UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDEN PARK ILLUMINATION, INC.,
LARSON ELECTRONICS LLC, FAR UV TECHNOLOGIES
and USHIO AMERICA, INC.

Petitioners,

v.

S. EDWARD NEISTER,

Patent Owner.

Case IPR2023-00695

U.S. Patent No. 11,246,951

CORRECTED PATENT OWNER PRELIMINARY RESPONSE

LIST OF EXHIBITS

Exhibit	Description
2001	Declaration of Mark T. Hernandez, Ph.D. in support of Patent Owner Preliminary Response
2002	Ma, *et al*., "Inactivation of Coronaviruses and Phage Phi6 from Irradiation across UVC Wavelengths," Environ. Sci. Technol. Lett. 2021, 8, 5, 425-430
2003	*Far UV-C Radiation: Current State of Knowledge*
2004	https://www.binghamton.edu/news/story/3616/new-study-proves-correct-dosage-for-ultraviolet-disinfection-against-covid
2005	U.S. Patent Publ. No. 2005/073,652 (Ressler)
2006	U.S. Patent No. 5,843,374 (Sizer)
2007	Healthe, Inc. Invalidity Claim Chart_Sosnin
2008	First, et al, Guidelines for the Application of Upper-Room Ultraviolet Germicidal Irradiation for Preventing Transmission of Airborne Contagion (1999).
2009	Xu, Peng et al., "Efficacy of ultraviolet germicidal irradiation of upper-room air in inactivating airborne bacterial spores and mycobacteria in full-scale studies." *Atmospheric Environment* 37 (2003)
2010	Xu, Peng et al., "Impact of Environmental Factors on Efficacy of Upper-Room Air Ultraviolet Germicidal Irradiation for Inactivating Airborne Mycobacteria." *Environmental Science & Technology* (2005)
2011	CDC, Upper Room UVGI, https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation/UVGI.html
2012	Sosnin et al., *The Effects of UV Irradiation and Gas Plasma Treatment on Living Mammalian Cells and Bacteria: A Comparative Approach,* 32 IEEE Transactions on Plasma Sci. 1544 (2004)

2013	Complaint in *Healthe, Inc. v. High Energy Ozone LLC et al*. (M.D. Fla. No. 6:20-cv-2233-Orl-37EJK)
2014	Buonanno, M.; Welch, D.; Shuryak, I.; Brenner, D. J., Far-UVC light (222 nm) efficiently and safely inactivates airborne human coronaviruses. Sci. Rep. 2020 June 24;10(1):10285
2015	Peccia, Jordan and Hernandez, Mark, "Photoreactivation in Airborne *Mycobacterium parafortuitum*." *Applied and Environmental Microbiology* (2001)
2016	Peccia, Jordan and Hernandez, Mark, "UV-Induced Inactivation Rates for Airborne *Mycobacterium bovis* BCG." *Journal of Occupational and Environmental Hygiene* (2004)
2017	Kuiundzic, Elmira et al., "Effects of Ceiling-Mounted HEPA-UV Air Filters on Airborne Bacteria Concentrations in an Indoor Therapy Pool Building." *Journal of the Air & Waste Management Association* (2005)
2018	Kuiundzic, Elmira et al., "UV Air Cleaners and Upper-Room Air Ultraviolet Germicidal Irradiation for Controlling Airborne Bacteria and Fungal Spores" *Journal of Occupational and Environmental Hygiene* (2006)
2019	CDC Infection Control, Glossary https://www.cdc.gov/infectioncontrol/guidelines/disinfection/glossary.html
2020	Tommasi, Stella, Mikhael F. Denissenko, and Gerd P. Pfeifer, "Sunlight Induces Pyrimidine Dimers Preferentially at 5-Methylcytosine Bases." *Cancer Research* 57 (1997)
2021	Pfiefer, Gerd P., Young-Hyun You, and Ahmad Besaratinia, "Mutations induced by ultraviolet light." *Mutation Research* 571 (2005)
2022	Campuzano, P, et al. "Kinetics and Mechanism of the Reaction of the Hydroxyl Radical with h8-Isoprene and d8-Isoprene: Ioprene Absorption Cross Sections, Rate Coefficients, and the Mechanism of

	Hydroperoxyl Radical Production." *J. Phys. Chem. A* 2004, 208, 1537-1551.
2023	UV Disinfection for Water and Wastewater Treatment, *EPRI's Community Environmental Center* (1995*)*
2024	Health and Environmental Effects of Ultraviolet Radiation: A summary of Environmental Health Criteria 160 Ultraviolet Radiation (1995).
2025	Narita, K., et al. "Chronic irradiation with 222-nm UVC light induces neither DNS damage nor epidermal lesions in mouse skin, even at high doses." *PLOS One* (2018)
2026	Welch, David, Marilena Aquino de Muro, Manuela Buonanno, and David J. Brenner. 2022. "Wavelength-Dependent DNA Photodamage in a 3-D Human Skin Model over the Far-UVC and Germicidal UVC Wavelength Ranges from 215 to 255 Nm." *Photochemistry and Photobiology* 98 (5): 1167–71. https://doi.org/10.1111/php.13602
2027	National Institute for Occupational Safety and Health, "A Recommendation Standard for Occupational Exposure to Ultraviolet Radiation" (1992).
2028	EPA "What's the Difference between products that disinfect, sanitize and clean surfaces?" https://www.epa.gov/coronavirus/whats-difference-between-products-disinfect-sanitize-and-clean-surfaces
2029	CDC Infection Control, Sterilization https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html
2030	https://scholar.google.com/scholar?cites=2256663173338736309&as_sdt=5,44&sciodt=0,44&hl=en

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.107, Patent Owner, S. Edward Neister, hereby submits the following Preliminary Response to the Petition for *Inter Partes* Review ("Petition") of claims 1-5 and 7-18 ("Challenged Claims") of U.S. Patent No. 11,246,951 ("the '951 Patent"), filed by Petitioners Eden Park Illumination, Inc., Larson Electronics LLC, Far UV Technologies, Inc., and Ushio America, Inc. (collectively, "Petitioners").

The Petition should be denied in its entirety. *First*, discretionary denial under 35 U.S.C. § 325(d) is appropriate because the USPTO recently considered both the priority date issue and the primary reference relied upon by Petitioners and allowed substantially similar claims over the same arguments. The USPTO considered and allowed those claims over the asserted art here. And in a Notice of Allowance on December 24, 2021, the USPTO removed a February 11, 2004 prior art reference (Ressler) based on evidence of Mr. Neister's prior invention date. This same evidence also pre-dates an indispensable part of Petitioner's Ground 1 argument (Sosnin). Accordingly, the Board need not reconsider this prior art or this decision on prior invention date.

Second, Ground 1 fails due to a lack of motivation to combine the asserted references. The person of ordinary skill in the art (POSITA) would not have combined Eckhardt with Sosnin because the latter would contradict the very purpose

of the former, which was to *cover* skin before exposing it to UV harmful light. Petitioners simply ignore teaching away by Eckhardt—the primary reference—to avoid exposing skin to UVC light because it is harmful. The combination also fails because Sosnin states that a Xenon Bromine (XeBr) excilamp at 282 nm works best for disinfection, but Eckhardt already discloses using Xenon flashes for disinfection. The combination further fails because Sosnin deals exclusively with the disinfection of glass-ware, not skin.

Finally (and fatally), Petitioners incorrectly assert that a POSITA at the time of the invention would have understood that it was "relatively safer" to use the claimed 222 nm wavelength than 254 nm wavelength—which Petitioners' own expert recognizes was known to be harmful to skin—at low doses. Even this relative comparison is wrong. Ex. 2001 at ¶ 66. Well-respected scientists (including those working for and with the Petitioners) are publishing peer-reviewed papers even today because they do not fully understand how or why 222 nm disinfects skin without also causing it damage. This evidence shows the claimed method could not have been obvious *twenty years ago*.

II. BACKGROUND

A. The '951 Patent

Mr. S. Edward Neister is the inventor of the '951 Patent. The '951 Patent discloses and claims a new ultra-violet (NUV) source of light for "disinfecting and

sterilizing all types of surfaces contaminated with microorganisms and toxic substances to render both inactive." Ex. 1001 at Abstract. The preferred embodiment of the invention "emits a highly intense narrow wavelength band of photons that correspond to the maximum absorption band for DNA proteins and other component bonds," and more specifically at 222 nm. *Id*. at 2:64-3:2.

