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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KEITH A KNISLEY, VISHNU T. MARLA, RACHEL RADSPINNER, PAUL A. SILVAGNI, JASON J, STRID, and MICHAEL J. VONESH

Appeal 2019-003612
Application 14/714,685
Technology Center 3700

Before: FRANCISCO C. PRATS, JOHN E. SCHNEIDER, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges.*

SCHNEIDER, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant appeals from the Examiner's decision to reject claims 1–5 and 18–23.[1] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies W.L. Gore & Associates, Inc. as the real party in interest. Appeal Br. 1.

CLAIMED SUBJECT MATTER

The claims are directed to improved biocompatible surfaces and devices incorporating the same. Claim 1 reproduced below, is illustrative of the claimed subject matter:

1. A blood contact surface comprising a synthetic biomaterial having a microstructure of interconnected fibrils morphologically analogous to microstructure of a natural human fibrin mat.

The prior art relied upon by the Examiner is:

Name	Reference	Date
Xu et al. (hereinafter "Xu")	US 2011/0039960 A1	February 17, 2011

The Examiner has rejected claims 1–5 and 18–23 under 35 U.S.C. § 102 as anticipated by Xu. [2, 3]

[2] Claims 6–17 are pending in the application but have been withdrawn from consideration. Final Act. 1.

[3] Claims 1–5 and 18–23 were also rejected under 35 U.S.C. §112, second paragraph as indefinite. Final Act. 2. That rejection has been withdrawn. Ans. 2.

OPINION

Issue

The issue to be decided in this appeal is whether a preponderance of the evidence supports the Examiner's conclusion that claims 1–5 and 18–23 are anticipated by Xu.

The Examiner finds that Xu discloses a synthetic biomaterial having microstructure comprising expanded polytetrafluoroethylene ("ePTFE") that is morphologically analogous to the microstructure of a natural mammalian fibrin mat. Final Act. 3.

Appellant contends that the microstructure shown in Figure 1 of Xu (reproduced below), as compared with the microstructure of a natural fibrin mat as shown in figure 21A (reproduced below) is "markedly different" and that Xu "does not teach or suggest" the material of the present Application shown in Figure 21 B (reproduced below). Appeal Br. 7.

Figure 1

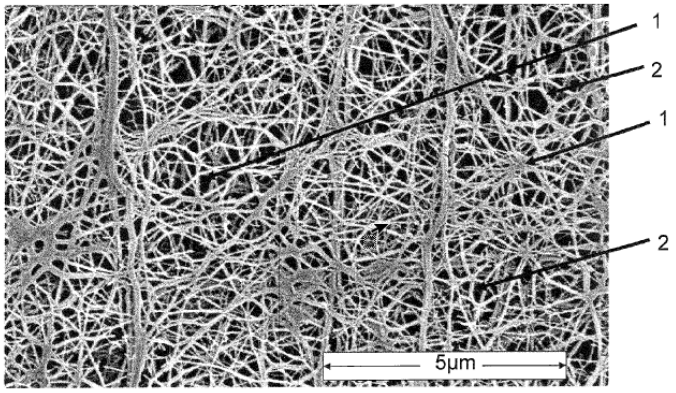

Figure 1 of Xu showing a Scanning Electron Micrograph ("SEM") of an expanded sheet of functional TPE copolymer taken at 10,000x magnification.

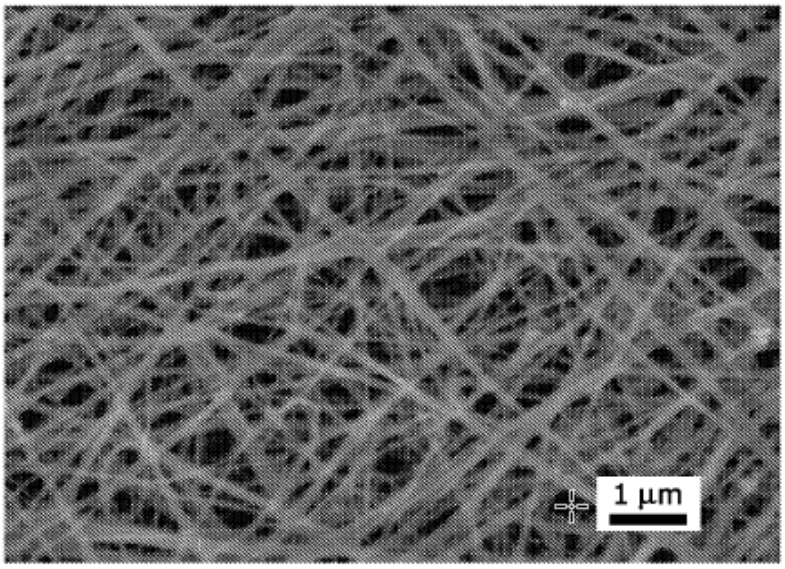

FIG. 21A

Figure 21A of the present Application showing a SEM of a natural fibrin mat.

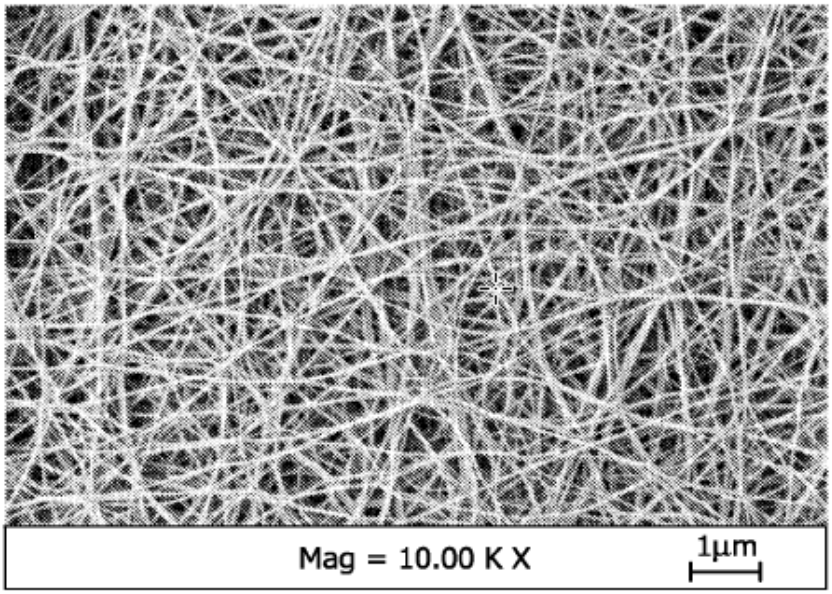

FIG. 21B

Figure 21B of the present Application is a SEM of a biocompatible surface of the present invention taken at 10,000x.

Appellant contends that the fibril structure of Xu I is "much thicker and more convoluted" and has "distinctly larger nodes" than the claimed invention of the natural fibrin mat. Appeal Br. 7. Appellant also argues that Xu does not teach or suggest "creating a blood contact surface with a structure that mimics or is morphologically similar to natural fibrin." *Id.*

With respect to claims 4 and 23, Appellant contends that these claims are limited to ePTFE. *Id*. Appellant contends that Xu discloses the use of tetrafluoroethylene copolymers and not "a blood contact surface of expanded PTFE with a morphology of natural human fibrin mat." *Id* at 7–8.

With respect to claims 2, 3, 5, and 17–22, Appellant argues that Xu does not disclose the limitations recited in these dependent claims. *Id.* at 8–9.

Principles of Law

> [T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the [S]pecification." *In re Hyatt,* 211 F.3d 1367, 1372 (Fed. Cir. 2000).

"The ordinary and customary meaning of a claim term may be determined by reviewing a variety of sources. Some of these sources include the claims themselves; dictionaries and treatises; and the written description, the drawings, and the prosecution history." *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d. 1294, 1298 (Fed. Cir. 2003) (citations omitted).

"Anticipation requires that all of the claim elements and their limitations are shown in a single prior art reference." *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009).

"[N]ot unlike a determination of infringement, a determination of anticipation, as well as obviousness, involves two steps. First is construing the claim,[] followed by, in the case of anticipation or obviousness, a comparison of the construed claim to the prior art." *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998).

Analysis

Appellant has presented separate arguments for three groups of claims, claim 1, claims 4 and 23, and claims 2, 3, 5, and 17–22. We will address the patentability of each group in turn.

Claim 1

The issue with respect to claim 1 is whether the expanded sheet of TFE copolymer disclosed in Xu meets the claim limitation "morphologically analogous to a mat comprising natural human fibrin." *See* Appeal Br. 5–7; Ans. 2–4.

To resolve this issue we must first construe the term "morphologically analogous." The Specification does not use or define the term. *See, e.g.,* Spec. ¶¶ 105–106 (comparison of the surface of the present invention with a natural fibrin surface). As used in claim 1, the term "morphologically analogous" does not require exact similarity but only requires some degree of similarity with a natural human fibrin mat. *See* Appeal Br. 10 (Claims App.).

We next look at the ordinary meaning of the term. Webster's defines the word analogous as "similar or comparable to something else either in general or in some specific detail." Merriam-Webster.com (accessed Sept. 18, 2020), https://www.merriam-webster.com/dictionary/analogous. Using this definition, we construe the term "morphologically analogous" to mean "having a generally similar morphology."

This construction is consistent with the discussion in the Specification where the material of the present invention is compared with a mat of natural fibrin. The Specification teaches "[i]t is interesting to note that there is some similarity in morphology between the inventive surface of the present

invention and natural fibrin surfaces occurring in a mammalian body that may foster attachment of endothelial cells." Spec. ¶ 105. The Specification goes on to state "the artificial microstructure of the present invention presents a morphology remarkably similar to that of natural fibrin, including having short fibrils (with a less than 5 micron internodal distance), fibrils intersecting at small nodal points, and the microstructure being approximately balanced in the x and y directions." *Id.* ¶ 106.

Applying this construction we agree with the Examiner that the fibrin mat disclosed in Figure 1 of Xu is morphologically analogous with the mammalian fibrin mat shown in Figure 21A of the Specification. Ans. 3. A comparison of Figure 1 of Xu with Figure 21A of the Specification shows "some similarity in morphology" with both structure having short fibrins intersecting at small nodal points. *Compare* Xu, Fig. 1 with Spec. Fig. 21A (Both reproduced above.)

Appellant contends that the structure of Xu is markedly different than the structure of the present invention. Appeal Br. 6–7. Appellant contends that the microstructure of Xu has a thicker and more convoluted microstructure and distinctly larger nodes. *Id.* We are not persuaded by Appellant's argument.

Appellant has not offered any evidence to support its contentions regarding the morphology of the structure shown in Xu but only presents attorney argument. "Attorneys' argument is no substitute for evidence." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

A visual comparison of Figure 1 of Xu with Figure 21A of the Specification reveals structures that are similar in morphology with fibrins of about the same length intersection nodes of about the same size.

Appellant also contends that Xu does not disclose creating a blood contact surface. Appeal Br. 7. We remain unpersuaded. The recitation of blood contact surface in the preamble of claim 1 merely describes an intended use of the material and does not otherwise limit the claim as the remainder of the claim is structurally complete. "Where . . . a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Based on the foregoing we conclude that a preponderance of the evidence supports the Examiner's conclusion that claim 1 is anticipated by Xu.

Claims 4 and 23

Claim 4 depends from claim 1 and adds the limitation that the surface of claim 1 comprises expanded polytetrafluoroethylene. Appeal Br. 10 (Claims App.). Claim 23 depends from claim 4 and thus includes the limitations of claim 4. 35 U.S.C. § 112, fourth para.

The Examiner contends that Xu discloses this limitation. Ans. 4. The Examiner contends that Xu uses ePTFE as a starting material and that polymerization reactions may not result in TFE copolymers. *Id.*

Appellant contends that Xu is specifically directed to functionalized TFE copolymers that comprise TFE and at least one copolymer having a functional group. Appeal Br. 8. Appellant contends that this is not the same as ePTFE. *Id.*

We have considered the arguments advanced by the Examiner and Appellant and find that Appellant has the better positon. Xu consistently

refers to the material used as "a functional TFE copolymer." *See, e.g.,* Xu, Abstr., ¶¶ 25, 45, 47, and 72. Xu defines a TFE copolymer as

> a TFE polymer comprising one or more comonomer at any concentration. As used herein the term functional TFE copolymer is defined as a TFE copolymer having functional groups that are pendant to the polymer chain wherein the functional TFE copolymer is formed by copolymerizing TFE with comonomers having a functional group.

Xu. ¶ 26.

The Specification teaches that while ePTFE and TFE copolymers are both fluoropolymers, they are separate species. *See* Spec. ¶ 80 (Listing ePTFE and TFE copolymer as separate examples of fluoropolymers.). We discern no teaching in Xu that teaches the use of ePTFE.

The Examiner contends that Xu teaches starting with ePTFE and then polymerizing the material to form the copolymer. Ans. 4 (citing Xu ¶ 31). The Examiner contends that "the polymerization reactions may or may not be performed on the ePTFE." *Id.*

We are not persuaded by this argument. Paragraph 31 of Xu teaches "At least one functional comonomer may be polymerized with TFE to provide a copolymer having a multiplicity of pendant functional groups." Xu ¶ 31. TFE in not the same as ePTFE which is a monomer used to make the polymers. *See id.* ¶ 25 ("The functional TFE copolymer comprises a polymer of TFE and at least one comonomer that contains a functional group.").

The Examiner also cites to paragraph 71 which refers to "Break Strength Test of Microporous ePTFE." Ans. 4. When read in context, this heading in Xu does not support the Examiner's finding that Xu discloses the use of ePTFE. In the very next paragraph Xu discloses that the material

tested is expanded TFE copolymer. Xu. ¶ 72. We find this disclosure fails to show "all of the claim elements and their limitations [] in a single prior art reference." *In re Skvorecz*, 580 F.3d at 1266. Based on the foregoing, we conclude that a preponderance of the evidence does not support the Examiner's conclusion that claims 4 and 23 are anticipated by Xu.

Claims 2, 3, 5, and 17–22

Claims 2, 3, 5, and 17–22 depend from claim 1 and add limitations calling for the use of fluoropolymers, specify various lengths of the fibrils, and recite the incorporation of the material into certain medical devices. *See* Appeal Br. 10–11 (Claims App.).

While the Examiner states that these claims are anticipated by Xu, the Examiner makes no specific findings with respect to the limitations recited in these claims. *See* Final Act. 3; *see also* Ans. 2–4. While Xu may disclose the elements recited in the dependent claims, the Examiner has not met the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. *See, e.g.,* Xu ¶ 70, Fig. 1. For this reason we reverse the rejection of claims 2, 3, 5, and 17–22.

CONCLUSION

The Examiner's rejection is affirmed in part.

More specifically,

A preponderance of the evidence supports the Examiner's conclusion that claim 1 is anticipated by Xu.

A preponderance of the evidence does not support the Examiner's conclusion that claims 4 and 23 are anticipated by Xu.

The Examiner has not established a prima facie case that claims 2, 3, 5, and 17–22 are anticipated by Xu.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–5, 17–23	102	Xu	1	2–5, 17–23

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART