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Paper 29
Date: June 10, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ETHICON, INC.,
Petitioner,

v.

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM,
Patent Owner.

IPR2019-00407
Patent 7,033,603 B2

Before SUSAN L. C. MITCHELL, AVELYN M. ROSS, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

MITCHELL, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background and Summary

Ethicon, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1, 2, 6, 11, 13, and 19 of U.S. Patent No. 7,033,603 B2 (Ex. 1001, "the '603 patent"). Pet. 1. The Board of Regents, The University of Texas System ("Patent Owner") did not file a preliminary response.

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition."

For the reasons set forth below, upon considering the Petition and evidence of record, we determine the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, we grant the Petition, and institute an *inter partes* review.

B. Real Parties in Interest

Petitioner identifies Ethicon, Inc.; Ethicon US, LLC; Ethicon Endo-Surgery, Inc.; Ethicon LLC; Ethicon Holding S.A.R.L.; Ethicon PR Holdings Unlimited Company; Janssen Pharmaceutical; JNJ Irish Investments ULC; JNJ International Investment LLC; OMJ Pharmaceuticals, Inc.; Medical Device Business Services, Inc.; Synthes, Inc.; DePuy Synthes, Inc.; Johnson & Johnson International; and Johnson & Johnson as real-parties-in-interest for this proceeding. Pet. 3. Patent Owner

identifies The Board of Regents, The University of Texas System, a real-party-in-interest as the sole owner of the '603 patent, and TissueGen, Inc., a real-party-in-interest as the exclusive licensee of the '603 patent. Paper 28, 1 (Patent Owner's Mandatory Notices).

C. Related Matters

Petitioner identifies pending parallel district court litigation styled *Board of Regents, The University of Texas System et al. v. Ethicon, Inc. et al.*, 1:17-cv-01084 (W.D. Tex.), in which Patent Owner and its licensee, TissueGen, Inc., asserted the '603 patent and its parent, U.S. Patent No. 6,596,296 ("the '296 patent") against Petitioner. Pet. 3, Paper 28, 1. Petitioner also identifies its co-pending petition, seeking to institute *inter partes* review of the '296 patent. Pet. 3; IPR2019-00406.

The '296 patent is asserted against other defendants in the following pending litigations:

> *Board of Regents, The University of Texas System et al. v. Boston Scientific Corporation*, 1:18-cv-00392 (D. Del.);
>
> *Board of Regents, The University of Texas System et al. v. Medtronic, Inc. et al.*, No. 1:17-cv-00942 (W.D. Tex.) (dismissed without prejudice on July 19, 2018); and
>
> *Board of Regents v. Boston Scientific Corp.*, No. 18-1700 (Fed. Cir.).

Pet. 3–4; Paper 28, 1. The '603 patent is also the subject of a separate IPR, *Medtronic, Inc. v. Board of Regents, the University of Texas System*, IPR2019-00038, Paper 2 (PTAB), that has been terminated due to settlement. Paper 24, 3.

D. The '603 Patent

The '603 patent, titled "Drug Releasing Biodegradable Fiber for Delivery of Therapeutics," issued on April 25, 2006.[1] Ex. 1001, codes (54), (45). The '603 patent is directed to fiber compositions of gels or hydrogels. *Id*. at Abst. More specifically, the '603 patent involves the composition of a gel or hydrogel loaded biodegradable fibers for delivery of a therapeutic agent. *Id*. at Abst., 1:15–17.

Generally, the drug delivery composition of the '603 patent comprises "at least one fiber, wherein said fiber comprises a first component and a second component, and wherein said first component is a biodegradable polymer and said second component is selected from the group consisting of a gel and a hydrogel." *Id*. at 3:8–13. The '603 patent further describes several variations of the disclosed fiber including where the second component is water, where the fiber comprises an emulsion of a gel or hydrogel, or where the fiber has a gel or hydrogel and a hollow bore. *Id*. at 3:13–26. The '603 patent also describes a scaffold composition comprising one or more fibers with a biodegradable polymer first component and a gel or hydrogel second component. *Id*. at 3:26–31.

[1] The '603 patent is a continuation-in-part of U.S. Application No. 09/632,475, which was filed on August 4, 2000, and is now the '296 patent. Ex. 1001, code (63). The '603 patent also claims priority to U.S. provisional application No. 60/147,827, filed on August 6, 1999. *Id*. at code (60). Although Petitioner asserts that the '603 patent is entitled to a priority date no earlier than May 2, 2003—the priority date of the application that issued as the '603 patent—Petitioner states that resolution of the priority date issue "does not bear on this Petition." Pet. 9, n.1. Because the priority date of the challenged claims currently is not at issue in this proceeding, we need not make any determination in this regard.

Some exemplary drawings depicting these various biodegradable fibers are Figures 3A–3D shown below.

