UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PALETTE LIFE SCIENCES, INC.,

Petitioner,

v.

INCEPT LLC,

Patent Owner.

Case No. IPR2020-00004

Patent No. 7,744,913 B2

PATENT OWNER'S AMENDED NOTICE OF APPEAL

Pursuant to 37 C.F.R § 90.2(a) and 35 U.S.C. § 142, and governing orders of the United States Court of Appeals for the Federal Circuit in appeal case numbers 2021-2063 and -2065 (Dkt. 27, 29), Patent Owner Incept LLC ("Patent Owner") hereby respectfully gives this Amended Notice that it maintains its appeal of the Patent Trial and Appeal Board's ("Board") Final Written Decision, dated April 13, 2021 (Paper 62), made final by the Order of the Director on November 22, 2021 denying review of the Final Written Decision (Paper 75), concluding that claims 1-25 of U.S. Patent No. 7,744,913 have been shown to be unpatentable, to the United States Court of Appeals for the Federal Circuit, including from all underlying orders, decisions, rulings, and opinions that are adverse to the Patent Owner, including, without limitation, those within the Decision on Institution of Inter Partes Review, entered April 17, 2020 (Paper 8).

For the limited purpose of providing the Director with the information requested in 37 C.F.R § 90.2(a)(3)(ii), issues in Patent Owner's appeal may include, but are not limited to, the Board's determination of unpatentability of claims 1-25 of U.S. Patent No. 7,744,913 under 35 U.S.C § 103, which is factually incorrect, not supported by law or substantial evidence, was not the result of a logical and rational process, and is incorrect as a matter of law; any findings and legal conclusions supporting the determinations under § 103, including, as relevant, findings regarding the scope and content of the prior art, motivation to

combine and a reasonable expectation of success, and secondary considerations of non-obviousness, including commercial success; the Board's failure to consider evidence and arguments of record fully and properly; the Board's legal errors in undertaking its obviousness analysis, including interpreting and applying the scope of the claims in a manner inconsistent with their plain and ordinary meaning and proper scope and meaning; the Board's findings that conflict with the evidence of record and are not supported by substantial evidence; any finding or determination supporting or related to these issues; and any other issues decided adversely to Patent Owner in any orders, decisions, rulings and opinions.

Simultaneous with this submission, a copy of the Amended Notice of Appeal is being filed electronically with the Patent Trial and Appeal Board. In addition, a copy of this Amended Notice of Appeal is being filed electronically with the Clerk's Office for the United States Court of Appeals for the Federal Circuit. Pursuant to the Federal Circuit's Order of December 16, 2021 in appeal case numbers 2021-2063, -2065 (Dkt. 29), no additional docketing fees are required for this Amended Notice of Appeal.

Respectfully submitted,

Dated: January 5, 2022

/Christopher J. Burrell/

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CERTIFICATE OF SERVICE

In accordance with 37 CFR § 90.2(a)(1) and § 104.2, I hereby certify that on January 5, 2022, in addition to being filed electronically through the Board's E2E System, the original version of the foregoing Patent Owner's Amended Notice of Appeal, including a copy of the Final Written Decision and Order denying request for Director review of the Final Written Decision, was filed by express overnight mail on the Director of the United States Patent and Trademark Office, at the following address:

Office of the General Counsel
United States Patent and Trademark Office
Madison Building East, Room 10B20
600 Dulany Street
Alexandria, VA 22314

CERTIFICATE OF SERVICE

I hereby certify that on January 5, 2022, a true and correct copy of the foregoing Patent Owner's Amended Notice of Appeal, along with a copy of the Final Written Decision and Order denying request for Director review of the Final Written Decision, was filed electronically with the Clerk's Office of the United States Court of Appeals for the Federal Circuit, at the following address:

United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W., Suite 401
Washington, DC 20005

CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(3)(1), the undersigned certifies that on January 5, 2022, a complete and entire copy of this Patent Owner's Amended Notice of Appeal was provided by email to the Petitioner by serving the email correspondence addresses of record as follows:

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Paper 62
Entered: April 13, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PALETTE LIFE SCIENCES, INC.,
Petitioner,

v.

INCEPT LLC,
Patent Owner.

IPR2020-00004
Patent 7,744,913 B2

Before ERICA A. FRANKLIN, ULRIKE W. JENKS, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review of claims 1–25 ("the challenged claims") of U.S. Patent No. 7,744,913 B2 (Ex. 1001, "the '913 patent"). We have jurisdiction under 35 U.S.C. § 6, and enter this Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Palette Life Sciences, Inc. ("Petitioner") has shown, by a preponderance of the evidence, that the challenged claims are unpatentable. *See* 35 U.S.C. § 316(e). Additionally, we deny Petitioner's Motion to Exclude Evidence.

A. Procedural History

Petitioner filed a Petition for an *inter partes* review of the challenged claims under 35 U.S.C. § 311. Paper 2 ("Pet."). Petitioner supported the Petition with the Declaration of Adam Dicker, M.D., Ph.D. (Ex. 1003). Incept LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

On April 17, 2020, pursuant to 35 U.S.C. § 314(a), we instituted trial to determine whether any challenged claim of the '913 patent is unpatentable based on the grounds raised in the Petition:

Claim(s) Challenged	**35 U.S.C. §[1]**	**References**
1–18, 20–24	103(a)	Wallace,[2] Ein-Gal[3]

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '913 patent issued was filed before that date, the pre-AIA version of § 103 applies.
[2] Wallace et al., US 6,624,245 B2, issued Sep. 23, 2003 ("Wallace," Ex. 1010).
[3] Moshe Ein-Gal, US 6,210,314 B1, issued Apr. 3, 2001 ("Ein-Gal," Ex. 1049).

Claim(s) Challenged	35 U.S.C. §[1]	References
19, 25	103(a)	Wallace, Ein-Gal, Griffith-Cima[4]
1–24	103(a)	Ball,[5] Carroll[6], Ein-Gal
25	103(a)	Ball, Carroll, Ein-Gal, Griffith-Cima

Paper 8 ("Institution Decision" or "Inst. Dec.").

Patent Owner filed a Corrected Patent Owner Response to the Petition. Paper 26 ("PO Resp."). Patent Owner supported the Response with the Declarations of Timothy N. Showalter, M.D., M.P.H. (Ex. 2001), Gary E. Wnek, Ph.D. (Ex. 2002), and Jessica Ray (Ex. 2026), as well as the Supplemental Declaration of Dr. Showalter (Ex. 2027). Petitioner filed a Reply to the Patent Owner Response. Paper 37 ("Pet. Reply"). Petitioner supported the Reply with a Supplemental Declaration from Dr. Dicker (Ex. 1109), along with the Declarations of Zhiban Guan, Ph.D. (Ex. 1110) and DeForest McDuff, Ph.D. (Ex. 1108). Patent Owner filed a Sur-Reply to Petitioner's Reply. Paper 47 ("PO Sur-Reply"). Petitioner filed a Motion to Exclude Evidence. Paper 48 ("Mot."). Patent Owner filed an Opposition to the motion. Paper 50 ("Opp."). Petitioner filed a Reply to Patent Owner's Opposition. Paper 51 ("Mot. Reply").

[4] Griffith-Cima et al., PCT Publication No. WO 94/25080 ("Griffith-Cima," Ex. 1011).
[5] Ball, A. B. S. et al., *Silicone Implant to Prevent Visceral Damage During Adjuvant Radiotherapy for Retroperitoneal Sarcoma*, 63 BRITISH J. RADIOLOGY 346–48 (1990) ("Ball," Ex. 1012).
[6] Carroll, US 6,375,634 B1, issued Apr. 23, 2002 ("Carroll," Ex. 1013).

On January 12, 2021, the parties presented arguments at an oral hearing. Paper 49. The hearing transcript has been entered in the record. Paper 56 ("Tr.").[7]

B. Real Parties-in-Interest

Petitioner identifies Palette Life Sciences, Inc. and Pharmanest AB as real parties-in-interest. Pet. 1. Petitioner also identifies Galderma S.A., Galderma Laboratories, Inc., Galderma Laboratories LP, Galderma Research & Development SNC, Nestlé Skin Health, Inc., Nestlé Skin Health S.A., Nestlé S.A., EQT Partners AB, Public Sector Pension Investment Board (PSP Investments), Luxinva, and Abu Dhabi Investment Authority as possible real parties-in-interest. *Id.*

Patent Owner identifies Incept LLC and Boston Scientific Corporation as real parties-in-interest. Paper 5, 1.

C. Related Proceedings

Petitioner filed a second petition for *inter partes* review of the '913 patent (IPR2020-00005), for which we denied institution. Pet. 2. Petitioner also filed petitions for *inter partes* review of related U.S. Patent No. 8,257,723 B2 in IPR2020-00002 (institution granted) and IPR2020-00003 (institution denied). *Id.*

Patent Owner states that it "is not presently aware of any proceedings other than those cited in the Petition." Paper 5, 1.

[7] With Board authorization, Patent Owner filed a Notice of Corrections to the hearing transcript. Paper 59.

D. The '913 Patent

The '913 patent relates to a method of placing a degradable filler between the radiation target tissue (e.g., the prostate) and other tissues (e.g., the rectum) to increase the distance between the two tissues, so that the other tissues receive less radiation than the target tissue. Ex. 1001, 2:28–31. The degradable filler is installed once before radiation treatment and does not require subsequent manipulation, repositioning, or removal. *Id.* at 2:31–35.

The '913 patent describes a filler as "a substance that occupies a volume after its introduction into a body." *Id.* at 4:34–35. Filler materials include alginate, collagen, gelatin, fibrin, fibrinogen, albumin, polyethylene glycol, thixotropic polymers, and thermoreversible polymers. *Id.* at 4:37–46. Biocompatible materials are preferred, especially collagen or hyaluronic acid. *Id.* at 5:3–4. Biodegradation is measured by palpitation or other methods to detect the change in volume of the filler after its introduction into a patient. *Id.* at 4:66–5:3. Biodegradation may occur over the course of weeks or months after introduction depending on the requirements for administering radiation therapy. *Id.* at 5:4–16.

The filler may be injected through a needle into the patient's body. *Id.* at 10:51–53. After introduction into the body, the filler may increase in volume and form a gel *in situ* through a variety of processes, depending on the material. *See id.* at 5:30–56, 7:42–53. A filler solution may have low viscosity when stored and higher viscosity after *in situ* self-assembly in the patient. *Id.* at 5:48–50.

The '913 patent also describes a study that shows a method of injecting collagen into Denonvillier's space, i.e., the region located between the rectum and the prostate, to displace the rectum away from the prostate during radiation therapy. *Id.* at 3:15–26. The combination of body

temperature and pH causes the collagen fibrils to cooperate to form a fibrin gel. *Id.* at 5:43–48. In reporting the results of the study described in Example 2, the Specification notes that "[t]he collagen degraded in less than about sixty days and required no procedures after its initial introduction into the patients." *Id.* at 3:20–22. Patients receiving the collagen injections "appeared to have minimal rectal side effects associated from their radiotherapy." *Id.* at 3:30–32.

E. Illustrative Claims

Of the challenged claims, claims 1 and 17, reproduced below, are the only independent claims and are illustrative of the claimed subject matter.

> 1. A method of delivering a therapeutic dose of radiation to a patient comprising
>
> introducing a biocompatible, biodegradable filler device between a first tissue location and a second tissue location to increase a distance between the first tissue location and the second tissue location, and
>
> treating the second tissue location with the therapeutic dose of radiation so that the presence of the filler device causes the first tissue location to receive less of the dose of radioactivity compared to the amount of the dose of radioactivity the first tissue location would receive in the absence of the filler device,
>
> wherein the filler device [that] is introduced [is] an injectable material and is a gel in the patient that is removed by biodegradation of the filler device in the patient
>
> wherein the first tissue location is associated with the rectum and the second tissue location is associated with the prostate gland.

Ex. 1001, 16:43–57 (spacing added).

> 17. A method of delivery a therapeutic dose of radiation to a patient comprising:
>
> (i) injecting anesthesia and
>
> (ii) injecting saline to expand the space between the first and second tissue location, wherein the first tissue location is associated with the rectum and the second tissue location is associated with the prostate gland and introducing a biocompatible, biodegradable filler device between the first tissue location and the second tissue location to increase a distance between the first tissue location and the second tissue location, said biocompatible,
>
> biodegradable filler being collagen and introducing collagen into Deno[n]villier's space and treating the second tissue location with a therapeutic dose of radiation,
>
> said therapeutic dose of radiation being 70 to 100 Gy, so that the presence of the filler device causes the first tissue location to receive less than 50% of the dose of radioactivity compared to the amount of the dose of radioactivity the first tissue location would have received in the absence of the filler device,
>
> wherein the filler device is removed by biodegradation of the filler device in the patient.

Id. at 17:31–18:15 (spacing added).

II. PATENTABILITY ANALYSIS

A. Principles of Law

To prevail in its challenges to the patentability of all claims of the '913 patent, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2019). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid. Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); *see also* 35 U.S.C. § 312(a)(3) (2012) (requiring *inter*

partes review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim"). That burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015); *see also In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375–78 (Fed. Cir. 2016) (discussing the burden of proof in *inter partes* review).

A claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made." 35 U.S.C. § 103(a) (2006); *see also 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 the scope and content of the prior art, any differences between the claimed subject matter and the prior art, the level of ordinary skill in the art, and objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). "An obviousness determination requires finding both 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–1368 (Fed. Cir. 2016)).

We analyze Petitioner's asserted grounds of unpatentability in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art ("POSA"), and thus we

begin by addressing the level of ordinary skill in the art. The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham*, 383 U.S. at 17–18; *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a POSA at the time of the invention would include someone having a medical degree with experience in radiation oncology, including knowledge of the side effects of radiation treatment. Pet. 11–12 (citing Ex. 1003 ¶¶ 30–31). Petitioner also asserts that a POSA at the time of the invention would have experience in performing radiation treatments and shielding normal tissue or organs from radiation. *Id.* at 12. Petitioner's expert, Dr. Dicker, explains that such experience "may come from the POSA's own experience, or may come through research or work collaborations with other individual(s) with experience in the medical or biotechnology industry, *e.g.*, as members of a research team or group." Ex. 1003 ¶ 29.

At the institution stage, we preliminarily adopted Petitioner's definition, with the clarification that the experience of the hypothetical POSA in the art includes an understanding of polymer science via their own research or collaborative work with a research team or group in the medical or biotechnology industry. Inst. Dec. 7 (citing Ex. 1003 ¶ 29). We explained that definition is consistent with the level of skill in the art at the time of the invention as reflected by the prior art. *Id.* We note that Patent Owner does not challenge that definition. PO Resp. 1. Accordingly, for this Decision we adopt the same definition, while also recognizing that this level of ordinary skill in the art is reflected in the prior art of record. *See Okajima*

v. Bourdeau, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art, itself, can reflect appropriate level of ordinary skill in art).

We have reviewed the credentials of Petitioner's declarant, Dr. Dicker, and Patent Owner's declarant Dr. Showalter, and consider each of them to be qualified to provide their opinion on the level of skill and the knowledge of a POSA at the time of the invention.[8] As discussed in the our Trial Practice Guide,

> An expert witness must be qualified as an expert by knowledge, skill, experience, training, or education to testify in the form of an opinion. Fed. R. Evid. 702. There is, however, no requirement of a perfect match between the expert's experience and the relevant field. *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010). A person may not need to be a person of ordinary skill in the art in order to testify as an expert under Rule 702, but rather must be "qualified in the pertinent art." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363–64 (Fed. Cir. 2008).

Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019 ("CTPG") (available at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf), 34.

Patent Owner challenges Petitioner's expert, Dr. Dicker, by asserting that he is not one of ordinary skill in the art. PO Resp. 3. Specifically, Patent Owner asserts that "Petitioner's expert makes no mention of research or collaborative work in polymer science, neither in his testimony (Ex. 1003 ¶¶ 2–12) nor in his CV (Ex. 1004)." *Id.* Thus, according to Patent Owner,

[8] Petitioner also submits the testimony of Dr. Guan and Patent Owner also submits the testimony of Dr. Wnek, relating to their qualifications and experience in polymer chemistry. *See* Exs. 1110, 2002. We consider both of those declarants to be sufficiently qualified to render their testimony for that matter.

"Dr. Dicker's conclusions regarding Wallace's disclosure therefore lack credibility and relevance to this proceeding, because they are not informed by the perspective of the POSA, as defined by the Board." *Id.*

Petitioner rebuts Patent Owner's challenge of Dr. Dicker's qualifications in the Reply by asserting that "Dr. Dicker has a bachelor's degree in Chemistry and a Ph.D. in Molecular Pharmacology and Therapeutics, where his research for both involved using polymer tools." Pet. Reply 7 (citing Ex. 1109 ¶ 17) (Dr. Dicker declaring that he completed classes that included polymer chemistry topics and concepts for his Bachelor's degree in Chemistry). Petitioner and Dr. Dicker explain also that his research has included cross-disciplinary projects working directly with material and polymer scientists that involved the use of polymers . . . ." *Id.* at 7; Ex. 1109 ¶¶ 18–19.

Patent Owner did not address or challenge Dr. Dicker's testimony regarding his education and experience in polymer science in Patent Owner's Sur-Reply.[9] Based on our consideration of Dr. Dicker's education and experience, we find that Petitioner has demonstrated, through properly submitted rebuttal evidence, that Dr. Dicker has a sufficient understanding

[9] Petitioner properly submitted Dr. Dicker's declaration in support of Petitioner's Reply as it provided testimony to rebut Patent Owner's challenge of Dr. Dicker's qualifications as one of ordinary skill in the art. As explained in our Trial Practice Guide, a party may submit rebuttal evidence in support of its reply. *See* CTPG at 73 (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1077–78 (Fed. Cir. 2015)). Patent Owner had an opportunity to cross-examine Dr. Dicker regarding that testimony and comment on the declaration and cross-examination in its Sur-Reply, *see id.*, but did neither, *see* Tr. 53:22–54:23 (Patent Owner's counsel confirming that it had an opportunity in its Sur-Reply to address Petitioner's Reply rebuttal arguments relating to Patent Owner's challenge of Dr. Dicker's qualifications but did not do so).

of polymer science through his education and collaborative work with a research team that qualify him to provide his opinions in this proceeding.

To the extent that Petitioner challenges Patent Owner's expert, Dr. Showalter, as lacking the foundation necessary to opine as a POSA, we address that as part of the weight to be given his testimony in our obviousness analysis. Pet. Reply 8–9. Insofar as Petitioner's challenge of Dr. Showalter may be viewed as an assertion that he is not qualified to provide an opinion on the level of skill and the knowledge of a POSA at the time of the invention, we disagree. According to Petitioner, it is undisputed that Dr. Showalter "lacked the requisite training to have gained an in-depth knowledge of the field of radiation oncology until well after the '913 patent's critical date," as he was only a second-year medical student at that time. *Id.* at 8. However, as Petitioner acknowledges, Dr. Showalter relied on his knowledge and training gained after 2002 to establish is knowledge from the perspective of one having ordinary skill in the art. *Id.*

Petitioner does not challenge Dr. Showalter's current level of education and training as not satisfying the definition of a person of ordinary skill in the art. Nor do we find any basis for doing so. Moreover, we find no basis to conclude that a testifying expert must have himself or herself possessed the requisite qualifications for a POSA as of the patent's critical date as opposed to obtaining such qualifications at some later point in time. To hold otherwise would arbitrarily impose an age requirement for expert witnesses testifying in patent cases. Thus, based on our consideration of Dr. Showalter's current education and training, we find that he is qualified to provide his opinion regarding the level of skill and the knowledge of a POSA at the time of the invention.

C. Claim Construction

Having defined the ordinarily skilled artisan, we now turn to claim construction. Where, as here, a Petition is filed on or after November 13, 2018, the Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 100(b) (2019).

Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317.

Petitioner offers proposed claim constructions for the term "consists essentially of collagen." Pet. 14–15. Claim 8 recites that the "filler consists essentially of collagen." Ex. 1001, 17:7–8. Petitioner asserts that the transition phrase "consists essentially of" "limits the scope of a claim to the specified ingredients and those that do not *materially affect the basic* and *novel* characteristic(s) of a composition." Pet. 14–15 (citing *In re Herz*, 537 F.2d 549, 551–52 (CCPA 1976)). Petitioner therefore argues that claim 8 "allows components other than collagen to be present so long as they do not prevent collagen from being used as a biocompatible, bioabsorbable filler." *Id.*

In our Institution Decision, we found Petitioner's construction to be consistent with the Specification and case law. Inst. Dec. 8. We also noted that the term "collagen" is used broadly by the Specification, encompassing more than just naturally occurring collagen. *Id.* at 8–9. According to the Specification, "collagen" may be "natural or synthetic," "human origin or non-human origin," and "material intelligently designed to mimic collagen or some of the structural or functional features of collagen." Ex. 1001, 7:65–8:10. Patent Owner has not challenged our preliminary construction for the term "consists essentially of collagen," *see generally* PO Resp., nor do we see any reason to modify it here. Accordingly, we maintain our construction for that term in this Decision.

Petitioner also offers a proposed claim constructions for the terms "filler device"/"filler." Pet. 13–14. Patent Owner does not challenge that proposed construction or offer any of its own proposed constructions for any other claim term. *See generally* PO Resp. Based upon our analysis of the patentability challenges, we determine that it is unnecessary to expressly construe the term "filler" or any other claim terms for purposes of rendering this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Obviousness over Wallace and Ein-Gal

Petitioner asserts that claims 1–18 and 20–24 are unpatentable as obvious over Wallace and Ein-Gal. Pet. 26–44; Pet. Reply 9–18. Patent Owner disagrees. PO Resp. 6–36.

1. Wallace

Wallace relates to a method of forming a biocompatible gel at a selected site within a patient's body. Ex. 1010, Abstract. In particular, Wallace relates to a "composition prepared by admixture of individually reactive polymer components, wherein the admixture initiates rapid crosslinking and gel formation." *Id.* at 1:16–19. The gel may be formed from an injectable reaction mixture, injected at a specific site within a patient's body, that crosslinks at the site of the injection. *Id.* at 10:8–12. Wallace states that the gel can "be used as a large space-filling device for organ displacement in a body cavity during surgical or radiation procedures, for example, to protect the intestines during a planned course of radiation to the pelvis." *Id.* at 33:64–67.

Wallace explains that the gel may be formed from a polymer including biodegradable segments or blocks that are hydrolyzed in the presence of water or enzymatically cleaved *in situ*. *Id.* at 19:3–19. Preferred naturally occurring hydrophilic polymers include collagen, albumin, fibrin, fibrinogen, carboxylated polysaccharides, and aminated polysaccharides, such as hyaluronic acid. *Id.* at 19:59–65, 20:1–3. The gels may include tensile strength enhancers, such as polyglycolide and polylactide fibers. *Id.* at 24:21–23.

2. Ein-Gal

Ein-Gal relates to a method of treating prostate cancer using radiation therapy. Ex. 1049, 1:4–6. Ein-Gal teaches injecting water in the area of Denonvillier's fascia to reflect the rectal wall away from the prostate and thus "reduce the adverse effects of radiation on healthy tissue, e.g., the rectal wall." *Id.* at 1:31–36; *see also id.* at 3:51–56.

3. Analysis

a) Independent claim 1

Petitioner provides a detailed analysis of each claim limitation as taught or suggested by the combined teachings of Wallace and Ein-Gal. Pet. 27–33. Petitioner asserts that Wallace teaches or suggests each and every limitation of the claim, except for displacing the rectum relative to the prostate gland. *Id.* at 26–27. For that limitation, Petitioner relies on Ein-Gal as teaching the introduction of an injectable material to displace the rectum relative to the prostate gland during radiation therapy. *Id.* at 27. The parties' disputes center on whether Wallace teaches or suggests a space-filling device that is both biocompatible and biodegradable. Thus, we begin by highlighting Petitioner's assertions regarding those limitations in claim 1.

Petitioner asserts Wallace teaches introducing a biocompatible and biodegradable gel as a space-filling device to displace tissues relative to one another during radiation therapy. *Id.* at 28–30 (citing, e.g., Ex. 1010, Abstract, 1:14–15, 3:43–49, 19:3–9, 19:9–19, 28:7–19, 33:64–67; Ex. 1003 ¶¶ 143–145). Petitioner asserts also that Wallace teaches introducing an injectable material that forms a gel in the patient. *Id.* at 32 (citing Ex. 1010, 1:39–45, 2:5–9, 10:9–12; Ex. 1003 ¶ 148). Petitioner further asserts that Wallace teaches polymers that include linking groups to promote hydrolysis or provide a site for enzymatic degradation. *Id.* at 32–33 (citing Ex. 1010, 16:44–47; Ex. 1003 ¶¶ 143–144). In view of those teachings, Petitioner asserts that Wallace teaches a biodegradable filler removable by biodegradation. *Id.* (citing Ex. 19:3–19; Ex. 1003 ¶¶ 148–149).

Petitioner asserts, "[t]o the extent Wallace does not explicitly disclose the use of a gel that is both biocompatible and biodegradable, Wallace teaches use of such a gel, rendering it obvious." *Id.* at 28. Petitioner argues

also that a person of ordinary skill in the art would have been aware that biocompatible filler devices were commonly used to displace organs during radiation therapy. *Id.* at 29 (citing Ex. 1003 ¶¶ 133–138). According to Petitioner, a person of ordinary skill would have understood that such devices could be made of materials that are either non-biodegradable or biodegradable, wherein non-biodegradable fillers "would need to be removed from the patient subsequent to therapy so that the displaced organ could return to its original position," whereas biodegradable fillers could be left in the patient's body to be absorbed over time, and obviate the need for surgical removal. *Id.* at 29–30 (citing Ex. 1003 ¶¶ 136–137, 143–152). In that regard, Petitioner asserts that Wallace teaches the degradation properties of its polymers. *Id.* (citing Ex. 1010, 7:25–29, 16:44–47; Ex. 1003 ¶¶ 143–144).

Petitioner contends that a person of ordinary skill in the art at the time would have had a reasonable expectation of successfully injecting Wallace's biocompatible, biodegradable material to displace the rectum relative to the prostate during radiation therapy as taught by Ein-Gal. *Id.* at 33–34. Petitioner asserts that "[b]oth Wallace and Ein-Gal recognize and appreciate the benefit of displacing tissue away from a site intended to be irradiated, as doing so would protect the tissue from the harmful effects of radiation." *Id.* at 34 (citing Ex. 1010, 33:64–67; Ex. 1049, 1:31–36; Ex. 1003 ¶ 151). Petitioner asserts also that Wallace teaches a person of ordinary skill would have "easily determine[d] the appropriate administration protocol to use with any particular composition having a known gel strength and gelation time." *Id.* at 34–35 (citing Ex. 1010, 28:39–41; Ex. 1003 ¶ 151).

Based on our review of the cited evidence, and the record as a whole, we find Petitioner's characterization of Wallace's teachings, as well as Dr.

Dicker's testimony as to the knowledge in the art, are supported by a preponderance of the evidence. Wallace discloses a method for the rapid formation of a biocompatible gel that may be carried out at a selected site within a patient's body. Ex. 1010, Abstract. Wallace explains that its method involves admixing two "biocompatible crosslinking component[s]" to form a gel in less than one minute. *Id.* Wallace also refers to the biocompatible components as "reactive components," because they "rapidly react with each other to form a crosslinked gel." *Id.* at 2:15–17. Wallace describes the admixtures, interchangeably, as a "biocompatible polymer compositions" and "reactive polymer composition[s]." *Id.* at 1:15–16; 2:13–14. Wallace states that "[t]he reactive compositions of the present invention can be used in a variety of different applications." *Id.* at 28:30–31. Wallace provides a "detailed description of several specific applications" of its compositions. In particular, as both parties have recognized, Wallace states that "[t]he compositions can also be used as a large space-filling device for organ displacement in a body cavity during surgical or radiation procedures, for example, to protect the intestines during a planned course of radiation to the pelvis." *Id.* at 33:64–67.

Patent Owner asserts that a POSA would not have interpreted Wallace's disclosure that "[t]he compositions can also be used as a large space-filling device for organ displacement in a body cavity" to refer to all of its disclosed compositions. PO Resp. 6–8 (quoting Ex. 1010, 33:64–67). Patent Owner asserts that a POSA would have instead understood Wallace's reference to "the compositions" that can be used as a space-filling device to encompass fewer than all of Wallace's disclosed compositions. *Id.* at 11–12. Based on those assertions, Patent Owner contends that a POSA would not have known which subset of Wallace's compositions could be used for such

purpose. *Id.* at 8–12. To support its contentions, Patent Owner attempts to demonstrate that Wallace uses the term "the compositions" to describe "a wide range of applications of its technology that demand entirely incompatible materials properties," such that the term must refer to some subset of the compositions. *Id*.

As its first example, Patent Owner asserts that Wallace discloses that "the compositions" may be used to promote adhesion of tissues to one another and also to prevent adhesion of tissues to one another. *Id.* at 8–9 (citing Ex. 1010, 31:41–44; 32:59–33:7). According to Patent Owner and Dr. Wnek, it would be "nonsensical to a POSA to have interpreted Wallace as disclosing that all of Wallace's compositions are able to both promote and prevent adhesion, entirely opposite functions." *Id.* at 9 (citing Ex. 2002 ¶ 16).

As its next example, Patent Owner asserts that Wallace teaches that "the compositions" may be used to repair or replace certain body tissues, ranging from synovial fluid and vitreous to bone. *Id.* at 9–10. According to Patent Owner and Dr. Wnek, a POSA "would not have understood Wallace as teaching that the same polymeric compositions suitable for replacing [synovial fluid and] the vitreous also would have been suitable for replacing bone," because their physical and mechanical properties are widely different. *Id.* at 11.

In the Reply, Petitioner addresses Patent Owner's argument by asserting, among other things, that "Wallace gives clear guidance on how the same composition can be used to both promote and prevent tissue adhesion through different application methods." Pet. Reply 12 (emphasis omitted). To support that assertion, Petitioner refers to Wallace's teaching to bring tissues together *before* crosslinking has occurred *to promote adhesion*,

whereas *preventing adhesion* involves bringing tissues together *after* crosslinking has reached equilibrium. *Id.* (citing Ex. 1010, 31:11–21; 32:58–33:8; Ex. 1110 ¶ 24) (emphasis added).

Similarly, Petitioner asserts that "Wallace provides straightforward guidance as to how a given composition can be adapted according to the type of tissue being repaired." *Id.* To support that assertion, Petitioner refers to Wallace's teaching optimizing concentration of each crosslinkable component and acknowledging ordinary skill in the art, along with Dr. Guan's comparison of Wallace's disclosures of sealant compositions to that of the '913 patent. *Id.* (citing Ex. 1010, 27:30–33; 28:39–41; Ex. 1110 ¶¶ 25, 28–29). Petitioner and Dr. Dicker note also that Wallace discloses the same steps for introducing the gel compositions for tissue augmentation and for use as a space-filling device. *Id.* at 12–13 (citing Ex. 1109 ¶¶ 34–35 (citing Ex. 1010, Abstract, 2:26–33, 19:3–19, 32:45–49, 33:64–67; Ex. 1110 ¶¶ 26–27)).

Based upon our review of the arguments and evidence, we determine that the preponderance of the evidence supports Petitioner's position that a POSA would have understood Wallace's disclosure that its compositions may be used as a space-filling device applies generally to all its compositions. When teaching that its compositions can be used as a large space-filling device for organ displacement in a body cavity during radiation procedures, Wallace does not limit that teaching to any "subset" of its disclosed compositions. Ex. 1010, 33:64–67. We are not persuaded otherwise by Patent Owner's assertion that Wallace teaches that the compositions may be used to promote or prevent adhesion to tissue, and to repair or replace a range of body tissues. As noted above, Wallace expressly states that it's the "compositions of the present invention can be used in a

variety of different applications." *Id.* at 28:30–31. Wallace provides a "detailed description of several specific applications" of its compositions. Wallace does not, however, separate or categorize the components used for those compositions based on those applications. Rather, as Petitioner has persuasively demonstrated, Wallace provides sufficient guidance on how the same general compositions can be used or adapted for those seemingly disparate applications. Pet. Reply 12–13. Indeed, we note that Patent Owner has not addressed nor challenged Petitioner's showing in that regard in the Patent Owner's Sur-Reply.

Next, Patent Owner asserts that, even if a POSA understood that Wallace's compositions are disclosed for use as a space-filling device, Petitioner has not shown that any particular composition has all of the claimed properties, i.e., one that is (a) biocompatible, (b) biodegradable, (c) introduced as an injectable material, (d) a gel in the patient, and (e) removable by biodegradation. PO Resp. 14–34.

As for biocompatibility of the composition, Patent Owner acknowledges that "Wallace repeatedly describes its compositions as 'biocompatible.'" *Id.* at 14–15. Despite Wallace's disclosure of the compositions being biocompatible, Patent Owner asserts that "a POSA would not have known whether any of them actually was biocompatible without testing them." *Id.* at 15. According to Patent Owner, Wallace's reported evidence regarding one of its compositions raises doubt about the biocompatibility of that composition. *Id.* In particular, Patent Owner asserts that Wallace's crosslinking chemistry involves either thiol-based nucleophilic substitution, which would require a pH significantly above physiologic pH, or free radial addition, which would require the presence of

potentially toxic initiators, "either of which would expose the surrounding tissue to substantial risk of damage." *Id.* at 15–17 (citing Ex. 2002 ¶ 27).

Regarding elevated pH concerns with nucleophilic substitution, Patent Owner draws support from two of its declarants, Drs. Wnek and Showalter. *Id.* at 18–24. Patent Owner asserts that Drs. Wnek and Showalter "agree that a POSA would have had substantial concern that a gel made according to Wallace's thiol crosslinking by nucleophilic substitution would not be compatible due to tissue inflammation" caused by elevated pH. *Id.* at–23 (citing Ex. 2001 ¶ 24; Ex. 2002 ¶ 36). In particular, Dr. Wnek testifies that "[t]he time that the elevated pH would persist is difficult to predict because it depends on several factors, but there nonetheless is a substantial risk that a 1-2 mL gel, as described in Wallace's examples, could persist as a pH reservoir for a week or more." Ex. 2002 ¶ 34. According to Dr. Wnek, materials for use *in vivo* "are invariably designed to have a pH of 7.4 (or very close to 7.4) to avoid tissue reactions, unless there is a specific therapeutic purpose to have some other pH that is sufficiently compelling to outweigh the risk of tissue damage a pH mismatch would be expected to cause." *Id.* ¶ 35.

Dr. Showalter testifies that a "POSA would have appreciated that exposing the organs and tissues within the body to a composition having pH lower or higher than pH 7.4 presents a substantial risk of injury from chemical damage to the cells of the organs and tissues," resulting in an inflammatory response from the body's immune system to repair the damage. Ex. 2001 ¶ 24. According to Dr. Showalter, "[b]ecause of this risk of tissue damage, products intended for placement inside the body are designed to have a pH as close to 7.4 as possible, unless some medical necessity dictates otherwise . . . ." *Id.* In Dr. Showalter's opinion, "the use

of a device to reduce radiation dose to nearby organs during radiation treatment does not present such medical necessity for a nonphysiologic pH." *Id.*

In the Reply, Petitioner relies on Dr. Dicker's testimony to assert that "treatment protocols often involve a risk-benefit analysis and the insertion of a foreign body for treatment purposes will almost always induce some type of inflammatory response." Pet. Reply 14 (citing Ex. 1109 ¶¶ 39–40, 46). According to Petitioner and Dr. Dicker, a radiation oncologist would have known that risk and would have been "willing to tolerate such risk when pursuing a protocol that would benefit patients in terms of their cancer treatment." *Id.* (citing Ex. 1109 ¶¶ 43–46). Dr. Dicker explains, "as with all therapeutic compositions reviewed by the U.S. Food & Drug Administration [("FDA")], the risks and benefits are taken into account when evaluating therapeutic drugs for approval." Ex. 1109 ¶ 40.

