United States Court of Appeals for the Federal Circuit

LIFENET HEALTH,
Plaintiff-Appellee

v.

LIFECELL CORPORATION,
Defendant-Appellant

2015-1549

Appeal from the United States District Court for the Eastern District of Virginia in No. 2:13-cv-00486-HCM-DEM, Senior Judge Henry C. Morgan Jr.

Decided: September 16, 2016

CONSTANTINE L. TRELA, JR., Sidley Austin LLP, Chicago, IL, argued for plaintiff-appellee. Also represented by JOSHUA JOHN FOUGERE, Washington, DC; MICHAEL SONGER, VINCENT JOHN GALLUZZO, MICHAEL H. JACOBS, Crowell & Moring, LLP, Washington, DC; STEPHEN EDWARD NOONA, Kaufman & Canoles, P.C., Norfolk, VA.

JOHN M. DESMARAIS, Desmarais LLP, New York, NY, argued for defendant-appellant. Also represented by PAUL A. BONDOR, DUSTIN GUZIOR, LAURIE STEMPLER; JEFFREY HOWARD LERNER, GEORGE FRANK PAPPAS, GARY RUBMAN, Covington & Burling LLP, Washington, DC.

Before PROST, *Chief Judge*, REYNA and CHEN, *Circuit Judges.*

PROST, *Chief Judge*.

Defendant-Appellant LifeCell Corporation ("LifeCell") appeals from a final judgment of the U.S. District Court for the Eastern District of Virginia entered in favor of Plaintiff-Appellee LifeNet Health ("LifeNet"). Following claim construction and trial, a jury found LifeNet's U.S. Patent No. 6,569,200 ("'200 patent") infringed by LifeCell and not invalid. The district court denied LifeCell's motion for a new trial and renewed motion for judgment as a matter of law ("JMOL") on, inter alia, claim construction, non-infringement, and invalidity. The district court subsequently entered a final judgment consistent with the jury's findings on infringement, validity, and damages. We affirm.

BACKGROUND

LifeNet's '200 patent claims plasticized soft tissue grafts suitable for transplantation into humans. Such grafts are useful in various medical, orthopedic, dental, and cosmetic surgery applications. The '200 patent explains that tissue grafts are typically preserved and provided in a dehydrated state, such as through freeze-drying, then rehydrated before implantation. The patent explains that the freeze-drying process is not optimal: it can cause the tissue to become brittle with a tendency to fracture; it requires time in the operating room to rehydrate the tissue; and even after rehydration the tissue's properties do not approximate that of normal tissue, and the graft can fail.

The '200 patent's "plasticized" tissue grafts avoid these problems. The tissue is preserved not by freeze-drying but by replacing the tissue's water with biocompat-

ible plasticizers, such as glycerol, that provide the hydrating functions of water. These plasticized grafts exhibit properties similar to that of normal tissue and avoid the rehydration process required for freeze-dried tissue.

The specification explains that, while the plasticizers *can* be removed prior to implantation, they need not be. It therefore discloses various options for the implanting clinician: (1) "direct implantation of the grafts without further processing following removal from the packaging"; (2) "implantation following a brief washing in sterile isotonic saline to remove any remaining traces of plasticizer associated with the immediate surfaces of the grafts"; or (3) "implantation following an extended (approximately 1 hour) washing with sterile isotonic saline to remove as much plasticizer as possible." '200 patent col. 12 ll. 9-16.

LifeNet asserted claims 1-4, 7, 8, and 10 in this case. Claims 1-4 are apparatus claims, while claims 7, 8, and 10 are method claims. All of the asserted claims require that "one or more plasticizers are not removed from [an] internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human" (or "the non-removal limitation"). For example, claim 1 recites:

> 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*.

Id. at col. 24 ll. 10-16 (emphasis added).

