

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANCELL PTY LTD.,
Petitioner,

v.

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

PGR2025-00029
Patent No. 12,125,603

DECLARATION OF CHARLES CONROY

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I, Charles Conroy, declare as follows:

I. QUALIFICATIONS

1. I have been retained by Counsel on behalf of ARTBIO, Inc. to provide opinions in this matter related to my experience and expertise. My opinions are based on my skills, knowledge, training, education, and experience in matters of this nature, and my examination of the materials utilized in preparing this report.

2. I have a Bachelor of Science in Pharmacy from Purdue University, West Lafayette, Indiana, which I completed in 1992. The coursework for my Bachelor of Science covered chemistry, biology and pharmaceutical science as well as pharmacology. This included studies in radiopharmacy. In 1999 I completed a Masters in Business Administration at the Stephen M. Ross School of Business at the University of Michigan.

3. Following graduation from Purdue in 1992, I worked in a range of sales, consulting and management roles within the pharmaceutical industry, with a focus on radiopharmaceuticals. These roles required me to have an understanding of the radiopharmaceutical industry including principles of radioisotope generation and the use of radioisotopes as radiopharmaceutical products.

4. For example, from 2005 to 2008 I worked as Director of Product Marketing, U.S. Nuclear Medicine and Global Director of Product Marketing, Imaging Solutions at Curium Pharma, a pharmaceutical company which produces

and supplies radiopharmaceuticals used in nuclear medicine as well as preparation kits for therapeutic doses of such medicines, and radioisotope generators. In this role I was responsible for marketing of the company's molybdenum-99 generator, used to generate technetium-99 which is used in a range of diagnostic imaging applications. In this role I was required to understand the principles used to design and manufacture radioisotope generators, as well as their operation. I was aware of all radioisotope generators which were on the market in Northern America as well as having an understanding of radioisotope generators which were under research or being used in clinical trials. This drew on my radiopharmaceutical knowledge gained during my pharmacy degree. Additionally, I was a practicing radiopharmacist from 1992 to 1999. I received my Board Certification in Nuclear Pharmacy (BCNP) in 1996.

5. In 2018 I joined Jubilant Pharma as its General Manager and directed its \$200 million radiopharmacy division, Jubilant Radiopharma, responsible for over 800 employees across 51 locations. Jubilant Radiopharma is an industry-leading pharmaceutical company specializing in nuclear medicine which develops, manufactures, commercializes and distributes diagnostic and therapeutic radiopharmaceutical agents. It is the second largest radiopharmaceutical company in the United States. Jubilant Radiopharma's products include various radioisotope generation systems. These include the RUBY-FILL Rb 82 generator, which

produced rubidium-82, a radioactive diagnostic agent indicated for positron emission tomography imaging of the myocardium. As General Manager with overall responsibility for the sales and operations of the company, I was required to have, and had, an understanding of the design, manufacturing and operation of the company's products as well as competing products in the market.

6. In September 2019 I left Jubilant Pharma and became the Chief Executive Officer of ARTMS Inc. a position which I held until 2022. ARTMS' technology was founded by a group of scientists from TRIUMF, Canada's particle accelerator center, to tackle projected Technetium-99m shortages after the decommissioning of the reactor at Chalk River. ARTMS' technology expanded the production capabilities of cyclotrons, providing a new way to produce Technetium-99m. ARTMS then developed other applications for its technology. This included technology to enhance production of germanium-68 generators to produce gallium-68, a radioisotope used for PET imaging, with applications across an array of clinical imaging, such as neuroendocrine tumours and more recently, prostate cancer. ARTMS was formed and operated as a stand-alone entity from 2016 and was acquired by Telix Pharmaceuticals in 2024. Again, at ARTMS I was required to maintain an understanding of the technical design and operation of our technology and the generators which it was designed to work with, and to keep

abreast with competitor products. I also had various radioisotope prototype generators demonstrated to me.

7. In 2022 I left ARTMS and founded Nucleus Radiopharma, an end-to-end contract-development and manufacturing company for targeted radiotherapies. I remained at Nucleus Radiopharma until July 2025 when I founded Radion Advisory Group, a biotech/radiopharmaceutical consultancy company.

8. I am a member of the following professional organizations: The Society of Nuclear Medicine and Molecular Imaging (SNMMI); and The European Association of Nuclear Medicine (EANM)

9. A copy of my *Curriculum Vitae*, attached as EX2003, contains further details on my education, experience, publications, and other qualifications to render an expert opinion in this matter.

II. SCOPE OF WORK

10. I understand that AdvanCell Pty Ltd. (AdvanCell) filed a petition with the United States Patent and Trademark Office for Post Grant Review of U.S. Patent No. 12,125,603 to Roy H. Larsen (“the ’603 patent,” EX1001), entitled “Production of Highly Purified ^{212}Pb .” I further understand that a trial was instituted based on that petition. I have been retained by ARTBIO, Inc. (“ARTBIO”) to offer an expert opinion relating to the arguments raised by AdvanCell regarding the claims of the ’603 patent. I receive \$750 per hour for my

services. No part of my compensation is dependent on my opinions or on the outcome of this proceeding.

11. I have been specifically asked to provide my opinion in response to the declaration of Dr. Saed Mirzadeh regarding the '603 patent (EX1002). I have reviewed the '603 patent, Dr. Mirzadeh's declaration, and the exhibits cited in that declaration.

III. LEGAL STANDARDS

12. I understand that the Patent Office may cancel issued claims of the '603 patent if the Petitioner (here, AdvanCell Pty Ltd.) demonstrates that the claims fail to satisfy the requirements of patentability. In particular, I understand that AdvanCell has raised grounds arguing that that the claims of the '603 patent were unpatentable for reasons including anticipation, obviousness, lack of written description, non-enablement, or indefiniteness. I understand that the claims should be understood according to their ordinary and customary meaning as understood by a person of ordinary skill in the art ("POSITA") at the time of the invention in light of the language of the claims, the specification, and the prosecution history of record. I have been provided a copy of the prosecution history of record as Exhibit 1006.

A. Legal Standard for Anticipation

13. I understand that for a claim to be anticipated each claim element must be disclosed, either expressly or inherently, in a single item of prior art, and the claimed arrangement or combination of those elements in the claim must also be disclosed, either expressly or inherently, in that same item of prior art.

14. A prior art reference can disclose a limitation that is not expressly disclosed in the reference if it is “inherently present” in the reference. I further understand that to be “inherently present,” the missing disclosure must necessarily and inevitably be present in the element or process described in the reference. It is my understanding that a limitation is not disclosed by inherency if the missing limitation is only probably present or if there is merely a possibility that it is present.

15. Material not explicitly contained in a single prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document. I understand that incorporation by reference provides a method for integrating material from various sources into a host document by citing such material in a manner that makes clear to one of ordinary skill in the art that the material is effectively part of the host document as if explicitly contained therein.

B. Legal Standard for Obviousness

16. I understand that a claimed invention is unpatentable for obviousness if the differences between the invention and the prior art are such that the subject matter, as a whole, would have been obvious to a POSITA at the effective filing date of the invention (i.e., at the critical date).

17. It is further my understanding that a determination of obviousness requires inquiries into: (1) the scope and contents of the prior art at the effective filing date; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art at the effective filing date; and, to the extent they exist, (4) secondary indicia of obviousness.

18. I understand that a claim is obvious if all of the claimed elements were known in the prior art and one skilled in the art would have combined the elements as claimed with a reasonable expectation of success. I understand that obviousness may also be shown by demonstrating that it would have been obvious to modify what is taught in a single piece of prior art to create the patented invention or by combining teachings of two or more references. I understand that in order for a claimed invention to be considered obvious, there must be some rational underpinning for the proposed combination. I understand that hindsight must not be used when determining whether a POSITA would make the proposed combination. Thus, a conclusion of obviousness must be firmly based on

knowledge and skill of a person of ordinary skill in the art at the time the invention was made without the use of post-filing knowledge.

19. I understand that in determining whether a particular combination of prior art teachings would have been obvious, the following are examples of approaches and rationales that may be considered:

- (a) Combining prior art elements according to known methods to yield predictable results;
- (b) Simple substitution of one known element for another to obtain predictable results;
- (c) Use of a known technique to improve similar devices (methods, or products) in the same way;
- (d) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) Applying a technique or approach that would have been “obvious to try” (choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success);
- (f) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; or

(g) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

20. I understand that obviousness may be established by showing that all of the claimed elements were known in the prior art and one skilled in the art would have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art.

C. Legal Standard for Written Description

21. I understand that, in deciding whether the patent satisfies the written description requirement, one must consider the description from the viewpoint of a person skilled in the field of technology at the effective filing date for the patent. The written description requirement is satisfied if the patent specifically reasonably conveys to a person of skill in the art to which it pertains or with which it is most nearly connected that the inventor actually possessed (i.e., invented) the full scope of the claimed invention at the effective filing date.

22. I have additionally been instructed that the written description requirement may be satisfied in appropriate circumstances by a combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent application.

23. I understand that the full scope of a claim or any particular requirement in a claim need not be expressed in the specification in the exact same words as in the claim, nor is doing so necessarily sufficient to find written description support for the claims. The test is whether the specification conveys to a person skilled in the field of technology of the patent at the time of filing that the applicant possessed (i.e., invented) the full scope of the claim (including each individual requirement) at the critical date.

D. Legal Standard for Enablement

24. I understand that a claim is unpatentable for lack of enablement if the specification does not contain a sufficiently full, clear, concise, and exact description of the manner and process of making and using the full scope of the claimed invention to enable a person of ordinary skill in the art to make and use the invention without undue experimentation at the critical date.

E. Legal Standard for Indefiniteness

25. I have been informed that the claims of a patent must particularly point out and distinctly claim the subject matter which the inventor regards as the invention.

26. I have been informed that a claim is indefinite if, read in light of the specification and the prosecution history, the claim fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

IV. OVERVIEW OF THE '603 PATENT

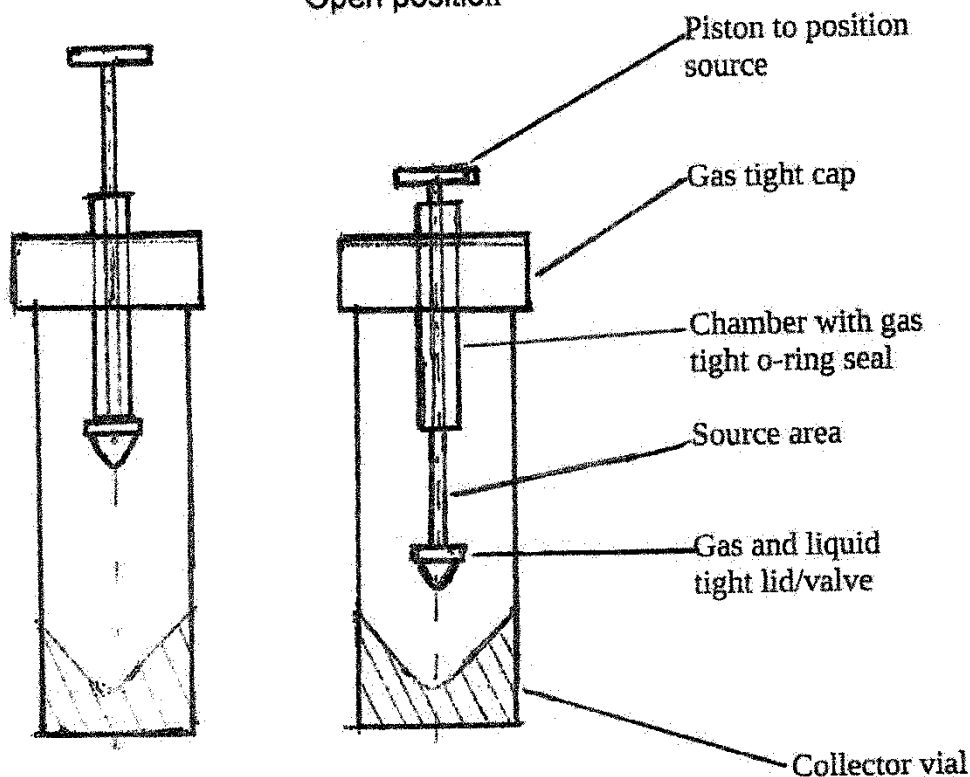
27. The title of the '603 patent is "Production of Highly Purified ^{212}Pb ." The '603 patent discloses methods and systems for producing highly purified radioisotopes, such as ^{212}Pb . *See* EX1001, Abstract. Radioisotopes such as ^{212}Pb have important applications as radiopharmaceuticals, including in cancer therapy. EX1001, 7:22-26, 9:58-67.

28. As the '603 patent explains, ^{212}Pb has a 10.6-hour half-life, making it a useful radioisotope for anti-cancer treatment because it decays rapidly, delivering a large dose of radiation, while also decaying quickly enough to mostly stop emitting radioactivity into the body shortly after treatment. *See* EX1001, 1:62-2:3. However, the short half-life also impedes centralized production, storage, and distribution (since the isotope will decay during storage and shipment), raising the need for methods of production that may be performed easily in the location where the radioisotopes are needed, such as a hospital. EX1001, 1:62-2:3, 6:1-14.

29. The '603 patent provides solutions to these problems, disclosing devices and methods for radioisotope generation different from those proposed in the past. These devices allow on-location generation of radioisotopes like ^{212}Pb safely, efficiently, and in high purity. *See* EX1001, Abstract. For example, Fig. 4 (below) depicts a device configured to generate radioisotopes and deposit them on the interior surface of a collector vial.

Closed position

Open position



EX1001, Fig. 4; *see also id.* 14:39-45, 18:19-35. The collector vial shown above is connected to a cap, and together, they produce a gas-tight seal, preventing gas from escaping to outside the collector vial. *See* EX1001, 14:39-45, 18:19-35, 13:64-14:26, Figs. 2, 4.

30. The rod moves between an open or closed position by sliding it up or down. *Id.* When the rod is moved to the open position (shown on the right), the isotope source is exposed to the volume inside the container, including the vial's interior collector surface, allowing decay products to emanate into the collector vial and collect on the walls. *Id.* By moving the rod to the closed position (shown

on the left), the radioisotope source is isolated from the remaining volume of the collector vial because it is sealed within the chamber in the center. This prevents gaseous decay products from emanating from the radioisotope source to the container walls. *See id.*

31. These features are reflected in the claims of the '603 patent. I have reproduced independent claims 1 and 12 below, with claim elements labeled to match the labels applied by Dr. Mirzadeh in EX1002:

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

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

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

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

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

[12pre] 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

[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.

V. LEVEL OF SKILL IN THE ART

32. I have been advised that “a person of ordinary skill in the art” (POSITA) is a hypothetical person to whom one could assign a routine task with reasonable confidence that the task would be successfully carried out. I have been advised further that, in determining the level of ordinary skill in the art that someone would have had at the time the claimed invention was made, one should consider: (1) the levels of education and experience of persons working in the field; (2) the types of problems encountered in the field; and (3) the sophistication of the technology. I understand that the Petitioner has identified the priority date for the '603 patent as December 5, 2019.

33. Dr. Mirzadeh has provided the following description of the person of ordinary skill:

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, nuclear chemistry, radiochemistry, chemical engineering, physics, or materials science, or a comparable field of study, plus approximately two to three years of professional experience with radioisotope generators, radiopharmaceutical

chemistry, nuclear medicine, or other relevant industry experience. Additional graduate education could substitute for professional experience, and significant experience in the field could substitute for formal education.

EX1002, ¶33.

34. According to the standard identified by Dr. Mirzadeh, I was at least a person of ordinary skill in the art as of the critical date he identifies for the '603 patent (December 5, 2019). Based on my specialized education, knowledge, training, and experience, I am familiar with the level of skill and understanding of a POSITA as of that date. In this declaration, I apply a level of skill in the art consistent with the standard adopted by Dr. Mirzadeh.

VI. CLAIM CONSTRUCTION

35. I have been advised that the claim terms of the '603 patent claims are to be given the plain and ordinary meaning that the terms would have to a person of ordinary skill in the art in question at the relevant priority date. I understand that the analysis focuses on how the patentee used the claim term in the claims, specification, and prosecution history. I also understand that dictionaries or other extrinsic sources may assist in determining the plain and ordinary meaning but cannot override a meaning that is unambiguous from the intrinsic evidence. I have followed these principles in my analysis throughout this declaration. I address

certain terms, including some terms for which Dr. Mirzadeh offered constructions, in the sections below.

A. “precursor isotope source”

36. Each of independent claims 1 and 12 recites a “precursor isotope source,” and the term also appears in dependent claims 2, 4, 5, 7, 8, 9, 10, 13, 14, 16, 17, 18, and 20. Dr. Mirzadeh does not offer a construction for the term “precursor isotope source.”

37. A POSITA would have understood the term “precursor isotope source,” in the context of the claims of the ’603 patent, to refer to a material that decays into one or more progeny isotopes. This understanding is supported by the language of the claims themselves, as each independent claim recites that the precursor isotope source decays. Claim 1, for example, recites a step of “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.” Claim 12 similarly recites “to allow the precursor isotope source to decay into one or more progeny isotopes emanated into the container.” Based on the language of the claims, a POSITA would have understood that the term “precursor isotope source” as recited in these claims refers to a material that decays into one or more progeny isotopes.

38. This understanding is consistent with the specification of the '603 patent, which includes many examples of the term “precursor isotope source” referring to a material that decays into progeny isotopes. One example provided is that “the ^{212}Pb precursor isotope source is selected from the group consisting of ^{232}Th , ^{228}Ra , ^{228}Ac , ^{228}Th and/or ^{224}Ra .” EX1001, 3:1-3; *see also id.*, 3:4-8 (may also be a mixture of these). Each of ^{232}Th , ^{228}Ra , ^{228}Ac , ^{228}Th and ^{224}Ra is a radioactive isotope that undergoes a sequence of radioactive decays (as shown in Fig. 1 of the '603 patent) to produce progeny isotopes such as ^{220}Rn and its decay products.

39. In another example, “the ^{212}Pb precursor isotope source is in the form of an inorganic or organic salt, such as RaCl_2 .” EX1001, 3:34-36. Here, the RaCl_2 salt also undergoes decay to produce progeny isotopes, with the radium decaying into radon, from which the radon emanates to produce radon gas, changing the salt into a form with an excess of chloride ions relative to radium ions.

40. The specification describes some embodiments in which the “precursor isotope source is bound to a non-radioactive material, such as particles or a holding material.” EX1001, 3:37-39. Here, the non-radioactive portion (the particles or holding material) is distinct from the precursor isotope source, which is the part that radioactively decays. In another example, the “precursor isotope source is deposited on a strip or sphere” made of various materials, or on a rod.

EX1001, 1:46-53; *see id.*, 8:12-13, claims 1, 9. Again in these examples, the specification distinguishes between the precursor isotope source that decays into progeny isotopes, and the materials used to hold the precursor isotope source.

41. In one instance, the specification states “The ^{212}Pb precursor isotope source can associated with a needle, rod or a strip of a material of which ^{212}Pb precursor isotope source is attached to allow diffusion of ^{220}Rn . The source may or may not contain a holder for the radioactive part and a grid or ring or similar surrounding the source to prevent cross contamination when the ^{212}Pb precursor isotope source is withdrawn from the container.” EX1001, 10:1-7. This passage is not inconsistent with my discussion of a POSITA’s understanding of the term precursor isotope source in these claims.

42. The second sentence indicates that the source *contains* a holder, not that it *is* a holder. For example, the precursor isotope source (a material that decays) could surround an element such as the “rod,” in which case the precursor isotope source contains (surrounds) the holder (rod). Likewise, the passage describes a “grid or ring or similar surrounding the source,” confirming that the “grid or ring or similar” is a different thing from the source. *Id.*

43. Regardless, the claims require the precursor isotope source to decay into progeny isotopes. Additionally, while the specification passage I quoted above indicates that the “source may or may not contain a holder...,” the claim

distinguishes between the precursor isotope source and the rod (e.g., holder) on which it is disposed.

B. “disposed on the rod”

44. The term “disposed on the rod” appears in independent claim 1, and the similar term “disposed on a rod” appears in independent claim 12. Each claim specifically requires that the precursor isotope source be disposed on the rod. I understand Dr. Mirzadeh construed the term “disposed on the rod” to refer to “directly or indirectly attaching to the rod.” EX1002, ¶35.

45. I do not agree that the term “disposed on the rod” means “directly or indirectly attached to the rod.” The ordinary meaning of the term “disposed” refers to where a thing is located, so the claims require that the precursor isotope source be located on the rod.

46. While Dr. Mirzadeh identifies examples in the specification in which a precursor isotope source can be attached to a rod (EX1002, ¶35 (citing EX1001, 3:54-58, 8:58-65)), this does not affect the interpretation a POSITA would have given to the term “disposed on the rod.” Attaching one object to another is a way that can result in one object being disposed on another; for example, if precursor isotopes are deposited on the surface of a rod, they can be both attached to and disposed on the rod. Similarly, if precursor isotopes are deposited on the surface of a strip or sphere that is attached directly to the surface of a rod, then precursor

isotopes can be disposed on both the strip or sphere and the rod, since they are located on both simultaneously. However, a precursor isotope source that was indirectly attached to a rod may not be disposed on the rod; for example, if it were hanging away from the rod. Because Dr. Mirzadeh's examples are consistent with the plain meaning of "disposed on the rod" as "located on the rod," and because his construction would encompass situations where the precursor isotope source is not located on the rod, a POSITA would not have understood "disposed on the rod" as meaning "attached directly or indirectly to the rod."

47. However, as I discuss below in regard to ground 1, even if "disposed on the rod" meant directly indirectly attached to the rod, the prior art relied on by Dr. Mirzadeh would still not satisfy the independent claims.

C. Claims 10 and 20

48. Claim 10 recites "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 20 recites "wherein the precursor isotope source is configured to decay and emanate the one or more progeny isotopes into the container for 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours."

49. Dr. Mirzadeh construes claim 10 to mean "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. I agree that this is the understanding a POSITA would have had for claim 10.

50. Dr. Mirzadeh identifies two constructions for claim 20: in one construction, “the precursor isotope source must be configured such that it decays and emanates the one or more progeny isotopes for exactly” one of the listed times, whereas in the others, it is configured to decay “for at least (or more than) one of the listed times.” EX1002, ¶39. Dr. Mirzadeh states that a POSITA would have chosen his first construction, but I disagree. He has inserted the word “exactly,” which does not appear in the claims. Claim 20 does not say that its list of times is exclusive—that is, it does not say that the precursor isotope source could not be capable of decaying and emanating for an amount of time different from those listed, so long as it was capable of decaying for one or more amounts of time matching the list. Indeed, since radioactive decay is a quantum mechanical process that is observed to produce progeny stochastically (randomly), a POSITA would have understood that a precursor isotope source would decay and emanate as a continuous process for various amounts of time based on the quantity of isotopes, and being configured to decay for (e.g.) 5 hours would not be inconsistent with also being configured to decay for 6 hours, 7 hours, etc.

VII. GROUND 1 – HASSFJELL-HOFF DOES NOT ANTICIPATE CLAIMS 1-6, 8, 11-17, AND 19

51. Hassfjell-Hoff (EX1003) has not been shown to anticipate or render obvious claims 1-6, 8, 11-17, and 19 because it has not been shown to teach each and every element of these claims in the configuration recited in the claims. I understand that claim 7 has been disclaimed and is thus no longer part of the '603 patent.

A. Claims 1 and 12: Hassfjell-Hoff has not been shown to teach the isolating and exposing steps

52. Claim element 1d recites “isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position,” and claim element 1a recites “exposing an interior surface of a container to a precursor isotope source by sliding a rod from a closed position in which the precursor isotope source is sealed off from the interior surface of the container to an open position in which the precursor isotope source is exposed to the interior surface of the container.” Similarly, claim 12 recites “the rod configured to slide between an open position in which the precursor isotope is exposed to an interior surface of a 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.” Hassfjell-Hoff has not been shown to disclose these elements.

53. Fig. 2 of Hassfjell-Hoff, depicting a generator, is reproduced below.

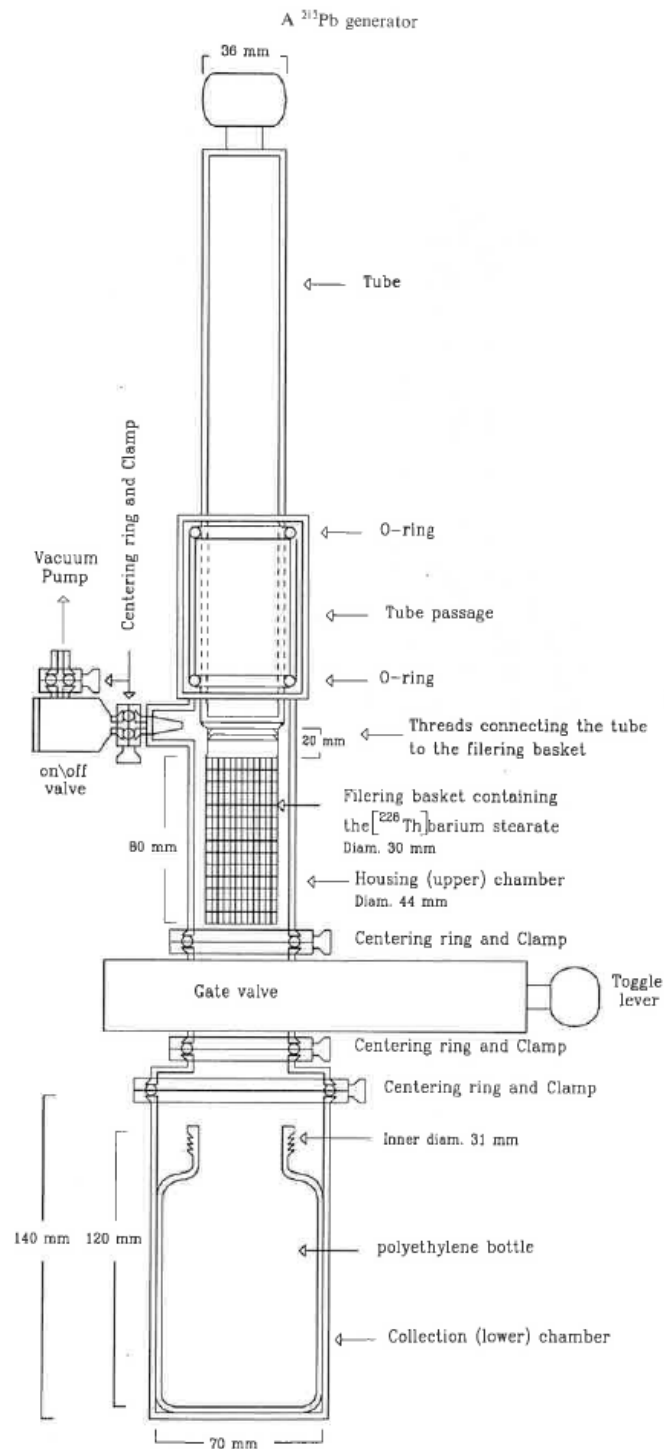


Fig. 2. The design of the generator showing functional details and operating mechanism.

EX1003, Fig. 2. I understand that Dr. Mirzadeh, when questioned regarding the operation of Hassfjell-Hoff's gate valve, testified that the gate valve is opened and

closed by actuating the toggle lever shown in the figure above. I agree. The generator shown in this figure has a tube that slides up and down and a gate valve that can be opened and closed by actuating a toggle lever shown on the right side of the diagram. *See id.*, 7; *see also id.*, Fig. 3 (photograph of generator, showing toggle lever with black handle on right). The tube has a “filtering basket” (which I understand to be a basket made of a material like embroidered lace) that hangs off of its end, and within that filtering basket are membrane packets that contain [^{228}Th]barium stearate, a material that decays to produce isotopes including ^{224}Ra and ^{220}Rn , among others. *See* EX1003, 7, Fig. 2. The ^{220}Rn produced by this decay emanates out of the packets as a gas. *See id.*

54. Dr. Mirzadeh maps the tube to the “rod” recited in the claims and identifies the “open position” as a position “when the gate valve is open and the tube is pushed down,” and the “closed position” as a position “when the tube is pulled up and the gate valve is closed.” EX1002, ¶52; *see also id.*, ¶¶92-93. However, these “positions” are not positions of the tube—they are configurations describing the location of the tube and the state of the gate valve. Sliding the tube does not take you between the open and closed positions identified by Dr. Mirzadeh. You can move the rod from down to up, for example, by sliding it, but that does nothing to the gate valve. I understand that Dr. Mirzadeh, in paragraph 56 of his declaration for PGR2025-00040, has described Hassfjell-Hoff’s gate valve

as follows: “Hassfjell-Hoff’s system includes a gate valve that is used to selectively fluidly couple or isolate the source (when it is retracted into the upper chamber) and the lower volume (i.e., lower collection chamber).” I agree that it is the gate valve that exposes or isolates the source from the container, not the sliding or positioning of Hassfjell-Hoff’s tube.

55. When the tube is down, the [^{228}Th]barium stearate is inside the polyethylene bottle in the lower chamber; when the tube is up, the [^{228}Th]barium stearate is in the upper chamber. Sliding the tube between these two positions does not expose the polyethylene bottle to or isolate the polyethylene bottle from the [^{228}Th]barium stearate.

56. When the gate valve is open, ^{220}Rn emanates from the [^{228}Th]barium stearate and fills the entirety of both the upper and lower chambers. Thus, regardless of the tube’s position, the polyethylene bottle is exposed to the [^{228}Th]barium stearate. Specifically, starting from a “down” position, raising the tube to an “up” position does not isolate the bottle from the [^{228}Th]barium stearate. I understand that when questioned, Dr. Mirzadeh testified that it is the closing of the gate valve that isolates the polyethylene bottle from the source. I agree. It is only by closing the gate valve that the bottle is isolated from the [^{228}Th]barium stearate.

