

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)

Post Grant Review

No. PGR2025-00029 | U.S. Patent No. 12,125,603

Petitioner's Presentation

Claim Construction

Term	Sciencons's Proposed Construction	AdvanCell Proposed Construction
"precursor isotope source...decay[s] into one or more progeny isotopes..." (claims 1 and 12)	No explicit construction, but implies that the source excludes anything other than radioactive material that decays	Plain and ordinary meaning
"disposed on the rod" (claims 1 and 12)	No explicit construction	"directly or indirectly attaching to the rod"
Claim 10	Plain and ordinary meaning	"allowing decay is inclusive and occurs for at least at least 5 hours."
Claim 20	Plain and ordinary meaning	Indefinite
Limitations 1a and 1d	No explicit construction, but implies sliding the rod must be the sole cause	Plain and ordinary meaning

POR at 10-17 and 19-24; Sur-Reply at 3-8

Pet. at 3-5 and Reply at 1-10

“precursor isotope source...decay[s] into one or more progeny isotopes” (claims 1 and 12)

Sciencons’s Proposed Construction	AdvanCell Proposed Construction
No explicit construction, but implies that the source excludes anything other than radioactive material that decays	Plain and ordinary meaning

POR at 10-13 and 19-24; Sur-Reply at 3-4

Reply at 1-2

“The source may or may not contain a holder for the radioactive part and a grid or ring or similar surrounding the source to”

EX1001 at 10:3-5



“petitioner must be afforded a reasonable opportunity in reply to present argument and evidence under that new construction”

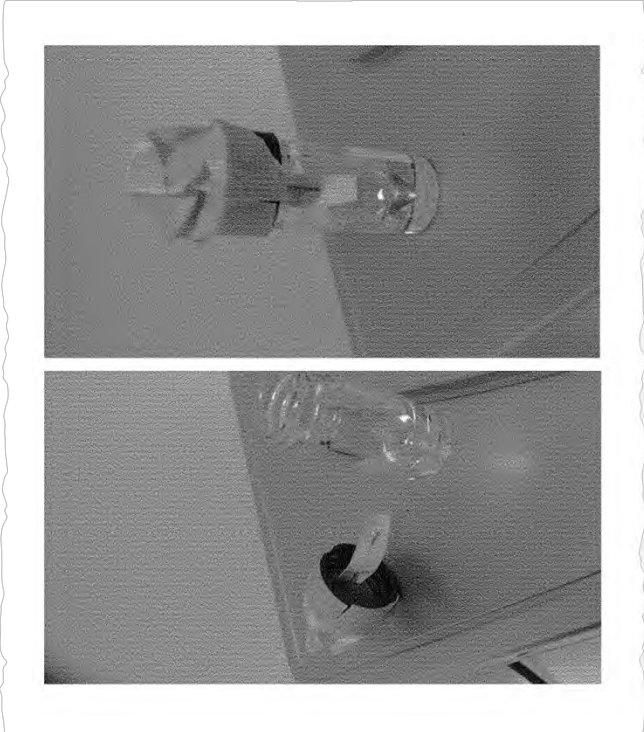
Axonics, Inc. v. Medtronic, Inc., 75 F.4th 1374, 1384 (Fed. Cir. 2023)

“disposed on the rod”

Sciencons’s Proposed Construction	AdvanCell Proposed Construction
No explicit construction	“directly or indirectly attaching to the rod”

POR at 14-16; Sur-Reply at 4-5

Pet. at 3-4; Reply at 2-6



EX1001 at Fig. 3

The second part of the assembly can, optionally, comprise a needle, rod or strip which may be supplied with a small ball of a material that can absorb radium or thorium including glass wool, quartz wool, mineral wool, metal, paper, cotton, stearate or another fatty acid, metal, cellulose, natural mineral, polymer, ion exchange resin, or other fibrous material. The composition of the holder of the precursor

EX1001 at 10:31-37

Claim 20 is Invalid Under Section 112

'603 Patent, Claim 10	
[10]	The method of claim 1, wherein allowing sufficient time for the precursor isotope source to decay comprises allowing 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours.

EX1001, Claim 10

'603 Patent, Claim 20	
[20]	The system of claim 12, wherein the precursor isotope source is configured to decay and emanate the one or more progeny isotopes into the container for 5 hours, 10 hours, 20 hours, 24 hours, 48 hours, 72 hours, or 96 hours.

EX1001, Claim 20

Pet. at 5, 58-59; POR at 16-17; Reply at 6-7, 21; Sur-Reply at 5-6

Limitations 1a and 1d Do Not Exclude Additional Steps

'603 Patent, Claim 1

[1pre]	A method of generating radioisotopes, the method <u>comprising</u> :
[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.

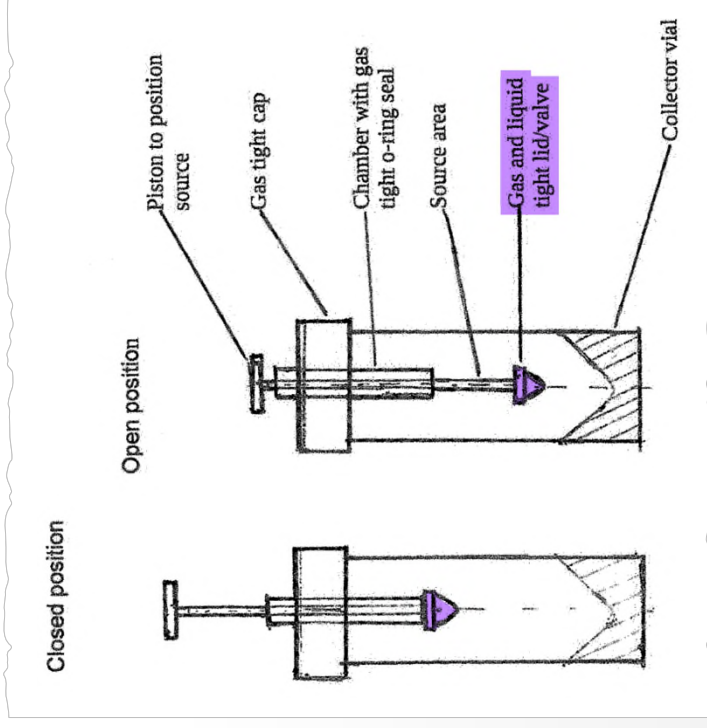
POR at 18-24; Reply at 7-10; Sur-Reply at 6-8

Limitations 1a and 1d



“‘comprising’ is inclusive or open-ended and does not exclude additional, unrecited elements or method steps”

CIAS, Inc. v. Alliance Gaming Corp., 504 F.3d 1356, 1360 (Fed. Cir. 2007)



EX1001 at Fig 4

PO Does Not Dispute Unpatentability Under the Board's Preliminary Analysis for Grounds 1-3

Ground	Claims	Stat. Basis	Prior Art
1	1-8, 11-17, 19	35 U.S.C. § 102	Hassfjell-Hoff
2	5-7, 110-11, 15-16, 20	35 U.S.C. § 103	Hassfjell-Hoff
3	9-10, 18, 20	35 U.S.C. § 103	Hassfjell-Hoff, O'Hara
4	1-3, 7-10, 12, 20	35 U.S.C. § 112	

Pet. at 5-57; POR; Reply at 10; Sur-Reply at 9-10

All Claims Challenged In Grounds 1-3 Are Unpatentable

PO Fails to Distinguish Any Elements in Limitation 1a

'603 Patent, Claim 1

[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,

EX1001, Claim 1

Applied Radiation and Isotopes



Editors-in-Chief
W. L. McLaughlin, NST, Galthersburg
D. M. Taylor, UWCC, Cardiff

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Advancell
Ex. 1028 Page 9

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

EX1003 at 7;
Pet. at 14-16

PO Fails to Distinguish Any Elements in Limitation 1d

'603 Patent, Claim 1

[1d]

isolating the precursor isotope source from the container by sliding the rod from the open position to the closed position.

EX1001, Claim 1

Applied Radiation and Isotopes



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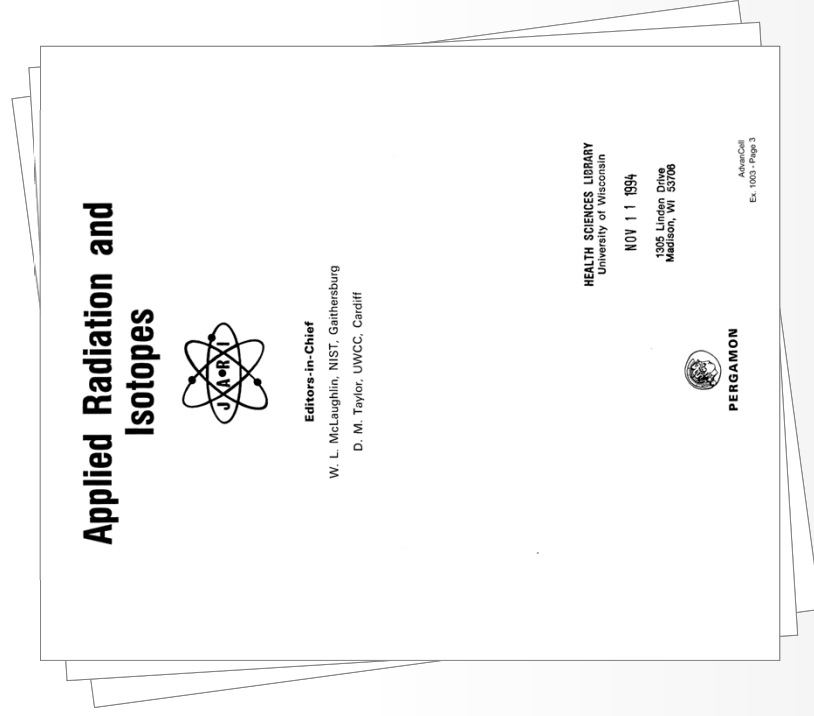
Advancell
Ex. 1028 - Page 3

