IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACERA SURGICAL, INC., RETECTIX, LLC, and WASHINGTON UNIVERSITY, Plaintiffs, v. NANOFIBER SOLUTIONS, LLC, PARAGEN TECHNOLOGIES LLC, ATREON ORTHOPEDICS LLC, and RENOVODERM LLC, Defendants, and NANOFIBER SOLUTIONS, LLC, and THE RESEARCH FOUNDATION FOR THE STATE UNIVERSITY OF NEW YORK, Counterclaim Plaintiffs, v. ACERA SURGICAL, INC., Counterclaim Defendant.	C.A. No. 20-980-CFC-JLH

REPORT AND RECOMMENDATION

Pending before the Court are the parties' claim construction disputes. There are seven patents at issue in this case. Plaintiffs Acera Surgical, Inc., Retectix, LLC, and Washington University (collectively, "Plaintiffs") are asserting four patents against Defendants Nanofiber Solutions, LLC ("Nanofiber"), Paragen Technologies LLC, Atreon Orthopedics LLC, and Renovoderm LLC. Defendant Nanofiber, as well as The Research Foundation for the State

University of New York (collectively, with the other defendants, "Defendants"[1]), are asserting three patents against Plaintiff Acera Surgical, Inc. All seven patents generally relate to biomedical patches and grafts made from electrospun nanofibers.

The parties' joint claim construction brief indicated that the parties had agreed upon two constructions and had disputes over seven terms spanning five of the patents-in-suit. (D.I. 120.) I held a Markman hearing on August 12, 2022. ("Tr. __.") Following a lengthy interchange, I instructed the parties to further meet and confer regarding three of the disputed terms. The parties subsequently submitted a joint letter in which they agreed on one term and modified their proposals regarding the other two. (D.I. 136.) Six terms remain in dispute.

I recommend that the parties' agreed-upon constructions be adopted as follows:

Term	**Recommended Construction**
multi-laminar '512 patent, claims 1-3, 5-10, 12-14	"multiple layers"
projection/projections '228 patent, claims 7, 8, 14, 19	"a protrusion or bulge"
indentation/indentations '228 patent, claims 7, 8, 10, 14, 16, 19	"a recess or depression"

[1] The parties' briefing refers to any party who isn't a Plaintiff as a "Defendant." (D.I. 120.) This Report and Recommendation will do the same.

Further, for the reasons discussed in more detail below, I recommend that the disputed terms be construed as follows:

Term	Recommended Construction
first layer/second layer '512 patent, claims 1, 8, 15	"first distinct and separately deposited thickness of material" "second distinct and separately deposited thickness of material"
first layer/second layer/third layer '687 patent, claims 1, 5, 7	"first distinct and separately deposited thickness of material" "second distinct and separately deposited thickness of material" "third distinct and separately deposited thickness of material"
first plurality/second plurality '444 patent, claims 1-8, 10, 16, 17	"first distinct and separately deposited grouping" "second distinct and separately deposited grouping"
prepared from at least one solution of at least one polymer utilizing a process selected from the group consisting of electro-spinning, electro-blowing, blowing-assisted electro-spinning, and solution blowing '166 patent, claim 26	Process limitation of a product-by-process claim
prepared from about 1 to about 5 solutions of from about 1 to about 5 polymers '166 patent, claim 27	Process limitation of a product-by-process claim

formed by electrospinning fibers '765 patent, claims 1, 49	Process limitation of a product-by-process claim

I. LEGAL STANDARDS

The purpose of the claim construction process is to "determin[e] the meaning and scope of the patent claims asserted to be infringed." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). When the parties have an actual dispute regarding the proper scope of claim terms, their dispute must be resolved by the judge, not the jury. *Id.* at 979. The Court only needs to construe a claim term if there is a dispute over its meaning, and it only needs to be construed to the extent necessary to resolve the dispute. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

"[T]here is no magic formula or catechism for conducting claim construction." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005). But there are guiding principles. *Id.* "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id.* at 1313. In some cases, the ordinary meaning of a claim term, as understood by a person of ordinary skill in the art, is readily apparent even to a lay person and requires "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. Where the meaning is not readily apparent, however, the court may look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Those sources include "the words of the claims themselves, the remainder of the specification, the prosecution history,

and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.*

"[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. For example, "the context in which a term is used in the asserted claim can be highly instructive." *Id*. Considering other, unasserted, claims can also be helpful. *Id.* "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition, the "claims must be read in view of the specification, of which they are a part." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The specification "is always highly relevant to the claim construction analysis." *Id.* (quoting *Vitronics*, 90 F.3d at 1582). The specification may contain a special definition given to a claim term by the patentee, in which case, the patentee's lexicography governs. *Id.* at 1316. The specification may also reveal an intentional disclaimer or disavowal of claim scope. *Id.* However, "even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal marks omitted).

Courts should also consider the patent's prosecution history. *Phillips*, 415 F.3d at 1317. It may inform "the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* Statements made by a patentee or patent

owner during inter partes review may also be considered. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017).

In appropriate cases, courts may also consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For example, dictionaries, especially technical dictionaries, can be helpful resources during claim construction by providing insight into commonly accepted meanings of a term to those of skill in the art. *Phillips*, 415 F.3d at 1318. Expert testimony can also be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.*; *see also Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331-32 (2015).

II. PLAINTIFFS' PATENTS

Plaintiffs' asserted patents span three families. The first includes U.S. Patent No. 10,617,512 (the "'512 patent"), titled "Biomedical Patches with Aligned Fibers." The second includes U.S. Patent Nos. 10,080,687 (the "'687 patent") and 10,682,444 (the "'444 patent"), both titled "Biomedical Patches with Spatially Arranged Fibers." The third includes U.S. Patent No. 10,632,228 (the "'228 patent"), titled "Tissue Substitute Materials and Methods for Tissue Repair." The parties have disputes over terms in the '512, '687, and '444 patents.

A. '512 patent: "first layer"/"second layer"

The first set of terms for which the parties seek construction are "first layer" and "second layer," found in independent claims 1, 8, and 15 of the '512 patent.

Claim 1 of the '512 patent provides:

> 1. A multi-laminar electrospun nanofiber scaffold for use in repairing a defect in a tissue substrate, the multi-laminar electrospun nanofiber scaffold comprising:
>
> *a first layer formed by a first plurality of deposited electrospun polymeric fibers*; and
>
> *a second layer formed by a second plurality of deposited electrospun polymeric fibers, wherein the second layer is combined with the first layer*,
>
> wherein at least a first portion of the multi-laminar electrospun nanofiber scaffold comprises a higher density of fibers than a second portion of the multi-laminar electrospun nanofiber scaffold, wherein the first portion comprises a higher tensile strength than the second portion,
>
> wherein the multi-laminar electrospun nanofiber scaffold is configured to degrade via hydrolysis after at least one of a predetermined time or an environmental condition,
>
> wherein the multi-laminar electrospun nanofiber scaffold is configured to be applied to the tissue substrate containing the defect,
>
> wherein the multi-laminar electrospun nanofiber scaffold comprises varying density to be sufficiently flexible to facilitate application of the multi-laminar electrospun nanofiber scaffold to uneven surfaces of the tissue substrate, and
>
> wherein the multi-laminar electrospun nanofiber scaffold comprises varying density to be sufficiently flexible to enable movement of the multi-laminar electrospun nanofiber scaffold by the tissue substrate.

(emphasis added). Independent claims 8 and 15 likewise require "a first layer formed by a first plurality of deposited electrospun polymeric fibers" and "a second layer formed by a second plurality of deposited electrospun polymeric fibers, wherein the second layer is combined with the first layer."

The parties' joint claim construction brief presented disputes over the terms "first layer"/"second layer" as well as "multi-laminar." Defendants contended that the "first layer"/"second layer" terms should be construed to require that each is "a distinct layer distinguishable from other layers" and that "multi-laminar" should be construed to mean "a plurality of distinct layers." (D.I. 120 at 11.) Plaintiffs did not propose constructions for any of those terms and instead took the position that "no construction [was] necessary." (*Id.*)

After carefully reviewing the briefs, and after a lengthy interchange at the hearing, it became clear to me that constructions were necessary. The parties had real disputes about claim scope and—contrary to Plaintiffs' proposal to not construe anything and put it to the jury—the disputes needed to be resolved by the Court. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it."). As became evident during the hearing, the fundamental dispute concerns what the word "layer" means and how one distinguishes between layers. (Tr. at 23-70.) Because the claims require a "first layer" and a "second layer," one needs to know what a "layer" is so that one can figure out if a particular device has two of them. I instructed the parties to meet and confer to try to come up with an agreed-upon construction or, failing that, to at least talk to each other about the nature of the dispute and propose competing constructions that actually reflect what the dispute is about.

After their post-hearing meet and confer, the parties filed a joint letter indicating their agreement that the term "multi-laminar" should be construed as "multiple layers." (D.I. 136 at 1.) But they still have a dispute over the terms "first layer" and "second layer." Defendants say that each "first layer" and "second layer" must be a "distinct and separately deposited thickness of

material." (*Id.*) Plaintiffs say that "first layer" and "second layer" should be construed as "first thickness of material" and "second thickness of material." (*Id.*)

I agree with Defendants and recommend adopting a modified version of Defendants' proposal. The main problem with Plaintiffs' proposal is that it does not resolve the dispute between the parties about what a layer is. How does an accused infringer know if its product has two layers or one layer and is therefore infringing or not? Take an ordinary scouring pad, for example. One could draw an imaginary horizontal cross section through it and therefore imagine that it has a first top "thickness of material" and a second bottom "thickness of material," which a jury might find meets Plaintiffs' proposed construction.

But no one, not even Plaintiffs, would say that an ordinary (single-layer) scouring pad has two layers. (*Id.* (Plaintiffs: "[I]t is understood the [claimed] multiple layers cannot be the same layer.").)

One possible solution would be to define a "layer" of material with reference to the fact that it has different properties than its neighboring layers. For example, a layer might consist of a different polymer, density, or fiber orientation than a neighboring layer. Sticking with the same analogy, imagine a dish sponge with a spongy side and a scouring pad side. Everyone would agree

that it has two layers because the spongy side and the scouring pad side have different physical characteristics.

But defining the meaning of layer by reference to its physical characteristics won't work for this patent because both sides agree that the claimed "first layer" and "second layer" can have the same physical characteristics. (*Id.* at 1, 3; Tr. at 44.)

Given that everyone agrees that we need some objective way of defining where one layer stops and the next starts (*i.e.*, we agree that an ordinary scouring pad only has one layer), and everyone agrees that something can have two layers even though the two layers have the same physical characteristics, what makes a "first layer" and a "second layer" within the meaning of the claims? The best answer—the one that "stays true to the claim language and most naturally aligns with the patent's description of the invention," *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)—is that the layers are formed separately from each other. Defendants try to capture that idea with its proposed construction that each layer be "distinct and separately deposited."

The claim language itself provides substantial support for Defendants' proposal. Not only do the claims require "a first layer formed by a first plurality of deposited electrospun polymeric fibers" and "a second layer formed by a second plurality of deposited electrospun polymeric fibers," they also require that "the second layer is *combined* with the first layer" (emphasis added).

That language suggests that the first layer must be distinct in the sense that it was formed separately, independent from the second layer. That understanding is consistent with the embodiments disclosed in the specification, which describe ways of "combin[ing]" layers "to create a multi-layer biomedical patch," including by creating a first layer and depositing a second layer on top, or separately creating a second layer and "overla[ying]" it on the first layer:

> FIG. 8 is an illustration of a biomedical patch layer 400 with a plurality of randomly oriented fibers 405 and a biomedical patch layer 410 with a plurality of radially aligned fibers 415. As shown in FIG. 8, biomedical patch layers 400 and 410 may be combined (e.g., overlaid) to produce a multi-layer biomedical patch 420 with both randomly oriented fibers 405 and radially aligned fibers 415, or any other combination of any number or type of fiber layers.
> . . . .
> In some embodiments, multiple biomedical patch layers 410 with radially aligned fibers 415 may be combined to create a multi-layer biomedical patch. For example, referring to FIGS. 1 and 3, after depositing a first set of fibers on collector 105, one may wait for the first set of fibers 165 to solidify completely or cure and then deposit a second set of fibers 165 on collector 105. The second set of fibers 165 may be deposited directly over the first set of fibers 165 on collector 105. Alternatively, the first set of fibers 165 may be removed from collector 105, and the second set of fibers 165 may be deposited on conductive surface 162 and/or collector 105 and then removed and overlaid on the first set of fibers 165.

('512 patent, 12:60-67, 13:13-25.)

Plaintiffs take issue with the word "distinct" in Defendants' proposed construction. According to Plaintiffs, the word "'distinct' would only add ambiguity and confuse the jury" because "the parties have agreed the layers do not need to be different in their composition, structure or other characteristics." (D.I. 136 at 1.) But that concern can be addressed by adding clarifying language to the construction, like the following: "The first layer and the second layer do

not need to be different in their composition, structure, or other characteristics." Should a party desire clarifying language, the parties should meet and confer and submit an agreed-upon proposal.

Plaintiffs also take issue with a construction that imposes a requirement that each layer be "separately deposited." Plaintiffs argue, among other things, that a "separately deposited" requirement would erroneously import a process limitation into the claim. I disagree. The Federal Circuit rejected a similar argument in *Regents of University of Minnesota v. AGA Medical Corp.*, 717 F.3d 929, 938 (Fed. Cir. 2013). The claim there required "first and second occluding disks" with "a central portion of the membrane of the first disk being affixed to a central portion of the membrane of the second disk to define a conjoint disk." *Id.* at 934. The Federal Circuit affirmed the district court's conclusion that the claim language "cover[ed] only a device made up of two physically separate disks that are attached to one another." *Id.* at 935. The court rejected the patentee's argument that the construction improperly incorporated a process limitation, reasoning that "words like 'affixed' or 'conjoint,' which when read in context describe the product more by its structure than by the process used to obtain it, are product limitations, not process limitations." *Id.* at 938 (cleaned up). It further stated that "[w]hen a patentee chooses to use these words, they should be given their ordinary meanings with respect to the claimed product's structure." *Id.*

The same reasoning applies here. The claim requires that the "first layer" and the "second layer" are each made from "deposited electrospun polymeric fibers" and that the two layers must be "combined" with each other. One could not be said to "combine" two things that did not exist separately before they were combined. Construing the terms to mean that, before combining, the layers existed separately does no more than give ordinary meaning to the claim language. Accordingly, the "separately deposited" language is an appropriate structural limitation that solves

the problem of distinguishing between single-layer products and multi-layer products where the layers have the same composition.

Plaintiffs also contend that a "separately deposited" requirement is inconsistent with certain embodiments disclosed in the specification. Plaintiffs point out that the '512 specification discloses an embodiment where a "single layer" is created by "simultaneously, sequentially and/or alternately" depositing radially aligned and non-radially aligned fibers. ('512 patent, 12:52-54.) But the mere fact that the specification says that a single layer might be made from differently-aligned fibers deposited sequentially does not suggest, as Plaintiffs contend, that a single deposit of fibers could form a claimed "first layer" and a "second layer" that have been "combined" with each other. The claim language itself requires that the layers must be created separately and combined.

Plaintiffs further argue that Defendants' construction is improper because it "excludes any post-electrospinning modifications to the product in a determination of whether the product contains the claimed 'layers.'" (D.I. 136 at 2.) Plaintiffs' argument, to the extent I understand it, is that Defendants' proposed construction would exclude a product with "layers" that are defined not by "combin[ing]" separate deposits, but by doing some other type of physical modification to a single deposit that would result in some of the fibers having different physical characteristics than other fibers. But Plaintiffs do not point to anywhere in the specification that refers to such modifications as creating layers. More importantly, the claims require that the layers be "combined." If Plaintiffs' point is that Defendants' proposed construction excludes a device with layers that weren't created separately and combined, then I agree, it does, and appropriately so.

