and the packet are each *a gas permeable barrier*. *See* §IV(I) (claim 8). Each of the filering basket and the packet *encapsulates the precursor isotope source*. EX1003, 7 (“The filter membrane with the precipitate was folded and wrapped up in two additional filter to avoid any loss of [<sup>228</sup>Th]barium stearate....The packets of [<sup>228</sup>Th]barium stearate are placed in a filering basket”). EX1002, ¶¶107-109. EX1017, ¶¶29-37, 56, 63.

**Q. Claim 19 “The system of claim 13, further comprising the container, wherein the interior surface of the container is configured to allow the <sup>212</sup>Pb to deposit on the interior surface.”**

Hassfjell-Hoff discloses this claim arranged as claimed and in an enabling manner. *See* §§IV(K)-(L) (claims 12, 13). Hassfjell-Hoff discloses “[t]he decay products from the emanated <sup>220</sup>Rn, <sup>212</sup>Pb and <sup>212</sup>Bi, deposit on the walls of the

bottle.” EX1003, 7. The walls of the bottle are the interior surface of the container.

See §IV(B)(2) (limitation 1a). EX1002, ¶¶110-112. EX1017, ¶¶29-37, 56-57, 64.

**V. GROUND 2: CLAIMS 5-7, 10-11, 15-16, 20 ARE OBVIOUS OVER HASSFJELL-HOFF**

**A. Hassfjell-Hoff**

See §IV(A). EX1002, ¶113. EX1017, ¶¶29-37.

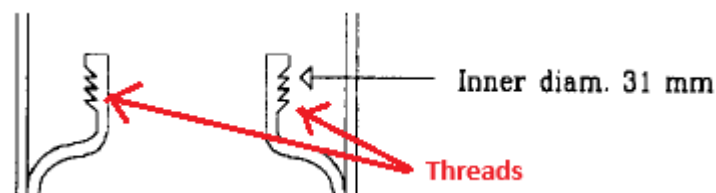
**B. Claim 5 “The method of claim 4, wherein withdrawing the precursor isotope source into a gas tight seal comprises sealing the rod within a tube using an O-ring to form the gas tight seal between the rod and the tube.”**

As explained above, this limitation is disclosed by Hassfjell-Hoff. See §IV(F) (claim 5). Moreover, this claim would have been obvious to a POSITA because such a feature would have been necessary to prevent the escape of any gas from the chamber containing the filtering basket that contains  $^{228}\text{Th}$  and which emanates gaseous  $^{220}\text{Rn}$ . For example, Hassfjell-Hoff states that all of the generator parts were “connected to standard high vacuum equipment to avoid leakage of radioactivity to the surroundings.” EX1003, 7. Furthermore, Hassfjell-Hoff states that “[d]espite the relatively strong  $^{228}\text{Th}$  source, no detectable leakage of any kind of radioactivity out of the generator has been observed.” EX1003, 7. Finally, Hassfjell-Hoff describes that it is known to enclose [ $^{228}\text{Th}$ ]barium stearate in a gas-tight collection chamber in order to collect  $^{212}\text{Pb}$  and  $^{212}\text{Bi}$ . EX1003, 6. Doing so would have been within the skill and knowledge of a POSITA, would have led to predictable results, would have created a reasonable expectation of success, would

have been compatible with Hassfjell-Hoff, and would have been a mere design choice. Motivation to do so arises from the desire and imperative to ensure that the radioactive materials are controlled and do not escape from the radioisotope generators. Such motivations would have been a matter of common sense and known to a POSITA. EX1002, ¶114. EX1017, ¶¶29-38, 41-44, 65-66.

**C. Claim 6 “The method of claim 1, the method further comprising turning the container before exposing the interior surface to the precursor isotope.”**

As explained above, this limitation is inherently disclosed by Hassfjell-Hoff because it is so broad that it covers actions of a technician at any time before placing the bottle in the collection chamber. See §IV(G) (claim 6). Moreover, this claim would have been obvious to a POSITA because to turn the container before exposing the interior surface to the precursor isotope is part of the design of the container itself in Hassfjell-Hoff. Figure 2 depicts that there are threads around the neck of the polyethylene bottle (container) as shown below:



EX1003, Fig. 2. EX1002, ¶115. EX1017, ¶¶29-38, 45-47, 67-68.

A POSITA would have appreciated that threads facilitate and encourage the bottle to be unscrewed or screwed (*e.g.*, from a lid) before a user places the bottle

within the collection (lower) chamber of Hassfjell-Hoff. Furthermore, a POSITA would have known to provide containers with lids so that the containers can be sterilized prior to use, or can be sterilized after use, or can be sealed to ensure the integrity of the contents. See EX1003, 6 (describing various prior art generators for radiation therapy). Doing so would have been desirable to ensure that the container could be sterilized either before or after use, or to seal the container to ensure the integrity of the contents of the container, and this would have been within the skill and knowledge of a POSITA, would have led to predictable results, would have created a reasonable expectation of success, would have been compatible with Hassfjell-Hoff, and would have been a mere design choice. EX1002, ¶116. EX1017, ¶¶29-38, 45-47, 67-68.

**D. Claim 7 “The method of claim 1, wherein exposing the interior surface of the container to the precursor isotope source [sic] exposing the interior surface of the container to the precursor isotope source without having the precursor isotope source touch the interior surface.”**

As explained above and below, this limitation is nonsensical or disclosed by Hassfjell-Hoff. See §IV(H) (claim 7); §VII(D). Moreover, this claim would have been obvious to a POSITA because Hassfjell-Hoff states that gaseous  $^{220}\text{Rn}$  has a “relatively short” diffusion distance at room temperature and atmospheric pressure. EX1003, 6. Hassfjell-Hoff also states that it is known to fill the volume of a collection chamber with  $^{220}\text{Rn}$  gas so that when the  $^{220}\text{Rn}$  decays, the resultant

$^{212}\text{Pb}$  will deposit on the walls of a collection chamber. EX1003, 6. Thus, it would be obvious to a POSITA that the interior surface of the container (*i.e.*, the polyethylene bottle) should be exposed to the precursor isotope such that only the  $^{220}\text{Rn}$  gas should emanate, thus meaning that the precursor isotope source (*i.e.*,  $^{228}\text{Th}$ ) does not touch the interior surface of the container. Doing so would have been within the skill and knowledge of a POSITA, would have led to predictable results, would have created a reasonable expectation of success, and would have been compatible with Hassfjell-Hoff. A POSITA would have been motivated to do so because doing so would prevent the contamination of the interior surface of the container with  $^{228}\text{Th}$  particles that could otherwise lead to radiation safety problems due to the 1.9 year half-life of  $^{228}\text{Th}$ . Such motivations would have been a matter of common sense and known to a POSITA. EX1002, ¶117. EX1017, ¶¶29-38, 48-51, 69-70.

**E. Claim 10 “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.”**

Hassfjell-Hoff renders this claim obvious. *See* §IV(B) (claim 1); §III(D)(3) (claim 10 construction). Hassfjell-Hoff explicitly discloses that “[f]ilter membrane packets with [ $^{228}\text{Th}$ ]barium stearate with  $^{228}\text{Th}$  at the kBq level have shown unchanged emanation ability for  $^{220}\text{Rn}$  during 1 yr...The generator has been operated with 40-50MBq (1.1-1.4mCi) of  $^{228}\text{Th}$  for 1 yr, and the total amount of

$^{212}\text{Pb}$  that can be collected inside the polyethylene bottle at saturation has decreased from 50 to 11% of the  $^{228}\text{Th}$  radioactivity.” EX1003, 7. A POSITA would recognize that this means that the generator was operated for “sufficient time” to allow the “precursor isotope source to decay” that included at least 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours. A POSITA would have understood that the 10.6 hour half-life of  $^{228}\text{Th}$  would have meant that the 50% of the maximum amount of  $^{228}\text{Th}$  would exist after 10.6 hours of collection. Allowing the system to emanate for 10.6 hours would have been obvious to try. A POSITA would have understood that selection of the exact time was a matter of routine optimization. *See* §VI(D) (claim 10); EX1007, Fig. 4, [0030]. EX1002, ¶¶118-121. EX1017, ¶¶29-38, 71-73.

Hassfjell-Hoff also describes conventional systems that have operating times that meet the claimed invention. *See generally* EX1003, 6. In one example, generators based on  $^{224}\text{Ra}$  were constructed that operated for 1-2 weeks based on the 3.7 day half-life of  $^{224}\text{Ra}$ . EX1003, 6. A POSITA would have recognized and been familiar with each of these prior art systems that were disclosed by Hassfjell-Hoff, and would also have understood that during their operation the  $^{228}\text{Th}$  was allowed to decay for 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours based on the generator being used for at least those times. Thus, it would have been obvious to a POSITA to permit the precursor isotope source to decay for

at least about 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours thereby forming the claimed progeny isotopes. Motivation to allow this amount of time for decay arises from the need to collect sufficient radioisotopes and is understood in the art as dependent on the half-lives of the precursor isotope sources. EX1007, Fig. 4, [0030]. A POSITA would have understood that selection of the exact time was a matter of routine optimization. EX1002, ¶121. EX1017, ¶¶29-38, 71-73.

