

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NANOFIBER SOLUTIONS, LLC,
Petitioner,

v.

ACERA SURGICAL, INC.,
Patent Owner.

IPR2021-01016
Patent 10,632,228 B2

Before GRACE KARAFFA OBERMANN, CHRISTOPHER L. CRUMBLEY,
and JULIA HEANEY, *Administrative Patent Judges*.

CRUMBLEY, *Administrative Patent Judge*.

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

I. INTRODUCTION

Nanofiber Solutions, LLC filed a Petition (Paper 2, “Pet.”) requesting the Board institute an *inter partes* review of claims 1–20 of U.S. Patent No. 10,632,228 B2 (Ex. 1001, “the ’228 patent”). Acera Surgical Inc. identified itself as the owner of the ’228 patent, but did not file a preliminary response to the Petition.

Upon consideration of the Petition and the evidence, we determined that Petitioner had demonstrated a reasonable likelihood that it would prevail with respect to at least one claim of the ’228 patent. Paper 9 (“Decision on Institution” or “DI”). Pursuant to the Supreme Court’s decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018), and USPTO Guidance,¹ we instituted review of all challenged claims on all asserted grounds. *Id.*

Following institution of trial, Patent Owner filed a Patent Owner Response (Paper 19, “PO Resp.”), Petitioner filed a Reply (Paper 23, “Reply”), and Patent Owner filed a Sur-reply (Paper 27, “Sur-reply”).

In support of their respective positions, Petitioner relies on the testimony of Gary E. Wnek, Ph.D. (Ex. 1002, “Wnek Declaration”; Ex. 1032, “Wnek Reply Declaration”) and Patent Owner relies on the testimony of Wolfgang Sigmund, Ph.D. (Ex. 2001, “Sigmund Declaration”). Patent Owner took cross-examination testimony of Dr. Wnek via deposition and submitted the transcript (Ex. 2003); Petitioner did the same with Dr. Sigmund (Ex. 1033).

¹ “If the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition.” *See* USPTO, Guidance on the Impact of SAS on AIA Trial Proceedings (April 26, 2018) (available at <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>) (“USPTO Guidance”).

An oral hearing was held on September 15, 2022, and a transcript of the hearing is included in the record (Paper 37, “Tr.”).

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1, 2, 4, 5–7, and 13 of the ’228 patent are unpatentable. Petitioner has not shown that the remaining challenged claims are unpatentable.

A. Related Proceedings

The parties indicate that the ’228 patent has been asserted by Patent Owner against Petitioner in a patent infringement action in the District of Delaware, in *Acera Surgical, Inc. v. Nanofiber Solutions, LLC*, Case No. 1:20-cv-00980-CFC-JLH. Pet. 1–2; Paper 5, 1.

B. The ’228 Patent

The ’228 patent, entitled “Tissue Substitute Materials and Methods for Tissue Repair,” issued April 28, 2020, with claims 1–20. Ex. 1001, codes (54), (45), 19:45–22:17. The ’228 patent describes using non-woven graft materials to repair tissue following surgical procedures, such as neurosurgical procedures. *Id.* at 1:6–13. In particular, the ’228 patent highlights the need for dura substitutes to repair defects in the dura mater, the barrier that encloses the cerebrospinal space, in order to prevent cerebrospinal fluid leakage and infection following the perforation or removal of the membrane. *Id.* at 1:24–27. Non-biologic or synthetic grafts may overcome some of the limitations of biologic grafts, but the patent

indicates that these materials typically have poor handling properties and low resorbability.² *Id.* at 2:23–40.

To overcome these challenges, the '228 patent proposes the use of non-woven graft materials that comprise at least two distinct types of fiber compositions, each having “independent mechanical, chemical, and/or biological properties.” *Id.* at 6:57–60. In one embodiment, these fiber compositions are combined into a single non-woven material through electrospinning,³ which results in a “blended” nonwoven material that has individual fibers that are interlaid, but not in an identifiable pattern or manner. *Id.* at 4:64–67, 10:22–26. The '228 patent provides a long list of polymers that may be used as the first and second fiber compositions of the nonwoven material, but identifies a “particularly suitable embodiment” that uses poly(lactic-co-glycolic acid) as the first fiber composition and polydioxanone as the second. *Id.* at 12:43–46. The issued claims of the patent, however, recite a different pair of polymers: poly(glycolic acid) (PGA) and poly(lactide-co-caprolactone) (PLCL). *Id.* at 19:47–53. The claims also specify that the non-woven graft material is in a single layer, and the two fibers are “commingled throughout a thickness” of the material. *Id.* at 19:45–46, 56–59.

² According to the '228 patent, a resorbable polymer is one that can “break down when the material is exposed to conditions that are typical of those present in a post-surgical site into degradation products” that are then removed by the body during post-surgical healing. Ex. 1001, 6:62–7:2.

³ Electrospinning is defined in the '228 patent as “a technology which produces nano-sized fibers” by providing a polymer solution to an electrically-charged orifice that causes a fine jet of the polymer solution to move toward an oppositely-charged collection grid, where it dries into ultrafine fibers. *Id.* at 5:66–6:18.

C. Illustrative Claim

Petitioner challenged claims 1–20 of the '228 patent. Pet. 6. Claims 1, 13, and 19 are independent; claim 1 is illustrative of the subject matter of all challenged claims, and reads as follows:

1. A resorbable non-woven graft material consisting of a single layer comprising:
 - a first electrospun non-woven fiber composition, wherein the first electrospun non-woven fiber composition consists of poly (glycolic acid) and
 - a second electrospun non-woven fiber composition, wherein the second electrospun non-woven fiber composition comprises poly(lactide-co-caprolactone),wherein the first electrospun non-woven fiber composition and the second electrospun non-woven fiber composition comprise different polymers, and
- wherein the first electrospun non-woven fiber composition and the second electrospun non-woven fiber composition are commingled throughout a thickness of the resorbable non-woven graft material.

Ex. 1001, 19:45–59.

D. Prior Art and Asserted Grounds of Unpatentability

Petitioner contends that claims 1–20 are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. §⁴	Reference(s)
1–5, 13	102(a)(2)	Johnson ⁵
6	103	Johnson
3, 7, 8, 10, 12, 14, 16, 18–20	103	Johnson, Liu ⁶
9, 11, 15, 17	103	Johnson, Liu, Cheng ⁷
1–6, 13	103	Johnson ’315, ⁸ Detamore ⁹
7, 8, 10, 12, 14, 16, 18–20	103	Johnson ’315, Detamore, Liu
9, 11, 15, 17	103	Johnson ’315, Detamore, Liu, Cheng

Pet. 6. Petitioner contends Johnson is prior art to the ’228 patent under 35 U.S.C. § 102(a)(2), while Liu, Cheng, Johnson ’315, and Detamore are prior

⁴ The Leahy-Smith America Invents Act (“AIA”) includes revisions to 35 U.S.C. §§ 102, 103 that became effective on Mar. 16, 2013. Pub. L. No. 112–29, §§ 3(b), 3(c), 3(n)(1), 125 Stat. 284, 287, 293 (2011). Because the application from which the ’228 patent issued was filed after Mar. 16, 2013, we apply the post-AIA versions of §§ 102, 103 to this Decision.