To be clear, the Court's construction is not intended to exclude any of the disclosed ways that the layers may be combined. Again, the specification explains that a multi-layer patch may be formed, for example, by creating a first layer and depositing a second layer on top, or by separately creating the layers and then overlaying them. The Court's construction is intended to be broad enough to cover both. Should either side desire clarifying language in the construction to make that clear, the parties should meet and confer and propose language.

Accordingly, I recommend that the Court adopt Defendants' proposed construction and consider adopting any clarifying language proposed by the parties that is consistent with the above discussion.

B. '687 patent: "first layer" / "second layer" / "third layer"

The second group of disputed terms are "first layer"/"second layer"/"third layer," found in claims 1, 5, and 7 of the '687 patent. Independent claim 1 provides:

> 1. A structure for use in repairing a defect in a substrate, the structure comprising:
>
> *a first layer formed by a first plurality of polymeric fibers*; and
>
> *a second layer formed by a second plurality of polymeric fibers, the second layer coupled to the first layer using a first coupling process*, the second layer having a plurality of densities formed by the second plurality of polymeric fibers, wherein the first and second layers are configured to separate after at least one of a predetermined time and an environmental condition and wherein the structure is configured to be applied to the substrate containing the defect.

(emphasis added).[2] Dependent claim 7 provides:

> 7. A structure in accordance with claim 1, further comprising *a third layer that is coupled to the first and second layers using the first coupling process*.

(emphasis added).

The dispute here is essentially the same as the previous dispute. Defendants say that each of the "first layer," "second layer," and "third layer" must be a "distinct and separately deposited thickness of material." Plaintiffs say that each is a "first/second/third thickness of material."[3] I again agree with Defendants.

Here, again, the claim language suggests that each layer must be distinct in the sense that it must be created separately and joined with the other layers through a coupling process. The claim language is consistent with the specification, which describes "coupling" separately-created layers together:

> In the exemplary embodiment, method 700 includes electrically charging 705 collector 105 at a first amplitude and/or polarity (e.g., negatively charging or grounding). Spinneret 120 is electrically charged 710 at a second amplitude and/or polarity opposite the first amplitude and/or polarity (e.g., positively charged). A polymer (e.g., a liquid polymer) is dispensed 715 from spinneret 120. In the exemplary embodiment, dispensed 715 polymers are collected 720 on collector 105 to form a plurality of polymeric fibers on or substantially near features 112 that creates a structure or patch. After the dispensed 615 polymers are collected 720 and a structure is created, the structure may undergo post-processing 725. Such post-processing 725 can include, but is not limited to, lamination, layer

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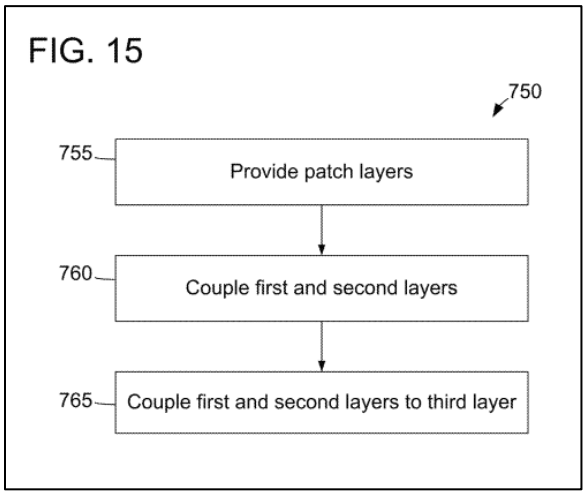
[2] Claim 5 is dependent on claim 1, and it specifies that "the first layer and second layer are configured to be applied to biological tissue."

[3] Prior to the *Markman* hearing, Plaintiffs took the position that "[n]o construction was necessary." (D.I. 120 at 29.) The parties presented their current positions after a post-hearing meet and confer. (D.I. 136.)

stacking, coupling and/or fusing, chemically treating, and applying a biological agent, growth factor, and/or drug.

FIG. 15 is a flowchart of an exemplary method 750 for fusing or coupling together structures or patch layers produced by method 700 shown in FIG. 14. Method 750 includes providing 755 a first, second, and third patch layer. First patch layer is coupled 760 to second patch layer using a first coupling technique. The coupled 760 first and second layers are then coupled 765 to the third patch layer using a second coupling technique different than the first coupling technique. In the exemplary embodiment, coupling techniques, include but are not limited to, heating, applying mechanical stress/pressure, chemical processing, cross-linking, and functionalization. While method 750 illustrates a first patch layer coupled to a second patch layer, it should be noted that multiple layers (e.g., 3, 5, 6,) can be coupled together simultaneously. Additionally, the process may be repeated to add layers to structures produced by method 750.



('687 patent, 11:62-12:26, Fig. 15.)

I recommend that the Court adopt Defendants' proposed construction and consider adopting any clarifying language proposed by the parties that is consistent with the above discussion.

C. ’444 patent: “first plurality” / “second plurality”

The third group of disputed terms are “first plurality” and “second plurality,” found in claims 1-8, 10, 16 and 17 of the ’444 patent. Only claim 1 is independent. It recites:

> 1. A three-dimensional electrospun nanofiber scaffold for use in repairing a defect in a tissue substrate, the three-dimensional electrospun nanofiber scaffold comprising:
>
> *a first plurality of electrospun polymeric nanofibers* having a diameter of 1-3000 nanometers; and
>
> *a second plurality of deposited electrospun polymeric nanofibers* having a diameter of 1-3000 nanometers,
>
> *the second plurality of deposited electrospun polymeric nanofibers being coupled to the first plurality of electrospun polymeric nanofibers*,
>
> the second plurality of deposited electrospun polymeric nanofibers forming one or more regions within the three-dimensional electrospun nanofiber scaffold, wherein the one or more regions comprise a density different from one or more other regions of the three-dimensional electrospun nanofiber scaffold, wherein the one or more regions are overlaid on a first portion of the first plurality of electrospun polymeric nanofibers, wherein the one or more regions are not overlaid on a second portion of the first plurality of electrospun polymeric nanofibers,
>
> wherein the three-dimensional electrospun nanofiber scaffold is configured to be applied to the tissue substrate containing the defect,
>
> wherein the three-dimensional electrospun nanofiber scaffold comprises a controlled separation rate of less than 30 days, wherein the first plurality of electrospun polymeric nanofibers and the second plurality of deposited electrospun polymeric nanofibers are adapted to separate within 30 days after application to the tissue substrate containing the defect.

Claim 2 contains the additional limitation that the "first plurality and "second plurality" are "coupled . . . by at least one of heating, applying mechanical stress, applying mechanical pressure, applying a glue, chemical processing, cross-linking, or surface functionalization." Claim 6 requires that the coupling occur by "cross-linking." The '444 patent has the same specification as the '687 patent.

The dispute here is essentially the same as the previous dispute, except that the '444 patent claims refer to a first and second "plurality" instead of a first and second "layer." Defendants say that "first plurality" and "second plurality" should be construed as "first distinct and separately deposited thickness" and "second distinct and separately deposited thickness." Plaintiffs say they should be construed as "first/second grouping of two or more [electrospun polymeric fibers]."[4]

One dispute between the parties is whether the claimed first and second pluralities must be "distinct" and "separately deposited," as Defendants propose. For the same reasons set forth above, I again agree with Defendants. Like claim 1 of the '687 patent, claim 1 of the '444 patent suggests that the first plurality of fibers must be distinct and separately deposited. It requires that the second plurality of electrospun polymeric nanofibers be "coupled" to the first plurality. It also requires that one or more regions of the second plurality be "overlaid" on a portion of the first plurality. Those requirements make clear that each claimed plurality of fibers is separately created and then combined together. And that understanding is consistent with the same portions of the specification of the related '687 patent cited in the section above.

[4] Prior to the *Markman* hearing, Plaintiffs took the position that "[n]o construction was necessary." (D.I. 120 at 31.) The parties presented their current positions after a post-hearing meet and confer. (D.I. 136.)