The non-removal limitation was added to the claims during prosecution in response to a rejection based on the Cavallaro reference, U.S. Patent No. 5,718,012 ("'012 patent"). Cavallaro also discloses using plasticizers in tissue constructs. In Cavallaro, the plasticizers are used to improve the tensile strength of collagen threads, and after such "conditioning treatment, the plasticizer must . . . be removed." '012 patent col. 7 ll. 40-43. Following the examiner's rejection for anticipation by Cavallaro, LifeNet amended its claims to add the requirement that "one or more plasticizers are not removed from an internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human." J.A. 192. As support for the amendment, LifeNet recited the following language from the specification: "Replacement of the chemical plasticizers by water prior to implantation is not required and thus, the . . . soft tissue plasticized product can be place[d] directly into an implant site without . . . ." J.A. 193 (first and third alterations in original).

LifeCell's accused products are soft tissue grafts preserved in a plasticizer solution called Solution E. It is undisputed that users of the accused products are instructed to soak the tissue grafts in saline solution for a minimum of two minutes prior to implantation and that a significant amount of plasticizers are removed during this two-minute rinse. LifeCell contends there is no evidence to suggest that surgeons have ever implanted the accused products without following those instructions.

During claim construction proceedings, the parties disputed the meaning of several terms, including the non-removal limitation. The parties' dispute at the time centered on the degree of plasticizer removal—whether this limitation required that *no* plasticizer be removed (LifeCell's position) or allowed for some, but not all, plasticizer to be removed (LifeNet's position). Specifically, LifeCell's proposed construction was that "no processing steps are taken, before transplantation into a human,

that result in *any amount* of the one or more plasticizers being taken out of the internal matrix of the plasticized soft tissue graft." J.A. 409 (emphasis added). LifeNet proposed that the term meant "*without complete replacement* of the plasticizer or plasticizers in the internal matrix of the tissue graft prior to direct implantation into a human." *Id.* (emphasis added). The district court concluded in its *Markman* order that construction of the entire term was "unnecessary," observing that the two-word phrase "'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." J.A. 65. The district court later denied LifeCell's motion for summary judgment that this limitation rendered claims 1-4 indefinite for allegedly including a method step in an apparatus claim.

At trial, LifeCell argued non-infringement based on evidence showing that as much as 50% of the plasticizer in the accused products is removed during the two-minute saline rinse. According to LifeCell, this undisputed removal of plasticizers meant that its products do not meet the claim limitation requiring that plasticizers are "not removed." In response, LifeNet did not dispute that plasticizers are removed from the accused tissue grafts during the two-minute rinse but maintained that no plasticizers are removed *from the internal matrix* of the tissue graft, as recited in the non-removal limitation. According to LifeNet's expert, Dr. David Kaplan, the only plasticizer removed during the rinse is "nonbound" plasticizer that exists in the gaps and voids of the tissue grafts, not plasticizer "bound" to the graft's internal matrix. J.A. 8230-31.

After a two-week trial, the jury found that LifeCell's accused tissue grafts infringed the '200 patent. It also found that LifeCell had failed to establish any of its invalidity defenses and awarded LifeNet $34,741,971 in damages. After briefing and oral argument, the district

court denied LifeCell's post-trial motions. LifeCell timely filed this appeal.

We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

LifeCell raises several issues on appeal. First, it submits that the district court erred by allowing the jury to resolve a dispute about the scope of the limitation "said one or more plasticizers are not removed from [an] internal matrix of [the] plasticized soft tissue graft" and that, because the accused products do not meet this limitation, JMOL of non-infringement is warranted. LifeCell also argues that JMOL of no direct infringement is warranted because, regardless of how the limitation is construed, LifeCell itself does not directly infringe; rather, independent surgeons or their assistants prepare the grafts for transplantation. LifeCell further argues that claims 1-4 are invalid as indefinite for covering both an apparatus and, through the non-removal limitation, a method of using that apparatus. Separately, LifeCell contends that the district court misconstrued "plasticized soft tissue graft" and that, under the correct construction, LifeCell does not infringe as a matter of law. Finally, it seeks JMOL of invalidity on grounds that the asserted claims are either anticipated by the Werner reference, U.S. Patent No. 4,357,274, or rendered obvious over Werner and the knowledge of a person of ordinary skill. In the alternative, LifeCell seeks a new trial on infringement or invalidity.

The district court's ultimate claim construction is a question of law reviewed de novo, with any subsidiary factual findings regarding extrinsic evidence reviewed for clear error. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). We review a district court's denial of JMOL or a new trial under the law of the regional circuit. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1318 (Fed. Cir.

2008). Under the law of the Fourth Circuit, we review the denial of JMOL de novo, "examin[ing] whether there is substantial evidence in the record upon which the jury could find for the prevailing party, viewing the evidence in the light most favorable to that party." *Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484, 488 (4th Cir. 2007) (citation and internal quotation marks omitted). Denial of a motion for a new trial is reviewed in the Fourth Circuit for abuse of discretion "and will not be reversed save in the most exceptional circumstances." *Minter v. Wells Fargo Bank, N.A.*, 762 F.3d 339, 346 (4th Cir. 2014) (citation and internal quotation marks omitted).

A

As noted above, the district court found that no further construction was needed for the limitation "said one or more plasticizers are not removed from [an] internal matrix of [the] plasticized soft tissue graft prior to transplantation." *See* J.A. 65. LifeCell argues that the district court's failure to resolve a legal dispute regarding the scope of that limitation constituted error under *O2 Micro International Ltd. v. Beyond Innovation Technology Co.*, 521 F.3d 1351 (Fed. Cir. 2008). LifeNet responds that the infringement dispute was properly presented to the jury as a factual issue: whether the two-minute wash of the accused products removes plasticizers *from the internal matrix* as opposed to the gaps and voids of the tissue graft.

In *O2 Micro*, we held that "[w]hen the parties raise an actual dispute regarding the proper scope of . . . claims, the court, not the jury, must resolve that dispute." *Id.* at 1360. There is not necessarily an *O2 Micro* issue, however, whenever further claim construction could resolve the parties' dispute. For instance, "[t]he fact that shortly before trial [a party] became dissatisfied with its own proposed construction and sought a new one does not give

rise to an *O2 Micro* violation." *Nuance Commc'ns, Inc. v. ABBYY USA Software House, Inc.*, 813 F.3d 1368, 1373 (Fed. Cir. 2016). Here, in light of LifeCell's failure to sufficiently request further construction of the relevant limitation leading up to and during trial, we find that it fails to properly raise an *O2 Micro* issue.

According to LifeCell, the district court should have instructed the jury that the asserted claims prohibit the removal of any plasticizer from any part of the tissue graft, i.e., whether that plasticizer is bound to the internal matrix or nonbound in the gaps and voids of the tissue graft. As an initial matter, we observe that LifeCell's arguments relate not only to the *degree* of non-removal required but also, more pertinently, *from where* those plasticizers are not to be removed. Regarding the degree of removal, the district court agreed with LifeCell at the *Markman* stage to the extent the two-word phrase "'not removed' means that no plasticizer is removed." J.A. 66. The court did not, however, go on to discuss the second issue presented to us: *from where* those plasticizers are not to be removed. Indeed, the parties did not dispute at the *Markman* stage that the non-removal, as expressly recited in the asserted claims, is directed to "the internal matrix of the . . . tissue graft." J.A. 1522.

For context, LifeNet's infringement theory at trial was that, while a two-minute wash of the accused products removes plasticizers from the gaps and voids of the tissue grafts, it does not remove plasticizer bound to the internal matrix. In other words, LifeNet did not dispute the *degree* of removal, as LifeCell contends, but looked to the remainder of the limitation to argue that, in the accused products, plasticizers are not removed "from [the] internal matrix." LifeCell now argues that this evidence does not support an infringement finding because the internal matrix and tissue graft are one and the same—removal of plasticizer from the gaps and voids of the tissue graft also constitutes removal from the internal matrix. *See* Open-

ing Br. 12 (asserting that "the internal matrix *is* the tissue graft").

The problem with LifeCell's argument is that it did not timely request modification of the district court's claim construction. LifeCell asserts that it raised the claim construction dispute with the district court, pointing us to a motion in limine, objections and arguments made during trial, and a Rule 50(a) JMOL motion. However, in those instances, LifeCell merely sought to exclude testimony contrary to the district court's claim construction (which, to be clear, was "[n]o further construction needed") or to have the court instruct the jury as to the *degree* of removal. LifeCell did not dispute that the plasticizer could not be removed "from the internal matrix of the soft tissue graft." J.A. 7790. The district court granted-in-part LifeCell's motion in limine but expressly allowed LifeNet to "offer testimony that the plasticizers removed do not come from the internal matrix." J.A. 7609. The court also overruled objections at trial on the same evidentiary issue. In doing so, the district court made clear, if it was not clear already, that it was not construing the limitation at issue to bar removal of plasticizer from the gaps and voids of the tissue graft.

Nevertheless, LifeCell did not request a new or modified claim construction. In its Rule 50(a) motion for JMOL filed at the close of LifeNet's infringement case, LifeCell continued to present the issue as a factual one, arguing that LifeNet offered testimony in violation of the court's in limine order and that there was insufficient evidence to find infringement.

LifeCell's objection to the district court's jury instructions at the end of trial was also insufficient to raise the *O2 Micro* issue that it presses on appeal. LifeCell merely asked the court to replace "No further construction needed" with a plain-meaning construction consistent with the court's prior statements: "Plain meaning, that no plasti-

cizer is deliberately removed from the internal matrix of the soft tissue graft prior to transplantation into a human." J.A. 7689. Even if the district court had agreed to that jury instruction, it would not have been the claim construction that LifeCell now seeks on appeal. LifeCell did not ask for clarification of what constitutes removal "from the internal matrix." In fact, the parties agreed to the construction of "internal matrix," as expressly defined in the '200 patent's specification to mean "the intercellular substance of such soft tissue including for example ligaments and tendons, including collagen and elastin fibers and base matrix substances." J.A. 1521; '200 patent col. 6 ll. 59-65. LifeCell never asked the court to adopt its argument that "internal matrix" is synonymous with "tissue graft."

In sum, LifeCell's evidentiary challenges and request for a claim construction did not adequately present the refashioned claim construction argument that it now raises on appeal. *Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1376 (Fed. Cir. 2010) ("[I]t was incumbent upon [the appellant] to raise its claim construction argument before the district court, and, having failed to do so, [it] cannot now resurrect that argument on appeal by pointing to ambiguous statements in the record."). LifeCell's discontent with the agreed-upon construction of "internal matrix" or with the district court's view of the longer phrase "said one or more plasticizers are not removed from [an] internal matrix of [the] plasticized soft tissue graft prior to implantation into a human" is not sufficient to give rise to an *O2 Micro* violation. *See Nuance*, 813 F.3d at 1373 (finding no *O2 Micro* issue when the district court adopted the appellant's proposed plain-meaning construction and the appellant

became dissatisfied with that construction shortly before trial).[1]

As LifeNet submits, the parties presented a factual dispute at trial as to whether a two-minute rinse removes plasticizers from the internal matrix of the accused tissue grafts. Although LifeCell does not expressly challenge the sufficiency of the evidence on this issue, it points to purported inconsistencies in LifeNet's evidence. For example, LifeCell argues that LifeNet's expert, Dr. Kaplan, contradicted his own sworn statements and that LifeNet's witnesses provided "uniform trial testimony . . . that the internal matrix *is the graft*." Opening Br. 35-37. We disagree with these characterizations of the evidence.

We do not accept LifeCell's argument that Dr. Kaplan's trial testimony regarding the non-removal of

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[1] Even if we were to reach the construction of the non-removal limitation, we see no error with the court's construction under the principles of *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). The patentee added the non-removal limitation in response to a rejection during prosecution and cited a passage from the specification stating that the claimed invention could be directly implanted into a patient without preparation. That statement, however, was just one example of the non-removal limitation (no rinse prior to transplantation) and did not necessarily disclaim other embodiments disclosed in the specification (e.g., a brief rinse or a one-hour wash prior to implantation) that are consistent with the specification's teaching that plasticizer need not be replaced by water prior to implantation. *See TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1125 (Fed. Cir. 2001) (rejecting argument that a claim amendment narrowed the claims at issue because the added limitation was already "present in the original claim").

