

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: S. Edward Neister
U.S. Patent No.: 11,246,951 Attorney Docket No. 00012-0216IP1
Issue Date: February 15, 2022
Appl. Serial No.: 15/645,480
Filing Date: July 10, 2017
Title: METHOD AND APPARATUS FOR STERILIZING AND
DISINFECTING AIR AND SURFACES AND PROTECTING A
ZONE FROM EXTERNAL MICROBIAL CONTAMINATION

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**PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT
NO. 11,246,951 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42**

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EXHIBIT LIST

Exhibit	Description
1001	U.S. Patent No. 11,246,951
1002	Prosecution History of U.S. Patent No. 11,246,951
1003	Declaration and Curriculum Vitae of Oliver R. Lawal
1004	U.S. Patent Publication No. 2003/0031586 to Eckhardt et al. (“Eckhardt”)
1005	Sosnin et al., <i>New bactericidal UV light sources: excilamps</i> , PROC. SPIE 5483, Atomic and Molecular Pulsed Lasers V, (3 May 2004)
1006	National Institute for Occupational Safety and Health, “A Recommended Standard for Occupational Exposure to Ultraviolet Radiation” (1992).
1007	Health and Environmental Effects of Ultraviolet Radiation: A Summary of Environmental Health Criteria 160 Ultraviolet Radiation (1995)
1008	U.S. Provisional App. No. 60/593,626
1009	PCT App. No. PCT/US2006/003393
1010	Declaration and Curriculum Vitae of June Ann Munford
1011	U.S. Patent Publication No. 2002/0146343 to Jenkins et al.
1012	HEALTH PHYSICS SOC’Y, <i>Ultraviolet Radiation and Public Health</i> , POSITION STATEMENT OF THE HEALTH PHYSICS SOC’Y (July 1998), https://web.archive.org/web/20000601171859/http://hps.org/documents/ultravioletradiation.pdf
1013	U.S. Patent Publication No. 2003/0153962 to Cumbie
1014	Int’l Publication No. WO87/02256 to Wilkinson
1015	U.S. Patent No. 6,283,986 to Johnson
1016	U.S. Patent No. 6,254,625 to Rosenthal et al.
1017	Thai et al., <i>Ultraviolet Light C in the Treatment of Chronic Wounds with MRSA: A Case Study</i> , 48 OSTOMY WOUND MGMT., no. 11, at 52–60 (Nov. 2002)
1018	U.S. Patent No. 5,364,645 to Lagunas-Solar et al.
1019	U.S. Patent Publication No. 2005/0079096 to Brown-Skrobot et al.
1020	Kogelschatz et al., <i>High-intensity sources of incoherent UV and VUV excimer radiation for low-temperature materials processing</i> , 168 APPLIED SURFACE SCI., May–June 2000, at 29
1021	HARVEY LODISH ET AL., MOLECULAR CELL BIOLOGY 651 (Sara Tenney et al. eds., 4th ed. 2001)

1022	James R. Bolton and Karl G. Linden, <i>Standardization of Methods for Fluence (UV Dose) Determination in Bench-Scale UV Experiments</i> , 129 J. OF ENV'T ENG'G 209 (March 2003)
1023	U.S. Patent No. 5,572,091 to Langer et al.
1024	U.S. Patent Publication No. 2005/0173652 to Ressler
1025	K982082, 510(K) SUMMARY: DERMA-WAND, NAT'L BIOLOGICAL CORP. (Oct. 28, 1998), https://www.accessdata.fda.gov/cdrh_docs/pdf/K982082.pdf
1026	Prosecution History of U.S. Patent No. 9,700,642
1027	Second Amended Complaint for Patent Infringement, <i>High Energy Ozone LLC et al. v. Larson Electronics LLC</i> , Case No. 3:21-cv-01166, Dkt. No. 67 (N.D. Tex. March 9, 2022)
1028	First Amended Complaint for Patent Infringement, <i>High Energy Ozone LLC et al. v. Eden Park Illumination, Inc.</i> , Case No. 3:22-cv-00425, Dkt. No. 50 (N.D. Tex. March 25, 2022)
1029	Second Amended Complaint for Patent Infringement, <i>High Energy Ozone LLC et al. v. Far UV Technologies</i> , Case No. 3:22-cv-00280, Dkt. No. 52 (N.D. Tex. March 25, 2022)
1030	"SPIE Conference Proceedings" website printout of https://spie.org/publications/conference-proceedings?SSO=1 (last accessed March 6, 2023)
1031	"About SPIE" website printout of https://spie.org/about-spie (last accessed March 6, 2023)
1032	Ian A. Ramsay et al., <i>The Synergistic Effect of Excimer and Low-Pressure Mercury Lamps on the Disinfection of Flowing Water</i> , 63 J. FOOD PROT. 1529 (2000)
1033	<i>Memorandum: Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation</i> (June 21, 2022) ("Director's Memo")
1034	Order Granting Joint Motion to Consolidate Related Actions for Pretrial, <i>High Energy Ozone LLC et al. v. Larson Electronics LLC</i> , Case No. 3:21-cv-01166, Dkt. No. 63 (N.D. Tex. March 8, 2022)
1035	Order Granting Joint Motion for Stay, <i>High Energy Ozone LLC et al. v. Larson Electronics LLC</i> , Case No. 3:21-cv-01166, Dkt. No. 77 (N.D. Tex. April 13, 2022)
1036	U.S. Patent No. 5,843,374 to Sizer et al.
1037	Sosnin et al., <i>The Effects of UV Irradiation and Gas Plasma Treatment on Living Mammalian Cells and Bacteria: A Comparative</i>

	<i>Approach</i> , 32 IEEE TRANSACTIONS ON PLASMA SCI. 1544 (Aug. 2004) (“Sosnin IEEE”)
1038	Clauß, M., Mannesmann, R. and Kolch, A., Photoreactivation of Escherichia coli and Yersinia enterocolitica after Irradiation with a 222 nm Excimer Lamp Compared to a 254 nm Low-pressure Mercury Lamp, 33 ACTA HYDROCHIMICA ET HYDROBIOLOGICA 579 (Dec. 2005)
1039	Von Sonntag, <i>Disinfection by free radicals and UV-radiation</i> , 4 WATER SUPPLY 11 (1986)
1040	Frederick L. Gates, <i>A study of the bactericidal action of ultra violet light. III. The absorption of ultra violet light by bacteria</i> , 14 J. GEN. PHYSIOLOGY 31 (1930)

I. INTRODUCTION

Eden Park Illumination, Inc., Larson Electronics LLC, Far UV Technologies, Inc., and Ushio America, Inc. (“Petitioners”) hereby petition for *inter partes* review (“IPR”) of claims 1-5 and 7-18 (the “challenged claims”) of U.S. Patent No. 11,246,951 (“the ’951 Patent,” EX1001), issued and assigned to S. Edward Neister (“Patent Owner”).

The invention of the ’951 Patent is not new. Rather, the claimed invention encompasses known methods of disinfecting substances and surfaces, including human or animal tissue, using ultraviolet (“UV”) light of particular wavelengths. The challenged claims of the ’951 Patent describe the invention as using UV technology and disinfection methods that were well-known in the prior art.

For the reasons set forth herein, Petitioners seek a final written decision that the challenged claims of the ’951 Patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. The Petitioners’ asserted ground for unpatentability and a comparison of the prior art to the challenged claims follows below. Evidentiary support for Petitioners’ conclusions is provided in the Declaration of Oliver Lawal. (See EX1003.) Mr. Lawal is an expert with over 20 years of experience in the areas of UV technology and applications of UV technology to disinfect substances and surfaces. Mr. Lawal’s declaration establishes that each of the challenged claims is rendered obvious in view of the prior art and confirms all of Petitioners’

assertions of unpatentability.

In summary, Eckhardt in view of Sosnin renders the challenged claims unpatentable as obvious under 35 U.S.C. § 103. (*See* EX1003 at ¶¶ 80-166.) Petitioners respectfully request IPR of the challenged claims.

II. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Grounds for Standing under 37 C.F.R. § 42.104(a)

Petitioners certify that the '951 Patent is available for IPR. Petitioners are not barred or estopped from requesting review. The Petitioners that are defendants in district court litigation were each served with a complaint of infringement of the '951 Patent less than one year prior to the filing of this Petition. (*See* EX1027 (complaint filed March 9, 2022); EX1028 (complaint filed March 25, 2022); EX1029 (complaint filed March 25, 2022).)¹

B. Challenge under 37 C.F.R. § 42.104(b) and Relief Requested

Petitioners request IPR of the challenged claims on the grounds set forth in the table shown below and a final written decision that each of the challenged claims are unpatentable as obvious under 35 U.S.C. § 103(a) based on the following ground and as established by the declaration of Oliver Lawal (EX1003):

¹ Petitioner Ushio America, Inc. ("Ushio") is not involved in litigation of the '951 Patent.

Ground	'951 Patent Claims	Asserted Prior Art
Ground 1	1-5, 7-18	§ 103 over Eckhardt in view of Sosnin and the knowledge of a POSITA

1. Effective Priority Date

The '951 Patent, titled “Method and Apparatus for Sterilizing and Disinfecting Air and Surfaces and Protecting a Zone from External Microbial Contamination,” issued from U.S. Patent App. No. 15/645,480, filed July 10, 2017. It is a continuation in-part that claims benefit to U.S. Patent App. No. 14/254,957 filed April 17, 2014, which is a continuation in-part of U.S. Patent App. No. 11/831,667, filed on July 31, 2007, which is a continuation in-part of PCT App. No. PCT/US06/03393, filed on January 31, 2006, which is a non-provisional application of U.S. Provisional App. No. 60/593,626, filed on January 31, 2005. (See EX1001, Cover.)

There is no presumption that a patent is entitled to an earlier effective filing date, rather, the “patentee bears the burden of establishing that its claimed invention is entitled to an earlier priority date than an asserted prior art reference.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375-76 (Fed. Cir. 2016). For the reasons discussed below, the claims of the '951 Patent are not entitled to claim priority back to the earlier applications.

(a) **Challenged claims are not supported by the provisional application**

The challenged claims are not supported under 35 U.S.C. § 112 by at least U.S. Provisional App. No. 60/593,626, because the '626 application does not disclose “wherein the substance or surface to be disinfected is human or animal tissue.” (EX1003, ¶¶ 77-78; *Compare* EX1001, cls. 1-5, 7-18 *with* EX1008.) The challenged claims are therefore not entitled to an effective filing date earlier than January 31, 2006.

During prosecution of the '951 Patent's parent application, when the applicant first claimed “support for skin disinfection” the applicant cited to only three lines of the provisional specification, which recite: “The apparatus of this invention is capable of irradiating food stuffs in conveyor assemblies, stationary carts and in handling routes during the movement from storage to food preparation processes.” (EX1026, 7 (citing EX1008, 18 (page 12 lines 12-14).) Disclosing disinfecting “food stuffs” does not disclose disinfecting human or animal skin or tissue. (EX1003, ¶ 77.)

The applicant first mentioned disinfecting skin in the specification of the PCT application, in a single statement: “Testing will determine the correct exposure limits to prevent any harmful effects that could occur when used to disinfect human skin, hands, animal surfaces such as skin, fur, and hair, [etc.]”

(EX1009, 27.) The applicant did not provide any more detail, however, until it added new matter during prosecution of U.S. Patent App. No. 14/254,957, the application to which the '951 Patent claims immediate priority. Here, the applicant added three full paragraphs with a suggestion for how the claimed method may be useful for disinfecting skin. (*See*, EX1026, 37; *see also id.*, 36-37.) Further, the applicant provided even more detail when it added new matter during prosecution of the application that resulted in the '951 Patent. Here, the applicant added **forty new paragraphs** disclosing disinfecting skin or tissue. (*See* EX1002, 977, 982-984, 990-994.)

Additionally, to the extent the “food stuffs” recited in the provisional application could be understood to read on “animal tissue,” this oblique disclosure does not provide written description support for the full claim limitation. Because the claim recites “human *or* animal skin,” the specification must support disinfecting human skin, but does not. *See Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1322, 1332-34 (Fed. Cir. 2008) (affirming invalidity for lack of written description for claim directed to “coupling said video type signal through a capacitor *or other circuit*,” where original specification did not disclose or support “through...other circuit”); *see also PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1309-11 (Fed. Cir. 2008) (affirming summary judgment of anticipation over intervening art where written description support was limited to new matter

added in a continuation-in-part application). Although dependent claims 12-18 further restrict “human or animal tissue” to one of the embodiments, they are directed to the tissue of either a human or a living animal. As explained above, the provisional application does not disclose disinfecting human tissue or living animal tissue. (EX1003, ¶ 78.)

Although Petitioners further contend these claims are not entitled to a priority date earlier than April 17, 2014, and subject to post-AIA 35 U.S.C. § 102,² the Board need not resolve that contention here. The sole ground challenging claims 1-5 and 7-18 relies on prior art published more than one year prior to January 31, 2006, and are therefore prior art under pre-AIA § 102(b) and post-AIA § 102(a).

(b) **Examiner Comment Does Not Substitute for
Priority Analysis**

In the notice of allowance of the '951 Patent, the Examiner mentioned the

² See, e.g., Fed. Reg., Vol. 78, No. 31 at 11043 Resp. to Cmt. 26, Feb. 14, 2013 (“If an application on filing contains at least one claim having an effective filing date before March 16, 2013, and at least one claim having an effective filing date on or after March 16, 2013, the application will be examined under AIA even if the latter claims are cancelled.”).

priority date of the application in passing, as she corrected the statutory basis for a rejection she had made, stating:

[T]he primary reason for allowance of the claims is due to filing and acceptance of the declaration under 37 C.F.R. 1.131 on 9/09/2021 which overcomes the prior art rejection (incorrectly indicated to be under 35 U.S.C. 102(a)(1) in the Office Action mailed 6/10/2021, but is more appropriate and correct under 35 U.S.C. 102(e) ***as the priority goes back to the provisional appl. no. 60/593,626 filed 1/31/2005***) in view of Ressler (20050173652).³

(EX1002 at 13.)

To the extent Patent Owner attempts to rely on this statement to argue that the Patent Office has somehow made a determination of priority, such argument fails. “Patent claims are awarded priority on a claim-by-claim basis based on the disclosure in the priority applications.” *Lucent Techs., Inc. v. Gateway, Inc.*, 543 F.3d 710, 718 (Fed. Cir. 2008). The Examiner did not purport to perform a priority analysis, either “claim-by-claim” or otherwise. Additionally, the Examiner’s statement is contradicted by her own earlier statement in an earlier notice of allowance, noting that a particular disclosure was not prior art because it was “not prior to the effective filing date of the claimed invention (7/31/2007).” (EX1002 at 349.) Thus, these statements are ambiguous at best, and do not provide a clear or reliable priority determination.

³ All emphasis added unless otherwise noted.

Further, presumption of priority does not attach to provisional applications or claims in a continuation-in-part patent. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1380 (Fed. Cir. 2015) (“[B]ecause the PTO does not examine provisional applications as a matter of course[,], such a presumption is...not justified” for patents seeking benefit of a provisional application); *PowerOasis*, 522 F.3d at 1305 (“When neither the PTO nor the [BPAI] has previously considered priority, there is...no reason to presume that claims in a CIP application are entitled to the effective filing date of an earlier filed application,” noting also that “[s]ince the PTO did not make a determination regarding priority, there is no finding for the district court to defer to.”).

Thus, the Examiner’s parenthetical comment is not a priority analysis and cannot satisfy Patent Owner’s burden to prove that its claims have written description support in the earlier applications. For the reasons explained above, even if this purported to be priority analysis, the Examiner clearly erred.

2. Public Availability and Prior Art Status

Eckhardt (EX1004)

Eckhardt (EX1004) is a published U.S. patent application titled “Method and Apparatus for Sterilizing or Disinfecting a Region through a Bandage,” and was filed on June 18, 2002, and published on February 13, 2003. Eckhardt was published more than one year prior to January 31, 2006, the earliest effective

priority date of the '951 Patent. Eckhardt is prior art under at least pre-AIA § 102(b) and post-AIA § 102(a)(1).

Sosnin (EX1005)

Sosnin (EX1005) is a printed publication titled “New bactericidal UV light sources: excilamps.” Sosnin was published in Volume 5483 of *Proceedings of SPIE* no later than May 2004. (EX1010, ¶¶ 28-31.) SPIE is the international society for optics and photonics established in 1955. SPIE publishes original research papers presented at SPIE conferences two to four weeks after the conference. (EX1030.) *Proceedings of SPIE* “offer access to the latest innovations in research and technology and are among the most cited references in patent literature.” (*Id.*) SPIE was well-known at the time as a professional association and major publisher of journals and conference proceedings in a variety of fields. (EX1031.) Cataloging dates extracted from library catalog records further corroborate the May 2004 public availability of Sosnin. (EX1010, ¶¶ 28-31.) This is supported by indicia in Sosnin, which shows that this research was presented at the “Atomic and Molecular Pulsed Lasers V” conference in 2003 in Tomsk, Russia. (EX1005, cover.) It bears a specific publication date of “3 May 2004” and “doi: 10.1117/12.563017.” (*See id.*; *see also* EX1010, ¶ 31 (discussing the library processing stamp).) Sosnin was published more than one year prior to January 31, 2006, the earliest effective priority date of the '951 Patent, and is prior

art under at least pre-AIA §§ 102(a), (b) and post-AIA § 102(a)(1).

III. THE '951 PATENT

A. Overview

The '951 Patent is directed to using UV light for “disinfecting and sterilizing” surfaces and substances, including human or animal skin.⁴ (EX1001, Abstract.) The '951 Patent specifically discloses disinfecting and sterilizing using a “new ultra-violet” source using “commercially available” “UV emitting lamps based on the excitation of excimers.” (EX1001, 2:26-38.) The “preferred embodiment” “emits a highly intense narrow wavelength band of photons” at 222 nm. (*Id.*, 2:64-3:2.) Other embodiments emit photons at 282 nm or 254 nm. (*Id.*, 3:3-15.)

The applicant acknowledged that the general concept of using UV light for germicidal use was already well known at the time the '951 Patent was filed. (*See, e.g., id.*, 1:24-41.) He also acknowledged that researchers had discovered and documented this phenomenon decades before the applicant’s alleged invention. (*See, e.g., id.*, 3:64-4:5, 6-10 (citing Von Sonntag, *Disinfection by free radicals and UV-radiation*, 4 WATER SUPPLY, at 11-18 (1986) (EX1039) and Gates, F. L., *A*

⁴ “Skin” encompasses “tissue” and “organ,” as skin is both a tissue and an organ. (EX1003, ¶ 166; *see also* EX1007, 13; EX1004, [0031].)

study of the bactericidal action of ultra violet light, 14 J. GEN. PHYSIOLOGY, at 31–42 (1930) (EX1040)).⁵ Researchers had also previously discovered the natural law underlying this phenomenon: “the light absorption capability of [] different virus and bacteria at” particular wavelengths. (EX1001, 1:34-37.) It was well understood that absorption of UV light by chemical bonds is a function of the light’s wavelength, and that the particular “wavelength of the applied radiation [correlates] to [] the observed effects.” (*Id.*, 2:2-6.)

Despite these acknowledgements, the ’951 Patent makes several misleading statements about the state of the art of germicidal applications for UV radiation as of its filing. (See EX1003, ¶¶ 59-66.) First, the applicant notes that “[c]laims have been made that UV-C [‘280 nm to 235 nm’] radiation is used to alter the DNA.” (EX1001, 1:65-67, 2:7-8.) Researchers believed this was because the UV energy produces dimers in DNA, which prevents replication. (*Id.*, 3:30-41.) But the applicant suggested that “[n]one of these claims make reference to any shorter wavelengths and to the absorption band that peaks at 200 nm.” (*Id.*, 2:10-15.) This is misleading. (EX1003, ¶ 59.) Researchers were already well aware of the

⁵ EX1039 is a printed publication publicly available no later than 1986. (See EX1010, ¶¶ 22-24.) EX1040 is a printed publication publicly available no later than June 1975. (See EX1010, ¶¶ 25-27.)

effect of the shorter wavelengths of light in the far UV (“235 nm” to “185 nm”) spectrum. (EX1001, 1:67-2:2; EX1003, ¶¶ 59, 62; *see also* EX1001, 3:62-4:5, 4:6-10 (citing prior art).) The applicant even acknowledged that “[i]t has been fairly well established that the peptide bonds in protein molecules are responsible for the steep rise in absorption” below 240 nm. (EX1001, 4:41-54 (citing McLAREN, ET AL., *Photochemistry of Proteins and Nucleic Acids*, Pergamon Press, Macmillan Company (1964)).) He noted that “[a]n organic chemist suggests that this lower wavelength is more effective in breaking bonds and producing dimers...” (*Id.*, 4:50-54.)

Second, the applicant stated that “all literature directs researchers away from using any shorter wavelengths” than 254 nm for sterilization and disinfection. (EX1001, 2:15-18.) This, too, was misleading. (EX1003, ¶ 62.) Sosnin, for example, teaches using an excimer ultraviolet lamp for sterilizing surfaces by irradiating bacteria using wavelengths of 222 nm and 282 nm, and includes bacterial survival curves resulting from the irradiation with KrCl ($\lambda = 222$ nm) excilamps. (EX1005, 320-21 (Figs. 3-5; EX1003, ¶¶ 86-87.) Other researchers, like Eckhardt, were using UV light in a range as low as 220 nm for disinfecting the surface of skin. (EX1004, [0069-70].) What the applicant was describing was an observation based on selection bias rather than insight. The applicant acknowledged that mercury lamps emitting 254 nm were “the most widely

available UV-C radiation source,” and often used for the important application of wastewater treatment where lower UV wavelengths could not be used due to their absorption by water. (EX1001, 2:7-10; EX1003, ¶¶ 62-63.) The historical focus of the literature centered on using 254 nm because the convenience of obtaining, and important need for, lamps generating that specific wavelength. (EX1003, ¶ 62.) It was not a teaching away from using other UV wavelengths for other germicidal applications such as sanitizing or disinfecting other substances or surfaces. (*Id.*) The rising commercial availability of excimer lamps that predated the ’951 Patent, (EX1001, 2:26-28), was the trigger for more widespread employment of other wavelengths. (EX1003, ¶ 62.)

An overview of the technology and history of the evolution of UV germicidal irradiation equipment and applications is provided in Section VIII in Mr. Lawal’s Declaration. (EX1003, ¶¶ 27-49.)

B. The Challenged Claims

The ’951 Patent includes 18 claims, of which claim 1 is the sole independent claim.

Independent Claim 1 and its dependents are directed to a method for disinfection using 222 nm light, wherein the substance or surface to be disinfected is human or animal tissue.

C. Prosecution History

During the initial prosecution of the '951 Patent, no rejections issued over any prior art references; instead, the applicant overcame a handful of § 112 and obviousness-type double patenting rejections. (*See, e.g.*, EX1002, 400-410, 441-446.) The applicant overcame these rejections and a notice of allowance issued for claims using “at least one of 207nm, 222nm, 280nm, 282nm, and 308nm” “wherein the substance or surface to be disinfected is human or animal tissue.” (*Id.*, 343-351; *id.*, 388 (claims).) The applicant then filed a request for continued examination based on references in a new IDS form. (*Id.*, 331.) This IDS disclosed the patent that issued from Eckhardt⁶ and Sosnin,⁷ for the first time. (*See id.*, 334-335.) In the list of references considered by the Examiner, the Sosnin

⁶ The IDS disclosed U.S. Pat. No. 5,730,113, which issued on May 4, 2004.

(EX1002, 334.) The Examiner does not identify whether she considered the Eckhardt '113 patent to be §102(a), §102(b), or §102(e) art to the claims.

⁷ Two additional references by Sosnin were also disclosed on this IDS, (EX1002, 335), including 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 (Aug. 2004) (EX1037, “Sosnin IEEE”).

references are crossed off, indicating that she did not consider them. (*See id.*, 308.)

The Examiner issued new rejections based on other art in the IDS. Specifically, the Examiner rejected the independent claims each over primary references not at issue here, arguing that Coogan disclosed using a 282 nm wavelength.⁸ (*Id.*, 293.) The Eckhardt patent was cited only as a secondary reference for dependent claims 5 and 8, as it disclosed “provid[ing]/position[ing] a wand in a process for destroying a DNA or RNA of a microorganism,” and disinfecting a wound. (*See id.*, 294-295.)

In response the applicant cancelled the claims related to disinfecting wounds and amended the independent claims to remove the 282 nm wavelength. (*See id.*, 255-265.) The Examiner then rejected certain claims over a different primary reference, Sizer (EX1036), (*see* EX1002, 192-194), which disclosed using 222 nm light, but not the “human or animal tissue” limitation in claim 21, (*see id.*, 191 (claim 21 rejection depending on claim 1 rejection); *id.*, 256-257 (claim 21)).

The applicant amended the claims and incorporated the “human or animal tissue” language into independent claim 1, (*see id.*, 180-183), and the Examiner

⁸ The Examiner made additional rejections on claims that were cancelled; these claims include additional limitations not at issue in this proceeding and are therefore not discussed herein.

issued a second notice of allowance, (*id.*, 158-161). The applicant then filed another request for continued examination with a new IDS, this time disclosing the invalidity contentions and invalidity claim charts produced in an unrelated district court litigation. (*Id.*, 113-121.)

The Examiner rejected the claims over yet another primary reference, Ressler, (EX1024), which disclosed the use of a 222 nm light as well as disinfecting human or animal tissue, (*id.*, 88-91). The applicant antedated Ressler with a 37 C.F.R. 131 affidavit, (*id.*, 53-55, 66-76), and the claims were allowed on this basis, (*id.*, 13).

D. Level of Ordinary Skill

A person of ordinary skill in the art (“POSITA”) of the ’951 Patent would have had at least a bachelor’s degree in an engineering discipline such as biological, chemical, environmental, electrical, mechanical, and/or systems engineering, or an equivalent degree such as one in physics or similar subject matter. (EX1003, ¶ 21.) Such a person would also have two to three years of work or research experience with UV disinfection technology and/or systems and would be familiar with the fundamentals of UV excimer lamps. (*Id.*) However, less education could be compensated by more experience and vice versa. (*Id.*)

IV. CLAIM CONSTRUCTION

The analysis of Section V below addresses the interpretation of certain claim

terms with reference to the specific prior art references advanced in this Petition.

Beyond these arguments, the challenged claims require no express construction to evaluate their patentability. Petitioners reserve the right to respond to any claim constructions proposed by Patent Owner.

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE

This Petition shows how the primary references above, (*see supra*, Section II(B)(2)), alone or in combination, disclose the limitations of the challenged claims, thereby invalidating claims 1-5 and 7-18 of the '951 Patent. As detailed below, this request shows a reasonable likelihood that Petitioners will prevail with respect to challenged claims 1-5 and 7-18 of the '951 Patent.

A. [GROUND 1] Claims 1-5 and 7-18 are rendered obvious by Eckhardt in view of Sosnin and the knowledge of a POSITA

1. Overview of Eckhardt

Eckhardt teaches a method for sterilizing or disinfecting a region of tissue and/or a catheter entrance site of a patient using ultraviolet (UV) light. (EX1004, [0029]; *see also* EX1003, ¶¶ 80-81.) Although Eckhardt discloses using a UV-transmissive bandage to apply light underneath the bandage, it further teaches that its UV “sterilization/disinfection units...are also designed to have a beneficial effect when used on bare skin” without a bandage. (EX1004, [0069].) “A region of tissue to be sterilized or disinfected may include unbreached skin, such as a

region where a surgical incision is to be made, or breached skin, such as a wound site or a catheter entrance site.” (*Id.*, [0029].) An example embodiment teaches sterilizing or disinfecting light is emitted by a light source 7 and exposed to wound 1 and/or surrounding tissue 5, where tissue 5 includes skin 3:

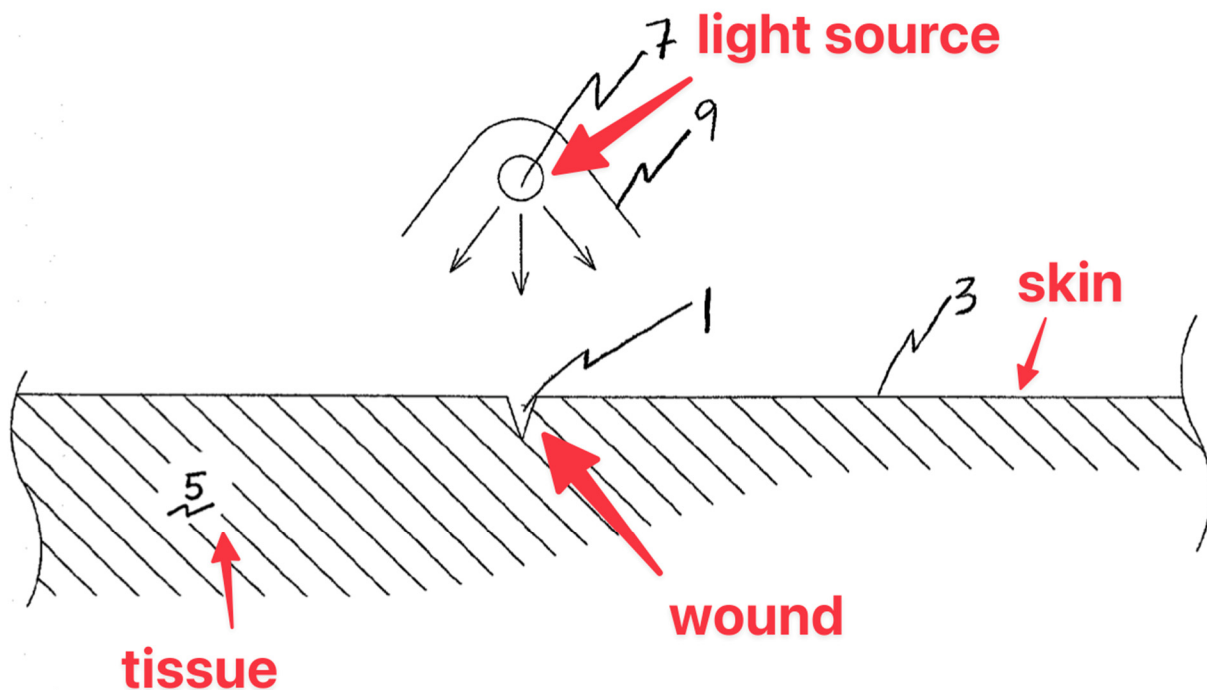


FIGURE 1

(*Id.*, [0031], Fig. 1 (annotated); EX1003, ¶ 82.)

The sterilization/disinfection units of Eckhardt can use “any light source that emits light capable of sterilization or disinfection,” including a “lamp [emitting] narrow spectrum light (e.g., a line spectrum) or broad spectrum light.” (EX1004, [0031]; EX1003, ¶ 83.) “Broad spectrum light may include, e.g., UVA, UVB, and UVC light, or UV light accompanied by light from another portion of the

electromagnetic spectrum.” (EX1004, [0031].) Although Eckhardt contemplates generating UVC light in the range of “220 to 310 nm,” (EX1004, [0070]; *see also id.* (“light with a wavelength shorter than 310 nm”), it does not explicitly state generating photons of 222 nm, specifically.

2. Overview of Sosnin

Sosnin discloses the effects that UV irradiation with excimer lamps has on bacteria. Specifically, Sosnin provides “[a] comparative study on UV [dose] effect of a barrier discharge KrCl-excimer lamp ($\lambda = 222$ nm) on *Staphylococcus aureus* and *Escherichia coli* inactivation[.]” (EX1005, 317; EX1003, ¶ 84.) Sosnin explains that while mercury lamps “have received wide acceptance” among other sterilization methods, these systems have disadvantages, including their “relative expensiveness and additional factors of danger in service of the system (for example, the use of high-voltage up to 30-40 kV).” (EX1005, 317-18.) Further, Sosnin explains that excimer lamps (i.e. excimer lamps or excimers), which have been actively studied in the “last 5-10 years” are an “[a]ttractive alternative” to mercury lamps because “the warming of excimer lamps bulbs is relatively low” in comparison, and “the absence of mercury in gas mixture” means the “UV-system becomes safe in operation and removes a problem of expensive recycling of lamp bulbs.” (*Id.*, 318; *see also id.* (“Development of these low-cost, effective light sources promises enormous potential for materials processing. One of potential application area is

disinfection”); EX1003, ¶ 85.)

Sosnin explains that the “spectra of these [excilamp] sources consist of narrow bands” and the primary band “possesses over 80-90% of the total radiation of the lamp.” (EX1005, 318; *see also* EX1003, ¶ 85.) Sosnin discloses testing with three excimer lamps—krypton chloride (KrCl), xenon bromide (XeBr), and xenon chloride (XeCl). These lamps emit narrow band light at 222 nm, 282 nm, and 308 nm. (EX1005, 319.)

First, Sosnin studied the effects of all three excimers on the inactivation of *E. coli* at different doses and “concluded that all the excilamps can provide pronounced bactericidal effect.” (*Id.*, 319.) Sosnin found that the “KrCl excilamp irradiation leads to inactivation 99.9% of *E. coli* during 8 seconds of exposure[.]” (*Id.*, 320.) Further, for the KrCl excilamp, “[w]ith increase of irradiation doze and exposure time the number of microorganisms is reduced,” (*id.*), and indeed, permits greater inactivation than the XeBr or XeCl excilamps, (*see id.*, Fig. 3). (EX1003, ¶ 86.) Next, Sosnin performs a comparative study on *E. coli* and *S. aureus* using lower doses of the KrCl 222 nm excilamp. Sosnin finds “KrCl-excilamp exerts strong bactericidal action on ... both cultures” and “[w]ith increase in UV irradiation doze as 21-25 mJ/cm² the KrCl-excilamp bactericidal effect became stronger.” (EX1005, 321) Sosnin concludes that “excilamps are promising systems for UV-sterilization.” (*Id.*)

3. Reasons to Combine Eckhardt and Sosnin

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. (EX1003, ¶¶ 40, 88; EX1004, [0031], [0069]; EX1005, 319-321.)

A POSITA would have been motivated to integrate the disclosures of Eckhardt and Sosnin for at least the following independent reasons. (EX1003, ¶¶ 89-109.)

First, a POSITA would have viewed Eckhardt's teaching of using "any light source that emits light capable of sterilization or disinfection" as an instruction to search for and incorporate other well-known UV germicidal light sources like Sosnin's. (EX1003, ¶ 90; EX1004, [0031]; EX1005, 319); *see In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012) ("[T]he test for obviousness is what the combined teachings of the references would have suggested to those having ordinary skill in the art."). For example, Eckhardt suggests using a lamp that "emit[s] narrow spectrum light (e.g., a line spectrum)" to disinfect skin. (EX1004, [0031].) A POSITA would have looked to using germicidal excimer lamps as taught in Sosnin, which emit "narrow band" spectra. (EX1003, ¶ 90; EX1005, 318.) Like the lamps in Eckhardt, Sosnin teaches using its excimer lamps to kill

bacteria—i.e., to disinfect or sterilize surfaces. (EX1003, ¶ 91; EX1005, 319-321.)

Second, a POSITA would have been motivated to supplement Eckhardt's high-level disclosure of using germicidal UVC light to disinfect human "tissue," such as "bare skin" and wounds, with the specific implementation details provided by Sosnin because doing so would have merely been a combination of prior art elements according to known methods to yield a predictable result. (EX1003, ¶ 92; EX1004, [0029-0031], 0069; EX1005, 319.) More specifically, using UVC light at a wavelength of 222 nm as discussed in Sosnin falls within the range expressly suggested by Eckhardt, and was also within the range known to produce the germicidal result described by Eckhardt. (EX1003, ¶ 93; EX1004, [0070]; EX1005, 319-321; *see also* EX1011, ¶ 0028 ("Light with a wavelength in the range of 160 to 300 nanometers is lethal to microorganisms. A total exposure of about 10 milliwatt-seconds of ultraviolet light energy per square centimeter will typically sterilize/disinfect a surface.").)

Third, the combination of Eckhardt and Sosnin would have yielded predictable results to disinfect skin because the effectiveness and relative safety of directing UVC light of wavelength 222 nm to bare skin for use in germicidal application was already understood by a POSITA at the time. (*See* EX1003, ¶¶ 94-95; EX1004, [0031], [0069]; *see also* EX1011, ¶ 0040 ("Sterilization/disinfection is accomplished primarily with UVC...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.”.) For example, the Health Physics Society noted in July 1998 that “UVC, used in germicidal lamps, causes almost no damage because of its low penetration of the skin.” (EX1003, ¶ 96; EX1012, 1; *see also* EX1013, ¶ 0008 (“Many other sources indicate that UVC cannot penetrate the skin or can do so only to a very limited depth. However, this depth is sufficient to treat infections since organisms are particularly susceptible to germicidal radiation.”); EX1007, 11 (Fig. 3 showing 254 nm UVC light has low depth of penetration into the epidermis.)

In fact, guidelines pre-dating the effective filing date of the ’951 Patent show that UVC light was even accepted for general occupational exposure at low levels. For instance, the National Institute for Occupational Safety and Health (“NIOSH”) released “A Recommendation Standard for Occupational Exposure to Ultraviolet Radiation” in 1992.⁹ (*See* EX1006; EX1003, ¶ 97.) Table 1-1 of the NIOSH guidelines show that the “Permissible 8-hour dose (mJ/cm²)” varies based on wavelength, and is higher for shorter wavelengths. (EX1006, 5; EX1003, ¶¶ 98-100.)

⁹ EX1006 is a printed publication publicly available no later than February 1993. (*See* EX1010, ¶¶ 32-35.)

Similarly, a 1995 World Health Organization (“WHO”) report titled “Health and Environmental Effects of Ultraviolet Radiation”¹⁰ shows even higher doses may be “safe.” (EX1007, 8; EX1003, ¶¶ 101-106.) At the peak wavelength for causing erythema (i.e., sunburn), a dose of 150-2000 J/m² would “produce[] a barely noticeable reddening on a previously unexposed skin.” (EX1007, 8; EX1003, ¶ 105.) And the WHO report shows that at lower wavelengths, skin could be exposed to even higher doses without risking damage. (EX1003, ¶ 106.) The WHO report explains that “[a]lthough UVC is very efficiently absorbed by nucleic acids, the overlying dead layers of skin absorb the radiation to such a degree that there is only mild erythema and, usually, no late sequelae, even after repeated exposures.” (EX1007, 11.)

Although there was a general caution against exposing skin to excessive ultraviolet radiation of any kind because of the potential for causing cancer or sunburn, (*see, e.g.*, EX1004, [0005]), a POSITA would have understood that the beneficial effects of disinfecting the surface of skin could outweigh any safety concerns and would still have been motivated to use light in the UVC spectrum for this purpose. (EX1003, ¶¶ 108-109; *see, e.g.*, EX1017 (teaching irradiating skin

¹⁰ EX1007 is a printed publication publicly available no later than June 1996. (*See* EX1010, ¶¶ 36-38.)

wounds with UVC.) For example, even though UVC light at around 254 nm was known to be a peak wavelength absorbed by and thus altering DNA, (*see* EX1001, 3:42-48, 4:7-10), researchers nevertheless were using 254 nm light to disinfect “surface wounds (i.e., those present in skin)” as well as internal wounds.

(EX1015, 2:54–62; *see also id.*, 2:22-67; EX1016, 2:23–26 (“UVC light having germicidal wavelengths, for example, a peak wavelength of about 254 nm, is used for inactivation of pathogenic organisms resident on the skin surface.”); EX1014, 3-9 (using UVC light to treat skin wounds in mammals); EX1007, 16 (noting that exposure limits “are generally below levels which are often used for the UV exposure of patients required as part of medical treatment and below levels associated with sunbed exposure.”); EX1017, 58 (treating chronic wounds with 254 nm and concluding that “UVC is a promising adjunctive therapy for chronic wounds infected with antibiotic-resistant bacteria such as MRSA.”).)¹¹

4. Analysis

[1pre] A process for destroying a DNA or RNA of a microorganism on a substance or on a surface comprising the steps of:

The combination discloses Element [1pre]. (EX1003, ¶¶ 111-113.)

¹¹ EX1017 is a printed publication publicly available no later than November 2002.

(*See* EX1010, ¶¶ 15-17.)

Eckhardt, for example, teaches using light source 7 to disinfect human or animal skin. (EX1003, ¶ 112; EX1004, Fig. 1, [0031] (“Sterilizing or disinfecting light is emitted by a light source 7 and exposed to wound 1 and/or surrounding tissue 5. Tissue 5 includes skin 3...”), [0029] (“A region of tissue to be sterilized or disinfected may include unbreached skin...”), [0032] (“deliver a sterilizing or disinfecting dosage,...of UVC, to all surfaces to be sterilized or disinfected.”).)

Eckhardt discloses that “[t]he sterilization or disinfection may occur by killing microorganisms, inactivating microorganisms (i.e., rendering the microorganisms unable to reproduce), or any combination thereof.” (EX1003, ¶ 113; EX1004, [0030].) A POSITA would understand that the statement in Eckhardt of “rendering the microorganisms unable to reproduce” refers to mutagenicity. (EX1003, ¶ 113.) Mutagenicity is permanent change of the structure of genetic material such as DNA or RNA, which can inhibit reproduction. (*Id.*) A POSITA would view the introduction of changes to DNA or RNA sufficient to prevent reproduction as “destroying” the DNA or RNA in the context of the ’951 Patent specification. (EX1001, 4:11-23, 8:13-17; EX1003, ¶ 113; *see also* EX1018, 7:36-45 (noting the “well-documented effect of UV radiation on cell division” that “UV photons in the 200 to 300 nm [range]...are strongly absorbed by nucleic acids and certain proteins, inducing chemical changes via photoactivation processes,” including “chromosome breakage, genetic mutations

and enzyme inactivation which can result in delay in growth (inhibition of cell division) or cellular death.”); *see also id.*, 7:45-50.)

[1A] generating photons of a wavelength corresponding to a peak absorption wavelength of proteins, or DNA, or RNA, the wavelength being 222 nm;

The combination discloses Element [1A]. (EX1003, ¶¶ 114-117.)

Eckhardt, for example, teaches that light source 7 can be “any light source that emits light capable of sterilization or disinfection,” including a “lamp emit[ting] narrow spectrum light (e.g., a line spectrum) or broad spectrum light.” (EX1003, ¶ 115; EX1004, [0031].) “Broad spectrum light may include, e.g., UVA, UVB, and UVC light, or UV light accompanied by light from another portion of the electromagnetic spectrum.” (EX1003, ¶ 115; EX1004, [0031].) Eckhardt teaches that light source 7 may be a “xenon flash lamp” that produces “UVC light” including “sterilizing light from a xenon flash having a wavelength in the range of 220 to 310 nm.” (EX1003, ¶ 115; EX1004, [0043], [0070].)

A POSITA would recognize that the range of wavelengths produced by light source 7 (220 to 310 nm) in Eckhardt would necessarily include generating photons of wavelength 222 nm. (EX1003, ¶ 116; EX1004, [0043], [0070].)

Further, Sosnin specifically discloses sterilizing through irradiation using a KrCl excimer lamp, which generates photons with wavelength 222 nm. (EX1003, ¶ 116; EX1005, 319-21.)

A POSITA would understand that a wavelength of 222 nm could, in the context of the '951 Patent's specification, correspond to proteins or DNA or RNA because the specification asserted that they were the absorption wavelengths of proteins and some of the amino acids that can be associated with DNA or RNA.¹² (EX1003, ¶ 116; *see also* EX1038, 580 (citing papers from 1952 and 1964 that

¹² Throughout the specification, it is unclear whether the '951 Patent conflates DNA/RNA with proteins, or is instead referring to a DNA or RNA complex with proteins which would exist naturally in cells. (*See, e.g.*, EX1001 at 7:19-22 (“This suggests that the closeness of the different amino acids to peptide bonds affect the DNA/RNA absorption at a specific wavelength.”).) To clarify, DNA and RNA are made of nucleic acids, while polypeptides or proteins are made of amino acids. (EX1003 at ¶ 64.) Amino acids are associated with peak absorption wavelengths near 222 nm and 282 nm, while DNA/RNA has a peak absorption wavelength near 200 nm and 254 nm, which the '951 Patent acknowledges. (*See* EX1001, 2:7-10, 3:62-64.) This distinction is clear from the article that the '951 Patent cites for Figure 9, which more accurately depicts the peak absorptions of DNA as being at 200 nm and 254 nm. (*See* EX1039, 60.) Figure 9 in the '951 Patent inexplicably appears to shift the spectrum ~20 nm to the right. (*Compare* EX1039, 16 with EX1001, FIG. 9.)

taught “peak UV absorption in the area of 280 nm and a higher one at 220 nm” for many common amino acids, including those that the ’951 Patent asserts can be associated with DNA or RNA such as “phenylalanin[e], tyrosin[e], tryptophan, cystein[e], cystin[e] and histidin[e]”); *see also id.*, (“Thus, proteins also show absorption maxima at 220 nm and 280 nm”); EX1018, 2:49-52, 3:1-7, 3:38-4:7, 7:38-50.)

Indeed, Sosnin itself explains that “[t]he specificity of biological action of various ranges of UV spectra was established in the end [of the 19th] century” and by 1942 it was found “that the nuclear acids served as basic target at lethal and bacteria is primarily due to the formation of thymine, thymine-cytosine (pyrimidine) and cytosine dimers in DNA.” (EX1005, 317; EX1003, ¶ 117.) Sosnin noted further that “[t]he most effective action has the radiation with wavelengths in a range 200-295 nm (so-called *bactericide* or *germicide* range).” (EX1005, 317.) The ’951 Patent reflects this arrangement, stating that “[c]ritical” to the invention is an NUV “source that emits a highly intense narrow wavelength band of photons that correspond to the maximum absorption band for DNA proteins and other component bonds,” with the “preferred embodiment” “source at 222 nm [that] targets these proteins and their peptide bonds.” (EX1001, 2:64-3:2; *see also id.*, 3:62-4:5, 6:51-64, FIGs. 9, 10; EX1003, ¶ 118.)

[1B] directing the photons to a substance or surface to be disinfected, whereby the photons are generated to destroy a plurality of chemical bonds within the proteins, DNA, or RNA of the microorganism; and

The combination discloses Element [1B]. (EX1003, ¶¶ 119-121.)

Eckhardt, for example, discloses “directing light emitted by light source 7 towards wound 1 and surrounding skin 3.” (EX1003, ¶ 120; EX1004, Fig. 1, [0031]; *see also id.*, [0032] (“deliver a sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm² of UVC, to all surfaces to be sterilized or disinfected.”).)

The combination discloses “whereby the photons are generated to destroy a plurality of chemical bonds within the proteins, DNA, or RNA of the microorganism” because it discloses directing photons of wavelength 222 nm to a substance or surface to be disinfected, which intrinsically destroys proteins and the chemical bonds in the proteins associated with the DNA or RNA of the microorganism. (EX1003, ¶ 121; *see also* EX1005, 319-21 (disclosing using excimer lamp with 222 nm wavelength to destroy *E. coli* and *S. aureus* microorganisms); *see supra*, Elements [1pre] and [1A].)

[1C] wherein the substance or surface to be disinfected is human or animal tissue.

The combination discloses Element [1C]. (EX1003, ¶¶ 122-128.)

Eckhardt discloses disinfecting the surface of a person or animal’s tissue 5 (e.g., skin 3) with light source 7. (EX1003, ¶ 122; EX1004, Fig. 1, [0029-0032].)

Eckhardt teaches that the UV lamp used “may emit narrow spectrum light (e.g., a line spectrum)[.]” (EX1003, ¶ 122; EX1004, [0031]; *see also* Element [1pre] and [1A].) A POSITA looking to implement Eckhardt’s teaching would have sought a UV source effective at low doses that could be used without damaging skin or tissue. (EX1003, ¶ 122.)

Claim 1 does not recite any particular level of safety or efficacy, only a process of generating and directing 222 nm photons to “human or animal tissue.” (EX1001, claim 1; EX1003, ¶ 123.) Claim 1 does not even require the tissue to be from a *live* human or animal; dependent claims 15-18 that require a “living” human or animal indicates claim 1 is broader and encompasses treating tissue from a deceased human or animal. Safety would obviously not be a concern when disinfecting dead tissue. (EX1003, ¶ 123.)

But even if the claims did require some level of efficacy or safety, these properties of Far UV light were long known. For instance, it was long known that Far UV light generally was effective for disinfecting. (EX1003, ¶¶ 95-109.) And it was already known that 222 nm excimer lamps were effective for surface disinfection at low dosages, (EX1005, 319-21; EX1036, 10:15-14:15; EX1032, 1531), including below the 100 mJ/cm² dosages described in the ’951 Patent, (*see* EX1001, 5:15-6:6, Figs. 11-12, 14; EX1003, ¶ 124). For instance, Sosnin showed inactivation of nearly 99.9% of *E. coli* with 222 nm light at a dose of ~90 mJ/cm²

and noted “KrCl excilamp exerts strong bactericidal action[.]” (EX1005, 320-21.)

Thus, low dosages of 222 nm light were already known to disinfect.

Regarding safety, as discussed above, it was known that UV light could penetrate the skin’s epidermis to some extent, but shorter wavelengths would penetrate less deeply. (EX1007, 11; EX1003 at ¶ 125.) It was known that even 254 nm light only penetrated the epidermis to a limited extent, and shorter wavelengths even less so:

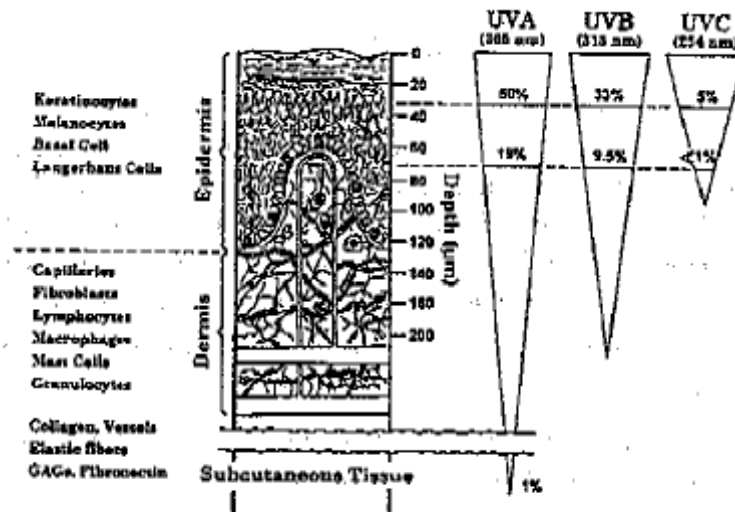


Figure 3: Depth of penetration of UV into the skin

(EX1007, 11.) The prior art already taught using 254 nm to disinfect skin.

(EX1017, 58.) A POSITA would have known that an even shorter wavelength like 222 nm would have been more “safe.” (EX1007, 11; EX1003 at ¶ 125; *see also*

EX1037 (Sosnin IEEE¹³ finding that mammalian cells “are extremely resistant to UV” and noting that “[i]rradiation with UV lamps may become a method of selective bacterial decontamination of wounds without killing the body cells that strive to repair the wound.”).)

The 1992 NIOSH guidelines and 1995 WHO report further support that a POSITA would have understood that 222 nm light could be used on skin or tissue. Table 1-1 of the NIOSH guidelines shows that the “Permissible 8-hour dose (mJ/cm²)” for 220 nm light was 25 mJ/cm². (EX1003, ¶ 126; EX1006, 5.) Likewise, the lowest dose of 222 nm that the WHO report found could cause erythema (i.e. sunburn) was 150 mJ/cm². (EX1003, ¶ 126; EX1007, 8.) Moreover, the WHO report also suggests even higher doses could be used without causing erythema—up to 2000 mJ/cm². (EX1003, ¶ 126; EX1007, 11.) Sosnin demonstrated that UV dosages ~40-260 mJ/cm² were effective to inactivate bacteria. (EX1003, ¶ 126; EX1005, 320-321.) Thus, a POSITA would have known that 222 nm light could be used to disinfect skin or tissue at levels that were known not to cause damage, or at least were within situationally acceptable levels.

¹³ Sosnin IEEE (EX1037) is a printed publication publicly available no later than October 2004. (See EX1010, ¶¶ 18–21.)

Additionally, in certain situations, exposure to increased levels of UV light was acceptable and even useful. The WHO report explains that exposure limits (ELs) “are generally below levels which are often used for the UV exposure of patients required as part of medical treatment[.]” (EX1007, 16; EX1003, ¶ 127.) Indeed, it was known that even “dangerous” wavelengths like 254 nm could be effective for use with severely ill patients. (EX1017, 58.)

Thus, it would have been obvious to a POSITA, starting with Eckhardt’s method of disinfecting skin using UV-C light using any light source to disinfect, to look for UV-C sources that could effectively disinfect at low dosages known to be within acceptable exposure limits, like Sosnin’s KrCl 222 nm excimer lamp. (EX1003, ¶ 128.)

[2] The process of claim 1 wherein the human or animal tissue is one of blood, an organ, or a wound.

The combination discloses Claim [2]. (EX1003, ¶¶ 129-130.)

Eckhardt discloses disinfecting a human or animal’s wound by directing light emitted by light source 7 towards wound 1. (EX1003, ¶ 130; EX1004, Fig. 1, [0029-0032].) “Wound 1 may be a lesion, cut, abrasion, or sore sustained by the patient,” or “may be an incision or puncture created by a healthcare professional.” (EX1004, Fig. 1, [0034].) Therefore, Eckhardt discloses disinfecting a wound. (EX1003, ¶ 130.)

[3] The process of claim 1 wherein the microorganism is at least one of a bacteria, a virus, a fungus, an amoeba, and a protozoa.

The combination discloses Claim [3]. (EX1003, ¶¶ 131-133.)

Eckhardt discloses sterilization or disinfection systems that address the problem of infection, specifically the problem of “[b]acteria and other potentially harmful microbes” that “can generate infections when they enter the body through wounds, catheter entrance sites, and other openings in the body, thereby bypassing the body’s natural defenses.” (EX1003, ¶ 132; EX1004, [0003]; *see also id.*, [0030] (“The sterilization or disinfection may occur by killing microorganisms, inactivating microorganisms (i.e., rendering the microorganisms unable to reproduce), or any combination thereof”); *see also id.*, [0036], [0041], [0062] (disinfecting microorganisms generally).) Eckhardt refers to “microorganisms” as including “bacteria and viruses.” (EX1004, [0091].) Eckhardt further teaches that multiple sources “may enhance the effectiveness of the light source, as the sensitivity of different microorganisms to light varies with the wavelength of the light.” (EX1003, ¶ 132; EX1004, [0031].)

Sosnin also discloses disinfection of “a bacteria, a virus, a fungus, an amoeba, and a protozoa” because Sosnin discloses testing showing the inactivation of two strains of bacteria—*E. coli* and *S. aureus*. (EX1003, ¶ 133; EX1005, 320-21.)

[4] The process of claim 1 wherein the step of directing is performed for approximately two seconds.

The combination discloses Claim [4]. (EX1003, ¶¶ 134-144.) Eckhardt, for example, discloses that “a high intensity source of sterilizing or disinfecting light where the sterilization dosage may be applied in less than a few minutes or seconds,” explaining that even “[t]he energy of a single flash may be sufficient to deliver a sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm² of UVC, to all surfaces to be sterilized or disinfected.” (EX1003, ¶ 135; EX1004, [0032].) Exposing a surface to be disinfected to photons for multiple seconds was also known in the art. (See, e.g., EX1004, [0032], [0056]; EX1036 at 2:31-36, 12:48-51; EX1019, [0023], [0056]; EX1003, ¶ 135.)

Notably, claim [4] does not require any particular level of disinfection of any particular type of microorganism. (EX1003, ¶ 136; EX1001, 2:50-53 (“The term[]...disinfection refers to all other levels of disinfection” besides the FDA-defined term “sterilization.”), 5:65-67 (“Future tests will generate survival plots of the other pathogens to determine the minimum dose for various log reductions.”).) A POSITA would therefore be motivated to try any treatment duration to arrive at the desired level of disinfection for a given target microorganism or set of microorganisms. (EX1003, ¶ 136; EX1015, 3:35-42.)

A POSITA would have readily understood that, at a given radiation

intensity, any particular UV dose (and therefore any level of disinfection) could be obtained simply by increasing or decreasing the exposure time (i.e. two seconds). (EX1003, ¶ 137; EX1004, [0030] (“the methods and apparatus described may be used to achieve a desired level (e.g., low or high) of sterilization or disinfection.”); EX1005, 319 (“Irradiation was performed within various time, irradiation doze, and use various type excilamps.... Primary and secondary irradiation of culture *E. coli* by capacitive discharge excilamps radiation during various periods of time were carried out.”).) By adjusting a limited number of variables, such as the intensity output of the UV lamp, the exposure time at a particular intensity or the distance of the UV source to the target surface or substance, a POSITA could provide any desired radiant dose needed to obtain a desired dose and/or “kill” of microorganisms on the target substance or surface (which, again, is not specified by claim 4). (EX1003, ¶ 137; EX1004, [0046]; EX1005, 319; *see also e.g.*, EX1036, 13:37-14:15; *see also id.*, 11:35-53; EX1001, 5:49-56.)

Sosnin expressly taught a negative correlation between survival rate of the microorganism and the irradiation dose from a KrCl (222 nm) excimer lamp based upon time. (EX1003, ¶ 138; EX1005, 320.) A POSITA would therefore understand and appreciate that the greater the applied UV dose, the greater the “kill” in a shorter amount of time, and vice versa. (EX1003, ¶ 138; EX1004, [0032], [0033], [0043]; *see also* EX1001, 5:49-60, FIG. 14.)

A POSITA would have also immediately recognized that the UV dose (and therefore the level of disinfection) could be adjusted simply by increasing or decreasing the exposure time while keeping other variables such as the light source, intensity and distance the same. (EX1003, ¶ 139; EX1005, 319 (“Usually, the exposure was made 5 cm distant from the lamp.”).) Alternatively, the same UV dose delivered in eight seconds in Sosnin could be applied in a shorter duration (e.g., two seconds) by increasing the UV lamp intensity or by decreasing the distance of the light source accordingly. (EX1003, ¶ 139; EX1004, [0046]; EX1015, 3:35-42 (“Application of UVC radiation to a wound is performed for a time sufficient to have a bacteriocidal[sic] effect on the wound.... *Of course*, the duration may be varied depending on the type and character of the wound, the microorganism to be eliminated, *and the intensity and position of the UVC source*.”).)

Adjusting the exposure time to two seconds to achieve a particular level of disinfection would have been a matter of routine optimization that a POSITA would have been well equipped to perform. (EX1003, ¶ 140.; *see also* EX1004, [0057] (exposure time must be “long enough to perform a complete sterilization or disinfection operation for each instance”); *see also id.*, [0050], [0071].)

A POSITA would have had a reasonable expectation of success of achieving some level of disinfection using 222 nm light directed to the target substance or

surface for two seconds because it was within the range of known effective disinfection times for microorganisms using available equipment. (EX1003, ¶ 141.) Eckhardt, for example, taught that in some embodiments disinfection could be achieved in “less than 200 microseconds[.]” (EX1004, [0043].) Sosnin taught a 99.9% disinfection rate for *E. coli* with 8 seconds of primary exposure. (EX1003, ¶ 141; EX1005, 320 (“KrCl-excilamp irradiation leads to inactivation 99.9 % of *E. coli* during 8 seconds of exposure at primary irradiation.”).) This exposure time was an equivalent dose of about 100 mJ/cm². (EX1003, ¶ 141; EX1005, Fig. 3 (showing 0.1% survival rate for KrCl exposure at about 100 mJ/cm²).) Using the same equipment, but only adjusting the exposure time (and therefore the UV dose), Sosnin’s survival curve teaches that a POSITA would still expect to achieve a significant disinfection of *E. coli*—about a log reduction, e.g., a 90% “kill”—with a two second exposure (equivalent to a 25 mJ/cm² dose). (EX1003, ¶ 142; EX1005, Fig. 3; *see also id.*, 321 (two second duration (i.e. 25 mJ/cm²) resulting in more than 99.6% inactivation of *S. aureus*).) Sosnin also teaches that *E. coli* is has “one of the most high resistance coefficients among enterobacteria,” suggesting that a two second exposure would be even more effective against other microorganisms. (EX1003, ¶ 143; EX1005, 318; *see also* EX1015, 3:44-5:24 (Tables 1-5 showing comparative disinfection rates of different microorganisms).)

Regarding safety, claim 4 depends from claim 1, and as discussed above,

claim 1 does not require the tissue to be from a live human or animal. (See Element [1C], *supra*; *see also cf.* with dependent claims 15-18 (requiring a “living” human or animal).) Safety would obviously not be a concern when disinfecting dead tissue. (EX1003, ¶ 144.) To the extent the process of claim 4 is performed on a live human, a POSITA would not have had concerns about trying this exposure time using UV dosages within the range the prior art taught was “safe” for occupational exposure. (See Section V(3), *supra*; EX1006, 5; EX1007, 8; EX1003, ¶ 144; *see also id.*, ¶¶ 95-109.)

[5] The process of claim 1 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.

The combination discloses Claim [5]. (EX1003, ¶¶ 145-148.) Eckhardt, for example, teaches selecting a hand held lamp as the source for generating photons. (EX1003, ¶ 145; EX1004, [0045] (“Batteries advantageously allow instantaneous sterilization/disinfection unit 16a to be portable and hand-held.”), [0051] (“continuous process sterilization/disinfection unit 16b...may be hand-held”).) Eckhardt further suggests that “a mechanism for attaching the unit to a site to be sterilized/disinfected” is not required for a “unit [that] may be hand-held.” (EX1003, ¶ 145; EX1004, [0051].) Thus, a POSITA would immediately understand that, like turning on and shining a hand-held flashlight in the dark, the combination discloses the step of activating a lamp within a wand and positioning

that wand over the surface or substance to be disinfected. (EX1003, ¶ 145; EX1004, [0045].)

Additionally, it would have been obvious to a POSITA to arrive at Claim [5] as a matter of common sense by positioning Eckhardt's hand held lamp over the surface or substance to be disinfected. (EX1003, ¶¶ 146-148.) Both Eckhardt and the '951 Patent address similar problems of balancing safety and portability of hand-held UV devices. (EX1003, ¶ 146.) Eckhardt "advantageously" discloses "portable and hand-held" UV disinfection units that includes a manual "switch" (e.g., "a button") for safe operation. (EX1003, ¶ 146; EX1004, [0045], 0051.) The '951 Patent similarly discloses using "switches" in the wand embodiment "that shut off the NUV source when the wand is not directed correctly to the desired treatment surface." (EX1003, ¶ 146; EX1001, 15:41-44.)

Eckhardt also teaches that the hand-held UV source includes a "light directing component," which can be "movable" so as "to reflect light from light source 7 to partially shadowed area[s]" and allows hand-held operation without the need for an attachment mechanism. (EX1003, ¶ 147; EX1004, [0064-0066]; *see also id.* at [0051].) The '951 Patent similarly discloses that the hand wand "needs to be waved or passed over the surface to obtain a high level of disinfection." (EX1003, ¶ 147; EX1001, 8:48-50.)

Therefore, the combination discloses Claim [5]. (EX1003, ¶¶ 145-148.)

[7] The process of claim 1 wherein the step of generating photons comprises activating a lamp.

The combination discloses Claim [7]. (EX1003, ¶¶ 149-150.)

Eckhardt teaches that the UV disinfection system has a “[h]ousing” that “includes a trigger switch” “to control activation of flash light source” in part to “enhance[] the safety of instantaneous sterilization/disinfection unit[.]” (EX1003, ¶ 150; EX1004, [0045].) Moreover, it would have been common sense to a POSITA that to use any lamp for disinfection, the first step would be turning it on—i.e., “activating” it. (EX1003, ¶ 150.)

[8] The process of claim 7 wherein the lamp comprises a cover, the cover transparent to 222 nm.

The combination discloses Claim [8]. (EX1003, ¶¶ 151-152.)

Eckhardt teaches that its UV light source is “optionally protected by a UV transmissive window or screen,” which “may be made from quartz, fused silica, a UV transmissive glass or screen, or a perforated sheet of metal or other material.” (EX1003, ¶ 152; EX1004, [0038].) This “UV transmissive window or screen” on the light source is a “cover” because it protects the light source. (EX1003, ¶ 152; see EX1011, 14:51-53 (“cover 6a is necessary to protect the NUV source”).) A POSITA would understand that the cover described in Eckhardt could be used with Sosnin’s 222 nm excimer lamp to permit 222 nm light to disinfect skin. (EX1003, ¶ 152; EX1005, 319-321.)

[9] The process of claim 1 wherein the step of directing the photons further comprises the step of providing 540 kJ/mole of photon energy to the substance or surface to be disinfected.

The combination discloses Claim [9] because it discloses directing photons of the wavelength 222 nm to the surface to be disinfected. (EX1003, ¶¶ 153-154; EX1005, 319-21; *see supra*, Element [1A].) Photon energy is a property related to the wavelength of the photon. (EX1001, 4:24-25 (“The energy of the emitted photon is determined by its wavelength.”); EX1003, ¶¶ 29, 154.) A POSITA would have readily known that photons of wavelength 222 nm necessarily correspond to approximately 540 kJ/mole of photon energy. (EX1003, ¶ 154; *see* EX1021, 651.)¹⁴ The energy of light is provided by the formula $E = N h \nu = \frac{N h c}{\lambda}$, where N is the number of moles, h is Planck’s constant, c is the speed of light, ν is the frequency, and λ is the wavelength of the photons. (EX1003, ¶¶ 29, 154; EX1021, 651.) Solving for E , the photon energy per mole of 222 nm light is approximately 540 kJ/mole. (EX1003, ¶ 154.)

[10] The process of claim 1 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.

The combination discloses Claim [10]. (EX1003, ¶¶ 155-164.) For

¹⁴ EX1021 is a printed publication publicly available no later than April 1999. (*See* EX1010, ¶¶ 12-14.)

example, the combination discloses “deliver[ing] a sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm² of UVC, to all surfaces to be sterilized or disinfected.” (EX1003, ¶ 156; EX1004, [0032]; *see also id.*, [0043] (producing “UVC energy intensity of about 20 mJ/cm²”).) This meets the limitations of Claim 10 because “a radiant dose of energy of 40 mJ/cm²” of photons is “greater than 10 mJ/cm² of UVC.” (EX1003, ¶ 156.) Additionally, Sosnin discloses using a range of radiant dose energies of photons of wavelength 222 nm between ~25 mJ/cm² and ~260 mJ/cm² to disinfect a surface by killing *E. coli*, thus encompassing the claimed 40 mJ/cm² dose. (EX1005, 320 (Fig. 3); *see also id.*, 321 (Fig. 5 showing greater than 99% inactivation of *S. aureus* at dose of 25-50 mJ/cm²); EX1003, ¶ 156.)

Additionally, it would have been obvious to a POSITA to arrive at Claim [10]. (EX1003, ¶ 157.) Specifically, it would have been obvious to provide a radiant dose energy of 40 mJ/cm² of 222 nm photons to the substance or surface to be disinfected. (*Id.*) A POSITA would have readily understood that, at a given intensity, any particular UV “dose” could be obtained simply by changing the exposure time. (EX1003, ¶ 158; EX1004, [0030] (“the methods and apparatus described may be used to achieve a desired level (e.g., low or high) of sterilization or disinfection.”); EX1005, 319 (“Irradiation was performed within various time, irradiation doze, and use various type excilamps[.]”); *see also e.g.*, EX1036, 11:35-

53 (table showing how dose at a specific intensity depends on exposure time).)

A POSITA would have also immediately recognized that the UV intensity could be adjusted simply by increasing or decreasing the distance of the UV light source to the surface or substance to be disinfected. (EX1003, ¶ 159; EX1005, 319 (“Usually, the exposure was made 5 cm distant from the lamp. Thereby the heating effect of substrate was minimised and values of irradiation were kept high.”); *see also, e.g.*, EX1036, 13:37-43 (only “a very small fraction...of the total lamp power...is incident on the samples at a height of 40 cm”).) By adjusting variables like exposure time at a particular intensity or distance of the UV source to the target surface or substance, a POSITA could provide any desired radiant dose needed to obtain a desired dose and/or “kill” of microorganisms on the target substance or surface. (EX1003, ¶ 159; EX1004, [0046]; EX1005, 319; *see also e.g.*, EX1036, 13:37-14:15; *see also id.*, 11:35-53; EX1001, 5:49-56 (FIG. 14 chart that “plots radiant dose against a log reduction of the target microorganism.”).) A POSITA would understand and appreciate that the greater the applied UV dose, the greater the kill in a shorter amount of time, and vice versa. (EX1003, ¶ 159; EX1004, [0032], [0033], [0043]; *see also* EX1001, 5:49-60, FIG. 14.)

Claim [10] does not recite any particular level of disinfection of any particular type of microorganism. (EX1003, ¶ 160; EX1001, 2:50-53, 5:65-67.) A POSITA would therefore be motivated to try any amount of UV dose to arrive at

the desired level of disinfection for a given target microorganism or set of microorganisms. (EX1003, ¶ 160.)

The combination also provides a suggestion to arrive specifically at a radiant dose of 40 mJ/cm² of the 222 nm wavelength light taught by Sosnin. (EX1003, ¶ 161.) Eckhardt provides a suggestion to try to achieve a “sufficient...sterilizing or disinfecting dosage...of UVC” applied to human skin. (See EX1003, ¶ 161; EX1004, [0032-0034], [0055], [0071]; *see also id.*, [0057] (exposure time must be “long enough to perform a complete sterilization or disinfection operation for each instance”).) And Eckhardt teaches producing a UV dose around 10 mJ/cm² or greater. (EX1003, ¶ 161; EX1004, [0032] (“greater than 10 mJ/cm²”), [0043] (“about 20 mJ/cm²”), [0104] (same).) Similarly, Sosnin teaches that using UV doses of 222 nm photons between ~25 mJ/cm² and ~260 mJ/cm² will kill *E. coli* bacteria. (EX1003, ¶ 161; EX1005, 320 (Fig. 3).) Thus, a POSITA would be motivated by these suggestions and teachings to try different UV doses at least around the ranges taught by Eckhardt and Sosnin, such as 40 mJ/cm². (EX1003, ¶ 161.)

A POSITA would have had a reasonable expectation of success of achieving some level of disinfection at a UV dose of 40 mJ/cm² of 222 nm light directed to the target substance or surface. (EX1003, ¶ 162.) Sosnin, for example, found that treating *E. coli* with ~25 mJ/cm² of 222 nm light resulted in inactivation of over

90% of the bacteria, and treatment with $\sim 60 \text{ mJ/cm}^2$ of 222 nm light resulted in inactivation of over 99% of the bacteria. (EX1005, 320 (Fig. 3); EX1003, ¶ 162.) Thus, a POSITA would have expected a high level of disinfection at a UV dose of 40 mJ/cm^2 . (EX1003, ¶¶ 162-163; EX1005, 320; *see also* EX1024, ¶¶ 0023-24, (“[I]ndividual light sources may be operated at different intensities and/or for different periods of time to achieve the desired sterilization results”).)

Regarding safety, claim 10 depends from claim 1, and as discussed above, claim 1 does not require the tissue to be from a live human or animal. (*See* Element [1C], *supra*; *see also cf.* with claims 15-18 (requiring a “living” human or animal).) Safety would obviously not be a concern when disinfecting dead tissue. (EX1003, ¶ 164.) To the extent the process of claim 10 is performed on a live human, a POSITA would not have had concerns about trying this dosage because this dosage is within the range the prior art taught was “safe” for occupational exposure. (*See* Section V(3), *supra*; EX1006, 5; EX1007, 8; EX1003, ¶ 164; *see also id.*, ¶¶ 95-109.)

[11] The process of claim 1 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.

The combination discloses or renders obvious Claim [11] for the reasons discussed with respect to Claim [10], *supra*. (EX1003, ¶¶ 155-167.) Eckhardt discloses directing the photons to provide a radiant dose energy of 60 mJ/cm^2 to

the substance or surface to be disinfected because it discloses “deliver[ing] a sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm² of UVC, to all surfaces to be sterilized or disinfected.” (EX1003, ¶ 166; EX1004, [0032]; *see also id.*, ¶ 0043.) Likewise, as discussed above, Sosnin discloses using a range of radiant dose energies of 222 nm light between ~25 mJ/cm² and ~260 mJ/cm² to kill *E. coli* and disinfect the surface, thus encompassing the claimed radiant dose energy of 60 mJ/cm². (EX1005, 320 (Fig. 3); EX1003, ¶ 166; *see also supra*, Claim [10].) Sosnin specifically shows that a UV dose of ~60 mJ/cm² results in inactivation of over 99% of the *E. coli* bacteria. (EX1005, 320 (Fig. 3); EX1003, ¶ 166.)

At the very least, it would have been obvious to deliver a radiant dose of 60 mJ/cm² because of, for example, the design incentive to provide a higher level of disinfection than what is provided at lower doses. (EX1003, ¶ 166; EX1004, [0030] (“the methods and apparatus described may be used to achieve a desired level (e.g., low or high) of sterilization or disinfection.”); *see also supra*, Claim [10].)

Regarding safety, claim 11 depends from claim 1, and as discussed above, claim 1 does not require the tissue to be from a live human or animal. (*See* Element [1C], *supra*; *see also cf.* with claims 15-18 (requiring a “living” human or animal).) Safety would obviously not be a concern when disinfecting dead tissue.

(EX1003, ¶ 167.) To the extent the process of claim 11 is performed on a live human, a POSITA would not have had concerns about trying this dosage because this dosage is within the range the prior art taught was “safe” for occupational exposure. (See Section V(3), *supra*; EX1006, 5; EX1007, 8; EX1003, ¶ 167; *see also id.*, ¶¶ 95-109.)

[12] The process of claim 1 wherein the human or animal tissue is skin.¹⁵

[13] The process of claim 1 wherein the human or animal tissue is human tissue.

[14] The process of claim 1 wherein the human or animal tissue is human skin.

[15] The process of claim 1 wherein the human or animal tissue is tissue of a living animal.

[16] The process of claim 1 wherein the human or animal tissue is tissue of a living human.

[17] The process of claim 1 wherein the human or animal tissue is skin of a living human.

[18] The process of claim 1 wherein the human or animal tissue is skin of a living animal.

The combination discloses or renders obvious Claims [12]-[18] for the reasons discussed with respect to Element [1C], *supra*. (EX1003, ¶¶ 168-169; *see also id.*, ¶¶ 122-128.) Eckhardt discloses treating a patient by disinfecting the

¹⁵ Due to the similarity in the evidence identifying these limitations in the prior art, claims 12 through 18 will be discussed collectively.

surface of a living person or animal’s “tissue”— including “skin”—with light source 7. (EX1003, ¶ 169; EX1004, [0030] (“a region of tissue or a catheter entrance site to be sterilized or disinfected may be that of either a person or an animal.”), [0031] (“FIG. I illustrates a method for sterilizing or disinfecting a region of skin or tissue of a patient using sterilizing or disinfecting light”); *see also id.*, Fig. 1, [0029]-[0032].) Eckhardt teaches that the UV lamp used “may emit narrow spectrum light (e.g., a line spectrum)[.]” (EX1003, ¶ 169; EX1004, [0031]; *see also* Element [1pre] and [1A].) A POSITA looking to implement Eckhardt’s teaching would have sought a UV source that was highly effective at low doses that could be used without damaging living skin or tissue. (EX1003, ¶ 169.) As discussed with respect to Element [1C], a POSITA would have known that Sosnin’s 222 nm excimer lamp could be used to disinfect skin or tissue at levels that were known not to damage, or at least were considered an acceptable risk, for living skin or tissue. (EX1003, ¶ 169; *see also* Element [1C], *supra*.)

VI. DISCRETION SHOULD NOT PRECLUDE INSTITUTION

A. The Board Should Not Exercise Discretion Under 35 U.S.C. 325(d)

The Board should not exercise its discretion to deny institution under 35 U.S.C. § 325(d) because the two-part framework set forth in *Advanced Bionics, LLC v. MED-El Elektromedizinische Geräte GmbH* is not satisfied. IPR2019-

01469, Paper 6 (Feb. 13, 2020).

1. Sosnin and Eckhardt Do Not Present “The Same or Substantially The Same” Arguments Used in Prosecution

The first prong of *Advanced Bionics* asks whether the art or arguments presented in the Petition are the same or substantially the same as those previously presented to the Office. Paper 6 at 8. While Sosnin and Eckhardt were of record during prosecution, neither was identified as being overcome by the applicant in any reason for allowance. (EX1002, 13, 349-350.) Further, the arguments presented here with respect to these references were not the same arguments presented by the applicant to overcome the four primary references the Examiner relied upon during prosecution of the '951 Patent, which were overcome as follows:

- **Coogan** – applicant argued Coogan did not disclose 222 nm wavelength; overcame rejection by removing wavelength of 282 nm. (See EX1002, 255-265.)
- **Sizer** – applicant argued Sizer did not disclose disinfecting human or animal tissue. (*Id.*, 180-183.)
- **Ressler** – applicant antedated Ressler with a 37 C.F.R. 131 affidavit to get behind Ressler’s disclosure of 222 nm wavelength. (*Id.*, 53-55, 66-68.)
- **Tribelsky** – applicant cancelled claims including the limitation “at least two single wavelengths.” (*Id.*, 257, 298.)

Apart from the Ressler prior art reference that was antedated, the arguments related to Sosnin and Eckhardt are not the same or substantially the same as those previously presented to the Office.

First, Sosnin presents new disclosures that were not substantively considered by the Examiner during prosecution (due to the antedating of Ressler), namely, inactivating microorganisms using 222 nm light at low doses. (*See* Section V(A)(2), *supra.*) As explained above, Sosnin is statutory § 102(b) art to the claims and as such cannot be antedated with an affidavit. *See* 37 C.F.R. § 1.131(a)(2); *Application of Foster*, 343 F.2d 980, 988 (C.C.P.A. 1965).

Sosnin was cited on one IDS, and was never considered by the Examiner during the continued examination. (EX1002, 308.) The fact that it was cited as one of dozens of pieces of art cited to the Examiner over multiple IDSs, without any explanation of why the claims were allowable over Sosnin, is of little probative value in a § 325(d) analysis, especially in light of the strong showing of obviousness presented herein. *See Navistar, Inc. v. Fatigue Fracture Tech., LLC*, IPR2018-00853, Paper 13 at 17 (P.T.A.B. Sept. 12, 2018) (“Under [Becton factors] (c), (d), and (f) . . . the fact that [references] were of record, but not applied in any rejection by the Examiner . . . provides little impetus for us to exercise our discretion to deny institution under [35 U.S.C.]§ 325(d).”).

Second, to the extent Patent Owner argues that Eckhardt is “substantially the

same art,” that was considered during prosecution, this ignores one critical difference between Eckhardt of this Petition and the Eckhardt ’113 patent before the Examiner. The Eckhardt here is §102(b) art that cannot be sworn behind. The Eckhardt ’113 patent before the Examiner was §102(e) art that the applicant could antedate with a Rule 1.131 declaration.¹⁶ Thus, when the Examiner found the Rule 1.131 declaration sufficient to antedate Ressler (and by proxy, the Eckhardt ’113 patent), she should have nevertheless considered the Eckhardt publication (§102(b) art) which disclose all of the claim limitations, as discussed herein. There is no indication in the prosecution history that the Examiner considered the prior publication of Eckhardt under §102(b) in any priority analysis. The Examiner’s failure to do so was among one of several material errors made during prosecution, further discussed below.

Additionally, this Petition presents additional evidence and arguments not before the Examiner during prosecution. Not only did the Examiner not have the combination of Eckhardt and Sosnin before her during prosecution, but the Examiner also did not make any rejection in light of what a POSITA would have known and understood with respect to the exposure limits finding human exposure

¹⁶ Eckhardt ’113 was issued on May 4, 2004, less than one year prior to the earliest alleged priority date of the provisional application filed Jan 31, 2005.

to 222 nm UV radiation permissible under certain conditions. (*See, e.g.*, EX1007, 8, 11, 15-16; EX1003, ¶¶ 95-109, 122-128, 168-169.)

2. The Examiner Materially Erred in Allowing The Claims

If the Board nevertheless considers the second prong of *Advanced Bionics*, the Examiner made at least two material errors that weigh against discretionary denial: (1) purportedly crediting the applicant's Rule 1.131 declaration without performing a priority analysis, and (2) overlooking key disclosures in Eckhardt that render the claims of the '951 Patent unpatentable.

(a) The Examiner erred in allowing claims lacking written description support in the alleged priority documents.

The Examiner only allowed the claims of the '951 Patent after the applicant submitted a § 1.131 declaration to antedate the Ressler prior art patent under 35 U.S.C. § 102(e). (EX1002, 13, 349-350.) This Petition, however, presents a Ground with references published more than one year prior to the effective filing date of the '951 Patent, which cannot be sworn behind. As discussed above, Eckhardt, for example, is a published U.S. patent application that is § 102(b) art and cannot be antedated. (*See* Section II(B)(2), *supra*.) The Examiner of the '951 Patent erred because she considered only the Eckhardt '113 patent and apparently overlooked the prior publication of Eckhardt that is prior art under § 102(b).

(EX1002 at 294, 334.)

The other reference, Sosnin, was also published more than one year prior to the effective filing date and cannot be antedated. As discussed in Section II(B)(1), *supra*, the challenged claims are not supported by the written description of the earlier provisional application. “[W]hen one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference,” “such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002). The same is true of the claims of the ’951 Patent. The Examiner who allowed the claims of the ’951 Patent did not demonstrate that she conducted a claim-by-claim priority analysis. Because the reason for allowance over Ressler was the § 1.131 declaration, the effective filing date was not questioned and then resolved by such an analysis. Neither applicant nor Examiner ever supported the priority claim in the prosecution of the ’951 Patent with citations to support in the written description of the earliest priority claims. Therefore, all the asserted art qualifies as § 102(b) art that cannot be antedated with a § 1.131 declaration. *See* 37 C.F.R. § 1.131(a)(2); *Application of Foster*, 343 F.2d 980, 988 (C.C.P.A. 1965).

(b) The Rule 1.131 Declaration cannot establish prior invention of the challenged claims

Even if a Rule 1.131 declaration could establish priority, the applicant’s

declaration does not support either conception or reduction to practice of the challenged claims with respect to, at minimum, disinfecting human skin. A showing of actual reduction to practice requires (1) construction of an embodiment or performance of a process that meets all the limitations of the claims at issue; (2) a determination that the invention would work for its intended purpose; and (3) sufficient evidence to corroborate inventor testimony regarding these events. *See, e.g., Medichem, S.A. v. Rolabo, S. L.*, 437 F.3d 1157, 1169 (Fed. Cir. 2006).

Inventor-generated documents are not independent information and cannot corroborate inventor testimony. *See Kolcraft Enters., Inc. v. Graco Children's Prods., Inc.*, 927 F.3d 1320, 1324 (Fed. Cir. 2019) (substantial evidence supported Board's finding reference could not be antedated where "[a]ll cited evidence of prior conception, however, originated with the inventors").

Here, the declaration consists solely of "inventor-generated documents": an undated report that the applicant wrote, (EX1002, 69-71), an undated single page from his lab notebook, (*id.*, 73), and undated photos untethered to the claims, (*id.*, 74-76). The only evidence of the dates of any alleged inventive activities were in the Rule 1.131 declaration itself. None of this corroborates that the inventor conceived or practiced a "process for destroying a DNA or RNA of a microorganism on a substance or on a surface...wherein the substance or surface to be disinfected is human or animal tissue." (*Id.*, 51; *see also* EX1001, claim 1.)

And even if it did, the applicant made no showing that he exercised the necessary diligence between conception and reduction to practice. *See, e.g., ATI Techs. ULC v. Iancu*, 920 F.3d 1362, 1369-70 (Fed. Cir. 2019) (“The diligence requirement implements the principle that, to antedate a reference, the applicant must not only have conceived the invention before the reference date, but must have reasonably continued activity to reduce the invention to practice.”).

It is telling that documents submitted to the examiner included “REDACTED” exactly where dates should appear, concealing the fact that years passed between the notebook entries and the first patent application that added new subject matter suggesting human skin as a target for surface disinfection. (EX1002, 73; *see also* Section II.B.1(a) (noting January 31, 2006 PCT application adds new subject matter first mentioning disinfecting skin).) The applicant did not otherwise deal with the years of delay in the declaration as required, making the declaration even less credible and giving extra force to the reason behind requiring corroboration. *See* MPEP 715.07 (noting that, despite redactions, “the actual dates of acts relied on to establish diligence must be provided.”); *see also Shu-Hui Chen v. Bouchard*, 347 F. 3d 1299, 1309-10 (Fed. Cir. 2003) (noting a party’s temptation “to describe his actions in an unjustifiably self-serving manner in order to obtain a patent or to maintain an existing patent.”).

Regarding the lab notebook, all it shows is that the applicant only “tested

lamp on back of hand” with 222 nm light and determined “no erythema marker next two days,” (EX1002, 73), meaning he was not sunburnt, (EX1003, ¶ 103). This was just a rudimentary safety test. It did not suggest anywhere that the applicant directed 222 nm light to skin *for the specific purpose* of testing the *disinfection of its surface*. Nor did it demonstrate that the applicant had determined that this directed exposure would work for its intended purpose of disinfecting by destroying a DNA or RNA of a microorganism on the surface of skin. *See Medichem*, 437 F.3d at 1169-70. Moreover, “in a case involving reduction to practice, an unwitnessed notebook,” like this one, “is insufficient on its own to support a claim of reduction to practice.” *Id.* Further, even if the lab notebook was a disclosure of successfully disinfecting human skin, the lab notebook provides no evidence whatsoever of disinfecting animal tissue (as opposed to “human tissue,” which the claims recite separately “animal tissue”). *See Tech. Licensing*, 545 F.3d at 1322, 1332-33.

The other documents the applicant submitted do not support a claim of reduction to practice either. Exhibit A is an “internal report to the Board of Directors at Powerspan Corp.,” (EX1002, 67), that describes “UV sources to kill water and air borne pathogens” in wastewater, drinking water and in the air. (*id.*, 69-71). The report makes no mention of testing on human or animal tissue. Likewise, Exhibits C-E are simple photographs of lamps; none depict or otherwise

describe disinfecting human or animal tissue. (*See id.*, 74-76.)

Because no determination was made that the invention would actually work for its intended purpose, reduction to practice was neither shown nor corroborated, and the Examiner materially erred in allowing the claims.

(c) The Examiner erred in ignoring key teachings in Eckhardt.

Even if Petitioners' arguments regarding Eckhardt are considered to be "substantially the same argument" before the PTO, the Examiner made a second material error in overlooking key teachings in Eckhardt.

Eckhardt was cited in a §103 rejection only as a secondary reference that disclosed dependent claims for "provid[ing]/position[ing] a wand in a process for destroying a DNA or RNA of a microorganism" and disinfecting a "wound." (*See* EX1002, 294-295, 300-301.) The Examiner relied on primary reference Coogan to disclose "at least one of 282nm and 308nm" light. (*Id.*, 293.) The applicant then dropped all wavelengths besides 222 nm and dropped claims relating to disinfecting a wound. (*Id.*, 255-265.) The Examiner thus materially erred by thereafter overlooking Eckhardt's teachings of using particular UV light sources and ranges to disinfect skin. (EX1004, [0031], [0043], [0069]-[0070].)

The Examiner did initially cite Eckhardt for "directing photons to a...surface to be disinfected being human or animal tissue...in the form of a wound,"

(EX1002, 295). But months later she allowed claims on what she had found in Eckhardt, (*see id.*, 158-160, 182), contending that the new primary reference, Sizer, “does not specifically teach or suggest that the substance or surface to be disinfected is human or animal tissue,” (*id.*, 159-160). The Examiner’s findings are internally inconsistent. It is apparent from the record that Eckhardt disclosed a key limitation the Examiner relied on to find the claims patentable over Sizer. Thus, the Examiner materially erred another time. *See Advanced Bionics*, Paper 6, 8.

For at least these reasons, discretionary denial under § 325(d) is not warranted.

B. The Board Should Not Exercise Discretion Under 35 U.S.C. 314(a)

Institution is consistent with the Director’s recent guidance on applying the *Fintiv* Factors. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv I*”); *see also* EX1033 (*Memorandum: Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* (June 21, 2022) (“Director’s Memo”). First and foremost, the merits of the Petition are “compelling,” and this “alone demonstrates that the PTAB should not discretionarily deny institution under *Fintiv*” even if it determines that the other factors favor discretionary denial. Director’s Memo, 3-5.

Ground 1 presents a theory of obviousness, which “if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.” *Id.*, 4. Regardless, even if the Board were to address the full *Fintiv* framework, a holistic analysis favors institution. *Fintiv I*, 6.

Factor 1 (possibility of a stay) favors institution. The three companion litigations have been consolidated and stayed pending the outcome of IPRs challenging two other patents-in-suit, (*see* EX1034; EX1035.), weighing strongly in favor of institution. *Snap, Inc. v. SRK Technology LLC*, IPR2020-00820, Paper 15 at 8-9, 19 (PTAB Oct. 21, 2020) (precedential).

Factor 2 (proximity of trial date to final written decision) favors institution. Because the case is stayed, no trial date has been scheduled. Final Written Decisions are expected in August 2023 and October 2023, meaning the litigation will remain stayed until at least October 2023. Petitioners expect the stay to continue through pendency of this third IPR proceeding too, weighing strongly in favor of institution.

Factor 3 (investment in parallel proceedings) favors institution. Before the stay, the cases were in early stages. Infringement contentions had only been served on two Petitioners (and none had been served on the new '951 Patent) and claim construction had not yet begun. Patent Owner added the '951 Patent to the litigation in amended complaints filed on March, 9, 2022 and March 25, 2022.

(EX1027; EX1028; EX1029.) The PTAB has determined in similar circumstances that this factor does not weigh against institution where parallel litigation is in early stages and the petition is filed proximate to the statutory bar date. *See e.g., Intel Corp. v. PACT XPP Schweiz AG*, IPR2020-00540, Paper 11 at 14-15 (PTAB September 10, 2020) (instituting IPR petition filed three days before bar date). Thus, factor three similarly favors institution.

Factor 4 (overlap in issues) is neutral. Petitioners ask the Board to consider the unique challenges raised in the Petition. If the Board institutes, Petitioners will not pursue district court invalidity challenges against the '951 Patent based on the same grounds in this Petition, thereby mitigating risk of duplicated effort between the district court and the PTAB.

Factor 5 (overlap in parties) favors institution because while Eden Park, Larson, and Far UV are defendants, Petitioner Ushio America is not. The lack of complete identity of parties weighs strongly in favor of institution. This fact also weighs factors two, three, and four even more strongly in favor of institution.

Factor 6 (other circumstances, including the merits) favors institution. A determination that evidence “presented at the institution stage presents a compelling unpatentability challenge” favors institution. (EX1033, 2-5, 9.) Compelling merits means it is “highly likely that the petitioner would prevail with respect to at least one challenged claim.” *See Opensky Indus., LLC et al. v. VLSI*

Tech. LLC, IPR2021-01064, Paper 107 at 4-5 (PTAB October 14, 2022). As explained herein and supported by Mr. Lawal's expert declaration, the strength of the Ground strongly favors institution. (EX1003, ¶¶ 1-170.)

Further evidence of the merits of Petitioners' challenge is the Board's decision instituting review of the '951 Patent's parent patent. *See Eden Park Illumination, Inc. et al. v. S. Edward Neister*, IPR2022-00381, Paper 12 (P.T.A.B. Aug. 15, 2022). Claim 1 of the parent patent is nearly identical to claim 1 of the '951 Patent, with the only substantive difference being removal of a 282 nm wavelength. The Board's analysis found Petitioners showed "a reasonable likelihood of prevailing on its obviousness challenge to claim 1." *See id.* at 18; *see also id.* at 14-18. The grounds here are equally strong, and institution would likely result in invalidation of the challenged claims.

For at least these reasons, discretionary denial under § 314(a) is not warranted.

VII. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioner authorizes the Patent and Trademark Office to charge any fees to Deposit Account No. 06-1050.

VIII. CONCLUSION

The Petitioners respectfully request institution of IPR for the challenged claims.

IX. MANDATORY NOTICES UNDER 37 C.F.R § 42.8(a)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Eden Park Illumination, Inc., Larson Electronics LLC, Far UV Technologies, Inc., and Ushio America, Inc. are the real parties-in-interest. Besides Petitioners, no other party had access to the Petition, and no other party had any control over, or contributed to any funding of, the preparation or filing of this Petition.

B. Related Matters under 37 C.F.R. § 42.8(b)(2)

Petitioners are not aware of any disclaimers, reexamination certificates, or petitions for *inter partes* review for the '951 Patent. The '951 Patent is the subject the following civil actions:

Caption	Case No.	District
<i>High Energy Ozone LLC et al. v. Larson Electronics LLC</i>	3:21-cv-01166	N.D. Tex.
<i>High Energy Ozone LLC et al. v Eden Park Illumination, Inc.</i>	3:22-cv-00425	N.D. Tex.
<i>High Energy Ozone LLC et al. v. Far UV Technologies</i>	3:22-cv-00280	N.D. Tex.

IPRs were previously filed by Petitioners against two additional patents asserted in the above captioned proceedings: the '951 patent's parent, U.S. Pat. No. 9,700,642 (*see* IPR2022-00381, filed Feb. 4, 2022), and another patent that shares an inventor and assignee with the '951 and '642 patents, U.S. Pat. No. 8,975,605

(see IPR2022-00682¹⁷, filed Mar. 25, 2022). The '605 patent is not legally related to the '951 and '642 patents. Both proceedings were instituted on August 15, 2022 and October 27, 2022, respectively.

C. Lead and Back-Up Counsel under 37 C.F.R. § 42.8(b)(3)

Petitioners provide the following designation of counsel, and Powers of Attorney (37 C.F.R. § 42.10(b)) are filed concurrently with this Petition.

Lead Counsel	Backup counsel
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D. Service Information

Please address all correspondence and service to the address listed above.

Petitioners consent to electronic service by email at IPR00012-0216IP1@fr.com.

¹⁷ Petitioner Ushio did not join the petition challenging the '605 patent.

Respectfully submitted,

Dated: Mar. 8, 2023

/David Conrad/

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CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,984 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated: Mar. 8, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on March 8, 2023, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided via Federal Express, to the Patent Owner by serving the correspondence address of record as follows:

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