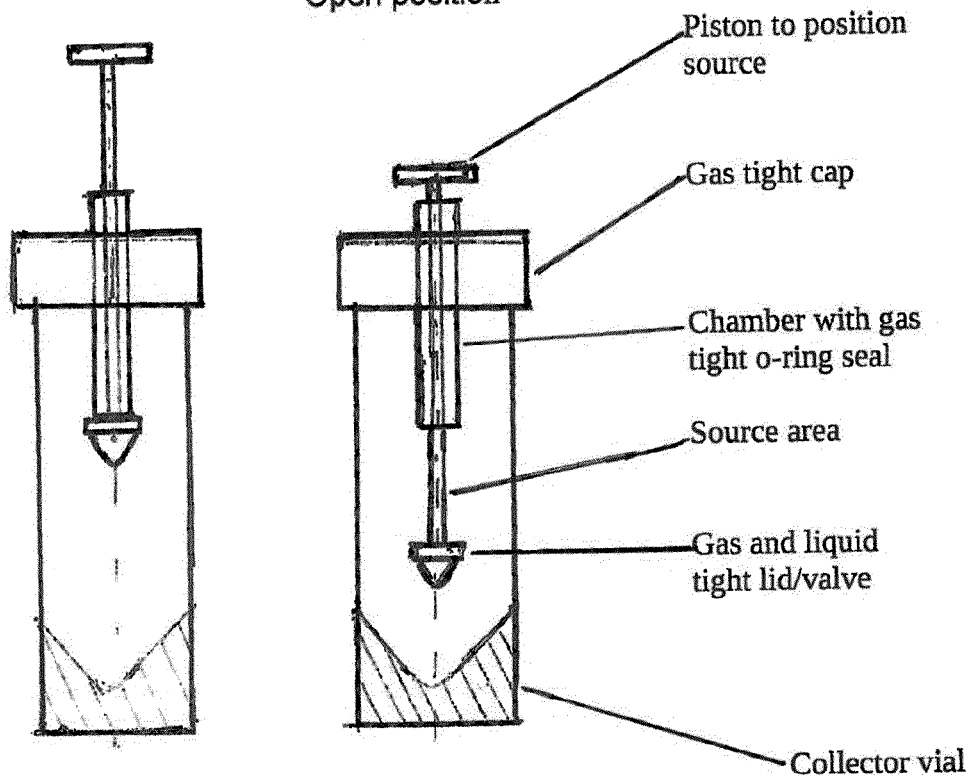
57. Conversely, starting from an up position with the gate valve closed, the bottle is isolated from the [^{228}Th]barium stearate. Lowering the tube from this position cannot expose the bottle to the [^{228}Th]barium stearate—it would run into the closed gate valve. By contrast, opening the gate valve exposes the bottle to the [^{228}Th]barium stearate without moving the rod at all—in either the upper or lower position of the tube, whenever the gate valve is open, the bottle is exposed to the [^{228}Th]barium stearate.

58. This aspect of Hassfjell-Hoff is distinct from the claims of the '603 patent, which expressly recite (in claim 1) steps of isolating and exposing the precursor isotope source by *sliding the rod*, and recite (in claim 12) a *rod* having open and closed positions that respectively expose or isolate the precursor isotope source from the container.

59. Examples of a generator in which this type of exposing and isolating is provided by sliding a rod are shown in Figs. 2 and 4 of the '603 patent, in which a rod with precursor isotopes on its surface is moved upwards and downwards to expose or isolate the precursor isotopes. This is most easily seen in Fig. 4, in which the source area labeled on the rod portion of the piston is exposed in the open position (right), but by sliding it upwards, it is sealed off in the closed position (right) because a valve at the bottom of the rod seals it within a chamber.

Closed position

Open position



EX1001, Fig. 4; *see id.*, 18:19-35 (example 11); *see also* Fig. 2 (showing rod with similar operation to expose or isolate precursor isotope source by sliding). This aspect of isolating by sliding a rod from a closed to an open position and exposing by sliding a rod from an open to a closed position, which is required expressly by the claims, is not present in Hassfjell-Hoff, since it only provides exposure of isolation of its [^{228}Th]barium stearate by opening or closing a gate valve, not by sliding a rod.

B. Claims 1 and 12: Hassfjell-Hoff has not been shown to teach a (or the) precursor isotope source disposed on a (or the) rod

60. Independent claim 1 recites “the precursor isotope source is disposed on the rod” and independent claim 12 recites “a precursor isotope source disposed on a rod.” Hassfjell-Hoff has not been shown to disclose these elements.

61. As I note above, Dr. Mirzadeh identifies Hassfjell-Hoff’s tube as the “rod” recited in each independent claim. *See* EX1002, ¶¶52, 92. However, this tube does not have a precursor isotope source on it.

62. Repeatedly throughout his declaration, Dr. Mirzadeh identifies the [²²⁸Th]barium stearate of Hassfjell-Hoff as the precursor isotope source. *See, e.g.*, EX1002, ¶¶52 (“precursor isotope source (i.e., packet of [²²⁸Th]barium stearate)”), 53 (“a precursor isotope source of [²²⁸Th]barium stearate”), 56 (“the precursor isotope source (i.e., the [²²⁸Th]barium stearate)”), 92 (“the precursor isotope source (i.e., packet of [²²⁸Th]barium stearate)”).

63. I understand that Dr. Mirzadeh, when questioned, testified that other than [²²⁸Th]barium stearate, there are no other sources shown in Hassfjell-Hoff, and that he further testified that Hassfjell-Hoff’s basket. I agree. No part of Hassfjell-Hoff’s system other than the [²²⁸Th]barium stearate decays into progeny isotopes or emanates progeny isotopes, so only the [²²⁸Th]barium stearate can constitute a precursor isotope source. While Dr. Mirzadeh in his declaration sometimes refers to the *packet of* [²²⁸Th]barium stearate, the filter membrane

material that forms the packet does not decay into progeny isotopes, so it is not part of a precursor isotope source.

64. However, the [^{228}Th]barium stearate is not disposed on Hassfjell-Hoff's tube as required by the independent claims. The [^{228}Th]barium stearate is encapsulated inside several layers of fiber membrane to form packets containing [^{228}Th]barium stearate, and several packets are placed at the bottom of the filering basket, which has threads above it that connect to the end of the tube. The [^{228}Th]barium stearate is thus not disposed on (located on) the tube, but rather hangs down in a basket well beyond the tube's end.

65. Nor is the [^{228}Th]barium stearate attached directly or indirectly to the tube, as required by Dr. Mirzadeh's construction. The [^{228}Th]barium stearate is encapsulated in packets of filter membrane, but neither the [^{228}Th]barium stearate nor the packets are attached to the filering basket: they are separate components hanging loosely at the bottom of the basket. Nor is either attached to the tube. Since the [^{228}Th]barium stearate is not attached to the packet material, the filering basket, or the tube, there is no direct or indirect attachment of the [^{228}Th]barium stearate to a rod. Accordingly, Hassfjell-Hoff has not been shown to disclose the "disposed on [a/the] rod" limitation of claims 1 and 12.

66. In one paragraph, Dr. Mirzadeh provides an alternative mapping in which "the combination of the [^{228}Th]barium stearate packets and basket is the

source of the precursor isotope in Hassfjell-Hoff, and those are directly connected to the rod.” EX1002, ¶54. The combination of separate components described by Dr. Mirzadeh in this sentence cannot be the precursor isotope source recited in the claims. Claims 1 and 12 require that the precursor isotope source “decay into one or more progeny isotopes” that emanate into the container. As I explained above, a POSITA would understand this requirement to mean that the “precursor isotope source” must be a material that undergoes such decay. Indeed, when addressing the decay recited in the independent claims, Dr. Mirzadeh only identifies the precursor isotope source as [^{228}Th]barium stearate, not as any other parts of Hassfjell-Hoff. EX1002, ¶56. This is because no other parts of Hassfjell-Hoff’s generator (such as the packets’ filter membrane or the filtering basket) decays into progeny isotopes, so a precursor isotope source that included such other elements would not satisfy the claims as understood by a POSITA.

