IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACERA SURGICAL, INC., RETECTIX, LLC, AND WASHINGTON UNIVERSITY,	)	
Plaintiffs,	)	
v.	)	C.A. No. 20-980-CFC-JLH
NANOFIBER SOLUTIONS, LLC, PARAGEN TECHNOLOGIES LLC, ATREON ORTHOPEDICS LLC, AND RENOVODERM LLC,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

Presently pending before the Court are Defendants' Motions to Dismiss for Failure to State a Claim. (D.I. 17; D.I. 35.) As announced at the hearing on July 16, 2021, I recommend that the motions be DENIED. My Report and Recommendation was announced from the bench at the conclusion of the hearing as follows:

> This is the Court's Report and Recommendation on Defendants' motions to dismiss for failure to state a claim. (D.I. 17; D.I. 35.) I will not be issuing a separate opinion, but we will put on the docket a written version that incorporates by reference a transcript of my oral ruling today. I want to emphasize before I start that, while I'm not issuing a separate opinion, we have followed a full process for making the decision that I'm about to state. There was full briefing on these motions, and those papers and the arguments today have been carefully considered.
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> For the reasons I will discuss, I recommend that Defendants' motions to dismiss be DENIED.
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> Plaintiffs Acera Surgical, Inc., Washington University, and Retectix, LLC (collectively, "Plaintiffs") filed this patent infringement action against Defendants Atreon Orthopedics LLC, Nanofiber Solutions, LLC, Paragen Technologies LLC and Renovoderm LLC (collectively, "Defendants") on July 23, 2020. (D.I. 1.)

Defendants moved to dismiss the original complaint for failure to state a claim on September 11, 2020. (D.I. 11.) Plaintiffs filed a first amended complaint on October 2, 2020. (D.I. 16.)

The FAC contained four counts, alleging infringement of four patents. In particular, it alleged that Defendants directly infringe U.S. Patent Nos. 10,617,512 ("the '512 patent"), 10,080,687 ("the '687 patent"), 10,682,444 ("the '444 patent"), and 10,632,228 ("the '228 patent") through their manufacture, use, offering for sale, selling and/or importation of two accused products: the Phoenix Wound Matrix and the Rotium Bioresorbable Wick. (D.I. 16.) On October 23, 2020, Defendants moved to dismiss the first amended complaint for failure to state a claim. That motion was fully briefed and remains pending before the Court. (D.I. 17; D.I. 18; D.I. 20; D.I. 22.)

On February 26, 2021, the parties filed a stipulation allowing Plaintiffs to file a second amended complaint to include allegations of direct infringement of a newly issued patent, U.S. Patent No. 10,888,409 ("the '409 patent"). (D.I. 30.) Plaintiffs filed the SAC on March 3, 2021. (D.I. 32.) Counts One through Four of the SAC are essentially unchanged from the FAC. Count Five alleges that Defendants directly infringe the '409 patent through their manufacture, use, offering for sale, selling, and importation of the Phoenix Wound Matrix product.

The parties agreed that, because Counts One through Four of the SAC were "substantially identical" to the FAC, the previously-filed motion to dismiss would not be re-briefed. Defendants filed another motion to dismiss on March 23, 2021, arguing that Count Five should also be dismissed, and that motion has also been fully briefed. (D.I. 35; D.I. 36; D.I. 39; D.I. 40; D.I. 41)

On April 26, 2021, the pending motions were referred to me for a Report and Recommendation. Argument was held on both motions to dismiss today, and this is my Report and Recommendation on those motions.

The patents-in-suit relate to polymeric fiber matrices for assisting wound healing. According to the SAC, Plaintiff Washington University is the owner by assignment of the '512, '409, '687, and '444 patents, and Plaintiffs Retectix and Acera are exclusive licensees. The SAC further alleges that Acera is the assignee of all rights related to the enforcement of the '228 patent. (D.I. 32 ¶¶ 22-26.)

> The SAC alleges that all four Defendants directly infringe the patents-in-suit through their manufacture, use, sale, and importation of the Phoenix Wound Matrix and Rotium Bioresorbable Wick products. (D.I. 32 ¶¶ 6, 15, 19, 27-28.)
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> I am not going to read into the record my understanding of the legal standard that applies to a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), or how that rule has been applied in the context of pleading direct infringement. I set forth those standards in my Report and Recommendation in *Boston Fog v. Ryobi*. And I incorporate those standards by reference here.[1]

[1] *Bos. Fog, LLC v. Ryobi Techs., Inc.*, No. 19-2310-LPS-JLH, 2020 WL 1532372, at *3 (D. Del. Mar. 31, 2020), *report and recommendation adopted,* No. 19-2310-LPS-JLH, 2020 WL 8079820 (D. Del. June 12, 2020). A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face when the complaint contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). A possibility of relief is not enough. *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

In determining the sufficiency of the complaint under the plausibility standard, all "well-pleaded facts" are assumed to be true, but legal conclusions are not. *Id.* at 679. "[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (internal marks omitted).

A complaint sufficiently pleads direct patent infringement when it puts the defendant "on notice of what activity . . . is being accused of infringement." *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (quoting *K-Tech Telecomms., Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1284 (Fed. Cir. 2013)); *see also BioMérieux, S.A. v. Hologic, Inc.*, No. 18-21-LPS, 2018 WL 4603267, at *3 (D. Del. Sept. 25, 2018). There is no requirement that the plaintiff "plead facts establishing that each element of an asserted claim is met." *Nalco*, 883 F.3d at 1350 (quoting *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1335 (Fed. Cir. 2012)).

The Federal Circuit has further directed that, at this stage of the litigation, the plaintiff is "entitled to all inferences in its favor on its theory [of infringement]." *Id.* at 1349. And district courts have been cautioned against resolving claim construction disputes at this stage. *Id.* (reversing the district court's dismissal because "Defendants' arguments boil down to objections to [Plaintiff's] proposed claim construction . . ., a dispute not suitable for resolution on a motion to dismiss").

Here, assuming the facts in the SAC to be true, I believe that Plaintiffs have met the threshold for alleging direct infringement by Defendants.

I will start with Count One, which alleges that Defendants' Phoenix Wound Matrix and Rotium Bioresorbable Wick infringe at least claim 1 of the '512 patent. (D.I. 32 ¶ 32.) I'm not going to read claim 1 into the record,[2] but it covers a "nanofiber scaffold for use in repairing" tissue. The claim requires, among other things, first and second layers of polymeric fibers, first and second portions of the scaffold having different tensile strengths, and it requires that the scaffold be configured to be applied to tissue containing the

[2] Claim 1 of the '512 patent recites:

> 1. A multi-laminar electrospun nanofiber scaffold for use in repairing a defect in a tissue substrate, the multi-laminar electrospun nanofiber scaffold comprising:
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> a first layer formed by a first plurality of deposited electrospun polymeric fibers; and
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> a second layer formed by a second plurality of deposited electrospun polymeric fibers, wherein the second layer is combined with the first layer,
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> 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,
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> 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,
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> wherein the multi-laminar electrospun nanofiber scaffold is configured to be applied to the tissue substrate containing the defect,
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> 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
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> 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.

defect, that it be flexible, and that it be configured to degrade via hydrolysis.[3]

In support of the assertion that the Phoenix Wound Matrix includes a nanofiber scaffold for use in repairing a tissue defect, the SAC points to documents that describe the Phoenix Wound Matrix as a conformable three-dimensional matrix made from two types of polymer fibers. (*See, e.g.*, D.I. 32 ¶¶ 28, 34-35, Exs. 5-7.) The SAC also points out that "Defendants' own publications" contain SEM micrographs that illustrate the nanofiber scaffold. (*See, e.g.*, *id.* ¶ 35, Ex. 7.) The SAC further alleges that the Phoenix Wound Matrix is advertised as being bioabsorbed after 14 to 21 days after degrading via hydrolysis. (*Id.* ¶¶ 28, 36, Exs. 5, 7.)

In addition, the SAC walks through every element of claim 1 and alleges that each claim element is met by the Phoenix Wound Matrix; many of those allegations parrot the language of the elements of claim 1 and state that the element is met "on information and belief."[4] (*Id.* ¶ 36.)

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[3] *See id.* I am attempting to describe the invention in a way that facilitates ease of reading and understanding. In so doing, I make some generalizations about the claim elements. Nothing I say here should be taken as the Court's views on any current or future claim construction (or any other) issues.

[4] Paragraph 36 states in its entirety:

> 36. The multi-laminar electrospun nanofiber scaffold includes multiple layers of fibers including 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. On information and belief, the multi-laminar electrospun nanofiber scaffold further includes at least a first portion of a higher density than a second portion of the multi-laminar electrospun nanofiber scaffold. On information and belief, the first portion also has a higher tensile strength than the second portion. The Phoenix Wound Matrix is also advertised as being configured to degrade via hydrolysis after 14-21 days, which is at least one of a predetermined time or an environmental condition. The Phoenix Wound Matrix is and configured to be applied to the tissue substrate containing the defect. Finally, the multi-laminar electrospun nanofiber scaffold making of the Phoenix Wound Matrix includes varying density to be sufficiently flexible to facilitate application of the multi-laminar electrospun nanofiber scaffold to uneven surfaces of the tissue substrate and to enable movement of the multi-laminar electrospun

As for the Rotium Bioresorbable Wick, the SAC alleges that it has substantially the same structure as the Phoenix Wound Matrix. (*Id.* ¶ 37.) The SAC also refers to a SEM micrograph that depicts the nanofibers of the Rotium product and points to exhibits that describe the product for use in healing rotator cuff injuries. (*Id.* ¶ 37, Exs. 8-10.) The SAC also alleges that the Rotium Bioresorbable Wick, as its name suggests, is advertised as being able to be absorbed by the body (i.e., that it degrades) over 3 to 4 months. (*Id.* ¶ 38, Ex. 10.)

The SAC also walks through every element of claim 1 and alleges that each claim element is met by the Rotium Bioresorbable Wick; many of those allegations parrot the language of the elements of claim 1 and state that the element is met "on information and belief."[5] (*Id.* ¶ 38.)

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nanofiber scaffold by the tissue substrate. These acts by Defendants constitute infringement of the '512 patent in violation of 35 U.S.C. § 271(a).

[5] Paragraph 38 states in its entirety:

> 38. The multi-laminar electrospun nanofiber scaffold includes multiple layers of fibers including 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. On information and belief, the multi-laminar electrospun nanofiber scaffold further includes at least a first portion of a higher density than a second portion of the multi-laminar electrospun nanofiber scaffold. On information and belief, the first portion also has a higher tensile strength than the second portion. The Rotium Bioresorbable Wick is designed to be fully absorbed by 3-4 months, which is at least one of a predetermined time or an environmental condition. The Rotium Bioresorbable Wick is configured to be applied to the tissue substrate containing the defect. Finally, the multi-laminar electrospun nanofiber scaffold making of the Rotium Bioresorbable Wick includes varying density to be sufficiently flexible to facilitate application of the multi-laminar electrospun nanofiber scaffold to uneven surfaces of the tissue substrate and to enable movement of the multi-laminar electrospun nanofiber scaffold by the tissue substrate. These acts by Defendants constitute infringement of the '512 patent in violation of 35 U.S.C. § 271(a).

