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This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.
The present invention relates to a cell-containing sheet that is useful as a medical implant. Spec. 1.

According to the Specification

In recent years, a technology whereby artificial alternatives or organized culture cells are used for implantation has been under development and gaining attention. Representative examples of such alternatives or cells to be implanted include artificial skin, artificial blood vessels, and tissue composed of culture cells. In the case of artificial skin made of synthetic polymers, for example, rejection or the like might occur, therefore such skin is not preferable for implantation. Meanwhile, tissue composed of cultured cells is made by culturing and organizing cells of a patient. Thus, there is no concern about rejection when using such tissue in the patient himself/herself. Therefore, the tissue is preferable for implantation. Such tissue composed of cultured cells is produced by collecting cells from a patient and culturing the cells for the patient.

Spec. 1.

STATEMENT OF CASE

The following claim is representative.

7. A method for producing a cell-containing fine pattern sheet comprising cells and a support comprising a bioabsorbable material that has a cell adhesion protein-containing layer on the surface thereof, comprising the steps of:
   a) providing epithelial cells, epidermal cells, renal cells, muscle cells, neural cells, hepatocytes, Langerhans cells, osteocytes, chondrocytes, lymphangial cells, or periodontal ligament-derived cells;
   b) contacting said cells with the surface of a substrate for cell arrangement having a cell adhesiveness-variation pattern comprising cell adhesiveness promoted regions having a water contact angle from 10° to 40°, and cell adhesiveness inhibited
regions, wherein said cells adhere solely to the cell adhesiveness promoted regions of said substrate;

c) culturing said cells adhering to the surface of said substrate;

d) contacting said substrate adherent cells with a cell adhesion protein-containing layer on the surface of a support wherein said substrate adherent cells also adhere to said support,

wherein the cell adhesion protein-containing layer has not been subjected to a patterning treatment; and

e) removing the substrate for cell arrangement to transfer said substrate adherent cells to said support;

wherein the support comprises an amnion in which a layer composed of cells is removed, and the support is supported by a biodegradable polymer,

wherein the cell-containing fine pattern sheet has a pattern not more than 3 mm in size and is an implant.

21. The method according to claim 7, wherein the amnion consists of stratum compactum and basal lamina.

Cited References

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<tr>
<td>Yui</td>
<td>US 5,723,010</td>
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<td>Fishman</td>
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Grounds of Rejection

1. Claims 7, 9–13, 20, 30, and 31 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Morita.
Claims 7, 9–13, and 20–29 are rejected under 35 U.S.C. §103(a) as being unpatentable over Morita, in view of Shimazaki (JP 2001-16153; English translation) in further view of Fishman.


FINDINGS OF FACT

The Examiner’s findings of fact are set forth in the Answer, at pages 2-17. The following facts are highlighted.

1. Figures 1 and 2 of the Specification are reproduced below.
Fig. 1 shows the procedures of the present invention for allowing cells to adhere to a substrate for cell arrangement. Spec. 7. Fig. 2 shows the procedures of the present invention for transferring cells to a support for cell cultivation. Id. The explanation of the symbols used in the figures is set forth below:

2. Morita, Figure 7 is reproduced below.

Figure 7 shows FIG. a schematic view showing an example of the method of constructing artificial cell tissue and base material of Morita.

Cells are inoculated on a cell array substrate (15) comprising regions having good cell adhesiveness (17) and regions having inhibited cell adhesiveness (18) patterned thereon. The cells are caused to adhere to form a pattern, so that a cell adhesion substrate is prepared. Subsequently, the cell adhesion substrate is caused to closely contact to a cell culture substrate (16), so as to transfer the

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1 Morita is also one of the inventors in the present application.
cells. The cells are then cultured. If necessary, the cells are
stimulated with a cell stimulating factor (22). Morita ¶ 250-251.

3. According to the present Specification

The support can be produced by allowing the cell adhesion
protein-containing layer to adhere to the surface of the
biodegradable polymer material. The cell adhesion protein­
containing layer can be formed by applying a cell adhesion
protein-containing solution to the surface of the biodegradable
polymer material. … Cell adhesion proteins are proteins having a
function of adhering to cells. Specific examples thereof include
various types of collagens, fibronectins, laminins, vitronectins,
cadherins, gelatins, fibrinogens, fibrins, and integrins. Preferably,
the cell adhesion protein-containing layer of the present invention
is a collagen-containing layer, since it is excellent in terms of cell
adhesiveness.

Spec. 10.