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

EX1003 at 7;

Pet. at 18

**“precursor isotope source disposed on the rod”
is Shown in Ground 1**



EX1003 at Fig. 2;
Pet. at 16-17

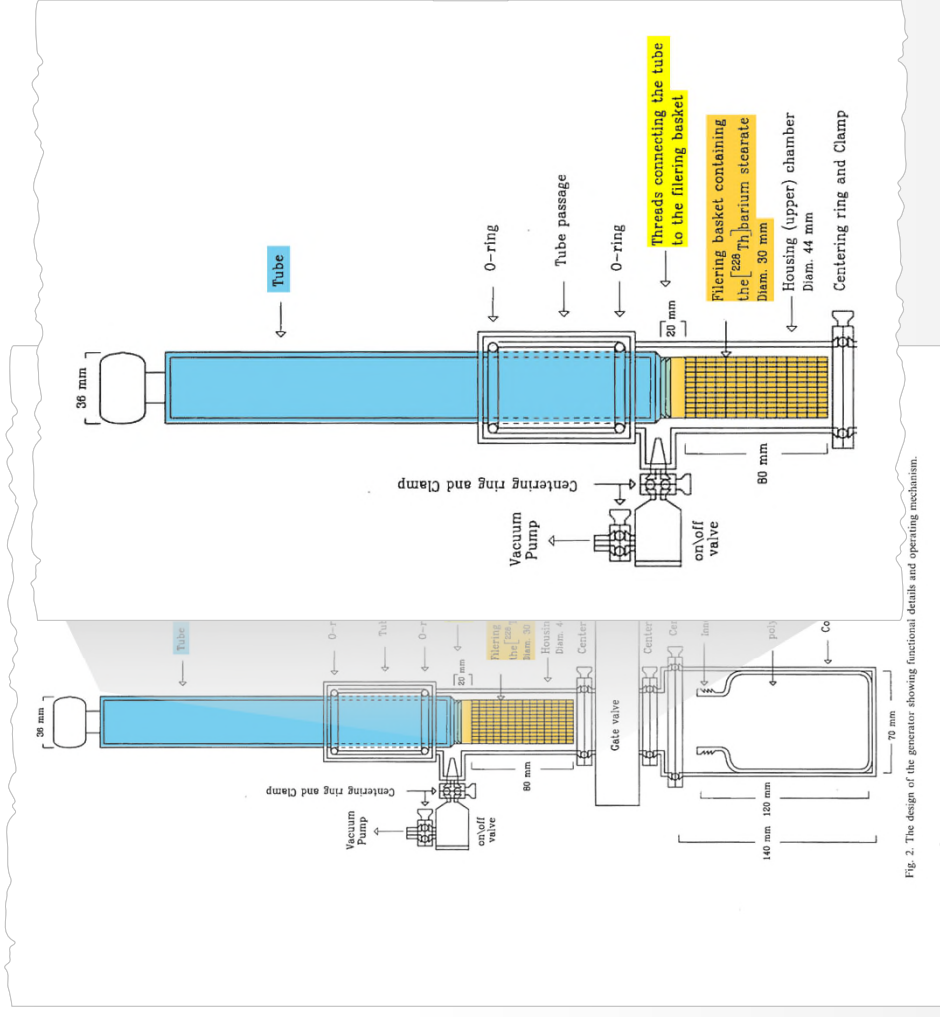


Fig. 2. The design of the generator showing functional details and operating mechanism

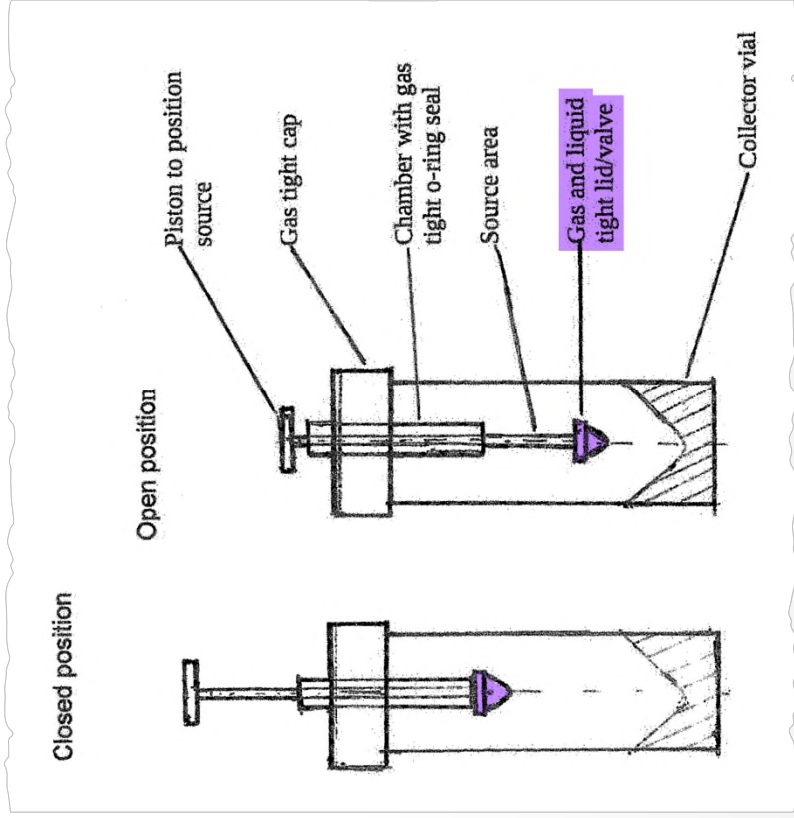
PO's "positions of the rod" Does Not Distinguish Hassfjell-Hoff

Sur-Reply at 14-15

'603 Patent, Claim 12

[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	<p>"When the tube is lowered, the filtering basket with the emanating [228Th]barium stearate becomes positioned inside the bottle. The decay products from the emanated 220 Rn, 212 Pb and 212 Bi, deposit on the walls of the bottle. After an appropriate collection time, the tube is pulled up, placing the 228 Th source in the upper compartment, and the gate valve is closed."</p> <p>EX1001, 7. Pet. at 32 citing §IV(B)(2) (limitation 1a)</p>
[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;	<p>"Figure 2 shows that if the tube is pulled upwards and the gate valve is closed, the precursor isotope source is sealed off from the polyethylene bottle in the collection (lower) chamber."</p> <p>Pet. at 32</p>

EX1001, Claim 12



EX1001 at Fig 4

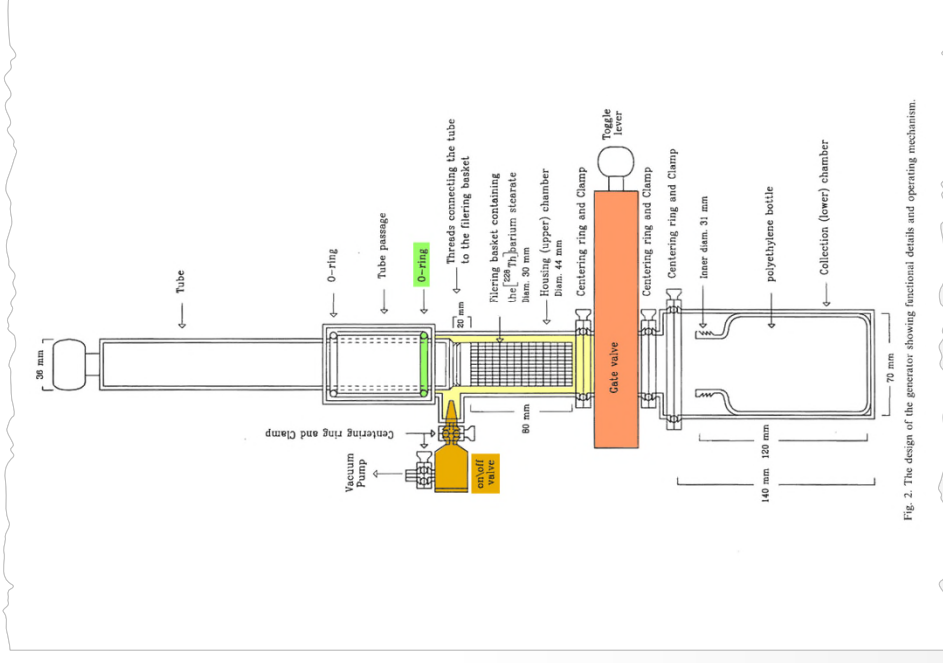
Claim 4

'603 Patent, Claim 4

[4]

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

- First raised in Sur-Reply at 15-18;
- Chamber having a gas tight seal is disclosed;
- Does not claim “gas-tight chamber”
- PO’s new argument is inconsistent with ’437 claim 4



EX1003 at Fig. 2

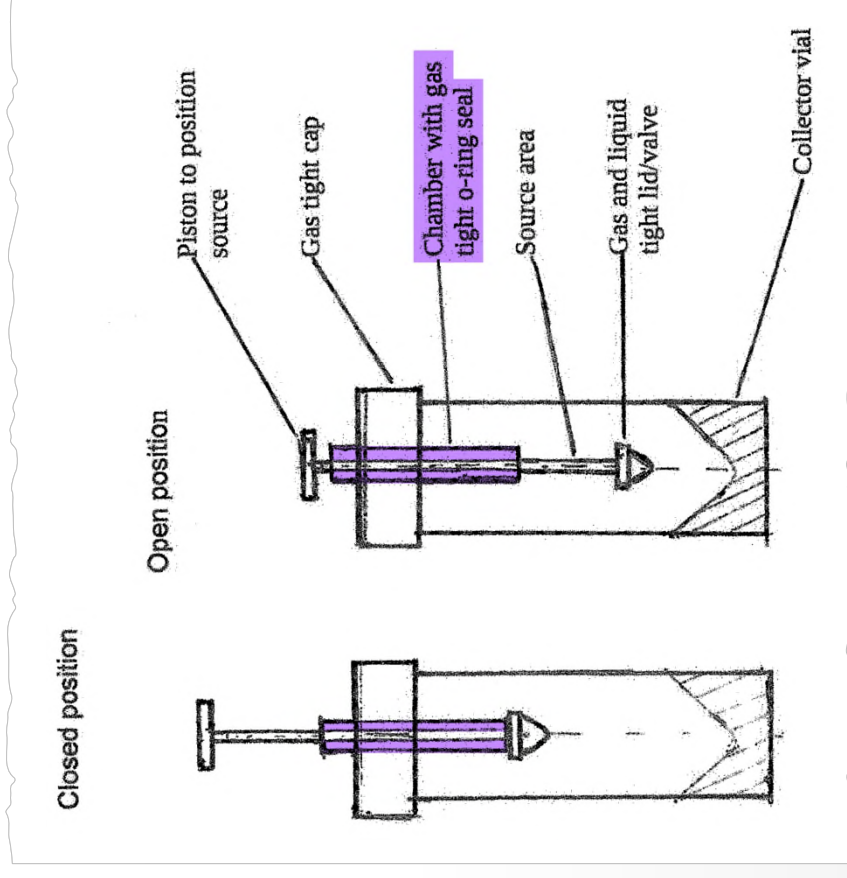
Claim 5

'603 Patent, Claim 5

[5]