⁵ U.S. Patent Application Publication No. 2016/0317706 A1 to Johnson, published November 3, 2016 (Ex. 1009).

⁶ Liu, Yaowen et al., *Electrospun Fibrous Mats on Lithographically Micropatterned Collectors to Control Cellular Behaviors*, 28 LANGMUIR 17134–42 (2012) (Ex. 1011).

⁷ Cheng, Qian et al., *Engineering the Microstructure of Electrospun Fibrous Scaffolds by Microtopography*, 14 BIOMACROMOLECULES 1349–60 (2013) (Ex. 1012).

⁸ U.S. Patent Application Publication No. 2014/0030315 A1 to Johnson, published January 30, 2014 (Ex. 1014).

⁹ International Patent Application Publication No. WO 2013/025819 A2 to Detamore et al., published February 21, 2013 (Ex. 1015).

art under § 102(a)(1). *Id.* at 4–5. Patent Owner did not contest the prior art status of any reference, and we find that the references are prior art to the '228 patent.

II. ANALYSIS

A. *Legal Standards*

To prevail in its challenge, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2019). In order to find a claim anticipated, we must find not only that all elements of a claim are disclosed within the four corners of a single prior-art reference, but that the elements are “arranged as in the claim.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time of the invention to a person having ordinary skill in the art. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence,¹⁰ objective indicia of obviousness or non-obviousness, such as commercial success, long-felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

¹⁰ Neither party has submitted any evidence of objective indicia of obviousness or non-obviousness.

To show obviousness, it is not enough to merely show that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). “This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR*, 550 U.S. at 418–419.

On the other hand, an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418; *accord In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined or modified the prior art references. *In re NuVasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016); *see also Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017) (“In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason why a person of skill in the art would have made the combination.”); *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed

invention.”) (citing *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014)).

B. Level of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *See Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)). The level of skill in the art also informs the claim-construction analysis. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 332 (2015) (explaining that claim construction seeks the meaning “a skilled artisan would ascribe” to the claim term “in the context of the specific patent claim” (emphasis omitted)).

Petitioner contends that:

A person of ordinary skill in the art (“POSITA”) at the time of filing the ‘228 Patent would have been a person having a bachelor's degree in science or engineering, for example in the fields of chemistry, chemical engineering, or biomedical engineering, with undergraduate research experience, coupled with at least three years of industry experience, that linked the fabrication of fibrous polymeric materials to performance requirements for scaffolds for the promotion of proliferation of biological cells and the growth and/or reconstruction of biological tissues.

Pet. 11–12 (citing Ex. 1002 ¶¶ 112–116).

In response, Patent Owner notes that all challenged claims recite electrospun fibers but that Petitioner’s proposed level of skill “requires (1) no coursework, training or experience with electrospinning and (2) improperly focuses on scaffolds for the promotion of proliferation of biological cells and the growth and/or reconstruction of biological tissues.” PO Resp. 7 (citing Ex. 2001, ¶¶ 38–39). But Patent Owner then concedes

that this “difference is immaterial to deciding the issues raised by the Petition.” *Id.* at 8.

C. Claim Construction

In an *inter partes* review filed on or after November 13, 2018, we construe claims “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Furthermore, we expressly construe the claims only to the extent necessary to resolve the parties’ dispute. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

The parties agree that the terms of the challenged claims should be given their “plain and ordinary meaning” and that no express claim construction is necessary to address Petitioner’s challenges. Pet. 12; PO Resp. 6. We agree that no claim terms require express construction for purposes of resolving the dispute between the parties.

D. Anticipation by Johnson

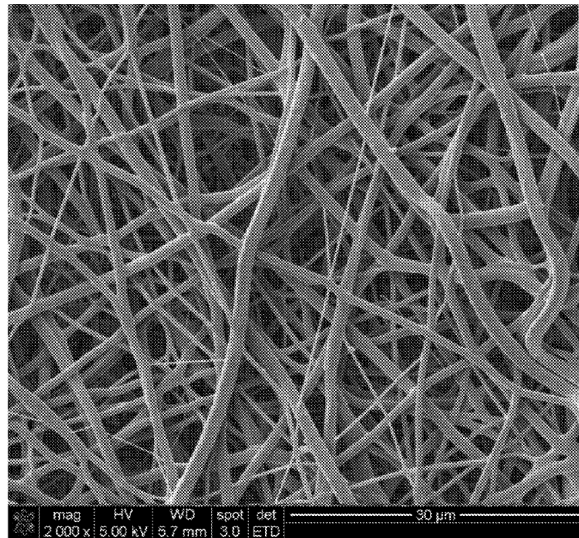
Petitioner contends that claims 1–5 and 13 are anticipated by Johnson, and therefore are unpatentable under 35 U.S.C. § 102(a)(2). Pet. 21–32. Patent Owner disagrees, contending that Johnson does not teach all claim limitations in a single example, either expressly or inherently. PO Resp. 8–

20. In addition, Patent Owner argues that Johnson fails to meet the pore size limitation of claim 3. *Id.* at 20–23.

Johnson discloses electrospun fiber scaffolds for use in the healing of wounds, in which the scaffold comprises a first material with a first degradation rate and a second material with a second degradation rate. Ex. 1009, Abstract. The scaffold may comprise a single layer, and Johnson discloses the manufacture of a scaffold using co-electrospun PLCL and PGA. *Id.* ¶¶ 98, 112. In this exemplary scaffold, Johnson reports a resulting material with “approximately 50% of the fibers being pure PGA and 50% of the fibers being pure PLCL.” *Id.* ¶ 112. Dr. Wnek notes Johnson’s “detailed description of the manufacturing” of the exemplary scaffold using an electrospinning process, and testifies that a person of ordinary skill in the art would have understood, based on the method of manufacture, that the resulting scaffold would be a non-woven material. Ex. 1002 ¶ 165.

Petitioner, relying on the testimony of Dr. Wnek, contends that Johnson discloses all elements of claims 1–5 and 13. Pet. 21–32. For example, Petitioner indicates how Johnson’s scaffolds are graft materials that may be non-woven, resorbable, and formed in a single layer. *Id.* at 21–23 (citing Ex. 1009 ¶¶ 86, 87, 98, 106, 111, 112, 120; Ex. 1002 ¶¶ 163–171). Petitioner cites to the ’228 patent’s definition of a “non-woven graft material” as “a material having a structure of individual fibers or threads which are interlaid, but not in an identifiable manner as in a knitted fabric.” *Id.* at 7, 21 (citing Ex. 1001, 4:64-67). Both the nonwoven graft materials of the ’228 patent and the scaffolds of Johnson are made using an electrospinning method, and both the ’228 patent and Dr. Wnek indicate that electrospinning results in a nonwoven material. Ex. 1001, 5:1–4; Ex. 1002

¶ 55. Figure 13A of Johnson, reproduced below, allegedly shows such a material, depicting the interlaid fibers of a scaffold made from electrospun PGA and PLCL:



Ex. 1009, Fig. 13A, ¶ 69.

Petitioner also contends that Johnson discloses a first fiber that consists of PGA and a second fiber that comprises PLCL, directing us to Johnson’s exemplary composition containing 50% pure PGA fibers and 50% pure PLCL fibers. Pet. 23–24 (citing Ex. 1009 ¶¶ 7, 77, 82, 95, 111, 112). Dr. Wnek submits that a person of ordinary skill in the art would have understood the co-spinning method of Johnson to result in a material in which the two fiber compositions are commingled. Ex. 1002 ¶¶ 176–178.

With respect to claim 13, it is substantially the same as claim 1, the primary distinction being that claim 1 requires only that the second fiber composition *comprise* PLCL, whereas claim 13 requires the second fiber composition *consists of* PLCL. Ex. 1001, 20:40–51. Petitioner sets forth this element of claim 13, indicating the exemplary material of Johnson in which the second fiber is said to be “pure PLCL.” Pet. 31 (citing Ex. 1009 ¶ 112).

Petitioner also sets forth how the elements of dependent claims 2–5 are disclosed in Johnson. Pet. 27–30. For example, Petitioner notes Johnson’s disclosure that its first and second fiber compositions may be present in a weight ratio of “about 1:1, . . . about 3:1, . . . about 1:3, or any range between any two of these values” (Ex. 1009 ¶ 97) meets claim 2’s requirement that the compositions be present in a ratio between about 10:1 to about 1:10. Pet. 27. Similarly, Petitioner sets forth how Johnson’s disclosure of fiber diameters in the range of about 0.1 μm to about 10 μm meets claim 4’s requirement of a mean fiber diameter of “less than 5 μm .” Pet. 29 (citing Ex. 1009 ¶ 81).

Claim 3 requires a mean pore size in the range of “about 10 μm^2 to about 10,000 μm^2 ,” and Petitioner argues that this is inherently met by Johnson’s Example 1 “based on the specific polymers, solvents, distances, and flow rates” in the example, as well as the resultant fiber diameters in the range of about 0.1 μm to about 10 μm . Pet. 28 (citing Ex. 1009 ¶¶ 81, 112).

With few exceptions, Patent Owner does not contest Petitioner’s assertions as to the disclosure of Johnson or how it teaches the elements of the challenged claims. We find that, on these uncontested elements, Petitioner has proven by a preponderance of the evidence that Johnson discloses a nonwoven fiber composition that meets these elements. We now turn to resolving the parties’ dispute as to the remaining elements.

1. Whether Petitioner Relies on Separate Embodiments

Patent Owner contends that Petitioner “improperly combines various teachings within Johnson to purportedly arrive at the claimed subject matter.” PO Resp. 9. Specifically, Patent Owner notes that the anticipation ground of the Petition primarily relies on Example 1 of Johnson, but that

example does not recite that the scaffold is a single layer. *Id.* For that disclosure, Petitioner instead relies on a disclosure from a different portion of the '228 patent, which states that the scaffold can be a single layer. Pet 22 (citing Ex. 1009 ¶ 98). Patent Owner thus concludes that Johnson does not disclose all elements of claim 1 “arranged as in the claim,” because “it is possible practicing Example 1 could result in multiple layers.” Sur-Reply 12.

Petitioner responds that Patent Owner’s anticipation analysis is improperly narrow, and that the anticipation ground does not combine disparate portions of Johnson. Reply 2. Example 1 is Johnson’s only example of a method of manufacturing its scaffold, and Petitioner argues that it is consistent with the disclosures of Johnson as a whole. *Id.* at 3.

Upon review, we are unpersuaded that Petitioner has improperly mixed and matched disclosures from Johnson to arrive at an anticipatory reference. Patent Owner is correct that Petitioner primarily relies on Example 1 as evidence for the method by which its scaffold is made. But the disclosure found in paragraph 98 is not a “distinct” teaching of the type described in *Net MoneyIN*; rather, it is a general description of the structures that may be created by Johnson’s method: “A scaffold may comprise any number of layers, including about 1 layer, about 2 layers, about 3 layers, about 4 layers, about 5 layers, and so on.” Ex. 1009 ¶ 98. Patent Owner has not directed us to anything in the disclosure of Johnson that indicates that this is a “distinct” teaching or embodiment, instead of a general description of the types of scaffolds that Johnson encompasses. We see no reason why the general disclosures regarding Johnson’s scaffolds should be limited to

specific embodiments, or precluded from applying to the method of Example 1.

2. *Whether Johnson Discloses Two Distinct Fiber Compositions*

Patent Owner also disputes whether Example 1 discloses forming a scaffold comprising two distinct fiber compositions. PO Resp. 10–20. Patent Owner notes that Example 1 does not expressly refer to two needle tips being used in its electrospinning process, and that Johnson does not expressly teach the formation of two distinct fibers. *Id.* at 10–11. Nor has Petitioner shown that two fibers are inherent in Johnson, Patent Owner contends. *Id.* Rather, Patent Owner argues that a skilled artisan “would not have believed that Example 1 of Johnson refers to a co-spinning process using two needles—one for the PLCL and a second for the PGA,” but instead “would have believed Example 1 utilized a single needle to spin both polymers into a single fiber containing both polymers.” *Id.* at 13. Patent Owner directs us to other prior art references, such as Bhaskar¹¹ and Lin,¹² in which multiple polymer solutions were co-spun through a single needle tip. *Id.* at 13–18.

Petitioner responds that Example 1 expressly refers to two syringes, each containing a type of polymer, and that a person of ordinary skill in the art would have understood that each syringe would be accompanied by a needle. Reply 11–12. Johnson states that its polymer injection system

¹¹ Bhaskar, S. et al., *Microstructured Materials Based on Multicompartmental Fibers*, 131 J. AM. CHEM. SOC. 6650-6651 (2009) (Ex. 2004).

¹² Lin, T. et al., *Self-Crimping Biocomponent Nanofibers Electrospun from Polyacrylonitrile and Elastomeric Polyurethane*, 17 ADVANCED MATERIALS 2699-2703 (2005) (Ex. 2005).

“may include multiple syringes and multiple needles.” Ex. 1009 ¶ 79.

Petitioner notes that Johnson never discloses a system where multiple syringes are connected to a single needle, unlike the disclosures of Bhaskar and Lin cited by Patent Owner. Reply 12, 15. Furthermore, Petitioner observes that the result of Johnson’s Example 1 is two sets of fibers, each being pure polymer of different types. *Id.* at 12–13. According to Petitioner, this is inconsistent with the use of a single needle and multiple syringes. *Id.* at 14.

Upon review, we believe Patent Owner’s interpretation of Johnson’s disclosure is inconsistent with the text. Johnson clearly states that the result of Example 1 is two sets of fibers, with approximately 50% being *pure* PGA and the other 50% being *pure* PLCL. Ex. 1009 ¶ 112. The only reasonable explanation given by either party for how such a structure could be formed by a cospinning process (where the solutions are simultaneously electrospun as required by Example 1) is by using multiple needles, each devoted to a single polymer. Patent Owner argues that, because feeding multiple polymers through one needle can result in a “sharp boundary” in the single fiber, “a skilled artisan could have referred to the fibers as containing a mixture of 50% of pure polymer A and 50% of pure polymer B.” PO Resp. 18. But that is not what Example 1 of Johnson says. Johnson does not recite *fibers* that contain a “mixture of pure polymer A and pure polymer B.” Rather, Johnson’s process results in “50% of the *fibers* being pure PGA and 50% of the *fibers* being pure PLCL.” Ex. 1009 ¶ 112. Patent Owner gives no persuasive explanation why a person of ordinary skill would have interpreted this disclosure of different *fibers* to simply refer to the presence of multiple polymers in the *same fiber*.

In our view, Example 1's recitation of "the needle tip" does not indicate that only one needle was used to electrospin Johnson's scaffold. The full sentence cited by Patent Owner comes after the example discloses multiple syringes and the fact that the process results in separate fibers, and reads as follows: "Both solutions were simultaneously electrospun (co-spun) onto the mandrel that was positioned 20 cm from the needle tip and rotated at 30 RPM." Ex. 1009 ¶ 112. The reference to "the needle tip" is therefore in the context of describing the distance between the tip and the mandrel, as opposed to describing the needle itself or the setup of the needles and polymer-containing syringes. Especially given the disclosure of multiple needles elsewhere in Johnson, and the further disclosure that each fiber is either *pure* PGA or *pure* PLCL, we agree with Petitioner that a person of ordinary skill in the art would have interpreted Example 1 of Johnson to describe the use of multiple needles to cospin two distinct fibers into a combined scaffold.

3. *Whether Johnson Discloses Pore Size*

Finally, with respect to claim 3, Patent Owner argues that Johnson fails to disclose the claimed mean pore size of about 10 μm^2 to about 10,000 μm^2 . PO Resp. 20. We agree. For this claim, the Petition relies on Johnson's disclosure of fiber diameters in the range of about 0.1 μm to about 10 μm , and argues that this inherently meets the pore size limitation. Pet. 28 (citing Ex. 1009 ¶¶ 81, 112). As we noted in our Institution Decision, we had doubts about the sufficiency of Petitioner's showing, because there was no satisfactory explanation in the Petition linking fiber size to pore diameter. DI 11–12. Patent Owner agrees, and notes that the mean pore size of an electrospun scaffold can depend on numerous variables, including the size of

the fibers. PO Resp. 20. As an example, Patent Owner cites Boland 2005,¹³ which has a fiber diameter similar to Johnson's but a pore area below the range required by claim 3. *Id.* at 21–22 (citing Ex. 2007, 119).

In response, Petitioner argues that claim 3's pore size range is extremely broad, encompassing three orders of magnitude, and that because mean pore size is "reasonably correlated" to pore diameter, it is reasonable to conclude that the mean pore size of the scaffold depicted in Figure 13A of Johnson falls within the claimed range. Reply 15.

We are unconvinced by Petitioner's arguments and evidence. While we recognize that the range of claim 3 is very broad, and it is possible that scaffolds having fiber diameters as set forth in Johnson could have a mean pore size falling within the range, inherency "may not be established by probabilities or possibilities." *Par Pharm., Inc. v. Twi Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014). Nor does Petitioner sufficiently explain why a person of ordinary skill in the art would have understood the process of Example 1 to necessarily result in the claimed mean pore size. We are also persuaded by Patent Owner's argument that Boland 2005's disclosure of a fiber diameter similar to Johnson's that nevertheless falls outside the claimed mean pore size range. We note that Petitioner never addresses Boland 2005 in its Reply.

4. *Conclusion as to Anticipation*

For these reasons, we find that Petitioner has met its burden of showing that claims 1, 2, 4, 5, and 13 are anticipated by Johnson, but has failed to meet its burden as to claim 3.

¹³ Boland, E. et al., *Electrospinning polydioxanone for biomedical applications*, 1 ACTA BIOMATERIALIA 115–123 (2006) (Ex. 2007).

E. Obviousness over Johnson

Petitioner also contends that the subject matter of claim 6 would have been obvious over Johnson alone. Pet. 32. Claim 6 depends from claim 1, and further requires that the two fibers are “independently distributed in a pattern throughout the material.” Ex. 1001, 20:7–10. Petitioner directs us to Johnson’s disclosure of an electrospinning system with multiple injectors, which Dr. Wnek testifies could be used to independently distribute two separate polymers in a pattern. Pet. 33 (citing Ex. 1009 ¶¶ 92–93; Ex. 1002 ¶¶ 225–226). Dr. Wnek also testifies that a person of ordinary skill in the art would have done so “in order to further improve the porosity during degradation of the first material and the support provided by the second material in order to further promote wound healing.” Ex. 1002 ¶ 227.

Patent Owner responds that the pattern required by claim 6 is not a pattern of the two fibers, but instead a “pattern throughout the material,” which must mean a “pattern in the material itself.” PO Resp. 24. According to Patent Owner, because all electrospun fibers are deposited in at least a random pattern, claim 6 must refer to more than simply the distribution of the fibers in the material. *Id.* Patent Owner refers us to WO ’889,¹⁴ which is part of the file history of the ’228 patent, and which shows patterning that can help promote cell growth. *Id.* at 25 (citing Ex. 1004, 213–75). Patent Owner contends that this is the type of “pattern” referred to in claim 6, as opposed to the fiber pattern of Johnson. *Id.* at 26.

Petitioner responds by directing us to the language of claim 6 itself, which states that the two electrospun fibers are “independently distributed in

¹⁴ International Patent Application WO 2011/159889 to MacEwan et al., published Dec. 22, 2011 (Ex. 1004, 213–75).

a pattern throughout the material.” Reply 16–17. We agree that this language indicates that “pattern” is not as limited to patterns as disclosed in WO ’889, as Patent Owner contends. Rather, the ’228 patent uses “pattern” to refer to the distribution of the *fibers* throughout the material.¹⁵ While we acknowledge Patent Owner’s contention that a random distribution of fibers should not be understood to be a “pattern” within the scope of claim 6, Petitioner does not rely on a random distribution. Rather, Petitioner indicates Johnson’s disclosure of a mandrel movement that results in a “nearly helical deposition” pattern, and another that results in a “roughly linear deposition.” Reply 17 (citing Ex. 1009 ¶ 92; Ex. 1032 ¶ 25). We find that both of these depositions would result in fibers that are “independently distributed in a pattern throughout the material.” We additionally find that Petitioner has proven that a person of ordinary skill in the art would have applied such a pattern to the scaffold of Example 1, in order to improve porosity and further promote wound healing. Pet. 33; Ex. 1002 ¶ 227. We note that Patent Owner does not contest that a person of ordinary skill would have had reason to make this modification. We, therefore, find that Petitioner has met its burden of proving that claim 6 would have been obvious over Johnson.

¹⁵ The written description of the ’228 patent does not assist with our interpretation of claim 6. The disclosure does not use the term “pattern” to refer to the distribution of fibers throughout the material; instead, it only refers to “patterns” of indentations or protrusions on the surface of the non-woven graft material. Ex. 1001, 9:22–24, 42–44, 62–65; 11:9–10, 29–30, 48–50. Nor does the written description provide any context for the term “throughout the material.”

F. Obviousness over Johnson and Liu

Petitioner contends that the subject matter of claims 3, 7, 8, 10, 12, 14, 16, and 18–20 would have been obvious over the combined disclosures of Johnson and Liu. Pet. 33–44. Liu discloses the use of micropatterning in the manufacture of electrospun scaffolds “to modulate cell distribution, growth, and functions for reconstructing the anisotropy in native tissues.” Ex. 1011, Abstract. The patterned mats disclosed in Liu have “distinct ridge and groove areas” that allow cell growth to be confined to precise locations, sizes, and shapes. *Id.* The fibrous mats are also porous, having an average pore size in the ridge area of around 5.9 μm and an average pore size in the groove area of around 7.2 μm . *Id.* at 17138. Liu discloses that these features “provide the potential to construct complex tissues of well organized multiple cell types and spatially distributed [extracellular matrix].” *Id.* at 17141.

Petitioner contends that a person of ordinary skill in the art would have had reason to combine the disclosures of Johnson and Liu, as both are directed to fiber scaffolds that increase cell growth and proliferation. Pet. 35. Dr. Wnek testifies that “Liu directly relates to providing surface topological features, *i.e.*, ridges and grooves, on electrospun biomaterials, the same type of materials disclosed in Johnson, in order to promote cell proliferation and improve wound healing.” Ex. 1002 ¶ 234. Petitioner argues that a person of ordinary skill in the art would have had a reasonable expectation of success in employing a patterned collector to add the ridges and grooves of Liu to the electrospun scaffolds of Johnson. Pet. 36.

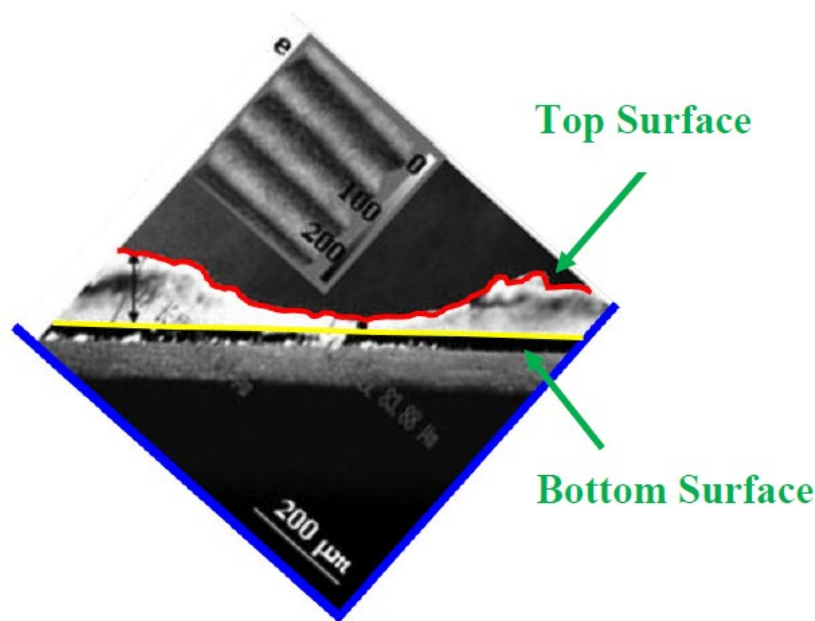
Patent Owner contends that the combined disclosures of Johnson and Liu do not satisfy all elements of the challenged claims. Patent Owner

argues that Liu does not disclose the required “projections” and “indentations” required by the claims (PO Resp. 29–32), and that any projections or indications are not “randomly distributed” (*id.* at 32–35). Furthermore, with respect to the pore size limitation of claim 3, Patent Owner contends that a person of ordinary skill in the art would not have had reason to incorporate Liu’s pore size in Johnson. *Id.* at 35–37. We address these issues in turn.

1. Whether Liu Discloses Projections and Indentations

As noted above, Petitioner relies on Liu’s “distinct ridge and groove morphologies” as teaching the “at least one projection arising from a surface of the non-woven graft material” and “at least one indentation in a surface of a non-woven graft material.” Pet. 33–44. The ’228 patent defines a “projection” as “a protrusion or bulge arising from a surface of the non-woven graft material.” Ex. 1001, 9:6–11. Similarly, an “indentation” is defined as “a recess or depression in a surface of the non-woven graft material.” Ex. 1001, 9:26–31.

Patent Owner argues that Liu’s ridge and groove morphologies cannot satisfy the “projections” or “indentations” limitations of the claims. PO Resp. 29–32. In particular, Patent Owner argues that Petitioner does not indicate the surface from which Liu’s alleged projections arise, or in which the alleged indentations are found. *Id.* at 29. Instead, in Patent Owner’s interpretation, Liu discloses an “undulating surface” that has neither projections nor indentations, as shown by the red line in the rotated, annotated version of Liu’s Figure 2e below:

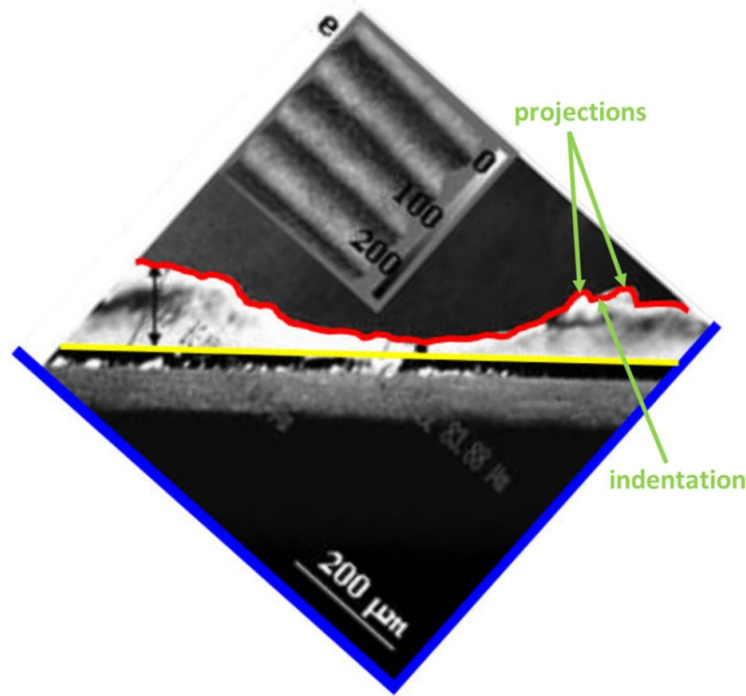


PO Resp. 31. Annotated Figure 2e of Liu shows an undulating top surface shown in red, and a generally flat bottom surface shown in yellow. *Id.*

Citing Dr. Sigmund’s testimony, Patent Owner argues that “skilled artisan looking at Figure 2E of Liu would have recognized there are no protrusions arising from the top of the white area.” *Id.* at 31–32 (citing Ex. 2001 ¶ 79).

Petitioner responds that Patent Owner’s interpretation of the claim terms is “nonsensical” because it interprets “a surface” to mean “the *entire surface*.” Reply 19–20. Under Patent Owner’s interpretation, Petitioner argues, no surface could ever have a projection or indentation because the entire surface itself would encompass every projection and indentation. *Id.* Petitioner contends that a person of ordinary skill in the art would have understood that “a surface” refers only to “*any portion of a given surface*.” *Id.* Petitioner contends that the portion of Liu’s surface that is higher is a “projection” from the lower portion of the surface, and the lower portion is an “indentation” from the higher portion.

In his Reply Declaration, Dr. Wnek also for the first time provides an annotated version of Liu Figure 2e, indicating a different set of potential projections and indentations:



Ex. 1032 ¶ 42. Dr. Wnek’s annotated Figure 2e notes potential projections and indentations, analyzed under what Dr. Wnek calls “Patent Owner’s own understanding,” as reflected in infringement contentions served in the copending litigation. *Id.*

Patent Owner argues that Dr. Wnek’s testimony on this point is new and was not included with the Petition, which only relied on Liu’s “ridge and groove morphologies” as showing the claimed projections and indentations. Sur-Reply 19. Patent Owner also contends that this is inconsistent with Dr. Wnek’s deposition testimony that it is more appropriate to identify indentations by looking at a macroscopic piece of material. *Id.* at 20.

Turning first to Petitioner’s identification of surface features in the Petition, namely the “ridge and groove morphologies” of Liu, we conclude based on the totality of the record that a person of ordinary skill in the art would have considered them to fall within the “projections” and “indentations” described in the ’228 patent. In reaching this conclusion, we have considered the express definitions of the terms in the patent itself. For example, the ’228 patent describes the projection as a “protrusion” or “bulge” and the indentation as a “recess” or “depression.” Ex. 1001, 9:6–7. These terms—especially “bulge” and “depression”—would encompass gradual changes in thickness such as the ridges of Liu. Furthermore, the ’228 patent is very expansive in its description of the projections, stating they can be “any desired shape” and “any desired height as measured from the surface of the material.” *Id.* at 9:11–16. The ’228 patent would not have given the person of ordinary skill in the art any indication that it intended to exclude “undulating surfaces,” as Patent Owner and Dr. Sigmund argue. PO Resp. 30–31; Ex. 2001 ¶¶ 77–80. Nor can we find support for Patent Owner’s argument, as expressed during oral hearing, that there must be a “distinct planar surface” that has projections and indentations. Tr. 33:15–34:10.

Given that we find that the ridge and groove morphologies of Liu satisfy the claim requirements of projections and indentations, we need not address Petitioner’s alternate argument made in the Reply, or determine whether it was an improper, late-arising argument.

We also find that a person of ordinary skill in the art would have had reason to incorporate Liu’s surface features in the scaffolds of Johnson, to “mimic the complex organization of multiple cell types and complex

extracellular matrices” and achieve Liu’s stated benefits of “guid[ing] cell spatial distribution within patterned areas, penetration into the fibrous scaffolds, and alignment along the fiber orientation, which provide the potential to construct complex tissues of well organized multiple cell types and spatially distributed ECM^[16].” Ex. 1011, 17134, 141. This combination would result in a scaffold meeting all elements of claim 7.

2. *Random Projections and Indentations*

Claims 8, 10, 12, 14, 16, and 18–20 additionally recite (directly or by dependency) that the projections or indentations are “randomly distributed” on the surface of the non-woven graft material. Petitioner contends that “because Liu discloses mimicking the ECM,” a person of ordinary skill in the art “would understand that a combination of ridges and grooves *could* be employed on the surface of a scaffold in a randomly distributed manner simply by randomly distributing those features on the patterned collector.” Pet. 40 (emphasis added) (citing Ex. 1002 ¶¶ 258, 279). But, as Patent Owner observes, neither Petitioner nor Dr. Wnek discuss why a random distribution is advantageous, or how it would “mimick the ECM.” PO Resp. 34–35. Upon review of Liu, its ridges and grooves appear to be uniformly or regularly distributed. Ex. 1011, Fig. 2 (*see also id.* at 17137 (“electrospun fibers on the patterned collector can form well organized topical structures.”)). And these “well organized” structures have the benefit of “provid[ing] the potential to construct complex tissues of well organized multiple cell types and spatially distributed ECM.” *Id.* at 141. Petitioner provides no reason why a person of ordinary skill in the art *would* have

¹⁶ ECM is shorthand for “extracellular matrix.” Ex. 1002 ¶ 58; Ex. 1015, 7:12–14.

altered Liu’s “well organized” arrangement into a random distribution, beyond merely pointing out that the artisan *could* have done so. *See Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1068 (Fed. Cir. 2018).

