

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

S. EDWARD NEISTER,
Patent Owner.

IPR2022-00381
Patent 9,700,642 B2

Before JEFFREY W. ABRAHAM, JULIA HEANEY, and
AVELYN M. ROSS, *Administrative Patent Judges*.

HEANEY, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes Review*
35 U.S.C. § 314

I. INTRODUCTION

Eden Park Illumination, Inc., Larson Electronics LLC, Far UV Technologies, Inc., and Ushio America, Inc. (collectively “Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–10 and 12–18 of U.S. Patent No. 9,700,642 B2 (Ex. 1001, “the ’642 patent”). Paper 5 (“Petition” or “Pet.”). S. Edward Neister (“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). With our authorization, Petitioner filed a Reply (Paper 10, “Reply”), and Patent Owner filed a Sur-reply (Paper 11, “Sur-reply”).

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a) (2018). Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of all claims and all grounds asserted in the Petition.¹

A. *Related Proceedings*

The parties identify the following litigation involving the ’642 patent: *Healthe, Inc. v. High Energy Ozone LLC et al.*, Case No. 6:20-cv-02233 (M.D. Fla.) and *High Energy Ozone LLC et al. v. Larson Electronics LLC*,

¹ *Guidance on the Impact of SAS on AIA Trial Proceedings* (Apr. 26, 2018), <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>; *see also SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

Case No. 3:21-cv-01166 (N.D. Tex.). Pet. 61–62; Paper 7, 1. Petitioner also identifies the following litigation involving the '642 patent: *High Energy Ozone LLC et al. v Eden Park Illumination, Inc.*, Case No. 1:21-cv-02753 (N.D. Ill.) and *High Energy Ozone LLC et al. v. Far UV Technologies*, Case No. 4:21-cv-00345 (W.D. Mo.). Pet. 62. Patent Owner also identifies the following litigation as related matters: *High Energy Ozone LLC et al. v. Eden Park Illumination, Inc.*, Case No. 3:22-cv-00425 (N.D. Tex.) and *High Energy Ozone LLC et al. v. Far UV Technologies*, Case No. 3:22-cv-00280 (N.D. Tex.). Paper 7, 1.

B. The '642 patent

The '642 patent, titled “Method and Apparatus for Sterilizing and Disinfecting Air and Surfaces and Protecting a Zone from External Microbial Contamination,” describes using ultra-violet (UV) lamps for the destruction of virus, bacteria, spores, and pathogens (microorganisms or VSP). Ex. 1001, [54], 1:33–40. The '642 patent explains that the broad ultraviolet spectrum has been divided into three regions, depending on its different effects on human skin: UV-A as having a band of wavelengths between 320 nm and 400 nm, UV-B as having a band of wavelengths between 280 nm and 320 nm, and UV-C as having a band of wavelengths between 280 nm and 235 nm. *Id.* at 1:66–2:9. Further, another band called “Far UV” is defined as having a band of wavelengths between 235 nm and 185 nm. *Id.* at 2:9–11. According to the '642 patent, “[c]laims have been made that UV-C radiation is used to alter the DNA” but “[n]one of these claims make reference to any shorter wavelengths and to the absorption band that peaks at 200 nm,” due to the high absorption of molecular water. *Id.* at 2:16–27. The '642 patent further explains that new ultra-violet (NUV)

emitting lamps are becoming commercially available, which have emitters that produce a single line or a narrow spectral emission at a particular wavelength. *Id.* at 2:35–38. Still, “[i]f the treatment lamp’s wavelength is chosen to match closely to the peak of protein absorption of the microorganism’s DNA, then a lethal dosage can be delivered to the VSPs in a shorter time.” *Id.* at 2:39–42.

The ’642 patent discloses that destruction of pathogens is significantly improved by targeting its DNA or RNA with the proper wavelength. *Id.* at 2:66–3:2. This targeting can be accomplished by using a “NUV source at 222 nm” which targets proteins and their peptide bonds. *Id.* at 3:11–12, 5:8–10, 5:33–35. The ’642 patent discloses that the “NUV source can also be made to emit photons at 282 nm to target a mixture of amino acids and some proteins that absorb at this longer wavelength” and “the NUV source may also produce 254 nm photons so as to target specific amino acids.” *Id.* at 3:13–17, 5:17. The ’642 patent discloses that these wavelengths do not damage the epidermis “and therefore can quickly and effectively disinfect human or animal skin without skin cell damage.” *Id.* at 8:45–48, 8:65–9:2.

The ’642 patent further discloses that the energy of the emitted photon is determined by its wavelength and different bonds in DNA are affected with photons of different energy. *Id.* at 4:34–37. According to the ’642 patent, 540 kJ/mole photon energy from NUV lamps exceeds the bond energies of many of the peptide bonds and “should cause physical damage to the microorganism.” *Id.* at 4:38–40.

C. The Challenged Claims

Petitioner challenges claims 1–10 and 12–18 of the ’642 patent.

