

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HYPERBRANCH MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

INCEPT LLC,
Patent Owner.

Case IPR2016-01836
Patent 7,009,034 B2

Before JAMES T. MOORE, SUSAN L. C. MITCHELL, and
KRISTI L. R. SAWERT, *Administrative Patent Judges*.¹

SAWERT, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

¹ Judge Murphy is no longer with the Board, necessitating a panel change.

I. INTRODUCTION

In this *inter partes* review, HyperBranch Medical Technology, Inc. (“Petitioner”) challenges the patentability of claims 1–6 and 8–12 of U.S. Patent No. 7,009,034 B2 (“the ’034 patent,” Ex. 1001), assigned to Incept LLC (“Patent Owner”). We have jurisdiction under 35 U.S.C. § 6. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–6 and 8–12 are unpatentable. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

A. Related Matter

The parties identify the following district court action as a related matter under 37 C.F.R. § 42.8(b)(2): *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, C.A. No. 15-819-LPS-CJB (D. Del.) (the “district court litigation”). Pet. 6; Paper 6, 2.

B. Procedural History

Petitioner filed a corrected Petition for an *inter partes* review of claims 1–12 of the ’034 patent. Paper 4 (“Pet.”). On April 4, 2017, the prior panel instituted an *inter partes* review of claims 1–6 and 8–12 of the ’034 patent on certain asserted grounds of unpatentability. Paper 14 (“Institution Decision” or “Inst. Dec.”).

After institution, Patent Owner filed a Patent Owner Response (Paper 17, “PO Resp.”), and Petitioner filed a Reply (Paper 26, “Reply”). On the Board’s Order (Paper 36), both parties filed Supplemental Briefs, and Patent Owner filed additional evidence relating to certain documents produced in the district court litigation. Paper 45 (“PO Suppl. Br.”); Paper 47 (“Pet.

Suppl. Br.”); *see also* Ex. 1055 (“First Transcript” or “First Tr.”). Both parties also filed Supplemental Rebuttal Briefs. Paper 51 (“PO Rebut.”); Paper 55 (“Pet. Rebut.”); *see also* Paper 58 (Order and Conduct of the Proceeding Reaffirming Rebuttal Briefing); Ex. 1056 (“Second Transcript” or “Second Tr.”).

Both parties filed motions to exclude evidence, and the briefing on those motions included oppositions and replies. *See* Papers 38, 41, 52, 54, 56, 57, 59, 60, and 61. Patent Owner filed Observations on Cross Examination, Paper 40, to which Petitioner responded, Paper 53. Patent Owner also filed an Unopposed Motion to Seal and for Entry of Protective Order. Paper 42.

The Board held an oral hearing on January 10, 2018. A transcript of the hearing has been entered into the record. Paper 63 (“Third Tr.”).

C. The '034 Patent

The '034 patent discloses and claims biocompatible crosslinked polymers that “are formed from water soluble precursors having electrophilic and nucleophilic functional groups capable of reacting and crosslinking in situ.” Ex. 1001, Abstract. Biocompatible crosslinked polymers, and especially hydrogels, were known in the art as useful for the prevention and treatment of surgical adhesions (i.e., the adhesion of tissues exposed during surgery to one another), tissue augmentation, medical device coating, surgical sealing, and drug delivery. *Id.* at 1:30–60. The '034 patent explains, however, that these prior-art hydrogels “are essentially colorless” and, therefore, “difficult to visualize, especially in the typically wet and moist surgical environment” and under “laparoscopic conditions.” *Id.* at

2:4–14. The inventors of the '034 patent “realized that use of color in biocompatible crosslinked polymers and precursors greatly improves their performance in a surgical environment.” *Id.* at 2:18–22. Thus, the hydrogel may contain a “visualization agent” that “reflects or emits light at a wavelength detectable to a human eye.” *Id.* 2:30–32; *see also id.* at 10:47–50 (“Where convenient, the biocompatible crosslinked polymer or precursor solutions (or both) may contain visualization agents to improve their visibility during surgical procedures.”).

The visualization agent, the '034 patent explains, allows a user to determine the thickness of the hydrogel as it is being applied. *Id.* at 5:9–10. Specifically, the visualization agent “lets a user applying the hydrogel observe the hydrogel and estimate its thickness and apply the hydrogel until it reaches a predetermined thickness.” *Id.* at 2:32–35; *see also id.* at 2:63–67 (“A preferred method of use is to form a hydrogel on the tissue until the color and/or color intensity of the hydrogel indicates that a pre-determined thickness of hydrogel has been deposited on the tissue.”). The visualization agent “makes the hydrogel change in its appearance until the user determines [its] thickness.” *Id.* at 5:50–51. “For example,” the '034 patent explains, “a blue dye in the hydrogel makes the hydrogel increasingly opaque as the thickness of the hydrogel increases.” *Id.* at 5:53–55. The '034 patent further explains that the hydrogel’s thickness may affect surgical outcomes: a hydrogel that is “too thick” will interfere with, for example, the closure of a wound or tissue movement, whereas “[a] hydrogel that is too thin will not serve its purpose, e.g., providing a barrier that prevents surgical adhesions or provides a strong seal against fluid leakage.” *Id.* at 5:2–9.

The '034 patent teaches that the visualization agents “may be selected from among any of the various non-toxic colored substances suitable for use in medical implantable medical devices,” *id.* at 10:53–55, and lists the preferred visualization agents as “FD&C Blue #1, #2, #3, D&C Green #6, and methylene blue,” *id.* at 2:46–47. The '034 patent also states that the visualization agent may be a fluorescent molecule. *Id.* at 2:47–48, 7:2–3.

The visualization agent “provides a color that is visible to the human eye, e.g., a color that is detected visually by the user or detected by a video camera and relayed to a video screen observed by the user.” *Id.* at 5:10–14. The '034 patent teaches that visually-observable visualization agents, i.e., those agents having a color detectable to a human eye, are preferred. *Id.* at 11:11; *see also id.* at 7:56–57 (“A visually observable visualization agent is an agent that has a color detectable by a human eye.”). But visualization agents not normally visible to the human eye may also be used, so long as those agents are “detectable at a different wavelength, e.g., the infra red or ultraviolet, when used in combination with a suitable imaging device, e.g., a video-camera.” *Id.* at 7:60–65.

Finally, the '034 patent teaches that “[c]onventional polymeric hydrogels” “have sometimes been mixed with image contrast agents to increase their visibility for medical imaging devices such as X-ray or magnetic resonance imaging (MRI) machines.” *Id.* at 5:15–22. But, “[a] characteristic of providing imaging to an X-ray or MRI machine is not a characteristic sufficient to establish function as a visually observable visualization agent.” *Id.* at 7:58–60.

D. Illustrative Claim

Claim 1 of the '034 patent is the only independent claim and is illustrative of the challenged claims:

1. A method of preparing a composition suitable to coat a tissue of a patient, the method comprising:

mixing reactive precursor species comprising nucleophilic functional groups, reactive precursor species comprising electrophilic functional groups, and a visualization agent such that the nucleophilic functional groups and electrophilic functional groups crosslink after contact with the tissue to form a hydrogel having an interior and an exterior, with the exterior having at least one substrate coating surface and the visualization agent being at least partially disposed within the interior and reflecting or emitting light at a wavelength detectable to a human eye to thereby provide a means for visualization of the coating by a human eye.

Ex. 1001, 39:56–40:2.

E. Prior Art References Relied Upon by Petitioner

Petitioner relies on the following prior art:

1. Woonza M. Rhee, et al., U.S. Patent 5,874,500 (filed Dec. 18, 1996) (issued Feb. 23, 1999) (“Rhee ’500”) (Ex. 1004);
2. Woonza M. Rhee, et al., U.S. Patent 5,614,587 (filed Jun. 7, 1995) (issued Mar. 25, 1997) (“Rhee ’587”) (Ex. 1005);
3. Lawrence S. Bass, et al., U.S. Patent 5,292,362 (filed Jul. 9, 1991) (issued Mar. 8, 1994) (“Bass”) (Ex. 1006); and
4. David S. Tse, et al., *Cyanoacrylate Adhesive Used to Stop CSF Leaks During Orbital Surgery*, ARCH OPHTHALMOL, 102:1337–39 (Sept. 1984) (“Tse”) (Ex. 1007).

F. Instituted Grounds of Unpatentability

The Board instituted *inter partes* review on the following grounds of unpatentability, each based on 35 U.S.C. § 103(a):

Claims	References
1–6, 8–12	Rhee ’500 in view of Bass
1–6, 8–12	Rhee ’500 in view of Tse
1–6, 8–12	Rhee ’587 in view of Bass
1–6, 8–12	Rhee ’587 in view of Tse

Instit. Dec. 27. Petitioner relies on the Declarations of Anthony M. Lowman, Ph.D., dated September 16, 2016 (Ex. 1003), and October 5, 2017 (Ex. 1041). In its Response, Patent Owner relies on the Declaration of Jimmy W. Mays, Ph.D., dated July 6, 2017 (Ex. 2006), and the Declaration of Amarpreet S. Sawhney, Ph.D., dated July 5, 2017 (Ex. 2007).

II. DISCUSSION

We have reviewed the parties’ respective briefs as well as the relevant evidence discussed in those papers. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–6 and 8–12 are unpatentable under 35 U.S.C. § 103(a) for obviousness. In particular, we determine that this case is one that falls within the Supreme Court’s characterization of obviousness as entailing an improvement that is no “more than the predictable use of prior art elements according to their established functions.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

A. Principles of Law

To prevail in its challenges to the patentability of claims 1–6 and 8–12, 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). “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) (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*, 550 U.S. at 406. 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). A petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *Magnum Oil*, 829 F.3d at 1380. Moreover, a decision on the ground of obviousness must include “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed.

Cir. 2006). We analyze the asserted grounds of unpatentability in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

We begin with the level of ordinary skill in the art. The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). The parties agree that the relevant “time of the invention” in this case is the November 9, 2001, filing date of the ’034 patent. Reply 3.

Upon review of the parties’ respective definitions of a person of ordinary skill in the art, we adopt Petitioner’s definition as

a person with either: (1) a Ph.D. in the field of chemistry, polymer chemistry, chemical engineering, materials science and/or a related field and having at least one year of educational or work experience in the synthesis and development of biocompatible polymer materials; (2) a bachelor’s degree in in [sic] the field of chemistry, polymer chemistry, chemical engineering, materials science and/or a related field and at least two years of work experience in the synthesis and development of biocompatible polymer materials; or (3) any education and experience equivalent to (1) or (2).

Pet. 22 (citing Ex. 1003 ¶ 49). We find that Patent Owner’s definition of the ordinarily skilled artisan, i.e., a person having “a Ph.D. degree, or equivalent education, in polymer chemistry, or a bachelor of science degree in chemistry or a closely related field and several years of experience in the development and manufacture of polymer materials for use as tissue sealants,” PO Resp. 15–16 (citing Ex. 2006 ¶ 27), does not differ materially

from Petitioner’s definition. Furthermore, our analysis would be the same under either parties’ definition.

We also find that the prior art itself is sufficient to demonstrate the level of ordinary skill in the art at the time of the invention. *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). And, based on the information presented, we consider both parties’ technical declarants—Dr. Lowman and Dr. Mays—qualified to opine from the perspective of an ordinary artisan at the time of the invention. *See* Ex. 1003, 99–111 (curriculum vitae of Dr. Lowman); Ex. 2006, 134–236 (curriculum vitae of Dr. Mays).

