

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



LIFENET HEALTH,

Plaintiff,

v.

Civil Action No. 2:13cv486

LIFECCELL CORPORATION,

Defendant.

OPINION AND ORDER

On Thursday, July 10, 2014, the Court conducted a Markman hearing for the purpose of construing eight (8) disputed terms in the patent at issue. Upon consideration of the parties' briefs, oral argument, and visual presentations in support thereof, the Court ruled from the bench and hereby issues this Opinion and Order further detailing the Court's claim construction.

I. FACTUAL BACKGROUND & 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 and Stratice Reconstructive Tissue Matrix, infringe certain claims in the '200 Patent. Id. ¶¶ 24–30.

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

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).

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 to mark, limitations on damages, prosecution history estoppel, patent exhaustion/implied license, and "other affirmative defenses." Doc. 12. On March 27, 2014, the Court entered its Rule 16(b) Scheduling Order. Doc. 29. The parties filed their claim construction briefs on June 10, 2014. Docs. 62, 65. Their reply briefs were filed on June 24, 2014. Docs. 83, 86. The joint claim construction statement was filed on July 3, 2014. Doc. 95.

II. LEGAL PRINCIPLES OF CLAIM CONSTRUCTION

A. General Principles

The purpose of a Markman hearing is to assist the Court in construing the meaning of the patent(s) at issue. Markman v. Westview Instruments, Inc., 517 U.S. 370, 371 (1996); Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). Patents consist of "claims," and the construction of those claims is a matter of law, to be determined by the Court. Markman, 52 F.3d at 970–71. A court need only construe, however, claims "that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) (citations omitted). To be clear,

"[c]laim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy." NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1311 (Fed. Cir. 2005) (quoting U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997)).

Claim construction begins with the words of the claims. Vitronics Corp. v. Conceptromc, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Words in a claim are generally given their ordinary meaning as understood by a person of ordinary skill in the art ("POSA") as of the effective date of the patent. Phillips v. AWH Corp., 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). This "person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. at 1313. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314. Often, however,

determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks 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.

Id. (internal quotation marks and citation omitted).

Further, the claims themselves can "provide substantial guidance as to the meaning of particular claim terms." Id. First, "the context in which a term is used in the asserted claim can be highly instructive." Id. In addition, other claims of the patent in question, both asserted and

unasserted, can also be useful because claim terms are "normally used consistently throughout the patent," and therefore "can often illuminate the meaning of the same term in other claims." Id.

The claims should not be read alone, however, but rather should be considered within the context of the specification of which they are a part. Markman, 52 F.3d at 979. As the Federal Circuit stated in Vitronics and restated in Phillips, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (internal quotation marks and citation omitted). Furthermore, a patentee is free to be his or her own lexicographer, and thus if the patentee defines a term in the specification differently than its ordinary meaning, the patentee's definition controls. Id. at 1316. The Court, however, must not read in limitations from the specification without clear intent to do so. Thorer v. Sony Comp. Entm't. Am. LLC, 669 F.3d 1362, 1366 (Fed. Cir. 2012).

In addition to consulting the specification, a court may also consider the patent's prosecution history, if in evidence, because it provides information regarding how the United States Patent and Trademark Office ("USPTO") and the inventor understood the patent. Phillips, 415 F.3d at 1317. It also enables the Court to determine if the inventor limited the invention during the course of prosecution. Id. The Court may also consult prior art references in the prosecution history. Vitronics, 90 F.3d at 1583. "[W]here an applicant whose claim is rejected on reference to a prior patent ... voluntarily restricts himself by an amendment of his claim to a specific structure, having thus narrowed his claim in order to obtain a patent, he may not by construction ... give the claim the larger scope which it might have had without the amendments." I.T.S. Rubber Co. v. Essex Rubber Co., 272 U.S. 429, 444 (1926).

These elements of the patent itself—the claims, the specification, and its prosecution history—constitute intrinsic evidence of claim construction. In addition to such intrinsic

evidence, a court may consider extrinsic evidence to determine the meaning of disputed claims. Phillips, 415 F.3d at 1317. Such extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. (quoting Markman, 52 F.3d at 980). However, the Court should not rely on extrinsic evidence when the intrinsic evidence removes all ambiguity. Vitronics, 90 F.3d at 1583.

Such extrinsic evidence is generally held as less reliable than the intrinsic evidence and "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of intrinsic evidence." Phillips, 415 F.3d at 1317–18. With respect to expert evidence, for example, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court . . . [and] a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." Id. at 1318 (internal quotation marks and citation omitted).

With respect to general usage dictionaries, the Federal Circuit noted that "[d]ictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words and have been used . . . in claim interpretation," and further noted that "a dictionary definition has the value of being an unbiased source 'accessible to the public in advance of litigation.'" Id. at 1322 (quoting Vitronics, 90 F.3d at 1585). However, the Federal Circuit cautions that (1) "a general-usage dictionary cannot overcome art-specific evidence of the meaning' of a claim term;" (2) "the use of the dictionary may extend patent protection beyond what should properly be afforded by the inventor's patent," and (3) that "[t]here is no guarantee that a term is used in the same way in a treatise as it would be by the patentee." Phillips, 415 F.3d at 1322 (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1321

(Fed. Cir. 2004)).¹ Indeed, "different dictionary definitions may contain somewhat different sets of definitions for the same words. A claim should not rise or fall based upon the preferences of a particular dictionary editor, . . . uninformed by the specification[.]" Phillips, 415 F.3d at 1322.

B. The "Canons of Claim Construction"

The Federal Circuit has recognized certain guideposts, or "canons of construction," to assist a court in determining the meaning of disputed claim terms and phrases. These are merely guideposts, however, and are not immutable rules:²

1. Doctrine of Claim Differentiation: Ordinarily, each claim in a patent has a different scope. See, e.g., Versa Corp. v. Ag-Bag Int'l Ltd., 392 F.3d 1325, 1330 (Fed. Cir. 2004). Ordinarily, a dependent claim has a narrower scope than the claim from which it depends. See, e.g., Phillips, 415 F.3d at 1315. Ordinarily, an independent claim has a broader scope than a claim that depends from it. See, e.g., Free Motion Fitness, Inc. v. Cybex, Int'l, Inc., 423 F.3d 1343, 1351 (Fed. Cir. 2005).
2. Ordinarily, claims are not limited to the preferred embodiment disclosed in the specification. See, e.g., Phillips, 415 F.3d at 1323.
3. Ordinarily, different words in a patent have different meanings. See, e.g., Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1119–20 (Fed. Cir. 2004).
4. Ordinarily, the same word in a patent has the same meaning. See, e.g., Phillips, 415 F.3d at 1314.
5. Ordinarily, the meaning should align with the purpose of the patented invention. See, e.g., Innovad Inc. v. Microsoft Corp., 260 F.3d 1326, 1332–33 (Fed. Cir. 2001).

¹ In Phillips, the Federal Circuit thus expressly discounted the approach taken in Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002), in which the court placed greater emphasis on dictionary definitions of claim terms. Phillips, 415 F.3d at 1319–24. The Federal Circuit reaffirmed the approach in Vitronics, Markman, and Innova as the proper approach for district courts to follow in claim construction, but acknowledged that there was "no magic formula" for claim construction, and that a court is not "barred from considering any particular sources . . . as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." Phillips, 415 F.3d at 1324.

² This list is derived from the one provided in the FEDERAL JUDICIAL CENTER, PATENT LAW AND PRACTICE, § 5.I.A.3.d (5th ed. 2006).

6. Ordinarily, general descriptive terms are given their full meaning. See, e.g., Innova/Pure Water, Inc., 381 F.3d at 1118.
7. If possible, claims should be construed so as to preserve their validity. See, e.g., Energizer Holdings, Inc. v. Int'l Trade Comm'n, 435 F.3d 1366, 1370–71 (Fed. Cir. 2006).
8. Ordinarily, absent broadening language, numerical ranges are construed exactly as written. See, e.g., Jeneric/Pentron, Inc. v. Dillon Co., 205 F.3d 1377, 1381 (Fed. Cir. 2000).
9. Ordinarily, absent recitation of order, steps of a method are not construed to have a particular order. See, e.g., Combined Sys., Inc. v. Def. Tech. Corp. of Am., 350 F.3d 1207, 1211–12 (Fed. Cir. 2003).
10. Absent highly persuasive evidentiary support, a construction should literally read on the preferred embodiment. See, e.g., Cytologix Corp. v. Ventana Med. Sys., Inc., 424 F.3d 1168, 1175 (Fed. Cir. 2005).

III. AGREED TERMS

The parties reached agreement on the following terms and accompanying constructions:

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

IV. DISPUTED TERMS

The parties dispute the following terms found in the '220 patent. The Court stated on the record the reasons for its constructions, and now explains its reasoning in greater detail.

a. **"plasticized soft tissue graft"**

The Court **ORDERS** that the proper construction of "plasticized soft tissue graft" is **"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."

The main issue before the Court was to determine how much language to pull from the specification. The Court was guided by the Federal Circuit's instruction that the inventor's lexicography governs. Phillips, 415 F.3d at 1316.

The '200 patent defines a "soft tissue graft" as:

load-bearing and non-load-bearing soft tissue products. Non load-bearing grafts include cadaveric skin. Load-bearing soft tissue grafts include for example: pericardium, dura mater, fascia lata, and a variety of ligaments and tendons. Soft tissue grafts are composed of an internal matrix which includes collagen, elastin and high molecular weight solutes where during cleaning cellular elements and small molecular weight solutes are removed.

'200 patent at 8:4–12. Additionally, "plasticization" is defined as "replacing free and loosely bound waters of hydration in a tissue(s) with one or more plasticizers without altering the orientation of the collagen fibers and associated mineral phase." Id. at 7:24–28. Thus, the Court believed a combination of these two definitions results in the proper construction.

Defendant argued that Network Commerce, Inc. v. Microsoft Corp., 422 F.3d 1353 (Fed. Cir. 2005)) compels a different result. However, that is not the case. In Network Commerce, the combination of two dictionary definitions there was "not a tenable theory in light of the specification." Network Commerce, 422 F.3d at 1360. Here, in light of the specification, the combination of the two definitions does make sense.

The Court declined to use the phrase "includes collagen, elastin and high molecular weight

solutes" from the definition found in the specification because the parties agreed on the proper construction of the term internal matrix, which varied somewhat from this language. See Phillips, 415 F.3d at 1314 ("claim terms are normally used consistently throughout the patent"). The Court also declined to use the phrase "and associated mineral phase of the tissue" because of expert disagreement as to whether a tissue can have a mineral phase, and because the phrase does not assist a jury in understanding the term at issue. See Badylak Decl. ¶ 32; Kaplan Decl. ¶ 42.

The Court included the language that "such that the mechanical properties, including the material, physical and use properties, of the tissue product are similar to those of normal hydrated tissue," because this language was also supported by the specification and clarified the term at issue. '200 patent at 9:14–18

b. "suitable for transplantation into a human"

After considering the parties' submissions and arguments, the Court **ORDERED** that this term required no further construction. The main dispute centered on whether the claim was limited to human-to-human transfers based on the use of the terms "implant" and "transplant" in the patent. The Court **FOUND** that the patent uses these terms interchangeably and they could cover both human and animal-derived tissue, and thus no construction was necessary. See O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd., 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("district courts are not (and should not be) required to construe every limitation present in a patent's asserted claims.").

c. "cleaned"

The Court **ORDERED** that the proper construction of this term was that proposed by Plaintiff, **"a process during which cellular elements and small molecular weight solutes are removed."**

This construction is supported by the plain language of the specification. See '200 Patent at 8:9–12 ("Soft tissue grafts are composed of an internal matrix which includes collagen, elastin and high molecular weight solutes where during cleaning cellular elements and small molecular weight solutes are removed."). The Court rejected Defendant's proposed additions of "some" and "and/or" into the construction because it would lead to an indefinite claim, in violation of the canons of claim construction. See, e.g., Energizer Holdings, Inc., 435 F.3d at 1370–71.

d. "plasticizer"

The Court **ORDERED** that the proper construction of the term was **"biocompatible compounds which are soluble in water and can easily displace/replace water at the molecular level."**

This construction was proposed by Defendant, and was defined in the specification. '200 Patent at 7:30–32. The Court rejected the additional language that Plaintiff proposed because it included a reference to bone grafts and the word "preferably" was used, indicating that it was not a requirement for a plasticizer. Id. at 7:32–41.

e. "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"

The Court **ORDERED** that this term required no further construction. Many of these terms were construed, and thus the Court found a separate construction for this long phrase was unnecessary. Additionally, "not removed" is easily understood by a person of ordinary skill in the art to have its plain meaning that no plasticizers are removed prior to transplantation.

This requirement that no plasticizer be removed prior to transplantation is necessary in the construction because during prosecution, Plaintiff was forced to amend the claim to its current form to avoid a prior art rejection; the "not removed" limitation was not contained in the original

patent application. See Doc. 63-3 (containing the initial application). The claim as initially drafted was rejected by the USPTO because Patent No. 5,718,012 ("Cavallaro") anticipated the claims. Id. at 66. The Examiner stated:

Cavallaro teaches a method of strength enhancement of collagen constructs intended for implantation to replace or repair tissue or organs. Cavallaro forms collagen threads from collagen harvested from a bovine common digital extensor tendon. During processing, the formed thread is rinsed with purified water or phosphate buffered saline (col. 5, lines 19-31). To improve tensile strength, a collagen thread or bundle comprising collagen threads is plasticized with water or aqueous solutions or buffers and/or glycerol.

Id. However, in order to preserve strength, "the plasticizer must also be removed." Cavallaro at 7:42–43. To overcome this objection, the claims were amended to include the limitation that is the term at issue. Doc. 63-3 at 72.

In addition to this intrinsic evidence, Defendant also provided an expert declaration stating that a POSA would know that in Cavallaro it would be impossible to remove all of the plasticizer. Badylak Decl. ¶ 38. Thus, a POSA would understand that to successfully distinguish Cavallaro, in which not all of the plasticizer would be removed, none of the plasticizer would have to be removed in the '200 patent. Id. ¶ 42. Therefore, a combination of the plain language, prosecution history, and the expert declaration all led the Court to conclude that "not removed" means that no plasticizer is removed, and that based on the plain meaning of "not removed" no further construction of the term was necessary. Plaintiff argues that some quantity of the plasticizer may escape during formulation or transplantation, but such events may be distinguished from deliberate removal.

f. "impregnating" / "impregnated"

The Court **ORDERED** that the proper construction of these terms were the plain meaning, **"filling" or "filled."** The Court rejected the arguments of both parties seeking to apply the

definition found in the specification.

The claim language is clear that it applies to soft tissue grafts. '200 patent at 24:39–50. However, the specification defined "impregnating" as "any processing conditions which result in filling the internal matrix of a bone graft with a plasticizer composition." Id. at 6:56–58. Plaintiff argued that the Court should apply this definition to soft tissue grafts; however, the Court rejected this invitation. Defendant made arguments that under ChefAmerica, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371 (Fed. Cir. 2004), and Braintree Labs., Inc. v. Novel Labs., Inc., 749 F.3d 1349, 1356 (Fed. Cir. 2014), the Court was required to adopt the express definition contained in the specification, even if the claim language was clear that the claim applied to soft tissue grafts and not bone grafts.

However, Defendant's arguments are also unpersuasive. In ChefAmerica, the Federal Circuit found that a claim that required dough be "heated to a temperature range of 400° F to 850° F" had to be interpreted as written, even though it was clear that the drafter meant "at." Chef America, 358 F.3d at 1374. This was because the claim language was unambiguous and the Federal Circuit has routinely held that "courts may not redraft claims, whether to make them operable or to sustain their validity." Id. Here, the Court is not redrafting the claim; it is declining to accept Defendant's invitation to litigate validity at the claim construction phase. The definition in the specification is clear in that it applies to bone grafts. The claim language applies to soft tissue grafts. Thus, the Court would be mistaken to apply the definition in the specification referring to bone grafts because the Court must treat soft tissue grafts and bone grafts differently, unless the patentee states otherwise. See, e.g., Innova/Pure Water, Inc., 381 F.3d at 1119–20 ("when an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms.").

Furthermore, Braintree does not compel a different conclusion. The Federal Circuit reversed the district court there because it modified two words despite "the clear language found in the specification." Braintree, 749 F.3d at 1356. Again, the Court is not modifying any language; it is simply declining to adopt a nonsensical construction that is not supported by the specification language. Thus, with no guidance from the specification on what impregnating means in the context of a soft tissue graft, the Court **ORDERED** that the term receive its plain meaning. See Doc. 64-9 at 17 (defining impregnating as "to be filled").

g. "without rehydration"

The Court **ORDERED** that the proper construction of the term **"without rehydration"** is **"without hydrating a plasticized soft tissue graft prior to implantation into a patient."** The Court relied on the definition found in the specification, but without the word "dehydrated." '200 patent at 7:64–67. The parties agreed that the addition of the word dehydrated was redundant, and thus unnecessary in the construction.

h. "incubating"

The same issue that arose for "impregnating" arose for "incubating." For the reasons stated in section "f," the Court **ORDERED** that the construction of the term would be its plain meaning, **"soaking or otherwise exposing."**³ See Doc. 64-9 at 18 (defining incubating in part as "to maintain ... under conditions favorable for ... reaction").

V. CONCLUSION

For the reasons stated on the record and elaborated herein, the Court constructed the

³ The specification defined incubating as "processing a bone graft in for example a plasticizer composition by soaking the graft in the composition, shaking the graft with the composition, subjecting the graft to flow of the composition where the flow is induced by negative or positive pressure, subjecting the graft and/or the composition to negative or positive pressure, or soaking the bone graft in a plasticizer composition in a negative pressure environment." '200 patent at 6:47–54.

disputed terms 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

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: July 16th, 2014