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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PAUL M. WEINBERGER, FREDERICK A. RUEGGEBERG, DONALD J. METTENBURG, and TANNER MOBLEY

Appeal 2019-000874
Application 14/472,683
Technology Center 1700

Before LINDA M. GAUDETTE, KAREN M. HASTINGS, and JANE E. INGLESE, *Administrative Patent Judges*.

INGLESE, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] requests our review under 35 U.S.C. § 134(a) of the Examiner's decision to finally reject claims 8–18 and 21–29.[2] We have jurisdiction over this appeal under 35 U.S.C. § 6(b).

We REVERSE.

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[1] We use the word "Appellant" to refer to the "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Augusta University Research Institute, Inc. as the real party in interest. Appeal Brief filed April 24, 2018 ("Appeal Br.") at 2.

[2] Final Office Action entered July 31, 2017 ("Final Act.") at 1.

CLAIMED SUBJECT MATTER

Independent claims 8 and 22 illustrate the subject matter on appeal, and are reproduced below with contested subject matter italicized:[3]

> 8. A bioreactor comprising a first and second media reservoir, wherein the first and second media reservoir comprise at least one opening on a cell culture surface of the reservoir, wherein the first and second reservoirs are positioned so that the cell culture surfaces containing the opening of each reservoir face each other and the opening of each reservoir aligns with the opening of the other reservoir; and
>
> a tissue culture cassette comprising a first and second gasket, wherein the first and second gaskets each comprise an opening that aligns when the first and second gaskets are combined, and
>
> *a cell culture matrix or scaffold sandwiched between the first and second gasket that covers the aligned openings of the gaskets to form an impermeable tissue culture cassette*,
>
> wherein *the tissue culture cassette is positioned between the first and second media reservoirs* so that the covered openings in the first and second gaskets align with the openings in the cell culture surfaces of the first and second media reservoirs *to form an impermeable barrier between the first and second media reservoirs*; and
>
> a means for applying sufficient pressure on the media reservoirs to produce a seal between the media reservoirs and the tissue culture cassette to prevent media leakage out of the openings in the cell culture surface of the media reservoirs.

[3] The Office issued a Notification of Non-Compliant Appeal Brief on May 8, 2018 because the claims included in the Claims Appendix to the Appeal Brief filed April 24, 2018 did not match those presented in the last-entered Amendment (filed April 18, 2017). Appellant filed a Response to the Notification of Non-Compliant Appeal Brief on May 29, 2018, which included a Claims Appendix setting forth a corrected copy of the appealed claims. We, accordingly, refer to the claims as presented in the corrected Claims Appendix in this Decision.

> 22. A bioreactor comprising a first and second media reservoir, wherein the first and second media reservoir comprise at least one opening on a cell culture surface of the reservoir, wherein the first and second reservoirs are positioned so that the cell culture surfaces containing the opening of each reservoir face each other and the opening of each reservoir aligns with the opening of the other reservoir; and
>
> a tissue culture cassette comprising a first and second gasket, wherein the first and second gaskets each comprise an opening that aligns when the first and second gaskets are combined, and
>
> *a cell culture matrix or scaffold sandwiched between the first and second gasket that covers the aligned openings of the gaskets to form an impermeable tissue culture cassette*,
>
> wherein *the tissue culture cassette is positioned between the first and second media reservoirs* so that the covered openings in the first and second gaskets align with the openings in the cell culture surfaces of the first and second media reservoirs *to form an impermeable barrier between the first and second media reservoirs*; and
>
> a seal between the media reservoirs and the tissue culture cassette to prevent media leakage out of the openings in the cell culture surface of the media reservoirs.

Response to Non-Compliant Appeal Brief filed May 29, 2018 (Claims Appendix) (emphasis added).

