

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

**DECLARATION OF MARK T. HERNANDEZ, PH.D.
IN SUPPORT OF PATENT OWNER PRELIMINARY RESPONSE**

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I. BACKGROUND AND QUALIFICATIONS

1. My name is Mark Hernandez. I have been a registered as a professional civil engineer since 1996. I currently hold the Archuleta endowed chair at the University of Colorado's flagship campus, where I have continuously served on the engineering faculty for 27 years. I attained all my civil engineering degrees – BS, MS and PhD – from the University of California at Berkeley, where I also served a post-doctoral fellowship in applied microbiology.

2. I have authored more than 100 peer-reviewed publications, 41 of which focus on the characterization and control of air- and surface-borne microorganisms in the built environment, and 12 of which focus specifically on the (UV) disinfection of airborne microbes.

3. In cooperation with the University of Colorado, I am the lead inventor on 5 US and PCT patents (3 issued and 2 pending).

4. I have served on four National Academy of Science, Engineering and Medicine committees focusing on secure containment for bioterrorism research, the microbiology of the indoor environments and disease transmission in urban settings.

5. My University of Colorado research laboratory has been leading UV disinfection research relevant to occupied indoor spaces, since its commissioning in 1998. It hosts several biological aerosol/surface disinfecting facilities, including one of the largest bioaerosol chambers in the country (10 m³); this chamber is specifically

used for studying the inactivation of potential pathogens (notably including coronavirus) under realistic indoor conditions. I currently have industrial gifts and grants-in-force, that are issued specifically to investigate the disinfection response of airborne and surface-associated microbial pathogens to ultraviolet light from non-conventional sources (LCDs, excimers and wafers), notably including narrow bandwidths circumscribing 222 nm, alone and in combination other light bandwidths, as well as light-activated chemicals. To date, I have been awarded over \$18.86 million in funding as a principal investigator or co-principal investigator, including over \$10.5 million from the National Science Foundation and over \$2.2 million from the National Institutes of Health.

6. As of the time of the invention of the '951 Patent, I was working in the field of disinfection and inactivation of microorganisms of air and surfaces. I consider myself an expert as of the same time. Contemporaneous examples of my work include: In 1997, I was awarded a US National Science Foundation CAREER Award as a principal investigator to study the biostability and UV photoreactivation of airborne bacteria, fungi, and their spores. The award ran from 1997 to 2003, during which time I co-authored papers on photoreactivation in airborne *Mycobacterium parafortuitum* (Ex. 2015 (Peccia 2001)) and the efficacy of UV germicidal irradiation of upper-room air (Ex. 2009 (Xu 2003)). In 2004, I co-authored a paper on UV-induced inactivation rates for airborne *Mycobacterium*

bovis BCG. (Ex. 2016 (Peccia 2004).) In 2005, I co-authored a paper on the effects of ceiling-mounted HEPA-UV air filters on airborne bacteria concentrations in an indoor therapy pool building. (Ex. 2017 (Kujundzic 2005).) In 2006, I co-authored a paper on UV air cleaners and upper-room air UVGI for controlling airborne bacteria and fungal spores. (Ex. 2018 (Kujundzic 2006).)

7. I have attached a current copy of my curriculum vita as **Appendix A** to this Declaration.

8. In preparing this Declaration, I have reviewed and considered all the materials listed by Mr. Lawal in his Declaration (Ex. 1003 at ¶ 14). I have listed my additional materials considered as **Appendix B** to this Declaration.

II. SCOPE OF OPINIONS

9. I have been engaged by counsel for Patent Owner, Mr. Neister, to review and comment on the opinions offered by Mr. Oliver Lawal (Ex. 1003) and the materials he relies upon to support them. I further have been engaged to consider and offer opinions in response to arguments made by Petitioners. And I have been engaged to offer my opinions regarding the validity of the challenged patent and claims, namely, claims 1-5 and 7-18 of U.S. Patent No. 11,246,951 (the “’951 Patent”). I base my opinions on my technical expertise and experience in the field and the materials I refer to and rely upon.

III. PERSON OF ORDINARY SKILL IN THE ART

10. I understand that Mr. Lawal and Petitioners have defined the person of ordinary skill in the art (“POSITA”) as follows: “the relevant POSITA would have had a Bachelor’s degree in biological, chemical, environmental, electrical, mechanical, and/or systems engineering, or an equivalent degree such as one in physics or similar subject matter, would be familiar with the fundamentals of UV gas discharge lamps (including excimer lamps), and would have had at least approximately two years of work or research experience in UV disinfection technology and/or systems. Also, an increase in experience could compensate for less education, and an increase in education could likewise compensate for less experience. My analysis is thus based on the perspective of a POSITA having this level of knowledge and skill in the timeframe leading up to the date of invention of the ’951 Patent. Ex. 1003 at 21. For purposes of my opinions here, I have applied that same definition of a POSITA and agree with it.

IV. TECHNICAL BACKGROUND

11. Ultraviolet light is a form of electromagnetic radiation with wavelengths between 100 nm and 400 nm. The UV spectrum is commonly divided into four regions: vacuum UV (100 to 200 nm), UV-C (200 to 280 nm), UV-B (280 to 315 nm), and UV-A (315 to 400 nm).

12. Ultraviolet light across this full spectrum is generated by the Sun. However, the Earth's atmosphere filters out most UV-B light and all UV-C and vacuum UV light. Therefore, the only UV-C light present on Earth is generated from artificial light sources.

13. By the late 1800s, scientists were beginning to understand the potential germicidal effects of UV-C light. In 1901, Peter Cooper Hewitt developed the first mercury vapor lamp, for which he was granted U.S. Patent No. 682,692. Low-pressure mercury lamps, like the one designed by Hewitt, emit a majority of their UV light at a wavelength of 254 nm. By the 1930s, scientists had determined that UV light had superior effectiveness for inactivating bacteria at wavelengths near the 254 nm output of mercury lamps. Ex. 1040. Relatively inexpensive to make and use, 254 nm mercury lamps quickly became the predominant light source used for UV-C disinfection.

14. Many early light sources used for germicidal UV purposes emitted radiation across a broad spectrum. For example, Niels Finsen, who received the Nobel Prize in 1903 for his invention of a light therapy for skin tuberculosis, relied upon a carbon arc lamp that would have transmitted a broad spectrum of light, primarily above 340 nm, in the UV-A spectrum. <https://pubmed.ncbi.nlm.nih.gov/15888127/> Mercury lamps are by far the most common commercially available lamp that emits light primarily in a narrow

spectrum, centered around 254 nm. While other types of light sources were known to emit narrow spectrum emissions centered around other wavelengths, these light sources were—and still are—largely limited to experiment use and do not have practical applications.

15. I understand that the parties dispute whether the priority date of the ‘951 Patent is in 2005 or 2006. *See* Petition at 4; Ex. 1003 at ¶ 22. Whether the Board determines that the priority date is in 2005 or 2006 my opinion about the state of the art and knowledge of a POSITA at the time of the invention would remain unchanged. Before and throughout the 2005 to 2006 time period, the most widely used UV-C light source for sterilization was the 254 nm mercury lamp. I disagree with Mr. Lawal that any other UV light source was “available” for anything other than laboratory associated experimental use. Mr. Lawal has not identified any other light source being used in any practical or commercial application, and I am aware of none.

16. Mr. Lawal explains that Krypton-Chloride and Xenon-Bromide were known to discharge wavelengths of 222 nm and 282 nm respectively. I disagree that any lamps utilizing these mixtures were available for anything other than experimental use. Mr. Lawal has not identified any use of such lamps—or any other lamps generating these UV wavelengths—in any practical or commercial application, and I am aware of none.

17. As explained in greater detail below, I disagree with Mr. Lawal that exposure to UV-C light was considered safe for humans at the time of the '951 Patent. Mr. Lawal offers two examples of UV light being used as a treatment for tuberculosis and polio. Ex. 1003 at ¶¶ 36, 45. Vaccines for these diseases were introduced in the 1920s and 1950s respectively. Even if the risks of such treatments could have been medically justified in the early 1900s, Mr. Lawal offers no evidence that a POSITA would have considered these or any other uses of UV light on humans or animals at the time of the invention of the '951 Patent.

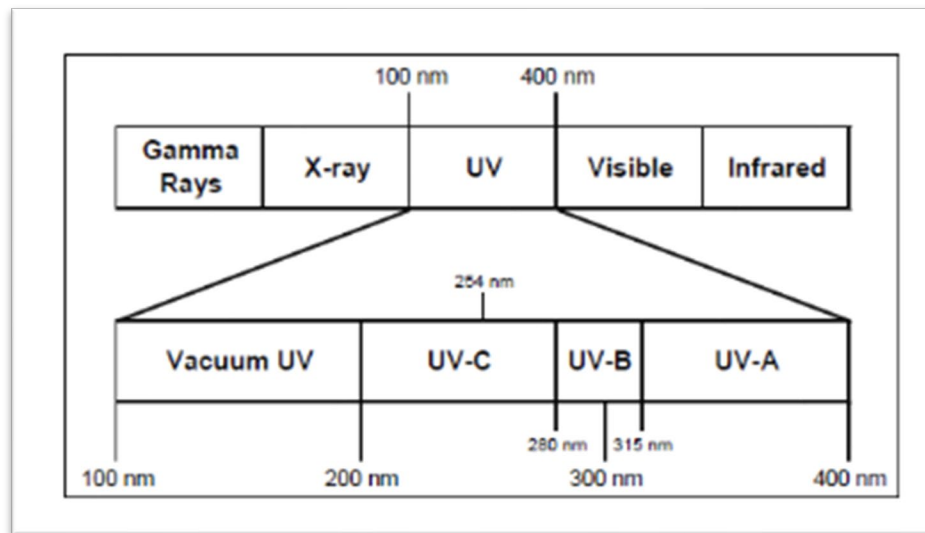
18. Moreover, Mr. Lawal offers no evidence that UV treatments of tuberculosis and polio relied upon UV light sources emitting narrow wavelengths of 222 nm, 254 nm, or 282 nm. *See, e.g.*, Ex. 1003 at 36, 45. Mr. Lawal offers no evidence of such wavelengths being used on humans or animals around the time of the invention, and I am aware of none.

19. I disagree with Mr. Lawal's discussion of the technology in several respects. In many ways, it reflects the perspectives of an individual who is not (and never was) familiar with the use of UV-C light, particularly 222 nm or 282 nm, on surfaces and substances (including skin). Certainly Mr. Lawal's opinions of how a POSITA would view the safety of these wavelengths in the presence of humans demonstrates that he is not qualified to offer opinions of this nature. Mr. Lawal has

never worked with 222 nm or 282 nm light with humans, and instead has overwhelmingly focused on the use of 254 nm light with water.

20. Mr. Lawal presents an extended and generalized background of UV science, much of which has no bearing on the salient theme of this proceeding; this is exemplified, among other lesser relevant physics history, by the pages discussing sunlight. Since UV-C defines the core of this argument, and because of well-known atmospheric processes (i.e., ozone reactions) UV-C does not persist through natural sunlight to ground level. Thus, a POSITA would not have considered sunlight sources in this context.

21. Lawal presents, refers and relies on a figure he included in Appendix B showing a common “textbook-like” rendition of the UV spectrum that was annotated with the labels for describing important descriptive technical usage understood at the time (*see* Ex. 1003 at ¶ 31). The fact that this figure specifically denotes 254 nm within the UV-C bandwidth; but does not consequently denote either 222nm or 282 nm wavelengths, indicates what was accepted as state of the art with regards to light-enabled UV-C disinfection accepted at that time (2003).



22. Notably in the Background section, but also throughout his declaration, Mr. Lawal misuses and/or confuses key technical terms that are widely accepted as standard concepts in sanitary engineering, disinfection science and outcomes of disinfection practice. Associated with casual lexicon misuse, he misinterprets and incorrectly cites/restates the salient themes presented in many references he cites in his declaration. An important example of this casual misuse is the term “**kill**”, which is absolutely critical in this UV disinfection context. Mr. Lawal erroneously defines the term *kill* in response to UV irradiation as “rendering the microorganism inactive and unable to interact with its surrounding environment, which eventually leads to its death” (*see* Ex. 1003 at ¶ 48). In this important context, his declaration definition and subsequent usage of the term “kill” contradicts the very EPA UV Disinfection Guidance manual he previously introduces as his credentialed experience (*see id.* at ¶ 27), which states the following on its page 124:

Damage to nucleic acid does not prevent the cell from undergoing metabolism and other cell functions. Although the microbial cell is alive after exposure to UV light, it cannot reproduce, and therefore it is incapable of infecting a host. To kill the microbial cell, the UV dose would need to be increased by orders of magnitude as compared to the UV dose needed to prevent replication.

23. Other important examples of technical lexicon misuse associated with disinfection science, is how Mr. Lawal uses and forwards an incorrect working definition of the term “**sterilize**” with respect to UV applications (*see* Ex. 1003 at ¶ 89). When restating the content of Ex. 1011 (*see* Ex. 1003 at ¶ 40), Mr. Lawal declares that “Sterilization / Disinfection is accomplished primarily with UVC”. Strictly defined, UVC in this context cannot possibly function as a “sterilizer”. The accepted working CDC definition of a sterilizer for practical applications is that “Sterilization destroys all microorganisms on the surface (of an article)” (*see* CDC (2008) Guidelines for Disinfection and Sterilization in Health Care) and that sterility is the “state of being free from all living microorganisms” (*see* CDC infection control Glossary).¹ UV, regardless of wavelength, in the disinfection and exposure context of the ‘951 Patent, cannot not ablate, destroy, or otherwise render any surface “free”

¹ Ex. 2019,
<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/glossary.html>.

of living microorganisms—this is impossible. There are many searchable glossaries available from government agency sources, including the EPA, that are available for any POSITA to review and use in practice.² Mr. Lawal chose not to use these accepted working definitions throughout his declaration.

V. PRIORITY

24. I have reviewed the Provisional Application to which the '951 Patent claims priority (Ex. 1008), and it is my opinion that a POSITA reading these disclosures would understand that the inventor intended for the invention to be used in a manner wherein the generated UV light (Far UV-C at 222 nm wavelength) would purposely come into direct contact with the air, surfaces, and humans occupying common indoor environments, and therefore disinfect, human or animal skin.

25. Paragraph 28 of the Provisional Application explains:

[The invention] 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,

² See, e.g., Ex. 2028, <https://www.epa.gov/coronavirus/whats-difference-between-products-disinfect-sanitize-and-clean-surfaces>; Ex. 2029, <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html>.

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 ¶ 028.

26. The Provisional Application offers several additional applications wherein UV radiation would be emitted in occupied areas, such as “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 breathe (¶ 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.

27. As the Board previously recognized, these disclosures “refer to sterilizing things in the presence of humans.” IPR2022-00381 Institution Decision (‘642 Patent) at 10. A POSITA would understand that emitting UV radiation in occupied areas without “restrict[ing] occupation and use of areas being treated,” such as requiring humans and animals to vacate the vicinity or wear protective equipment, will result in UV radiation coming into contact with the skin of the humans and animals present. Assuming adequate power and exposure time, skin that

is contacted by this UV radiation, would be disinfected in the same manner that any other surface would.

28. The only way to prevent human and animal skin from being disinfected is to place restrictions on the occupation or use of the area being treated, such as by requiring occupants to vacate the area or wear personal protective equipment. For example, many commercial UV light products include remote or time delayed switches, which allow the device to be activated with a human being physically present. Such products also rely upon timers to deactivate the device so that a human does not need to be present during operation. Many such products also contain infrared or other motion-based proximity sensors enabling the device to sense the presence of a human or animal that re-enters the vicinity during operation and shut itself off.

29. In applications where humans must be present, such as in research settings, personal protective equipment such as coats, gloves, and facemasks are used to minimize UV exposure to the greatest extent possible. By disclosing that such restrictions on occupation or use of the area being treated are not necessary, a POSITA would have been surprised at the claim being made by the inventor—that 222 nm was safe to use on skin—but there would have been no doubt that the inventor possessed such a method.

VI. GROUND 1

A. Eckhardt (Ex. 1004)

30. Eckhardt³ is a published patent application, not a peer-reviewed journal article. It contains no data or 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.

31. Eckhardt focused on 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.

32. Using source controls and materials (bandages) to attenuate UV incident on skin, Eckhardt explicitly seeks to minimize UV dose to afflicted areas (compromised skin). A POSITA would recognize Eckhardt’s salient theme: reduce

³ For ease of reference herein, I refer to relevant articles and publications by the first author’s/inventor’s name.

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). It is self-evident that 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.

33. Eckhardt states that “the light source 7 may be *any light source* that emits light capable of sterilization or disinfection.” *See* Ex. 1004 at ¶ 31.⁴ 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, which I consider below—the POSITA reading this laundry list of UV 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, I disagree.

⁴ Emphasis added unless otherwise noted.

34. 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/cm² of UVC.” *See id.* at ¶ 32. The only other energy intensity disclosed for the xenon flash lamp embodiment in Eckhardt is “about 20 mJ/cm².” *See id.* at ¶¶ 43, 104. And the POSITA would have understood that higher doses of radiation were not desirable because of harmful exposure.

35. 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. As described herein and in Section VI.C, below, 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.

36. 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 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.*

37. Eckhardt also includes one sentence in a section titled, “UV-Transmissive Bandage,” that refers 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 I disagree. 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.

38. 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 at the time—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.

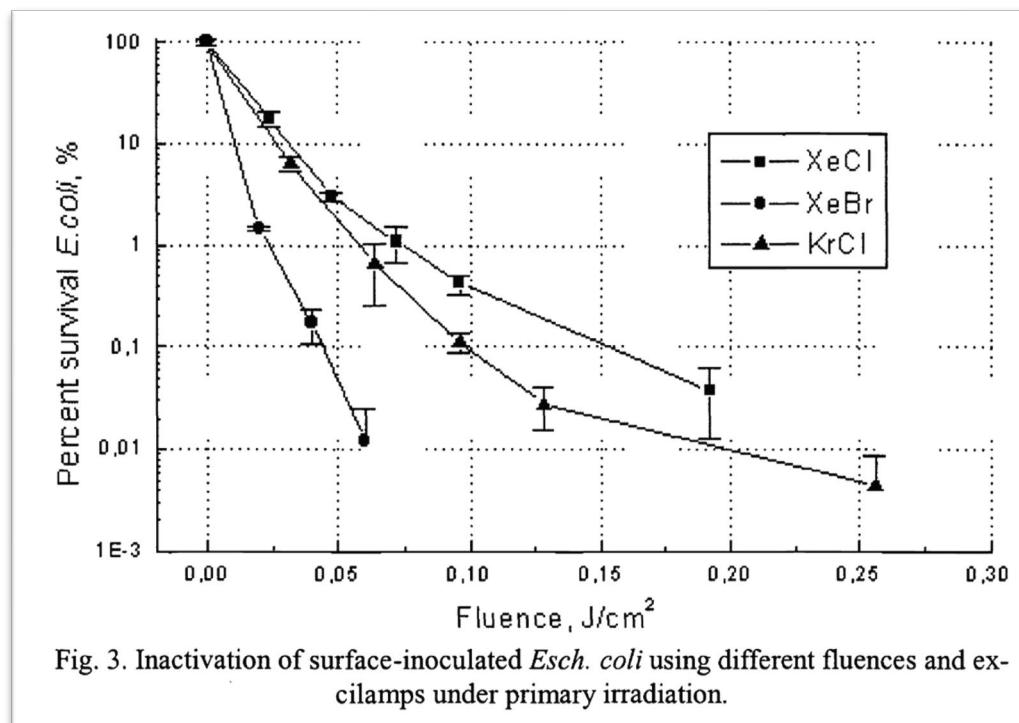
B. Sosnin (Ex. 1005)

39. Sosnin is a paper titled, “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).

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

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



42. 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).

43. As shown above (Fig. 3), 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.

C. No Motivation to Combine Eckhardt with Sosnin with a Reasonable Expectation of Success

44. Mr. Lawal opines that a POSITA at the time of the invention would have been motivated to combine the “Method and Apparatus for Sterilizing or Disinfecting a Region Through a Bandage,” of Eckhardt with the “Comparative Approach” described in Sosnin to arrive at the claimed invention with a reasonable expectation of success. Ex. 1003 at ¶¶ 88-109. These include the following three reasons:

- First, that Eckhardt was calling for “an instruction to search for and incorporate other well-known germicidal light sources, particularly like the excimer lamps disclosed in Sosnin.” *Id.* at ¶ 90.

- Second, that a POSITA would have “taken Eckhardt’s known method of using germicidal UV light of wavelengths anywhere from 220-310 nm to disinfect human ‘tissue,’ such as ‘bare skin’ and wounds, and implemented it using Sosnin’s disclosed KrCl or XeBr excimer lamps with 222 nm and 282 nm emissions, and thus the combination would have been no more than combining prior art elements according to known methods.” *Id.* at ¶ 92.
- And third, that a POSITA “would have been motivated to combine the teachings of Eckhardt and Sosnin based on the POSITA’s general knowledge at the time of invention.” *Id.* at ¶ 94.

Supported by the critical deconstruction of Eckhardt and Sosnin presented above, I disagree with each of these reasons.

45. **First**, Eckhardt describes a generic list of light sources, including each of UV-A, UV-B, and UV-C. *See* Ex. 1004 at ¶31. The POSITA would not have been motivated, as Mr. Lawal states, to search for an excimer lamp described in Sosnin. Instead, the POSITA would have read that list and questioned the practical testing and availability of most sources listed by Eckhardt at that time. Further, a POSITA understood that at least 254 nm UV light that was well-known for disinfection purposes because its potent DNA damage potential had been unequivocally demonstrated in the peer-reviewed literature well before that time.

46. The POSITA would have understood that 254 nm UV light was harmful to skin based not only upon Eckhardt's express disclosure but from prior publications on experimentation with skin and eye tissues (including NIOSH and others, discussed below), which prompted occupation exposure regulations to UV-C emissions at 254 nm. *See, e.g.*, Ex. 2020, Tommasi, et al, 1997; Ex. 2021, Pfiefer et al, 2005. This would have led a POSITA to question the legitimacy of Eckhardt's suggestion to use UV directly on skin (without a bandage), given literature warnings at the time and because there was no data supporting otherwise.

47. And, stating the obvious, a POSITA would have known that 222 nm UV light would not be able to penetrate the bandages described in Eckhardt like the pulsed xenon lamp or the mercury lamp could, so the entire purpose of Eckhardt would have led the POSITA away from 222 nm light. *See, e.g.*, Ex. 2022, Campuzano-Jost (2004).

48. Even if a POSITA would have looked to different UV light sources than the xenon flash lamp described in the first embodiment (she likely would not), the POSITA would have been looking for transient UV sources that could "pulse" or "flash." Such a search would have *de facto* taught away from the use of 222 nm light, that still (to this day) is not used in rapid, transient exposure modes, and toward the higher wavelength sources including 254 nm or 282 nm, for example. Instead,

the POSITA more likely would have tuned a xenon flash lamp to a specific wavelength to achieve adequate disinfection.

49. And the POSITA would not have looked to different light sources to replace the conventional mercury lamp described in the second embodiment because Eckhardt itself suggests that the POSITA should seek to reduce the *intensity* of that light, not change the *wavelength*. Because mercury lamps were so prevalent and commercially accessible, it is far more likely that the POSITA would have experimented with those suggestions regarding reducing intensity rather than seeking out a rare and expensive lamp like a KrCl or XeBr excimer lamp, especially where there was no data or evidence suggesting that a 222 nm or 282 nm excimer would be safe for human skin.

50. For example, even the very publication Mr. Lawal relies upon to show commercial availability of these lamps shows the opposite. *See* Ex. 1003 at ¶ 44 (citing Appendix C). I have included a more complete copy. Ex. 2023, UV Disinfection for Water and Wastewater Treatment, *EPRI's Community Environmental Center* (1995)). Mr. Lawal's incomplete version of Chapter 4, titled "Emerging Technologies," omitted the opening paragraph, which described them as "several non-conventional applications of UV radiation for disinfection of water and wastewater." *Id.* at 4-1. Furthermore, Table 5 shows a "Summary of Emerging Technologies," and comments that the "Narrow-Band Excimers" are "presently

experimental model[s] only.” *Id.* at Table 5. And even the portion Mr. Lawal includes shows these lamps are expensive—\$50,000 for a pulsed xenon system, and \$25,000 for a “small excimer lamp and power supply,” like KrCl. *Id.* at 4-5, 4-6, respectively.

51. ***Second***, even if a POSITA wanted to look for a light source to extend methods described in Eckhardt, she would not have found Sosnin. Sosnin describes laboratory tests of irradiation of two kinds of bacteria in petri dishes. These tests were designed to demonstrate sterilization of glassware, not skin, and gave no indication whatsoever that the excilamps of the study could be used on human skin.

52. Even if the POSITA found Sosnin, she would have selected the XeBr lamp described as having the “best” characteristics and effectiveness for disinfection, reported by Sosnin—not the KrCl lamp chosen with hindsight by Mr. Lawal and Petitioners.

53. ***Third***, each of Eckhardt and Sosnin expressly demonstrate strong caution about applying UV light to human skin and call for additional testing before it would ever be done. Between the fact that Eckhardt is only a patent application publication with no data or peer-review, coupled with the fact that Sosnin has no teaching or suggestion of disinfecting human skin with 222 nm wavelengths, the POSITA would not have believed that a method for disinfecting human skin with

222 nm UV light would be possible, let alone obvious. And there would be no reasonable expectation of success in doing so.

54. Ignoring the express cautions and flaws of Eckhardt and Sosnin collectively, Mr. Lawal relies upon additional sources to claim that research showed it was relatively safer to use 222 nm UV light than 254 nm UV light on skin, and that the POSITA “would have been motivated to try using it to disinfect skin, and would have expected it to successfully disinfect.” Ex. 1003 at ¶ 109. Indeed, she would not have been so motivated. Mr. Lawal’s opinion is baseless and contradicted by the weight of literature and history of regulatory activity in the field as demonstrated below. I further have set forth in detail in Section VII.D, why his opinion could not be true as of the time of the invention, as it remains controversial even today.

VII. A POSITA WOULD NOT HAVE UNDERSTOOD 222 NM WAVELENGTH LIGHT TO BE “RELATIVELY SAFE” AND “EFFECTIVE” TO DISINFECT SKIN AT THE TIME OF THE ‘951 PATENT.

A. None of the references relied upon by Mr. Lawal demonstrate the effectiveness or relative safety of 222 nm UV light for disinfection of skin.

55. Petitioners argue and rely upon Mr. Lawal’s opinion that “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,” but that opinion is contradicted by record evidence. *See* Pet. at 22-23 (citing Ex. 1003 at ¶¶ 94-95; Ex.

1004 at [0031], [0069]; Ex. 1011 at [0040]). Taken in turn, none of the sources relied upon by Mr. Lawal support his opinion.

56. First, paragraph 31 of Eckhardt refers to Figure 1 and generically discloses the use of any and all kinds of light, including the entire spectrum of UVA, UVB, and UVC light. Ex. 1005 at [0031]. The only “light source[s]” referred to by name include “an ultraviolet (UV) light source such as 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 devices.” *Id.*

57. And paragraph 69 of Eckhardt includes a statement that the “sterilization/disinfection units previously described are also designed to have a beneficial effect when used on [1] bare skin, ... [2] with traditional bandages if the bandage is temporarily removed for the exposure to the sterilizing light, ... or [3] disinfection described herein may be implemented with a UV-transmissive bandage in place over the region to be sterilized/disinfected.” Ex. 1005 at [0069].

58. As described above, however, (*see, e.g.*, Section VI.A), the disclosures of Eckhardt would not have motivated the POSITA to use 222 nm light to disinfect bare skin. Instead, these were general teachings of all kinds of light and a few limited and known options of the time that could perform rapid microbial inactivation of bacteria on moist surfaces (near or in a wound)—namely, a pulsed xenon light (from wavelengths between 220-310 nm) and continuous mercury vapor lamp (254 nm).

There is no data or further evidence in Eckhardt to convince the POSITA that 222 nm light could be safely used to disinfect healthy human skin. Accordingly, the POSITA would not have understood the “effectiveness and relative safety” of using 222 nm wavelengths on bare skin based on these disclosures of Eckhardt.

59. Second, Jenkins is similarly lacking in data or a plausible solution for sterilization of skin. Mr. Lawal quotes one passage from Jenkins: “Sterilization/disinfection 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 (UV < 300 nm) is safe to use at level that would sterilize and/or disinfect the skin surface.” Ex. 1011 at [0040]. Jenkins itself cites to no authority, nor does Mr. Lawal cite any authority, credible peer-reviewed archival source, or any other validated data source to support a statement like the one from the Jenkins patent. The POSITA would have looked for and expected data for these conclusions, and without it, would not have had a general knowledge that using 222 nm light on skin was safe. Mr. Lawal’s adoption of this statement as true only contradicts other parts of his declaration (including by Eckhardt and Sosnin, for example), where he recognizes that 254 nm wavelengths were known to damage skin. Accordingly, the POSITA would not have understood the “effectiveness and relative safety” of using 222 nm wavelengths on bare skin based on these disclosures in Jenkins.

60. Third, Mr. Lawal says his opinion is “further corroborated” by the Health Physics Society (HPS) newsletter (Ex. 1012) and Cumbie (Ex. 1013). Lawal at ¶ 96. The POSITA would not have relied upon either one, nor would they have provided any motivation to combine Eckhardt with Sosnin to arrive at the claimed invention.

61. Regarding HPS, it was not a peer-reviewed publication but a generic “position statement” in the form of a newsletter that was meant to warn its members to reduce their exposure to the damaging effects of UV, with a focus on the sun (and tanning booths). It was not meant, nor did it infer, that UVC does not damage skin, nor did it suggest in any way that selected UVC wavelengths induced differing biological effects from any others. Mr. Lawal relies upon a single sentence stating: “UVC, used in germicidal lamps, causes almost no damage because of its low penetration of the skin.” Ex. 1012 at ¶ 2. But the POSITA would not have relied upon that publication as support for the safety of 222 nm wavelengths on skin. HPS’s statement was certainly sensational for its time, reflecting a poor understanding of the broadband definition and nature of UVC and the biophysical consequences of UVC exposures.

62. Mr. Lawal’s reliance on the HPS newsletter also contradicts his prior acknowledgements regarding UVC damage potential in his declaration at, for example, paragraph 49 (“UV light at 254 nm was generally known to be harmful to

organic tissue, such as skin”). Like Jenkins, HPS’s statement is an obvious logical fallacy and a potentially dangerous oversight; this would be apparent to a POSITA, both then and now. Indeed, HPS provided no context or leads to technical authority in this context and is not credible in the eyes of a POSITA, then or now. Indeed, a search on Google Scholar reveals that in 25 years since its publication, it has only been cited a total of 5 times and only 3 unique times. Ex. 2030.⁵

63. Regarding Cumbie, Mr. Lawal plucks one statement that “[m]any other sources indicate that UVC cannot penetrate the skin or can do so only to a very limited depth.” Ex. 1013 at ¶ [008]. This is an excerpt and paraphrase of HPS (Ex. 1012) that, itself, presents an unsubstantiated (and dangerous) statement about UVC exposure. As articulated above, HPS is a newsletter, was not quantitative, and did not suggest to isolate 222 nm from other UVC, and has no reasonable or customary scientific support.

64. Cumbie also incorrectly recites the United Nation INTERSUN project (2003), which actually confirms that UVC (254 nm) does penetrate human skin and warns of the associated human health risk in an epidemiological context. *See* Ex. 2024, Health and Environmental Effects of Ultraviolet Radiation – A summary of environmental Health Criteria 160 Ultraviolet Radiation (1995). With respect to

⁵

https://scholar.google.com/scholar?cites=2256663173338736309&as_sdt=5,44&sciodt=0,44&hl=en

skin cancer, the report clearly states that “the effectiveness of UVC is unknown except for one wavelength (254 nm).” *Id.* at 10. Thus, a POSITA reading this UN report would understand that the potential effects of 222 nm exposure, either alone or in combination with 254 nm on skin, was not well understood at the time.

65. Mr. Lawal’s uses circular citations between HPS and Cumbie and, like his reliance on INTERSUN, these sources have nothing to do with the isolation of 222 nm as somehow being safer for skin and eyes than other wavelengths. Accordingly, the POSITA would not have understood the “effectiveness and relative safety” of using 222 nm wavelengths on bare skin based on these disclosures in HPS and Cumbie.

66. In summary, contrary to Mr. Lawal’s opinion, there was no published, peer-reviewed literature or data showing that the POSITA would have understood the “effectiveness and relative safety” of using 222 nm to safely disinfect skin. Mr. Lawal cannot even support his limited opinions based on relative terms. In fact, all of the literature and general understanding at the time of the invention directed against using *any* wavelength in the UV-C band with *any* degree of safety.

B. Occupational guidelines for UV light would have not motivated the POSITA to shine 222 nm light on bare skin.

67. Mr. Lawal states that “the Health Physics Society was not alone in its assessment, as guidelines from this period and early [sic] show that UVC light was even accepted for general occupational use at low dosages.” Ex. 1003 at ¶ 97. Mr.

Lawal is applying the guidelines as a license or incentive to use UV light, whereas the POSITA would have not seen occupational exposure guidelines as generally promoting UVC skin exposure, regardless of wavelength, but just the opposite: a warning to use PPE carefully to limit UVC exposure, and otherwise stay away.

68. Because of this well-known damage caused by 254 nm wavelengths, peer-reviewed literature and associated regulatory frameworks presented strict exposure guidelines to formative UVC exposures of the skin and eyes. *See* Ex. 1006, National Institute for Occupational Safety and Health, “A Recommendation Standard for Occupational Exposure to Ultraviolet Radiation” (1992) (“NIOSH”). NIOSH would not have provided any motivation to combine Eckhardt and Sosnin to shine 222 nm light on bare skin, for at least the following three reasons.

69. First, and as Mr. Lawal admits, anyone looking at the NIOSH guidelines would be trying to figure out the *least* amount of exposure of light permissible for specialized workers. *See* Ex. 1003 at ¶ 98. The introductory section of this regulatory document conservatively addresses uncertainty stating these exposure criteria are compiled in “recognition of the limited use of present measuring devices and the need for use of work practices and protective clothing and goggles.” Ex. 1006 at 1. Thus, a POSITA would recognize the regulatory criteria here as conservatively limited to occupational exposure contexts (with PPE), which was used at the time of the invention of the ‘951 Patent and still used today. This is

consistent with the general knowledge at the time (and still today) that UV light causes damage to human skin and eyes. For this reason alone, the POSITA would not have read NIOSH as a motivating factor to use UV light on bare skin.

70. Second, even if the POSITA was considering the use of UV light on bare skin (she would not have been), the POSITA would have recognized the uncertainties surrounding the data presented by NIOSH. NIOSH shows a table of UV light, but this table reflects what little was known as of 1992 (and expressly relying on Threshold Limit Values from 1972) when it was published about UV light sources other than those producing 254 nm wavelengths. For example, wavelengths are identified in whole numbers (200, 210, 220, 230, etc.). In fact, the only wavelength specifically identified on this table was 254 nm, which is produced by a mercury lamp. Mr. Lawal points to the disclosure of “220 nm” (which inexplicably appears twice) but there is no known light source that produces wavelengths of 220 nm—other than tuned lasers—which were not available at that time. By 2005, the POSITA would have recognized that NIOSH and its recommendations from decades earlier were highly uncertain, especially for any data other than 254 nm.

71. Third, NIOSH presents the recommended UV(C) exposure standards based on the 1972 ACGIH Threshold Limit Values, acknowledging they are highly non-linear (figure I-1). Because of these uncertainties, NIOSH chose 270 nm as the benchmark (1.0) for relative spectral effectiveness. In other words, every other value

is compared to 270 nm. Comparatively, the chart reflects that wavelengths of “220 nm” have a spectral effectiveness of only “0.12”—a mere fraction of the effectiveness at 270 nm. So if the POSITA was motivated to use these guidelines for anything, it is more likely she would have been motivated to use exposure systems near the spectral effectiveness benchmark (1.0 at 270 nm), where (i) the most exposure response data were available at the time, and (ii) where uncertainties associated with co-exposures to other UVC wavelengths were minimized.

72. Mr. Lawal next relies upon another reference from 1994 about sunburn (i.e., erythema). Ex. 1007, “Health and Environmental Effects of Ultraviolet Radiation – A summary of Environmental Health Criteria 160 Ultraviolet Radiation,” 1995 (“WHO”). Mr. Lawal points to a graphic purportedly showing that UVC penetrates into skin less than each of UVA and UVB waves. The “UVC” portion of the graphic, however, is specifically limited to 254 nm. That is consistent with the limited knowledge of a POSITA about UVC in 1995, but it does not explain anything about the penetration of 222 nm. That is especially true because sunlight (the focus of WHO) does not include 222 nm wavelengths, which is filtered by the ozone layer.

73. Mr. Lawal focuses on the action spectrum reported by WHO, reproduced below, and accurately states that it is a “composite curve.” *See* Ex. 1003 ¶¶ 104-06. While a POSITA would recognize the action spectra of two independent erythematic curves, she would also immediately recognize the robust statistical nature, but only where the curves overlap: the entire range below 245 nm, corresponding to the lower end of the CE curve, shown in yellow below.

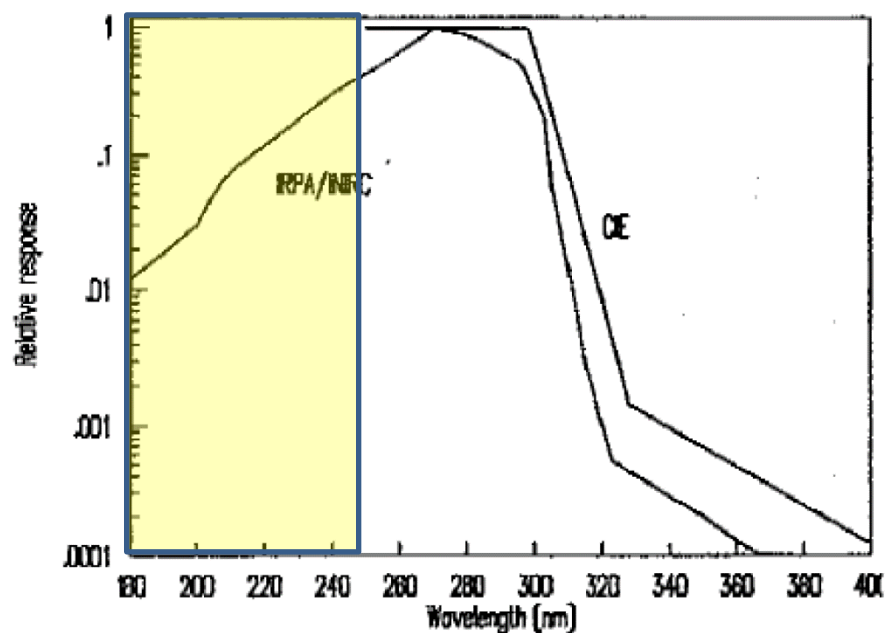


Figure 2: Action spectrum for erythema

74. A POSITA would also recognize that subjective qualitative visual endpoints of skin reddening (onset of erythema), are not representative of the range of chronic biological damage different skin types realize from UVC exposures. Indeed, a POSITA would rely on quantitative epidemiological endpoints for designing UV exposures at the time. Accordingly, I disagree with Mr. Lawal’s conclusion—drawn from Figure 2 of WHO—that a POSITA would understand that

222 nm showed a 10-fold improvement over 260 nm, or that the “barely noticeable reddening” of skin would be the relevant clinical endpoint to the POSITA.

75. At bottom, Mr. Lawal relies upon NIOSH and WHO to argue that the “POSITA would have understood from these documents that 222 nm light was already considered to be relatively safer than the 254 nm light[.]” Ex. 1003 at ¶ 109. This is not possible, because neither NIOSH nor WHO credibly provided any data about 222 nm wavelengths at all, so there is nothing to compare. These publications merely highlight the fact that the POSITA was not thinking about using UVC to disinfect skin, let alone 222 nm wavelengths specifically.

C. The POSITA would not have believed that 222 nm light was effective at low dosages, especially based on data from other light sources.

76. Mr. Lawal further asserts that a “POSITA would have understood from [NIOSH and WHO] that 222 nm light was an effective surface disinfectant at or below the levels that were considered comparatively safe for human exposure.” Ex. 1003 at ¶ 109. This summary is not supported by any reference or citation, nor is it an accurate reflection of what the POSITA would have understood at the time.

77. Relatedly, Mr. Lawal asserts that “[i]t was known in the art that UV Dose values considerably lower than 150-2000 mJ/cm² were known to disinfect effectively.” *Id.* at ¶ 107. This is obviously incorrect. To support this generic assertion that is agnostic as to wavelength, Mr. Lawal relies upon Eckhardt and

Sosnin, along with two patents, Sizer (Ex. 1036) and Johnson (Ex. 1015). Critically, none of these publications present any data that would motivate or otherwise lead a POSITA to apply 222 nm UV light for the disinfection of skin at any dosage, because these attempts were applied in reconnaissance of potential acute microbial infection response on inanimate, cold, surfaces (i.e., agar, glass, etc.).

78. First, Mr. Lawal relies on Eckhardt's disclosure of a "sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm² of UVC." Ex. 1004, ¶¶ 32, 43. That statement, of course, was the energy of a "single flash," where the only flash light source of Eckhardt was a "xenon flash lamp" that is undisputedly not producing photons at 222 nm. As shown above (Section VI.A.), and conceded by Mr. Lawal (Ex. 1003 at 83), Eckhardt "does not explicitly state generating 222 nm wavelength photons, specifically." Eckhardt, therefore, does nothing to support Mr. Lawal's assertion that the POSITA would know that 222 nm is effective to disinfect at low dosages. A POSITA would also purposely not elect 222 nm based on the fact that it cannot be applied in a pulsed scenario.

79. Second, Mr. Lawal points to Sosnin's disclosure that UV Doses of ~40-260 mJ/cm² were highly effective at inactivating *E. coli*. Ex. 1005 at 319-321. While this may be true, *E. coli* is an enteric bacterium that a POSITA would not have used as an example to suggest that 222 was effective against other pathogenic microorganisms and certainly not on skin (*E. coli* is associated with mammalian

feces) based on that data alone. A POSITA also would recognize that *E. coli* were much more sensitive to UVC considering other microbial exposure models at the time. More importantly, Sosnin's tests were performed in a petri dish using porous gelatin infused with beef meat wastes. Under no condition would Sosnin's results indicate to a POSITA this could be logically extended to a microbial disinfection response on the skin and that any associated 222 nm exposure would not damage skin. The POSITA would not have been able to even consider effectiveness without considering the impact of safety on skin in tandem.

80. Third, Sizer does not speak to the effectiveness (or safety) of using 222 nm light on skin at any dosage; indeed, Sizer does the express opposite and combines 222 nm with chemicals for synergistic effect on non-biological materials. Sizer involved the use of a hydrogen peroxide-UV light combination treatment on packaging material, which is readily distinguishable from the '951 Patent claims. *See* Ex. 1036 at Example 1. Mr. Lawal points to Table 3, which reports increasing doses of UV in combination with peroxide. Sizer shows the use of low UV dosages to predictably activate peroxide into a more potent disinfectant (hydroxyl radical), but the POSITA would know that these highly reactive radicals should never be in contact with human tissues. There is no way to isolate the UV dose/response from the data; nor would a POSITA be motivated to apply this technique to skin alone or in combination.

81. Fourth, Johnson also says nothing about the effectiveness of 222 nm UV light at low dosages. To the contrary, Johnson uses higher UV-C intensities with shorter durations in an open wound site (< 1 minute for bacteria and < 146 seconds for fungi). *See* Ex. 1015 at Tables 1-5. Johnson uses a 254 nm lamp and the lowest UVC bandwidth disclosed is 240 nm, which is *not* within the Far UVC (207-222 nm) range specified by the '951 Patent. This disclosure would not have taught the POSITA anything about the effectiveness of a low dose of 222 nm UV.

82. In summary, it is impossible to separate the effectiveness of a UV dose of 222 nm photons for disinfection of skin without also simultaneously considering the safety (or lack thereof) of doing so. Mr. Lawal's attempt to separate the two only shows that he fails to appreciate what the POSITA would have known and understood about UV disinfection as of the time of the '951 Patent. Mr. Lawal presents no data to support the effectiveness or relative safety of 222 nm on skin, alone or collectively, and the POSITA would not have agreed with his assertions.

D. The record shows that 222 nm light is still being researched today.

83. As indicated above, even twenty years after the claimed invention, academic researchers are still investigating how UV wavelength at or near 222 nm can concurrently inactivate local air- and surface-borne bacteria and viruses without causing damage to human or animal skin. Yet this research comes more than a decade after Mr. Neister's claimed method for doing just that. Established

researchers in the field have only recently presented enough collective evidence that 222 nm UV light can be delivered indoors as an effective disinfect while presenting acceptable levels of dermal and ocular health risk. *See, e.g.*, Ex. 2014, Buonanno et al.; Ex. 2025, Narita et al. (2018); Ex. 2002, Ma, et al. (2021); Ex. 2026, Welch et al. (2021).

84. And the very guidelines upon which Mr. Lawal and Petitioners rely demonstrate that the relative safety of 222 nm UV light has only been recently confirmed. For example, the ACGIH Threshold Limit Value (TLV) has remained at $0.2 \mu\text{W}/\text{cm}^2$ ($6 \text{ mJ}/\text{cm}^2$ averaged over 8 an hour exposure period) since 1972. Ex. 1006 [NIOSH] at Table I-1. It was not until *December 30, 2021*, that the ACGIH specifically *increased* the Threshold Limit Values specifically for the amount of UVC exposure at 222 nm. *See* Ex. 2003, IUVA Article at 20. In 2021, the thresholds increased from the previous value of $23 \text{ mJ}/\text{cm}^2$ to $161 \text{ mJ}/\text{cm}^2$ for eyes; and from $25 \text{ mJ}/\text{cm}^2$ to $479 \text{ mJ}/\text{cm}^2$ for skin—an increase of about 7 times concerning skin and over 20 times concerning eyes—over that previously published by the ACGIH. *Compare* Ex. 2027 at I-1; *with* Ex. 2003 at 20.

85. Thus, peer-reviewed literature and the history of regulations both confirm that relative safety of skin and eye exposure to 222 nm was not well understood by the photochemistry community until well after the ‘951 Patent was

awarded, and only recently recognized as being less harmful than previously thought for use in the presence of human skin and eyes.

VIII. THE PRIOR ART DOES NOT TEACH OR SUGGEST THE ADDITIONAL LIMITATIONS OF THE DEPENDENT CLAIMS.

86. I further understand that Petitioners challenge the patentability of dependent claims 2-5 and 7-18. It is my opinion that the combination of Eckhardt and Sosnin does not render any of these claims unpatentable. I address certain of the dependent claims below and reserve my right to set forth additional opinions if the Board institutes review.

A. Claim 2

87. I understand that claim 2 depends from claim 1 and further recites “wherein the human or animal tissue is one of blood, an organ, or a wound.”

88. 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.

B. Claim 3

89. I understand that 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.

C. Claim 4

90. I understand that claim 4 depends from claim 1 and further recites “wherein the step of directing is performed for approximately two seconds.” Neither Eckhardt nor Sonsin 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.

91. 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.

92. 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. I disagree. 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.

93. 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.

D. Claim 5

94. I understand that 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.”

95. Petitioners do not appear to argue that Sosnin discloses a wand, and I agree it does not. Petitioners argue, however, that Eckhardt discloses a wand (or some equivalent) because it describes a “hand held lamp.” Petition at 40. I disagree. 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.

E. Claim 8

96. 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 disinfect skin." Petition at 42. I disagree. 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 pure conjecture.

F. Claims 10 and 11

97. I understand that 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/cm² to the substance or surface to be disinfected." I further understand that 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/cm² 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/cm²) of 222 nm photons "simply by changing the exposure time." Petition at 44. Neither Eckhardt nor Sosnin, individual or in combination, suggest cumulative effective 222 nm dosing for skin-associated microbes; they reference only inactivation in/on microbial media (or aqueous environments).

98. 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/cm² of UVC.” *See id.* at ¶ 32. The only other energy intensity disclosed for the xenon flash lamp embodiment in Eckhardt is “about 20 mJ/cm².” *See id.* at ¶¶ 43, 104. And the POSITA would have understood that higher doses of UV radiation were not desirable because of harmful exposure.

99. As explained above, the POSITA would not have combined Eckhardt with Sosnin to arrive at the claimed invention. Sosnin describes laboratory tests of irradiation of two kinds of bacteria in petri dishes. These tests were designed to demonstrate sterilization of glassware, not skin, and gave no indication whatsoever that the excilamps of the study could be used on human skin. And even if the POSITA found Sosnin, she would have selected the XeBr lamp described as having the “best” characteristics and effectiveness for disinfection, reported by Sosnin—not the KrCl lamp chosen with hindsight by Mr. Lawal and Petitioners.

100. Even assuming it was possible the POSITA would have looked to Sosnin's teachings for anything (she would not), she would not believe that the "instantaneous sterilization or disinfection unit" could be used with a 222 nm light source instead of the xenon flash Lamp described by Eckhardt. That is because 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.

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.*

G. Claims 12-18

102. I understand that claim 12 depends from claim 1 and further recites “wherein the human or animal tissue is skin.” I further understand that Claim 13 depends from claim 1 and further recites “wherein the human or animal tissue is human tissue.” I further understand that claim 14 depends from claim 1 and further recites “wherein the human or animal tissue is human skin.” And I understand that claim 15 depends from claim 1 and further recites “wherein the human or animal tissue is tissue of a living animal.” I understand that claim 16 depends from claim 1 and further recites “wherein the human or animal tissue is tissue of a living human.” And I understand that claim 17 depends from claim 1 and further recites “wherein the human or animal tissue is skin of a living human.” Additionally, I understand that claim 18 depends from claim 1 and further recites “wherein the human or animal tissue is skin of a living animal.”

103. For the reasons articulated above in Section VII, it is my opinion that a POSITA would not read Eckhardt or Sonsin 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. My opinions are the same, regardless if the tissue is skin.

I reserve the right to change my opinions in this report if Petitioners or Mr. Lawal modifies their opinions. Without waving those reservations, I have preliminarily reached the conclusions and opinions in this declaration based on the analysis I have made and for the reasons set forth above.

June 26, 2023

Mark Hernandez
PhD PE

Digitally signed by Mark
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Date: 2023.06.26 17:22:10
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Mark T Hernandez
Mark T. Hernandez, PhD, PE