4. According to the Specification the

synthetic support compris[es] a bioabsorbable material that can be
used contains a biodegradable polymer material and a cell
adhesion protein-containing layer adhering to the surface of the
material. The biodegradable polymer material is not particularly
limited as long as it can be degraded and absorbed via in vivo
hydrolysis, enzymatic degradation, or the like and as long as it has
a certain level of mechanical strength. Preferred examples of such
material that can be used include polyglycolic acid, polylactic acid,
a copolymer of glycolic acid and lactic acid, polydioxanone, a
copolymer of glycolic acid and trimethylene carbonate, and a
mixture of polyglycolic acid and polylactic acid. The form of such
biodegradable polymer material is not particularly limited and is
designed in accordance with the purposes thereof.

Spec. 9, italicized emphasis added.
5. According to the Specification, the support comprising a bioabsorbable material, may be an organism derived support. Spec. 11.

6. According to the Specification, the organism-derived support is not particularly limited as long as it is derived from membranous tissue in vivo and it has a low level of antigenicity. Examples thereof include an amnion-derived support and a chorion-derived support. Spec. 11.

7. According to the Specification

Amnion in vivo is composed of an epithelial layer, basal lamina, \textit{stratum compactum}, a fibroblast layer, and stratum spongiosum. Preferably, a layer composed of cells is removed from the amnion in vivo such that a membrane comprising stratum compactum and basal lamina is used as an amnion-derived support. Since basal lamina is rich in collagen, it functions as a cell adhesion protein-containing layer in an organism-derived support comprising stratum compactum and basal lamina. Also, since stratum compactum is rich in collagen, it can function as a cell adhesion protein-containing layer and a membrane consisting of stratum compactum may be used as the support of the present invention.

Spec. 12.

8. According to the Specification

Origins of these collagens which may be used are not particularly limited. In general, such collagens that can be used are obtained from skin, bones, cartilages, tendons, organs, or the like of mammals including primates such as humans and monkeys, rodents such as rabbits, mice and rats, pet animals such as canines and felines, bovines, swines, sheep, horses, and the like. In addition, collagen-like proteins obtained from fishes, birds, or the like also can be used.
Spec. 11.

9. Fishman discloses a microfabricated tissue as a substrate for pigment epithelial cells transplantation for ocular implants. The tissue may be prepared by contacting membranous tissue with a substrate including a bioabsorbable material, which may be submersed in phosphate buffered saline, or by coating a surface of a membranous tissue with a bioabsorbable material, and modifying the membranous tissue either before or after coating or contacting the tissue with the substrate. Suitable bioabsorbable materials include collagen; glycosaminoglycans; chitosan; poly(hydroxyalkanoates); poly(a-hydroxy acids); polyglycolic acid (PGA); polylactic acid (PLA); etc. ¶ 11; Final Act. 11.

10. Fishman defines the term membranous tissue

To mean any tissue of an animal that forms a sheet or sheath; membranous tissue commonly encloses or delimits a tissue, or divides an organ or tissue into separate compartments. “Ocular membranous tissue” is used herein to mean membranous tissue derived from the eye of an animal; lens capsule tissue and inner limiting membrane are examples of ocular membranous tissue, as are corneal membranes, Bruch’s membrane, and other membranous tissues of the eye. ¶ 44.

11. Shimazaki (translation) discloses a cell piece for transplantation. This cell piece for transplantation comprises an amnion, an epithelial stem cell tissue made to adhere onto the amnion, and an epithelial cell proliferated from the stem cell tissue so as to cover the amnion surface. Abstract.

12. Shimazaki (translation) discloses that the amnion is pretreated to make it easy to remove the unnecessary upper cortex and sponge layer which constitute an amnion. The procedure of this pretreatment can be processed with ammonia water 10%, for example, although there is no limitation in particular. Translation ¶ 42; Ans. 7.

13. Amemiya discloses the development of human amniotic membrane (AM), which has been cultured, and comprises mucosal
epithelia and periodontal ligament (PDL) cells prepared in sheet biomaterials from human oral epithelia and PDL cells for oral reconstruction. Synopsis; Ans. 11.

14. Amemiya discloses that the Amnionic epithelial cells were exfoliated and eliminated just before cell culturing. P. 91, col. 1.