The inventor reported "[u]sing a lamp that emits 222 nm, a comparison test with and without water was made to determine the effect of this radiation on organisms." *Id*. at 4:66-5:6. "Three wavelengths were tested: 222, 253, 259 nm." *Id*. at 7. The test results indicated that 222 nm light was, as compared to the other tested wavelengths, "very effective in causing mutations and destruction in microorganisms." *Id*. at 5:24-26.

The present invention can be used to disinfect air, liquids, and a large number of surfaces and other substances. *See generally, id*. at 8:4-11:25. Though the inventor specifically disclosed how 222 nm light was effective in disabling viruses (*see id*. at 4:66-5:35 regarding the MS-2 virus), experts in the field still express surprise and praise over this discovery as recently as last year. *See, e.g*., Ex. 2002, Ma, *et al*., "Inactivation of Coronaviruses and Phage Phi6 from Irradiation across UVC Wavelengths," Environ. Sci. Technol. Lett. 2021, 8, 5, 425-430 (hereinafter, the "Ma Article"). The Ma Article reports:

> *Little is known about UVC action on enveloped viruses across UVC wavelengths*. In this study, we determined inactivation efficiencies … using five commonly available UVC devices that uniquely emit light at different wavelengths spanning 222 nm emitting krypton chloride (KrCl) excimers to 282 nm emitting UVC LEDs. Our results show that enveloped viruses can be effectively inactivated using UVC devices, among which the KrCl excimer had the best disinfection performance.

Id.[1]

It is also important to note that that because 222 nm wavelengths "are not damaging to the epidermis, [they] can quickly and effectively disinfect human or animal skin without skin cell damage." Ex. 1001 at 8:37-39. Not only does this permit use of the claimed invention in skin and/or wound disinfection (*see id*. at 8:56-9:22), it also allows continuous use of the claimed invention in spaces occupied by humans. This particular discovery—made by the inventor over two decades ago—is also still a source of recent surprise and praise by experts in the field. *See, e.g.*, *Far UV-C Radiation: Current State of Knowledge* (hereinafter, "IUVA Article")

[1] All emphasis added unless otherwise noted.

(attached hereto as Ex. 2003).[2] This study was published by the IUVA Task Force on Far UV-C Radiation for Disinfection of Air and Surfaces comprising some of the leading experts in this field, including notable members from the real parties in interest of this proceeding.[3] They report that "[m]ultiple recent studies of health effects from Far UV-C exposures of the eye and skin indicate that the wavelengths below about 230 nm are substantially safer than longer UV-C wavelengths … including for whole-room exposure in occupied settings." *Id.* (citing various studies between 2013 and 2021).

Still others in the field remain highly skeptical that 222 nm light can be safely used on humans, reporting that "[w]avelengths below 260 nanometers can be deployed only in unoccupied spaces because they can damage human skin and eyes."

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[2] https://iuva.org/resources/covid-19/Far%20UV-C%20Radiation-%20Current%20State-of%20Knowledge.pdf.

[3] Holder Claus is the Vice President of Technology at Ushio America Inc., Sung-Jin Park is the Chief Technology Officer and co-founder of Eden Park Illumination, Inc., Patrick J (PJ) Piper is the Founder and CEO of Far UV Technologies, and Karl Linden served as the expert witness for Healthe, Inc. *See* Ex. 2003, IUVA Article at 29-30.

See Ex. 2004.[4] Thus, the state of the art today cuts sharply against Petitioners' and its expert's unsupported assertions that it would have been obvious and known to safely use 222 nm UV light for disinfection of skin twenty years ago.

B. Relevant Prosecution History

1. '642 Patent (Parent)

Mr. Neister filed U.S. Patent Application No. 14/254,957 on April 17, 2014. In relevant part, the examiner rejected pending claim 16 (issued claim 1) over Ressler (U.S. Patent Publ. No. 2005/073,652), attached hereto as Ex. 2005, and Sizer (U.S. Patent No. 5,843,374), attached hereto as Ex. 2006. *See* Ex. 1002 at 130-31. Mr. Neister amended claim 16 to add the "wherein the surface to be disinfected is human or animal skin" to overcome these rejections. *Id.* at 159.

2. '951 Patent (Child)

Mr. Neister filed U.S. Patent Application No. 17/280,480 on July 10, 2017 as a continuation of the '642 Patent. Mr. Neister filed a terminal disclaimer over the '642 Patent, which was accepted. Ex. 1038 at 371. During prosecution, Mr. Neister overcame prior art rejections based upon Eckhardt (Ex. 1004). *See* Ex. 1038 at 295. On March 22, 2021, the examiner issued a Notice of Allowance and Mr. Neister paid

[4] https://www.binghamton.edu/news/story/3616/new-study-proves-correct-dosage-for-ultraviolet-disinfection-against-covid.

the issue fee. *Id.* at 154. But at the same time, Mr. Neister and his company were in patent litigation with a third party, Healthe, Inc. ("Healthe").[5] On March 29, 2021, Healthe served more than 100 pages of invalidity contentions plus 20 claim charts against the '642 Patent, relying upon more than 200 obviousness combinations.

Out of an abundance of caution, on April 12, 2021, Mr. Neister withdrew the issue fee, filed an IDS, and petitioned to file a Request for Continued Examination (RCE) for the USPTO to consider this extensive set of prior art and invalidity arguments by Healthe. Ex. 1002 at 113. These invalidity contentions contained invalidity charts based upon Sosnin IEEE (Ex. 1037), among many others. *See* Ex. 1038 at 117, 119. This claim chart, which was submitted with Mr. Neister's April 12, 2021 IDS, is attached hereto as Ex. 2007 (Sosnin IEEE). After considering this dearth of materials, the examiner again rejected the claims based upon Ressler. *Id.* at 89.

On September 8, 2021, Mr. Neister filed a Rule 1.131 Declaration to swear behind Ressler, dated February 11, 2004. *Id.* at 66-76. Attached to his Declaration, Mr. Neister relied upon business documents describing testing of his 222 nm UV

[5] *See Healthe, Inc. v. High Energy Ozone LLC d/b/a Far-UV Sterilray, et al.*, No. 6:20-cv-0223 (M.D. Fla. filed Dec. 2020) (presently stayed for bankruptcy proceedings by Healthe).

lamp by the University of New Hampshire, a page from his lab notebook describing an experiment Mr. Neister performed on his own hand using a 222 nm UV lamp for purposes of the claimed method to disinfect skin, and photographs of the devices used to carry out the method. *Id.*

On December 24, 2021, the examiner allowed the claims based upon this Rule 1.131 Declaration, agreeing that conception and reduction to practice of Mr. Neister's inventions was before February 11, 2004 by Ressler. *Id.* at 13.

C. Prior Art Relied Upon by Petitioners

1. Eckhardt (Ex. 1004)

Eckhardt is a published patent application, not a peer-reviewed journal article. It neither contains data nor statistical analyses, nor does it describe how any light source disclosed in it would perform "disinfection" or "sterilization" of human skin. A POSITA would recognize its misuse of the term "sterilization" given the lack of data and would not view its disclosure as realistic or describing a practical application of UV light. Ex. 2001 at ¶ 30.

Eckhardt dealt with controlling the amount of UV light exposure to the skin and only suggests the use of otherwise damaging UV light, because the skin is wounded and is a risk of acute, local infection. Reconstructing the perspective of a POSITA, the purpose of Eckhardt—then and now—was to minimize (further) harm to the skin by inactivating bacteria at the immediate site of a defined wound. A

POSITA would not look to Eckhardt to determine how to safely use specific wavelengths of UV light on otherwise uncompromised skin. Ex. 2001 at ¶ 31.

Using source controls and materials (bandages) to attenuate UV incident on skin, Eckhardt seeks to minimize UV dose to afflicted areas (compromised skin). A POSITA recognizes Eckhardt's primary point: reduce UV skin exposure to the minimum possible because of the potential for acute harmful effects that are associated with conventional UV exposures (not 222 nm). A POSITA would not review Eckhardt's minimizing approach and respond by seeking the exact opposite of this invention: leverage unprotected UV exposures for safer use of specific UV light wavelengths on otherwise uncompromised skin. Ex. 2001 at ¶ 32.

