

**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

Plaintiffs Acera Surgical, Inc., Retectix, LLC, and Washington University (collectively, “Plaintiffs”) brought this patent infringement action against Defendants Nanofiber Solutions, LLC, Paragen Technologies LLC, Atreon Orthopedics LLC, and Renovoderm LLC (collectively, “Defendants”) on July 23, 2020.

Currently pending before the Court are the parties’ claim construction disputes regarding two terms in U.S. Patent No. 11,224,677 (the ’677 patent). I previously issued a Report and

Recommendation in this case on October 12, 2022 (D.I. 147) resolving other claim construction disputes, which the Court ultimately adopted (D.I. 177). At that time, the '677 patent was not yet in the case. On November 7, 2022, Plaintiffs added a claim of direct infringement of the '677 patent against Defendants. (D.I. 152.) I held a *Markman* hearing on April 14, 2023 to address the '677 disputes. (“Tr ___.”)

For the reasons discussed below, I recommend that the disputed terms be construed as follows:

Term	Recommended Construction
“commingled in the non-woven electrospun polymeric scaffold” (claim 15)	plain and ordinary meaning (<i>i.e.</i> , the two fibers sets are mixed or blended in the scaffold)
“poly(lactide-co-caprolactone)” (claim 22)	poly(L-lactide-co-caprolactone), poly(D-lactide-co-caprolactone), or poly(D,L-lactide-co-caprolactone)

Further, I recommend that the parties’ agreed-upon constructions¹ be adopted as follows:

Term	Recommended Construction
“first set of non-woven electrospun polymeric fibers”/“second set of non-woven electrospun polymeric fibers”	first group of non-woven electrospun polymeric fibers/ second group of non-woven electrospun polymeric fibers
“pores formed by the first set of non-woven electrospun polymeric fibers and the second set of non-woven electrospun polymeric fibers”	open spaces between fibers
“top surface”/“bottom surface”	top exterior boundary of the scaffold/ bottom exterior boundary of the scaffold
“protrusions arising from the top or bottom surface”	protrusions arising from the top or bottom exterior boundary of the scaffold
“depressions in the top or bottom surface”	depressions in the top or bottom exterior boundary of the scaffold. A mere pore, is not a “depression” in the surface.

¹ (See D.I. 184 at 1.)

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.*

“The 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. DISCUSSION

My Report and Recommendation was announced from the bench on April 14, 2023, as follows:

I’m prepared to issue a Report and Recommendation on the disputes argued today. I will not be issuing a separate written Report and Recommendation, but we will file a document that incorporates a transcript of what I’m going to say today.

Today’s claim construction disputes were limited to U.S. Patent No. 11,224,677, which was more recently added to this case. The ’677 patent issued from a continuation of one of the Plaintiffs’ other applications that led to the ’228 patent, which is also asserted in this case.

I want to emphasize before I announce my recommendations that while I am not issuing a separate written opinion, we have followed a full and thorough process before making the recommendations I am about to state. We carefully reviewed the patent-in-suit. There was also full briefing on the two disputed terms. The parties’ joint claim construction briefing also included numerous exhibits that included, among other materials, portions of the prosecution histories relied on by the parties as well as some extrinsic evidence, including an expert declaration from Defendants’ expert, Dr. Wnek. Neither party put on live testimony.

And to be clear, while my oral ruling will cite to the evidence that I conclude best supports my recommended constructions, my failure to cite to other evidence provided by the parties does not mean that I ignored or failed to consider it. As I stated, I have considered all of the arguments and evidence cited by the parties.

I am not going to read into the record my understanding of the general legal principles of claim construction. I set forth the legal standard in my opinion in *3Shape v. Align*,² and I incorporate that articulation by reference here.

["commingled in the non-woven electrospun polymeric scaffold"]

The first term to be construed is “commingled in the non-woven electrospun polymeric scaffold.” That is found in claim 15 of the ’677 patent.³

² *3Shape A/S v. Align Tech., Inc.*, No. 18-886, 2020 WL 2188857, at *1–2 (D. Del. May 6, 2020).

³ Claim 15 recites:

15. A bioabsorbable non-woven graft material for facilitating regeneration of tissue, the bioabsorbable non-woven graft material consisting of:

a single non-woven electrospun polymeric scaffold, the non-woven electrospun polymeric scaffold formed by a first set of non-woven electrospun polymeric fibers and a second set of non-woven electrospun polymeric fibers, wherein the first set of non-woven electrospun polymeric fibers and the second set of non-woven electrospun polymeric fibers are commingled in the non-woven electrospun polymeric scaffold,

the first set of non-woven electrospun polymeric fibers formed by depositing via electrospinning a first polymer composition comprising glycolic acid, the second set of non-woven electrospun polymeric fibers formed by depositing via electrospinning a second polymer composition, the first polymer composition and the second polymer composition comprising different compositions;

the non-woven electrospun polymeric scaffold further comprising a plurality of pores formed by the first set of non-woven electrospun polymeric fibers and the second set of non-woven electrospun polymeric fibers;

the non-woven electrospun polymeric scaffold further comprising a top surface and a bottom surface comprising one or more different physical properties, wherein the one or more different physical properties comprise areal density;

the non-woven electrospun polymeric scaffold comprising sufficient flexibility for applying the bioabsorbable non-woven graft material to tissue, and the non-woven

Plaintiffs say that the phrase should be given its “plain and ordinary meaning (*i.e.*, the two fibers sets are mixed or blended in the scaffold).” Defendants say it should be construed to mean “the first and second sets of fibers are each randomly oriented, but not together in a single layer.”

After carefully reading the briefs, and listening to the oral arguments today, it became clear that the essence of the parties’ dispute was this: does the claim term exclude a product that would result from co-spinning, which is a scaffold in which two types of fibers are commingled (or mixed) with each other in a layer? This dispute has been characterized in a number of different ways in the briefs and in the oral argument—including as being a dispute about multilayers versus single layers—but that is the essence of the dispute.

Defendants say the claim cannot cover what you would get from co-spinning and that the first and second set of fibers have to be laid down separately or sequentially. Plaintiffs say that the first and second set of fibers do not have to be laid down separately or sequentially.

I agree with Plaintiffs. Starting with the claim language, I don’t think there’s anything in the language of claim 15 itself that would suggest to a person of ordinary skill that the first and second set of fibers could not be commingled through a co-spinning process. Stated another way, nothing in the claim restricts it to multi-layer scaffolds resulting from sequential electrospinning of two types of polymers.

I also agree with Plaintiffs that, to the extent dependent claim 16 has any value in resolving this dispute, it tends to support Plaintiffs’ construction, as it would be awkward to say that a multi-layer scaffold with different types of fibers in each layer (as Defendants propose) amounts to a material where the different types

electrospun polymeric scaffold comprising sufficient mechanical strength for the bioabsorbable non-woven graft material to be trimmable, wherein the bioabsorbable non-woven graft material is configured to facilitate regeneration of tissue.

of fibers are substantially uniformly distributed throughout the material.⁴

Turning to the specification, Defendants contend that column 10, lines 29 through 33, which refers to the electrospinning process described earlier in the specification, supports their view that the claimed material cannot result from co-spinning and can only include a situation where the two sets of polymers are deposited sequentially. I've carefully reviewed the cited portions and I disagree.

Defendants argue the prosecution history supports their argument. Defendants' argument is complicated. Suffice it to say, I've read it. I understand the argument. But I agree with Plaintiffs that the prosecution history actually supports Plaintiffs' proposed construction. At a minimum, I disagree that the prosecution history requires importing a limitation into the claim that would essentially exclude co-spinning and require that the first and second set of fibers be laid down separately or sequentially.

[Accordingly,] I recommend Plaintiffs' construction.

["poly(lactide-co-caprolactone)"]

The second disputed term is poly(lactide-co-caprolactone). That term appears in claim 22, which is dependent on claim 15. Claim 22 recites: "The bioabsorbable non-woven graft material of claim 15, wherein the first polymer composition comprises poly(glycolic) acid, and wherein the second polymer composition comprises poly(lactide-co-caprolactone)."

Plaintiffs say that the term should be construed as poly(L-lactide-co-[ε-]caprolactone). Defendants say that the term should be construed as covering poly(L-lactide-co-caprolactone), poly(D-lactide-co-caprolactone), or poly(D,L-lactide-co-caprolactone).⁵

⁴ Claim 16 recites:

16. The bioabsorbable non-woven graft material of claim 15, wherein the first set of non-woven electrospun polymeric fibers and the second set of non-woven electrospun polymeric fibers are substantially uniformly distributed throughout the bioabsorbable non-woven graft material.

⁵ Defendants originally proposed "and/or" instead of "or." (See D.I. 184 at 12.) Defendants agreed at the hearing that it should be "or." (Tr. 49.)

There is no dispute that poly(lactide-co-caprolactone) refers to a copolymer of lactide and caprolactone.⁶ I don't take there to be any material dispute about the inclusion of the epsilon in the construction either.⁷

The dispute between the parties is this: is the term restricted to copolymers where the lactide components are the L-enantiomer, as Plaintiffs propose? Or does the term also cover copolymers where the lactide components are in the D-enantiomer and copolymers where the lactide components are a mixture of the D and L enantiomers, as Defendants propose? On this dispute, I side with Defendants.