15. Yui et al. teach a medical device that is implantable and tissue-regenerative including an artificial blood vessel (col. 1, lines 6-15), and the device consists essentially of stratum compactum of tissue membrane including amnion (col. 3, lines 5-8; col. 4, lines 36-44). Yui et al. teach the use of stratum compactum as a substrate for cell culture/growth (col. 8, lines 13-18). Yui et al. teach that a reinforcing material can be used for the membranous material consisting of stratum compactum of amniotic membrane, and the material is a bioabsorbable material such as polyglycolic acid, polylactic acid or a copolymer thereof (col. 6, lines 43-58). Ans. 3.

16. Yui discloses that its method comprises the steps of: separating tissue membrane including stratum compactum from tissue; sterilizing or disinfecting the separated tissue membrane; and removing all other layers except the stratum compactum from the sterilized or disinfected tissue membrane using an enzyme. Abstract.

17. Yui discloses that the human amnion comprises: epithelium and basement membrane; stratum compactum having a width of about 10 µm; and fibroblast. A medical device according to the present invention consists essentially of stratum compactum, excluding epithelium, basement membrane and fibroblast from human amnion. Col. 4, l. 64-col. 5, l. 3.

PRINCIPLES OF LAW

In making our determination, we apply the preponderance of the evidence standard. See, e.g., Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427
(Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”


**Obviousness Rejection 1 – Morita and Yui**

The Examiner finds that

Morita et al. teach a method of producing a cell culture substrate comprising steps of adhering cells to the surface of a cell array substrate having a pattern of cell-adhesiveness area and cell adhesiveness inhibiting area, and transferring the adhered cells in a finely patterned state onto a cell culture base material (abstract and par. 11, 13, 19). Morita et al. particularly disclose an embodiment using vascular endothelial cells (par. 19) which is used for forming artificial blood vessel as intended by Morita et al.

Ans. 2.

Morita further discloses that the regions having good cell adhesiveness and the cell adhesiveness variation pattern have water contact angles between 10° and 40° (par. 14). Ans. 3–4. Morita teach that the pattern is formed with lines having widths of between 20 µm and 200 µm, the space widths are between 300 and 1000 µm (par. 19), and thus meets the limitation of fine pattern having no more than 3 mm in size as claimed currently. *Id.* The Examiner finds that the substrate of Morita has a pattern and the cells adhering along the pattern are considered to be a cell arrangement. *Id.* The Examiner admits that Morita does not particularly teach the support being amnion in which a layer composed of cells being removed. Ans. 3.
The Examiner relies on Yui to make up for this deficiency. FF 16, 17. Yui teaches “a medical device that is implantable and tissue-regenerative including an artificial blood vessel (col. 1, lines 6-15), and the device consists essentially of stratum compactum of tissue membrane including amnion (col. 3, lines 5-8; col. 4, lines 36-44). Yui et al. teach the use of stratum compactum as a substrate for cell culture/growth (col. 8, lines 13-18).” Ans. 3. Yui further teaches that a reinforcing material can be used for the membranous material consisting of stratum compactum of amniotic membrane, and the reinforcing material is a bioabsorbable material such as polyglycolic acid, polylactic acid or a copolymer thereof (col. 6, lines 43–58). Id.

The Examiner concludes that

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the amnion consisting of stratum compactum of Yui et al. as a support ... [for] the patterned cells of Morita et al. Id.

Appellants contend that Morita does not teach that the cell culture substrate may comprise an amnion supported by a biodegradable polymer, as required by the claimed methods. App. Br. 9. Appellants argue that, “the basis for this rejection rests on the assumption that one of ordinary skill in the art will consider the ‘cell culture substrate’ disclosed in Morita et al. as equivalent to the amniotic membrane disclosed by the secondary reference, Yui et al.” Id. Appellants argue that this assumption is erroneous. Id.

Appellants argue that

Morita et al. provide clear guidance to one of ordinary skill in the art regarding the intended use for the cell culture substrate such as tissue or organ, in disclosing that “through direct transfer of cells ... to such biomaterial, the cells can be directly cultured in a pattern on such
tissue or organ” ([paragraph [00275]]. Therefore, taken in the context of the application of the cell culture substrate as expounded by Morita et al., the biomaterial taught by Morita et al. will be understood by one of ordinary skill in the art to mean organs and tissues derived from a patient for implantation into the patient.

App. Br. 10. Appellants further rely on the Declaration of Dr. Hattori, as evidence, and for the proposition that

one of ordinary skill in the art as of the priority date of the present application would have understood that the cell culture substrate for implantation mentioned in Morita et al. is limited to biomaterials derived from the subject to be treated, or alternatively organs for transplantation into the subject and does not extend to biomaterials for application to the site of treatment,” such as the amnion in Yui et al. (page 2 of the Declaration).

App. Br. 10. Appellants submit that,

Dr. Hattori concludes that one of ordinary skill in the art “would understand that, in Morita et al., the cell adhesion substrate for implantation is an organ or tissue that the patient needs” and therefore one of ordinary skill in the art “would not have a reason to substitute amnion for the cell culture substrate of Morita et al., because the patient’s body does not need amnion.”

App. Br. 11.

The issues are: Does the combination of Morita and Yui teach that the cell culture substrate or support comprises an amnion in which a layer composed of cells is removed, and the support is supported by a biodegradable polymer, as claimed? Has the Examiner provided a reason to combine Morita with Yui?
ANALYSIS

We select claim 7 as representative claim for each of the pending rejections, as Appellants have not provided separate arguments for individual claims in the Appeal Brief. We agree with the Examiner’s fact finding, statement of the rejection and responses to Appellants’ arguments as set forth in the Answer. We find that the Examiner has provided evidence to support a prima facie case of obviousness. We provide the following additional comment to the Examiner’s argument set forth in the Final Rejection and Answer.

During ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. See, Cuozzo Speed Technologies, LLC v. Lee, 136 S. Ct. 2131, 2144 (2016); In re Zletz, 893 F.2d 319, 321 (Fed. Cir. 1989).

With respect to the claim language “amnion in which cells have been removed,” we reference the Specification, which states that

Amnion in vivo is composed of an epithelial layer, basal lamina, stratum compactum, a fibroblast layer, and stratum spongiosum. Preferably, a layer composed of cells is removed from the amnion in vivo such that a membrane comprising stratum compactum and basal lamina is used as an amnion-derived support.

Spec. 12. We find that amnion material containing stratum compactum only is amnion in which cells have been removed.

Appellants argue that

Yui et al. does not teach the use of stratum compactum as a cell substrate, as alleged by the Examiner. See column 8, lines 19-20 of Yui et al. (disclosing in part that “the medical device [according to the
claimed invention] allows the regeneration, growth and self-repair of defective tissue.”). There is no teaching or suggestion in Yui et al. regarding the use of the stratum compactum of amnion as a substrate for culturing cells in vitro.

App. Br. 12, bracketing original, italicized emphasis added. Appellants argue that there is no reason to substitute the stratum compactum of Yui for the organ cells of Morita. App. Br. 10–11.

We are not persuaded by Appellants’ argument. Claim 7 is directed to “A method for producing a cell-containing fine pattern sheet comprising cells and a support comprising a bioabsorbable material that has a cell adhesion protein-containing layer on the surface thereof.” Claim 7 is not specifically directed to a method of use of stratum compactum of amnion as a substrate for culturing cells in vitro. Yui fairly discloses a medical device or tissue prosthesis which is a sandwich-like layered structure prepared by stitching the membrane made of stratum compactum with a fibrous material made of bioabsorbable material. Col. 7. The bioabsorbable material may be a polylactic acid or copolymer. Col. 7. The tissue is formed by cell growth using the stratum compactum as a substrate (Col. 8), in a manner similar to that claimed.

With respect to the Appellants’ argument regarding motivation to combine Morita with Yui (App. Br. 10-11), we are not persuaded. Both of Morita and Yui are directed to artificial cell tissue for medical tissue replacement and methods of preparing this tissue. Morita ¶ 2; Yui, col. 1. Both of the tissue replacement materials of Morita and Yui employ a substrate for cell growth. In Morita, the substrate may be a collagen sheet or biomaterial derived from a living body which include tissues or organs. Morita ¶ 274. In Yui, the substrate for cell growth is amnion stratum
compactum, connected to a polylactic acid fibrous material. Col. 8. We agree with the Examiner that it would have been obvious to one of ordinary skill in the art at the time of the invention to replace one well known substrate for cell growth with another, e.g., the substrate of Yui for that of Morita. Yui’s substrate for cell growth is essentially the same as that claimed, except for cell patterning. Put another way, Morita discloses that it was well known in the art at the time of the invention to pattern cells on a substrate for cell growth used for preparing artificial skin, etc. Morita ¶2. Thus, alternatively, it would have been obvious to one of ordinary skill in the art to modify the substrate of Yui having the substrate for cell growth is amnion stratum compactum, connected to a polylactic acid fibrous material, to include patterning as disclosed by Morita. This is because Morita discloses that, “[c]ulture of cells on such substrate enables adhesion of a greater number of cells to a surface on which collagen or the like has been patterned.” Morita ¶6. In addition, an advantage of substrate cell patterning is that

Through the formation of such cell adhesiveness variation pattern, vascular endothelial cells caused to adhere and then transferred in a linear pattern efficiently form a tissue; that is, a linear capillary vessel. When a cell pattern where a plurality of lines are arranged without crossing each other is formed, the space widths between the lines on which cells are adhered are each set to be equal to or above a specific value as described above. Accordingly, the cells can be prevented from extending pseudopodia between the lines at the time of their tissue formation, which would distort the lines.

