

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.

PGR2025-00040
Patent No. 12,249,437

DECLARATION OF CHARLES CONROY

TABLE OF CONTENTS

I.	QUALIFICATIONS	1
II.	SCOPE OF WORK.....	4
III.	LEGAL STANDARDS	5
	A. Legal Standard for Anticipation.....	5
	B. Legal Standard for Obviousness	6
	C. Legal Standard for Indefiniteness	9
IV.	OVERVIEW OF THE '437 PATENT	9
V.	LEVEL OF SKILL IN THE ART	13
VI.	CLAIM CONSTRUCTION	15
	A. “fluidly coupled”	15
	B. “gas tight seal”.....	16
	C. “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal”	21
VII.	GROUND 1 – HASSFJELL-HOFF DOES NOT ANTICIPATE OR RENDER OBVIOUS CLAIMS 1, 3-4, 7-9, 11-12, 14-19, 22-26, 28-29, 31-32, 35-36 AND 38	25
VIII.	GROUND 2 – NORMAN HAS NOT BEEN SHOWN TO ANTICIPATE OR RENDER OBVIOUS CLAIMS 1, 3, 5-7, 15-16, 18, 20-22, 29-33, AND 35-37.....	30
IX.	GROUND 3 – HASSFJELL-HOFF AND NORMAN HAVE NOT BEEN SHOWN TO RENDER CLAIMS 1, 3-9, 11-12, 14-26, 28-33, AND 35-38 OBVIOUS	34
X.	FOUND 4-8 DO NOT SHOW OBVIOUSNESS OF ANY CLAIM	39

XI.	GROUND 9 – CLAIMS 1-9, 11-15 AND 35-38 ARE NOT INDEFINITE	39
XII.	CONCLUDING STATEMENTS.....	40
XIII.	EXHIBIT LIST.....	42

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. 12,249,437 to Roy H. Larsen (“the ’437 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 ’437 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 '437 patent (EX1002). I have reviewed the '437 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 '437 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 '437 patent were unpatentable for reasons including anticipation, obviousness, 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 Indefiniteness

21. 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.

22. 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 '437 PATENT

23. The title of the '437 patent is "Production of Highly Purified ²¹²Pb." The '437 patent discloses methods and systems for producing highly purified radioisotopes, such as ²¹²Pb. *See* EX1001, Abstract. Radioisotopes such as ²¹²Pb

have important applications as radiopharmaceuticals, including in cancer therapy.

EX1001, 7:22-25, 9:58-67.

24. As the '437 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, 5:67-6:13.

25. The '437 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.

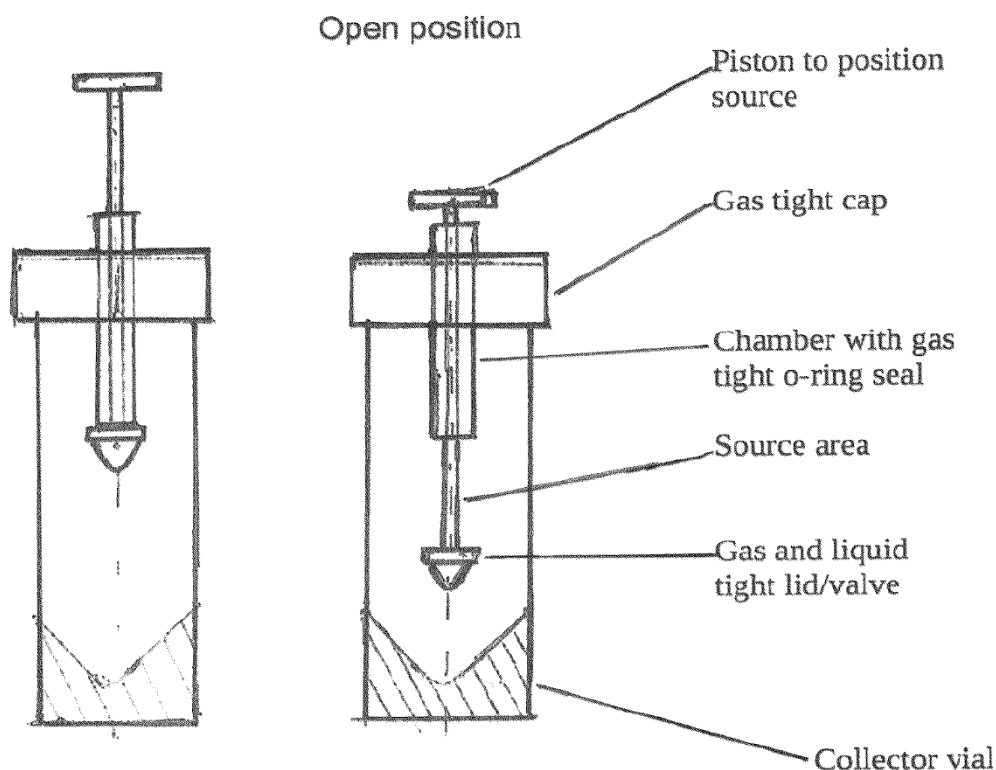


Fig. 4A

Fig. 4B

EX1001, Fig. 4; *see also id.* 14:37-43, 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, 14:37-43, 18:19-35, 13:63-14:24, Figs. 2, 4. The rod moves between an open or closed position by moving it up or down. *Id.* In the open position, the ^{220}Rn emanates throughout the collector vial container, the ^{220}Rn gas decays into ^{216}Po and ^{212}Pb , and the emanation process completes by depositing these decay products on the container's interior surface. *See* EX1001; *see also id.*, 2:27-47, 13:63-14:24.

26. In this open configuration, although gas is emanated from the precursor isotope source in the central rod or piston, a gas tight seal formed at the interface between the collector surface and the cap prevents gas from escaping to the outside. *See* EX1001, Fig. 4 (indicating open position with “Gas tight cap”). Thus, when in the open position, the device uses a gas-tight seal to provide fluid coupling within the volume between the precursor isotope source and the collector surface, while also confining the ^{220}Rn gas emanated from the precursor isotope source to the volume (since the seal on the collector surface remains gas-tight when providing the fluid coupling). The device disclosed in the specification allows for efficient, safe production of ^{212}Pb . EX1001, 1:20-27.