Pet. 1. Claims 2–10 depend from claim 1, and claims 13–18 depend from

claim 12. Claim 1, reproduced below, is illustrative of the subject matter of the challenged claims:

1. A process for destroying a DNA or RNA of a micro-organism on a substance or surface comprising the steps of:

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;

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

wherein the substance or surface to be disinfected is human or animal skin.

Ex. 1001, 14:26–37.

D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

| Challenged Claim(s) | 35 U.S.C. ² | Reference(s)/Basis |
|---------------------|------------------------|--|
| 1–10 | § 103(a) | Eckhardt, ³ Sosnin ⁴ |

² The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because the ’642 patent issued from an application filed before March 16, 2013, we apply the pre-AIA versions of the statutory bases for unpatentability.

³ US Patent Pub. No. 2003/0031586 A1 to Eckhardt et al., published Feb. 13, 2003 (Ex. 1004).

⁴ 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 (Ex. 1005).

| Challenged Claim(s) | 35 U.S.C. ² | Reference(s)/Basis |
|---------------------|------------------------|---|
| 12–18 | § 103(a) | Brown-Skrobot, ⁵ Clauß ^{6, 7} |

Pet. 3. Petitioner relies on the Declaration of Oliver R. Lawal (Ex. 1003).

II. ANALYSIS

A. Claim Construction

Petitioner asserts that “the Challenged Claims require no express construction to evaluate their patentability.” Pet. 19.

Patent Owner does not propose that the Board explicitly construe any claim terms. *See* Prelim. Resp. We determine we need not explicitly construe any claim terms at this stage of the proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

B. Level of Ordinary Skill in the Art

Factors pertinent to a determination of the level of ordinary skill in the art include “(1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and

⁵ US Patent Pub. No. 2005/0079096 A1 to Brown-Skrobot et al., published Apr. 14, 2005 (Ex. 1006).

⁶ Clauß, M., Mannesmann, R., and Kolch, A., *Photoreactivation of Escherichia coli and Yersinia enterocolitica after Irradiation with a 222 nm Excimer Lamp Compared to a 254 nm Low-pressure Mercury Lamp*, 33 ACTA HYDROCHIMICA ET HYDROBIOLOGICA 579–84, Dec. 2005 (Ex. 1007).

⁷ Petitioner refers to this reference as “Claus,” rather than “Clauß.”

(6) educational level of workers active in the field.” *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.*

Petitioner argues a person of ordinary skill in the art at the time of the invention “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.” Pet. 18 (citing Ex. 1003 ¶ 21).

Petitioner further argues that “[s]uch 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” but, “less education could be compensated by more experience and vice versa.” *Id.* at 19.

Patent Owner does not dispute the level of ordinary skill in the art. Prelim. Resp. 10. For purposes of this decision, we adopt Petitioner’s definition of the level of ordinary skill in the art because it is consistent with the ’642 patent and the asserted prior art.

C. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying

factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, evidence such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *see KSR*, 550 U.S. at 407 (“While the sequence of these questions might be reordered in any particular case, the [Graham] factors continue to define the inquiry that controls.”).

The Supreme Court made clear that we apply “an expansive and flexible approach” to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. Reaching this conclusion, however, requires more than merely showing that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention “would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.*

D. Effective Filing Date

The application that issued as the ’642 patent was filed on April 17, 2014. Ex. 1001, code (22). The ’642 patent is a continuation-in-part that claims the benefit of application 11/831,667, filed on July 31, 2007 (“the ’667 application,” issued as U.S. Patent No. 8,753,575), which is a

continuation-in-part of PCT App. No. PCT/US2006/003393 (“the PCT application”), filed on January 31, 2006, which claims the benefit of U.S. Provisional App. No. 60/593,626 (“the ’626 provisional application”), filed on January 31, 2005. *Id.* at codes (60), (63). Petitioner contends the earliest possible effective filing date for claims 1–10 of the ’642 patent is January 31, 2006, i.e., the filing date of the PCT application. Pet. 4. Petitioner contends the earliest possible effective filing date for claims 12–18 of the ’642 patent is July 31, 2007, i.e., the filing date of the ’667 application. We address these respective contentions below.

1. Claims 1–10

Petitioner contends the ’626 provisional application does not provide written description support for the limitation “wherein the substance or surface to be disinfected is human or animal skin” as recited in claim 1, and therefore claims 1–10 are not entitled to an effective filing date earlier than January 31, 2006. Pet. 4. Petitioner argues a passage from the ’626 provisional application that describes “irradiating food stuffs in conveyor assemblies, stationary carts and in handling routes during the movement from storage to food preparation processes,” which Mr. Neister relied on as support for the skin disinfection limitation, does not actually provide support because it does not disclose skin, and that the PCT application included the first mention of disinfecting human skin. *Id.* (citing Ex. 1002, 7; Ex. 1003 ¶ 73; Ex. 1008, 18; Ex. 1009, 27).

Patent Owner responds that the ’626 provisional application includes many disclosures relating to the use of 222 nm wavelengths “in the presence of humans” which demonstrate that Mr. Neister possessed the claimed

invention as of the '626 provisional application filing date. Prelim. Resp. 16 (citing Ex. 1008 ¶¶ 1, 4, 28–31, 38, claims 11, 12).

Having reviewed the disclosures of the '626 provisional application relied upon by Patent Owner, we do not agree that they would convey to a person of ordinary skill in the art that Mr. Niester had possession of using 222 or 282 nm wavelengths to disinfect human or animal skin. While they refer to human activity such as travel, surgery, and food preparation, the disclosures do not refer to disinfecting skin. Rather, they refer to sterilizing things in the presence of humans, such as surfaces and air, but not human or animal skin itself. Therefore, we determine that Petitioner has satisfied its initial burden of production on the effective-filing-date issue by identifying the absence of specific supporting disclosure for claim 1 from the '626 provisional application. *See Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1379–1380 (Fed. Cir. 2015) (discussing burden framework in *inter partes* review). Based on this record, we find that Petitioner has demonstrated a reasonable likelihood that it will prevail in establishing that challenged claims 1–10 are not entitled to an effective filing date earlier than the filing date of the PCT application. The parties will have an opportunity to develop their positions on the issue of the effective filing date of claims 1–10 during trial.

2. Claims 12–18

Petitioner contends the PCT application does not provide written description support for the limitation “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” as recited in claim 12, and therefore claims 12–18 are not entitled to an effective filing date earlier than

July 31, 2007. Pet. 6. Petitioner argues generating photons of at least two single line wavelengths was not disclosed in either the '626 provisional application or the PCT application, and that a 282 nm wavelength was not disclosed in either of these applications. *Id.* at 6–7. Petitioner argues Mr. Neister did not cite to or rely on any disclosure in the '626 provisional application or the PCT application for those limitations, but rather during prosecution relied on disclosure of new matter in the '667 application. *Id.* at 7–8. Petitioner further argues the only UV light sources disclosed in the PCT application generate only one single line wavelength. *Id.* at 8 (citing Ex. 1003 ¶ 74).

Patent Owner does not dispute the prosecution history, but rather argues Petitioner misconstrues the meaning of “generating photons of at least two single line wavelengths corresponding to a peak absorption wavelength of DNA or RNA.” Prelim. Resp. 17–19. Specifically, Patent Owner responds that Petitioner’s argument is based on “misreading” claim 12, because claim 12 does not require “a generation of specific wavelengths of light in the binary sense.” *Id.* at 17–18. According to Patent Owner, a person of ordinary skill would understand that a “single line wavelength” can correspond to a range of wavelengths which may involve more than one peak wavelength across the distribution, depending on the light source. *Id.* Patent Owner appears to be making a claim construction argument, although Patent Owner has not expressly proposed that we construe any claim term.

To the extent we understand Patent Owner’s argument, we do not find it persuasive. It appears to be contrary to the plain language of claim 12 which states “at least two” single line wavelengths; Patent Owner’s explanation that “a single line wavelength” can correspond to a range of

wavelengths does not explain how “at least two” would be understood to mean less than two. Patent Owner’s discussion of claim 12’s objective of creating photons that correspond to a peak absorption wavelength of DNA (*id.* at 19) does not explicate this conundrum. Further, Patent Owner’s argument concerning the meaning of “at least two” appears to be inconsistent with its arguments in other parts of the Preliminary Response. *See e.g. id.* at 39–40 (“No motivation is provided in the Petition to combine Brown-Skrobot and Clauß to ‘generate photons of at least two single line wavelengths,’ *one of which* is at 282 nm.”)(emphasis added).

Therefore, we determine that Petitioner has satisfied its initial burden of production on the effective-filing-date issue by identifying the absence of specific supporting disclosure for claim 12 from the PCT provisional application, and demonstrated a reasonable likelihood that it will prevail in establishing that claims 12–18 are not entitled to an effective filing date earlier than the filing of the ’667 application. The parties will have an opportunity to develop their positions on the issue of the effective filing date of claims 12–18 during trial.

E. Alleged Obviousness Based on Eckhardt and Sosnin

Petitioner argues claims 1–10 are rendered obvious by Eckhardt in view of Sosnin. Pet. 19–40. In support, Petitioner and Mr. Lawal describe where each limitation of the challenged claims is disclosed in the references, and the reasons a person of ordinary skill would have been motivated to combine the disclosures of the references. *See e.g., id.* at 21–40; Ex. 1003 ¶¶ 82–92, 105–146.

1. Overview of Eckhardt (Ex. 1004)

Eckhardt is titled “Method and Apparatus for Sterilizing or Disinfecting a Region Through a Bandage” and “relates generally to the field of sterilization or disinfection systems and methods.” Ex. 1004 at [54], ¶ 2. Eckhardt discloses that a region of tissue to be sterilized or disinfected may include unbreached or bare skin. *Id.* ¶¶ 29, 69. The sterilization or disinfection may occur via killing microorganisms or via inactivating microorganisms by rendering the microorganisms unable to reproduce. *Id.* ¶ 29. Sterilizing or disinfecting light is emitted by a light source. *Id.* ¶ 31. Eckhardt discloses that the light source “may be any light source that emits light capable of sterilization or disinfection,” such as a xenon flash lamp. *Id.* ¶¶ 31, 43. For example, a lamp may be used to “emit narrow spectrum light (e.g., a line spectrum) or broad spectrum light” and the 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.” *Id.* ¶ 31. Eckhardt further discloses that the energy from the light source of a single flash of greater than 10 mJ/cm² of UVC may be sufficient to deliver a sterilizing or disinfecting dosage. *Id.* ¶ 32. A material can be used to transmit sterilizing light “from a xenon flash having a wavelength in the range of 220 to 310 nm.” *Id.* ¶ 70.

2. Overview of Sosnin (Ex. 1005)

Sosnin is titled “The Effects of UV Irradiation and Gas Plasma Treatment on Living Mammalian Cells and Bacteria: A Comparative Approach.” Ex. 1004, 1544. Sosnin studies bacterial deactivation in mammalian cells by UV radiation from narrow-band UV lamps such as excilamps. *Id.* The excilamps (or excimer lamps) provide UV irradiance up

to 10 mW/cm² and a spectra of narrow bands. *Id.* at 1545. Sosnin uses an XeBr lamp that produces an emission peak at about 282 nm for sterilization. *Id.* According to Sosnin, “the inactivation of bacteria is mainly related to the DNA/RNA damage, and the maximum absorption of DNA and RNA occurs at the photon wavelength between 240 and 300 nm.” *Id.* Sosnin discloses that in a study of irradiation of *E. Coli* bacteria using an XeBr lamp and also a KrCl lamp that produces an emission peak at about 222 nm, the UV doses needed to deactivate *E. Coli* bacteria “are much lower than the ones that cause necrosis in fibroblasts.” *Id.* at 1547, Figs. 8, 9.

3. Claim 1

Petitioner contends Eckhardt teaches a process for destroying DNA or RNA of a microorganism on a substance or surface, as recited in the preamble⁸ of claim 1, because it discloses using a light source to disinfect human or animal skin. Pet. 25 (citing Ex. 1003 ¶ 7; Ex. 1004 ¶¶ 29, 21–32). Petitioner specifically relies on Eckhardt’s disclosure that sterilization or disinfection may occur by “rendering the microorganisms unable to reproduce” (Ex. 1004 ¶ 30) as teaching “destroying” DNA or RNA of the microorganisms. Pet. 25-26 (also citing Ex. 1003 ¶ 108; Ex. 1001, 4:21–33, 7:61–66; Ex. 1019, 7:36–50).

Petitioner contends Eckhardt teaches “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,”

⁸ Neither party argues whether the preamble limits claim 1 (or claim 12, as discussed below). Although we find that the evidence supports that the prior art teaches the preamble, we make no determination at this stage of the proceeding whether the preamble of claim 12 is limiting.

as recited in claim 1, because Eckhardt's light source 7 may include a lamp emitting narrow or broad spectrum light, including UVA, UVB, and UVC light, and "sterilizing light from a xenon flash having a wavelength in the range of 220 to 310 nm." Pet. 26–27 (citing Ex. 1003 ¶¶ 109–112; Ex. 1004 ¶¶ 31, 43, 70). Petitioner contends a person of ordinary skill would have recognized that the range of wavelengths produced by light source 7 would include generating wavelengths of 222 nm and 282 nm. *Id.* at 27 (citing Ex. 1003 ¶ 111). Petitioner further contends Sosnin expressly discloses sterilizing through irradiation using XeBr and KrCl excimer lamps, which generate wavelengths of 282 and 222 nm, respectively. *Id.* (citing Ex. 1005, 1545, 1547).

Petitioner contends Eckhardt teaches directing the photons to the substance or surface to be disinfected, as recited in claim 1, because it discloses directing light towards wound 1 and surrounding skin 3. Pet. 29 (citing Ex. 1003 ¶ 114; Ex. 1004 ¶¶ 31–32). Petitioner contends Sosnin teaches the photons destroy a plurality of chemical bonds within the DNA or RNA of the microorganism because it discloses using 222 and 282 nm excimer lamps to destroy *E. coli*. *Id.* (citing Ex. 1003 ¶ 115; Ex. 1005, 1545, 1547).

Petitioner contends Eckhardt teaches disinfection of human or animal skin, as discussed above, and that Sosnin also discloses "[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." Pet. 30 (citing Ex. 1005, 1547).