Starting with the claims, nothing in the claims restricts the term to copolymers where the lactide components are in the L arrangement.

Moving on to the specification, it reflects that the patentee knew how to refer to L lactide when it wanted to refer to polymers that only contain lactide in the L arrangement. For example, in the lists of polymers in column 3, there is a reference to poly(L-lactide), where the L arrangement is specified; a separate reference to poly(D,L-lactide), which suggests a polymer where the lactide is in a mixture of D and L enantiomers; and another separate reference to poly(lactide-co-glycolide), which doesn't specify what arrangement the lactide components are in.

What should a person skilled in the art take from this? One thing that can be said is that it appears the patentee didn't always specify the configuration of the lactide components in the specification. Another thing that can be said is that the patentee knew how to specify a polymer in which the lactide components are only in the L arrangement. And the latter point provides some support for the idea that if the patentee intended the claims to be limited to lactide in the L configuration, the patentee would have specified that.

Plaintiffs point out that the only type of poly(lactide-co-caprolactone) described in the specification is poly(L-lactide-co-ε-caprolactone). Sometimes it's difficult for a court to determine whether a proposed construction falls on the side of interpreting a claim term in view of the specification—which the court is required

⁶ (*See, e.g.*, Tr. 48, 50–51; D.I. 184 at 55–56, 60.)

⁷ (*See, e.g.*, D.I. 185, Ex. 24 ¶ 46.)

to do—or whether it falls on the side of importing a limitation or embodiment from the specification into the claim term—which is generally inappropriate. This dispute, however, presents no such difficulties, as I agree with Defendants that Plaintiffs’ proposal clearly falls on the side of improperly importing a limitation from the specification.

Plaintiffs point to certain positions taken by Defendants in the IPR for the ’228 patent. I’ve reviewed them and find that they don’t support Plaintiffs’ position here.

I think that this dispute can be resolved solely by looking at the intrinsic evidence. However, the extrinsic evidence also supports Defendants’ position. In particular, Defendants’ expert, Dr. Wnek, submitted a declaration in which he explains that a person of skill in the art would understand poly(lactide-co-caprolactone) to refer to either poly(L-lactide-co-caprolactone), poly(D-lactide-co-caprolactone), or poly(D,L-lactide-co-caprolactone).⁸ I find the declaration persuasive. [Plaintiffs] have not proffered an expert to challenge Dr. Wnek’s testimony on this point, nor have they put forth an expert to say that a person of skill in the art reading the claim in the context of this patent would understand that the term necessarily refers to the L-lactide arrangement. And I make an express factual finding based on the intrinsic and extrinsic record that a person of skill in the art would understand the disputed term to cover the specified copolymers that contain lactide in any of its spacial arrangements, *i.e.*, poly(L-lactide-co-caprolactone), poly(D-lactide-co-caprolactone), or poly(D,L-lactide-co-caprolactone).

Plaintiffs accuse Defendants of taking inconsistent positions, and they refer the court to allegations in Defendants’ inequitable conduct counterclaim at D.I. 159. I reviewed those as well and I don’t see the inconsistency.

Plaintiffs point out that Defendants didn’t ask for a construction of this same term as it appears in the ’228 patent. I don’t think that says much of anything, as there are a lot of reasons I can think of why Defendants might not have done that. And it is clear to me that the parties have a dispute here as to what this term means in this patent, and the Court needs to resolve that dispute. Just because Defendants didn’t ask for a construction of this term in the ’228 patent doesn’t suggest that Plaintiffs’ construction is appropriate here, especially since, as I have mentioned, Plaintiffs are

⁸ (See D.I. 185, Ex. 24.)

seeking a construction that is narrower than what a person of skill in the art would understand the term to mean.

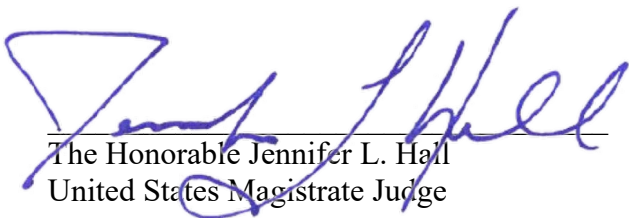
And that concludes my Report and Recommendation.

III. CONCLUSION

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.

Absent any objections, the parties shall file a Proposed Order consistent with this Report and Recommendation for the Court's approval.

Dated: May 25, 2023


The Honorable Jennifer L. Hall
United States Magistrate Judge