

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**AdvanCell Pty Ltd.**

Petitioner

v.

**Sciencons AS and ARTBIO, Inc.,**

Patent Owner

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Case No. PGR2025-00029

Patent No. 12,125,603

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**PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION TO  
EXCLUDE EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)**

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| 1001        | U.S. Patent Number 12,125,603.                                                                                                                                                                                                                                                                                                     |
| 1002        | Declaration of Saed Mirzadeh.                                                                                                                                                                                                                                                                                                      |
| 1003        | Hassfjell, Sindre P. and Hoff, Per, “A Generator for Production of $^{212}\text{Pb}$ and $^{212}\text{Bi}$ ”, Appl. Radiat. Inst., vol. 45, no. 10, pp 1021-25 (1994) (“ <b>Hassfjell-Hoff</b> ”).                                                                                                                                 |
| 1004        | WorldCat Index for <b>Hassfjell-Hoff</b> .                                                                                                                                                                                                                                                                                         |
| 1005        | International Publication Number WO 01/60417.                                                                                                                                                                                                                                                                                      |
| 1006        | File History of U.S. Patent No. 12,125,603.                                                                                                                                                                                                                                                                                        |
| 1007        | US Patent Application Publication No. 2018/0047474 A1 (“ <b>O’Hara</b> ”).                                                                                                                                                                                                                                                         |
| 1008        | Hassan, Ahmed and Alnaser, Ibrahim Abdullah, “A Review of Different Manufacturing Methods of Metallic Foams” ACS Omega 2024 9 (6), 6280-6295 DOI: 10.1021/acsomega.3c08613 (“ <b>Hassan</b> ”).                                                                                                                                    |
| 1009        | Lefebvre, Louis-Philippe, Banhart, John, and Dunand, David C., “Porous Metals and Metallic Foams: Current Status and Recent Developments,” Advanced Engineering Materials, 10, September 9, pp. 775-787, 2008 <a href="https://doi.org/10.1002/adem.200800241">https://doi.org/10.1002/adem.200800241</a> , (“ <b>Lefebvre</b> ”). |
| 1010        | U.S. Patent Number 3,087,807.                                                                                                                                                                                                                                                                                                      |
| 1011        | “Radioisotopes,” International Atomic Energy Agency, <a href="https://www.iaea.org/topics/nuclear-science/isotopes/radioisotopes">https://www.iaea.org/topics/nuclear-science/isotopes/radioisotopes</a> (last accessed February 11, 2025).                                                                                        |
| 1012        | File History of U.S. Patent Application Serial No. 18/680,605.                                                                                                                                                                                                                                                                     |
| 1013        | File History of U.S. Patent Application Serial No. 18/680,372.                                                                                                                                                                                                                                                                     |
| 1014        | Hassfjell, Sindre, “A $^{212}\text{Pb}$ generator based on a $^{228}\text{Th}$ source”, Appl. Radiat. Isot., vol. 55, no. 4, pp 433-439 (2001) (“ <b>Hassfjell-2001</b> ”).                                                                                                                                                        |
| 1015        | U.S. Patent Number 6,592,843.                                                                                                                                                                                                                                                                                                      |
| 1016        | “O-Ring Handbook,” Parker Hannifin Corporation, <a href="https://www.hdslippers.com/cgi-bin/pdf/Catalogues/05-O-Ring-Handbook_ODE5705-EN%20Luglio%202015.pdf">https://www.hdslippers.com/cgi-bin/pdf/Catalogues/05-O-Ring-Handbook_ODE5705-EN%20Luglio%202015.pdf</a> (last accessed March 7, 2025).                               |
| 1017        | Declaration of Per Hoff.                                                                                                                                                                                                                                                                                                           |
| 1018        | Excerpts of Merriam-Webster’s Collegiate Dictionary, 11 <sup>th</sup> ed. (2018).                                                                                                                                                                                                                                                  |
| 1019        | Declaration of Jennifer Librach Nall                                                                                                                                                                                                                                                                                               |
| 1020        | U.S. Patent Number 12,394,533.                                                                                                                                                                                                                                                                                                     |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| 1021               | Conroy Exhibit 3: Fraiser Kansteiner, “Nucleus RadioPharma Links Up With ARTBIO to Help Produce Prostate Cancer Candidate for Clinical Trials,” Fierce Pharma (May 7, 2024), <a href="https://www.fiercepharma.com/pharma/nuclear-medicine-cdmo-nucleus-links-artbio-help-produce-prostate-cancer-radiotherapy">https://www.fiercepharma.com/pharma/nuclear-medicine-cdmo-nucleus-links-artbio-help-produce-prostate-cancer-radiotherapy</a> .                                                                                                            |
| 1022               | Conroy Exhibit 4: ARTBIO, “ARTBIO and Nucleus RadioPharma Announce Collaboration to Manufacture GMP-Grade Therapeutic Products Containing Radioisotope Pb-212 to Support Emerging Clinical Trials” (May 7, 2024), <a href="https://artbio.com/artbio-nucleus-radiopharma-collaboration-manufacture-gmp-grade-therapeutic-products-radioisotope-pb-212-support-emerging-clinical-trials">https://artbio.com/artbio-nucleus-radiopharma-collaboration-manufacture-gmp-grade-therapeutic-products-radioisotope-pb-212-support-emerging-clinical-trials</a> . |
| 1023               | Conroy Deposition Transcript.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1024               | National Library of Medicine, “Study of Alpha Radioligand Therapy AB001 in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) (ARTISAN)” (last updated Apr. 7, 2026), <a href="https://clinicaltrials.gov/study/NCT07214961">https://clinicaltrials.gov/study/NCT07214961</a>                                                                                                                                                                                                                                                          |
| 1025               | ARTBIO, “ARTBIO Announces Dosing of Two Cohorts with AB001 in ARTISAN, a Phase 1 Alpha Radioligand Therapy Clinical Trial for Metastatic Castration Resistant Prostate Cancer” (Jan. 12, 2026), <a href="https://artbio.com/ARTBIO-Announces-dosing-of-Two-Cohorts-with-AB001">https://artbio.com/ARTBIO-Announces-dosing-of-Two-Cohorts-with-AB001</a>                                                                                                                                                                                                   |
| 1026               | ARTBIO, “ARTBIO and Nucleus RadioPharma Announce Collaboration to Manufacture GMP-Grade Therapeutic Products Containing Radioisotope Pb-212 to Support Emerging Clinical Trials” (May 7, 2024), <a href="https://artbio.com/artbio-nucleus-radiopharma-collaboration-manufacture-gmp-grade-therapeutic-products-radioisotope-pb-212-support-emerging-clinical-trials">https://artbio.com/artbio-nucleus-radiopharma-collaboration-manufacture-gmp-grade-therapeutic-products-radioisotope-pb-212-support-emerging-clinical-trials</a> .                   |
| 1027               | U.S. Patent No. 12,406,776                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

## **I. INTRODUCTION**

Patent Owner's Motion to Exclude should be denied in its entirety. Every argument Patent Owner advances attacks the weight and sufficiency of Petitioner's evidence, not its admissibility. Patent Owner contends that Dr. Mirzadeh applied the "incorrect legal standard," that Mr. Hoff's opinions are "conclusory," and that certain testimony is not "relevant" to the grounds advanced in the Petition. Paper 31 at 2-5. These are merits arguments directed to the weight the Board should accord the testimony on the full record, not to its admissibility.

Moreover, Patent Owner has waived its objections under Federal Rules of Evidence (F.R.E.) 701, 703, and 802 by failing to develop any argument under those rules. And Patent Owner's alternative request for a limiting instruction under Rule 105 has no application in a bench proceeding before the Board.

Both EX1002 (the Declaration of Dr. Saed Mirzadeh, ¶¶152-63) and EX1017 (the Declaration of Dr. Per Hoff) are admissible in their entirety. The Motion should be denied.

## **II. THE MOTION IMPROPERLY SEEKS TO USE THE RULES OF EVIDENCE TO ATTACK THE WEIGHT AND SUFFICIENCY OF PETITIONER'S EVIDENCE**

Every argument in the Motion is a merits argument dressed up as an evidentiary objection. Patent Owner contends that Dr. Mirzadeh applied the "incorrect legal standard," that Mr. Hoff's opinions are "conclusory," and that

certain testimony is not “relevant” to the grounds advanced in the Petition. Paper 31 at 1-5. Although Patent Owner casts these contentions as challenges to admissibility, each one in substance disputes how much weight the testimony should receive and whether Petitioner has carried its burden on the challenged claims. As the Board’s Consolidated Trial Practice Guide provides, arguments of this kind belong in the parties’ merits briefing, not in a motion to exclude. Trial Practice Guide, at 79 (“A motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay) but may not be used to challenge the sufficiency of the evidence to prove a particular fact. A motion to exclude is not a vehicle for addressing the weight to be given evidence—arguments regarding weight should appear only in the merits documents.”).

A motion to exclude is not the vehicle for such arguments. The Trial Practice Guide confirms that “[t]he Board has broad discretion to assign weight to be accorded expert testimony. *Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010).” Trial Practice Guide, 35. And where the Board finds that “[e]xpert testimony that does not disclose the underlying facts or data on which the opinion is based,” the remedy is that such testimony “is entitled to little or no weight” under 37 C.F.R. § 42.65(a), and not exclusion. Trial Practice Guide, 35. These mechanisms exist precisely because the Board is an expert tribunal fully capable of weighing evidence on its merits. To the extent Patent Owner believes that Dr.

Mirzadeh's or Mr. Hoff's testimony is insufficiently supported or unpersuasive, the proper course is to argue for reduced weight in the merits papers, not to seek exclusion. Accordingly, the Motion should be denied.

### **III. PATENT OWNER HAS WAIVED ITS F.R.E. 701, 703, AND 802 OBJECTIONS BY FAILING TO ARGUE THEM**

Although Patent Owner's objections purported to challenge both EX1002 and EX1017 under F.R.E. 701, 703, and 802, the Motion advances no argument whatsoever under those rules. Paper 31 at 1. A movant must do more than list rule numbers in its objections; it must explain, with particularity, why the challenged evidence is inadmissible under each rule invoked. 37 C.F.R. § 42.64(c) (a motion to exclude "must explain the objections"); *see also* Trial Practice Guide at 79 (a motion to exclude should "[e]xplain the basis and grounds for each objection").

By failing to develop any argument under F.R.E. 701, 703, or 802, Patent Owner has waived those objections, and the Board should not consider them. Any belated attempt to resurrect these objections in reply would be improper and should be disregarded. *See* 37 C.F.R. § 42.23(b); *see also* Trial Practice Guide at 74 (a reply "that raises a new issue or belatedly presents evidence may not be considered").

#### **IV. EXHIBIT 1002 (MIRZADEH DECLARATION)**

##### **A. Dr. Mirzadeh's Testimony Satisfies F.R.E. 702**

Patent Owner's sole basis for seeking exclusion of paragraphs 152-63 of the Mirzadeh Declaration under F.R.E. 702 is that Dr. Mirzadeh purportedly applied the "incorrect legal standard" because paragraphs 8-28 of his declaration recite legal standards only for anticipation and obviousness, and he testified that he has no legal training. Paper 31 at 1-2 (citing EX2004, 35:17-19, 36:6-11, 37:4-39:5). This argument fundamentally mischaracterizes both Dr. Mirzadeh's testimony and the nature of the § 112 analysis.

Dr. Mirzadeh's challenged testimony is not offered to instruct the Board on § 112 law. It is offered to explain the technical predicates for Petitioner's § 112 grounds: what the claim language would require as would be understood by a POSITA, what the specification discloses, and whether the claimed radioactive decay and emanation events are physically possible. That is proper expert testimony. See Trial Practice Guide at 34-35 (expert testimony may be used to explain the relevant technology and help determine a fact in issue).

For enablement and written description, the challenged paragraphs identify concrete technical problems with the asserted claim scope. Dr. Mirzadeh explained that if claim 1 requires "the same one or more progeny isotopes to emanate into the container," only one progeny isotope,  $^{220}\text{Rn}$ , is gaseous and can emanate, so "it is

impossible for there to be more than one progeny isotope that both decays from the precursor isotope source disclosed by the 603 patent and that also emanates into the container.” EX1002, ¶152. He also explained that claim 2’s  $^{228}\text{Th}$  only alternative is not physically possible because “the radioactive decay of  $^{228}\text{Th}$  into  $^{224}\text{Ra}$  cannot be stopped or even slowed down,” meaning that any  $^{228}\text{Th}$  source must include some  $^{224}\text{Ra}$  as a POSITA would understand. EX1002, ¶¶153–54. Those opinions concern radiochemistry and the understanding of a POSITA, not legal instruction to the Board. The lack of a legal standard for enablement in Dr. Mirzadeh’s declaration is of no moment because when something is impossible, there is no enablement under any standard. *See Trustees of Boston Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1362 (Fed. Cir. 2018) (“We can safely conclude that the specification does not enable what the experts agree is physically impossible.”).

The same is true for indefiniteness. Dr. Mirzadeh explained that claim 2’s “further comprising” clause is uncertain because, under one alternative, there is no  $^{228}\text{Th}$  present, so “it is not reasonably certain to a POSITA whether this claim requires allowing the (nonexistent)  $^{228}\text{Th}$  to decay.” EX1002, ¶154. He also explained that claim 7’s language is “non-sensical” and that a POSITA “would not have known which correction is covered by the claim as written.” EX1002, ¶¶157-

59. Whether those facts satisfy the legal standard for indefiniteness is for the Board to decide. The technical testimony supporting that determination is admissible.

