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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte R. LANE SMITH, DENNIS R. CARTER, and DAVID J. SCHURMAN

Appeal 2018-006463
Application 14/553,869
Technology Center 1600

Before TAWEN CHANG, RYAN H. FLAX, and CYNTHIA M. HARDMAN, *Administrative Patent Judges.*

HARDMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 11, 18–20, and 23–28. *See* Final Act. 2. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as "The Board of Trustees of the Leland Stanford Junior University." Appeal Br. 3.

CLAIMED SUBJECT MATTER

The claims are directed to a hydrostatic pressure vessel comprising human chondrocytes. Claim 11, reproduced below, is illustrative of the claimed subject matter:

> 11. A hydrostatic pressure vessel comprising human chondrocytes isolated from a human having osteoarthritis, wherein the chondrocytes are present within a scaffold.

Appeal Br. 9 (Claims Appendix).

REFERENCE

The Examiner relied on the following prior art reference: Lafeber et al., *Intermittent Hydrostatic Compressive Force Stimulates Exclusively the Proteoglycan Synthesis of Osteoarthritic Human Cartilage*, Vol. 31, No. 7, British Journal of Rheumatology, 437–442 (1992) ("Lafeber").

REJECTION

Claims 11, 18–20, and 23–28 stand rejected under pre-AIA 35 U.S.C. § 102(b) as being anticipated by Lafeber. Final Act. 6.

OPINION

Claim 11 is the only independent claim on appeal. Appellant did not provide separate arguments for any of the dependent claims. Accordingly, we focus our analysis on independent claim 11, and the dependent claims stand or fall with this claim. 37 C.F.R. § 41.37(c)(1)(iv); *cf. In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.").

Claim 11 is directed to "[a] hydrostatic pressure vessel comprising human chondrocytes isolated from a human having osteoarthritis, wherein

the chondrocytes are present within a scaffold." Appeal Br. 9 (Claims Appendix). The Examiner asserted that "natural articular cartilage contains chondrocytes in an extracellular matrix" (citing Lafeber 437), and thus concluded that the claim term "human chondrocytes . . . present within a scaffold" reads on human articular cartilage. Final Act. 5.

The Examiner found that Lafeber placed samples of human articular cartilage in microtitre plates with a culture medium, placed those plates in a pressure chamber, and subjected the samples to intermittent hydrostatic compressive forces. Final Act. 6–7 (citing Lafeber 438). The Examiner found that "[t]he samples of *normal* cartilage, present in the microtitre plates in the culture medium, provided in the pressure chamber *before* application of any pressure . . . read[] on the [claimed] composition." Final Act. 7. More specifically, the Examiner stated: "The pressure vessel reads on a hydrostatic pressure vessel. Healthy human articular cartilage inherently contains human chondrocytes present within a scaffold (the extracellular matrix of cartilage reads on a scaffold)." *Id.*

Appellant argues that it is unreasonable to interpret the claim term "scaffold" to include the extracellular matrix ("ECM") of cartilage, and that "one of skill in the art would readily recognize that the 'scaffold' recited in Claim 11 is a *non-ECM support structure*." Appeal Br. 8. Appellant asserts that "[b]ecause Lafeber does not disclose chondrocytes present within a scaffold as required by Claim 11, Lafeber cannot anticipate." *Id.*

To determine whether Lafeber anticipates, we must determine whether the claim term "human chondrocytes . . . present within a scaffold" reads on human articular cartilage, as asserted by the Examiner. Final Act. 5. We determine that it does not.

During patent examination, claim terms are given "the broadest reasonable meaning . . . in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Here, Appellant's Specification does not provide an express definition for the term "scaffold." The Specification uses the term "scaffold" in only two instances. The first instance occurs in paragraph 52, which states:

> "*De novo* formation" means production of cartilage connective tissue, fibrocartilage, tendon and bone as a result of adherence by chondrocytes, fibroblasts, fibrochondrocytes, tenocytes and osteoblasts within a support structure (**scaffold or collagen matrix**) following exposure to loading interval.

Spec. ¶ 52 (emphasis added). The second instance occurs in paragraph 83, which states:

> For *in vitro* treatment, damaged cartilage tissue is removed from a patient by surgical means. The interval loading regimen can be applied to the **intact tissue** such as osteochondro cartilage graft for *ex vivo* treatment. For *in vitro* treatment, **the normal or diseased cartilage matrix is degraded** and the interval loading regimen is applied to **the resulting cartilage cells cultured in suspension within scaffold/support** or as monolayers. After the application of the loading regimen, **the resulting *de novo* formed tissue or collection of cells is re-implanted** into a patient. Preferably, but not necessarily, the transplant is autologous.

Spec. ¶ 83 (emphasis added).

We find little support in these paragraphs for equating a native cartilage sample with "human chondrocytes . . . present within a scaffold" as recited in claim 11. Final Act. 5. Paragraphs 52 and 83 in the Specification

both use the term "scaffold" in connection with discussing the *de novo* production of cartilage. Paragraph 52 discusses the "*de novo* formation" of cartilage as a result of adherence by cells "within a support structure (scaffold or collagen matrix) following exposure to a loading interval."[2] Spec. ¶ 52. Use of the disjunctive "or" in paragraph 52 signifies a difference between a scaffold and a collagen matrix, but does little to elucidate whether the claim reads on a native cartilage sample. A "collagen matrix" conceivably could be found within or outside of a native cartilage sample, and thus we find that this passage does not clearly distinguish a scaffold from a native cartilage sample.

Paragraph 83, however, is more instructive. This paragraph first describes application of the loading regimen to "intact tissue" for *ex vivo* treatment. Spec. ¶ 83; *see also id.* ¶ 86 (teaching that in the *ex vivo* method, torn or shredded cartilage is surgically removed as a cartilage graft and subjected to the loading regimen). The paragraph then describes an *in vivo* treatment, wherein *de novo* tissue can be formed. In this method, a sample of normal or diseased cartilage matrix is degraded, the resulting cartilage cells are cultured in suspension with a scaffold/support or as monolayers, the interval loading regimen is applied, and the resulting *de novo*-formed tissue is re-implanted into the patient. Spec. ¶ 83. Thus, paragraph 83 of the Specification distinguishes between treatment of a sample of native, intact tissue and of tissue generated *de novo* from cells cultured in suspension with a scaffold/support.

[2] The Specification describes a "loading interval" as stimulation of treated tissue or isolated cells with repeated periods of applied hydrostatic pressure followed by periods of recovery. Spec. ¶ 68.

Thus, on this record, we determine that the Specification distinguishes between intact tissue (such as the sample of excised, native cartilage in Lafeber) and tissue generated *de novo* from cells cultured in suspension with a scaffold/support. We conclude that the sample of excised, native cartilage in Lafeber therefore does not read on the claim term "human chondrocytes . . . present within a scaffold."

This understanding of claim 11 is consistent with the excerpts of the O'Brien and Chan articles cited in the record.[3] Appellant reproduced Figure 1 from O'Brien in its Appeal Brief. *See* Appeal Br. 6. This figure indicates that the scaffold and cells are distinct materials that are added together to form engineered tissue, with the scaffold "act[ing] as a template for tissue formation." Appeal Br. 6 (quoting O'Brien Fig. 1). Thus, like the guidance in the Specification, O'Brien discusses the use of a scaffold in the context of tissue formation/engineering. We see nothing in the O'Brien excerpts that indicates a person of ordinary skill in the art would have considered a sample of excised, native cartilage like that in Lafeber to read on the claim term "human chondrocytes . . . present within a scaffold."

The quoted excerpts from Chan indicate that "scaffolds in engineered tissues" are designed to perform functions analogous to the functions of the "extracellular matrix (ECM) in native tissues." Appeal Br. 7 (quoting Chan

[3] In its Appeal Brief, Appellant quoted two articles, O'Brien, F.J. 14(3) Materials Today 88–95 (2011) ("O'Brien") and Chan & Leong, *Scaffolding in tissue engineering: general approaches and tissue-specific considerations*, Eur. Spine J. Suppl. 4:S467–S479 (2008) ("Chan"). Appellant did not make copies of these articles of record, although it appears that the Examiner located a copy of the Chan article. Ans. 7. Because the record lacks copies of the referenced O'Brien and Chan articles, we limit our analysis to the portions of the articles that are quoted in the record.

Table 1). Again, like the Specification and O'Brien, Chan discusses the use of a scaffold in the context of tissue formation/engineering. Nothing in the cited excerpts from Chan uses the term "scaffold" in connection with a sample of native tissue.

The Examiner quoted the Chan reference as stating: "Intuitively, the best scaffold for an engineered tissue should be the ECM of the target tissue in its native state." Ans. 7 (quoting Chan S468) (emphasis omitted). While this quote suggests that ECM in its native state could be an ideal scaffold on which to build an engineered tissue, it does not support the notion that a person of ordinary skill in the art would have considered a sample of human articular cartilage as removed from a human to read on the claim term at issue. Instead, Chan distinguishes "scaffolds in engineered tissue" from "ECM in native tissues." *See* Appeal Br. 7 (quoting Chan S468).

Although this does not impact our ultimate disposition of the case, we note that we are also not persuaded by Appellant's argument that "scaffold" should be construed to mean "a non-ECM support structure." Appeal Br. 8. We see no support for such a construction in the Specification, because paragraphs 52 and 83—the only paragraphs in the Specification that expressly mention scaffolds—do not speak to the materials with which scaffolds can or cannot be made. Moreover, we agree with the Examiner that "[t]he reproduced sections of O'Brien et al and Chan et al are considered to show that an artificial or exogenous material *may* serve as a scaffold material in tissue engineering, but [are] not considered to appropriately define 'scaffold' as being *limited* to artificial or exogenous materials." Ans. 7. More importantly, the issue at hand is not what materials the scaffold can be made of, but whether natural articular cartilage

containing chondrocytes in ECM reads on "human chondrocytes . . . present within a scaffold" as recited in claim 11, as addressed above.

For the reasons discussed above, we determine that the claim term "human chondrocytes . . . present within a scaffold" does not read on a sample of human articular cartilage as removed from a human, as taught in Lafeber. "Anticipation requires that all of the claim elements and their limitations are shown in a single prior art reference." *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009). Because we determine that Lafeber does not disclose each and every limitation of claim 11, we reverse the anticipation rejection. We also reverse the rejection of claims 18–20 and 23–28, which depend from claim 11, for the same reason. *In re Fritch*, 972 F.2d at 1266.

CONCLUSION

We reverse the Examiner's rejection of claims 11, 18–20 and 23–28 under pre-AIA 35 U.S.C. § 102(b) as being anticipated by Lafeber.

DECISION SUMMARY

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
11, 18–20 23–28	102(b)	Lafeber		11, 18–20 23–28

REVERSED