plasticizers from the internal matrix of the accused products "deserves no weight" because it supposedly contradicted his *Markman* declaration. *See id.* at 36. LifeCell points to an excerpt of Dr. Kaplan's declaration stating that the '200 patent discloses plasticizing in a new way that "does not require rehydration, or even washing, to remove the plasticizer(s) from the internal matrix of the graft." J.A. 1220. LifeCell interprets that testimony to imply that removal of plasticizer is not difficult, contrasting it with Dr. Kaplan's trial testimony that removing plasticizer from the internal matrix would be "very difficult because it's strongly bound into the surrounding structures" and that a two-minute rinse would not remove plasticizer from the internal matrix. J.A. 8196, 8234. We see no inconsistency in Dr. Kaplan's testimony. In the declaration excerpt, he was speaking to an advantage of the claimed invention over the prior art, not to the degree of difficulty of removing plasticizer from the internal matrix. Nor did Dr. Kaplan say at trial that plasticizer can never be removed from the internal matrix, only that, in the context of the technology at issue, such removal would disrupt the matrix.

We also reject LifeCell's assertion that LifeNet's witnesses agreed that an internal matrix is the same as a tissue graft, such that the asserted claims prohibit removal of plasticizer from anywhere in the tissue graft. LifeCell points to the testimony of a LifeNet witness, Dr. Qin, who said that "when we implant the tissue it's basically just the matrix." J.A. 7955. However, not only did Dr. Qin qualify his testimony, but that testimony was also in response to a question about revascularization, not what "internal matrix" means relative to "tissue" in the context of the '200 patent. Dr. Kaplan, meanwhile, did opine on "internal matrix" in the context of the '200 patent and stated that it is composed of the components left after a soft tissue graft has been cleaned. When asked if anything other than the internal matrix would be

"left behind," he responded: "Yes. When you go through this process, you are going to leave a huge number of voids in the tissue, . . . and also you'll have a great deal of water left in the [t]issue." J.A. 8188. On cross-examination, he again differentiated the internal matrix from the tissue graft, opining that the graft "includes [the] internal matrix, . . . but there's other [sic] plenty of loose water, unbound water," as well as "voids and other spaces where you've decellularized." J.A. 8274-75. As noted above, the parties agreed to the construction of "internal matrix," which was drawn from an express definition in the specification that did not refer to voids or gaps, and Dr. Kaplan's testimony was consistent with that construction.

Against this background, we find that there was substantial evidence to support the jury's determination that plasticizer is not removed "from the internal matrix" of the accused tissue grafts before transplantation. The jury was free to rely on Dr. Kaplan's testimony and to find, as a factual matter, that the accused products meet the limitation at issue. The district court did not err in denying JMOL or a new trial on non-infringement.

B

Based on the non-removal limitation and under the law of divided infringement, LifeCell also argues that it cannot be liable for direct infringement regardless of how that limitation is construed. Direct infringement of an apparatus claim "requires that each and every limitation set forth in a claim appear in an accused product." *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005). Direct infringement of a method claim requires all steps of the claimed method to be performed by or attributable to a single entity. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379-81 (Fed. Cir. 2007). Although we may attribute a third party's performance of method steps to a single entity in

some circumstances, *see Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) (en banc) (per curiam), LifeNet did not pursue an attribution theory at trial.

LifeCell posits that the non-removal limitation cannot be met until an independent third party, such as a surgeon, actually prepares and uses the accused products, and it is unknown at the time that LifeCell sells a graft if and how that graft will be used for transplantation.[2] LifeNet counters that "the final product that leaves LifeCell's hands is complete and . . . infringes in that condition" without affirmative action by a third party. Response Br. 44. We agree with LifeNet.

Functional limitations recited in the negative may describe a capability or structural element. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003) (holding that "non-naturally occurring" and "not isolated" were structural elements defining the source of the claimed material, rather than steps for obtaining it). Here, the preceding language in each asserted claim states that the relevant plasticizers are already part of the tissue graft. *See, e.g.*, '200 patent col. 24 l. 12 ("plasticizers contained in [the] internal matrix"); *id.* at col. 24 ll. 41-42 ("impregnating a cleaned, soft tissue graft with one or more plasticizers"). The non-removal limitation simply provides a negative limitation that those plasticizers remain in the internal matrix prior to transplantation.

LifeCell relies on *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005), and *Centillion Data Systems, LLC v. Qwest Com-*

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[2] LifeCell does not argue that the apparatus and method claims should be treated differently in our divided infringement analysis.

munications International, Inc., 631 F.3d 1279 (Fed. Cir. 2011), to argue that there can be no direct infringement by a single entity when a limitation is absent until a third party takes action. However, those cases are distinguishable. In *Cross Medical*, we held that surgical implants with an interface that had to be "operatively joined" to a segment of bone could not be directly infringed by the manufacturer insofar as that party "d[id] not itself make an apparatus" with the relevant portion already in contact with bone. 424 F.3d at 1311. Rather, a third party surgeon had to "actually bring the [relevant part] into contact with bone." *Id.* at 1310. Similarly, in *Centillion*, we held that the accused infringer, who provided software to customers, did not itself practice a limitation requiring a "personal computer data processing means" because "it is entirely the decision of the customer whether to install and operate th[e] software on its personal computer data processing means." 631 F.3d at 1287. The claimed inventions in *Cross Medical* and *Centillion* affirmatively required action by a third party, without which a limitation would be absent. Here, in contrast, the non-removal limitation clarifies that the recited plasticizer has not been removed and, because the plasticizer is biocompatible, can remain in the internal matrix of the tissue graft during transplantation, i.e., it need not ever be removed. This limitation is met without action by a third party. It is satisfied by the graft from the moment it is manufactured unless and until the plasticizer is removed from the internal matrix before transplantation.

Therefore, the non-removal limitation does not relieve LifeCell of direct infringement.

C

LifeCell also contends that because the non-removal limitation describes a method of use while the remainder of claims 1-4 describes an apparatus, those claims are indefinite for covering both an apparatus and a method of

using that apparatus. The ultimate determination of indefiniteness is a question of law reviewed de novo, "although, as with claim construction, any factual findings by the district court based on extrinsic evidence are reviewed for clear error." *UltimatePointer, LLC v. Nintendo Co.*, 816 F.3d 816, 826 (Fed. Cir. 2016).

LifeCell relies on *IPXL Holdings, LLC v. Amazon.com, Inc.*, 430 F.3d 1377 (Fed. Cir. 2005), in which we held a claim invalid for indefiniteness when "as a result of the combination of two separate statutory classes of invention, a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus." *Id.* at 1384. As explained above, however, the non-removal limitation defines a property of the recited plasticizer in that the plasticizer is biocompatible and does not need to be removed from the internal matrix before transplantation in the context of apparatus claims 1-4, so no later action by a user of the tissue graft is necessary. Those claims therefore do not mix an apparatus with a method of using that apparatus, and the district court did not err in denying JMOL as to indefiniteness.

D

LifeCell separately argues that the district court erred in its construction of "plasticized soft tissue graft." The district court construed this limitation to require, inter alia, that "free and loosely bound waters of hydration in the tissue have been *replaced* with one or more plasticizers." J.A. 63 (emphasis added).

LifeCell contends that the district court mistakenly failed to also require that the tissue graft be "dehydrated," in the sense that the tissue can only have "low residual moisture." Opening Br. 43-44. Under that construction, LifeCell contends there can be no infringe-

ment as a matter of law because the accused products have at least 60% moisture. LifeNet responds that "dehydration," as that word is used in the '200 patent, merely means that some of the water has been replaced with plasticizer and that the district court's construction already includes that understanding.

We agree with LifeNet. Although LifeCell is correct that the written description repeatedly uses the word "dehydrated," it does so broadly. For example, the specification discusses "soft tissue which is preserved by dehydration, such drying methods including for example, freeze-drying, and/or sublimation and/or air drying *and/or liquid substitution*." '200 patent col. 6 ll. 35-39 (emphasis added). Although the specification states that "[t]he present invention provides a dehydrated or freeze-dried plasticized bone or soft tissue product, preferably containing less than 5% residual moisture," *id.* at col. 5 ll. 29-31, we decline to confine the claims to such an embodiment where, as in this context, there is no indication that the "patentee . . . intend[ed] for the claims and the embodiments in the specification to be strictly coextensive," *Phillips*, 415 F.3d at 1323. There is no support for the proposition that the claimed soft tissue graft must be dehydrated to a certain degree or completely desiccated. The addition of the word "dehydrated" to the claim construction would be redundant of the requirement for plasticizer to replace some water, which is already properly part of the district court's construction.

We decline to adopt LifeCell's proposed construction of "plasticized soft tissue graft," and LifeCell does not otherwise argue that the jury's infringement verdict lacks substantial evidence. Therefore, we do not disturb the court's denial of JMOL of non-infringement or a new trial on this ground.

E

Finally, we address LifeCell's argument that the asserted claims are either anticipated by Werner or obvious in view of Werner and the knowledge of a person of ordinary skill. Anticipation is a question of fact reviewed for substantial evidence. *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1252 (Fed. Cir. 2014). Obviousness is a question of law reviewed de novo, with underlying factual findings, such as whether a reference discloses a limitation, reviewed for substantial evidence. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1324 (Fed. Cir. 2008).

Werner is a patent that discloses a process for treating a soft tissue with hydrogen peroxide and other steps to increase biological stability. At trial, LifeNet disputed whether Werner meets two limitations of the asserted claims: "cleaned" and "plasticized soft tissue graft." LifeCell argues on appeal that "[t]he evidence allows only one reasonable conclusion"—that Werner discloses both limitations and therefore anticipates the asserted claims. Opening Br. 57. Alternatively, it argues that Werner "at most . . . would lack a sufficient degree of 'cleaning' the tissue, which would have been an obvious modification to a person skill in the art at the time of the invention." *Id.*

With respect to a "plasticized soft tissue graft," the district court construed that limitation to specifically require, inter alia, that plasticization occur "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*." J.A. 69 (emphases added). LifeCell does not direct us to any evidence from its affirmative case to support its burden of showing that Werner discloses a "plasticized soft tissue graft." *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013) ("[T]he burden of persuasion

[as to invalidity] remains with the challenger during litigation."). Aside from arguing for a different construction of "plasticized soft tissue graft," which we have rejected, LifeCell focuses on trying to undermine Dr. Kaplan's testimony that Werner's process renders the mechanical properties of tissue different from native tissue.

A review of the record shows that there is substantial evidence to support a jury finding that Werner does not disclose a plasticized soft tissue graft under the district court's construction. Dr. Kaplan explained that, unlike the '200 patent, in Werner, "the mechanical properties are altered significantly from native tissue," namely by "increas[ing] . . . tensile strength by a factor of 1.7 to 7.0." J.A. 9262-63; *see also* J.A. 9279 (explaining that Werner does not retain the "mechanical properties of the native-like tissue"). Although Dr. Kaplan conceded on cross-examination that the data was not statistically different, he maintained that the difference in mechanical properties between Werner's tissue and native tissue was still a basis for finding those properties *not* similar enough to meet the court's construction of "plasticized soft tissue graft." LifeCell's expert, Dr. Stephen Badylak, testified that he could not say whether or not the tensile strength difference that Dr. Kaplan relied on was "similar" under the court's construction. J.A. 9099. However, he agreed on cross-examination that "the mechanical properties, including the physical and use properties" of Werner "have changed" and stated that he was "starting to think [the change in tensile strength] is different." J.A. 9097-99.

The ultimate issue on this record was a classic factual dispute that the jury was free to resolve in LifeNet's favor. *See, e.g.*, *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1361 (Fed. Cir. 2012) ("[S]ubstantial evidence supports the jury's implied factual finding that none of these references disclosed the [limitation at is-

sue]."). Since there is substantial evidence to support a finding that Werner fails to disclose "plasticized soft tissue graft," we need not reach the "cleaned" limitation. The district court did not err in denying LifeCell's request for JMOL or a new trial with respect to anticipation.

LifeCell only argues obviousness on appeal with respect to the "cleaned" limitation. It does not point to any evidence that a "plasticized soft tissue graft," if not disclosed by Werner, would have been an obvious modification to a person of ordinary skill in the art. As LifeCell fails to provide a basis for disclosure of a "plasticized soft tissue graft" outside of Werner, the district court also did not err in denying JMOL or a new trial on obviousness.

CONCLUSION

For the foregoing reasons, we affirm the district court's judgment.

AFFIRMED