

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

Case No. PGR2025-00040
Patent No. 12,249,437

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

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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 ”).
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1021	Excerpts of The American Heritage Dictionary of the English Language, 5 th ed. (2016).

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1023	Conroy Deposition Transcript.
1024	Conroy Deposition Exhibit 6, Excerpt of homedepot.com
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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), https://artbio.com/artbio-nucleus-radiopharma-collaboration-manufacture-gmp-grade-therapeutic-products-radioisotope-pb-212-support-emerging-clinical-trials .
1027	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), https://www.fiercepharma.com/pharma/nuclear-medicine-cdmo-nucleus-links-artbio-help-produce-prostate-cancer-radiotherapy .
1028	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), https://artbio.com/artbio-nucleus-radiopharma-collaboration-manufacture-gmp-grade-therapeutic-products-radioisotope-pb-212-support-emerging-clinical-trials .
1029	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), https://clinicaltrials.gov/study/NCT07214961
1030	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), https://artbio.com/ARTBIO-Announces-dosing-of-Two-Cohorts-with-AB001
1031	Declaration of Jennifer Librach Nall Dated May 14, 2026
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I. INTRODUCTION

PO's Opposition confirms that EX2002 should be excluded. Petitioner's Motion rests on a straightforward threshold defect: PO offers Mr. Conroy's declaration as an opinion from the perspective of a POSITA, but he lacks ordinary skill in the relevant art. PO does not dispute the most important facts. Mr. Conroy has a Bachelor of Science in Pharmacy, not a degree in chemistry, nuclear chemistry, radiochemistry, chemical engineering, physics, or materials science. EX2002, ¶2; EX2003, 5. Nor does PO allege that a Bachelor of Science in Pharmacy was a comparable field. PO instead belatedly asks the Board to stretch the POSITA definition beyond recognition—so that pharmacy coursework, product use, marketing, sales, and management experience become substitutes for *relevant* industry experience. Opp. at 3-4. That is not the law. General experience in a related field does not suffice when the patent issues require specific product-design skill, and the Federal Circuit has held that an expert must at least possess ordinary skill in the art to offer opinions from the vantage point of a POSITA. *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022). The Board should therefore exclude EX2002 under F.R.E. 702 and 37 C.F.R. § 42.64(c).

II. MR. CONROY DOES NOT MEET THE POSITA DEFINITION

A. PO Fails in its Burden to Prove Pharmacy is a Comparable Degree or that Mr. Conroy's Experience is Relevant

It is undisputed that Mr. Conroy does not have a bachelor's degree in one of the enumerated fields. Instead, PO is proffering Mr. Conroy as a POSITA as someone with a bachelor's degree in a comparable field of study. Opp. at 3 ("Mr. Conroy satisfies the educational requirements of Petitioner's definition.").

PO argues that Petitioner's POSITA definition "cast a wide net" because it refers to a "comparable field of study." Opp. at 2. As such, PO's burden was to prove that a bachelor's degree in Pharmacy is comparable. *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333, 1339 (Fed. Cir. 2025) (citing 2023 amendments to Rule 702). But PO did not do that in its briefing in this matter. And, Mr. Conroy's statement that his pharmacy degree included some courses in some of those fields does not establish that the field of **Pharmacy** is itself a comparable **field**.

PO's reliance on Petitioner's statement that "nuclear medicine" is a related field does not cure the defect in PO's failure to prove that Mr. Conroy is a POSITA. PO offers no evidence that a Pharmacy degree is in a **field** comparable to a degree in nuclear medicine, nor does PO offer evidence that experience marketing or dispensing radiopharmaceuticals is a substitute for the lack of one of the required degrees or the lack of relevant experience. And, PO fails to show that Mr. Conroy's experience supervising radiopharmacists for one year satisfies two to three years of radiopharmaceutical chemistry experience.

B. Mr. Conroy's Assertion Does Not Prove He is a POSITA

PO relies on Mr. Conroy's statement that he was "at least a person of ordinary skill in the art" and was familiar with the level of skill of a POSITA. Opp. at 7, citing EX2002, ¶30. But the admissibility inquiry is for the Board, not the witness, and PO cannot satisfy Rule 702 merely by citing the witness's assertion that he qualifies. Fed. R. Evid. 702; *EcoFactor*, 137 F.4th at 1339.

Moreover, the '437 patent concerns a highly technical method and system for producing ^{212}Pb using radioisotope generator technology, and Petitioner's Motion explained that a POSITA opining on claim construction and validity must have relevant experience with radioisotope generators, not merely marketing or use for pharmaceutical dispensing. PO's contrary reading would improperly allow adjacent commercial or clinical experience to substitute for technical ordinary skill in the art.

C. PO's Attempt to Distinguish Petitioner's Authorities Fails

PO argues that *Billerud*, *BOE*, and *Calco* are distinguishable because the POSITA definitions in those cases expressly required specific experience. Opp. at 3. But those cases support the broader principle that a witness who lacks the ordinary skill required in the relevant art cannot offer admissible POSITA testimony. They also illustrate that experience with adjacent products, commercial activity, or related fields does not substitute for ordinary skill in the specific technology at issue.

Billerud excluded testimony where the witness lacked the paperboard-manufacturing specialization required by the definition of a POSITA. *Billerud Aktiebolag (Publ) v. Westrock MWV, LLC*, IPR2023-01206, Paper 60 at 61 (P.T.A.B. Mar. 12, 2025). *BOE* excluded testimony where the witness’s work did not involve designing the LCD display itself but instead involved a product meant to work with a pre-existing LCD display. *BOE Technology Group Co., Ltd. v. Optronic Sciences LLC*, IPR2024-01130, Paper 47 at 22-23 (P.T.A.B. Jan. 26, 2026) (“Because Dr. Baker does not have the requisite experience designing LED backlights for LED displays, he is not qualified to offer expert testimony from the vantage point of a person ordinary skill in the art...”). *Calco* excluded an expert who did not have development experience, holding that drafting patent applications is not the same as developing the goods oneself. *Calco v. Ossur Ams., Inc.*, 2026 WL 939211, at *4 (C.D. Cal. Apr. 2, 2026). Those decisions are directly analogous because Mr. Conroy’s experience likewise concerns adjacent commercial, managerial, and use-based activities rather than relevant experience. PO’s attempt to distinguish *Grantley* fares no better. PO says *Grantley* involved an expert who supervised others, lacked understanding of technical details, and relied on another expert. Opp. at 7-8. But the central point of *Grantley* is that an MBA and decades of marketing experience in a related industry could not substitute for development experience in the patented technology. *Grantley Patent Holdings, Ltd. v. Clear*

Channel Commc'ns, Inc., No. 9:6-CV-259, 2008 WL 7701186, at *3 (E.D. Tex. Apr. 4, 2008) (“[the expert] does have an M.B.A. in marketing and forty years in the radio industry in marketing and as a program director. But he did not develop billing or yield management software or the like.”). Mr. Conroy’s background mirrors that defect because his professional experience is centered on marketing, business administration, management, and product use, while he conceded that he never designed or built a radioisotope generator and has never even used the type of emanation radioisotope generators that are at issue in this IPR.

III. PO’S SANCTIONS ARGUMENT IS BASELESS

PO’s request that the Board sanction Petitioner is extraordinary and unsupported. Petitioner moved to exclude EX2002 because Mr. Conroy is not a POSITA and therefore his opinions are inadmissible under Rule 702. The Motion’s alternative request that the Board assign no weight to testimony from an interested witness does not convert a threshold Rule 702 motion into an improper merits sur-reply. Moreover, PO’s sanctions theory also fails because the Motion caused no cognizable prejudice. The Board should reject that invitation and decide the Motion on the governing admissibility standard.

IV. CONCLUSION

For the foregoing reasons, and for the reasons stated in Petitioner’s Motion, the Board should exclude EX2002 as inadmissible under F.R.E. 702.

Dated: July 14, 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 14, 2026, a true and correct copy of **PETITIONER’S REPLY TO PATENT OWNER’S OPPOSITION TO MOTION TO EXCLUDE EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)** was served was served by electronic mail to the attorneys of record, at the following addresses:

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