67. Accordingly, Hassfjell-Hoff has not been shown to anticipate independent claims 1 or 16.

C. Dependent claims 5, 14, and 15

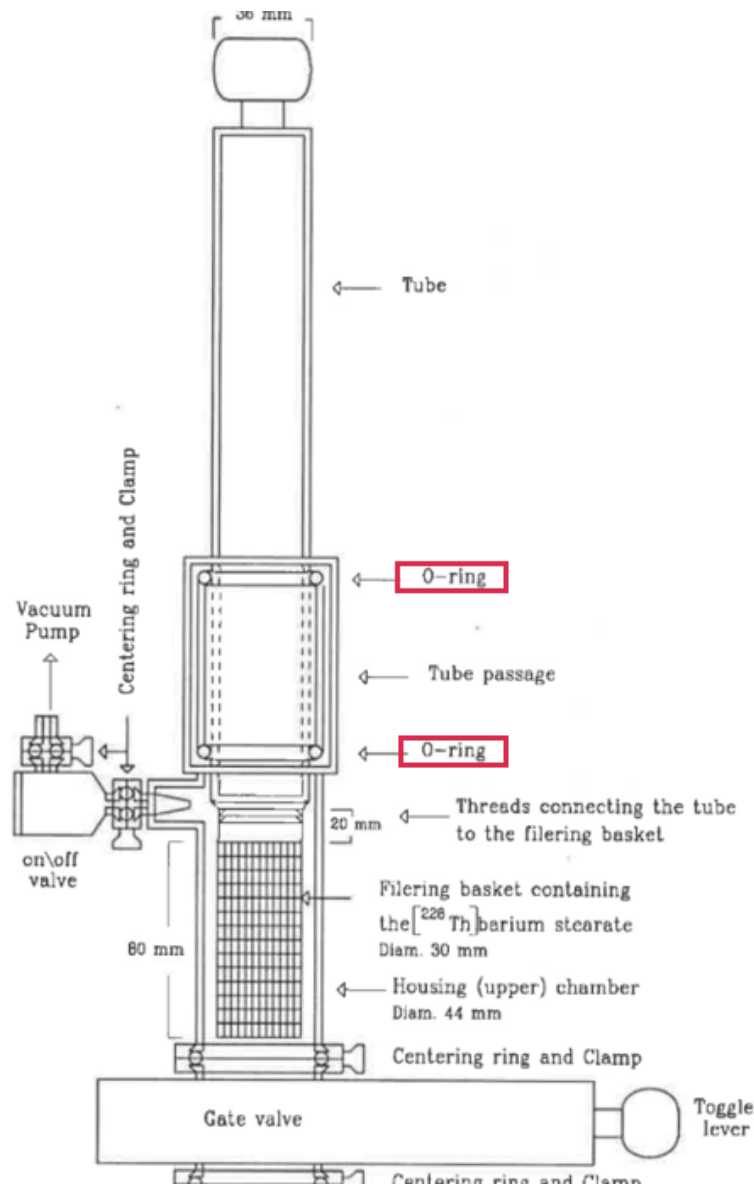
68. Claim 4 recites “The method of claim 1, wherein isolating the precursor isotope source from the container further comprises withdrawing the precursor isotope source into a chamber having a gas tight seal,” and claim 5 recites “The method of claim 4, wherein withdrawing the precursor isotope source

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.”

69. Claim 14 recites “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.” Claim 15 depends from claim 14 and recites “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.”

70. Hassfjell-Hoff has not been shown to disclose the limitations of claims 5, 14, and 15.

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



EX1002, ¶¶70-71 (marking up EX1003, Fig. 2). And Dr. Mirzadeh identifies Hassfjell-Hoff's "tube" as the "rod" recited in claim 5. *See id.* I understand that when questioned, Dr. Mirzadeh testified that Hassfjell-Hoff's tube is never contained entirely within the tube passage. I agree. While Hassfjell-Hoff's tube passes through the identified tube passage, it is not *sealed within the tube passage*

as required by claim 5. Hassfjell-Hoff's tube extends below (as well as above) the identified tube passage, so it is not sealed *within* it.

72. Dr. Mirzadeh relies on his analysis of claim 5 to meet the similar limitations of claims 14-15. *See* EX1002, ¶¶98-103. Because his analysis of claim 5 is defective, it also fails to show the limitations of claims 14 and 15.

73. Hassfjell-Hoff fails to anticipate claims 14 and 15 for additional reasons as well. Claim 14 requires that the "rod forms a gas tight seal with a tube in which the rod slides to isolate the precursor isotope source from the interior surface." But the seals Dr. Mirzadeh identifies (seals provided by the marked o-rings) are not formed to isolate the precursor isotope source from the interior surface; rather, those seals remain present at all times. They merely prevent gas from escaping to the environment; they do not isolate the precursor isotope source from the interior surface.

74. Regarding claim 15, this claim further recites that "the rod includes at least one O-ring to form the gas tight seal with the tube in the closed position." However, Hassfjell-Hoff's tube (which Dr. Mirzadeh maps to the "rod" recited in the claims) does not "include" the O-ring; rather, the O-ring is affixed to the tube passage (mapped to the "tube"), with the rod sliding through it.

75. Accordingly, Hassfjell-Hoff has not been shown to anticipate claims 5, 14, and 15.

D. Dependent claims 8 and 17

76. Dependent claim 8 recites “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.” Claim 17 recites “The system of claim 12, wherein the precursor isotope source is encapsulated in a gas permeable barrier.” Hassfjell-Hoff has not been shown to disclose these elements.

77. Dr. Mirzadeh identifies the “gas permeable barrier” as one or both of “the filtering basket and the packet filter material.” EX1002, ¶86; *see id.*, ¶109. However, this mapping is inconsistent with the “alternative” mapping he described for limitation 1b (EX1002, ¶54), because in that mapping the precursor isotope source includes not just the [²²⁸Th]barium stearate but also the packets and filtering basket.

78. These elements cannot be both part of the precursor isotope source *and* the gas permeable barrier. Claim 17 recites that the gas permeable barrier must encapsulate the precursor isotope source, so it is a distinct element. Likewise, claim 8 recites allowing “progeny isotopes to emanate into the container from the precursor isotope source through a gas permeable barrier.” This similarly requires that the gas permeable barrier be a distinct element from the precursor isotope

source. Accordingly, even if the precursor isotope source could encompass Hassfjell-Hoff's packet membrane and filtering basket (which as I explained above, it cannot for either independent claim), neither claims 8 nor 17 would be satisfied by such a mapping.

79. And as I further explained above for claims 1 and 12, under Dr. Mirzadeh's mapping of the [²²⁸Th]barium stearate to the precursor isotope source, the independent claims' requirement that the precursor isotope source be "disposed on [a/the] rod" is not satisfied because the [²²⁸Th]barium stearate is not disposed on a rod. Accordingly, Dr. Mirzadeh has not shown that Hassfjell-Hoff anticipates claims 8 and 17.

80. As each of claims 3-4, 7-12, 14-5, 17-19, 22-26, 28-29, 31-32, 34-36 and 38 depends from claim 1 or 16, Hassfjell-Hoff has also not been shown to anticipate or render obvious claims 3-4, 7-12, 14-5, 17-19, 22-26, 28-29, 31-32, 35-36 and 38.

VIII. GROUND 2 – CLAIMS 5-6, 10-11, 15-16, AND 20 HAVE NOT BEEN SHOWN TO BE OBVIOUS OVER HASSFJELL-HOFF

81. Ground 2 addresses only elements of dependent claims 5-6, 10-11, 15-16, and 20. *See* EX1002, ¶¶113-28. Each of these claims depends directly or indirectly from independent claim 1 or independent claim 12. None of Dr. Mirzadeh's discussion relating to obviousness for Hassfjell-Hoff addresses the

deficiencies I discussed above for independent claims 1 and 12, so ground 2 fails to show the obviousness of any of claims 5-6, 10-11, 15-16, and 20.

82. Dr. Mirzadeh's analysis of claims 5 and 15 in ground 2 is also independently flawed because the modifications he proposes fail to remedy the deficiencies of Hassfjell-Hoff that I discussed in ground 1.

83. Regarding claim 5, Dr. Mirzadeh asserts that it would have been obvious to prevent escape of radioisotopes from the generator by making Hassfjell-Hoff's components such as o-rings gas-tight. EX1002, ¶114. However, that does not address the deficiencies I discussed above regarding claim 5's limitations. For example, even making Dr. Mirzadeh's proposed modification would not change the fact that that Hassfjell-Hoff's tube (which he maps to the claimed "rod") is not sealed within the Hassfjell-Hoff's tube passage (which he maps to the "tube" of claim 5).

84. Claim 15 depends from claim 14, and Dr. Mirzadeh's ground 2 arguments do not address the deficiencies I discussed above regarding claim 14. Moreover, in ground 2, Dr. Mirzadeh argues that it would be obvious for Hassfjell-Hoff's tube to *touch* an O-ring. EX1002, ¶124. However, claim 15 recites that the rod *includes* an O-ring, not merely that it touches one. A POSITA would not have understood the configuration shown in Hassfjell-Hoff to be a rod including an o-ring, and Dr. Mirzadeh does not propose modifying Hassfjell-Hoff's tube to

incorporate (as oppose to merely contact) an o-ring, so claim 15 has not been shown to be obvious over Hassfjell-Hoff for this reason as well.

IX. GROUND 3 – CLAIMS 9-10, 18, 20 HAVE NOT BEEN SHOWN TO BE OBVIOUS OVER HASSFJELL-HOFF AND O’HARA

85. Ground 3 addresses only elements of dependent claims 9-10, 18, and 20. *See* EX1002, ¶¶129-51. Each of these claims depends directly or indirectly from independent claim 1 or independent claim 12. None of Dr. Mirzadeh’s discussion relating to obviousness over Hassfjell-Hoff and O’Hara addresses the deficiencies I discussed above for independent claims 1 and 12, so ground 2 fails to show the obviousness of any of claims 5-6, 10-11, 15-16, and 20.

86. Dr. Mirzadeh’s analysis of claims 9 and 18 in ground 3 is also independently flawed due to inconsistencies between his arguments for their limitations and the arguments in the independent claims.

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

88. For claim 9, Dr. Mirzadeh asserts that a “POSITA would have been motivated to combine Hassfjell-Hoff and O’Hara to implement the filter membrane packets and surrounding filtering basket disclosed by Hassfjell-Hoff with the O’Hara gas permeable metal or mineral membrane, screen, filter, or porous disc (each are a sponge) containing the precursor isotope source.” EX1002, ¶140. Dr. Mirzadeh characterizes O’Hara as teaching “various examples of the precursor isotope source disposed on a mineral sorbent that is on a ‘permeable metal membrane, screen, [] filter’ or ‘porous disc,’” which he asserts are each a “sponge.” EX1002, ¶¶139-40, (quoting EX1007, [0020]-[0022]).

89. Like with claims 8 and 17, Dr. Mirzadeh’s mapping of the precursor isotope source in claims 9 and 18 is not consistent with the mapping in the independent claims that identifies the filtering basket and packet membrane as part of the precursor isotope source. When Dr. Mirzadeh discusses a precursor isotope source for claims 9 and 18, he talks about disposing radioactive isotopes in a sponge. But if the precursor isotope source were to include the filtering basket and packet membrane, claims 9 and 18 would require these elements also to be disposed in or on the recited sponge. This is not what Dr. Mirzadeh proposes; indeed, it would make no sense to do so.

90. On the other hand, as discussed above for ground 1, under a mapping in which the precursor isotope source is a radioactive material (as is necessary for

claims 9 and 18, as well as for the independent claims), Hassfjell-Hoff's generator (alone or as modified in view of O'Hara) fails to meet the "disposed on the rod" limitations of the independent claims. Accordingly, regardless of what the precursor isotope source is identified as, Hassfjell-Hoff and O'Hara have not been shown to render claims 9 and 18 obvious.

X. GROUND 4 – CLAIMS 1-3, 8-10, 12, AND 20 HAVE NOT BEEN SHOWN TO BE UNPATENTABLE FOR LACK OF WRITTEN DESCRIPTION, NON-ENABLEMENT, OR INDEFINITENESS

91. Dr. Mirzadeh has asserted that claims 1-3, 8-10, 12, and 20 are unpatentable for various reasons including lack of written description, lack of enablement, or indefiniteness. *See* EX1002, ¶¶152-63. However, Dr. Mirzadeh fails to identify any defects rendering any of these claims unpatentable.

A. Claims 1 and 12

92. Dr. Mirzadeh asserts that claims 1 and 12 are non-enabled and lack written description because they recite allowing time for the precursor isotope source to decay into "one or more progeny isotopes" and emanate the one or more progeny isotopes into the chamber. EX1002, ¶¶152, 162. Dr. Mirzadeh does not dispute that Fig. 1 shows several decay products from precursor isotopes, such as ^{220}Rn , ^{216}Po , and ^{212}Pb . But when discussing Fig. 1, Dr. Mirzadeh asserts that only ^{220}Rn emanates because it is a gas, but the other isotopes shown in Fig. 1 do not emanate because they are not gases. *See* EX1002, ¶152 ("Only ^{220}Rn is in the

gaseous state, therefore only ^{220}Rn can emanate.”). Dr. Mirzadeh states that the claims are non-enabled and lack written description “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 and that also emanates into the container.” *Id.*

93. Dr. Mirzadeh is incorrect. Certainly the specification discloses that ^{220}Rn , as a noble gas, will emanate into the container. *See, e.g.*, EX1001, 6:28-38 (^{220}Rn “will diffuse from the source”), 18:25-29 (“In the open position the source will be exposed inside the container and emanate ^{220}Rn and cause deposit of ^{212}Pb onto the inner surface.”). But other progeny isotopes also emanate into the container: as Fig. 1 shows, ^{220}Rn decays with a 55.6 s half-life into ^{216}Po , which quickly decays (with a half-life of 145 ms) into ^{212}Pb . *See* EX1001, 2:27-47, Fig. 1, Table 1.

94. Consistent with this, the specification describes that the ^{220}Rn “after decay settle[s] as ^{212}Pb onto the inner walls of the container.” EX1001, 13:64-14:25; *see also id.*, 2:27-47 (describing allowing time for “ ^{220}Rn , ^{216}Po , and/or ^{212}Pb to settle onto the inner walls of the single chamber container assembly”), 18:25-29 (deposition of ^{212}Pb onto surface). I understand that Dr. Mirzadeh, when questioned, testified that the decay products of ^{220}Rn — ^{216}Po and ^{212}Pb —will continue to move until they collide with a surface like the container wall and stick

to it. I agree. In other words, the ^{220}Rn decays while emanating as a gas, and at that point, its decay products will also be moving similarly to how they moved as gas as they continue emanating into the container, up until they settle as ^{212}Pb on the walls of the container. A POSITA would thus understand the emanation process described in the '603 patent as involving multiple progeny isotopes emanating— ^{220}Rn emanates as a gas, and while emanating as a gas decays into ^{216}Po , which continues emanating briefly before decaying into ^{212}Pb , which completes the emanation by converting into a coating on the container surface.

95. The specification confirms that decay of ^{220}Rn was known to occur, and in fact was a challenge for prior “emanation and diffusion systems” whose long transport distances lost efficiency “due to decay of ^{220}Rn before reaching the collection vessels,” as the resulting ^{212}Pb would deposit away from the target container surfaces. EX1001, 2:4-12. This description, along with the POSITAs’ own understanding of how radioactive decay and emanation of gas particles occurs, confirms that the '603 patent describes an emanation process that can include multiple emanating isotopes, such as ^{220}Rn , ^{216}Po , and/or ^{212}Pb .