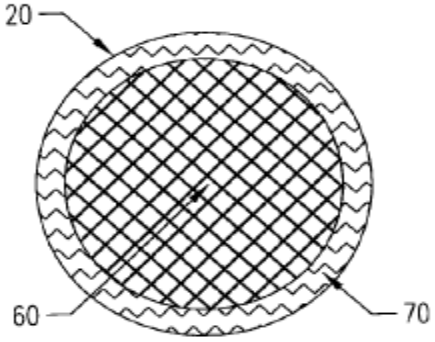

FIG. 3A

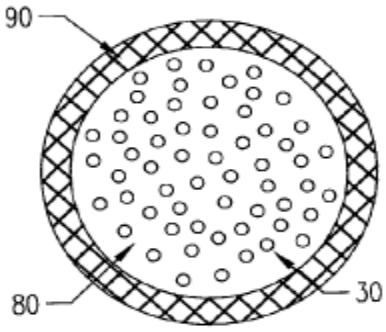

FIG. 3C

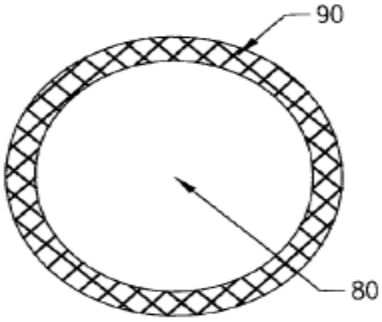

FIG. 3B

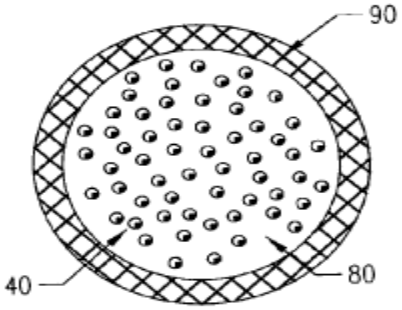

FIG. 3D

The ’603 patent describes Figures 3A through 3D depicted above as follows.

> FIG. 3A depicts a bicomponent fiber with a gel or hydrogel bore (60) and a wall comprising a hydrophobic polymer (20) that comprises a drug (70).
>
> FIG. 3B depicts a bicomponent fiber with a polymer bore (80) surrounded by a gel or hydrogel wall (90).
>
> FIG. 3C depicts a bicomponent fiber with a polymer bore (80) comprising a water emulsion (30) that is surrounded by a gel or hydrogel wall (90).
>
> FIG. 3D depicts a bicomponent fiber with a polymer bore (80) comprising a gel or hydrogel emulsion (40) that is surrounded by a gel or hydrogel wall (90).

Ex. 1001, 4:1–11.

The '603 patent describes the types of drugs to be used in the biodegradable fibers to include "synthetic and naturally occurring toxins and bioaffecting substances as well as recognized pharmaceuticals." *Id*. at 8:30–33. The '603 patent defines the term "drug" to be preferably "any substance intended for use in the treatment or prevention of disease." *Id*. at 8:28–30.

E. Illustrative Claims

Petitioner challenges claims 1, 2, 6, 11, 13, and 19. Pet. 1. Of these, claims 1 and 19 are independent. Challenged claims 2, 6, and 13 depend directly from claim 1, and challenged claim 11 depends from claim 6. *See* Ex. 1001, 35:46–48, 58–59, 36:1–10, 13–14.

Independent claims 1 and 19 are illustrative and are reproduced below.

> 1. A drug delivery composition comprising at least one fiber having a bore and a wall, wherein said fiber comprises a first component and a second component, and wherein said first component is a biodegradable polymer and said second component is selected from the group consisting of a gel and hydrogel.

Ex. 1001, 35:41–45.

> 19. A drug delivery composition comprising a fiber, wherein said fiber comprises an emulsion consisting essentially of a gel or hydrogel.

Id. at 36:30–33.

F. Evidence

Petitioner relies on the following evidence to establish the unpatentability of the challenged claims.

Reference or Declaration	Date	Exhibit No.
Michael J. Groves, U.S. Patent No. 5,186,936 (filed Aug. 6, 1990) ("Groves")	Feb. 16, 1993	1007
Kamalesh Sirkar et al., WO 95/23598 (filed Feb. 28, 1995) ("Sirkar")	Sept. 8, 1995	1008
Joseph P. Vacanti and Robert S. Langer, U.S. Patent No. 5,759,830 (filed Feb. 28, 1994) ("Vacanti")	June 2, 1998	1009
Declaration of David J. Mooney, Ph.D.	Dec. 7, 2018	1002

G. Prior Art and Asserted Grounds

Petitioner asserts that claims 1, 2, 6, 11, 13, and 19 of the '603 patent are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 2, 6, 11, 13, and 19	102/103 (pre-AIA)	Groves
19	102/103 (pre-AIA)	Sirkar
1, 2, 13	102/103 (pre-AIA)	Vacanti

II. ANALYSIS

A. Legal Standards

"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) (citing 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")). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics*,

Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in inter partes review).

To show anticipation under § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims in order to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). It is also permissible to take into account not only the literal teachings of the prior art reference, but also the inferences an ordinarily skilled person would draw from the reference. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017); *In re Preda*, 401 F.2d 825, 826 (CCPA 1968).

Turning to obviousness, a claim is unpatentable under 35 U.S.C. § 103(a) if 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 to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness when presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the

specific subject matter of a challenged claim is not necessary to establish obviousness. *Id*. Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id*. at 420. Accordingly, a party who petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted).

At this preliminary stage, we determine whether the information presented shows a reasonable likelihood that Petitioner would prevail in establishing that at least one of the challenged claims would have been anticipated by or obvious over the proposed prior art.

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

We review the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time of invention. *Graham*, 383 U.S. at 17. Petitioner contends that a person having ordinary skill in the art would have had

> a Ph.D. in chemistry, chemical engineering, materials science, or a related field and several years of experience working in the fields of the patent, drug delivery and tissue engineering.

Pet. 18 (citing Ex. 1002 ¶ 34).

Although the level of ordinary skill proffered by Petitioner appears rather high, at this stage of the proceeding, Patent Owner has not contested this articulation or offered its own statement of the level of ordinary skill in the art. Petitioner does not indicate that the outcome of any arguments made in this case would change depending on the level of ordinary skill in the art. For purposes of this Decision, and based on the record currently presented, we find we do not need an express articulation of the level of ordinary skill in the art and rely on the prior art of record that reflects the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Any final determination pertaining to the level of ordinary skill in the art shall be made on the full trial record.

C. Claim Construction

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)." 37 C.F.R. § 42.100 (2019). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art ("POSA"), at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.* Only those terms that are in controversy need be construed and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner provides constructions for the claim terms "gel," "hydrogel," and "said fiber comprises an emulsion consisting essentially of a gel or hydrogel," that are consistent with the construction of these terms as set forth by the District Court in the parallel litigation in the Western District of Texas against Ethicon. *See* Pet. 13–17; Ex. 1013, 5, 14–17. Petitioner contends, however, that none of these terms require express construction to resolve whether we should institute an *inter partes* review. Pet 15 (stating that construing "gel" and "hydrogel" is not necessary because each of the prior art references, Groves, Sirkar, and Vacanti, disclose a "hydrogel" or "gel"), 17 (stating under either the District Court's claim construction or Patent Owner's construction proffered in the parallel litigation, claim 19, requiring "an emulsion consisting essentially of a gel or hydrogel," is unpatentable over Groves or Sirkar).

Petitioner asserts that the District Court construed the claim terms as follows:

- **"hydrogel"**: "a colloid in which a dispersed phase (colloid) is combined with a continuous phase (water) to produce a viscous jellylike product"
- **"gel"**: "a colloidal system with at least two phases, one of which forms a continuous three-dimensional network that acts as an elastic solid"
- **"an emulsion consisting essentially of a gel or hydrogel"**: "an emulsion having only the following material elements: a gel or hydrogel"

Pet. 14 (quoting Ex. 1013, 5, 14–17).

Although Petitioner's arguments do not rest exclusively on the construction of these terms, we find it useful to examine the construction of these terms here.

"Gel" and "Hydrogel"

The District Court relied on an express definition set forth in the '603 patent that states that "gel" is defined as "a colloidal system with at least two phases, one of which forms a continuous three-dimensional network that acts as an elastic solid." Ex. 1001, 5:36–39. The District Court also relied on an express definition of "hydrogel" in the '603 patent that states that a "hydrogel" is "a colloid in which a dispersed phase (colloid) is combined with a continuous phase (water) to produce a viscous jellylike product." *Id.* at 5:39–42. We agree with Petitioner and the District Court that "gel" and "hydrogel" should be construed in accordance with the express definitions provided in the '603 patent, but also add to the definitions that precursors are also encompassed by the terms "gel" and "hydrogel" as expressly stated in the '603 patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1320–21 (Fed. Cir. 2015) (stating that the specification acts as a dictionary when a claim term is expressly or impliedly defined); Ex. 1002 ¶¶ 50–51.

For instance, we note that the '603 patent also expressly provides that the terms "gel" and "hydrogel" include "the formed gel or hydrogel as well as the appropriate precursor molecules involved in the formation of gels and hydrogels." Ex. 1001, 9:51–55. Also, dependent claim 12 requires that the claimed gel or hydrogel "is a precursor gel or precursor hydrogel," indicating that the requirement of a gel or hydrogel of claim 1, from which claim 12 depends, must include precursors. Pet. 8 (citing Ex. 1001, 36:11–12; *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1351 (Fed Cir. 2005) (applying the claim differentiation doctrine, i.e., the presumption

that each claim in a patent has different scope, to determine that an independent claim must have more than one cable when its dependent claim is limited to a single cable) (citing *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998)).

