

Case IPR2024-01312
U.S. Patent No. 11,697,028

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH,
BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG
Petitioner

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner

Case IPR2024-01312

U.S. Patent No. 11,697,028

**PETITIONER'S AUTHORIZED RESPONSE TO PATENT OWNER'S
REQUEST FOR DIRECTOR REVIEW UNDER 37 C.F.R. § 42.75**

TABLE OF CONTENTS

I.	Introduction.....	1
II.	The Board Applied the Agreed-Upon Construction of “Uniformly Illuminate”	2
III.	The Board Properly Considered Petitioner’s Rebuttal Evidence within the Scope of Reply	7
	A. The Petition Discusses the Combination of Lundahl and Larsen	7
	B. Petitioner’s Evidence was Submitted as Rebuttal Evidence in a Reply, and the Board Properly Considered This Evidence.....	8
IV.	De-Institution Is Improper, Particularly Where the Board’s Decision Is the Only Final Agency Decision and the ITC Is Reviewing the Initial Determination.....	9
	A. Patent Owner Has Unequivocally Told the ITC the Records Differ Between the ITC and PTAB.....	10
	B. The ITC ID Is Not a Proper Basis for De-Institution.....	11
	C. Patent Owner’s Arguments Based on Alleged Inconsistent Claim Constructions Are Inaccurate and Do Not Warrant De- Institution.....	13
	D. Once the Board Has Issued a FWD, De-Institution Is Improper	15
V.	Conclusion	15

TABLE OF AUTHORITIES

Page(s)

Cases

<i>Application of Swinehart</i> , 439 F.2d 210, 212-13 (Cust. Ct. 1971).....	6
<i>BASF Corp. v. Johnson Matthey Inc.</i> , 875 F.3d 1360 (Fed. Cir. 2017)	6
<i>In re Blue Buffalo Enters., Inc.</i> , No. 2024-1611, 2026 WL 100470 (Fed. Cir. Jan. 14, 2026).....	5
<i>Bradium Techs. LLC v. Iancu</i> , 923 F.3d 1032 (Fed. Cir. 2019)	8
<i>Cochlear Bone Anchored Sols. AB v. Oticon Med. AB</i> , 958 F.3d 1348 (Fed. Cir. 2020)	15
Coke Morgan Stewart, Acting Under Sec’y of Com. for Intell. Prop. & Acting Dir., U.S. Patent & Trademark Off., <i>Memorandum for Members of the Patent Trial & Appeal Bd., PTAB Consideration of Prior Findings of Fact and Conclusions of Law</i> (Sept. 16, 2025).....	1
<i>Cuozzo Speed Techs. v. Com. for Intell. Prop.</i> , 579 U.S. 261 (2016).....	11, 12
<i>In re Ethicon, Inc.</i> , 844 F.3d 1344 (Fed. Cir. 2017)	11
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	11
<i>Novartis AG v. Noven Pharms. Inc.</i> , 853 F.3d 1289 (Fed. Cir. 2017)	11
<i>In re Schreiber</i> , 128 F.3d 1473 (Fed. Cir. 1997)	5

<i>Sinclair Pharma Ltd. et al. v. Hydrafacial, LLC</i> , IPR2025-00145, Paper 41	12
<i>Standard Oil Co. v. Am. Cyanamid Co.</i> , 774 F.2d 448 (Fed. Cir. 1985)	15
<i>Streck, Inc. v. Research & Diagnostic Sys., Inc.</i> , 659 F.3d 1186 (Fed. Cir. 2011)	13
<i>Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.</i> , 774 F.3d 968 (Fed. Cir. 2014)	8
<i>Univ. of Strathclyde v. Clear-Vu Lighting LLC</i> , 17 F.4th 155 (Fed. Cir. 2021)	11
<i>Verizon Connect Inc., v. Omega Patents, LLC</i> , IPR2023-01162, Paper 35, 1	12
Statutes	
28 U.S.C. § 1295(a)(4)(A)	15
35 U.S.C. 314	15
35 U.S.C. 316(c)	15
35 U.S.C. § 318(a)	15
35 U.S.C. § 319	15

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,697,028 by Thomas Boyajian et al. entitled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis” (“’028 Patent”)
1002	File History for U.S. Patent No. 11,697,028 provided in Application No. 17/942,353
1003	Reserved
1004	U.S. Patent Publication No. 2005/0075703 by Eric Larsen entitled “Photodynamic Stimulation Device and Methods” (“Larsen”)
1005	U.S. Patent Publication No. 2004/0068305 by Vineet Bansal et al. entitled “Phototherapy System and Device” (“Bansal”)
1006	Reserved
1007	Reserved
1008	U.S. Patent No. 7,033,381 (“Lundahl ’381”)
1009	Office Action dated March 23, 2021, from file history of Application No. 17/009,871
1010	Office Action dated October 25, 2021, from file history of Application No. 16/791,004
1011	WO 99/56827 by Scott Lundahl et al. entitled “Illuminator for Photodynamic Therapy”
1012	Reserved
1013	U.S. Patent No. 11,179,574 by Thomas Boyajian et al. entitled “Method of administering 5-aminolevulinic acid (ALA) to a patient”
1014	U.S. Patent No. 6,223,071 (“Lundahl”)
1015	Declaration of Dr. Robert Grove
1016	Declaration of Dr. Michael Ehrenreich
1017	U.S. Pat. No. 5,079,262 (“Kennedy”)
1018	Complaint filed in <i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Inc.</i> , Civil Action No. 1:24-cv-11637 (D. Mass) (filed on June 25, 2024)
1019	Plaintiff’s Infringement Contentions submitted as Exhibit 4 attached to complaint filed in <i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH,</i>

	<i>Biofrontera AG, and Biofrontera Inc.</i> , Civil Action No. 1:24-cv-11637 (D. Mass) (filed on June 25, 2024)
1020	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411 (complaint filed on June 25, 2024)
1021	Agostinis et. al., <i>Photodynamic Therapy of Cancer: An Update</i> , <i>CA Cancer J Clin.</i> Author manuscript; available in PMC 2012 July 1 (also published in final edited form at <i>CA Cancer J Clin.</i> 2011 ; 61(4): 250–281)
1022	Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20% Initial U.S. Approval: 1999, Revised 3/2010
1023	Michael H. Gold, <i>Therapeutic and Aesthetic Uses of Photodynamic Therapy, Part Two of a Five-Part Series, Lasers and Light Treatments for Acne Vulgaris, Promising Therapies</i> , <i>Journal of Clinical and Aesthetic Dermatology</i> , Vol. 1(3), pp. 28-34 (September 2008)
1024	Declaration of Brian Larivee in Support of Pro Hac Vice Motion
1025	Declaration of Chad Landmon in Support of Pro Hac Vice Motion
1026	Supplemental Declaration of Dr. Robert Grove
1027	Deposition Transcript of Nan Marie Jokerst, Ph.D., taken July 22, 2025
1028	Deposition Transcript of Heather J. Roberts, M.D., FAAD, taken July 25, 2025
1029	Deposition Transcript of Thomas D. Vander Veen, Ph.D., taken July 29, 2025
1030	Complainant’s Post-Hearing Brief (Public Version) filed in <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411 ¹
1031	Trial Transcript Day 3 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411
1032	Trial Transcript Day 4 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411

1033	Trial Transcript Day 2 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411
1034	Notice of a Commission Determination to Review in Part a Final Initial Determination Finding a Violation of Section 337; Request for Written Submission on Remedy, the Public Interest, and Bonding, issued <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA1411(issued January 28, 2026)
1035	Notice of a Commission Determination to Extend the Date for Determining Whether to Review a Final Initial Determination and the Target Date for Completion of the Investigation, issued <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411(issued December 17, 2025)

I. INTRODUCTION

Patent Owner’s request for Director Review (Paper 54 or “Request”) raises issues already thoroughly considered by the Board and should be denied. First, the Final Written Decision’s (Paper 53 or “FWD”) claim construction was fully consistent with agreed-upon claim construction, and Patent Owner’s arguments to the contrary are unsupported and inconsistent with the Patent Owner’s previous statements. Second, Patent Owner’s positions on alleged post-institution arguments were considered and properly rejected by the Board, even though Patent Owner had failed to properly challenge them. In its September 2025 guidance, the Acting Director left open the possibility that the Board and the International Trade Commission (“ITC”) could reach different conclusions, provided the Board “explain[s] in the institution or final written decision why a different outcome is warranted.”¹ That is precisely what the Board did. The Acting Director’s guidance is particularly instructive here, where the ITC is reviewing² the ALJ’s Initial

¹ Coke Morgan Stewart, Acting Under Sec’y of Com. for Intell. Prop. & Acting Dir., U.S. Patent & Trademark Off., *Memorandum for Members of the Patent Trial & Appeal Bd., PTAB Consideration of Prior Findings of Fact and Conclusions of Law* (Sept. 16, 2025), (“Sept. 2025 Memorandum”)

² See EX1034, EX1035.

Determination (EX2090), leaving the Board's FWD as the only final agency decision speaking to the validity of the '028 Patent. Third, Patent Owner's brief includes inaccuracies, including an assertion that Petitioner advanced indefiniteness positions where it did not. Ultimately, the Board completed its work, and found a "strong case of obviousness," FWD, 34, with one PTAB Judge remarking during the hearing, "that I can't think of something more obvious." Paper 51 ("Tr."), 51:22-23.

II. THE BOARD APPLIED THE AGREED-UPON CONSTRUCTION OF "UNIFORMLY ILLUMINATE"

Patent Owner's assertion that the FWD applied an inconsistent claim construction for "uniformly illuminate a treatment surface"/"uniformly illuminating a treatment surface" (the "uniform illumination" or "uniformity" limitations) is a smokescreen to obscure the fact that the only final agency decision on the matter found the '028 Patent obvious. There is no inconsistency.

At the ITC, the parties agreed to construe uniform illumination to mean "irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." EX2033, 13. The application of the agreed-to construction in this IPR was acknowledged by both parties and the Board. For instance, Patent Owner urged the Board to apply the "60%" construction (Paper 14 ("POR"), 18-19), and Petitioner argued that "the combination of Lundahl and Larsen *would meet the ITC*

construction of ‘uniformly illuminate a treatment surface.’” Paper 29 (“Reply”), 6.³ During the hearing, the Board acknowledged the 60% construction as a matter of course. Tr., 18:11-20, 73:1-7 (Mr. Ha: “... uniformly illuminate had a particular construction that was agreed upon by both parties...at least within 60 percent requirement...Judge Weatherly: And why isn't Lundahl's teaching of 60 percent enough?”). Finally, the FWD explicitly stated that:

A claim construction order was issued in the related ITC proceeding...including adopting the parties' agreed-to construction of the term “uniformly illuminate/illuminating a treatment surface” (i.e., to require “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum”)...our Decision is not inconsistent with the claim constructions set forth in the ID.

FWD, 13 n. 7. Patent Owner’s three arguments to the contrary are specious at best.

First, while Patent Owner takes issue with the Board’s observation that “the recited ‘treatment area’ is unspecified, and therefore includes very small and/or flat areas of a patient’s body...” (FWD, 27), this analysis is in no way inconsistent with the claim term itself or with the agreed-to construction. As the Board correctly recognized, both the claim term (“uniformly illuminate/uniformly illuminating *a treatment surface*”) and its agreed-to construction (“the measured irradiance at *a*

³ Emphasis is always added unless noted otherwise.

treatment surface of the patient is at least within 60%...) broadly recite “a treatment surface” without further limitation. Had Patent Owner wished to narrow its claim scope, it could have recited a particular sized treatment surface in the claims or argued for a narrowing construction of “treatment surface” before the Board or at the ITC. It did not do either of these things. Patent Owner’s attempt to use the Director Review process to narrow its claim scope to preserve validity *after it secured an infringement finding* at the ITC⁴ based on that scope, should be rejected.

Further, Patent Owner’s accusation that Petitioner is “seeking broader constructions at the Board to support a patentability challenge while seeking narrower constructions in litigation to avoid infringement liability...” makes no sense. Request, 3. At the ITC, Petitioner did not dispute that its device met the uniformity limitations and therefore couldn’t possibly benefit from any supposed narrower construction in that forum. To manufacture an inconsistency, Patent Owner argues that “Biofrontera premised its non-infringement arguments at the ITC on the understanding that...all five panels are used.” Request, 2-3. This is irrelevant for two reasons. First, the non-infringement arguments Patent Owner refers to pertained to method claims of a different patent, U.S. Pat. No. 11,446,512, not the ’028 Patent at

⁴ While the full Commission is reviewing the ALJ’s Initial Determination as to the validity of the ’028 Patent, the ALJ’s infringement findings are not under review. EX1034.

issue here. EX2097, 29-31; EX2095, 99. Second, the FWD’s reference to a “single panel” does not relate to the number of illuminated panels required by the claims, as Patent Owner argues. Request, 2-3. Instead, the FWD was merely referring to it to describe the potential size of a treatment area that the claims could encompass – *i.e.*, “a small, flat treatment area covered by a single panel.” FWD, 28.

Second, Patent Owner makes too much of the Board’s finding that an illuminator “‘configured to uniformly illuminate a treatment surface’ is a functional limitation” requiring that “the combination is ‘capable of’ uniformly illuminating a treatment area.” FWD, 27. It is black letter law that “a patent application is free to recite features of an apparatus either structurally or functionally.” *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997). The Federal Circuit recently clarified that “configured to” can mean “capable of” just as the Board found here. *In re Blue Buffalo Enters., Inc.*, No. 2024-1611, 2026 WL 100470, at *1 (Fed. Cir. Jan. 14, 2026). Nor does naming a limitation “functional” impart any special broader claim scope, as Patent Owner implies. As explained in *Application of Swinehart*, which Patent Owner cites:

[T]he characterization ‘functional’...indicate[s] nothing more than the fact that an attempt is being made to define something...by what it does rather than by what it is...‘Functional’ terminology may render a claim quite broad...This is not to say, however, that every claim containing ‘functional’ terminology is broad. Indeed, in many cases it will be

obvious that only a very limited group of objects will fall within the intended category.

439 F.2d 210, 212-13 (Cust. Ct. 1971); *see also* *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1366 (Fed. Cir. 2017).

Third, far from “conflat[ing] ‘uniform’ illumination with ‘gap-free’ illumination” (Request, 5), as Patent Owner accuses, the FWD specifically recognized that “[c]ontinuous illumination does **not** mean uniform illumination.” FWD, 44. Nor did the FWD rely solely on Larsen to find that uniformity was obvious, as Patent Owner alleges. Request, 5-6. What the FWD found was that

[i]t is not in dispute that, separately, **Lundahl** is configured to provide uniform illumination (**including at the 60% measured radiance**)...[U]niform illumination is **emphasized** in both Lundahl and Larsen⁵...[A] POSITA would have used their knowledge to retain the essential, functional teachings of the references-in this case, maintaining light uniformity-while converting Lundahl's U-shaped

⁵ In finding that Larsen emphasized and disclosed a device configured to provide uniformity, the FWD cited paragraphs 151 and 154 of “Ex. 2018” and paragraph 72 of Larsen (EX1004). FWD, 27. “Ex. 2018” appears to be a typographical error, with EX2082 (Bretschneider Declaration) being intended. In paragraphs 151 and 154, Dr. Bretschneider explains how various sections of Larsen (including paragraph 72) emphasize and encourage uniformity. A simple typo does not rise to the level of “legal error and a due process violation,” as Patent Owner alleges. Request, 6-7.

fluorescent tube arrangement and accompanying structure into LEDs on adjustable panels in view of Larsen.

FWD, 27-28. Thus, rather than Patent Owner’s alleged “implicit broadening” of the claim scope (Request, 6-7), the FWD once again acknowledged the agreed-upon claim construction and found it obvious in view of the prior art.