C. Broadest Reasonable Interpretation

Having defined the ordinarily skilled artisan, we now turn to the claim terms in dispute in this review. In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, we presume that a claim term carries its “ordinary and customary meaning,” which “is the meaning that the term would have to a person of ordinary skill in the art in question” at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) (“Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent

with the specification and prosecution history.”). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. “*visualization agent*”

In its Petition, Petitioner proposed interpretations of certain claim terms. Pet. 18–22. The Board determined in its Institution Decision, however, that only the term “visualization agent” required express interpretation. Inst. Dec. 8 (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”)). The Board set forth the broadest reasonable interpretation of “visualization agent” as “an agent that reflects or emits light at a wavelength detectable to a human eye so that a human eye may visualize the hydrogel coating.” *Id.* at 9. Neither party challenges that interpretation. *See, e.g.*, Third Tr. 6:15–17. We have reassessed that determination in light of the arguments and evidence adduced at trial, and maintain that determination based on the full record.

2. “*suitable to coat a tissue of a patient*”

During trial, a dispute arose between the parties about whether the preamble of claim 1, which recites a composition “suitable to coat a tissue of a patient,” is limiting. Third Tr. 6:17–19. The parties’ dispute relates to deposition testimony that Patent Owner’s expert, Dr. Mays, provided in the co-pending district court litigation, and that was entered into evidence in this case. Dr. Mays testified that “the claim requiring the composition be

suitable to coat a tissue of a patient calls for a biocompatible material.”

Ex. 2020, 321:14–16; *see also* Pet. Suppl. Br. 4–6. Patent Owner’s position, based on that testimony, is that the preamble phrase “suitable to coat a tissue of a patient” is limiting, and means that the hydrogel composition must be biocompatible. PO Rebut. 2–3. Petitioner, however, contends that the preamble is not limiting because the “claim body recites an otherwise complete invention” and the “preamble of claim 1 is merely a statement of purpose.” Pet. Suppl. Br. 4.

“In general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quotation omitted). “Conversely, a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Id.* Here, we determine that the preamble phrase “suitable to coat a tissue of a patient” is not merely a statement of purpose, but instead represents the “essence or a fundamental characteristic of the claimed invention.” *Vizio, Inc. v. Int’l Trade Com’n*, 605 F.3d 1330, 1340 (Fed. Cir. 2010).

In *Vizio*, the Federal Circuit held that a preamble reciting “for decoding” certain data “is properly construed as a claim limitation” because the apparatus and method claims reciting that preamble “would have little meaning without the intended objective of decoding.” *Id.* at 1341. Similarly here, we determine that the method step of claim 1—namely, mixing reactive nucleophilic precursor species, electrophilic precursor species, and a

visualization agent—would have little meaning without the intended objective of forming a hydrogel coating on the tissue of a patient. Put differently, there would be no reason to perform the method step of claim 1 but for forming a hydrogel coating on the patient’s tissue. See Ex. 1001, 39:56–40:2 (claim 1) (providing that the reactive precursors crosslink after contact with the tissue to form a hydrogel in the form of a coating). Thus, we determine that “suitable to coat a tissue of a patient” is limiting in this case because it gives “life and meaning” to method claim 1.

We further find that the arguments and evidence in this case show that skilled artisans would reasonably interpret “suitable to coat a tissue of a patient” as encompassing a biocompatibility requirement. Although Petitioner correctly notes that “[n]one of challenged claims recite the term ‘biocompatible,’” Petitioner acknowledges that skilled artisans understand “that hydrogels are, by their nature as water-swelled materials, known to be biocompatible.” Pet. Suppl. Br. 4–5. Petitioner’s expert, Dr. Lowman, declared that “biocompatibility is presumed as a fundamental aspect of the claimed and disclosed inventions.” Ex. 2018 ¶ 40. And in his deposition, Dr. Lowman testified that skilled artisans would understand “biocompatible” to mean that the hydrogel composition is “*suitable for use* and tolerated by a patient.” Ex. 2019, 13:2–11 (emphasis added). Thus, we agree with Patent Owner that “suitable to coat a tissue of a patient” reasonably encompasses a biocompatibility requirement for the hydrogel composition.

3. Other claim terms

Based on our review of the record, we determine that no other claim terms require an express interpretation to resolve the issues presented by the Petitioner's patentability challenges. *See Vivid Techs.*, 200 F.3d at 803.

D. Scope and Content of the Prior Art

The technology in this case concerns hydrogels. Hydrogels comprise a network of crosslinked polymer molecules that are capable of absorbing water. Ex. 1003 ¶¶ 29–30; Ex. 1041 ¶ 18. The polymer molecules may be crosslinked by chemical reactions between complementary electrophilic and nucleophilic groups present on the polymer molecules that form chemical bonds. Ex. 1003 ¶ 31; Ex. 2006 ¶ 34. Hydrogels are known in the art as useful for medical applications in the body, including for tissue augmentation, medical device coating, surgical sealing, drug delivery, and for the prevention of post-operative adhesions. *See, e.g.*, Ex. 1001, 1:54-60; Ex. 1018 (Abstract). Post-operative adhesions occur when, following surgery, bridges of fibrous tissue form between adjacent tissues and organs, thus causing the tissues and organs to “stick” together. Ex. 1018, 1153. These adhesions often result in pain and other complications. *Id.*; *see also* Ex. 1001, 1:30–38.

Petitioner's obviousness challenges can be organized by two sets of references: (1) Rhee '500 and Bass or Tse; and (2) Rhee '587 and Bass or Tse. Although each set of references stands independently, we choose to address Rhee '500 and Rhee '587 together because both references teach biocompatible crosslinked polymers formed by a chemical reaction between electrophilic and nucleophilic reactive groups. Pet. 23–25. The additional

references—Bass and Tse—teach the use of dyes in polymeric materials. *Id.* at 25–28. The remaining reference described below—Wallace—was filed by Patent Owner during the trial as late supplemental information under 37 C.F.R. § 42.123(b). *See* Paper 36. An overview of these references is provided below.

1. Rhee '500

Rhee '500 discloses crosslinked polymer compositions that comprise “a first synthetic polymer containing multiple nucleophilic groups” and “a second synthetic polymer containing multiple electrophilic groups.” Ex. 1004 (Abstract). The first synthetic polymer and the second synthetic polymer “covalently bond[] to one another to form a three dimensional matrix.” *Id.* at 2:27–32. Rhee '500 teaches that the crosslinked polymer compositions may be used as, for example, “bioadhesives, for tissue augmentation, in the prevention of surgical adhesions.” *Id.* at 1:17–19. Specifically, the crosslinked polymer compositions may be used to “coat tissues in order to prevent the formation of adhesions following surgery or injury to internal tissues or organs.” *Id.* at 19:6–9.

Rhee '500 teaches that the crosslinked polymer composition is made by mixing the first synthetic polymer with the second synthetic polymer. *Id.* at 3:9–19. The resulting “reaction mixture” may then be “applied to tissue comprising, surrounding, or adjacent to a surgical site.” *Id.* Rhee '500 teaches to apply the resulting mixture “before substantial crosslinking has occurred between” the nucleophilic groups of the first synthetic polymer and the electrophilic groups of the second synthetic polymer. *Id.* “[T]he

reaction mixture is allowed to continue crosslinking in situ until equilibrium crosslinking has been achieved.” *Id.*

Rhee ’500 teaches that the time required for crosslinking varies, depending on “the types and molecular weights of the two synthetic polymers and, most particularly, the concentrations of the two synthetic polymers.” *Id.* at 17:33–38. In particular, Rhee ’500 discloses crosslinking times from 5.0 seconds to more than 90 minutes. *Id.* at 24:8–24 (Table 6).

Rhee ’500 teaches that the preferred synthetic polymers are hydrophilic in nature, such as various polyethylene glycols. *Id.* at 7:52–55. And Rhee ’500 discloses several examples of crosslinked polymer compositions comprising hydrophilic polymers, *see id.* at 4:17–18 (Figs. 4–13), including crosslinked polymer compositions containing linkages “subject to hydrolysis under physiological conditions,” *id.* at 8:8–13.

Rhee ’500 teaches that the crosslinked polymer composition may also comprise “[n]aturally occurring proteins,” such as collagen, albumin, fibrin, and fibrinogen. *Id.* at 11:3–12, 13:30–33. These proteins may react with the functional groups of the synthetic polymers, such that “their presence during mixing and/or crosslinking of the first and second synthetic polymer will result in formation of a crosslinked synthetic polymer-naturally occurring polymer matrix.” *Id.* at 11:3–12. Rhee ’500 further teaches the incorporation of biologically active agents into the crosslinked synthetic polymer compositions “for localized delivery” of the agents. *Id.* at 14:60–65, 15:38–43.

2. *Rhee '587*

Rhee '587 also discloses crosslinked polymer compositions, but limited to those comprising collagen crosslinked with a multifunctionally activated synthetic hydrophilic polymer. Ex. 1005, 4:51–54. *Rhee '587* defines “multifunctionally activated” polymers as “synthetic hydrophilic polymers which have, or have been chemically modified to have, two or more functional groups located at various sites along the polymer chain and are capable of reacting with primary amino groups on collagen molecules.” *Id.* at 8:16–23. *Rhee '587* teaches that the compositions are “useful as biological or surgical adhesives” “to effect adhesion between a first surface and a second surface, wherein at least one of the first and second surfaces is preferably a native tissue surface.” *Id.* at 1:20–27.

In one example, *Rhee '587* prepares a bioadhesive composition by mixing methylated collagen with “difunctionally activated” succinimidyl glutarate-polyethylene glycol (“SG-PEG”). *Id.* at 8:50–67. *Rhee '587* explains that the difunctionally activated SG-PEG was obtained by chemically modifying the PEG molecule to provide functional groups along its length capable of “covalent binding” with collagen reactive groups. *Id.* *Rhee '587* applied the mixture “onto a bloody wound site on the liver of a previously sacrificed rabbit and allowed to gel for 1 minute.” *Id.* at 19:11–23. *Rhee '587* states that the methylated collagen—SG-PEG gel “adhered very well to the liver, [but] not as well to the skin.” *Id.* at 19:22–23.

Rhee '587 teaches that the collagen-based bioadhesive compositions may also comprise biologically active agents “in order to facilitate adhesion of tissues or healing of adhered tissues.” *Id.* at 7:12–15.

3. Bass

Bass discloses a composition “adapted to bond separated tissues together or to coat tissues or prosthetic materials.” Ex. 1006, 1:9–11. The composition comprises, as a first component, naturally occurring peptides and/or synthetic peptides, which function to provide tensile strength. *Id.* at 4:29–34, 53–56. The composition further comprises, as a second component, a compound “adapted to support the first component producing an improved degree of inter-relationship among the molecules of the first component.” *Id.* at 4:34–38. These include “natural or synthetic proteoglycans, glycoproteins, saccharides, polyalcohols, protein gels, gelatins, . . . and mixtures thereof.” *Id.* at 5:12–19.

Bass teaches that “[t]he composition of the present invention may also include indogenous [sic] or exogenous chromophores to facilitate visualization of the material during placement into warm blooded animals.” *Id.* at 11:18–21. In particular, Bass explains, the “[u]se of a chromophore will allow material which becomes displaced from the desired application site to be easily visualized, and subsequently removed using a cellulose sponge, gauze pad, or other absorbing material.” *Id.* at 11:21–25. Bass also teaches that exogenous chromophores may be used “for aid in the placement of biological glues.” *Id.* at 11:29–34.

Examples of chromophores include “fluorescein isothiocyanate, indocyanine green, silver compounds such as silver nitrate, rose bengal, Nile blue and Evans Blue, Q-Switch™, a dye made by Kodak, Inc., Sudan III, Sudan Black B and India Ink.” *Id.* at 11:35–40. Bass also claims “methylene blue” as a preferred chromophore. *Id.* at 20:1–3 (claim 31).

4. *Tse*

Tse teaches the use of cyanoacrylate adhesive to stop leakage of CSF (cerebrospinal fluid) during orbital surgery. Ex. 1007, 7. Specifically, Tse reports that topical application of butyl-2-cyanoacrylate (Histoacryl Blue) immediately stopped CSF leakages during surgery. *Id.* Tse explains that the tissue adhesive is “applied as a thin film over the prepared” tissue site to form an “adhesive plaque.” *Id.* Tse further teaches that the tissue adhesive contains a “color additive” “which facilitates visualization and assessment of plaque thickness.” *Id.*

5. *Wallace*

Wallace teaches “two-part polymer compositions that rapidly form covalent linkages when mixed together” that are useful “in the prevention of surgical adhesions.” Ex. 2014 (Abstract). The first part of the composition comprises multiple sulfhydryl groups, and the second part of the composition comprises sulfhydryl-reactive groups. *Id.* at 4:28–40. The polymer compositions may also contain additional compounds. *Id.* at 7:61–8:38. Wallace describes the addition of collagen and amino-group containing proteins as “improv[ing] biocompatibility of the matrix” and “contribut[ing] to the structural integrity of the matrix.” *Id.* at 8:9–23.

In Example 4, Wallace presents the results of biocompatibility experiments performed on New Zealand white rabbits. *Id.* at 12:54–13:58 (Example 4). Up to six subcutaneous pockets were made on the backs of the rabbits, and the components of each composition listed in Table 4 were delivered to those pockets. *Id.* As shown in Table 3, below, gross and histological observations were made and graded from “normal” with “no

inflammation,” (-), to “severe foreign body response” and “severe inflammation,” (++++). *Id.* at 12:66–13:13 (Table 3).

TABLE 3		
Grading Key for Biocompatibility Experiments		
Score	Gross Observations	Histological Observations
-	all tissues appeared normal	all tissues appeared normal, no inflammation
+	mild foreign body response	mild inflammation
++	moderate foreign body response	moderate inflammation
+++	marked foreign body response	marked inflammation
++++	severe foreign body response	severe inflammation

Table 3 shows the grading key for biocompatibility experiments for various hydrogel compositions. Ex. 2014, 13:1–13.

As shown in Table 4, “Test C” hydrogel—made with tetra-amino PEG—produced a severe foreign body response, severe inflammation, and “thick encapsulation of the hydrogel and abscess formation.” *Id.* at 13:38–41. In contrast, “Test D” hydrogel—made with tetra-sulfhydryl PEG—produced a “moderate foreign body response” and “moderate inflammation.” *Id.* at 13:41–43. Wallace states that “[b]y substitution of sulfhydryl-PEG for amino-PEG . . . , the biocompatibility of the hydrogel is significantly improved.” *Id.*

TABLE 4

Results for Biocompatibility Experiments			
Test	Description	Results	
		Gross Observations	Histo-logical Observations
A	surgical control	–	+
B	fibrillar collagen	–	+
C	20% w/v tetra-SG PEG 10,000 + 20% w/v tetra-amino PEG 10,000	++++	++++
D	20% w/v tetra-SG PEG 10,000 + 20% w/v tetra-sulphydryl PEG 10,000	++	++
E	20% w/v tetra-SG PEG 10,000 + 20% w/v tetra-amino PEG 10,000; gelled ex-vivo; treated with mono-SG PEG 5000	+	++
F	20% w/v tetra-SG PEG 10,000 + 20% w/v di-sulphydryl PEG 3,400; gelled ex-vivo; treated with di-amino PEG 3400	++++	++++

Table 4 shows the results of biocompatibility experiments for various hydrogel compositions. Ex. 2014, 13:14–35.

Wallace defines “biocompatible” as “the ability of the compositions of the present invention to be applied to tissues without eliciting significant inflammation and fibrosis or other adverse tissue responses.” *Id.* at 3:64–67.

E. Obviousness over the Rhee references² in view of Bass or Tse

Petitioner contends that claims 1–6 and 8–12 are unpatentable as obvious over Rhee ’500 in view of Bass or Tse, and Rhee ’587 in view of Bass or Tse. Pet. 8. Petitioner argues that the Rhee references teach biocompatible crosslinked polymers formed by a chemical reaction between electrophilic and nucleophilic reaction groups for use in medical applications such as tissue coating, and that Bass and Tse teach the use of dyes to allow visualization of polymeric compositions used to bond or coat tissues. See generally Pet. 1–5. Petitioner argues that a person of ordinary skill in the art

² For convenience, we use the phrase “Rhee references” or the term “Rhee” when collectively referring to both Rhee ’500 and Rhee ’587.

would have been motivated to combine the references, and would have had a reasonable expectation of success. *Id.* at 39–48, 54–59 (citing Ex. 1003).

For the reasons explained below, we agree with Petitioner.

1. The prior art teaches or suggests each and every limitation of the challenged claims

Petitioner contends that the prior art discloses or suggests each element of the challenged claims, *see* Pet. 33–46, and presents arguments and claim charts mapping the language of the claims to the disclosures of the Rhee references, Bass, and Tse, Pet. 34–39, 43–44, 46, 50–54, 57. We have reviewed Petitioner’s claim charts and arguments and find that a preponderance of the evidence supports Petitioner’s contentions.

Specifically, as to the preamble of claim 1 (i.e., “[a] method of preparing a composition suitable to coat a tissue of a patient”), we agree with Petitioner that the Rhee references teach crosslinked polymer compositions used to coat tissues in a surgical patient. *See* Ex. 1004, 19:6–10 (“Another use of the crosslinked polymer compositions of the invention is to coat tissues in order to prevent the formation of adhesions following surgery or injury to internal tissues or organs.”); Ex. 1005, 1:20–27 (“This invention relates generally to compositions useful as biological or surgical adhesives”); *see also* Pet. 34, 50.

We also agree with Petitioner that the Rhee references teach mixing the reactive precursor species recited in claim 1 (i.e., the reactive precursor species comprising nucleophilic functional groups and the reactive precursor species comprising electrophilic functional groups). Pet. 34, 50. Specifically, Rhee ’500 teaches that “a first synthetic polymer containing two or more nucleophilic groups is mixed with a second synthetic polymer

containing two or more electrophilic groups.” Ex. 1004, 3:9–19. Rhee ’587 teaches mixing methylated collagen with difunctionally activated SG-PEG. Ex. 1005, 19:12–19; *see also* Ex. 1003 ¶ 104 (explaining that methylated collagen is a reactive precursor species comprising nucleophilic functional groups and that SG-PEG is a reactive precursor species comprising electrophilic functional groups).

We further agree with Petitioner that the Rhee references teach that these reactive precursor species crosslink in situ to form a hydrogel on the tissue, where the hydrogel has an interior surface and an exterior surface having at least one substrate coating surface. Ex. 1004, 3:9–19 (stating that “the reaction mixture is applied to tissue comprising, surrounding, or adjacent to a surgical site before substantial crosslinking has occurred between the nucleophilic groups and the electrophilic groups” and that “the reaction mixture is allowed to continue crosslinking in situ until equilibrium crosslinking has been achieved”); Ex. 1005, 19:12–23; *see also* Pet. 35, 50. In particular, we have reviewed and credit Dr. Lowman’s explanation that Rhee’s resulting hydrogel has a three-dimensional matrix structure, and therefore necessarily has an interior and an exterior with at least one substrate coating surface. Ex. 1003 ¶¶ 73 (citing Ex. 1004, 2:25–32), 76 (citing Ex. 1005, 19:12–19).

Neither Rhee reference teaches a “visualization agent . . . being at least partially disposed within the interior and reflecting or emitting light at a wavelength detectable to a human eye to thereby provide a means for visualization of the coating by a human eye.” *See* Ex. 1001, 39:56–40:2 (claim 1). Instead, Rhee ’500, for example, teaches that “the crosslinked

polymer compositions are optically clear.” Ex. 1004, 3:28–29; *see also* Ex. 1005, 4:23–27 (stating that the “nonfibrillar collagen-based adhesive compositions of the present invention are optically clear”). As to this “visualization agent” limitation, Petitioner relies on Bass, or alternatively, Tse. After reviewing the record and evidence, we agree with Petitioner that each of Bass and Tse teaches the “visualization agent” limitation.

Specifically, Bass teaches a tissue-coating composition comprising a visualization agent in the form of an “[e]ndogenous or exogenous chromophore[]” that is used to “facilitate visualization of the material during placement into warm blooded animals.” Ex. 1006, 11:18–21. The chromophore, Bass explains, “will allow material which becomes displaced from the desired application site to be easily visualized.” *Id.* at 11:21–25. Bass also teaches that chromophores may be used “for aid in the placement of biological glues.” *Id.* at 11:29–34. And Bass claims “methylene blue” as a preferred chromophore. *Id.* at 20:1–3 (claim 31). Similarly, Tse teaches a cyanoacrylate adhesive polymer that comprises a “color additive in the tissue adhesive, which facilitates visualization and assessment of . . . thickness” of the polymer. Ex. 1007, 7; *see also id.* at 8 (Fig. 1) (showing “[f]aint gray-blue tine indicates adequate thickness of the adhesive film”). Thus, we are persuaded that Bass’s chromophores and Tse’s blue dye constitute a “visualization agent . . . being at least partially disposed within the interior and reflecting or emitting light at a wavelength detectable to a human eye to thereby provide a means for visualization of the coating by a human eye.”

Petitioner also shows, by a preponderance of the evidence, that the Rhee references account for the limitations in dependent claims 2–6 and 8–12. Pet. 34–39, 51–54. We have reviewed Petitioner’s claim charts and find that a preponderance of the evidence supports Petitioner’s contention that the cited references collectively disclose or suggest each and every limitation of claims 2–6 and 8–12. Pet. 35–39 (citing Ex. 1004, 2:25–32, 2:56–64, 4:17–18, 7:52–55, 8:8–12, 8:64–9:2, 11:3–12, 13:30–33, 14:60–65, 15:38–43, 17:31–38, 24:8–24 (Table 6)), 51–54 (citing Ex. 1005, 4:50–54, 6:50–57, 7:12–15, 8:15–28, 9:31–36, 17:43–60 (Table 2), 19:12–23). We therefore adopt the teachings set forth in the claim charts as mapped to the limitations of the challenged claims as our own findings.

2. Additional arguments as to claims 9, 10, and 11

Claim 9 provides that “the hydrogel forms within 60 seconds after contact with the substrate,” and claim 10 provides that “the hydrogel forms within 5 seconds after contact with the substrate.” Ex. 1001, 40:21–24. As explained above, Petitioner relies on the Rhee references for teaching gelation within those time frames. Pet. 37–38 (citing Ex. 1004, 17:33–38, 24:8–24 (Table 6)), 53 (citing Ex. 1005, 17:43–60 (Table 2)). Patent Owner asserts that claims 9 and 10 of the ’034 patent “distinguish the proposed combinations” of references, however, because the tables of gel formation times that Rhee provides involve only the reaction of the nucleophilic and electrophilic precursor species. PO Resp. 48–49. Put differently, Patent Owner asserts that Rhee’s tables are “not representative of gelation time for a *mixture* of a visualization agent with a reactive precursor species having nucleophilic functional groups and a reactive precursor species having

electrophilic functional groups, as required in claims 9 and 10.” *Id.* (citing Ex. 2006 ¶¶ 121, 124, 166, 168, 215, 217, 257).

Although Patent Owner is correct that Rhee’s tables do not provide gelation times for a mixture of all three components (i.e., a visualization agent, a reactive precursor species having nucleophilic functional groups, and a reactive precursor species having electrophilic functional groups), we nonetheless agree with Petitioner that Rhee, along with the general knowledge in the art, suggests hydrogels that form within those time frames. Reply 21–22.

First, Rhee ’500 teaches that the time required for complete crosslinking depends on a number of factors, including “the types and molecular weights of the two synthetic polymers and, *most particularly, the concentrations of the two synthetic polymers* (i.e., higher concentrations result in faster crosslinking times).” Ex. 1004, 17:33–38 (emphasis added). Thus, on its face, Rhee ’500 teaches that faster gelation times can be achieved by adding higher concentrations of the reactive precursors.

Second, Rhee ’587 teaches *immediate* gelation times, Ex. 1005, 17:43–60, and a skilled artisan would not have expected the addition of inert dyes such as methylene blue to cause chemical reactivity that would slow the gelation time. *See infra* § II.E.3.b.i.

Third, we observe that Dr. Mays admitted during cross examination that ordinarily skilled artisans understood how to apply the teachings of Rhee ’500 to achieve gel times under 5 seconds. Ex. 1037, 67:22–68:10 (“Yes, I believe it’s fair to say that one would foresee the potential to make

gels even faster by adjusting concentration and pH.”). This admission undermines Patent Owner’s arguments to the contrary.

Claim 11 depends from claim 1 and further provides that “the biodegradable hydrogel is adherent to the tissue.” Ex. 1001, 40:25–26. As explained above, Petitioner relies on the Rhee references for teaching this limitation. Pet. 38–39 (citing Ex. 1004, 2:56–64), 53 (citing Ex. 1005, 19:12–23). Patent Owner asserts that Rhee only refers to “tissue adhesion” rather than “tissue coating,” as recited in independent claim 1, and therefore does not teach a hydrogel “coating” having “a free surface (exterior) that is not adhered to tissue.” PO Resp. 51–52.

We disagree with Patent Owner’s arguments. Rhee ’500 expressly teaches a tissue coating. Ex. 1004, 19:6–10 (“Another use of the crosslinked polymer compositions of the invention is to coat tissues in order to prevent the formation of adhesions following surgery or injury to internal tissues or organs.”). Thus, even under Patent Owner’s understanding of “adherent to the tissue” in claim 11 as requiring “one free surface,” Rhee ’500’s hydrogel adheres to the tissue and has a free surface to prevent the formation of adhesions to other tissues or organs. *See id.* at 19:21–23 (explaining that, once crosslinking has occurred “tissues which are brought into contact with the coated tissues will not stick to the coated tissues”).

Even so, we disagree with Patent Owner that the plain language of claim 11 excludes hydrogels used as tissue adhesives. The ’034 patent uses the term “adherent” in its ordinary manner—namely, to mean “to adhere” to a tissue surface. *See* Ex. 1001, 36:65 (stating that the hydrogel coating of Example 18 was “observed to be well *adherent* to the tissue surface”

(emphasis added)), 5:39–43 (describing a hydrogel coating as “having one free surface that is *not adherent* to any tissue but is instead freely movable” (emphasis added)). In embodiments where the hydrogel affects adhesion between two tissues—such as those taught by both Rhee ’500 and Rhee ’587—we find that the hydrogel must *adhere* to the tissue surface, and thus satisfies the plain language of claim 11. See Ex. 1005, 1:20–27; Ex. 1004, 2:56–64.

3. *Motivation to combine the prior art references and reasonable expectation of success*

Even “[i]f all elements of the claims are found in a combination of prior art references,” “the factfinder should further consider whether a person of ordinary skill in the art would [have been] motivated to combine those references, and whether in making that combination, a person of ordinary skill would have [had] a reasonable expectation of success.” *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 833 (Fed. Cir. 2015). The “motivation to combine” and “reasonable expectation of success” factors are subsidiary requirements for obviousness subsumed within the *Graham* factors. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007).

a. *motivation to combine*

Petitioner contends that it would have been obvious to a skilled artisan “who wanted to visualize the hydrogels” of Rhee to “take advantage of the general knowledge in the art that dyes and other colorants can be mixed with the hydrogel precursors.” Pet. at 40–41, 47. In particular, Petitioner asserts that an ordinarily skilled artisan would look to the “visualization teachings” of Bass, which also discloses bonding or coating tissues (*id.* at 40–41, 55–56), or to Tse, which concerns coating of a patient with an adherent material

(*id.* at 46–47, 58–59). We agree with Petitioner that the record establishes by a preponderance of the evidence that the ordinarily skilled artisan would have been motivated to combine the teachings of the Rhee references with Bass or Tse.

To begin, we find that the record supports, by a preponderance of the evidence, Petitioner’s explanation that visualization agents have been used in polymeric materials for medical applications for many years. Pet. 10–12 (citing Ex. 1003 ¶¶ 33–38; Ex. 1006, 11:18–21, 19:66–68 (claim 30); Ex. 1007, 7; Ex. 1009, 1; Ex. 1010; Ex. 1011, 2; Ex. 1012, 3:41–43, 8:56–58; Ex. 1018, 11:54). For example, we credit Dr. Lowman’s testimony that Histoacryl® and Histoacryl® Blue are polymeric tissue adhesives that have been used in surgical applications since the 1970s. Ex. 1003 ¶ 33; *see also* Ex. 1009, 1 (stating that Histoacryl Blue “has been used extensively in Europe since the early 1970s for a variety of clinical conditions including middle ear surgery, bone and cartilage grafts, repair of cerebrospinal fluid leaks, and skin closure”). We also credit Dr. Lowman’s testimony that these two polymer tissue adhesives differ only in one respect—namely, Histoacryl is translucent whereas Histoacryl Blue contains a blue dye. Ex. 1003 ¶ 33 (citing Ex. 1010, 1); *see also* Ex. 1037, 104:19–105:9 (deposition testimony of Dr. Mays confirming that Histoacryl Blue has been in use since at least 1984, and that it contains a blue dye).

A preponderance of the evidence shows that ordinarily skilled artisans understood, then, that adding blue dye to Histoacryl made the polymeric material easier to see during surgical operations. *See* Ex. 1011, 2 (“Histoacryl Blue . . . is colored to increase its visibility in surgical use.”);

Ex. 1007, 7 (stating that “color additive in the tissue adhesive . . . facilitates visualization”); *see also* Ex. 1003 ¶ 33. Thus, we agree with Petitioner that the addition of a visualization agent, such as a dye, to an otherwise optically clear polymeric composition used in surgical operations, for the purpose of increasing its visibility, was an improvement well known in the art.

Ex. 1003 ¶¶ 33–38; *see also* Ex. 1012, 3:41–43, 8:56–58 (discussing the addition of “inert components such as . . . dyes and pigments to increase visibility” of polymer compositions); Ex. 1018, 1154 (describing the addition of fluorescent polystyrene beads to polymer precursors “to aid in the visualization of the hydrogel coatings”).

Given that knowledge, we find that a preponderance of the evidence supports Petitioner’s position that an ordinarily skilled artisan would have had a reason to look to the visualization agents previously employed in polymeric materials to visualize the newer-generation hydrogels disclosed in the Rhee references. *See KSR*, 550 at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”). In particular, we agree with Petitioner that the ordinarily skilled artisan would have been motivated to similarly improve the optically clear polymeric compositions of Rhee with the addition of the visualization agents taught by Bass or Tse. Pet. 40–41, 46–47, 55–56, 58–59.

For example, Rhee ’500 broadly discloses crosslinked polymer compositions as useful in a variety of surgical operations, such as: “augmenting soft or hard tissue within the body,” Ex. 1004, 2:65–66,

“preventing the formation of adhesions following surgery,” *id.* at 3:9–10, and “coating a surface of a synthetic implant,” *id.* at 3:20–21. Bass expressly uses chromophores “to facilitate visualization of the [bioadhesive] material during placement into warm blooded animals.” Ex. 1006, 11:18–21. And Tse teaches a “color additive in the tissue adhesive, which facilitates visualization and assessment of . . . thickness” of the polymer. Ex. 1007, 7. An ordinarily skilled artisan, therefore, wanting to visualize the hydrogels of Rhee ’500 during surgical operations (such as the prevention of surgical adhesions), would reasonably look to Bass or Tse for its teaching of chromophores and color additives as visualization agents for medical applications. Indeed, Bass specifically claims methylene blue as a specific chromophore that “allow[s] visualization of the composition.” *Id.* at 19:66–20:3.

We have carefully considered Patent Owner’s arguments and evidence, but remain persuaded that Petitioner has provided sufficient reason with rational underpinning for combining the Rhee teachings with Bass or Tse. See PO Resp. 20–24. First, Patent Owner argues that an ordinarily skilled artisan would not have looked to either Rhee reference as a starting point to make colored biocompatible compositions because those references “are focused on making ‘optically clear’ compositions that are particularly suited for ophthalmic use.” *Id.* at 21–22 (citing Ex. 1004, 2:28–29; Ex. 2006 ¶¶ 60, 134). Second, Patent Owner argues that it would not have been obvious to combine the teachings of Bass or Tse with Rhee because Bass and Tse “ha[ve] nothing to do with the creation of a degradable, crosslinked hydrogel, as described in the Rhee references.” *Id.* at 29, 43.

Although Patent Owner is correct that Rhee '500, for example, states that “[a] feature of the invention is that the crosslinked polymer compositions are optically clear” and therefore “particularly suited for use in ophthalmic applications,” Ex. 1004, 3:28–32, Rhee '500's teachings are not limited to optically clear compositions. To the contrary, the Rhee references expressly describe “opaque” crosslinked polymer compositions comprising fibrillar collagen. *Id.* at 13:6–13; *see also id.* at 18:3–6 (stating that the crosslinked polymers “which *do not contain* collagen” have optical clarity (emphasis added)); Ex. 1005, 6:50–57.

The Rhee references further state that the polymer compositions are preferred for “long-term persistence in vivo, if optical clarity is not a requirement.” Ex. 1004, 13:6–13; *see also* Ex. 1005, 6:50–57. Thus, we find that the Rhee references expressly teach embodiments lacking optical clarity. We have not been directed to, nor do we find, description in either Rhee reference criticizing or discouraging non-optically clear hydrogel compositions in such a manner as to deter one of skill in the art.

We also find that the Rhee references do not limit use of the crosslinked polymer compositions to ophthalmic applications, as Patent Owner suggests, but instead expressly contemplate hydrogel applications in which optical clarity is not a requirement. Ex. 1004, 13:6–13, 18:3–6; Ex. 1005, 6:50–57. As explained above, Rhee '500, for example, teaches that the crosslinked polymer compositions are useful in many surgical applications, including to “prevent the formation of adhesions following surgery or injury to *internal tissues or organs.*” *Id.* at 19:6–9 (emphasis added).

Next, Patent Owner invokes a “lead compound analysis,” arguing that the Rhee references had the “specific aim” to “achieve optical clarity” and that dropping “this advantageous property” would make little sense. PO Resp. 21–22 (citing *Eisai Co. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1357 (Fed. Cir. 2008); Ex. 2006 ¶¶ 60, 134). As an initial matter, we disagree with Patent Owner that the “lead compound analysis” applies to the facts of this *inter partes* review.³ The Federal Circuit explained in *Eisai* that, where “the patent at issue claims a chemical compound, the analysis of the third *Graham* factor (the differences between the claimed invention and the prior art) often turns on the structural similarities and differences between the claimed compound and the prior art compounds.” 533 F.3d at 1356–57. “Obviousness based on structural similarity . . . can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound.” *Id.* at 1357.

Here, in contrast, the ’034 patent does not claim a novel chemical compound. *See, e.g.*, Ex. 1001, 39:56–40:2 (claim 1). And Petitioner’s obviousness theory relies not on structural similarity between chemical compounds, but on the notion that the ordinarily skilled artisan would recognize that adding a visualization agent to Rhee’s hydrogels would

³ As with its “lead compound” argument, we find that Patent Owner’s “obvious to try” argument has no bearing on the facts of this case and similarly fails. *See* PO Resp. 23–24 (citing “Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*,” 75 Fed. Reg. 53643, 53654 (Sept. 1, 2010)).

improve their use in certain medical applications, similarly to how visualization agents have been previously used with other polymeric materials in medical applications. *KSR*, 550 U.S. at 417. As explained above, both Bass and Tse expressly teach that visualization agents are desirable for use in surgical sealants and adhesives, and thus provide an express motivation for adding a visualization agent to Rhee’s hydrogels. *See* Ex. 1006, 11:18–44; Ex. 1007, 7; *see also* Ex. 1037, 70:1–14, 106:10–107:6.

Finally, additional record evidence confirms that skilled artisans would have been motivated to add a visualization agent to Rhee’s hydrogels, even if Rhee’s hydrogels were limited to ophthalmic applications. Specifically, Bass incorporates by reference Nasaduke.⁴ Ex. 1006, 11:29–34 (citing Ex. 1024). Nasaduke describes a “biodegradable, nontoxic intraocular glue” colored with fluorescein and methylene blue to “permit[] accurate visualization of the sealant at the time of surgery.” Ex. 1024, 324–25. Nasaduke, therefore, rebuts Patent Owner’s argument that ophthalmic applications always require optically clear formulations.

We now turn to Patent Owner’s argument about the relevancy of Bass and Tse. Patent Owner argues that Bass is “irrelevant to a hydrogel” because “[t]he composition disclosed in Bass is used as a bioadhesive where the stability of the material is of great concern.” PO Resp. 29–30. And, Patent Owner continues, “[i]t would have been entirely illogical for a POSA to select the particular chromophores in Bass for use in the Rhee hydrogels,

⁴ Irene Nasaduke & Gholam A. Peyman, *The Use of Autogenous Rabbit Fibrin Sealant to Plug Retinal Holes in Experimental Detachments*, ANN. OPHTHALMOL., 18:324–27 (Nov. 1986) (“Nasaduke”) (Ex. 1024).

which do not involve application of electromagnetic energy or laser light for initiation of polymerization.” *Id.* at 30–31. As to Tse, Patent Owner points out that that reference is directed to butyl-2-cyanoacrylate (Histoacryl Blue)—a type of “super glue”—and asserts that cyanoacrylate chemistry “is entirely different from nucleophilic-electrophilic chemistry” described in Rhee. *Id.* at 43–44.

We agree with Petitioner that Patent Owner’s arguments about the particular chemistries of Bass’s and Tse’s polymeric materials “rel[y] on an overly-narrow application of obviousness principles.” Reply 6. In particular, Patent Owner takes “a blinkered focus” on Bass and Tse, without reading those references “in context, taking account of ‘demands known to the design community,’ ‘the background knowledge possessed by a person having ordinary skill in the art,’ and ‘the inferences and creative steps that a person of ordinary skill in the art would employ.’” *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (quoting *KSR*, 550 U.S. at 418).

Taking account the record as a whole, the preponderance of the evidence supports Petitioner’s argument that adding visualization agents to polymeric compositions provided a well-known benefit of improving visibility during surgical operations. Bass and Tse teach visualization agents are desirable in surgical applications. Specifically, Bass teaches chromophores that “facilitate visualization of the material during placement into warm blooded animals.” Ex. 1006, 11:18–21. And Tse teaches a blue dye that “facilitates visualization and assessment of . . . thickness” of the applied glue. Ex. 1007, 7; *see also* Ex. 1037, 106:10–107:6 (cross-examination testimony of Dr. Mays confirming that persons of ordinary skill

knew that adding a blue dye to Histoacryl Blue improved visualization of the material). Thus, we are not persuaded that an ordinarily skilled artisan would disqualify the teachings of Bass and Tse even if those references teach a different type of biocompatible polymer. *KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”).

For these reasons, we find that Petitioner has shown, by a preponderance of the record, that an ordinarily skilled artisan would have been motivated to combine the teachings of Bass or Tse to Rhee ’500 and Rhee ’587 to achieve the claimed invention.

b. reasonable expectation of success

We next consider whether Petitioner has shown by a preponderance of the evidence that the skilled artisan would have had a reasonable expectation of success in achieving the method claimed in the ’034 patent. We find that, after consideration of the entirety of the evidence, the reasonable expectation of success requirement has been met.

“The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). Thus, in this case, the question before us is whether the ordinarily skilled artisan would have had a reasonable expectation that adding the visualization agents of Bass or Tse to the crosslinked polymer compositions of Rhee would successfully result in

the claimed method of preparing a composition suitable to coat a tissue of a patient that is also visible to the human eye. In particular, because we have interpreted “suitable to coat a tissue of a patient” as limiting and as encompassing a biocompatibility requirement, *see supra* § II.C.2, the ordinarily skilled artisan must have had a reasonable expectation that mixing the reactive nucleophilic precursor species, the reactive electrophilic precursor species, and the visualization agent would result in a biocompatible hydrogel composition.

Relying on the testimony of Dr. Lowman, Petitioner argues that an ordinarily skilled artisan “would have every reason to expect success in combining the hydrogels of Rhee ’500 with the visualization agents of Bass [or Tse] to produce colored hydrogels.” Pet. 41–42 (citing Ex. 1003 ¶¶ 89–90), 48 (citing Ex. 1003 ¶ 102), 56 (citing Ex. 1003 ¶ 121), 59 (citing Ex. 1003 ¶ 129). Petitioner also characterizes visualization agents as “inert components.” *Id.* at 12 (citing Ex. 1003 ¶ 36). Patent Owner argues that Dr. Lowman’s statements are conclusory and insufficient, and that, in any event, an ordinarily skilled artisan would not have reasonably expected success when combining the visualization agents of Bass or Tse with the hydrogels of Rhee. *See, e.g.*, PO Resp. 24–29, 30, 42, 44–48.

For the purpose of our analysis, we have summarized the properties that the parties argue are relevant to the question of reasonable expectation of success as follows: chemical reactivity, toxicity, and biocompatibility. We address each property below.

i. chemical reactivity

As stated above, Petitioner alleges that the skilled artisan would have had a reasonable expectation of success because visualization agents, such as those disclosed in Bass and Tse, are inert, and thus are not chemically reactive to the crosslinking chemistry required for Rhee's compositions. Pet. 12; Reply 14–16. Patent Owner disagrees, and argues that the visualization agents disclosed in Bass and Tse have high reactivity and bulky groups, and thus would interfere with hydrogel formation, and that, at bottom, an ordinarily skilled artisan could not predict whether those visualization agents would interfere with the crosslinking chemistry required for Rhee's compositions. PO Resp. 26–28; Ex. 2006 ¶¶ 74, 143, 193, 235.

Upon review of the evidence, we find that a preponderance of the evidence supports Petitioner's position that an ordinarily skilled artisan would not have expected interfering chemical reactivity between the visualization agents of Bass or Tse and the nucleophilic/electrophilic precursors of Rhee.

First, we find that the evidence shows that at least some of the chromophores that Bass discloses are, in fact, chemically inert. Specifically, indocyanine green, gentian violet, and methylene blue have tertiary amine groups, which, as Dr. Mays confirmed in an expert report filed in the district court litigation, “are non-reactive.” Ex. 1040 ¶ 64; *see also* PO Resp. 34 (stating that indocyanine green contains sulfonate groups, a tertiary amine, and a cyclic ammonium structure (citing Ex. 2006 ¶ 78)), 39 (stating that gentian violet contains tertiary amine groups (citing Ex. 2006 ¶ 96)), 40 (stating that methylene blue contains tertiary amine groups (citing Ex. 2006

¶ 98)); Ex. 1006, 20:1–3 (claiming compositions comprising the chromophores indocyanine green, gentian violet, and methylene blue⁵). That a skilled artisan might have expected *other* visualization agents to detrimentally react with Rhee’s precursors is of no moment. *See Pfizer*, 480 F.3d at 1366 (“the mere possibility that some salts may not form does not demand a conclusion that those that do are necessarily non-obvious”).

Second, we find that, because only small amounts of visualization agent are necessary to see the hydrogel coating with the human eye, the skilled artisan would not have expected the visualization agents of Bass or Tse to detrimentally react with, or physically block via steric hindrance, the formation of Rhee’s hydrogels. *See* PO Resp. 34, 39–40; Ex. 2006 ¶¶ 79, 99. Bass teaches that the disclosed chromophores can be used to “enhance visualization” at amounts as low as 0.01% of the total weight of the composition. Ex. 1006, 11:40–42. Bass claims, for example, a polymeric coating composition comprising a chromophore selected from the group consisting of indocyanine green, fluorescein, rose Bengal, gentian violet, and methylene blue at an amount of from 0.01 to 50% by weight of the total composition. *Id.* at 20:1–6 (claims 31 & 32). We credit Dr. Lowman’s

⁵ Patent Owner contends that an ordinarily skilled artisan would not have been motivated to use methylene blue as a visualization agent because it is only slightly soluble in water, and therefore the skilled artisan would have expected it to form aggregates in the aqueous medium of a hydrogel. PO Resp. 40 (citing Ex. 2006 ¶¶ 98–99). We disagree. As Petitioner points out—and Dr. Mays confirms—aqueous solutions of methylene blue were well known in the art. Reply 12–13 (citing Ex. 1037, 81:14:–83:7; Ex. 1039, 1767). Thus, the skilled artisan seeking to use Tse’s blue dye as a visualization agent, for example, would have readily known to use drops of methylene blue and water. *See* Ex. 1007, 7; Ex. 1037, 267:13–268:4.

testimony that, because the challenged claims do not require any particular concentration of visualization agent, only the minimum amount of dye needed to make the hydrogel visible to the human eye is necessary.

Ex. 1041 ¶ 26, Ex. 1003a ¶ 90 (stating that dye concentration need only be “in sufficient quantity to allow visualization of the composition”).

Third, we observe that Dr. Mays’s testimony about chemical reactivity and steric hindrance did not take the concentration effects of the visualization agent into account. *See* Ex. 1037, 49:7–9 (“I simply haven’t studied the concentration effects.”). During cross-examination, however, Dr. Mays admitted that the extent of chemical reactivity and steric hindrance between the visualization agent and Rhee’s reactive precursors would depend on the concentration of the dye added. Ex. 1037, 48:13–19. Dr. Mays further admitted that lower concentrations of dye would have fewer effects—both as to chemical reactivity and steric hindrance. Ex. 1037, 48:20–49:19, 269:2–15. Thus, we do not find Dr. Mays’s declaration testimony about chemical reactivity and steric hindrance, *see* Ex. 2006 ¶¶ 74, 143, 193, 235, persuasive because he did not take concentration effects into account when formulating those opinions. Indeed, as Petitioner persuasively explains, the ratio of dye to Rhee’s precursors would be so low, that skilled artisan would still expect gel formation even if the dye reacted with some of those precursors. *See* Ex. 1041 ¶¶ 38–39, 43–44, 60–62.

Next, the parties disagree about the extent to which “unpredictability” in the art affects whether the skilled artisan would have had a reasonable expectation of success. Patent Owner argues that it was “entirely

unpredictable” whether the presence of visualization agents of Bass or Tse “within a mixture of reactive precursors containing nucleophilic functional groups and electrophilic functional groups would affect the precursors’ ability to crosslink and produce a hydrogel suitable as a tissue coating.” PO Resp. 32 (citing Ex. 2006 ¶¶ 59, 63, 183, 190, 197). Indeed, it was not until the inventors’ own experimental work, Patent Owner continues, that the “addition of a visualization agent to the mixture of the nucleophilic and electrophilic reactive precursor species forming the biodegradable hydrogel” was successfully accomplished. *Id.* Petitioner argues that Patent Owner “overlook[s] the routine nature of the problem to be solved,” and that Patent Owner’s arguments about “unpredictability” are “inconsistent with the advanced state of the art.” Reply 16–17.

Again, we find that the preponderance of the evidences supports the Petitioner’s position. In making our findings as to “reasonable expectation of success,” we keep in mind that we cannot demand absolute certainty. See *Intelligent Bio-Sys.*, 821 F.3d at 1367 (“While the definition of ‘reasonable expectation’ is somewhat vague, our case law makes clear that it does not require a certainty of success.”); see also *Pfizer*, 480 F.3d at 1364 (“[C]ase law is clear that obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.”).

Here, although Patent Owner’s argument—that an ordinarily skilled artisan could not predict absolutely the influence of a visualization agent on Rhee’s crosslinking chemistry without testing—is not without some merit, the simplicity and routine nature of the testing required to confirm

compatibility persuades us that the skilled artisan would have had at least a reasonable, if not absolute, expectation of success. *Pfizer*, 480 F.3d at 1364.

Specifically, a preponderance of record evidence shows that the confirmation testing would have been well within the skill set of an ordinary artisan. For example, Dr. Mays testified during cross-examination that there was “nothing especially out of the ordinary in the experiments that were done in the ’034 patent, for example, to determine suitable amounts of the material to serve as a visualization agent.” Ex. 1037, 255:8–18. Dr. Mays also stated that the skilled artisan “simply ha[d] to make some different solutions and see what sort of opacity you get.” *Id.* And “[t]o determine gel times with and without the dye, that can be done as well.” *Id.*

Dr. Mays’s testimony is consistent with Dr. Lowman’s declaration testimony that “one of ordinary skill in the art would not find any technical challenge or uncertainty in adding a dye to a hydrogel composition.” Ex. 1041 ¶ 29. We credit Dr. Lowman’s explanation that “[d]yes are standard molecules used in various applications in chemistry,” that “there is nothing out of the ordinary or unusual about the dyes in Bass or the other dyes known in the art that would cause a POSA to view them any differently than any other low level additive or impurity present in a chemical reaction.” *Id.* ¶¶ 30, 32. We further credit Dr. Lowman’s declaration testimony that “there are no technical challenges to adding a dye to the hydrogels of Rhee,” and that “[o]ne of skill in the art would readily know how to make a dye solution and then add enough dye to one of the solutions of the hydrogel forming materials before mixing them to form the hydrogel.” *Id.* ¶ 33.

The Rhee references further support Dr. Lowman’s opinion that only routine testing would be required to verify that Rhee’s hydrogels could form even with an added visualization agent. *Id.* Specifically, both Rhee references state that various materials may be added to the crosslinked polymer compositions, without warning as to any interference between those materials and the crosslinking chemistry required to form the hydrogels. *See* Ex. 1004 (Abstract) (“The compositions may further comprise other components, such as naturally occurring polysaccharides or proteins.”), 10:63–65 (“The crosslinked polymer compositions can also be prepared to contain various imaging agents such as iodine or barium sulfate, or fluorine”); Ex. 1005, 7:11–26 (listing additives).

ii. toxicity

We now turn to Patent Owner’s argument that an ordinarily skilled artisan would not have had a reasonable expectation of success in creating the claimed invention because “[i]n many cases, the proposed dyes are toxic,” and “thus would have been outright rejected by a POSA for use in a hydrogel.” PO Resp. 7. In particular, Patent Owner states that certain chromophores that Bass discloses are toxic, i.e., silver nitrate, rose Bengal, Sudan Black B, gentian violet, and methylene blue. *Id.* at 34 (citing Ex. 2006 ¶ 80), 35 (citing Ex. 2006 ¶ 82), 37 (citing Ex. 2006 ¶ 88), 39 (citing Ex. 2006 ¶ 97), 40 (citing Ex. 2006 ¶ 99).

We find, however, that the preponderance of the evidence supports Petitioner’s argument that many of the same dyes—including methylene blue, rose Bengal, and gentian violet—are well known in the art for use in medical applications. *See* Reply 9 (citing Ex. 2006 Ex. M, 472 (describing

rose Bengal as “extensively used” in diagnosing ocular disease and therapeutic for pneumococcal infections and viral eye infections), Ex. Z-9, 680, 682 (describing gentian violet as a drug with extensive medical uses “generally considered safe for use on children and breastfeeding mothers”). For example, the record confirms that methylene blue is a “World Health Organization Essential Drug,” and, as such, is considered one of “the most effective and safe medicines needed in a health system.” See Ex. 1034; Ex. 1037, 241:3–17, 268:13–269:1; Ex. 2006 Ex. Z-13, 714. Thus, we determine that the skilled artisan would not have been deterred from using these dyes for their known and intended purpose—visualization.

iii. biocompatibility

As noted above, on the Board’s Orders (Papers 36, 58), Petitioner and Patent Owner filed briefs addressing the biocompatibility of the Rhee hydrogels, and Patent Owner filed additional evidence relating to certain documents produced in the district court litigation. Paper 45 (“PO Suppl. Br.”); Paper 47 (“Pet. Suppl. Br.”); Paper 51 (“PO Rebut.”); Paper 55 (“Pet. Rebut.”); Ex. 2016 (Expert Report of Dr. Anthony Lowman Regarding Invalidity); Ex. 2017 (Rebuttal Expert Report and Declaration of Dr. Jimmy W. Mays); Ex. 2018 (Reply Expert Report of Dr. Lowman); Ex. 2019 (Deposition transcript of Dr. Lowman); Ex. 2020 (Deposition transcript of Dr. Mays). The parties’ respective briefing and the evidence relate to the prior-art reference Wallace, and its effect on this proceeding. See Paper 36, 4.

Patent Owner contends that “Wallace specifically directs a POSA away from using the tetra-amino PEG and tetra-succinimidyl PEG hydrogels

on which Petitioner ‘critically’ relies.” PO Suppl. Br. 2 (emphasis omitted). Patent Owner contends that “[e]ach of Rhee ’500 and Rhee ’587 describes the aim of making compositions that, at the very least, are not inflammatory and not immunogenic.” *Id.* at 2–3 (citing Ex. 1004, 3:28–35). But Wallace, Patent Owner asserts, tested the tetra-amino PEG and tetra-succinimidyl PEG hydrogels exemplified in Example 6 of Rhee ’500 *in vivo*, and found that those hydrogels produced “a severe foreign body response” and “thick encapsulation of the hydrogel and abscess formation.” *Id.* at 4 (quoting Ex. 2014, 13:37–41; citing Ex. 2017 ¶¶ 48, 49, 307; Ex. 2020, 333:5–16). Patent Owner argues that, given these results, the ordinarily skilled artisan “would not have selected a hydrogel known to produce the most severe response that includes ‘severe inflammation’ and ‘thick encapsulation of the hydrogel and abscess formation.’” *Id.* (quoting Ex. 2014, 13:37–41); *see also* Ex. 2020, 339:14–19 (testimony of Dr. Mays that Wallace “would be telling one of ordinary skill in this area don’t use these amine terminated tetrafunctional PEGs for an application”).

Patent Owner contends that the disclosure of Wallace defeats Petitioner’s obviousness challenges in two respects: (1) by “directly refut[ing] Petitioner’s prima facie case of obviousness which relies on the tetra-amino PEG and tetra-succinimidyl PET hydrogels of Example 6 in Rhee ’500,” and (2) by refuting Petitioner’s assertion that an ordinarily skilled artisan would have had a reasonable expectation of success. PO Suppl. Br. 5–9. With respect to the latter, Patent Owner argues that Wallace teaches away because it shows that the hydrogels in Rhee ’500 and Rhee ’587 are not biocompatible, and therefore “were known to be unsuitable to

coat the tissue of a patient.” *Id.* at 7–9; *see also id.* at 9–10 (arguing that tetra-amino PEG and tetra-succinimidyl PEG hydrogels are not biocompatible).

As an initial matter, we make clear that the teachings of Wallace do not affect Petitioner’s patentability challenge of claims 1–6 and 8–12 based on the combination of Rhee ’587 and Bass or Tse. Petitioner relied on methylated collagen—disclosed in Rhee ’587—as a hydrogel precursor in the Petition. Pet. 48–49 (relying on methylated collagen for the claimed “reactive precursor species comprising nucleophilic functional groups”); *see also* Ex. 1003 ¶¶ 103, 109, 114. Patent Owner’s teaching-away arguments about Wallace, although mentioning Rhee ’587, relate only to the use of tetra-amino PEG as the nucleophilic precursor. PO Suppl. Br. 5–6. Patent Owner has not pointed us to testimony of Dr. Mays as to how Wallace is relevant to Petitioner’s obviousness challenge based on Rhee ’587 in combination with Bass or Tse. *See generally id.* For these reasons, we conclude that Wallace has no bearing on the Petitioner’s ground of unpatentability based on Rhee ’587 in combination with Bass or Tse.

We now turn to the question of whether Wallace defeats Petitioner’s patentability challenge based on Rhee ’500 in combination with Bass or Tse. Specifically, Patent Owner argues that Wallace “directly refut[es] Petitioner’s prima facie case of obviousness which relies on the tetra-amino PEG and tetra-succinimidyl PET hydrogels of Example 6 in Rhee ’500.” *Id.* at 5–7.

We disagree with Patent Owner that Petitioner’s unpatentability challenge based on Rhee ’500 in view of Bass or Tse “relies exclusively” on

Rhee's disclosure of tetra-amino PEG and tetra-succinimidyl hydrogels disclosed in Example 6. To the contrary, Petitioner described Rhee '500 as disclosing "a first synthetic polymer containing two or more nucleophilic groups" and "a second synthetic polymer containing two or more electrophilic groups." Pet. 34 (citing Ex. 1004, 3:9–19). This disclosure is not limited to tetra-amino PEG and tetra-succinimidyl hydrogels. Indeed, Rhee '500 teaches that multi-functionally activated synthetic polymers include di-functionally activated, tri-functionally activated, tetra-functionally activated, and star-branched polymers. Ex. 1004, 6:4–21. And, in addition to primary amino groups, Rhee '500 also lists two or more thiol groups as preferred nucleophilic synthetic polymers. *See, e.g., id.* at 6:33–45.

As explained above, Patent Owner asserted in its Response, based on the Declaration of Dr. Mays, that an ordinarily skilled artisan would have expected the dyes of Bass and Tse to chemically interfere with hydrogel formation. PO Resp. 26–28. In reply, Petitioner called Dr. Mays's "opinions scientifically unsound," because Dr. Mays did not take the dyes' concentration effects into account when making his opinions. Reply 13–14. Dr. Lowman presented, as an example, a polymer composition comprising tetra-amino PEG and tetra-succinimidyl precursors in a concentration of 10% (such as those disclosed in Example 6 of Rhee '500) and dye in a concentration of 0.01%.

Dr. Loman explained that this example has a mass ratio of electrophiles:nucleophiles:dye of 1000:1000:1—thus showing how low amounts of dye would, at most, cause negligible interference with gel formation. Ex. 1041 ¶¶ 43–44; *see also* Reply, 14. Dr. Lowman also

pointed out that, because they are tetra-functional, the precursors disclosed in Example 6 of Rhee '500 have “a large number of reactive functional groups on each precursor” and therefore would “readily achieve a crosslinked three-dimensional network as opposed to, for instance a hydrogel made from, for example, one di-functional and one tri-functional precursors.” Ex. 1041 ¶ 37.

Taking this exchange in context, then, we do not view Petitioner's obviousness challenge as resting exclusively or critically on Example 6 of Rhee '500, or on Rhee '500's disclosure of tetra-amino PEG and tetra-succinimidyl PET hydrogels. Instead, we view the point of Dr. Lowman's testimony as rebutting Dr. Mays's opinions, which were premised on large concentrations of dye interfering with the crosslinking reaction between the nucleophilic precursors and the electrophilic precursors. Above, we explain why we agree with Dr. Lowman's analysis.

We acknowledge that Petitioner relied on Example 6 of Rhee '500 to teach gel times of “within 60 seconds” and “within 5 seconds,” as recited in claims 9 and 10, respectively, of the '034 patent. *See* Pet. 38–39 (citing Ex. 1004, 24:8–24 (Table 6)). Table 6 shows the effect of pH on the gel formation times for tetra-amino PEG/tetra SE-PEG formulations. Ex. 1004, 24:8–24. And Dr. Lowman testified that these tetra-functional “readily achieve a crosslinked three-dimensional network.” Ex. 1041 ¶ 37.

Arguendo, if we disregard the teachings in Example 6 of Rhee '500, we find that the preponderance of the evidence in the record as such still supports Petitioner's argument that an ordinarily skilled artisan would have had a reasonable expectation of success in achieving the claimed invention,

in light of (1) our finding that at least some dyes, such as indocyanine green, gentian violet, and methylene blue, are chemically inert and therefore would not be expected to interfere with the nucleophilic-electrophilic crosslinking chemistry forming a hydrogel, *supra* § II.E.3.b.ii; Ex. 1040 ¶ 64; (2) our finding that ordinarily skilled artisans understood to apply the teachings of Rhee '500 to achieve gel times under 5 seconds, *supra* § II.E.2; Ex. 1037, 67:22–68:1; and (3) the fact that Wallace itself confirms the skilled artisan's ability to achieve gel times under 5 seconds through control of pH, *see* Ex. 2014, 9:37–40 (explaining that the pH of the aqueous buffer solution should be adjusted using routine optimization to achieve a final pH “that is conducive to rapid gelation”).

Next, we address Patent Owner's argument that Wallace teaches away from the use of Rhee '500's hydrogels because Wallace's *in vivo* testing shows that those hydrogels are not biocompatible. PO Suppl. Br. 6–10. “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). A reference does not teach away “‘if it merely expresses a general preference for an alternative invention but does not ‘criticize, discredit, or otherwise discourage’ investigation into the invention claimed.” *Id.* at 1327 (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)).

We found above that the arguments and evidence in this case show that skilled artisans would reasonably interpret “suitable to coat a tissue of a

patient,” as recited in claim 1 of the ’034 patent, as encompassing a biocompatibility requirement. *Supra* § II.C.2. But we do not assign a certain *level* of biocompatibility to a hydrogel “suitable to coat a tissue of a patient. Wallace defines “biocompatible” as “the ability of the compositions of the present invention to be applied to tissues without eliciting significant inflammation and fibrosis or other adverse tissue responses.” Ex. 2014, 3:64–67.

Wallace presents the results of biocompatibility experiments performed on New Zealand white rabbits. *Id.* at 12:54–13:58 (Example 4). As shown in Table 4, “Test C” hydrogel—made with tetra-amino PEG—produced a severe foreign body response, severe inflammation, and “thick encapsulation of the hydrogel and abscess formation.” *Id.* at 13:38–41. Thus, contrary to Petitioner’s argument otherwise, the “Test C” hydrogel cannot fairly be categorized as “biocompatible” under Wallace’s definition. Wallace appears to assign the severe inflammation to the use of tetra-amino PEG, because when tetra-amino PEG is replaced with tetra-sulfhydryl PEG—as in the “Test D” hydrogel—only a “moderate foreign body response” and “moderate inflammation” is produced. *Id.* at 13:41–43. Thus, “Test D” hydrogel can fairly be categorized as “biocompatible” under Wallace’s definition. Wallace confirms this by stating that “[b]y substitution of sulfhydryl-PEG for amino-PEG . . . , the biocompatibility of the hydrogel is significantly improved.” *Id.*

The question before us, then, is: Do the results of “Test C” in Wallace sufficiently teach away from the various hydrogels disclosed in Rhee ’500, because it suggests that those hydrogels are not biocompatible and therefore

would not be “suitable to coat a tissue of a patient”? We answer in the negative.

Wallace itself teaches that a skilled artisan understood how to increase the biocompatibility of a tetra-amino PEG: by replacing it with tetra-sulfhydryl PEG as the nucleophilic precursor species. Ex. 2014, 13:41–43. This teaching is consistent with Rhee ’500’s teaching that preferred nucleophilic synthetic polymers are those comprising two or more thiol groups. Ex. 1004, 6:33–45. Wallace also explains the tradeoffs associated with increased gelation time and tissue irritation. Ex. 2014, 1:52–58. (“[O]ptimizing the composition to enhance gel formation may worsen tissue inflammation at the site of administration. A possible explanation for this effect is that highly reactive composition components that are capable of rapid gel formation may adversely affect tissue surfaces.”). We agree with Petitioner, therefore, that an ordinarily skilled artisan would have expected hydrogels with rapid gel times to be more irritating, and would have weighed that drawback with the benefit of fast gel times. Pet. Suppl. Br. 10; *see also Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”).

4. *Secondary considerations*

Patent Owner presents arguments and evidence of objective indicia of nonobviousness that we must consider before reaching our conclusion on obviousness *vel non*. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). Patent Owner argues that objective evidence of a long-felt, but

unmet, need for a hydrogel tissue coating product, industry praise, and commercial success (“secondary considerations”) support the nonobviousness of the challenged claims. PO Resp. 55–58. “For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.” *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (quotation and emphasis omitted). We apply “a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product is the invention disclosed and claimed in the patent.” *WBIP*, 829 F.3d at 1329 (quotation omitted). That presumption, however, is rebuttable. *Id.*

a. presumption of nexus

Patent Owner presents evidence that, on April 7, 2005, Confluent Surgical, Inc., received FDA approval to market a hydrogel tissue coating product known as DuraSeal®. Ex. 2007 ¶ 4; PO Resp. 55. Patent Owner characterizes DuraSeal as “employ[ing] electrophilic-nucleophilic chemistry, in particular *in situ* crosslinking of water-soluble PEG reactive end groups (electrophilic functional groups) and amino acid with reactive end groups (nucleophilic functional groups).” PO Resp. 55 (citing Ex. 2007 ¶ 6). Patent Owner explains that DuraSeal comprises “[a] dye present in the mixture of precursors known as FD&C Blue #1 allows a user to visualize and gauge the thickness of the hydrogel as it is applied.” *Id.* at 55–56. Patent Owner contends that “DuraSeal® is covered by claims 1, 3–6, and 9–12 of the ‘034 Patent,” *id.* at 56 (citing Ex. 2007 ¶¶ 11, 38), and that “[a]t the time of its launch, DuraSeal® was the only commercial hydrogel tissue

coating formulation made by reacting nucleophilic functional groups and electrophilic functional groups,” *id.* (citing Ex. 2007 ¶¶ 17–18).

Given these facts, which Petitioner does not dispute, we agree with Patent Owner that it is entitled to a presumption of nexus between the proffered evidence of secondary considerations and the claims of the ’034 patent. *See* Third Tr. 58:17–21.

b. commercial success

Patent Owner offers evidence of the commercial success of DuraSeal to support the nonobviousness of the challenged method claims. PO Resp. 58. “When a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention.” *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997); *WBIP*, 829 F.3d at 1829. Here, Patent Owner’s evidence of commercial success consists of (1) sales figures for DuraSeal in 2005–2006, (2) 100% market share, and (3) the sale of Confluent Surgical, Inc. to Covidien for \$245M on July 14, 2006. *Id.* (citing Ex. 2007 ¶¶ 32–35, 37–43).

As to sales figures, Patent Owner states that DuraSeal had sales in excess of \$9.2M during the last three quarters of 2005, sales in excess of \$10.5M during just the first two quarters of 2006, and sales in excess of \$2M during July 2006. *Id.* (citing Ex. 2007 ¶¶ 32–35). The record shows that DuraSeal enjoyed a steady increase in sales almost every month from its entry into the market in April 2005 until the sale of Confluent Surgical, Inc. in July 2006. Ex. 2007 ¶¶ 32–37. Thus, we find that DuraSeal was commercially successful, and as explained above, presume that that

commercial success is tied to the claims of the '034 patent. *See Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1361 (Fed. Cir. 1999) (“sales figures alone are also evidence of commercial success”).

We also find that Petitioner has failed to rebut that presumption with evidence. *WBIP*, 829 F.3d at 1329 (stating that “a patent challenger cannot successfully rebut the presumption with argument alone—it must present evidence”). In particular, Petitioner merely states in a conclusory manner that “[c]ustomer demand for DuraSeal was mostly attributable to properties of DuraSeal that were present regardless whether it was colored.” Reply 25 (citing Ex. 1038, 54:1–13, 63:18–65:17).

Patent Owner’s evidence of 100% market share evidence, however, is somewhat less persuasive of commercial success due to barriers to entry, as DuraSeal was the only FDA-approved dural sealant. Ex. 2007 ¶ 32. *See Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) (“Because market entry by others was precluded . . . , the inference of non-obviousness . . . , from evidence of commercial success, is weak.”).

Finally, we do not find evidence of the sale of Confluent Surgical to Covidien to be heavily persuasive of commercial success, because, as Petitioner explains and supports with evidence, the \$245M purchase price included other products, employees, other patents, equipment, and trade secrets. *See* Reply 26 (citing Ex. 1038, 70:21–71:3; 73:15–74:4; 76:18–80:1). Moreover, Patent Owner has not provided a purchase price allocation in the record. *Id.* (citing Ex. 1038, 74:13–19). Thus, because it is not clear whether the sale of Confluent Surgical to Covidien was due to the subject matter recited in the claims of the '034 patent, we determine that Petitioner

presents sufficient evidence to rebut the presumption of nexus between that sale and the '034 patent.

However, we find that DuraSeal has been commercially successful, and determine that this commercial success supports the nonobviousness of the challenged claims to some extent.

c. long-felt need

Patent Owner contends that there was a long-felt need for improved techniques for closing the dura following cranial surgery, and that DuraSeal was the only commercial hydrogel tissue coating formulation for that purpose. PO Resp. 56 (citing Ex. 2007 ¶¶ 17–18). Patent Owner relies on statements by Dr. Steven J. Haines, a neurosurgeon at the University of Minnesota, who states, “This is clearly an application for which we need a good product,” as well as Dr. Annapurni Jayam-Trouth, a pediatric neurologist and Chair of Neurology at Howard University Hospital, who states, “[T]here’s definitely a need for some material to, you know, close CSF leaks, and I think the clinicians are struggling with that, and they put all types of autologous materials in there for which we don’t have any data at all.” *Id.* at 56–57 (citing Ex. 2007 at ¶¶ 25, 27).

As Petitioner points out, however, those statements are directed to the need for a hydrogel formulation for closing the dura following surgery, without differentiating between a hydrogel with a visualization agent and a hydrogel without. Reply 24. And neither were commercially available before the commercial launch of DuraSeal. Ex. 2007 ¶¶ 17–18. Thus, we find that Patent Owner’s evidence of long-felt need is weak, and does not support the nonobviousness of the challenged claims.

d. industry praise

Finally, Patent Owner presents evidence of praise from Dr. Michael Egnor, a pediatric neurosurgeon and Vice Chairman of Neurosurgery at the State University of New York at Stonybrook, Andrew K. Balo, an industry representative and Vice President of Regulatory and Clinical at DexCom, Dr. Mary Lee Jensen, an interventional neuroradiologist and Director of Interventional Neuroradiology at the University of Virginia, and Dr. David MacLaughlin, Associate Director of Pediatric Surgical Research Labs at the Massachusetts General Hospital. PO Resp. 57–58 (citing Ex. 2007 ¶¶ 22–24, 26).

Patent Owner also contends that “‘Orthopedics This Week’ lauded DuraSeal® as the first synthetic, absorbable hydrogel for use as an adjunct to sutured dural repair cranial surgery.” *Id.* at 58 (citing Ex. 2007 ¶¶ 28–30). As with long-felt need, however, the proffered statements offer weak proof of industry praise, as none differentiate between a hydrogel with a visualization agent and a hydrogel without. Moreover, as Petitioner points out and Dr. Sawhney conceded, the “Orthopedics This Week” article is a copy of a press release provided by Confluent, thus calling the “praise” into question. *See* Reply 24 (citing Ex. 2007 Ex. A, Ex. E; Ex. 1038, 43:20–50:22). Thus, we find Patent Owner’s evidence of industry praise somewhat weak, and not heavily supportive of the nonobviousness of the challenged claims.

5. Conclusion as to obviousness

In sum, we find that the combinations of Rhee ’500 with Bass or Tse, and Rhee ’587 with Bass or Tse teach or suggest each and every element of

claims 1–6 and 8–12. We also find that an ordinarily skilled artisan would have been motivated to combine the Rhee references with Bass or Tse, and would have had a reasonable expectation of success in achieving the claimed invention. We find that DuraSeal was commercially successful, and determine that there is a nexus between that commercial success and the challenged claims of the '034 patent. We also find that Patent Owner failed to persuasively show long-felt, but unmet, need, or industry praise.

After carefully considering the arguments and evidence, we find that that the record as a whole weighs in favor of a conclusion of obviousness, especially given the disclosures of the art of record in this case and strength of the obviousness case based on the first three *Graham* factors.

Even though Patent Owner shows commercial success, we find that the strong evidence of motivation to combine and reasonable expectation of success leads to a conclusion of obviousness. Specifically, the record shows that chromophores and dyes, such as those disclosed in Bass and Tse, were well known in the art as providing a means for visualizing polymeric materials in surgical operations. The majority of the evidence also shows that an ordinarily skilled artisan would have reasonably expected that adding those chromophores and dyes to Rhee's hydrogels would have similarly provided a means for visualizing those polymeric materials during surgical operations.

There is very little, if any, credible evidence in the record that combining the well-known visualization agents with the hydrogels taught in the Rhee references would have been outside the ordinary skill of such an artisan. Thus, we determine that this case is one that falls within the

Supreme Court’s characterization of obviousness as entailing an improvement that is no “more than the predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. 417.

For these reasons, we conclude that Petitioner has satisfied its burden of demonstrating, by a preponderance of the evidence, the unpatentability of claims 1–6 and 8–12 of the ’034 patent over Rhee ’500 with Bass or Tse, and Rhee ’587 with Bass or Tse.

III. MOTIONS TO EXCLUDE EVIDENCE

We now turn to the parties’ respective motions to exclude certain evidence from the record.

A. Petitioner’s Motions to Exclude

In its first Motion to Exclude, Petitioner moves to exclude portions of Exhibit 2006, the Declaration of Dr. Mays, and Exhibit 1037, the transcript of Dr. Mays’s deposition. Paper 41, 1. In its second Motion to Exclude, Petitioner moves to exclude Wallace (Ex. 2014) as well as certain exhibits filed in the district court litigation that the Board ordered Patent Owner to also submit in this case (i.e., Exhibits 2017 and 2020). Paper 59, 1–9. Because we find that the totality of that evidence supports Petitioner’s position that the challenged claims are unpatentable, we *dismiss as moot* Petitioner’s Motions to Exclude.

B. Patent Owner’s Motion to Exclude

Patent Owner moves to exclude the following exhibits: 1010, 1014, 1024, 1025, 1026, 1028, 1029, 1030, 1031, 1035, 1036, 1039, 1043, 1044, 1045, 1046, 1047, and 1048. Paper 38, 1–3. We do not rely on Exhibits 1014, 1025, 1026, 1028, 1029, 1030, 1031, 1035, 1036, 1043, 1044, 1045,

1046, 1047, or 1048 in this Decision. Thus, we *dismiss as moot* Patent Owner’s Motion to Exclude as it relates to these exhibits.

Exhibit 1010 is webpage relating to “Histoacryl® Topical Skin Adhesive” dated October 4, 2015. Patent Owner contends that Ex. 1010 should be excluded from evidence because it lacks relevance under Federal Rules of Evidence (FRE) 402. Specifically, because it postdates the November 9, 2001, filing date of the ’034 patent, Patent Owner alleges that Ex. 1010 “is irrelevant to the pertinent legal question of whether ‘the subject matter as a whole would have been obvious at the time the invention was made.’” PO Resp. 1 (quoting 35 U.S.C. § 103(a)). We disagree.

We rely on Exhibit 1010 as evidence supporting Dr. Lowman’s testimony that Histoacryl is translucent whereas that Histoacryl® Blue contains a blue dye. *See supra* § II.E.2.a. Thus, Exhibit 1010 is relevant to the knowledge of the ordinarily skilled artisan during the relevant time period. Moreover, Dr. Mays verified that Histoacryl Blue has existed since at least 1984, and that it contains a blue dye. Ex. 1037, 104:19–105:9. Thus, we find that Exhibit 1010 is relevant and admissible in this proceeding.

Exhibit 1024 is Nasaduke, and Exhibit 1039 is a copy of the Aldrich Catalog Handbook of Fine Chemicals, dated 1996–97 (“Aldrich Catalog”). Patent Owner alleges that Exhibits 1024 and 1039 represents improper reply evidence, used to supplement the disclosures of the references Petitioner relies on in this proceeding. Paper 38, 3. We disagree.

As to Exhibit 1039, Dr. Mays raised the Aldrich Catalog during his cross-examination. Ex. 1037, 82:4–83:7. Thus, Petitioner is entitled to submit that document into evidence.

As to Exhibit 1024, we disagree with Patent Owner that Nasaduke is outside the scope of a proper reply. Nasaduke describes a “biodegradable, nontoxic intraocular glue” colored with fluorescein and methylene blue to “permit[] accurate visualization of the sealant at the time of surgery.” Ex. 1024, 324–25. Nasaduke, therefore, rebuts Patent Owner’s argument presented in the Patent Owner Response that ophthalmic applications always require optically clear formulations. *See, e.g., Genzyme Therapeutic Prods. Ltd. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1365–66 (Fed. Cir. 2016). Thus, we find that Petitioner’s reference to Nasaduke does not exceed the proper scope of reply under 37 C.F.R. § 42.23(b).

For these reasons, we *deny* Patent Owner’s Motion to Exclude as it relates to Exhibits 1010, 1024, and 1039.

IV. MOTION TO SEAL

Patent Owner filed an unopposed Motion to Seal and for Entry of Protective Order. Paper 42, 1. Patent Owner states that Petitioner does not oppose the motion. *Id.* at 2.

Patent Owner seeks to seal Exhibit 2016 (Expert Report of Dr. Anthony Lowman Regarding Invalidity), Exhibit 2017 (Rebuttal Expert Report and Declaration of Dr. Jimmy W. Mays), Exhibit 2018 (Reply Expert Report of Dr. Lowman), Exhibit 2019 (Deposition transcript of Dr. Lowman) and Exhibit 2020 (Deposition transcript of Dr. Mays). Paper 42, 2. Patent Owner also seeks entry of a proposed IPR Protective Order

(Exhibit 2021) in this proceeding. *Id.* at 3. Patent Owner states that the parties “have conferred and agreed to the provisions of the [Proposed] Stipulated Confidentiality Protective Order (“IPR Protective Order”) set forth in Exhibit 2021, and have stipulated to be bound to the terms set forth therein.” *Id.*

The record for an *inter partes* review shall be made available to the public, except as otherwise ordered, and a document filed with a motion to seal shall be treated as sealed until the motion is decided. 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.14. The standard for granting a motion to seal is “good cause.” 37 C.F.R. § 42.54. “There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an *inter partes* review which determines the patentability of claims in an issued patent and therefore affects the rights of the public.” *Garmin Int’l v. Cuozzo Speed Techs., LLC*, IPR2012–00001, slip op. at 1–2 (PTAB Mar. 14, 2013) (Paper 34). The moving party bears the burden of showing that the relief requested should be granted. 37 C.F.R. § 42.20(c). That includes showing that the information is truly confidential, and that such confidentiality outweighs the strong public interest in having an open record. *See Garmin* at 2–3.

Patent Owner states that Exhibits 2016, 2017, and 2018 are expert reports of the parties that were filed in the district court litigation. Paper 42, 3. Patent Owner points out that these Exhibits are designated “HIGHLY CONFIDENTIAL—OUTSIDE COUNSEL EYES ONLY” under the District Court Protective Order, and assert that they “contain highly confidential information, including technical and/or competitive information

not generally available to the public.” *Id.* Patent Owner states that Exhibits 2019 and 2020 are deposition transcripts that are also designated highly confidential information under the District Court Protective Order. *Id.* Patent Owner asserts that these transcripts “contain highly confidential information, namely the testimony of the experts concerning their respective submitted expert reports.” *Id.*

In reviewing Exhibits 2016–2020, we conclude that they may contain confidential information. We also are mindful that these Exhibits were filed in this proceeding only on the Board’s Order. *See* Paper 36. Accordingly, we are persuaded that good cause exists to have Exhibits 2016–2020 remain under seal, and the Motion for Entry of the Default Protective Order and To Seal is granted.

The parties are reminded, however, that confidential information that is subject to a protective order ordinarily becomes public 45 days after final judgment in a trial. *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). This panel interprets “final judgment” to include the resolution of appellate proceedings, if any. Also, there is an expectation that information will be made public where the existence of the information is identified in a final written decision following a trial. *Id.* After final judgment in a trial, a party may file a motion to expunge confidential information from the record prior to the information becoming public. *See* 37 C.F.R. § 42.56.

This Final Decision is entered as a non-public version covering protective order material because it references and cites to several documents subject to the Motion to Seal. No later than five (5) business

days after entry of the Final Written Decision, the parties shall jointly submit, as an Exhibit, a proposed redacted version of the Final Written Decision that will be publicly available. If the parties are of the impression that the Final Written Decision may be made publicly available without any redactions, the parties may notify the Board via email stating as such.

V. CONCLUSION

For the foregoing reasons, and based on the evidence and arguments, we are persuaded that Petitioner has demonstrated by a preponderance of the evidence that claims 1–6 and 8–12 of the '034 patent are unpatentable under 35 U.S.C. § 103(a).

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–6 and 8–12 of U.S. Patent 7,009,034 have been shown to be unpatentable under 35 U.S.C. § 103 for obviousness;

FURTHER ORDERED that Petitioner's Motions to Exclude Evidence are dismissed;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is dismissed-in-part and denied-in-part;

FURTHER ORDERED that Patent Owner's Motion for Entry of the IPR Protective Order and To Seal is granted;

FURTHER ORDERED that no later than five (5) business days after entry of this Order, the parties shall jointly submit, as an Exhibit, a proposed redacted version of the Final Written Decision that will be publicly available; and

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

IPR2016-01836
Patent 7,009,034 B2

FOR PETITIONER:

Orion Armon
oarmon@cooley.com

FOR PATENT OWNER:

Paul Rivard
privard@bannerwitcoff.com

John Iwanicki
jiwanicki@bannerwitcoff.com

Christopher McKee
cmckee@bannerwitcoff.com

Jason Shull
jshull@bannerwitcoff.com