27. These features are reflected in the claims of the '437 patent. I have reproduced independent claims 1 and 16 below, with claim elements labeled to match the labels applied by Dr. Mirzadeh in EX1002:

[1pre] A radioisotope generator comprising:

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

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

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

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

[16pre] A method of generating a progeny radioisotope, the method comprising:

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

[16b] the solid precursor isotope source comprising a precursor isotope;

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

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

V. LEVEL OF SKILL IN THE ART

28. 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 '437 patent as December 5, 2019.

29. 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 437 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.

30. 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 '437 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

31. I have been advised that the claim terms of the '437 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. “fluidly coupled”

32. The term “fluidly coupled” appears in independent claims 1 and 16, as well as in dependent claims 18, 29, and 38. I understand Dr. Mirzadeh construed the term “fluidly coupled” to mean “capable of being connected or linked together using a gas or liquid.” EX1002, ¶35.

33. I agree that “fluidly coupled” refers to being connected or linked together using a fluid (with gas and liquid being two examples of fluids). However, I disagree with Dr. Mirzadeh’s statement that something *capable of being connected or linked* suffices for it to be fluidly coupled. A POSITA would have

understood the term “fluidly coupled” to require actual connection or linkage, not merely capacity to be connected or linked.

34. For example, claim 1 describes a radioisotope generator in which the “solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal.” This requires that the generator have a configuration in which the *solid precursor isotope source* and the *volume including a collector surface with a gas tight seal* are actually connected or linked using a fluid.

35. Similarly, claim 16 recites a method including a step of “fluidly coupling a volume including a collector surface to the solid precursor isotope source using a gas tight seal.” This requires that the solid precursor isotope source and the volume including a collector surface actually be connected or linked together by a fluid, using a gas tight seal.

B. “gas tight seal”

36. The term “gas tight seal” appears in independent claims 1 and 16. Dr. Mirzadeh did not provide a construction of the term “gas tight seal.” However, in various places, Dr. Mirzadeh identified certain elements as gas tight seals even when they did not provide a gas tight seal. For example, Dr. Mirzadeh identifies valves as being gas tight seals even when it is open, and thus lets gas flow freely through it. *See, e.g.*, EX1002, ¶¶57, 85, 133.

37. A POSITA would not understand the term “gas tight seal” to include a valve in an open position (i.e., a valve that does not prevent the flow of gas). Rather, a POSITA would understand the term “gas tight seal” to refer to an interface between components that prevents gas from flowing through the interface.

38. For example, Fig. 3A of the '437 patent shows a bottle with a lid screwed on the top of it, such that gas is prevented from escaping through any gap between the bottle and lid. EX1001, Fig. 3A. The place where the bottle contacts the lid is a gas tight seal. When the lid is detached from the bottle, as shown in Fig. 3B, there is no gas tight seal. *See* EX1002, Fig. 3B. Figs. 3A-B are reproduced below.



Fig. 3A



Fig. 3B

39. Similarly, the bottles shown in Fig. 5A have gas tight seals where they contact their lids, whereas the bottle shown in Fig. 5B does not have a gas tight seal because the cap is off. Figs. 5A-B are reproduced below.