III. THE BOARD PROPERLY CONSIDERED PETITIONER’S REBUTTAL EVIDENCE WITHIN THE SCOPE OF REPLY

A. The Petition Discusses the Combination of Lundahl and Larsen

Patent Owner’s argument that the Petition only discusses Lundahl and Larsen individually fails both factually and legally. Patent Owner’s argument fails factually because it ignores the Petition’s extensive discussion of the motivation to combine and reasonable expectation of success of the **combination** of Lundahl and Larsen. *See* Petition, 25-34. This discussion includes substituting fluorescent tubes with LEDs, for reasons including “inconsistent light output within the [fluorescent] tube itself, as acknowledged in Lundahl” and the improved practicality of using LEDs “to reduce spacing between light sources and the edges of the panels, as opposed to the bulky metal couplings at the end of fluorescent tubes, to reduce optical dead space across the light surface.” Petition, 31. Thus, not only does the Petition address the “gaps” and “uniformity” issues allegedly missing from the Petition, but it discusses these issues for the ***proposed combination*** of Lundahl and Larsen.

Patent Owner’s argument also fails legally because it is contrary to well settled Federal Circuit precedent on the capabilities of a POSITA. Applying the correct law, the Board found that a POSITA would have reasonably expected to achieve at least the same uniformity using LEDs that had already been achieved by Lundahl using fluorescent tubes. FWD, 27-28; *see Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978 (Fed. Cir. 2014) (“One of ordinary skill is also one of ‘ordinary creativity’ that knows how to combine familiar prior art elements to achieve the same functions.”). This is particularly true here, where the **combination of Lundahl and Larsen** substitutes the more predictable light output from LEDs for “output from a fluorescent tube [which is] not inherently uniform.” EX1014, 6:9-11; *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019) (cannot overcome obviousness of a combination by “attacking references individually”).

B. Petitioner’s Evidence was Submitted as Rebuttal Evidence in a Reply, and the Board Properly Considered This Evidence

Patent Owner then goes one step further by falsely alleging that the Board credits Petitioner’s Reply arguments “as if those arguments were present in the Petition itself.” Request, 9. Patent Owner bases this theory on Petitioner’s arguments supported by Dr. Grove’s Supplemental Declaration, which the Board credits as “directly refuting Dr. Jokerst’s testimony regarding gaps and uniform illumination.” FWD, 25 (citing Ex. 1026). Far from treating Petitioner’s rebuttal evidence as

though it was part of the original Petition, the Board properly considered it as directly responding to Patent Owner's mischaracterization of LED light distribution.

Patent Owner's expert Dr. Jokerst stated in a declaration *filed after institution* that "LEDs, unlike fluorescent tubes, are discrete, point source, directional illuminators with a Lambertian output characteristic." EX2050, 27-28. Yet, this same declaration cited the Ndjiongue reference, which contradicted Dr. Jokerst. EX2050, 27 (citing Ex. 2013). Petitioner properly rebutted this argument by identifying the contradictory teachings of the Ndjiongue reference, *entered into the record by Patent Owner*, to show how the Lambertian distribution for LEDs would not produce gaps on the treatment surface.

The Board considered this rebuttal evidence as "within the proper scope of reply, contrary to Patent Owner's argument otherwise." FWD, 25 (citing Patent Owner's Mot. 9). Indeed, Patent Owner's request fails to mention that the Board denied Patent Owner's Motion to Exclude Petitioner's rebuttal evidence. FWD, 50-52. As admitted by Patent Owner, "the Board is well-equipped to decipher which portions of the Reply contain new arguments." FWD, 52; Paper 44, 5.

IV. DE-INSTITUTION IS IMPROPER, PARTICULARLY WHERE THE BOARD'S DECISION IS THE ONLY FINAL AGENCY DECISION AND THE ITC IS REVIEWING THE INITIAL DETERMINATION

The Director should not de-institute the IPR in view of the ITC proceedings here, where the ALJ's initial determination of no invalidity over the prior art is under

review by the full Commission. EX1034, 3.

A. Patent Owner Has Unequivocally Told the ITC the Records Differ Between the ITC and PTAB

Patent Owner should not be rewarded for brazenly taking irreconcilable positions before the PTO and the ITC. To the ITC, Patent Owner states “[t]he PTAB reached its decision on a different evidentiary record and under a lower, different standard of proof—distinctions the PTAB repeated throughout its decision.” EX2093, 1. In so doing, Patent Owner unequivocally told the ITC that Petitioner “never submitted [Dr. Grove’s IPR Supplemental Declaration] testimony before the ITC, and thus it cannot be the basis of a decision here.” *Id.*, 16. In contrast, to the Director, Patent Owner states that “no new ‘critical’ arguments or evidence were presented in the IPR that the ALJ did not hear in the ITC proceeding” and “**The Board Substantively Considered The Same Arguments That The ALJ Considered.**” Request, 10, 12 (emphasis in original). Patent Owner’s irreconcilable presentation to two federal agencies on the same issue should be given little weight.

To the Director, the Patent Owner essentially concedes the challenged argument has not been considered when it argues that the inventor testimony is “commensurate” with the evidence proffered in the ITC by Patent Owner’s inventors. Request, 11. While the inventor testimony and the Grove Supplemental Declaration point to the same conclusion—achieving uniform illumination was

routine optimization and not inventive—the fact remains that Dr. Grove’s Supplemental Declaration report is different evidence presented in a different way.

Next, Patent Owner’s misplaced argument that the FWD and Petitioner’s arguments rely on the ’028 Patent itself regarding uniform illumination and gaps between panels is a misreading of well-settled obviousness principles, and Patent Owner’s reliance on *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 167 (Fed. Cir. 2021) is inapposite. Request, 11-12. The ’028 Patent does not provide discussion on how to space LEDs to achieve the claimed uniformity. EX1026, 9-11 (citing EX1001, 3:56-60, 6:24-37, 8:43-44); *see also* Petition, 40 (spacing provides uniformity), 48 (describing how to combine light spacing teachings of Lundahl with LED teachings of Larsen). As the FWD correctly concluded, the ’028 Patent’s lack of disclosure on how to achieve uniformity by spacing the LEDs suggests “that achieving uniformity was routine optimization within the level of ordinary skill.” FWD, 28-29; *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“finite number of identified, predictable solutions”); *In re Ethicon, Inc.*, 844 F.3d 1344, 1351 (Fed. Cir. 2017). The *Strathclyde* case is distinguishable because, in that case, the prior art did not disclose use of photosensitizer, but the challenged patent did. 17 F.4th at 164-66. The inverse is true here: the prior art Lundahl discloses the spacing to achieve the claimed uniformity but the ’028 Patent does not.

B. The ITC ID Is Not a Proper Basis for De-Institution

The Supreme Court, Federal Circuit, and the Patent Office’s own guidance leave open the possibility of different outcomes between the Patent Office and other tribunals. See *Cuozzo Speed Techs. v. Com. for Intell. Prop.*, 579 U.S. 261, 282 (2016); *Novartis AG v. Noven Pharms. Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017) (“the PTAB properly may reach a different conclusion based on the same evidence”); Sept. 2025 Memorandum. In particular, the Patent Office’s September 2025 Memorandum simply requires “a more detailed explanation” when the Board’s conclusion differs from the ITC’s conclusion. That is precisely what has happened here. The reasoning of *Cuozzo Speed* and the September 2025 Memorandum is especially compelling here, where the full ITC is reviewing the initial determination. Both *Sinclair Pharma Ltd. et al. v. Hydrafacial, LLC*, IPR2025-00145, Paper 41, and *Verizon Connect Inc., v. Omega Patents, LLC*, IPR2023-01162, Paper 35, 1, are distinguishable on the facts. Unlike *Sinclair Pharma*, the Board here issued a Final Written Decision **and, critically**, the full ITC is reviewing the ALJ’s ID, meaning the Board’s FWD here is the first and only final agency decision. See EX1034, 3. *Verizon Connect* is also distinguishable, as the Director found it involved “seven prior challenges to the patent claims” and not, as here, an ID under review by the full ITC. IPR2023-01162, Paper 40, 1.⁶ The ITC’s decision to review the ID suggests

⁶ Patent Owner quotes Paper 35, a brief from the patent owner in *Verizon*, not the Director’s decision. Paper 35 explains the patent claims had previously been

it may be infected with clear error on its legal and factual conclusions. Rather than de-institute because of an ID that may yet be reversed, the Director should let the FWD stand and allow the Federal Circuit appeal process to play out.

Finally, Patent Owner's reliance on *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186 (Fed. Cir. 2011), about live testimony are entitled to little weight, where the ALJ took all direct witness testimony in the underlying investigation by written witness statement, not live testimony. See EX2090 (ID relying on over 200 citations to written witness statements).

C. Patent Owner's Arguments Based on Alleged Inconsistent Claim Constructions Are Inaccurate and Do Not Warrant De-Institution

The only claim construction that Patent Owner has identified as bearing on the PTAB decision is "uniformly illuminate." Request, 1. Yet, as discussed in Section II *supra*, Petitioner expressly adopted the parties agreed-upon construction for "uniformly illuminate" in the IPR Petition, and the Board found the claims obvious even in light of that. See FWD, 13, FN7; *see also id.* at 26-29 (Board addressing Patent Owner's arguments on the "uniformly illuminate" limitation at length). Patent Owner's disagreement with the Board's factual findings regarding the prior art teaching of "uniformly illuminate" is not a basis for de-institution.

subject to validity challenges, including "five ex parte reexaminations; and in district court proceedings, including a jury verdict," and not an ITC ID subject to review.

Patent Owner also argues that Petitioner has taken inconsistent positions with this IPR by arguing that four limitations of the '028 Patent were indefinite in the ITC. Request, 14 (citing EX2033). However, this not true – Petitioner argued the limitation “photodynamically diagnosing or treating a patient” be given its “plain and ordinary meaning” and proposed a construction for the term “within approximately four inches of the treatment surface” to mean “less than or equal to four inches from the treatment surface.” EX2033, 25-26, 42-43. Petitioner’s constructions of these terms in the ITC is consistent with how Petitioner argued the prior art in this IPR, and Patent Owner has not suggested otherwise. *See* Petition, 35 (Lundahl discloses “photodynamic treatment (PDT) or diagnosis (PD) of ... a patient.”), 45 (“The disclosed distances of 2 inches and 4 inches of Lundahl are within approximately four inches of the treatment surface.”).

Finally, Patent Owner's argument that “de-institution is also warranted here to ensure no further expenditure of the Board’s resources” makes little sense where the Board has already invested the sources to issue the FWD. Nonetheless, with regards to the other two claim limitations that Patent Owner raised, Petitioner’s indefinite arguments are based on a theory that the limitations cover multiple different alternatives, which is not inconsistent with Petitioner’s unpatentability arguments that would render the claims obvious under these alternatives. *See* EX2033, 16, 37-38 (summarizing Petitioner’s arguments on the “higher intensity” and “five panel”).

Indeed, claims can be both indefinite and obvious in a scenario like this:

Here, even if claim 10 is indefinite, such a conclusion would not imply that it is incapable of being compared to prior art to determine if one of its alternatives is anticipated or would have been obvious on the grounds asserted.

Cochlear Bone Anchored Sols. AB v. Oticon Med. AB, 958 F.3d 1348, 1360 (Fed. Cir. 2020); *see also Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 453–55 (Fed. Cir. 1985) (patent was invalid for both indefiniteness and obviousness). That is the case here, and Patent Owner provides no analysis or argument to the contrary.

D. Once the Board Has Issued a FWD, De-Institution Is Improper

To preserve its right on appeal, if necessary, Petitioner notes that the Director does not have the power to de-institute an IPR after a final written decision. The text of the AIA does not grant that power to the Director. *See* 35 U.S.C. 314 (standard and timing of institution decision); 35 U.S.C. 316(c). Once a final written decision is issued, the final written decision provides a right to appeal. *See* 28 U.S.C. § 1295(a)(4)(A) (jurisdiction to the Federal Circuit “at the instance of a party who exercised that party’s right to participate in the applicable proceeding before or appeal to the Board”); 35 U.S.C. § 318(a); 35 U.S.C. § 319.

V. CONCLUSION

For the foregoing reasons, the Request should be denied.

Dated: April 2, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the accompanying Petitioner's Authorized Response to Director Review Request is being served via electronic mail on April 2, 2026 upon the following:

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