

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*.

JUDGMENT
Final Written Decision
Granting-in-Part and Denying-in-Part Patent Owner's Non-Contingent Motion to
Amend
35 U.S.C. § 318(a)

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 2. Swift Medical, Inc. (“Patent Owner”) did not file a Preliminary Response (deadline of August 17, 2022). We instituted *inter partes* review of the challenged claims on all asserted grounds. Paper 6. After institution, Patent Owner filed a Non-Contingent Motion to Amend. Paper 8 (“Mot.”). The motion cancels claims 1–20 and moves to substitute the cancelled claims with claims 21–38. *Id.* at 1. A hearing was conducted on August 8, 2023, and a hearing transcript is included in the record. Paper 25. Petitioner opposed the motion to amend. Paper 12 (“Opp.”). We issued preliminary guidance on Patent Owner’s motion. Paper 14. Patent Owner filed a Reply to the Opposition. Paper 15, “Reply.” Petitioner filed a sur-reply. Paper 22, “Sur-Reply”).

Patent Owner moved to withdraw substitute claims 25 and 26. Paper 16. We granted the motion. Paper 19.

We have jurisdiction under 35 U.S.C. § 6. This decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Having reviewed the complete trial record and based on the non-contingency of the motion to amend, we grant-in-part the non-contingent Motion to Amend as to cancelling original claims 1–20 of the ’345 patent. As a result, we do not reach the grounds of unpatentability asserted in the Petition against these original claims.

We also deny-in-part the Motion to Amend as to adding proposed substitute claims to the ’345 patent because Petitioner has proven by a preponderance of the evidence that proposed substitute claims 21–24 and 27–38 of the ’345 patent are unpatentable.

A. Related Matters

Petitioner states “[t]here are currently no litigation matters that could be affected by a decision in this proceeding.” Pet. 1. Patent Owner similarly states “[t]here are currently no litigation matters that could be affected by a decision in this proceeding.” Paper 4, 1 (Patent Owner’s Mandatory Notices).

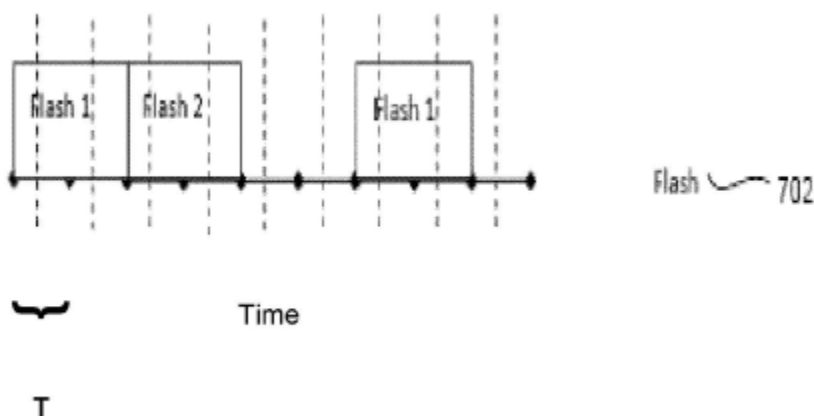
B. The ’345 Patent

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.* at 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

The non-contingent motion to amend proposes three independent claims, claims 21, 28, and 32. Claims 21, 28, and 32 are respectively directed to an apparatus, system, and method. Claim 21 is illustrative and reproduced below:

21. A portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising:
- a portable housing defining an aperture extending through the portable housing, wherein the portable housing is for detachable attachment proximal to an image capturing unit;
 - an emission filter covering the aperture, wherein the emission filter is selected from;
 - a long pass filter with a cut-on wavelength of 450 ± 25 nm; or
 - a bandpass filter allowing transmission through the emission filter in the 425-750 nm wavelength range and having a lower cut-on wavelength of 450 ± 25 nm; and
 - an illumination unit comprising one or more narrow band light sources positioned around the aperture and 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;
 - each of the m flashes has an identical duration equal to $50x$ milliseconds, wherein x is a whole number; and
 - each of the m flashes are performed consecutively.

Mot. Appendix A, ii–iv.

D. Asserted Grounds

Petitioner asserts that claims 21–24 and 27–38 are unpatentable on the following grounds. Opp. 1–2.

	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
20A	21, 23, 24, 28–32, 37	103	Fawzy ¹ , Petit ² , Brunk ³ , Cross ⁴
20B	21, 23, 24, 28–32, 34, 36–38	103	Fawzy, DaCosta ⁵ , Brunk, Cross
21	22	103	Fawzy, Petit or DaCosta, Brunk, Cross, Polidor ⁶
22	27	103	Fawzy, Petit or DaCosta, Brunk, Cross, O’Neill ⁷
23	33, 35	103	Fawzy, Petit or DaCosta, Brunk, Cross, Garcia ⁸
24	36, 38	103	Fawzy, Petit or DaCosta, Brunk,

¹ Ex. 1008, Fawzy, U.S. Patent Application Publication 2018/0188108 A1, July 5, 2018 (“Fawzy”). Petitioner incorrectly identifies this exhibit as Exhibit 1007, and similarly identifies some other exhibit numbers incorrectly when identifying asserted grounds. Opp. 2.

² Ex. 1020, Petit, et al., International Patent Publication WO 2019/092509 A1, November 12, 2018 (“Petit”). We note that Petit incorporates U.S. Provisional Patent Application No. 62/584,404, filed November 10, 2017, by reference. Ex. 1020 ¶ 1; *see also* Ex. 1021 (provisional application).

³ Ex. 1022, Brunk et al., U.S. Patent Application Publication 2016/0187199 A1, June 3, 2016 (“Brunk”).

⁴ Ex. 1006, Cross et al., U.S. Patent Application Publication 2019/0216326 A1, July 18, 2019 (“Cross”).

⁵ Ex. 1014, DaCosta, U.S. Patent Application Publication 2017/0236281 A1, Aug. 17, 2017 (“DaCosta”).

⁶ Ex. 1010, Polidor et al., U.S. Patent No. 5,690,417, Nov. 25, 1997 (“Polidor”).

⁷ Ex. 1011, O’Neill et al., U.S. Patent Application Publication 2015/0042877 A1, Feb. 12, 2015 (“O’Neill”).

⁸ Ex. 1012, Garcia, U.S. Patent No. 9,696,897 B2, July 4, 2017 (“Garcia”).

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E. Testimony

Petitioner relies on declaration testimony of Dr. Irene Georgakoudi, Ph.D. (Ex. 1004, “the Georgakoudi Declaration”; Ex. 1025, “the supplemental Georgakoudi Declaration”). Opp. *passim*; Ex. 1004; Ex. 1025. Patent Owner relies on the declaration testimony of Dr. Milan Sonka. Mot. 1; Ex. 2001 (“the Sonka Declaration”).

II. ELIGIBILITY FOR POST-GRANT REVIEW

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

⁹ Ex. 1023, Krieger et al., U.S. Patent Application Publication 2015/0145966 A1, May 28, 2015 (“Krieger”).

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 established by a preponderance of the evidence that proposed claims 21–24 and 27–38 are unpatentable 35 U.S.C. § 103.

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.*

Patent Owner argues that “a bachelor's degree in engineering is not necessary and a degree in physics and/or optics would also provide relevant coursework to provide a person with ordinary skill in the art.” Mot. 3. Patent Owner also argues that Petitioner's suggestion of “*at least* two years of work experience” is unclear.

Based on the record as a whole with emphasis on the technical level the '345 patent's disclosure and asserted prior art, we agree with Patent Owner that a degree in physics and/or optics rather than engineering could be sufficient. We disagree, however, that "at least two years work experience" is unclear. "At least two years work experience" refers to two or more years of experience working in the field of design, operation, and functioning of imaging systems.

We, thus, determine that 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, physics, or optics 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))).

We also note that our decision here would be the same under either party's asserted level of ordinary skill in the art.

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)).

In the Petition, 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.

In the Motion to Amend, Patent Owner argues that no express constructions are required. Mot. 3. When opposing the Motion to Amend, Petitioner agrees that “no explicit construction is necessary when applying the prior art presented.” Opp. 4–5.

For purposes of this decision, we determine that express claim construction is unnecessary. Our decision here would be the same whether based on plain and ordinary meaning or based on the various alternatives Petitioner presents when addressing claim construction. Pet. 9–14.

C. Obviousness Law

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. Burden on Motion to Amend

The patent owner does not bear the burden of persuasion to demonstrate patentability of substitute claims presented in a motion to amend. *Lectrosonics, Inc., v. Zaxcom, Inc.*, IPR2018-01129, IPR2018,01130, Paper 15, 4 (PTAB Feb.

25, 2019) (precedential). Rather, “the burden of persuasion ordinarily will lie with the petitioner to show that any proposed substitute claims are unpatentable by a preponderance of the evidence.” *Id.* Moreover, the Board may determine whether substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record. *Id.*

E. Weight Afforded to Declarations of Dr. Georgakoudi

Patent Owner argues that the declaration of Dr. Georgakoudi is nearly a word-for-word copy of Petitioner’s arguments presented in its Opposition. Reply 1–2. Patent argues that Dr. Georgakoudi’s testimony, thus, should be given no weight. *Id.* To support its position, Patent Owner cites, for example, the Director’s decision in Reply 1 (citing *Xerox Corp. v. Bytemark, Inc.*, No. IPR2022-00624, Paper 12, 5 (PTAB Feb. 10, 2023)).

In *Xerox*, the Director held that the Board correctly gave little weight to the Petitioner’s expert where “the expert declaration merely offered conclusory assertions without underlying factual support and repeated, *verbatim*, Petitioner’s conclusory arguments.” *Xerox Corp.*, No. IPR2022-00624, Paper 12 at 5. The declaration at issue in *Xerox* did “not provide any technical detail, explanation, or statements supporting *why* the expert determines that the feature in question was required or would have been obvious based on the prior art disclosure.” *Id.* Moreover, “[t]he declaration set[] forth Petitioner’s conclusory assertions as though they are facts, rather than setting forth facts and evidence in support of Petitioner’s assertions.” *Id.*

The matter now before us is distinguishable from *Xerox*. As we explain below, Petitioner establishes unpatentability of the amended claims by extensively citing evidence including the prior art at issue. Petitioner and Dr. Georgakoudi properly map the Patent Owner’s amended claims to the explicit teachings of the

asserted art. Sur-Reply 1–2. Thus, the position of Petitioner and Dr. Georgakoudi is not unduly conclusory. Rather, Dr. Georgakoudi’s testimony is generally credible because it is consistent with and tied closely to the teachings of the cited art. Thus, when choosing whether or not to cite Dr. Georgakoudi’s testimony and consider whether or not it is credible with respect to any given issue, we do so while considering the record as a whole.

F. Ground 20A: Fawzy, Petit, Brunk, and Cross

For ground 20A, Petitioner asserts that proposed claims 21, 23, 24, 28–32, and 37 are obvious over Fawzy, Petit, Brunk, and Cross. Opp. 6–17. Below, we first provide an overview of the asserted art. We then assess motivation to combine with reasonable expectation of success. Then we address independent claim 21. Finally, we address 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. Overview of *Petit*

Petit teaches a lighting and filtering device that emits at multiple wavelengths to capture an image of a patient's illuminated skin. Ex. 1020, (57), ¶ 96. Petit teaches that its device may monitor a wide range of dermatological conditions. *Id.* ¶ 88. Petit teaches light filter 45 configured to be disposed in front of a lens of the camera. *Id.* ¶ 97. The light filter 45 can be a band-pass filter in a range of 550 nm and 750 nm or a long-pass filter configured to attenuate light that is less than a predetermined wavelength in a range of 400 nm to 450 nm. *Id.* ¶¶ 98, 99.

3. Overview of *Brunk*

Brunk teaches an “image capture device, such as a smartphone or point of sale scanner, is adapted for use as an imaging spectrometer, by synchronized

pulsing of different LED light sources as different image frames are captured by the image sensor.” Ex. 1022, (57). Brunk explains that “by illuminating a scene with several different brief . . . light sources, even a common Bayer pattern CMOS camera can effectively become an image spectrometer.” *Id.* ¶ 6. Brunk teaches that the imaging apparatus may, in a sample application, be used for medical applications including diagnosing “normal versus abnormal” tissue through spectral analysis. Ex. 1022 ¶ 171. Brunk teaches that flash duration is consecutive and identical, for example, in providing an illustrative example of four sequential flashes of different wavelengths taken at 30 Hz over two fifteenths of a second period. *Id.* ¶¶ 101, 139, Fig. 8.

4. *Overview of Cross*

Cross teaches “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.

5. *Reason to Combine*

We first address the combination of Petit and Fawzy. Petitioner argues that it would have been obvious to a person having ordinary skill in the art to combine Petit's long pass filter with Fawzy's imaging apparatus. Opp. 8. Petitioner's argument is supported by a preponderance of the evidence. Both Fawzy and Petit teach devices for capturing and analyzing images of dermatological conditions based on light wavelengths reflecting off a patient's skin. *Id.* (citing Ex. 1008 ¶¶ 89, 92; Ex. 1020 ¶ 88). The preponderance of evidence supports that a person of ordinary skill in the art would have understood that emission filters, such as those taught by Petit, are a well-known mechanism to predictably filter out wavelengths of light that are not relevant to the imaging at hand. *Id.* (citing Ex. 1020 ¶ 87). A person of ordinary would have understood that filtering out undesired wavelengths could avoid undesired interference. *Id.* at 8–9 (citing Ex. 1008 ¶¶ 44, 80).

Petit teaches a long-pass filter having a cut-on wavelength of 450 ± 25 nm. Ex. 1020 ¶ 98. Such a filter would be helpful in accomplishing Fawzy's goal of

“control[ling] optical coupling of the digital camera to capture only reflected light originating from the interaction of light from the spectral light source with an object being imaged.” Ex. 1008 ¶ 107. The combination would also be helpful for determining effective treatment as Petit teaches. Ex. 1020 ¶ 87. As such, we determine that a person having ordinary skill in the art would have had reason to combine Petit’s long pass filter with Fawzy’s imaging apparatus and would have had a reasonable expectation of success in making the combination.

Patent Owner argues that Petitioner had not adequately explained why a person having ordinary skill in the art “would have modified Fawzy’s *reflectance*-based imaging system with Petit’s filter for capturing *fluorescence* signals.” Reply 2–3. Patent Owner argues that Fawzy and Petit are different imaging technologies. *Id.* at 3. Patent Owner argues that Fawzy describes a camera device that seeks to “accurately characterize the color of an object based on its spectral reflectivity.” *Id.* (citing Ex. 1008 ¶¶ 3, 16, 45; Ex. 2003 ¶¶ 55–58). Patent Owner further argues that combining Petit’s filter with Fawzy would not enable a user to determine effective treatment without also adding a short-wavelength light source to excite certain bacteria to fluoresce. *Id.* (citing Ex. 2003 ¶¶ 61–62).

Petitioner, however, persuasively argues that combining reflectance-based and fluorescence-based systems was known at the time of and prior to the invention and was a predictable combination that a person of ordinary skill in the art would have had reason to pursue. Sur-Reply 3 (citing Ex. 1001, 6:34–37, 18:49–53; Ex. 1026, 30:22–36:9, 37:3–39:2, 42:25–47:6; Ex. 1014 ¶¶ 7, 60). Moreover, the evidence supports that a short-wavelength light at 400–405 nm would excite biological tissues to produce fluorescent light and that Fawzy’s light source emits light in the 400–405 nm range. *Id.* (citing Reply 10; Ex. 2003 ¶ 92; Ex. 1008 ¶ 89, 90). Fawzy teaches that different wavelengths can be used to

produce and analyze different illumination effects. Ex. 1008 ¶¶ 44, 71, 80, 89, 90. For example, Fawzy explains that it may use groups of LEDs where each group of LEDs “emits light of a particular wavelength.” *Id.* at ¶ 71. Fawzy also teaches use of a filter. *Id.* ¶ 80 (“Light reflected from the shutter 358 is filtered through tunable filters or acousto-optic filters 256 to produce light of discrete wavelengths.”). Given the combined teachings of Fawzy and Petit, a person having ordinary skill in the art would have understood that Fawzy’s light source would cause fluorescent light emissions and would have understood that filtering unwanted light would be helpful in assessing those emissions. *Id.* (citing Reply 10; Ex. 2003 ¶ 92; Ex. 1020 ¶ 98; Ex. 2003 ¶¶ 92–94). The preponderance of the evidence further supports that Petit’s filter, when combined with Fawzy, would help determine effective patient treatment. Sur-Reply 4 (citing Ex. 1020 ¶ 87; Ex. 1025 ¶¶ 22–24).¹⁰

We next address the combination of Fawzy, Brunk and Cross. All three references are directed to an attachment unit for a camera of a mobile device such as a smart phone. Opp. 15; Ex. 1008 (57); Ex. 1022 ¶ 180; Ex. 1006 ¶ 63, Fig. 4A–4D. Fawzy acknowledges spectral sensitivities and the need to “deal with” ambient light. Ex. 1008 ¶¶ 18, 49; Ex. 1025 ¶ 42. Brunk teaches optimizing flash duration / exposure time in order to address ambient light. Ex. 1022 ¶¶ 166, 168; Ex. 1025 ¶ 44. Cross teaches that its device may be used with an LG Nexus 5 which is programmed to drop frame rate to as low as 20 fps (which is equivalent to 50 ms exposure time). Ex. 1006, Fig. 8 (illustrating use of Nexus 5 camera with Cross); Ex. 1017 (illustrating LG Nexus 5 camera with features matching Cross Figure 8);

¹⁰ Also, although DaCosta is not part of Ground 20A, the DaCosta reference factually evidences that there is no conflict with using reflectance imaging and tissue fluorescence in combination. Ex. 1014 ¶ 60 (its imaging device “may utilize a combination of white light, tissue fluorescence, and reflectance imaging”).

Ex. 1024, 2 (Ferenczi article evidences Nexus 5 ability to drop frame rate to 20 fps in low light); Ex. 1025 ¶ 45. Fawzy, Brunk, and Cross also teach that acquisition time may be “synchronized” with illumination time. Ex. 1008 ¶¶ 19–20, 22, 64; Ex. 1025 ¶ 46.

Patent Owner argues that Brunk and Cross teach away from a 50 ms exposure time and 50x ms flash duration. Reply 5–6. Patent Owner provides evidence that Brunk and Cross use short exposure times to minimize the effect of ambient lighting. *Id.* (citing Ex. 1022¹¹ ¶¶ 101, 139, 161, 166; Ex. 2003 ¶ 64, 66–70, 73, 77–78). Patent Owner further argues that while the LG Nexus 5 “*may* use a 20 fps frame rate,” a person having ordinary skill in the art would not use this frame rate in conjunction with Cross. *Id.* at 6–7 (citing Ex. 2003 ¶ 70, 72–76; Ex. 1024, 1, 2).

We do not agree that Brunk or Cross teaches away from a 50 ms exposure time or 50x ms flash duration. A reference may teach away if a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. *Allied Erecting and Dismantling, Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1382 (Fed. Cir. 2016) (holding that reference did not militate against combining references’ teachings where it merely “express[ed] doubt as to whether [claimed movable jaws were] an *optimal* design feature”). Here, Brunk merely provides an example where a lower exposure time may be used to minimize ambient light. Ex. 1022 ¶ 166. Brunk does not teach that ambient light should be minimized in every situation; rather, Brunk read as a

¹¹ When addressing this issue, Patent Owner provides a number of cites to Exhibit 1020 (Petit). Reply 5–6. It appears that this is a typographical error, and Patent Owner intended to cite Exhibit 1022 (Brunk).

whole suggests that exposure time and flash duration should be adjusted depending on particular conditions. *Id.* ¶¶ 166 (teaching short exposure time “presum[ing] a pretty bright LED source”), 168 (teaching using measurement of ambient light “to adjust correction factors to compensate for the contribution of this ambient light”).

The teachings of Cross reinforce that, in at least some circumstances, a person of ordinary skill in the art would want to use a longer exposure time and flash duration. Cross teaches use of the LG Nexus 5 phone camera. Ex. 1006, Fig. 8; Ex. 1017; Ex. 1025 ¶ 45. The evidence supports that the LG Nexus 5 uses a longer exposure time in low light conditions. Ex. 1024 ¶ 2 (“In low light, the Nexus 5 drops its frame rate to as low as 20 fps, presumably to allow for slower shutter speeds.”). In low light, consistent with Brunk, there would be less of a need to compensate for contribution of ambient light such that a longer exposure and flash time would be appropriate. Ex. 1022 ¶ 168. Patent Owner argues that Cross teaches a flash with high powered LEDs such that the 20 fps setting would not be necessary (Reply 7 (citing Ex. 2003 ¶¶ 74–76)), but this argument lends support to Petitioner’s core argument that a person having skill in the art would know to adjust exposure and flash time as necessary to achieve desired results given the available conditions.

Patent Owner also argues that Petitioner did not articulate a reason to combine all four references. Opp. 8–9. In particular, Patent Owner argues that Petitioner did not adequately explain why a person having ordinary skill in the art would want to employ Petit’s filter with Fawzy while also setting a flash duration to 50x ms. *Id.* (citing, for example, Ex. 1025 ¶¶ 41–47; Ex. 2003 ¶¶ 82, 84–87). As explained above, however, Petitioner establishes by a preponderance of the evidence that a person having ordinary skill in the art would have had reason to combine Petit’s filter with Fawzy with reasonable expectation of success.

Petitioner also establishes that a person having skill in the art would have known to adjust flash duration as necessary based on conditions and desired result. Reaching an appropriate flash duration would have been a matter of routine optimization even when a filter is employed. Sur-Reply 11–12 (citing Ex. 2003 ¶ 85).

Based on the above, we determine that a person having ordinary skill in the art would have had reason to combine the teachings of Fawzy, Brunk, and Cross and, based on those teachings, a person of ordinary skill in the art would have understood that flash and acquisition duration and timing could be adjusted to address ambient light including, if desired, employing a LG Nexus 5 with 50 ms flash duration and exposure time or otherwise employing a 50 ms flash duration and exposure time. A person of ordinary skill in the art would have had a reasonable expectation of success in employing Fawzy with a 50 ms flash duration.

6. *Independent Claim 21*

Petitioner provides arguments and evidence, including the supplemental Georgakoudi Declaration, to support its contention that independent claim 21 is obvious over Fawzy, Petit, Brunk, and Cross. *See* Pet. Opp. 5–14; Ex. 1025 ¶¶ 19–37.

Claim 21[pre]¹² recites, “[a] portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising.” To the extent claim 21’s preamble is limiting, Petitioner contends that Fawzy discloses this recitation. Pet. 62; Opp. 6 (explaining that Ground 20A relies on Fawzy in a manner similar to Ground 3 of the Petition). The preponderance of the evidence supports that Fawzy teaches or suggests this recitation. Ex. 1008, Figs. 1A, 2A, ¶¶ 63, 78, 88; Ex. 1004 ¶ 137.

¹² For clarity of presentation, we refer to claim elements using the same notion as Patent Owner. Mot., App. A., ii.

Claim 21[a] recites “a portable housing defining an aperture extending through the portable housing, wherein the portable housing is for detachable attachment proximal to an image capturing unit.” Petitioner contends that Fawzy discloses this recitation. Pet. 83 (addressing this recitation in the context of originally filed claim 5); Opp. 10. The preponderance of the evidence supports that Fawzy teaches or suggests this recitation. Ex. 1008, Fig. 2A, ¶45, claim 11.

Claim 21[b] recites “an emission filter covering the aperture, wherein the emission filter is selected from.” Petitioner contends that Fawzy discloses this recitation. Opp. 6–7. The preponderance of the evidence supports that Fawzy teaches or suggests this recitation. For example, Fawzy teaches “an optical lens system with an optical axis of a camera such as a smartphone camera . . . wherein the lens is arranged to control optical coupling of the digital camera to capture only reflected light originating from the interaction of light from the spectral light source with an object being imaged” and also discloses that the system may include “tunable or acousto-optic filters 356” to filter light reflected from a target surface. Ex. 1008 ¶¶ 21, 80, claim 14. Also, as explained below, the preponderance of the evidence supports that Petit teaches such a reference.

Claim 21[c] and claim 21[d] recite “a long pass filter with a cut-on wavelength of 450 ± 25 nm; or a bandpass filter allowing transmission through the emission filter in the 425–750 nm wavelength range and having a lower cut-on wavelength of 450 ± 25 nm.” This claim language requires the recited long pass filter *or* the recited bandpass filter; not both. Petitioner contends that Petit teaches a device for monitoring skin conditions that includes light filter 45 that can be a band-pass filter in a range of 550–750 nm or a long-pass filter that attenuates light at a wavelength of less than 400 nm to 450 nm. Opp. 7–8. A preponderance of the evidence supports Petitioner’s position. Ex. 1020 ¶ 98; Ex. 1021 ¶ 72; Ex.

1025 ¶ 22. Also, as we explain above in III.F.5, Petitioner adequately establishes that it would have been obvious to use Petit’s filters with Fawzy’s system.

Claim 21[e] recites “an illumination unit comprising one or more narrow band light sources positioned around the aperture and configured to shine m flashes of light on a target area of the tissue at n predetermined wavelengths..” Petitioner contends that Fawzy discloses this recitation. Pet. 83; Opp. 10, 20. A preponderance of the evidence supports that Fawzy teaches or suggests this recitation. Ex. 1008, Fig. 2A, ¶ 45, claim 11; Ex. 1025 ¶ 27.

Claim 21[f] recites “ $n/4 \leq m \leq n$; 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 (λ_1 to λ_n). 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; Opp. 10–11. A preponderance of the evidence supports Petitioner’s position. Ex. 1008 ¶¶ 58, 74, 80–81, 85; Ex. 1004 ¶ 140.

Claim 21[g] recites “each of the m flashes has an identical duration equal to 50x milliseconds, wherein x is a whole number.” Petitioner argues that Fawzy teaches pulsed signals which would be of identical duration as recited. Opp. 11–12. A preponderance of the evidence supports Petitioner’s position. Ex. 1008 ¶¶ 45, 70, 81, 84; Ex. 1025 ¶¶ 30–31.

Petitioner admits that Fawzy does not explicitly disclose the duration of flashes being 50x milliseconds where x is a whole number. Opp. 11. Petitioner argues that Brunk teaches a device similar to Fawzy. Opp. 11–12. Petitioner argues

that Brunk teaches that “flash and frame duration can be varied depending on the intensity of the flashes with respect to ambient light conditions.” *Id.* at 12.

Petitioner argues that Brunk teaches a method of “leverag[ing] light measurement devices to measure ambient light, and then uses the measurement to adjust correction factors to compensate for this ambient light in spectral measurements.” *Id.* (quoting Ex. 1022 ¶ 168). Brunk teaches, for example, that strobing the light can make effects of ambient light negligible. Ex. 1022 ¶¶ 112, 114; Ex. 1025 ¶ 34. A preponderance of the evidence supports Petitioner’s position. Ex. 1022, Abstract, ¶¶ 101, 112, 114, 139, 166, 168, 171, Fig. 8; Ex. 1025 ¶ 32–34.

Petitioner further argues that Cross teaches an imaging device with a light source module configured to generate light at discrete wave lengths. Petitioner argues that Cross Figure 8 depicts a LG Nexus 5 smartphone and further argues that the LG Nexus 5 is programmed to, in low light, use a 50 ms exposure time (corresponding to a 20 fps frame rate). A preponderance of the evidence supports Petitioner’s position. Ex. 1006, Fig. 8, ¶¶ 142; Ex. 1017 (article reviewing LG Nexus 5 and providing a picture corresponding to picture in Cross Figure 8); Ex. 1024, 2 (Ferenczi teaching that Nexus 5 can employ a 20 fps frame rate in low light); Ex. 1025 ¶ 35.

The preponderance of the evidence, as we identify above, supports that a person of ordinary skill in the art would have understood, based on the combined teachings of Brunk and Cross, that flash duration may be adjusted to adjust for ambient lighting conditions and to improve capture of desired information. Flash duration is, thus, a result effect variable, and the particular recitation of a 50x milliseconds flash duration would have been obvious. *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (“where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

experimentation.”); *see also In re Boesch*, 617 F.2d 272, 276 (CCPA 1980) (“[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.”). The 50x millisecond flash duration is also obvious as taught by Cross’s use of the LG Nexus 5 smartphone.

Claim 21[h] recites “each of the m flashes are performed consecutively.” Petitioner argues that Fawzy teaches turning off a first spectral light and turning on a spectral light with the same trigger signal in a flash sequency and that this operation produces flashes “consecutively” as claimed. Opp. 10–11. A preponderance of the evidence supports that Fawzy teaches or suggests this recitation. Ex. 1008, ¶ 81, 84; Ex. 1025 ¶ 28–29.

To summarize, Petitioner has shown by a preponderance of the evidence that the combined teachings of Fawzy, Petit, Brunk, and Cross teach or reasonably suggest all of the elements of claim 21 in the manner claim 21 recites. Thus, we are persuaded that Petitioner has established by a preponderance of the evidence that the combination of Fawzy, Petit, Brunk, and Cross renders claim 21 obvious.

7. *Claims 23–24, 28–32, and 37*

Claims 28 and 32 are independent claims directed to a “tissue imaging system” having “an illumination unit” (claim 28) and “[a] method for generating visualizations of tissue” (claim 32). To the extent the recitations of these two claims are substantially the same as the recitations of claim 21, Petitioner adequately accounts for the recitations for the reasons explained above. To the extent the recitations are different, Petitioner adequately accounts for the recitations. Petitioner provides a detailed explanation as to how Fawzy, Petit, Brunk, and Cross disclose, teach, or suggest the limitations of these claims and why it would have been obvious to combine those teachings with a reasonable

expectation of success, citing Dr. Georgakoudi's two declarations for support. Pet. 60–64, 66–70, 71–77; Opp. 6–17; Ex. 1004; Ex. 1025.

Claims 23–24, 29–31, and 37 correspond to originally filed claims 3, 4–6, 10–13, and 21. Mot. 23–24. Petitioner adequately accounts for the recitations of these claims by, in the Petition and Opposition, accounting for the independent claims these claims depend from and by, in the Petition, accounting for the recitations of the dependent claims. Petitioner provides a detailed explanation as to how Fawzy, Petit, Brunk, and Cross disclose, teach, or suggest the limitations of these claims and why it would have been obvious to combine those teachings with a reasonable expectation of success, citing Dr. Georgakoudi's two declarations for support. Pet. 60–64, 66–70, 71–77; Opp. 6–17; Ex. 1004; Ex. 1025.

We are persuaded that Petitioner has demonstrated that all of the limitations recited in claims 23–24, 29–31, and 37 would have been obvious over Fawzy, Petit, Brunk, and Cross. Patent Owner provides no arguments regarding these claims outside of the arguments discussed above. *See generally* Reply. Having reviewed Petitioner's arguments and supporting evidence, we are persuaded that Petitioner has established by a preponderance of the evidence that claims 23–24, 29–31, and 37 are unpatentable under § 103(a) over Fawzy, Petit, Brunk, and Cross.

G. Ground 20B: Fawzy, DaCosta, Brunk, and Cross

For ground 20B, Petitioner asserts that proposed claims 21, 23, 24, 28–32, 34, and 36–38 are obvious over Fawzy, DaCosta, Brunk, and Cross. Opp. 6–17. Below, we first provide an overview of DaCosta. We then assess motivation to combine the references with a reasonable expectation of success. Then we address independent claim 21. Finally, we address other independent and dependent claims collectively.

1. Overview of DaCosta

DaCosta teaches a similar imaging device designed to collect and analyze data for diagnostic purposes. Ex. 1014 (54), (57). DaCosta teaches that the device is intended for dermatology in evaluating and tracking bacterial load in a wound over time (*id.* ¶ 2) and provides examples of detecting common bacteria in typical wounds using a dual emission band (450-505 nm and 590-650 nm) emission filter. *Id.* ¶¶ 116, 136, 137.

2. Reason to Combine

Petitioner argues that Fawzy and DaCosta or both are directed to telemedicine and wound care. Opp. 18. Petitioner argues that DaCosta teaches that detecting fluorescence elicited from a wound using different wavelengths of light may be useful in detecting bacteria and infection. *Id.* (citing Ex. 1014 ¶ 70). A person of ordinary skill in the art would have had reason to combine DaCosta's filter in combination with Fawzy's imaging apparatus in order to allow early recognition of high-risk wounds and identification of factors underlying wound healing. Opp. 19; Ex. 1014 ¶¶ 3, 46; Ex. 1025 ¶ 55. Also, such a filter would be helpful in accomplishing Fawzy's goal of "control[ling] optical coupling of the digital camera to capture only reflected light originating from the interaction of light from the spectral light source with an object being imaged." Ex. 1008 ¶ 21.

Patent Owner argues that Petitioner has not shown a motivation to combine Fawzy and DaCosta. Reply 10–11. In particular, Patent Owner argues that DaCosta describes an "autofluorescence detection and collection device" and uses a filter to block excitation light. *Id.* (citing, for example, Ex. 1014 (57), ¶ 47; Ex. 2003 ¶¶ 90–96). Patent Owner further argues that a person of skill in the art would not have been motivated to use DaCosta's filter with Fawzy and that Petitioner does

not adequately establish that this modification would provide alleged benefits. *Id.* (citing Ex. 2003 ¶¶ 94–95).

The preponderance of the evidence, however, establishes that a person of ordinary skill in the art would have understood, as we explain above when addressing Ground 20A, that Fawzy teaches that it may emit light that would elicit a fluorescent response. Ex. 1008 ¶¶ 44, 71, 80, 89, 90; Ex. 2003 ¶ 92. DaCosta teaches that observing the fluorescent response of a wound is beneficial. Ex. 1014 (57) (explaining that bacterial autofluorescence data may be used to track changes in bacterial load), ¶ 46 (“Precise identification of the systemic, local, and molecular factors underlying the wound healing problem in individual patients may allow better tailored treatments.”); ¶¶ 51–52 (explaining how device may be used to provide various useful indications and wound imaging). Moreover, DaCosta explicitly teaches that its imaging device “may utilize a combination of white light, tissue fluorescence, and reflectance imaging.” Ex. 1014 ¶ 60. Based on the combined teachings of Fawzy and DaCosta, a person of ordinary skill in the art would have understood that DaCosta’s filter could be usefully combined with Fawzy to allow the device to filter out unwanted light and better analyze fluorescent response.

For the reasons above, we determine that a person having ordinary skill in the art would have had reason to combine DaCosta’s filter with Fawzy’s imaging apparatus and would have had a reasonable expectation of success in making the combination.

Patent Owner also argues that the cited references do not disclose or teach a flash timing and exposure time of 50x ms. Reply 11. Our analysis is the same as we explain above when addressing Ground 20A.

Patent Owner also argues that Petitioner does not articulate a reason to combine all four references. Reply 11–12. Again, our analysis is the same as we explain above when addressing Ground 20A. Moreover, DaCosta teaches that fluorescent imaging might be conducted with low ambient light. Ex. 1014 ¶ 88 (“Room lights ... were turned off during FL [fluorescent] imaging.”). The use of low ambient light would encourage use of a longer flash and exposure times. *See, e.g.*, Ex. 1024, 2 (explaining that LG Nexus 5 drops frame rate in low light “to allow for slower shutter speeds”).

3. *Claim 21*

To the extent Petitioner’s position regarding claim 21 relies on Fawzy, Brunk, and Cross, the position is supported by the preponderance of the evidence for the for the reasons we explain when addressing Ground 20A. Opp. 17–20.

Claim 21[b] recites “an emission filter covering the aperture, wherein the emission filter is selected from.” Petitioner contends that Fawzy discloses this recitation. Opp. 6–7. The preponderance of the evidence supports that Fawzy teaches or suggests this recitation. For example, Fawzy teaches “an optical lens system with an optical axis of a camera such as a smartphone camera . . . wherein the lens is arranged to control optical coupling of the digital camera to capture only reflected light originating from the interaction of light from the spectral light source with an object being imaged” and also discloses that the system may include “tunable or acousto-optic filters 356” to filter light reflected from a target surface. Ex. 1008 ¶¶ 21, 80, claim 14. Also, as explained below, the preponderance of the evidence supports that DaCosta renders such a filter obvious.

Claim 21[c] and claim 21[d] recite “a long pass filter with a cut-on wavelength of 450 ± 25 nm; or a bandpass filter allowing transmission through

the emission filter in the 425–750 nm wavelength range and having a lower cut-on wavelength of 450 ± 25 nm.” This claim language requires the recited long pass filter *or* the recited bandpass filter; not both. Petitioner contends that DaCosta teaches an imaging device for collecting and analyzing data for diagnostic purposes. Opp. 17. Petitioner contends that DaCosta teaches a dual emission band (450-505 nm and 590-650 nm) emission filter which is a bandpass filter within the claimed 425-750 nm wavelength range. Opp. 17–18. A preponderance of the evidence supports Petitioner’s position. Ex. 1014, (54), (57), ¶¶ 92, 116, 136–137; Ex. 1025 ¶ 50. Also, as we explain above, Petitioner adequately establishes that it would have been obvious to use DaCosta’s filters with Fawzy’s system.

4. *Claim 23, 24, 28–32, 34, 36–38*

Claims 28 and 32 are independent claims directed to a “tissue imaging system” having “an illumination unit” (claim 28) and “[a] method for generating visualizations of tissue” (claim 32). To the extent the recitations of these two claims are substantially the same as the recitations of claim 21, Petitioner adequately accounts for the recitations for the reasons explained above. To the extent the recitations are different, Petitioner adequately accounts for the recitations. Petitioner provides a detailed explanation as to how Fawzy, DeCosta, Brunk, and Cross disclose, teach, or suggest the limitations of these claims and why it would have been obvious to combine those teachings with a reasonable expectation of success, citing Dr. Georgakoudi’s two declarations for support. Pet. 60–64, 66–70, 71–77; Opp. 6–17; Ex. 1004; Ex. 1025.

Claims 23, 24, 29–31, 36 and 37 correspond to originally filed claims 3–4, 9, 11, 12, 17, and 20. Mot. 23–24. Claim 38 is new. *Id.* at 24. Petitioner adequately accounts for the recitations of these claims. Petitioner provides a detailed explanation as to how Fawzy, DeCosta, Brunk, and Cross disclose, teach, or

suggest the limitations of these claims and why it would have been obvious to combine those teachings with a reasonable expectation of success, citing Dr. Georgakoudi's two declarations for support. Pet. 60–66, 70, 78; Opp. 20–23; Ex. 1004; Ex. 1025.

We are persuaded that Petitioner has demonstrated that all of the limitations recited in claims 23, 24, 28–32, 34, 36–38 would have been obvious over Fawzy, DeCosta, Brunk, and Cross. Patent Owner provides no arguments regarding these claims outside of the arguments discussed above. *See generally* Reply. Having reviewed Petitioner's arguments and supporting evidence, we are persuaded that Petitioner has established by a preponderance of the evidence that claims 23, 24, 28–32, 34, 36–38 are unpatentable under § 103(a) over Fawzy, DeCosta, Brunk, and Cross.

H. Grounds 21–24

Petitioner additionally uses various references to address dependent claims. In particular, Petitioner relies on Polidor to address claim 21, O'Neill to address claim 27, Garcia to address claims 33 and 35, and Krieger to address claims 36 and 38. Opp. 2. Petitioner adequately accounts for the recitations of these claims. Petitioner provides a detailed explanation as to how the cited references disclose, teach, or suggest the limitations of these claims and why it would have been obvious to combine those teachings with a reasonable expectation of success, citing Dr. Georgakoudi's two declarations for support. Pet. 60–78, 83–104; Opp. 23–25; Ex. 1004; Ex. 1025. Patent Owner does not provide substantive arguments addressing these grounds aside from the Ground 20A and Ground 20B arguments addressing the independent claims. Reply 12.

We are persuaded that Petitioner has demonstrated that all of the limitations recited in claims 21, 27, 33, 35, 36, and 38 would have been obvious over the cited

references. Patent Owner provides no arguments regarding these claims outside of the arguments discussed above. *See generally* Reply. Having reviewed Petitioner’s arguments and supporting evidence, we are persuaded that Petitioner has established by a preponderance of the evidence that claims 21, 27, 33, 35, 36, and 38 are unpatentable under § 103(a) over the cited references of Grounds 21 through 24.

IV. CONCLUSION

Petitioner’s original challenges to these claims, summarized below, are moot.

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 4–13, 17, 20	102	Cross		
1, 4–13, 17, 20	103	Cross		
1, 3, 4, 8–11, 13, 17, 18, 20	102	Fawzy		
1, 3, 4, 8–11, 13, 17, 18, 20	103	Fawzy		
3, 18	103	Cross in view of Fawzy		
5, 6, 12	103	Fawzy in view of Cross		
2	103	Cross in view of Polidor		
2	103	Fawzy in view of Polidor		
5–7	103	Cross in view of O’Neill		
5, 6	103	Fawzy in view of Cross and O’Neill		

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
7	103	Fawzy in view of O'Neill		
14	103	Cross in view of Garcia		
14	103	Fawzy in view of Garcia		
15	103	Cross in view of DaCosta		
15	103	Fawzy in view of DaCosta		
16	103	Cross in view of DaCosta and Garcia		
16	103	Fawzy in view of DaCosta and Garcia		
19	103	Fawzy in view of Gutkowicz-Krusin		
19	103	Cross in view of Fawzy and Gutkowicz-Krusin		
Overall Outcome				

The Table below summarizes our conclusions as to Patent Owner's Motion to Amend the claims.

Non-Contingent Motion To Amend Outcome	Claims
Original Claims Canceled by Amendment	1–20
Substitute Claims Proposed in the Amendment	21–38
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	21–24, 27–38
Substitute Claims: Not Reached	25–26

Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

V. ORDER

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

ORDERED that, due to Patent Owner's Non-Contingent Motion to Amend, claims 1–20 of U.S. Patent No. 11,266,345 B2 are cancelled;

FURTHER ORDERED that Patent Owner's Motion to Amend (Paper 8) is denied;¹³ and

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

¹³ As we note above, we do not address substitute claims 25 and 26 because we previously granted Patent Owner's motion to withdraw those two claims.

PGR2022-00041
Patent 11,266,345 B2

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