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MERCHANT & GOULD P.C. P.O. BOX 2903 MINNEAPOLIS, MINNESOTA 55402-0903 UNITED STATES OF AMERICA			PYLA, EVELYN Y	
			ART UNIT	PAPER NUMBER
			1651	
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			06/14/2018	ELECTRONIC

**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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO23552@merchantgould.com

**Office Action Summary****Application No.**

14/954,335

**Applicant(s)**

Lough, Denver M.

**Examiner**

E. Y PYLA

**Art Unit**

1651

**AIA 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 2/6/2018.  
 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) 1-19 and 21-64 is/are pending in the application.  
5a) Of the above claim(s) 1-18,23-37 and 62-64 is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_ is/are allowed.
- 7)  Claim(s) 19,21-22,38-39,42,44,47,50,53,56 and 59 is/are rejected.
- 8)  Claim(s) \_\_\_\_ 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](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10)  The specification is objected to by the Examiner.
- 11)  The drawing(s) filed on \_\_\_\_ 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 \_\_\_\_.
- 3)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 4)  Other: \_\_\_\_.

***Notice of Pre-AIA or AIA Status***

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 1-19 and 21-64 are currently pending. Claims 1-18, 23-37 and 62-64 are withdrawn. Claims 38-64 are newly added. Claims 19, 21 and 22 are currently amended.

***Election/Restrictions***

Applicant previously elected, without traverse, the invention of Group III (previously included claims 19-22). Applicant's newly added claims 38, 39, 42, 44, 47, 50, 53, 56 and 59 depend directly or indirectly from claim 19 and are included in the invention of Group III.

Newly submitted claim 40, and its dependent claims (41, 43, 45, 46, 48, 49, 51, 52, 54, 55, 57, 58, 60 and 61) are directed to an invention that is distinct from the invention originally claimed (Invention Group III, claims 19-22) for the following reasons: the Group III invention requires the step of adding a mesenchymal-derived cell population, which is not required of the method of claim 40 and the method of claim 40 requires the step of separating fat and hypodermal elements from dermal and epidermal compartments of a mammalian tissue specimen to provide a partially processed mammalian tissue specimen. Thus, the methods have different modes of operation.

Newly submitted claims 62-64 are directed to compositions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40, 41, 43, 45, 46, 48, 49, 51, 52, 54, 55, 57, 58 and 60-64 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 10/9/2017 and 10/31/2017 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***

Applicant's amendment is accepted.

### ***Claim Objections***

The cancellation of claim 20 obviates the objection previously made to this claim.

### ***Claim Interpretation***

Regarding claim 19, claim 19 has been amended to recite the following:

*“(a) extracting at least one minimally polarized functional unit from a mammalian tissue specimen wherein the minimally polarized functional unit*

*comprises at least a portion of a follicular bulge, wherein the portion of the follicular bulge comprises LGR-expressing stem cells;...”*

It is considered that any LGR expressing cell obtained from a follicular bulge is minimally polarized.

### ***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.

### **Rejection Withdrawn**

**RE: Rejection of claims 19-22 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:**

Applicant's amendment obviates the rejection previously made to claims 19-22.

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.

**Rejection Withdrawn**

**RE: Rejection of claims 19-22, under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite:**

Regarding claim 19, claim 19 has been amended to recite the following:

*“(a) extracting at least one minimally polarized functional unit from a mammalian tissue specimen wherein the minimally polarized functional unit comprises at least a portion of a follicular bulge, wherein the portion of the follicular bulge comprises LGR-expressing stem cells;...”*

Therefore, Applicant has clarified that a minimally polarized unit comprises at least a portion of a follicular bulge, wherein the portion of the follicular bulge comprises LGR-expressing stem cells. Therefore, it is considered that any LGR expressing cell obtained from a follicular bulge is minimally polarized.

Further regarding claim 19, Applicant has amended the claim to clarify that the LGR-expressing cells are LGR-expressing stem cells, thus providing clarity as to where the stem cells originate to create at least one epithelial stem cell functional singularity unit.

***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.

### **Rejection Withdrawn**

**RE: Rejection of claims 19-22 under 35 U.S.C. 103 as being unpatentable over Sugihara, in view of Biedermann, as evidenced by Gao:**

Due to the claim amendments the rejection under 35 U.S.C. 103 has been withdrawn, however the amendments have necessitated a new ground of rejection, as set forth below.

### **New ground of rejection, necessitated by amendment**

**Claims 19, 21, 39, 47, 50, 53, 56 and 59 are rejected under 35 U.S.C. 103 as being unpatentable over Snippert et al., (*Science Magazine*, 2010; IDS 1/7/2016) (“Snippert”), in view of Ohyama et al., (*Dermatology*, 2007; see PTO-892) (“Ohyama”) and Stenn et al., (*Current Opinion in Biotechnology*, 2005; see PTO-892) (“Stern”), in further in view of**

**Zanzottera et al., (*Journal of Cosmetics, Dermatological Sciences and Applications*, September 2014; see PTO-892) (“Zanzottera”), as evidenced by Dictionary.com (retrieved from the internet, see dictionary.com/cornification) (“Dictionary.com”).**

Snippert is directed to stem cell compositions that generate the formation of new hair follicles. These stem cells have positive expression for Lgr6, i.e. Lgr6+ and in addition to generating new hair follicles, the Lgr6+ stem cells executed long term wound repair (Abstract).

**Regarding claim 19**, Snippert’s Fig. 1E illustrates the Lgr6+ stem cells are located at a portion of the follicular bulge and Fig. 4 illustrates the Lgr6+ stem cells contribute to wound healing and hair neogenesis. Snippert teaches the Lgr6+ stem cells were extracted from the dorsal skin of mice and subsequently transplanted on the backs of nude mice wherein the transplanted Lgr6+ stem cells reconstituted fully formed HFs (hair follicles) (left column, 2<sup>nd</sup> paragraph, page 1388; Supporting Online Material, Materials and methods: Cell sorting and Flow cytometry). Given that Snippert’s stem cells are Lgr6+ cells isolated from mouse skin (i.e. mammalian tissue specimen), and Snippert’s Fig. 1 illustrates the Lgr6+ cells are located at a portion of the follicle bulge, Snippert’s extracted Lgr6+ cells are considered minimally polarized functional units. Therefore, Snippert’s method reads on “*extracting at least one minimally polarized functional unit from a mammalian tissue specimen wherein the minimally polarized functional unit comprises at least a portion of a follicular bulge, wherein the portion of the follicular bulge comprises LGR-expressing cells*”, thus meeting the limitation of claim 19, step (a).



Regarding claim 19, steps (b) and (c), although Snippert teaches processing the subcutaneous tissue and the fat from the dorsal skin by gentle scraping to remove from the extracted skin (Supporting Online Material, Materials and methods: Cell sorting and Flow cytometry), Snippert does not teach whether or not the processing provides a mesenchymal-derived cellular population or if a portion of a mesenchymal-derived cellular population is added to the isolated Lgr6+ stem cells. However, Ohyama is directed to studies of stem-cell-enriched hair follicle bulge cells (Abstract) and specifically teaches the stem-cell-enriched hair follicle bulge cells can provide an excellent source of cells for regenerative medicine, specifically noting that hair follicle reconstitution was shown to be possible by transplanting a mixture of keratinocytes and *mesenchymal-derived cells* onto nude mice (**Future Directions of Bulge Cell Investigation**, right column, page 349).

Stenn is likewise directed to bioengineering of the hair follicle and specifically teaches that isolated hair follicle epithelial stem cells must be combined with inductive dermal cells (Abstract). Stern notes that in fetal skin, hair follicles develop from two major cell types: (1) epithelium and (2) mesenchyme, and crosstalk between these two cell populations is critical, and in the adult, the interaction of the epithelial stem cells in the bulge with adjacent mesenchymal-derived dermal papilla cells reforms the hair follicle with each new hair cycle (**Introduction**, page 493).

Although Ohyama and Stern do not disclose the mesenchymal-derived cell population is derived from processing hypodermis and subdermal fat cellular components, Zanzottera is directed to adipose-derived stem cells and growth factors applied on hair follicle transplants. Zanzottera specifically teaches obtaining the adipose-derived mesenchymal stem cells by processing the discarded scalp tissue

(comprising hypodermis and adipose tissue) used to isolate the follicular units (Abstract; **3.2 Cellular Suspension Obtainment**, page 269; and Figure 2).

Zanzottera teaches the application of the adipose-derived mesenchymal stem cells to the hair follicles provided faster healing and improved the outcome for the patient , as well as providing increased growth factors which eased the healing process and helped growth and engraftment of the transplanted hair follicles (Abstract and 6. Discussion, page 273).

Therefore, given that both Ohyama and Stern teach the importance of combining mesenchymal-derived cells with epithelial stem cells for promoting hair follicle reconstitution and Zanzottera specifically demonstrates processing hypodermis and fat cellular components to obtain adipose-derived mesenchymal stem cells for application to follicular units to improve follicle engraftment and wound healing, it would have been prima facie obvious to one having ordinary skill in the art at the time of filing to modify the method of Snippert to include processing of hypodermis and subdermal fat cellular components to provide a mesenchymal-derived cellular population to be added to the Lgr6+ epithelial stem cells, as taught by Zanzottera, for the predictable result of successfully improving hair follicle reconstitution in the method of Snippert, thus meeting the limitation of claim 19, steps (b) and (c). One of ordinary skill in the art would have been motivated by the teachings of Ohyama, Stenn and Zanzottera to modify the method of Snippert in order to provide the necessary mesenchymal-derived cell population that is important for hair follicle reconstitution and results in improved healing and engraftment of hair follicles since the intention of Snippert is to generate the formation of new hair follicles. Zanzottera has shown processing hypodermis and subdermal fat cellular components to obtain adipose-derived mesenchymal stem cells

and growth factors for application (i.e. addition) to follicular units to improve follicle engraftment and wound healing; thus one would have had a reasonable expectation of successfully processing hypodermis and subdermal fat cellular components to obtain adipose-derived mesenchymal stem cells and growth factors for the addition to the Lgr6+ epithelial stem cells in the method of Snippert, thus creating at least one epithelial stem cell functional singularity unit.

As to claim 19, step d) Zanzottera has shown processing hypodermis and subdermal fat cellular components to obtain adipose-derived mesenchymal stem cells and growth factors for application (i.e. addition) to follicular units (i.e. at least one epithelial stem cell functional singularity unit) to improve follicle engraftment and wound healing. The inclusion of the growth factors is considered to read on “enriching the at least one epithelial stem cell functional singularity unit”.

As to claim 19, step e), “*adding the at least one enriched epithelial stem cell functional unit to a delivery substrate*”, it is noted that Zanzottera teaches delivering the cell composition via needle and syringe which is considered a delivery substrate, thus meeting the limitation of claim 19, step e).

As to claim 19 and the limitation “*to provide the composition*”, as discussed immediately above, Zanzottera provides the composition via syringe and needle delivery, thus meeting the limitation of claim 19.

As to claim 19 and the recitation “*wherein the composition is capable of assembling functional polarized tissue*”, Snippert discloses reconstitution of fully formed HFs (hair follicles) employing Lgr6+ epithelial stem cells obtained from a portion of the follicular bulge. It is noted that a whereby/wherein clause in a method claim “is not given weight when it simply expresses the intended result of a process step

positively recited” (MPEP 2111.04). As discussed above, Snippert teaches the same method step of providing LGR6 expressing stem cells obtained from a portion of the follicular bulge, as disclosed in the instant specification (paragraphs [0122]-[0123]), thus the method disclosed by the combined references would necessarily result in assembling functional polarized tissue.

**Regarding claim 21**, Snippert transplanted the Lgr6+ stem cells on the backs of nude mice wherein the transplanted cells reconstituted fully formed hair follicles (Fig. 4E). Thus, given cornification is defined as the formation of horny structures such as hair (dictionary. com/cornification; see PTO-892), it is considered that the native, in vivo environment on the backs of the mice adds an appropriate cornification medium as recited in claim 21.

**Regarding claim 39**, Zanzottera teaches the mesenchymal-derived cellular population comprises stromal vascular fractions (1. Background and 2. Aim), thus meeting the limitation of claim 39.

**Regarding claims 47 and 50**, Snippert teaches applying the composition to wounds on the backs of nude mice (Fig. 4), thus meeting the limitations of claims 47 and 50.

**Regarding claim 53**, Snippert teaches excision of 1 cm<sup>2</sup> of full thickness back skin, which reads on “the select target is an injury involving multiple tissue elements”, thus meeting the limitation of claim 53.

**Regarding claims 56 and 59**, Snippert teaches applying the Lgr6+ cells directly to the wound by transplantation (left column, 2<sup>nd</sup> paragraph to middle column, 2<sup>nd</sup> paragraph, page 1388), thus meeting the limitations of claims 56 and 59.

**Claim 22 is rejected under 35 U.S.C. 103 as being unpatentable over Snippert, in view of Ohyama and Stenn, and in further in view of Zanzottera, as evidenced by Dictionary.com, as applied to claims 19, 21, 39, 47, 50, 53, 56 and 59 above, and further in view of Limat et al., (*The Journal of Investigative Dermatology*, 1986; see PTO-892) (“Limat”).**

Snippert, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com is set forth above.

