

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit	: 1651	Customer No. 035811
Examiner	: Davis, Ruth A.	
Appl. No.	: 14/759,895	Docket No.: SYG-19-1252US/ 426329-002
Appl. Filed	: July 8, 2015	
First Named		
Inventor	: Ryanne Early	Confirmation No.: 3358
Title	: Decellularized Biomaterial from Non-Mammalian Tissue	Dated: July 2, 2019

RESPONSE

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

Sir:

In response to the Non-Final Office Action dated January 10, 2019, (the “Office Action”), the Applicant amends the application as follows:

In the Claims

1-4. (Cancelled)

5. (Previously Presented) A tissue graft comprising extracellular matrix components derived from a Urodele, said tissue graft derived by:

- 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.

6-19. (Cancelled)

20. (Previously Presented) A sterile medical implant comprising sterile, isolated, decellularized Urodele Extracellular Matrix (ECM) or a sterile Urodele fraction derived from the isolated, decellularized Urodele ECM produced by a process comprising:

- a. obtaining a tissue sample from a urodele, which tissue sample comprises extracellular matrix;
- b. decellularizing and sterilizing 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.

21. (Previously Presented) The sterile medical implant of claim 20, wherein the implant is a biocompatible sheet, mesh, gel, graft, tissue or device.

22. (Previously Presented) A material coated with, impregnated with, encapsulating, or having attached thereto isolated, decellularized Urodele ECM 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.

23-25. (Cancelled)

26. (Currently Amended) A device comprising a tissue graft according to claim 5 comprising at least two sheets of isolated Urodele decellularized ECM laminated to one another, wherein said extracellular matrix components are derived from a Urodele, said tissue graft derived by:

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.

27-35. (Cancelled)

36. (Previously Presented) The tissue graft of claim 5, wherein said decellularizing comprises subjecting said tissue sample to an alkaline treatment.

37. (Previously Presented) The tissue graft of claim 36, wherein said process further comprises subjecting said sample to sterilization.

38. (Previously Presented) The tissue graft of claim 5, wherein the Urodele is an Axolotl.

39. (Cancelled)

40. (Previously Presented) The sterile medical implant of claim 20, wherein the Urodele ECM includes basement membrane.

41. (Previously Presented) The sterile medical implant of claim 20, wherein the Urodele

ECM is derived from Axolotl tissue.

42. (Previously Presented) The sterile medical implant of claim 20, wherein the Urodele 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, or a drug.

43. (Previously Presented) The sterile medical implant of claim 20, further comprising a human cell and wherein the Urodele ECM is infused with, coated with, or attached to the human cell.

44. (Previously Presented) The sterile medical implant of claim 20, wherein the Urodele extracellular matrix (ECM) or a sterile Urodele fraction derived from the isolated, decellularized Urodele ECM is a sheet.

45. (Previously Presented) The sterile medical implant of claim 20, wherein the Urodele ECM is in the form of Urodele ECM particles.

46. (Previously Presented) The sterile medical implant of claim 20, wherein the Urodele ECM is a reconstituted gel.

47. (Previously Presented) The material of claim 22, wherein the Urodele ECM is Axolotl ECM.

48. (Previously Presented) The device of claim 26, wherein the Urodele ECM is Axolotl ECM.

49. (Previously Presented) A tissue graft according to claim 5 comprising sterile, isolated, decellularized Urodele extra cellular matrix (ECM), wherein the ECM is a powder, a paste, a gel, 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.

50. (Previously Presented) The tissue graft of claim 49, wherein the ECM is a powder.

51. (Previously Presented) The tissue graft of claim 50, wherein the powder has a particle size between 125 and 850 microns.
52. (Previously Presented) The tissue graft of claim 50, wherein the powder has a particle size of less than 250 microns.
53. (Previously Presented) The tissue graft of claim 49, wherein the ECM is a paste.
54. (Previously Presented) The tissue graft of claim 49, wherein the ECM is a gel.
55. (Previously Presented) The tissue graft of claim 54, wherein the gel comprises a synthetic polymer.
56. (Previously Presented) The tissue graft of claim 49, wherein the ECM is a mesh.
57. (Previously Presented) A tissue graft according to claim 5 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.
58. (Previously Presented) The tissue graft of claim 57, wherein the agent is an anti-microbial agent.
59. (Previously Presented) The tissue graft of claim 57, wherein the agent is a growth factor.
60. (Previously Presented) The tissue graft of claim 57, wherein the sheet is at least two sheets of isolated Urodele decellularized ECM laminated to one another.

61. (Previously Presented) The tissue graft according to claim 49 wherein the Urodele ECM is Axolotl ECM and is in a form selected from the group consisting of: a powder; a paste; a gel; a mesh; a sheet of parietal ECM, mesothelial ECM, thoracic cavity ECM, abdominal cavity ECM, pericardium ECM or dermal tissue ECM, and wherein 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; and at least two sheets of isolated Urodele decellularized ECM laminated to one another.

62-65. (Cancelled)

66. (New) A method for making the tissue graft of claim 5, 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.

67. (New) The method according to claim 66, 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.

68. (New) A method of using the tissue graft according to claim 5, providing said tissue graft to a xenograft recipient in need thereof in a sufficient amount and in a form adapted to the need of said recipient.

69. (New) The method according to claim 68, wherein said form is a biocompatible sheet, mesh, gel, graft, tissue, device, or is a material coated with, impregnated with, encapsulating, or having attached thereto isolated, decellularized Urodele ECM.

70. (New) A method for making the sterile medical implant of claim 20, 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 comprised within said sterile medical implant, 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.

71. (New) The method according to claim 70, wherein the implant is a biocompatible sheet, mesh, gel, graft, tissue or device, or is a material coated with, impregnated with, encapsulating, or having attached thereto isolated, decellularized Urodele ECM.

72. (New) The method according to claim 70, 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.

73. (New) A method of using the sterile medical implant according to claim 20 which comprises providing said tissue graft to a xenograft recipient in need thereof in a sufficient amount and in a form adapted to the need of said recipient.

74. (New) The method according to claim 73, wherein said form is a biocompatible sheet, mesh, gel, graft, tissue, device, or is a material coated with, impregnated with, encapsulating, or having attached thereto isolated, decellularized Urodele ECM.

75. (New) The method according to claim 74, wherein said Urodele 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, or a drug.

76. (New) The method according to claim 75, wherein said ECM is sterile.
77. (New) The method according to claim 76, wherein said ECM is in the form of a powder, a paste, a gel, a sheet, or a mesh.
78. (New) The method according to claim 77, wherein the ECM is parietal ECM, mesothelial ECM, thoracic cavity ECM, abdominal cavity ECM, pericardium ECM or dermal tissue ECM.
79. (New) The method according to claim 77, wherein the ECM is in the form of a powder, a paste or a gel, in which said ECM has a particle size between 125 and 850 microns.
80. (New) A method for making the material coated with, impregnated with, encapsulating, or having attached thereto isolated, decellularized Urodele ECM of claim 22, 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.

Remarks

Following entry of the present amendment, the status of the claims is as follows: claims 1-4, 6-19, 23-25, and 62-65 canceled herein, claims 34-35 and 39 previously canceled, Claim 26 currently amended, Claims 5, 20-22, 26, 27-33, 36-38, and 40-61 allowed, and Claims 66-80 newly added.

New method claims 66-80 are introduced herein as being commensurate with the allowed product claims, which are produced and used by the method as claimed in the newly introduced method claims. Support for the new method claims can be found throughout the specification, including for example: paragraphs [0022] and [0038] Claims 66-69 method for making and using a tissue graft (biologic material); paragraph [0031] Claims 70-78 method for making a sterile medical implant; and paragraphs [0029], [0032] and [0035] Claim 79 method for making a material coated with, impregnated with, encapsulating, or having attached thereto isolated, decellularized Urodele ECM. Please also note that the allowed product by process claims themselves provide substantial support for the method of making claims.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Examiner Interview

Applicant thanks Examiner Davis for her time and consideration of the pending claims during a telephone interview on June 28, 2019. During the telephone interview, Applicant's representatives requested rejoinder of previously restricted claims. The subject matter of the rejoinder claims include "method of making" and "method of use" claims that correspond to the device/product claims which the Examiner has indicated to be allowable in the January 10, 2019, office action.

II. Rejection under 35 U.S.C. §112(a)

The Office Action rejected claims 62-65 under 35 U.S.C. §112(a), as failing to comply with the written description requirement. By this Amendment, claims 62-65 are canceled thereby rendering the rejection moot. Reconsideration and withdrawal of the rejection is respectfully requested.

III. Rejection under 35 U.S.C. §112(b)

Applicant acknowledges withdrawal of the rejections based on 35 U.S.C. §112(a).

IV. Rejection under 35 U.S.C. §102(a)(1)

Applicant acknowledges withdrawal of the rejections based on 35 U.S.C. §102(a)(1).

V. Rejections Under 35 U.S.C. §103

The Office Action rejects Claims 26 and 48 under 35 U.S.C. §103 as being unpatentable over Asem et al. (US 6485969) in view of Seifert et al. (2012). According to the Office Action, Asem teaches decellularized ECM comprising basement membranes derived from amphibians that are adhered together (or laminated). Without acquiescing to the rejection, and solely in the interest of advancing prosecution, Applicant has herein amended Claim 26 to incorporate the subject matter of the allowed claims, and, since Claim 48 depends upon Claim 26, the amendment is considered to carry through to Claim 48. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

VI. Allowable Subject Matter

Claims 5, 20-22, 36-38, 40-47, and 49 -61 were allowed in the January 10, 2019 Office Action.

VII. Request for Rejoinder

As stated above, during the telephone interview on June 28, 2019, Applicant requested rejoinder of previously restricted subject matter, which the Examiner indicated she felt appropriate in light of allowance of the relevant product claims. Accordingly, Applicant submits herewith new claims 66-80, which include all the limitations of the allowed claims.

Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

If the Examiner has any questions or believes that any outstanding issues may be resolved with minor amendments or a phone discussion, the Examiner is invited to contact the Applicant's representative, Sima Singadia Kulkarni, at (215) 656-2478 or sima.kulkarni@diapiper.com.

Respectfully submitted,

/sima singadia kulkarni/

Sima Singadia Kulkarni
Reg. No. 43,732



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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/759,895	07/08/2015	Ryanne Early	SYG-19-1252/426329-002	3358
35811 7590 07/03/2019 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
			1651	
			NOTIFICATION DATE	DELIVERY MODE
			07/03/2019	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@dlapiper.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 14/759,895	Applicant(s) Early, RYANNE		
	Examiner RUTH A DAVIS	Art Unit 1651	AIA (First Inventor to File) Status Yes	Page 1 of 2

All participants (applicant, applicants representative, PTO personnel):

1. RUTH A DAVIS (Primary Examiner); Telephonic 2. Sima Kulkarni (Attorney of Record); Telephonic
3. Gerard Bencen (Attorney); Telephonic

Date of Interview: 28 June 2019

Claims Discussed: Proposed amendments were made as appended here to.

Amendment proposed: See attached.

Brief Description of the main topic(s) of discussion: Applicant's representative proposed amendments to the claims so that additional products and process claims may be rejoined with the allowable products.

Issues Discussed:

Proposed Amendments:
Applicant proposed amendments to the claims so as to add method claims that may be eligible for rejoinder.

Attachment(s): Proposed Amendments,

	/RUTH A DAVIS/ Primary Examiner, Art Unit 1651
Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04 Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing	

U.S. Patent and Trademark Office
PTOL-413/413b (Rev. 01/01/2015)

Interview Summary

Paper No. 20190628

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.



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

167127 7590 01/13/2020
Ryenne Early
2785 S Bay St. G
Eustis, FL 32726

EXAMINER	
DAVIS, RUTH A	
ART UNIT	PAPER NUMBER

1651

DATE MAILED: 01/13/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/759,895	07/08/2015	Ryenne Early	SYG-19-1252US/426329-002	3358

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	\$500	\$0.00	\$0.00	\$500	04/13/2020

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 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity 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 and an extra copy of the form should be submitted. 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.

167127 7590 01/13/2020
Ryenne Early
2785 S Bay St. G
Eustis, FL 32726

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.
14/759,895	07/08/2015	Ryenne Early	SYG-19-1252US/426329-002	3358

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	\$500	\$0.00	\$0.00	\$500	04/13/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
DAVIS, RUTH A	1651	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/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 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
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/759,895	07/08/2015	Ryanne Early	SYG-19-1252US/426329-002	3358
167127	7590	01/13/2020	EXAMINER	
Ryanne Early 2785 S Bay St. G Eustis, FL 32726			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 01/13/2020				

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. 14/759,895	Applicant(s) Early, Ryanne	
	Examiner RUTH A DAVIS	Art Unit 1651	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 Interview on January 7, 2020.
☐ 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 5,20-22,26,36-38,40-61,66-67,70-72 and 80. 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. <u>01-07-2020</u> .	5. ☒ Examiner's Amendment/Comment 6. ☐ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
---	--

	/RUTH A DAVIS/ Primary Examiner, Art Unit 1651
--	---

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

Claims 5, 20 – 22, 26, 36 – 38, 40 – 61 are allowable. The restriction requirement between the product and methods of making the product, as set forth in the Office action mailed on September 9, 2016, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Specifically, the restriction requirement of September 9, 2019 is withdrawn. Claims 66 – 67, 70 – 72 and 80, directed to methods of making the allowable product are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is 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 a 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.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Sima Kulkarni on January 7, 2020.

The application has been amended as follows:

In claim 71, line 2, the first recitation of "or" is deleted and replaced with --,--.

In claim 71, line 2, the term "encapsulating" is deleted and replaced with --encapsulated with--.

In claim 71, line 3, --, the-- has been inserted after the recitation of "thereto".

Claim 68 – 69 and 73 – 79 are canceled.

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 on 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, Renee Claytor can be reached on 571-272-8394. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/RUTH A DAVIS/
Primary Examiner, Art Unit 1651

<i>Examiner-Initiated Interview Summary</i>	Application No. 14/759,895	Applicant(s) Early, Ryanne		
	Examiner RUTH A DAVIS	Art Unit 1651	AIA (First Inventor to File) Status Yes	Page 1 of 2

All participants (applicant, applicants representative, PTO personnel):

1. RUTH A DAVIS (Primary Examiner); Telephonic 2. Sima Kulkarni (Attorney of Record); Telephonic

Date of Interview: 07 January 2020

Claims Discussed: 68 - 69, 73 - 79.

Amendment proposed: See Examiner's amendment.

Brief Description of the main topic(s) of discussion: Applicant's representative requested an Examiner Amendment to cancel claims 68 - 69 and 73 - 79 in response to the previous office action. Additional amendments are included to address 112,B of record, relative to claim 71.

Issues Discussed:

Proposed Amendments:
See attached Examiner's amendment.

Attachment(s): Proposed Amendments,

	/RUTH A DAVIS/ Primary Examiner, Art Unit 1651
Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04 Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing	

U.S. Patent and Trademark Office
PTOL-413/413b (Rev. 01/01/2015)

Interview Summary

Paper No. 20190815

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview .

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.



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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/759,895	04/14/2020	10617790	SYG-19-1252US/426329-002	3358

35811 7590 03/25/2020
IP GROUP OF DLA PIPER LLP (US)
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 5000
PHILADELPHIA, PA 19103

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

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 Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Ryanne Early, Fleming Island, FL;
ISE Professional Testing & Consulting Services, Inc., Eustis, FL;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.