B. Claim 2

96. Claim 2 recites “wherein exposing the interior surface to the precursor isotope source comprises exposing the interior surface to a thorium 228 isotope (^{228}Th) and/or a radium 224 isotope (^{224}Ra), the method further comprising

allowing the ^{228}Th to decay into at least one of a radon 220 isotope (^{220}Rn) and a lead 212 isotope (^{212}Pb).” Dr. Mirzadeh asserts that the first half of claim 2 is indefinite and non-enabled because he views its “and/or” as requiring the claim to reach three different embodiments: (i) exposing the interior surface to a thorium 228 isotope; (ii) exposing the interior surface to a radium 224 isotope; and (iii) exposing the interior surface to a mix of the two isotopes. EX1002, ¶153. He further asserts that “any ^{228}Th source must include some portion of ^{224}Ra as would be apparent to a POSITA,” so he says that example (i) is impossible. *Id.*

97. This reasoning is mistaken for multiple reasons. First, the claim does not say that it must encompass exposing the interior surface to thorium-228 but *not* to radium-224. Claim 2 says exposing to thorium-228 and/or radium-224. This requirement is satisfied so long as either of these isotopes is exposed, regardless of whether the other isotope is present or absent. For example, so long as a precursor isotope source includes thorium-228 when it is exposed to the interior surface, this element is satisfied. This requirement is clear and a POSITA would have known how to perform it based on the teachings of the ’603 patent.

98. Furthermore, Dr. Mirzadeh’s assertion that it is impossible to have ^{228}Th without also including some portion of ^{224}Ra is wrong. While ^{228}Th might eventually decay into ^{224}Ra , this does not prevent a source from initially being pure ^{228}Th prior to such decay. For example, if the “precursor isotope source” referred to

a plurality of ^{228}Th atoms that had not yet decayed at the moment that the source was exposed to the interior surface, this claim element would nonetheless be satisfied.

99. Dr. Mirzadeh also asserts that because the second part of claim 2 recites “further comprising allowing the ^{228}Th to decay into at least one of a radon 220 isotope (^{220}Rn) and a lead 212 isotope (^{212}Pb),” this renders the claim indefinite because it requires ^{228}Th to be included in the precursor isotope source. EX1002, ¶154. Specifically, Dr. Mirzadeh says that this rules out his alternative (ii), in which “there is no ^{228}Th .” *Id.* But this does not render the claim indefinite: rather, it confirms that Dr. Mirzadeh’s dividing of claim 2 into multiple alternatives was mistaken. Claim 2 is not required to encompass all possible embodiments, and the language of this limitation simply confirms that the precursor isotope source includes some ^{228}Th that decays to produce at least one of ^{220}Rn and ^{212}Pb .

C. Claim 3

100. Claim 3 recites “The method of claim 2, the method further comprising allowing the ^{212}Pb to deposit on the interior surface of the container.” Dr. Mirzadeh says that claim 3 is indefinite because claim 2 encompasses some cases in which a precursor isotope decays into ^{220}Rn but has not yet decayed into ^{212}Pb , but claim 3 requires ^{212}Pb to deposit on the interior surface of the container. *See* EX1002, ¶¶155-56.

101. Claim 3 depends from claim 2. It is my understanding that a dependent claim narrows the scope of the claim it depends from because it incorporates each limitation of its parent claim and adds further limitations, meaning that some embodiments encompassed by the parent claim will not be encompassed by the dependent claim. Even if claim 2 encompasses cases where decay from ^{220}Rn to ^{212}Pb has not yet occurred, there is nothing inconsistent with claim 3 ruling out those embodiments by specifying that ^{212}Pb must be produced and deposit on a surface. A POSITA would interpret the scope of claim 3 consistent with this understanding and would be able to practice it by following the teachings of the '603 patent.

D. Claims 8 and 9

102. Claims 8 and 9 depend from claim 1. Dr. Mirzadeh asserts that claims 8 and 9 are indefinite because each uses the term “the at least one progeny isotopes,” whereas claim one refers to the progeny isotopes as “one or more progeny isotopes.” EX1002, ¶160. In particular, he asserts that “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.

103. However, prior to the use of the term “the at least one progeny isotopes” in each of claims 8 and 9, there is only one term used referring to progeny isotopes: claim 1’s recitation of “one or more progeny isotopes.” A POSITA would further have understood that “one or more” and “at least one” are two different ways of saying the same thing. With this understanding, the POSITA would have understood that the antecedent referred to by “the at least one progeny isotopes” in claims 8 and 9 is the “one or more progeny isotopes” recited in claim 1. Thus, as a POSITA would have been able to determine, with reasonable certainty, the scope of claims 8 and 9, these claims have not been shown to be indefinite.

E. Claims 10 and 20

104. I addressed claims 10 and 20 above in section VI.C. Dr. Mirzadeh asserts that claim 10 is indefinite and lacks written description “[t]o the extent that claim 10 is construed to require exactly one of the listed times.” EX1002, ¶161. However, as both Dr. Mirzadeh and I agree, this is not the correct construction, so claim 10 is neither indefinite nor does it lack written description.

105. Dr. Mirzadeh also asserts that claim 10 is indefinite because, in his opinion, “a POSITA would not know whether ‘allowing’ refers to the time the source decays or the time the bottle is left in the apparatus.” *Id.* However, claim 10 recites “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” and it refers to claim 1, which recites “allowing sufficient time for the precursor isotope source to decay into one or more progeny isotopes and to emanate the one or more progeny isotopes into the container.” Neither claim 10 nor claim 1 refer to “the time the bottle is left in the apparatus”; they refer to allowing time for the precursor isotope source to decay. A POSITA would thus not have been confused about the time referred to in claim 10.

106. Regarding claim 20, Dr. Mirzadeh states that “To the extent that claim 20 is construed to require exactly one of the listed times, in my opinion, 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.” EX1002, ¶163. However, as I explained above in section VI.C, this is not how a POSITA would have understood claim 20. For example, claim 20 does not use the word “exact,” and a POSITA would not have interpreted claim 20’s list of times for which the precursor isotope is configured to decay and emanate to mean that the device must be capable only of those exact times.

107. For this same reason, claim 20 has not been shown to be indefinite, because Dr. Mirzadeh’s claim of indefiniteness relies on a POSITA not understanding “whether the claim requires cessation of decay at an exact time.” *Id.*

Because a POSITA would not have ascribed this interpretation to claim 20, claim 20 has not been shown to be indefinite.

108. Furthermore, Dr. Mirzadeh appears to have overlooked that claim 20 recites that the times are how long the precursor isotope source is configured “to decay and emanate the one or more progeny isotopes into the container.” The ’603 patent teaches configurations in which a precursor isotope source can decay and emanate into a container for various amounts of time, including those recited in claim 20, by sealing the precursor isotope source after the appropriate span of time spent decaying and emanating.

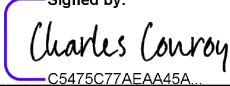
109. Accordingly, claims 1-3, 8-10, 12, and 20 have not been shown to be indefinite.

XI. CONCLUDING STATEMENTS

110. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

111. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: February 4, 2026

By:  Signed by:
C5475C77AEAA45A...
Charles Conroy

XII. EXHIBIT LIST

A. Petitioner's Exhibits Cited Herein

Exhibit No.	Description
1001	U.S. Patent No. 12,125,603 to Roy H. Larsen
1002	Declaration of Saed Mirzadeh
1003	Hassfjell, Sindre P. & Hoff, Per, "A Generator for Production of ^{212}Pb and ^{212}Bi " ("Hassfjell-Hoff")
1006	Prosecution History of U.S. Patent No. 12,125,603
1007	US Patent Application Publication No. 2018/0047474 A1("O'Hara")

B. Patent Owner's Exhibits Cited Herein

Exhibit No.	Description
2003	<i>Curriculum vitae</i> of Charles Conroy