

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFECCELL CORPORATION,
Petitioner,

v.

LIFENET HEALTH,
Patent Owner.

Case IPR2015-01888
Patent 9,125,971

Before MICHAEL W. KIM, SHERIDAN K. SNEDDEN, and
MICHAEL L. WOODS, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

LifeCell Corporation (“Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–13 (Paper 1, “Pet.”) of U.S. Patent No. 9,125,971 B2 (Ex. 1001, “the ’971 Patent”). LifeNet Health (“Patent Owner”) did not file a Patent Owner Preliminary Response.

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon consideration of the above-mentioned Petition, we conclude that Petitioner has established that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. We institute an *inter partes* review as to claims 1–13 of the ’971 Patent.

A. *Related Proceedings*

Patent Owner identifies the following co-pending case involving the ’971 Patent: *LifeCell Corporation v. LifeNet Health*, Civil Action No. 3:15-cv-06701 (D.N.J). Paper 9.

According to the parties, the following judicial matter would affect or be affected by the decision in this proceeding: *LifeNet Health v. LifeCell Corporation* (Civil Action No. 2:13-cv-486 (E.D. Va.)), presently on appeal to the United States Court of Appeals for the Federal Circuit (Appeal. No. 2015-1549). Pet. 1; Papers 6 and 9.

B. *The ’971 Patent (Ex. 1001)*

The ’971 Patent discloses plasticized dehydrated or freeze-dried soft tissue graft compositions that require no special conditions for storage (*e.g.*,

refrigeration or freezing). Ex. 1001, 1:16–22. The '971 Patent defines the term “soft tissue grafts” 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.

Id. at 8:8–17.

A process of making such plasticized compositions is also disclosed. *Id.* at 1:16–22. To make plasticized soft tissue, soft tissue grafts may be cleaned and processed using conventional methods. *Id.* at 10:14–16. Once cleaned, the graft is plasticized by adding one or more plasticizers or a plasticizer composition. *Id.* at 10:16–36.

The plasticization process involves replacing water present in soft tissue grafts “with one or more plasticizers including for example, glycerol (glycerin USP) (liquid substitution) such that the graft does not need to be rehydrated or washed to remove the plasticizer prior to clinical implantation.” *Id.* at 5:25–31. The plasticized soft tissue product “preferably contain[s] less than 5% residual moisture.” *Id.* at 5:32–36.

C. Challenged claims

Petitioners challenge claims 1–13 of the '971 Patent. Independent claims 1 and 9 are illustrative, and reproduced below:

1. A soft tissue graft, comprising:
soft tissue obtained from a human or animal donor; and

a plasticizer composition comprising one or more alcohols, wherein cellular elements are substantially removed from said soft tissue, and said plasticizer composition is contained in said soft tissue.

9. A method for producing a soft tissue graft, comprising:
substantially removing cellular elements from soft tissue obtained from a human or animal donor;
impregnating the soft tissue with a biocompatible, water-soluble plasticizer composition comprising one or more alcohols.

Ex. 1001, 24:18–56. Claims 2–8 depend directly from claim 1. Claims 10–13 depend directly from claim 9.

Claim 2 further recites that the “one or more alcohols” may include ethanol or isopropyl alcohol. *Id.* at 24:24–25. Claim 3 is limited to ethanol. *Id.* at 24:26–27. Claim 8 further recites that the “one or more alcohols” may include “glycerol, adonitol, sorbitol, . . . ethylene glycol, triethylene glycol, propylene glycol, mannitol, xylitol, or mesoerythritol.” *Id.* at 24:38–41.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–13 of the ’971 Patent on the following grounds.

References	Basis	Claim[s] challenged
Livesey ¹	§ 103(a)	1, 4–9, 1213

¹ Stephen A. Livesey et al., U.S. Patent No. 5,336,616, issued Aug. 9, 1994. Ex. 1003 (“Livesey”).