Morita ¶41.
The Examiner, additionally, concludes that based on the given broad definition of the term “biomaterial” for use as a substrate for cell growth in Morita (which may be a biomaterial (tissue or organ) derived from a living body), one skilled in the art would understand that the scope of the biomaterial for use as a substrate for cell growth in Morita includes any known material derived from living bodies, and includes amnion or amniotic membrane which is derived from a placenta (an organ). Ans. 13.

The Examiner further concludes that Yui discloses that the amnion-derived substrates are used for cell carriers, and for implantation, and one skilled in the art would recognize that the amnion-derived substrates taught by Yui et al., as a suitable biomaterial for the method of Morita et al. Id.

We agree with the Examiner that the evidence of record supports the Examiner’s finding that the combination of Morita and Yui teach that the cell culture substrate or support comprises an amnion in which a layer composed of cells is removed, and the support is supported by a biodegradable polymer, as claimed.

We carefully considered the Declaration of Dr. Hattori, and have considered his conclusion that from his reading of Morita, that the cell adhesion substrate for implantation described therein is an organ or tissue that the patient needs, for instance for the purpose of replacement. Declaration p. 2–3.

In spite of the technical conclusion of Dr. Hattori in his Declaration that the biomaterial substrate of Morita is limited to organs or tissues, the Board has broad discretion as to the weight to give to declarations offered in the course of prosecution. See Velander v. Garner, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (“[A]ccord[ing] little weight to broad conclusory statements
[in expert testimony before the Board] that it determined were unsupported by corroborating references [was] within the discretion of the trier of fact to give each item of evidence such weight as it feels appropriate.”). Furthermore, Dr. Hattori’s conclusion has no specific relevance as to the legal conclusion whether it would have been obvious to one of ordinary skill in the art to substitute one well known cell growth substrate for another, in a tissue prosthesis.

Unexpected Results

Appellants argue that the method of the invention produces a cell-containing fine pattern sheet that possesses unexpected and superior properties that distinguish it as being unobvious in the context of the cited references. Appellant had previously highlighted that the mechanical strength of amnion allows it to be fixed on the site to be treated by suturing. See Response filed March 24, 2016 (describing that “[w]hen the cell containing sheet of the present invention is sutured at the site, the cell pattern on the sheet is fixed to the site keeping the contact between the site and the aligned cells in a predesigned manner for a sufficient period of time,” facilitating rapid recovery).

App. Br. 15.

The Examiner responds, arguing Appellants have not provided an evidentiary showing of synergistic effect provided by the claimed method and device layering, or unexpected results. Ans. 16. In particular, the Examiner argues that,

Even if the alleged synergistic effect is considered, there is no clear evidence supporting the unexpected synergism. The alleged synergism is based on the use of the cell containing sheet of the instant invention (i.e. amnion) by suturing it onto the tissue site. Appellant alleged that Example 4 of the instant specification
demonstrates such alleged effect. However, it is the Examiner’s position that the alleged “synergism” has not been established. Example 4 does not show any evidence other than the use of the periodontal ligament-derived cell containing sheet made of an amnion-derived support, and the results obtained from the implantation of the sheet secured by suturing on to the parietal bone. The data shown in Example 4 compare the control group (with the amnion sheet only) and the experimental group (with the cell-containing sheet on which the pattern of human periodontal ligament cells). It is the Examiner’s understanding that the results of “rapid recovery” are shown in the experimental group which contains periodontal ligament cell in pattern compared to the control group having no cells on the amnion-derived sheet. There is no “synergism” shown in Example 4 based on the use of amnion and suturing as alleged.

*Id.*

For the reasons cited by the Examiner, we are not persuaded by Appellants’ arguments or evidence of unexpected results.

We find no error in the Examiner’s prima facie case of obviousness. We do not find Appellants have provided evidence to rebut the Examiner’s prima facie case of obviousness. The preponderance of the evidence supports the Examiner’s obviousness rejection.