Petitioner contends a person of ordinary skill in the art would have been motivated to combine the teachings of Eckhardt and Sosnin for several

reasons: (1) Eckhardt’s teaching of using any light source capable of sterilization or disinfection, and specifically “narrow spectrum light (e.g., a line spectrum)” would have suggested to a person of ordinary skill in the art to incorporate other well-known germicidal UV light sources like Sosnin’s, and both references teach that their light sources kill bacteria; (2) a person of ordinary skill would have implemented Eckhardt’s high-level disclosure of using UV-C light to disinfect skin with Sosnin’s 222 nm excimer lamp because Sosnin’s lamp’s wavelength is within the range of 220 to 310 nm suggested by Eckhardt; (3) the effectiveness and relative safety of directing UV-C light of 222 nm on bare skin for disinfection was already understood by persons of ordinary skill in the art, even though there was general caution against exposing skin to excessive UV radiation. Pet. 22–24 (citing Ex. 1003 ¶¶ 40, 81–92; Ex. 1004 ¶¶ 5, 31, 69, 70; Ex. 1005, 1545–1547; Ex. 1011 ¶¶ 28, 40; Ex. 1013 ¶ 8; Ex. 1015, 2:22–67; Ex. 1016, 2:23–26; Ex. 1017, 58).

Patent Owner does not dispute that the references disclose the limitations of claim 1. Prelim. Resp. 28–36. Rather, Patent Owner argues that both references “strongly teach away from the use of UV light on skin.” *Id.* at 29. Patent Owner argues that Eckhardt cautions against the damage UV-C light, particularly 254 nm wavelength, can cause to skin, and therefore teaches bandages to provide cover from direct UV light. *Id.* at 30 (citing Ex. 1004 ¶¶ 5, 28, 56). Patent Owner argues that Eckhardt’s disclosure of an optical filter and light pulsing instead of continuous exposure also teach away from directly disinfecting skin with UV light. *Id.* (citing Ex. 1004 ¶¶ 46, 56). As to Sosnin, Patent Owner argues at least half of the paper is focused on gas plasma treatment, not UV irradiation, and the

UV experiments are limited to a laboratory and caution against the risk of cellular damage by UV. *Id.* at 29, 31 (citing Ex. 1005, 1544, 1549).

Patent Owner further argues that combining the references would directly contradict Eckhardt's teaching (which was "consistent with conventional wisdom") to prevent exposing skin to 254 nm UV-C wavelengths. Prelim. Resp. 32. Patent Owner argues Mr. Lawal's opinion that "the relative safety of directing UVC light of wavelength 222 nm to bare skin for use in germicidal application was already understood" by persons of ordinary skill in the art as of the dates of Eckhardt and Sosnin is unsupported and contradicted by record evidence. *Id.* at 35 (citing Ex. 1003 ¶ 89).

Having considered the evidence and arguments presented by both parties on the present record, we are persuaded Petitioner sufficiently shows that Eckhardt and Sosnin teach or suggest all of the limitations in claim 1, and sufficiently explains how a person of ordinary skill in the art would have used Eckhardt's teaching of narrow spectrum light in the range of 220 to 310 nm to disinfect skin, with Sosnin's implementation of excimer lasers including 222 and 282 nm to kill bacteria, to arrive at the method of claim 1 with a reasonable expectation of success.

We disagree with Patent Owner's argument that Eckhardt teaches away from the use of UV light on skin because it is based on a mischaracterization of Eckhardt, which does not teach bandages as a way to provide cover from direct UV light, but rather, compensates for application of UV light through a bandage by controlling the UV light intensity. Indeed, Eckhardt's embodiment that Petitioner relies upon is titled "UV-Transmissive Bandage" and explains how to choose bandage materials that transmit UV-C light. *See* Ex. 1004 ¶¶ 69–72.

We also disagree, on this record, with Patent Owner's argument that Sosnin would dissuade a person of ordinary skill from using 222 or 282 nm wavelengths to disinfect skin . Although Patent Owner is correct that Sosnin refers to the need for additional testing before using its technology outside of a laboratory (Prelim. Resp. 31), Mr. Lawal directs us to evidence supporting his testimony that it was general knowledge in the art at the time of the invention that even though UV light poses safety risks to human skin, UV-C light of 222 nm on bare skin for disinfection was relatively safe. Ex. 1003 ¶¶ 88–91 (citing Exs. 1013, 1015, 1016, 1017). Patent Owner presents only attorney argument in response to Mr. Lawal's testimony and supporting evidence. We invite the parties to continue to develop this issue during trial.

Accordingly, we determine that Petitioner has shown a reasonable likelihood of prevailing on its obviousness challenge to claim 1.

4. Claims 2–10

Petitioner identifies where every limitation of challenged claims 2–10 are found in the combination of Eckhardt and Sosnin. Pet. 30–41. Patent Owner does not present separate arguments as to these dependent claims. *See generally* Prelim. Resp. We have reviewed Petitioner's evidence and argument, including the relevant portions of the Lawal Declaration, and are persuaded, based on the current record, that Petitioner has shown a reasonable likelihood of prevailing on its obviousness challenge to claims 2–10.