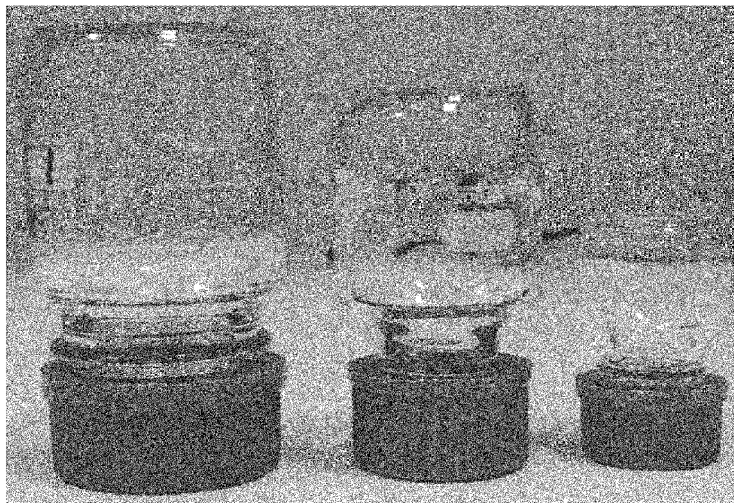


Fig. 5A

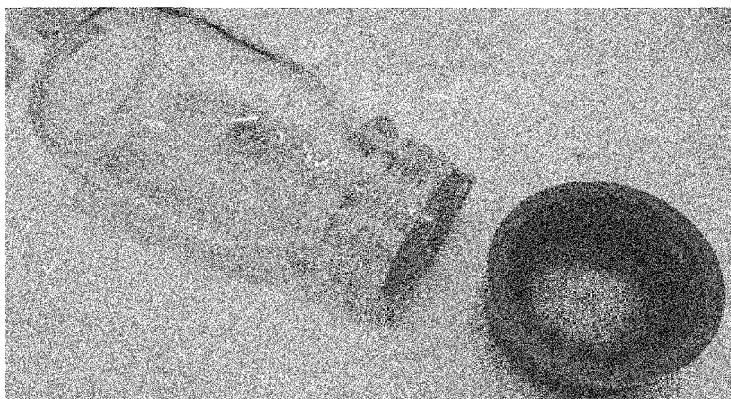


Fig. 5B

40. Fig. 4 (reproduced below) of the '437 patent provides further illustration of a gas tight seal.

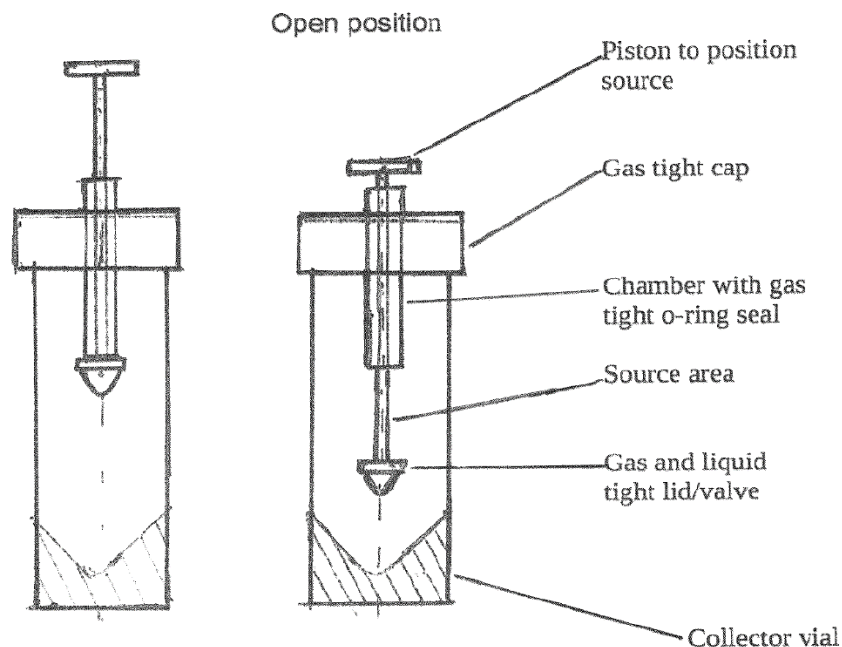


Fig. 4A

Fig. 4B

Like with Figs. 3 and 5, Fig. 4B shows a gas tight seal between the collector vial and the gas tight cap. While not depicted, the specification describes (consistent with the labels in Fig. 4B) that there is also a gas tight seal provided by an o-ring near the top of the tube labeled as a chamber in the middle of the generator.

EX1001, 18:21-23 (“The rod in FIG. 2 (piston in FIGS. 4A-4B) slides in a tube with o rings or similar at the top to secure gas tight seal.”). A POSITA would have understood that these o-rings prevent the escape of gas out through the cap by contacting surfaces of the piston and tube (chamber) and forming a seal that is gas tight regardless of whether the piston is up (as in Fig. 4A) or down (as in Fig. 4B).

41. By contrast, a POSITA would not have understood the valve shown in Fig. 4B as having a gas tight seal, because the valve is open and lets gas pass freely. Indeed, when jointly describing Figs. 2 and 4A-B, the specification confirms that the “valve at the bottom of the rod is gas and liquid tight in the closed position for the unit” (that is, in the configuration shown in Fig. 4A), not in the open position. EX1001, 18:23-24. Rather, 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. In the closed position the source is sealed off...” EX1001, 18:25-29. Thus, in Fig. 4B, a POSITA would have understood that the only part having a gas tight seal is the cap (where it contacts the collector surface of the vial as shown, as well as in the o-rings that are described but not shown). The valve in Fig. 4B is not a gas tight seal—only in Fig. 4A does the valve have a gas tight seal, as it contacts the tube and seals it off.

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

42. Limitation 1c reads “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal.” Dr. Mirzadeh discusses the construction of this term in his declaration. *See* EX1002, ¶¶36-39. Dr. Mirzadeh advances what he calls “three possible constructions”: (1) “The entire volume has a gas tight seal (with the

precursor isotope source inside the volume)”; (2) “Just the collector surface, not the entire volume, has a gas tight seal (when the precursor isotope source is inside the collector)”; and (3) “The system is configured to selectively couple, using a gas tight seal, a volume with the solid precursor isotope source and a volume with a collector surface.” EX1002, ¶36.

43. Having read the section in which Dr. Mirzadeh discusses his “possible” constructions of limitation 1c, I find his reasoning confusing and self-contradictory. For example, Dr. Mirzadeh suggests that his three possible constructions arise because the phrase “with a gas tight seal” could correspond to “configured to,” “fluidly coupled,” or “volume.” EX1002, ¶36. However, he does not explain how he arrives at his possible constructions from this. Indeed, it is not even clear which term corresponds to which of his three possible constructions.

44. As another example, his second possible construction specifies that “the entire volume” *does not* have a gas tight seal (“Just the collector surface, not the entire volume, has a gas tight seal”), but he subsequently states that “under the second possible construction, a POSITA would have understood the limitation to require that the precursor isotope source is fluidly coupled to a fully enclosed volume that has a gas-tight seal.” EX1002, ¶¶36, 38. Dr. Mirzadeh’s discussion of his second possible construction contradicts the construction itself because they disagree about whether the volume has a gas tight seal.

45. Dr. Mirzadeh's possible constructions also introduce requirements not found in the claims without explaining where these requirements come from or why the language of the claims mandates them. For example, the first two possible constructions refer to an "entire volume" that seems to be different from the "volume" recited in limitation 1c; however, he does not explain where the claim refers to this other ("entire") volume or why the claim should be read to add this term. As another example, his third construction refers to two different volumes ("a volume with the solid precursor isotope source and a volume with a collector surface") and also to selective coupling, but claim 1 neither describes selective coupling nor multiple volumes. Accordingly, it is not my opinion that any of Dr. Mirzadeh's constructions corresponds to a POSITA's understanding of limitation 1c.

46. I understand that to construe a claim requires interpretation of the words of the claim as a POSITA would understand them. I further understand that while the specification can aid in understanding those words, it is inappropriate to construe claims by reading elements into the claim from the specification. The language of limitation 1c says "wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal." A POSITA would have understood from the plain meaning of this language that the phrase "with a gas tight seal" refers to the "collector surface." In

other words, it is required by this limitation that the collector surface have a gas tight seal.

