

What is claimed:

1. Decellularized extracellular matrix (ECM) derived from a Urodele said decellularized ECM derived by:
 - a. obtaining a tissue sample from a urodele, which tissue sample comprises ECM; and
 - b. decellularizing said tissue sample to produce decellularized ECM by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial making it suitable for use as a xenograft.
2. The decellularized ECM of claim 1, wherein said decellularizing comprises subjecting said tissue sample to an alkaline treatment.
3. The decellularized ECM of claim 1, wherein said decellularized ECM is subjected to sterilization.
4. The decellularized ECM of claim 3 further comprising devitalized cells.
5. The decellularized ECM of claim 1 wherein the ECM is derived from Axolotl tissue.
6. The decellularized ECM of claim 1, wherein the ECM includes basement membrane.
7. The decellularized ECM of claim 1, wherein the ECM is infused with, coated with, or attached to an agent xenogenic to a Urodele that is a growth factor, a cytokine, a chemokine, a protein, a carbohydrate, a sugar, a steroid, an antimicrobial agent, a synthetic polymer, an adhesive, a drug or a human agent.
8. The decellularized ECM of claim 7, wherein the agent is a cell, optionally a human cell

9. The decellularized ECM of claim 1, wherein the ECM is in a form selected from the group consisting of a sheet, a powder, a gel, a paste, a sheet, or a mesh, and wherein the ECM is parietal ECM, mesothelial ECM, thoracic cavity ECM, abdominal cavity ECM, pericardium ECM or dermal tissue ECM.

10. The decellularized ECM according to claim 1 contained within a package.

11. A tissue culture system comprising (a) a decellularized ECM according to claim 1, (b) tissue culture medium, and (c) cells xenogenic to a Urodele.

12. The tissue culture system of claim 11, wherein the cells are human cells.

13. A method for making a decellularized extracellular matrix (ECM) according to claim 1 derived from a Urodele said decellularized ECM derived by:

a. obtaining a tissue sample from a urodele, which tissue sample comprises ECM;
and

b. decellularizing said tissue sample to produce decellularized ECM by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial making it suitable for use as a xenograft.

14. The method of claim 13, wherein the method further comprises performing the decellularization in a manner to retain structural and functional integrity of the decellularized ECM sufficient to permit the decellularized ECM to be useful as a matrix upon and within which cells can grow.

15. The method of claim 13, further comprising homogenizing the decellularized ECM to form a powder, and, optionally reconstituting the powder as a gel.

16. The method of claim 13, further comprising sterilizing the decellularized ECM.

17. The method of claim 13, further comprising attaching the decellularized ECM to an agent xenogenic to a Urodele.

18. The ECM according to claim 9, wherein the powder has a particle size between 125 and 850 microns.

19. The ECM according to claim 9, wherein the powder has a particle size of less than 250 microns.

20. The ECM of claim 1, wherein the ECM is a paste.

21. The ECM of claim 1, wherein the ECM is a gel.

22. The ECM of claim 21, wherein the gel comprises a synthetic polymer.

23. The ECM of claim 1, wherein the ECM is a mesh.

24. The ECM according to claim 1 comprising sterile, isolated, decellularized Urodele extra cellular matrix (ECM), wherein the ECM is a sheet, wherein the ECM is parietal ECM, mesothelial ECM, thoracic cavity ECM, abdominal cavity ECM, pericardium ECM or dermal tissue ECM, and the sheet of ECM is infused with, coated with, or attached to an agent xenogeneic to a Urodele that is a growth factor, a cytokine, a chemokine, a protein, a carbohydrate, a sugar, a steroid, an antimicrobial agent, a synthetic polymer, an adhesive, or a drug.

25. The ECM of claim 24, wherein the agent is an anti-microbial agent.

26. The ECM of claim 24, wherein the agent is a growth factor.

27. The ECM of claim 1, wherein the sheet is at least two sheets of isolated Urodele decellularized ECM laminated to one another.

28. A method for making the ECM of claim 1, comprising extracellular matrix components derived from a Urodele, said method comprising:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises extracellular matrix; and
- b. decellularizing said tissue sample to produce decellularized extracellular matrix by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial making it suitable for use as a xenograft.

29. The method according to claim 28, wherein said decellularizing comprises subjecting said tissue sample to an alkaline treatment, and wherein said process further optionally comprises subjecting said sample to sterilization, and wherein the Urodele is an Axolotl.

30. A method for making the ECM of claim 29, comprising sterile, isolated, decellularized Urodele Extracellular Matrix (ECM) or a sterile Urodele fraction derived from the isolated, decellularized Urodele ECM, said method comprising:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises extracellular matrix;
- b. decellularizing and sterilizing said tissue sample, to produce the sterile decellularized extracellular matrix, by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial, making it suitable for use as a xenograft; and sterilizing said tissue.

31. The method according to claim 30, wherein the ECM is a biocompatible sheet, mesh, gel, graft, tissue, device, or is a material coated with, impregnated with, encapsulated with or that is encapsulated by, or having attached thereto the isolated, decellularized Urodele ECM.

32. The method according to claim 30, wherein said decellularizing comprises subjecting said tissue sample to an alkaline treatment, wherein said process further comprises subjecting said sample to sterilization, wherein the Urodele is an Axolotl.

33. A method for making the material coated with, impregnated with, encapsulating, or having attached thereto isolated, decellularized Urodele ECM of claim 1, wherein said isolated, decellularized Urodele ECM is produced by a process comprising:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises extracellular matrix;
- b. decellularizing said tissue sample to produce decellularized extracellular matrix by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial making it suitable for use as a xenograft; and sterilizing said tissue.

34. A biomaterial comprising decellularized extracellular matrix (ECM) derived from a Urodele said decellularized ECM derived by:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises ECM; and
- b. decellularizing said tissue sample to produce decellularized ECM by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial making it suitable for use as a xenograft.

35. A method of making a biomaterial comprising decellularized extracellular matrix (ECM) derived from a Urodele said decellularized ECM said method comprising:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises ECM; and
- b. decellularizing said tissue sample to produce decellularized ECM by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial making it suitable for use as a xenograft.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/801,956	02/26/2020	Ryanne Early	SYG-19-1252US-CON2	9621
35811 7590 08/18/2022 IP GROUP OF DLA PIPER LLP (US) ONE LIBERTY PLACE 1650 MARKET ST, SUITE 5000 PHILADELPHIA, PA 19103			EXAMINER DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1699	
			NOTIFICATION DATE	DELIVERY MODE
			08/18/2022	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):

pto.phil@us.dlapiper.com

Office Action Summary	Application No. 16/801,956	Applicant(s) Early, Ryanne	
	Examiner RUTH A DAVIS	Art Unit 1699	AIA (FITF) 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 06.21.2022.

☐ 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) 1-35 is/are pending in the application.

5a) Of the above claim(s) 11-17,28-33 and 35 is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-10,18-27 and 34 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 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 ____ 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)

3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

4) ☐ Other: ____.

Paper No(s)/Mail Date ____.

DETAILED ACTION

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.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1 – 10, 18 – 27 and 34 in the reply filed on June 21, 2022 is acknowledged.

Claims 1 – 35 are pending; claims 11 – 17, 28 – 33 and 35 are withdrawn; claims 1 – 10, 18 – 27 and 34 have been considered on the merits.

Applicant is reminded that non-elected claims may be considered for rejoinder when all claims directed to the elected invention are in condition for allowance. In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. In order to retain the right to rejoinder, applicant is advised that the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention. Failure to do so may result in a loss of the right to rejoinder. MPEP 821.04

Information Disclosure Statement

The information disclosure statements (IDS) submitted on February 26, July 27, and November 12, 2020; March 12, June 16 and September 23 2021 are in compliance with the

provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

Claims 8 and 9 are objected to because of the following informalities:

Claims 8 fails to end with a “.”

Claim 9 recites “a sheet” in duplicate.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

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 7 – 8 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 applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 7 is drawn to a decellularized extracellular matrix (ECM), however is rendered vague and indefinite for reciting “human agent” as the phrase is not adequately defined by the claim language or specification.

Claim 8 is rendered indefinite because the claim does not appear to further define the claim on which it depends. Claim 7 requires the decellularized ECM to be infused with one of the listed agents. However, a cell or human cell does not further characterize any of the recited listed agents, rendering the scope of the claim unclear.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §

2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-L.jsp.

Claims 1 – 10, 18 – 27 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 – 17 of U.S. Patent No.10,617,790. Although the claims at issue are not identical, they are not patentably distinct from each other because the only distinction is that the issued claims are recited as a tissue graft that implies a specific use of the decellularized ECM as currently claimed. Both the issued claims and those pending are otherwise drawn to the same decellularized ECM, obtained from the same source, having the same treatments, additives and characteristics. Regarding the intended use of the ECM in the issued claims, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in both compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUTH A DAVIS whose telephone number is (571)272-0915. The examiner can normally be reached Monday - Friday (8am - 4pm).

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, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RUTH A DAVIS/
Primary Examiner, Art Unit 1699

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit	: 1699	Customer No. 035811
Examiner	: Ruth A. Davis	
Appl. No.	: 16/801,956	Confirmation No.: 9621
Appl. Filed	: February 26, 2020	
First Named Inventor	: Ryanne Early	Docket No.: SYG-19- 1252US-CON2
Title	: DECELLULARIZED	
	: BIOMATERIAL	
	: FROM NON-MAMMALIAN	
	: TISSUE	Dated: November 11, 2022

RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Official Action dated August 18, 2022, the Applicant amends the application as follows:

In the Claims

1. (Currently Amended) Decellularized extracellular matrix (ECM) derived from a Urodele said decellularized ECM derived by:

a. obtaining a tissue sample from a urodele, which tissue sample comprises ECM; and
b. decellularizing said tissue sample to produce decellularized ECM by removing sufficient cellular components of the sample to reduce or eliminate antigenicity ~~of the biomaterial~~, making it suitable for use as a xenograft.

2. (Original) The decellularized ECM of claim 1, wherein said decellularizing comprises subjecting said tissue sample to an alkaline treatment.

3. (Original) The decellularized ECM of claim 1, wherein said decellularized ECM is subjected to sterilization.

4. (Original) The decellularized ECM of claim 3 further comprising devitalized cells.

5. (Original) The decellularized ECM of claim 1 wherein the ECM is derived from Axolotl tissue.

6. (Original) The decellularized ECM of claim 1, wherein the ECM includes basement membrane.

7. (Currently Amended) The decellularized ECM of claim 1, wherein the ECM is infused with, coated with, or attached to an agent xenogenic to a Urodele that is a growth factor, a cytokine, a chemokine, a protein, a carbohydrate, a sugar, a steroid, an antimicrobial agent, a synthetic polymer, an adhesive, a drug or a cell ~~human agent~~.

8. (Currently Amended) The decellularized ECM of claim 7, wherein the agent is a ~~cell, optionally a~~ human cell.

9. (Currently Amended) The decellularized ECM of claim 1, wherein the ECM is in a form selected from the group consisting of a sheet, a powder, a gel, a paste, ~~a sheet~~, or a mesh, and wherein the ECM is parietal ECM, mesothelial ECM, thoracic cavity ECM, abdominal cavity ECM, pericardium ECM or dermal tissue ECM.

10. (Original) The decellularized ECM according to claim 1 contained within a package.

11-12. (Cancelled)

13. (Withdrawn-Currently Amended) A method for making a decellularized extracellular matrix (ECM) according to claim 1 derived from a Urodele said decellularized ECM

derived by:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises ECM; and
- b. decellularizing said tissue sample to produce decellularized ECM by removing sufficient cellular components of the sample to reduce or eliminate antigenicity ~~of the biomaterial~~, making it suitable for use as a xenograft.

14. (Withdrawn) The method of claim 13, wherein the method further comprises performing the decellularization in a manner to retain structural and functional integrity of the decellularized ECM sufficient to permit the decellularized ECM to be useful as a matrix upon and within which cells can grow.

15. (Withdrawn) The method of claim 13, further comprising homogenizing the decellularized ECM to form a powder, and, optionally reconstituting the powder as a gel.

16. (Withdrawn) The method of claim 13, further comprising sterilizing the decellularized ECM.

17. (Withdrawn) The method of claim 13, further comprising attaching the decellularized ECM to an agent xenogenic to a Urodele.

18. (Original) The ECM according to claim 9, wherein the powder has a particle size between 125 and 850 microns.

19. (Currently Amended) The ECM according to claim ~~9~~ 18, wherein the powder has a particle size of less than 250 microns.

20. (Original) The ECM of claim 1, wherein the ECM is a paste.

21. (Original) The ECM of claim 1, wherein the ECM is a gel.

22. (Original) The ECM of claim 21, wherein the gel comprises a synthetic polymer.

23. (Original) The ECM of claim 1, wherein the ECM is a mesh.

24. (Currently Amended) The ECM according to claim 1 comprising sterile, isolated, decellularized Urodele extra cellular matrix (ECM), wherein the ECM is ~~[[a]]~~ in the form of one or more sheets, wherein the ECM is parietal ECM, mesothelial ECM, thoracic cavity ECM, abdominal cavity ECM, pericardium ECM or dermal tissue ECM, and the sheet of ECM is infused with, coated with, or attached to an agent xenogeneic to a Urodele that is a growth factor, a cytokine, a chemokine, a protein, a carbohydrate, a sugar, a steroid, an antimicrobial agent, a synthetic polymer, an adhesive, or a drug.

25. (Original) The ECM of claim 24, wherein the agent is an anti-microbial agent.

26. (Original) The ECM of claim 24, wherein the agent is a growth factor.
27. (Original) The ECM of claim 1, wherein the sheet is at least two sheets of isolated Urodele decellularized ECM laminated to one another.
28. (Withdrawn-Currently Amended) A method for making the ECM of claim 1, comprising extracellular matrix components derived from a Urodele, said method comprising:
- a. obtaining a tissue sample from a urodele, which tissue sample comprises extracellular matrix; and
 - b. decellularizing said tissue sample to produce decellularized extracellular matrix by removing sufficient cellular components of the sample to reduce or eliminate antigenicity ~~of the biomaterial~~, making it suitable for use as a xenograft.
29. (Withdrawn) The method according to claim 28, wherein said decellularizing comprises subjecting said tissue sample to an alkaline treatment, and wherein said process further optionally comprises subjecting said sample to sterilization, and wherein the Urodele is an Axolotl.
30. (Withdrawn-Currently Amended) A method for making the ECM of claim 29, comprising sterile, isolated, decellularized Urodele Extracellular Matrix (ECM) or a sterile Urodele fraction derived from the isolated, decellularized Urodele ECM, said method comprising:
- a. obtaining a tissue sample from a urodele, which tissue sample comprises extracellular matrix;
 - b. decellularizing and sterilizing said tissue sample, to produce the sterile decellularized extracellular matrix, by removing sufficient cellular components of the sample to reduce or eliminate antigenicity ~~of the biomaterial~~, making it suitable for use as a xenograft; and sterilizing said tissue.
31. (Withdrawn) The method according to claim 30, wherein the ECM is a biocompatible sheet, mesh, gel, graft, tissue, device, or is a material coated with, impregnated with, encapsulated with or that is encapsulated by, or having attached thereto the isolated, decellularized Urodele ECM.
32. (Withdrawn) The method according to claim 30, wherein said decellularizing comprises subjecting said tissue sample to an alkaline treatment, wherein said process further comprises subjecting said sample to sterilization, wherein the Urodele is an Axolotl.
33. (Cancelled)
34. (Original) A biomaterial comprising decellularized extracellular matrix (ECM)

derived from a Urodele said decellularized ECM derived by:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises ECM; and
- b. decellularizing said tissue sample to produce decellularized ECM by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial making it suitable for use as a xenograft.

35. (Withdrawn) A method of making a biomaterial comprising decellularized extracellular matrix (ECM) derived from a Urodele said decellularized ECM said method comprising:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises ECM; and
- b. decellularizing said tissue sample to produce decellularized ECM by removing sufficient cellular components of the sample to reduce or eliminate antigenicity of the biomaterial making it suitable for use as a xenograft.

Remarks

The Specification is amended to correct obvious typographic errors.

The “250 mm” is clearly a typographic error, as supported by the following comments and evidence.

Para. [0071] states:

A #60 screen can be used to restrict the collected powder size to a desired size, for example less than 250 mm....

A #60 screen permits particles smaller than 250 microns to pass through, as follows:

US Sieve Size	Tyler Equivalent	Opening	
		mm	in
No. 60	60 Mesh	0.250	0.0098

See the attached pdf and the listing of standard US Sieve Sizes Tyler Equivalents, mm and inch opening sizes, <https://www.azom.com/article.aspx?ArticleID=1417#>.

See also, Example 4, pages 25 and 26, and, in particular, page 26, lines 1-3, which provides:

The final particle size distribution can be varied depending on duration and sieving, post cryomilling, between 125 and 850 microns....

This disclosure, therefore, defines a range of 125-850 microns, thereby bracketing 250 microns.

250 mm, by contrast, would be a 25 cm sized opening which would permit similarly sized “particles” to pass through. This, of course, is clearly not what is intended, as such a size does not only not require sieving, but it is difficult to obtain intact tissue samples of such a size.

See also that size range claimed in original Claim 18, thereby making the 250 micron size a selection within that size range defined by the 125-850 micron range.

Note that Claim 19 correctly states the selected size 250-125 microns, upon being amended to depend from Claim 18.

The term “cyromilling” is likewise an obvious error. There is no such English term, and the correct term, “cryomilling” appears on page 25, second to last line, within Example 4.

The claims are amended, starting on page 3 herein above, to clarify the claims, ensure antecedent basis, and put the claims in condition for allowance.

Rejoinder of withdrawn method claims upon allowance of the product claims is earnestly solicited.

Claims 1, 7-9, 19, 24, 28, and 30 have been amended to clarify the claimed subject matter and to remove superfluous terms (“of the biomaterial”), from Claims 1, 13, 28, and 30 for which there is no antecedent basis in the claim. Note that the “biomaterial” limitation is maintained in Claims 34 and 35, for which there is antecedent basis.

Claims 11, 12 and 33 have been cancelled without prejudice or disclaimer.

Claims 13-17, 28-32, 34 and 35 stand withdrawn.

The Applicant respectfully requests rejoinder of method Claims 13-17, 28-32, 34 and 35 upon allowance of the elected product claims.

Claims 8 and 9 are objected to over informalities. Claims 8 and 9 have been amended as helpfully suggested by the Examiner. Withdrawal of the objection is respectfully requested.

Claims 7 and 8 are rejected under 35 USC §112(b) as being indefinite. Specifically, the rejection states that the term “human agent” in Claim 7 is unclear and that Claim 8 does not appear to further limit Claim 7.

Claim 7 has been amended to replace the term “human agent” with the term “cell.” Thus, Claim 8 further limits Claim 7 inasmuch as Claim 8 requires that the cell is a human cell.

Accordingly, the Applicant respectfully submits that Claims 7 and 8 are clear and definite. Withdrawal of the rejection is respectfully requested.

The dependency of Claim 19 to Claim 18 has been corrected to ensure a bounded lower limit to the range specified in Claim 19 is provided.

The language of Claim 24 has been amended to provide proper antecedent basis for Claim 27, which depends from Claim 24.

Claims 1-10, 18-27 and 34 are rejected on the ground of non-statutory double patenting over Claims 1-17 of US Pat. No. 10, 617,790. In light of the Terminal Disclaimer filed herewith, the Applicant respectfully submits that the rejection has been rendered moot.

In light of the foregoing, the Applicant respectfully requests examination of the application on the merits and expeditious issuance to patent.

Respectfully submitted,

/Chris Halliday/

Christopher I. Halliday
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Enclosure
AZO Materials PDF

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	TERMINAL DISCLAIMER TO OBIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	
Application Number	16801956	
Filing Date	26-Feb-2020	
First Named Inventor	Ryanne Early	
Attorney Docket Number	SYG-19-1252US-CON2	
Title of Invention	DECELLULARIZED BIOMATERIAL FROM NON-MAMMALIAN TISSUE	
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.		
Owner	Percent Interest	
ISE Professional Testing & Consulting Services, Inc.	100%	
The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s) 10617790 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.		

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.	
Applicant claims the following fee status: ☒ Small Entity ☐ Micro Entity ☐ Regular Undiscounted	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number <u>31750</u> ☐ A sole inventor ☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ☐ A joint inventor; all of whom are signing this request	
Signature	/T. Daniel Christenbury/
Name	T. Daniel Christenbury

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
 Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16801956

Filing Date: 26-Feb-2020

Applicant/Patent under Reexamination: Early

Electronic Terminal Disclaimer filed on November 11, 2022

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

35811 7590 01/24/2023
IP GROUP OF DLA PIPER LLP (US)
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 5000
PHILADELPHIA, PA 19103

EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1699

DATE MAILED: 01/24/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/801,956	02/26/2020	Ryanne Early	SYG-19-1252US-CON2	9621

TITLE OF INVENTION: DECELLULARIZED BIOMATERIAL FROM NON-MAMMALIAN TISSUE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	04/24/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

35811 7590 01/24/2023
IP GROUP OF DLA PIPER LLP (US)
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 5000
PHILADELPHIA, PA 19103

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/801,956	02/26/2020	Ryanne Early	SYG-19-1252US-CON2	9621

TITLE OF INVENTION: DECELLULARIZED BIOMATERIAL FROM NON-MAMMALIAN TISSUE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	04/24/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
DAVIS, RUTH A	1699	424-093100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/801,956	02/26/2020	Ryanne Early	SYG-19-1252US-CON2	9621
35811 7590 01/24/2023 IP GROUP OF DLA PIPER LLP (US) ONE LIBERTY PLACE 1650 MARKET ST, SUITE 5000 PHILADELPHIA, PA 19103			EXAMINER DAVIS, RUTH A	
			ART UNIT 1699	PAPER NUMBER
DATE MAILED: 01/24/2023				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/801,956	Applicant(s) Early, Ryanne	
	Examiner RUTH A DAVIS	Art Unit 1699	AIA (FITF) Status Yes

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to reply filed 11.11.2022.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ 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.

3. ☒ The allowed claim(s) is/are 1-10,13-32 and 34-35. As a result of the allowed claim(s), 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**.

4. ☐ 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)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.	5. ☒ Examiner's Amendment/Comment 6. ☐ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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	/RUTH A DAVIS/ Primary Examiner, Art Unit 1699
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DETAILED ACTION

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.

Applicant's amendment, reply and terminal disclaimer filed November 11, 2022 have been received and entered into the case. Claims 11 – 12 and 33 are canceled; claims 1 – 10, 13 – 32 and 34 – 35 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

Previous objections are withdrawn due to applicant's amendments.

Claim Rejections - 35 USC § 112

Previous rejections under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, are withdrawn due to applicant's amendment removing unclear language.

Double Patenting

The previous nonstatutory double patenting rejection is withdrawn due to applicant's filing of a proper terminal disclaimer on November 11, 2022.

Election/Restrictions

Claims 1 – 10, 18 – 27 and 34 are allowable. Claims 13 – 17, 28 – 32 and 35, previously withdrawn from consideration as a result of a restriction requirement, require all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), **the restriction requirement between inventions I - V, as set forth in the Office action mailed on April 28, 2022, is hereby withdrawn** and claims 13 – 17, 28 – 32 and 35 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Allowable Subject Matter

Claims 1 – 10, 13 – 32 and 34 – 35 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUTH A DAVIS whose telephone number is (571)272-0915. The examiner can normally be reached Monday - Friday (8am - 4pm).

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

Art Unit: 1699

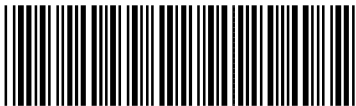
encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RUTH A DAVIS/

Primary Examiner, Art Unit 1699

Issue Classification 	Application/Control No. 16/801,956	Applicant(s)/Patent Under Reexamination Early, RYANNE	
	Examiner RUTH A DAVIS	Art Unit 1699	

CPC						
Symbol					Type	Version
A61L	/	27	/	3687	F	2013-01-01
A61K	/	9	/	70	I	2013-01-01
A61L	/	27	/	58	I	2013-01-01
A61L	/	27	/	60	I	2013-01-01
A61L	/	27	/	54	I	2013-01-01
A61L	/	27	/	362	I	2013-01-01
A61L	/	27	/	3691	I	2013-01-01
A61K	/	38	/	1703	I	2013-01-01
A61K	/	35	/	12	I	2013-01-01
A61L	/	27	/	3625	I	2013-01-01
A61L	/	27	/	3604	I	2013-01-01
A61L	/	27	/	3633	I	2013-01-01
A61L	/	27	/	38	I	2013-01-01
A61K	/	35	/	65	I	2013-01-01
A61L	/	27	/	52	I	2013-01-01
C12N	/	5	/	0625	I	2013-01-01
A61L	/	2430	/	40	A	2013-01-01
A61L	/	2430	/	34	A	2013-01-01
A61L	/	2300	/	64	A	2013-01-01
A61L	/	2300	/	606	A	2013-01-01
A61L	/	2300	/	604	A	2013-01-01
A61L	/	2300	/	412	A	2013-01-01
A61L	/	2300	/	252	A	2013-01-01
C12N	/	2533	/	90	A	2013-01-01
C12N	/	2533	/	92	A	2013-01-01

CPC Combination Sets					
Symbol				Type	Set

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 32	
/RUTH A DAVIS/ Primary Examiner, Art Unit 1699 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure NONE

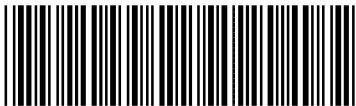
<i>Issue Classification</i> 	Application/Control No. 16/801,956	Applicant(s)/Patent Under Reexamination Early, RYANNE
	Examiner RUTH A DAVIS	Art Unit 1699

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61L27/36	/	27	/ 36
A61L27/54	/	27	/ 54
A61K35/12	/	35	/ 12
A61L27/52	/	27	/ 52
NON-CLAIMED			
	/		/

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 32	
/RUTH A DAVIS/ Primary Examiner, Art Unit 1699 (Primary Examiner) _____ (Date) _____		14 January 2023 (Date)	O.G. Print Claim(s) 1
			O.G. Print Figure NONE

Issue Classification 	Application/Control No. 16/801,956	Applicant(s)/Patent Under Reexamination Early, RYANNE
	Examiner RUTH A DAVIS	Art Unit 1699

☐ Claims renumbered in the same order as presented by applicant
 ☐ CPA
 ☒ T.D.
 ☐ R.1.47

CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	12	10	11	19	26	28								
2	2		11	13	20	27	29								
3	3		12	14	21	28	30								
4	4	21	13	15	22	29	31								
5	5	22	14	16	23	30	32								
6	6	23	15	17	24		33								
7	7	24	16	18	25	31	34								
8	8	25	17	19	26	32	35								
9	9	10	18	20	27										

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 32	
/RUTH A DAVIS/ Primary Examiner, Art Unit 1699 (Primary Examiner) _____ (Date) 14 January 2023		O.G. Print Claim(s) 1	O.G. Print Figure NONE