F. Alleged Obviousness Based on Brown-Skrobot and Clauß
Petitioner argues claims 12–18 are rendered obvious by Brown-Skrobot in view of Clauß. Pet. 41–53. In support, Petitioner and Mr. Lawal describe where each limitation of the challenged claims is disclosed in the references,

and the reasons a person of ordinary skill would have been motivated to combine the disclosures of the references. *See e.g., id.* at 43–49; Ex. 1003 ¶¶ 99–104, 147–155.

1. Overview of Brown-Skrobot (Ex. 1006)

Brown-Skrobot is titled “Method and Apparatus of Sterilization Using Monochromatic UV Radiation Source” (Ex. 1006, at code [54]) and describes an apparatus for delivering UV radiation to a medical device for sterilization. *Id.* ¶ 22. Brown-Skrobot defines “monochromatic ultraviolet radiation” as “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.* ¶ 33. Preferably, “the majority of radiation is within a bandwidth of 2 nm, more preferably within 1 nm.” *Id.* Further,

[t]he preferred monochromatic UV radiation has the majority wavelength or wavelengths within about 220 to 320 nm, more preferably within 240 to 280 nm. Preferably the total monochromatic UV radiation is within the range from 220 to 320 nm, more preferably within from 240 to 280 nm. A wavelength or wavelengths within these ranges are the most preferred, because those wavelengths are the most effective at rendering a microorganism sterile. The more preferred wavelength ranges comprise 257 nm, and presently, the most preferred range has the majority of radiation at 257 nm.

Id. Monochromatic UV radiation sources include excimer lasers; Brown-Skrobot describes examples of gas mixtures used in excimer lamps that produce monochromatic UV radiation, including krypton and chlorine (KrCl), xenon and iodine (XeI), and xenon and bromine (XeBr). *Id.* ¶¶ 34, 38. Multiple monochromatic UV radiation sources can be used together to provide same or different amounts of energy, and different wavelengths “may provide increased levels of sterility.” *Id.* ¶ 42.

Brown-Skrobot also discloses that “[n]on-ionizing radiation such as monochromatic ultraviolet (UV) light is known to damage the DNA of exposed cells. The UV radiation causes thymine to dimerize which inhibits replication of DNA during cell reproduction.” *Id.* ¶ 6.

2. *Clauß (Ex. 1007)*

Clauß is titled “Photoreactivation of *Escherichia coli* and *Yersinia enterocolitica* after Irradiation with a 222 nm Excimer Lamp Compared to a 254 nm Low-pressure Mercury Lamp.” Ex. 1007, 579. Clauß explains that “monochromatic emission of 254 nm almost corresponds with the maximum of DNA absorption at approx. 260 nm” and that “[t]his absorption causes damage to DNA by altering nucleotide base pairing, especially 6–4 photoproducts and thymine dimers formation,” which can lead to cell death. *Id.* at 580. Clauß further explains that UV radiation can also damage proteins’ amino acids and that photoreactivation is a repair mechanism for DNA damage. *Id.* Using KrCl excimer lamps, Clauß investigates irradiation of bacteria at a wavelength of 222 nm (near protein absorption maximum), and using low-pressure mercury lamps, irradiation at a wavelength of 254 nm (near DNA absorption maximum). *Id.* Clauß concludes that “without photoreactivation, the inactivation with UV radiation with 254 nm wavelength near the absorption maxima of DNA is most effective.” *Id.* at 583. Clauß also notes its “results indicate the damage of other molecules at 222 nm among the DNA” and “[i]t is assumed that protein damage is most probable.” *Id.*

3. *Claim 12*

Petitioner contends Brown-Skrobot teaches a process for destroying DNA or RNA of a microorganism on a substance or surface, as recited in the preamble of claim 12, because it discloses sterilization using monochromatic ultraviolet radiation from one or more monochromatic UV radiation sources, and that “every surface...receives a sterilizing dose of radiation.” Pet. 45 (citing Ex. 1003 ¶ 149; Ex. 1006 ¶¶ 2, 34). Petitioner contends Brown-Skrobot also teaches that monochromatic UV light is known to damage DNA because UV radiation causes thymine to dimerize which inhibits replication of DNA during cell reproduction. *Id.* at 45–46 (citing Ex. 1003 ¶ 149; Ex. 1006 ¶ 6).

Petitioner contends Brown-Skrobot teaches “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,” as recited in claim 12, because it discloses “two or more monochromatic [UV] radiation sources can be used together to provide . . . the same or different amount of energy at different wavelengths,” and a preferred embodiment of monochromatic UV radiation having the majority of wavelengths within about 220 to 320 nm and concentrated within a bandwidth of 3 nm, “preferably within a bandwidth of 2 nm, more preferably within 1 nm.” Pet. 46 (citing Ex. 1003 ¶ 151; Ex. 1006 ¶¶ 33, 42). Petitioner contends a person of ordinary skill in the art would have recognized that the wavelengths recited in claim 12 fall within Brown-Skrobot’s expressly disclosed monochromatic UV radiation range of 220 to 320 nm, and that monochromatic radiation sources such as the excimer lasers disclosed in Brown-Skrobot would generate photons of a single line wavelength. *Id.* at 46–47 (citing Ex. 1003 ¶ 51; Ex. 1006 ¶¶ 34,

38, 54). Petitioner further contends a person of ordinary skill in the art would have understood Brown-Skrobot's teaching of KrCl, XeI, and XeBr excimer lamps as monochromatic UV radiation sources that would generate photons at about 222 nm, 253 nm, and 282 nm, respectively. *Id.* at 47 (citing Ex. 1003 ¶ 152; Ex. 1006 ¶ 38; Ex. 1020 ¶ 30).

