

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, ELIZABETH M. ROESEL, and
JULIA HEANEY, *Administrative Patent Judges*.

HEANEY, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

Determining All Challenged Claims Unpatentable
Denying Patent Owner's Revised Contingent Motion to Amend
35 U.S.C. § 318(a)

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”). We determined the information presented in the Petition established that there was a reasonable likelihood that Petitioner would prevail in challenging at least one of claims 1–10 and 12–18 of the ’642 patent, and we instituted this *inter partes* review as to all challenged claims. Paper 12 (“Dec. on Inst.”).

During the course of trial, Patent Owner filed a Patent Owner Response (Paper 25, “PO Resp.”); Petitioner filed a Reply to the Patent Owner Response (Paper 36, “Pet. Reply”); and Patent Owner filed a Sur-reply (Paper 40, “PO Sur-reply”).

Patent Owner also filed a Corrected Contingent Motion to Amend, seeking to amend claim 12 and proposing contingent new claim 19 if the original claims were found unpatentable. Paper 32 (“MTA”). After we issued Preliminary Guidance on the MTA (Paper 35), Patent Owner filed a Corrected Second Contingent Motion to Amend, seeking to cancel claims 12–18 and proposing contingent substitute claims 19–25 if the original claims were found unpatentable. Paper 39. We refer to Paper 39 herein as Patent Owner’s Revised Contingent Motion to Amend (“RMTA”). Petitioner filed an Opposition to the RMTA (Paper 41, “Opp. RMTA”).

Petitioner filed the Declaration of Oliver R. Lawal (Ex. 1003) in support of the Petition. Petitioner also filed declarations of Mr. Lawal with its Reply (Ex. 1048) and its Opposition to the RMTA (Ex. 1053). Patent Owner filed the Declaration of Mark Hernandez, Ph.D. (Ex. 2016) with its Response. Patent Owner also filed a declaration of Dr. Hernandez (Ex. 2047) in support of its RMTA. The parties also filed transcripts of the depositions of Mr. Lawal (Ex. 2019) and Dr. Hernandez (Ex. 1051).

An oral hearing was held on June 29, 2023, and a transcript of the hearing is included in the record. Paper 48 (“Tr.”).

Following the oral hearing, we requested additional briefing on legal precedent under 35 U.S.C. § 112 on the issue of priority of claim 12. Paper 49. Petitioner and Patent Owner submitted supplemental briefs. Papers 50 and 53, respectively.

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims 1–10 and 12–18 of the ’642 patent and Patent Owner’s proposed contingent substitute claims 19–25. For the reasons discussed below, we hold that Petitioner has demonstrated by a preponderance of the evidence that claims 1–10 and 12–18 of the ’642 patent and Patent Owner’s proposed contingent substitute claims 19–25 are not patentable, and we deny Patent Owner’s RMTA.

A. Real Parties-in-Interest

Petitioner identifies itself, Eden Park Illumination, Inc., Larson Electronics LLC, Far UV Technologies, Inc., and Ushio America, Inc. as the real parties-in-interest. Pet. 61. Patent Owner identifies itself, S. Edward Neister, as the real party-in-interest. Paper 7.

B. 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*, 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.

C. 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.

D. 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. Claims 1 and 12 are reproduced below, with bracketed text added to correspond with Petitioner’s designation of claim elements:

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

[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;

[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

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

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

[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

[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.

Ex. 1001, 14:26–37, 15:11–20; *see* Pet. 25–30, 45–49.

E. Instituted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Challenged Claim(s)	35 U.S.C. ¹	Reference(s)/Basis
1–10	§ 103(a)	Eckhardt, ² Sosnin ³
12–18	§ 103(a)	Brown-Skrobot, ⁴ Clauß ^{5, 6}

Pet. 3.

II. ANALYSIS

A. 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

¹ 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 statutes.

² US Patent Pub. No. 2003/0031586 A1 to Eckhardt et al., published Feb. 13, 2003 (Ex. 1004).

³ 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).

⁴ US Patent Pub. No. 2005/0079096 A1 to Brown-Skrobot et al., published Apr. 14, 2005 (Ex. 1006).

⁵ 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).

⁶ Petitioner refers to this reference as “Claus,” rather than “Clauß.”

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.*

B. Claim Construction

We apply the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary

skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

In our Decision on Institution, we determined that we did not need to explicitly construe any claim terms. Dec. on Inst. 6; *see Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (stating “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))).

During trial, Patent Owner addressed claim construction for two claim terms: (1) “single line wavelength,” which appears in each of the independent claims; and (2) “a source,” which appears in dependent claims 2, 8, 10, and 18. PO Resp. 9–11. We discuss each of these terms below.

1. “single line wavelength”

Patent Owner argues that “single line wavelength” is defined in the specification as being synonymous with “narrow spectral emission,” and that meaning should govern here. PO Resp. 9. Patent Owner relies on the following portions of the specification:

These emitters produce single line or narrow spectral emission at a wavelength determined by the gas composition of the lamp. (Ex. 1001, 2:37–39).

The NUV [new ultraviolet] source apparatus is made to supply a narrow emission band of UV light that is close to the peak

absorption of the targeted organism or chemical with sufficient photon energy that breaks bonds. (Ex. 1001, 7:55–58).

PO Resp. 9–10 (also citing Ex. 1001, 4:52–54, 5:8–43, 8:65–9:31, 12:23–37, Fig. 1a).

Petitioner does not challenge Patent Owner’s proposed construction of “single line wavelength.” Pet. Reply 2.

We determine that the specification supports the construction of “single line wavelength” as “narrow spectral emission,” and therefore apply that construction. *Phillips*, 415 F.3d at 1316.

2. “a source”

In the table below, we set forth Petitioner’s and Patent Owner’s positions on the term “a source,” and our construction after considering the entire record.

Petitioner	Patent Owner	PTAB
one or more sources	a single source	one or more sources

Patent Owner argues “a source” for generating the photons means a single source of photons. PO Resp. 10–11; PO Sur-reply 2. Petitioner disagrees, arguing that “a source” should be construed to mean one or more sources. Pet. Reply 2–4.

It is a well-settled principle of claim construction that “an indefinite article ‘a’ or ‘an’ in patent parlance carries the meaning of ‘one or more’ in an open-ended claim containing the transitional phrase ‘comprising.’” *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000). “The exceptions to this rule are extremely limited: a patentee must ‘evinced[] a clear intent’ to limit ‘a’ or ‘an’ to ‘one.’” *Baldwin Graphic Sys., Inc. v.*

Siebert, Inc., 512 F.3d 1338, 1342 (Fed. Cir. 2008) (quoting *KCJ*, 223 F.3d at 1356)). “An exception to the general rule that ‘a’ . . . means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule.” *Id.* at 1342–43.

Patent Owner argues that the specification requires a single light source that emits two or more wavelengths. PO Resp. 10–11 (citing Ex. 1001, 7:66, 8:65–9:2, 9:4–11). We disagree. None of the cited specification passages show a clear intent to depart from the general rule for the indefinite article “a” in the phrase, “a source.” One of the embodiments Patent Owner identifies (Ex. 1001, 8:65–9:2) actually describes two sources where “two wavelengths may be emitted by an excimer lamp or lamps” and further describes “two separate lamps may be used, the two lamps in close proximity to each other.” *Id.* at 9:2–5.

The specification describes an embodiment having a dual annulus lamp that generates multiple wavelengths. Ex. 1001, 9:5–10. The specification expressly refers to this embodiment as “emitting the two wavelengths simultaneously and from a single source.” *Id.* at 9:9–10. This suggests that the patentee specified the singular when he intended to do so.

Patent Owner further argues that the language of claims 8, 10, and 18 forecloses an interpretation of “one or more” because “a source” provides antecedent basis for “the source” in each claim. PO Sur-reply 2–3 (“Claims 8, 10, and 18 only make sense if ‘a source’ is indeed referring to a single source.”). Patent Owner’s argument is contrary to Federal Circuit precedent, which recognizes that the definite article “the” refers back to earlier language as an antecedent, such that the reference-back “the” language takes

its meaning from the meaning of the antecedent. *ABS Global, Inc. v. Cytonome/ST, LLC*, 2023 WL 6885009 at *4 (Fed. Cir. Oct. 19, 2023) (“[I]f ‘a sample stream’ has a plural-allowing meaning, so does the reference-back ‘the sample stream’ phrase.”). Therefore, the language “the source” in claims 8, 10, and 18 does not require construction of “a source” as singular.

For these reasons, we disagree with Patent Owner that the facts of this case justify a departure from the presumption that, in a patent claim, the indefinite article “a” means “one or more.” In contrast to *Harari v. Lee*, 656 F.3d 1331, 1341 (Fed. Cir. 2011), cited by Patent Owner (PO Resp. 10–11), the ’642 patent does not emphasize that two or more wavelengths must be generated by a single source or lamp. Therefore, we construe “a source” in claims 8, 10, and 18 as not limited to a single source, as argued by Patent Owner.

C. Level of Ordinary Skill in the Art

Factors pertinent to a determination of the level of ordinary skill in the art include the “(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 (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. PO Resp. 9. We adopt Petitioner’s definition of the level of ordinary skill in the art in this Decision because it is consistent with the ’642 patent and the asserted prior art.

D. Effective Filing Date

The ’642 patent 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 claims the benefit 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. Ex. 1001, 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. *Id.* at 9. We address these contentions below.

1. Principles of Law

In an *inter partes* review, the petitioner bears the ultimate burden of persuasion to show unpatentability, which never shifts to the patent owner.

Dynamic Drinkware LLC v. National Graphics, Inc., 800 F.3d 1375, 1379–1380 (Fed. Cir. 2015). “However, when a patent owner attempts to antedate an asserted prior art reference, the patent owner takes on a temporary burden of production.” *Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, 68 F.4th 1298, 1303 (Fed. Cir. 2023) (citing *Dynamic Drinkware*, 800 F.3d at 1378–79)). “Once that burden is met, the burden shifts back to the petitioner.” *Id.*

“[A] patent’s claims are not entitled to an earlier priority date because the patentee claims priority. . . . Rather, for a patent’s claims to be entitled to an earlier priority date, the patentee must demonstrate that the claims meet the requirements of 35 U.S.C. § 120,” including a written description in the earlier-filed application that satisfies § 112. *In re NTP, Inc.*, 654 F.3d 1268, 1276–77 (Fed. Cir. 2011) (citations omitted)); *see also Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870–71 (Fed. Cir. 2010).

“[T]he hallmark of written description is disclosure,” and “the test [for satisfaction of the written description requirement] requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The written description “must ‘clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed,’” and “reasonably” convey to those skilled in the art “that the inventor had possession of the claimed subject matter as of the filing date.” *Id.* (alteration in original). Stated another way, “one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims.” *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000).

To provide sufficient written description support, “[a] ‘disclosure need not recite the claimed invention *in haec verba*.’” *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362, 1370 (Fed. Cir. 2022). A broad disclosure of a genus provides written description support for a claimed species when it provides “blaze marks” toward the claimed species. *In re Ruschig*, 379 F.2d 990, 994–95 (CCPA 1967).

“Whether a claim satisfies the written description requirement is a question of fact.” *Nalpropion Pharms., Inc. v. Actavis Labs. FL, Inc.*, 934 F.3d 1344, 1348 (Fed. Cir. 2019) (citing *Ariad*, 598 F.3d at 1351).

2. 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, the filing date of the PCT application. Pet. 4.

In our Decision on Institution, we determined Petitioner demonstrated a reasonable likelihood that it would prevail on its effective filing date contention. Dec. on Inst. 10.

Having considered the parties’ arguments on this issue in light of the trial record, we determine that Petitioner’s challenge of claims 1–10, based on the combination of Eckhardt and Sosnin, does not require us to determine the effective priority date of claims 1–10. Eckhardt and Sosnin were published in 2003 and 2004, respectively, which pre-dates the filing date of the ’626 provisional application. Neither party disputes that both references are pre-AIA § 102(b) prior art, even assuming claim 1’s effective filing date is the filing date of the ’626 provisional. Accordingly, we need not reach the

issue of whether the '626 provisional provides sufficient written description support for claims 1–10. *See Bos. Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (non-precedential) (recognizing that the “Board need not address issues that are not necessary to the resolution of the proceeding”).

3. Claims 12–18

The Parties' Positions

Petitioner argues that 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” was not disclosed in either the '626 provisional application or the PCT application. Pet. 6–7. Petitioner argues that, during prosecution, Mr. Neister did not cite to or rely on any disclosure in the '626 provisional application or the PCT application as support for this limitation, but instead relied on disclosure of new matter in the '667 application. *Id.* at 7–8. Petitioner further argues each UV light source disclosed in the PCT application generates only one single line wavelength. *Id.* at 8 (citing Ex. 1003 ¶ 74).

Citing Petitioner's evidence, Patent Owner argues that there is sufficient support for “generating photons of at least two single line wavelengths” because UV-C lamps emit photons across a spectrum containing multiple single line wavelengths. PO Resp. 16–17 (citing Ex. 1003 ¶¶ 40–41, 43, App. B⁷ at Figs. 2.12, 2.13, 4.4, F.12). Patent Owner argues that one of claim 12's objectives is to create photons that correspond to a peak absorption wavelength of DNA and that the '626 provisional

⁷ U.S. Environmental Protection Agency, *Ultraviolet Disinfection Guidance Manual*, EPA 815-D-03-007 (June 2003 Draft) (“EPA Manual”).

application identifies “the principal action spectra of the DNA absorption” as 245–280 nm. *Id.* at 18 (citing Ex. 1008 ¶¶ 9, 18). Additionally, according to Patent Owner, “since UV light can be created in narrow spectral emissions,” the ’626 provisional’s disclosure of DNA absorption from 245–280 nm is “sufficient to describe ‘generating photons’ at a single line wavelength of 282 nm.” *Id.* at 18 (citing Ex. 2016 ¶¶ 30–33); *see also* PO Sur-reply 5.

Analysis

We find that the disclosure of the ’626 provisional application is not sufficient to provide adequate 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.^{8,9}

To antedate Brown-Skrobot and Clauß, Patent Owner has the burden of producing evidence that the inventor had possession of the claimed invention at the time the ’626 provisional application was filed. Because the above-quoted limitation recites “at least two” of a group of three single line wavelengths (222 nm, 254 nm, and 282 nm), the question arises whether Patent Owner must show written description support for all three recited single line wavelengths, or need only show written description support for two of them. *See, e.g.* Tr. 15:11–15. Pursuant to our authorization (Paper

⁸ Our findings address the ’626 provisional application (filed January 31, 2005) because it is determinative of whether Brown-Skrobot (published Apr. 14, 2005) and Clauß (published Dec. 2005) are prior art to the ’642 patent.

⁹ As discussed in Section II.B.1 above, we construe “single line wavelength” as a narrow spectral emission.

49), the parties submitted supplemental briefs addressing the effect of *Markush* claiming on a written description analysis (Papers 50, 53).

Petitioner argues persuasively that, to satisfy the written description requirement, a patent application must show that the inventor had possession of the claimed invention as a whole, including each member of a *Markush* group. Paper 50, 1–3; see *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) (written description analysis requires “[t]aking each claim . . . as an integrated whole rather than as a collection of independent limitations”). Patent Owner argues “[t]here is no special rule for applying the requirements of 35 U.S.C. § 112 to a *Markush* group” and agrees that written description law requires “disclosure of each species in the *Markush* group.” Paper 53, 3–4. Based on the parties’ submissions, we determine that Patent Owner has a temporary burden of production to show written description support for all three single line wavelengths.

Patent Owner has not met its temporary burden of production to demonstrate written description support in the ’626 provisional application for generating photons of at least two single line wavelengths, or for generating a single line wavelength at or around 282 nm. As to generating photons of at least two single line wavelengths, we find that the ’626 provisional does not provide written description support for generating more than one single line wavelength. Although the ’626 provisional discloses two separate UV sources – an excimer lamp emitting at 222 nm (Ex. 1008 ¶ 12) and a low-pressure mercury gas lamp emitting at 254 nm (*id.* ¶ 8) – it does not disclose using them in combination. The ’626 provisional discloses

The preferred embodiment is a NUV source at 222 nm, but other lines can also be used . . . The NUV source is chosen to supply the single line emission that matches the peak absorption of the targeted organism or chemical.

Ex. 1008 ¶ 27.

We find credible Mr. Lawal’s explanation that the ’626 provisional’s description of the 222 nm source describes a single source having a single line emission, and a person of ordinary skill in the art would not have understood that the inventor had possession of generating more than one single line wavelength. Ex. 1045 ¶¶ 4–5. Further, although the ’626 provisional discloses using other sources such as a mercury lamp (Ex. 1008 ¶¶ 8, 14, claim 9), none of those disclosures describe using any source with the 222 nm excimer lamp. Therefore, we find that the ’626 provisional does not indicate to a person of ordinary skill that the inventor possessed generating a combination of a 222 nm single line wavelength with a 254 nm single line wavelength, or another single line wavelength. *See* Ex. 1045 ¶¶ 1–5.

Patent Owner’s assertion that “UV-C lamps emit photons at a broad range of wavelengths, but often with a plurality of ‘single line wavelengths’ across that spectrum” (PO Resp. 16–17) does not support its argument that the ’626 provisional provides written description support for generating photons of at least two single line wavelengths. Patent Owner mischaracterizes Figures 2.12(b) and 2.13 from Appendix B of Mr. Lawal’s declaration (Ex. 1003), by arguing that these two figures depict multiple single line wavelengths. PO Resp. 17 (citing Ex. 2016 ¶¶ 30–33). As Mr. Lawal credibly explains, these figures depict the spectral output of *polychromatic* medium-pressure mercury vapor lamps, which a person of

ordinary skill in the art would understand is different from a *monochromatic* excimer lamp or low-pressure mercury vapor lamp disclosed in the '626 provisional. Ex. 1048 ¶¶ 4–5. In other words, a person of ordinary skill considering applications for using an excimer lamp, as described in the '626 provisional, would not have viewed the spectral output of an excimer lamp to be polychromatic in the general usage of that term. See Ex. 1048 ¶ 5 (citing Ex. 1026, 1529; Ex. 1036, 6:2–3; Ex. 1003, Appendix C,¹⁰ 4–5, Fig. 16; Ex. 1005, 1545; Ex. 2016 ¶ 82; *see also* Ex. 1008 ¶¶ 13–15 (describing test setup 222, 253, and 259 nm lamps). On this point, Dr. Hernandez's testimony is consistent with Mr. Lawal's testimony. Ex. 2016 ¶ 82 (stating that “[a] POSITA would not understand these [excimer] lamps to have any other peak frequency”). We find that Mr. Lawal's testimony effectively rebuts Patent Owner's assertion that the '626 provisional describes excimer lamps that produce a spectrum of single line wavelengths. Patent Owner's “spectrum of single line wavelengths” assertion based on the spectral emissions of a different type of lamp, namely a polychromatic medium-pressure mercury vapor lamp, therefore is not sufficient evidence that the '626 provisional provides written description support for generating multiple single line wavelengths.

The prosecution history of claims 12–18 supports our finding. During prosecution, the applicant relied on the '667 application as providing support for pending claim 37 which recited “generating photons of at least two single line wavelengths . . . the at least two wavelengths being at least two of 222nm, 254 and 282 nm.” Ex. 1002, 161–162 (referring to “original claim

¹⁰ Black & Veatch and Electric Power Research Institute, *UV Disinfection for Wastewater Treatment*, Report CR-105252 (Dec. 1995).

17” in the ’667 application as support for new claim 37); Ex. 1037, 761 (’667 application original claim 16 reciting “generating photons of at least one wavelength . . .” and original claim 17 reciting “wherein the wavelength is at least one of 222 nm, 254 nm, and 282 nm”). *See* Pet. 6–7. The applicant did not rely on any disclosure in the PCT application or the ’626 provisional as providing written description support for claim 37. Patent Owner does not address this prosecution history (*see generally* PO Resp.), which is inconsistent with its current argument that the ’626 provisional provides written description support for generating photons of at least two single line wavelengths.

As to claim 12’s recitation of generating a single line wavelength at 282 nm, Patent Owner does not direct us to any disclosure in the ’626 provisional of generating photons at a single line wavelength around 282 nm. Although the ’626 provisional discloses DNA absorption in the range of 245–280 nm (Ex. 1008 ¶ 9), it does not discuss generating photons at single line wavelengths across this entire range. Rather, it only discusses sources emitting at 222 nm and around 254 nm, and makes a general suggestion that “other [single line wavelengths] can also be used.” Ex. 1008 ¶ 27. This disclosure is not sufficient to provide written description support for generating a single line wavelength around 282 nm. *See Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326–27 (Fed. Cir. 2000) (“[O]ne cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.”).

We disagree with Patent Owner's assertion that the '626 provisional's disclosure of the principal action spectra of DNA absorption in the range 245–280 nm, and its specific example of a DNA absorption peak at 280 nm (Ex. 1008 ¶¶ 9, 18), are sufficient to provide written description of generating a single line wavelength around 282 nm. *See* PO Resp. 18 (citing Ex. 2016 ¶ 33). The disclosures Patent Owner relies on are references to DNA absorption spectra, not sources for generating 280 nm light. Specifically, we do not find persuasive Dr. Hernandez's opinion that, based on the '626 provisional's example of the tobacco mosaic virus as having an X-protein whose DNA curve peaks at 280 nm, a person of ordinary skill in the art would have understood that the inventor contemplated generating a single line wavelength around 282 nm to sterilize such microorganisms. That example pertains to the wavelength the virus absorbs, and does not relate to generating photons of that wavelength. "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (quotations omitted).

Further, Patent Owner presents inconsistent arguments. On the one hand, Patent Owner argues that the '626 provisional's description of DNA absorption in the range of 245–280 nm provides sufficient written description for generating a single line wavelength of 282 nm. PO Resp. 19. On the other hand, Patent Owner argues that Brown-Skrobot's range of 240–280 nm does not teach or suggest generating a 282 nm wavelength. *Id.* at 43. Although we do not accept either argument, the inconsistency demonstrates the weakness in Patent Owner's positions. Patent Owner asserts its arguments are not inconsistent because Brown-Skrobot only

teaches the use of lasers. PO Sur-reply 6; PO Resp. 41. This mischaracterizes Brown-Skrobot's teaching. As we discuss in Section II.F below, Brown-Skrobot also teaches the use of excimer lamps, including an XeBr lamp having a characteristic wavelength of 282 nm. Ex. 1006 ¶¶ 22, 34, 38, 40, 54.

Thus, we determine Patent Owner does not meet its temporary burden of production for demonstrating the inventor's possession in the '626 provisional application of generating a single line wavelength of 282 nm wavelength, or generating photons of at least two single line wavelengths.

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.

1. 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, [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, 30. According to Eckhardt's method, sterilizing or disinfecting light is emitted by a light source and directed to a wound and surrounding skin. *Id.* ¶ 31, Fig. 1.

Eckhardt discloses that the light source “may be any light source that emits light capable of sterilization or disinfection,” for example, “an ultraviolet (UV) light source” such as a xenon flash lamp or standard

germicidal mercury vapor lamp. *Id.* ¶¶ 31, 43, 55. 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. One embodiment describes using a UV-transmissive bandage that transmits 80% of sterilizing light from a xenon flash having a wavelength in the range of 220 to 310 nm. *Id.* ¶ 70.

2. *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. 1005, 1544. Sosnin compares the effects of UV radiation on living mammalian cells (fibroblasts)¹¹ with data on UV bacterial inactivation. *Id.* Sosnin states that fibroblasts are a cell type involved in wound repair. *Id.* According to Sosnin, “UV irradiation can lead to cell death (necrosis) in fibroblasts, but the doses that cause such damage are much higher than those need to destroy *Escherichia Coli*.” *Id.* (abstract).

Sosnin describes mammalian cell experiments using two narrow-band UV sources: (1) a xenon-bromine (XeBr) excimer lamp (or excilamp) with a peak emission wavelength at ~282 nm; and (2) a low-pressure iodine lamp with a peak emission wavelength at ~206 nm. *Id.* at 1545. Sosnin discloses that, in general, “[e]xcilamps provide UV irradiance up to 10 mW/cm²” and

¹¹ Sosnin uses Chinese Hamster Ovary (CHO-K1) cells. Ex. 1004, 1544.

“their spectra consist of narrow bands.” *Id.* According to Sosnin, “the XeBr lamp is most efficient in sterilization” because “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 compares survival curves for the mammalian cell irradiation experiments (Figure 7) with survival curves for *E. Coli* when irradiated with a XeBr excilamp (Figure 8) and a KrCl excilamp having a peak wavelength at 222 nm (Figure 9). *Id.* at 1547, Figs. 8, 9. Sosnin observes that “UV doses needed to deactivate *E. Coli* are much lower than the ones that cause necrosis in fibroblasts.” *Id.*

3. Reason to Combine

Petitioner contends it would have been obvious to a person of ordinary skill in the art to combine (1) Eckhardt’s method of disinfecting skin using any light source that emits light capable of sterilization or disinfection, with (2) Sosnin’s KrCl or XeBr light sources, which generate photons having a wavelength of 222 nm and 282 nm, respectively. Pet. 21–22 (citing Ex. 1003 ¶¶ 40, 81; Ex. 1004 ¶¶ 31, 69; Ex. 1005, 1547).

Petitioner contends a person of ordinary skill 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, 1545–47; Ex. 1011 ¶¶ 28, 40; Ex. 1013 ¶ 8; Ex. 1015, 2:22–67; Ex. 1016, 2:23–26; Ex. 1017, 58).

Patent Owner argues that both references teach away from the use of UV light on skin, and neither reference demonstrates that 222 nm or 282 nm light was safe to use on skin. PO Resp. 20–28. Patent Owner further argues that a person of ordinary skill in the art would not have been motivated to combine the references because: it would involve a fundamental change to Eckhardt's disinfection methods; the light sources in Eckhardt and Sosnin are different; the references do not provide data about the relative safety of UV-C light on skin; and changing Eckhardt's method to improve safety of the light sources would be incompatible with substituting a light source from Sosnin. *Id.* at 31–39.

