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| EXAMINER | |
|---|---|
| PYLA, EVELYN Y | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. 14/954,335 | Applicant(s) LOUGH, DENVER M. | |
|---|---|---|---|
| | Examiner YVONNE PYLA | Art Unit 1651 | AIA (First Inventor to File) Status Yes |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12/14/2016*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims***

5)☒ Claim(s) *1-37* is/are pending in the application.

5a) Of the above claim(s) *1-18 and 23-37* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *19-22* is/are rejected.

8)☒ Claim(s) *20* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

**Application Papers**

10)☒ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *11/30/2015* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *4/20/2016, 1/7/2016*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

## DETAILED ACTION

Claims 1-37 are currently pending.

### *Election/Restrictions*

Applicant's election without traverse of Group III (claims 19-22) in the reply filed on 12/14/2016 is acknowledged.

Claims 1-18 and 23-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/14/2016.

### *Priority*

Acknowledgement is made of the instant application which claims the benefit of provisional application No. 62/086,526, filed December 2, 2014.

### *Information Disclosure Statement*

The information disclosure statements (IDS) submitted on 1/7/2016 and 4/20/2016 were received. The submissions are in compliance with the provisions of 37

CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### *Specification*

The use of trademarks, such as Synth-a-Freeze®, Countess™, Nunc®, Upcell™ and Mr. Frosty ™, for example, has been noted in this application. Trademarks should be indicated by capitalized lettering, i.e. COUNTESS™, wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Objections*

Claim 20 is objected to because of the following informalities: typographical error in line 3. It appears that the word “the”, preceding the word “confirming” should be deleted so the claim, at line 3 reads: “subjecting the epithelial stem cell singularity units to digestion and confirming”. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it

> is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan

that the inventor had possession at that time of the later claimed subject matter." Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See M.P.E.P. § 2163.02. In this case, the skilled artisan would not have reasonably concluded at the time of the invention that applicant was in possession of the entire invention as claimed.

The current application claims a method of producing a minimally polarized micro-aggregate multi-cellular composition comprising the steps of:

a) obtaining a tissue specimen;

b) extracting minimally polarized functional units containing LGR expressing cells from the specimen;

c) processing of hypodermis and subdermal fat cellular components from an appropriate source;

d) adding the processed hypodermis and subdermal fat components to the extracted minimally polarized functional units to create epithelial stem cell singularity units;

e) enriching the epithelial stem cell singularity units;

f) adding the epithelial stem cell singularity units to a construct scaffold; and g) verifying the maintenance of minimum polarization of the obtained composition (claim 19).

Regarding the claimed step of obtaining a tissue specimen, it is noted the claims are not limited to a particular tissue specimen species, specifically comprising LGR expressing cells, just generically any tissue specimen which encompasses animal tissue such as blood, or any plant or fungal tissue, for example.

The "written description" requirement may be satisfied by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. See Noelle v. Lederman, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) and Lockwood v. American Airlines, Inc., 107 F.3d at 1572, 41 USPQ2d at 1966. A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." Regents of the University of California v. Eli Lilly & Co., 119 F.3 at 1568, 43 USPQ2d at 1406 (Fed. Cir. 1997). See also Fiers v. Ravel, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (Fed. Clarification is required. 1993) (discussing Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)). See M.P.E.P. § 2163.

The written description requirement is in place to ensure that "when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function." Ariad Pharms. Co. v. Eli Lilly & Co., 94 U.S.P.Q.2d 1161, 1172 (Fed. Cir. 2010) (en banc). A consideration of the four corners of the specification

does not reflect that applicants have actually invented the claimed invention, since the disclosure mentions tissue specimens containing LGR expressing cells (paragraph [0029]), LGR expressing cells of cutaneous origin (paragraph [0076]) and harvesting living human/mammalian tissue (paragraph [0050]) without describing other varieties of tissues, e.g. plant, animal, fungal, that are specific for containing LGR expressing cells. The specification does not permit the skilled artisan to visualize or recognize all of the members of the genus (i.e. a tissue specimen) being utilized in the claimed methods to specifically produce a minimally polarized micro-aggregate multi-cellular composition that contains LGR expressing cells.

Likewise, regarding the claimed step of processing hypodermis and subdermal fat cellular components, it is noted the claims are not limited to a particular processing step species, specifically yielding the stromal vascular fraction (SVF) and adipocytes that are required for creating the epithelial stem cell singularity units. The claims generically recite any processing step, which encompasses shipping or delivery of the hypodermis and subdermal fat, or pouring the sample from one tube to another, for example.

The four corners of the specification does not reflect that applicants have actually invented the claimed invention, since the disclosure mentions processing the hypodermis and subdermal fat by incubating the fat sample with a digestive enzyme solution (collagenase and dispase-based) for a period of time (paragraph [00153]), stopping the digestion (paragraph [0154], centrifuging the suspension to form a soft pellet (paragraph [0155]; separating the adipose population from stromal vascular

fraction (SVF) and collecting the adipose population and the stromal vascular fraction (paragraph [0156]), without describing other processing steps that are specific for yielding an adipose population and the stromal vascular fraction. The specification does not permit the skilled artisan to visualize or recognize all of the members of the genus (i.e. processing hypodermis and subdermal fat) being utilized in the claimed methods to specifically produce adipocytes and stromal vascular fraction.

Since each of claims 20-22 depend directly or indirectly from claim 19 they each inherit the deficiency thereof, and thus are rejected on the same basis.

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-22 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

**Regarding claim 19**, claim 19 recites "…producing a minimally polarized micro-aggregate multi-cellular composition…" The term "minimally polarized" is a relative term which renders the claim indefinite. The term "minimally polarized" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite

degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The 'metes and bounds' of the claim are unclear as to what level of polarization is “minimally polarized”. There is ambiguity with respect to the level of polarization to be provided.

In the interest of compact prosecution, it is considered that any LGR expressing cell is minimally polarized. However, despite the above interpretation, this rejection to claim 19 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, stands and must be addressed. Since each of claims 20-22 depend directly or indirectly from claim 19 they each inherit the deficiency thereof, and thus are rejected on the same basis. Appropriate correction is required.

**Further regarding claim 19**, as to the phrase “minimally polarized functional unit”, it is noted the phrase "minimally polarized functional unit" is not defined by the claim and the specification does not provide a specific definition that defines the specific components. Claim 19 does indicate that the minimally polarized functional unit contains LGR expression cells. Thus, in the interest of compact prosecution, “minimally polarized functional unit” is interpreted as any LGR expressing cell. However, despite the above interpretation, this rejection to claim 19 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, stands and must be addressed. Since each of claims 20-22 depend directly or indirectly from claim 19 they each inherit the deficiency thereof, and thus are rejected on the same basis. Appropriate correction is required.

**Further regarding claim 19**, claim 19, step (d) recites the limitation "..the processed hypodermis and subdermal fat components…". There is insufficient

antecedent basis for this limitation in the claim since claim 19, step (c) recites "processing of hypodermis and subdermal fat cellular components". Since each of claims 20-22 depend directly or indirectly from claim 19 they each inherit the deficiency thereof, and thus are rejected on the same basis.

It is additionally noted that claim 19, step (d) recites "to create epithelial stem cell singularity units". It is unclear as to where the stem cells are provided in the method since step (b) only requires LGR expressing cells and is not limited to stem cells or epithelial stem cells. It is unclear if the combination with the fat components in some way de-differentiates the LGR expressing cells that are extracted in step (b)?

Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 19-22 are rejected under 35 U.S.C. 103 as being unpatentable over Sugihara et al., (*In Vitro Cell. Dev. Biol.*, 1991; see PTO-892) ("Sugihara"), in view of Biedermann et al, (*J. of Investigative Dermatology*, 2010; see PTO-892) ("Biedermann"), as evidenced by Gao et al., (*International Journal of Molecular Medicine*, 2014; see PTO-892) ("Gao").**

Sugihari is directed to in vitro reconstructed skin comprising epidermis, dermis and hypodermis, useful as a transplantation graft (Summary, page 142).

**Regarding claim 19**, Sugihari (Materials and Methods, page 142), specifically teaches obtaining skin specimens from two sources:

(i) abdominal skin containing hypodermal fatty tissue from Wistar rats; and

(ii) human chest skin, which reads on "***obtaining a tissue specimen***".

The hypodermal fatty tissue was separated from the skin and subjected to:

(i) digestion with collagenase; and

(ii) filtration and centrifugation, thus producing mature fat cells and immature preadipocytes, which reads on "***processing of hypodermis and subdermal fat cellular components from an appropriate source***".

The epidermis with attached dermis was subjected to enzymatic digestion using trypsin to separate the epidermis layer from the dermis layer. Further digestion released epidermal cells and dermal fibroblasts.

Sugihari teaches preparing the reconstructed skin by forming a three layered construct, as shown in Fig. 1. The reconstructed skin is prepared by forming:

(i) a basal layer (first layer) by combining a collagen solution and the mature fat cells, which was then poured into a dish comprising a nitrocellulose membrane bottom (comparable to the hypodermis);

(ii) forming a second layer by combining a collagen solution with the pre-adipocytes and dermal fibroblasts (comparable to the dermis). This second layer is poured over the basal (first) layer to constitute a middle layer; and

(iii) forming a third layer by overlaying keratinocytes on the middle layer.

The construct was cultured using minimum essential medium with 20% fetal bovine serum and various supplements.

Sugihari (Discussion, left column, page 145) teaches the reconstructed skin consisted of stratified epidermis with keratinization and will serve well as a transplant graft particularly for treating deep, chronic ulcers. Moreover, Sugihari teaches that other types of cells may be included in the reconstructed skin, such as placing sweat gland cells into the dermal or hypodermal layer.

Sugihari differs from the instant invention in that Sugihari does not teach LGR expressing cells extracted from the specimen, or that the addition of the hypodermal

and subdermal fat components to the extracted cells creates epithelial stem cell singularity units.

However, Sugihari does suggest the addition of sweat gland cells to the dermal or hypodermal layers of the reconstructed skin and Biedermann discloses that sweat glands are considered to be a possible source of epidermal stem cells and provide an additional source of keratinocytes that can generate a stratified epidermis (Abstract). Biedermann specifically prepared an *in vitro* cultured composite skin substitute consisting of a dermal and a multi-layered epidermal equivalent comprising isolated human sweat gland cells (Materials and Methods, Organotypic cultures; page 2006). After *in vitro* culture, the composite was transplanted onto the backs of rats and incubated for 14 days prior to excision and histological analysis (Materials and Methods, Transplantation of cultured dermo-epidermal composites, page 2007; and Fig. 1).

Sugihari teaches that the histological analysis revealed that the composites seeded with the human sweat gland cells formed stratified epidermis, consisting of a basal layer, suprabasal layers and a well-differentiated anuclear stratum corneum (Fig. 1h).

Therefore, given that Sugihari has shown preparing a reconstructed skin substitute, and suggests the addition of sweat gland cells in the dermal or hypodermal layers, and given that Biedermann has employed human sweat gland cells in a reconstructed skin composite resulting in a stratified epidermis, it would have been prima facie obvious to one having ordinary skill in the art at the time of the invention to modify the method of Sugihari to include the addition of sweat gland cells in the dermal or hypodermal layers,

as taught by Biedermann, for the predictable result of successfully producing a reconstructed skin having stratified epidermis in the method of Sugihari, thus meeting the limitation of claim 19, step (b). One of ordinary skill in the art would have been motivated to modify the method of Sugihari in order to provide an additional source of cells that can generate a stratified epidermis since the intention of Sugihari is to produce a multi-layered reconstructed skin. Biedermann has shown that including human sweat gland cells in a reconstructed skin composite resulted in a stratified epidermis. Thus one would have had a reasonable expectation of successfully including human sweat gland cells in the method of Sugihari.

It is noted that Gao evidences that human sweat gland cells comprise epithelial stem cells that express LGR5 (Abstract and Results, *Expression of LGR5 in SGECs*, page 1001), therefore, absent evidence to the contrary, Biedermann's sweat gland cells necessarily comprise epithelial stem cells that express LGR5.

Therefore, the combination of Sugihari and Biedermann, as evidenced by Gao, meets the limitation of extracting LGR expressing cells, as recited in claim 19, step (b). It is further noted, as set forth above, the phrase “minimally polarized functional unit” is interpreted as any LGR expressing cell; thus the combined references meet the limitation of “*extracting minimally polarized functional units containing LGR expressing cells from the specimen*”.

As to claim 19, step (d), Biedermann teaches the addition of the sweat gland cells to the hypodermal layer of the reconstructed skin, which comprise fat components obtained from the tissue specimen hypodermal and subdermal fat and, as set forth

above, the LGR5 expressing sweat gland cells are considered "minimally polarized functional units", thus the combination of the LGR5 expressing sweat gland cells to the hypodermal layer of the reconstructed skin would necessarily create epithelial stem cell singularity units, as recited in claim 19, step (d).

As to claim 19, step (e), Biedermann employs an in vitro, organotypic culture of the sweat gland cell seeded composite in Rheinwald and Green medium, which promotes the growth and proliferation of the sweat gland cells, which reads on "***enriching the epithelial stem cell singularity units***".

As to claim 19, step (f), the combined references teach adding the sweat gland cells to the hypodermal layer comprising a collagen scaffold, thus meeting the limitation of claim 19, step (f).

As to claim 19, step (g), and the limitation "verifying the maintenance of minimum polarization of the obtained composition", it is noted that Biedermann's Fig. 1 shows stratified multi-layered epidermis comprising LGR5 expressing cells, which reads on "***verifying the maintenance of minimum polarization of the obtained composition***".

**Regarding claim 20,** as to the limitation "*subjecting the epithelial stem cell singularity unit to digestion and the confirming microaggregate confluence before verification*", it is first noted that, in obtaining the sweat gland cells from the donor specimen, Biedermann teaches digestion of the donor skin sample to release the sweat gland cells from native components including fat (Materials and Methods, Establishment of primary cell cultures, page 2006). Thus, it is considered that the donor skin sample included native LGR5 expressing sweat gland cells in combination with native,

hypodermal and subdermal fat components, which reads on epithelial stem cell units. Thus, the digestion step to release the sweat gland cells from native components reads on "subjecting the epithelial stem cell singularity units to digestion". Given this step was performed prior the *in vitro* culture of the reconstructed skin, and subsequent verification step, this step would read on subjecting the epithelial stem cell singularity units to digestion before verification. As to confirming microaggregate confluence, it is noted that the reconstructed skin construct was subjected to *in vitro* culture that resulted in confluence prior to *in-vivo* transplant, which took place prior to the histological analysis shown in Biedermann Fig. 1h. Thus, microaggregate confluence occurred prior to histological verification of the stratified epithelium (i.e. verification of maintenance of minimal polarization), which reads on confirming microaggregate confluence before verification. Therefore, Biedermann discloses both steps of subjecting the epithelial stem cell singularity units to digestion and confirming microaggregate confluence before histological verification, thus meeting the limitations of claim 20.

**Regarding claim 21**, Biedermann (Fig. 1d and 1f) confirm maintenance of the reconstructed composite comprising the LGR5 expressing sweat gland cells, which as set forth above are considered polarized cells. The *in vitro*, organotypic culture included 3 weeks of culturing at the air/liquid interface, producing stratified epithelium. Thus, it is considered that polarization has been maintained for 48 hours. Biedermann then transplanted the composite on the backs of rats for 14 days and performed histological analsyis (Fig. 1h) showing corneum stratum. Thus, it is considered that the native, in vivo environment on the backs of the rats adds an appropriate cornification medium

following confirmation that polarization has been maintained for 48 hours, as recited in claim 21.

**Regarding claim 22**, as to the limitation "cryopreserving the obtained composition", Biedermann discloses subjecting the composite to cryopreservation and cryosectioning, thus meeting the limitation of claim 22.

## *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YVONNE PYLA whose telephone number is (571)270-7366. The examiner can normally be reached on Monday -Friday 9am - 6pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Renee Claytor can be reached on 571-272-8394. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE PYLA/
Examiner
Art Unit 1651

/THANE UNDERDAHL/
Primary Examiner, Art Unit 1657

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