Petitioner contends Clauß teaches generating photons "corresponding to a peak absorption wavelength of DNA or RNA," as recited in claim 12, because it teaches selecting lamps emitting photons of single line wavelengths of 222 nm and 254 nm 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. Pet. 47–48 (citing Ex. 1003 ¶ 153; Ex. 1007, 580; Ex. 1001, 2:16–24, 6:33–46).

Petitioner contends Brown-Skrobot teaches directing the photons to the substance or surface to be disinfected, as recited in claim 12 (*see* Pet. 48–49 (citing Ex. 1003 ¶ 155; Ex. 1006 ¶¶ 34, 40), and that Clauß teaches photon wavelengths selected to destroy a plurality of bonds within the DNA or RNA of the microorganisms. *Id.* at 49 (citing Ex. 1003 ¶ 155).

Petitioner contends a person of ordinary skill in the art would have been motivated to combine the teachings of Brown-Skrobot and Clauß for several reasons: (1) both references teach using a KrCl excimer lamp for germicide purposes, while Brown-Skrobot suggests the use of other monochromatic UV sources, which a person of ordinary skill in the art would have understood to include Clauß's low-pressure mercury lamp; (2) a person of ordinary skill in the art 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,"

specifically, Brown-Skrobot's KrCl excimer lamp at 222 nm and Clauß's low-pressure mercury lamp at 254 nm which falls within Brown-Skrobot's preferred wavelength range of monochromatic UV light, because it would have combined prior art elements by known methods to yield a predictable result; (3) the 222 nm and 254 nm wavelengths of Brown-Skrobot and Clauß were known to be effective for disinfecting substances and surfaces; and (4) a person of ordinary skill in the art would have understood that using multiple light sources of 222 nm and 254 nm wavelengths would yield predictable advantages, based on Brown-Skrobot's teaching that "different wavelengths may provide increased levels of sterility," and the known synergistic effect of using multiple light sources of different wavelengths for germicidal use. Pet. 43–45 (citing Ex. 1001, 2:16-26, 4:28–33; Ex. 1003 ¶¶ 81, 84, 101–104; Ex. 1006 ¶¶ 33, 38, 42; Ex. 1007, 580–81; Ex. 1026, 1529).

Patent Owner argues Brown-Skrobot does not teach using a KrCl excimer lamp at 222 nm, and instead discourages using such a lamp. Prelim. Resp. 37. Specifically, Patent Owner argues Brown-Skrobot's preferred embodiment is a contact lens manufacturing process where monochromatic UV radiation preferably between 240 and 280 nm is applied to the sealed contact lens containers; Brown-Skrobot recognizes the drawbacks of using radiation below 240 nm because such wavelengths are known to damage the polymers used in contact lenses. *Id.* at 38 (citing Ex. 1006 ¶¶ 47, 54). Patent Owner argues Brown-Skrobot's reference to a KrCl lamp is "a sole, passing reference ... set within numerous other examples of monochromatic radiation." *Id.* at 39. Patent Owner further argues Brown-Skrobot does not teach using a XeBr excimer lamp at 282 nm, nor that any wavelength other

than 257 nm is preferred for its manufacturing process. Prelim. Resp. 40. Patent Owner acknowledges 282 nm is within the range of wavelengths taught by Brown-Skrobot, but argues that teaching of a broad genus does not necessarily disclose every species within that genus. *Id.* at 40-41.

Patent Owner argues even if Brown-Skrobot does not teach away from using a 222 nm lamp, there would have been no reason to combine Brown-Skrobot's 222 nm lamp with Clauß's 254 nm lamp in a sterilization process, because Brown-Skrobot already discloses 257 nm as the most preferred embodiment. Prelim. Resp. 41–42. Patent Owner argues there would have been no motivation to add any UV radiation source below 240 nm to Brown-Skrobot. *Id.*

On the present record, we are persuaded that Petitioner has shown sufficiently at this stage of the proceeding that a person of ordinary skill in the art would have been able to perform the method of claim 12 based on the teachings of Brown-Skrobot in view of Clauß. We do not agree with Patent Owner's arguments for several reasons. As to Brown-Skrobot, Patent Owner's argument that it teaches away from radiation below 240 nm is based on one embodiment, contact lens manufacturing, without considering the reference as a whole. Further, Patent Owner's argument that Brown-Skrobot "nowhere" discloses a 222 nm lamp for use with any embodiment (Prelim. Resp. 39) does not credit its disclosure of a KrCl lamp and other examples of monochromatic UV radiation sources; regardless of whether those examples are tied to a particular embodiment in Brown-Skrobot, Patent Owner offers no reason why a person of ordinary skill in the art would have been unable to use that teaching from Brown-Skrobot in the combination Petitioner proposes.