In Reply, Petitioner changes arguments and focuses instead on Patent Owner’s infringement contentions from the related district court litigation, specifically Patent Owner’s arguments that the accused products have randomly distributed projections and indentations. Reply 23–25. Though Patent Owner responds that this is an improper reply argument (Sur-Reply 22–23), we need not reach that question because Petitioner’s argument is unconvincing even if considered. Beyond a simple statement that “Liu Figure 2e is comparable to” the images from the infringement contentions (Reply 25), Petitioner does not explain how the images are comparable or why Patent Owner’s infringement contentions—which concern the features of an accused infringing product—have any bearing on the wholly separate question of how a person of ordinary skill in the art would have sought to modify the disclosure of Liu. Whether or not the accused infringing products have random surface features, Petitioner has not explained why a person of ordinary skill in the art would have modified Liu’s “well organized” ridges and grooves into a random arrangement.

For these reasons, we are unable to conclude that a person of ordinary skill in the art would have combined Johnson and Liu in a manner that would have resulted in a scaffold having the random distribution of projections and indentations required by claims 8, 10, 12, 14, 16, and 18–20. Petitioner has not met its burden on this ground as to those claims.

3. *Reason to Incorporate Liu's Pore Size in Johnson*

As discussed above, claim 3 recites a mean pore size of about $10\text{ }\mu\text{m}^2$ to about $10,000\text{ }\mu\text{m}^2$, and we have found that Johnson alone does not disclose such a feature. Petitioner alternatively relies on the combination of Johnson and Liu for this claim, directing us to Liu's disclosure that its "fibrous mats deposited in the ridge area indicated an average pore size of around $5.9\text{ }\mu\text{m}$," while the groove areas had "[s]ignificantly larger pore sizes of around $7.2\text{ }\mu\text{m}$." Pet. 37 (citing Ex. 1011, 17138). Petitioner contends that a person of ordinary skill in the art would have understood that pores having these diameters would have had areas of about $27.34\text{ }\mu\text{m}^2$ and $40.72\text{ }\mu\text{m}^2$, respectively, within claim 3's recited range. *Id.* at 38 (citing Ex. 1002 ¶ 242).

Patent Owner disputes Petitioner's showing by noting that the pores of Liu are not circular in shape, but instead elongated, and estimating mean pore size by assuming circular pores "leads to a significant estimation of the pore size." PO Resp. 36 (citing Ex. 2001 ¶ 87). Furthermore, Patent Owner argues that without knowledge of the distribution of diameters, there is no way to calculate the average pore size based simply on the average diameter. *Id.* (citing Ex. 2001 ¶ 88). Finally, Patent Owner argues that Petitioner has not provided any reason to modify Johnson to use Liu's pore size. *Id.* at 37. While Petitioner responded to Patent Owner's arguments regarding pore size, the Reply contains no response on the issue of reason to modify. Reply 25–27.

Because we agree with Patent Owner on this latter point, we need not resolve the parties' dispute over Petitioner's calculation of Liu's mean pore size. Petitioner has not articulated a sufficient rationale why a person of

ordinary skill in the art would have used Liu's pore size in Johnson's graft material. The Petition discusses a "Motivation to Combine Johnson and Liu," but this section focuses entirely on Liu's disclosure of patterned fibrous mats and why a skilled artisan would have applied similar patterns to Johnson. Pet. 34–37. Similarly, Dr. Wnek's testimony on this topic does not mention the pore size of Liu, any benefit from using Liu's pore size, or any other reason why the pore size would have been incorporated into Johnson. Ex. 1002 ¶¶ 229–237. As Patent Owner observes, Johnson and Liu disclose different polymers, and Petitioner gives no reason why the pore sizes of Liu's polymers would be incorporated into Johnson's different polymers. PO Resp. 37. For this reason, on this record we cannot conclude that a person of ordinary skill in the art would have considered the subject matter of claim 3 obvious in light of Johnson and Liu.

G. Obviousness over Johnson, Liu, and Cheng

Petitioner contends that the subject matter of claims 9, 11, 15, and 17 would have been obvious over the combined disclosures of Johnson, Liu, and Cheng. Pet. 44–47. Cheng discloses fabricating electrospun fibrous scaffolds and materials "with defined microstructures," which "provides a powerful means of engineering the three-dimensional structure of electrospun fibrous scaffolds for cell and tissue engineering." Ex. 1012, Abstract. The structure of Cheng's scaffolds was designed to "resemble the structure and function of extracellular matrix," to assist in wound healing and tissue engineering. *Id.* at 1349. In particular, Cheng discloses templates that have patterns with various sidewall shapes and degrees of slope. *Id.* at 1352, Fig. 2.

Petitioner contends that a person of ordinary skill in the art would have had reason to combine the disclosures of Cheng with Johnson and Liu, as all three references are directed to electrospinning fibrous materials that assist in cell growth and proliferation. Pet. 44–45. Dr. Wnek testifies that a person of ordinary skill in the art “would have had a reasonable expectation of success in employing a patterned collector to add the ridges and grooves disclosed in Liu, with a gradual gradient as disclosed in Cheng, to the electrospun scaffolds of Johnson.” Ex. 1002 ¶ 333.

Each of claims 9, 11, 15, and 17 depends from an independent claim that recites the “randomly distributed” limitation discussed above in the context of the Johnson/Liu obviousness ground. We found above that Liu failed to disclose a random distribution, and Petitioner had not provided a sufficient explanation why a person of ordinary skill in the art would have modified Liu’s surface features to incorporate a random distribution.

Petitioner does not rely on Cheng to supply the teachings we found missing from the Johnson/Liu combination. Rather, as noted, Petitioner cites Cheng for its disclosure of protrusions having a gradual gradient. Pet. 46 (citing Ex. 1002 ¶¶ 338, 344, 350, 356). Petitioner does not indicate that Cheng teaches or suggests a random distribution of its protrusions (*id.*); nor do we discern any such teaching in the reference. The addition of Cheng to the combination of references, therefore, does not remedy the disclosures we found missing from Johnson and Liu above. For this reason, we find that Petitioner has failed to meet its burden that the subject matter of claims 9, 11, 15, and 17 would have been obvious over the combined disclosures of Johnson, Liu, and Cheng.

H. Obviousness Grounds Based on Johnson '315 and Detamore

Petitioner also sets forth alternate grounds of unpatentability based on the combined disclosures of Johnson '315 and Detamore. Pet. 48–71. Like Johnson, Johnson '315 discusses electrospun synthetic grafts useful for implantation in a biological organism:

This construct includes a synthetic construct suitable for transplantation into a biological organism, comprising: a two-dimensional or three-dimensional polymer scaffold, wherein the shape and dimensions of the polymer scaffold are based on a native biological structure, wherein the polymer scaffold further includes at least one layer of polymer fibers that have been deposited by electrospinning.

Ex. 1014 ¶ 7. Whereas Johnson discloses PGA and PLCL as polymers to be used together in its scaffold, however, Petitioner acknowledges that Johnson '315 only discloses the use of PGA and polycaprolactone (PCL) as resorbable polymers. Pet. 53–55; Ex. 1014 ¶ 26. Detamore is further afield, disclosing a scaffold that is primarily PCL and may incorporate “faster degrading polymers like poly (lactic-co-glycolic acid) (PLGA) into the PCL.” Ex. 1015, 7:3–11. Petitioner notes that Detamore “provides other examples of polymer fibers that can be employed, including PGA,” but also concedes that Detamore discloses the use of PCL, “as opposed to PLCL.” Pet. 54.

Dr. Wnek testifies that a person of ordinary skill in the art would have had reason to use PGA as a first polymer, and PLCL as a second polymer, based on the combined disclosures of Johnson '315 and Detamore. For example, Dr. Wnek testifies that the skilled artisan would have used PLCL as the second polymer instead of the PCL disclosed by Johnson '315 and Detamore because it “would be a simple replacement for PCL in view of

their similar degradation rates.” Ex. 1002 ¶ 383. As we noted in our Institution Decision, however, Dr. Wnek did not provide any evidence setting forth these degradation rates; nor did he establish that skilled artisans at the time of the invention considered PCL and PLCL to be simple substitutes for one another.

In its Reply, Petitioner cites a different portion of Detamore that allegedly “expressly teaches that PLCL is a reasonable substitute for PCL.” Reply 31 (citing Ex. 1015, 22:9–11, Ex. 1032 ¶ 58). Although Petitioner attempts to cast this citation as a proper reply to Patent Owner’s argument that PCL and PLCL are used in different situations (*id.* at 30–31 (citing PO Resp. 45)), we do not accept that it is. This is not a situation where “Dr. Wnek is simply citing additional Detamore support for the same opinion previously offered,” as Petitioner contends. *Id.* There cannot be *additional* “Detamore support” in Dr. Wnek’s Reply Declaration because his original Declaration provided no Detamore support in the first place. As noted above, the Petition expressly conceded that Detamore and Johnson ’315 disclose PCL “*as opposed to PLCL.*” Pet. 54 (emphasis added). There is no discussion in the Petition, nor in Dr. Wnek’s original Declaration, of Detamore’s disclosure of PLCL as a potential substitute for PCL. As we pointed out at institution, Petitioner instead supported its substitution argument with a bare statement by Dr. Wnek that substituting one polymer for the other was a “simple replacement” that would have been recognized by a person of ordinary skill. Ex. 1002 ¶ 383. Dr. Wnek did not cite Detamore for this proposition. It is improper for Petitioner to raise this evidence, necessary to support its case-in-chief, for the first time with its Reply.

Based on the information set forth in the Petition, and disregarding Petitioner's improper reply arguments, we find that a person of ordinary skill in the art would not have combined Johnson '315 and Detamore to result in a graft material of cospun PGA and PLCL as required by the claims. But even if we were to consider Petitioner's late-arising evidence as to the substitution of PLCL for Detamore's PCL, it would not alter our ultimate patentability determinations in this case. This is due to the fact that Petitioner relies on the combination of Johnson '315 and Detamore for essentially the same purposes in these grounds as it relied on Johnson alone in the previous set of grounds. In other words, for the grounds above where we found Johnson, or Johnson and Liu, sufficient to show unpatentability of certain claims, reliance on Johnson '315 and Detamore is unnecessary. And for grounds above where the evidence was insufficient to show unpatentability, Johnson '315 and Detamore do not remedy any of the deficiencies we found in those grounds. For example, with respect to claim 3, we found above that Johnson alone did not teach the claimed mean pore size. Petitioner relies on Johnson '315 and Detamore in an identical manner with respect to mean pore size, unconvincingly attempting to correlate fiber diameter with mean pore size. Pet. 57–58. That argument is no more convincing with Johnson '315 and Detamore than it was for Johnson alone. The same is true of the remaining combinations with Johnson '315 and Detamore. For example, combining Johnson '315 and Detamore with Liu does not remedy any deficiency as to claim 3's claimed mean pore size, for the same reasons Liu did not remedy the deficiencies we found to exist in Johnson.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has satisfied its burden of demonstrating, by a preponderance of the evidence, that claims 1, 2, 4–7, and 13 of the '228 patent are unpatentable, and resolve the asserted grounds of unpatentability as follows:

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–5, 13	102(a)(2)	Johnson	1, 2, 4, 5, 13	3
6	103	Johnson	6	
3, 7, 8, 10, 12, 14, 16, 18–20	103	Johnson, Liu	7	3, 8, 10, 12, 14, 16, 18–20
9, 11, 15, 17	103	Johnson, Liu, Cheng		9, 11, 15, 17
1–6, 13	103	Johnson '315, Detamore		1–6, 13
7, 8, 10, 12, 14, 16, 18–20	103	Johnson '315, Detamore, Liu		7, 8, 10, 12, 14, 16, 18–20
9, 11, 15, 17	103	Johnson '315, Detamore, Liu, Cheng		9, 11, 15, 17
Overall Outcome			1, 2, 4–7, 13	3, 8–12, 14–20

Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice*

Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See 84 Fed.

Reg. 16,654 (Apr. 22, 2019). We note that, in any such proceeding, Patent Owner is precluded from taking action inconsistent with this Decision, including obtaining any claim that is not patentably distinct from a canceled claim. 37 C.F.R. § 43.7(d)(3). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has established by a preponderance of the evidence that claims 1, 2, 4, 5–7, and 13 of the '228 patent are unpatentable;

FURTHER ORDERED that Petitioner has not established by a preponderance of the evidence that claims 3, 8–12, or 14–20 of the '228 patent are unpatentable;

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.

IPR2021-01016
Patent 10,632,228 B2

For PETITIONER:

Megan O'Gara
Andrew P. Zappia
TROUTMAN PEPPER HAMILTON SANDERS LLP
megan.ogara@troutman.com
andrew.zappia@troutman.com
Megan Bowers
DLA Piper LLP
megan.bowers@us.dlapiper.com

For PATENT OWNER:

Jonathan Bachand
Shannon Lam
KNOBBE, MARTENS, OLSON & BEAR, LLP
2jeb@knobbe.com
2sxl@knobbe.com