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

- First raised in Sur-Reply at 15-18



EX1001 at Fig 4

Claim 5 is Disclosed by Hassfjell-hoff

POR at 31-33

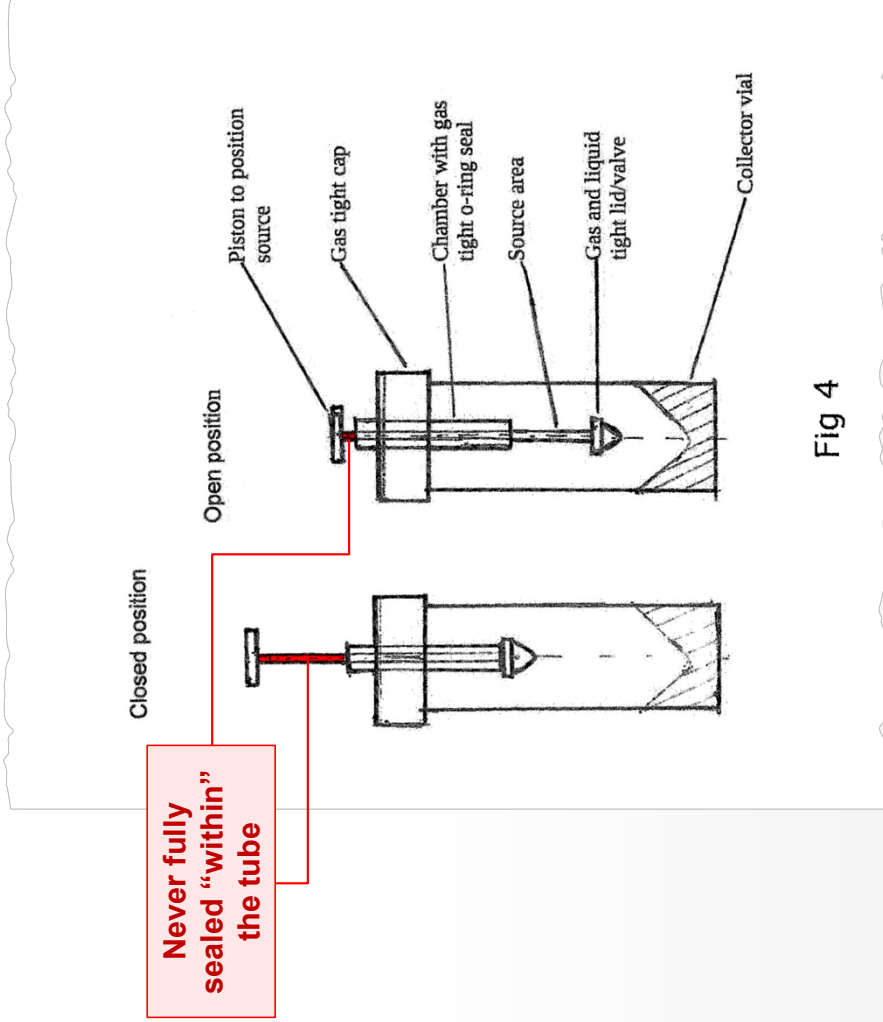


Fig 4

EX1001 at Fig 4

Pet. at 21-23; Reply at 16-17

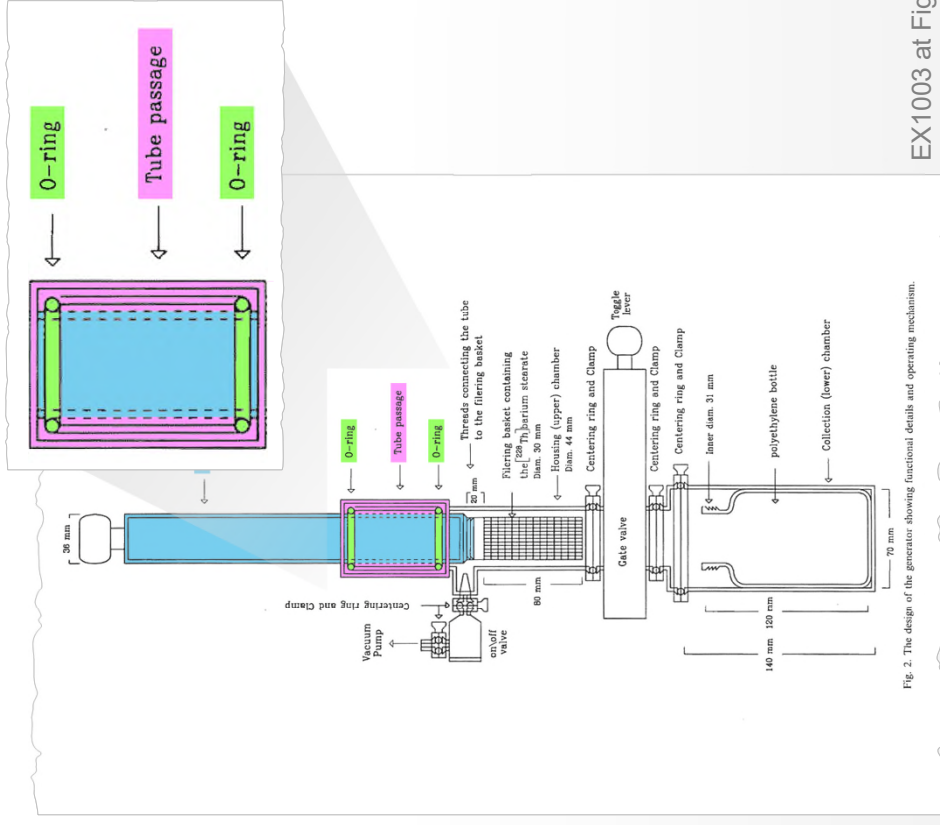


Fig. 2 The design of the generator showing functional details and operating mechanism.

EX1003 at Fig. 2

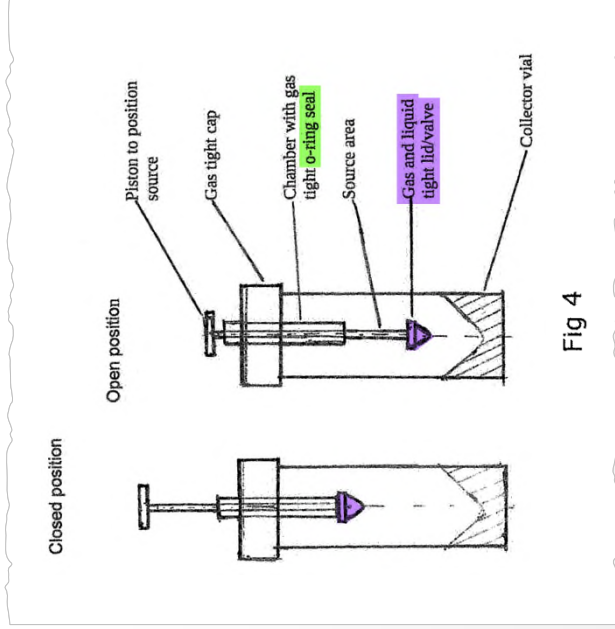
Claim 14 is Disclosed by Hassfjell-hoff

'603 Patent, Claim 14

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

[14]

EX1001, Claim 14



EX1001 at Fig 4;
Pet. at 34-35; Reply at 19

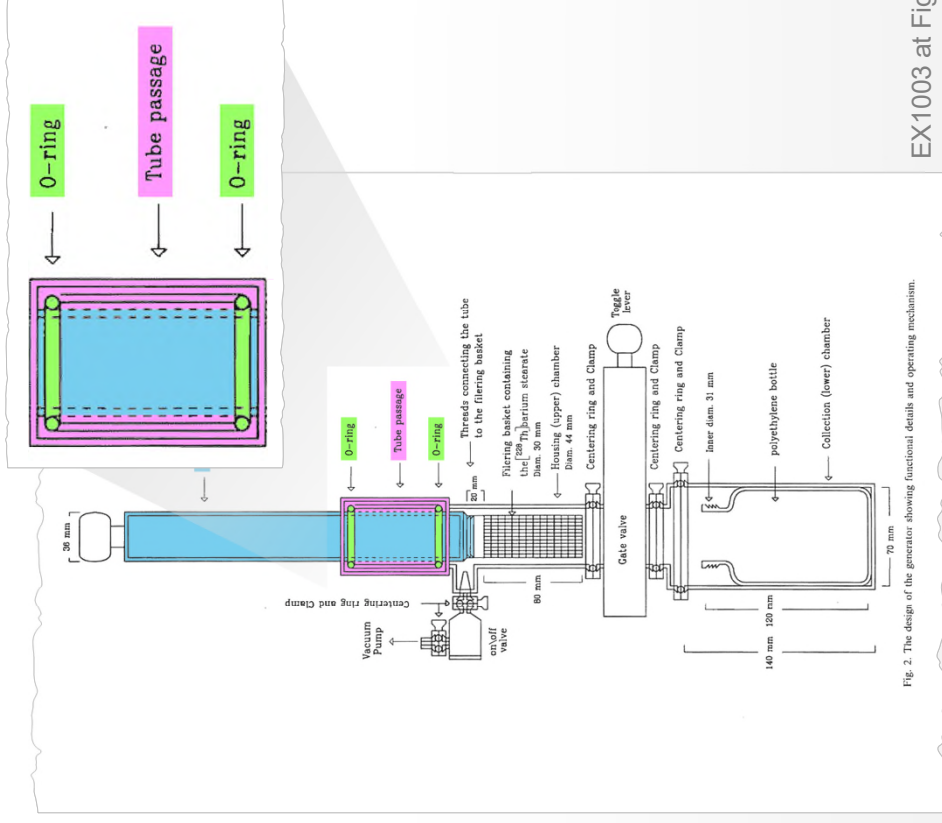


Fig. 2. The design of the generator showing functional details and operating mechanism.

