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EXAMINER	
DIOP, ROKHAYA	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ZEKE ELLER, JOHN WILLIAM HALL,
ROBERT S. KELLAR, RACHEL LYNN SIMMONS,
ROBERT J. RADFORD, and BART DOLMATCH

Appeal 2017-010572[1]
Application 14/044,050
Technology Center 3700

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Appellants identify Merit Medical Systems, Inc. as the real party-in-interest. App. Br. 3.

SUMMARY

Appellants file this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–10, 12–17, 19, 21, and 22. Specifically claims 1–10, 13–17, 19, 21, and 22 stand rejected as unpatentable under 35 U.S.C. § 103(a) (pre-AIA) as being obvious over Anneaux et al. (US 2011/0030885 A1, February 10, 2011) ("Anneaux").

Claim 12 stands rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Anneaux and Lee et al. (US 2007/0276477 A1, November 29, 2007) ("Lee").

Claims 1–10, 13, 14, 17, 19, 21, and 22 stand rejected as unpatentable under the nonstatutory doctrine of obviousness-type double patenting.[2]

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellants' invention is directed to a prosthesis coated with layers of electrospun polytetrafluoroethylene (PTFE), by which the electrospun PTFE of certain porosities may permit endothelial cell growth within the prosthesis. Abstr.

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[2] Appellants do not argue or otherwise mention the obviousness-type double patenting rejections in their Appeal Brief. We consequently summarily affirm the Examiner's rejections on this ground. *See* 37 C.F.R. § 41.37(c)(iv) ("[A]ny arguments or authorities not included in the appeal brief will be refused consideration by the Board for purposes of the present appeal.").

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

1. A vascular prosthesis, comprising:

a tubular body comprising

a first layer of electrospun polytetrafluoroethylene (PTFE);

an impermeable layer, configured to be impermeable to tissue ingrowth through the impermeable layer, the impermeable layer comprising a polymer material and wherein a portion of the polymer material of the impermeable layer is disposed between openings in the first layer of electrospun PTFE; and

a second layer of electrospun PTFE,

wherein at least one of the first and second layers of electrospun PTFE has an average pore size of between about 2 microns and about 8 microns.

App. Br. 17.

ISSUES AND ANALYSIS

We are persuaded by, and expressly adopt, the Examiner's findings, reasoning, and conclusion that Appellants' claims are *prima facie* obvious over the prior art. We address the arguments raised by Appellants below.

Issue 1

Appellants argue the Examiner erred because a person of ordinary skill in the art would not have a reasonable expectation of success of the proposed modification. App. Br. 9.

Analysis

Independent claims 1 and 17 require first and second layers of electrospun PTFE and an impermeable layer having a portion disposed between openings in the first layer.

The Examiner finds that, in one embodiment, Anneaux discloses a vascular prosthesis comprising a tubular body, first and second outer layers of expanded PTFE having a pore size between 0.05 microns and 50 microns, and an inner impermeable layer of electrospun PTFE in direct contact with the first and second outer layers. Final Act. 7–8 (citing Anneaux ¶¶ 14, 20, 25, 28, 32, Fig. 4).

The Examiner finds that Anneaux does not expressly teach an embodiment with electrospun PTFE in the first and second outer layers. Final Act. 8. The Examiner finds that Anneaux also does not expressly teach that a portion of the impermeable layer is disposed between openings in the first outer layer. *Id.*

The Examiner finds that Anneaux teaches, in a different embodiment, using electrospun PTFE in an outer layer to improve tissue infiltration with the advantage of replicating the structure of the extracellular matrix. Final Act. 8 (citing Anneaux ¶¶ 17, 61–64). The Examiner finds that Anneaux teaches optimizing the porosity of different layers of the vascular device by using electrospun PTFE. *Id.* (citing Anneaux ¶¶ 14, 15, 25Fig. 4). The Examiner also finds that Anneaux teaches bonding different layers by pressing and heating. *Id.* (citing Anneaux ¶¶ 26, 47–55).

The Examiner concludes that it would have been obvious to a person of ordinary skill in the art to use electrospun PTFE in the first and second outer layers of the prosthesis using the bonding technique, which would

result in a portion of the electrospun PTFE of the impermeable layer being disposed between openings in the first layer of electrospun PTFE. Final Act. 9. The Examiner further concludes that a person of ordinary skill in the art would have had a reasonable expectation of success using electrospun PTFE in the innermost and outermost layers, because Anneaux teaches a number of advantages of electrospun PTFE, including replicating the extracellular matrix, providing greater control of cellular response, and improving tissue infiltration. *Id.* at 8, 13.

Appellants argue the Examiner erred because a person of ordinary skill in the art at the time of the invention would not have a reasonable expectation of success of replacing expanded PTFE with electrospun PTFE. App. Br. 9. Appellants argue that electrospun PTFE and expanded PTFE have very different microstructures, preventing "one of skill in the art from equating properties of electrospun PTFE with [expanded PTFE] in any attempt to substitute electrospun PTFE for [expanded PTFE]." *Id.* at 11. Appellants argue the different microstructures would have a direct impact on biological response precluding a reasonable expectation of successfully interchanging electrospun PTFE with expanded PTFE. *Id.* (citing Declaration of Mr. John Hall ¶¶ 11–12 (the "Hall Declaration")).[3]

The Examiner responds that Anneaux offers a number of advantages of incorporating "an espin layer that closely mimics . . . the extracellular matrix affording greater control of cellular response." Ans. 7 (citing

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[3] Mr. John Hall, one of the named inventors of the instant application, received his BSME degree from the University of Utah and is presently R&D Manager at Merit Medical Systems. We have reviewed Mr. Hall's credentials and consider him qualified to render an expert opinion.

Anneaux ¶ 17). The Examiner finds that: "[a] skilled artisan could have substituted the [expanded PTFE] layers of Anneaux with layers of electrospun PTFE by known methods with no change in their respective functions, and the modification would have predictably yielded a functional vascular graft in view of the teachings in Anneaux." Ans. 8.

We are not persuaded by Appellants' arguments. "Obviousness does not require absolute predictability of success. . . . For obviousness under [section] 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988). The Examiner's proposed modifications to Anneaux (substituting expanded PTFE with electrospun PTFE) do not appear to be uniquely challenging, and Appellants have not presented persuasive evidence that a person of ordinary skill in the art would not have had a reasonable expectation of success in making the proposed modifications to Anneaux.

Anneaux acknowledges the different microstructures of electrospun PTFE ("fibers in a random orientation") and expanded PTFE ("a microstructure consisting of solid nodes interconnected by fine, highly oriented fibrils") are "designed to enhance, inhibit or retard the migration of endothelium during the early phase of healing." Anneaux ¶¶ 16 and 32. Anneaux further teaches the same functional layers as the claimed invention:

> The espin material selection can be adjusted to improve bonding properties between layers and the espin layer can be used to inhibit cellular proliferation through the middle on the construction. In this instance, it may be advantageous to allow cells to migrate and proliferate from both sides (luminal and abluminal in the case of a graft) but communication between the two may not be desired. The middle espin layer can be designed with a porosity that will inhibit this cellular communication.

Id. ¶ 24. In addition to the three-layer structure with an electrospun impermeable layer, Anneaux teaches a stent with an electrospun layer that provides "a substantially different pore size and structure on the luminal or abluminal surface depending on the application." *Id.* ¶¶ 21, 61. Anneaux provides a number of reasons to use electrospun PTFE in the inner and outer layers including:

> 1) [T]he ability to incorporate layers with vastly different pore structures and sizes, these different structural layers can be used to manipulate mechanical properties, cellular proliferation, cellular permeability, fluid permeability, adhesion to a structural frame, and/or incorporation of an active therapeutic component; 2) the ability to make a composite construction with vastly different components enabling a broader range of therapeutic uses and structures; 3) improved bonding of PTFE layers to structural frames and to other layers of the construct; 4) the ability to incorporate an espin layer that closely mimics that of the extracellular matrix affording greater control of cellular response; and 5) enabling the coating of complex geometries that otherwise could not be covered with expanded PTFE or other materials alone.

Id. ¶ 17.

As discussed above, Anneaux teaches that expanded PTFE and electrospun PTFE are both suitable materials for stent layers. Anneaux also teaches both reasons to modify the layers and the expected benefits of the modification. Given these teachings, we agree with the Examiner that a person of ordinary skill in the art would have had a reasonable expectation of success in making a stent having inner and outer layers of electrospun PTFE. It is within the general skill of a worker in the art to select a known material based on its suitability for the intended use as a matter of obvious

design choice. *See In re Leshin*, 277 F.2d 197, 199 (CCPA 1960) (Selection of a known plastic to make a container of a type made of plastics was held to be obvious.).

Issue 2

Appellants argue that the Examiner erred because the proposed modification renders the prior art unsatisfactory for its intended purpose. App. Br. 14.

Analysis

Appellants argue that the proposed modification would result in a covering composed solely of electrospun PTFE that would be inoperable for its intended purpose. App. Br. 14. Appellants assert that because electrospun PTFE has much lower tensile strength and creep resistance as compared to expanded PTFE, the proposed covering would lack sufficient structural strength for implantation into a body lumen. *Id.* 15 (citing Hall Declaration ¶ 10).

We do not find Appellants' arguments to be persuasive. The Examiner asserts "the proposed modification yields a vascular graft made from the same materials and having the same structure as Appellant[s'] device; therefore it would function in the same manner." Ans. 10. We agree with the Examiner's broadest reasonable interpretation of Appellants' claimed invention that encompasses a device composed solely of electrospun PTFE. For example, claim 2, depending from claim 1, specifically recites a device wherein all three layers comprise electrospun PTFE. The device of

claim 2 encompasses the same all electrospun PTFE device that Appellants argue "lacks sufficient structural integrity." App. Br. 14; Reply Br. 5.

Moreover, Anneaux teaches manipulating the mechanical properties of an electrospun PTFE device, including tensile strength and creep resistance. Specifically, Anneaux teaches "different structural layers can be used to manipulate mechanical properties" and "[t]he devices of the present disclosure can be prepared with controlled fiber, node and fibril sizes and manipulated mechanical values such as bond strength, *elongation properties* and *tensile strengths*." Anneaux ¶ 31 (emphasis added). As such, we are not persuaded that an all electrospun PTFE device, with its mechanical properties manipulated, as taught by Anneaux, would lack sufficient structural integrity.

Issue 3

Appellants argue that unexpected results rebut any *prima facie* case of obviousness. App. Br. 11.

Analysis

Appellants submit experimental data as evidence of an "unexpected biologic response." App. Br. 11–12 (citing Hall Declaration ¶¶ 13–24). In particular, "the electrospun PTFE (MME 1) . . . had a lower inflammatory score when accounting for both the inside diameter ("ID") and outer diameter ("OD"), than any of the commercially available (expanded PTFE) grafts." *Id.* at 12 (emphasis in original). Appellants argue that these results are unexpected as expanded PTFE has "been the gold standard for biological contact layers of vascular prosthesis, and that suitable substitutes are generally unavailable." *Id.* at 13.

Even if the experimental data indicates a lower inflammatory response, we do not find Appellants' arguments persuasive.

As an initial matter, we are not persuaded that the commercially available expanded PTFE grafts are the closest prior art to the Appellants' claimed invention. The commercially available expanded PTFE grafts do not include electrospun PTFE. Instead, the closest prior art is Anneaux, which teaches a stent including at least one electrospun PTFE layer inner and/or outer layer. At best, the experimental results indicate electrospun PTFE, as taught in the prior art, would induce a lower inflammatory response than expanded PTFE devices. "Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

Furthermore, "evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention." *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014). In addition, "[u]nexpected results that are probative of nonobviousness are those that are different in kind and not merely in degree from the results of the prior art." *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013). We address each of these principles in turn.

First, there is no indication that the superior properties of electrospun PTFE used in an outer or inner layer are unexpected. "[I]n order to properly evaluate whether a superior property was unexpected, the court should have

considered what properties were expected." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007).

Appellants argue that "[n]ot only would one of ordinary skill in the art not expect electrospun PTFE to perform as well as [expanded PTFE] . . . but it would have been even more unexpected for the electrospun PTFE materials to outperform commercially optimized [expanded PTFE] prosthesis." App. Br. 13. Appellants explain what would not have been expected, but do not explain what properties were expected.

Second, the experimental results show a decrease of average inflammatory score in terms of percentages. "Results which differ by percentages are differences in degree rather than kind, where the modification of the percentage is within the capabilities of one skilled in the art at the time." *Galderma Labs.* 737 F.3d at 739. Anneaux teaches that incorporating an electrospun PTFE layer affords greater control of cellular response. The evidence indicates that skilled artisans were capable of adjusting the cellular response of the electrospun layer and the results constitute a difference in degree, not kind. On balance then, we do not find that Appellants' argument claiming unexpected results outweighs the other evidence of record that the claims are *prima facie* obvious over the combined cited prior art. *See also Pfizer,* 480 F.3d at 1372 (Unexpected results are not sufficient to outweigh a stronger showing of obviousness.).

Appellants do not argue the dependent claims separately, relying on their arguments for claims 1 and 17. We consequently affirm the Examiner's rejection of claims 1–10, 12–17, 19, 21, and 22.

DECISION

The Examiner's rejection of claims 1–10, 13–17, 19, 21, and 22 under 35 U.S.C. § 103(a) is affirmed.

The Examiner's rejection of claims 1–10, 13, 14, 17, 19, 21, and 22 under the nonstatutory doctrine of obviousness-type double patenting is affirmed.

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

AFFIRMED