

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**AdvanCell Pty Ltd.
Petitioner**

v.

**Sciencons AS
Patent Owner**

Post Grant Review No.: PGR2025-00040

DECLARATION OF PER HOFF

I hereby declare under penalty of perjury under the laws of the United States of America that the following is true and correct, and that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I understand that willful false statements are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code.

4/1/2025 | 14:52 PDT

Date

Signed by:

Per Hoff

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
I. BACKGROUND AND QUALIFICATION	2
A. Materials Considered.....	3
II. LEGAL STANDARDS	3
A. Legal Standards for Anticipation	3
B. Legal Standards for Obviousness.....	3
III. PERSON OF ORDINARY SKILL IN THE ART OF THE 437 PATENT	8
IV. OVERVIEW OF HASSFJELL-HOFF.....	9
V. GROUND 1: CLAIMS 1, 3-4, 7-12, 14-18, 22-26, 28-29, 31-32, 34- 36, AND 38 ARE ANTICIPATED BY HASSFJELL-1994.....	16
A. Claim 1	16
B. Claim 3 “The radioisotope generator of claim 1, further comprising a valve associated with the solid precursor isotope source.”	16
C. Claim 4 “The radioisotope generator of claim 1, further comprising a vacuum pump attached to the volume.”	16
D. Claim 7 “The radioisotope generator of claim 1, wherein the precursor isotope comprises a thorium 228 isotope (228Th) and/or a radium 224 isotope (224Ra), the one or more gaseous progeny isotopes comprises a radon 220 isotope (220Rn), and the one or more solid progeny isotopes comprises a lead 212 isotope (212Pb).”	17
E. Claim 8 “The radioisotope generator of claim 1, wherein the collector surface is an interior surface of a container, and wherein the volume is an internal volume of the container.”	17
F. Claim 9 “The radioisotope generator of claim 8, wherein the solid precursor isotope source is configured to be connected to an opening of the container.”	18
G. Claim 10 “The radioisotope generator of claim 8, further comprising the container.”	18

H.	Claim 11 “The radioisotope generator of claim 10, wherein the container is configured to removably connect to the solid precursor isotope source.”	18
I.	Claim 12 “The radioisotope generator of claim 10, further comprising a chelator disposed on the interior surface, the chelator configured to chelate the one or more solid progeny isotopes.”	18
J.	Claim 14 “The radioisotope generator of claim 10, wherein the volume is configured to receive a solvent configured to dissolve the one or more solid progeny isotopes from the interior surface.”	18
K.	Claim 15 “The radioisotope generator of claim 1, wherein the radioisotope generator is configured to be converted from a first configuration in which the collector surface is not in fluid communication with the solid precursor isotope source, and a second configuration in which the collector surface is in fluid communication with the solid precursor isotope source.”	19
L.	Claim 16	19
M.	Claim 17 “The method of claim 16, further comprising flushing the collector surface.”	19
N.	Claim 18 “The method of claim 16, wherein fluidly coupling the volume to the solid precursor isotope comprises opening a valve associated with the solid precursor isotope source.”	19
O.	Claim 22 “The method of claim 16, wherein the precursor isotope comprises a thorium 228 isotope (228Th) and/or a radium 224 isotope (224Ra), the one or more gaseous progeny isotopes comprises a radon 220 isotope (220Rn), and the one or more solid progeny isotopes comprises a lead 212 isotope (212Pb).”	20
P.	Claim 23 “The method of claim 16, wherein the collector surface is an interior surface of a container, and wherein the volume is an internal volume of the container.”	20
Q.	Claim 24 “The method of claim 23, further comprising connecting the solid precursor isotope source to an opening of the container.”	20

