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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SIAMAK AGHA-MOHAMMADI[1]

Appeal 2017-002136
Application 13/197,393
Technology Center 1600

Before TAWEN CHANG, JOHN E. SCHNEIDER, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving the Examiner's rejection of claims directed to methods for harvesting stem cells which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).[2]

We AFFIRM.

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[1] Appellant identifies the real party in interest as the inventor, Siamak Agha-Mohammadi. Br. 3.
We have considered and herein refer to the Specification of Aug. 3, 2011 ("Spec."); Final Office Action of Apr. 17, 2015 ("Final Act."); Appeal Brief of Mar. 17, 2016 ("Br."); and Examiner's Answer of Oct. 4, 2016 ("Ans.").
[2] An oral hearing was held on Nov. 1, 2018. A transcript of the hearing will be added to the file when it becomes available.

STATEMENT OF THE CASE

"Regenerative medicine is a rapidly growing field that uses laboratory-grown or therapeutically-induced human tissue as a replacement for treating injuries, diseases, or cosmetic applications." Spec. ¶ 2. "One . . . aspect of regenerative medicine revolves around taking advantage of the capability of regenerative cells found within adipose tissues." Spec. ¶ 3. "However, there are not many suitable methods for harvesting adipose derived [adult stem cells] in today's medical practices." Spec. ¶ 8.

The present specification describes "processes, devices and systems for separating and concentrating stem and stromal cells, specifically from adipose tissues, using a combination of mechanical disruption and filtration-centrifugation in the absence of enzymatic dissociating agents to obtain a highly enriched population of stem cells." Spec. ¶ 11.

Claims 1–23 and 27–29 are on appeal. Claim 1 is illustrative and reads as follows:

> 1. A method of enriching stromal cell and stem cell populations from adipose tissue in the absence of a dissociating reagent comprising:
>
> a) injecting a physiological infiltration fluid into a subject in one or more areas where fat is to be removed;
>
> b) mechanically dissociating fatty tissue in the infiltrated area with a tubular device and removing the dissociated fatty tissue via aspiration;
>
> c) collecting a first lipo-aspirate in a first vessel, wherein the first vessel comprises at least one first filter;
>
> d) passing the first lipo-aspirate through the first filter, whereby adipocyte globules and/or aggregates in the first lipo-aspirate stay above the first filter in the first vessel, and whereby the physiological infiltration fluid comprising enriched

> mesenchymal cells pass through the first filter resulting in a second lipo-aspirate;
>
> e) collecting the second lipo-aspirate in a second vessel, wherein the second vessel comprises a second filter; and
>
> f) passing the second lipo-aspirate through the second filter, wherein the mesenchymal cells pass through the second filter and pellet below the second filter, whereas a majority of the physiological infiltration fluid and any cell debris is collected above the second filter after the second lipo-aspirate is passed through the second filter.

The claims stand rejected as follows:

Claims 1–23 and 27–29 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Hedrick[3]combined with Katz '05[4], Yoshimura[5], Katz '98[6], Mitchell[7], and Dahm.[8]

Claims 1–23 and 27–29 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Ramsay[9] combined with Sklar[10], Katz '98 and Dahm.

DISCUSSION

Appellant's arguments with respect to both rejections go to the same issue – whether the references teach or suggest the step of passing the

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[3] Hedrick et al., US 7,585,670 B2, issued Sept. 8, 2009 ("Hedrick").
[4] Katz et al., us 2005/0153442 A1, published July 14, 2005 ("Katz '05").
[5] Yoshimura et al., US 2007/0148766 A1, published June 28, 2007 ("Yoshimura").
[6] Katz et al., US 5,786,207, issued July 28, 1998 ("Katz '98").
[7] Mitchell, US 3,300,051, issued Jan. 24, 1967 ("Mitchell").
[8] Dahm et al., US 7,211,433 B1, issued May 1, 2007 "Dahm").
[9] T.G. Ramsay and R.W. Rosebrough, *Hormonal regulation of postnatal chicken preadipocyte differentiation in vitro,* 136 Comp. Biochem. Physiol. Part B 245 (2003) ("Ramsay").
[10] Sklar et al., US 5.601,711, issued Feb. 11, 1997 ("Sklar").

second lipo-aspirate through the second filter, wherein the mesenchymal cells pass through the second filter and pellet below the second filter, whereas a majority of the physiological infiltration fluid and any cell debris is collected above the second filter after the second lipo-aspirate is passed through the second filter ("step (f)"). Br. 10–11. For this reason, we address the rejections together.

The issue before us is whether step (f) is taught or suggested by the references. For purposes of this Appeal, Appellant concedes that the remaining steps recited in the claims are taught by the references.

The Examiner finds that step (f) is taught by Dahm. The Examiner finds that

> Dahm teaches processes using the centrifugation vessel divided by the porous barrier wherein the solution comprising the cells of interest is greater than the volume below the porous barrier, centrifuging the centrifugation vessel, the cells of interest pellet at the bottom of the centrifugation vessel, and the insert with the porous barrier is removed along with the excess solution remaining above the porous barrier.

Final Act. 11–12. The Examiner concludes that

> a person of ordinary skill in the art at the time of the invention would find it obvious to position the second filter of the multi-filter centrifuge tube close enough to the bottom of the tube so that removal of the second filter and the vessel(s) above it, either as an insert or a detachable part of the centrifugation vessel would allow the removal of the majority of the PIF because Dahm teaches one can remove extraneous fluid above a porous barrier when enriching cells of interest by removing the upper vessel comprising the porous barrier and because removing the majority of the PIF retained above the second filter would allow

> the mesenchymal cells to be recovered in a more concentrated form.

Final Act. 12.

Analysis

We find the Examiner has established, on the existing record, that step (f) is taught by Dahm. Appellant has not produced evidence showing, or persuasively argued, that the Examiner's determinations with respect to Dahm are incorrect. Only those arguments made by Appellant in the Briefs have been considered in this Decision.[11] Arguments not presented in the Briefs are waived in the present appeal. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015). Appellant concedes that all claims stand or fall together. Br. 11.

Appellant's sole argument with respect to Dahm is that Dahm is limited to creating a gradient for centrifugation and does not teach formation of pellets under a filter. Br. 17.

We find Appellant's argument unpersuasive. As the Examiner points out in the Answer,

> Dahm teaches enriching cells by carrying out centrifugation in a vessel which is divided by a porous barrier which can be a filter

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[11] At oral argument, Appellant presented additional arguments related to Dahm. We decline to consider these arguments in this appeal as the arguments were not presented in the appeal brief, depriving the Examiner of a meaningful opportunity to consider them, and Appellant did not file a reply raising the new arguments. 37 C.F.R. § 41.47(e)(1). Moreover, Appellant has not shown good cause why we should consider them now. 37 C.F.R. § 41.47(e)(2). *Ex parte Borden*, 93 USPQ2d 1473, 1477 (BPAI 2010) (informative) ("Properly interpreted, the Rules do not require the Board to take up a belated argument that has not been addressed by the Examiner, absent a showing of good cause.").

> with a pore size of 20 - 100 μm wherein cells pass through the porous barrier, the solution comprising cells of interest is greater than the volume below the porous barrier, the cells of interest pellet at the bottom of the centrifugation vessel, and the insert with the porous barrier is removed along with the excess solution remaining above the porous barrier.

Ans. 24 (citing Dahm col. 5, ll. 9–19; 28–40 and figure 4.) The Examiner continues

> Dahm clearly describes that when the cells of higher density pass through the porous barrier, liquid from the lower compartment is forced up into the upper compartment (col. 5, ll. 28-40) and Dahm clearly depicts centrifugation with a volume of liquid above the porous barrier wherein the volume of liquid is greater than the volume between the porous barrier and the bottom of the centrifuge tube (steps f and g) which, after centrifugation, results in the cells of interest (tumor cells labeled 'tc') pelleted in the bottom of the tube with excess liquid remaining above the porous membrane (steps h and i), allowing the excess liquid above the porous barrier to be removed from the tube containing the pelleted cells without disturbing the cell pellet (step j).

Ans. 25.

Appellant also argues that the remaining references do not teach or suggest step (f). Br. 14–20. While Appellant's contention with respect to the remaining references may be correct, the argument is unpersuasive. As

discussed above, the Examiner cites Dahm as teaching step (f), and a preponderance of evidence of record supports the Examiner's conclusion.

Conclusion of Law

We conclude that a preponderance of the evidence of record supports the Examiner's conclusion that claim 1 would have been obvious over the cited references. The other appealed claims fall with claim 1.

SUMMARY

We affirm the rejection under 35 U.S.C. § 103(a).

TIME PERIOD FOR RESPONSE

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