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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DAVID HALTER, RALPH KURT, EMIEL PEETERS, ROEL PENTERMAN, DIRK JAN BROER, and RUDOLF MATHIAS JOHANNES NICOLAAS LAMERICHS[1]

Appeal 2015-001024
Application 13/130,939
Technology Center 1600

Before ULRIKE W. JENKS, JOHN G. NEW, and RYAN H. FLAX, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims directed to a tissue scaffold attached to a labeling agent. The Examiner rejects the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] According to Appellants, the real party in interest is Koninklijke Philips N.V. (App. Br. 3.)

STATEMENT OF THE CASE

Claims 8–14 and 16 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claims 8 and 10 are representative of the claims on appeal, and read as follows (emphasis added):

> 8. A scaffold material useful for the manufacture of scaffold for tissue and/or organ engineering, wherein said scaffold material *includes at least one anchoring unit incorporated in the scaffold material*, and a labelling agent chemically bound to the anchoring unit.
>
> 10. A scaffold material and/or a scaffold, obtainable by a method comprising *the addition of* at least one anchoring unit in the scaffold material and/or a scaffold for chemically binding a labelling agent.

Appellants request review of the Examiner's rejection of claims 8–14 and 16 under 35 U.S.C. § 102(b) as being anticipated Atala.[2]

The Examiner finds that Atala teaches linking a scaffold/matrix that bears at least one anchoring unit for chemically binding a labeling agent through "the covalent conjugation of carboxylated gadolinium nanoparticles (i.e., labeling agent) with the scaffold material using EDC/sulfo-NHS chemistry" (Final Act. 8).

Appellants contend that "[i]n Atala there is no anchoring unit disclosed which is attached, or incorporated, to the scaffold and to which the labelling agent can be attached <u>later on</u>" (App. Br. 7).

The issue is: Does a preponderance of the evidence of record support the Examiner's finding that Atala's disclosure of binding quantum dots to a scaffold matrix anticipates the claimed binding of a labeling agent to an anchoring agent?

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[2] Atala et al., US 2006/0204445 A1, published Sept. 14, 2006 ("Atala").

Findings of Fact

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art as set out in the Final Action and Answer. For emphasis only, we highlight the following:

FF1. Atala teaches "monitoring remodeling of an artificial tissue construct using image enhancing or enhancing agents . . . incorporated within, or on, a scaffold matrix before seeding with cells. . . . This is particularly useful for monitoring remodeling once the artificial tissue construct has been implanted in the body of a subject" (Atala ¶ 6; Final Act. 4). The matrix can be collagen as well as polymers made up of natural and synthetic components (Atala ¶ 6, *see* ¶¶ 149–152, claims 1–10).

FF2. Fig. 2 of Atala, reproduced below, shows the coupling of quantum dots to heparin.

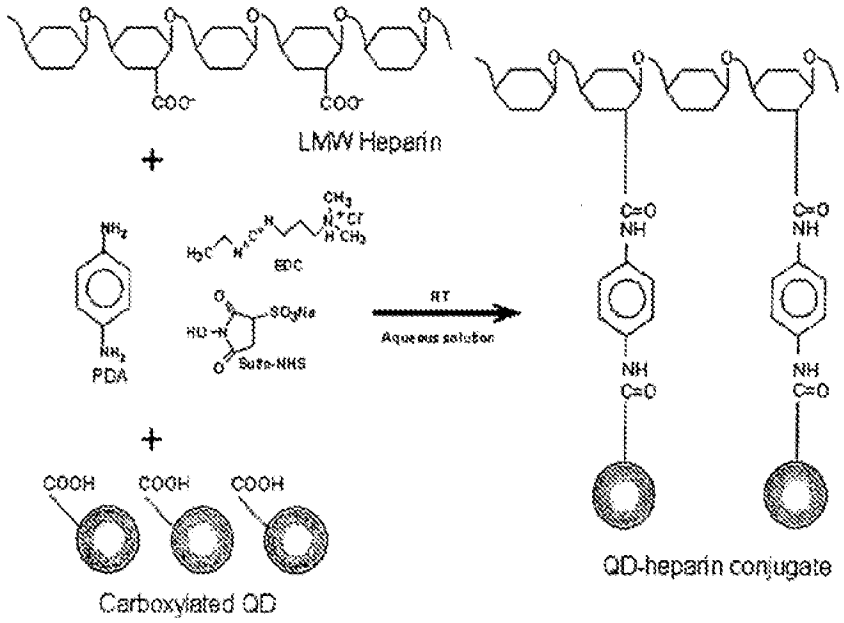

Fig. 2 shows the coupling using the EDC (1-ethyl-3(3-dimethly aminopropyl)carbodiimide) and sulfo-NHS (N-hydrocyl- sulfo-

succinimide) chemistry that links, in this example, quantum dots with a heparin scaffold (*Id.* ¶ 162). The same chemistry can apply to other matrix scaffolds, such as collagen scaffolds, as well. (*See id.* ¶ 113.)

FF3. Atala teaches the incorporation of a contrast agent into the scaffold matrix.

> In one embodiment, the agents are joined to the matrix by peptide bonds. For example, nanoparticles can be incorporated as part of the matrix using EDC (1-ethyl-3(3- dimethly aminopropyl)carbodiimide) and sulfo-NHS (N-hydrocyl- sulfo-succinimide) to form peptide bonds. . . . For external functionalization, a peptide bond can be created between the matrix and carboxylated gadolinium nanoparticles using the EDC/sulpho-NHS method to form peptide bonds between the carboxylates and amino groups. . . . Thus, a matrix functionalized with a contrasting agent allows the degradation of the matrix to be monitored.

(*Id.* ¶ 113, *see* ¶ 198; Ans. 5.)

FF4. The Examiner finds that the activated "amino group of the scaffold material used to form the peptide bond is considered to be the anchoring unit" (Final Act. 5). The Examiner explains:

> [T]he amino groups cannot be considered "anchoring units" until they are activated by EDC/sulfo-NHS (if the scaffold and carboxylated gadolinium nanoparticles were mixed without activation by EDC/sulfo-NHS, no binding of the nanoparticles to the scaffold would occur; thus, activation with EDC/sulfo-NHS serves to add anchoring units to the scaffold by activating the capability of the amino groups of the scaffold to serve as anchoring units).

(Ans. 6.)

FF5. According to the Specification:

> The term "anchoring unit for a labelling agent", as used herein, refers to a component of a multiple-component system, in

> which the components (i.e., at least the anchoring unit for a labelling agent and a labelling agent) may be attached to one another either covalently or non-covalently. In this multiple-component system, the anchoring unit is attached, or incorporated, to the scaffold, whereas the labelling agent is later attached to the anchoring unit either covalently or non-covalently.
>
> (Spec. 5.)

Principle of Law

"A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *In re Paulsen*, 30 F.3d 1475, 1478–79 (Fed. Cir. 1994).

Analysis

Claims 8, 9, 11–14, and 16

Appellants contend that in "Atala there is no anchoring unit disclosed which is attached, or incorporated, to the scaffold and to which the labelling agent can be attached <u>later on</u> (e.g., after implantation of the scaffold into the body of a patient)" (App. Br. 7). According to Appellants, Atala does not disclose anchoring units (*id.*). "At most, Atala teaches simply a mechanical/physical attachment of its image enhancing agents within the fibers and pores of the scaffold matrix, but is silent with regards to any anchoring unit for *chemically* binding a labelling agent" (*id.* at 8).

We are not persuaded by Appellants contentions. We adopt the Examiner's finding regarding the scope and content of the art as set out in the Final Action and Answer as our own (*see* FF1–FF4).

The Specification explains that an anchor refers to a component that may "be attached to one another either covalently or non-covalently" (FF5). We agree with the Examiner, that

> [b]ased on this definition, the only requirement for the anchoring unit is that i[t] be attached or incorporated to the scaffold such that the labeling agent can then be later attached either covalently or noncovalently. . . . The definition in the specification and the language of the claims do not [otherwise] specify how [and when] the anchoring unit is attached or incorporated to the scaffold.

(Ans. 5; FF4). Thus, amino acids that are part of the matrix "are an integral part of the scaffold, [because] they are incorporated in the scaffold" (Ans. 6).