R.	Claim 25 “The method of claim 23, further comprising removably connecting the solid precursor isotope to an opening of the container.”	20
S.	Claim 26 “The method of claim 23, further comprising chelating the one or more solid progeny isotopes using a chelator disposed on the interior surface.”	20
T.	Claim 28 “The method of claim 23, further comprising receiving a solvent in the volume, and dissolving the one or more solid progeny isotopes from the interior surface in the solvent.”	21
U.	Claim 29 “The method of claim 16, wherein fluidly coupling the volume to the solid precursor isotope source comprises converting a radioisotope generator from a first configuration in which the collector surface is not in fluid communication with the solid precursor isotope source to a second configuration in which the collector surface is in fluid communication with the solid precursor isotope source.”	21
V.	Claim 31 “The method of claim 18, further comprising closing the valve to isolate the volume from the solid precursor isotope source.”	21
W.	Claim 32 “The method of claim 16, wherein the solid precursor isotope is bound to a non-radioactive material.”	21
X.	Claim 34 “The method of claim 23, forming at least a portion of a single chamber with the solid precursor isotope source and the container.”	22
Y.	Claim 35 “The radioisotope generator of claim 3, wherein the valve is configured to isolate the solid precursor isotope from the volume in a closed position.”	22
Z.	Claim 36 “The radioisotope generator of claim 1, wherein the solid precursor isotope is bound to a non-radioactive material.”	22
AA.	Claim 38 “The radioisotope generator of claim 10, wherein the solid precursor isotope source and the container form at least a portion of a single chamber when fluidly coupled.”	22
VI.	GROUND 2: CLAIMS 14, 28, 32, AND 36 ARE RENDERED OBVIOUS BY HASSFJELL-1994	22

A.	Claim 14 “The radioisotope generator of claim 10, wherein the volume is configured to receive a solvent configured to dissolve the one or more solid progeny isotopes from the interior surface.”	22
B.	Claim 28 “The method of claim 23, further comprising receiving a solvent in the volume, and dissolving the one or more solid progeny isotopes from the interior surface in the solvent.”	23
C.	Claim 32 “The method of claim 16, wherein the solid precursor isotope is bound to a non-radioactive material.”	23
D.	Claim 36 “The radioisotope generator of claim 1, wherein the solid precursor isotope is bound to a non-radioactive material.”	23
VII.	AVAILABILITY FOR CROSS-EXAMINATION	24

INDEX OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent Number 12,249,437.
1002	RESERVED
1003	Hassfjell, Sindre P. and Hoff, Per, “A Generator for Production of ^{212}Pb and ^{212}Bi ”, Appl. Radiat. Isot., vol. 45, no. 10, pp 6-25 (1994) (“ Hassfjell-Hoff ”).

I, Per Hoff, declare as follows:

I. INTRODUCTION

1. My name is Per Hoff. I have been asked by Petitioner AdvanCell Pty Ltd. (“Petitioner”) to provide my expert opinions in support of the above-identified petition for *post grant* review of U.S. Patent No. 12,249,437 (“437 patent,” EX1001). I have been informed that the 437 patent is owned by Sciencons AS (“Sciencons AS”).

2. I currently hold the opinions set forth in this Declaration.

3. I am being compensated for my time at the rate of \$300 per hour. I also will have no compensation that is contingent upon my performance, the outcome of this matter, or any issues involved in or related to this matter.

4. In summary, it is my opinion that the references cited below render unpatentable the Challenged Claims. My detailed opinions on the claims are set forth below. In this Declaration, I offer opinions on the following grounds:

Ground	Claims	Prior Art
1	1, 3-4, 7-12, 14-18, 22-26, 28-29, 31-32, 34-36, 38	Anticipated by Hassfjell-Hoff

I. BACKGROUND AND QUALIFICATION

5. All of my opinions stated herein are based on my own personal knowledge, professional judgment, and analysis of the materials and information I considered in preparing this Declaration. In forming my opinions, I have relied on my knowledge and experience in designing, developing, researching, and teaching the technology referenced in this Declaration.

6. I am over 18 years of age and, if I am called upon to do so, I would be competent to testify as to the matters set forth herein. Here are the basic details of my education and professional and academic experience:

Education:

- 1970-1974 - Studies to Bachelor at University of Oslo Norway
- 1974-1976 - Studies to Master Nuclear Chemistry at University of Oslo Norway

Employments:

- Jan. 1977 -March 1981 - Research Assistant at the Neutron research lab, Studsvik Swedeb
- April 1981- June 1983 - Research fellow at CERN, ISOLDE Group Switzerland
- Oct 1983 - Dr. Philos University of Oslo Norway.
- Oct 1983 - Nov 1984 - Ultrasounds engineer at CMI Bergen Norway

- Jan 1985 - Dec 1991- Assistant Professor (førsteamanuensis) Nuclear Chemistry University of Oslo
- Jan 1992 - July 2013 – Professor of Nuclear Chemistry at University of Oslo

Publications:

- Author/coauthor of about 100 articles in international journals

A. Materials Considered

7. In preparing this Declaration, I have reviewed and/or considered at least the documents cited in the Index of Exhibits, and the documents referenced in this Declaration.

II. LEGAL STANDARDS**A. Legal Standards for Anticipation**

8. I have been informed that a prior art reference “anticipates” an asserted claim, and thus renders the claim invalid, if all elements of the claim are disclosed in that prior art reference, either explicitly or inherently (*i.e.*, necessarily present), arranged as claimed and in an enabling manner.

9. I have been informed that anticipation must be shown by a preponderance of the evidence.

B. Legal Standards for Obviousness

10. I have been informed that even if a patent claim is not anticipated, it is still invalid if the differences between the claimed subject matter and the prior art

are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the pertinent art.

11. I have been informed that a person of ordinary skill in the art provides a reference point from which the prior art and claimed invention should be viewed. This reference point prevents one from using his or her own insight or hindsight in deciding whether a claim is obvious.

12. I also have been informed that an obviousness determination includes the consideration of various factors such as (1) the scope and content of the prior art, (2) the differences between the prior art and the asserted claims, (3) the level of ordinary skill in the pertinent art, and (4) the existence of secondary considerations such as commercial success, long-felt but unresolved needs, failure of others, etc.

13. I have been informed that an obviousness evaluation can be based on a combination of multiple prior art references. I have been informed that the prior art references themselves may provide a suggestion, motivation, or reason to combine, but other times the nexus linking two or more prior art references is simple common sense. I further have been informed that obviousness analysis recognizes that market demand, rather than scientific literature, often drives innovation, and that a motivation to combine references may be supplied by the direction of the marketplace.

14. I have been informed that if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

15. I have been informed that practical and common-sense considerations should guide a proper obviousness analysis, because familiar items may have obvious uses beyond their primary purposes. I have been informed that a person of ordinary skill in the art looking to overcome a problem will often be able to fit together the teachings of multiple publications. I have been informed that an obviousness analysis therefore takes into account the inferences and creative steps that a person of ordinary skill in the art would employ under the circumstances.

16. I have been informed that a particular combination may be proven obvious merely by showing that it was obvious to try the combination. For example, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp because the result is likely the product not of innovation but of ordinary skill and common sense.

17. I have been informed that the combination of familiar elements according to known methods is likely to be obvious when it does no more than

have predictable results. I have been informed that when a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. I have also been informed that if a person of ordinary skill can implement a predictable variation, the patent claim is likely obvious.

18. I have been informed that a proper obviousness analysis focuses on what was known or obvious to a person of ordinary skill in the art, not just the patentee. I have been informed that any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

19. I have been informed that a proposed obviousness combination does not need to be the preferred, or most desirable, combination available, in order to render a claim obvious. I have been informed that, instead, there must be something that suggests the desirability of the proposed combination, not necessarily something that suggests that the proposed combination is the most desirable combination available.

20. Similarly, I have been informed that for purposes of obviousness, when a motivating benefit comes at the expense of another benefit, that does not nullify the proposed obviousness combination or modification. Likewise, I have

been informed that a proposed obviousness combination does not fail merely because it may be inferior to other systems used for the same use.

21. I have been informed that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements between the multiple references. I have been informed that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. Instead, I have been informed that the test is whether a claim is rendered obvious by the teachings of the prior art as a whole.

22. I have been informed that a claim can be obvious in light of a single reference, without the need to combine references, if the elements of the claim that are not found explicitly or inherently in the reference can be supplied by the common sense of one of skill in the art.

23. I have been informed that secondary indicia of non-obviousness may include: (1) a long felt but unmet need in the prior art that was satisfied by the invention of the patent; (2) commercial success of processes covered by the patent; (3) unexpected results achieved by the invention; (4) praise of the invention by others skilled in the art; (5) taking of licenses under the patent by others; (6) deliberate copying of the invention; (7) failure of others to find a solution to the long felt need; and (8) skepticism by experts.

24. I have been informed that there must be a relationship between any such secondary considerations and the invention. I have been informed that contemporaneous and independent invention by others is a secondary consideration supporting an obviousness determination.

25. In sum, my understanding is that prior art teachings are properly combined where a person of ordinary skill in the art having the understanding and knowledge reflected in the prior art and motivated by the general problem facing the inventor, would have been led to make the combination of elements recited in the claims. Under this analysis, the prior art references themselves, or any need or problem known in the field of endeavor at the time of the invention, can provide a reason for combining the elements of multiple prior art references in the claimed manner.

26. I have been informed that obviousness in a post grant review must be shown by a preponderance of the evidence.

III. PERSON OF ORDINARY SKILL IN THE ART OF THE 437 PATENT

27. In my opinion, a person of ordinary skill in the art at the time of the alleged invention of the 437 patent as of December 5, 2019 would have had a bachelors' degree in chemistry, chemical engineering, physics, nuclear chemistry, 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.

28. I was a person of ordinary skill in the art at the time of the alleged invention of the 437 patent.

IV. OVERVIEW OF HASSFJELL-HOFF

29. I am one of the authors of Hassfjell-Hoff.

30. Hassfjell-Hoff is a journal article published in 1994 and entitled “A Generator for Production of ^{212}Pb and ^{212}Bi .” EX1003, 1-6. Hassfjell-Hoff was included in volume 45, number 10, of the “Applied Radiation and Isotopes” Journal (EX1003, 5 (Contents)), which was published in October 1994. EX1003, 1 (cover page).

31. I have personal knowledge that Hassfjell-Hoff was publicly accessible in 1994.

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

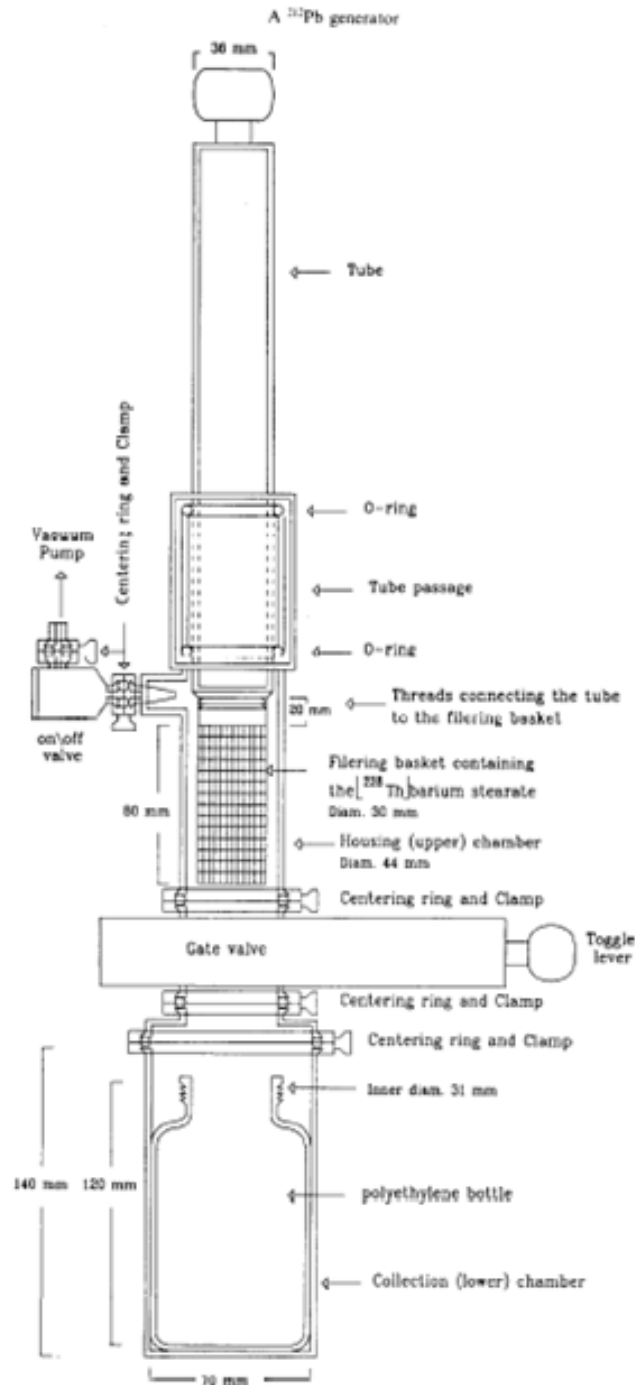


Fig. 2. The design of the generator showing functional details and operating mechanism.

EX1003, Fig. 2.

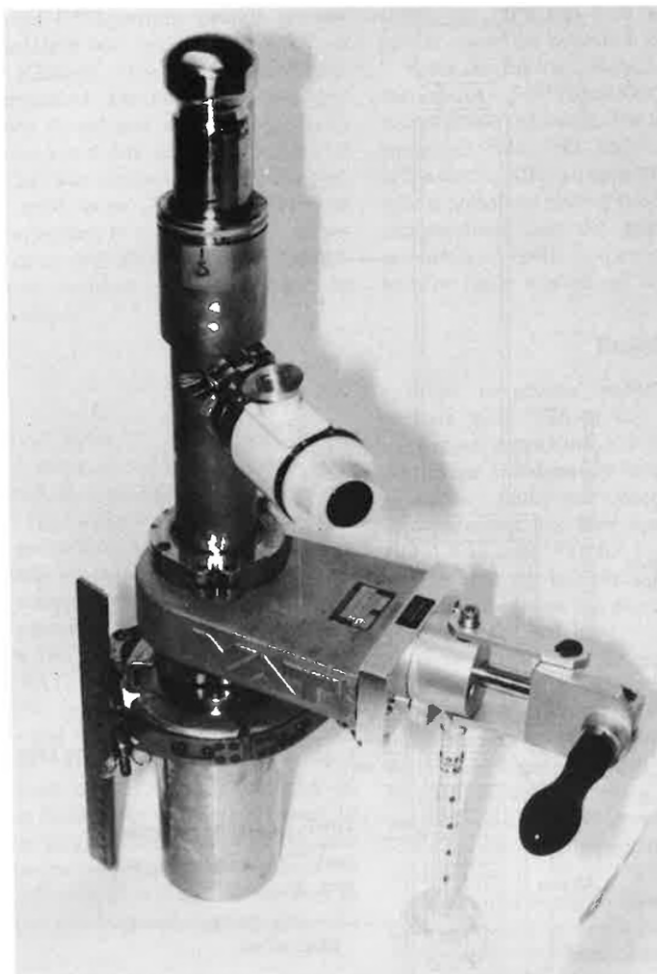


Fig. 3. A picture of the generator.

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

All generator parts were made of stainless steel, and connected to standard high vacuum equipment to avoid leakage of radioactivity to the surroundings. The generator was made with

two compartments, a lower compartment which is a collection chamber and an upper compartment which is a housing chamber for the source when the collection chamber is removed. These two compartments are connected via a gate valve (VAT). The packets of [^{228}Th]barium stearate are placed in a filering basket¹ mounted by threads to the end of a long tube closed in both ends.... The tube can slide on two O-rings, thus facilitating the filering basket to move between the two chambers, through the gate valve.

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

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

¹ Throughout Hassfjell-Hoff, the document refers to a “filering basket.” To the best of my recollection, the name of the commercially available packet membrane we used was called a “filering.” This word (filering) is a Norwegian word that means a lace-like material.

bottle is then removed, and the radioactivity easily washed off with a suitable solution.

EX1003, 7.

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

34. Hassfjell-Hoff is in the field of endeavor of radioisotope generators. *See* EX1003, 6 (describing various prior art generators for obtaining ^{212}Pb by decaying ^{220}Rn gas in a collection chamber).