Accordingly, we determine that Petitioner has shown a reasonable likelihood of prevailing on its obviousness challenge to claim 12.

4. *Claims 13–18*

Petitioner identifies where every limitation of challenged claims 13–18 is found in the combination of Brown-Skrobot and Clauß. Pet. 49–53. Patent Owner does not present separate arguments as to these dependent claims. *See generally* Prelim. Resp. We have reviewed Petitioner’s evidence and arguments, including the relevant portions of the Lawal Declaration, and are persuaded, based on the current record, that Petitioner has shown a reasonable likelihood of prevailing on its obviousness challenge to claims 13–18.

III. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 325(d)

Patent Owner argues we should exercise discretion under § 325(d) and deny institution of review, on the basis of the USPTO’s prior consideration of substantially the same art and arguments during prosecution of a continuation of the ’642 patent, Application No. 17/280,480, which issued as U.S. Patent No. 11,246,951 (“the ’951 patent” or “child”). *See* Prelim. Resp. 20–26; Sur-reply, *generally*. Petitioner provides opposing arguments. *See* Pet. 60; Pet. Reply, *generally*. For the reasons discussed below, we do not invoke our discretion to deny institution under § 325(d).

Under § 325(d), in determining whether to institute an *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.”⁹ Our § 325(d) analysis employs a

⁹ The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

two-prong framework: (1) whether the arguments presented in the petition are the same or substantially the same as those previously presented to the Office; and (2) if so, whether the petitioner has demonstrated a material error by the Office in its prior consideration of those arguments. *Advanced Bionics, LLC v. Med-El Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (“*Advanced Bionics*”), 8 (PTAB Feb. 13, 2020) (precedential).¹⁰

We consider several non-exclusive factors as set forth in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”), which “provide useful insight into how to apply the framework” under § 325(d). *Advanced Bionics*, 9. These non-exclusive factors include:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

¹⁰ We note that *Advanced Bionics* does not expressly extend the § 325(d) inquiry to art considered in a related application, such as the child ’951 application.

Becton, Dickinson, 17–18 (formatting added). “If, after review of factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner has demonstrated a material error by the Office.” *Advanced Bionics*, 10.

Patent Owner argues two bases in the ’951 patent prosecution history for exercising discretion under § 325(d): (1) “the USPTO credited Mr. Neister’s date of conception and reduction to practice as prior to February 11, 2004;” and (2) “the USPTO had before it Eckhardt, Sosnin, and research related to Clauß by the same authors a year later, that was used in substantially the same way that Petitioner had presented them again here.” Prelim. Resp. 21. Both of these bases relate to the first ground of the Petition, and do not reach the second ground. As to the USPTO crediting Mr. Neister’s evidence, a Rule 1.131 declaration asserting an earlier conception and reduction to practice date, Patent Owner’s argument is based on claim 1 of the ’951 patent and Patent Owner’s assertion that it is directed to substantially the same subject matter as claim 1 of the ’642 patent. *See* Prelim. Resp. 22. Patent Owner does not make a similar assertion as to claim 12 of the ’642 patent. Thus, even if Patent Owner persuaded us that Mr. Neister presented the USPTO with substantially the same argument concerning priority of claim 1 of the ’642 patent when he presented the Rule 1.131 declaration concerning claim 1 of the ’951 application (and we note Petitioner’s arguments as to the differences between those claims, *see* Pet. Reply 3), Patent Owner effectively is requesting that we exercise discretion only as to the first ground of the Petition.

As to Patent Owner's argument that the USPTO had substantially the same art before it in the '951 prosecution, that argument also does not reach the second ground, because it does not address Brown-Skrobot, the primary reference of the Petition's second ground. Further, Patent Owner does not argue that the USPTO considered any of the art in light of claim 12's limitation "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," which is not present in claim 1 of the '951 application.

For the foregoing reasons, Patent Owner's § 325(d) arguments do not implicate sufficiently the Petition as a whole. As such, we decline to exercise discretion to deny institution.

IV. CONCLUSION

Based on the arguments in the Petition and the evidence of record, we determine that Petitioner has established a reasonable likelihood of prevailing in showing that claims 1–10 and 12–18 of the '642 patent are unpatentable.

Our factual findings, conclusions of law, and determinations at this stage of the proceeding are preliminary, and based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that an *inter partes* review of all challenged claims of the '642 patent is instituted with respect to all grounds set forth in the Petition; and

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FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '642 patent is hereby instituted commencing on the entry date of this Decision, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

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