

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOLECULIGHT, INC.,
Petitioner,

v.

SWIFT MEDICAL INC.,
Patent Owner.

PGR2022-00041
Patent 11,266,345 B2

Before LYNNE H. BROWNE, JEREMY M. PLENZLER, and
BRIAN D. RANGE, *Administrative Patent Judges*.

RANGE, *Administrative Patent Judge*.

DECISION
GRANTING INSTITUTION OF POST-GRANT REVIEW
35 U.S.C. § 324

I. INTRODUCTION

Moleculight, Inc. (“Petitioner”) filed a Petition (“Pet.”) for post-grant review of claims 1–20 of U.S. Patent No. 11,266,345 B2 (“the ’345 patent”) (Ex. 1001) pursuant to 35 U.S.C. §§ 321–329. Paper 1. Swift Medical, Inc. (“Patent Owner”) did not file a Preliminary Response (deadline of August 17, 2022). Petitioner

challenges the patentability of claims 1–20 of the '345 patent under 35 U.S.C. §§ 102 and 103. Patent Owner did not file a preliminary response. We have jurisdiction under 35 U.S.C. § 324(a), which provides that a post-grant review may be instituted only if “the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.”

The following findings of fact and conclusions of law are not final, but are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the full trial record, including any response timely filed by Patent Owner. Any arguments not raised by Patent Owner in a timely-filed response may be deemed waived.

After considering the Petition, as well as all supporting evidence, we are persuaded that it is more likely than not that Petitioner would prevail in showing that at least one of the challenged claims is unpatentable under §§ 102 or 103. Thus, applying the standard set forth in 35 U.S.C. § 324(a), we hereby institute a post-grant review of claims 1–20 of the '345 patent based upon Petitioner's asserted grounds of unpatentability.

A. Related Matters

Petitioner states “[t]here are currently no litigation matters that could be affected by a decision in this proceeding.” Pet. 1.

B. The '345 Patent

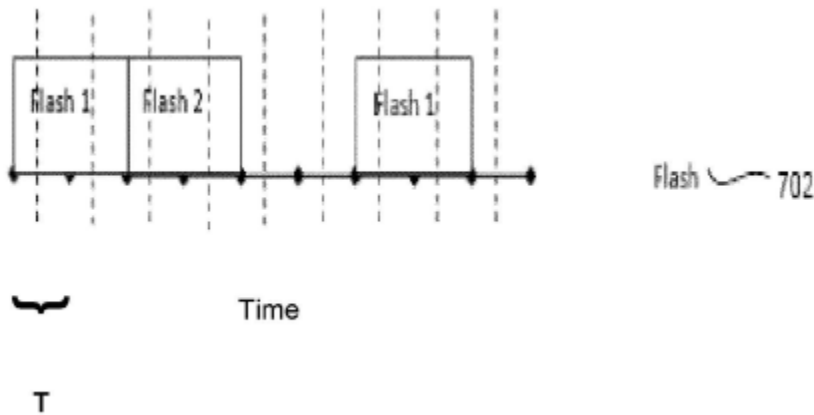
The '345 patent relates to a tissue imaging system configured to capture measurement data and comprising a tissue visualization application that extracts visualizations of tissue health indicators from the measurement data. Ex. 1001, Abst. In particular, the patent's system seeks to employ a portable diagnostic tool that is more accessible to a patient than large, clinical-grade tools. *Id.* at 4:60–6:37.

The system addresses chronic wounds assessable by “multispectral (hyperspectral) imaging” including three example visualizations. *Id.* at 1:32–54. First, a visualization of oxyhemoglobin and deoxyhemoglobin shows perfusion and oxygenation of tissue. *Id.* at 1:42–45. Second, a visualization of subepidermal moisture and water distribution shows pressure injury. *Id.* at 1:46–49. Third, a visualization of fluorescence shows bacterial burden. *Id.* at 1:51–53.

In embodiments of the invention, a tissue imaging system 105 includes a computing device 108, an image capturing unit 103 (e.g., an RGB camera), an illumination unit 104 with an output of selectable intensity, wavelength, and duration (e.g., multi-spectral flash), and a tissue visualization application 112 that extracts, aggregates, and transmits visualizations of tissue health indicators (e.g., for review by a physician). *Id.* at 6:58–7:67, 11:23–60, Fig. 3. The computing device 108 “may be an off-the-shell [sic, shelf] computing device (for example, a mobile device, smartphone, tablet, laptop, a personal computer).” *Id.* at 6:58–62. The image capturing unit 103 and tissue visualization application 112 are part of the included computing device 108. *Id.* at 11:23–27, Fig. 3. The illumination unit 104 is connected to the smartphone 108. *Id.* at 11:38–60, Fig. 3.

The tissue visualization app 112 controls the illumination of the patient tissue targeted for imaging/measurement, e.g., adjusting the illumination intensity to the distance of the image capture unit 103 from the target area and to the current intensity of the light source. *Id.* at 13:30–44. Further, the tissue visualization app 112 may include a positioning unit 324 that facilitates positioning of the image capture unit 103 to target an area of tissue for measurement, e.g., movement forwards/backwards and closer/farther. *Id.* at 12:46–13:29. And, the tissue visualization app 112 may include a pre-processing unit 326, calibration unit 328, and app processing unit 330. *Id.* at 12:46–48. The app processing unit 330

compares images/measurements of a “suspicious area” of the patient to corresponding images/measurements of a “non-affected area” of the patient. *Id.* at 13:50–14:4. The ‘345 patent’s Figure 7, reproduced below, “is an example of an illumination and image capturing schema according to some embodiments.” *Id.* at 17:10–11.



The ‘345 patent’s Figure 7, reproduced above, “is an example of an illumination and image capturing schema according to some embodiments.” 17:10–11.

The illumination schema (cycle) consists of m flashes (with $m=2$ in the example of Figure 7) and one period without flash, with $n/4 \leq m \leq n$, where n is the number of wavelengths. *Id.* 17:19–24. The exposure time (T) for each frame (in milliseconds) can be selected as $T=k/2*f$, where k is an integer, and f is the utility frequency (e.g., 60 Hz). *Id.* at 17:25–2. The duration of each flash can be T or any whole number multiple of T which eases optical synchronization between illumination unit and image capturing unit. *Id.* at 17:35–38. In Figure 7, the cycle consists of m back to back flashes with duration $2T$ milliseconds each and followed by a no-lit period $2T$ milliseconds long. *Id.* at 17:38–41.

The system 105 can capture a single image frame of tissue illuminated at multiple wavelengths; e.g., 480 and 660 nm wavelengths captured as blue and red,

respectively, by different color wavelengths of an RGB camera. *Id.* at 17:42–48. The illumination unit 104 can use narrow band-high-efficiency light sources 300 such as single wavelength or multi-wavelength LEDs. *Id.* at 18:21–24. The illumination unit 104 can output a flash of light sources producing the same wavelength “or the possibility of multiple wavelengths shining in a single flash.” *Id.* at 18:16–19.

The outcome of the smartphone system 105 can be a “false color or grayscale 2D map” of the imaged/measured tissue health indicators. *Id.* at 14:17–18. The maps are displayed by an included display interface 318 and/or transmitted, for example, to a physician for review. *Id.* at 14:18–31.

C. Illustrative Claim

Claims 1–15 are challenged, of which claims 1, 8, and 13 are independent. Claims 1, 8, and 13 are respectively directed to an apparatus, system, and method. Claim 1 is illustrative and reproduced below:

1. A portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising:
a portable housing for detachable attachment proximal to an image capturing unit; and
an illumination unit comprising one or more narrow band light sources configured to shine m flashes of light on a target area of the tissue at n predetermined wavelengths, wherein: $n/4 \leq m \leq n$; and m is a number of light flashes in one cycle and n is a number of wavelengths.

D. Asserted Grounds

Petitioner asserts that claims 1–20 are unpatentable on the following grounds. Pet. 3–5.

	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1, 4–13, 17, 20	102	Cross ¹
2	1, 4–13, 17, 20	103	Cross
3	1, 3, 4, 8–11, 13, 17, 18, 20	102	Fawzy ²
4	1, 3, 4, 8–11, 13, 17, 18, 20	103	Fawzy
5	3, 18	103	Cross in view of Fawzy
6	5, 6, 12	103	Fawzy in view of Cross
7	2	103	Cross in view of Polidor ³
8	2	103	Fawzy in view of Polidor
9	5–7	103	Cross in view of O’Neill ⁴
10	5, 6	103	Fawzy in view of Cross and O’Neill
11	7	103	Fawzy in view of O’Neill
12	14	103	Cross in view of Garcia ⁵
13	14	103	Fawzy in view of Garcia
14	15	103	Cross in view of DaCosta ⁶
15	15	103	Fawzy in view of DaCosta
16	16	103	Cross in view of DaCosta and Garcia
17	16	103	Fawzy in view of DaCosta and Garcia
18	19	103	Fawzy in view of Gutkowicz-Krusin ⁷

¹ Ex. 1006, Cross et al., U.S. Patent Application Publication 2019/0216326 A1, July 18, 2019 (“Cross”).

² Ex. 1008, Fawzy, U.S. Patent Application Publication 2018/0188108 A1, July 5, 2018 (“Fawzy”).

³ Ex. 1010, Polidor et al., U.S. Patent 5,690,417, Nov. 25, 1997 (“Polidor”).

⁴ Ex. 1011, O’Neill et al., U.S. Patent Application Publication 2015/0042877 A1, Feb. 12, 2015 (“O’Neill”).

⁵ Ex. 1012, Garcia, U.S. Patent 9,696,897 B2, July 4, 2017 (“Garcia”).

⁶ Ex. 1014, DaCosta, U.S. Patent Application Publication 2017/0236281 A1, Aug. 17, 2017 (“DaCosta”).

⁷ Ex. 1013, Gutkowicz-Krusin et al., U.S. Patent 6,208,749 B1, March 27, 2001 (“Gutkowicz-Krusin”).

19	19	103	Cross in view of Fawzy and Gutkowicz-Krusin
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E. Testimonial Evidence

Petitioner relies on declaration testimony of Irene Georgakoudi, Ph.D. (Ex. 1004, “the Georgakoudi Declaration”). Pet. 1.

II. ELIGIBILITY FOR POST-GRANT REVIEW

As a threshold matter, we must determine whether Petitioner has shown that the ’345 patent is eligible for post-grant review. *See Commonwealth Sci. & Indus. Res. Org. v. BASF Plant Sci. GmbH*, PGR2020-00033, Paper 11 at 7 (PTAB Sept. 10, 2020); *Mylan Pharms. Inc. v. Yeda Res. & Dev. Co.*, PGR2016-00010, Paper 9 at 10 (PTAB Aug. 15, 2016); *US Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019, Paper 17 at 9–12 (PTAB Jan. 29, 2016).

The post-grant review provisions in section 6(d) of the Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (September 16, 2011) (“AIA”) apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (stating that the provisions of section 6(d) “shall apply only to patents described in section 3(n)(1)”). Patents subject to the first-inventor-to-file provisions are those that issue from applications that contain or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after [March 16, 2013]; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA § 3(n)(1).

Here, Petitioner certifies as follows:

the '345 patent is available for post grant review under 35 U.S.C. § 321 and that Petitioner is not barred or estopped from requesting post grant review of the '345 patent on the grounds identified in this Petition. The '345 patent was filed under the first inventor to file provisions of the AIA and issued on March 8, 2022, and this Petition has been timely-filed on or before December 8, 2022.

Pet. 3. We agree that the '345 patent's claims are eligible for post grant review. The '345 patent's earliest possible priority date is July 18, 2018, well after March 16, 2013. Also, Petitioner filed for post grant review within nine months of the '345 patent's March 8, 2022, issuance.

III. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard, under 35 U.S.C. § 324(a), for instituting review.

A. *Level of Ordinary Skill in the Art*

Petitioner asserts that a person of ordinary skill in the art as of the date of the invention would "have had at least a bachelor's degree in engineering with relevant coursework, and the equivalent of at least two years of work experience in the design, operation, and functioning of imaging systems, amounting to familiarity with concepts related to illumination and detection schemes for optical imaging systems." Pet. 14 (citing Ex. 1004 ¶ 48). Petitioner further asserts that "[a]dditional relevant work experience could substitute for a bachelor's degree, and additional education or training could substitute for relevant work experience." *Id.*

We find Petitioner's proposed definition is consistent with the cited prior art and the disclosure of the '345 patent. Thus, for purposes of this decision, we determine that a person of ordinary skill in the art as of the date of the invention

would have had a bachelor’s degree in engineering with relevant coursework, and the equivalent of at least two years of work experience in the design, operation, and functioning of imaging systems, amounting to familiarity with concepts related to illumination and detection schemes for optical imaging systems. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

We need only construe terms that are in controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Here, Petitioner “submits that no explicit construction is necessary when applying the prior art presented,” but notes “the Board may wish to construe ‘a central aperture of the illumination unit’ in claim 5[, construe] ‘proper distance’ in claim 13, and [consider] application of 35 U.S.C. § 112(f) in view of the prosecution history of the ‘345 patent.” Pet. 10. Petitioner also addresses “a central aperture of the illumination unit” as claim 5 recites and “proper distance” as claim 13 recites. *Id.* at 10–11. Petitioner also addresses the possibility of various terms invoking 35 U.S.C. § 112(f). *Id.* at 11–13.

For purposes of this decision, we determine that claim construction is unnecessary for institution of this post grant review. As we explain herein, Petitioner adequately establishes that it is more likely than not that Petitioner would prevail in showing that at least one of the challenged claims is unpatentable under §§ 102 or 103. This is true whether based on plain and ordinary meaning or

based on the various alternatives Petitioner presents when addressing claim construction. Pet. 9–14

C. Relevant Law

To establish anticipation under 35 U.S.C. § 102, each and every element in a claim, arranged as recited in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). Each element of the challenged claim must be found, either expressly or inherently, in the single prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Although the elements must be arranged or combined in the same way as in the claim, “the reference need not satisfy an ipsissimis verbis test,” i.e., identity of terminology is not required. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009); *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). Thus, the dispositive question is whether one skilled in the art would have reasonably understood or inferred from a prior art reference that every claim element is disclosed in that reference. *Eli Lilly v. Los Angeles Biomedical Research Inst. at Harbor–UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017).

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter

and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

D. Grounds 1 and 2: Cross (Ex. 1006)

For ground 1, Petitioner asserts that claims 1, 4–13, 17, and 20 are anticipated by Cross. Pet. 17–60. For ground 2, Petitioner asserts that the same claims are obvious over Cross. *Id.* We have reviewed Petitioner’s arguments and evidence and have found them to be sufficient to meet the threshold of § 324(a). Below, we address independent claim 1 while addressing other independent and dependent claims collectively.

1. Overview of Cross

Cross is directed to “multispectral mobile tissue assessment.” Ex. 1006, Title. Cross describes illuminating tissue with discrete wavelengths of light and taking images with a portable imaging device:

The inventors have found that discriminating tissue [of] a diabetic limb ulcer from healthy viable tissue may be done by evaluating the tissue region for certain physiological markers such as, but not limited to, wound oxygenation, perfusion (i.e. total hemoglobin), methemoglobin and water content. . . . [T]he inventors have found that changes in certain measures of these physiological markers, when taken alone or in a certain combination, may serve as an early warning of the onset of tissue damage before the presentation of clinical symptoms or even a wound. The inventors have also found that these physiological markers can be determined by illuminating the tissue region using several different discrete wavelengths of light instead of using a continuum of wavelengths thereby allowing for the development of a portable imaging device.

* * *

For example, the images that are obtained with the portable imaging device are obtained while the tissue region is being illuminated by a light source that generates several separate monochromatic light

signals having different, discrete wavelengths in the range of about 600 nm to about 1,000 nm. The images can then be combined and multispectral unmixing, which may also be referred to as multispectral decomposition, can then be used to obtain images or maps of certain physiological markers of interest such as, but not limited to, oxy-hemoglobin, deoxy-hemoglobin, total hemoglobin (tHb), oxygen saturation, methemoglobin (metHb), water, and melanin.

Id. ¶¶ 66–67.

Cross discloses a light source configured for the above operations. *See, e.g., id.* ¶¶ 5–13. Generally speaking, Cross describes a portable light source unit configured to illuminate a tissue region for imaging and configured for use with a mobile device having a camera. *Id.* ¶ 5, Fig. 1. A light source module of the light source unit generates “N single discrete wavelengths” in the visible light and near infrared (NIR) spectrums. *Id.* ¶ 10. The camera of the mobile device is sensitive to the visible light and NIR spectrums output by the light source unit. *Id.* ¶ 72.

The light source module includes an aperture and encircling light-emitting diodes (LEDs) that align with the camera of the mobile device when the light source unit is mounted on the mobile device. *Id.* ¶ 12. The light source module also includes N LED drivers and N LEDs; each LED configured to generate a light signal having a single discrete unique wavelength in the range of about 600 nm to 1,000 nm. *Id.* ¶¶ 11, 74–75. The N discrete wavelengths of the light source module are selected based on N physiological markers of interest, which are measured when the tissue region is imaged. *Id.* ¶¶ 13, 72. The physiological markers for the marker maps include at least one of total hemoglobin, oxygen saturation, methemoglobin, water, and melanin. *Id.* ¶¶ 19, 82.

Cross describes performing a remote tissue assessment for a tissue region by: selecting imaging parameters; obtaining M image datasets of the tissue region when the tissue region is illuminated by a light signal having a unique discrete

wavelength selected from M discrete unique frequencies; obtaining a reference image dataset of the tissue region when the tissue region is not illuminated; processing the M+1 image datasets to obtain M marker maps where each marker map corresponds to a different physiological marker; and analyzing at least one of the marker maps to determine whether a physiological condition exists at the tissue region or to monitor the status of an existing physiological condition at the tissue region. *Id.* ¶¶ 14–15, 73, 89, 106. The assessment includes selecting discrete wavelengths in the range of about 600 nm to 1,000 nm, e.g., discrete wavelengths of 620, 630, 700, 810, 880 and 940 nm. *Id.* ¶¶ 17, 82. The analysis involves combining at least two of the marker maps to create a combined marker map and performing measurements on the combined marker map. *Id.* ¶¶ 18, 106.

2. *Independent Claim 1*

Petitioner provides arguments and evidence, including the Georgakoudi Declaration, to support its contention that independent claim 1 is anticipated and obvious over Cross. *See* Pet. 44–59; Ex. 1004 ¶¶ 69–93.

Claim 1 first recites, “[a] portable illumination apparatus for facilitating visualizations of tissue.” Petitioner contends “Cross discloses or renders obvious a portable illumination apparatus for facilitating visualizations of tissue” by disclosing, for example, “a system that includes a portable imaging device for remote tissue assessment that includes a light source unit 10 (highlighted in green below) and a mobile device 12 (e.g., a smartphone) (highlighted in yellow below) having a camera 32.” Pet. 18. Based on the current record, we find Petitioner’s assertion to be sufficiently persuasive and supported to justify institution of review. *See* Ex. 1006, ¶¶ 1, 71, 96; Ex. 1004 ¶¶ 71–72.

Claim 1 next recites “a portable housing for detachable attachment proximal to an image capturing unit.” Petitioner contends that cross teaches such a housing as follows:

Cross discloses various housings (Figs. 4A–4D, 8) including “a housing 250 that can be used for the light source unit 10” with “an attachment mechanism that can releasably engage the housing of the mobile device 12 in a ‘snap-on’ and ‘snap-off’ fashion” to allow “the light source unit 10 to be easily attached or detached to a variety of mobile devices.” Cross, [0128].

* * *

An aperture 262 in housing 250 is “disposed at a location that corresponds with a location of the camera of the mobile device when the housing 250 is mounted to the mobile device,” and, therefore, proximal to the image capturing unit. Cross, [0130].

Fig. 8 of Cross also depicts a housing 250 of a light source unit 10 having a clip-on case. . . . Cross, [0141][;] [s]ee also Ex. 1004, ¶¶ 73–76.

Pet. 20–24. Based on the current record, we find Petitioner’s assertion to be sufficiently persuasive and supported to justify institution of review. *See* Ex. 1006, Figs. 4A–4D, 8, ¶¶ 128, 141; Ex. 1004 ¶¶ 73–76.

Claim 1 next recites “an illumination unit comprising one or more narrow band light sources configured to shine m flashes of light on a target area of the tissue at n predetermined wavelengths.” Petitioner contends that Cross discloses a light source module with a plurality of LED drivers controllable to generate multiple flashes of light at different discrete wavelengths. Pet. 22. For example, Petitioner contends that light source 10 can output “discrete wavelengths [of] 620, 630, 700, 810, 880 and 940 nm” and “may sequentially generate light signals having discrete wavelengths and direct them at a target.” Pet. 23–24 (citing Ex. 1006 ¶¶ 17, 71). Based on the current record, we find Petitioner’s assertion to

be sufficiently persuasive and supported to justify institution of review. Ex. 1006, Fig. 6, ¶¶ 17, 71, 64, 74, 75, 82, 107, 148; Ex. 1004 ¶ 77.

Claim 1 next recites “wherein: $n/4 \leq m \leq n$; and m is a number of light flashes in one cycle and n is a number of wavelengths.” We note that this claim language could be satisfied if there are one to four times as many flashes as wavelengths. For example, the number of light flashes and the number of wavelengths in one cycle could be equal.

Petitioner contends that Cross discloses or suggests an imaging cycle that outputs one flash for each discrete wavelength. Pet. 24–25. Cross teaches, for example, that a “sequence of images may be obtained while illuminating a tissue region with a sequence of different wavelengths of . . . light.” Ex. 1006 ¶ 64. Thus, based on the current record, we find Petitioner’s assertion to be sufficiently persuasive and supported to justify institution of review. Ex. 1006 ¶¶ 64, 107, 148; Ex. 1004 ¶¶ 78–79.

Based on the evidence in the present record, we are persuaded that Petitioner has shown sufficiently, for purposes of this decision, that Cross discloses (for anticipation) or teaches or reasonably suggests (for obviousness) all elements of claim 1. Thus, we are persuaded that Petitioner has sufficiently established that Petitioner is more likely than not to prevail in showing that claim 1 is unpatentable under §§ 102 or 103.

3. *Claims 4–13, 17, and 20*

Petitioner accounts for the limitations recited in claims 4–13, 17, and 20. Pet. 25–59. Petitioner provides detailed explanations as to how Cross discloses (for anticipation) or teaches or reasonably suggests (for obviousness) the limitations of these claims, citing Dr. Irene Georgakoudi’s declaration for support. *Id.* (citing Ex. 1004).

4. *Conclusion for Grounds 1 and 2*

Based on the evidence in this present record, we are persuaded that Petitioner has shown sufficiently for purposes of this decision that Cross discloses, teaches, or reasonably suggests all of the limitations recited in claims 4–13, 17, and 20. Having reviewed Petitioner’s arguments and supporting evidence in the present record, we are persuaded that Petitioner has sufficiently established that Petitioner is more likely than not to prevail in showing that at least claim 1 is unpatentable under §§ 102 or 103 in view of Cross.

E. *Grounds 3 and 4: Fawzy (Ex. 1008)*

For ground 3, Petitioner asserts that claims 1, 3, 4, 8–11, 13, 17, 18, and 20 are anticipated by Fawzy. Pet. 60–78. For ground 4, Petitioner asserts that the same claims are obvious over Fawzy. *Id.* We have reviewed Petitioner’s arguments and evidence and have found them to be sufficient to meet the threshold of § 324(a). Below, we address independent claim 1 while addressing other independent and dependent claims collectively.

1. *Overview of Fawzy*

Fawzy is directed to “spectral reflectance imaging using digital cameras” (Ex. 1008, at [54]) and providing “spectral intensity calibration devices for cameras” (*id.* ¶ 2). Fawzy describes its use of a digital camera sensitive to different wavelengths of light as follows:

Spectral reflectivity can be used to characterize the surface of an object. . . . [D]igital cameras are not optimized for measuring spectral reflectance or for quantitative color measurements.

* * *

Typical digital cameras have detectors sensitive to each of: red (R), green (G), and blue (B) light.

* * *

Because of the limitations of RGB digital cameras, . . . [they] have limited application in color reproduction for tele-medicine, image archiving and follow-up, color matching and measurements, and tissue characterization and quantification in cancer characterization.

One method for obtaining accurate information about the color of a surface using a RGB digital camera is to use the camera to obtain images while illuminating the surface with spectral light at different wavelengths. . . . If the sensitivity of the sensors of the RGB camera at the wavelengths of the spectral light are known and the intensity of illumination in the different bands of the spectral light are known then the resulting set of images can be processed to determine the spectral reflectance of the surface.

* * *

[T]he invention provides a spectral light source having an embedded (built-in) spectral intensity calibration module combined with a digital camera-based device, for use in multi-spectral imaging and/or true color shade measurements. The spectral light source and calibration module may be provided as an accessory or add-on to the digital camera or may be built-in to the digital camera.

* * *

[T]he invention provides cameras equipped with shutters having surfaces that have a known, preferably flat spectral response. The shutters, may, for example, be coated with a white or grey surface coating. Such shutters may be used to calibrate the cameras . . . [and] built into a camera or added as an accessory.

Id. ¶¶ 3–8, 17–19 (consolidating paragraphs).

Fawzy describes a light source and controllers configured for multi-spectral imaging of tissue in combination with the above calibrating. *See, e.g., id.* ¶¶ 20–25. The Fawzy multispectral imaging system includes: a digital camera having an imaging lens; a spectral intensity calibration module having an electromechanical shutter coated with a lens-facing material of known reflectance (for example, a white or grey coating); a spectral light source configured to illuminate the object or electromechanical shutter in the viewing field of the lens (depending on whether

the shutter is open or closed); and a control module that triggers the light source to emit bands of one or more different wavelengths for image acquisition and synchronizes the light source with the desired shutter position. *Id.* ¶¶ 19–21, 60, 68–69.

Fawzy may comprise multiple LEDs, (for example, an array). *Id.* ¶ 22. The light source outputs light in the visible light or visible and near-infrared spectrums. *Id.* ¶ 71. LEDs may simultaneously output different respective wavelengths bands, e.g., blue, green, and red bands of the visible light spectrum for imaging by an RGB camera. *Id.* ¶¶ 58, 84–85. The LEDs may also output the different respective wavelengths to acquire a corresponding series of multi-spectral images. *Id.* ¶¶ 61–62, 81.

Using such means, the invention illuminates a skin lesion under a plurality of different wavelengths configured to contrast the skin lesion with the surrounding tissue at a respective plurality of different tissue-depths. *Id.* ¶ 89. The contrast images are transformed into two-dimensional, cross-section images of the tissue at different depths. *Id.*

2. *Independent Claim 1*

Petitioner provides arguments and evidence, including the Georgakoudi Declaration, in support of its contention that independent claim 1 is anticipated and obvious over Fawzy. *See* Pet. 62–64; Ex. 1005 ¶¶ 133–140.

Claim 1 first recites, “[a] portable illumination apparatus for facilitating visualizations of tissue.” Petitioner contends “Fawzy discloses or renders obvious a portable illumination apparatus for facilitating visualizations of tissue” by disclosing, for example, “a system that includes a multi-spectral imaging apparatus 200 (e.g., including shutter 104, spectral sampling module 106, and controller 108) and a digital camera 102 (e.g., a smartphone camera).” Pet. 62. Based on the

current record, we find Petitioner's assertion to be sufficiently persuasive and supported to justify institution of review. Ex. 1008 ¶ 63; Ex. 1004 ¶ 137.

Claim 1 next recites, "a portable housing for detachable attachment proximal to an image capturing unit." Petitioner contends "the optical lens systems disclosed by Fawzy are 'aligned with an optical axis of a camera such as a smartphone camera' such that they may 'limit[] the field of view of the camera to the area defined by the distal opening in the housing.' Fawzy, [0021]." Pet. 62–63 (also citing Ex. 1004 ¶ 138) (alteration in original). Based on the current record, we find Petitioner's assertion to be sufficiently persuasive and supported to justify institution of review. Ex. 1008 ¶ 21; Ex. 1004 ¶ 138.

Claim 1 next recites, "an illumination unit comprising one or more narrow band light sources configured to shine m flashes of light on a target area of the tissue at n predetermined wavelengths." Petitioner contends that Fawzy teaches groups of LEDs where each group emits light of a particular wavelength and which is sequentially flashed. Pet. 63. Based on the current record, we find Petitioner's assertion to be sufficiently persuasive and supported to justify institution of review. Ex. 1008 ¶¶ 45, 69, 71, 90; Ex. 1004 ¶ 139.

Claim 1 next recites, "wherein: $n/4 \leq m \leq n$; and m is a number of light flashes in one cycle and n is a number of wavelengths." Petitioner addresses this recitation by referring to Fawzy sequentially illuminating a target with different wavelengths:

Fawzy discloses that the apparatus 200 sequentially illuminates the target 216 to capture a series of images of the target ($It1$ to $It2$), each illumination and image corresponding to a single wavelength ($\lambda1$ to λn). Fawzy, [0074]. In this example, $m=n$. Accordingly, Fawzy discloses that $n/4 \leq m \leq n$ where m is a number of light flashes in one cycle and n is a number of wavelengths.

Pet. 63–64. Based on the current record, we find Petitioner’s assertion to be sufficiently persuasive and supported to justify institution of review. Ex. 1008 ¶¶ 58, 74, 85; Ex. 1004 ¶ 140.

Based on the evidence in the present record, we are persuaded that Petitioner has shown sufficiently, for purposes of this decision, that Fawzy discloses (for anticipation) or teaches or reasonably suggests (for obviousness) all elements of claim 1. Thus, we are persuaded that Petitioner has sufficiently established that Petitioner is more likely than not to prevail in showing that claim 1 is unpatentable under §§ 102 or 103.

3. *Claims 3, 4, 8–11, 13, 17, 18, and 20*

Petitioner accounts for the limitations recited in claims 3, 4, 8–11, 13, 17, 18, and 20. Pet. 64–78. Petitioner provides detailed explanations as to how Fawzy discloses (for anticipation) or teaches or reasonably suggests (for obviousness) the limitations of these claims, citing Dr. Irene Georgakoudi’s declaration for support. *Id.* (citing Ex. 1004).

4. *Conclusion for Grounds 3 and 4*

Based on the evidence in this present record, we are persuaded that Petitioner has shown sufficiently for purposes of this decision that Fawzy discloses, teaches, or reasonably suggests all of the limitations recited in claims 1, 3, 4, 8–11, 13, 17, 18, and 20. Having reviewed Petitioner’s arguments and supporting evidence in the present record, we are persuaded that Petitioner has sufficiently established that Petitioner is more likely than not to prevail in showing that at least claim 1 is unpatentable under §§ 102 or 103 in view of Fawzy.

F. *Grounds 5 through 19*

With the additional grounds, Petitioner accounts for the limitations recited in claims 2, 3, 5–7, 12, 14–16, 18, and 19. Pet. 72–106. Petitioner provides detailed

explanations of how each combination of cited art teaches or reasonably suggests the limitations of the claims associated with each ground, and Petitioner provides a persuasive explanation for combining the teachings of the cited art. *Id.* In addition to the cited references, Petitioner cites Dr. Irene Georgakoudi's declaration for support. *Id.* (citing Ex. 1004); *see also* Ex. 1004 ¶¶ 177–234.

IV. CONCLUSION

For the reasons above, we determine that the information presented in the Petition sufficiently demonstrates that Petitioner would, more likely than not, prevail in showing at least one of the challenged claims is unpatentable. Nothing in this decision should be construed as a final finding or determination with respect to any issue or claim.

V. ORDER

After due consideration of the record before us, and for the foregoing reasons, it is:

ORDERED that, pursuant to 35 U.S.C. § 324, a post-grant review is hereby instituted for claims 1–20 of the '345 patent with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 324(a), a post-grant review of the '345 patent shall commence on the entry date of this Order, and pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

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Patent 11,266,345 B2

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