The Examiner further explains that the amino acids that are part of the matrix become anchoring units upon activation through the EDC/sulfo-NHS chemistry.

> [T]he amino groups cannot be considered "anchoring units" until they are activated by EDC/sulfo-NHS (if the scaffold and carboxylated gadolinium nanoparticles were mixed without activation by EDC/sulfo-NHS, no binding of the nanoparticles to the scaffold would occur; thus, activation with EDC/sulfo-NHS serves to add anchoring units to the scaffold by activating the capability of the amino groups of the scaffold to serve as anchoring units).

(Ans. 6; FF4.) We agree with the Examiner's finding that that EDC/sulfo-NHS chemistry would activate free carboxyl groups (*see* FF2 & FF3), and one of ordinary skill in the art would recognize that in proteins free carboxyl groups are limited to acidic amino acids, such as aspartic acid and glutamic acid. We find no error with the Examiner's reasonable interpretation that the activation by EDC/sulfo-NHS creates or adds the anchoring units to the scaffold or matrix. *See In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). Accordingly, we agree with the Examiner's findings that Atala teaches scaffolds that contain a chemically bound labeling agent that attaches to the scaffold via an anchoring unit. We address Appellants contentions below:

According to Appellants, an "'anchoring unit incorporated in the scaffold material' necessarily requires a separate, discrete anchoring unit which is incorporated in the separate material which forms the scaffold" (Reply Br. 7). We are not persuaded.

Appellants do not direct us to any part of the Specification, or adduce any other evidence, that supports the interpretation that the anchoring units must be a separate material from the scaffold. "Attorney's argument in a brief cannot take the place of evidence." *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974). As explained by the Examiner, neither the claims nor the Specification requires this limitation. Indeed, the Specification indicates that the anchoring unit for a labelling agent "refers to a component of a multiple-component system" there is nothing in this description that would exclude an amino acid that is part of a larger protein as being a component of a multi component system. (Spec. 5.) After all, proteins ordinarily contain more than one amino acid in a chain and, thereby, proteins can reasonably be considered to be made up of multiple components. The Examiner explains that, in Atala, the peptide bonds form "between the carboxylates (i.e., on the gadolinium nanoparticles)" and the amino acid side chain carboxylates that are part of the larger protein matrix using EDC/sulfo-NHS (Ans. 5; *see* FF2–FF4).

Appellants contend that "[i]n Atala there is no anchoring unit disclosed which is attached, or incorporated, to the scaffold and to which the labelling agent can be attached <u>later on</u> (e.g., after implantation of the scaffold into the body of a patient)" (App. Br. 7). We are not persuaded.

Claim 1 does not recite any temporal requirements for the attachment of the anchoring units. There is no requirement that the attaching of the

anchoring unit or label occurs before or after implantation of the scaffold matrix. Furthermore, it is well established that limitations not appearing in the claims cannot be relied upon for patentability. *In re Self*, 671 F.2d 1344, 1348 (CCPA 1982).

On the record before us, we conclude the Examiner did not err in rejecting claims 8, 9, 11–14, and 16 under 35 U.S.C. § 102(b) as anticipated by Atala.

Claim 10

Appellants contend that "it is clear that the amino groups, which are cited as being the anchoring units, are not 'added' to the scaffold or scaffold material within the plain meaning of the term" (Reply Br. 8; *see* App. Br. 5, 8 ("anchoring unit <u>incorporated in the scaffold material</u>")).

We are not persuaded by Appellants contention that Atala does not add anchoring unit as claimed. As explained by the Examiner, in Atala "the amino groups [of the matrix or scaffold] must first be activated by EDC/sulfo-NHS before the [quantum dot] nanoparticles can bind to the scaffold" (Ans. 6; FF2–FF4). In other words, the amino acids in the matrix or scaffold of Atala become anchoring units only upon activation with EDC/sulfo-NHS (FF2 & FF3). We find no error with the Examiner's interpretation that in light of the Specification the chemical activation of the matrix adds the anchoring unit as required by the claim. We conclude that a preponderance of the evidence supports a prima facie case of anticipation with respect to claim 10.

SUMMARY

We affirm the rejection of claims 8–14 and 16 under as anticipated Atala. No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED