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Paper No. 8
Date: April 17, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PALETTE LIFE SCIENCES, INC.,
Petitioner,

v.

INCEPT LLC.,
Patent Owner.

IPR2020-00002
Patent US 8,257,723 B2

Before ERICA A. FRANKLIN, ULRIKE W. JENKS, and TINA E. HULSE, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Palette Life Sciences, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–24 of U.S. Patent No. 8,257,723 B2 (Ex. 1001, "the '723 patent"). Paper 2 ("Petition" or "Pet."). Incept LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the argument and evidence presented in the Petition and Preliminary Response, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 1–24 of the '723 patent.

A. 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.

B. Related Proceedings

Petitioner has filed a second petition for *inter partes* review of the '723 patent as IPR2020-00003. Pet. 2. Petitioner also filed petitions for *inter partes* review of related U.S. Patent No. 7,744,913 B2 in IPR2020-00004 and IPR2020-00005. Pet. 2.

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

C. The '723 Patent

The '723 patent relates to a method of placing a degradable filler between the radiation target tissue (e.g., prostate) and other tissues (e.g., rectum) to increase the distance between the target tissue and the other tissues, so that the other tissues receive less radiation than the target tissue. *Id.* at 2:28–32. The degradable filler is installed once before radiation treatment and does not require subsequent manipulation, repositioning, or removal. *Id.* at 2:31–35. Fillers are biodegradable by either hydrolysis, proteolysis, the action of cells in the body, or by a combination of those mechanisms. *Id.* at 4:66–5:1. The Specification explains that "[b]iodegradation may be measured by palpitation or other observations to detect the change in volume of a filler after its introduction into a patient." *Id.* at 5:1–3. 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 '723 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 4:35–46. Biocompatible materials are preferred, especially collagen or hyaluronic

acid. *Id.* at 5:3–4. Fillers may also include osmotic agents and contain drugs. *Id.* at 5:17–29.

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 '723 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; 15:1–16:32 (Example 2). The Specification explains that the combination of body temperature and pH causes the collagen fibrils to cooperate to form a fibrin gel. *Id.* at 5:43–48. "The 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.

D. Illustrative Claim

Petitioner challenges claims 1–24 of the '723 patent. Claim 1, reproduced below, is the only independent claim and is 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 between an organ and a nearby tissue to increase a distance between the organ and the tissue, and treating the tissue with a therapeutic dose of radiation so that the presence of the filler causes the organ to receive less of the dose of radiation compared to the amount of the dose of radiation the

> organ would receive in the absence of the filler, wherein the filler is introduced as an injectable material and is a gel in the patient, and wherein the filler is removable by biodegradation in the patient.

Ex. 1001, 16:49–59.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–24 would have been unpatentable on the following grounds.

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1, 6, 8–12, 14, 15, 17–22	102(e)	Wallace[1]
1–6, 8–12, 14–24	103(a)	Wallace
7, 13	103(a)	Wallace, Griffith-Cima[2]
1–12, 14–24	103(a)	Ball,[3] Carroll[4]
13	103(a)	Ball, Carroll, Griffith-Cima

Petitioner also relies on the Declaration of Adam Dicker, M.D., Ph.D. (Ex. 1003).

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art at the time of the invention would include someone having a medical degree with practical, academic, or industrial experience in radiation oncology, including

[1] Wallace et al., US 6,624,245 B2, issued Sep. 23, 2003 ("Wallace," Ex. 1010).
[2] Griffith-Cima et al., PCT Publication No. WO 94/25080, published Nov. 10, 1994 ("Griffith-Cima," Ex. 1011).
[3] 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).
[4] Carroll, US 6,375,634 B1, issued Apr. 23, 2002 ("Carroll," Ex. 1013).

knowledge of the side effects of radiation treatment. Pet. 11–12 (citing Ex. 1003 ¶¶ 30–31). Petitioner also asserts that a person of ordinary skill in the art at the time of the invention would have experience in performing radiation treatments known at the time of the invention, and methods of shielding or protecting normal tissue or organs from harmful effects of such radiation treatments. *Id.* at 12. 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 ¶ 30.

Patent Owner contests Petitioner's definition of the person of ordinary skill. Prelim. Resp. 1. Patent Owner argues that Petitioner has not explained how a physician meeting its definition of a person having ordinary skill in the art "would have had requisite training or experience to know how to design or select a material that could be used as a filler according to the claimed invention." *Id.* In particular, Patent Owner asserts that "Petitioner does not explain how or why a person trained in providing clinical care to patients would have known enough polymer science to understand how to design or select a 'biocompatible, biodegradable filler device that satisfies [the claimed features].'" *Id.* at 2. Patent Owner does not, however, propose its own definition of the level of ordinary skill in the art in the Preliminary Response. *See* Prelim. Resp. 1–4.

At this stage of the proceeding, we adopt Petitioner's definition, with the clarification that the experience of the hypothetical person of ordinary skill 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. *See* Ex. 1003 ¶ 30. That definition is consistent

with the level of skill in the art at the time of the invention as reflected by the prior art. *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))).

If either party disagrees with our finding of the level of ordinary skill, they are encouraged to develop the argument further at trial.

B. 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); *see* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018).

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 "filler" and "consists essentially of collagen." Pet. 13–14. Patent Owner does not propose any constructions of its own for any claim terms. *See generally* Prelim. Resp. For purposes of this Decision, we address only Petitioner's proposed construction for the term "consists essentially of collagen."

Dependent claim 17 recites, in part, that the "biocompatible, biodegradable material consists essentially of collagen." Ex. 1001, 18:1–2. Petitioner asserts that "[t]he 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 (quoting *In re Herz*, 537 F.2d 549, 551–52 (CCPA 1976)) (emphasis added by Petitioner). Therefore, according to Petitioner, claim 17 "allows components other than collagen to be present so long as they do not prevent collagen from being used as a biocompatible, bioabsorbable filler." Pet. 14.

On this record, we agree with Petitioner's construction as consistent with the Specification and case law. We also note that the claim term "collagen" is used broadly by the Specification, encompassing more than just naturally occurring collagen. 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.

At this stage of the proceeding, 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)).

C. Anticipation by Wallace

Petitioner asserts that claims 1, 6, 8–12, 14, 15, and 17–22 are anticipated by Wallace. Pet. 24–30. Patent Owner disagrees. Prelim. Resp. 4–16.

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. Analysis

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Regarding claim 1, Petitioner asserts that Wallace discloses each and every element of the claim. Pet. 24. In particular, Petitioner asserts that Wallace discloses using polymer gel compositions as a space-filling device to displace organs, such as the intestines and pelvis, relative to one another in a patient to increase the distance between such organs during radiation therapy to, thereby, protect the intestines during radiation to the pelvis. *Id.* at 25–26. Petitioner asserts that the polymer gel composition is biocompatible and biodegradable. *Id.* at 25 (citing Ex. 1010, Abstract, 1:14–15, 3:43–49, 19:3–9, 19:9–19, 28:7–19; Ex. 1003 ¶ 121). Petitioner asserts also that Wallace discloses injecting its composition into a patient's body where it forms a gel. *Id.* at 27 (citing Ex. 1010, 1:14–15, 1:39–45, 2:5–9, 2:12–16, 2:26–32, 3:43–49, 10:9–12, 19:3–19; Ex. 1003 ¶¶ 125–126).

According to Petitioner, a person having ordinary skill in the art "would have appreciated that the compositions, when left in the patient's body, would be removed by biodegradation." *Id.* at 27 (citing Ex. 1003 ¶ 126). Petitioner asserts that Wallace "expressly discloses such an effect" by explaining that the compositions have "biodegradable segments" that are "hydrolyzed in the presence of water and/or enzymatically cleaved in situ." *Id.* (quoting Ex. 1010, 19:3–9).

Patent Owner asserts that Petitioner has not demonstrated that a person of ordinary skill in the art would have known enough polymer science to pick and choose among the many options disclosed by Wallace to arrive at a composition that reads on the claimed invention. Prelim. Resp. 4–6. Regarding the "biodegradable" limitation, Patent Owner argues Wallace does not describe compositions that are biodegradable or removable by biodegradation. *Id.* at 9–14. Patent Owner argues also that Petitioner has not shown that Wallace's disclosure of using its compositions as a "space-filling device for organ displacement" necessarily involves compositions having the specifically claimed properties, i.e., introduced as an injectable material, is a gel in the patient, and is removable by biodegradation. *Id.* at 14–15.

We have considered each of Patent Owner's arguments, but do not find them sufficient at this stage of the proceeding to deny the Petition. Instead, on this record, we find Petitioner's arguments and evidence sufficient to show that each limitation of claim 1 is disclosed by Wallace. In particular, Wallace teaches that its compositions can be used as a large space-filling device for organ displacement in a body cavity during radiation procedures, without limiting such teaching to any specific combination of disclosed components. Ex. 1010, 33:64–67. Additionally, Wallace expressly discloses a method wherein its compositions form biocompatible gels at a selected site within a patient's body. *Id.* at Abstract, 1:15–16, 2:25–31, 42:63. Wallace also discusses "the degradative properties of the compositions after administration and resultant gel formation," and teaches that linking groups may be used to alter such properties to promote hydrolysis, discourage hydrolysis, or to provide a site for enzymatic degradation. *Id.* at 16:23–24, 44–47. Wallace also describes using polymers

including biodegradable segments and blocks, either distributed throughout the polymer's molecular structure or present as a single block, as in a block copolymer. *Id.* at 19:3–6. Petitioner's declarant, Dr. Dicker, refers to such descriptions by Wallace for his testimony that the disclosed compositions would have been degradable and removable by degradation. *See, e.g.*, Ex. 1003 ¶¶ 100, 121, 126 (citing Ex. 1010, 19:3–9). Wallace's teaching that, ideally, such polymers are "essentially nondegradable in vivo over a period of at least several months," does not teach otherwise. Ex. 1010, 7:25–29. Rather, such teaching signals that the polymers are degradable after some pre-determinable term. On this record, we find Dr. Dicker's unrebutted testimony sufficient in view of Wallace's teachings regarding the biodegradable properties of its polymers. Ex. 1010, 19:3–10.

To the extent Patent Owner questions the credibility of Dr. Dicker's testimony for lack of expertise in polymer chemistry, we find his testimony to be sufficiently supported at this stage of the proceeding, as that testimony is guided by the disclosures in Wallace. *See* Ex. 1003 ¶¶ 121–122. Moreover, as explained above, on this record, we consider the level of ordinary skill in the art to include experience with polymer science via their own research or collaborative work with a research team in the medical or biotechnology industry. To the extent Patent Owner questions Dr. Dicker's expertise during trial, we will consider his experience (particularly relative to Patent Owner's expert) when determining what weight to ultimately give to the testimony.

Accordingly, having considered the arguments and evidence presented by the parties, we find Petitioner has shown a reasonable likelihood of prevailing on its assertion that claim 1 of the '723 patent is anticipated by Wallace.

Petitioner has also identified the disclosure in Wallace that teaches each of the specific components of the filler composition set forth in dependent claims 6, 8–12, 14, 15, and 17–22. *See* Pet. 27–30. Patent Owner challenges Petitioner's showing for some of those claims, i.e., dependent claims 6, 8–12, and 17–20, by repeating its assertion that a skilled artisan would have lacked sufficient knowledge of polymer science to prepare a composition comprising the specific elements recited in those claims. Prelim. Resp. 7–9. For the same reasons stated above, we are not persuaded at this stage of the proceeding that Petitioner's person of ordinary skill in the art would have lacked sufficient knowledge to reach the claimed composition.

Further, Patent Owner asserts, regarding dependent claims 6, 8–12, and 17–20, that Wallace's disclosure of the specific components recited by those claims does not teach that the filler comprises those elements because such components are subsequently chemically-modified to include reactive groups and optional linkers. *Id.* at 8–9. On the current record, we find the specific materials recited in the dependent claims should be construed to include derivatives of the materials, as set forth in the '723 patent specification, which, for example, refers to "alginate" to include both naturally occurring alginate and modified derivatives. *See, e.g.*, Ex. 1001, 8:21–48 (describing "[n]aturally occurring alginate" and "modified alginate" derivatives).

Accordingly, we find Petitioner has shown a reasonable likelihood of prevailing on its assertion that claims 6, 8–12, 14, 15, and 17–22 are unpatentable as anticipated by Wallace.

D. Obviousness over Wallace

Petitioner asserts that claims 1–6, 8–12, and 14–24 are unpatentable over Wallace. Pet. 30–37. Patent Owner disagrees. Prelim. Resp. 16–22.

We incorporate here our discussion of Wallace set forth above in Section II. C.

1. Analysis

A patent claim is unpatentable under 35 U.S.C. § 103(a) 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 the subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416.

For its obviousness ground over Wallace alone, Petitioner refers to its anticipation ground based upon Wallace and asserts that, "to the extent Wallace does not explicitly disclose the use of a gel that is both biocompatible and biodegradable, Wallace renders use of such a gel obvious." Pet. 30. Petitioner and Dr. Dicker rely upon Wallace's teachings that (a) the polymers used in its compositions are "essentially nondegradable over a period of at least several months," and (b) the linking groups used to form the composition may promote or discourage hydrolysis, or provide a site for enzymatic degradation. *Id.* at 30–31 (citing Ex. 1003 ¶¶ 143–157). According to Petitioner and Dr. Dicker, those teachings would have given a person having ordinary skill in the art at the time of the invention "[a] reason to use, and a reasonable expectation of success in using, a gel, like those

taught by Wallace, which was both biocompatible and biodegradable to displace an organ for radiation therapy." *Id.* at 31 (citing Ex. 1003 ¶152).

In particular, Petitioner asserts 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.* (citing Ex. 1003 ¶¶ 144–147, 153–154). Petitioner asserts also that a person of ordinary skill would have understood that 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." *Id.* at 31–32 (citing Ex. 1003 ¶ 151). Petitioner asserts that, on the other hand, the skilled artisan would have known that if a biodegradable filler was used, it could be left in the patient's body and absorbed over a set period of time, thus obviating the need to surgically remove the filler after radiation therapy concludes. *Id.* at 31–32 (citing Ex. 1003 ¶ 151). Further, Petitioner asserts that a person of ordinary skill in the art at the time would have had a reasonable expectation of success in using a biocompatible, biodegradable gel to displace an organ during radiation therapy "because Wallace expressly taught gel compositions that may be successfully configured to be both biocompatible and biodegradable and that may be successfully used as a tissue-displacement device." *Id.* at 32 (citing Ex. 1003 ¶¶ 150–157).

Patent Owner refers to its arguments raised regarding the anticipation ground and asserts that they apply "with equal force to Petitioner's obviousness challenged over Wallace." Prelim. Resp. 16. Specifically, Patent Owner asserts that "Petitioner still does not show that its POSA would have had the ability to design [a biocompatible and biodegradable] filler based on Wallace and the clinical training of a radiation oncologist." *Id.*

We have considered each of Patent Owner's arguments, *see* Prelim. Resp. 16–22, and do not find them sufficient at this stage of the proceeding to deny the Petition. As explained for the anticipation ground, on this record, we find Petitioner's arguments and evidence sufficient to show that each limitation of claim 1 is taught by Wallace. "[A]nticipation is the epitome of obviousness." *In re McDaniel,* 293 F.3d 1379, 1385 (Fed. Cir. 2002).

Insofar as Wallace may be viewed as not teaching each claim limitation, we agree with Petitioner that, based on the current record and unrebutted testimony of Dr. Dicker, Wallace at least suggested to a person of ordinary skill in the art to select and prepare a biocompatible, biodegradable polymer gel 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 polymers are essentially *degradable* in vivo over a period of *more than* at least several months.