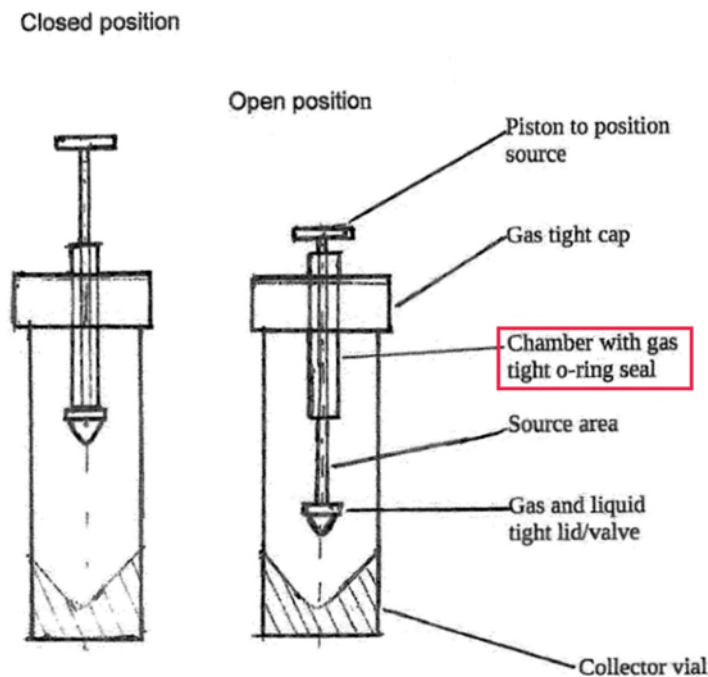
**F. Claim 11 “The method of claim 1, the method further comprising changing an orientation of the container before exposing the interior surface to the precursor isotope.”**

As explained above, this limitation is inherently disclosed by Hassfjell-Hoff because it is so broad that it covers actions of a technician at any time before placing the bottle in the collection chamber. *See* §IV(J) (claim 11). Moreover, this claim would have been obvious to a POSITA because the most efficient way to open a bottle is to unscrew the cap from that bottle, thereby changing the bottle’s angular orientation during that step. *See* EX1003, Fig. 2 (showing that the polyethylene bottle that corresponds to the claimed container has threads at the top which are designed to screw the bottle and/or a cap to the bottle and/or the bottle to another threaded orifice). A POSITA would also understand that bottles are provided with caps. Thus, in Figure 2 of Hassfjell-Hoff where the polyethylene bottle does not have a cap, a POSITA would understand and expect that the bottle

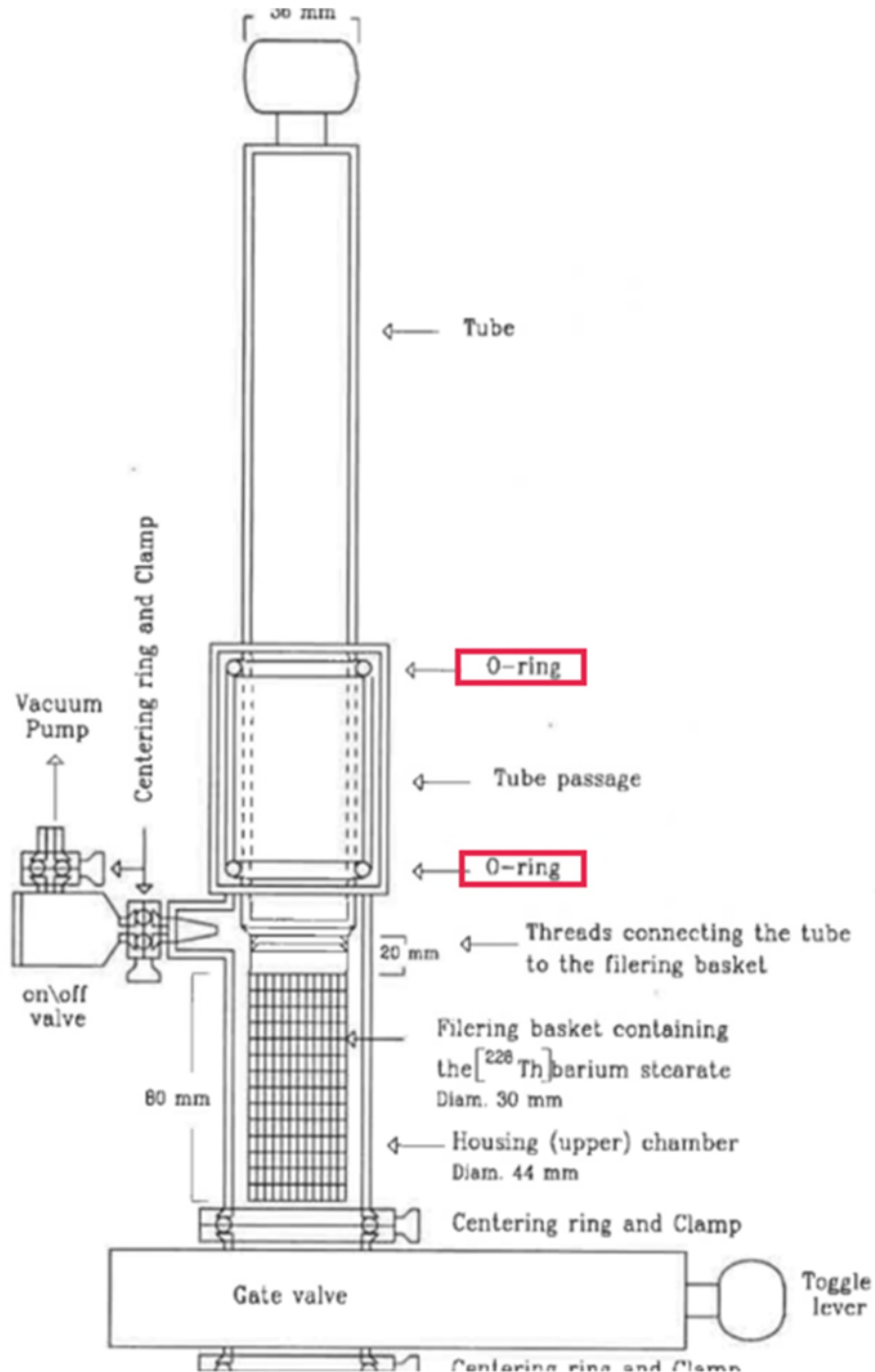
would have had a corresponding cap. EX1003, Fig. 2. It would therefore be obvious to unscrew the cap before inserting the bottle into the radioisotope generator shown by Hassfjell-Hoff in Fig. 2. It is also obvious that the bottle will have been manufactured and transported, and that those actions would comprise changing the angular orientation (*i.e.*, turning it). This means that the step of changing the orientation of the container before exposing the interior surface to the precursor isotope would have been obvious because the bottle (*i.e.*, *container*) would have been turned before inserting it into the collection (lower) chamber. EX1003, Fig. 2. Changing an orientation of the container before exposing the interior surface to the precursor isotope would have been within the skill and knowledge of a POSITA, would have led to predictable results, and would have created a reasonable expectation of success, would have been compatible with Hassfjell-Hoff, and would have been a mere design choice. Motivation to do so arises from a POSITA's knowledge regarding how to work with bottles (*e.g.*, make bottles or remove the caps from bottles). Such motivations would have been a matter of common sense and known to a POSITA. EX1002, ¶122. EX1017, ¶¶29-38, 53-55, 74-75.