At most, Patent Owner identifies a reason to discount particular legal phrasing in the declaration. That is not a basis to exclude the underlying technical testimony. The Board can assign appropriate weight to any legal phrasing in the declaration while still considering the testimony about what a POSITA would understand and what the science permits.

Patent Owner's citation of *U.S. Gypsum Co. v. Lafarge N. Am. Inc.*, 670 F. Supp. 2d 737, 745 (N.D. Ill. 2009), does not compel a different result. As discussed above, Dr. Mirzadeh's analysis on lack of enablement and indefiniteness is technical in nature and is correct based on the proper legal standard whether or not those standards were stated in his declaration. And, unlike *U.S. Gypsum* in which the expert applied a legally incorrect standard under the CFAA, PO makes no showing of any error in Dr. Mirzadeh's conclusions on either indefiniteness or enablement under the correct legal standards. Thus, there is no sound legal basis to exclude his testimony. Moreover, that case addressed expert testimony in a district court jury trial under *Daubert*, not threshold admissibility before an expert administrative tribunal. The Board is fully capable of assessing the testimony without excluding it from the record.

**B. Dr. Mirzadeh's § 112 Testimony Is Relevant and Not Unfairly Prejudicial Under F.R.E. 401-403**

The threshold for relevance under Rule 401 is low: evidence is relevant if “(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action.” F.R.E. 401. Dr. Mirzadeh’s testimony regarding written description, enablement, and indefiniteness is directly relevant to Petitioner’s § 112 grounds, which Patent Owner itself concedes remain live as to claims 2, 3, and 20. Paper 31 at 2. Dr. Mirzadeh’s opinions are plainly relevant to those claims. Moreover, his analysis of the patent specification and POSITA knowledge provides necessary technical context for the § 112 issues as a whole.

Patent Owner’s contention that Petitioner “abandoned” § 112 arguments for certain claims by streamlining its positions in its Reply does not retroactively strip relevance from the underlying technical testimony. Narrowing the claims at issue on reply is a commonplace exercise in PTAB practice; it does not render inadmissible the technical opinions that provide the analytical foundation for the remaining arguments.

Nor is there any basis for exclusion under F.R.E. 403. This is a bench proceeding before three technically trained administrative patent judges. There is no jury to confuse or mislead, and no risk of unfair prejudice. The Board is fully capable of considering Dr. Mirzadeh’s testimony and according it whatever weight

it deems appropriate in light of the parties' merits submissions. Exclusion under F.R.E. 403 is neither necessary nor appropriate.

**V. EXHIBIT 1017 (HOFF DECLARATION)**

**A. Mr. Hoff's Testimony Satisfies F.R.E. 702**

Patent Owner's assertion that paragraphs 38-82 of Mr. Hoff's declaration are "textbook illustrations of improper conclusory testimony," is inaccurate and, more fundamentally, does not state a basis for exclusion. Patent Owner cherry-picks isolated summary sentences, such as "In my opinion, Hassfjell-Hoff discloses this claim" (e.g., EX1017, ¶¶38, 56), while ignoring the surrounding analysis and the declaration as a whole.

Mr. Hoff's declaration must be evaluated in its entirety and in the context of the record, including the Hassfjell-Hoff article (EX1003) it analyzes. Read that way, his opinions are amply supported by his first-hand technical expertise and by the disclosures of the reference. Mr. Hoff is not merely an expert witness; he is one of the authors of the Hassfjell-Hoff article. EX1017, ¶29 ("I am one of the authors of Hassfjell-Hoff."). His claim-by-claim analysis is replete with substantive reasoning tied to the disclosures of the reference: the gate valve that formed a gas-tight seal when closed (¶42); the two O-rings around the sliding tube forming a gas-tight seal (¶44); the bottle turned relative to its cap when unscrewed (¶¶46-47); the tube size that prevented the filtering basket from touching the interior surface

(¶¶50-51); and detailed obviousness analysis explaining, inter alia, that the 10.6-hour half-life of  $^{212}\text{Pb}$  dictates how the system “would need to run for 10.6 hours to create approximately half the maximum amount of  $^{212}\text{Pb}$  that is expected to exist” (¶¶72-73, 81-82).