The parties also dispute whether the construction should use the word "thickness," as Defendants propose, or the word "grouping" as Plaintiffs propose. The intrinsic evidence does not strongly point one way or the other. Nor has either side explained how choosing between "thickness" and "grouping" will resolve anything at issue in the litigation. It seems to me that any "grouping" of objects made out of atoms will by definition have a "thickness." That said, the claims only require a "plurality," which is commonly understood to mean two or more, and the term "thickness" might lead the jury to believe that something more is required. I suggest going with "grouping."

Accordingly, I recommend that the terms "first plurality" and "second plurality" be construed as "first distinct and separately deposited grouping [of electrospun polymeric nanofibers]" and "second distinct and separately deposited grouping [of electrospun polymeric nanofibers]." As before, I also recommend that the Court consider adopting any clarifying language proposed by the parties that is consistent with the above discussion.

III. DEFENDANTS' PATENTS

Defendants are asserting two patents against Plaintiffs: U.S. Patent No. 8,222,166 (the "'166 patent"), titled "High Flux and Low Fouling Filtration Media," which has two phrases to be construed, and U.S. Patent No. 7,172,765 (the "'765 patent"), titled "Biodegradable and/or Bioabsorbable Fibrous Articles and Methods for Using the Articles for Medical Applications," which has one phrase to be construed.

A. '166 patent: "prepared from at least one solution of at least one polymer utilizing a process selected from the group consisting of electro-spinning, electro-blowing, blowing-assisted electro-spinning, and solution blowing"

The next disputed phrase is "prepared from at least one solution of at least one polymer utilizing a process selected from the group consisting of electro-spinning, electro-blowing,

blowing-assisted electro-spinning, and solution blowing," found in claim 26 of the '166 patent. Claim 26 depends on claim 23, and they recite as follows:

> 23. An article comprising a nanofibrous scaffold comprising: fibers having a diameter of from about 1 nm to about 20,000 nm; voids with an effective diameter of from about 2 nm to about 200 μm; and a thickness of from about 1 μm to about 500 μm.
>
> 26. The article of claim 23 wherein the nanofibrous scaffold comprises at least one layer *prepared from at least one solution of at least one polymer utilizing a process selected from the group consisting of electro-spinning, electro-blowing, blowing-assisted electro-spinning, and solution blowing*.

(emphasis added).

Plaintiffs argue that the disputed phrase is a process limitation of a product-by-process claim. Defendants argue that the phrase is not a process limitation of a product-by-process claim.

A "'product-by-process' . . . claim 'is one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 159 n.* (1989) (quoting Donald S. Chisum, *Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement* § 8.05 (1988)); *see also Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1291-94 (Fed. Cir. 2009) (holding that product claims with process limitations are only infringed by products made by the claimed processes).

The parties are not asking the Court to construe the "prepared from" phrase; they merely want the Court to rule on whether it is a process limitation of a product-by-process claim. Even after hearing oral argument, it is still not clear to me what the point of the parties' dispute is, or whether resolving it might actually affect the outcome of the case one way or the other. (*See* Tr. 70-92.) However, because characterizing something as a product-by-process claim can affect the

invalidity analysis,[5] I do not think it is inappropriate to resolve this dispute as part of the claim construction process. *See In re Biogen '755 Patent Litig.*, No. 10-2734, 2016 WL 7340311, at *5 (D.N.J. Mar. 28, 2016) (collecting cases) ("As part of the claim construction process, courts are routinely tasked with making determinations that are not strictly limited to the technical meaning of claim terms and limitations.").

I agree with Plaintiffs that the disputed phrase is a process limitation of a product-by-process claim. Claim 26 covers an "article" and is thus a product claim. The phrase "at least one layer prepared from at least one solution of at least one polymer utilizing a process selected from the group consisting of electro-spinning, electro-blowing, blowing-assisted electro-spinning, and solution blowing" describes how the claimed "layer" must be prepared and is clearly a process limitation. *See Biacore v. Thermo Bioanalysis Corp.*, 79 F. Supp. 2d 422, 456 (D. Del. 1999) ("Typically, it is the wording of the claim which indicates that it is a product-by-process claim. For example, product-by-process claims employ terms such as 'prepared in accordance with,' [and] 'by the process of' . . . ."). Claim 26 is a product claim with a process limitation; thus, it is a product-by-process claim.

The cases cited by Defendants do not support their position. Those cases stand for the proposition that when claim phrases "connote with equal force a structural characteristic of the product or a process of manufacture," it is usually appropriate to interpret them "in their structural sense." *See 3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003) (holding that the term "multiple embossed patterns" did not include a process limitation that

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[5] *See Bonito Boats*, 489 U.S. at 159 n.* (citing *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985)).

the patterns be created sequentially); *see also Vanguard Prods. Co. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000) (holding that the claim term "integral" described a structural relation, not the particular manufacturing process recited in the specification); *Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (concluding that "chemically engraved" was not a process term because, "read in context, [it] describe[d] the product more by its structure than by the process used to obtain it").

Those cases are inapposite, as the claim phrase "layer prepared from [a] . . . solution . . . using a process selected from the group of [four scientific techniques]" doesn't connote the structure of the claimed layer. The phrase refers to preparing the claimed layer from a "solution" of polymers, and there is no dispute that the claimed resulting product does not contain a "solution." (Tr. at 80); *see Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1353 (Fed. Cir. 2016) (holding that the phrase "derived from 8α[ ]" did not describe the structure of the claimed product and was thus a process limitation). In addition, the disputed phrase actually uses the word "process" to refer to how the claimed layers have to be prepared.

I recommend that the Court hold that the disputed phrase is a process limitation of a product-by-process claim.

B. '166 patent: prepared from about 1 to about 5 solutions of from about 1 to about 5 polymers"

The next disputed phrase is found in claim 27 of Defendants' '166 patent. It depends on claim 23, and it provides:

> 27. The article of claim 26 wherein the nanofibrous scaffold comprises from about 1 to about 5 layers *prepared from about 1 to about 5 solutions of from about 1 to about 5 polymers*.

(emphasis added).

Plaintiffs argue that the phrase "prepared from about 1 to about 5 solutions of from about 1 to about 5 polymers" is a process limitation of a product-by-process claim. Defendants say it is not.

This is essentially the same dispute as the previous dispute. I agree with Plaintiffs for the same reasons. I recommend that the Court hold that the disputed phrase is a process limitation of a product-by-process claim.

C. '765 patent: "formed by electrospinning fibers"

The final disputed phrase is "formed by electrospinning fibers," found in claims 1 and 49 of the '765 patent. They provide:

> 1. A biodegradable and/or bioabsorbable fibrous article *formed by electrospinning fibers* of biodegradable and/or bioabsorbable fiberizable material comprising a composite of different biodegradable and/or bioabsorbable fibers.
>
> 49. A fibrous article *formed by electrospinning different fibers* of different materials, comprising a composite of different fibers which comprises fibers of at least one biodegradable material and fibers of at least one non-biodegradable material.

(emphasis added).

Plaintiffs argue that "formed by electrospinning fibers" is a process limitation of a product-by-process claim. Defendants say it is not.[6]

If, instead, the disputed phrase was "electrospun fibers," Defendants might have had an argument that the phrase connotes structure. But the claimed "formed by electrospinning fibers"

[6] The parties haven't asked the Court to determine whether the preamble of either claim is limiting.

clearly refers to a process. Accordingly, I agree with Plaintiffs, and I recommend that the Court hold that the disputed phrase is a process limitation of a product-by-process claim.

IV. CONCLUSION

I recommend that the Court adopt the constructions set forth above. Should either side desire to include clarifying language consistent with the above analysis for the "first layer"/"second layer"/"third layer" terms or the "first plurality"/"second plurality" terms, the parties should meet and confer and file a joint status letter within fourteen days.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated March 7, 2022, a copy of which can be found on the Court's website.

Dated: October 12, 2022

The Honorable Jennifer L. Hall
United States Magistrate Judge