**Obviousness Rejection 2 – Morita, Shimizaki, and Fishman**

Morita is relied on by the Examiner for its disclosure discussed above. The Examiner further relies on Shimazaki as teaching

an amniotic membrane (AM) carrier for cell transplantation, and the AM carrier is obtained from amniotic membrane with a sponge layer (stratum spongy) and an upper cortex (epithelial layer) being removed, resulting in a dense layer (stratum compactum) and a basement membrane (basal lamina) left (see par. 44 of the English translation).
Ans. 7. The Examiner concludes that it would have been obvious to replace the amnionic carrier for cell transplantation of Shimazaki for the cell culture substrate of the method of Morita because both of the tissue replacement materials of Morita and Shimazaki employ a substrate for cell growth. In Morita, the substrate may be a collagen sheet or biomaterial derived from a living body which include tissues or organs. Morita ¶ 274. In Shimazaki, the substrate for cell growth (cultivation ¶ 55) is amnion stratum compactum (cells removed), which is used to prepare cell pieces for transplant. Shimazaki translation ¶¶ 1, 14, 23, 42. We agree with the Examiner that it would have been obvious to one of ordinary skill in the art at the time of the invention to replace one well known substrate for cell growth with another, e.g., the substrate of Shimazaki for that of Morita.

Fishman discloses that a microfabricated membranous tissue layer such as amniotic membrane on a carrier matrix aids in its implantation into the body. Fishman ¶¶ 11, 68-69, 79. The carrier matrix of Fishman may be a biodegradable, bioabsorbable polymeric material such as polylactic acid (par. 11, 68-69, 79). Ans. 8.

It would therefore have been obvious to a person skilled in the art to modify the AM carrier of Shimazaki et al. to have a biodegradable carrier matrix as a support. Since the use of the biodegradable carrier matrix for the support of a membranous tissue is known in the art as taught by Fishman et al., and the AM carrier of Shimazaki et al. is considered the same membranous tissue of Fishman et al., one skilled in the art would combine prior art elements according to the known method to yield predictable results.

Final Act. 8.
Regarding this rejection, Appellants rely on their previous arguments with respect to Morita, the Declaration of Hattori, and unexpected results. App. Br. 18–20. We are not persuaded by these arguments for the reasons presented herein, and the rejection Claims 7, 9–13 and 20, 22–29 is affirmed.

Claim 21

While not specifically indicating argument of claim 21, Appellants do argue that, “a combination of the cited references will not lead one of ordinary skill in the art to the claimed invention, since the claimed method comprises the use of amnion that consists of stratum compactum and basal lamina (See Figure on page 17, Amendment filed February 7, 2012),” which is the subject matter of claim 21. App. Br. 20.

We are not persuaded that the Examiner has provided evidence to support a prima facie case of obviousness of claim 21. According to Appellants’ Specification, the amnion is composed of an epithelial layer, basal lamina, stratum compactum, a fibroblast layer, and stratum spongiosum. Shimizaki translation indicates that the amnion is treated to remove the epithelial layer, sponge layer and upper cortex. ¶14, 64. The Examiner does not indicate and Shimazaki does not appear to disclose that the fibroblast layer has been removed from the amnion. The rejection of claim 21 is reversed.

Obviousness Rejection 3 – Morita, Amemiya and Fishman

The disclosures and arguments with respect to Morita and Fishman are discussed above, herein. Amemiya is relied on by the Examiner for the
disclosure of amniotic membrane (AM) carrier being used for sheets comprising human oral epithelial cells or periodontal ligament cells for oral reconstruction. … Amemiya et al. teach that amniotic epithelial cells were exfoliated and eliminated (see p. 91, left col. “Human AM preparation”).

Regarding this rejection, Appellants rely on their previous arguments with respect to Morita, the Declaration of Hattori, and unexpected results. App. Br. 18-20.

Appellants further argue that the amniotic membrane allegedly taught by Amemiya “is not equivalent to the amnion of the claimed method. The claimed method encompasses an amnion in which a layer composed of cells is removed, which comprises stratum compactum and basal lamina as defined by the specification (page 12, lines 6-9).” App. Br. 23.

We are not persuaded. Amemiya et al. teach that amniotic epithelial cells were exfoliated and eliminated (see p. 91, left col. “Human AM preparation”). Thus, Amemiya discloses removal of a layer of amnionic cells.

The obviousness rejection is affirmed.

CONCLUSION OF LAW

The cited references support the Examiner’s obviousness rejections, which are affirmed for the reasons of record. The rejection of claim 21 over Morita in view of Shimizaki and Fishman is reversed. Arguments not made are waived.
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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART