IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

LIFENET HEALTH,

Plaintiff,

v. **Civil Action No. 2:13cv486**
****Public Version****

LIFECELL CORPORATION,

Defendant.

OPINION AND ORDER

This matter came before the Court on Defendant's Motion for Summary Judgment, Doc. 137, and Plaintiff's Motion for Partial Summary Judgment, Doc. 182. A hearing was held on October 22, 2014. Ruling from the bench, the Court **DENIED** the Motions. It now issues this Opinion and Order explaining its reasoning.

1. BACKGROUND AND PROCEDURAL HISTORY

A. Procedural History

On September 6, 2013, Plaintiff LifeNet Health ("Plaintiff" or "LifeNet") filed a one-count Complaint, alleging that Defendant LifeCell Corporation ("Defendant" or "LifeCell") has infringed U.S. Patent No. 6,569,200 ("the '200 patent"). Doc. 1. Essentially, Plaintiff is alleging that two of Defendant's products, AlloDerm RTM Ready to Use ("AlloDerm RTU") and Strattice Reconstructive Tissue Matrix ("Strattice"), infringe certain claims in the '200 patent.[1] Id. ¶¶ 24–30. Defendant filed its Answer on November 22, 2013, denying it has infringed the '200 Patent, and additionally asserted the affirmative defenses of non-infringement, invalidity, laches, failure

[1] During discovery, Plaintiff identified other potentially infringing products.

to mark, limitations on damages, prosecution history estoppel, patent exhaustion/implied license, and "other affirmative defenses." Doc. 12.

On July 10, 2014, the Court held a Markman hearing for the purpose of construing eight (8) disputed claim terms. Doc. 116. On July 16, the Court entered its Opinion and Order explaining its claim construction. Doc. 122.

On August 7, 2014, the Court held a telephonic hearing to address cross Motions to Compel, Docs. 46 & 74, filed by the parties. Doc. 127. In an Opinion and Order entered August 19, the Court granted the Motions to Compel in part. Doc. 130.

Defendant's Motion for Summary Judgment ("Defendant's Motion") was filed on August 27, 2014. Doc. 137. Plaintiff responded in opposition on September 11, 2014. Doc. 149. Defendant's submitted its reply brief on September 19. Doc. 195.

Plaintiff's filed its cross Motion for Partial Summary Judgment on September 16, 2014. Doc. 185. Defendant responded in opposition on October 2, 2014. Doc. 210. Plaintiff filed its reply brief on October 9, 2014.[2] Doc. 255.

A two-week jury trial in this case is scheduled to commence on November 3, 2014.

B. Overview of Patent-in-Suit

The '200 patent was issued on May 27, 2003 and is titled "Plasticized Soft Tissue Grafts, and Methods of Making and Using Same." The '200 patent generally describes and claims "a plasticized dehydrated bone and/or soft tissue product that does not require special conditions of storage, for example refrigeration or freezing, exhibits materials properties that approximate those properties present in normal hydrated tissue, is not brittle and does not necessitate rehydration

[2] All of the briefing filed on the two instant Motions before the Court was submitted partially under seal.

prior to clinical implantation." '200 patent at 1:8–13. Essentially, the patent relates to improving the preservation method of soft tissue grafts, resulting in a lesser chance of the graft failing. Doc. 62 at 3–4. According to Plaintiff, this is done "by providing plasticized soft tissue products that are similar in physical, chemical, and biological properties as compared to normal tissue (fresh soft tissues) yet lack the inherent disadvantages ... of fresh-frozen, dehydrated, and freeze-dried soft tissue products." Doc. 65 at 3.

The '200 patent contains fifteen (15) claims, five (5) of which are independent (Claims 1–3, 7, and 15). Plaintiff is asserting claims 1–4, 7–8, and 10. Doc. 65 at 4. These claims are reproduced below.

- ***Claim 1:*** A plasticized soft tissue graft suitable for transplantation into a human, comprising:

  a cleaned soft tissue graft having an internal matrix; and

  one or more plasticizers contained in said internal matrix;

  said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

- ***Claim 2:*** A plasticized soft tissue graft, comprising:

  a cleaned, soft tissue graft; and

  one or more plasticizers, wherein said cleaned soft tissue graft is impregnated with one or more plasticizers, and said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

- ***Claim 3:*** A plasticized soft tissue graft, comprising:

  a cleaned, soft tissue graft comprising one or more plasticizers, and said one or more plasticizers are not removed from an internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

- ***Claim 4:*** The soft tissue graft of any one of claims **1, 2, 3,** wherein said soft tissue graft is suitable for direct transplant into a human without rehydration.

- ***Claim 7:*** A method for producing a plasticized soft tissue graft suitable for transplantation into a human, comprising;

impregnating a cleaned, soft tissue graft with one or more plasticizers to produce a plasticized soft tissue graft, and said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

- ***Claim 8:*** The method of claim 7, said step of impregnating, comprising:

  incubating said cleaned, soft tissue graft with a plasticizer composition comprising one or more plasticizers and one or more biocompatible solvents.

- ***Claim 10:*** The method of claim 8, wherein incubating comprises soaking said cleaned, soft tissue graft in said plasticizer composition.

The Court construed eight (8) disputed terms in the above claims as follows:

Disputed Term	The Court's Construction
"plasticized soft tissue graft"	a load-bearing and/or non-load-bearing soft tissue product, including skin, pericardium, dura mater, fascia lata, and a variety of ligaments and tendons composed of an internal matrix where free and loosely bound waters of hydration in the tissue have been replaced with one or more plasticizers without altering the orientation of the collagen fibers, such that the mechanical properties, including the material, physical and use properties, of the tissue product are similar to those of normal hydrated tissue
"suitable for transplantation into a human"	No further construction needed
"cleaned"	a process during which cellular elements and small molecular weight solutes are removed
"plasticizer"	biocompatible compounds which are soluble in water and can easily displace/replace water at the molecular level.
"said one or more plasticizers are not removed from [an/said] internal matrix of said plasticized soft tissue graft prior to transplantation into a human"	No further construction needed
"impregnating" / "impregnated"	filling or filled
"without rehydration"	without hydrating a plasticized soft tissue graft prior to implantation into a patient
"incubating"	soaking or otherwise exposing

Doc. 122 at 14. The Court also adopted the parties agreed constructions for the following three (3) terms:

1. **internal matrix:** the intercellular substance of such soft tissue including for example ligaments and tendons, including collagen and elastin fibers and base matrix substances

2. **plasticizer composition:** composition which includes one or more plasticizers and one or more biocompatible solvents

3. **biocompatible solvents:** any solvent material which does not provoke an adverse response in the patient

Id. at 7.

2. UNDISPUTED FACTS

A. Infringement/Non-infringement

Plaintiff has accused Defendant's Strattice and AlloDerm RTU products of infringing the '200 patent. Doc. 140-1 at 3.[3] Strattice and AlloDerm RTU are dermal tissue grafts preserved using [redacted]. Id. Cells have been removed from the accused products to make them acellular or de-cellularized. Id. at 14.

Defendant has admitted that the following claim limitations can be found in AlloDerm RTU and Strattice:

a. In claim 1: "a soft tissue graft having an internal matrix" and "one or more plasticizers contained in said internal matrix"
b. In claim 2: "a cleaned, soft tissue graft" and
c. In claim 3: "a cleaned, soft tissue graft comprising one or more plasticizers."

Doc. 190-1 at 6. The accused grafts are [redacted]

[3] Citations to the parties' briefs are to the sealed versions. The parties submitted redacted versions that could be viewed by the public.

[redacted]. Id. at 8, 17–18. Plasticizers are contained within the internal matrix of the accused products. Id. at 9; Doc. 214 at 24. No plasticizers are removed from the internal matrix prior to the manufacture and sale of the products. Doc. 190-1 at 13. Prior to packaging, [redacted]. Id.

The Instructions for Use ("IFU") for the accused products instruct the user to "[s]oak the device for a minimum of 2 minutes using a sterile basin and room temperature saline or room temperature lactated Ringer's solution to cover the mesh." Doc. 140-1 at 3–4; see also Doc. 152-1 at 3–4. Defendant asserts that no evidence exists that surgeons have implanted the accused grafts without following the IFU. Doc. 140-1 at 4; Doc. 152-1 at 4. Defendant has conducted a study showing that a two minute rinse of Alloderm RTU removes [redacted] from the grafts; while Plaintiff does not dispute that such testing occured, Plaintiff argues that the testing is incomplete, does not show if the plasticizer comes from the internal matrix, and is not a material fact. Doc. 140-1 at 4; Doc. 152-1 at 5–6.

Two other accused products are at issue, Conexa and [redacted]. Doc. 140-1 at 4–5. Conexa is a version of Strattice distributed by a third-party, and for the purposes of these Motions, there are no differences between Conexa and Strattice. Id. at 5. The parties dispute whether [redacted] was ever "made, used, offered for sale, or sold" by Defendant. Id.

B. Anticipation

On November 2, 1982, the United States Patent and Trade Office issued Patent No. 4,357,274 ("Werner") and Werner is prior art to the '200 patent. Doc. 140-1 at 5. Werner teaches a dura mater graft, which this Court construed as an example of a soft tissue graft in its

Markman Order.[4] Id. at 5. Werner teaches that the dura mater graft is suitable for transplantation into a human; that the dura mater graft has an internal matrix; that the soft tissue graft is impregnated with a solution containing glycerol, which is a plasticizer; and that water is the solvent for the glycerol solution, which is described in the '200 patent as a suitable biocompatible solvent. Id. at 5–7. The parties dispute whether Werner teaches the necessary elements of a plasticized soft tissue graft, because Plaintiff argues that the process in Werner would change the material properties of the graft. Doc. 152 at 8–9. Plaintiff also disputes the characterization that glycerol is not removed from the graft prior to implantation. Id. at 9. Plaintiff also disputes whether the graft in Warner is cleaned, as taught in the '200 patent. Id. at 8.

