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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEPHANIE M. KLADAKIS,
SRIDEVI DHANARAJ, and ROBERT BOOCK

Appeal 2020-000884
Application 10/775,034
Technology Center 3700

Before RICHARD M. LEBOVITZ, JOHN G. NEW, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

The Examiner rejected the claims under 35 U.S.C. § 103 as obvious. Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject the claims. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[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 Depuy Synthes Products, Inc., a Johnson & Johnson company. Appeal Br. 1.

STATEMENT OF THE CASE

The Examiner rejected the claims in the Final Office Action ("Final Act") as follows:

Claims 1, 3, 9, 10, 13–15, 17, 18, 20, 21, 24, 25, 30, 31, 34–36, 38, 39, 42–47, and 50–55 under pre-AIA 35 U.S.C. § 103(a) as obvious in view of Harle (US 5,769,897, issued June 23, 1998) ("Harle"), Mueller et al. (US 5,837,235, issued Nov. 17, 1998) ("Mueller"), and Peterson et al. (US, 6,200,606 B1, issued Mar. 13, 2001) ("Peterson"). Final Act 3.

Claims 4, 16, 26, 37, 48, and 49 under pre-AIA 35 U.S.C. § 103(a) as obvious in view of Harle, Mueller, Peterson, and Binnette et al. (US 8,637,066 B2, issued Jan. 28, 2014) (Binnette"). Final Act. 6.

Claim 1 is representative and reproduced below:

> 1. A composite implant for repairing a tissue defect in a patient, comprising:
>
> a wedge-shaped porous tissue scaffold formed from a bioresorbable, synthetic polymeric material and including at least one pocket containing finely minced fragments of viable tissue that are not suspended in a carrier,
>
> wherein the tissue scaffold has opposed side walls, opposed top and bottom walls, and an end wall, the pocket has an opening formed in one of the opposed side walls, the opposed top and bottom walls, and the end wall, and the pocket is closed along a remainder of the opposed side walls, the opposed top and bottom walls, and the end wall; and
>
> wherein the viable tissue comprises naturally occurring cells and their extracellular matrix, and the naturally occurring cells and their extracellular matrix being native to the viable tissue.

REJECTIONS BASED ON HARLE, MUELLER, AND PETERSON

The Examiner finds that Harle describes a wedge-shaped porous tissue scaffold with a pocket filled with viable tissue fragments, meeting the

corresponding first limitation of claim 1. Final Act. 3. The Examiner acknowledges that Harle does not describe the fragments as being "finely minced fragments of viable tissue" as recited in the claim. However, the Examiner finds that Mueller describes minced tissue fragments. *Id.* at 3–4. The Examiner determined it would have been obvious to one of ordinary skill in the art to use minced fragments in Harle's scaffold "such that the particles enhance or are easily exposed to cells for promoting tissue regeneration." *Id.* at 4.

The Examiner also finds that Harle does not describe using cells "not suspended in a carrier" as recited in the claim. Final Act. 4. The Examiner determines it would have been obvious to one of ordinary skill in the art to omit the carrier from the cells in view of the teaching in Peterson that cells can be administered without a carrier. *Id.* The Examiner also determines it would have been obvious to omit the carrier from the cells introduced into the tissue scaffold pocket described by Harle "in order to provide immediate cellular response by not providing a carrier to shield or encase the viable cells, thus leaving them exposed." *Id.*

Appellant argues that that the modification proposed by the Examiner is contrary to the teachings in Mueller and Peterson. Appeal Br. 5.

With respect to Mueller, Appellant contends that Muller teaches a seven step method, of which two steps are necessary and not optional. *Id.* The two necessary steps, according to Appellant are:

> (a) "*preparation of a suspension of tissue particles* of endogenic omentum or other fatty tissue," and (b) "*application of the tissue particles to the carrier* by filtering the suspension through the carrier (porous or pulverulent carrier), by filtering with the carrier (pulverulent carrier), filtering off and subsequent counterfiltration with a gelling liquid (gel-like carrier) or mixing

> with a not completely solidified gel (gel-like carrier)." [Mueller] at col. 5, lines 1-25 (emphasis added).

Appeal Br. 6.

Appellant argues that one of ordinary skill in the art would not have disregarded Mueller "by not suspending the tissue particles after acquiring the tissue particles and by not using a carrier" because it is a necessary step and omitting it would "change[] the principle of operation under which Mueller is designed to operate. Appeal Br. 6.

This argument does not persuade us that the Examiner erred. The Examiner cites Mueller for its teaching of using minced tissue fragments and provides a clear explanation of why one of ordinary skill in the art would have used them in Harle's tissue scaffold. Final Act. 3–4. Thus, the teaching in Mueller that a carrier is necessary is not pertinent because the Examiner relied on the publication only for its description of minced tissue. Appellant did not identify a flaw in the Examiner's reasoning.

The rejection does not change the "principle of operation" of Mueller as asserted by Appellant. Mueller applies its tissue suspension to the carrier by filtering the suspension through it. Mueller, col. 5, ll. 8–15 ("application of the tissue particles to the carrier by filtering the suspension through the carrier (porous or pulverulent carrier)"). Thus, the suspension is necessary for its application to the carrier material. Harle's scaffold has a void for depositing the tissue, and therefore does not require the tissue to be in a suspension for its application to the scaffold. Thus, in the Examiner's rejection, Mueller's carrier is replaced by the pocket for tissue described by Harle which (like Mueller's carrier) retains the tissue. Therefore, the principle of operation of Mueller has not been changed.

Appellant argues that the rejection is also contrary to the teachings in Peterson. Appellant states that Peterson teaches the necessity of a carrier (Appeal Br. 7) because the "carrier insures that the cells are retained on the porous surface of the implant device-for a useful time period" (Peterson, col. 12, ll. 28–30). This argument does not persuade us that the Examiner erred. There is no evidence on this record that the problem described in Peterson would be encountered when Harle is used as the tissue support in the manner proposed by the Examiner. As explained by the Examiner, and discussed above, Harle's scaffold has a pocket in which the tissue is placed, providing a space to retain the tissue. *See, e.g.*, Ans. 7–8.

For the foregoing reasons, the rejection of claim 1 as obvious is affirmed.

Claims 42, 46, and 52

Claim 42, depends from claim 1, and further recites "wherein cells from the viable tissue in the pocket of the scaffold populate at least a portion of the scaffold." Claims 46 and 52 depend on different independent claims, but recite the same feature. Appellant states that the rejection is improper because "by the Examiner's own admission, Harle, Mueller, and Peterson fail to teach or suggest features identical to the language of claim 42." Appeal Br. 9.

The Examiner does not make such an admission. The Examiner states that it can be "deduced" from the teachings in the cited publications that the cells populate the scaffold or carrier. Final Act. 6. In other words, the Examiner finds with respect to this claim that cited publications reasonably

suggest the claim limitation. Appellant does not identify a deficiency in the Examiner's findings, which were made explicit in the Final Action.

Claims 43, 47, and 53

Claim 47, depends from claim 1, and further recites "wherein at least a portion of the scaffold is capable of being populated with cells from the native tissue following implantation." Claims 47 and 53 depend on different independent claims, but recite the same feature. Appellant states that the rejection is improper for the reasons as for claim 42. Appeal Br. 9. However, the Examiner did not admit the limitations in claims 43, 47, and 53 are not described in the cited publications. Rather, the Examiner cited specific disclosure in Harle at column 8, lines 50–53 ("The communication established by these micropores and capillary ducts in the second component 2 greatly facilitates the biointegration") as teaching that "the cells of the native tissue are capable of integrating in the scaffold once implanted." Final Act. 6.

Claim 54

Claim 54, depends from claim 1, and further recites "wherein the pocket has the opening in the end wall, and the opening is centrally located in the end wall." Appellant states that this limitation has advantages, as described in the Specification, in simplifying loading of the implant and facilitating migration of the tissue through the entire scaffold in all directions. Appeal Br. 10. In contrast, Appellant contends the void in Harle's scaffold "is in a slanted top wall extending between the first component's large end 1B and small end 1C" and is not described as being centrally

located and is silent as to the void's location and size. *Id.* at 10–11. Appellant further argues that the recited limitation solves the stated problem and serves a different function and purpose than described in Harle. *Id.* at 11.

Fig. 2 of Harle is copied below:

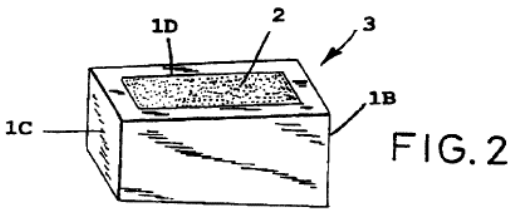

FIG. 2

Figure 2 shows the wedge-shaped body with a void 1D on one side of the body for incorporating biomaterial 2. Harle, col. 7, ll. 45–58. Claim 54 does not require the end wall to be smaller than any other side wall. Therefore, the depiction of void 1D in one end of the wedge and centrally located, meets the limitations of the claim. While it may be true that Harle does not disclose in words that void is centrally located, Figure 2 shows it located centrally and a picture is no less a description of something than the written words that could be used to describe it. Contrary to Appellant's argument (Appeal Br. 11), the Examiner does not rely on the measurements or scale of the drawing, but rather relies on the explicit depiction of a void in the center of the scaffold. *Hockerson-Halberstadt, Inc. v. Avia Group Intern., Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000), cited by Appellant, had to do with the proportions of a groove in a drawing and whether it was inconsistent with statements made during prosecution. The statement in *Hockerson-Halberstadt* that "patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue" related to the issue of

the proportions of grooves and fins in footwear. *Id.* Here, the precise proportions of the void is not at issue, just whether it is centrally located, and the figure expressly shows this. "Drawings and pictures can anticipate claims if they clearly show the structure which is claimed." MPEP 2125.I. (Ninth Ed., Rev. 10.2019, Last Revised June 2020). The centrally located void in Harle would possess the same advantages described in the Specification. Appeal Br. 10.

To the extent, it would be implied that the claimed "end wall" is placed at the end, this meaning, as discussed by the Examiner, is an "intended use" of the scaffold because it depends on its orientation when placed in the patient. Ans. 9–10.

Conclusion

For the foregoing reasons, the rejection of claim 1, 42, 43, 46, 47, 52, 53, and 54 is affirmed. Separate arguments were not provided for claims 3, 4, 9, 10, 13–15, 16, 17, 18, 20, 21, 24, 25, 26, 30, 31, 34–36, 37, 38, 39, 44, 45, 48, 49, 50, 51, and 55. The rejections of these claims are therefore affirmed, as well. 37 C.F.R. 41.37(c)(1)(iv).

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 3, 9, 10, 13–15, 17, 18, 20, 21, 24, 25, 30, 31, 34–36, 38, 39, 42–47, 50–55	103	Harle, Mueller, Peterson	1, 3, 9, 10, 13–15, 17, 18, 20, 21, 24, 25, 30, 31, 34–36, 38, 39, 42–47, 50–55	
4, 16, 26, 37, 48, 49	103	Harle, Mueller, Peterson, Binnette	4, 16, 26, 37, 48, 49	
Overall Outcome			1, 3, 4, 9, 10, 13–18, 20, 21, 24–26, 30, 31, 34–39, 42–55	

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED