IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	S. Edward Neister	
U.S. Patent No.:	9,700,642	Attorney Docket No.: 00012-0170IP1
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Filing Date:	April 17, 2014	
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. 9,700,642 PURSUANT TO 35 U.S.C. §§ 311-319, 37 C.F.R. § 42

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EXHIBITS

Exhibit #	*Description*
1001	U.S. Patent No. 9,700,642
1002	Prosecution History of U.S. Patent No. 9,700,642
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., *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) ("Sosnin")
1006	U.S. Patent Publication No. 2005/0079096 to Brown-Skrobot et al. ("Brown-Skrobot")
1007	Clauss, M., Mannesmann, R. and Kolch, A., *Photoreactivation of Escherichia coli and Yersinia enterolytica 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) ("Clauss")
1008	U.S. Provisional App. No. 60/593,626
1009	PCT App. No. PCT/US2006/003393
1010	Declaration and Curriculum Vitae of Jacob Robert Munford
1011	U.S. Patent Publication No. 2002/0146343 to Jenkins et al.
1012	HEALTH PHYSICS SOC'Y, *Ultraviolet Radiation and Public Health*, 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., *Ultraviolet Light C in the Treatment of Chronic Wounds with MRSA: A Case Study*, 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 No. 8,975,605 to Neister
1020	Kogelschatz et al., *High-intensity sources of incoherent UV and VUV excimer radiation for low-temperature materials processing*, 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, *Standardization of Methods for Fluence (UV Dose) Determination in Bench-Scale UV Experiments*, 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	Ian A. Ramsay et al., *The Synergistic Effect of Excimer and Low-Pressure Mercury Lamps on the Disinfection of Flowing Water*, 63 J. FOOD PROT. 1529 (2000)
1027	Complaint for Patent Infringement, *High Energy Ozone LLC et al. v. Far UV Technologies*, Case No. 4:21-cv-00345, Dkt. No. 1 (W.D. Mo. May 17, 2021)
1028	Complaint for Patent Infringement, *High Energy Ozone LLC et al. v Eden Park Illumination, Inc.*, Case No. 1:21-cv-02753, Dkt. No. 1 (N.D. Ill. May 20, 2021)
1029	Complaint for Patent Infringement, *High Energy Ozone LLC et al. v. Larson Electronics LLC*, Case No. 3:21-cv-01166, Dkt. No. 1 (N.D. Tex. May 21, 2021)
1030	Order re Plaintiff's Suggestion of Bankruptcy, *Healthe, Inc. v. High Energy Ozone LLC et al.*, Case No. 6:20-cv-2233, Dkt. No. 114 (M.D. Fl. Dec. 16, 2021)
1031	Joint Status Report and Request for Conference re Eden Park and Far UV Stays Pending Transfer, *High Energy Ozone LLC et al. v. Larson Electronics LLC*, Case No. 3:21-cv-01166, Dkt. No. 42 (N.D. Tex. Nov. 30, 2021)
1032	Electronic Minute Entry re Status Conference, *High Energy Ozone LLC et al. v. Larson Electronics LLC*, Case No. 3:21-cv-01166, Dkt. No. 45 (N.D. Tex. Dec. 8, 2021)
1033	Scheduling Order, *High Energy Ozone LLC et al. v. Larson Electronics LLC*, Case No. 3:21-cv-01166, Dkt. No. 30 (N.D. Tex. Oct. 18, 2021)

1034	Plaintiff Preliminary Infringement Contentions, *High Energy Ozone LLC et al. v. Larson Electronics LLC*, (Nov. 24, 2021)
1035	Plaintiff Initial Infringement Contentions, *High Energy Ozone LLC et al. v Eden Park Illumination, Inc.*, (Oct. 26, 2021)
1036	U.S. Patent No. 5,843,374 to Sizer et al.
1037	Prosecution History of U.S. Patent No. 8,753,575
1038	Prosecution History of U.S. Patent No. 11,246,951
1039	Von Sonntag, *Disinfection by free radicals and UV-radiation*, 4 WATER SUPPLY 11 (1986)
1040	Frederick L. Gates, *A study of the bactericidal action of ultra violet light. III. The absorption of ultra violet light by bacteria*, 14 J. GEN. PHYSIOLOGY 31 (1930)
1041	1600 PTAB & Beyond: How reliable are trial dates relied on by the PTAB in the *Fintiv* analysis?, Perkins Coie, https://www.1600ptab.com/2021/10/how-reliable-are-trial-dates-relied-on-by-the-ptab-in-the-fintiv-analysis/ (last accessed Feb. 3, 2022)
1042	Order Granting Joint Motion for Extension of Time to Serve Disclosure of Preliminary Invalidity Contentions, *High Energy Ozone LLC et al. v. Larson Electronics LLC*, Case No. 3:21-cv-01166, Dkt. No. 48 (N.D. Tex. Jan. 25, 2022)
1043	First Amended Complaint (with redline), *High Energy Ozone LLC et al. v. Larson Electronics LLC*, Case No. 3:21-cv-01166, Dkt. No. 47 (N.D. Tex. Jan. 18, 2022)

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 1–10 and 12–18 (the "Challenged Claims") of U.S. Patent No. 9,700,642 (the "'642 Patent," EX1001), issued and assigned to S. Edward Neister ("Patent Owner").

The invention of the '642 Patent is not new. Rather, the claimed invention encompasses known methods of disinfecting substances and surfaces using ultraviolet ("UV") light of particular wavelengths. The Challenged Claims of the '642 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 '642 Patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. A specific listing of Petitioners' asserted grounds 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 Challenged Claims 1–10 unpatentable as obvious under 35 U.S.C. § 103. (*See* EX1003 at ¶¶ 75-92, 105-146.)

Additionally, Brown-Skrobot in view of Clauss renders Challenged Claims 12–18 unpatentable as obvious under 35 U.S.C. § 103. (*See id.*, ¶¶ 93-104, 147-172.)

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 '642 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 '642 Patent less than one year prior to the filing of this Petition. (*See* EX1027 (complaint filed May 17, 2021); EX1028 (complaint filed May 20, 2021); EX1029 (complaint filed May 21, 2021).)[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

[1] Petitioner Ushio America, Inc. ("Ushio") is not involved in litigation of the '642 Patent.

Claims are unpatentable as obvious under 35 U.S.C. § 103(a) based on the following grounds and as established by the declaration of Oliver Lawal (EX1003):

Ground	'642 Patent Claims	Asserted Prior Art
Ground 1	1–10	§ 103 over Eckhardt in view of Sosnin
Ground 2	12–18	§ 103 over Brown-Skrobot in view of Clauss

1. Effective Priority Date

The '642 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. 14/254,957, filed April 17, 2014. It is a continuation-in-part that claims benefit to U.S. Patent App. No. 11/831,667, filed on July 31, 2007, which is a continuation-in-part of PCT App. No. PCT/US2006/003393, 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 '642 Patent are not entitled to claim priority back to the earlier applications.

(a) Claims 1-10 are not supported by the provisional application

Claims 1–10 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 skin." (EX1003, ¶ 73; *Compare* EX1001, cls. 1–10 *with* EX1008.) Claims 1–10 are therefore not entitled to an effective filing date earlier than January 31, 2006.

During prosecution, as "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." (EX1002, 7 (citing EX1008, 18 (page 12 lines 12-14).) Disclosing disinfecting "food stuffs" does not disclose disinfecting human or animal skin. (EX1003, ¶ 73.)

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, and critical plastics and materials used in medical devices." (EX1009, 27.) The applicant did not provide any more detail, however, until it added new matter during prosecution of the application that

resulted in the '642 Patent. Here, the applicant added three full paragraphs with a suggestion for how the claimed method may be useful for disinfecting skin. (*See,* EX1002, 37; *see also id*., 36-37.)

Additionally, to the extent the "food stuffs" recited in the provisional application could be understood to read on "animal skin," 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, 1332-33 (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 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. All grounds challenging claims 1–10 rely 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) **Claims 12-18 are not supported by either the provisional application or the original non-provisional application**

Similarly, claims 12–18 are not supported under 35 U.S.C. § 112 by at least PCT App. No. PCT/US2006/003393, which does not disclose "generating photons of at least two single line wavelengths…, the at least two single line wavelengths being at least two of 222 nm, 254 nm and 282 nm." (EX1003, ¶ 74; *Compare* EX1001, cls. 12–18 *with* EX1009.) Claims 12–18 are therefore not entitled to an effective filing date earlier than July 31, 2007.

During prosecution, generating photons of at least two wavelengths was not

[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.").

disclosed in either the provisional application or the PCT application. In fact, use of a 282 nm wavelength at all was not disclosed in either of these applications[3]. Instead, the idea first appeared in the continuation-in-part application filed on July 31, 2007 (U.S. App. No. 11/831,667, issued as U.S. Pat. No. 8,753,575), which added new matter not disclosed in the PCT application. (*See, e.g.*, EX1037, 743-744 (disclosing a source that can emit photons at 282 nm).) The applicant argued that it was this disclosure that supported the limitation "at least two single line wavelengths being at least two of 222 nm, 254 nm and 282 nm" in the '642 Patent. (*See* EX1002, 161-162 (applicant pointing for support for claim 37 to "original claim 17 in the application as filed, as well as at page three, second and third paragraphs of the summary.").) The "original claim 17" refers to claim 17 originally filed with U.S. App. No. 11/831,667. (*See* EX1037, 761 ("17. The process of claim 16, wherein the wavelength is at least one of 222 nm, 254 nm, and 282 nm.").) "[P]age three, second and third paragraphs of the summary" refer to the disclosures in the specification

[3] Because claims 1-10 discussed in Section II(B)(1)(a) also claim using a 282 nm wavelength, they are likewise not entitled to an effective filing date earlier than July 31, 2007. But the Board need not make this finding for claims 1-10 because, as noted above, all of the art relied upon pre-dates the PCT filing by more than a year.

introducing for the first time using "282 nm to target a mixture of amino acids and some proteins that absorb at this longer wavelength." (*Id*., 744.) The applicant did not cite to or rely on any disclosures in the earlier provisional or PCT applications.[4] Notably, even these disclosures do not explicitly refer to using more than a single wavelength. (*Compare id*., 744 *with* Ex. 1002, 37 (expressly describing using two wavelengths).) Additionally, the only UV light sources disclosed in the PCT application generate only one single line wavelength. (EX1003, ¶ 74.)

For the same reasons explained in Section II(B)(1)(a), to obtain an earlier effective filing date for a particular claim, the written description provided therein must support each part of the claim limitations. *See Tech. Licensing*, 545 F.3d at 1322, 1332-33; *PowerOasis*, 522 F.3d at 1309-11. Here, the earliest specification

[4] Petitioner notes that the specification filed on July 31, 2007 appears to be a heavily amended version of the PCT specification, though the changes are not marked or otherwise provided. (*Compare* EX1009, 20-32, *with* EX1037, 741-758.) The applicant filed an amended specification consisting of the original PCT specification bearing minimal underlined changes. (*Compare* EX1037, 715-724, *with* EX1009, 20-32.) When the applicant filed the application that led to the '642 Patent, he reverted back to the July 31, 2007 amended specification and incorporated substantial additions, primarily about disinfecting skin. (*See* EX1002, 27-44.)

which could arguably support a claim to 282 nm wavelength or the use of more than one single line wavelength is the July 31, 2007 specification in the '575 Patent's file history.

Thus, the Board need not resolve whether claims 12–18 are entitled to a later priority date or subject to post-AIA § 102. All grounds challenging Claims 12–18 rely on prior art patents, patent applications, or printed publications published more than one year prior to July 31, 2007, and are therefore prior art under at least pre-AIA § 102(b) and post-AIA § 102(a).

(c) Examiner Comment in Related Application Does Not Substitute for Priority Analysis

The Patent Office recently allowed a child application of the '642 Patent, U.S. Pat. App. 15/645,480, which issued on January 26, 2021 as U.S. Pat. No. 11,246,951. (*See* EX1038 at 12-14.) In the notice of allowance, the Examiner mentioned the 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)(l) 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).

(EX1038 at 12.)

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)." (EX1038 at 348.) Thus, these statements are ambiguous at best, and do not provide a clear or reliable priority determination.

Further, presumption of priority does not attach to provisional applications or claims in a continuation-in-part patent. With respect to priority to provisional applications, the Federal Circuit has ruled that "because the PTO does not examine provisional applications as a matter of course[,] such a presumption is…not justified" for patents that seek to claim the benefit of a provisional application, as is the case here for claims 1-10. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1380 (Fed. Cir. 2015). Similarly, no presumption is assumed for claims in a continuation-in-part application, as all the claims are here. *See 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 as such, cannot satisfy Patent Owner's burden to prove that its claims have written description support in the earlier applications. For the reasons explained above, they do not.

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 '642 Patent. Eckhardt is prior art under at least under pre-AIA § 102(b) and post-AIA § 102(a)(1).

Sosnin (EX1005)

Sosnin (EX1005) is a printed publication titled "The Effects of UV Irradiation and Gas Plasma Treatment on Living Mammalian Cells and Bacteria: A

Comparative Approach." Sosnin was published in Volume 32, Issue No. 4 of *Institute of Electrical and Electronics Engineers (IEEE) Transactions on Plasma Science* no later than October 2004. (EX1010, ¶¶ 28–31.) *IEEE Transactions on Plasma Science* was an international journal for peer-reviewed plasma science and engineering articles published by The Institute of Electrical and Electronics Engineers, Inc., well-known at the time as a professional association and major publisher of literature in the electrical and electronics engineering, computer science, and related fields. (EX1003, ¶ 79.) Cataloging dates extracted from library catalog records further corroborate the October 2004 public availability of Sosnin. (EX1010, ¶¶ 28–31.) This is supported by indicia in Sosnin, which bears an issue date of "August 2004," copyright date of "2004," and a library stamp from the Linda Hall library dated "Oct 14 2004." (*See generally* EX1005; *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 '642 Patent, and is prior art to claims 1–10 at least under pre-AIA §§ 102(a), (b) and post-AIA § 102(a)(1).

Brown-Skrobot (EX1006)

Brown-Skrobot (EX1006) is a published U.S. patent application titled "Method and Apparatus of Sterilization Using Monochromatic UV Radiation Source," and was filed on September 13, 2004, and published on April 14, 2005.

Brown-Skrobot was published more than one year prior to July 31, 2007, and is prior art to challenged claims 12–18 at least under pre-AIA §§ 102(a), (b) and post-AIA § 102(a)(1).

Clauss (EX1007)

Clauss (EX1007) is a printed publication titled "Photoreactivation of *Escherichia coli* and *Yersinia enterolytica* after Irradiation with a 222 nm Excimer Lamp Compared to a 254 nm Low-pressure Mercury Lamp." Clauss was published in Volume 33, Issue No. 6, of *Acta hydrochimica et hydrobiological* no later than January 2006. (EX1010, ¶¶ 13–15.) *Acta hydrochimica et hydrobiological* was an international journal for peer-reviewed scientific articles published by Wiley, well-known at the time as a major publisher of scientific journals and texts. (*Id.*, ¶ 13.) Cataloging dates extracted from library catalog records further corroborate the December 2005 public availability of Clauss. (*Id.*, ¶¶ 14–15.) This is supported by indicia in Clauss, which bears an issue date of "December 2005," copyright date of "2005," and a library stamp from the Linda Hall library dated "Jan 09 2006." (*See generally* EX1007; *see* EX1010, ¶ 15 (discussing the library processing stamp).) Clauss was published more than one year prior to July 31, 2007, and is prior art to Claims 12–18 at least under pre-AIA §§ 102(a), (b) and post-AIA § 102(a)(1).

III. THE '642 PATENT

A. Overview

The '642 Patent is directed to using UV light for "disinfecting and sterilizing" surfaces and substances, including human or animal skin. (EX1001, Abstract.) The '642 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, 2:35–47.) The "preferred embodiment" "emits a highly intense narrow wavelength band of photons" at 222 nm. (EX1001, 3:6–11.) Other embodiments emit photons at 282 nm or 254 nm. (EX1001, 3:12–25.) Another embodiment emits 207 nm, or a combination of 207 nm and 222 nm using two lamps, or a dual annulus lamp filled with two different gasses to generate the two wavelengths. (EX1001, 8:65–9:10.)

The applicant acknowledged that the general concept of using UV light for germicidal use was already well known at the time the '642 Patent was filed. (*See, e.g.*, EX1001, 1:33–50.) He also acknowledged that researchers had discovered and documented this phenomenon decades before the applicant's alleged invention. (*See, e.g.*, EX1001, 4:6–14, 16–19 (citing Von Sonntag, *Disinfection by free radicals and UV-radiation*, 4 WATER SUPPLY, at 11-18 (1986) (EX1039) and Gates, F. L., *A 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, 1:43–46.) 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." (EX1001, 2:11–15.)

Despite these acknowledgements, the '642 Patent makes several misleading statements about the state of the art of germicidal applications for UV radiation as of its filing. (*See* EX1003, ¶¶ 59-65.) 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, 2:7–9, 16–17.) Researchers believed this was because the UV energy produces dimers in DNA, which prevents replication. (EX1001, 3:39–50.) 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." (EX1001, 2:19–24.) This is misleading. (EX1003, ¶ 59.) Researchers were already well aware of the effect of the shorter wavelengths of light in the far UV ("235 nm" to "185 nm")

[5] EX1039 is a printed publication that was publicly available no later than 1986. (*See* EX1010, ¶¶ 32-34.) EX1040 is a printed publication that was publicly available no later than June 1975. (*See* EX1010, ¶¶ 35-37.)

spectrum. (EX1001, 2:9–11; EX1003, ¶¶ 59, 61; *see also* EX1001, 4:6–14, 16–19 (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, 4:52–65 (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…" (EX1001, 4:62–65.)

Second, the applicant stated that "all literature directs researchers away from using any shorter wavelengths" than 254 nm for sterilization and disinfection. (EX1001, 2:24–27.) This, too, was misleading. (EX1003, ¶ 61.) Sosnin, for example, teaches using an excimer ultraviolet lamp for sterilizing surfaces by irradiating bacteria such as *E. coli* using wavelengths of at least 222 nm and 282 nm, and includes "typical bacterial survival curves, resulting from the irradiation of *E. Coli* with XeBr and KrCl (λ = 222 nm) excilamps[.]" (EX1005, 1547; *see also id.*, FIG. 9; EX1003, ¶ 81.) Brown-Skrobot teaches sterilization of surfaces using excimer lamps in a "preferred" range as low as "220 nm." (EX1006, ¶¶ 0033–0034.) 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, 2:16-19; EX1003, ¶¶ 61-62.) 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, ¶ 61.) 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 '642 Patent, (EX1001, 2:35–37), was the trigger for more widespread employment of other wavelengths. (EX1003, ¶ 61.)

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 '642 Patent includes 18 claims, of which claims 1 and 12 are independent.

Independent Claim 1 and its dependents are directed to a method for disinfection using photons of wavelength 222 nm or 282 nm, wherein the substance or surface to be disinfected is human or animal skin.

Independent Claim 12 and its dependents are directed to a method for

disinfection by generating photons of at least two single line wavelengths selected from 222 nm, 254 nm, or 282 nm.

C. Prosecution History

Challenged independent Claim 1 of the '642 Patent was initially presented during prosecution by preliminary amendment as originally filed Claim 16 and did not include the step of directing the photons to human or animal skin. (EX1002, 99.) The examiner rejected prosecution Claim 16 as anticipated by, among others, a reference called Sizer. (EX1002, 131.) The applicant then amended Claim 16 to incorporate a dependent claim allowable in view of Sizer, which included the additional limitation "wherein the surface to be disinfected is human or animal skin." (EX1002, 159; *see also id.*, 206.) This amendment was "the primary reason for allowance." (EX1002, 192.)

Challenged independent Claim 12 was initially presented during prosecution by claim amendment as Claim 37. (EX1002, 161.) It did not face a rejection in view of prior art.

D. Level of Ordinary Skill

A person of ordinary skill in the art ("POSITA") of the '642 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 1–10 and 12–18 of the ’642 Patent. As detailed below, this request shows a reasonable likelihood that Petitioners will prevail with respect to challenged claims 1–10 and 12–18 of the ’642 Patent.

A. [GROUND 1] Claims 1–10 are rendered obvious by Eckhardt in view of Sosnin

1. Overview of Eckhardt

Eckhardt teaches a method for sterilizing or disinfecting a region underneath a bandage on a patient by applying UV light to the region through the bandage.

(EX1004, Abstract, ¶ 0031.) Eckhardt accomplishes this by using a UV-transmissive bandage and 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.)

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.) "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), it does not explicitly state generating photons of 222 nm or 282 nm, specifically.

2. Overview of Sosnin

Sosnin discloses the differential effects that UV irradiation and gas plasma treatment have on mammalian cells compared to bacteria. Specifically, Sosnin studied "the reaction of living mammalian cells to UV radiation, using narrow-band UV lamps (excilamps) and *Chinese Hamster Ovary* (CHO-K1) cells in culture as a model system" and compared "the effects of UV radiation on cells with data on UV bacterial deactivation." (EX1005, 1544.) Sosnin explains that "[e]xcimer lamps (or so-called excilamps) are a subclass of electric discharge lamps emitting in UV or

vacuum UV spectral ranges," and "[t]he main feature which distinguishes excilamp from other UV sources is that their spectra consist of narrow bands (the band halfwidth rarely exceeds 5-8 nm)." (*Id.*, 1545.)

Sosnin studied the effects of a xenon and bromine (XeBr) excimer lamp, which "produces a spectrum with an emission peak at $\lambda \sim 282$ nm," noting that, "as confirmed in our previous experiments, the XeBr lamp is most efficient in sterilization." (*Id*.) Further, Sosnin also compared the effects observed of XeBr irradiation on mammalian cells with previous studies testing XeBr irradiation and KrCl (krypton and chlorine) excimer lamp irradiation on *E. coli* bacteria. (*See id*., 1547 (referring to Figures 8 and 9 as "typical bacterial survival curves").) KrCl excilamps produce photons with a wavelength of 222 nm. (*See id*.; EX1003, ¶¶ 40, 81.) Sosnin found that the mammalian cells "are extremely resistant to UV" in comparison to the *E. coli* bacteria, which require "much lower" UV doses. (EX1005, 1547.) Sosnin concludes 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." (*Id*.)

3. Reasons to Combine Eckhardt and Sosnin

In combination, Eckhardt's method of disinfecting "bare skin" using "any light source that emits light capable of sterilization or disinfection" is performed using the KrCl or XeBr excimer light sources of Sosnin, which generate photons

having a wavelength of 222 nm or 282 nm. (EX1003, ¶¶ 40, 81; EX1004, ¶¶ 0031, 0069; EX1005, 1547.) Neither Eckhardt nor Sosnin was before the examiner during prosecution of the '642 Patent.

A POSITA would have been motivated to integrate the disclosures of Eckhardt and Sosnin for at least the following independent reasons. (EX1003, ¶¶ 82-92.)

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, ¶ 84; EX1004, ¶ 0031; EX1005, 1547); *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 spectra that "consist of narrow bands (the band halfwidth rarely exceeds 5-8 nm)." (EX1003, ¶ 84; EX1005, 1545.) Like the lamps in Eckhardt, Sosnin teaches using its excimer lamps to kill bacteria—i.e., to sterilize surfaces. (EX1003, ¶ 85; EX1005, 1546-1547.)

Second, a POSITA would have been motivated to supplement Eckhardt's

high-level disclosure of using germicidal UVC light to disinfect "bare skin" 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, ¶ 86; EX1004, ¶¶ 0031, 0069; EX1005, 1547.) 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, ¶ 87; EX1004, ¶ 0070; EX1005, 1547; *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 safely 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, ¶ 89; EX1004, ¶¶ 0031, 0069; EX1005, 1547; *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, ¶ 90; 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.").)

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, ¶ 91; *see, e.g.*, EX1017 (teaching irradiating skin 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, 3:51–54, 4:16–19), 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."); 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.").)[6]

4. Analysis

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

The combination discloses Element [1pre]. (EX1003, ¶¶ 106-108.)

Eckhardt, for example, teaches using light source 7 to disinfect human or animal skin. (EX1003, ¶ 107; EX1004, ¶ 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, ¶ 108; EX1004, ¶ 0030.) A POSITA would understand that the statement in Eckhardt of "rendering the microorganisms unable to reproduce" refers to mutagenicity. (EX1003, ¶ 108.) Mutagenicity is permanent change of the structure of genetic material such as DNA

[6] EX1017 is a printed publication that was publicly available no later than November 2002. (*See* EX1010, ¶¶ 25–27.)

or RNA, which can inhibit reproduction. (EX1003, ¶ 108.) 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 '642 Patent specification. (EX1001, 4:21–33, 7:61–66; EX1003, ¶ 108; *see also* EX1019, 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 at least one wavelength corresponding to a peak absorption wavelength of DNA or RNA, the at least one wavelength being at least one of 222 nm and 282 nm;

The combination discloses Element [1A]. (EX1003, ¶¶ 109-112.)

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, ¶ 110; 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, ¶ 110; 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, ¶ 110; 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 wavelengths 222 nm and 282 nm. (EX1003, ¶ 111; EX1004, ¶¶ 0043, 0070.) Further, Sosnin specifically discloses sterilizing through irradiation using XeBr and KrCl excimer lamps, which generate photons with wavelengths of 282 nm and 222 nm, respectively. (EX1003, ¶ 111; EX1005, 1545, 1547.)

A POSITA would understand that wavelengths of 222 nm and 282 nm could, in the context of the '642 Patent's specification, correspond to DNA or RNA because the specification asserted that they were the absorption wavelengths of some of the amino acids that can be associated with DNA or RNA.[7] (EX1003, ¶ 112; *see also*

[7] Throughout the specification, it is unclear whether the '642 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 6:67-7:3 ("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 ¶ 63.) Amino acids have peak absorption wavelengths near 222 nm and

EX1007, 580 (teaching "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 '642 Patent asserts can be associated with DNA or RNA such as "phenylalanin[e], tyrosin[e], tryptophan, cystein[e], cystin[e] and histidin[e]"); EX1018, 2:49–52, 3:1–7, 3:38–4:7; EX1019, 7:38–50.) The '642 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, 3:6-11; *see also id.*, 4:4-14, 6:33-46, FIGs. 9, 10.)

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282 nm, while DNA/RNA has a peak absorption wavelength near 200 nm and 254 nm, which the '642 Patent acknowledges. (*See* EX1001 at 2:16-19, 4:4-6.) This distinction is clear from the article that the '642 Patent cites for Figure 9, which more accurately depicts the peak absorptions of DNA as being at 200 nm and 254 nm. (*See* EX1039 at 60.) Figure 9 in the '642 Patent inexplicably appears to shift the spectrum ~20 nm to the right. (*Compare* EX1039, 16 *with* EX1001, FIG. 9.)

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

The combination discloses Element [1B]. (EX1003, ¶¶ 113-115.)

Eckhardt, for example, discloses "directing light emitted by light source 7 towards wound 1 and surrounding skin 3." (EX1003, ¶ 114; EX1004, ¶ 0031; *see also id.*, ¶ 0032 ("deliver a sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm^2 of UVC, to all surfaces to be sterilized or disinfected.").)

The combination discloses "whereby the photons are selected to destroy a plurality of chemical bonds within the DNA or RNA of the microorganisms" because it discloses directing photons of wavelengths of 222 nm and 282 nm to the substance or surface to be disinfected, which intrinsically destroys chemical bonds in the proteins associated with the DNA or RNA of the microorganisms. (EX1003, ¶ 115; *see also* EX1005 at 1545, 1547 (disclosing using excimer lamps with wavelengths of 222 nm and 282 nm to destroy *E. coli* microorganisms); *see supra*, Elements [1pre] and [1A].)

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

The combination discloses Element [1C] (EX1003, ¶ 116.)

Eckhardt discloses disinfecting the surface of a person or animal's skin with light source 7. (EX1003, ¶ 116; EX1004, ¶¶ 0029–0032.) Likewise, Sosnin discloses that an excimer lamp with a wavelength of 282 nm selectively kills harmful

microorganisms, such as *E. coli*, at "much lower" UV doses than those that cause damage to human cells, concluding 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." (EX1005, 1547; *see also supra*, Element [1pre].)

[2] The process of claim 1 further comprising the step of providing an [sic] new ultra violet source for generating the photons.

The combination discloses Claim [2] because it discloses generating the photons with a "new excimer lamp" whose spectrum "consist[s] of narrow bands …rarely exceeding 5-8 nm[.]" (EX1003, ¶ 117; EX1005, 1545.) Sosnin specifically discloses using XeBr and KrCl excimer lamps, which generate photons at a narrow wavelength band of 282 nm and 222 nm. (EX1003, ¶ 117; EX1005, 1545, 1547.) The '642 Patent similarly explains that "a new ultra-violet (NUV) source…emits a highly intense narrow wavelength band of photons that correspond to the maximum absorption band for DNA proteins and other component bonds" and the "preferred embodiment is the NUV source at 222 nm" to "target[] these proteins and their peptide bonds." (EX1003, ¶ 117; EX1001, 3:6–11.) Thus, the scope of this claim element is broad enough to include a UV light source that emits a highly intense narrow wavelength band of photons at 222 nm or 282 nm, as Sosnin's UV light source does.

[3] The process of claim 1 wherein the directing step is performed by reflecting the photons to a desired surface.

The combination discloses Claim [3]. (EX1003, ¶ 118.) Eckhardt discloses a "reflector 9" "disposed near light source 7 to aid in directing light emitted by light source 7 towards wound 1 and surrounding skin 3." (*Id*.; EX1004, ¶ 0031; *see also id.*, FIG. 1.)

[4] 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 [4] because it discloses directing photons of the wavelength 222 nm to the surface to be disinfected. (EX1003, ¶ 122; EX1005, 1547; *see supra,* Element [1A].) Photon energy is a property related to the wavelength of the photon. (EX1001, 4:34–35 ("The energy of the emitted photon is determined by its wavelength."); EX1003, ¶¶ 29, 122.) A POSITA would have readily known that photons of wavelength 222 nm necessarily correspond to approximately 540 kJ/mole of photon energy. (EX1003, ¶¶ 122; *see* EX1020, 651.)[8] The energy of light is provided by the formula $E = Nh\nu = \frac{Nhc}{\lambda}$, 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

[8] EX1021 is a printed publication that was publicly available no later than April 1999. (*See* EX1010, ¶¶ 19–21.)

the wavelength of the photons. (EX1003, ¶¶ 29, 122; EX1020, 651.) Solving for *E*, the photon energy per mole of 222 nm light is approximately 540 kJ/mole. (EX1003, ¶ 122.)

[5] The process of claim 1 wherein the step of directing the photons further comprises directing the photons to provide a radiant dose energy of 40 mJ/cm^2 to the substance or surface to be disinfected.

The combination discloses Claim [5]. (EX1003, ¶¶ 123-131.) For example, the combination discloses "deliver[ing] a sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm^2 of UVC, to all surfaces to be sterilized or disinfected." (EX1003, ¶ 124; EX1004, ¶ 0032; *see also id.*, ¶ 0043 (producing "UVC energy intensity of about 20 mJ/cm^2").) This meets the limitations of Claim 5 because "a radiant dose of energy of 40 mJ/cm^2" of photons is "greater than 10 mJ/cm^2 of UVC." (EX1003, ¶ 124.) Additionally, Sosnin discloses using a range of radiant dose energies of photons of wavelength 222 nm between ~25 mJ/cm^2 and ~210 mJ/cm^2 to disinfect a surface by killing *E. coli*, thus encompassing the claimed 40 mJ/cm^2 dose. (EX1005, 1547 (FIG. 9); EX1003, ¶ 124.) Similarly, Sosnin discloses using a range of radiant dose energies or photons of wavelength 282 nm between ~5 mJ/cm^2 and ~34 mJ/cm^2 will also kill *E. coli* and disinfect a surface. (EX1005, 1547 (FIG. 8); EX1003, ¶ 124.)

Additionally, it would have been obvious to a POSITA to arrive at Claim [5]. (EX1003, ¶ 125.) Specifically, it would have been obvious to provide a radiant dose

energy of 40 mJ/cm^2 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 increasing or decreasing the exposure time. (EX1003, ¶ 126; EX1005, 1546 ("UV radiation was dosed by varying the treatment time between 2 and 5 min, while the lamp irradiance was kept constant at 4 mW/cm^2 for the XeBr lamp," (*see* FIG. 7)); *see also e.g.*, EX1036, 11:35–53 (providing a table showing how the dose received 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, ¶ 127; EX1005, 1546 ("For UV treatment, Petri dishes were placed at a 5.5-cm distance from the UV lamp. At this distance the heating effect of substrate was minimized, while the irradiance could be sufficiently 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 any number of variables, such as 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. (EX1003, ¶ 127; EX1004, ¶ 0046 ("A UV dosage control mechanism may also be

included to vary the intensity of the UV light generated[.]"); EX1005, 1546; *see also e.g.*, EX1036, 13:37–14:15; *see also id.*, 11:35–53; EX1001, 5:59–66 (describing FIG. 14 as a 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, ¶ 127; EX1004, ¶¶ 0032, 0033, 0043; *see also* EX1001, 5:59–6:3, FIG. 14.)

Claim [5] does not require any particular level of disinfection of any particular type of microorganism. (EX1003, ¶ 128; EX1001, 2:59–62 ("The term[]…disinfection refers to all other levels of disinfection" besides the FDA-defined term "sterilization."), 6:8–10 ("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 amount of UV dose to arrive at the desired level of disinfection for a given target microorganism or set of microorganisms. (EX1003, ¶ 128.)

The combination also provides a suggestion to arrive specifically at a radiant dose of 40 mJ/cm^2 of the 222 nm or 282 nm wavelength light taught by Sosnin. (EX1003, ¶ 129.) Eckhardt provides a suggestion to try to achieve a "sufficient…sterilizing or disinfecting dosage…of UVC" applied to human skin. (*See* EX1003, ¶ 129; EX1004, ¶¶ 0032–34, 0055; *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/cm^2 or greater. (EX1003, ¶ 129; EX1004, ¶ 0032 ("greater than 10 mJ/cm^2"), ¶ 0043 ("about 20 mJ/cm^2"), ¶ 0104 (same).) Similarly, Sosnin teaches that using UV doses of 222 nm photons between ~25 mJ/cm^2 and ~210 mJ/cm^2 or 282 nm photons between ~5 mJ/cm^2 and ~34 mJ/cm^2 will kill *E. coli* bacteria. (EX1005, 1547 (FIGs. 8-9).) 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/cm^2. (EX1003, ¶ 129.)

A POSITA would have had a reasonable expectation of success of achieving some level of disinfection at a UV dose of 40 mJ/cm^2 of 222 nm or 282 nm light directed to the target substance or surface. Sosnin, for example, found that treating *E. coli* with 34 mJ/cm^2 of 282 nm light resulted in a "kill" of over 99.9%. (EX1005, 1547 (FIG. 8); EX1003, ¶ 130; *see also* EX1005, 1547 (FIG. 9 showing that treatment with 50 mJ/cm^2 of 222 nm light results in a kill of over 99% *E. coli*).) Because the level of disinfection only increases with the UV dose applied, a POSITA would also have expected an even greater level of disinfection at a higher UV dose than that taught by Sosnin at a 282 nm wavelength, such as 40 mJ/cm^2. (EX1003, ¶ 130; EX1005, 1547; *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").)

[6] The process of claim 1 wherein the step of directing the photons further comprises directing the photons to provide a radiant dose energy of 60 mJ/cm^2 to the substance or surface to be disinfected.

The combination discloses or renders obvious Claim [6] for the reasons discussed with respect to Claim [5], *supra*. (EX1003, ¶¶ 123-131.) 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/cm^2 of UVC, to all surfaces to be sterilized or disinfected." (EX1003, ¶ 133; 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/cm^2 and ~210 mJ/cm^2, and of 282 nm light between ~5 mJ/cm^2 and ~34 mJ/cm^2 to kill E. coli and disinfect the surface, thus encompassing the claimed radiant dose energy of 60 mJ/cm^2. (EX1005, 1547 (FIGs. 8-9); EX1003, ¶ 133; *see also supra*, Claim [5].)

At the very least, it would have been obvious to deliver a radiant dose of 60 mJ/cm^2 because of, for example, the design incentive to provide a higher level of disinfection than what is provided at lower doses. (EX1003, ¶ 133; *see also supra*, Claim [5].)

[7] The process of claim 1 wherein the step of directing the photons further comprises providing a radiant dose energy of 10 mJ/cm^2 to the substance or surface to be disinfected.

The combination discloses or renders obvious Claim [7] for the reasons discussed with respect to Claims [5] and [6], *supra*. (EX1003, ¶¶ 123-133.) Eckhardt discloses directing the photons to provide a radiant dose energy of 10 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/cm^2 of UVC, to all surfaces to be sterilized or disinfected." (EX1003, ¶ 135; EX1004, ¶ 0032; *see also id.*, ¶ 0043.) Moreover, Sosnin discloses that using a 282 nm light with a radiant dose energy of 10 mJ/cm^2 results in a more than 99% kill of E. coli. (EX1003, ¶ 135; EX1005, 1547 (FIG. 8); *see also supra,* Claims [5], [6].)

[8] The process of claim 1 further comprising the step of selecting a source for generating the photons, the source for generating the photons selected to produce an irradiance of approximately 100 mw/cm^2 or less.

The combination discloses or renders obvious Claim [8]. (EX1003, ¶¶ 138-139.) Sosnin discloses a UV source where, due to the positioning of the irradiated surface relative to the source, the "irradiance was kept constant at 4 mW/cm^2 for the XeBr lamp" while treating mammalian cells, and was varied at "different levels of UV irradiance (up to 10 mW/cm^2)" while treating *E. coli*. (EX1003, ¶ 139; EX1005, 1546.) Because 4 mW/cm^2 and 10 mW/cm^2 are "approximately 100 mW/cm^2 or less," the combination discloses Claim [8]. (EX1003, ¶ 139.)

[9] The process of claim 1 wherein the step of directing the photons further comprises exposing the substance or surface to be disinfected to the generated photons for less than 0.1 second [sic].

The combination discloses Claim [9]. (EX1003, ¶¶ 140-141.) Eckhardt, for example, discloses directing photons to the substance or surface to be disinfected for "less than 200 microseconds." (EX1003, ¶ 141; EX1004, ¶ 0043.) Exposing a surface to be disinfected to photons for less than 0.1 seconds was also known in the art. (*See, e.g.*, EX1036, 8:1-7 (disclosing that the "excimer ultraviolet lamp 20 provides for the substantial irradiation of the material 36" and, "[i]n this manner, the material is sterilized within milliseconds[.]"); EX1003, ¶ 141.)

[10] The process of claim 1 further comprising the step of selecting a source for generating the photons, wherein the source for generating photons is a hand held lamp, and wherein the step of directing the photons further comprises the step of waving the hand held lamp over the surface or substance to be disinfected, exposing the surface or substance to the generated photons for approximately 0.1 second or less.

The combination discloses Claim [10]. (EX1003, ¶¶ 142-146.) Eckhardt, for example, teaches selecting a hand held lamp as the source for generating photons. (EX1003, ¶ 142; 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,

¶ 142; EX1004, ¶ 0051.) Thus, a POSITA would immediately understand that, like shining a hand-held flashlight in the dark, the combination discloses the step of waving the hand held lamp over the surface or substance to be disinfected. (EX1003, ¶ 142; EX1004, ¶ 0045.)

Additionally, it would have been obvious to a POSITA to arrive at Claim [10] as a matter of common sense by waving Eckhardt's hand held lamp over the surface or substance to be disinfected. (EX1003, ¶ 143.) Both Eckhardt and the '642 Patent address similar problems of balancing safety and portability of hand-held UV devices. (EX1003, ¶ 143.) Eckhardt "advantageously" discloses "portable and hand-held" UV disinfection units that includes a manual "switch" (e.g., "a button") for safe operation. (EX1003, ¶ 143; EX1004, ¶¶ 0045, 0051.) The '642 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, ¶ 143; EX1001, 13:39–41.)

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, ¶ 144; EX1004, ¶¶ 0064–66; *see also id.* at ¶ 0051.) The '642 Patent similarly discloses that the hand wand "needs to be waved or passed over the surface to obtain a high level of disinfection." (EX1003, ¶ 144;

EX1001, 8:27–29.)

Thus, a POSITA would have immediately recognized as a matter of common sense that waving Eckhardt's hand-held UV device was likely to result in the desired outcome of instantaneous disinfection within a reasonable measure of safety. (EX1003, ¶ 145.) And a POSITA would have been further motivated to make that change in view of their knowledge at the time and in view of the state of the art. (EX1003, ¶ 145.) More specifically, a POSITA would know that UV-wand devices were a commercially viable disinfection method in the industry. (EX1003, ¶ 145.) *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."); *Perfect Web Tech., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328 (Fed. Cir. 2009) ("Common sense has long been recognized to inform the analysis of obviousness if explained with sufficient reasoning."); *In re Bozek*, 416 F.2d 1385, 1390 (C.C.P.A. 1969) (explaining that a patent examiner may rely on "common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference").

A POSITA would further recognize the combination discloses "exposing the surface or substance to the generated photons for approximately 0.1 second or less"

for the same reasons described for Claim [9], *supra*. (EX1003, ¶ 146.) Therefore, the combination discloses Claim [10]. (EX1003, ¶¶ 142-146.)

B. [GROUND 2] Claims 12-18 are rendered obvious by Brown-Skrobot in view of Clauss

1. Overview of Brown-Skrobot

Brown-Skrobot teaches the "sterilization of medical devices using monochromatic ultraviolet radiation from one or more monochromatic UV radiation sources." (EX1006, ¶ 0002.) Examples of "monochromatic UV radiation sources" include lasers and excimer lamps, but "[t]hese are only examples [and] other monochromatic UV radiation sources can be used." (*Id*., ¶¶ 0034, 0038 (disclosing, among others, "krypton and chlorine (KrCl)," "xenon and iodine (XeI)," and "xenon and bromine (XeBr)" excimer lamps).) Brown-Skrobot teaches that "'monochromatic UV radiation' [is] radiation having a wavelength or wavelengths between from 160 to 400 nm, and the majority of the radiation is concentrated within a bandwidth of 3 nm." (*Id*., ¶ 0033.) "Preferably the total monochromatic UV radiation is within the range from 220 to 320 nm, more preferably within from 240 to 280 nm." (*Id*.)

Brown-Skrobot also teaches that "multiple monochromatic radiation sources…can be used together to accomplish sterilization." (*Id*., ¶ 0042.) "Two or more monochromatic uv radiation sources can be used together to providethe same

or different amounts of energy at different wavelengths of monochromatic uv radiation[.]" (*Id*.) Brown-Skrobot teaches that "[t]he different wavelengths may provide increased levels of sterility[.]" (*Id*.)

2. Overview of Clauss

Clauss describes an investigation into "irradiation [of bacteria samples] with a 222 nm krypton-chloride excimer lamp compared to a 254 nm mercury lamp." (EX1007, 579.) Clauss notes that the wavelength of 254 nm traditionally used for disinfection corresponds with the maximum wavelength of DNA absorption, causing damage to the DNA. (*Id*., 580.) But Clauss also teaches that other aspects of cells can be targeted for damage, such as the "important" damage done to amino acids in proteins with a peak UV absorption wavelength around 222 nm. (*Id*., 580.)

Clauss was concerned with a "well researched" process called "photoreactivation," which is a mechanism by which cells can remove UV-induced DNA damage by subsequent exposure to certain wavelengths of light. (*Id*.) This leads to problems when substances treated with UV light are later exposed to other light, and organisms that have been inactivated begin to reactivate. (*Id*.) Thus, Clauss investigated the extent of photoreactivation of bacteria "after irradiation with wavelengths in the range of the absorption maxima of proteins" (e.g., 222 nm). (*Id*.)

Clauss concluded that 254 nm was the more effective wavelength for disinfection when photoreactivation is not present. (*Id*., 583.) When bacteria get the

chance to reactivate, however, exposure at 222 nm required less irradiation than at 254 nm to overcome photoreactivation. (*Id*.) The authors of Clauss assumed that "protein damage is [the] most probable" mechanism for the effectiveness of 222 nm. (*Id*.)

3. Reasons to Combine Brown-Skrobot in view of Clauss

In combination, Brown-Skrobot's method of sterilizing with "[t]wo or more monochromatic uv radiation sources" "having a wavelength or wavelengths between from 160 to 400 nm" is performed using the 222 nm KrCl excimer lamp and 254 nm low-pressure mercury lamp of Clauss. (EX1003, ¶ 99; EX1006, ¶¶ 0033, 0042; EX1007, 580.)

A POSITA would have been motivated to integrate the disclosures of Brown-Skrobot and Clauss for at least the following independent reasons. (EX1003, ¶¶ 100-104.)

First, a POSITA would have combined Brown-Skrobot and Clauss based on the UV sources they disclosed. Brown-Skrobot expressly taught using a KrCl excimer lamp, and suggested the use of other monochromatic UV sources. (EX1003, ¶ 101; EX1006, ¶ 0038.) Clauss's low-pressure mercury lamp is just such a monochromatic UV radiation source because a POSITA would have understood that the majority of the radiation was concentrated within a bandwidth of about 3 nm. (EX1003, ¶ 101; EX1007, 580, 581, FIG. 1.) Additionally, Clauss also disclosed

using a KrCl excimer lamp as well. (EX1003, ¶¶ 81, 84; EX1007, 579.) Like the UV sources expressly disclosed in Brown-Skrobot, Clauss teaches using these lamps for germicide purposes. (EX1003, ¶ 101; EX1007, 580.)

Second, a POSITA would have been motivated to supplement Brown-Skrobot's high-level disclosure of using multiple monochromatic UV radiation sources with the implementation details provided by Clauss because doing so would have merely been a combination of prior art elements according to known methods to yield a predictable result. (EX1003, ¶ 102.) More specifically, using a KrCl excimer lamp at 222 nm was disclosed by Brown-Skrobot, and the low-pressure mercury lamp at 254 nm taught by Clauss falls within the "preferred" wavelength range of monochromatic UV light expressly suggested by Brown-Skrobot. (EX1003, ¶ 102; EX1006, ¶ 0033.)

Third, the combination of Brown-Skrobot and Clauss to disinfect a surface using multiple light sources emitting 222 nm and 254 nm monochromatic UV radiation would yield predictable results. (EX1003, ¶ 103.) Both wavelengths were known to be effective for disinfecting substances and surfaces. (EX1003, ¶ 103; EX1007, 580; *see also* EX1001, 2:16–24.)

Fourth, a POSITA would have understood and appreciated that using a UV light source comprising 222 nm and 254 nm wavelengths as taught by Clauss would yield certain predictable advantages. Brown-Skrobot teaches using multiple light

sources because "different wavelengths may provide increased levels of sterility," or require less energy to sterilize. (EX1003, ¶ 104; EX1006, ¶ 0042.) Moreover, the synergistic effect of using multiple light sources of different wavelengths for germicidal use, including specifically sources emitting monochromatic 222 nm and 254 nm wavelengths, was known. (EX1003, ¶ 104; EX1026, 1529 (noting suggestion in literature "that bactericidal action at 254-nm radiation could be improved by supplementary radiation from excimer lamps" and finding "[s]ynergy was demonstrated between radiations at 222 and 254 nm in the treatment of" various bacteria); *id.*, 1532; *see also* EX1001, 4:28–33.)[9]

4. Analysis

[12pre] A process for destroying a DNA or RNA of a microorganism on a substance or surface comprising the steps of:

The combination discloses Element [12pre]. (EX1003, ¶¶ 148-149.)

The combination discloses "sterilization…using monochromatic ultraviolet radiation from one or more monochromatic UV radiation sources." (EX1003, ¶ 149 EX1006, ¶ 0002.) It discloses that "every surface…receives a sterilizing dose of radiation." (EX1003, ¶ 149; EX1006, ¶ 0034.) It also teaches that "monochromatic

[9] EX1026 is a printed publication that was publicly available no later than November 2000. (*See* EX1010, ¶¶ 22–24.)

ultraviolet (UV) light is known to damage the DNA of exposed cells" because "UV radiation causes thymine to dimerize which inhibits replication of DNA during cell reproduction. (EX1003, ¶ 149; EX1006, ¶ 0006.)

[12A] generating photons of at least two single line wavelengths corresponding to a peak absorption wavelength of DNA or RNA, the at least two single line wavelengths being at least two of 222 nm, 254 nm and 282 nm; and

The combination discloses Element [12a]. (EX1003, ¶¶ 150-153.)

The combination discloses at least two single line wavelengths: "Two or more monochromatic [UV] radiation sources can be used together to provide…the same or different amounts of energy at different wavelengths of monochromatic [UV] radiation." (EX1003, ¶ 151; EX1006, ¶ 0042.) The combination discloses that "'monochromatic UV radiation' means radiation having a wavelength or wavelengths between from 160 to 400 nm, and the majority of the radiation is concentrated within a bandwidth of 3 nm." (EX1003, ¶ 151; EX1006, ¶ 0033.) "The preferred monochromatic UV radiation has the majority wavelength or wavelengths within about 220 to 320 nm[.]" (EX1003, ¶ 151; EX1006, ¶ 0033.) The radiation source may be "excimer lasers or lamps" but may also be other sources of monochromatic UV radiation. (EX1003, ¶ 151; EX1006, ¶¶ 0034, 0038, 0054.) It also discloses that "[p]referably the majority of [monochromatic UV] radiation is within a bandwidth of 2 nm, more preferably within 1 nm." (EX1003, ¶ 151; EX1006, ¶ 0033.) A POSITA would recognize that 222 nm, 254 nm, and 282 nm

wavelengths fall within the expressly disclosed monochromatic UV radiation range of "220 to 320 nm." (EX1003, ¶ 151.) A POSITA would also understand that a "monochromatic" light source such as an excimer lamp where "the majority of radiation within a bandwidth of 2 nm, more preferably within 1 nm" generates photons of a single line wavelength. (EX1003, ¶ 151.)

The combination also discloses generating photons of single line wavelengths of at least 222 nm, 254 nm and 282 nm. (EX1003, ¶ 152.) To begin, Brown-Skrobot teaches KrCl, XeI, and XeBr excimer lamps as exemplary monochromatic UV radiation sources that can be used with its disclosed invention, which a POSITA would understand would generate photons at about 222 nm, 253 nm, and 282 nm, respectively. (EX1003, ¶ 152; EX1006, ¶ 0038; EX1020, 30.)[10] Clauss further teaches using a low-pressure mercury lamp generating photons at 254 nm, in addition to a KrCl excimer lamp emitting 222 nm radiation. (EX1003, ¶ 152; EX1007, 580.)

Clauss teaches selecting lamps emitting photons of single line wavelengths 222 nm and 254 specifically because they are absorption wavelengths of DNA/RNA or the amino acids that the '642 Patent asserts can be associated with DNA or RNA.

[10] EX1020 is a printed publication that was publicly available no later than January 2001. (*See* EX1010, ¶¶ 16–18.)

(EX1003, ¶ 153; EX1007, 580.) For example, Clauss teaches selecting 254 nm because it was known to be a maximum absorption wavelength that causes damage to DNA by altering nucleotide base pairing. (EX1003, ¶ 153; EX1007, 580 ("254 nm almost corresponds with the maximum of DNA absorption"); EX1001, 2:16–24, FIG. 9.) Clauss also teaches selecting 222 nm because it is near a "peak UV absorption…at 220 nm" for many common amino acids, including those that the '642 Patent asserts can be found associated with DNA or RNA such as "phenylalanin[e], tyrosin[e], tryptophan, cystein[e], cystin[e] and histidine" among others. (EX1003, ¶ 153; EX1007, 580; EX1001, 6:33–46, FIGs. 9, 10; EX1018, 7:38–50; EX1019, 2:49–52, 3:1–7, 3:38–4:7; *see also* Element [1A], *supra*.)

Therefore, the combination discloses that "multiple monochromatic radiation sources" of UV light at 222 nm, 254 nm, and 282 nm wavelengths can be used for destroying microorganisms. (EX1006, ¶¶ 0038, 0042; EX1007, 580.)

[12B] directing the photons to the substance or surface to be disinfected, whereby the photons are selected to destroy a plurality of chemical bonds within the DNA or RNA of the microorganisms.

The combination discloses Element [12B]. (EX1003, ¶¶ 154-155.)

For example, Brown-Skrobot teaches directing the photons to the substance or surface to be disinfected. (EX1003, ¶ 155; EX1006, ¶¶ 0034 ("The only requirement is that every surface of the medical device receives a sterilizing dose of radiation."), 0040 ("The monochromatic UV radiation source may be used in

conjunction with other structural and optical elements to direct the radiation at the target.").) Clauss teaches that the photon wavelengths are selected to destroy a plurality of chemical bonds within the DNA or RNA of the microorganisms. (*See supra*, Element [12A].) Therefore, the combination teaches Claim [12]. (EX1003, ¶ 155.)

[13] The process of claim 12 wherein the directing step is performed by reflecting the photons to a desired surface.

The combination discloses Claim [13]. (EX1003, ¶¶ 156-157.) For example, the combination discloses reflection: "The monochromatic UV radiation source may be used in conjunction with other structural and optical elements to direct the radiation at the target. The excimer lamp is preferably used in conjunction with a reflector or reflectors." (EX1006, ¶ 0040; EX1003, ¶ 157.) Therefore, the combination teaches Claim [13]. (EX1003, ¶ 157.)

[14] The process of claim 12 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 [14]. (EX1003, ¶¶ 158-159.) For example, the combination discloses directing photons of the wavelength 222 nm to the substance or surface to be disinfected, and the wavelength 222 nm inherently corresponds to a photon energy of 540 kJ/mole. (EX1003, ¶ 159; EX1007, 580 (teaching using UV light of wavelength 222 nm); *see supra*, Ground 1, Claim [4].)

[15] The process of claim 12 wherein the step of directing the photons further comprises directing the photons to provide a radiant dose energy of 40 mJ/cm^2 to the substance or surface to be disinfected.

The combination discloses Claim [15]. (EX1003, ¶¶ 160-166.) For example, the combination discloses that each microorganism has a "'D_{value}' [that] is the amount of energy required to kill 90% of the organisms present." (EX1003, ¶ 161; EX1006, ¶ 0031.) The D_{value} of *Bacillus stearothermophilus* "is at least 23.7 milliJoule per square centimeter (mJ/cm^2) for monochromatic ultraviolet radiation to the spore." (EX1003, ¶ 161; EX1006, ¶ 0021, FIG. 4.) The D_{value} of *Aspergillus niger* was determined to be "241.5 mJ/cm^2." (EX1003, ¶ 161; EX1006, ¶¶ 0070–80, FIG. 5.) Brown-Skrobot further teaches "subjecting [a] medical device to monochromatic ultraviolet radiation wherein the minimum total energy density of said monochromatic ultraviolet radiation which reaches the microorganisms present on said medical device is at least 25 mJ/cm^2," or similarly "exposing said medical device to monochromatic radiation whereby the D_{value} of" a specific organism is delivered to the spore. (EX1003, ¶ 162; EX1006, ¶ 0021.) And Brown-Skrobot also teaches exposing the aforementioned microorganisms to dose energies ranging from 0 to 568 mJ/cm^2. (EX1003, ¶ 162; EX1006, ¶¶ 0021, 0041, 0053, 0055–58, 0062, 0067–70, 0078, FIGs. 4, 5.) Each increasing dose energy disinfects an increasing number of colonies through a point where no survivors remain. (EX1003, ¶ 162 (citing EX1006, FIGs. 4, 5).)

Brown-Skrobot further teaches that, when choosing a UV source to deliver the dose, "[p]referably the total monochromatic UV radiation is within the range from 220 to 320 nm," and that the "monochromatic ultraviolet radiation can be generated and directed to the container by one or more monochromatic UV radiation sources, e.g. lasers or excimer lasers or lamps," including "KrCl" excimer lamps. (EX1006, ¶¶ 0033, 0038, 0054.) Clauss teaches that KrCl lamps generate 222 nm photons. (EX1007, 579.) A POSITA would immediately recognize that the claimed radiant dose of 40 mJ/cm^2 is within the required D_{value} of "at least 23.7 mJ/cm^2" to achieve a particular "sterility assurance level" of a surface. (EX1006, ¶ 53.) Thus, the combination discloses Claim [6]. (EX1003, ¶ 163.)

At the very least, it would have been obvious to a POSITA to deliver a radiant dose of 40 mJ/cm^2 to the substance or surface to be disinfected. (*See also* Ground 1, Claim [5].) Clauss teaches delivering varying radiant dose energies using a 222 nm KrCl excimer lamp to achieve a 4 log reduction of bacteria colonies, and Brown-Skrobot teaches D_{values} of "at least 23.7 milliJoule per square centimeter (mJ/cm^2) for monochromatic ultraviolet radiation to the spore." (EX1003, ¶ 164; EX1006, ¶ 0021, FIG. 4; EX1007, 581–82.) Brown-Skrobot further teaches delivering radiant doses of 50 mJ/cm^2 and higher to achieve a better "sterility assurance level." (EX1003, ¶ 164; EX1006, ¶¶ 0021, 0030–31, 0041, 0053, FIGs. 4, 5.) A POSITA would have been motivated to use the 222 nm excimer lamp taught by Clauss with

the radiant doses taught by Brown-Skrobot to achieve a desired level of disinfection. (EX1003, ¶ 165.) Thus, the combination teaches delivering a radiant dose energy of 40 mJ/cm^2 to the surface to be disinfected. (EX1003, ¶¶ 160-166.)

[16] The process of claim 12 wherein the step of directing the photons further comprises directing the photons to provide a radiant dose energy of 60 mJ/cm^2 to the substance or surface to be disinfected.

The combination discloses or renders obvious Claim [16] for the reasons discussed with respect to Claim [15], *supra*. (EX1003, ¶¶ 160-166.) Brown-Skrobot 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 "a single monochromatic UV radiation source can be used to sterilize the medical device as long as at least 50 mJ/cm^2, more preferably at least 100 mJ/cm^2, most preferably at least 200 mJ/cm^2 of UV radiation reaches all the microorganisms and/or all surfaces of the medical device to be sterilized." (EX1003, ¶ 168; EX1006, ¶ 0041.) At the very least, it would have been obvious to deliver a radiant dose of 60 mJ/cm^2. (EX1003, ¶ 168; *see supra*, Claim [15].)

[17] The process of claim 12 wherein the step of directing the photons further comprises providing a radiant dose energy of 10 mJ/cm^2 to the substance or surface to be disinfected.

The combination discloses or renders obvious Claim [17] for the reasons discussed with respect to Claims [15] and [16], *supra*. (EX1003, ¶¶ 160-168.) Clauss discloses directing the photons to provide a radiant dose energy of 10 mJ/cm^2 to the

substance or surface to be disinfected because it discloses "an irradiation of 106 J/m^2 at 222 nm was sufficient for *E. coli* for a 4 log reduction," and a POSITA would immediately recognize that 106 J/m^2 is mathematically equivalent to 10.6 mJ/cm^2 which is effectively the same as 10 mJ/cm^2. (EX1003, ¶ 170; EX1007, 581–82.) Clauss further teaches delivering radiant doses ranging from 0 to nearly 20.0 mJ/cm^2. (EX1003, ¶ 170; EX1007, FIG. 2.) At the very least, it would have been obvious to deliver a radiant dose of 10 mJ/cm^2. (EX1003, ¶ 170; *see supra,* Claims [15], [16].)

[18] The process of claim 12 further comprising the step of selecting a source for generating the photons, the source for generating the photons selected to produce an irradiance of approximately 100 mw/cm^2 or less.

The combination discloses or renders obvious Claim [18]. (EX1003, ¶¶ 171-172.) Specifically, Clauss discloses a 222 nm UV source for generating photons with an irradiance of "3.55 W/m^2" in the "whole UV region (200…380 nm)" and, "[i]n the UV-C region (200…280 nm)…3.38 W/m^2." (EX1007, 580, 583.) A POSITA would immediately recognize that 3.38 W/m^2 is mathematically equivalent to 0.338 mW/cm^2. (EX1003, ¶ 172.) Because 0.388 mW/cm^2 is "approximately 100 mW/cm^2 or less," the combination discloses Claim [18]. (EX1003, ¶ 172.)

VI. DISCRETION SHOULD NOT PRECLUDE INSTITUTION

A. The Board should not exercise its discretion under 35 U.S.C. § 314(a)

As explained below, consideration of the factors enumerated in the Board's precedential *Fintiv* decision favors institution. *Apple Inc. v. Fintiv, Inc.*, IPR2020–

00019, Paper 11, 5-6 (PTAB Mar. 20, 2020) (precedential); *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020–01019, Paper 12, 20-21 (PTAB Dec. 1, 2020) (precedential); *Snap, Inc. v. SRK Technology LLC*, IPR2020–00820, Paper 15, 19 (PTAB Oct. 21, 2020) (precedential); *Sand Revolution LLC v. Cont'l Intermodal Grp. Trucking LLC*, IPR2019-01393, Paper 24, 7–13 (PTAB June 16, 2020).

1. Factor 1: Institution will increase likelihood of stay

The validity of the '642 Patent is at issue in three pending district court litigations.[11] Notably, the *High Energy Ozone LLC et al v. Eden Park Illumination, Inc.* lawsuit, Case No. 1:21-cv-02753 pending in the Northern District of Illinois ("Eden Park Lawsuit") and *High Energy LLC et al. v. Far UV Technologie*s lawsuit,

[11] A fourth district court litigation, *Healthe, Inc. v. High Energy Ozone LLC et al.*, Case No. 6:20-cv-02233, is currently stayed pending bankruptcy proceedings for declaratory judgment Plaintiff Healthe. (*See* EX1030.) Because the case is now "administratively close[d]," (*id*., 1), its proceedings will have no impact on the adjudication of the validity of the '642 Patent, and thus institution of this proceeding will not be duplicative of that litigation. *See, e.g., Snap*, 8-9 (agreeing that a "District Court's stay of the litigation…allays concerns about inefficiency and duplication of efforts.").

Case No. 4:21-cv-00345 pending in the Western District of Missouri ("Far UV Lawsuit") are currently stayed pending severance of patent-related issues and transfer to and consolidation with the *High Energy Ozone LLC et al. v. Larson Electronics* lawsuit, Case No. 3:21-cv-01166 pending in the Northern District of Texas (the "Larson Lawsuit").[12] The Northern District of Texas will then adjudicate validity and infringement issues of the '642 Patent for the Eden Park, Far UV, and Larson Lawsuits. (*See* EX1031; EX1032.) Accordingly, only the Northern District of Texas need decide a single motion to stay for all Lawsuits.

Further, each of the litigations is in early stages. Plaintiff has only served infringement contentions in the actions against Eden Park (on October 26, 2021) and against Larson (on November 24, 2021). (*See* EX1034, EX1035.) No infringement contentions have been served against Far UV. None of the three parties have yet served invalidity contentions. Indeed, the Court recently granted a joint motion for extension of time for Larson to serve preliminary invalidity contentions, postponing the deadline for all parties in the forthcoming consolidated action to be set one week after the Court orders consolidation. (*See* EX1042.) As of the filing of this Petition, consolidation had not yet been ordered. Additionally, Plaintiff recently filed an Amended Complaint, notifying the parties of its intent to assert claims from an

[12] The earliest filed complaint was on May 17, 2021. (EX1027.)

additional patent which was allowed on December 24, 2021, which will necessarily impact the case schedule. (*See* EX1043, 1, 46.)

Institution of the present Petition would enable the Board to resolve validity, and a finding of invalidity would advance judicial efficiency by obviating the need for the Northern District of Texas to conduct jury trials on the '642 Patent. Even a finding that only certain of the challenged claims are invalid would significantly narrow the issues for trial. Accordingly, as soon as institution occurs, Petitioners intend to move to stay the district court litigation. Because of the early stage of the case and the ongoing delays associated with consolidation and the addition of another patent, Petitioners believe a stay is likely.

Stay of the companion litigations pending the Board's final written decision ("FWD") would weigh strongly in favor of institution. *Snap,* 8-9, 19.

2. Factor 2: No trial date has been set in the companion litigations

No trial dates are currently set in the Eden Park Lawsuit and Far UV Lawsuit, as these litigations are being transferred and consolidated with the Larson Lawsuit. Although there is a trial set in the Larson Lawsuit, this trial is not set to occur until sometime between June 5 and 23, 2023, (EX1033, 1), around the same time the Board would issue its final written decision. The remoteness of any scheduled trials makes this factor, at best, neutral. Additionally, as noted above the Larson Lawsuit

has already seen significant delays and additional delays are expected due to the consolidation and addition of an additional asserted patent. Furthermore, a recent study concluded that trial dates are an unreliable factor, finding that out of 51 cases denied institution based in part upon predicted trial dates, only three trials were conducted on the expected timeline.[13] (EX1041, 1.)

3. Factor 3: Petitioners' investment in IPR outweighs the parties' minimal investment in litigation to date

As discussed above, the companion litigations are all in early stages, and comparatively little has been invested in the substantive aspects of the litigations to date. Plaintiff has only served infringement contentions in the actions against Eden Park and Larson. (*See* EX1034, EX1035.) No infringement contentions have been served against Far UV. None of the three parties have yet served invalidity contentions, which, as noted above, have been delayed pending consolidation of the litigations. (EX1042.) As such, claim construction briefing has not begun, claim construction issues have not yet been heard, and trial has only recently been set in the Larson Lawsuit. Under the current scheduling order, claim construction briefing will be completed at the end of April 2022, with a *Markman* hearing scheduled for

[13] Excluding the four cases where trial had already occurred when the Board denied institution. (EX1041, 1.)

May 17, 2022, after the Board would likely issue its institution decision. (*See* EX1033, 4-5.) These facts weigh strongly in favor of institution. *See Fintiv*, 9-10 ("If, at the time of the institution decision, the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution[.]"); *see also Snap*, 11 ("Where the District Court has not issued claim construction orders and the discovery process is not yet complete, the remaining investment of time and effort likely necessary to bring co-pending litigation to trial appears to far outweigh that which has already been invested.") (citing *Juniper Networks, Inc. v. Packet Intelligence LLC*, IPR2020-00336, Paper 21, 18 (PTAB Sept. 10, 2020)).

4. Factor 4: No overlap between issues raised in the Petition and in the parallel proceedings

Petitioners ask the Board to consider the unique challenges raised in the Petition. *See Fintiv*, 12-13. If the Board institutes the present Petition, Petitioners will not pursue district court invalidity challenges that have been raised in this Petition, thereby eliminating any risk of duplicated effort between the district court and the PTAB. *See, e.g., CoolIT Sys., Inc. v. Asetek Danmark A/S*, IPR2021-01196, Paper 10, 14 (PTAB Dec. 28, 2021) (finding similar stipulation weighed against discretionary denial). Additionally, only a subset of the Challenged Claims are at issue in the co-pending litigations. (*See* EX1034 and EX1035 (asserting claims 1, 5,

7, 9, 12, 15, 17 in both litigations)); *see Facebook, Inc. v. Blackberry Ltd.*, IPR2019-00899, Paper 15, 12 (PTAB Oct. 8, 2019) (discretionary denial disfavored when petition challenged claims beyond those reviewed by the district court). This lack of overlapping issues weighs in favor of institution.

5. Factor 5: Same parties

The parties are not the same in this IPR and the district court lawsuits. Although Eden Park, Larson, and Far UV are defendants in their respective actions, Petitioner Ushio is not. The lack of complete identity of parties with the district court litigation weighs strongly in favor of institution. *See Fintiv*, 13-14 ("If a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact against exercising discretion to deny institution under *NHK*.").

6. Other circumstances support institution

As *Fintiv* noted, "if the merits of a ground raised in the petition seem particularly strong…the institution of a trial may serve the interest of overall system efficiency and integrity[.]" *Fintiv*, 14–15. The grounds raised herein are strong, and institution would result in invalidation of the Challenged Claims.

For all of the reasons discussed herein, Petitioner therefore respectfully requests that the Board not exercise its discretion under § 314(a), and instead institute IPR.

B. The Board should not exercise its discretion under 35 U.S.C. § 325(d)

None of the four references asserted here was cited or disclosed to the Examiner during prosecution of the '642 Patent. Petitioners are aware that Patent Owner disclosed two of the references during prosecution of a related child patent, and only one of which was cited by the examiner in rejecting a dependent claim that the applicant subsequently cancelled. The *Advanced Bionics* framework for assessing § 325(d) does not expressly apply to child patents. *Advanced Bionics. LLC v. MED-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8-9 (Feb. 13, 2020) (precedential); *see also Apple Inc. v. SEVEN Networks, LLC*, IPR2020-00285, Paper 10, 31 (July 28, 2020). Additionally, the Board has found evidence in child patents to be less relevant, particularly where "there is no evidence that the Examiner considered the particular disclosures…in the Petition." *Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00483, Paper 10, 15 (July 15, 2015). The issued claims from the child Patent also differ in critical ways from those here, including that wavelength 282 nm was removed from the claims during prosecution to overcome prior art. Additionally, the Examiner erred in several respects during prosecution. Should Patent Owner make a § 325(d) argument based on evidence from the prosecution of the child Patent, Petitioners reserve their right to respond.

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

Petitioner authorizes the PTO to charge Deposit Account No. 06-1050 for the fee set in 37 C.F.R. § 42.15(a) for this Petition and further authorizes payment for any additional fees to be charged to this Deposit Account.

VIII. CONCLUSION

The cited prior art references identified in this Petition provide new, non-cumulative technological teachings which indicate a reasonable likelihood that the Challenged Claims of the ’642 Patent are not patentable. Accordingly, 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)

Petitioners 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 ’642 Patent. The ’642 Patent is the subject the following civil actions:

Caption	Case No.	District
Healthe, Inc. v. High Energy Ozone LLC et al.	6:20-cv-02233	M.D. Fla.
High Energy Ozone LLC et al. v. Larson	3:21-cv-01166	N.D. Tex.

Electronics LLC		
High Energy Ozone LLC et al. v Eden Park Illumination, Inc.	1:21-cv-02753	N.D. Ill.
High Energy Ozone LLC et al. v. Far UV Technologies	4:21-cv-00345	W.D. Mo.

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
David Conrad, Reg. No. 60,788 Fish & Richardson P.C. 3200 RBC Plaza 60 South Sixth Street Minneapolis, MN 55402 Tel: 612-335-5070 Fax: 612-288-9696 Email: IPR00012-0170IP1@fr.com	Lance Wyatt, Reg. No. 68,837 Fish & Richardson P.C. 3200 RBC Plaza 60 South Sixth Street Minneapolis, MN 55402 Tel: 612-335-5070 Fax: 612-288-9696 Email: PTABInbound@fr.com

D. Service Information

Please address all correspondence and service to the address listed above. Petitioners consent to electronic service by email at IPR00012-0170IP1@fr.com (referencing No. 00012-0170IP1 and cc'ing PTABInbound@fr.com).

Respectfully submitted,

Dated: February 4, 2022

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(Control No. IPR2022-00381)

Attorneys for Petitioner

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 13,945 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated Feb. 4, 2022

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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 February 4, 2022, 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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