REJECTIONS

The Examiner maintains the following rejections in the Examiner's Answer entered September 11, 2018 ("Ans."):

I. Claims 8, 10, 11, 13, 21–23, 25–27, and 29 under 35 U.S.C. § 102(b) as anticipated by Welter et al. (US 2007 /0042490 Al, published February 22, 2007); and

II. Claims 9, 12, 14–18, 24, and 28 under 35 U.S.C. § 103 as unpatentable over Welter.

FACTUAL FINDINGS AND ANALYSIS

Upon consideration of the evidence relied upon in this appeal and each of Appellant's contentions, we reverse the Examiner's rejection of claims 8, 10, 11, 13, 21–23, 25–27, and 29 under 35 U.S.C. § 102(b), and rejection of claims 9, 12, 14–18, 24, and 28 under 35 U.S.C. § 103, for reasons set forth in the Appeal and Reply Briefs, and below.

Rejection I

We first address the Examiner's rejection of claims 8, 10, 11, 13, 21–23, 25–27, and 29 under 35 U.S.C. § 102(b) as anticipated by Welter.

We find no definition of "impermeable" as recited in independent claims 8 and 22 in Appellant's Specification, and we, therefore, interpret this term according to its plain and ordinary meaning as "not permitting passage (as of a fluid) through its substance." Merriam-Webster.com (accessed February 25, 2020) https://www.merriam-webster.com/dictionary/impermeable.

Consistent with this definition of "impermeable," independent claims 8 and 22 both require the recited bioreactor to comprise, in part, first and second gaskets that each comprise an opening that aligns when the gaskets are combined, and a cell culture matrix or scaffold sandwiched between the gaskets that covers the aligned openings of the gaskets to form a tissue culture cassette that does not permit the passage of fluid (an impermeable tissue culture cassette). Independent claims 8 and 22 further require the tissue culture cassette to be positioned between first and second media reservoirs, to form a barrier between the reservoirs that does not permit passage of fluid between the reservoirs.

The Examiner finds that Welter discloses an apparatus for tissue engineering (a bioreactor) comprising first 104 and second 106 outer chambers for receiving a second liquid medium, which the Examiner finds correspond to the first and second media reservoirs recited in claims 8 and 22. Final Act. 5. The Examiner finds that Welter discloses that the tissue engineering apparatus (bioreactor) further comprises frame 20 sandwiched between first 22 and second 24 membranes, and first 90 and second 92 gaskets that secure membranes 22, 24 to frame 20 to form a leak-proof seal, or an impermeable barrier, which the Examiner finds corresponds to the tissue culture cassette recited in claims 8 and 22. Ans. 5 (citing Welter ¶¶ 40–42, 58, Figs. 2–4). The Examiner finds that Welter discloses that frame 20 and membranes 22, 24 define growth chamber 30 comprising cells seeded on scaffolds, which, the Examiner finds, "results in the scaffold being located between the two gaskets and outside of the outer chambers (media reservoirs)." Ans. 5 (citing Welter ¶¶ 11, 75–78; Figs. 2 and 9).

On the record before us, however, for reasons expressed by Appellant (Reply Br. 3) and discussed below, the Examiner does not provide a sufficient factual basis to establish that Welter discloses a cell culture scaffold that covers aligned openings in first and second gaskets to form an impermeable tissue culture cassette positioned between first and second media reservoirs, which cassette forms a barrier between the reservoirs that does not permit passage of fluid between the reservoirs, as required by claims 8 and 22 as we have interpreted them.

Welter discloses bioreactor system 10 including housing 12 comprising inner frame 20 sandwiched between first membrane 22 and second membrane 24. Welter ¶¶ 39, 40; Figs. 2–4. Welter discloses that at

least a portion of at least one of first 22 and second 24 membrane can be substantially gas impermeable. Welter ¶ 56. Welter discloses that bioreactor system 10 also includes first 90 and second 92 gaskets having an annular configuration similar in shape to inner frame 20. Welter ¶ 58; Fig. 4. Welter discloses that first 90 and second 92 gaskets secure membranes 22, 24 to inner frame 20, and form a leak-proof seal between inner frame 20 and each of first 22 and second 24 membranes. Welter ¶ 58; Figs. 2–4. Welter discloses that inner frame 20 defines growth chamber 30 containing liquid growth medium 31, which surrounds and suspends cells 15. Welter ¶¶ 41, 51; Figs. 2–4. Welter discloses an alternative embodiment in which cells are seeded onto a scaffold, and the cell-seeded scaffold is introduced into the bioreactor growth chamber. Welter ¶¶ 75, 77.

Welter discloses that outer frames 26, 28 secure membranes 22, 24 and gaskets 90, 92 to inner frame 20, and outer frames 26, 28 can include openings that form first 104 and second 106 outer chambers for receiving second liquid medium 110. Welter ¶ 60; Figs. 2 and 4.

Although Welter thus discloses that bioreactor system 10 includes first 90 and second 92 gaskets that each comprise an opening that aligns when the first and second gaskets are combined, and discloses that a scaffold may be introduced into growth chamber 30 defined by inner frame 20, such that the scaffold would be "sandwiched" between first 90 and second 92 gaskets (Fig. 2), we find no disclosure in Welter indicating that the scaffold covers the aligned openings of gaskets 90, 92 to form a tissue culture cassette positioned between first and second media reservoirs, such that the tissue culture cassette forms a barrier between the reservoirs that does not

permit passage of fluid between the reservoirs, as required by claims 8 and 22 as we have interpreted them.

The Examiner appears to find that the gas-impermeable nature of first 22 and second 24 membranes yields an impermeable tissue culture cassette when first 22 and second 24 membranes secure first 90 and second 92 gaskets to frame 20. Final Act. 5; Ans. 5. Claims 8 and 22, however, require the *cell culture matrix or scaffold* to form an impermeable tissue culture cassette by explicitly reciting that the scaffold "covers the aligned openings of the gaskets to form an impermeable tissue culture cassette." Claims 8 and 22 further require the tissue culture cassette to form a barrier between first and second media reservoirs that does not permit passage of a fluid between the reservoirs (an impermeable barrier).

The Examiner does not identify any disclosure in Welter indicating that the scaffold described in the reference as "introduced into the bioreactor chamber" covers the aligned openings of gaskets 90, 92 to form a tissue culture cassette positioned between first and second media reservoirs, which cassette forms a barrier between the reservoirs that does not permit passage of a fluid between the reservoirs, as required by claims 8 and 22.

We, accordingly, do not sustain the Examiner's rejection of independent claims 8 and 22, and claims 10, 11, 13, 21, 23, 25–27, and 29, which each depend from either claim 8 or claim 22, under 35 U.S.C. § 102(b) as anticipated by Welter.

Rejection II

We also do not sustain the Examiner's rejection of claims 9, 12, 14–18, 24, and 28 under 35 U.S.C. § 103 as unpatentable over Welter because this rejection suffers from the same deficiencies as Rejection I discussed

above, and the Examiner does not identify any disclosure in Welter, or provide any other evidence or reasoning, establishing that one of ordinary skill in the art would have been led to modify Welter's bioreactor system 10 to include a cell culture matrix or scaffold sandwiched between first and second gaskets that covers aligned openings in the gaskets to form an impermeable tissue culture cassette, which is positioned between first and second media reservoirs to form an impermeable barrier between the first and second media reservoirs. Final Act. 8–10.

CONCLUSION

Claims	35 U.S.C. §	Reference	Affirmed	Reversed
8, 10, 11, 13, 21–23, 25–27, 29	102(b)	Welter		8, 10, 11, 13, 21–23, 25–27, 29
9, 12, 14–18, 24, 28	103	Welter		9, 12, 14–18, 24, 28
Overall Outcome				8–18, 21–29

REVERSED