To the extent Patent Owner again questions the credibility of Dr. Dicker's testimony for lack of expertise in polymer chemistry, we consider his testimony to be sufficiently supported at this stage of the proceeding for the reasons discussed in the anticipation ground. In particular, we note that, on the current record, Dr. Dicker's testimony is unrebutted and appears to be appropriately guided by the teachings in Wallace set forth above and its acknowledgment that a person of ordinary skill in the art would have "easily determine[d] the appropriate administration protocol to use with any particular composition having a known gel strength and gelation time." Ex. 1003 ¶ 151 (quoting Ex. 1010, 28:39–41). Additionally, as explained above, on this record, we consider the level of ordinary skill in the art to include experience with polymer science via their own research or collaborative work with a research team in the medical or biotechnology industry.

Accordingly, having considered the arguments and evidence presented by the parties, we determine that Petitioner has shown a reasonable likelihood of prevailing on its assertion that claims 1–6, 8–12, and 14–24 of the '723 patent are unpatentable as obvious over Wallace.

E. Obviousness over Wallace and Griffith-Cima

Petitioner asserts that claims 7 and 13 are unpatentable as obvious over Wallace and Griffith-Cima. Pet. 37–38. Patent Owner disagrees. Prelim. Resp. 23–25.

We incorporate here our discussion of Wallace set forth above in Section II. C.

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 12–13. Griffith-Cima teaches that hydrogel materials include polysaccharides such as alginate. *Id.* at 15:27–34.

2. Analysis

Claims 7 and 13 depend from claim 1. Claim 7 recites that the filler comprises alginate. Ex. 1001, 17:4–5. Claim 13 recites that the filler comprises a thermoreversible polymer. *Id.* at 13:16–17. Regarding claim 7, 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. 37 (citing Ex. 1010, 19:59–67; Ex. 1011, 11:28–12:8; Ex. 1003 ¶ 184). Moreover, Petitioner asserts that "[A]pplicant 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 parent application to the '723 patent. *Id.* (citing Ex. 1006, 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 38 (citing Ex. 1003 ¶¶ 183–184).

Regarding claim 13, 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. Pet. 38 (citing Ex. 1010, 8:26–30; Ex. 1003 ¶¶ 185-188). 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. 1006, 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).

In response, Patent Owner argues that Petitioner fails to explain how its person of ordinary skill in the art would have been able to reach the claimed subject matter or why a person of ordinary skill in the art would have selected a filler comprising alginate or a thermoreversible polymer such as Pluronics. Prelim. Resp. 23–25.

For the same reasons stated above in our discussion of the previous grounds, we find Petitioner's arguments and evidence with respect to the knowledge of the person of ordinary skill the art to be sufficient at this stage of the proceeding. We also find Dr. Dicker's testimony that a person of ordinary skill in the art would have found it obvious to use alginate and Pluronics based on Wallace's general teaching and Griffith-Cima's specific use of those gel compositions sufficient on this record, with the understanding that the record will be developed further at trial.

Accordingly, having considered the arguments and evidence presented by the parties, we find Petitioner has shown a reasonable likelihood that it

would prevail on its assertion that claims 7 and 13 are unpatentable as obvious over Wallace and Griffith-Cima.

F. Obviousness over Combinations including Ball and Carroll

Petitioner asserts that claims 1–12 and 14–24 are unpatentable as obvious over Ball and Carroll. Pet. 38–51. Petitioner asserts also that claim 13 is unpatentable as obvious over Ball, Carroll, and Griffith-Cima. *Id.* at 51–52. Patent Owner disagrees. Prelim. Resp. 26–30.

We incorporate here our discussion of Griffith-Cima set forth above in Section II. E.

1. Ball

Ball relates to the use of a silicone implant to prevent visceral damage during adjuvant radiation therapy for cancerous tissue. Ex. 1012, 346. Ball states that "[b]y securing a silicone gel-filled implant . . . in the tumour bed after excision of the tumour, adjacent viscera are displaced from the site of maximum irradiation and may thereby be protected." *Id.* at Abstract. Ball teaches surgically removing the implant after radiation therapy. *Id.* However, Ball reports side effects potentially caused by the silicone implant, including infection and bowel perforation. *Id.* at 348. Because removing the implant at an earlier stage would inflict further surgery on the patient, Ball proposes using an expandable prosthesis that could be withdrawn during the initial treatment, "or a prosthesis made entirely from absorbable material." *Id.*

2. Carroll

Carroll relates to a method of encapsulating a tissue and treating the tissue with radiation therapy. Ex. 1013, Abstract. Carroll explains that "[c]ollateral damage to normal tissues adjacent to cancerous tumors [] limits the effectiveness of radiation therapy." *Id.* at 2:38–39. Carroll states that

improved radiation therapy can be conducted with encapsulation. *Id.* at 3:3–7.

Carroll describes the encapsulating material as physiologically compatible, biodegradable, and resorbable. *Id.* at 10:23–25, 15:1–4, 23:32. The material may be injected and *in situ* crosslinked in the patient. *Id.* at 4:14–21. Carroll describes encapsulating materials as including hydrogel-forming materials, such as hyaluronic acid, and synthetic or naturally occurring resorbable materials, such as collagen, polyethylene glycol polymers, alginate, and polymers of polyglycolic and polylactic acids. *Id.* at 7:62–8:59.

3. Analysis

Petitioner asserts that Ball describes a method of radiation therapy including the step of introducing a biocompatible implant between normal tissue and cancerous tissue to increase distance between tissues and reduce the amount of radiation to the normal tissue. Pet. 38–40 (citing Ex. 1012, 346; Ex. 1003 ¶¶ 236–237). Petitioner asserts Ball teaches the implant must be surgically removed after treatment, and recognizes the advantage of a biodegradable implant that would not require surgical removal. *Id.* Petitioner asserts that Carroll describes biocompatible, biodegradable hydrogels used to encapsulate malignant tumors treated with radiation therapy. *Id.* at 39–40 (citing Ex. 1013, 1:18–20, 1:62–65; 3:66–4:17, 6:26–28, 17:32–35, 23:25–32; Ex. 1003 ¶ 238). Petitioner asserts Carroll's hydrogel is introduced as an injectable material and forms an elastic solid or semi-solid in the patient's body. *Id.* at 42 (citing Ex. 1013, 3:66–4:17, 7:54–57, 9:28–42; Ex. 1003 ¶ 243). Petitioner asserts that Ball describes the need for absorbable implants to be used in radiation therapy. *Id.* at 44 (Ex. 1012, 348; Ex. 1003 ¶ 237).

According to Petitioner, regarding claims 1–12 and 14–24, a person of ordinary skill in the art would have had a reason to use Carroll's biodegradable material to displace healthy tissue during radiation therapy, as taught by Ball, to eliminate the need for further surgery to remove the implant device. *Id.* at 44 (citing Ex. 1003 ¶ 239). Further, Petitioner asserts that the person of ordinary skill in the art would have had a reasonable expectation of success in combining the references because Carroll teaches biodegradable hydrogels for filling a desired space within the patient's body for protecting healthy tissue, and Ball suggests using biodegradable spacers. *Id.* at 44–45 (citing Ex. 1003 ¶ 239). To reach dependent claim 13, Petitioner additionally relies on Griffith-Cima in the combination as teaching of a filler that includes a thermoreversible polymer. *Id.* at 51–52.

Patent Owner argues that Petitioner's analysis is vague and fails to provide a rationale to combine the references. Prelim. Resp. 26–30. For example, Patent Owner argues Petitioner does not explain how Ball would have been modified by a person of ordinary skill in the art in view of Carroll. *Id.* at 26–27. Patent Owner argues Petitioner has failed to explain its challenge with particularity in this regard. *Id.* Additionally, Patent Owner argues that "Petitioner does not explain how any material from Carroll could replace a part of Ball's implant while allowing the implant to maintain its structure as a gel-filled prosthesis and be securable in a tumor bed . . . ." *Id.* at 28. More specifically, Patent Owner argues that replacing Ball's silicone implant with Carroll's hydrogel would render Ball's implant unsuitable for its intended purpose of being fastened in place. *Id.* at 28–29.

Having considered the arguments and evidence, we agree with Patent Owner that Petitioner has not explained sufficiently how a person of ordinary skill in the art would have combined Ball and Carroll to reach the

claimed invention of claims 1–12 and 14–24, or combined Ball, Carroll, and Griffith-Cima to reach claim 13.

Specifically, it is unclear how Petitioner combines the implant device of Ball with the encapsulating hydrogel of Carroll. Petitioner asserts Ball recognizes the advantages of using "a prosthesis made entirely from absorbable material" to eliminate the need for surgical removal. Pet. 44 (quoting Ex. 1012, 348; citing Ex. 1003 ¶ 237). Petitioner asserts also that a person of ordinary skill in the art would have considered it obvious to use a biocompatible, biodegradable hydrogel composition like Carroll to displace a tissue location to protect an organ from radiation's harmful effects, as taught by Ball. *Id.* (citing Ex. 1003 ¶ 239). It is unclear from the Petition, however, whether Petitioner argues a person of ordinary skill in the art would have filled the Ball implant with the hydrogel of Carroll, or if Petitioner argues that it would have been obvious to replace the Ball implant altogether with the encapsulating hydrogel of Carroll. According to Petitioner's Explanation of Multiple Petitions, the approach of the instant Petition "is the use of an injection of a gel filler to displace an organ from a tissue that is the target of radiation, without using a biodegradable envelope for the gel filler." Paper 3, 3. This approach is not clear from the argument set forth in the Petition and, therefore, may not be considered on the merits because it presents a new argument.

In any event, even if we were to consider Petitioner's explanation, it remains unclear why or how a person of ordinary skill in the art reading Carroll's encapsulation method would have combined Carroll's teaching with that of Ball to reach the claimed invention. According to Petitioner, Carroll teaches placing a biocompatible, biodegradable hydrogel "between a tumor's site and surrounding healthy tissue to act as a barrier that protects

the healthy tissue during a course of treatment." Pet. 43 (citing Ex. 1013, 10:46–52; Ex. 1003 ¶ 238). We find this to be an oversimplification of Carroll. Carroll teaches "methods in which a channel is provided around a tissue of the organism, and an encapsulating composition is infused into the channel to encapsulate the tissue in a capsule." Ex. 1013, Abstract.

Put simply, Petitioner's argument lacks clarity and we are not inclined to decipher Petitioner's argument for ourselves. We, therefore, find Petitioner has not established a reasonable likelihood of succeeding on its assertion that claims 1–12 and 14–24 are unpatentable over Ball and Carroll, or that claim 13 is unpatentable over Ball, Carroll, and Griffith-Cima.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that at least one claim of the '723 patent is unpatentable. In *SAS Institute Inc. v. Iancu*, the Supreme Court held that the Board's final written decision in an instituted *inter partes* review must address every claim challenged by a petitioner. 138 S. Ct. 1348, 1354 (2018). In light of *SAS*, the "the Board will either (1) institute as to all claims challenged in the petition and on all grounds in the petition, or (2) institute on no claims and deny institution." Patent Trial and Appeal Board Consolidated Trial Practice Guide 64 (Nov. 2019), *available at* https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf. We, accordingly, institute an *inter partes* review of all of the challenged claims on all asserted grounds.

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any claim term and, thus, leaves undecided any remaining fact issues necessary to determine whether sufficient evidence supports Petitioner's contentions

by a preponderance of the evidence in the final written decision. *See Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing *id.* § 316(e)).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–24 of the '723 patent is instituted, commencing on the entry date of this decision; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of review.

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