

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

**PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

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INDEX OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 12,249,437.
1002	Declaration of Saed Mirzadeh.
1003	Hassfjell, Sindre P. and Hoff, Per, “A Generator for Production of ^{212}Pb and ^{212}Bi ”, Appl. Radiat. Inst., vol. 45, no. 10, pp 1021-25 (1994) (“ Hassfjell-Hoff ”).
1004	WorldCat Index for Hassfjell-Hoff .
1005	International Publication Number WO 01/60417.
1006	File History of U.S. Patent No. 12,249,437.
1007	U.S. Patent No. 5,038,046 (“ Norman ”).
1008	International Atomic Energy Agency, “Radiotracer Generators for Industrial Applications”, IAEA Radiation Technology Series No. 5, IAEA, Vienna (2013) (“ IAEA ”).
1009	Westrøm, Sara; Generalov, Roman; Bønsdorff, Sara B.; and Larsen, Roy H., “Preparation of ^{212}Pb -labeled monoclonal antibody using a novel ^{224}Ra -based generator solution”, Nuclear Medicine and Biology, vol. 51, pp 1-9 (August 2017) (“ Westrøm ”).
1010	WorldCat Index for Westrøm .
1011	Hassfjell, Sindre, “A ^{212}Pb generator based on a ^{228}Th source”, Appl. Radiat. Isot., vol. 55, no. 4, pp 433-439 (2001) (“ Hassfjell-2001 ”).
1012	U.S. Patent Application Publication No. 2006/0286130 (“ Bhagwatwar ”).
1013	U.S. Patent No. 2,130,523.
1014	WorldCat Index for IAEA .
1015	U.S. Patent No. 6,592,843.
1016	Xanjiao Xie, “Dissolution, Formation, and Transformation of the Lead Corrosion Product PbO_2 : Rates and Mechanisms of Reactions that Control Lead Release in Drinking Water Distribution Systems”, All Theses and Dissertations (ETDs), 387 (January 2010), available at https://openscholarship.wustl.edu/etd/387 (“ Xie ”).
1017	U.S. Patent No. 9,281,089.
1018	U.S. Patent No. 6,932,111 (“ Ishigaki ”).
1019	Declaration of Per Hoff.
1020	WorldCat Index for Xie .

Petitioner submits this Reply pursuant to the Board's email dated 8/18/25.

I. CONSTRUCTION OF LIMITATION 1C

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 a preliminary matter, the recitation of “is *configured to be* fluidly coupled” rather than simply “is fluidly coupled” indicates that the claimed generator can be placed into a first configuration in which the isotope source is not fluidly coupled to the volume and a second configuration in which the isotope source is fluidly coupled to the volume.

This two-configuration capability is acknowledged in the POPR, which explains that the source's “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” and stating that the Figure 4A/B “device disclosed in the specification allows for efficient, *safe* production.” POPR, 3 (emphasis added) (citing EX1001, 1:62-2:3, 5:67-6:13). Fig. 4's “gas and liquid tight lid/valve” (discussed below) is for safety so that the radioactive gas does not emanate into the container unless the rod is pushed down. EX1001, 13:63-14:24. It is the ability to selectively place the generator into the two configurations that provides for the safe production referenced by PO: the generator's non-fluidly

coupled configuration is selected during storage/shipment and when changing containers to prevent radioactive gas escape; and the fluidly coupled configuration is selected when production of the radioisotopes for collection is desired. Figs. 3 and 5 also include two configurations, including one wherein fluid coupling is accomplished using a gas tight seal and one without fluid coupling. Thus, contrary to PO's assertion that Petitioner rewrites the "fluidly coupled" limitation to inject a "selectively" requirement (POPR, 7), the "configured to be" term mandates this construction. Indeed, PO improperly rewrites the term "is configured to be fluidly coupled" as "is fluidly coupled," rendering "configured to be" superfluous.

This does not end the inquiry because the structure of the claim does not make clear which part of limitation 1c is modified by "with a gas tight seal," a problem exacerbated by the absence of any discussion of fluidly coupled in the specification. Pet., 5-8. That it is unclear which of the following three possible constructions is correct demonstrates indefiniteness. Pet., §XIV(A).

A. The "With a Gas Tight Seal" Modifies "Configured to be Fluidly Coupled" Construction

One possibility is that "with a gas tight seal" modifies "configured to be fluidly coupled," meaning that the change in the configuration of the generator between the non-fluidly coupled and fluidly coupled configurations is accomplished using a gas-tight seal. Pet., 5 (third construction). This construction aligns with the embodiments in the '437 patent, particularly the embodiment of

Figs. 4A/B addressed in the POPR. This embodiment has three gas-tight seals (annotated in red) and three distinct spaces (annotated in yellow, blue, and beige):

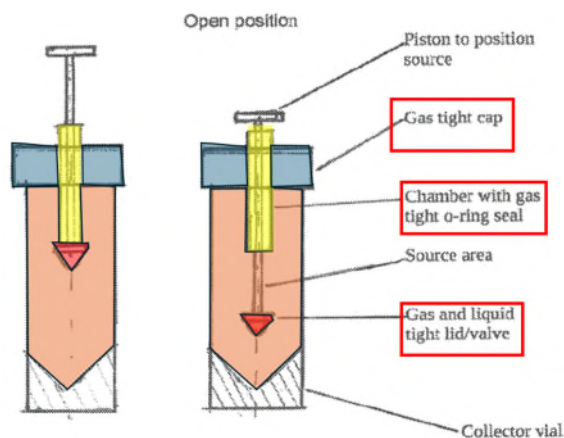
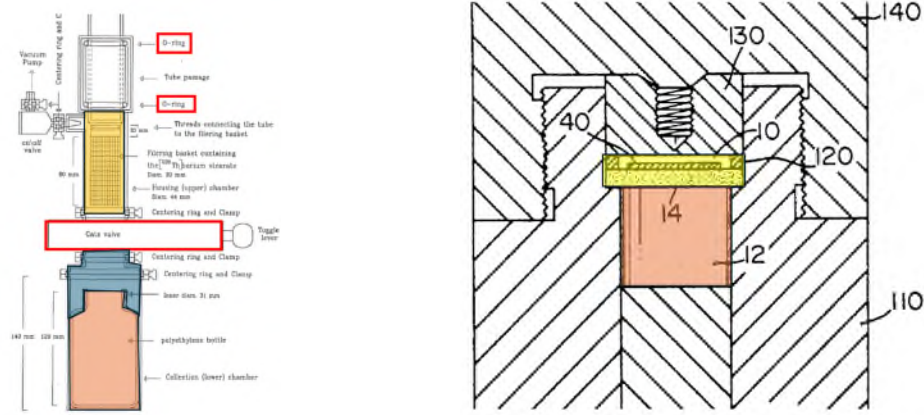


Fig. 4A

Fig. 4B

EX1001, Fig. 4. In Fig. 4A, the precursor isotope is located in the yellow volume that is **not** fluidly coupled to the beige volume corresponding to the collector vial/surface or the blue volume corresponding to the cap—it is isolated from these volumes by the “gas and liquid tight lid/valve” shown in red in Figs. 4A/B. In the configuration shown in Fig. 4B, the precursor isotope has become fluidly coupled to both the beige and blue volumes that include the collector vial/surface as a result of opening the “gas and liquid-tight lid/valve” via pressing down on the rod. Thus, consistent with the Petition’s third construction, the requirement of limitation 1c for the precursor isotope source to be fluidly coupled is accomplished with/using a gas-tight seal, the “gas and liquid-tight lid/valve.” In this respect, the gas tight lid/valve works the same way as the gate valve in the Hassfjell-Hoff reference and the stopcock in the Norman reference: the fluid coupling of the isotope source and

the volume with the collector surface is created when these devices are **open**:



EX1003, Fig. 2; EX1007, Fig. 2. PO’s criticisms of the Petition’s challenges based on Hassfjell-Hoff’s gate valve and Norman’s stopcock as corresponding to the claimed “gas tight seal” (POPR, 14-19 and 30-31) are therefore without merit.

B. The “With a Gas Tight Seal” Modifies “A Volume” Construction

It is also possible to construe limitation 1c as requiring that “a gas tight seal” modifies “a volume,” i.e., that the claimed generator has a volume with a gas tight seal. Pet., 5-6 (first construction). This construction is independent of whether the claim requires two configurations as discussed above. Under this construction, the volume includes both the volume where the source is located and the volume corresponding to the collector surface. Pet., 5-6 (first construction). Using the above annotated Figure 4B as an example, the volume that is sealed includes the yellow volume of the tube, the blue volume of the cap, and the beige volume of the container. The entire volume of the apparatus “includ[es] a collector surface” (EX1001, claim 1) and has a gas-tight seal by the combination of the “gas tight

cap” and the “gas tight o-ring seal.” As established in the Petition, Norman’s Fig. 2 (annotated above yellow and beige) satisfies this construction because the volume including both the chamber 10 in which the precursor isotope source is located and the chamber 12 in which the collector surface is located is sealed by the seal elements of Fig. 2. Pet., 53-54 (citing EX1007, 7:65-8:24). The POPR’s criticism that Norman’s chamber 12 does not have a gas-tight seal (POPR, 28) is inapposite because under the Petition’s first construction, the “entire volume has a gas tight seal (with the precursor isotope source inside the volume)” (Pet., 5), and the entire volume of Norman therefore necessarily includes the chamber 10. The Petition also establishes that Hassfjell-Hoff’s Figure 2 has a gas tight seal when the gate valve is open (annotated above yellow, blue, and beige). Pet., 19-21.

C. The “With a Gas Tight Seal” Modifies “A Collector Surface” Construction

Finally, it is possible to construe limitation 1c to require a gas tight seal on only the volume defined by the collector surface. Figs. 3A/B and 5A/B show this configuration. In contrast, the Fig. 4A/B embodiment does not because, in addition to the beige volume, the sealed volume includes (1) the volume corresponding to the cap (annotated blue), and (2) the volume inside the tube (annotated yellow) when the valve is open. As PO takes the position that Fig. 4 is within the scope of the claims (POPR, 4-13), that is further support for Ground 11 (indefiniteness).

Date: August 26, 2025

Respectfully submitted,

/s/ Jennifer Librach Nall

Jennifer Librach Nall

Reg. No. 57,053

DLA Piper LLP (US)

303 Colorado Street, Suite 3000

Austin, Texas 78701

Phone: 512.457.7249

Fax: 512.721.2249

jennifer.nall.ptab@dlapiper.com

Attorney for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies pursuant to 37 C.F.R. §§ 42.6(e) that on August 26, 2025 a true and correct copy of this brief and any new exhibits was served by emailing a copy of same to the following:

Michael T. Rosato
Email: mrosato@wsgr.com

Patrick M. Medley
Email: pmedley@wsgr.com

Michael J. Hostetler
Email: mhostetler@wsgr.com

Date: August 26, 2025

/s/ Jennifer Librach Nall
Jennifer Librach Nall
Reg. No. 57,053
DLA Piper LLP (US)
303 Colorado Street, Suite 3000
Austin, Texas 78701
Phone: 512.457.7249
Fax: 512.721.2249
jennifer.nall.ptab@dlapiper.com

Attorney for Petitioner