In any event, the degree to which an expert articulates his reasoning goes to the weight of his testimony, not its admissibility. The authorities Patent Owner cites, *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363 (Fed. Cir. 2008), and *Meyer Intellectual Properties Ltd. v. Bodum, Inc.*, 690 F.3d 1354 (Fed. Cir. 2012), do not support Patent Owner’s position. Both arose in the district-court jury trial context and addressed the sufficiency of expert reports under Fed. R. Civ. P. 26(a) and their helpfulness to a lay jury, not threshold admissibility before an expert administrative tribunal.

If Patent Owner believes Mr. Hoff’s opinions lack adequate explanation, the proper course is to argue for reduced weight in its merits papers, not wholesale exclusion from the record. The Trial Practice Guide makes clear that “[t]he Board has broad discretion to assign weight to be accorded expert testimony,” and that expert testimony lacking a sufficient factual basis “is entitled to little or no weight” under 37 C.F.R. § 42.65(a). See Trial Practice Guide at 35. The Board should exercise that discretion here rather than granting the extraordinary remedy of exclusion.

**B. Paragraphs 32-37 and the Remainder of Mr. Hoff's Declaration Are Relevant and Not Prejudicial Under F.R.E. 401-403**

Patent Owner's relevance challenge to paragraphs 32-37, which describe how the device in Mr. Hoff's article actually worked, should be rejected. See Paper 31 at 4. Mr. Hoff is a technical expert with direct, personal knowledge of the Hassfjell-Hoff device. His description of how the device functioned, including the two-compartment construction, the filtering basket, the sliding tube on two O-rings, the polyethylene collection bottle, the 11-step operating sequence (§36), and the gas-tight seals such that "no detectable leakage of any kind of radioactivity out of the generator has been observed" (§37, quoting EX1003, at 7), bears directly on whether the claimed functionality was disclosed or obvious to a POSITA at the relevant time.

This testimony is plainly relevant under the low bar of F.R.E. 401 and probative of the disclosures and capabilities underlying Petitioner's grounds. It does not inject a "new theory;" it provides admissible technical context illuminating the very reference on which Petitioner's grounds rest. The Trial Practice Guide confirms that expert testimony properly may be used to "explain the relevant technology to the panel," "establish the level of skill in the art," and describe "the teachings of the prior art and how they relate to the patentability of the challenged claims." See Trial Practice Guide at 34-35.

Patent Owner's F.R.E. 403 argument fails for the same reason it fails with respect to EX1002: this is a bench proceeding before technically trained administrative patent judges. There is no jury to confuse and no risk of unfair prejudice before the Board. The Board can determine which portions of Mr. Hoff's testimony are pertinent to the issues presented and accord them appropriate weight.

Patent Owner's complaint that the "remainder" of the declaration "describes background and legal standards" that Mr. Hoff purportedly did not apply is likewise not a ground for exclusion. Background, foundational, and contextual testimony is routinely admitted in Board proceedings. Trial Practice Guide at 34-35 (expert testimony may be used to "explain the relevant technology to the panel" and "establish the level of skill in the art"). Questions about how much of that context bears on the disputed issues go to weight, not admissibility.

#### **VI. PATENT OWNER'S ALTERNATIVE REQUEST UNDER F.R.E. 105 SHOULD BE DENIED**

Patent Owner's fallback, that the challenged testimony be "restricted and given no weight" under F.R.E. 105 should likewise be denied. F.R.E. 105 provides for limiting instructions to a jury regarding evidence admissible for one purpose but not another. It has no application in a bench proceeding before the PTAB and provides no basis for directing the Board to disregard admissible evidence.

The weight to be given the declarations of Dr. Mirzadeh and Mr. Hoff is committed to the Board's sound discretion as factfinder, to be exercised on the full

record after consideration of the parties' merits arguments, not preordained through a motion to exclude. *See* Trial Practice Guide at 35 (“[t]he Board has broad discretion to assign weight to be accorded expert testimony.”).

Patent Owner's invocation of F.R.E. 105 is yet another attempt to relitigate the merits in the guise of an evidentiary motion. It should be denied for the same reasons the Motion as a whole should be denied.

## **VII. CONCLUSION**

For the foregoing reasons, Petitioner respectfully requests that Patent Owner's Motion to Exclude be denied in its entirety.

Dated: July 7, 2026

Respectfully submitted,

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## CERTIFICATE OF SERVICE

The undersigned certifies pursuant to 37 C.F.R. §§ 42.6(e) that on July 7, 2026, a true and correct copy of **PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)** was served by electronic mail to the attorneys of record, at the following addresses:

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