47. This corresponds to the plain reading of the claim language, as the prepositional phrase “with a gas tight seal” appears immediately after the term “collector surface,” whereas other claim terms are more distant. While the language also recites that (1) the volume includes collector surface; and (2) the solid precursor isotope source is configured to be fluidly coupled to that volume, neither the volume nor the coupling is what “with a gas tight seal” refers to, since that phrase is located distant from each of these terms.

48. This understanding is consistent with the specification of the ’437 patent. Indeed, each of figures 2-5 depicts embodiments matching this understanding of limitation 1c. Figs. 3A and 5A, which I reproduced above, each show bottles with caps secured on top of them. I understand that Dr. Mirzadeh, when questioned, testified that Figs. 3A and 5A each have a gas tight seal on the collector surface, and that it is the bottles’ cap that forms a gas tight seal. *See also* EX1002, ¶38 (applying “second possible construction” to Figs. 3 and 5). I agree. The surfaces of the bottle to which gas emitted from precursor isotopes located inside the bottle can flow are collector surfaces, and each collector surface has a gas tight seal where the bottle contacts the cap.

49. The same applies to Fig. 4, including the open position shown in Fig. 4B. I understand that Dr. Mirzadeh, when asked to explain all the ways gas tight seals were shown in this figure, testified that it has a gas tight seal when the cap is closed, and that is all. I agree. Fig. 4B has a gas tight seal where the collector vial's inner surface meets the gas tight cap (as well as a gas-tight seal where the o-rings in the cap contact the piston). Likewise, Fig. 2 is shown to have a cap forming a gas-tight seal with the collector surface of the container (C).

50. Because the plain and ordinary meaning of limitation 1c indicates that "with a gas tight seal" refers to "collector surface," this interpretation is consistent with the claim language, and none of Dr. Mirzadeh's "possible constructions" is either sensible or corresponds to the language of the claim, a POSITA would have understood that limitation 1c requires that the collector surface have a gas tight seal.

VII. GROUND 1 – HASSFJELL-HOFF DOES NOT ANTICIPATE OR RENDER OBVIOUS CLAIMS 1, 3-4, 7-9, 11-12, 14-19, 22-26, 28-29, 31-32, 35-36 AND 38

51. Hassfjell-Hoff (EX1003) has not been shown to anticipate or render obvious claims 1, 3-4, 7-9, 11-12, 14-19, 22-26, 28-29, 31-32, 35-36 and 38 at least because it has not been shown to teach limitations 1c and 16c of the independent claims. I understand that claims 10 and 34 have been disclaimed and are thus no longer part of the '437 patent.

52. I note that Dr. Mirzadeh identifies ground 1 as being a ground of anticipation or obviousness, but he provides almost no discussion relating to obviousness. I further understand that what Dr. Mirzadeh calls “ground 1” corresponds to two grounds (ground 1, covering anticipation, and ground 2, covering obviousness) in the petition.

53. Limitation 1c reads “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal.” As I discussed above, this limitation requires that the collector surface has a gas tight seal.

54. Dr. Mirzadeh does not assert that Hassfjell-Hoff discloses limitation 1c under his second possible construction, which is the only one of his possible constructions that refers to a collector surface with a gas tight seal. *See* EX1002, ¶¶55-57. Dr. Mirzadeh thus fails to show that Hassfjell-Hoff discloses limitation 1c.

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

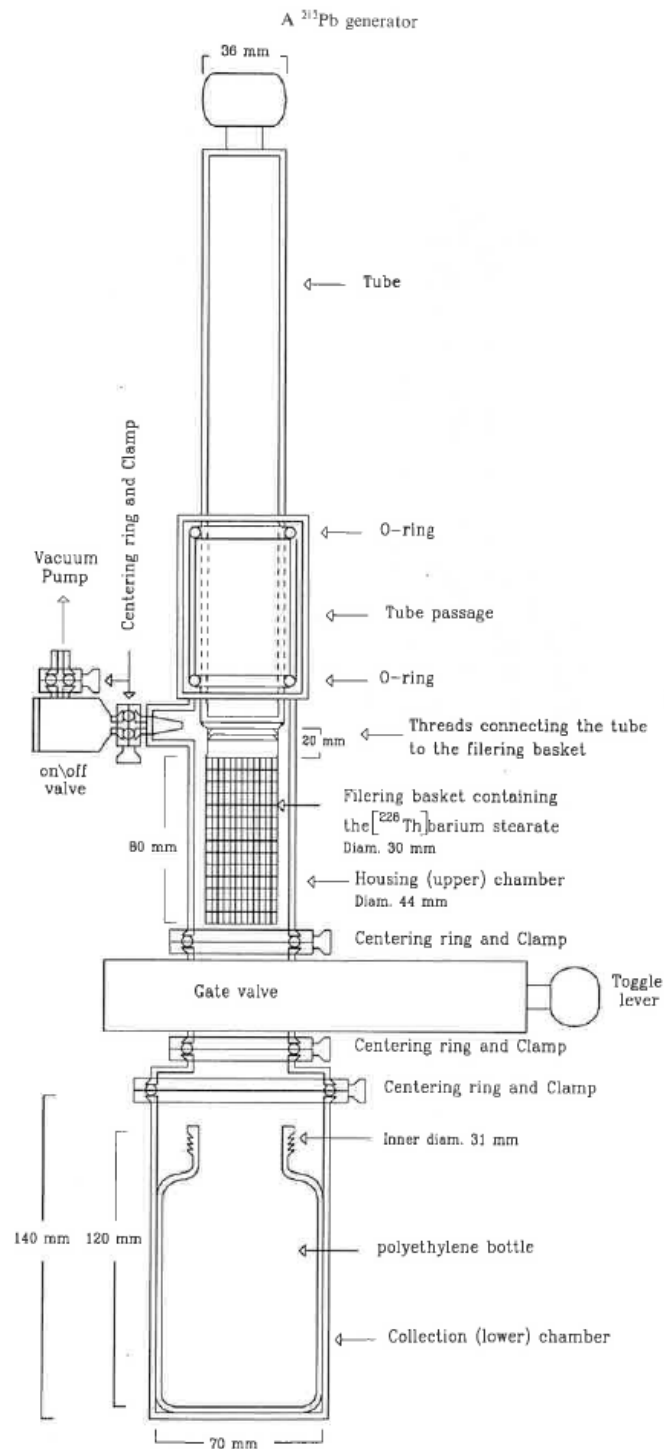


Fig. 2. The design of the generator showing functional details and operating mechanism.

EX1003, Fig. 2. Dr. Mirzadeh identifies “the interior walls of the polyethylene bottle” in Hassfjell-Hoff’s generator as the “collector surface” (EX1002, ¶¶56, 58),

but the polyethylene bottle does not have a gas tight seal. *See* EX1003, 7, Fig. 2. Indeed, nowhere does Hassfjell-Hoff describe a gas tight seal being formed on or with the polyethylene bottle. *See generally* EX1003. Accordingly, as Hassfjell-Hoff has not been shown to disclose each and every limitation of claim 1, it has not been shown to anticipate claim 1.

56. With regard to claim 16, Dr. Mirzadeh refers back to his discussion of limitation 1c for limitation 16c, which recites “fluidly coupling a volume including a collector surface to the solid precursor isotope source using a gas tight seal.” Each of Dr. Mirzadeh’s arguments for limitation 1c applies to an incorrect construction (that is, his first or third constructions); accordingly, those arguments fail to map the prior art to the claims as written.

57. In discussing limitation 16c, Dr. Mirzadeh states that the limitation is met by “opening the gate valve to connect the upper volume to the lower volume.” EX1002, ¶84. He further states the following: “When the (gas tight seal) gate valve is closed, the solid precursor isotope source is not fluidly coupled. When the (gas tight seal) gate valve is open, the solid precursor isotope source is fluidly coupled.” EX1002, ¶85.

58. As Dr. Mirzadeh states, there is no fluid coupling when Hassfjell-Hoff’s gate valve is closed, only when it is opened. Yet when the gate valve is opened it does not provide a gas tight seal, since gas flows through it. An open

valve like Hassfjell-Hoff's gate valve does not have a gas tight seal. Since the gate valve of Hassfjell-Hoff lacks a gas tight seal when fluid coupling is present, Hassfjell-Hoff fails to disclose "fluidly coupling a volume including a collector surface to the solid precursor isotope source using a gas tight seal" as recited in limitation 16c.

59. Dr. Mirzadeh also states that "Hassfjell-Hoff discloses and renders obvious lowering the tube so that the filtering basket is placed into the polyethylene bottle and the chamfered surface near the bottom of the tube forms a gas-tight seal with the bottle opening." EX1002, ¶84. Dr. Mirzadeh also does not cite to any part of Hassfjell-Hoff as providing this disclosure, nor does he explain why it would have been obvious to modify Hassfjell-Hoff to include such a feature.¹ He refers back to his discussion of limitation 1c, but this discussion also does not cite to anything as teaching this type of seal. Indeed, I have read Hassfjell-Hoff, and I see no discussion of this.

60. Accordingly, Hassfjell-Hoff has not been shown to anticipate or render obvious independent claims 1 or 16. As each of claims 3-4, 7-12, 14-5, 17-

¹ I address obviousness arguments regarding this limitation below in addressing the proposed combination of Hassfjell-Hoff and Norman, which Dr. Mirzadeh covers separately in the section he labels as ground 3.

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, 7-9, 11-12, 14-5, 17-19, 22-26, 28-29, 31-32, 35-36 and 38.

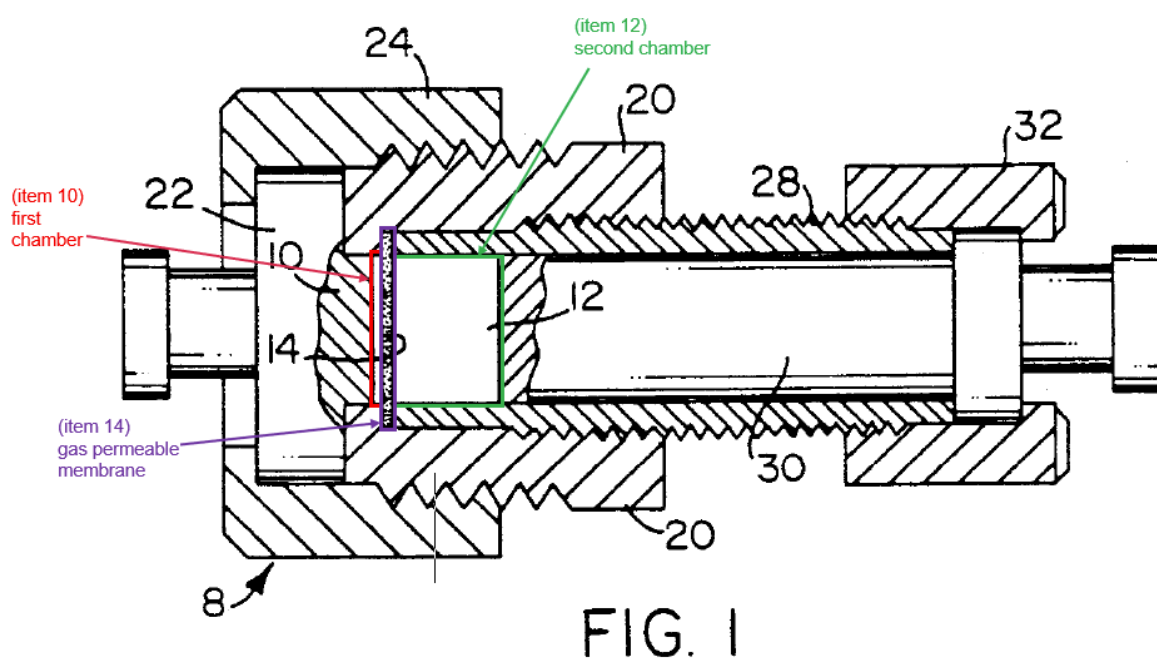
VIII. GROUND 2 – NORMAN HAS NOT BEEN SHOWN TO ANTICIPATE OR RENDER OBVIOUS CLAIMS 1, 3, 5-7, 15-16, 18, 20-22, 29-33, AND 35-37

61. Norman (EX1007) has not been shown to anticipate or render obvious claims 1, 3, 5-7, 15-16, 18, 20-22, 29-33, and 35-37 at least because it has not been shown to teach limitations 1c and 16c of the independent claims. I understand that Dr. Mirzadeh’s ground 2 corresponds to grounds 3 (covering anticipation) and 4 (covering obviousness) in the petition.

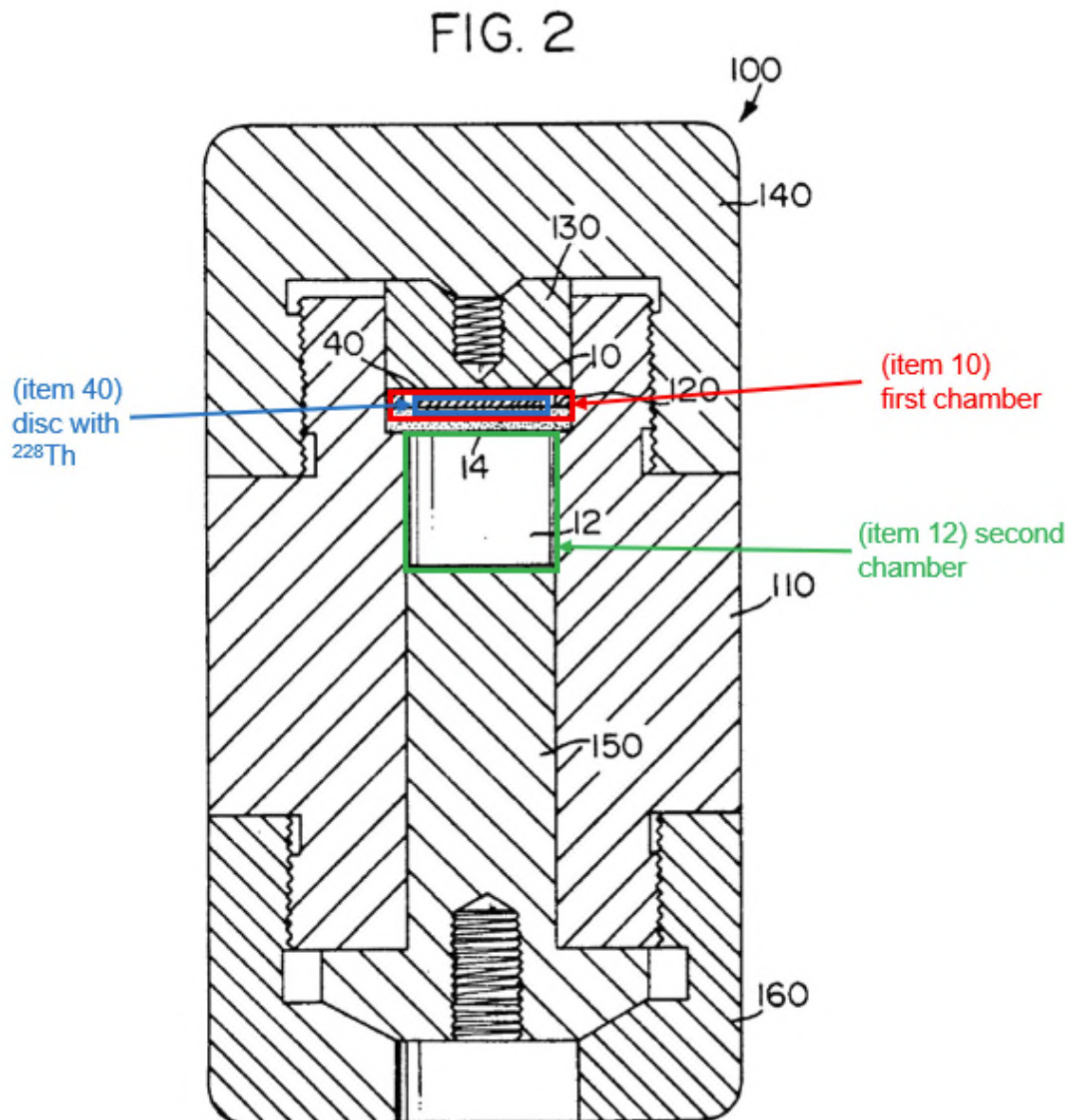
62. As I discussed above, limitation 1c requires that the collection surface have a gas tight seal. Limitation 1c reads “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface with a gas tight seal.” But in addressing limitation 1c, Dr. Mirzadeh quotes claim language not found in any of the claims: “wherein the solid precursor isotope source is configured to be fluidly coupled to a volume including a collector surface using a gas tight seal, and” EX1002, ¶128. Because Dr. Mirzadeh does not compare the language actually found in the claims to the teachings of Norman, he does not show that limitation 1c is taught by Norman.

63. However, even applying the teachings of Norman he does cite, Dr. Mirzadeh does not show that Norman discloses limitation 1c. Dr. Mirzadeh

identifies the collector surface as “the sides of the collecting chamber 12” in Fig. 1 of Norman, or alternatively a porous medium contained by that surface. EX1002, ¶130; *see* EX1007, Fig. 1, 3:4-20. Fig. 1 of Norman is reproduced below, with labeling provided by Dr. Mirzadeh. The collecting chamber (or “receiving chamber”) is labeled as “item 12 (second chamber)” in this figure.



EX1007, Fig. 1 (as labeled in EX1002, ¶129). Dr. Mirzadeh also relies on Fig. 2 of Norman, which he discusses interchangeably with Fig. 1. Dr. Mirzadeh’s mark-up of Fig. 2 of Norman is reproduced below:



EX1007, Fig. 2 (as labeled in EX1002, ¶125). I do not agree that Figs. 1 and 2 are interchangeable, as they depict different embodiments of Norman. However, as I discuss below, neither embodiment discloses limitation 1c.

64. Dr. Mirzadeh asserts that his second possible construction for limitation 1c (which among other things requires a collector surface with a gas

tight seal) is satisfied by Norman. EX1002, ¶128. However, he does not identify a gas tight seal on Norman's collector surface. Instead, as Dr. Mirzadeh labels in Fig. 1, the surface of the receiving chamber abuts a gas-permeable membrane. The same gas-permeable membrane is present on the end of the second chamber in Fig. 2. *See* EX1007, 6:12-16 ("As shown in FIGS. 1 and 2, the generator comprises a parental chamber 10, a receiving chamber 12, and a gas elute means such as gas permeable membrane 14 interposed between and separating the two chambers 10 and 12."). A gas-permeable membrane is not a gas tight seal; indeed, the fact that it is gas permeable means specifically that it is not gas tight. Accordingly, Norman has not been shown to teach limitation 1c.

65. Dr. Mirzadeh relies exclusively on his discussion of limitation 1c to map Norman to limitation 16c. *See* EX1002, ¶149. As Dr. Mirzadeh fails to show that the correct construction for limitation 1c is met, and his remaining arguments apply to incorrect constructions (that is, his first or third constructions), those arguments fail to map the prior art to the claims as written.

66. Moreover, with regard to his discussion of the first and third constructions, this discussion fails to show that limitation 16c is satisfied. Dr. Mirzadeh identifies the "volume" recited in the claims as "second chamber 12" (EX1002, ¶128), yet as I discussed above, this volume does not use a gas tight seal—it uses a gas-permeable membrane.

67. Dr. Mirzadeh also identifies an alternative embodiment in Norman that involves a stopcock inserted between the first and second chambers as allegedly teaching a gas tight seal. EX1002, ¶133; *see* EX1007, 8:33-41. However, similar to the gate valve of Hassfjell-Hoff, this stopcock does not fluidly couple the precursor isotope source to the collector surface using a gas tight seal—as Dr. Mirzadeh admits, when the “stopcock is closed, the solid precursor isotope source is not fluidly coupled,” whereas “the gaseous ^{220}Rn diffuses from parental chamber 10 into the collection chamber 12” only when it is opened (and thus does not use a gas tight seal). EX1002, ¶133. Thus, in addition to failing to teach limitation 1c, these teachings of Norman have also not been shown to teach or suggest limitation 16c.

68. None of Dr. Mirzadeh’s discussion relating to obviousness for Norman addresses these deficiencies. Accordingly, Norman has not been shown to anticipate or render obvious independent claims 1 or 16. As each of claims 3, 5-7, 15, 18, 20-22, 29-33, and 35-37 depends from claim 1 or 16, Norman has also not been shown to anticipate or render obvious claims 3, 5-7, 15, 18, 20-22, 29-33, and 35-37.

IX. GROUND 3 – HASSFJELL-HOFF AND NORMAN HAVE NOT BEEN SHOWN TO RENDER CLAIMS 1, 3-9, 11-12, 14-26, 28-33, AND 35-38 OBVIOUS

69. Hassfjell-Hoff (EX1003) and Norman (EX1007) have not been shown to render obvious claims 1, 3-9, 11-12, 14-26, 28-33, and 35-38 at least because it

has not been shown that a POSITA would have been motivated to arrive at the combination of Hassfjell-Hoff and Norman discussed by Dr. Mirzadeh in ground 3. I understand that Dr. Mirzadeh's ground 3 corresponds to ground 5 in the petition.

70. In ground 3, Dr. Mirzadeh proposes to "modify Hassfjell-Hoff such that its tube forms a gas-tight seal with the polyethylene bottle when the filtering basket is lowered into the interior of the polyethylene bottle." EX1002, ¶177. I agree that forming this type of gas-tight seal would constitute a modification of Hassfjell-Hoff, as nowhere does Hassfjell-Hoff disclose forming or using such a seal. However, I disagree that a POSITA would be led to such a modification based on the teachings of Hassfjell-Hoff and Norman.

71. Dr. Mirzadeh asserts that "Norman discloses using a gas tight seal on the collection chamber." EX1002, ¶178 (citing EX1007, 7:22-25). However, as I explained above, Norman's collection chamber (chamber 12) does not have a gas tight seal—instead, it contacts a gas permeable membrane that freely permits gas to flow through it. The part of Norman cited by Dr. Mirzadeh relates to the generator as a whole, not to the collection chamber. *See* EX1007, 7:22-25.

72. Furthermore, the components of Norman Dr. Mirzadeh points to are unlike the seal he proposes. Norman describes inserting a pair of plungers secured with end caps to prevent escape of radon from the generator. EX1007, 7:22-25. By contrast, Dr. Mirzadeh proposes modifying a plastic (polyethylene) bottle and a

chamfered end of a metal tube to mate when the tube is lowered to contact the end of the bottle. *See* EX1002, ¶177. These are entirely different configurations of parts, and Dr. Mirzadeh does not explain how a POSITA would be led from one to the other. Dr. Mirzadeh suggests that the bottle and tube could be modified to form an “interference fit,” but he does not suggest that such a fit is taught by Norman or by any other reference. EX1002, ¶177.