C. Willfulness

Plaintiff filed this suit on September 6, 2013. Doc. 140-1 at 6. Prior to filing suit, Plaintiff did not send Defendant notice of the '200 patent. Id. Plaintiff claims it sells three products covered by the '200 patent: DermACELL, OraCELL, and ArthroFlex. Id. Plaintiff did not move for a preliminary injunction in this case. Id. at 7.

3. LEGAL STANDARD

Summary judgment under Rule 56 is appropriate only when the court, viewing the record as a whole and in the light most favorable to the nonmoving party, determines that there exists no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. See, e.g., Celotex Corp. v. Catrett, 477 U.S. 317, 322–24 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248–50 (1986); Terry's Floor Fashions v. Burlington Indus.,

[4] Plaintiff disputes this, focusing on the fact the Court construed the phrase "plasticized soft tissue graft." Doc. 152-1 at 7. However, the Court's construction combined two definitions from the specification to reach its construction: "plasticization" and "soft tissue graft." Doc. 122 at 8. The specification lists a dura mater graft as an example of a soft tissue graft. Id.

763 F.2d 604, 610 (4th Cir. 1985). Once a party has properly filed evidence supporting the motion for summary judgment, the nonmoving party may not rest upon mere allegations in the pleadings, but must instead set forth specific facts illustrating genuine issues for trial. Celotex, 477 U.S. at 322–24. Such facts must be presented in the form of exhibits and sworn affidavits. Failure by plaintiff to rebut defendants' motion with such evidence on his behalf will result in summary judgment when appropriate. "[T]he plain language of Rule 56(c) mandates the entry of summary judgment...against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322.

A mere scintilla of evidence is insufficient to withstand a motion for summary judgment. Rather, the evidence must be such that the fact-finder reasonably could find for the nonmoving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). Although the court must draw all justifiable inferences in favor of the nonmoving party, in order to successfully defeat a motion for summary judgment, a nonmoving party cannot rely on "mere belief or conjecture, or the allegations and denials contained in his pleadings." Doyle v. Sentry Ins., 877 F. Supp. 1002, 1005 (E.D. Va. 1995) (citing Celotex, 477 U.S. at 324).

4. DISCUSSION

Defendant asked for summary judgment on the following grounds: (1) that Defendant has not infringed the '200 patent because the plasticizer is removed from the internal matrix of the grafts prior to transplantation into a human; (2) that the claims in the '200 patent are invalid as indefinite; (3) that the claims in the '200 patent are invalid as anticipated; and (4) that Defendant has not willfully infringed the '200 patent. Plaintiff asked for partial summary judgment on the

issue of infringement.

A. Infringement/Non-infringement

Defendant moved the Court to find non-infringement on the ground that plasticizers are removed from its skin grafts prior to transplantation. Plaintiff moved for summary judgment on claim of infringement on the ground that Defendant's products meet every claim limitation in the asserted claims.

"'[W]ho ever without authorization makes, uses, offers to sell, or sells any patent invention, within the United States or imports into the United States any patented invention during the term of the patent therefor [directly] infringes the patent.'" Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1310 (Fed. Cir. 2005) (quoting 35 U.S.C. § 271(a)). When conducting an infringement analysis, after properly construing the claims, the Court compares the construed claims "to the allegedly infringing device to determine whether all of the claim limitations are present[.]" Innovention Toys, LLC v. MGA Entm't, Inc., 637 F.3d 1314, 1318 (Fed. Cir. 2011). "In order to prove direct infringement, a patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd., 501 F.3d 1307, 1313 (Fed. Cir. 2007). "[S]ummary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue whether the accused device is encompassed by the claims." Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1341 (Fed. Cir. 2001) (internal quotation marks omitted).

Defendant argued that in its products, plasticizer is removed from the internal matrix of the grafts prior to transplantation, and thus necessarily falls outside the scope of the claim language.

The Instructions for Use ("IFU") for the products instruct surgeons to rinse the grafts in either a saline solution or lactated Ringer's solution for a minimum of two minutes. Doc. 140-1 at 9. Defendant offered a study in support of its motion showing that [redacted], is removed from the grafts by rinsing it in saline for two minutes. Id. at 10.

Plaintiff presented five arguments in opposition. First, Plaintiff argued that the IFU are irrelevant to the infringement analysis, because there is no temporal limitation in the claims. Doc. 152-1 at 11. Second, Plaintiff argued that the Federal Circuit has rejected arguments similar to Defendant's. Id. at 12. Third, Plaintiff argued that the Cavalarro patent, which this Court considered in its claim construction, only discussed the removal of plasticizers during manufacturing, and thus does not control the removal of plasticizer after manufacturing. Id. at 14. Fourth, Plaintiff argued that Defendant offered no evidence that the rinse is necessary. Id. at 16. Fifth, Plaintiff also argued that Defendant's study is not dispositive on the issue of whether plasticizer is removed. Id.at 17.

First, the Court's Markman order is clear: "not removed" means that no plasticizer is removed. Doc. 122 at 11. Second, while the Court did not construe the phrase "prior to transplantation into a human," the Court did find that the plain language required no construction. Id. at 10. Moreover, in construing the term "suitable for transplantation into a human," the Court found that the words "implant" and "transplant" were used interchangeably in the patent. Id. at 9. The focus at the Markman hearing was on the "not removed" limitation, and neither party's argument focused on the precise term "prior to transplantation" in terms of temporal scope; rather, they focused on whether the term covered human and/or animal tissue. Doc. 122 at 9. However,

Plaintiff cannot argue that "prior to transplantation" refers to prior to packaging; the claims could have so read if that is what it intended.

For similar reasons, Plaintiff's argument that the rinse is not necessary does not defeat summary judgment. The claim language does not state that the plasticizers "need not" be removed but that they "are not" removed. See Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 832 (Fed. Cir. 1991) (finding that "the accused device, to be infringing, need only be capable of operating in the page mode" when the operative word in the claim was "programmable"); see also Fantasy Sports Properties, Inc. v. Sportsline.com, 287 F.3d 1108, 1117–18 (Fed. Cir. 2002) ("Intel [ ] does not stand for the proposition, as argued by Fantasy, that infringement may be based upon a finding that an accused product is merely capable of being modified in a manner that infringes the claim of a patent."). Accordingly, the fact that the graft could be transplanted into a human without undergoing the saline rinse, thus potentially removing the plasticizers, is not relevant when the claim language states that the plasticizers are "not removed." Additionally, the claim language states that the accused graft is one where plasticizers are not removed prior to transplantation; the final act is transplantation, and the graft can only infringe upon the patent if there is no removal of plasticizers. Thus, the fact that the graft is transplanted after Defendant sells it is entirely relevant to the infringement analysis. See Fantasy Sports, 287 F.3d at 1118 ("in every infringement analysis, the language of the claims, as well as the nature of the accused product, dictates whether an infringement has occurred.").

However, a genuine dispute of material fact exists as to whether plasticizer is removed from the grafts prior to transplantation. Defendant's strongest piece of evidence is the rinse study that shows that portions of the plasticizers are removed after a two-minute rinse in saline. Doc.

141-4. Defendant's expert states that these results are consistent with the basic scientific principle of diffusion, as does the inventor of the patent. Doc. 140-1 at 8.

Plaintiff, however, countered that the study is not conclusive. AlloDerm RTU and Strattice are packaged wet in [redacted]. Doc. 152-1 at 17 n.3. Plaintiff thus argued that this can explain why Defendant's study shows that plasticizer is "removed." Id. at 17. If the plasticizer does not come from the internal matrix, but rather comes from the exterior of the graft, then there would be no removal from the internal matrix. Plaintiff's expert argues that "the study does not provide enough information to properly draw conclusions regarding the removal of [the plasticizers]" and whether they plasticizers came from the internal matrix. Doc. 157-1 at 9. According to Plaintiff's expert, because the graft is [redacted], the study needs to know all of the starting inputs, and argues that one of the major assumptions in the study is incorrect. Id. at 10. Thus, a genuine dispute exists as to whether the two-minute rinse removes plasticizer from the internal matrix of the accused products. See Hilgraeve, 265 F.3d at 1344 (reversing a grant of summary judgment of non-infringement when the Federal Circuit found the tests offered by Defendant in support of its motion were inconclusive).

Moreover, Defendant's argument that the process of diffusion, in which molecules transfer from an area of high concentration to low concentration, also provide definitive proof that plasticizer is removed from the internal matrix of the skin grafts, thus rending them outside the claim language, does not compel a contrary conclusion. Doc. 140-1 at 10. Plaintiff's expert explains that the diffusion process can take longer than two minutes to remove the plasticizers from the internal matrix. Doc. 157-1 at 13. Thus, if Plaintiff's expert is to be believed over Defendant's expert, a reasonable jury could find that no plasticizer is removed from the graft prior

to transplantation, and thus find that the accused devices infringe. Both experts have impressive resumes, no motions to strike the experts' declarations have been filed, and these are the same experts proffered by the parties when the Court issued its Markman Order. Accordingly, the Court **DENIED** Defendant's Motion on the grounds of non-infringement.

Furthermore, this same dispute as to the removal of plasticizers precludes summary judgment in favor of the Plaintiff. If a reasonable jury were to believe Defendant's expert over Plaintiff's, than it could find that plasticizer is removed from the internal matrix of the grafts prior to transplantation by soaking the product in a two-minute rinse, and thus find that Defendant has not infringed the '200 patent. As discussed above, the cases in which the Federal Circuit state that a product only need to be capable of infringing do not apply because the claim language does not state "need not be removed" but states "are not removed." See Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358, 1370 (Fed. Cir. 2009) (finding infringement where eyeglasses were not sold in an infringing manner, but are capable of being using in an infringing way because claim language required the eyeglass to be "capable of engaging magnetic members from the top."). Accordingly, the Court **DENIED** Plaintiff's Motion for Partial Summary Judgment.[5]

B. Indefiniteness

Defendant next argued that the "not removed" and "plasticized" limitations in the claims renders the patent invalid for indefiniteness.

Whether a patent is invalid is a legal question. Enzo Biochem, Inc. v. Applera Corp., 599 F.3d 1325, 1331 (Fed. Cir. 2010). "[A] patent is invalid for indefiniteness if its claims, read in

[5] The Court notes that Plaintiff brought forth arguments on all of the claim limitations, and that Defendant vigorously opposed these grounds for summary judgment as well. The Court did not consider these additional issues at the hearing, because the "not removed" limitation is found in all of the asserted claims, and thus precludes a summary judgment of infringement as to any of the asserted claims.

light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014). "'Because a patent is presumed to be valid, the evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence.'" Enzo Biochem, 599 F.3d at 1331 (quoting Young v. Lumenis, Inc., 492 F.3d 1336, 1344 (Fed. Cir. 2007)). "[W]here the ... 'clear and convincing evidence requirement applies, the trial judge's summary judgment inquiry as to whether a genuine issue exists will be whether the evidence presented is such that a jury applying that evidentiary standard could reasonably find for either the plaintiff or the defendant.'" Talecris Biotherapeutics, Inc. v. Baxter Intern. Inc., 510 F. Supp. 2d 356, 359 (D. Del. 2007) (quoting Anderson, 477 U.S. at 255–56)).

Defendant focused on two limitations in the claims: "not removed" and "plasticized soft tissue graft." Defendant argued that the "not removed" limitation is indefinite for two reasons: (1) that it claims a product with a limitation on how it is used and (2) if the claims permit some removal of plasticizer before transplantation, then all asserted claims would be indefinite for failing to convey the scope of its claims with reasonable certainty. Doc. 140-1 at 16–19. Defendant further argued that the "plasticized soft tissue graft" limitation renders the claims indefinite because the Court's construction of the term fails to give a clear meaning, as evidenced by the inventors' deposition testimony. Id. at 19–20.

Plaintiff countered that Defendant fails to offer evidence of how an ordinary person in the art would read the claims at the time the patent was filed, and thus its motion necessarily fails. Doc. 152-1 at 19–20. Plaintiff also argued that the "not removed" limitation does not improperly mix a product and method claim. Id. at 21–22. Plaintiff also argued that the inventor's testimony

stating that they do not understand the Court's claim construction does not resolve the issue of indefiniteness. Id. at 23–24.

1. "Not removed"- improper claiming of a product with a limitation on how it can be used

Defendant's first argument focused on how the asserted product claims (claims 1-4) are indefinite because they claim a product with a limitation on how the product can be used. Doc. 140-1 at 17.

"Courts must generally take care to avoid reading process limitations into an apparatus claim, because the process by which a product is made is irrelevant to the question of whether that product infringes a pure apparatus claim." Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1344 (Fed. Cir. 2008) (internal citations omitted). The Federal Circuit has applied the principle that "reciting both an apparatus and a method for using that apparatus renders a claim indefinite[.]" IPXL Holdings, L.L.C. v. Amazon.com, Inc., 430 F.3d 1377, 1384 (Fed. Cir. 2005). However, "apparatus claims are not necessarily indefinite for using functional language." Microprocessor Enhancement Corp. v. Texas Instruments, Inc., 520 F.3d 1367, 1375 (Fed. Cir. 2008).

Defendant argued that the "not removed" language impermissibly includes a method step in a product claim, while Plaintiff argued that the language is not a method step but describes a feature of the graft. Defendant pointed to the following excerpt from the Markman hearing, when the following exchange occurred:

> THE COURT: I don't think you can deliberately remove it when you open the container and get ready to transplant it or implant it, which could be more than saying the patient, nor do I think you can argue that the patent says you can. But, I mean, losing some in the formulation process is not removing it, I believe.

> PLAINTIFF: Okay. Thank you, Your Honor. My last point is this, is that the words there, one of ordinary skill in the art, when it says are not removed, would not be viewed as a step. It would be viewed as a property. Plasticizer are not removed as a property of what's in there, and that would not necessarily mean it has to all be in. So thanks.
>
> THE COURT: I mean, if you're applying it and some of the plasticizer escapes in the transplantation process, that is not removing it, in my view. But I don't think you can take the step of remove.

Doc. 120 at 68–69.

The Court's concern on the Markman hearing was not that Plaintiff was advocating the combination of a method and product claim, but rather its attempts to argue that "not removed" allowed for "some" removal. Additionally, the language of the patent uses "not removed" in both the apparatus claim and the method claim, and thus the Court referring to a "step" does not compel a finding of invalidity at this stage in the proceeding. For example, in IPXL Holdings, the claim clearly recited a system and a method, reading, "The system of claim 2 [including an input means] ... and the user uses the input means to either change the predicted transaction information or accept the displaced transaction type and transaction parameters." IPXL Holdings, 430 F.3d at 1384 (quoting '055 patent, at 22:8–13). Thus, it was "unclear whether infringement of claim 25 occurs when one creates a system that allows the user to change the predicted transaction information or accept the displayed transaction, or whether infringement occurs when the user actually uses the input means to change transaction information or uses the input means to accept a displayed transaction." Id.

This case, however, is more akin to HTC Corp. v. IPCom GmbH & Co., KG, 667 F.3d 1270 (Fed. Cir. 2012). In HTC, the disputed claim read "A mobile station for use with a network including a first base station and a second base station that achieves a handover from the first base

station to the second base station by [implementing six functions], the mobile station comprising an arrangement for reactivating the link with the first base station if the handover is unsuccessful." Id. at 1274 (quoting '830 patent at 8:12–32). If the mobile station implemented the functions, the claims would be indefinite because it would impermissibly claim an apparatus and method; if the network performed the functions, the claims would not indefinite because it would simply describe the environment in which the mobile station must be used. Id. The Federal Circuit said that the claim language made it clear "that infringement occurs when one makes, uses, offers to sell, or sells the claimed apparatus: the mobile station—which must be used in a particular environment." Id. at 1277.

Likewise, here the apparatus claims are the graft itself, one in which no plasticizer has been removed prior to transplantation. The Court's explanation from the bench is not dispositive on this issue; it was referring to the process by which one gets to the claimed graft. The method by which the graft is produced can be found in a separate claim, claim 7. See '200 patent at 24:39–45. The Court was not clearly referring to the apparatus claim on the bench, it was discussing the language of "are not removed," which is included in the method claim. Thus, the method in claim 7, not removing the plasticizer, results in the product found in claims 1–4, a skin graft in which plasticizers are not removed. Therefore, the Court's Markman Order does not compel a finding of invalidity.

2. Failure to convey the scope of the claims with reasonable certainty

Defendant next argued that if the Court were to find that the claims permit deliberate actions to remove plasticizer, then the claims would be indefinite for creating a zone of uncertainty, because a surgeon would not know when s/he would be infringing the patent. Doc.

140-1 at 18–19. Plaintiff argued that this argument necessarily fails because Defendant fails to argue how one of ordinary skill in the art would view the patent at the time it was filed, and second the parties dispute the qualifications of one of ordinary skill in the art so as to itself create a genuine dispute of material fact. Doc. 152-1 at 19–20.

However, this argument assumes the Court is taking, or will take, a position that it has not. The Court has made it clear that Plaintiff cannot argue that some removal would be permissible, but can explain that some may escape in the transplantation process. Even if a surgeon would conclude that a two-minute rinse removes all of the plasticizer, that conclusion would not come from the language of the claim itself. The Court made it clear that the language of the claims itself was clear: no plasticizer can be removed. Thus, the Court can find the claims are not indefinite, regardless of whether the parties dispute who the person of ordinary skill in the art is.[6]

3. The "plasticized soft tissue graft" renders the claims indefinite

Defendant next argued that the Court's claim construction, in which it adopted the majority of Plaintiff's proposed construction of this term, renders the claims indefinite. Doc. 140-1 at 19. Defendant offered the testimony of two of the inventors of the '200 patent who testified in their depositions they do not understand the Court's construction. Id. at 19–20. Plaintiff argued that this testimony is not dispositive. Doc. 152-1 at 23–24.

The Court adopted the following construction of a plasticized soft tissue graft:

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[6] Defendant argues that a person of ordinary skill in the art ("POSA") is someone with "a Master of Science degree in biology, biochemistry, physiology, pathology, toxicology, biomaterials engineering, biomedical engineering or a related field, and a minimum of five years of experience related to processing tissue for implantation into humans or animals." Doc. 64 at 5. Alternatively, in lieu of a M.S., a POSA could have a Ph.D., M.D., or D.V.M., and three years of relevant experience. Id. Plaintiff instead argues that a POSA has "a bachelor of science degree in biology, chemistry, physiology, biochemistry, or related field, and five years of research or work experience related to preparing and processing tissue for transplantation into a human patient" or alternatively a M.S. and three years of relevant experience. Doc. 157 at 6. Both parties' experts asserted that at claim construction, this issue of a different POSA did not alter their arguments. Doc. 64 at 6, Doc. 88 at 6.

> a load-bearing and/or non-load-bearing soft tissue product, including skin, pericardium, dura mater, fascia lata, and a variety of ligaments and tendons composed of an internal matrix where free and loosely bound waters of hydration in the tissue have been replaced with one or more plasticizers without altering the orientation of the collagen fibers, such that the mechanical properties, including the material, physical and use properties, of the tissue product are similar to those of normal hydrated tissue.

Doc. 122 at 7–8. All of this language came from the specification; the issue was how much language to pull from the specification. Id. Defendant now states that the inventors of the patent do not know what this language means.

One of the inventors, Dr. Robert K. O'Leary testified that the phrase "the mechanical properties, including the material, physical and use properties, of the tissue product are similar to those of normal hydrated tissue" was "too vague" and that "[y]ou don't really get an understanding of what he means." Doc. 138-6 at 4. He also testified, however, "It could refer to slipperiness. It could refer to flexibility. It could refer to color." Id. Another inventor, Dr. Lloyd Wolfinbarger, Jr., testified that he had "no earthly idea what the Court was thinking about." Doc. 141-7 at 4. Thus, according to Defendant, a zone of uncertainty is created. Neither inventor offered an alternate construction of the term plasticized soft tissue graft.

Plaintiff argued, however, that the inventor's testimony is not dispositive of this issue. Doc. 152 at 23. Moreover, Plaintiff argued that the deposition questions were misleading. Id. at 24.

This Court is bound by the Federal Circuit on this issue, which has reversed a district court for using "inventor testimony, obtained in the context of litigation" to make a finding of invalidity under section 112, paragraph 2. Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1380 (Fed. Cir. 2000); see also Markman v. Westview Instruments, Inc., 52 F.3d 967, 985 (Fed. Cir. 1995)

("The subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim[.]"). Defendant offered no other evidence in support of its proposition that the plasticized soft tissue graft limitation is indefinite other than the inventor testimony. Moreover, Plaintiff's expert disputes the characterization of the inventors, stating that a person of ordinary skill in the art would understand the plasticized soft tissue graft limitation. Doc. 157-1 at 30–31. Thus, summary judgment is inappropriate.

Accordingly, the Court **DENIED** summary judgment on the grounds of indefiniteness.

C. Anticipation

Defendant's next argument was that the '200 patent was anticipated by prior art, the Werner patent. Plaintiff responded that Werner does not disclose a "plasticized soft tissue graft" nor does it disclose the "cleaned" limitation.

"To show that a patent claim is invalid as anticipated, the accused infringer must show by clear and convincing evidence that a single prior art reference discloses each and every element of a claimed invention." Kippelz v. Ford Motor Co., 667 F.3d 1261, 1265 (Fed. Cir. 2012). Anticipation is a question of fact, but "'it may be decided on summary judgment if the record reveals no genuine dispute of material fact.'" Leggett & Platt, Inc. v. VUTEk, Inc., 537 F.3d 1349, 1352 (Fed. Cir. 2008) (quoting Golden Bridge Tech. Inc. v. Nokia, Inc., 527 F.3d 1318, 1321 (Fed. Cir. 2008)). "Summary judgment is proper if no reasonable jury could find that the patent is not anticipated." Zenith Elecs. Corp. v. PDI Commc'n Sys., Inc., 522 F.3d 1348, 1357 (Fed. Cir. 2008).

1. Plasticized soft tissue graft

Werner teaches a dura mater graft, which the '200 patent explains is an example of a soft

tissue graft. Doc. 140-1 at 22. The parties' dispute focused on whether the graft is plasticized. Defendant argued that the Werner graft is plasticized because it meets the construction of the "plasticized soft tissue graft." First, Defendant argued Werner "discloses that plasticizer replaces free and loosely bound waters of hydration." Id. at 23. Second, Defendant argued that Werner uses a suitable plasticizer because it uses glycerol, a suitable plasticizer in the '200 patent, and Werner uses the same concentration of glycerol that is preferred in the '200 patent. Id. Finally, Defendant argued that the graft in Werner has similar properties to that of normal hydrated tissue. Id. at 24.

Plaintiff argued that the process disclosed in Werner, manufacturing sclera proteins, are distinct from the preservation of tissue grafts in the '200 patent. Doc. 152-1 at 26. Additionally, Plaintiff argued that the orientation of the collagen fibers is altered in Werner, thus changing the material properties of the graft. Id. Finally, Plaintiff argued that the graft in Werner is strengthened, thus showing that it is not the "plasticized soft tissue graft" created in the '200 patent. Id. at 27. Defendant argued that Plaintiff's arguments are contradicted by the disclosures in the '200 patent. Doc. 198-1 at 17.

The experts in this case disagree as to this issue, and summary judgment is normally inappropriate when a material dispute exists "as to the credibility and weight that should be afforded to conflicting expert reports[.]" Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp., 635 F.3d 1373, 1384 (Fed. Cir. 2011). Thus, the Court believed a genuine dispute of material fact existed as to this issue, precluding it from granting Defendant's Motion on this issue.

2. Cleaned

The Court construed "cleaned" to mean "a process during which cellular elements and small molecular weight solutes are removed." Doc. 122 at 9. Defendant argued that "Werner discloses a cleaning process in which raw dura mater is 'put into 2% to 20%, preferable 5% H_2O_2 for 48 hours,' then 'degreased' in 'acetone-diethylether 1:1 for 4 hours,' and finally 'rinsed for 12 to 24 hours with water.'" Doc. 140-1 at 24 (quoting '274 patent at 2:50–57). According to Defendant's expert, this would "remove cellular elements and small molecular weight solutes from the soft tissue graft." Id. at 25; see also Doc. 142-1 at 6. Plaintiff argued that Werner fails to disclose a cleaned soft tissue graft, or at the very least, there is a genuine dispute as to whether it does. Doc. 152-1 at 27.