**G. Claim 15 “The system of claim 14, wherein the rod includes at least one O-ring to form the gas tight seal with the tube in the closed position.”**

As explained above, this limitation is disclosed by Hassfjell-Hoff. See §IV(N) (claim 15). Moreover, this claim would have been obvious to a POSITA because such a feature would have been necessary to prevent the escape of any gas from the chamber containing the filtering basket that contains  $^{228}\text{Th}$  and which emanates gaseous  $^{220}\text{Rn}$ . See §§IV(K), (M) (claims 12, 14). The disclosure in the 603 patent of a rod including an O-ring matches the disclosure of Hassfjell-Hoff. Compare EX1001, Fig. 4 with EX1003, Fig. 2.



EX1001, Fig. 4.



EX1003, Fig. 2. This feature would have been obvious to a POSITA because Figure 2 of Hassfjell-Hoff already shows in detail that the O-ring is positioned so that it is touching the tube (*i.e.*, *rod*). Therefore, the Hassfjell-Hoff rod “includes”

and renders obvious at least one O-ring to form the gas tight seal with the tube in the closed position. This would have been obvious to a POSITA because Hassfjell-Hoff explicitly shows a configuration where the O-ring is touching the tube (*i.e.*, *rod*) to seal it. EX1002, ¶¶123-124. EX1017, ¶¶29-37, 56, 58-59, 76-77.

**H. Claim 16 “The system of claim 12, wherein the rod holds the precursor isotope source without having the precursor isotope source touch the interior surface.”**

As explained above, this limitation is inherently disclosed by Hassfjell-Hoff. *See* §IV(O) (claim 16). Moreover, this claim would have been obvious to a POSITA because it is desirable to prevent the precursor isotope source from becoming deposited on the interior surface of the container, thereby preventing radiation contamination. EX1003, 6 (describing how the Rn gas fills the volume of the collection chamber and by this action decays and deposits the  $^{212}\text{Pb}$  onto the walls of the container). Therefore, and as shown in Hassfjell-Hoff, it would have been obvious to a POSITA that to design the system such that the rod holds the precursor isotope source without having the precursor isotope source touch the interior surface. EX1003, Fig. 2. Doing so would have been within the skill and knowledge of a POSITA, would have led to predictable results, would have created a reasonable expectation of success, would have been compatible with Hassfjell-Hoff, and would have been a mere design choice. Such motivations would have

been a matter of common sense and known to a POSITA. EX1002, ¶125. EX1017, ¶¶29-37, 56, 60-62, 78-79.