Having considered the evidence and arguments, we determine that the preponderance of the evidence favors Petitioner. Petitioner demonstrates persuasively that a person of ordinary skill in the art would have had reasons to combine Eckhardt's teaching of narrow spectrum UV light in the range of 220 to 310 nm to disinfect skin (Ex. 1004 ¶¶ 31, 69–70), with Sosnin's teaching of KrCl and XeBr excimer lamps having narrow band UV emissions at 222 nm and 282 nm, respectively, to kill bacteria (Ex. 1005, 1545, 1547, Figs. 8, 9). In particular, Petitioner shows that a person of

ordinary skill in the art would have wanted to obtain the benefits of Eckhardt's teaching of disinfecting skin using any light source capable of sterilization or disinfection, and would therefore have considered Eckhardt's suggestion of using narrow spectrum UV light in combination with Sosnin's disclosure of using germicidal excimer lamps within the range of wavelengths taught by Eckhardt. *See KSR*, 550 U.S. at 417 (stating that the "mere application of a known technique to a piece of prior art ready for the improvement" suggests obviousness).

The teachings of both Eckhardt and Sosnin support Petitioner's combination. In particular, both references teach using UV lamps with narrow bands or monochromatic emissions to sterilize surfaces. Eckhardt teaches "light source 7 may be any light source that emits light capable of sterilization or disinfection" and may be a UV light source such as a lamp that "may emit narrow spectrum light (e.g., a line spectrum) or broad spectrum light" including UVA, UVB, and UVC light. Ex. 1004 ¶ 31. Eckhardt also teaches flash light source 7a generates a flash sufficient for sterilization or disinfection may be a xenon flash lamp having a wavelength in the range of 220 to 310 nm. *Id.* ¶¶ 43, 70. Additionally, Eckhardt teaches "[t]he sterilization/disinfection units previously described are designed to have a beneficial effect when used on bare skin." *Id.* ¶ 69. Sosnin teaches using excimer lamps for sterilization and specifically discloses XeBr and KrCl lamps which generate photons having wavelengths of 282 and 222 nm, respectively. Ex. 1005, 1545, 1547.

We find that Eckhardt would have led a person of ordinary skill to consider using 222 and 282 nm excimer lamps because those wavelengths fall within the range of UV light (220–310 nm) suggested by Eckhardt, and

the range known to provide disinfection. Ex. 1004 ¶ 70; Ex. 1005, 1547 (stating that “very low UV doses reduce the bacterial population by two decades”). We find that Eckhardt supports Petitioner’s contention that it was within the knowledge of a person of ordinary skill in the art to use UV light in the range of 254 nm for disinfection, even though that wavelength presented safety concerns. Ex. 1004 ¶¶ 54, 56. *See* Pet. 24.

We find that Eckhardt’s teaching of improved safety associated with applying low intensity UV light to human skin (Ex. 1004 ¶¶ 5, 54 (stating “the lower intensity of the light generated by instantaneous sterilization/disinfection unit 16a does not present as much of a safety concern”)) would have led a person of ordinary skill to consider Sosnin’s excimer lamps. Sosnin suggests using excimer lamps to selectively kill bacteria without damaging skin. Ex. 1005, 1547, Figs. 8, 9. More particularly, based on a comparison of survival curves for living mammalian cells (fibroblasts) and *E. Coli* bacteria after irradiation with UVB and UVC light, Sosnin concludes that “fibroblasts are extremely resistant to UV” and “Irradiation 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.* Sosnin provides survival curves for fibroblasts (CHO-K1 cells) after irradiation with UVC and UVB light from iodine and XeBr lamps, respectively (Fig. 7) and “typical bacterial survival curves” resulting from irradiation of *E. coli* with XeBr (282 nm) and KrCl (222 nm) excimer lamps (Figs. 8, 9). Based on these curves, Sosnin observes that “UV doses needed to deactivate *E. Coli* are much lower than the ones that cause necrosis in fibroblasts” and “very low UV doses reduce the bacterial population.” *Id.* at 1547. Sosnin’s teachings suggest that irradiation with

UV light from XeBr (282 nm) and KrCl (222 nm) excimer lamps would be able to kill bacteria without damaging the surrounding living cells, providing strong support for Petitioner's combination of Eckhardt's skin sterilization method with Sosnin's 282 nm and 222 nm excilamps. *See* Ex. 1003 ¶ 89.

We also find support for Petitioner's contention that, despite the general caution against exposing skin to excessive UV light, a person of ordinary skill would have been motivated by the beneficial effect of disinfecting skin to use light in the UVC spectrum for disinfection. Pet. 24. 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." Ex. 1012, 1.

We disagree with Patent Owner's argument that Eckhardt teaches away from the use of UV light on skin. Patent Owner's argument is based on an unduly narrow view of Eckhardt's disclosure, limited to Eckhardt's description of "exactly two" (PO Resp. 20) disinfection units: unit 16a using xenon flash bulb light source 7a (Ex. 1004 ¶¶ 37–48); and unit 16b using 254 nm mercury gas lamp light source 7b (*id.* ¶¶ 49–61). Contrary to Patent Owner's characterization, Eckhardt's teachings are not limited to those two embodiments. *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012) ("A reference may be read for all that it teaches, including uses beyond its primary purpose."). As discussed above, Eckhardt also teaches any light source that emits light capable of sterilization or disinfection. Ex. 1003 ¶ 69. And, Patent Owner misstates the record by asserting that Mr. Lawal admitted Eckhardt never suggested using a different wavelength (PO Resp. 22, citing Ex. 2019, 170:15–171:7, 199:8–22). In addition to the portion of

his deposition Patent Owner selectively relies on, Mr. Lawal testified that Eckhardt

does talk about any other wavelength which was why I use that as a reference in combination with Sosnin. And Eckhardt [sic] own suggestion that it could be any other wavelength.

Ex. 2019, 199:4–7; *see also* Ex. 2019 171:23–172:19.

We disagree, for similar reasons, with Patent Owner’s arguments that a person of ordinary skill would not have been motivated to substitute a different light source in the disinfection methods described by Eckhardt, or to substitute Sosnin’s light sources for Eckhardt’s 254 nm mercury lamp or xenon flash lamp. PO Resp. 29–30. We do not find these arguments persuasive because they unduly limit Eckhardt’s teachings to the two embodiments describing disinfection units 16a and 16b. Also, Patent Owner’s assertion that “there is no overlap in the light sources” (*id.* at 30) overlooks Eckhardt’s teaching that “Light source 7 may be any light source that emits light capable of sterilization or disinfection.” Ex. 1004 ¶ 31.

Patent Owner argues that Eckhardt’s continuous disinfection method 16b using a 254 nm light source “was known at the time (and today) to be not safe” and that Eckhardt does not suggest switching to a safer wavelength like 222 nm. PO Resp. 21–22 (citing Ex. 2016 ¶ 42; Ex. 1004 ¶ 56). Patent Owner’s argument about safety is not consistent with Eckhardt’s description of method 16b, which also states that 254 nm source 7b “may[]be illuminated for long periods of time (e.g., hours or days) without damage to skin 3.” Ex. 1004 ¶ 56.

Patent Owner argues that a person of ordinary skill in the art “would have understood that 222 nm light could not even penetrate the bandage materials described in Eckhardt” and if she were trying to improve upon

Eckhardt, would have optimized the intensity of the 254 nm light source in Eckhardt's method 16b, rather than substituting a light source from Sosnin. PO Resp. 31. Patent Owner's argument unduly limits Eckhardt and overlooks its express teaching of disinfecting skin directly with no bandage. *See* Ex. 1004 ¶¶ 62–69, 78.

Patent Owner argues that “Sosnin does not teach or suggest that 222 nm or 282 nm UV light could be safely used to disinfect skin.” PO Resp. 27. Patent Owner's argument is based on its assertion that Sosnin's experimental setup and results do not include a KrCl lamp at 222 nm wavelength, and “had nothing to do with skin.” PO Resp. 24–26. Contrary to Patent Owner's argument, Sosnin describes that the CHO-K1 cell cultures in its studies are fibroblasts involved in “wound repair” (Ex. 1005, 1544) and further states: “Irradiation 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.* at 1547. Further, Mr. Lawal provides un rebutted testimony that CHO cells are routinely used as an initial proxy for mammalian and human cells, and that a person of ordinary skill seeking to safely disinfect human skin would have been motivated by Sosnin's disclosures. Ex. 1048 ¶ 25. Patent Owner's argument fails to credit the ability of a person of ordinary skill in the art to make reasonable inferences. *See KSR*, 550 U.S. at 417 (“[A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”).

Patent Owner argues that Sosnin “failed to test a KrCl lamp as part of its experiments or test any form of UV light on human skin or skin cells.” PO Resp. 24. In our view, however, it is irrelevant whether Sosnin actually ran tests or relied on pre-existing data. Sosnin provides survival curves for

E. coli irradiated with a KrCl excimer lamp and draws conclusions based on that data. Ex. 1005, 1547, Fig. 9. Contrary to Patent Owner’s arguments (PO Resp. 27–28), Petitioner is not required to show that Sosnin is enabling. *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991) (“a non-enabling reference may qualify as prior art for the purpose of determining obviousness”). Further, Sosnin provides at least as much information as the ’642 patent about testing on skin cells. *See* Ex. 1001, 8:37–41; *Titanium Metals Corp. of America v. Banner*, 778 F. 2d 775, 781 (Fed. Cir. 1985) (answering the prior art enablement question by comparison with appellee’s own patent application).

Patent Owner and Dr. Hernandez observe that Sosnin does not include an emission spectrum for a KrCl lamp (in contrast to the emission spectra it provides for an iodine lamp and XeBr lamp (Ex. 1005, Fig. 2)), and does not provide a citation or attribution for the KrCl survival curve it depicts (*id.* at Fig. 9). PO Resp. 30–31 (citing Ex. 2016 ¶¶ 43–51). Based on these observations, Dr. Hernandez’ opines that a person of ordinary skill in the art would have questioned the validity of Sosnin’s disclosures “and any scientific position to use them for comparative purposes.” Ex. 2016 ¶¶ 45–48. Although some of Dr. Hernandez’s observations about Sosnin are accurate, we disagree that they would have led a person of ordinary skill in the art away from combining Sosnin’s teachings with Eckhardt. We credit Mr. Lawal’s testimony that a person of ordinary skill in the art would have known the emission characteristics of a KrCl lamp (Ex. 1048 ¶ 21, citing Ex. 1026, 1529; Ex. 1036, 6:2–3). Further, Mr. Lawal notes that Sosnin discloses Figure 9 is a “typical bacterial survival curve”, and provides citations to six references, which a person of ordinary skill would have been

able to review. Ex. 1048 ¶ 22 (citing Ex. 1005, 1547). Patent Owner does not rebut this evidence. We find that Patent Owner's attack on Sosnin's reliability is not justified, because Sosnin includes a detailed explanation of the scientific methods used to collect the data presented, and the data supports Sosnin's conclusions.

Patent Owner argues a person of ordinary skill in the art would not have combined Eckhardt and Sosnin because they would not have had a general understanding that 222 nm light was safe for disinfecting skin. PO Resp. 36. Patent Owner criticizes Mr. Lawal's opinion about the relative safety of using 222 nm light on skin (Ex. 1003 ¶¶ 88–92) on the ground that he lacks experience and credentials,¹² and that the references he relies on do not support his opinion. PO Resp. 32–35 (discussing Exs. 1011, 1012, 1013, 1015, 1016). Specifically, Patent Owner asserts that none of the references directly refer to the use of 222 nm light on skin or is supported “with any microbiological or other data.” *Id.* at 35 (citing Ex. 2019, 216:3–232:17). Having considered Patent Owner's argument concerning safety of 222 nm light, we are nonetheless persuaded by the Petition's rationale for combining Eckhardt and Sosnin. The Petition explains that a person of ordinary skill in the art would have known that despite general caution against exposing skin to UV radiation, 254 nm light was being used to disinfect skin, and therefore a person of ordinary skill would have understood that the beneficial effects of disinfecting skin with UV light could outweigh safety concerns. Pet. 24

¹² We find that Mr. Lawal's education and experience are within the level of a person of ordinary skill in the art we apply here, and which the parties do not dispute. *See* Section II.C. Patent Owner's arguments concerning the comparative experience of Dr. Hernandez and Mr. Lawal do not persuade us to accord Mr. Lawal's opinions less weight.

(citing Ex. 1003 ¶ 91; Ex. 1004 ¶ 5; Ex. 1015, 2:54–62; Ex. 1016, 2:23–26; Ex. 1017, 58). Further, as discussed above, we find that Sosnin teaches low doses of 222 nm light were relatively safe (Ex. 1005, 1547, Fig. 9), and this supports Petitioner’s contention that a person of ordinary skill in the art would have reasonably expected disinfecting with 222 nm light to be successful.

Patent Owner argues that “without any testing or other proof that 222 nm UV could be used to safely disinfect skin—and the fact that reputabl[e] researchers are still investigating the safety of 222 nm wavelengths on skin today” (PO Resp. 38–39), it would not have been obvious to combine Eckhardt and Sosnin to yield predictable results. Contrary to Patent Owner’s argument, experimental data is not required for a finding of reasonable expectation of success. “A finding of a reasonable expectation of success does not require absolute predictability of success.” *Almirall, LLC v. Amneal Pharms. LLC*, 28 F.4th 265, 275 (Fed. Cir. 2022).

Petitioner shows that a person of ordinary skill in the art would have reasonably expected that Sosnin’s XeBr and KrCl excimer lamps would provide a safe alternative to the light sources taught by Eckhardt in view of Sosnin’s teaching that “UV doses needed to deactivate *E. Coli* are much lower than the ones that cause necrosis in fibroblasts,” which are used as a proxy for human cells. Ex. 1005, 1547, Figs. 7–9; Ex. 1048 ¶ 25. Further, strong evidence that a person of ordinary skill in the art would have understood the safety and effectiveness of XeBr and KrCl excimer lamps is provided by Sosnin’s teaching 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.* at 1547.

For the foregoing reasons, we find that Petitioner has established that it would have been obvious to combine the teachings of Eckhardt and Sosnin.

4. Claim 1

[1pre]

Petitioner contends Eckhardt teaches a process for destroying DNA or RNA of a microorganism on a substance or surface, as recited in the preamble 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).

Patent Owner does not dispute Petitioner’s contention. We find that the combination of Eckhart and Sosnin discloses the preamble of claim 1, for the reasons set forth in the Petition, as summarized above.

[1A]

Petitioner contends the combination of Eckhardt and Sosnin discloses claim element [1A], which recites “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.” Petitioner contends Eckhardt’s light source 7 includes 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 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).

Patent Owner argues Sosnin and Eckhardt do not teach or suggest that 222 nm or 282 nm light could be safely used to disinfect skin, and disputes Petitioner's contentions regarding reasons for combining the prior art teachings and a reasonable expectation of success. PO Resp. 20–30. We have addressed these arguments, and explained why we disagree with them, in Section II.E.3. above. Aside from these arguments, Patent Owner does not dispute Petitioner's contention that the combination of Eckhardt and Sosnin discloses claim element [1A].

Based on the evidence before us, we determine that Petitioner has shown by a preponderance of evidence that the combination of Eckhardt and Sosnin discloses claim element [1A]. We find that Eckhardt's disclosure of a lamp emitting sterilizing light in the range of 220 to 310 nm (Ex. 1004 ¶¶ 31, 43, 70), combined with Sosnin's disclosure of irradiation of *E. coli* with XeBr and KrCl excimer lamps, generating wavelengths of 282 and 222 nm respectively (Ex. 1005, 1547, Figs. 8, 9), which correspond to peak absorption wavelengths of DNA or RNA (Ex. 1001, 6:33–46), discloses claim element [1A].

[1B]

Petitioner contends the combination of Eckhardt and Sosnin discloses claim element [1B], which recites “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.” Ex. 1001, 14:32–35. 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).

Patent Owner argues Sosnin and Eckhardt do not teach or suggest directing photons selected to destroy DNA and RNA of microorganisms on a surface to be disinfected, and disputes Petitioner’s contentions regarding reasons for combining the prior art teachings and a reasonable expectation of success. PO Resp. 20–30. We have addressed these arguments, and explained why we disagree with them, in Section II.E.3. above. Aside from these arguments, Patent Owner does not dispute Petitioner’s contention that the combination of Eckhardt and Sosnin discloses claim element [1B].

Based on the evidence before us, we determine that Petitioner has shown by a preponderance of evidence that the combination of Eckhardt and Sosnin discloses claim element [1B]. We find that Eckhardt’s disclosure of directing sterilizing light in the range of 220 to 310 nm toward a surface to be disinfected (Ex. 1004 ¶¶ 31–33, 43, 70), combined with Sosnin’s

disclosure of bacterial survival curves resulting from irradiation of *E. coli* with XeBr and KrCl excimer lamps (Ex. 1005, 1547, Figs. 8, 9), discloses claim element [1B].

[1C]

Petitioner contends the combination of Eckhardt and Sosnin discloses claim element [1C], which recites “wherein the substance or surface to be disinfected is human or animal skin.” Petitioner contends Eckhardt teaches disinfection of human or animal skin. Pet 29 (citing Ex. 1004 ¶¶ 29–32). Petitioner contends Sosnin teaches a 282 nm excimer lamp selectively kills microorganisms such as *E. coli* at much lower doses than those that cause damage to human cells, concluding “[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).

Patent Owner argues Eckhardt teaches away from the use of UV light on skin and Sosnin does not sufficiently teach disinfecting skin with 222 nm light, and disputes Petitioner’s contentions regarding reasons for combining the prior art teachings and a reasonable expectation of success. PO Resp. 20–30. We have addressed these arguments, and explained why we disagree with them, in Section II.E.3. above.

Based on the evidence before us, we determine that Petitioner has shown by a preponderance of evidence that the combination of Eckhardt and Sosnin discloses claim element [1C]. We find that Eckhardt’s teaching of disinfecting human or animal skin (Ex. 1004), combined with Sosnin’s teaching of using XeBr and KrCl excimer lamps to selectively kill bacteria

without damaging skin (Ex. 1005, 1544, 1547, Figs. 7–9), discloses claim element [1C].

Conclusion as to Claim 1

For the reasons set forth above, we determine that Petitioner has shown by a preponderance of the evidence that claim 1 would have been obvious over the combination of Eckhardt and Sosnin.

5. Claims 2–4, 7–10

Claims 2–4 and 7–10 depend from claim 1. Petitioner identifies where every additional limitation of challenged claims 2–4 and 7–10 is found in the combination of Eckhardt and Sosnin. Pet. 30–41. Patent Owner does not present separate arguments as to these dependent claims. For the reasons set forth as to each claim below, in addition to the reasons discussed above regarding claim 1, we find that Petitioner has shown by a preponderance of evidence that the subject matter of claims 2–4 and 7–10 would have been obvious over the combination of Eckhardt and Sosnin.

Claim 2 depends from claim 1 and additionally recites the step of providing a “new ultra violet light source for generating the photons.” Ex. 1001, 14:39–40. Petitioner shows that the combination of Eckhardt and Sosnin discloses this limitation. Pet. 30 (citing Ex. 1003 ¶ 117, Ex. 1005, 1545, 1547). Petitioner contends that a “new ultra violet light source” as recited in claim 2, encompasses a UV light source that emits narrow wavelength bands of photons at 222 nm and 282 nm. *Id.* In support of this construction, Petitioner relies on the specification’s statement 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.” *Id.* at 30 (citing Ex. 1001, 3:6–11) (alteration in original). Based on Petitioner’s evidence and explanation, we find that Sosnin teaches a new ultra violet light source source. *Id.*

Claim 3 depends from claim 1 and additionally recites that “the directing step is performed by reflecting the photons to a desired surface.” Ex. 1001, 14:41–42. Petitioner shows that the combination of Eckhardt and Sosnin discloses this limitation, because Eckhardt discloses reflector 9 disposed near light source 7 to aid in directing light towards wound 1 and surrounding skin 3. Pet. 31 (citing Ex. 1004 ¶ 31, Fig. 1).

Claim 4 depends from claim 1 and additionally recites that the directing step “further comprises the step of providing 540 kJ/mole of photon energy to the substance or surface to be disinfected.” Ex. 1001, 14:43–45. Petitioner shows that the combination of Eckhardt and Sosnin discloses this limitation based on evidence showing Eckhardt discloses directing photons of 222 nm to the surface to be disinfected, and that a person of ordinary skill would have readily known that photons of wavelength 222 nm necessarily correspond to approximately 540 kJ/mole of photon energy. Pet. 31 (citing Ex. 1003 ¶¶ 29, 122; Ex. 1005, 1547, Ex. 1021, 651).

Claim 7 depends from claim 1 and additionally recites that the directing step “further comprises directing the photons to provide a radiant dose energy of 10 mJ/cm² to the substance or surface to be disinfected.” Ex. 1001, 14:56–57. Petitioner asserts that Eckhardt teaches delivering “a sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm² of UVC, to all surfaces to be sterilized or disinfected.” Pet. 37 (citing Ex. 1003 ¶ 135; Ex. 1004 ¶¶ 32, 43). Petitioner asserts that Sosnin teaches that a 282 nm light

with a radiant dose energy of 10 mJ/cm² results in a more than 99% kill of *E. coli*. *Id.* (citing Ex. 1005, 1547, Fig. 8; Ex. 1003 ¶ 135). We find that the references support these assertions, and Petitioner shows that the combination of Eckhardt and Sosnin discloses this limitation.

Claim 8 depends from claim 1 and additionally comprises “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/cm² or less.” Ex. 1001, 14:58–61. Petitioner asserts that Sosnin teaches a UV source having irradiance kept constant at 4 mW/cm² for the XeBr lamp, and varied at different levels of UV irradiance up to 10 mW/cm² for treating *E. coli*. Pet. 37 (citing Ex. 1005, 1546). Petitioner asserts that these levels are within the claimed range of approximately 100 mw/cm² or less. *Id.* (citing Ex. 1003 ¶ 139). We find that the references support Petitioner’s assertions, and Petitioner shows that the combination of Eckhardt and Sosnin discloses this limitation.

Claim 9 depends from claim 1 and additionally recites that the directing step “further comprises exposing the substance or surface to be disinfected to the generated photons for less than 0.1 second.” Ex. 1001, 14:63–64. Petitioner asserts that Eckhardt teaches directing photons to the surface to be disinfected for less than 200 microseconds (Pet. 38 (citing Ex. 1004 ¶ 43)), and that exposure for less than 0.1 second was known in the art. *Id.* (citing Ex. 1003 ¶ 41; Ex. 1036, 8:1–7). Mr. Lawal also testifies that it was within the knowledge of a person of ordinary skill in the art to increase or decrease the exposure time of a UV light source to a surface. Ex. 1003 ¶ 126. We find that the references support Petitioner’s assertions, and

Petitioner shows that the combination of Eckhardt and Sosnin discloses this limitation.

Claim 10 depends from claim 1 and additionally comprises the steps of selecting a hand held lamp as a source for generating the photons, and waving the lamp over the surface to be disinfected, exposing the surface or substance to the generated photons for approximately 0.1 second or less. Ex. 1001, 15:1–6. Petitioner asserts that Eckhardt teaches selecting a hand held lamp having a movable light directing component, and allowing hand held operation without the need for an attachment mechanism. Pet. 38–39 (citing Ex. 1004 ¶¶ 45, 51, 64–66). Petitioner argues that a person of ordinary skill in the art would have immediately recognized that Eckhardt’s hand held device was likely to provide disinfection, and would be capable of exposing the surfaces to be disinfected to the generated photons for less than 0.1 second, for the reasons asserted for claim 9. *Id.* at 38–40 (citing Ex. 1003 ¶¶ 142–145). We find that Eckhardt and Mr. Lawal’s testimony support these assertions, and Petitioner shows that the combination of Eckhardt and Sosnin discloses the elements of claim 10.

6. Claims 5 and 6

Claim 5 depends from claim 1 and additionally recites that the directing step “further comprises directing the photons to provide a radiant dose energy of 40 mJ/cm² to the substance or surface to be disinfected.” Ex. 1001, 14:48–50. Claim 6 recites a radiant dose energy of 60 mJ/cm². *Id.* at 14:53.

Petitioner asserts that the combination of Eckhardt and Sosnin discloses the limitations of claims 5 and 6. Pet. 32 (citing Ex. 1003 ¶¶ 123–131). Petitioner asserts that Eckhardt’s teaching of a disinfecting dosage of

greater than 10 mJ/cm², and producing UVC energy intensity of about 20 mJ/cm², teaches the dose energies of claims 5 and 6. *Id.* (citing Ex. 1004 ¶¶ 32, 43). Petitioner also asserts that Sosnin teaches a range of radiant dose energies between 25 mJ/cm²–210 mJ/cm² (222 nm source) and 5 mJ/cm²–34 mJ/cm² (282 nm source) to disinfect a surface by killing *E. coli*. *Id.* (citing Ex. 1005, 1547). Petitioner further argues a person of ordinary skill in the art would have understood how, at a given intensity, a particular dose could be obtained by increasing or decreasing the exposure time or distance of the UV light source from the surface. *Id.* at 33 (citing Ex. 1003 ¶¶ 126–27; Ex. 1005, 1546; Ex. 1036, 11:35–53, 13:37–43). Petitioner further argues a person of ordinary skill in the art would have been motivated to combine the references as described in Section II.E.3 above, and to try different UV doses around the ranges taught by Eckhardt and Sosnin, with a reasonable expectation of achieving some level of disinfection at those doses. *Id.* at 34–35 (citing Ex. 1003 ¶¶ 129–130).

Patent Owner argues that neither Eckhardt nor Sosnin teach a radiant dose energy of 40 mJ/cm² or 60 mJ/cm². PO Resp. 39. Patent Owner argues that the highest dose energy Eckhardt expressly discloses is 20 mJ/cm² and a person of ordinary skill would not believe a xenon flash lamp could provide a higher disinfection dose because Eckhardt cautions against higher exposure. *Id.* at 39–40 (citing Ex. 1004 ¶ 43; Ex. 2016 ¶¶ 37–42; Ex. 2019, 165:5–11). Patent Owner further argues Eckhardt does not enable a radiant dose higher than 20 mJ/cm². *Id.* at 40. Patent Owner further argues, as discussed in Section II.E.3 above, that Sosnin does not teach or suggest directing photons having a 222 nm wavelength to disinfect skin, or perform testing with a 222 nm source. PO Sur-reply 13–14. Patent Owner argues

Sosnin does not provide guidance as to what dose is both successful at sterilizing *E. coli* and safe for human skin. *Id.* at 13 (citing Ex. 1005, 1548).

Based on the evidence before us, we determine that Petitioner has shown by a preponderance of evidence that the combination of Eckhardt and Sosnin teaches or suggests the limitations of claims 5 and 6. We find that the range of dose energies taught by Eckhardt and Sosnin encompass the values of 40 mJ/cm² and 60 mJ/cm² in claims 5 and 6, because Eckhardt teaches delivering a dosage greater than 10 mJ/cm² (Ex. 1004 ¶¶ 32, 43; Ex. 1003 ¶ 124) and Sosnin teaches radiant dose energies between 25 mJ/cm²–210 mJ/cm² (222 nm source) and 5 mJ/cm²–34 mJ/cm² (282 nm source). Ex. 1005, 1547; Ex. 1003 ¶ 124. Further, Mr. Lawal’s testimony that it was within the knowledge of a person of ordinary skill in the art to increase or decrease the exposure time or distance of the UV light source from the surface, in order to adjust the dose (Ex. 1003 ¶ 126), supports Petitioner.

We do not agree with Patent Owner’s assertion that Eckhardt cautions against higher exposure, because it unduly limits Eckhardt’s teachings, as we discuss in Section II.E.3 above. Further, Eckhardt is presumed to be enabling, and Patent Owner has not met its burden to show otherwise. As we also discuss in Section II.E.3 above, we disagree with Patent Owner’s assertion that Sosnin does not provide guidance as to dosing, because Sosnin teaches kill dosages for *E. coli* and selective bacterial decontamination using UV excimer lamps.

For the reasons set forth above, we determine that Petitioner has shown by a preponderance of the evidence that claims 5 and 6 would have been obvious over the combination of Eckhardt and Sosnin.

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.

1. Brown-Skrobot (Ex. 1006)

Brown-Skrobot is titled “Method and Apparatus of Sterilization Using Monochromatic UV Radiation Source” (Ex. 1006, [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 lamps; 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. Brown-Skrobot discloses that 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 enterocolytica* 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.¹³ *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.* Clauß observes, “[d]ue to the fact that the photoreactivation only repairs DNA damage[,] it would be interesting to investigate the photoreactivation of bacteria after irradiation with wavelengths in the range of the absorption maxima of proteins.” *Id.*

Clauß describes experiments comparing photoreactivation of bacteria after irradiation with a KrCl excimer lamp at a wavelength of 222 nm (near

¹³ We understand that 6-4 photoproducts and thymine dimers are both structural alterations of DNA formed in a photochemical reaction induced by UV radiation that results in the coupling of consecutive nucleotide bases on a strand of DNA. See https://en.wikipedia.org/wiki/Pyrimidine_dimer.

protein absorption maximum) and a low-pressure mercury lamp at a wavelength of 254 nm (near DNA absorption maximum). Ex. 1007, 580–82, Figs. 2, 3 (inactivation curves for *E. coli* ATCC 11229 and *Y. enterocolitica* ATCC 4780 at 222 nm and 254 nm with and without photoreactivation). Based on these experiments, Clauß observes, “[w]hen the photoreactivation after irradiation is excluded, the mercury lamp with 254 nm clearly shows better results regarding inactivation. Whereas, on the other hand with photoreactivation afterwards the excimer lamp with 222 nm wavelength obviously shows better results.” *Id.* at 582.

Clauß concludes that “without photoreactivation the inactivation with UV radiation with 254 nm wavelength near the absorption maxima of DNA is most effective” and “[t]o get the same inactivation results with 222 nm wavelength the necessary irradiation has to be 50% higher.” Ex. 1007, 583. Clauß further concludes,

But when the bacteria get the chance to photoreactivate, the ratios change. With photoreactivation and irradiation with 254 nm the bacteria has to be irradiated 300% more to obtain the same reduction as without photoreactivation. At 222 nm a higher irradiation of only 25% for *E. coli* and 50% for *Y. enterocolitica* are necessary to get the same inactivation as without photoreactivation.

Id. According to Clauß, these results indicate that irradiation at 222 nm damages molecules other than DNA, and photoreactivation is a DNA repair process only and not able to repair damage to other molecules. *Id.*

3. Reason to Combine

Petitioner contends it would have been obvious to combine the teachings of Brown-Skrobot and Clauß, wherein “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.” Pet. 43 (citing Ex. 1003 ¶ 99; Ex. 1006 ¶¶ 33, 42; Ex. 1007, 580). Petitioner contends a person of ordinary skill would have been motivated to combine the teachings of Brown-Skrobot and Clauß for several reasons. Pet. 43–45 (citing Ex. 1003 ¶¶ 100–104). For example, Petitioner contends that using “different wavelengths may provide increased levels of sterility” and “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.” Pet. 45 (citing Ex. 1003 ¶ 104; Ex. 1006 ¶ 42; Ex. 1008, 1529).

Patent Owner argues that “Brown-Skrobot discourages the use of both 222 nm and 282 nm wavelengths from light sources other than lasers,” that “Clauß is a study of two separate excimer lamps and the effect of photoreactivation on the produced wavelengths,” and that “the POSITA would not have been motivated to combine Brown-Skrobot with Clauß to arrive at the claimed invention with a reasonable expectation of success.” PO Resp. 40, 44, 46 (emphasis omitted).

After considering the parties’ submissions, we determine that the preponderance of the evidence favors Petitioner. The evidence shows that a POSITA would have had reasons to combine (1) Brown-Skrobot’s teaching of using two or more monochromatic UV radiation sources having different wavelengths between 160 to 400 nm for sterilization (Ex. 1006 ¶¶ 33, 42) with (2) Clauß’s teaching of a 222 nm KrCl excimer lamp and 254 nm low-pressure mercury lamp for disinfection (Ex. 1007, 579).

Petitioner demonstrates a person of ordinary skill would have wanted to obtain the benefits of combining two or more monochromatic UV radiation sources that emit different wavelengths, as taught by Brown-Skrobot (Ex. 1006 ¶ 42) and would have selected 222 nm and 254 nm in order to obtain the advantages of irradiating bacteria with these wavelengths, as taught by Clauß (Ex. 1007, 579, 582, 583). Petitioner's combination of teachings fits comfortably within the obviousness scenarios discussed in *KSR*. See, e.g., 550 U.S. at 417 (stating that “when a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious,” quoting *Sakraid v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

Petitioner's combination is supported by the teachings of both Brown-Skrobot and Clauß. Brown-Skrobot teaches a process of sterilizing a medical device by irradiating the device with monochromatic UV radiation to kill microorganisms. Ex. 1006, [57], claim 1. Significantly, Brown-Skrobot teaches that “[t]wo 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.” *Id.* ¶ 42. Regarding the wavelengths of monochromatic UV radiation, Brown-Skrobot teaches a preferred range of 220 to 320 nm. *Id.* ¶ 33, claim 13. Brown-Skrobot teaches various sources of monochromatic UV radiation, including a KrCl excimer lamp. *Id.* ¶¶ 34, 38, claims 10, 12. According to Brown-Skrobot, “[t]hese are only examples, other monochromatic UV radiation sources can be used.” *Id.* ¶ 38.

Petitioner's combination is also supported by Clauß, which describes two monochromatic UV radiation sources, a 222 nm KrCl excimer lamp and a 254 nm low-pressure mercury lamp, for disinfection and deactivating bacteria. Ex. 1007, 579 (title and abstract).

Petitioner shows persuasively that a person of ordinary skill would have found it obvious to implement the sterilization method disclosed in Brown-Skrobot by combining the monochromatic UV sources disclosed in Clauß. Pet. 43–45; Pet. Reply 22–27; Ex. 1048 ¶¶ 29, 33. Brown-Skrobot's teaching concerning the benefits of using two or more monochromatic UV radiation sources having different wavelengths supports Petitioner's contention.

The different wavelengths may provide increased levels of sterility, because different microorganisms that have to be sterilized on a medical device may have greater or lesser sensitivities to uv radiation at different wavelengths; therefore, multiple monochromatic uv radiation sources can be used which produce monochromatic uv radiation at different wavelengths which when used together will successfully sterilize all the microorganisms, that might not otherwise be sterilized, or would require greater levels of energy if only one monochromatic uv radiation source is used.

Ex. 1006 ¶ 42. The above-quoted passage in Brown-Skrobot provides strong evidence that a person of ordinary skill would have had a reason to combine two or more monochromatic UV radiation sources having different wavelengths. Particularly persuasive is Brown-Skrobot's teaching that different microorganisms have different sensitivities to different wavelengths of radiation such that combining sources that emit different wavelengths will provide more effective sterilization. *Id.* Brown-Skrobot also teaches that combining two or more monochromatic UV radiation

sources having different wavelengths may require less energy than using a single monochromatic UV radiation source to provide the same level of sterilization. *Id.*

We find that Brown-Skrobot would have led a person of ordinary skill to consider a combination of two or more monochromatic UV radiation sources that emit wavelengths of 222 nm and 253 nm. Brown-Skrobot discloses various monochromatic UV radiation sources, including a KrCl excimer lamp, which emits a wavelength of 222 nm, and a xenon-iodine (XeI) excimer lamp, which emits a wavelength of 253 nm. Ex. 1006 ¶¶ 38, 39, claims 10, 12; *see also* Ex. 1003 ¶¶ 40, 44 (listing characteristic wavelengths of various gas mixtures used in excimer lamps), 93 (summarizing Brown-Skrobot). Krypton-chlorine and xenon-iodine are among just ten gas mixtures listed in paragraph 38 and claim 12 of Brown-Skrobot. Ex. 1006 ¶ 38, claim 12. Petitioner shows persuasively that “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.” Pet. 44 (citing Ex. 1003 ¶ 102; Ex. 1006 ¶ 33).

Petitioner also shows persuasively that 222 nm and 254 nm wavelengths were known to be effective for disinfecting substances and surfaces: light of wavelength 254 nm because it destroys DNA through dimer production and of wavelength 222 nm due to the absorption maxima of protein. Pet. 44 (citing Ex. 1003 ¶ 103; Ex. 1007, 580). Petitioner’s contention is supported by Brown-Skrobot, which discloses that monochromatic UV radiation is known to damage the DNA of exposed cells

by causing dimerization of thymine,¹⁴ which inhibits replication of DNA during cell reproduction. Ex. 1006 ¶ 6. Petitioner’s contention is also supported by Clauß, which discloses that a low-pressure mercury lamp’s “nearly monochromatic emission of 254 almost corresponds to the maximum DNA absorption at approx. 260 nm” and that “proteins show absorption maxima at 220 nm and 280 nm.” Ex. 1007, 580. Petitioner’s evidence concerning target molecules provides a persuasive reason why a person of ordinary skill would have selected 222 nm and 254 nm wavelengths for use in Brown-Skrobot’s sterilization method.

Our finding regarding a reason for combining prior art teachings is further supported by Clauß, which compares a 222 nm KrCl excimer lamp with a 254 nm low-pressure mercury lamp as sources of UV radiation for deactivating bacteria and disinfection. Ex. 1007, 579. Clauß teaches that these two radiation sources provide complementary benefits. Clauß addresses the problem of photoreactivation, whereby microorganisms that have been inactivated by exposure to UV radiation are reactivated when they are exposed to visible light. Ex. 1007, 579–580; *see also* Ex. 1003 ¶ 97 (discussing Clauß); Ex. 1048 ¶ 31 (explaining photoreactivation). Clauß’s Figures 2 and 3 are inactivation curves for particular bacteria¹⁵ after irradiation with a 222 nm KrCl excimer lamp and a 254 nm low-pressure mercury lamp, with and without subsequent photoreactivation. Ex. 1007, 582. Based on these curves, Clauß concludes:

¹⁴ Thymine is one of the nucleotide bases that make up DNA. *See* n. 9, *supra*.

¹⁵ The bacteria used in Clauß’s experiments were *E. coli* ATCC 11229 (Fig. 2) and *Y. enterocolitica* ATCC 4780 (Fig. 3). Ex. 1007, 582.

When the photoreactivation after irradiation is excluded, the mercury lamp with 254 nm clearly shows better results regarding inactivation. Whereas, on the other hand with photoreactivation afterwards the excimer lamp with 222 nm wavelength obviously shows better results.

Id.; *see also id.* at 579, 583 (similar disclosures in Clauß’s abstract and discussion section). In other words, the 254 nm low-pressure mercury lamp provides better results when photoreactivation is excluded, whereas the 222 nm KrCl excimer lamp provides better results when photoreactivation occurs. *Id.* at 579, 582, 583. Other evidence confirms that a 254 nm mercury lamp has “greater bactericidal power” than a 222 nm excimer lamp. Ex. 1026, 1531, Table 1.

Based on Clauß’s teachings, a person of ordinary skill would have recognized that combining a 222 nm KrCl excimer lamp with a 254 nm low-pressure mercury lamp would provide complementary benefits—improved resistance to photoreactivation and improved inactivation, respectively. As Clauß teaches, these complementary benefits are attributable to the different mechanisms by which these wavelengths cause disinfection. Whereas 254 nm photons damage a microorganism’s DNA, 222 nm photons damage its proteins and their constituent amino acids. Ex. 1007, 580; *see also* Ex. 1003 ¶ 98. As Clauß explains, DNA damage can be repaired when the microorganism is subsequently exposed to light, but protein damage cannot be repaired. Ex. 1007, 580, 583. Based on these teachings, Petitioner presents persuasive argument, supported by Mr. Lawal’s testimony, that a person of ordinary skill would have sought to avoid or mitigate photoreactivation that occurs after irradiation with 254 nm photons by irradiating with 222 nm photons. Pet. 45; Ex. 1003 ¶ 104 (discussing

reasons to use 254 nm and 222 nm wavelengths in the context of combining Brown-Skrobot and Clauß).

We also find support for Petitioner’s contention that “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.” Pet. 45 (citing Ex. 1003 ¶ 104; Ex. 1006 ¶ 42; Ex. 1026, 1529, 1532; Ex. 1001, 4:28–33). Petitioner’s contention is supported by Ramsay,¹⁶ which discloses that, under certain conditions, “synergy between 222- and 254-nm radiations was indeed observed in the disinfection” of some bacteria, e.g., *E. coli*. Ex. 1026, 1529, 1531, Table 2, 1532. Although no synergy was shown when the mercury lamp was operated at full power and the flow rate was at an industrially useful level (*id.* at 1531, Table 1, 1532), this does not negate that synergy was shown at reduced mercury lamp power and flow rate (*id.* at 1531, Table 2, 1532).

Our findings regarding a reason for combining prior art teachings are also supported by Mr. Lawal’s testimony, which provides effective support for Petitioner’s contentions. Ex. 1003 ¶¶ 99–104.

Patent Owner argues that “Brown-Skrobot discourages the use of both 222 nm and 282 nm wavelengths” from light sources other than lasers. PO Resp. 40–41 (emphasis omitted). Patent Owner’s argument is based on an unduly narrow view of Brown-Skrobot’s teachings. According to Patent Owner, Brown-Skrobot’s preferred embodiment is a contact lens manufacturing and packaging process in which lenses are exposed to

¹⁶ Ex. 1026, Ramsay, I. et al., *The Synergistic Effect of Excimer and Low-Pressure Mercury Lamps on the Disinfection of Flowing Water*, 63 J. FOOD PROT. 1529 (2000) (“Ramsay”).

monochromatic UV radiation and the process takes place in a light-tight chamber to prevent photoreactivation. *Id.* at 41–42; Ex. 1006 ¶¶ 47, 58, Fig. 1. Contrary to Patent Owner’s characterization, Brown-Skrobot’s sterilization process applies to any medical device, not just contact lenses. Ex. 1006, [57], ¶ 2 (“This invention relates broadly to sterilization of medical devices.”); *id.* ¶¶ 21–23, 45 (“Examples of medical devices which may be used in the process of this invention include, for example, catheters, surgical equipment, implants, stents, sutures, packing, staples, and bandages.”). Although Brown-Skrobot’s preferred embodiment relates to sterilization of contact lenses, its teachings are not so limited. *In re Mouttet*, 686 F.3d at 1331.

According to Patent Owner, Brown-Skrobot focuses almost exclusively on the use of lasers and “there is no teaching or disclosure of anything other than a single UV laser to sterilize the contact lenses.” PO Resp. 46. We disagree. Brown-Skrobot discloses excimer lamps as a source of monochromatic UV radiation, including for sterilizing contact lenses. Ex. 1006 ¶¶ 22, 34, 36, 38–40, 54 (“[T]he high intensity monochromatic ultraviolet radiation can be generated and directed to the [contact lens] container by one or more monochromatic UV radiation sources, e.g. lasers or excimer lasers or lamps.”); *id.* at claims 10, 12 (claiming a process of sterilizing a medical device with radiation from an excimer lamp).

Patent Owner additionally argues that Brown-Skrobot’s wavelength ranges “encompassing the entirety of the Far-UV spectrum would not point a POSITA to the wavelengths of the claims.” PO Resp. 41. Patent Owner’s argument fails to take into account Brown-Skrobot’s disclosure of excimer lamps containing gas mixtures that emit particular wavelengths of

monochromatic UV radiation. Ex. 1003 ¶ 40; Ex. 1006 ¶ 38, claim 12; Pet. 47 (asserting that “Brown-Skrobot teaches KrCl, XeI, and XrBr excimer lamps as exemplary monochromatic UV radiation sources that can be used with its disclosed invention, which a POSITA would understand generate photons at about 222 nm, 253 nm, and 282 nm, respectively.”).

Next, Patent Owner argues that Brown-Skrobot “teaches away from using a radiation source below 240 nm.” PO Resp. 42–43 (citing Ex. 1006 ¶ 54); *id.* at 18–19 (similar argument). Patent Owner’s argument is based on the following disclosure in Brown-Skrobot.

For many polymers which are commonly used for contact lens containers and contact lenses, which were described earlier, radiation at wavelengths less than 240 nm is absorbed by the polymers and may cause chain scissions within the polymers. Since the laser emits at a single wavelength or a narrow range of wavelengths, a source which produces radiation below 240 nm can be avoided which is a benefit over broad band radiation sources.

Ex. 1006 ¶ 54. Patent Owner’s argument overlooks the breadth of Brown-Skrobot’s disclosure, which is not limited to contact lenses or lasers, as discussed above. Nor is Brown-Skrobot’s process limited to sterilization of polymeric materials; the medical devices that may be sterilized include those made from metals. Ex. 1006 ¶ 45; Ex. 1048 ¶ 35. The disclosure of a preferred embodiment does not, in any event, teach away from non-preferred embodiments. *Mouttet*, 686 F.3d at 1333–34; *see also In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (“The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.”).

Patent Owner argues that “the 222 nm KrCl lamp was rare and expensive and could only be obtained by researchers and not in a commercial setting.” PO Resp. 52. Contrary to Patent Owner’s argument, the evidence shows that 222 nm KrCl lamps were commercially available at the time of the invention. The ’642 patent itself states that “[d]uring the past few years, new UV emitting lamps based on the excitation of excimers are becoming commercially available.” Ex. 1001, 2:35–37. Several prior art references identify commercial sources for KrCl excimer lamps. Ex. 1007, 583 (“Special thanks go to the Radium Lampenwerk GmbH for the supply of the KrCl excimer lamp.”); Ex. 1026, 1530 (KrCl excimer lamp used in 2000 study was “purchased from Heraeus Noblelight Ltd., Cambridge, UK.”). Mr. Lawal testifies that the KrCl excimer lamp “has been around for over 60 years” and that “KrCl lamps emitting 222 nm wavelengths, were becoming commercially available as early as . . . 1996.” Ex. 1003 ¶¶ 43, 44 (referencing Appendix C to his declaration).¹⁷ At deposition, Mr. Lawal testified that he saw 222 nm KrCl excimer lamps being manufactured by Heraeus in Germany. Ex. 2019, 50:8–51:16. And Patent Owner’s expert, Dr. Hernandez, did not disagree that, at the time of Neister’s invention, a researcher who wanted to investigate a specific wavelength of light generated by an excimer lamp could obtain one for research purposes. Ex. 1051, 83:7–21.

¹⁷ *UV Disinfection for Water and Wastewater Treatment*, Report CR-105252 prepared by Black & Veatch, Kansas City, MO and The Electric Power Research Institute, Community Environmental Center, Washington University, St. Louis, MO (December 1995) (Ex. 1003, 563–573).

Patent Owner argues that “Clauß is a study of two separate excimer lamps” and does not disclose or suggest the combination of 222 nm and 254 nm wavelengths. PO Resp. 44–45. We disagree. Although there is no explicit disclosure of this combination, Clauß suggests that 222 nm and 254 nm wavelengths provide complementary benefits. As discussed above, Clauß discloses that a 254 nm low-pressure mercury lamp provides better results when no photoreactivation occurs, and a KrCl excimer lamp provides better results when photoreactivation does occur. Ex. 1007, 579, 582, 583. By combining these two UV sources, a person of ordinary skill would achieve a process that provides effective disinfection, regardless of whether the sample subsequently undergoes photoreactivation. Even if a person of ordinary skill uses a light-tight chamber, as disclosed in Brown-Skrobot, there would still be a benefit to employing a combination of 222 nm and 254 nm UV sources to achieve both improved resistance to photoreactivation and improved inactivation because exposure to light is generally inevitable. *See* Ex. 1005, 579, 582, 583, Figs. 2, 3; Ex. 1048 ¶ 32.

Patent Owner asserts that Petitioner’s combination would not have been obvious because the mercury lamp and excimer lamp of Clauß are not monochromatic UV sources as required by Brown-Skrobot. PO Resp. 47. Patent Owner’s assertion is not supported by Clauß, which identifies the lamps as a “222 nm excimer lamp” and a “254 nm low-pressure mercury lamp,” using a single wavelength to characterize the lamps. Ex. 1007, *passim*. Clauß expressly states that low-pressure mercury lamps have a “nearly monochromatic emission of 254 nm.” *Id.* at 580. Brown-Skrobot likewise characterizes excimer lamps, including a KrCl lamp, as monochromatic. Ex. 1006 ¶¶ 34, 38, 54, claims 10, 12. Mr. Lawal testifies

that both mercury and KrCl lamps “emit light predominately in a narrow wavelength range, known as ‘monochromatic’ light.” Ex. 1003 ¶ 40.

Patent Owner and Dr. Hernandez do not effectively rebut Petitioner’s evidence. *See* PO Resp. 47–48; Ex. 2001 ¶¶ 65, 67. Dr. Hernandez testifies that “a POSITA would not consider a UV lamp to be a monochromatic UV light source because UV lamps emit radiation across a broad spectrum.” Ex. 2001 ¶ 67 (citing Ex. 1007, 580). According to Dr. Hernandez, Clauß explains that “mercury lamps and excimer lamps emit radiation ‘in the whole UV region’ between 200 and 380 nm).” *Id.* The quoted portion of Clauß states: “Figure 1 shows the measured irradiance of both lamps plotted logarithmically against the wavelength. The irradiance of the mercury lamp in the whole UV region (200 ... 380 nm) is 22.10 W/m² and therefore much higher than that of the excimer lamp with 3.55 W/m².” Ex. 1007, 580. We find that Dr. Hernandez’s testimony is not supported by Clauß, which is simply noting the difference in overall output irradiance between the two kinds of lamps. Mr. Lawal’s testimony, Brown-Skrobot, and Clauß all support that, in the relevant field of UV radiation for sterilization, excimer lamps are considered monochromatic UV radiation sources. Ex. 1003 ¶ 40; Ex. 1006 ¶¶ 34, 38, 54; Ex. 1007, 580; Ex. 1048 ¶ 5 (“[W]hile excimer lamps may emit at other wavelengths, generally over 90% of the light is emitted in a single narrow band. An excimer lamp is thus considered to have an emission centered around a single wavelength—i.e. is effectively monochromatic.”).

Patent Owner criticizes Petitioner’s argument for “disregard[ing]” Brown-Skrobot’s preferred embodiment that uses a 257 nm laser and “cherry-pick[ing] the single reference to a KrCl lamp” and combining it with

Clauß's 254 nm low-pressure mercury lamp. PO Resp. 48. We disagree with Patent Owner's characterization. A KrCl excimer lamp is disclosed in *both* Brown-Skrobot and Clauß, and the lamp is taught for the same purpose—deactivating bacteria. Ex. 1006 ¶ 38, claim 12; Ex. 1007, 579. Combining a KrCl excimer lamp with Clauß's 254 nm low-pressure mercury lamp flows naturally from the disclosure of these references and particularly Clauß, which compares these UV sources and provides reasons to combine them in a process for disinfection. Ex. 1007, 579, 582, 583. We do not agree with Patent Owner's characterization of Brown-Skrobot as presenting “over 58,000 possible combinations” of wavelengths within the range 160 nm to 400 nm. PO Resp. 50. Patent Owner's argument overlooks Brown-Skrobot's disclosure of only ten gas mixtures, two of which generate wavelengths of 222 nm and 253 nm. Ex. 1003 ¶ 40; Ex. 1006 ¶ 38, claim 1.

Patent Owner argues that a person of ordinary skill would have had no reason to believe that the combination of a 254 nm wavelength with a 222 nm wavelength would be successful, and there was no testing to show the effectiveness of the combination. PO Resp. 50–51 (“[A] POSITA could not know this without testing.”). Patent Owner applies an incorrect legal standard. *See Almirall*, 28 F.4th at 275. “[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). Petitioner does not need to show that the combination of 222 nm and 254 nm wavelengths *would* succeed, only that it would have been reasonable to expect it to do so. *Id.* Testing to show the effectiveness of the combination is not required. *See Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1345 (Fed. Cir. 2021) (“[W]hat is

required is not proof that the recited method would *actually* bring about the recited result, but rather proof that a person of ordinary skill in the art would have had a reasonable expectation that performing the recited method would bring about the recited result.”).