For example, Dr. Dicker provides a list of FDA approved therapeutic compositions that are administered either above or below a physiologic pH of 7.4, including: furosemide injection (pH between 8.0–9.3); phenytoin injection (adjusted to pH 12 with sodium hydroxide); DuraSeal (a two-component mixture with one component dissolved in a pH 10 buffer and a second component dissolved in a pH 4 buffer); and insulin glargine (pH 4). Ex. 1109 ¶ 41; *see* Pet. Reply 14.

Dr. Dicker further challenges Dr. Showalter's opinion by noting that Dr. Showalter admitted in his deposition that the SpaceOAR rectal tissue spacer, a commercial product that Patent Owner purports to be covered by the '913 patent, is injected in a basic pH composition upon administration. Ex. 1109 ¶ 41 (citing Ex. 1106, 94:16–95:1). Dr. Dicker also observes that "[n]either Dr. Showalter nor Dr. Wnek point to any experiments or

disclosure in their declaration that support a long-term harm if the pH is higher or lower than pH 7.4." *Id.* ¶ 42 (citing Ex. 1110 ¶ 30) (Dr. Guan's testimony that he disagrees that an elevated pH would discourage a polymer chemist from employing Wallace's polymers and noting that "Dr. Wnek points to no experiments or disclosure in his declaration that support a long-term harm if a basic formulation is used in the body.")).

In Dr. Dicker's opinion, Dr. Showalter's testimony that a POSA would have been discouraged from using Wallace's polymer compositions based on pH alone is not credible based on FDA approved products having a pH above or below 7.4, as set forth above, and Dr. Wnek's deposition testimony that a polymer chemist would not be able to conclude that a composition introduced as an injectable material is not biocompatible based solely on the fact that is has a pH of 8.5. *Id.* (citing Ex. 1111, 35:15–36:2). Further, Petitioner and Dr. Dicker explain that "[i]t was understood homeostasis within the body was achieved fairly quickly, even with compositions requiring basic pH conditions." Pet. Reply 16 (citing Ex. 1109 ¶ 44).

Based upon our review of the arguments and evidence, we find that the preponderance of the evidence supports Petitioner's position that a POSA would not have doubted the biocompatibility of Wallace's polymer compositions based on an elevated pH required for nucleophilic substitution. To begin, as Patent Owner acknowledges, PO Resp. 14–15, Wallace expressly discloses that its compositions are biocompatible. *See, e.g.*, Ex. 1010, Title ("Rapid-Gelling Biocompatible Polymer Composition and Associated Methods of Preparation and Use."), 1:15–16 ("This invention relates generally to biocompatible polymer compositions that rapidly crosslink to form a gel."). Moreover, Wallace discloses use of the same

polymeric materials, including hyaluronic acid and collagen, that the '913 patent identifies as "biocompatible." *Compare* Ex. 1001, 5:3–4 ("Biocompatible materials are preferred, especially collagen or hyaluronic acid") *with* Ex. 1010, 19:59–65, 20:1–3 (identifying hyaluronic acid and collagen among preferred polymers).

Patent Owner has not persuasively demonstrated otherwise based upon the testimony of Drs. Wnek and Showalter that a skilled artisan would have had "substantial concern that a gel made according to Wallace's thiol crosslinking by nucleophilic substitution would not be compatible due to tissue inflammation" caused by elevated pH. PO Resp. 22–23 (citing Ex. 2001 ¶ 24; Ex. 2002 ¶ 36). We do not assign persuasive weight to their testimony because, as Drs. Dicker and Guan have observed, "[n]either Dr. Showalter nor Dr. Wnek point to any experiments or disclosure in their declaration that support a long-term harm if the pH is higher or lower than pH 7.4." Ex. 1109 ¶ 42 (citing Ex. 1110 ¶ 30).

At most, we find that Patent Owner, through the testimony of Drs. Wnek and Showalter, has established that introducing Wallace's polymer composition *in vivo* may result in an inflammatory response to a temporarily elevated pH,[10] and that such risk of tissue inflammation is analyzed in the context of the potential benefit to a patient for whom treatment with the composition is being considered. That showing does not contradict Wallace's disclosure or demonstrate that Wallace's compositions are not biocompatible. As Petitioner persuasively argues, "treatment protocols often involve a risk-benefit analysis and the insertion of a foreign body for

[10] *See* Ex. 2002 ¶ 34 (Dr. Wnek testifying that the duration of pH reservoir is difficult to predict, but Wallace's exemplary gels would likely persist for a week or more.).

treatment purposes will almost always induce some type of inflammatory response." Pet. Reply 14 (citing Ex. 1109 ¶¶ 39–40, 46).

The risk potential of a treatment alone does not dictate its biocompatibility. Indeed, as Dr. Dicker credibly demonstrates, a number of FDA-approved treatments involve similar risks related to variations in pH. On the other hand, we have a somewhat bare assertion from Dr. Showalter that, in his opinion, "the use of a device to reduce radiation dose to nearby organs during radiation treatment does not present such medical necessity for a nonphysiologic pH." Ex. 2001 ¶ 24. Dr. Showalter reaches that conclusion after discussing "a substantial concern of tissue damage" based on exposing tissue to an elevated pH, "especially if the composition were to remain in contact with the tissue for any length of time." *Id.* However, to the extent that Dr. Showalter conducted any risk-benefit analysis to reach his conclusion that the risk posed by an elevated pH outweighed the benefit provided by the composition in radiation patients, we do not assign persuasive weight to his conclusion. As Dr. Dicker noted, Dr. Showalter's testimony that a POSA would not have viewed Wallace's compositions as biocompatible based on an elevated pH is undermined by the deposition testimony of Dr. Wnek that even a polymer chemist would not be able to conclude that a composition introduced as an injectable material is not biocompatible based solely on the fact that is has a pH of 8.5, i.e., an elevated pH. Ex. 1109 ¶ 42 (citing Ex. 1111, 35:15–36:2).

Accordingly, based on the preponderance of the evidence, we find that a person of ordinary skill in the art would have not have doubted the biocompatibility of Wallace's polymer compositions, or otherwise been discouraged from employing those compositions, based on an elevated pH

required for nucleophilic substitution for the reasons discussed by Petitioner and Drs. Dicker and Guan.[11]

Patent Owner also relies on the testimony of Drs. Showalter and Wnek to assert that the radical initiators required for crosslinking by free radical addition and identified by Wallace, i.e., organic peroxides and azo compounds, cleave or decompose into toxic chemicals that "should not be introduced into a patient without a very clear medical necessity for their specific presence, which is not the case for the fillers of the challenged claims." PO Resp. 23–24 (citing Ex. 2001 ¶¶ 26–29; Ex. 2002 ¶ 37).

In the Reply, Petitioner notes that "the '913 patent encompasses fillers that 'are crosslinked by a radical reaction upon contact with a radical initiator,'" and refers to prior art disclosures of *in situ* formation of free-radical polymerizable and UV-light irradiated hydrogels. Pet. Reply 17 (citing Ex. 1001, 9:37–54; Ex. 1110 ¶¶ 41–42). Petitioner and Dr. Guan note that those reactions described in the prior art cited in the '913 patent "are similar to those described in Wallace and were well-recognized chemical reactions that were capable of producing a biocompatible product." *Id.* (citing Ex. 1110 ¶ 43; Ex. 1109 ¶¶ 52–53).

Based on our consideration of the evidence and arguments, we find Dr. Guan's testimony that Wallace's use of free-radical initiated and UV-irradiation for hydrogel polymerization is a "well-recognized and accepted chemical reaction, and depending upon the monomers chosen is able to produce a biocompatible product," Ex. 1110 ¶ 43, to be credible and persuasive. As Petitioner and Dr. Guan demonstrate, at the time of the

[11] We note that Patent Owner has not responded to Petitioner's Reply arguments or evidence relating to the biocompatibility of Wallace's compositions in Patent Owner's Sur-Reply. *See* PO Sur-Reply.

invention, preparing free-radical cross-linked polymers was known to be a suitable technique that was even employed in the '913 patent. *Id.* ¶¶ 41–42; Pet. Reply 17.

Patent Owner asserts also that "Petitioner does not explain how Wallace provides any meaningful guidance to the reader about how to pick and choose particular pairs of component cores, molecular weights, reactive groups, linkers, and other ingredients to achieve compositions having the claimed properties of gelation, injectability, and removability by degradation." PO Resp. 33.

In the Reply, Petitioner asserts that "the type of compositions taught by Wallace are expressly contemplated as "suitable fillers" by the '913 patent through its incorporation of Rhee."[12] Pet. Reply 15 (citing Ex. 1001, 4:49–53; Ex. 1109 ¶¶ 49–50; Ex. 1110 ¶ 35). Petitioner asserts that "[t]he compositions disclosed by Rhee greatly overlap with those discussed in Wallace." *Id.* at 10–11 (citing Ex. 1110 ¶¶ 35–40). According to Petitioner, "Rhee provides just as many, if not more, options," as Wallace, so that as Patent Owner considered Rhee's disclosure is enabling, it must recognize that Wallace is also. *Id.* at 17–18 (citing *In re Paulsen*, 30 F.3d 1475, 1481 n.9 (Fed. Cir. 1994) (noting specification would not be enabling if held to the same standard urged for the reference); Ex. 1110 ¶ 19. Patent Owner has not responded to these assertions by Petitioner in its Patent Owner's Sur-Reply. *See* PO Sur-Reply.

[12] Rhee et al., US Patent No. 5,874,500, issued Feb. 23, 1999 ("Rhee," Ex. 1136).

Having considered the record, as a whole, we disagree with Patent Owner's assertion that "the range of compositions within the ambit of Wallace's disclosure is so vast that a POSA could neither have 'at once envisaged' all of them nor have known what properties any particular one of them would have." PO Resp. 32 (quotation marks omitted). That assertion by Patent Owner is based on its argument that Wallace does not exemplify biocompatible compositions. *See* PO Resp. 27. However, as explained in the preceding discussion, we do not find persuasive support for that position in view of Wallace's express teaching to the contrary and upon weighing the testimony of the parties' experts.

We have also found Wallace's biocompatible filler compositions to be biodegradable, and removable by biodegradation as Wallace teaches that the compositions include "biodegradable segments" that are "hydrolyzed in the presence of water and/or enzymatically cleaved in situ." Ex. 1010, 19:3–9. We have additionally found that Wallace teaches that its compositions may be introduced as an injectable material, *id.* at 1:39–45, 2:5–9, 10:9–12, and form a gel in the patient, *id.* at 1:14–15, 1:39–45, 2:5–9, 2:12–16, 2:26–32, 3:43–49, 19:3–19. Wallace's disclosure of various options for each component of its composition does not change those characteristics of its filler composition that are recited by
claim 1.

Accordingly, having considered the record as a whole, including the teachings of the cited references, the testimony of the parties' experts, and the arguments by the parties, we determine that Petitioner has shown by a preponderance of the evidence that Wallace teaches an injectable composition for use as a space-filling device for organ displacement in a body cavity during surgical or radiation procedures that is both

biocompatible and biodegradable. We also find that Petitioner has established by a preponderance of the evidence that Wallace teaches each of the other limitations of claim 1, except for using its composition to displace the rectum relative to the prostate. There is no dispute that Ein-Gal teaches that remaining limitation. Thus, we determine that Petitioner has shown by a preponderance of the evidence that the combined teachings of Wallace and Ein-Gal teach or suggest each limitation of independent claim 1, and that based on those teachings, along with the knowledge in the art, a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to use Wallace's compositions for its disclosed purpose of displacing an organ for radiation therapy, including displacing the rectum relative to the prostate gland, wherein the composition is eventually removed by biodegradation, as required by claim 1.

Even if Wallace were to be viewed as not teaching a space-filling device that is both biocompatible and biodegradable, we agree with Petitioner that, based on the record as a whole and the persuasive testimony of Drs. Dicker and Guan, Wallace would have suggested to a person of ordinary skill in the art to select and prepare a biocompatible, biodegradable polymer gel, according to its disclosure, for use as a filler between an organ and nearby tissue during radiation therapy to minimize the dose of radiation received by the nearby tissue, with a reasonable expectation of success. Wallace refers to its compositions as being "biocompatible" throughout the disclosure. *See generally* Ex. 1010. Additionally, Wallace describes using its compositions as a space-filling device for organ displacement in radiation procedures to protect nearby tissue from exposure to such radiation. *Id.* at 33:64–67. Wallace dedicates much of the Specification to the topic of forming polymer compositions to achieve certain biological characteristics,

including degradation and biodegradability. *See, e.g.*, *id.* at 3:30–40, 7:25–29, 16:22–23, 44–64, 19:3–19, 20:46–47. Indeed, as we mentioned above, Wallace's teaching that all suitable polymers disclosed are "essentially nondegradable in vivo over a period of at least several months," *id.* at 7:25–29, teaches, or at least suggests, that those disclosed polymers are essentially *degradable* in the body over a period of *more than* at least several months.

b) Claims 2–15, 17–18, and 20–24

Petitioner has demonstrated how the combination of Wallace and Ein-Gal teaches or suggests each additional limitation of dependent claims 2–16,[13] 18, and 20–24. *See* Pet. 39–44. Petitioner has also demonstrated how the combination of Wallace and Ein-Gal teaches or suggest each limitation of independent claim 17. *See* Pet. 35–39 (citing Ex. 1010, 3:50–55, 9:1–19,

[13] Patent Owner refers to claim 16 when it argues that "the POSA could not have known, with any reasonable certainty, whether including Wallace's 'biodegradable segments and blocks' . . . in the core component(s) could provide a composition . . . that further is biodegradable within a specified timeframe, such as "between three months and twelve months," as required by claim 16." PO Resp. 32–33 (emphasis omitted). Claim 16, however, does not recite that limitation. None of the challenged claims does. To the extent that Patent Owner meant to refer to claim 6, and its limitation that "the filler is biodegradable in vivo in less than approximately 90 days," Ex. 1001, 17:3–4, we find that Petitioner has established persuasively, through the teachings of Wallace and the testimony of Dr. Dicker, that a POSA would have known how to configure Wallace's compositions to biodegrade within a predetermined time, such as less than approximately 90 days. *See* Pet. 43 (citing Ex. 1010, 1:34–38, 19:3–19, 20:44–47; Ex. 1003 ¶ 175). Indeed, Patent Owner's expert, Dr. Showalter, does not address claim 6, and Patent Owner's polymer scientist, Dr. Wnek, concludes, without sufficient analysis, that Wallace does not provide enough guidance "to suggest achieving a desired, specific timeframe is even feasible." Ex. 2002 ¶¶ 48–49.

19:59–60, 20:2–21:35; Ex. 1049, 1:31–36; Ex. 1003 ¶¶ 155–160). Patent Owner does not raise any additional arguments challenging Petitioner's showing for those claims in this ground. Thus, for the same reasons stated above in relation to independent claim 1, from which claims 2–15, 18, and 20–24 depend, along with Petitioner's arguments and evidence set forth for those dependent claims and independent claim 17, we find that Petitioner has shown by a preponderance of the evidence that the limitations of each of those claims are taught or suggested by Wallace and Ein-Gal, and that a person of ordinary skill in the art would have motivated with a reasonable expectation of success to perform the methods recited by claims 2–15, 17–18, and 20–24.

We continue our analysis below with a discussion of Patent Owner's asserted secondary considerations of nonobviousness for claim 1.

c) Secondary Considerations

Regarding independent claim 1 of the '913 patent, Patent Owner asserts that the commercial success of the claimed invention demonstrates its nonobviousness. PO Resp. 37. Patent Owner explains that real party-in-interest Boston Scientific Corporation markets an implantable synthetic hydrogel, SpaceOAR®. *Id.* According to Patent Owner, "[t]he FDA-cleared SpaceOAR procedure practices claim 1 of the '913 patent and has enjoyed major success since its introduction, approximately doubling its case volume year after year until, by 2019, it was used in over half of the prostate radiation therapies in the U.S." *Id.* Patent Owner sets forth in a claim chart a comparison of challenged claim 1 to the SpaceOAR procedure. *Id.* at 38–39. Patent Owner asserts that the FDA cleared SpaceOAR hydrogel for marketing in April 2015. *Id.* at 45.

Patent Owner and its declarant, Jessica Ray, set forth the following table as evidence of the SpaceOAR's commercial success:

Year	SpaceOAR hydrogel units, U.S.
2015	1,029
2016	3,963
2017	7,192
2018	17,289
2019	32,099

Id.; Ex. 2026 ¶ 22. The table has two columns: the left column is labeled "Year" and includes 5 rows indicating years 2015–2019; the right column in the table is labeled "SpaceOAR hydrogel units, U.S." and includes figures for each corresponding year listed in the left column. PO Resp. 45; Ex. 2026 ¶ 22. Patent Owner asserts that "[t]he sales data was obtained from its custodian, Boston Scientific Corporation Senior Accountant, Jessica Ray, who describes how the data is stored and was retrieved from the company's business records." PO Resp. 45 (citing Ex. 2026 ¶¶ 1–21; Ex. 2027 ¶ 42). Ms. Ray introduces the table in her declaration by stating, "[i]n summary, my review of Boston Scientific Corporation's business records of the number of Space OAR hydrogel units indicates the following annual unit shipments to external customers (i.e., physicians and hospitals) in the United States." Ex. 2026 ¶ 22. Patent Owner asserts that "Dr. Showalter has been a provider of SpaceOAR hydrogel placement since June 2016 and therefore has personal knowledge and experience that corroborates the numbers reported in [Ms. Ray's declaration]." PO Resp. 45 (citing Ex. 2001 ¶ 44).

Relying on the testimony of Dr. Showalter, and data from the table for year 2019, Patent Owner asserts that "about 55% of all prostate cancer radiation therapy treatments that year are estimated to have included Space OAR placement." *Id.* at 47 (citing Ex. 2027 ¶ 43). Dr. Showalter reaches that placement percentage estimate by first referring to an estimated 174,650 new cases of prostate cancer in the United States in 2019. Ex. 2027 ¶ 43. From there, Dr. Showalter refers to reporting that 545 of 1,653 men underwent radiotherapy during a trial in the United Kingdom. *Id.* (citing Ex. 2020, 147)[14]. According to Dr. Showalter, the rate of radiation therapy is about the same in the United States. *Id.* Based on that opinion, Dr. Showalter testifies that roughly one third of prostate cancer cases are treated with radiation in the United States. *Id.* He explains that because one third of the estimated 174,650 new cases of prostate cancer in the United States is 58,217, that is the number of patients in the United States who received radiation therapy in 2019. *Id.*

Therefore, according to Dr. Showalter, based on the 32,099 SpaceOAR cases in 2019, about 55% of all prostate cancer radiation therapy treatments that year are estimated to have included SpaceOAR placement. *Id.* Patent Owner asserts that Dr. Showalter "attributes this enormous growth and success of SpaceOAR hydrogel to the substantial improvements to speed, safety, and efficacy that SpaceOAR hydrogel provides in prostate cancer radiation therapy." PO Resp. 47 (citing Ex. 2001 ¶ 47).

Petitioner asserts, among other things, that Patent Owner's evidence does not demonstrate SpaceOAR's commercial success. Pet. Reply 22. In

[14] Gay et al., *Radiation Therapy for Prostate Cancer*, 115 (2) J. MISSOURI MED. 146–150 (2018) (Ex. 2020).

particular, Petitioner asserts that Patent Owner's evidence is insufficient because it does not include information such as a detailed analysis of the SpaceOAR sales. *Id.* at 22–23.[15] Additionally, Petitioner asserts also that Dr. Showalter's estimate that the SpaceOAR enjoys 55% market-penetration is unreliable because he "relies on flawed inputs and incorrect assumptions" because: (a) his "conclusions regarding the percent of prostate cancer cases receiving radiation treatment . . . are based on a relatively small, randomized sample size of men in the U.K. treated over ten years ago," (b) his "assumptions regarding market penetration are based on newly diagnosed cases in 2019 . . . rather than the entire pool of patients who could receive radiotherapy in a given year, resulting in Dr. Showalter overstating SpaceOAR's market penetration," and (c) he failed to compare SpaceOAR to the several competing radiotherapy spacer options available on the market. *Id*. at 24–25.

Having considered the arguments and evidence presented by the parties, we agree with Petitioner that Patent Owner has not met its burden of production for its assertion of commercial success. *Id.* at 22 (citing *ZUP, LLC v. Nash Manufacturing, Inc.*, 896 F.3d 1365, 1373 (Fed. Cir. 2018). In particular, we find Patent Owner's evidence is insufficient. Commercial success is "usually shown by significant sales in a relevant market." *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).

[15] Petitioner asserts also that Patent Owner's nexus analysis is insufficient. Pet. Reply 25. Although that argument appears to have merit, we do not reach the issue of nexus, as we determine that Patent Owner has not provided sufficient evidence that the SpaceOAR was a commercial success.

Patent Owner bases its alleged commercial success on units shipped and not sales data. In the Patent Owner Response, Patent Owner asserts that SpaceOAR has achieved commercial success because "its *case volume* in the US has roughly doubled year-on-year through 2019." PO Resp. 45 (emphasis added). In support of that assertion, Patent Owner sets forth the table prepared by its declarant, Ms. Ray, and states that "[t]he *sales data* was obtained from its custodian . . . Jessica Ray." *Id.* at 45 (citing Ex. 2026 ¶ 22) (emphasis added). Ms. Ray, however, does not describe the data in the table as "sales" data. Nor does she use the term "case volume." Rather, Ms. Ray specifically states that her summary table entries for the number of SpaceOAR hydrogel units indicate "annual unit shipments." Ex. 2026 ¶ 22. Ms. Ray's explains that units shipped include "regular sales, replacement units, and free sample units." *Id.* ¶ 7.

For years 2015, 2016, and 2017, Ms. Ray discusses in her declaration what portion of the total units for each year represent regular sales, replacement units and free samples, but then combines them to provide the total units shipment data for each of those years in her summary table. *Id.* ¶¶ 10–15.[16] For years 2018 and 2019, she explains that the software used to access the units shipped did not distinguish regular sales, replacement units and sample units. *Id.* ¶¶ 16, 19. Thus, the record does not specify the

[16] Among other issues with Ms. Ray's reported data, we note that the report generated for shipment and sales data for years 2015–2017 was based on a yearly search without identifying when shipments or sales began in 2015. *See, e.g.*, Ex. 2026 ¶¶10–11. Thus, even in terms of shipments increasing between 2015 and 2016, we are unaware whether that comparison involves twelve months of shipments in 2015. When questioned about the 2015 data at the hearing, Patent Owner's counsel responded by stating, "I'm pretty certain it's not a full year of sales. But I believe it's about a half year of sales." Tr. 35:7–11.

regular sales portion of the total units reported for each of those years. In any event, for the three years that sales data was available for SpaceOAR, Patent Owner does not relay or rely on such data in its Patent Owner Response or in its Sur-Reply. *See* PO Resp. 37–50; PO Sur-Reply 1–12. Rather, Patent Owner refers only to the data reflecting the total units shipped annually during 2015–2019, when it asserts that SpaceOAR's "case volume in the US has roughly doubled year-on-year through 2019" as evidence of commercial success. PO Resp. 45.

Patent Owner has not shown how the units of product shipped, alone, demonstrates commercial success based on sales. Based upon our review, we find the shipment data, without more, is insufficient to draw that conclusion. As noted above, the number of units shipped relied upon by Ms. Ray include products that were given away as samples or replacements, and the record does not demonstrate whether the year-over-year increase in units shipped is attributable to increased sales as opposed to an increase in samples and replacements that were shipped. Moreover, even if Patent Owner's evidence demonstrated "consistent doubling of U.S. sales year after year, from about 1,000 units in 2015 to over 32,000 units in 2019," PO Sur-Reply 2, neither Ms. Ray nor Dr. Showalter have explained how those sales exhibit a commercial success in the context of the market as a whole. Accordingly, we do not find that the evidence of product shipment submitted sufficiently demonstrates commercial success of claim 1 so as to support a finding of nonobviousness.

Insofar as Patent Owner seeks to establish commercial success by asserting that "about 55% of all prostate cancer radiation therapy treatments that year are estimated to have included Space OAR placement," PO Resp. 47 (citing Ex. 2027 ¶ 43), we find that the evidence relied upon for that

assertion is not sufficiently supported. To begin, that assertion relies, in part, on Dr. Showalter's estimate of "new cases" of prostate cancer in the United States in 2019. Ex. 2027 ¶ 43. He has not explained why he limits his analysis to only new cases in that year, as opposed to all existing cases at that time. *Id.* Next, Dr. Showalter inexplicably relies on data from a United Kingdom radiotherapy trial to provide a rate of radiation therapy cases in the United States. *Id.* (citing Ex. 2020, 147).

Further, the referenced United Kingdom trial did not purport to include all new or existing radiotherapy patients in the United Kingdom for a given year, but rather, it merely involved a number of "recruited" men from a specific age category for its study. *See* Ex. 2020, 147 ("The trial recruited 1643 men 50 to 69 years old."). Yet, Dr. Showalter relied on that number of recruited men and the subset of those men who were randomly administered radiotherapy in that trial to support his opinion that "[r]oughly one third of prostate cancer cases are treated with radiation." Ex. 2027 ¶ 43 (citing Ex. 2020, 147).

As additional support, Dr. Showalter relies on his own experience "based on percentage of cases referred to [him] by urologist," that roughly one third of prostate cancer patients in the United States undergo radiation therapy. *Id.* Finally, Dr. Showalter relies on Ms. Ray's data for the number of SpaceOAR units shipped as his evidence of the number of SpaceOAR placement or treatments in patients for that year. Neither Patent Owner nor Dr. Showalter point to any evidence in the record that the units shipped is equivalent to the units actually administered (or sold) in a given year. Indeed, Ms. Ray's testimony suggests that those figures are not equivalent at least based on the fact that the units shipped includes replacement units. *See* Ex. 2026 ¶ 7.

Based on at least the foregoing deficiencies, we do not find Dr. Showalter's testimony that about 55% of all prostate cancer radiation therapy treatments in 2019 included SpaceOAR placement to be credible, as his calculations are insufficiently supported by the evidence. Accordingly, we do not find that Dr. Showalter's testimony in that regard demonstrates commercial success of the SpaceOAR product that would be sufficient to support a finding of nonobviousness.

d) Conclusion as to Obviousness

We base our final determination regarding obviousness upon an analysis of the foregoing arguments and evidence. We have considered each of the *Graham* factors and determine that Petitioner has met its overall burden of proving obviousness based on this challenge. As part of that analysis, we have considered the asserted secondary considerations of nonobviousness and, as explained above, Patent Owner has not met its burden of production regarding commercial success. Accordingly, based upon the preponderance of the evidence, we conclude that claims 1–18, and 20–24 of the '913 patent are unpatentable as obvious over Wallace and Ein-Gal.

E. Obviousness over Wallace, Ein-Gal, and Griffith-Cima

Petitioner asserts that claims 19 and 25 are unpatentable as obvious over Wallace, Ein-Gal, and Griffith-Cima. Pet. 44–45, Pet. Reply 9–18. Patent Owner disagrees. PO Resp. 6–36.

We incorporate here our discussion of Wallace and Ein-Gal set forth above in Section II.D.

1. Griffith-Cima

Griffith-Cima relates to slowly polymerizing, biocompatible, biodegradable hydrogels that promote engraftment and provide three

dimensional templates for new cell growth. Ex. 1011, 9:32–37. Griffith-Cima teaches a method of suspending cells in a hydrogel solution and injecting the solution directly into a site in a patient, where the hydrogel hardens into a matrix with cells dispersed in it. *Id.* at 10:3–7. Ultimately, the hydrogel degrades, leaving only the resulting tissue. *Id.* at 10:12–13. Griffith-Cima teaches that hydrogel materials include polysaccharides such as alginate. *Id.* at 15:27–34.

2. Analysis

Claims 19 and 25 depend from claim 1 and further recite that the filler includes alginate and a thermoreversible polymer, respectively. Ex. 1001, 18:19–20, 31–32. Regarding claim 19, Petitioner asserts that Wallace discloses that the compositions may include a carboxylated polysaccharide and that an ordinary artisan would have understood alginate to be a carboxylated polysaccharide that was known to form a hydrogel *in situ*, as taught by Griffith-Cima. Pet. 44 (citing Ex. 1010, 19:59–67; Ex. 1003 ¶¶ 177–178). Moreover, Petitioner asserts that "Applicant cited to Griffith-Cima to overcome an enablement rejection as evidence that alginate was known to form a hydrogel prior to the time of invention," during prosecution of the '913 patent. *Id.* at 44–45 (citing Ex. 1005, 199, 254). According to Petitioner, a person of ordinary skill in the art would have, thus, "appreciated the similarities between alginate and the materials disclosed in Wallace," and therefore "found the use of alginate in the gel compositions of Wallace to be well-known, well-understood, and predictable." *Id.* at 45 (citing Ex. 1003 ¶¶ 177–178).

Regarding claim 25, Petitioner asserts that Wallace teaches that the gel compositions may include synthetic hydrophilic polymers, including poly(ethylene oxide)-poly(propylene oxide) copolymers and block polymers.

Id. at 45 (citing Ex. 1010, 8:26–30; Ex. 1003 ¶ 179). Petitioner notes that during prosecution, Applicant cited Pluronics as an example of a block copolymer based on ethylene oxide and propylene oxide that is a well-known thermoreversible polymer that can form a gel. *Id.* (citing Ex. 1005, 256, 273). Petitioner asserts that Griffith-Cima teaches the use of Pluronics to form a biocompatible hydrogel that may be crosslinked by temperature. *Id.* (citing Ex. 1011, 15:20–34). Thus, Petitioner asserts that a person of ordinary skill in the art would have found the use of thermoreversible polymers in the gel compositions to be well known, well understood, and predictable. *Id.* (citing Ex. 1003 ¶¶ 181–182).

Regarding this ground, Patent Owner asserts only that "claims 9 and 25 should be confirmed as patentable over Wallace, Ein-Gal, and Griffith-Cima," apparently for the same reasons Patent Owner raised for Petitioner's challenge based on Wallace and Ein-Gal. PO Resp. 36.

Thus, for the same reasons set forth in our analysis for the ground based on Wallace and Ein-Gal, along with Petitioner's arguments and evidence set forth for dependent claims 9 and 25, we find that Petitioner has shown by a preponderance of the evidence that the limitations of those dependent claims are taught or suggested by the combination of Wallace, Ein-Gal, and Griffith-Cima, and that a person of ordinary skill in the art would have motivated with a reasonable expectation of success to combine alginate in the filler, as required by claim 9, and to combine a thermoreversible polymer in the filler, as required by claim 25.

Patent Owner does not raise any secondary considerations regarding the methods recited by claims 9 and 25. Accordingly, based on the foregoing, we determine that Petitioner has shown by a preponderance of the

evidence that claims 9 and 25 are rendered obvious by the combined teachings of Wallace, Ein-Gal, and Griffith-Cima.

F. Remaining Grounds of Obviousness

In the remaining grounds of obviousness, Petitioner asserts: (1) claims 1–24 are unpatentable as obvious over Ball, Carroll, and Ein-Gal, Pet. 45–62, Pet. Reply 18–21; and (2) claim 25 is unpatentable as obvious over Ball, Carroll, Ein-Gal, and Griffith-Cima, Pet. 62–63. Patent Owner disagrees. PO Resp. 50–55, PO Sur-Reply 12–13. Because Petitioner challenges the same claims in these grounds that we conclude are unpatentable based upon obviousness grounds involving Wallace, we decline to reach these remaining grounds. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, Nos. 2019-1594, -1604, -1605, 2020 WL 2071962, at *4 (Fed. Cir. Apr. 30, 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

III. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Exhibits 2001, 2002, 2026, and 2027. Mot. 1; Mot. Reply 1. Patent Owner opposes the motion. Opp. 1. As the moving party, Petitioner has the burden of proof to establish that it is entitled to the requested relief. 37 C.F.R. § 42.20(c).

Petitioner asserts that Exhibits 2001, 2002, 2026, and 2027 should be excluded in their entirety under Federal Rules of Evidence ("FRE") 401 and 402 as irrelevant evidence, FRE 403 as prejudicial, confusing, a waste of

time, duplicative or other reasons, and for failing to comply with FRE 702, 703, and 705 relating to testimony and opinions of an expert witness. Mot. 1. The challenged exhibits are the declarations of Patent Owner's experts. Exhibit 2001 is the declaration of Dr. Showalter, Exhibit 2002 is the declaration of Dr. Wnek, Exhibit 2026 is the declaration of Ms. Ray, and Exhibit 2027 is the supplemental declaration of Dr. Showalter.

Generally, Petitioner's objections implicate the weight and sufficiency of the testimony of these declarants, rather than their admissibility. We are in a position to discern whether such testimony should be entitled to weight, either as a whole or with regard to specific issues. And, as set forth in our analysis of patentability, we have done just that. Accordingly, we deny the Motion to Exclude Exhibits 2001, 2002, 2026, and 2027.

IV. CONCLUSIONS

For the foregoing reasons, we conclude that Petitioner has shown by a preponderance of the evidence that claims 1–18 and 20–24 of the '913 patent are unpatentable as obvious over Wallace and Ein-Gal; and claims 19 and 25 are unpatentable as obvious over Wallace, Ein-Gal, and Griffith-Cima.[17] Additionally, we deny Petitioner's Motion to Exclude.

[17] 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).

In summary:

Claims	35 U.S.C. §	References	Claims Shown Unpatentable [18]	Claims Not shown Unpatentable
1–18, 20–24	103(a)	Wallace, Ein-Gal	1–18, 20–24	
19, 25	103(a)	Wallace, Ein-Gal, Griffith-Cima	19, 25	
1–24	103(a)	Ball, Carroll, Ein-Gal		
25	103(a)	Ball, Carroll, Ein-Gal, Griffith-Cima		
Overall Outcome			1–25	

V. ORDER

Accordingly, it is hereby:

ORDERED that based on a preponderance of the evidence claims 1–25 of the '913 patent are unpatentable;

FURTHER ORDERED Petitioner's Motion to Exclude is denied; and

FURTHER ORDERED because this is a final written decision, the 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.

[18] As discussed in Section II.F. above, we do not reach the grounds based upon Ball and Carroll, as we have determined that those claims are unpatentable based on the Wallace grounds set forth in this table.

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Paper 75
Entered: November 22, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDERSECRETARY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

PALETTE LIFE SCIENCES, INC.,
Petitioner,

v.

INCEPT LLC,
Patent Owner.

IPR2020-00002 (Patent 8,257,723 B2)
IPR2020-00004 (Patent 7,744,913 B2)

Before ANDREW HIRSHFELD, *Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

ORDER

The Office has received a request for Director review of the Final Written Decision in each of the above-captioned cases. *See, e.g.*, IPR2020-00002, Ex. 3100. The requests were referred to Mr. Hirshfeld, Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

It is ORDERED that the request for Director review in each case is denied; and

FURTHER ORDERED that the Patent Trial and Appeal Board's Final Written Decision in each case is the final decision of the agency.

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