35. Hassfjell-Hoff depicts the decay mode of the ^{228}Th to the therapeutically desired ^{212}Pb , including intermediate and subsequent isotopes:

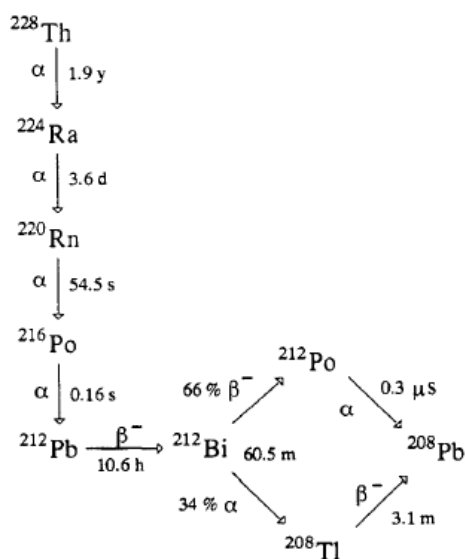


Fig. 1. The decay mode of ^{228}Th to stable ^{208}Pb .

EX1003, Fig. 1.

36. As disclosed by the article, the Hassfjell-Hoff system was designed to be used in the following manner:

1. The tube was lowered, and packets of [^{228}Th]barium stearate were put into the basket on the bottom of the tube;
2. The tube was raised, and the gate valve was sealed;
3. A polyethylene bottle was opened by unscrewing the bottle and cap from each other; and the bottle was then inserted into the lower volume;
4. The lower volume was attached to the system and sealed using the centering rings and clamps;
5. The gate valve was opened;

6. The tube was pushed down such that the threads of the tube connected with the top of the polyethylene bottle;
 7. The basket remained in the polyethylene bottle for a collection time period such that we collected a sufficient amount of therapeutically desirable ^{212}Pb . The collection time varied based the strength of the amount needed. The half-life is 10.6 hours, so the collection time of our process varied based on how much therapeutically desirable ^{212}Pb was needed;
 8. The tube was pulled up, and the gate valve was closed;
 9. The lower volume clamps were disengaged, and the polyethylene bottle was removed;
 10. The therapeutically desired ^{212}Pb was removed from the interior of the polyethylene bottle using a washing method with water;
 11. Steps 3 through 10 were repeated.
37. As disclosed by the article, the Hassfjell-Hoff system was designed with gas-tight seals (*e.g.*, the o-rings and the gate valve) such that there was no leakage detected. EX1003, 7 (“Despite the relatively strong ^{228}Th source, no detectable leakage of any kind of radioactivity out of the generator has been observed.”).

V. GROUND 1: CLAIMS 1, 3-4, 7-12, 14-18, 22-26, 28-29, 31-32, 34-36, AND 38 ARE ANTICIPATED BY HASSFJELL-1994

A. Claim 1

A radioisotope generator comprising:

**a solid precursor isotope source configured to emanate one or more gaseous progeny isotopes,
the solid precursor isotope source comprising a precursor isotope;
and
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
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.**

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

B. Claim 3 “The radioisotope generator of claim 1, further comprising a valve associated with the solid precursor isotope source.”

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

C. Claim 4 “The radioisotope generator of claim 1, further comprising a vacuum pump attached to the volume.”

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

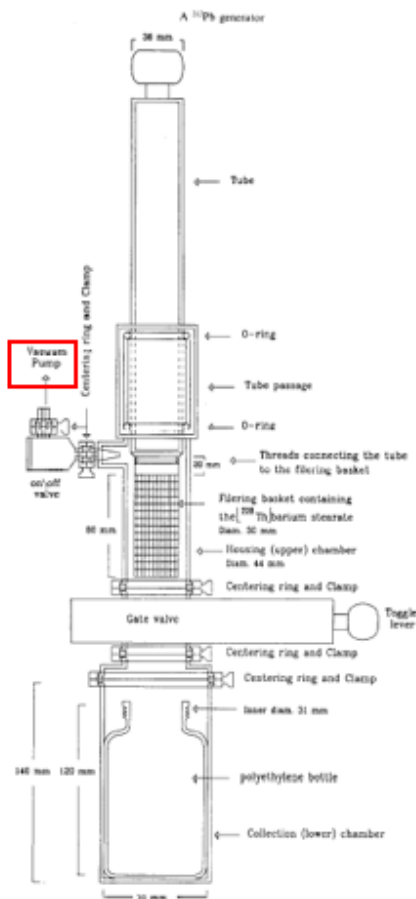


Fig. 2. The design of the generator showing functional details and operating mechanism.

D. Claim 7 “The radioisotope generator of claim 1, wherein the precursor isotope comprises a thorium 228 isotope (^{228}Th) and/or a radium 224 isotope (^{224}Ra), the one or more gaseous progeny isotopes comprises a radon 220 isotope (^{220}Rn), and the one or more solid progeny isotopes comprises a lead 212 isotope (^{212}Pb).”

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

E. Claim 8 “The radioisotope generator of claim 1, wherein the collector surface is an interior surface of a container, and wherein the volume is an internal volume of the container.”

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

F. Claim 9 “The radioisotope generator of claim 8, wherein the solid precursor isotope source is configured to be connected to an opening of the container.”

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

G. Claim 10 “The radioisotope generator of claim 8, further comprising the container.”

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

H. Claim 11 “The radioisotope generator of claim 10, wherein the container is configured to removably connect to the solid precursor isotope source.”

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

I. Claim 12 “The radioisotope generator of claim 10, further comprising a chelator disposed on the interior surface, the chelator configured to chelate the one or more solid progeny isotopes.”

46. In my opinion, Hassfjell-Hoff discloses this claim. “About 70% of the radioactivity inside the polyethylene bottle can be easily washed off with approx. 30 ml of distilled water. By increasing the ionic strength of the washing solution or by adding a *chelating agent*, the yield increases.” EX1003, 7 (emphasis added).

J. Claim 14 “The radioisotope generator of claim 10, wherein the volume is configured to receive a solvent configured to dissolve the one or more solid progeny isotopes from the interior surface.”

47. In my opinion, Hassfjell-Hoff discloses this claim. Water is a well-known solvent. We disclosed the use of water to dissolve the ²¹²Pb from off the inside of the polyethylene bottle: “About 70% of the radioactivity inside the

polyethylene bottle can be easily washed off with approx. 30 ml of distilled water.”

EX1003, 7.

K. Claim 15 “The radioisotope generator of claim 1, wherein the radioisotope generator is configured to be converted from a first configuration in which the collector surface is not in fluid communication with the solid precursor isotope source, and a second configuration in which the collector surface is in fluid communication with the solid precursor isotope source.”

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

L. Claim 16

A method of generating a progeny radioisotope, the method comprising: allowing one or more gaseous progeny isotopes to emanate from a solid precursor isotope source, the solid precursor isotope source comprising a precursor isotope; fluidly coupling a volume including a collector surface to the solid precursor isotope source using a gas tight seal; and allowing one or more solid progeny isotopes of the one or more gaseous progeny isotopes to deposit on the collector surface.

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

M. Claim 17 “The method of claim 16, further comprising flushing the collector surface.”

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

N. Claim 18 “The method of claim 16, wherein fluidly coupling the volume to the solid precursor isotope comprises opening a valve associated with the solid precursor isotope source.”

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

O. Claim 22 “The method of claim 16, wherein the precursor isotope comprises a thorium 228 isotope (^{228}Th) and/or a radium 224 isotope (^{224}Ra), the one or more gaseous progeny isotopes comprises a radon 220 isotope (^{220}Rn), and the one or more solid progeny isotopes comprises a lead 212 isotope (^{212}Pb).”

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

P. Claim 23 “The method of claim 16, wherein the collector surface is an interior surface of a container, and wherein the volume is an internal volume of the container.”

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

Q. Claim 24 “The method of claim 23, further comprising connecting the solid precursor isotope source to an opening of the container.”

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

R. Claim 25 “The method of claim 23, further comprising removably connecting the solid precursor isotope to an opening of the container.”

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

S. Claim 26 “The method of claim 23, further comprising chelating the one or more solid progeny isotopes using a chelator disposed on the interior surface.”