Through the testimony of its expert, Petitioner shows persuasively that the combination of a 254 nm wavelength with a 222 nm wavelength would yield predictable results. Mr. Lawal testifies: “Both wavelengths were known to be effective for disinfecting substances and surfaces: light of wavelength 254 nm because it destroys DNA through dimer production and of wavelength 222 nm due to the absorption maxima of protein.” Ex. 1003 ¶ 103 (citing Ex. 1007, 580). Mr. Lawal’s testimony is supported by Clauß, which teaches that UV radiation at 254 nm wavelength causes damage to DNA and at 222 nm wavelength causes damage to proteins and their constituent amino acids. Ex. 1007, 580. In view of Clauß’s teaching, Mr. Lawal reasonably concludes that the combined effects of these wavelengths were predictable. Ex. 1003 ¶ 103. Mr. Lawal also reasonably concludes that using a UV light source comprising 222 nm and 254 nm wavelengths would yield predictable advantages, including the potential for increased levels of sterility and reduced energy expenditure. Ex. 1003 ¶ 104 (citing Ex. 1006 ¶ 42). These advantages are expressly disclosed by Brown-Skrobot (Ex. 1006 ¶ 42) and reinforced by Clauß’s disclosure that these wavelengths target different molecules within a microorganism (Ex. 1007, 580).

Patent Owner argues that “Mr. Lawal’s own study from 2017 regarding potential synergy between 260 and 280 nm showed that no synergy existed.” PO Resp. 49 (citing Ex. 2018; Ex. 2019, 118:10–18).

That argument does not effectively rebut Petitioner’s evidence for two reasons. First, it does not address Petitioner’s proposed combination of 254 nm and 222 nm wavelengths, and second, it is based on post-invention date information. *Bristol-Myers Squibb Co. v. Teva Pharmaceuticals, Inc.*, 752 F.3d 967, 976 (Fed. Cir. 2014) (stating that “the skilled artisan’s reasonable expectation of success is measured ‘as of the date of the invention’” (quoting *Amgen Inc. v. Hoffman-La Roche*, 580 F.3d 1340, 1362 (Fed. Cir. 2009))).

Patent Owner relies on Ramsay’s observation that, at maximum mercury lamp intensity and industrially useful flow rates, “no additional bacterial kill” was observed when 254 nm radiation was supplemented with radiation at 222 nm. PO Resp. 49 (citing Ex. 1026, 1532). As discussed above, Ramsay’s observation does not negate that, for some bacteria, synergy was shown at reduced mercury lamp power and flow rate. Ex. 1026, 1531, Table 2, 1532 (“Synergy between the sterilizing effects of irradiation at 222 and 254 nm in aqueous solution has been established in the case of” some bacteria, including *E. coli.*); *see also* Ex. 1048 ¶ 34 (“Ramsay clearly notes a level of synergy between 222 nm and 254 nm light.”).

Patent Owner argues that Petitioner has not shown synergy. PO Resp. 49; PO Sur-reply 5. We disagree. As discussed above, Petitioner has shown some evidence of synergy. Regardless, it is ***not necessary*** for Petitioner to show that a POSITA would have expected to achieve a synergistic effect by combining 254 nm and 222 nm wavelength radiation. As the patent challenger, Petitioner is required to show that a POSITA would have had a reason to combine the teachings of the prior art references with a reasonable expectation of achieving the claimed invention. *PAR*

Pharm., Inc. v. TWI Pharm., Inc., 773 F.3d 1186, 1193 (Fed. Cir. 2014). In this case, the claims do not require synergy between the two photon wavelengths. Therefore, Petitioner can show a reason to combine and a reasonable expectation of success by demonstrating that a POSITA would have expected to achieve a beneficial result that was **additive**, but not necessarily synergistic. *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021) (“The reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention.”); *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (“The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention.”).

Patent Owner argues that Ramsay, Brown-Skrobot, and Clauß each “points in the same direction—toward using a 254 nm lamp or a 257 nm laser and away from using a 222 nm lamp.” PO Resp. 51. We disagree. As discussed above, Brown-Skrobot teaches the potential benefits of using multiple wavelengths (Ex. 1006 ¶ 42), and Clauß teaches that a 222 nm lamp provides better results than a 254 nm lamp when photoreactivation occurs (Ex. 1007, 579, 582, 583). A person of ordinary skill would have had a reason to combine these wavelengths to obtain the cumulative benefits of both.

For these reasons, we find that Petitioner has established that it would have been obvious to combine the teachings of Brown-Skrobot and Clauß.

4. Claim 12

[12pre]

Petitioner contends the combination of Brown-Skrobot and Clauß discloses the preamble of claim 12, because Brown-Skrobot teaches a process for destroying DNA or RNA of a microorganism on a substance or surface, by teaching 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).

Patent Owner does not dispute Petitioner’s contention. We find that the combination of Brown-Skrobot and Clauß discloses the preamble of claim 12, for the reasons set forth in the Petition, as summarized above.

[12A]

Petitioner contends the combination of Brown-Skrobot and Clauß discloses this claim element. 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,” 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. 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 ¶ 151; 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,” 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. *Id.* at 47–48 (citing Ex. 1003 ¶ 153; Ex. 1007, 580; Ex. 1001, 2:16–24, 6:33–46).

As discussed in Section II.F.3 above, Patent Owner disputes Petitioner’s contentions regarding reasons for combining Brown-Skrobot and Clauß and a reasonable expectation of success, and certain teachings of the references that Patent Owner contends support its arguments. *See* PO Resp. 41–46. We have considered those arguments to the extent they also relate to the references’ disclosures of claim element [12A], as discussed below.

Based on the evidence before us, we determine that Petitioner has shown by a preponderance of evidence that the combination of Brown-Skrobot and Clauß discloses claim element [12A]. We find that Brown-Skrobot’s disclosure that “[t]wo or more monochromatic uv radiation

sources can be used together to provide . . . the same or different amounts of energy at different wavelengths” (Ex. 1006 ¶ 42) teaches “generating photons of at least two single line wavelengths,” as recited in claim element [12A].

Our finding concerning claim element [12A] is further supported by Brown-Skrobot’s definition of “monochromatic UV radiation” as having “a wavelength or wavelengths between from 160 to 400 nm,” preferably “within about 220 to 320 nm” and “the majority of the radiation is concentrated within a bandwidth of 3 nm,” preferably “within a bandwidth of 2 nm, more preferably within 1 nm.” Ex. 1006 ¶ 33. The wavelengths recited in claim element [12A]—“222 nm, 254 nm and 282 nm”—fall within Brown-Skrobot’s disclosed preferred range of 220 to 320 nm. *See* Ex. 1003 ¶ 151.

Our finding concerning claim element [12A] is further supported by Brown-Skrobot’s disclosure of excimer lamps as sources of monochromatic UV radiation. Ex. 1006 ¶ 34 (“Examples of monochromatic UV radiation sources that produce monochromatic UV radiation include . . . excimer lamps.”); *id.* ¶ 38 (“Other sources of monochromatic UV radiation include gas discharge tubes filled with gas mixtures in . . . an excimer lamp which produce excimers in an electric discharge.”); *id.* ¶ 54 (“[T]he high intensity monochromatic ultraviolet radiation can be generated and directed to the container by one or more monochromatic UV radiation sources, e.g. . . . excimer lasers or lamps.”); *id.* at claims 1, 10.

Patent Owner does not dispute that Brown-Skrobot’s definition of “monochromatic UV radiation” as having “the majority of the radiation is concentrated within a bandwidth of 3 nm,” preferably “within a bandwidth

of 2 nm, more preferably within 1 nm” (Ex. 1006 ¶ 33) describes a “single line wavelength[]” as recited in claim element [12A]. We credit Mr. Lawal’s testimony that a “POSITA would have also understood 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.” Ex. 1003 ¶ 151 (quoting Ex. 1006 ¶ 33). Mr. Lawal’s testimony is supported by Brown-Skrobot, which describes excimer lamps as monochromatic UV radiation sources. Ex. 1006 ¶ 34, 38, 54.

Our finding concerning claim element [12A] is further supported by Brown-Skrobot’s teaching of particular excimer lamps that emit single line wavelengths of 222 nm, 253 nm, and 282 nm. Petitioner presents the un rebutted testimony of Mr. Lawal that “Brown-Skrobot teaches KrCl, XeI, and XrBr excimer lamps as exemplary monochromatic UV radiation sources that can be used with its disclosed invention, which a POSITA would understand generate photons at about 222 nm, 253 nm, and 282 nm, respectively.” Ex. 1003 ¶ 152 (citing Ex. 1006 ¶ 38). Mr. Lawal’s testimony is supported by Brown-Skrobot, which discloses that “sources of monochromatic UV radiation include gas discharge tubes filled with gas mixtures in a laser or an excimer lamp which produce excimers in an electric discharge.” Ex. 1006 ¶ 38. According to Brown-Skrobot, “[e]xamples of gas mixtures that produce excimers include krypton and chlorine (KrCl), . . . xenon and iodine (XeI), . . . [and] xenon and bromine (XeBr).” *Id.* Patent Owner and Dr. Hernandez do not dispute Mr. Lawal’s testimony that gas mixtures of krypton-chlorine (KrCl), xenon-iodine (XeI), and xenon-

bromine (XeBr) have a “characteristic wavelength” of 222 nm, 253 nm, and 282 nm, respectively. Ex. 1006 ¶ 40.

Our finding concerning claim element [12A] is further supported by Clauß’s disclosure of a 222 nm KrCl excimer lamp and a 254 nm low-pressure mercury lamp as sources of UV radiation for deactivating bacteria and disinfection. Ex. 1007, 579, 581–82, Figs. 2, 3. For the reasons discussed above, we determine that it would have been obvious to combine Brown-Skrobot’s teaching to use two or more monochromatic UV radiation sources in a method of sterilizing a medical device with Clauß’s teaching of a 222 nm KrCl excimer lamp and a 254 nm low-pressure mercury lamp as sources of UV radiation for disinfection.

[12B]

Petitioner contends the combination of Brown-Skrobot and Clauß discloses this claim element. Petitioner contends Brown-Skrobot teaches directing the photons to the substance or surface to be disinfected (*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). Patent Owner does not dispute Petitioner’s contention for claim element [12B].

Based on the evidence before us, we determine that Petitioner has shown by a preponderance of evidence that the combination of Brown-Skrobot and Clauß discloses claim element [12B]. Brown-Skrobot’s disclosure that “[t]he monochromatic UV radiation source,” such as an excimer lamp, “may be used in conjunction with other structural and optical elements to direct the radiation at the target” supports our finding. Ex. 1006

¶ 40; *see also id.* ¶ 23 (“The process and apparatus of the invention is used to provide sterilized medical devices.”); ¶ 34 (“The radiation geometry provided by the apparatus can be beam expanded, line focused or spot scanned. The only requirement is that every surface of the medical device receives a sterilizing dose of radiation.”). Brown-Skrobot also teaches that “monochromatic ultraviolet (UV) light is known to damage the DNA of exposed cells.” *Id.* ¶ 6.

Our finding is further supported by Clauß, which discloses deactivating bacteria with UV radiation from a 222 nm KrCl lamp and a 254 nm low-pressure mercury lamp and teaches that photon wavelengths of 222 nm and 254 nm damage a microorganism’s proteins and DNA, respectively. Ex. 1007, 579, 580.

Conclusion as to Claim 12

For the reasons set forth above, we determine that Petitioner has shown by a preponderance of the evidence that claim 12 would have been obvious over the combination of Brown-Skrobot and Clauß.

5. Claims 13–17

Claim 13 depends from claim 12 and additionally recites that “the directing step is performed by reflecting the photons to a desired surface.” Ex. 1001, 15:21–22. Petitioner shows that the combination of Brown-Skrobot and Clauß discloses this limitation, because Brown-Skrobot describes its excimer lamp is preferably used in conjunction with a reflector or reflectors. Pet. 49 (citing Ex. 1006 ¶ 40; Ex. 1003 ¶ 157). Patent Owner does not dispute this assertion. We find that Petitioner has shown by a preponderance of evidence that claim 13 would have been obvious over Brown-Skrobot and Clauß.

Claim 14 depends from claim 12 and additionally recites that the directing step “further comprises the step of providing 540 kJ/mole of photon energy to the substance or surface to be disinfected.” Ex. 1001, 16:2–4. Petitioner shows that the combination of Brown-Skrobot and Clauß discloses this limitation. Petitioner asserts that wavelength 222 nm inherently corresponds to photon energy of 540 kJ/mole. Pet. 49 (citing Ex. 1007, 580; Ex. 1003 ¶ 159). Patent Owner does not dispute this assertion. We find that Petitioner has shown by a preponderance of evidence that claim 14 would have been obvious over Brown-Skrobot and Clauß.

Claim 15 depends from claim 12 and additionally recites that the directing step “further comprises directing the photons to provide a radiant dose energy of 40 mJ/cm² to the substance or surface to be disinfected.” Ex. 1001, 16:6–8. Petitioner shows that the combination of Brown-Skrobot and Clauß discloses this limitation. Petitioner asserts that Brown-Skrobot’s teaching of the D_{value} of certain pathogens (i.e., the amount of energy required to kill 90% of the organisms present), and further teaching of “subjecting [a] medical device to monochromatic ultraviolet radiation wherein the minimum total energy density . . . which reaches the microorganisms present on said medical device is at least 40 mJ/cm²,” and exposing microorganisms to dose energies ranging from 0 to 568 mJ/cm², teaches this limitation. Pet. 50 (citing Ex. 1006 ¶¶ 21, 31, 41, 53, 55–58, 62, 67–80, Figs. 4, 5; Ex. 1003 ¶ 160–166). Petitioner further relies on Brown-Skrobot’s teachings of preferable monochromatic UV radiation within the range of 220 to 320 nm, combined with Clauß’s teaching that KrCl excimer lamps generate 222 nm photons, in asserting that a person of ordinary skill would immediately recognize that the claimed dose is within the D_{value} of at

least 23.7 mJ/cm^2 to achieve a particular sterility assurance level. *Id.* at 51 (citing Ex. 1006 ¶¶ 21, 30–31, 33, 38, 41, 53, 54; Ex. 1007, 579, 581–82; Ex. 1003 ¶¶ 163–164). Patent Owner does not dispute these assertions. We find that Petitioner has shown by a preponderance of evidence that claim 15 would have been obvious over Brown-Skrobot and Clauß.

Claim 16 depends from claim 12 and additionally recites that the directing step “further comprises directing the photons to provide a radiant dose energy of 60 mJ/cm^2 to the substance or surface to be disinfected.” Ex. 1001, 16:10–12. Petitioner shows that the combination of Brown-Skrobot and Clauß discloses this limitation. Petitioner asserts that the evidence and reasons supporting its contention as to claim 15, also support its contention as to claim 16. Patent Owner does not dispute these assertions. We find that Petitioner has shown by a preponderance of evidence that claim 16 would have been obvious over Brown-Skrobot and Clauß.

Claim 17 depends from claim 12 and additionally recites that the directing step “further comprises directing the photons to provide a radiant dose energy of 10 mJ/cm^2 to the substance or surface to be disinfected.” Ex. 1001, 16:13–16. Petitioner shows that the combination of Brown-Skrobot and Clauß discloses this limitation. Petitioner argues that a person of ordinary skill in the art would immediately recognize that Clauß’s teaching of irradiation of 10.6 mJ/m^2 at 222 nm is mathematically equivalent to 10 mJ/cm^2 . Pet 53 (citing Ex. 1007, 581–82; Ex. 1003 ¶ 170). Petitioner also asserts that Clauß teaches delivering radiant doses ranging from 0 to nearly 20 mJ/cm^2 . Patent Owner does not dispute these assertions. We find that Petitioner has shown by a preponderance of evidence that claim 17 would have been obvious over Brown-Skrobot and Clauß.

6. *Claim 18*

Claim 18 depends from claim 12 and additionally comprises “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/cm² or less.” Ex. 1001, 16:18–21. Petitioner asserts that Clauß discloses a 222 nm UV source for generating photons with an irradiance of 3.55 W/cm² in the whole UV region (200 ... 380 nm) and an irradiance of 3.38 W/cm² in the UV-C region (200 ... 280 nm). Pet. 53 (citing Ex. 1003 ¶¶ 171–72; Ex. 1007, 580, 583. Petitioner argues a person of ordinary skill in the art would immediately recognize that 3.38 W/cm² is equivalent to 0.338 mW/cm², which falls within the claimed range. *Id.*

Patent Owner argues that neither Brown-Skrobot nor Clauß describe the use of more than one monochromatic wavelength from “a source for generating the photons,” because each reference describes the use of at least two lamps to generate the photons. PO Resp. 53. Patent Owner further argues Petitioner’s purported motivation to combine the references is premised on Brown-Skrobot’s suggestion to use two or more monochromatic UV radiation sources. *Id.* at 54 (citing Ex. 1006 ¶ 42).

Patent Owner’s arguments are based on its construction of “a source” as “a single source,” a construction we do not adopt for the reasons discussed in Section II.B.2. Aside from these arguments, and those discussed in Section II.F.3 *supra*, Patent Owner does not dispute Petitioner’s contention that the combination of Brown-Skrobot and Clauß teaches claim 18.

We find that Petitioner shows that the combination of Brown-Skrobot and Clauß discloses the additional step of claim 18, and has shown by a

preponderance of evidence that claim 18 would have been obvious over Brown-Skrobot and Clauß.

III. REVISED CONTINGENT MOTION TO AMEND

Patent Owner filed a Revised Contingent Motion to Amend, to cancel claims 12–18 if they were found unpatentable and propose substitute claims 19–25. RMTA. For the reasons discussed above, we have determined that Petitioner has shown original claims 12–18 of the '642 patent to be unpatentable by a preponderance of the evidence; therefore, we proceed to address Patent Owner's Revised Contingent Motion to Amend.

As a replacement of claim 12, Patent Owner proposes revised substitute claim 19 (hereinafter "claim 19"). RMTA 2. Claim 19 is reproduced below with Patent Owner's annotations showing amendments to claim 12, and bracketed text added at the beginning of each claim element to correspond with Petitioner's designation of claim elements:

19. [19pre] A process for destroying a DNA or RNA of [a microorganisms] viral and bacterial agents on a substance or surface comprising the steps of:

[19A] 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[, and 254 nm[, and 282 nm]; and

[19B] 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.

RMTA, Claims Appendix 4–5. Patent Owner proposes revised substitute claims 20–24 to replace claims 13–17; claims 20–24 do not include any amendments, except for noting their dependency from claim 19. *Id.* at 5.

Patent Owner proposes revised substitute claim 25 as a replacement of claim 18. Claim 25 is reproduced below with Patent Owner's annotations showing amendments to claim 18:

25. 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 or less.~~

19 wherein:

the process for 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 two of 222 nm and 254 nm is performed using a handheld apparatus; and

the substances is air.

RMTA, Claims Appendix 6.

A. Asserted Grounds of Unpatentability of Proposed Substitute Claims

Petitioner challenges the patentability of the proposed substitute claims on the following grounds:

Challenged Claim(s)	35 U.S.C.	References
19–24	§ 103(a)	Brown-Skrobot, Clauß
25	§ 103(a)	Brown-Skrobot, Clauß, Eckhardt
25	§ 103(a)	Brown-Skrobot, Clauß, Hunter ¹⁸

B. Motion to Amend– Statutory and Regulatory Requirements

“Before considering the patentability of any substitute claims, . . . the Board first must determine whether the motion to amend meets the statutory

¹⁸ US Patent Pub. No. 2007/0102280 A1 to Hunter et al., published May 10, 2007 (Ex. 1052).

and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.” *See Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential). Patent Owner bears the burden of persuasion to show, by a preponderance of the evidence, that the RMTA meets those requirements. 37 C.F.R. § 42.121(d)(1).

“A motion to amend may be denied where . . . [t]he amendment does not respond to a ground of unpatentability involved in the trial.” 37 C.F.R. § 42.121(a)(2)(i). Patent Owner asserts that the proposed revised substitute claims are patentable over the combination of references that forms the basis of the obviousness ground on which we instituted trial. RMTA 2. Petitioner does not argue otherwise. *See generally* Opp. RMTA. Therefore, we determine that Patent Owner has met this requirement.

A motion to amend must “propose a reasonable number of substitute claims.” 35 U.S.C. § 316(d)(1)(B); *see* 37 C.F.R. § 42.121(a)(3) (“A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims.”). Patent Owner proposes the same number of substitute claims as the original challenged claims that are cancelled, i.e., a one-to-one substitution for a total of seven substitute claims. RMTA 2–3. “There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim.” *Lectrosonics*, Paper 15 at 4; *see* 37 C.F.R. § 42.121(a)(3). Petitioner does not argue otherwise. *See generally* Opp. RMTA. Therefore, we determine that Patent Owner proposes a reasonable number of substitute claims.

A motion to amend “may not enlarge the scope of the claims of the patent” 35 U.S.C. § 316(d)(3). Patent Owner asserts that claim 19 does not enlarge the scope of original claim 12. RMTA 2. Petitioner does not

argue otherwise. *See generally* Opp. RMTA. Therefore, we determine that Patent Owner has met this requirement.

1. Support in an Earlier-filed Disclosure

“A motion to amend may be denied where . . . [t]he amendment seeks to . . . introduce new subject matter.” 37 C.F.R. § 42.121(a)(2)(ii). *See also* 35 U.S.C. § 316(d)(3) (a motion to amend may not introduce new matter). New subject matter is any addition to the claims that lacks sufficient support in the subject patent’s original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“When [an] applicant adds a claim . . . , the new claim[] must . . . find support in the original specification.”). Rule 42.121 requires a motion to amend to “set forth: (1) The support in the original disclosure of the patent for each claim that is added or amended; and (2) The support in an earlier-filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought.” 37 C.F.R. § 42.121(b).

Patent Owner asserts that claims 19–25 are entitled to the priority date of the ’626 provisional application. RMTA 3. Patent Owner sets forth in a claim chart its assertion that a person of ordinary skill would have understood, based on the disclosure of each application in the ’642 patent’s chain of priority back to the ’626 provisional, that Mr. Neister had possession of the amended claims. *Id.* at 4–20. Specifically, Patent Owner argues that the ’626 provisional provides written description support for generating single line wavelengths of 222 nm and 254 nm, and need not support 282 nm because that wavelength is deleted from claim 19. *See id.* at 9. Patent Owner identifies four disclosures from the ’626 provisional that it contends provide written description support for generating photons of at

least two single line wavelengths. *Id.* at 9 (citing Ex. 1008 ¶¶ 8, 12, 27, claim 9).

Petitioner argues “[s]ubstantial new matter was introduced after both the PCT App. and the Provisional that belies reliance on the written description of either application,” and neither application provides written description support for claims 19–25. Opp. RMTA 3–4. Specifically, Petitioner argues “[w]hile Patent Owner’s amendment removed one limitation identified as lacking priority to the Provisional (i.e. using 282 nm UV light), the other limitation identified remains: “generating photons of at least two single line wavelengths.” *Id.* at 4 (citing RMTA 7; Pet. 6–9).

As discussed in Section II.C.3 above, we determine in connection with our analysis of the effective filing date of original claims 12–18 that Patent Owner does not meet its burden to demonstrate the inventor’s possession in the ’626 provisional of generating photons of at least two single line wavelengths. Having considered the additional disclosures of the ’626 provisional Patent Owner points to in its RMTA (*see* RMTA 9), we find that none of these disclosures describe using both 222 nm and 254 nm single line wavelengths. *See* Ex. 1008 ¶¶ 8, 12, 27, claim 9; Ex. 2047, 6–9. For example, the recitation of “apparatus that consists of a NUV source, ESP, ozone generator, mercury lamps, and humidifier with controls as defined in claims 3–8 and any combination therein” in claim 9 of the ’626 provisional generally identifies various sources that may be used, but would not have indicated to a person of ordinary skill that the inventor had possession of generating single line wavelengths of 222 nm and 254 nm. Mr. Lawal’s testimony supports this finding. Ex. 1053 ¶¶ 1–12. Accordingly, we determine that Patent Owner does not meet its burden to

demonstrate written description support for generating photons of at least two single line wavelengths, in claims 19–25 of its RMTA.¹⁹

Because Patent Owner has not satisfied the statutory and regulatory prohibition against introducing new matter in the revised proposed substitute claims, we deny the RMTA as to claims 19–25. 35 U.S.C. § 326(d)(3); 37 C.F.R. § 42.221(a)(2)(ii). Accordingly, we need not reach the patentability challenges Petitioner raises with regard to claims 19–25.

IV. CONCLUSION

Petitioner has shown by a preponderance of the evidence, that claims 1–10 and 12–18 are unpatentable as summarized below:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1-10	103(a)	Eckhardt, Sosnin	1–10	
12-18	103(a)	Brown-Skrobot, Clauß	12–18	
Overall Outcome			1–10, 12–18	

We further conclude that Patent Owner has not satisfied its burden on its motion to amend, and Petitioner has demonstrated by a preponderance of the evidence that proposed substitute claims 19–25 lack sufficient descriptive support. Thus, the preponderance of evidence indicates proposed

¹⁹ We also determine that claim 19 does not particularly point out and distinctly claim the invention sought to be patented, as required by 35 U.S.C. § 112(b), because “the microorganisms” in element [19B] lacks antecedent basis.

substitute claims 19–25 lack written description support, and we deny the Revised Contingent Motion to Amend as summarized below:

Motion to Amend Outcome	Claims
Original claims cancelled by amendment	
Substitute claims proposed in the amendment	19–25
Substitute claims: motion to amend granted	
Substitute claims: motion to amend denied	19–25
Substitute claims: not reached	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has shown that claims 1–10 and 12–18 of the '642 patent are unpatentable;

FURTHER ORDERED that Patent Owner's Revised Contingent Motion to Amend is *denied*; and

FURTHER ORDERED that because this is a Final Written Decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Patent 9,700,642 B2

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