Eckhardt states that "the light source 7 may be *any light source* that emits light capable of sterilization or disinfection." *See* Ex. 1004 at ¶ 31.[6] Eckhardt then provides generic descriptions of possible UV light sources that span the breadth of the UVC and into the UVB spectrum without specifying wavelengths or bandwidths. *Id.* Specifically, it lists: "a mercury vapor lamp, a xenon flash lamp, a continuous arc lamp, UV light emitting diodes (LEDs), a UV laser, or any other solid state or non-solid state UV light-emitting device." *Id.* Other than the first two in the list—a mercury vapor lamp and a xenon flash lamp—the POSITA reading this list of UV

[6] Emphasis added unless otherwise noted.

light sources would not have known anything about whether she could use any specific wavelength (including 222 nm) to disinfect or "sanitize" skin, and to the extent Petitioners and Mr. Lawal state otherwise, they are incorrect. Ex. 2001 at ¶ 33.

Eckhardt describes two embodiments in detail, neither of which reference or use 222 nm light. The first embodiment is an "instantaneous sterilization or disinfection" unit (16a) having a "xenon flash bulb" light source (7a). Ex. 1004 at ¶¶ 37-48. Eckhardt further states that the xenon flash bulb has wavelengths between 220 and 310 nm. *Id.* at ¶ 70. Eckhardt specifically describes the practice of using rapid, transient UV exposures of such short durations, characterized as "pulses" or "flashes," and the "energy of a single flash may be sufficient to deliver a sterilizing or disinfecting dosage, *e.g.*, greater than 10 mJ/cm^2 of UVC." *See id.* at ¶ 32. The only other energy intensity disclosed for the xenon flash lamp embodiment in Eckhardt is "about 20 mJ/cm^2." *See id.* at ¶¶ 43, 104. The POSITA would have understood that higher doses of radiation were not desirable because of harmful exposure. Ex. 2001 at ¶ 34.

A POSITA would not believe that the "instantaneous sterilization or disinfection unit" could be used with a 222 nm light source instead of its xenon flash lamp. A 222 nm light source, namely the Krypton-Chloride (KrCl) lamp, was quite rare and expensive, so the POSITA would not have thought to use it. Moreover,

even today, 222 nm light sources are not designed to deliver these energy levels (*i.e.*, greater than 10 Joules or even 20 Joules), nor are they configured to be used in pulses or flashes. Ex. 2001 at ¶ 35.

Eckhardt describes a second embodiment, a "continuous process sterilization or disinfection" unit (16b) having a "mercury gas lamp" light source (7b). *Id.* at ¶¶ 49-61. Eckhardt states that a "continuous light source 7b may be a standard germicidal mercury vapor lamp … that produces most of [its] energy at a wavelength of approximately 253.7 nm." *Id.* at ¶ 55. Eckhardt states that "if the intensity of the UV light at skin 3 is low enough, continuous light source 7b may be illuminated for long periods of time (e.g., hours or days) without damage to skin 3." *Id.* at ¶ 56. But Eckhardt recognizes that "[c]ommonly available mercury lamps typically produce an intensity incompatible with continuous operation, unless the light level is attenuated with an optical filter or the electrical drive to continuous light source 7b is controlled to reduce the intensity of the emitted light. A reduction in the intensity of the light output may be accomplished by turning continuous light source 7b alternatively on and off." *Id.* Ex. 2001 at ¶ 36.

Eckhardt also includes one sentence in a section titled, "UV-Transmissive Bandage" referring to using UV light on "bare skin": "The sterilization/disinfection units previously described are also designed to have a beneficial effect when used on *bare skin*, and they may be used with traditional bandages if the bandage is

temporarily removed for the exposure to sunlight." *See id.* at ¶ 69; Fig. 1. Petitioners and Mr. Lawal rely upon this single sentence to show that Eckhardt teaches the use of UV light on bare skin, but this is a misreading of Eckhardt. This sentence refers back to the two embodiments described above—the instantaneous disinfection unit with a xenon flash lamp, and the continuous disinfection unit with a 254 nm mercury lamp. Ex. 2001 at ¶ 37.

A POSITA would recognize that the overwhelming peer-reviewed literature consensus at the time was to avoid direct UV-C skin and eye exposures, which would apply to each of the xenon flash bulb and mercury lamp light sources employed by Eckhardt. *See, e.g.*, *id.* at ¶ 5 ("Common wisdom and practice has encouraged the non-exposure of skin to ultraviolet radiation."); *see also* Ex. 1012 (Health Physics Society) (recommendations to "avoid the use of tanning beds or sun lamps" and "protect yourself from the sun" to reduce risk of skin cancer); Ex. 2008, First et al, 1999; Ex. 2009, Xu et al 2003; Ex. 2010, Xu et al 2005. This consensus would persist for the balance of the decade. Ex. 2011 (CDC, Upper Room UVGI, https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation/UVGI.html). A POSITA—consistent with the caution expressed in Eckhardt—would recognize that to shine xenon flash bulb or mercury lamp light sources directly on living tissue, even in a limited capacity, was a special consideration even for wounded skin. Ex. 2001 at ¶ 38.

2. Sosnin (Ex. 1005)

Sosnin is entitled, "New bactericidal UV light sources: excilamps," published May 3, 2004 in Proceedings of SPIE ("Sosnin"). "Comparison of capacitive discharge excilamp characteristics with other conventional UV light sources is presented." Ex. 1005 at 317 (Abstract). The paper does not test UV radiation on skin; rather it tests the "sterilization of glass-ware." *Id.* (Introduction). Ex. 2001 at ¶ 39.

Sosnin tested effectiveness of three lamps, KrCl (λ = 222 nm), XeCl (λ = 308 nm), and XeBr (λ = 282 nm). *Id.* at 319 (2.1 UV lighting sources). The tests were carried out on two kinds of bacterial cultures, *E. coli* and S*taphylococcus aureus*, grown on beef-extract agar. *Id.* at 319 (2.2 Bacterial cultures). Ex. 2001 at ¶ 40.

The results of the study show that each of the UV light sources inactivated the test bacteria, with the results of the E. coli study shown below (Fig. 3, page 320):

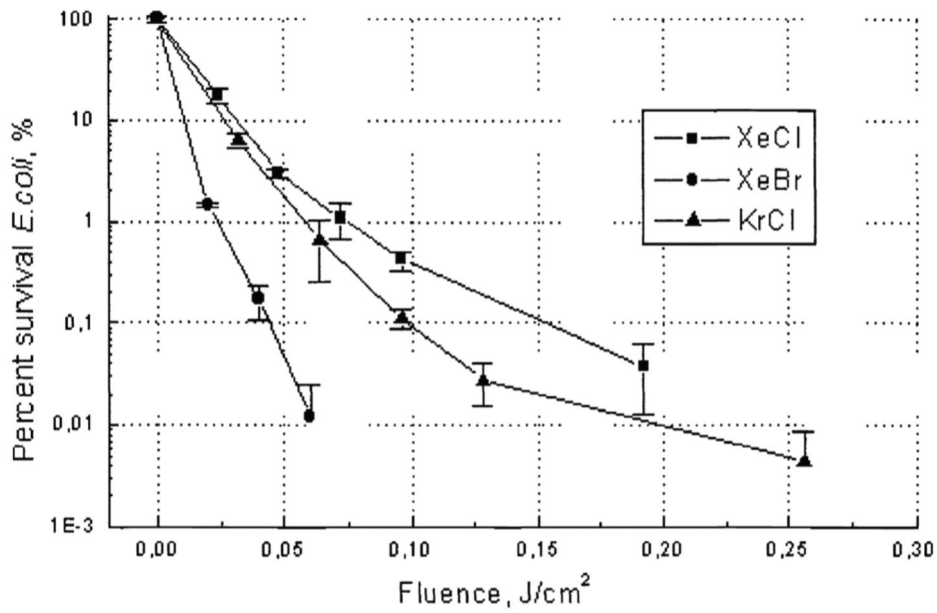

Fig. 3. Inactivation of surface-inoculated *Esch. coli* using different fluences and excilamps under primary irradiation.

The authors report that "all the excilamps can provide pronounced bactericidal effect on testing cultures both to primary and secondary UV-irradiation." Ex. 1005 at 319 (Results). Ex. 2001 at ¶¶ 41-42.

Sosnin is explicit, including in Fig. 3, that the XeBr lamp was most effective. The authors report that irradiation 99.9% of *E. coli* took 8 seconds for the KrCl lamp, while it only took 6 seconds for the XeBr lamp. *Id.* at 320. The authors report that the "best results can be obtained using XeBr-excilamp under primary as well as secondary radiation (Fig. 3)." *Id.* And "this lamp [XeBr] has the best characteristics in respect to power expenses for producing of bactericide radiation." *Id.* at 321. Ex. 2001 at ¶ 43.

III. THE PERSON OF ORDINARY SKILL IN THE ART

For purposes of deciding whether to institute this Petition, Mr. Neister does not disagree with the qualifications of a person of ordinary skill in the art (POSITA) set forth by Petitioners. *See* Pet. at Section III.D.; Ex. 2001 at ¶ 10.

IV. THE CHALLENGED CLAIMS FIND WRITTEN DESCRIPTION SUPPORT IN THE PRIORITY APPLICATIONS.

The ’951 Patent claims priority to (i) U.S. Provisional Application No. 60/593,626 filed January 31, 2005, (ii) International Application No. PCT/US2006/003393 filed January 31, 2006, and (iii) U.S. Application No. 11/831,667 filed July 31, 2007. The challenged claims find written description for priority purposes in each disclosure. Ex. 2001 at ¶¶ 24-29.

Petitioner incorrectly asserts, however, that Mr. Neister may not rely upon the applications to which he properly claimed priority. Indeed, the Federal Circuit set forth the requirements that must be satisfied for an applicant to claim priority to a provisional application. *See New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). These include the following:

- The two applications must share at least one common inventor;
- The written description of the provisional must adequately support the claims of the non-provisional application;

- It must have at least one drawing, but need not contain any claims; and
- It must contain a specific reference to the provisional application.

Id. The purpose of the written description requirement is to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991). Here, the prior applications meet these requirements for each of the Challenged Claims.

Petitioners argue that the Provisional Application does not disclose the challenged claims "wherein the substance or surface to be disinfected is human or animal tissue." Pet. at 4. The provisional application meets each of the requirements to properly claim priority. *See New Railhead Mfg.*, 298 F.3d at 1294.

Specifically, regarding written description, Petitioners ignore the many disclosures throughout the provisional relating to the use of 222 nm wavelengths in the presence of humans, *i.e.*, for use on human or animal skin. Ex. 2001 at ¶¶ 25-29. These passages demonstrate that Mr. Neister possessed the claimed invention as of its filing date (indeed, much earlier). *Vas Cath*, 935 F.2d at 1563–64. For example, paragraph 28 in its entirety is directed to this very use:

> This makes for a cost effective method for sterilizing air, clothing, surfaces and food *during normal daily activity, preventing the previous*

> *need to restrict occupation and use of areas that are being treated*. Furthermore, the apparatus is capable of effectively and efficiently decontaminating floors, hand rails, clothing and objects that are in constant contact with transient populations for the purpose of preventing transmission of disease and toxic substances that can cause injury or illness to these populations.

Ex. 1008 at ¶ 0028.

Moreover, the provisional contains many other references to use of the claimed invention in or around people in occupied space including "surgical operation zones … in a hospital operating room" (¶¶ 001, 30, 38); "surgical operation zones … on the battle field" (¶¶ 001, 30); in and around the preparation of food, including the persons that handle, prepare, or cook the food (¶¶ 004, 31, 43); generally for making air hospitable for humans and animals to breath (¶ 029), and for use in "protected zones" on a "cruise ship, airplane, or high rise building with thousands of inhabitants" (¶ 030); *see also id.* at claims 11-12.

In sum, the provisional application provides a basis for Mr. Neister's claim of priority. As a result, Sosnin (with a publication date of May 2004) is not, as Petitioners claim, prior art under 35 U.S.C. 102(b).

V. THE BOARD SHOULD EXERCISE ITS DISCRETION AND DENY INSTITUTION PURSUANT TO 35 U.S.C. § 325(d).

Good reasons exist for the Board to exercise its discretion and deny institution of this Petition pursuant to 35 U.S.C. § 325(d). "In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d).

In *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GMBH*, the PTAB established the following "two-part framework" for evaluating whether to exercise discretion under Section 325(d):

> 1. whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
>
> 2. if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential) ("*Advanced Bionics*"). Here, both of the *Advanced Bionics* factors weigh in favor of discretionary denial.

First, the Examiner considered substantially the same art during examination—including the Patent that ultimately issued from Eckhardt and a publication from Sosnin describing the same 222 nm excimer lamp Petitioners rely upon here. Petitioners' arguments are substantially the same as those before the Examiner when she was considering this art.

Second, the Examiner made no material error. Examiner correctly found that the '951 Patent claimed priority to the '626 Application. *See supra* Section IV. Petitioners have likewise failed to show that the Examiner erred by declining to find that Eckhardt and Sosnin—or any other combination of human treatment with a 222 nm light—was obvious from the prior art. *See infra*, Section VI. Petitioners' arguments are substantially similar to those considered by the Examiner.

Both Eckhardt and Sosnin were considered in depth by the Examiner. Eckhardt was relied upon by the Examiner to initially reject the claims as obvious before that objection was overcome. Likewise, even after the initial allowance of the application, Mr. Neister submitted a detailed invalidity chart related to Sosnin. The Examiner considered and allowed the application over both of these references.

A. The Examiner considered and discussed Eckhardt in detail.

The Examiner examined the disclosure of Eckhardt in detail. She understood and explained that:

> Eckhardt ('113) ***discloses a process for disinfection of a substance or surface by destroying a DNA or RNA*** (see entire document, particularly Col. 3 lines 13-41) comprising: activating a lamp (7a, 7b) positioned within a wand (16a, 16b) (see entire document, particularly Figures 1-2, 5B, 6B); and positioning the wand (16a; 16b) and ***directing photons to a substance or surface to be disinfected being human or animal tissue*** (3, 5) in the form of a wound (1) (see entire document, particularly Figures 1-3, 5A-5B, 6B, 7A, 7C, 12-14A, and 14C, Col. 3 lines 35-36, Col. 4 lines 26-39), ***in order to sterilize/disinfect human tissue*** (see entire document, particularly Col. 3 lines 12-36).

This discussion by the Examiner tracks closely with the arguments Petitioners make here. Indeed, the Examiner, like Petitioners, asserted that Eckhardt discloses every limitation of Claim 1 of the '951 Patent except the generation of 222 nm light.

Petitioners likewise acknowledge that this limitation is not explicitly disclosed in Eckhardt and rely upon Sosnin to fill this gap: "In combination, Eckhardt's method of disinfecting human tissue, including bare skin and wounds, using 'any light source that emits light capable of sterilization or disinfection' is performed using the KrCl excimer light source of Sosnin, which generate photons having a wavelength of 222 nm." Pet. at 21 (citations omitted). Petitioners offer no new

argument about what Eckhardt discloses that was not already discussed by the Examiner.

Petitioners argue that Eckhardt was considered only for certain dependent claims. However, Petitioners ignore the fact that Mr. Neister overcame this combination by citing deficiencies as to the limitations of independent claim, not the dependent claims: "Eckhardt does not teach the claim limitations of claim 1 that are missing from Coogan." Ex. 1002 at 261. The Examiner apparently credited this argument because Eckhardt was thereafter removed as a ground for rejection. *See* Ex. 1002 at 188-196.

Whether Eckhardt is considered as Section 102(b) art or Section 102(e) art is irrelevant. There is no indication in the record that the Examiner disregarded Eckhardt based upon a priority issue. Mr. Neister overcame Examiner's objection in view of Coogan and Eckhardt by arguing that neither disclosed a 222 nm lamp. Ex. 1002 at 261. This occurred well before Mr. Neister filed his Rule 1.131 declaration.

B. The Examiner was provided a detailed analysis of Sosnin, which she rejected.

Petitioners likewise ignore the fact that, although the Sosnin publication upon which they rely was only cited once during prosecution, a substantially similar publication from Sosnin, et al. ("Sosnin IEEE"), was cited *and extensively detailed* during prosecution. Ex 2012. Indeed, Petitioners relied upon Sosnin IEEE in its prior

IPR proceeding challenging U.S. Patent No. 9,700,642, which is a parent of the ’951 Patent. *See* IPR2022-00381, Paper 1. Mr. Neister explained to the Board in that proceeding that Sosnin IEEE was extensively considered by the Examiner during the prosecution of the ’951 Patent. *See Eden Park Illumination, Inc., et al. v. S. Edward Neister,* IPR2022-00381, Paper 9 at 20-27; *cf. Navistar, Inc. v. Fatigue Fracture Tech., LLC*, IPR2018-00853, Paper 13 at 17 (P.T.A.B. Sept. 12, 2018).

Petitioners appear to have switched horses in an attempt to avoid this argument. However, their arguments regarding what elements are disclosed by Sosnin, and why a POSITA would be motivated to combine them with Eckhardt, are identical. In each Petition, Petitioners argue that Sosnin/Sosnin IEEE teach germicidal excimer lamps that emit narrow band wavelengths and teach using these lamps to disinfect skin. In each Petition, they argue that the lamps disclosed in Sosnin/Sosnin IEEE fall within the disclosed range of wavelengths in Eckhardt. In each Petition, they argue that 222 nm was known to be safe and effective. These arguments as applied to Sosnin IEEE are substantially similar—indeed *identical*—to the considerations the Examiner would have given to Sosnin. Petitioners attempt to change horses, but not arguments, should be afforded no weight.

While the ’951 Patent was still under examination, Mr. Neister was sued by Healthe, Inc. (“Healthe”) seeking a declaration that Healthe did not infringe several of Mr. Neister’s patents, including the ’642 Patent. Ex. 2013 at ¶¶ 98-113. On March

22, 2021, the Examiner initially issued a Notice of Allowance, and Mr. Neister paid the issue fee. One week later, Healthe served more than 100 pages of invalidity contentions plus 20 claim charts against the '642 Patent, relying upon more than 200 obviousness combinations.

Out of an abundance of caution, on April 12, 2021, Mr. Neister withdrew the issue fee, filed an IDS, and petitioned to file a Request for Continued Examination (RCE) for the USPTO to consider this extensive set of prior art and invalidity arguments by Healthe. Ex. 1002 at 113. These invalidity contentions included detailed invalidity charts for Sosnin IEEE. *See* Ex. 2007.

The Examiner considered the detailed claim charts prepared by Healthe. Indeed, she relied upon one of these charted references, Ressler, in her subsequent rejection of the claims. Ex. 1002 at 188-191; *see also id.* at 103, 105 (showing Mr. Neister attached charts related to Ressler to his IDS). That she credited Ressler but not Sosnin IEEE indicates that the Examiner considered Healthe's detailed analysis and rejected it.

As Petitioners tell it, the combination of Coogan and Eckhardt was rejected because Coogan did not disclose a 222 nm wavelength. Petition at 51 (citing Ex. 1002 at 255-265). However, if all the Examiner needed to reject the claims on obviousness grounds was a disclosure of a 222 nm wavelength lamp, Mr. Neister

prepared that disclosure on a silver platter. *See* Ex. 2007 at 3-5 (showing the disclosure of a 222 nm KrCl lamp in Sosnin IEEE).

Eckhardt and Sosnin IEEE were far more than mere cited references. The Examiner had everything she needed to find a combination of Eckhardt and Sosnin IEEE. That she did not indicates that she understood, as explained above, that a POSITA would not be motivated to combine Eckhardt and Sosnin/Sosnin IEEE to achieve the claimed invention.

C. The Examiner made no material error.

1. The Examiner correctly concluded that the invention was entitled to the priority date of the '626 Application.

The Examiner made no material error in examining Eckhardt and Sosnin. The Examiner concluded that "the priority goes back to the provisional appl. no. 60/593,626 filed 1/31/2005." Ex. 1002 at 13. This is a clear and unambiguous statement of the Examiner's conclusions regarding priority. And as explained above, this conclusion is correct. Examiner's statement regarding when "priority goes back to" can be interpreted as nothing other than a priority analysis. While priority must be analyzed on a claim-by-claim basis, nothing requires that the Examiner write out a detailed explanation for her analysis for each claim individually.

Even if the '951 Patent is not entitled to a January 2005 priority date (it is), Petitioners have made no showing that this error is material. There is nothing in the

record that indicates the Examiner rejected either Sosnin or Eckhardt as prior art based upon priority dates. Rather, as explained below, it is clear that the Examiner rejected Sosnin and Eckhardt, among many other references, because a POSITA would not have combined these references "to direct photons of a wavelength 222 nm … to human or animal tissue." Ex. 1002 at 160. This conclusion is correct. *See infra* Section VI.B.

2. Petitioners fail to show any deficiency in the Rule 1.131 Declaration.

Because the Examiner correctly concluded that the '626 Application provided support for the '951 Patent, Petitioner's arguments regarding supposed deficiencies in Mr. Neister's Rule 1.131 declaration are irrelevant. Moreover, there is no indication that the Examiner relied on priority to reject either Eckhardt or Sosnin IEEE as prior art references. Mr. Neister overcame a rejection based upon Eckhardt and the Examiner declined to rely on the invalidity chart of Sosnin IEEE *before* Mr. Neister ever filed his Rule 1.131 declaration. The Examiner's November 17, 2020 Office Action withdrew Eckhardt as a ground for rejection. Ex. 1002 at 190. The Examiner's June 10, 2021 Office Action did not use the previously filed invalidity chart of Sosnin IEEE (included in the April 12, 2021 IDS), instead relying on Ressler, which was also charted. *Id.* at 88. Mr. Neister did not file his Rule 1.131 Declaration until September 8, 2021, well after the Examiner had considered both

Eckhardt and Sosnin IEEE and determined they were not invalidating prior art. *Id.* at 66.

Nonetheless, the Rule 1.131 declaration shows that Mr. Neister tested the invention on his own hand in doses sufficient to disinfect his hand, with successful results—his skin was unharmed. Ex. 1002 at 66-76. Mr. Neister's declaration and supporting documentation show that he diligently reduced his invention to practice.

3. Petitioners fail to show that a POSITA would have combined Sizer with Eckhardt or any other reference.

Petitioners fault the Examiner for concluding that Sizer "does not specifically teach or suggest that the substance or surface to be disinfected is human or animal tissue," while ignoring references like Eckhardt that teach this limitation. Petition at 60 (citing Ex. 1002 at 159-60). However, Examiner did not ignore such references. In the same portion of her analysis, she acknowledged that other references, such as Wilkinson and Cumbie, teach "irradiating human tissue with UV radiation in the UV-C wavelength range" but do not "teach use of 222 nm to generate photons that will destroy a plurality of chemical bonds within proteins, DNA, or RNA of microorganisms." Ex. 1002 at 160. Examiner's conclusion in light of this discussion is clear—a POSITA would not be motivated to combine these references to arrive at the claimed invention:

> it would not have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to direct photons of a wavelength 222 nm corresponding to a peak absorption wavelength of proteins, or DNA, or RNA of microorganisms to human or animal tissue in a process for destroying a DNA or RNA comprising steps as set forth in the claims.

Id. Petitioners do nothing to demonstrate that this conclusion is wrong. In particular, Petitioners do nothing to show that a POSITA would have been motivated to combine Sizer and Eckhardt. Indeed, Petitioners seem to understand that the claimed invention would ***not*** be obvious in view of this combination because they do not on rely on this combination as a ground here.

VI. THE PETITION FAILED TO ESTABLISH OBVIOUSNESS OF ANY CHALLENGED CLAIM.

A. Petitioner Did Not Establish a Prima Facie Case of Obviousness with Eckhardt in View of Sosnin.

Petitioner's obviousness analysis of the Ground 1 references is the *sine qua non* of improper hindsight. It is undisputed that Eckhardt does not teach, disclose or suggest using 222 nm for any purpose, much less "wherein the substance or surface to be disinfected is human or animal tissue." Petitioners admit this fact. *See* Petition at 19 (noting Eckhardt "does not explicitly state generating photons of 222 nm"). Instead, Eckhardt teaches the use of two specific types of light sources: (i) a mercury

vapor lamp (254 nm) and (ii) a xenon flash lamp (from between 220-310 nm). Ex. 1004 at [0043], [0055]; *see also* Ex. 2001 at ¶¶ 34, 36.

What's more, Eckhardt teaches the very opposite of the claimed invention. While the claimed invention covers a method for *directing* photons of 222 nm to a substance or surface to be disinfected, Eckhardt teaches methods of *preventing* UV light of knowingly harmful 254 nm and other wavelengths from reaching the skin by applying a bandage, using a light filter, or reducing the dose—either by reducing the intensity of the light or reducing the exposure time. Ex. 2001 at ¶¶ 31-32, 46-47.

Petitioners' attempt to combine Eckhardt with Sosnin fails for two primary reasons, and ultimately relies upon nothing but hindsight. First, Sosnin does not teach disinfection of "human or animal tissue." Sosnin instead is concerned with "*glass-ware*." Ex. 1005 at 2. Second, Sosnin is explicit that "[t]he best results have been obtained during *XeBr* excilamp irradiation." *Id*. XeBr is 282nm, not 222 nm. And Eckhardt already discloses 282 nm as an embodiment. This combination is the essence of trying to fit a square peg in a round hole. Ex. 2001 at ¶¶ 51-52.

Worse still, Petitioners are flat wrong in relying upon occupational safety guidelines as a motivator for the POSITA to use 222 nm light. If anything, those guidelines operated as a clear warning to stay away from 222 nm light as dangerous and requiring eye and skin protection, even for the workers being exposed to the

levels described in the guidelines. Ex. 2001 at ¶¶ 67-68. Petitioners' expert, Mr. Lawal argues only in relative terms: that the POSITA would have known it was ***relatively safer*** to use 222 nm than 254 nm, but that premise is flawed, dangerous, and belied by both published literature at the time. *Id.* at ¶¶ 55-66. In fact, researchers and regulators even today—twenty years later—still debate the safety of 222 nm on skin. *Id.* at Section VII.D.

As described below, the POSITA would have neither the motivation to combine nor a reasonable expectation of success in applying the Ground 1 references to render obvious the claimed method.

B. There is No Motivation to Combine Eckhardt with Sosnin to Arrive at the Claimed Invention.

1. Petitioners fail to identify any reference that could show the effectiveness and relative safety of using 222 nm on skin.

Mr. Lawal opines that the claims are obvious, premised on his assertion that the "effectiveness and relative safety of directing UVC light of wavelength 222 nm to bare skin for use in germicidal application was already known at the time." *See* Pet. at 22-23 (citing Ex. 1003 at ¶¶ 94-95; Ex. 1004 at [0031], [0069]; Ex. 1011 at [0040]). But none of these references support his conclusion, and Patent Owner's expert, Dr. Mark Hernandez, disagrees that any of them would motivate the POSITA to combine Eckhardt and Sosnin to arrive at the claimed invention with any reasonable expectation of success. Ex. 2001 at ¶¶ 44-54, Section VII.

Petitioner's own expert expressly acknowledges that "UV light at 254 nm was generally known to be harmful to organic tissue, such as skin." Ex. 1003 at ¶ 49. And its primary reference, Eckhardt, recognizes the dangers to skin posed by UV light to render the claimed invention not obvious. *See, e.g.*, *Chemours Co. FC, LLC v. Daikin Indus. Ltd.*, 4 F.4th 1370, 1376 (Fed. Cir. 2021) (reversing PTAB decision because "the Board appears to have ignored the express disclosure in [the prior art] that teaches away from the claimed invention"). For example, the very title of the primary reference (Eckhardt) dissuades a POSITA away from the idea of using 222 nm wavelengths to disinfect skin, titled a "Method and apparatus of disinfecting or sterilizing a region through a bandage," whereby such bandages block and/or significantly reduce penetration of the skin by the tested UV wavelengths.

At its core, Eckhardt is focused on use of the most prevalent form of UV light in the prior art, use of 254 nm wavelengths. *See* Ex. 1004 at [0055] ("These lamps produce most of their energy at a wavelength of approximately 253.7 nanometers, in the middle of the UVC sterilizing band."). This wavelength is known to cause damage to human skin and other tissue; Eckhardt itself repeatedly cautions the POSA from using this UV light on skin. Ex. 2001 at ¶ 38. For example, Eckhardt teaches that "[w]hile ultraviolet radiation has been used for the sterilization of disinfection of objects in some applications, ultraviolet light has long been associated with skin cancer, sunburns, and other harmful skin effects. Common

wisdom and practice has encouraged the non-exposure of skin to ultraviolet radiation." *Id.* at [0005]. Furthermore, "ultraviolet light is potentially harmful to the skin. Consequently, many individuals take precautions against exposure. Because of its perceived dangerous nature, ultraviolet light has not been contemplated for the sterilization or disinfection of skin, including wounded skin and healthy skin, or catheter entrance sites." *Id.* at [0028].

Instead of encouraging the use of UV light on bare skin, Eckhardt discloses several techniques to reduce exposure to these wavelengths. *See, e.g.*, Ex. 2001 at ¶¶ 31-32, 57. Most obviously, Eckhardt discloses a host of bandages intended to cover wounds and provide cover for such wounds from exposure to direct UV light. Eckhardt encourages the use of other mechanisms to protect skin include, for example, an optical filter (*see* Ex. 1004 at [0038]) and a "UV dose control mechanism" that "may be continuously variable or variable in discrete steps determined by a switch." *Id.* at [0046]. Furthermore, to reduce harmful exposure, Eckhardt suggests pulsing the 254 nm light instead of continuously exposing the skin. *Id.* at [0056]. In sum, the POSITA does not walk away from Eckhardt motivated in any way to directly disinfect skin with UV light. Ex. 2001 at ¶ 58.

Petitioner throws this caution to the wind, instead suggesting the POSITA would remove the bandages and increase UV exposure but fails to offer any motivation to combine or reasonable expectation of success that existed at the time

of the invention. In fact, the sources Petitioner and Mr. Lawal rely upon to do so consist of high-level statements about UVC—none of which are specific to 222 nm light, and none of which are supported with any data or citations. Ex. 2001 at ¶ 66. In sum total, these statements include:

- "The skin is nearly opaque to UVC light. Current data appears to indicate that it (UV < 300 nm) is safe to use at level that would sterilize and/or disinfect the skin surface." Jenkins, Ex. 1011 at [0040].
- "UVC, used in germicidal lamps, causes almost no damage because of its low penetration of the skin." Health Physics Society (HPS) Newsletter, Ex. 1012 at ¶ 2.
- "Many other sources indicate that UVC cannot penetrate the skin or can do so only to a very limited depth." Cumbie, Ex. 1013 at ¶ [008] (relying on HPS).

Consistent with Mr. Lawal's own concession (Ex. 1003 at 49), the POSITA would have known wavelengths in the UVC band, including 254 nm, was ***harmful*** to skin and stayed away. Ex. 2001 at ¶¶ 55-66.

2. <u>Decades old occupational guidelines would have steered the POSITA away from UVC, not provided a motivation to use it on skin.</u>

Petitioners and Mr. Lawal lean on the occupational guidelines published in 1992—relying upon data from 1972—to argue a POSITA would believe that 222

nm was "relatively safer" than 254 nm and would be effective at performing disinfection. *See, e.g.*, Ex. 1003 at ¶ 97. The POSITA would disagree, at least for the following three reasons: (i) the NIOSH guidelines themselves would send a strong message of deterrence to a POSITA to even consider using 222 nm on skin and are fraught with uncertainties (Ex. 2001 at ¶¶ 67-71); (ii) the WHO reference is limited to sunburn and 254 nm wavelengths and speaks nothing to motivate the POSITA to use 222 nm to disinfect skin (*see id.* at ¶¶ 72-74); and (iii) the POSITA would not have been able to understand the effectiveness of 222 nm on skin based upon the data presented by Petitioners—none of which tests 222 nm on skin (*see id.* at ¶¶ 75-82).

First, Petitioners turn the NIOSH guidelines on their head. The whole purpose for the NIOSH guidelines was to tell employers in 1992 the most exposure any worker should experience because it was known to be dangerous. But these workers were wearing personal protective equipment (PPE) at the same time. This would have included eye and skin protection. No POSITA would consider utilizing this dose that was considered a maximum exposure to disinfect bare skin. Ex. 2001 at ¶¶ 67-69.

Even if the POSITA was considering NIOSH, she would have recognized the uncertainties in the data that would have steered her away. These included the fact that the values reported were based on data from 1972, and that the only wavelength

identified with specificity was 254 nm—every other wavelength was reported in whole numbers (i.e., 210, 220, 230, etc.). Ex. 2001 at ¶ 70. Moreover, the "spectral effectiveness" in the table reflects that the benchmark, or most effective wavelength, is 270 nm (i.e., spectral effectiveness of "1.0"), while "220 nm" has an effectiveness of "0.12." Ex. 1006 at Fig. I-1. If the POSITA was looking to reduce uncertainty in the data, she would be motivated to rely on the most effective wavelength (270 nm), not the one that performs at a fraction of its effectiveness (220 nm). Ex. 2001 at ¶ 71. If the POSITA was even considering NIOSH for this purpose, there were enough objective red flags to undercut the reliability of the data.

Second, Mr. Lawal points to a 1994 paper about sunburn to argue that the POSITA would have known that 222 nm light was relatively safer than 254 nm while still effective to disinfect skin. The POSITA would not have agreed, at least because the paper broadly categories the entire spectrum of "UVC" as being directed specifically to "254 nm," and because sunlight does not include 222 nm light because it is filtered out by the ozone layer. Ex. 2001 at ¶73. Petitioners and Mr. Lawal overstate the data presented in WHO as purportedly showing a 10-fold increase in safety for 220 nm over 260 nm because the POSITA would recognize the statistical and clinical limitations of the data itself. Ex. 2001 at ¶¶ 73-74. Ultimately, even if the POSITA would see that all UVC penetrates the skin less, it is still penetrating

the skin and causing damage such that the POSITA would not be motivated to consider the disinfection of bare skin with those wavelengths. *Id.* at ¶ 75.

Third, Petitioners and Mr. Lawal leap to the conclusion that disinfection data from low dosages of ***any*** wavelength would motivate the POSITA to try disinfection using 222 nm wavelengths to achieve the same results. This is far from true. None of the examples relied upon by Petitioners and their expert reflect an "apples to apples" comparison. *Id.* at ¶ 77. For example, the Sizer patent (Ex. 1036) demonstrates nothing more than it only takes low dosages of UV to activate the disinfection power of peroxide; it does not disclose 222 nm wavelengths. *Id.* at ¶ 80. But Eckhardt (Ex. 1004) and Johnson (Ex. 1015) rely on wavelengths from a xenon flash bulb and mercury lamps, respectively, and both involve administration in flash doses and other precautions to reduce exposure. Here, again, the POSITA would learn nothing about whether 222 nm could disinfect in these limited ways. *Id.* at ¶¶ 78, 81. Finally, although Sosnin tested 222 nm wavelengths, it did so only on two specific bacteria and in a petri dish—not on skin. *Id.* at ¶ 79. None of these tests would have motivated the POSITA to believe that low dosages of 222 nm wavelengths could effectively disinfect skin without a risk of causing damage. *Id.* at ¶ 82.

3. <u>Scientists still today debate the safety and efficacy of use of UVC on human skin so there was no reasonable expectation of success in 2005 (or the years that followed).</u>

As described in more detail above, even twenty years after the claimed invention, researchers are still investigating how exactly 222 nm wavelengths can effectively deactivate and destroy bacterial and viruses without causing damage to human or animal skin. Ex. 2001 at ¶ 83. Yet this research comes decades behind Mr. Neister's claimed method for doing just that. In addition to the IUVA Article and the Ma Article described above, other researchers in the field have only recently concluded that 222 nm UV light is safe to use on human skin. *See, e.g.*, Buonanno, M.; Welch, D.; Shuryak, I.; Brenner, D. J., Far-UVC light (222 nm) efficiently and safely inactivates airborne human coronaviruses. Sci. Rep. 2020 June 24;10(1):10285 (attached hereto as Ex. 2014); *see also* Ex. 2001 at ¶ 83.

The lynchpin of Petitioners' argument is Mr. Lawal's opinion that it is was known that 222 nm relatively safer than 254 nm and effective to disinfect skin as of the time of the invention—nearly twenty years ago—but that opinion is unsupported and flatly contradicted by record evidence. *See* Pet. at 22-23 (citing Ex. 1003 at ¶¶ 94-95; Ex. 1004 at [0031], [0069]; Ex. 1011 at [0040]). The evolution of the very guidelines (NIOSH) that Petitioners rely upon as motivation to combine Eckhardt and Sosnin demonstrate that the relative safety of 222 nm light has only recently been confirmed. Ex. 2001 at ¶¶ 84-85. Only in 2021 did the governing body (ACGIH) increase the threshold limits of UV exposure for occupational safety, which is consistent with the knowledge of the POSITA. These increases were

significant—a 7-fold increase for the limit for skin, and a 20-fold increase in the limit for eyes. *Id.*

Petitioners' cited evidence of alleged safety does not hold up to the rigors the POSITA would require. For example, Mr. Lawal quotes a passage from a patent to Jenkins (Ex. 1011 at [0040]) that is facially unbelievable:

> Sterilization/disinfection is accomplished primarily with UVC (i.e., wavelengths shorter than 300 nm) light. The skin is nearly opaque to UVC light. Current data appears to indicate that it is safe to use at levels that would sterilize and/or disinfect the skin surface.

Ex. 1003 at ¶ 49 (quoting Jenkins). This sweeping statement can be easily disproven—even by Petitioner's own expert and the primary reference upon which he relies (Eckhardt)—because it was well known that 254 nm is harmful to skin, and in fact, penetrates into the upper epidermis. *See, e.g.*, Ex. 2001 at ¶¶ 38, 46. Figure 11 of the IUVA Article provides a helpful illustration:

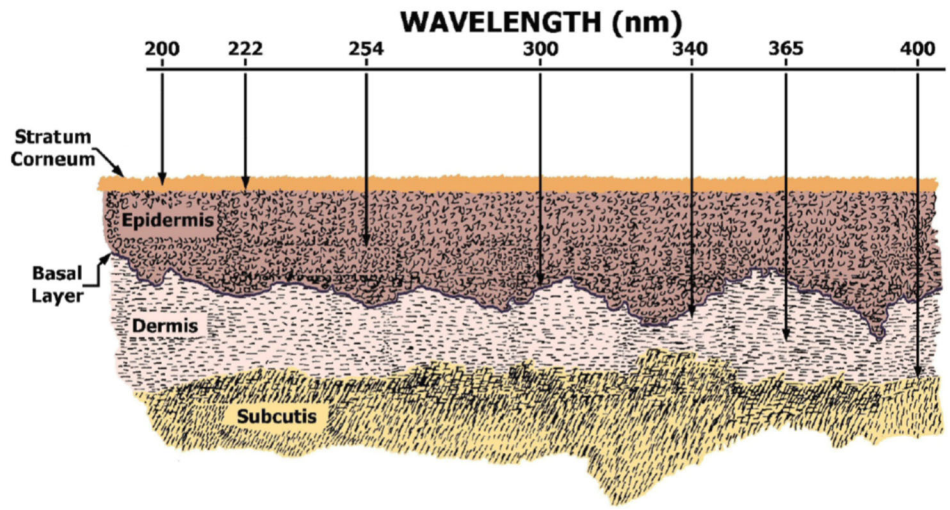

Figure 11. Penetration of UV wavelengths into human skin; arrows represent an estimate of 90% absorption depth. UV-C wavelengths at 222 nm do not appear to penetrate the stratum corneum; whereas, 254 nm does penetrate into upper epidermis. UV-B wavelengths, such as 300 nm, do penetrate to the critically important germinative (basal) layer of the epidermis and have sufficient energy to mutate DNA. UV-A wavelengths at 340 nm, 360 nm, and 400 nm penetrate well into the dermis, but the lower photon energies are far less damaging than 300 nm. [Figure courtesy of DH Sliney].

Ex. 2003, IUVA Article at 17 (Fig. 11).

Accordingly, Mr. Lawal's opinion is not consistent with what the POSITA would have understood and should be entitled to no weight. Because Petitioners' obviousness argument relies upon this opinion, Petitioners failed to show a reasonable likelihood of prevailing in establishing that claim 1 is invalid.

C. The Dependent Claims Are Likewise Valid.

Petitioners challenge the patentability of dependent claims 2-5 and 7-18. As with claim 1, the combination of Eckhardt and Sosnin does not render any of these claims unpatentable.

A. Claim 2

Claim 2 depends from claim 1 and further recites "wherein the human or animal tissue is one of blood, an organ, or a wound."

As described above, neither Eckhardt nor Sosnin teach, disclose or suggest disinfecting "human or animal tissue." As "blood, and organ, or a wound" is a subset of "tissue," neither reference teaches, discloses or suggests disinfecting any of these items either. Eckhardt expressly discloses placing a bandage *over* a wound before exposure to light. Ex. 2001 at ¶ 88.

B. Claim 3

Claim 3 depends from claim 1 and further recites "wherein the microorganism is at least one of a bacteria, a virus, a fungus, an amoeba, and a protozoa." While Eckhardt and Sosnin disclose disinfection of microorganisms, neither provides any disclosure of doing so using 222 nm light, particularly on human or animal tissue. Ex. 2001 at ¶ 89.

C. Claim 4

Claim 4 depends from claim 1 and further recites "wherein the step of directing is performed for approximately two seconds." Neither Eckhardt nor Sosnin teach, disclose or suggest that the generated photons are directed to a substance or surface to be disinfected for approximately two seconds, much less involving 222 nm light on skin.

Regarding Eckhardt, only an extremely broad range of exposure durations is disclosed. *See* Ex. 1004 at [0032]. There is no disclosure of "approximately two seconds" or anything close to it. At most there is a disclosure of "a few minutes or seconds" or "a single flash" *i.e.,* "less than 200 microseconds." *Id*. at [0032], [0043]. None of these durations are disclosed in reference to a 222 nm light source.

Petitioners, via Mr. Lawal's Declaration, argue that a POSITA would "adjust[] exposure time to two seconds to achieve a particular level of disinfection" as "a matter of routine optimization." Petition at 38. But arriving at "approximately two seconds" is not mere "routine optimization." The chosen time for directing UV light at a substance or surface for disinfection has numerous variables, including the identity of the microorganism to be targeted, the distance between the light source and the microorganism, and the intensity of the light source.

The fact that prior art references allegedly disclosed "exposing a surface to be disinfected to photons for multiple seconds" does not alter this conclusion. *See* Petition at 36. Multiple seconds merely means more than one second. No cited reference on page 36 of the Petition suggests to a POSITA that "approximately two seconds" is the desired or preferred duration of time. Ex. 2001 at ¶¶ 90-93.

D. Claim 5

Claim 5 depends from claim 1 and further recites "wherein the step of generating photons comprises activating a lamp positioned within a wand, and wherein the step of directing comprises positioning of the wand."

Petitioners do not appear to argue that Sosnin discloses a wand. Petitioners argue, however, that Eckhardt discloses a wand (or some equivalent) because it describes a "hand held lamp." Petition at 40. This is wrong. The claim requires "a lamp positioned within a wand." Eckhardt only discloses the lamp itself. There is no disclosure of a "wand" with a "lamp positioned within" the same. Ex. 2001 at ¶ 95.

E. Claim 8

Claim 8 depends from claim 7 and recites "wherein the lamp comprises a cover, the cover transparent to 222 nm." Petitioners argue that a POSITA would have known to use Eckhardt's "transmissive window or screen" with Sosnin to "permit 222 nm light to disinfest skin." Petition at 42. This is incorrect. Even if Sosnin discloses a 222 nm lamp (which it does not), there is no suggestion in Sosnin to use (or not use) that lamp with a cover. In fact, there is no description at all of any lamps used in Sosnin, or whether a "cover" would be an appropriate, desirable or feasible feature. To argue that a POSITA would know to use Eckhardt's

"transmissive window or screen" with Sosnin is speculative, at best. Ex. 2001 at ¶ 96.

F. Claims 10 and 11

Claim 10 depends from claim 1 and recites "wherein the step of directing the photons further comprises providing a radiant dose energy of 40 mJ/cm^2 to the substance or surface to be disinfected." Claim 11 depends from claim 1 and recites "wherein the step of directing the photons further comprises providing a radiant dose energy of 60 mJ/cm^2 to the substance or surface to be disinfected." Petitioners argue that this would have been obvious to provide either radiant dose energy (40 or 60 mJ/cm^2) of 222 nm photons "simply by changing the exposure time." Petition at 44. Neither Eckhardt nor Sosnin, however, support such a conclusion.

Eckhardt describes two embodiments in detail, neither of which utilize 222 nm light. The first embodiment is an "instantaneous sterilization or disinfection" unit (16a) having a "xenon flash bulb" light source (7a). Ex. 1004 at ¶¶ 37-48. Eckhardt further states that the xenon flash bulb has wavelengths between 220 and 310 nm. *Id.* at ¶ 70. Eckhardt specifically describes the practice of using rapid, transient UV exposures of such short durations, characterized as "pulses" or "flashes," and the "energy of a single flash may be sufficient to deliver a sterilizing or disinfecting dosage, *e.g.*, greater than 10 mJ/cm^2 of UVC." *See id.* at ¶ 32. The only other energy intensity disclosed for the xenon flash lamp embodiment in Eckhardt is "about 20

mJ/cm^2." *See id.* at ¶¶ 43, 104. And the POSITA would have understood that higher doses of UV radiation were not desirable because of harmful exposure. *See, e.g.*, Ex. 2001 at ¶¶ 38, 46.

Sosnin, on the other hand, describes laboratory testing of irradiation of two kinds of bacteria in Petri dishes. These tests were designed to test sterilize glass-ware, not human or animal tissue. Even if a POSITA were to look to Sosnin, she would not be motivated to select a KrCl 222 nm light source to use with anything, much less human or animal tissue. Instead, she would have selected the XeBr 282 nm excilamp consistently described by the authors as having the "best" characteristics for disinfection. Ex. 2001 at ¶ 99.

A POSITA would also not believe that the "instantaneous sterilization or disinfection unit" could be used with a 222 nm light source instead of its xenon flash. lamp. A 222 nm light source, namely the Krypton-Chloride (KrCl) lamp, was quite rare and expensive, so the POSITA would not have thought to use it. Ex. 2001 at ¶ 50. Moreover, even today, 222 nm light sources are not designed to deliver these energy levels (i.e., greater than 10 Joules or even 20 Joules), nor are they configured to be used in pulses or flashes. *Id.* at ¶ 101.

Eckhardt describes a second embodiment, a "continuous process sterilization or disinfection" unit (16b) having a "mercury gas lamp" light source (7b). Ex. 1005 at ¶¶ 49-61. Eckhardt states that a "continuous light source 7b may be a standard

germicidal mercury vapor lamp … that produces most of [its] energy at a wavelength of approximately 253.7 nm." *Id*. at ¶ 55. Eckhardt states that "if the intensity of the UV light at skin 3 is low enough, continuous light source 7b may be illuminated for long periods of time (e.g., hours or days) without damage to skin 3." *Id*. at ¶ 56. But Eckhardt itself recognizes that "[c]ommonly available mercury lamps typically produce an intensity incompatible with continuous operation, unless the light level is attenuated with an optical filter or the electrical drive to continuous light source 7b is controlled to reduce the intensity of the emitted light. A reduction in the intensity of the light output may be accomplished by turning continuous light source 7b alternatively on and off." *Id*. Ex. 2001 at ¶¶ 98-102.

G. Claims 12-18

Claim 12 depends from claim 1 and further recites "wherein the human or animal tissue is skin." Claim 13 depends from claim 1 and further recites "wherein the human or animal tissue is human tissue." Claim 14 depends from claim 1 and further recites "wherein the human or animal tissue is human skin." Claim 15 depends from claim 1 and further recites "wherein the human or animal tissue is tissue of a living animal." Claim 16 depends from claim 1 and further recites "wherein the human or animal tissue is tissue of a living human." Claim 17 depends from claim 1 and further recites "wherein the human or animal tissue is skin of a

living human." Claim 18 depends from claim 1 and further recites "wherein the human or animal tissue is skin of a living animal."

For the reasons articulated above, a POSITA would not read Eckhardt or Sosnin to teach, disclose, or suggest using 222 nm light to disinfect human or animal tissue, and including the tissue of a living human or animal. Ex. 2001 at ¶ 103; Section VII.

VII. CONCLUSION

Mr. Neister respectfully requests that the Board refuse to institute this Petition, at least because the USPTO recently has correctly considered and decided issues of validity based upon substantially the same art and arguments, and because Petitioner has failed to show that there is a reasonable likelihood that it would prevail as to at least one of the challenged claims.

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

The undersigned certifies that the foregoing PATENT OWNER'S PRELIMINARY RESPONSE complies with the type-volume limitation in 37 C.F.R. § 42.24(b)(1). According to the word-processing system's word count, the brief contains 9,946 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

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