73. Dr. Mirzadeh also fails to support his assertion that a “POSITA would have understood that there were well-known ways to create a gas-tight seal on the collection chamber, for example using sealed containers that are compatible with radiopharmaceuticals.” EX1002, ¶178. He cites to EX1017, Cover, Figs. 3-9 as allegedly teaching this type of gas-tight seal for a collection chamber like Hassfjell-Hoff’s polyethylene bottle. I find this citation puzzling. I have reviewed the cited figures and cover of U.S. Patent No. 9,281,089 (EX1017), and they do not show a gas tight seal resembling the type of seal proposed by Dr. Mirzadeh. Indeed, the examples shown in those figures describe preventing escape of line-of-sight radiation (e.g., gamma rays), not emanation of radioactive gas (which is not limited to line-of-sight). *See* EX1017, 3:28-39 (“the container 12 is specifically constructed to prevent any form of line-of-sight radiation from exiting the container 12”). Dr. Mirzadeh does not explain why he thinks the reference he cites discloses the type of seal he proposes forming. Accordingly, it is my opinion that

Dr. Mirzadeh has not shown that the prior art taught or suggested the type of seal he proposes modifying Hassfjell-Hoff to produce.

74. Additionally, Dr. Mirzadeh's reasons for arriving at his proposed combination also would not make sense to a POSITA. Dr. Mirzadeh asserts that a "POSITA would have been motivated to configure the Hassfjell-Hoff system to form a gas-tight seal between the tube and the polyethylene bottle to enhance safety for the worker that is replacing the collection container, and would have had a reasonable expectation of success because such gas-tight seals are well-known." EX1002, ¶177. He further asserts that this modification "would reduce the possibility of outside contamination or allowing radioactivity to escape the container." EX1002, ¶178.

75. However, the proposed combination would not prevent escape of radon gas from the container (that is, the polyethylene bottle). The proposed combination would involve the following sequence of steps: (1) opening the gate valve; (2) lowering Hassfjell-Hoff's tube with the filtering basket hanging off of it into the lower compartment until the filtering basket entered the polyethylene bottle; (3) contacting the top of the polyethylene bottle with the bottom of the tube, which Dr. Mirzadeh suggests would be modified to form a gas tight seal; (4) waiting as radon continues emanating into the bottle; (5) breaking the seal; (6) lifting the tube until the filtering basket was in the upper compartment; and (7)

closing the gate valve. From step 1 to step 3, and from step 5 to step 7, the [^{228}Th]barium stearate in the filtering basket will be exposed to the entire generator interior, including the part of the lower compartment outside of the polyethylene bottle. This exposure will cause ^{220}Rn gas to flow to all of these areas, with the result that radioactive material (^{220}Rn and its decay products such as ^{212}Pb) will reach these volumes and coat their surfaces. A POSITA would thus not believe that Dr. Mirzadeh's proposed modification would prevent contamination outside of the polyethylene bottle.

76. Furthermore, a POSITA would not believe Dr. Mirzadeh's rationale for modification applied to Hassfjell-Hoff based on Hassfjell-Hoff's own teachings. Hassfjell-Hoff teaches that there are no contamination concerns with its system, explaining that "[n]o contamination from ^{228}Th or ^{224}Ra outside the filter membrane packets has been detected." EX1007, 7. Regarding the emanations from these radioisotopes, ^{220}Rn has a half-life of under 1 minute, and ^{216}Po of less than one second, so as a practical matter the only source of radioactive contamination is ^{212}Pb . But Hassfjell-Hoff teaches that "99% of the ^{212}Pb can be washed off the walls of the bottle" using a simple saline solution. *Id.* Based on these teachings, a POSITA would conclude that contamination is not a concern in Hassfjell-Hoff's device. Because the modification Dr. Mirzadeh proposes would add greater complexity and cost to Hassfjell-Hoff's device, without providing any benefit to

justify the change, a POSITA would have not have been motivated to make Dr. Mirzadeh's proposed modification.

77. Because Dr. Mirzadeh has not shown either that his proposed modification was taught in the prior art nor that a POSITA would have had reason to adopt that modification, it is my opinion that none of claims 1, 3-9, 11-12, 14-26, and 28-38 have been shown to be obvious over Hassfjell-Hoff and Norman.

X. GROUNDS 4-8 DO NOT SHOW OBVIOUSNESS OF ANY CLAIM

78. Grounds 4-8 are limited to discussing obviousness of dependent claims based on combinations of Hassfjell-Hoff or Norman with other references. As none of grounds 4-8 remedies the deficiencies of Norman or Hassfjell-Hoff with regard to the elements of independent claims 1 or 16, they do not show the obviousness of any claim they address.

XI. GROUND 9 – CLAIMS 1-9, 11-15 AND 35-38 ARE NOT INDEFINITE

79. Dr. Mirzadeh has asserted that claims 1-9, 11-15 and 35-38 are indefinite because he alleges that limitation 1c of claim 1 is indefinite. *See* EX1002, ¶¶289-90. However, he does not provide any reasoning for this conclusion beyond referring back to his “three equally possible meanings” for this limitation and asserting that “a POSITA reading the 437 patent would be unable to determine the scope of the claims with reasonable certainty.” *Id.*

80. As I explained above in §VI.C, none of Dr. Mirzadeh’s “possible constructions” corresponds to an interpretation that a POSITA would have given to limitation 1c. Instead, a POSITA would have understood limitation 1c according to its plain and ordinary meaning, which requires “a collector surface with a gas tight seal.” Determining whether a collector surface does or does not have a gas tight seal is well within the skill of a POSITA, so I disagree with Dr. Mirzadeh’s assertion that a POSITA would not be able to determine the scope of claim 1 (or its dependent claims) with a reasonable degree of certainty.

81. Accordingly, claims 1-9, 11-15 and 35-38 have not been shown to be indefinite.

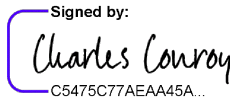
XII. CONCLUDING STATEMENTS

82. 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.

83. 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

XIII. EXHIBIT LIST**A. Petitioner's Exhibits Cited Herein**

Exhibit No.	Description
1001	U.S. Patent No. 12,249,437 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. 12,249,437
1007	U.S. Patent No. 5,038,046 ("Norman")
1017	U.S. Patent No. 9,281,089 ("Isensee")

B. Patent Owner's Exhibits Cited Herein

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