UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

S. EDWARD NEISTER, Patent Owner.

IPR2022-00381 Patent No. 9,700,642

PETITIONERS' OPPOSITION TO PATENT OWNER'S MOTION TO AMEND U.S. PATENT 9,700,642

UPDATED EXHIBIT LIST

Exhibit	Description				
1001	U.S. Patent No. 9,700,642				
1002	Prosecution History of U.S. Patent No. 9,700,642				
1003	Declaration and Curriculum Vitae of Oliver R. Lawal				
1004	U.S. Patent Publication No. 2003/0031586 to Eckhardt et al.				
	("Eckhardt")				
1005	Sosnin et al., The Effects of UV Irradiation and Gas Plasma				
	Treatment on Living Mammalian Cells and Bacteria: A Comparative				
	Approach, 32 IEEE TRANSACTIONS ON PLASMA SCI. 1544 (Aug. 2004)				
	("Sosnin")				
1006	U.S. Patent Publication No. 2005/0079096 to Brown-Skrobot et al.				
	("Brown-Skrobot")				
1007	Clauss, M., Mannesmann, R. and Kolch, A., Photoreactivation of				
	Escherichia coli and Yersinia enterolytica after Irradiation with a 222				
	nm Excimer Lamp Compared to a 254 nm Low-pressure Mercury				
	Lamp, 33 ACTA HYDROCHIMICA ET HYDROBIOLOGICA 579 (Dec. 2005)				
	("Clauss")				
1008	U.S. Provisional App. No. 60/593,626				
1009	PCT App. No. PCT/US2006/003393				
1010	Declaration and Curriculum Vitae of Jacob Robert Munford				
1011	U.S. Patent Publication No. 2002/0146343 to Jenkins et al.				
1012	HEALTH PHYSICS SOC'Y, Ultraviolet Radiation and Public Health,				
	POSITION STATEMENT OF THE HEALTH PHYSICS SOC'Y (July 1998),				
	https://web.archive.org/web/20000601171859/http://hps.org/documen				
	ts/ultravioletradiation.pdf				
1013	U.S. Patent Publication No. 2003/0153962 to Cumbie				
1014	Int'l Publication No. WO87/02256 to Wilkinson				
1015	U.S. Patent No. 6,283,986 to Johnson				
1016	U.S. Patent No. 6,254,625 to Rosenthal et al.				
1017	Thai et al., Ultraviolet Light C in the Treatment of Chronic Wounds				
	with MRSA: A Case Study, 48 OSTOMY WOUND MGMT., no. 11, at 52–				
	60 (Nov. 2002)				
1018	U.S. Patent No. 5,364,645 to Lagunas-Solar et al.				
1019	U.S. Patent No. 8,975,605 to Neister				
1020	Kogelschatz et al., High-intensity sources of incoherent UV and VUV				
	excimer radiation for low-temperature materials processing, 168				
	APPLIED SURFACE SCI., May–June 2000, at 29				

1021	HARVEY LODISH ET AL., MOLECULAR CELL BIOLOGY 651 (Sara Tenney et al. eds., 4th ed. 2001)
1022	James R. Bolton and Karl G. Linden, <i>Standardization of Methods for</i>
1022	Fluence (UV Dose) Determination in Bench-Scale UV Experiments,
	129 J. OF ENV'T ENG'G 209 (March 2003)
1023	U.S. Patent No. 5,572,091 to Langer et al.
1024	U.S. Patent Publication No. 2005/0173652 to Ressler
1025	K982082, 510(K) SUMMARY: DERMA-WAND, NAT'L BIOLOGICAL CORP. (Oct. 28, 1998),
	https://www.accessdata.fda.gov/cdrh docs/pdf/K982082.pdf
1026	Ian A. Ramsay et al., The Synergistic Effect of Excimer and Low-
	Pressure Mercury Lamps on the Disinfection of Flowing Water, 63 J. FOOD PROT. 1529 (2000)
1027	Complaint for Patent Infringement, High Energy Ozone LLC et al. v.
	Far UV Technologies, Case No. 4:21-cv-00345, Dkt. No. 1 (W.D.
	Mo. May 17, 2021)
1028	Complaint for Patent Infringement, High Energy Ozone LLC et al. v
	Eden Park Illumination, Inc., Case No. 1:21-cv-02753, Dkt. No. 1
	(N.D. Ill. May 20, 2021)
1029	Complaint for Patent Infringement, High Energy Ozone LLC et al. v.
	Larson Electronics LLC, Case No. 3:21-cv-01166, Dkt. No. 1 (N.D.
	Tex. May 21, 2021)
1030	Order re Plaintiff's Suggestion of Bankruptcy, Healthe, Inc. v. High
	Energy Ozone LLC et al., Case No. 6:20-cv-2233, Dkt. No. 114 (M.D.
	Fl. Dec. 16, 2021)
1031	Joint Status Report and Request for Conference re Eden Park and Far
	UV Stays Pending Transfer, <i>High Energy Ozone LLC et al. v. Larson</i>
	<i>Electronics LLC</i> , Case No. 3:21-cv-01166, Dkt. No. 42 (N.D. Tex.
1022	Nov. 30, 2021)
1032	Electronic Minute Entry re Status Conference, <i>High Energy Ozone</i>
	<i>LLC et al. v. Larson Electronics LLC</i> , Case No. 3:21-cv-01166, Dkt.
1022	No. 45 (N.D. Tex. Dec. 8, 2021)
1033	Scheduling Order, <i>High Energy Ozone LLC et al. v. Larson</i>
	<i>Electronics LLC</i> , Case No. 3:21-cv-01166, Dkt. No. 30 (N.D. Tex.
1024	Oct. 18, 2021) Plaintiff Draliminary Infringement Contentions, High Energy Orang
1034	Plaintiff Preliminary Infringement Contentions, <i>High Energy Ozone</i>
	LLC et al. v. Larson Electronics LLC, (Nov. 24, 2021)

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1035	Plaintiff Initial Infringement Contentions, <i>High Energy Ozone LLC et</i>					
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1036	U.S. Patent No. 5,843,374 to Sizer et al.					
1037	Prosecution History of U.S. Patent No. 8,753,575					
1038	Prosecution History of U.S. Patent No. 11,246,951					
1039	Von Sonntag, Disinfection by free radicals and UV-radiation, 4					
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1040	Frederick L. Gates, A study of the bactericidal action of ultra violet					
	light. III. The absorption of ultra violet light by bacteria, 14 J. GEN.					
	PHYSIOLOGY 31 (1930)					
1041	1600 PTAB & Beyond: How reliable are trial dates relied on by the					
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1045	Declaration of Oliver R. Lawal in Support of Petitioners' Opposition					
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1046	EPA 811-R-96-002, "Ultraviolet Light Disinfection Technology in					
	Drinking Water Application—An Overview," September 1996.					
1047	U.S. Patent Pub. No. 2005/0163648 to Liang ("Liang")					

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I. INTRODUCTION

The Board should deny Patent Owner's Corrected Contingent Motion to Amend¹ (Paper No. 32, "MTA") seeking to substitute proposed claims 12-19² ("substitute claims") for original claims 12-18 challenged in Petitioners' Ground 2. (MTA at 1-3.) For the reasons discussed below, Petitioners request that the Board deny the MTA because each substitute claim: (1) does not meet the statutory requirements; and (2) remains unpatentable in view of the prior art and on additional statutory grounds.

II. THE SUBSTITUTE CLAIMS DO NOT MEET THE STATUTORY REQUIREMENTS FOR AMENDMENT

Prior to any patentability analysis, a patent owner's proposed substitute claims must first meet the statutory requirements of 35 U.S.C. §316(d) and the procedural requirements of 37 C.F.R. §42.121. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 3-8 (PTAB Feb. 25, 2019) (precedential). In particular, a patent owner must demonstrate: (1) the amendment proposes a reasonable number of substitute claims; (2) the proposed claims are supported in the original disclosure

¹ On January 18, 2023, the Board approved a joint stipulation to extend the page limit to 32 pages for Patent Owner's MTA and Petitioners' Opposition.

² Despite the Board's order requiring Patent Owner propose substitute claims with sequential numbering, (Paper No. 31), Patent Owner has not yet done so.

(and any earlier filed disclosure for which the benefit of a filing date is sought); (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter. *See* 35 U.S.C. §316(d); 37 C.F.R. §42.121.

Here, Patent Owner makes only two substantive amendments to independent claim 12: (i) replacing destroying a DNA or RNA of "a microorganism" with destroying a DNA or RNA of "viral and bacterial agents"; and (ii) generating photons of at least two single line wavelengths "of 222 nm and 254 nm," instead of "of 222 nm, 254 nm and 282 nm." (MTA, 5, 8.) As a preliminary matter, despite Patent Owner's assertion that "each contingent amendment is responsive to a ground of unpatentability involved in this proceeding," (*id.*, 1), the first amendment does not respond to a ground of unpatentability. Destroying "a microorganism," as opposed to a viral or bacterial agent, was not central to a ground of unpatentability in either the Petition or the Institution Decision. In fact, as discussed below in Section III(B)(2), the prior art discloses using UV light to destroy viruses and bacteria, thus nullifying any practical import of this amendment.

In addition, despite alleging that "each amendment proposes only one substitute claim for each conditionally canceled claim," (*id.*), Patent Owner proposes an additional claim, claim 19, that does not substitute for any cancelled claim, in contravention of the Board's precedential guidance in *Lectrosonics*. Paper No. 15,

5 ("All proposed claims should be traceable to an original challenged claim as a proposed substitute claim for that challenged claim."). On a motion to amend, a statutory presumption exists "that only one substitute claim would be needed to replace each challenged claim[.]" 37 C.F.R. §42.121(a)(3). If patent owner "seeks to propose more than one substitute claim for each cancelled claim," patent owner should explain "the need for the additional claims and why the number of proposed substitute claims is reasonable." *Lectrosonics*, Paper No. 15, 5. Here, Patent Owner provides no explanation for claim 19, let alone a showing of need. (*See* MTA, 3.)

Therefore, the substitute claims fail in the first instance to comply with the statutory requirements for claims put forth on a motion to amend.

III. THE SUBSTITUTE CLAIMS ARE UNPATENTABLE

Even if the substitute claims are found to meet the statutory requirements, the substitute claims are nevertheless unpatentable. The patentability of Patent Owner's substitute claims appears to rest on excluding Clauss as prior art by establishing an earlier priority date for these claims. Contrary to Patent Owner's assertion, however, the amendments found in the substitute claims do not cure the priority issue identified in the Petition, (Pet., 6-9), and credited by the Board, (I.D., 10-12). For the reasons discussed below, Patent Owner's priority claim remains flawed on both procedural and substantive grounds. Thus, each of the substitute claims remains obvious over the combination of Brown-Skrobot and Clauss. Additionally, new

proposed claim 19 is unpatentable as obvious over the combination of Brown-Skrobot, Clauss, and Liang. Finally, regardless of priority date, all of the substitute claims are invalid for lack of patentable subject matter under 35 U.S.C. § 101.

A. The Substitute Claims Cannot Claim Priority to the '626 Provisional Application

1. <u>Patent Owner Has Not Met Its Burden of Production to Show</u> Written Description Support in Each Intermediate Application

Patent Owner's amended claims are predicated on obtaining priority back to the '626 provisional application. But Patent Owner has not met its burden. A patent owner seeking the benefit of an earlier priority date in an IPR bears an initial burden of production to demonstrate entitlement to priority. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379-80 (Fed. Cir. 2015) (the initial burden of production for showing an earlier priority date rests with the patent owner); *see also Google LLC, ZTE (USA), Inc. et al. v. Cywee Grp. Ltd.,* IPR2018-01257, Paper No. 87 at 91 (PTAB Jan. 9, 2020) (citing 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2) for the proposition that a motion to amend requires setting forth support in an earlierfiled disclosure for each claim for which an earlier priority date is sought).

At minimum, a patent owner's initial burden of production under 35 U.S.C. §119(e)/120 requires the patent owner to identify support in each application including *each intermediate* application in the chain—stretching back to the first application to which a priority date is sought. The need to identify how each intermediate application independently satisfies the requirements of §120 is born out of the statutory language requiring each earlier application to be "similarly entitled to the benefit of the filing date of the first application[.]" 35 U.S.C. §120; *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1349-52 (Fed. Cir. 2010) (interpreting "similarly entitled" to require each intermediate application to independently satisfy all §120 requirements).

Here, Patent Owner has not met its burden of production for priority purposes under §119(e)/120. Patent Owner cites only the very first application (the '626 provisional application) and the very last application (the '957 application) in the priority chain that resulted in the '642 patent. (MTA 5-23.) Patent Owner fails to even acknowledge that, not only are two other intermediate applications in the priority chain³, but both the '957 application and one of the intermediate applications are continuation-in-part (CIP) applications that added new matter. These intermediate applications are necessary for Patent Owner to satisfy the co-pendency requirement of §119(e)/120, because the '626 provisional application had already been abandoned as of its 1-year anniversary (on Jan. 31, 2006) by the time the '957 application was filed (on April 17, 2014). Patent Owner makes no showing as to

³ PCT App. No. PCT/US2006/003393 (filed Jan. 31, 2006) and U.S. App. No. 11/831,667 (filed July 31, 2007).

these two applications, nor does Patent Owner provide any analysis or argument apart from its citations to the '626 provisional application and the '957 application.

This absence of evidence, coupled with the absence of argument in Patent Owner's motion, constitutes a failure to satisfy the burden of production under \$119(e)/120, including the requirement that each intermediate application must have co-pendency, a common inventor, a specific reference to earlier applications, and adequate support under \$112(a) for each claim. *See Google*, Paper No. 87 at 92; *see also Encyclopaedia Britannica*, 609 F.3d at 1349-52. As but one example, neither intermediate application discloses or supports the "generating photons of at least two single line wavelengths" limitation in substitute claim 12. (*See* Pet., 6-8.)

Patent Owner's failure in its motion to meet its burden under *Dynamic Drinkware* means that no proposed new substituted claim is entitled to a priority date earlier than the actual filing date of the '957 application (i.e., Apr. 17, 2014).

2. <u>The '626 Provisional Application Does Not Provide Written</u> <u>Description for the Invention As Claimed</u>

Assuming arguendo that Patent Owner did meet its burden of production, for the reasons described below, the '626 provisional application does not provide written description support for the substitute claims. As a result, the relevant date for purposes of obviousness is no earlier than the filing date of the '667 application (i.e., July 31, 2007), and Clauss remains prior art to the substitute claims.

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In short, while Patent Owner's amendment removed one limitation Petitioners identified as lacking priority to the provisional application (i.e. using 282 nm UV light), the other limitation Petitioners identified remains in the claims: "generating photons of at least two single line wavelengths[.]" (MTA, 8; *see also* Pet., 6-9.) As Petitioners and their expert, Mr. Oliver Lawal, explained, the use of more than a single line wavelength was not disclosed in either the '626 provisional application or the PCT application that followed. (*See* Pet., 6-9; Ex. 1003, ¶ 74.) During prosecution Patent Owner instead relied on disclosures in the later CIP application filed on July 31, 2007 to support this claim limitation. (*See* Pet., 7-8.) Notably, Patent Owner fails to address this prosecution history, either in its MTA or its POR.

In its MTA, Patent Owner's only attempt to show written description support for the substitute claims is a claim chart. (*See* MTA, 5-23.) For the "generating photons of at least two single line wavelengths" limitation, however, Patent Owner identifies only four quotes and Figure 9 from the '626 provisional application, none of which disclose using more than one single line wavelength:

- "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." (EX1008, cl. 9 (emphasis added by Patent Owner).)
- "The commercial light source for UV irradiation near a principal absorption peak of DNA has been produced by using mercury as the source for generating protons. The mercury gas and its pressure in the lamp determine the wavelength of the emitting light. For low-pressure (LP) and low-pressure high

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output (LPHO) lamps, the emitting wavelength is 254 nm." (*Id.*, \P 8.)

- "An excimer lamp emitting at 222 nm is considered the most effective source because DNA chains and biochemical's[sic] have greater absorption at this wavelength." (*Id.*, ¶ 12.)
- "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." (*Id.*, ¶ 27.)

(MTA, 8-9.) Patent Owner provides no other explanation or accompanying argument.⁴ (*See id.*) A plain reading demonstrates that neither the quotes nor the figure, either alone or taken together, disclose the use of more than one single line wavelength. (*Id.*; EX1045, ¶¶ 1-7.) The '626 provisional application plainly states that "[t]he NUV source is chosen to supply *the single line emission*" in question—not multiple single line emissions. (EX1008, ¶ 27 (emphasis added).) Nor does

⁴ In its POR, Patent Owner argued that a UV lamp inherently discloses multiple single line wavelengths because such lamps "generate light over a range of wavelengths, which may involve more than one peak wavelength across the distribution." (*See* POR, 16; *see id.*, 17-18.) The Board rejected this argument, however, (I.D., 11-12), and Patent Owner does not repeat this argument in its MTA. Petitioners reserve the right to further respond to the argument should Patent Owner raise it either on reply or in a Revised MTA.

Patent Owner's expert, Dr. Hernandez, provide any additional support; rather, Dr. Hernandez's declaration simply mirrors the claim chart. (*Compare* MTA, 5-23 *with* EX2045, 4-27.) Notably, for at least one claim, Patent Owner does not provide *any* written description support from the '626 provisional application. (*See* MTA, 20-21 (no support from provisional for substitute claim 18).)

For these reasons, simply removing 282 nm UV light from the substitute claims does not cure the deficient written description support identified in the Petition, (Pet., 6-9), and credited by the Board, (I.D., 10-12), regarding the "generating photons of at least two single line wavelengths" limitation. Thus, the earliest effective filing date for the substitute claims is July 31, 2007.⁵

B. Brown-Skrobot and Clauss Render the Substitute Claims Obvious

Because the earliest effective filing date of the claims is July 31, 2007, both Brown-Skrobot (published April 14, 2005) and Clauss (published December 2005) remain prior art to the substitute claims under at least pre-AIA §§102(a), (b), and post-AIA §102(a)(1). (*See* Pet., 12-13; *see also* EX1010, ¶¶ 13-15.) Therefore, Petitioners incorporate herein the evidence and arguments presented regarding Ground 2 in the Petition, (Pet., 41-53), Petitioners' expert's declaration (EX1003,

⁵ Petitioners reserve the right to rebut any additional priority analysis or argument from Patent Owner, including by introducing additional prior art if warranted.

¶¶ 93-104, 147-172), Petitioners' forthcoming Reply brief, and any expert declarations filed on behalf of Petitioners either concurrently with this Opposition, (i.e. EX1045), or in support of any forthcoming brief. For all of the same reasons presented in the Petition and any additional briefing, including all of the reasons adopted by the Board in finding the original claims 12-18 of the '642 Patent unpatentable⁶, Patent Owner's proposed substitute claims are similarly unpatentable over the combination of Brown-Skrobot and Clauss. A brief summary of the combination as applied to the amended claim limitations is included below.

1. <u>"generating photons of at least two single line wavelengths ...</u> being two of 222 nm and 254 nm"

Brown-Skrobot teaches the key limitation at issue in the amended claims, namely that at least two single line wavelengths can be used to disinfect substances: "[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." (EX1006, \P 0042.) Brown-Skrobot explains that the radiation source used may be "excimer lasers or lamps" but may also be other sources of monochromatic UV radiation. (*Id.*, $\P\P$ 0034, 0038, 0054.) Brown-

⁶ Consideration of the instant motion is contingent on the Board finding challenged claims 12-18 unpatentable over Brown-Skrobot and Clauss.

Skrobot teaches that "'monochromatic UV radiation' means radiation having a wavelength or wavelengths between from 160 to 400 nm, and the majority of the radiation is concentrated within a bandwidth of 3 nm." (*Id.*, ¶ 0033.) The "preferred monochromatic UV radiation" of Brown-Skrobot "has the majority wavelength or wavelengths within about 220 to 320 nm" and "preferably...within a bandwidth of 2 nm, more preferably within 1 nm." (*Id.*) As Mr. Lawal explains, a POSITA would recognize that 222 nm and 254 nm wavelengths fall within the disclosed UV radiation range of "220 to 320 nm." (EX1045, ¶ 20; EX1003, ¶ 151.) Further, a POSITA would also understand that a "monochromatic" light source such as an excimer lamp where "the majority of radiation within a bandwidth of 2 nm, more preferably within 1 nm" generates photons of a single line wavelength. (*Id.*)

The combination of Brown-Skrobot and Clauss also explicitly discloses generating photons of single line wavelengths of 222 nm and 254 nm. (EX1045, ¶ 21; EX1003, ¶ 152.) For example, Brown-Skrobot teaches KrCl and XeI excimer lamps as exemplary monochromatic UV radiation sources that can be used with its disclosed invention, which a POSITA would understand would generate photons at about 222 nm and 253 nm, respectively. (EX1006, ¶ 0038; EX1020, 30.) Clauss further teaches using a low-pressure mercury lamp generating photons at 254 nm, in addition to a KrCl excimer lamp emitting 222 nm radiation. (EX1007, 580; *see also* EX1003, APPXB at 2-16 (Fig. 2.12(a) showing spectrum of low-pressure mercury

lamp emitting narrow wavelength 254 nm UV light).)

Further, Clauss teaches selecting lamps emitting photons of single line wavelengths 222 nm and 254 specifically because they are absorption wavelengths inherent to DNA/RNA or the amino acids that the '642 Patent asserts can be associated with DNA/RNA. (EX1045, ¶ 22; EX1003, ¶ 153; EX1007, 580.) For example, Clauss teaches selecting 254 nm because it was known to be a maximum absorption wavelength that causes damage to DNA by altering nucleotide base pairing. (EX1007, 580 ("254 nm almost corresponds with the maximum of DNA absorption"); EX1001, 2:16-24, FIG. 9.) Clauss also teaches selecting 222 nm because it is near a "peak UV absorption...at 220 nm" for many common amino acids, including those that the '642 Patent asserts can be found associated with DNA or RNA such as "phenylalanin[e], tyrosin[e], tryptophan, cystein[e], cystin[e] and histidine[e]" among others. (EX1007, 580; EX1001, 6:33-46, FIGs. 9, 10; EX1018, 7:38-50; EX1019, 2:49-52, 3:1-7, 3:38-4:7.) Notably, the absorption maxima of DNA/RNA and amino acids were natural phenomena known long before the filing of the '642 Patent. (See, e.g., EX1001, 4:4-11 (citing EX1039, a 1986 publication disclosing DNA absorption); EX1045, ¶ 23; EX1003, ¶¶ 47-48, 53, 59-67.)

Therefore, Brown-Skrobot and Clauss disclose that "multiple monochromatic radiation sources" of UV light at 222 nm and 254 nm wavelengths can be used for destroying microorganisms. (EX1006, ¶¶ 0038, 0042; EX1007, 580.)

2. "destroying a DNA or RNA of viral and bacterial agents"

The combination of Brown-Skrobot and Clauss likewise discloses destroying viruses and bacteria using UV light. For example, in Brown-Skrobot, the term "sterile" or "sterilization" used throughout the specification is defined by a condition "which is free of all living cells, all viable spores (and other resistant and disseminative forms), and all viruses and subviral agents capable of replication," (EX1006, ¶ 0030), and viruses in particular are noted as being "susceptible to UV radiation," (*id.*, ¶ 0053). (EX1045, ¶ 13.) Brown-Skrobot also specifically teaches using 257 nm UV light to inactivate bacteria. (EX1006, ¶¶ 0053, 0068-0069; EX1045, ¶ 13.) Likewise, Clauss expressly teaches using both 222 nm and 254 nm UV light to irradiate (i.e. destroy) bacteria. (*See, e.g.*, EX1007, 579; EX1045, ¶ 14.) Specifically, Clauss identifies 254 nm UV light as specifically targeting DNA, in line with the claim limitation at issue here. (EX1007, 580; EX1045, ¶ 14.)

Indeed, the '642 Patent itself explains that "commercially available" UV lamps emitting at 254 nm were already known as an "effective treatment" for "the destruction of 'virus, bacteria, spores and pathogens' (microorganisms or VSP)[.]" (EX1001, 1:33-43; *see also* EX1015, Table 4 (disclosing energy needed at 253.7 nm to achieve 100% kill of several common viruses).) In fact it had been known for decades that the "inactivation spectrum of bacteria and viruses is very close to the absorption spectrum of DNA[.]" (EX1039, 16; EX1045, ¶ 15.) Even further, viruses

were known to be susceptible to UV light at about 222 nm. (*See, e.g.*, EX1024, [0011] (disclosing sterilization systems "effective in inactivating viral and bacterial microorganisms" using "discrete wavelengths" including 222 (+/-5 nm)); EX1046, 1-4 (disclosing that tobacco mosaic virus was "more sensitive to ultraviolet light emitted at 220 nm), *see also* EX1001, 5:8-15 (referencing EX1046).) Thus, the "viral and bacterial agents" amendment does not rescue the claim's patentability.

For at least the above reasons, substitute claim 12 is obvious over Brown-Skrobot and Clauss.⁷

C. Substitute Claim 19 is Unpatentable Over Brown-Skrobot, Clauss, and Liang

Substitute claim 19 depends from independent substitute claim 12 and specifies that the substance to be disinfected is air. Using UV light to disinfect air was long known in the art, however, and was specifically disclosed by Liang,⁸ among others. Liang (EX1047) is a published U.S. patent application titled "Method

⁷ Because Patent Owner acknowledges that claims 13-18 have not been substantively amended, (MTA, 3), these claims are not addressed separately here.

⁸ Liang is prior art of record (EX1006) in IPR2022-00682, a related proceeding filed by a subset of the instant Petitioners challenging U.S. Pat. No. 8,975,605. The Board instituted review of the '605 Patent on October 27, 2022, (Paper 10).

and Apparatus for Sterilizing Air in Large Volumes By Radiation of Ultraviolet Rays," filed on January 26, 2004, and published on July 28, 2005. Liang was published more than one year prior to July 31, 2007, and is prior art under at least pre-AIA §§102(a), (b) and post-AIA §102(a)(1). Liang was not before the examiner during prosecution of the '642 Patent. (*See* EX1002.)

1. <u>Overview of Liang</u>

Liang teaches "an air sterilizing method and apparatus to destroy all live microorganisms in the air in large volumes to satisfy the increasing needs for the purposes of anti infectious disease and anti-terrorism." (EX1047, ¶ 0012; EX1045, ¶ 29.) Liang explains that "[t]he air transmission of harmful bacteria, viruses and other microorganisms is one of the most common causes of infectious disease in the world today," and notes that "[t]he worldwide outbreak of SARS (caused by coronaviruses) has become a serious global concern since Jan. 2003," leading to concerns about both airborne diseases as well as "non-airborne harmful bacteria and viruses [that] can become airborne when they are in the form of aerosols or microdroplets." (EX1047, ¶¶ 0004-0005.)

Liang describes that his invention is "designed for a killing rate higher than 99.999% by adjusting the number of UV lamps and extending the length of the circuitous sterilizing chamber(s)," which serve to "increas[e] exposure to UV radiation that is used to kill all live microorganisms that pass through the chamber."

(*Id.*, ¶ 0012; EX1045, ¶ 30.) Liang employs UV radiation at "about 253.7 nm" because it is "very effective in killing microorganisms" and "is the most sensitive UV radiation to all microorganisms." (EX1047, ¶¶ 0013, 0047.) Liang explains that the "fundamental difference of this invention from prior art methods and apparatus" is the "UV radiation exposure intensity." (*Id.*, ¶ 0048.) Specifically, the "basic formula is that the product (UV radiation value) of UV power multiplying exposure time must be higher than the UV death value of any microorganisms." (*Id.*) In other words, "the sterilizing dosage of UV radiation should be high enough that there will not be any microorganism survived." (*Id.*)

To kill the microorganisms, Liang uses a circuitous sterilizing chamber, "which can increase both the traveling time of the sterilized air and the number of UV lamps installed[.]" (*Id.*, ¶ 0049; *see also id.* ("Increasing the number of UV lamps can increase the sterilizing power of the apparatus."); EX1045, ¶ 31-32.) Further, Liang uses UV lamps that are specifically "germicidal lamps" which "have the characteristics of higher UV power output and lower cost." (EX1047, ¶ 0050; EX1045, ¶ 32; *see also* EX1047, FIG. 3.) The apparatus also includes an "inspection window...for taking air samples for live microorganisms inspection to supervise sterilizing effect and air quality." (EX1047, ¶ 0045.)

Thus, Liang teaches using 253.7 nm wavelength UV light to effectively kill microorganisms and thus sterilize an air stream. (*Id.*, ¶ 0013, 0048-0050; EX1045,

¶ 33.) Liang's invention "can be added onto existing air conditioning systems, or stand alone, for hospitals, biomedical, pharmaceutical, biotechnology, genetic research, universities, laboratories, food processing" purposes. (EX1047, ¶ 0013.)

2. <u>Reasons to Combine Liang with Brown-Skrobot and Clauss</u>

In combination, Liang's "air sterilizing method and apparatus to destroy all live microorganisms in the air in large volumes" is performed using Clauss's 222 nm KrCl excimer lamp and 254 nm low-pressure mercury lamp, as taught by Brown-Skrobot's teaching to use "[t]wo or more monochromatic uv radiation sources[.]" (EX1047, ¶ 0012; EX1006, ¶¶ 0033, 0042; EX1007, 580; EX1045, ¶ 34.)

A POSITA would have been motivated to integrate the disclosures of Liang with the combination of Brown-Skrobot and Clauss, (*see* Pet., 43-45; EX1003, ¶¶ 99-104), for at least the following independent reasons. (EX1045, ¶¶ 34-40.)

First, a POSITA would have been motivated to optimize Liang even further to maximize the killing of the microorganisms in the air. (*Id.*, ¶ 36.) Liang explains the importance of achieving maximum sterility, criticizing prior art devices which could not destroy >99.999% of microorganisms in the air, or across large volumes. (*See* EX1047, ¶ 0009.) Specifically, Liang explained how airborne transmission of "harmful bacteria, viruses and other microorganisms is one of the most common causes of infectious disease in the world today," leading to thousands of deaths worldwide. (*Id.*, ¶ 0004.) With the rise of coronaviruses like SARS and anthrax, the need to produce devices and methods that could maximize killing of these microorganisms was critical. (See id., $\P\P$ 0005, 0007; EX1045, \P 36.)

Second, a POSITA would have sought to produce such devices and methods using known techniques. A POSITA would have known that photons around 254 nm, like the 253.7 nm photons disclosed in Liang, inactivated microorganisms by damaging the DNA/RNA structure, preventing the microorganisms from replicating. (See EX1045, ¶ 37; see also EX1003, ¶¶ 46-48.) As Mr. Lawal explains, a POSITA would have known that when these treated microorganisms were subsequently exposed to certain kinds of light, they could repair their DNA in a process called photoreactivation, and survive. (EX1045, ¶ 37; see also EX1003, APPXB, 97; EX1007, 580.) Given the importance of maximizing killing microorganisms, a POSITA would have sought to mitigate photoreactivation. (EX1045, ¶ 37.) A POSITA would have known from Clauss that using a 222 nm excimer lamp prevented photoreactivation. (EX1007, 583; EX1045, ¶ 37; EX1026, 1529 (noting research "suggested that bactericidal action at 254-nm radiation could be improved by supplementary radiation from excimer lamps.").) Specifically, he would have understood that 222 nm photons kill microorganisms by damaging the peptide bonds found in proteins, rendering the microorganisms inactive. (EX1045, ¶ 37.) Unable to repair this kind of damage, the microorganisms would subsequently die, thus achieving the purpose of Liang's air sterilization method. (Id.)

Third, a POSITA would have understood and appreciated that using multiple UV wavelengths (and, specifically, the 222 nm and 254 nm wavelengths taught by Clauss, Brown-Skrobot, and Liang) would yield certain predictable advantages. The synergies of combining the two wavelengths were already appreciated; thus, applying them to air sterilization was an obvious next step. (*Id.*, ¶ 38.)

Brown-Skrobot taught that "different wavelengths may provide increased levels of sterility, because different microorganisms...may have greater or lesser sensitivities to uv radiation at different wavelengths" and "therefore, multiple monochromatic uv radiation sources can be used which...when used together will successfully sterilize all the microorganisms, that might not otherwise be sterilized[.]" (EX1006, ¶ 0042; see also EX1015, 3:43-5:25 (tables showing different microorganisms requiring different doses to achieve disinfection); EX1045, ¶ 39.) As previously discussed, a POSITA would have been motivated to combine Brown-Skrobot and Clauss to generate a device that achieved such increased levels of sterility. (See Pet., 43-45; EX1003, ¶¶ 99-104.) A POSITA would have sought to apply such a device to Liang's air sterilization device to maximize sterilization and achieve Liang's purpose of achieving a "killing rate higher than 99.999%" in the air in large volumes. (EX1047, ¶ 0012; EX1045, ¶ 39.)

Finally, a POSITA would have been motivated to apply the combination of Brown-Skrobot and Clauss to Liang because Brown-Skrobot taught sterilization of a medical device in one particular embodiment, (EX1006, \P 0042), and Liang's invention could be used in "hospitals, biomedical, pharmaceutical, [and] biotechnology" environments, (EX1047, \P 0013). (*See* EX1045, \P 40.)

3. <u>Analysis</u>

[19] The process of claim 12 wherein the substances is air.

The combination of Liang, Brown-Skrobot, and Clauss discloses substitute claim [19]. (EX1045, ¶¶ 41-46.)

To begin, the combination discloses directing (and exposing) an air stream to UV photons. (*Id.*, ¶ 43.) Specifically, Liang teaches "an air sterilizing method and apparatus to destroy all live microorganisms in the air in large volumes[.]" (EX1047, ¶ 0012.) Liang's "circuitous sterilizing chamber" "increase[s] both the traveling time of the sterilized air and the number of UV lamps installed[.]" (*Id.*, ¶ 0049; *see also id.*, FIG. 3.) For UV radiation, Liang uses "non-ozone germicidal lamps" which "have the characteristics of higher UV power output and lower cost," (*id.*, ¶ 0050), and, specifically, 253.7 nm wavelength radiation, (*id.*, ¶¶ 0013, 0047). A POSITA familiar with commercially-available UV light sources would immediately recognize that Liang's description of "253.7 nm" light describes the light generated by a mercury lamp, which the '642 Patent describes as emitting light "principally at 254 nm." (EX1045, ¶ 43; EX1003, ¶¶ 52-56; EX1001, 1:36-37.)

Next, as discussed above, the combination discloses using at least two

wavelengths: "Two or more monochromatic [UV] radiation sources can be used together to provide...the same or different amounts of energy at different wavelengths of monochromatic [UV] radiation." (EX1006, ¶ 0042; EX1045, ¶ 44.) Using multiple wavelengths was desirable to maximize sterilization of different kinds of microorganisms. (*Id.*)

More specifically, the combination discloses generating photons of single line wavelengths of 222 nm and 254 nm. (EX1045, \P 45.) In addition to Liang's disclosure of using 254 nm radiation generally, Brown-Skrobot teaches that KrCl, and XeI excimer lamps are exemplary monochromatic UV radiation sources that can be used to deactivate microorganisms. (EX1006, \P 0038; EX1020, 30.) As Mr. Lawal explains, a POSITA would understand that these lamps generate photons at about 222 nm and 253 nm, respectively. (*Id.*; EX1045, \P 45.)

It would have been obvious to a POSITA reading Liang, which emphasizes the importance of maximizing sterility, to incorporate the multiple wavelengths taught by Brown-Skrobot and Clauss, where these wavelengths are specifically utilized to deactivate the DNA/RNA and proteins of microorganisms. (EX1045, ¶ 46.) Thus, the combination teaches directing an air stream to the generated photons of at least two wavelengths selected from the group consisting of 222 nm and 254 nm, and disinfecting the air stream by exposing it to the generated photons. (*Id.*)

For all of these reasons, substitute claim 19 is unpatentable over the prior art.

D. The Substitute Claims Are Unpatentable Under 35 U.S.C. § 101

In addition to being unpatentable over the prior art, the substitute claims are also unpatentable under 35 U.S.C. §101. Amazon.com, Inc. v. Uniloc Lux. S.A., IPR2017-00948, Paper 34 at 5 (PTAB Jan. 18, 2019) (precedential) (grounds of unpatentability are not limited in response to a motion to amend). Specifically, the claims are not patent-eligible under §101 because they attempt to monopolize the natural, germicidal effect of UV light. As described in the '642 Patent, researchers in the 1900s discovered that DNA absorbing UV photon energies led to a germicidal effect, especially near certain wavelengths. The known natural law underlying that process-the relationship between photon wavelength and DNA absorption-is expressly captured by the substitute claims without any meaningful limitation on how those steps are carried out. For example, the claims cover any means of "generating photons," including by UV lamps admitted as prior art, and "directing the photons" requires no more than ensuring photons reach the particular surface to be disinfected. The claims read on any manner of UV disinfection, previously or soon-to-be discovered, that uses photons at wavelengths already known for their germicidal properties, such that they "pre-empt the use of [the] natural law." Mayo Collaborative Servs. v. Prometheus Lab'ys., Inc., 566 U.S. 66, 72 (2012). The substitute claims therefore "simply recite a law of nature and then add the instruction 'apply the law'" by any means necessary, and therefore are not patentable. *Id.* at 78.

1. <u>UV Light's Germicidal Properties Were Well-Known as of the</u> Filing Date of the '642 Patent

The applicant acknowledged that the general concept of using UV light for germicidal use was already well known. (See, e.g., EX1001, 1:33-50.) He also acknowledged that researchers had discovered and documented this phenomenon decades before. (See, e.g., id., 4:6-14, 16-19.) Researchers had already discovered the natural law underlying this phenomenon: "the light absorption capability of [] different virus and bacteria at" particular wavelengths. (Id., 1:43-46.) It was well understood that absorption of UV light by chemical bonds is a function of the light's wavelength, and that the particular "wavelength of the applied radiation [correlates] to [] the observed effects." (Id., 2:11-15.) Although DNA molecules absorb photons over a range of wavelengths, there are "peak" wavelengths "at 260 nm and [] at 200 nm" where this relationship is strongest. (Id., 4:3-6; see also id., 3:51-52 ("The DNA molecule absorbs light from about 180 nm to about 300 nm."), 4:4-20 (describing the two absorption peaks), FIGs. 9, 10.) Prior art from 1930 and 1986 included as Figures 9 and 10 of the '642 Patent-"graphically show this relationship" and the two absorption peaks. (*Id.*, 4:4-20, FIGs. 9, 10.)

It had "been fairly well established" that each peak relates to a certain chemical bond in DNA. (*See, e.g., id.* at 4:55-65.) "Researchers believe that the energy" absorbed from a 254 nm photon causes disruptive bonds to form in the

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DNA, while "higher energy 222 nm photons" could break bonds and "cause physical damage to the microorganism." (*Id.*, 3:39-50, 4:21-40.)

The applicant acknowledged that germicidal UV lamps have long practiced natural laws. "A standard commercial light source for UV irradiation near the 260 nm absorption peak of DNA [was] being produced by using mercury as the source for generating photons" before the '642 Patent. (*Id.*, 3:58-60.) These "low-pressure" UV lamps emit photons "principally at 254 nm." (*Id.*, 1:36-37, 3:62-64.) Other commercially available lamps could emit photons ranging "from 200 nm to above 300 nm" by changing the "gas and its pressure in the lamp[.]" (*Id.*, 3:60-4:3.) The '642 Patent concedes that it was commonplace to use commercially-available UV lamps to generate 200 to 300 nm wavelengths for sanitization.

As described above, Patent Owner admittedly did not discover the natural laws underlying the germicidal effect of UV light. Nor was he the first to conceive of a UV sanitation lamp. That work was achieved years and decades prior. The applicant was also not the first to discover the process of photoreactivation after UV disinfection with 254 nm UV light, nor the use of 222 nm UV light from excimer lamps to counteract it. (*Id.*, 4:28-33; EX1045, ¶ 37; *see also* EX1003, APPXB, 97; EX1007, 580-581; EX1026, 1529 (noting research "suggested that bactericidal action at 254-nm radiation could be improved by supplementary radiation from excimer lamps.").) Yet he seeks exclusive rights to the application of this common

knowledge in the field. Specifically, the substitute claims are directed to the known use of known wavelengths to disinfect a surface. (*See* MTA, APPX A, 3-5.)

The specification states that "[c]ritical to this apparatus is the development of a new ultra-violet (NUV) source" for emitting narrow wavelengths corresponding to the maximum absorption band target components, (EX1001, 3:6-11), but the substitute claims are not directed to "new" sources. The applicant acknowledged that these gas lamps were known, noting that "[d]uring the past few years" "excimer lamps"—which the applicant describes as UV lamps where photon wavelengths are a function of the "gas composition of the lamp"—were "becoming commercially available." (Id., 2:35-39.) What is notable about the applicant's mention of excimer lamps is that they were already known to produce a single line emission at certain UV wavelengths, including 207 nm and 222 nm. (Id., 8:65-9:6.) These are, unsurprisingly, the specific embodiments of the "NUV source" the applicant describes, and the source of specific wavelengths claimed. (Id., Claims 1 and 11; MTA, substitute claim 12.) The substitute claims are therefore not directed to a truly "new" UV source, but are merely an attempt to ensure the use of commercial excimer lamps for UV disinfection was preempted.

2. The Substitute Claims Are Directed to Ineligible Subject Matter

The substitute claims are invalid under §101 because they (1) are directed to a natural law, namely the relationship between photon wavelength and DNA/RNA

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absorption peaks; and (2) do not contain an "inventive concept...sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014). The '642 Patent concedes that the applicant did not discover this natural law; the claimed application—disinfecting with a UV light source—was well known and conventional.

(i) Alice Step 1: The claims are directed to a law of nature.

The first step of the *Alice* framework asks whether the claims are directed to a patent-ineligible concept. This step evaluates "the focus of the claimed advance" to determine whether the claim, in light of the specification, is directed to excluded subject matter. *Trading Techs. Int'l, Inc. v. IBG LLC*, 921 F.3d 1378, 1384 (Fed. Cir. 2019). Here, the claimed advance of the '642 Patent is a patent-ineligible law of nature—the relationship between (1) the wavelength of UV light and (2) absorption by a microorganism's DNA or RNA. This natural relationship manifests as the claimed advance in the language of each substitute claim, consistent with the specification. Thus, the claims are directed to a natural law.

(a) The substitute claims recite a law of nature.

Substitute claim 12 recites a method for disinfecting a substance or surface by emitting light (i.e., "generating photons") of particular wavelengths "corresponding to a peak absorption wavelength of DNA or RNA" of a microorganism. (*See* MTA,

8.) This step recites the natural law (i.e., the relationship between photon wavelength and DNA/RNA absorption peaks) and requires generating photons using any process whatsoever so long as some photon wavelengths align with known DNA or RNA absorption peaks. As discussed above, discovery of this natural law predates the '642 Patent by many years. (EX1001, 1:43-46, 2:11-15, 4:4-20, FIGs. 9, 10.) And emitting photons at the same wavelengths as DNA/RNA absorption peaks is simply the natural law as exhibited by excimer lamps that were then "commercially available." (*See id.*, 1:33-40, 2:16-19, 2:35-39, 3:58-4:3.) This step does not require any human interaction and, therefore, only serves to convey the natural law itself.

The second step of substitute claim 12 recites "directing the photons" to a contaminated surface and ends by invoking a natural phenomenon (i.e., "whereby the photons are selected to destroy" the microorganism's DNA or RNA). (MTA, 9.) But the "generated photons" must go somewhere, and the '642 Patent admits the destruction of chemical bonds is a "well established," naturally occurring consequence of the wavelength-DNA/RNA absorption relationship. (EX1001, 3:39-50, 4:21-40, 4:55-65.) This step, too, simply describes a natural phenomenon.

The specification supports the conclusion that the substitute claims are directed to a natural law. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 751 (Fed. Cir. 2019) (consulting specification in determining claims were directed to patent ineligible subject matter). The '642 Patent highlights

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the applicant's assertions that the claimed advance is the natural law. Photon wavelengths "correspond[ing] to the maximum absorption band for DNA" are "critical" to the claims and the underlying "concept" of the "invention." (EX1001, 2:31-34, 2:66-3:11, 4:36-43, 6:18-22.) Nothing in the specification suggests the claims require anything more than the natural law "with no meaningful non-routine steps in between." *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017). Thus, the claims are directed to a natural law.

The §101 case law also supports the conclusion that the substitute claims are directed to a law of nature. The Supreme Court in *Mayo* concluded that claims directed to "relationships between concentrations of certain metabolites [of a thiopurine drug] in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm" were based on "entirely natural processes" and were therefore drawn to a law of nature. *Mayo*, 566 U.S. at 77. The same is true of the relationship set out here: relationships between photon wavelengths and DNA/RNA absorption peaks and the resulting destruction of chemical bonds are both naturally occurring relationships explaining the process of UV disinfection.

(b) The substitute claims are not directed to a patent-eligible application of the natural law.

The substitute claims do not recite "a particular, useful application" of a natural law, (*Mayo*, 566 U.S. at 84), such as "a new and useful laboratory technique"

(Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1048 (Fed Cir. 2016)) or "a particular method of treatment," (Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC, 918 F.3d 1338, 1345 (Fed. Cir. 2019)).

The *CellzDirect* case presents a counter-factual situation that highlights the distinction between a patent-eligible application of a natural law (present in *CellzDirect*) and the lack thereof (as in the substitute claims here). In *CellzDirect* the claims were directed to an innovative laboratory technique, not a law of nature. Although the claims included a newfound natural property of hepatocytes discovered by the inventors—"said hepatocytes being capable of being frozen and thawed at least two times"—the "end result" of the claims *applied* the discovery of a natural property of hepatocytes "to create a new and improved way of preserving hepatocyte cells for later use." CellzDirect, 827 F.3d at 1048 ("The inventors certainly discovered the cells' ability to survive multiple freeze-thaw cycles, but that is not where they stopped, nor is it what they patented."). That result was due to the particular steps the inventors designed *based on* applying the natural property they uncovered, which were recited in the claimed process. Id. at 1047-48. The claimed invention went beyond applying a known laboratory technique to a newly discovered natural phenomenon and, instead, created an entirely new laboratory technique.

In contrast, the claimed method steps here do not recite a new laboratory technique or using any old laboratory technique in a new or unconventional way.

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Patent Owner does not claim to have discovered a previously unknown law, nor does he claim new or improved ways of "generating photons" at a particular wavelength or "directing them" to a target. Instead, the substitute claims recite admittedly known and conventional detail about the natural law and how to use the natural law, and that is where each claim stops. Nothing differentiates the steps from those conventional methods of UV disinfection using "commercially available" UV lamps. (EX1001, 2:16-19; see also id. at 1:33-40, 2:35-39, 3:58-4:3.) The claims do not prescribe a particular way of performing these steps, instead conferring patent coverage if those goals are achieved by one skilled in the art using any method, including prior art lamps, or a newly discovered method of emitting photons. The inventor simply acknowledged the conventional practice of UV sanitation, and then applied for claims for a method of UV sanitation specifying wavelengths in the UV spectrum that were generated by commercially available UV lamps and known to correspond to DNA/RNA absorption. Thus, the claims "amount[] to nothing more than observing or identifying the ineligible concept itself." Athena, 915 F.3d at 751.

The Federal Circuit distinguished the patent claims analyzed in *Natural Alternatives* from those that "did not do significantly more than simply describe the natural relationships," holding instead that eligible claims "require specific steps be taken in order to bring about a change in a subject" being treated. *Nat. Alts.*, 918 F.3d at 1345. In particular, the claims recited "using a natural product in unnatural quantities to alter a patient's natural state, to treat a patient with specific dosages outlined in the patents." *Id.* at 1346. In contrast, the claims here do not recite any particular UV dosage (e.g., exposure time or area) necessary to bring about the desired results. The substitute claims are like those claims held ineligible where the claims lack "the specificity required to transform [the] claim from one claiming only a result to one claiming a way of achieving it." *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018) (collecting cases). This is true "where, as here, [the claims] on [their] face clearly invoke[] a natural law, and nothing more, to achieve a claimed result." *Am. Axle & Mfg., Inc. v. Neapco Holding, LLC*, 967 F.3d 1285, 1297 (Fed. Cir. 2020). Accordingly, the substitute claims fail *Alice* step one.

(ii) Alice Step 2: The substitute claims do not contain an inventive concept.

Because the substitute claims are directed to a law of nature, they can only be patent-eligible if they recite "an 'inventive concept'—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Alice*, 573 U.S. at 217-18 (quoting *Mayo*, 566 U.S. at 78-79).

Considered individually, the claimed steps are at best "standard techniques to be applied in a standard way." *Athena*, 915 F.3d at 753. Both "commercially available ultra-violet (UV) lamps" and "new UV emitting lamps based on the excitation of excimers" were commercially used to generate and direct photons at particular wavelengths, (EX1001, 1:33-35, 2:35-37), meaning this step requires engaging only in well-understood, routine, and conventional activity previously engaged in by researchers in the field.

Considered as an ordered combination, the claimed steps add nothing inventive to the underlying natural law or UV technology. Anyone who wants to make use of these laws must first generate photons and direct them to a surface, "and so the combination amounts to nothing significantly more than an instruction to [the reader] to apply the applicable laws when" disinfecting with UV light. *Mayo*, 566 U.S. at 79. The '642 Patent describes the process of UV disinfection as well-understood, routine, and conventional activity already engaged in by the scientific community. Any additional steps, "when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id.* at 79-80.

Perhaps the applicant had, in fact, come up with a novel UV source for generating 222 nm and 254 nm wavelength UV light. (*See, e.g.,* EX1001, 12:23–60, Fig. 1b.) Perhaps not. But the substitute claims are not directed to this specific invention, and instead claim the natural law it employs. The substitute claims thus lack an "inventive concept" and are not patentable.

IV. CONCLUSION

For the above reasons, Patent Owner's Motion to Amend should be denied.

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Respectfully submitted,

Dated January 30, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned certifies that on January 30,

2023, a complete and entire copy of this Petitioners' Opposition to Patent Owner's

Motion to Amend U.S. Patent 9,700,642 was provided via email, to the Patent

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