Plaintiff's expert focuses on two facts: first, that the degreasing process identified in Werner would remove lipids, and that while some cellular material may be extracted, there likely remain cellular elements in the graft; and second, that the cleaning process used in Werner was insufficient, as many patients contracted mad cow disease as a result of insufficient cleaning in dura mater grafts. Doc. 157 at 34–35.

While the Court's claim construction does not require that all of the cellular elements be removed, the fact that the grafts in Werner were capable of passing disease indicates that they were not "cleaned." As a result of the mad cow issue, cleaning practices were amended to reduce the risk of transmission. Doc. 151-35 at 2–3. The '200 patent was concerned with reducing the risk of disease transmission from the grafts. See, e.g., '200 patent, Abstract. The description of the cleaning process in the specification discusses a process where "virtually all" cellular elements are removed. Id. at 11:5–6. Thus, there is a genuine dispute as to whether the Werner grafts were

"cleaned" as the term was construed by the Court.

Accordingly, the Court **DENIED** Defendant's motion as to anticipation.

D. Willful Infringement

For its last argument, Defendant argued that it is entitled to summary judgment of no willful infringement, because it has reasonable defenses, and furthermore because Plaintiff did not file for a preliminary injunction, it is at the least entitled to a finding of no willful infringement post-filing. Doc. 140-1 at 27–30.

A finding of willful infringement permits recovery of enhanced damages. Virginia Innovation Scis., Inc. v. Samsung Elecs. Co., Ltd., 983 F. Supp. 2d 713, 746 (E.D. Va. 2014) (citing In re Seagate Tech., 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc)). This requires the patentee to make a showing of objective recklessness. Virginia Innovation, 983 F. Supp. 2d at 746. To meet this standard, "a patentee must demonstrate 'by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.'" Id. (quoting In re Seagate Tech., 497 F.3d at 1371). "[O]n willful infringement at the summary judgment stage, the burden remains on Plaintiff to establish by clear and convincing evidence that Defendants willfully infringed the asserted patents." Virginia Innovation, 983 F. Supp. 2d at 747. Generally, if a reasonable defense of infringement exists, the objective prong of the test is not met. Id. (quoting Bard Peripheral Vascular, Inc. v. WL Gore & Associates, 682 F.3d 1003, 1005–6 (Fed. Cir. 2012). "While the fact that an issue was submitted to a jury does not automatically immunize an accused infringer from a finding of willful infringement," it is relevant to the analysis. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314, 1337 (Fed. Cir. 2009).

As a threshold matter, the fact that Plaintiff did not file for a preliminary injunction does not create a per se bar to a finding of post-filing willful infringement. Netscape Commc'ns. Corp. v. ValueClick, Inc., 684 F. Supp. 2d 699, 728 (E.D. Va. 2010). However, it is relevant to the issue of willfulness. Id.

Plaintiff has provided enough evidence at this stage on the subjective prong to defeat summary judgment. Defendant was given notice of a patent that cited the '200 patent as a reference in its rejected patent application.

Defendant argued, however, that Virginia Innovation controls in this case, and that this subjective evidence carries no weight. However, Virginia Innovation is distinguishable. As this Court noted, "a mere assertion of an invalidity defense will not necessarily negate a claim of willful infringement." Virginia Innovation, 983 F. Supp. 2d at 747. When the defense at issue is invalidity, "where there is a genuine issue of material fact which prevents a decision at the summary judgment stage and the factual question is a close one on which the jury could find for either party, the defense of invalidity is a reasonable one." Virginia Innovation, 983 F. Supp. 2d at 748. The defendant in Virginia Innovation, however, actually had its motion for summary judgment granted in part, whereas LifeCell's invalidity motion was denied in its entirety. Id.

Moreover, while the Court believes a dispute of material fact exists as to LifeCell's defenses, they may not be as strong as Defendant would like the Court to believe. For example, Plaintiff has argued that Defendant's two-minute rinse defense may not remove all plasticizers, or any from the internal matrix, and that Defendant's IFU are more like guidelines than bright-line rules. Additionally, the Court noted the conflicting views of the parties on the issue of testing. Furthermore, Defendant's invalidity argument stretched the Court's claim construction beyond

what it intended, and also relied on a point of law that may give controlling weight to the inventor's deposition testimony. Additionally, the battle of the experts as to the anticipation defense may not be as close as Defendant argues. Thus, at this stage, the Court cannot make a finding of no willful infringement as a matter of law.

Accordingly, the Court **DENIED** summary judgment as to willfulness. The Court did caution that Plaintiff should not raise the issue of willfulness in its opening statement, as Defendant may renew its motion for judgment as a matter of law on this issue at the close of Plaintiff's case-in-chief.

5. CONCLUSION

Accordingly, the cross Motions for Summary Judgment, Docs. 137 & 182, were **DENIED**.

The Clerk is **REQUESTED** to deliver a copy of this Order to all counsel of record.

It is so **ORDERED**.

/s/
Henry Coke Morgan, Jr.
Senior United States District Judge.
HENRY COKE MORGAN, JR.
SENIOR UNITED STATES DISTRICT JUDGE

Norfolk, VA
Date: October 27, 2014