References	Basis	Claim[s] challenged
Werner ² and Klement ³	§ 103(a)	1, 4–9, 12–13
Walker ⁴ and Wang ⁵	§ 103(a)	1–3, 9–11

Petitioner relies also on the Declaration of Dr. Stephen Badylak in support of the proposed ground of unpatentability. Ex. 1008 (“Badylak Declaration” or “Badylak Decl.”).

II. ANALYSIS

A. Claim Interpretation

We interpret claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 890 (mem.) (2016). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249,

² Heinz-Helmet Werner, U.S. Patent No. 4,357,274, issued Nov. 2, 1982. Ex. 1004 (“Werner”).

³ Petr Klement et al., U.S. Patent No. 4,776,853, issued Oct. 11, 1998. Ex. 1005 (“Klement”).

⁴ Donald Walker, International Patent Application Publication No. WO 98/07452, published Feb. 26, 1998. Ex. 1006 (“Walker”).

⁵ Su Wang, U.S. Patent No. 5,558,875, issued Sept. 24, 1996. Ex. 1007 (“Wang”).

1257 (Fed. Cir. 2007). “Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed Cir. 2004). “Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We determine that no explicit construction of any specific claim term is necessary to determine whether to institute a trial in this case. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). At this stage of the proceeding, we have not made a final determination as to the construction of any claim term.

B. Petitioner’s Asserted Obviousness Grounds

1. Ground 1: Obviousness of Claims 1, 4–9, and 12–13 in view of Livesey

Petitioner contends that claims 1, 4–9, and 12–13 are unpatentable under 35 U.S.C. § 103 in view of Livesey. Pet. 27–41. Livesey describes “[a] method for processing and preserving an acellular collagen-based tissue matrix for transplantation.” Ex. 1003, Abstract. “The method includes the steps of processing biological tissues with a stabilizing solution to reduce procurement damage, treatment with a processing solution to remove cells, treatment with a cryoprotectant solution followed by freezing, drying,

storage and rehydration under conditions that preclude functionally significant damage and reconstitution with viable cells.” *Id.*

Petitioner contends that Livesey discloses decellularizing skin grafts to produce an extracellular collagen matrix of the dermis. Pet. 19 (citing Ex. 1003, 7:36–51, 23:65–67; Badylak Decl., ¶ 46). Petitioner contends that, after decellularization, the skin grafts are incubated in a preservation solution containing propylene glycol or glycerol. *Id.* at 28–29 (citing Ex. 1003, 11:17–23, 11:49–55, 12:3–7, 12:27–30; Badylak Decl., ¶ 47). Petitioner also provides a detailed claim chart explaining how each claim limitation is disclosed or suggested in Livesey. Pet. 31–41.

At this stage of the proceeding, we determine that Petitioner has offered sufficient evidence and argument to institute trial. We conclude, based on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 1, 4–9, and 12–13 are unpatentable as obvious in view of Livesey.

2. Ground 2: Obviousness of Claims 1, 4–9, and 12–13 Over the Combination of Werner and Klement

Petitioner contends that claims 1, 4–9, and 12–13 are unpatentable over the combination of Werner and Klement. Pet. 20–24, 42–53.

Petitioner directs our attention to the following teachings of Werner. *Id.* Werner discloses a process for improving the biological stability of the sclero protein transplants (or soft tissue grafts composed of collagen, keratin, and elastin). Ex. 1004, 1:43–45; Badylak Decl., ¶ 58. Werner discloses that “[t]he desired characteristics can be achieved by introducing the sclero protein material into a glycerin solution, after prior conventional procedural

steps of purifying and antigen separation.” Ex. 1004, 2:1–6. Water may be removed with a glycerin or polyethylene glycol, which impregnates the transplant material by diffusion. *Id.* The transplant material is then dried. *Id.* at 2:6–10.

According to Petitioner, Klement “discloses techniques for processing various types of soft tissue—including dura mater and skin—to prepare the soft tissues for transplantation by ‘complete removal’ of all ‘cell membranes, cytoplasm, nuclear material,’ and other cellular components which ‘could initiate an immunological rejection response.’” Pet. 23 (citing Ex. 1005, 3:6-26, 4:34-42; Badylak Decl., ¶ 63). Petitioner contends that a person of ordinary skill in the art “would have recognized that Klement’s ‘complete removal’ of cellular elements meant cellular elements had been substantially removed from that graft.” *Id.* (citing Badylak Decl., ¶ 64).

Petitioner also provides a detailed claim chart explaining how each claim limitation is disclosed or suggested in the combination of Werner and Klement. Pet. 44–53.

In combining the teachings of Werner and Klement, Petitioner contends that, “while Werner discloses processing techniques that would remove some cellular material . . . Klement (which was filed years after Werner) recognizes the benefits of ‘complete removal’ of all cellular material that ‘could initiate an immunological rejection response’ and discloses improved processes to achieve this.” *Id.* at 43 (citing Ex. 1005, 3:13-17; Badylak Decl., ¶ 59).

At this stage of the proceeding, we determine that Petitioner has offered sufficient evidence and argument to institute trial. We conclude, based on the current record, that Petitioner has established a reasonable

likelihood of prevailing on its assertion that claims 1, 4–9, and 12–13 are unpatentable as obvious over the combination of Werner and Klement.

3. Ground 3: Obviousness of Claims 1–3 and 9–11 Over the Combination of Walker and Wang

Petitioner contends that claims 1–3 and 9–11 are unpatentable under 35 U.S.C. § 103 over the combination of Walker and Wang. Pet. 24–25, 53–60. According to Petitioner, both Walker and Wang disclose methods of making soft tissue grafts that involve soaking the soft tissue in an alcohol solution in order to preserve its mechanical properties. *Id.* at 53 (citing Badylak Decl., ¶¶ 72, 75).

Petitioner contends that Walker discloses methods for “plasticization” of soft tissue using a 50% glycerol/50% ethanol solution. *Id.* at 54 (citing Ex. 1006, 19:17–23, 20:3–11). Petitioner further contends that “Walker explains that this ‘plasticization’ preserves the tissue ‘for implantation into a human or animal body.’” *Id.* at 54 (citing Ex. 1006, 4:33–36).

With regard to Wang, Petitioner contends that Wang discloses the importance of removing the cellular elements from soft tissue in order to reduce the antigenicity and rejection of the tissue after implantation into a patient. *Id.* (citing Ex. 1007, 3:9–13). Petitioner further articulates the following rationale to combine the teachings of Wang and Walker:

One skilled in the art would have had reason to use the rigorous cellular removal techniques of Wang to decellularize a soft tissue graft before incubating the graft according to Walker’s glycerol and ethanol solution. (Badylak Decl., ¶ 73). In particular, a POSA would have had reason to incorporate Wang’s cellular removal techniques into Walker’s process to minimize

any immunogenic reaction upon implantation of Walker's plasticized soft tissue grafts in a patient. (Badylak Decl., ¶ 74).
Id. at 54.

At this stage of the proceeding, we determine that Petitioner has offered sufficient evidence and argument to institute trial. We conclude, based on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 1–3 and 9–11 are unpatentable as obvious over the combination of Walker and Wang.

III. CONCLUSION

We conclude that Petitioner has established a reasonable likelihood of prevailing on its assertions that claims 1–13 of the '971 Patent are unpatentable as obvious.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and upon completion of the current record.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on the following grounds:

- A. Claims 1, 4–9, and 12–13 as obvious in view of Livesey;
- B. Claims 1, 4–9, and 12–13 as obvious over the combination of Werner and Klement; and
- C. Claims 1–3 and 9–11 as obvious over the combination of Walker

and Wang.

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

PETITIONER:

Andrea G. Reister
Gregory S. Discher
Grant D. Johnson
Covington & Burling LLP

areister@cov.com
gdischer@cov.com
gjohnson@cov.com

PATENT OWNER:

William Jackson Matney, Jr.
Andrew Koopman
Christopher Blaszkowski
RatnerPrestia

akoopman@ratnerprestia.com
wjmatney@ratnerprestia.com
cblaszkowski@ratnerprestia.com