Determining whether a complaint is plausible is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense."[6] I conclude that the allegations set forth in count 1 of the SAC are sufficient to put Defendants on notice of the infringing activity. The SAC specifically identifies two accused products, and it alleges that those products contain every limitation of at least claim 1 of the '512 patent. It also points to promotional materials and other exhibits that demonstrate Plaintiff's view as to how at least some of claim elements of a representative claim are met by the accused products. Under these circumstances, I conclude that the claim is plausible.[7]

Defendants argue that the allegations are insufficient because the SAC fails to plead "specific facts . . . connecting the features of the Accused Products to . . . any claim limitations." I reject that argument. For one thing, as I just explained, the SAC does plead some facts that plausibly suggest that the accused products have some of the claim limitations. For example, the SAC expressly refers to attached exhibits that plausibly support its allegations that the accused products are used for repairing a defect in a tissue substrate, that they contain a nanofiber scaffold, and that they degrade via hydrolysis after a certain period of time. And there is no requirement that the plaintiff "plead facts establishing that each element of an asserted claim is met."[8]

Defendants take issue with Plaintiff's allegations "on information and belief" with respect to the remaining claim elements. But pleading upon information and belief is permissible

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[6] *Iqbal*, 556 U.S. at 679.

[7] *See Align Tech., Inc. v. 3Shape A/S*, 339 F. Supp. 3d 435, 444 (D. Del. 2018) (finding complaint sufficient where it alleged that the accused products practice a representative claim and provided examples drawn from product documentation demonstrating that the accused product possessed at least some of the requirements of the representative claim); *see also Vitaworks IP, LLC v. Prinova US LLC*, No. 19-2260-CFC, 2020 WL 7771040, at *2 (D. Del. Dec. 30, 2020) (denying motion to dismiss notwithstanding plaintiff's contention that the complaint failed to allege facts showing how the accused process practiced each step of the claimed method (citing *Nalco* and *Align Tech.*); *Dynamic Data Techs., LLC v. Brightcove Inc.*, No. 19-1190-CFC, 2020 WL 4192613, at *2 (D. Del. July 21, 2020).

[8] *Nalco*, 883 F.3d at 1350 (quoting *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1335 (Fed. Cir. 2012)); *Dynamic Data*, 2020 WL 4192613, at *2.

where the requisite facts are particularly within the defendant's knowledge and control.[9]

Here, Plaintiffs contend—and Defendants don't seriously dispute—that "given the nature of the technology, it is difficult to determine from a finished product whether the internal structure" of the accused products meets certain claim limitations, for example, the requirement that the claimed nanofiber scaffold have a "first layer" and a "second layer." (D.I. 20 at 19.)

Plaintiffs also contend—and Defendants don't seriously dispute—that Defendants, at least at the time of briefing, had declined to provide discovery that would demonstrate whether the accused products have more than one layer. I'm not saying that Defendants' refusal to provide discovery was inappropriate, but it is a fact. Plaintiffs argue that it is unclear "from publicly available information" whether the accused products have more than one layer (D.I. 20 at 20; D.I. 39 at 11), and Defendants appear to have taken the position that samples of the accused products are not available to the public or competitors for testing or reverse engineering (D.I. 40, Ex. 1). Under these circumstances, I find that Plaintiffs' allegations "on information and belief" are appropriate. I do not recommend dismissal of Count One on that basis.

Defendants also point out that Count Four of the SAC alleges that the accused products infringe the '228 patent, which requires a single layer. According to Defendants, the accused products cannot both infringe the two-layer claims in the '512 patent (Count One) and the single layer claims of the '228 patent (Count Four). And that, according to Defendants, makes both counts implausible. I disagree. It is permissible to plead in the alternative.[10] Moreover, whether the accused products have one layer or multiple layers is a fact that Plaintiffs say they don't have access to and Defendants do. And there are also potential issues with respect to claim construction that are implicated. So, I do not recommend dismissal on that basis.

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[9] *NNCrystal US Corp. v. Nanosys, Inc.*, No. 19-1307-RGA, 2020 WL 616307, at *3 (D. Del. Feb. 10, 2020); *Derma Focus LLC v. Ulthera, Inc.*, 201 F. Supp. 3d 465, 469 (D. Del. 2016) ("So long as plaintiffs do not use 'boilerplate and conclusory allegations' and 'accompany their legal theory with factual allegations that make their theoretically viable claim plausible,'" pleading upon information and belief is permissible under *Twombly/Iqbal* where the requisite facts are peculiarly within the defendant's knowledge or control." (citing *McDermott v. Clondalkin Grp., Inc.*, 649 F. App'x 263, 268 (3d Cir. 2016)).

[10] *Cf. Lifetime Indus., Inc. v. Trim-Lok, Inc.*, 869 F.3d 1372, 1381 (Fed. Cir. 2017) ("[T]he Federal Rules permit a party to plead in the alternative." (citation omitted)).

Defendants' arguments for dismissal of Counts Two through Five mirror Defendants' arguments for dismissal of Count One. I reject Defendants' arguments for the same reasons. Of course, Counts Two through Five pertain to different patents, each of which have different claims with different elements.[11] Counts Three and Five refer only to the Phoenix Wound Matrix product. But the allegations set forth in Counts Two through Five are in substantially the same format as those in Count One. And they state plausible claims for the same reasons that Count One states a plausible claim. In sum, I conclude that Counts One through Five state plausible claims.

I also note that the parties have already negotiated, and the Court has entered, a Protective Order, which means that the discovery that Plaintiffs say they need should be able to be produced if it hasn't already. (D.I. 38.) I also note that the parties have agreed upon the form of a scheduling order that requires the Plaintiffs to provide infringement contentions 30 days after receiving core technical documents and the Plaintiffs have represented at the hearing today that they could provide contentions within approximately 30 days once the scheduling order is entered. (D.I. 26.) Thus, Defendants will soon have more clarity as to what the allegations are. If Plaintiffs press an unsupportable claim of infringement, the Court will deal with that scenario in the appropriate manner at the appropriate time.

Defendants next argue that Counts One through Five should be dismissed as to Defendants Atreon and Paragen on the basis that [the SAC] "fails to provide sufficient notice [to those defendants] of the allegedly infringing conduct." (D.I. 18 at 11.)

I disagree. Essentially, the SAC alleges that each Defendant did everything. Defendants Paragen, RenovoDerm and Atreon are alleged to be subsidiaries of Nanofiber, with the same leadership team. (D.I. 32 ¶¶ 10-11.) The SAC alleges that all Defendants jointly control and direct the manufacture and sale of the accused products (*id.* ¶ 15), and that they are engaged in the business of manufacturing, selling, offering for sale, and/or importing the Phoenix Wound Matrix and the Rotium Bioresorbable Wick, among

[11] (D.I. 32 ¶¶ 39-44 (infringement of '687 patent), 45-49 (infringement of '444 patent), 50-55 (infringement of '228 patent; citing attached exhibits and alleging that the accused products contain poly(glycolic acid) and poly(lactide-co-caprolactone), as required by claim 1), 56-60 (infringement of '409 patent; citing attached exhibits and alleging that the Phoenix Wound Matrix contains more than one type of polymer, as required by claim 44)).

other nanofiber scaffold products. (*Id.* ¶¶ 19, 27, 28, 30.) At this stage, those allegations must be taken as true.[12]

Moreover, regarding Paragen specifically, it is alleged to have been involved in funding the development and commercialization of the Phoenix Wound Matrix. (*Id.* ¶¶ 11-12.) The SAC also contends that Paragen's website refers to nanofiber scaffolds as "our technology." (*Id.* ¶ 7.)

Regarding Atreon specifically, the SAC alleges that its website advertises the Rotium Bioresorbable Wick and that it contains a SEM image illustrating the nanofiber scaffold of that product. (*Id.* ¶¶ 30, 37.) Further, Exhibit 10 is a brochure for the Rotium Bioresorbable Wick and it has Atreon's name on it. It appears to have been put out by Atreon. (*Id.*, Ex. 10.)

That is enough to move forward against all the Defendants at this stage.

For the foregoing reasons, I recommend that the Court deny the motions to dismiss.

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.

Dated: July 28, 2021

The Honorable Jennifer L. Hall
United States Magistrate Judge

[12] *See Align Technology, Inc.*, 339 F. Supp. 3d at 447 ("[Plaintiff] is alleging that both of the Defendants did everything. The allegations must at this stage, be taken as true. Time will tell if plaintiff can prove them.").