**I. Claim 20 “The system of claim 12, 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.”**

Hassfjell-Hoff renders this claim obvious. See §IV(K) (claim 12); §V(E) (claim 10); §III(D)(4) (claim 20 construction). To the extent this claim is construed to mean at least (or more than) one of the listed times, Hassfjell-Hoff explicitly discloses that “[f]ilter membrane packets with [ $^{228}\text{Th}$ ]barium stearate with  $^{228}\text{Th}$  at the kBq level have shown unchanged emanation ability for  $^{220}\text{Rn}$  during 1 yr...The generator has been operated with 40-50MBq (1.1-1.4mCi) of  $^{228}\text{Th}$  for 1 yr, and the total amount of  $^{212}\text{Pb}$  that can be collected inside the polyethylene bottle at saturation has decreased from 50 to 11% of the  $^{228}\text{Th}$  radioactivity.” EX1003, 7. A POSITA would recognize that this means that the generator was operated in a way “configured to decay and emanate the one or more progeny isotopes into the container” for at least 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours. A POSITA would have understood that the 10.6 hour half-life of  $^{228}\text{Th}$  would have meant that 50% of the maximum amount of  $^{228}\text{Th}$  would exist after 10.6 hours of collection. Allowing the system to emanate for 10.6 hours would have been obvious to try. A POSITA would have understood that selection of the

exact time was a matter of routine optimization. See §VI(F) (claim 20); EX1007, Fig. 4, [0030]. EX1002, ¶¶126-128. EX1017, ¶¶29-37, 56, 80-82.

**VI. GROUND 3: CLAIMS 9-10, 18, 20 ARE OBVIOUS OVER HASSFJELL-HOFF AND O’HARA**

**A. Hassfjell-Hoff**

See §IV(A). EX1002, ¶129. EX1017, ¶¶29-37.

**B. O’Hara**

US Patent Application Publication No. 2018/0047474 to O’Hara was published on February 15, 2018 and entitled “System, Emanation Generator, and Process for Production of High-Purity Therapeutic Radioisotopes.” EX1007, cover. O’Hara therefore qualifies as prior art under 35 U.S.C. §102(a) (post-AIA). There is no evidence that any of the 35 U.S.C. §102(b) exceptions apply. EX1002, ¶130.

O’Hara was cited in the 603 patent in the International Search Report for PCT/EP2020/084701 dated February 17, 2021. However, the USPTO never rejected any claims of the 603 patent over O’Hara (or any other reference). EX1001, cover; EX1006. Therefore, Petitioner respectfully submits that the Examiner erred by failing to consider O’Hara. EX1002, ¶131.

O’Hara discloses an isotope production system, emanation generator, and process for production of high-purity radioisotopes, such as <sup>212</sup>Pb and/or <sup>212</sup>Bi, suitable for therapeutic applications. EX1007, [0005]. The isotope production system, emanation generator, and processor of O’Hara address various problems in

prior art isotope production systems including high radiolytic degradation and breakthrough of high energy isotopes such as  $^{224}\text{Ra}$  and  $^{228}\text{Th}$  that can contaminate the recovered isotopes. EX1007, [0005]. EX1002, ¶132.

O'Hara is analogous art to the 603 patent and was not considered during prosecution of the 603 patent. EX1001; EX1006. EX1002, ¶¶133-135.

**C. Claim 9 “The method of claim 1, 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.”**

Claim 9 is obvious by Hassfjell-Hoff in view of O'Hara. See §IV(B) (claim 1). EX1002, ¶¶136-140.

### **1. Hassfjell**

Hassfjell-Hoff discloses 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 isotope to emanate into the container from the filering basket, and that the filering basket has a capacity of 3-4 [ $^{228}\text{Th}$ ]barium stearate packets. EX1003, 7. EX1017, ¶¶29-37. The [ $^{228}\text{Th}$ ]barium stearate packets emanate gaseous  $^{220}\text{Rn}$  which then decays into  $^{212}\text{Pb}$ . EX1003, 7. EX1017, ¶¶29-37. However, Hassfjell-Hoff does not detail whether the filering basket and the [ $^{228}\text{Th}$ ]barium stearate packets contained therein are 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. EX1002, ¶138.

## 2. O'Hara

O'Hara discloses a radioisotope generator (§VI(B)) with a precursor isotope source disposed in a metal or mineral sponge. O'Hara discloses various examples of the precursor isotope source disposed on a mineral sorbent that is on a “permeable metal membrane, screen, [] filter” or “porous disc.” EX1007, [0020]-[0022]. A POSITA would have understood and found it obvious that the mineral sorbent, metal gas-permeable membrane, metal screen, metal filter, and mineral/metal porous disc are each a “sponge.” As evidenced by Hassan and Lefebvre, gas-permeable membranes, screens, filters, and porous discs would have been known in the art to have been formed of open-celled metallic foams. *See* EX1008, 2 (Table 1); EX1009, 2 (“metal sponge refers to highly porous materials with complex and interconnected porosity where the porosity cannot be subdivided into well defined cells”); EX1010. A POSITA would recognize that O'Hara's disclosure of mineral sorbent, gas-permeable membrane, screen, filter, and porous disc would have contained open pores (*i.e.*, a sponge) to allow gaseous  $^{220}\text{Rn}$  to emanate from the  $^{228}\text{Th}$ . EX1002, ¶139.

### 3. Motivation to Combine

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. A POSITA would have understood that doing so would have been advantageous because the isotope-bearing membranes, screens, filters, and porous discs of O'Hara enable a greater quantity of the source isotope or a more dispersed source isotope to be assembled within a fixed diameter or geometry in the emanation generator to provide maximum emanation power for generating the emanation gas (*e.g.*,  $^{220}\text{Rn}$ ). EX1007, [0014]. This modification would have been within the skill and knowledge of a POSITA, would have led to predictable results, would have created a reasonable expectation of success, would have been compatible with Hassfjell-Hoff, and would have been a mere design choice.

Therefore, Hassfjell-Hoff in view of O'Hara renders claim 9 obvious. EX1002, ¶140.

**D. Claim 10 “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.”**

Claim 10 is obvious by Hassfjell-Hoff in view of O'Hara. See §IV(B) (claim 1); §III(D)(3) (claim 10 construction). As explained above, a POSITA would have

understood in view of Hassfjell-Hoff alone that it would have been obvious for Hassfjell-Hoff's precursor isotope source configured to decay for at least 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours. *See* §V(E) (claim 10). EX1002, ¶¶141-145. EX1017, ¶¶29-38, 71-73.

In addition, O'Hara discloses a precursor isotope source configured to decay for at least 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours. Specifically, O'Hara discloses an analogous radioisotope generator. EX1007, [0015], [0018] (disclosing a "radon emanation generator" that contains installed Ra-224 that eventually decays and emanates Rn-220 and thereby forms Pb-212 and/or Bi-212). Similar to Hassfjell-Hoff, O'Hara discloses that the radioactive gas can be captured and collected by a collection device and retained for a time sufficient to allow the decay of the radioactive gas to yield one or more high-purity daughter isotopes. EX1007, [0005]. EX1002, ¶143.

A POSITA would have understood O'Hara to disclose that this amount of time can be various amounts. For example, FIG. 4 shows the results of tests of emanated gas when the emanation is performed for a time period of 0-3 days, or 0-72 hours. EX1007, Fig. 4, [0030]. Of those tests shown in Figure 4, O'Hara performs tests at around 1 day (about 24 hours) and about 2.7 days (about 64 hours). EX1007, Fig. 4. O'Hara also discloses a separate example where the collection column was removed after about 2 days and the Pb-212 product isotopes

resulting from Rn-220 decay were detected. EX1007, [0031]. O'Hara also fits a dotted line that estimates the emanated Rn count rate (cps) as a function of the time. EX1007, Fig. 4. POSITA would understand that this discloses that the claimed ranges of 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours would have been obvious to select based on the rising emanated count rate over time. EX1002, ¶144.

Based on O'Hara, a POSITA would have found it obvious to implement Hassfjell-Hoff to not only allow sufficient time for the precursor isotope source to decay, but also that the amount of time that the precursor isotope source is allowed to decay could be an amount of time of about 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours. This is because O'Hara discloses that the decay of the radioactive gas to yield one or more high-purity daughter isotopes occurs over the amount of time claimed. EX1007, [0005]. A POSITA would have understood that, in the field of obtaining radioisotopes for therapeutics, this is beneficial because it provides a pure Pb-212 that is suitable for therapeutic use. EX1007, [0017]-[0018]. EX1002, ¶145.

- E. Claim 18 “The system of claim 12, wherein 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.”**

Claim 18 is obvious by Hassfjell-Hoff in view of O’Hara. See §IV(K) (claim 12). As explained above, a POSITA would have modified Hassfjell-Hoff in view of O’Hara such 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. See §VI(C) (claim 9). EX1002, ¶¶146-148.

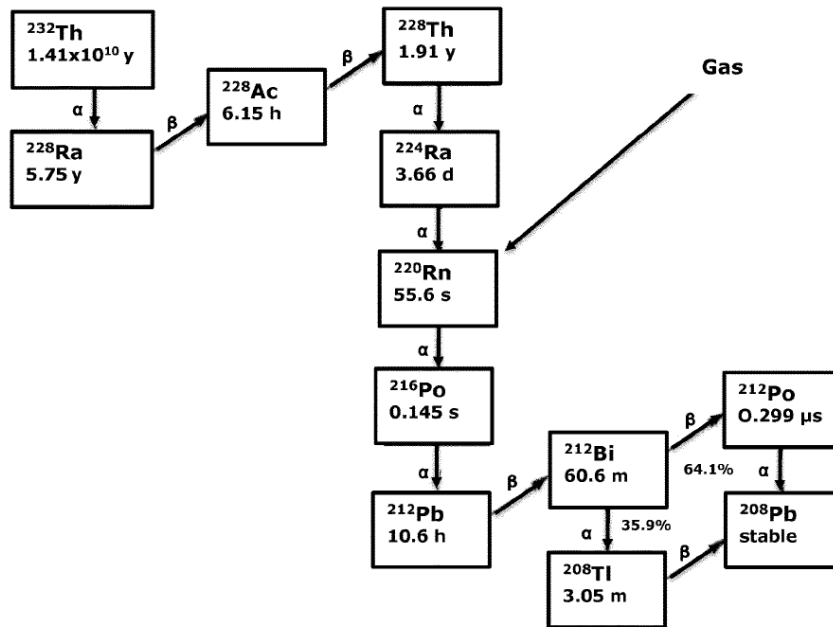
- F. Claim 20 “The system of claim 12, wherein the precursor isotope source is configured to decay and emanate the one or more progeny isotopes into the container for 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours.”**

Claim 20 is obvious by Hassfjell-Hoff in view of O’Hara. See §IV(K) (claim 12); §III(D)(4) (claim 20 construction). As explained above, a POSITA would have modified Hassfjell-Hoff in view of O’Hara to allow the precursor isotope source 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. See §VI(D) (claim 10). EX1002, ¶¶149-151. EX1017, ¶¶29-38, 56, 80-82.

**VII. GROUND 4: CLAIMS 1-3, 7-10, 12, 20 ARE UNPATENTABLE  
UNDER 35 U.S.C. §112**

**A. Claim 1 is non-enabled and lacks written description**

Claim 1 recites “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.” EX1001, cl. 1. As written, claim 1 requires sufficient time to be allowed for the precursor isotope source to decay into one or more progeny isotopes and **the same** one or more progeny isotopes to emanate into the container. In each embodiment of the 603 patent, only one progeny isotope ( $^{220}\text{Rn}$ ) both decays from the precursor isotope source and emanates into the container because only  $^{220}\text{Rn}$  emanates in gaseous form. *See, e.g.*, EX1001, 18:25-27, 19:30-33 Figure 1 of the 603 patent denotes the gaseous nature of  $^{220}\text{Rn}$  as shown below:



EX1001, FIG. 1. Therefore, because it is impossible for there to be more than one progeny isotope that both decays from the precursor isotope source disclosed by the 603 patent that also emanates into the container, this feature lacks written description and is not enabled. EX1002, ¶152.

### B. Claim 2 is indefinite and non-enabled

Claim 2 recites “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 ( $^{228}\text{Th}$ ) and/or a radium 224 isotope ( $^{224}\text{Ra}$ ), the method further comprising allowing the  $^{228}\text{Th}$  to decay into at least one of a radon 220 isotope ( $^{220}\text{Rn}$ ) and a lead 212 isotope ( $^{212}\text{Pb}$ ).” The wherein clause of claim 2 sets forth alternative precursor isotopes to which the interior surface is exposed.

Specifically, three alternatives are effectively listed as possible: (i)  $^{228}\text{Th}$ , (ii)  $^{224}\text{Ra}$ , and (iii) a combination of  $^{228}\text{Th}$  and  $^{224}\text{Ra}$ . However, of these possibilities, (i) is not possible, because the radioactive decay of  $^{228}\text{Th}$  into  $^{224}\text{Ra}$  cannot be stopped or even slowed down, and therefore any  $^{228}\text{Th}$  source must inherently include some portion of  $^{224}\text{Ra}$  as would be apparent to a POSITA. The full scope of Claim 2 is therefore not enabled and indefinite. EX1002, ¶153.

Moreover, the “further comprising” portion of claim 2 renders the claim indefinite because under alternative (ii) there is no  $^{228}\text{Th}$ , so it is not reasonably certain to a POSITA whether this claim requires allowing the (nonexistent)  $^{228}\text{Th}$  to decay. Under alternative (ii), if the claim does require allowing  $^{228}\text{Th}$  to decay, then it is not enabled. EX1002, ¶154.

**C. Claim 3 is indefinite and non-enabled**

Claim 3 recites “The method of claim 2, the method further comprising allowing the  $^{212}\text{Pb}$  to deposit on the interior surface of the container.” However, in claim 2 the  $^{228}\text{Th}$  is allowed to decay into (i)  $^{220}\text{Rn}$ , (ii)  $^{212}\text{Pb}$ , or (iii) a combination of  $^{220}\text{Rn}$  and  $^{212}\text{Pb}$ . The literal scope of this claim covers allowing the  $^{228}\text{Th}$  to decay into  $^{220}\text{Rn}$  only, which is not possible. Moreover, even if it were possible, then no  $^{212}\text{Pb}$  is present to be deposited on the interior surface of a container. As such, claim 3 is indefinite and non-enabled for similar reasons as claim 2. EX1002, ¶¶155-156.

**D. The language of Claim 7 is non-sensical, therefore indefinite**

Claim 7 recites “The method of claim 1, wherein exposing the interior surface of the container to the precursor isotope source exposing the interior surface of the container to the precursor isotope source without having the precursor isotope source touch the interior surface.” As shown by the yellow and green highlighting, claim 7 repeats language requiring *exposing*, which is non-sensical. There are at least three ways to fix this claim:

- adding “comprising” as discussing in §III(D)(2)
- or adding “consisting”
- deleting the repeated phrase and adding the words “further comprising”

A POSITA would not have known which correction is covered by the claim as written, and therefore this claim is indefinite. EX1002, ¶¶157-159.

**E. Claims 8 and 9 are indefinite for lack of antecedent basis**

Each of claims 8 and 9 recites “allowing sufficient time for *the at least one progeny isotopes* to emanate into the container.” Claim 1, from which each of claims 8 and 9 depend, does not recite “at least one progeny isotopes.” In addition, a POSITA would not be aware of the meaning of such term in the context of either claim because it would not be 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. EX1002, ¶160.

**F. Claim 10 is indefinite and lack written description**

To 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. 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. EX1002, ¶161.

**G. Claim 12 is non-enabled and lacks written description**

For the same reasons as claim 1, claim 12 is non-enabled and lacks written description. §VII(A). EX1002, ¶162.

**H. Claim 20 is indefinite, lacks written description, and is non-enabled**

To the extent that claim 20 is construed to require exactly one of the listed times, there is no written description support or enabling disclosure regarding how a POSITA would 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). It is impossible to “configure” a precursor isotope source to decay for an exact amount of time, because unstable precursor isotopes will continue to emit ionizing radiation (*i.e.*, decay) for as long as a portion of the precursor isotope source is made up of unstable isotopes. Radioactive decay continues regardless of any action

taken by a user (there will always be some amount of isotope emitting radiation too faint to detect). Therefore claim 20 is not enabled. Moreover, claim 20 is indefinite because a POSITA would not know whether the claim requires cessation of decay at an exact time. EX1002, ¶163.

## **VIII. DISCRETIONARY DENIAL IS NOT WARRANTED**

### **A. 35 U.S.C. §314(a) Analysis**

The *Fintiv* factors weigh against discretionary denial because there is no parallel district court litigation. PGR2020-00019, Paper 11, 5-6 (PTAB Mar. 20, 2020) (precedential).

### **B. 35 U.S.C. §325(b) Analysis**

Applying the two-part framework discussed in *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH*, PGR2019-01469, Pap. 6, \*8-9, the Board should not exercise its §325(d) discretion to deny institution.

None of the challenges are substantially the same as those considered during prosecution.

Hassfjell-Hoff is not cumulative of the other prior art considered during prosecution of the 603 patent. Though Hassfjell-2001, a different article by the same author, was cited during prosecution, it is materially different from Hassfjell-Hoff because Hassfjell-2001 discloses a radioisotope generator that includes a bubbler where  $^{220}\text{Rn}$  is collected by passing dry air continuously through a cage, carrying emanated  $^{220}\text{Rn}$  out of the cage and into a glass bubbler rather than a

radioisotope generator having multiple chambers. *Compare* EX1014 with EX1003.

Though Hassfjell-Hoff was cited during the prosecution of related patents, the pending claims in the related patents are materially different from the 603 patent claims.

If the challenges herein are found to be based on prior art that is the same as or cumulative to prior art considered by the examiner during prosecution, the examiner has made a clear error in allowing the claims over such prior art. In the Reasons for Allowance in the Notice of Allowance for the 603 patent, the examiner stated:

The prior art in general discloses the decay of solid precursor isotopes in a collection container in general, but does not provide adequate detail to address the inventive features of including said precursor on a rod that can operate the exposure in an open or closed configuration.

EX1006, 264. The information contained in this petition clearly discloses including a precursor isotope source on a rod in contravention of the examiner's Reasons for Allowance. The challenges in this Petition are compelling, and allowing the claims over such prior art is therefore clear error.

## **IX. MANDATORY NOTICES UNDER 37 C.F.R. §§42.8(B)(1)-(4)**

### **A. Real Party-In-Interest**

AdvanCell Pty Ltd. is the real party-in-interest.

**B. Related Matters**

The 603 patent is not subject any related matters.

**C. Lead and Backup Counsel**

| <b>Lead Counsel</b>                                                                                                                                                                                                    | <b>Backup Counsel</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
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|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**D. Service Information**

Service information for lead and backup counsel is provided in the designation of lead and backup counsel above. Petitioner consents to electronic service to lead and back-up counsel and to:

Sciencons-AIP-IPR@us.dlapiper.com

**X. CONCLUSION**

All Challenged Claims of the 603 patent should be found unpatentable for the reasons discussed in this Petition.

Date: March 10, 2025

Respectfully submitted,

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**CERTIFICATE OF WORD COUNT**

Pursuant to 37 C.F.R. §42.24(d), Petitioner certifies that this petition includes 11,725 words, as measured by Microsoft Word, exclusive of the table of contents, mandatory notices under §42.8, certificates of service, word count, claim listing, and exhibits.

Date: March 10, 2025

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**CERTIFICATE OF SERVICE**

The undersigned certifies pursuant to 37 C.F.R. §§42.6(e) and 42.105 that on March 10, 2025, a true and correct copy of the Petition for post-grant review of U.S. Patent No. 12,125,603 was served via overnight mail on the Patent Owner at the below correspondence address of record:

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Respectfully submitted,

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