56. In my opinion, Hassfjell-Hoff discloses this claim. “About 70% of the radioactivity inside the polyethylene bottle can be easily washed off with approx. 30 ml of distilled water. By increasing the ionic strength of the washing solution or by adding a *chelating agent*, the yield increases.” EX1003, 7 (emphasis added).

- T. Claim 28 “The method of claim 23, further comprising receiving a solvent in the volume, and dissolving the one or more solid progeny isotopes from the interior surface in the solvent.”**

57. In my opinion, Hassfjell-Hoff discloses this claim. Water is a well-known solvent. We disclosed the use of water to dissolve the ^{212}Pb from off the inside of the polyethylene bottle: “About 70% of the radioactivity inside the polyethylene bottle can be easily washed off with approx. 30 ml of distilled water.” EX1003, 7.

- U. Claim 29 “The method of claim 16, wherein fluidly coupling the volume to the solid precursor isotope source comprises converting a radioisotope generator from a first configuration in which the collector surface is not in fluid communication with the solid precursor isotope source to a second configuration in which the collector surface is in fluid communication with the solid precursor isotope source.”**

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

- V. Claim 31 “The method of claim 18, further comprising closing the valve to isolate the volume from the solid precursor isotope source.”**

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

- W. Claim 32 “The method of claim 16, wherein the solid precursor isotope is bound to a non-radioactive material.”**

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

61. In my opinion, a person of ordinary skill in the art reading Hassfjell-Hoff would have understood that the filering packet was a commonly used non-radioactive material.

X. Claim 34 “The method of claim 23, forming at least a portion of a single chamber with the solid precursor isotope source and the container.”

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

Y. Claim 35 “The radioisotope generator of claim 3, wherein the valve is configured to isolate the solid precursor isotope from the volume in a closed position.”

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

Z. Claim 36 “The radioisotope generator of claim 1, wherein the solid precursor isotope is bound to a non-radioactive material.”

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

65. In my opinion, a person of ordinary skill in the art reading Hassfjell-

Hoff would have understood that the filering packet was a commonly used non-radioactive material.

AA. Claim 38 “The radioisotope generator of claim 10, wherein the solid precursor isotope source and the container form at least a portion of a single chamber when fluidly coupled.”

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

VI. GROUND 2: CLAIMS 14, 28, 32, AND 36 ARE RENDERED OBVIOUS BY HASSFJELL-1994

A. Claim 14 “The radioisotope generator of claim 10, wherein the volume is configured to receive a solvent configured to dissolve the one or more solid progeny isotopes from the interior surface.”

67. In my opinion, Hassfjell-Hoff renders obvious this claim. Water is a well-known solvent. We disclosed the use of water to dissolve the ²¹²Pb from off the inside of the polyethylene bottle: “About 70% of the radioactivity inside the

polyethylene bottle can be easily washed off with approx. 30 ml of distilled water.”

EX1003, 7.

B. Claim 28 “The method of claim 23, further comprising receiving a solvent in the volume, and dissolving the one or more solid progeny isotopes from the interior surface in the solvent.”

68. In my opinion, Hassfjell-Hoff renders obvious this claim. Water is a well-known solvent. We disclosed the use of water to dissolve the ^{212}Pb from off the inside of the polyethylene bottle: “About 70% of the radioactivity inside the polyethylene bottle can be easily washed off with approx. 30 ml of distilled water.”

EX1003, 7.

C. Claim 32 “The method of claim 16, wherein the solid precursor isotope is bound to a non-radioactive material.”

69. In my opinion, Hassfjell-Hoff renders obvious this claim.

70. In my opinion, a person of ordinary skill in the art reading Hassfjell-Hoff would have understood that the filering packet was a commonly used non-radioactive material.

D. Claim 36 “The radioisotope generator of claim 1, wherein the solid precursor isotope is bound to a non-radioactive material.”

71. In my opinion, Hassfjell-Hoff renders obvious this claim.

72. In my opinion, a person of ordinary skill in the art reading Hassfjell-Hoff would have understood that the filering packet was a commonly used non-radioactive material.

VII. AVAILABILITY FOR CROSS-EXAMINATION

73. In signing this Declaration, I recognize 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 also recognize that I may be subject to cross-examination in the case and that cross-examination may take place within the United States.