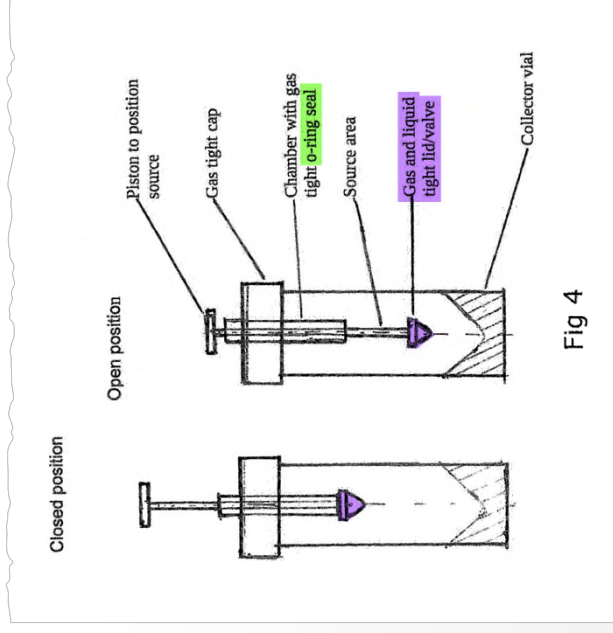
EX1003 at Fig. 2

Claim 15 is Disclosed by Hassfjellhoff

'603 Patent, Claim 15

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

EX1001, Claim 15



EX1001 at Fig 4;
Pet. at 34-35; Reply at 19

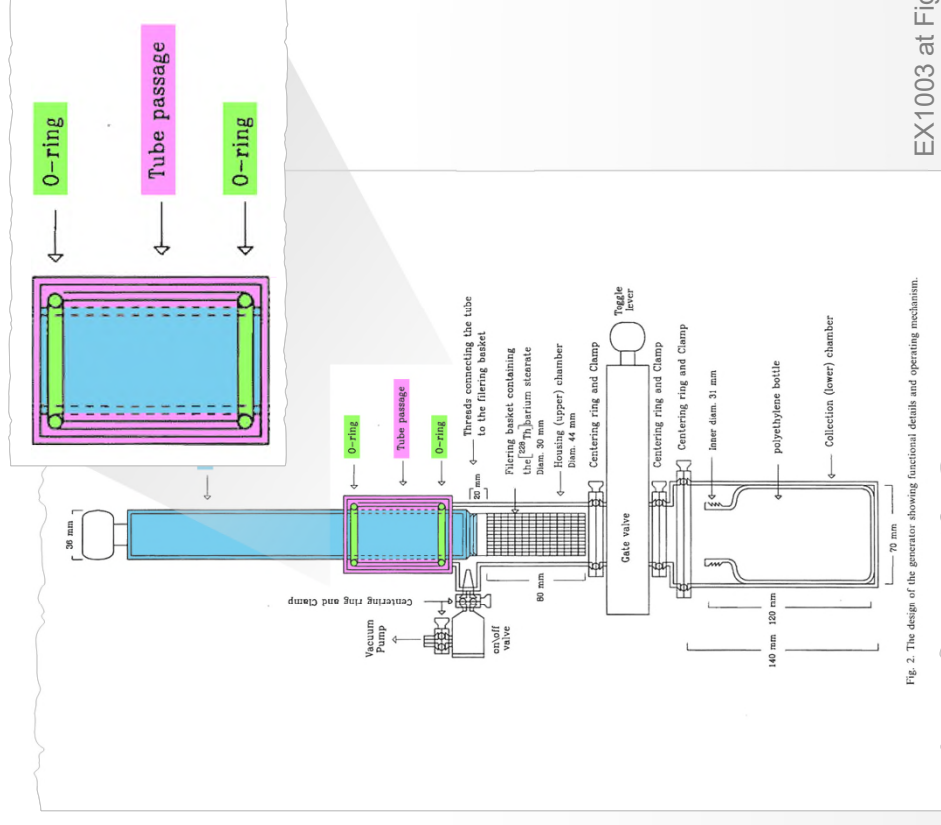


Fig. 2. The design of the generator showing functional details and operating mechanism.

Claims 8 & 17 are Disclosed by Hassfjell-hoff

'603 Patent, Claim 8	<p>[8]</p> <p>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.</p>
'603 Patent, Claim 17	<p>[17]</p> <p>The system of claim 12, wherein the precursor isotope source is encapsulated in a gas permeable barrier.</p>

EX1001, Claims 8, 17

EX1003 at Fig. 2;
Pet. at 29-30; Reply at 19-20

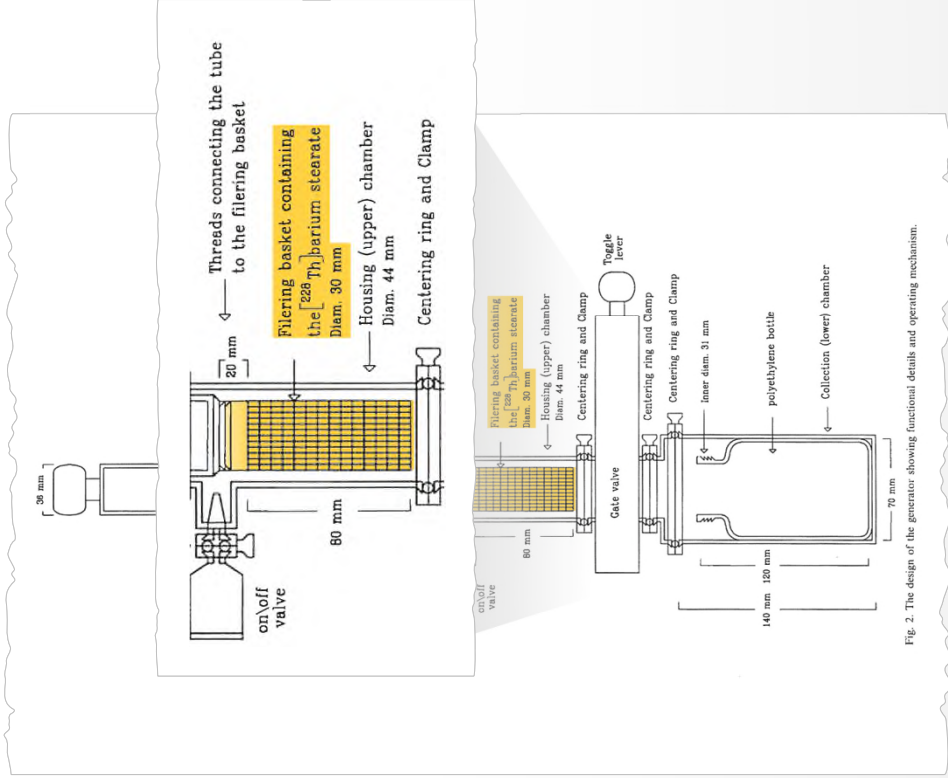


Fig. 2. The design of the generator showing functional details and operating mechanism.

Claims 2 & 3 are Invalid Under Section 112

'603 Patent, Claim 2

[2]

The method of claim 1, wherein exposing the interior surface to the precursor isotope source comprises exposing the interior surface to a thorium 228 isotope (^{228}Th) **and/or** a radium 224 isotope (^{224}Ra), the method further comprising allowing the ^{228}Th to decay into at least one of a radon 220 isotope (^{220}Rn) and a lead 212 isotope (^{212}Pb).

EX1001, Claim 2;
Pet. at 58-59; Reply at 21

Mr. Conroy is Not a POSITA and His Declaration Deserves No Weight

- Mr. Conroy has an MBA and a degree in Pharmacy
.....
- Mr. Conroy is a radiopharmacist with experience in using radioisotope generators to dispense
.....
- Mr. Conroy is biased because he has financial ties that benefit directly from the '603 patent's validity

Reply at 22-27; Motion to Exclude, Paper 32