**Regarding claim 22**, as to the limitation “further comprising cryopreserving the composition”, the combined references do not teach subjecting the stem cell composition to cryopreservation. However, Limat is directed to cultivation of single cell suspensions of keratinocytes that have been isolated from hair follicles (Cell Isolation and Cultivation, page 485) and subsequently subjected to cryopreservation for storage and future recovery (Cryopreservation, page 485). Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time of filing to modify the method of Snippert, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com to include cryopreservation of the cell composition, as taught by Limat, for the predictable result of successfully storing the cells for future use, thus meeting the limitation of claim 22. One of ordinary skill in the art would have been motivated by the teachings of Limat to modify the method in order to store the cell composition for future use, thus permitting flexibility in the timing of the cell transplant. Limat has shown successful cryopreservation and recovery of the keratinocytes obtained from the hair follicles; thus one would have had a reasonable expectation of successfully cryopreserving the cell composition in the method of

Snippert, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com.

**Claim 42 is rejected under 35 U.S.C. 103 as being unpatentable over Snippert, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com, as applied to claims 19, 21, 39, 47, 50, 53, 56 and 59 above, and further in view of Lee et al., (Tissue Engineering, 2011; see PTO-892) (“Lee”).**

Snippert, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com is set forth above.

**Regarding claim 42**, the combined references do not teach the delivery substrate is selected from those recited in claim 42. However, Lee is directed to procedures for reconstitution of hair-producing skin wherein epidermal and dermal stem cells are transplanted (i.e. delivered) to the wound by seeding a scaffold, i.e. Integra, with the cells (Results, *A simplified procedure to generate hairs arrange in a single normally oriented plane*, paragraphs 1-3, page 392; FIG. 1). Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time of filing to modify the method to include a three-dimensional scaffold, as taught by Lee, for the predictable result of successfully transplanting the hair-producing stem cells, thus meeting the limitation of claim 42. One of ordinary skill in the art would have been motivated to modify the method of the combined references in order to provide a three-dimensional scaffold that allows proper organization of the hair-producing stem cells. Lee has shown reconstitution of hair-producing skin by employing a three-dimensional scaffold, i.e. Integra; thus one would have had a reasonable expectation of successfully

using a three-dimensional scaffold as the stem cell delivery substrate in the method of Snippet, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com.

**Claims 38 and 44 are rejected under 35 U.S.C. 103 as being unpatentable over Snippet, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com, as applied to claims 19, 21, 39, 47, 50, 53, 56 and 59 above, and further in view of Wong et al., (*International Journal of Biomaterials*; see PTO-892) (“Wong”).**

Snippet, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com is set forth above.

**Regarding claim 38**, the combined references do not teach the Lgr6+ cells (at least one minimally polarized functional unit) further comprising at least one supportive cellular entity, as recited in claim 38. However, Wong is directed to stem cell niches for skin regeneration (Abstract). Wong specifically teaches that matrix components (i.e. extracellular matrix) are important for generating three-dimensional environments that constitute stem cell niches (6. Engineering Niches through Biomaterials, right column, 1<sup>st</sup> paragraph, page 4). Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time of filing to include matrix components to support the stem cell niche, as taught by Wong, for the predictable result of successfully providing a stem cell support environment, thus meeting the limitation of claim 38. One of ordinary skill in the art would have been motivated to modify the method of the combined references in order to provide extracellular matrix that provides a stem cell niche for the hair-producing stem cells. Wong specifically teaches that matrix components (i.e.

extracellular matrix) are important for generating three-dimensional environments that constitute stem cell niches; thus one would have had a reasonable expectation of successfully using a matrix components to provide stem cell support in the method of Snippert, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com.

**Further regarding claim 44**, although the combined references do not further teach adding enhancing factors to the cell composition, Wong teaches various components, such as TGF- $\beta$  and BMPs are relevant to epidermal stem cell function (3. The Epidermal Stem Cell Niche, page 2). Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time of filing to include components such as TGF- $\beta$  and BMPs, as taught by Wong, for the predictable result of successfully to enhancing stem cell function, thus meeting the limitation of claim 44. One of ordinary skill in the art would have been motivated to modify the method of the combined references in order to enhance stem cell function. Wong specifically teaches various components, such as TGF- $\beta$  and BMPs are relevant to epidermal stem cell function; thus one would have had a reasonable expectation of successfully adding these enhancing factors in the method of Snippert, in view of Ohyama and Stern, and in further in view of Zanzottera, as evidenced by Dictionary.com.



### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. YVONNE PYLA whose telephone number is (571)270-7366. The examiner can normally be reached on M-F 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

***/THOMAS J. VISIONE/  
Primary Examiner, Art Unit 1651***