Based on these express teachings in the Specification of the '603 patent, we agree with District Court's claim construction of the claim terms "gel" and "hydrogel," but also clarify that the '603 patent also expressly defines "gel" and "hydrogel" more broadly to include precursors.

"An Emulsion Consisting Essentially of a Gel or Hydrogel"

The District Court interpreted the claim phrase "an emulsion consisting essentially of a gel or hydrogel" in terms of the transitional phrase "consisting essentially of" to limit the term to "an emulsion having only the following material elements: a gel or hydrogel." *See* Ex. 1013, 15–16 (citing *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998)). We agree with the District Court that this is a proper interpretation of the claim phrase in light of the limiting transitional phrase "consisting essentially of."

We also agree with the District Court that the terms "gel" and "hydrogel," as used in claim 19, are not limited to "a dispersed gel or hydrogel phase," as asserted by the Patent Owner. The District Court's claim interpretation, however, does not further define the meaning of the term "emulsion." We invite the parties to address further the construction of "an emulsion consisting essentially of a gel or hydrogel," and particularly, what is meant by "emulsion" in the claim phrase.

At this stage of the proceeding, we determine that it is not necessary to provide an express construction for any other term to resolve whether to

institute an *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'")).

We encourage the parties to address the construction of these terms in subsequent briefing so that we have the benefit of Patent Owner's views in making a final determination concerning claim construction.

D. Alleged Anticipation by or Obviousness over Groves (Ground 1: Claims 1, 2, 6, 11, 13, and 19)

Petitioner contends claims 1, 2, 6, 11, 13, and 19 are unpatentable as anticipated by or obvious over Groves. Pet. 1. Petitioner directs us to portions of Groves that purportedly disclose all the limitations in the challenged claims. *Id.* at 18–33. Petitioner also relies on the testimony of Dr. Mooney to support its arguments. *See id.*

1. Groves (Ex. 1007)

Groves describes packing material to treat infections of the teeth and gums. Ex. 1007, Abst. Specifically, Groves describes:

> A biocompatible, polymeric carrier material, typically calcium al[gi]nate, has dispersed therein an antibiotic ester which typically defines at least one ester group of 10 to 18 carbon atoms per molecule. The antibiotic ester is present in the polymeric carrier in an initial concentration sufficient to allow the continuous, controlled release of at least an inhibitory concentration of free antibiotic as a hydrolysis product from the antibiotic ester.

Id. Bacterial lipase that is present in a higher concentration of infectious bacteria causes the release of higher concentrations of free antibiotic that is hydrolyzed from the ester, creating a feedback loop. *Id*.

> Groves further describes that the polymeric carrier for the antibiotic
>
> may be of any desired shape, preferably being of string or fibrous form. The string or fiber used as the polymeric carrier material containing an antibiotic ester may be a solid string or fiber, or a hollow string or fiber having a lumen. If desired, the lumen may contain a relatively large supply of antibiotic ester in accordance with this invention or another medicament, or a mixture thereof. The inner core of the fiber, (the terms "string" and "fiber" being synonymous) may contain a polymeric carrier a hydrogel which defines ionic polymer units of one charge, positive or negative, and, of course, accompanying simple ions of the other charge such as calcium or chloride. The fiber also may define an outer coating which comprises a hydrogel which defines ionic polymer units of the opposite charge to that of the hydrogel of the inner core. The antibiotic ester is substantially carried in the inner core, and/or in a lumen defined in the inner core, while the outer coating acts as controlled release barrier to limit generation of free antibiotic. Thus, by control of the outer coating, the antibiotic release rates of the packing material of this invention may be controlled to conform to a large variety of desirable clinical programs.

Id. at 3:53–4:9.

2. Analysis

Claim 1

Petitioner asserts that Groves teaches "[a] drug delivery composition" set forth in the preamble of claim 1. We find, on the record before us and for institution, that the preamble calling for "[a] drug delivery composition" is limiting because it adds structure to the claimed composition, i.e., requiring a drug, that is not recited elsewhere in the claim. *See, e.g.*, *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Petitioner points to Groves teaching of a "controlled release vehicle for antibiotics" in the form of a "packing material . . . for the treatment of infections." Pet. 24 (citing Ex. 1007, 1:30–32, 45–46, 66–67,

6:26–56 (claims 1–6)); Ex. 1002 ¶ 71. Petitioner also points to Groves' statement that its "packing material" is a "biocompatible, polymeric carrier material carrying therein an antibiotic ester." *Id*. (citing Ex. 1007, 2:66–3:5, 6:26–27 (claim 1) (reciting a "packing material for the treatment of infections" containing a "metronidazole ester")).

We agree with Petitioner that it has shown sufficiently that Groves teaches "[a] drug delivery composition" as required by claim 1.

Petitioner relies on Groves statement that "the polymeric carrier may be of any desired shape, preferably being of string or fibrous form," to show that Groves teaches that its drug delivery composition comprises "at least one fiber." Pet. 24 (citing Ex. 1007, 3:53–54; 6:42–56). Groves also teaches that these fibers have the required "bore and a wall" and "a first component and a second component," Petitioner asserts, because Groves teaches that "[t]he string or fiber used as a polymeric carrier material" may have an "inner core" and an "outer coating." *Id*. at 25 (citing Ex. 1007, 54–4:1); Ex. 1002 ¶ 73. Petitioner also mentions that the '603 patent uses the same terminology as Groves, i.e., "inner core" to refer to its fiber's bore, and "Gel Coated Polymer Fiber" to refer to an example of a hydrogel wall. Pet. 25 (citing Ex. 1001, 10:40–41, 13:31–34, 26:25–29 (Example 2 title)); Ex. 1002 ¶ 74.

Thus, we agree with Petitioner that it has shown sufficiently that Groves teaches a drug delivery composition "comprising at least one fiber having a bore and a wall, wherein said fiber comprises a first component and a second component."

Petitioner points to Groves teaching that the "outer coating" of the fiber contains "pectin, chitosan [or] chitin," to establish that Groves teaches that "said first component is a biodegradable polymer." Pet. 26; Ex. 1002

¶¶ 76–77. The '603 patent identifies "chitin" as a biodegradable polymer. Pet. 26 (citing Ex. 1001, 9:56–61 (describing pectin, chitosan, and chitin as polysaccharides that are a class of naturally derived biodegradable polymers), 16:1–29; Ex. 1019, 1141); Ex. 1002 ¶ 77. Petitioner also asserts that Groves expressly states that the inner core of its fiber contains "a hydrogel," thus teaching "said second component is selected from the group consisting of a gel and a hydrogel." Pet. 27 (citing Ex. 1001, 6:44–56, 3:60–4:12); Ex. 1002 ¶ 78.

Finally, we agree with Petitioner on this record that it has shown sufficiently that Groves teaches "said first component is a biodegradable polymer and said second component is selected from the group consisting of a gel and a hydrogel," as further required in challenged claim 1 of the '603 patent. Because we find on this record that Petitioner has sufficiently shown that each limitation of claim 1 arranged as in the claims is taught by Groves as supported by Groves disclosure and Dr. Mooney's testimony, we determine that Petitioner has shown a reasonable likelihood of succeeding in showing that claim 1 of the '603 patent is anticipated by Groves.

With regard to claim 1, Petitioner further asserts that Patent Owner admitted during prosecution of a very similar claim in European prosecution that Groves discloses the limitations of claim 1. Pet. 19–22. To distinguish Groves, Petitioner asserts, Patent Owner added the limitation "the concentration of the gel or the hydrogel varies of as a function of distance along the long axis of the fiber," a limitation that is not in claim 1 here. Because we determine independently that Groves teaches all of the limitations of claim 1 for purposes of institution, we need not reach this additional reason for unpatentability of claim 1 over Groves. We invite the parties to address this issue in further briefing.

Claim 19

Petitioner explains how Groves teaches the limitations of independent claim 19, arranged as in the claim, under both the District Court's claim construction, and Patent Owner's claim construction that it offered in the District Court parallel litigation. *See* Pet. 32–33; Ex. 1002 ¶¶ 94–100. Under the District Court's claim construction, Petitioner shows where Groves teaches "a drug delivery composition comprising a fiber," in which the "'material' elements of the claimed fiber must be a gel or hydrogel." Pet. 32; Ex. 1002 ¶ 96–97. As we stated in our claim construction analysis, however, we question whether this interpretation of claim 19 sufficiently takes into account that "said fiber comprises *an emulsion* consisting essentially of a gel or a hydrogel." *See supra* Section II.C (emphasis added).

In accordance with Patent Owner's interpretation of claim 19—an emulsion consisting of essentially a dispersed gel or hydrogel phase—Figure 11, among other figures, and Example 16 of the '603 patent appears to support Patent Owner's definition. *See* Ex. 1001, 32:40–33:21. For instance, Figure 11 set forth below is described as depicting "the flow of a ther[a]peutic through the walls of an *emulsion-loaded* fiber." *Id*. at 5:1–2 (emphasis added).

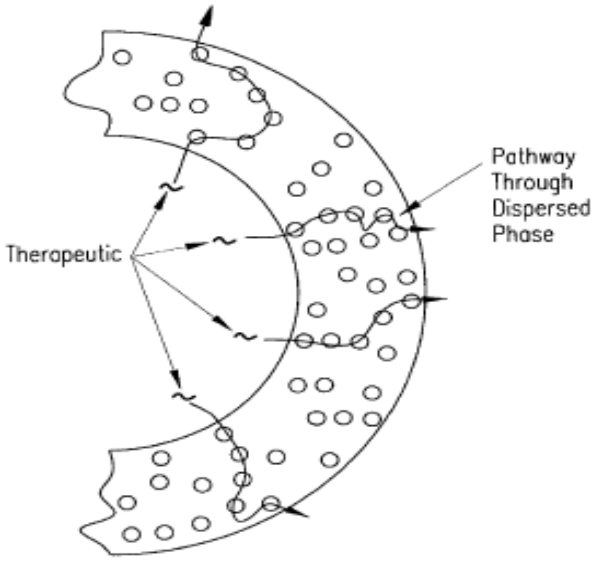

FIG. 11

Id. at Figure 11. As can be seen from the description provided on Figure 11, the flow of a therapeutic through the walls of an *emulsion-loaded* fiber is described as a "pathway through *dispersed phase*." *See id*. (emphasis added).

By the same token, Example 16 describes the "creation of a gel or hydrogel core in a biodegradable polymer sheath that contains a *dispersed aqueous phase*." *Id*. at 32:41–43 (emphasis added). Example 16 describes gel bored fibers that contain therapeutic agents in a dispersed aqueous, gel or hydrogel phase within a biodegradable polymer fiber wall. This "dispersed aqueous, gel or hydrogel phase" is further defined as "a water-in-oil type emulsion." *Id*. at 33:4–7. Specifically, Example 16 is explained as follows.

> Once the polymer is dissolved in solvent (A), an aqueous solution or a gel or a hydrogel (including precursors) containing both the biomolecules(s) of interest and a surfactant is added to the polymer solution. . . .
>
> Using some form of mechanical energy such a sonication, vortexing, or shear forces generated by forcing the liquid through a small orifice, a water-in-oil type emulsion is formed between the aqueous and organic-phases. Depending

> on the volume of aqueous solution relative to the polymer solution, emulsification can be accomplished in stages, using partial additions of the aqueous phase until the total volume is incorporated into the polymer solution. This emulsion must be stable for periods far in excess of time required for extrusion to insure homogeneity of the emulsion throughout the extrusion process. The size of the dispersed aqueous phase droplets is primarily dependent on the quality of the surfactant, and the total amount of mechanical energy imparted to the system in forming the emulsion. The aqueous phase size is an important variable in both release kinetics and mechanical properties of the fiber. This emulsion is then used as the polymer solution, and all other details are the same as explained in example 1.

Id. at 32:50–33:21.

We tend to agree with Patent Owner on this record concerning how claim 19 should be interpreted. We determine that the use of the term "emulsion" in claim 19 has meaning and would require something, such as a drug, to be dispersed in the gel or hydrogel to create an emulsion. Petitioner asserts that Groves teaches a "polymeric carrier material" containing "dispersed" antibiotic ester, and the preparation of fibers with "dispersed" drug. Pet. 32–33 (citing Ex. 1007, Abst., 5:16–19). Petitioner further provides:

> Groves explains that the antibiotic ester is "typically . . . distributed throughout the mass of the polymeric carrier" ([Ex. 1007,] 2:29–37), and describes using a hydrogel as the "polymeric carrier" for the drug. *Id*. at 3:60–65. Further, Groves encourages a POSA to tailor its drug-delivery fibers to meet clinical needs. Ex. 1007 at 2:63–68 (the fiber carrier "can be tailored to an optimum clinical program for the treatment of chronic infections"); *id*. at 3:53–55 ("The polymeric carrier may be of any desired shape. . ."); *id*. at 4:4–8 ("[B]y control of the outer coating, the antibiotic release rates of the packing material of this invention may be controlled to conform to a large variety of desirable clinical programs."). A POSA would have been motivated by Groves' disclosures to disperse the

> drug-loaded hydrogel taught by Groves as an additional means of controlling drug release, with a reasonable expectation of success. Ex. 1002 ¶ 99.

Pet. 33.

From this explanation, we agree with Petitioner that it has shown sufficiently on this record that Groves teaches all of the limitations of claim 19 arranged as in the claim, or at least teaches or suggests the subject matter of claim 19.

3. Conclusion

Because we have determined that Petitioner satisfies the threshold showing under 35 U.S.C. § 314(a) for institution of trial with respect to at least one challenged claim of the '603 patent, a trial will proceed on all challenged claims and grounds. *See PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (indicating that a decision whether to institute an *inter partes review* "require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"); Guidance on the Impact of SAS on AIA Trial Proceedings (April 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appealboard/trials/guidance-impact-sas-aia-trial. Therefore, we need not address these dependent grounds here. We do note that Petitioner has provided what appears to be on this record sufficient support for where in Groves each of the additional limitations of dependent claims 2, 6, 11, and 13 are taught. *See* Pet. 27–31; Ex. 1002 ¶¶ 81–93.

E. Alleged Anticipation by or Obviousness over Sirkar (Ground 2: Claim 19)

Petitioner contends claim 19 is unpatentable as anticipated by or obvious over Sirkar. Pet. 9. Petitioner directs us to portions of Sirkar that

purportedly disclose all the limitations in the challenged claims. *Id.* at 34–38. Petitioner also relies on the testimony of Dr. Mooney to support its arguments. *See id.*

1. Sirkar (Ex.1008)

Sirkar describes "[a] novel controlled release device employing microporous membranes with or without a nonporous coating and aqueous-organic partitioning of the bioreactive substances[, such as pharmaceuticals, pest-control substances, hormones, nutrients, and fragrances,] to be delivered" to humans, animals, or any environment. Ex. 1008, Abst. This novel controlled release device is further described by Sirkar as a porous hollow fiber as a polymeric membrane containing reservoir in the lumen of the fiber, with microporous membranes preferred. *Id*. at 4:3–17, 5:30–33; 6:9–11 (describing short length of a porous hollow fiber containing the selected agent in an organic solvent in the fiber lumen); 8:16–19. By using "biocompatible or biodegradable materials for membranes and biocompatible solvents, the invention may be used as an implant or ingestible substance for controlled release of drugs." *Id*. at 4:28–33, 5:34–37.

One particular embodiment is described as follows.

> In one embodiment, a short length of a porous hollow fiber containing the selected agent in an organic solvent in the fiber lumen is employed. The pores of the wall of the hollow fiber contain water or an appropriate aqueous solution. Further, the two ends of the fiber lumen can be sealed with appropriate sealant or heat-sealed. Such a chopped hollow fiber is then applied by means of a backing with appropriate adhesive to any surface intended for delivery of a pharmaceutical, pest-control substance, hormone, nutrient or fragrance, referred to herein as a "selected agent". The agent present in the organic solvent in the fiber lumen will partition into the water or aqueous solution

> in the fiber pores and then diffuse through the pores to the fiber exterior surface for release to the desired surface on which the controlled release device rests. In another embodiment, the fiber contains the selected agent in water. The pores of the wall of the fiber contain an organic solvent.

Id. at 6:9–26.

To further extend the delivery of a selected agent to ambient atmosphere where water in the pores of the hollow fiber wall may be more readily volatilized, Sirkar suggested that "water or organic solvent in the pore wall is gelled by the addition of appropriate gelling agents." *Id*. at 7:19–25. Sirkar also states that regenerated cellulose may be used to make the "[h]ydrogel hollow fibers" of the "present invention" described in Sirkar. *Id*. at 10:8–10. These microporous hollow fibers may also be hydrophobic or hydrophilic. *Id*. at 12–13.

2. Analysis

Petitioner asserts that Sirkar teaches "[a] drug delivery composition comprising at least one fiber" as required by claim 1 because Sirkar teaches "microporous hollow fibers" that are "controlled release devices" for the delivery of "pharmaceuticals." Pet. 35–36 (citing Ex. 1008, Abst., 2:1–18, 19–7 (claim 1)); Ex. 1002 ¶ 103.

Petitioner also points to claims 1 and 7 of Sirkar claiming that the "membrane is a hydrogel" as satisfying the balance of claim 19's requirements that "the "material elements" of the claimed fiber must be a gel or hydrogel." Pet. 36 (citing Ex. 1008, 19:1–7, 20–21); Ex. 1002 ¶ 111. As we have previously indicated, we are not satisfied with this interpretation of the requirements of claim 19 because it does not account for the claim term "emulsion."

Petitioner, however, points to teachings in Sirkar that evidence "a dispersed gel or hydrogel phase" is also taught. Pet. 36–37. Dr. Mooney testifies that:

> Sirkar describes filling the pores of its porous hollow fibers with either water or organic solvent. Ex. 1008 at 6:11–26. Sirkar further explains that '[i]f the selected agent is to be delivered to ambient atmosphere having considerable potential for volatilizing the water in the pores of the hollow fiber wall, **it is preferred that water or organic solvent in the pore wall is gelled** by the addition of appropriate gelling agents." *Id*. at 7:19–23 (emphasis added). Sirkar thus discloses a porous polymer fiber with a gel or hydrogel dispersed throughout the fiber. *Id*. Accordingly, in my opinion, Sirkar teaches a polymer fiber with a dispersed gel or hydrogel phase, and therefore discloses all limitations of claim 19 under Patent Owner's construction.

Ex. 1002 ¶ 112, *cited in* Pet. 37.

From this explanation, we agree with Petitioner that it has shown sufficiently on this record that Sirkar teaches all of the limitations of claim 19 arranged as in the claim. Therefore, we conclude that Petitioner has shown sufficiently a reasonable likelihood of succeeding in showing that claim 19 is anticipated by Sirkar. We need not reach Petitioner's obviousness analysis.

F. Alleged Anticipation by Vacanti (Ground 3: Claims 1, 2, and 13) or Obviousness over Vacanti (Ground 3: Claim 13)

Petitioner contends claims 1, 2, and 13 are unpatentable as anticipated by or obvious over Vacanti. Pet. 9. Petitioner directs us to portions of Vacanti that purportedly disclose all the limitations in the challenged claims, arranged as in the claims, and in the alternative, offers a reason why one of skill in the art would apply such teachings to arrive at the claimed inventions

with a reasonable expectation of success. *Id.* at 38–41. Petitioner also relies on the testimony of Dr. Mooney to support its arguments. *See id.*

1. Vacanti (Ex. 1009)

Vacanti describes a cell-scaffold composition that "is prepared in vitro for implanting to produce functional organ tissue in vivo. The scaffold is three-dimensional and is composed of fibers of a biocompatible, biodegradable, synthetic polymer." Ex. 1009, Abst., 5:19–29, 50–53 (describing polymer scaffolding that degrades over time). Vacanti indicates that a "fibrillary structure" is preferred, and the fibers "may be round, scalloped, flattened, star shaped, solitary or entwined with other fibers." *Id.* at 11:16–19.

The fibers of Vacanti's scaffold are further described as hollow or solid fibers "made from a polyanhydride, polyorthoester, polyglycolic acid or polymethacrylate," which degrade over time by hydrolysis at a controlled rate and reabsorbed, and "may have a coating which enhances cell attachment." *Id.* at Abst., 5:56–60. The coating may be a "gelatin or agarose to enhance cell attachment." *Id.* at 5:61–64. More specifically, "[i]n some embodiments, attachment of the cells to the polymer is enhanced by coating the polymers with compounds such as basement membrane components, agar, agarose, gelatin, gum arabic, collagens types I, II, III, IV, and V, fibronectin, laminin glycosaminoglycans, mixtures thereof, and other materials known to those skilled in the art of cell culture." *Id.* at 10:43–49, 19:40–52 (describing use of polymer coated with crosslinked 11% gelatin).

Vacanti further states that:

> Another advantage of the biodegradable material is that compounds may be incorporated into the matrix for slow release during degradation of the matrix. For example,

> nutrients, growth factors, inducers of differentiation or de-differentiation, products of secretion, immunomodulators, inhibitors of inflammation, regression factors, biologically active compounds which enhance or allow ingrowth of the lymphatic network or nerve fibers, and drugs can be incorporated into the matrix or provided in conjunction with the matrix, in solution or incorporated into a second biodegradable polymer matrix.

Id. at 6:10–20.

2. Analysis

Petitioner points to Vacanti's teaching of biodegradable polymer matrices or scaffold composed of fibers for growing cells in which biologically active compounds such as nutrients and drugs can be incorporated into Vacanti's matrix as teaching claim 1's "drug delivery composition comprising at least one fiber." Pet. 40–41 (citing Ex. 1009, Abst., 6:13–18, 10:30–33); Ex. 1002 ¶¶ 122–123. Petitioner asserts that Vacanti's teaching that its fibers may be coated with material to enhance cell attachment to the scaffold discloses claim 1's requirement that the fiber have a bore and a wall. Pet. 41–42 (citing Ex. 1009, 10:43–49, 18:35–39, 19:39–41); Ex. 1002 ¶¶ 124–125.

Finally, for the requirement of claim 1 that a first component be a "biodegradable polymer," Petitioner points to Vacanti's teaching that the biocompatible, biodegradable synthetic polymer fibers of Vacanti be made for example with polyglycolic acid or polyanhydride. Pet. 43 (citing Ex. 1009, Abst., 5:56–60). These polymers are disclosed in the '603 patent as preferred biodegradable polymers. Pet. 43 (citing Ex. 1001, 15:46–59, 16:5–29). For the requirement of claim 1 that a second component be "selected from the group consisting of a gel and a hydrogel," Petitioner points to Vacanti's teaching that the fibers may be coated gelatin. Pet. 42

(citing Ex. 1009, 18:53–54). Petitioner cites to a passage in the '603 patent that states that "gelatin" is a material that can form a hydrogel. Pet. 43 (citing Ex. 1001, 17:36–46); *see also* Ex. 1002 ¶ 128 (explaining cross-linked gelatin disclosed as a coating for fibers in Vacanti is a "gel"); Ex. 1021, 142.

From this explanation, we agree with Petitioner that it has shown sufficiently on this record that Vacanti teaches all of the limitations of claim 1 arranged as in the claim. Therefore, we conclude that Petitioner has sufficiently shown a reasonable likelihood of succeeding in showing that claim 1 is anticipated by Vacanti. We do not address further dependent claims 2 or 13 challenged in Ground 3 here. We do note that Petitioner has provided what appears to be on this record sufficient support for where in Vacanti each of the additional limitations of dependent claims 2 and 13 are taught. *See* Pet. 44–47; Ex. 1002 ¶¶ 130–136.

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the petition establishes that petitioner has shown a reasonable likelihood of succeeding in showing that at least one claim of the '603 patent is unpatentable. Accordingly, we institute *inter partes* review of all challenged claims and all grounds presented in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. §314(a), an *inter partes* review of claims 1, 2, 6, 11, 13, and 19 of U.S. Patent No. 7,033,603 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. §314(c) and 37 C.F.R. § 42.4, notice is hereby give of the institution of a trial, which will commence on the entry date of this Decision.

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