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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/847,337	04/13/2020	Steven Clyde Pettit	50091-US-CNT2	7927
23589	7590	09/01/2020		
Hovey Williams LLP 10801 Mastin Blvd., Suite 1000 Overland Park, KS 66210			EXAMINER HOLLAND, PAUL J	
			ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
			09/01/2020	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):

uspatents@hoveywilliams.com

Office Action Summary**Application No.**

16/847,337

Applicant(s)

Pettit et al.

Examiner

PAUL J HOLLAND

Art Unit

1656

AIA (FITF) Status

No

-- 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 04/13/2020.

☐ 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) 1-17 is/are pending in the application.

5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-17 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 04/13/2020 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 07/01/2020

DETAILED CORRESPONDENCE

Application Status

1. The present application is being examined under the pre-AIA first to invent provisions.
2. Claims 1-17 are pending and examined on the merits.

Priority

3. Acknowledgement is made of this continuation of U.S. Non-provisional Application No. 15/188478, filed on 06/21/2016, which is a continuation of U.S. Non-provisional Application No. 12/708,462, filed on 02/18/2010, which is claims domestic priority to U.S. Provisional Application No. 61/154,204, filed on 02/20/2009.

Information Disclosure Statement

4. The IDSs filed on 07/01/2020 have been considered by the examiner and copies of the Form PTO/SB/08 are attached to the office action.

Drawings

5. The Drawings filed on 04/13/2020 are objected to for the following informalities. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicants should identify nucleotide sequences of at least 10 nucleotides and amino acid sequences of at least 4 amino acids in the specification by a proper sequence identifier, i.e., "SEQ ID NO:" (see MPEP 2422.01). If these sequences have not been listed in the computer readable form and paper

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copy of the sequence listing, applicant must provide an initial computer readable form (CRF)

copy of the "Sequence Listing", an initial paper copy of the "Sequence Listing", as well as an

amendment directing its entry into the specification, and a statement that the content of the

paper and CRF copies are the same and, where applicable, include no new matter as required

by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). In the instant case, Figures

1 and 5 of the Drawings filed on 04/13/2020 contain sequence disclosures encompassing the

definition of amino acid and nucleotide sequences.

Specification

6. The disclosure is objected to for the following minor informalities. The status of U.S.

Non-provisional Application No. 15/188,478 in the "CROSS-REFERENCE TO RELATED

APPLICATIONS" section does not reflect the issuance of the '478 application as U.S. Patent No.

10,618,951. Appropriate correction is suggested.

Claim Rejections - 35 USC § 112(b), or Second Paragraph

7. 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.

8. Claims 4-5 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the

invention.

Regarding claim 4 (claim 5 dependent therefrom), there is insufficient antecedent basis for the limitation “said transgenic plant” in the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim(s) 1-6 and 9-13 is/are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Deeter et al. (**WO2007/002762 A2**; cited on IDS filed on 07/01/2020) as evidenced by Davies (**US Patent Application 5,917,022**; cited on IDS filed on 07/01/2020).

11. Claims 1-6 and 9-13 are drawn to a method for enhancing cell growth in culture, said method comprising a) culturing cells in a cell culture media supplemented with a plant-produced recombinant mammalian albumin supplement, wherein said plant-produced recombinant mammalian albumin has less than 1 EU of endotoxin/mg of albumin and less than 2% aggregated albumin.

12. With respect to claims 1-6 and 9-13, Deeter et al. teach methods for enhancing cell growth in a cell culture comprising culturing cells in a cell culture media supplemented with components of cell culture medium produced from plant cells that improve the growth of a cell in the cell culture medium wherein the medium comprises human serum albumin produced in rice [see Abstract; paragraphs 0009 and 0116; Examples 8-9]. Deeter et al. also teach clarifying the extracted rice human serum albumin by filtration and purification to approximately 98%

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(interpreted as no aggregation) [see paragraph 0116]. Although Deeter et al. does not explicitly teach that the supplement comprises less than about 1 EU of Endotoxin/mg of albumin, the reference of Davies is cited in accordance with MPEP 2131.01.II to demonstrate that endotoxin is only found as lipopolysaccharides in the cell wall of Gram-negative bacteria [see Column 1, lines 17-48]. Since the recombinant human serum albumin is produced in rice and is not a bacteria, then the human serum albumin taught by Deeter et al. would inherently lack any endotoxin.

With respect to claim 2, Deeter et al. teach the method wherein said cell culture media is fetal bovine serum free media [see Examples 8-9].

With respect to claim 3, Deeter et al. teach the method wherein said albumin is recombinant human serum albumin [see paragraph 0119].

With respect to claims 4-5, Deeter et al. teach the method wherein said transgenic plant is transgenic rice [see Abstract; paragraph 0016].

With respect to claim 6, Deeter et al. teach the method wherein said recombinant mammalian albumin supplement is added to said cell culture media at the beginning of said culturing [see Examples 8-9].

Regarding claims 9-13, Deeter et al. is silent as to the presence of heat-shock proteins, for example those recited in claims 11-13, in the albumin preparation. Deeter's method of preparing recombinant albumin from rice grain [see Example 3 at paragraphs 103-105; Example 7 at 116-117], however, is identical to the one employed by applicants [see Example 3 and Example 5]. It is the examiner's position that absent evidence otherwise, these proteins would be inherent to the recombinant human serum albumin produced by Deeter et al. MPEP 2112.I

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states “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999)”. Since the Office does not have the facilities for examining and comparing applicants’ protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the rice albumin of the prior art does not possess the same material structural and functional characteristics of the claimed supplement comprising recombinant albumin). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claim Rejections - 35 USC § 103

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

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 7-6 and 14-17 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Deeter et al. (**WO2007/002762 A2**; cited on IDS filed on 07/01/2020) as evidenced by Davies (**US Patent Application** 5,917,022; cited on IDS filed on 07/01/2020) in view of Luyten et al. (**US Patent** 6,617,161, 2003; cited on IDS filed on 07/01/2020) and Potter et al. (**US Patent** 5,985,289, 1999; cited on IDS filed on 07/01/2020).

15. The relevant teachings of Deeter et al. as applied to claims 1-6 and 9-13 are set forth above.

With respect to claims 7-6 and 14-17, Deeter et al. teach components of cell culture medium produced from plant cells that improve the growth of a cell in the cell culture medium wherein the medium comprises the addition of albumin, lactotransferrin, or transferrin recombinantly produced from plants [see Abstract; paragraphs 0006, 0009, 0061, 0071, and 0116; Example 7] at concentrations of 0.01-50 mg/mL of lactoferrin [see Example 5; paragraph 0111].

However, Deeter et al. does not teach the method of claim 7, wherein said plant producing recombinant mammalian albumin supplement is added to said culture media before day 4 of said culturing; the method of claim 8, wherein said plant producing recombinant mammalian albumin supplement is added to said cell culture media daily during said culturing; the method of claim 14 comprising both albumin and lactoferrin; the method of claim 15, wherein said ratio of said lactoferrin to said recombinant mammalian albumin is 1:3 to 1:0.33; the method of claim 16 comprising both albumin and transferrin; and the method of claim 17, wherein said ratio of said transferrin to said recombinant albumin is 1:50 to 1:5000.

Luyten et al. teach a complete culture medium for mammalian cells comprising 6.25 μ g (0.00625mg) transferrin and 1.25mg bovine serum albumin per mL, i.e. a ratio of 1 to 200 [see Column 3, lines 16-62; Table 1; see also Example 1, using the medium]. Regarding the full scope of ratios, Luyten et al. teach that the concentrations of the components can be adjusted to suit cell lines as necessary. [Column 3, lines 64-67].

Potter et al. teach that transferrin and lactoferrin are both iron-chelating proteins [see Column 7, lines 15-16]. Lactoferrin is therefore a “transferrin-related protein.” Potter et al. also teach that iron-chelating proteins can be employed in culture media at varying concentrations

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to modulate iron content in the media as necessary for the cells [see Column 6, line 66, through column 7, line 21].

At the time the invention was made it would have been obvious to one of ordinary skill in the art to combine the teachings of Deeter et al., Luyten et al., and Potter et al. according to the teachings of Luyten et al. and Potter et al. because Deeter et al. teach that albumin, transferrin, or lactoferrin produced in plants can be used to improve the growth of cells in a culture medium. Luyten et al. teach that the albumin and transferrin can be combined in a culture medium for cell growth. Potter et al. teach that lactotransferrin or transferrin can be employed in culture media at varying concentrations to modulate iron content in the media necessary for the cells. An ordinarily skilled artisan would have had a reasonable expectation of success, a reasonable level of predictability, and would have been motivated to combine the teachings of Deeter et al., Luyten et al., and Potter et al. because Luyten et al. acknowledges that albumin and transferrin can be combined in cell culture growth medium and Potter et al. acknowledges that both lactotransferrin and transferrin can be added to culture medium to modulate iron content. Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Furthermore, MPEP 2144.06.I states "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried

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detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious).” In the instant case, the improvement in cell growth by addition of plant derived albumin, lactotransferrin, or transferrin was known in the prior art as taught by Deeter et al. Therefore, it would have been obvious to one of ordinary skill in the art to combine these proteins as part of a culture medium to improve cell growth.

Although the combination of Deeter et al., Luyten et al., and Potter et al. do not explicitly teach wherein said supplement is added before day 4 of said culturing, added daily during culturing and the ratios of lactoferrin of 1 to 3, to 1 to 0.33, MPEP 2144.05.II.A states, “Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)”. In the instant case, it would be obvious to one of ordinary skill in the art to determine the appropriate workable ranges based on the teachings of Deeter et al., Luyten et al., and Potter et al. and one of ordinary skill in the art would desire to do so in order to maximize cell growth in the culture.

Conclusion

16. Status of the claims:

Claims 1-17 are pending.

Claims 1-17 are rejected.

No claims are in condition for an allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL J HOLLAND whose telephone number is (571)270-3537. The examiner can normally be reached on Monday to Friday from 8AM to 5PM.

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, Manjunath Rao can be reached on 571-272-0939. 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 <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

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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.

/PAUL J HOLLAND/

Primary Examiner, Art Unit 1656



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NOTICE OF ALLOWANCE AND FEE(S) DUE

23589 7590 03/10/2021
Hovey Williams LLP
10801 Mastin Blvd., Suite 1000
Overland Park, KS 66210

EXAMINER	
HOLLAND, PAUL J	
ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 03/10/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/847,337	04/13/2020	Steven Clyde Pettit	50091-US-CNT2	7927

TITLE OF INVENTION: CELL CULTURE MEDIA CONTAINING COMBINATIONS OF PROTEINS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	06/10/2021

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
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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.

23589 7590 03/10/2021
Hovey Williams LLP
10801 Mastin Blvd., Suite 1000
Overland Park, KS 66210

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.
16/847,337	04/13/2020	Steven Clyde Pettit	50091-US-CNT2	7927

TITLE OF INVENTION: CELL CULTURE MEDIA CONTAINING COMBINATIONS OF PROTEINS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	06/10/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
HOLLAND, PAUL J	1656	435-326000

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,

(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.

1 _____
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. _____



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EXAMINER				
HOLLAND, PAUL J				
ART UNIT			PAPER NUMBER	
1656				
DATE MAILED: 03/10/2021				

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. 16/847,337	Applicant(s) Pettit et al.	
	Examiner PAUL J HOLLAND	Art Unit 1656	AIA (FITF) Status No

-- 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 amendment filed 12/01/2020.
☐ 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 1-26. 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>20210304</u> .	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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/PAUL J HOLLAND/
Primary Examiner, Art Unit 1656

DETAILED CORRESPONDENCE

Application Status

The present application is being examined under the pre-AIA first to invent provisions.

Applicant's amendment to the claims filed on 12/01/2020 in response to the Non-Final Rejection mailed on 09/01/2020 is acknowledged and entered into the record.

Applicant's remarks and rule 132 declaration filed on 12/01/2020 in response to the Non-Final Rejection mailed on 09/01/2020 have been fully considered and are deemed persuasive to overcome the prior rejections of record.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in the prior Office Action.

Withdrawn Drawings

The objection to the drawings is withdrawn in view of applicant's remarks filed on 12/01/2020.

Withdrawn Specification

The objection to the disclosure is withdrawn in view of applicant's amendment to the specification filed on 12/01/2020 to reflect the issuance of the 15/188,478 application as U.S. Patent No. 10,618,951.

Withdrawn Claim Rejections - 35 USC § 112(b), or Second Paragraph

The rejection of claims 4-5 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, for indefiniteness is withdrawn in view of applicant's amendment to the claims.

Withdrawn Claim Rejections - 35 USC § 102

The rejection of claims 1-6 and 9-12 under pre-AIA 35 U.S.C. 102(b) as being anticipated by Deeter et al. (**WO2007/002762 A2**; cited on IDS filed on 07/01/2020) as evidenced by Davies (**US Patent Application** 5,917,022; cited on IDS filed on 07/01/2020) is withdrawn in view of applicant's remarks and declaration filed on 12/01/2020.

Withdrawn Claim Rejections - 35 USC § 103

The rejection of claims 7-6 and 14-17 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Deeter et al. (**WO2007/002762 A2**; cited on IDS filed on 07/01/2020) as evidenced by Davies (**US Patent Application** 5,917,022; cited on IDS filed on 07/01/2020) in view of Luyten et al. (**US Patent** 6,617,161, 2003; cited on IDS filed on 07/01/2020) and Potter et al. (**US Patent** 5,985,289, 1999; cited on IDS filed on 07/01/2020) is withdrawn in view of applicant's remarks and declaration filed on 12/01/2020.

Examiner's Amendment to the Claims

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

Art Unit: 1656

Authorization for this examiner's amendment was given in a telephone interview with Ms. Crissa Cook, Reg. No. 64,054, on 03/02/2021.

Please replace claims 1 and 26 in the claim set filed on 12/01/2020 with the following re-written claims 1 and 26.

1. (Currently Amended) A method for enhancing cell growth in culture, said method comprising:
a) culturing cells in a cell culture media supplemented with a plant-produced recombinant mammalian albumin supplement, wherein said plant-produced recombinant mammalian albumin has less than 1 EU of endotoxin/mg of albumin and less than 2% aggregated albumin, wherein said cell growth in culture is enhanced relative to a culture without said plant-produced recombinant mammalian albumin supplement.

26. (Currently Amended) The method of claim 1, ~~wherein cell growth in said culture is enhanced~~ further comprising culturing said cells having enhanced growth for *in vitro* fertilization, testing an effect of a compound or drug on said cells, synthesizing biologics, propagation and differentiation of stem cells, vaccine production, or tissue engineering.

Examiner's Statement of Reasons for Allowance

The following is an examiner's statement of reasons for allowance. Claims 1-26 are drawn to methods for enhancing cell growth in culture, said method comprising: a) culturing cells in a cell culture media supplemented with a plant-produced recombinant mammalian albumin supplement, wherein said plant-produced recombinant mammalian albumin has less than 1 EU of endotoxin/mg of albumin and less than 2% aggregated albumin, wherein said cell growth in culture is enhanced relative to a culture without said plant-produced recombinant mammalian albumin supplement. The closest prior art of record is the reference of Deeter et al. (WO 2007/002762 A2; cited on IDS filed on 07/01/2020) [see prior Office Actions]. However, applicant's declaration filed under Rule 1.132 which demonstrates that the compositions of Deeter et al. are incapable of achieving the claimed less than 1 EU of endotoxin/mg of albumin [see Table E3 and Table E4] and that the levels of endotoxins in the culture medium were not

Art Unit: 1656

appreciated at the time of Deeter's invention is found to be persuasive. Furthermore, Example 7 in the specification demonstrates that the mammalian albumin produced in a transgenic plant has differential effects on the cultured cells in comparison to other expression systems, which the disclosure attributes to heat shock proteins found in plants. Accordingly, the methods of claims 1-26 are allowable over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee, and to avoid processing delays, should preferably accompany the issue fee. Such admissions should be clearly labeled "Comments on Statement of Reasons of Allowance".

Quick Path Information Disclosure Statement

For situations when the applicant needs to file an IDS *after issue fee has been paid*, The United States Patent and Trademark Office (USPTO) has implemented a Quick Path Information Disclosure Statement (QPIDS) program intended to reduce pendency and applicant costs. This pilot program will permit an examiner to consider an IDS after payment of the issue fee without the need to reopen prosecution, effectively obviating the need to pursue a Request for Continued Examination (RCE). Where the examiner determines that no item of information in the IDS necessitates reopening prosecution, the Office will issue a corrected notice of allowability. In addition to reducing pendency, this program will promote efficiency in the examination process. There will be no fee required to use this program, beyond existing fees, e.g., fees for IDS submission. More information on this and other new initiatives at the Patent Office can be found at http://www.uspto.gov/patents/init_events/patapp-initiatives-timeline.jsp or by calling the examiner or his/her supervisor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL J HOLLAND whose telephone number is (571)270-3537.

The examiner can normally be reached on Monday to Friday from 8AM to 5PM.

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, Manjunath Rao can be reached on 571-272-0939. 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 <https://ppair-my.uspto.gov/pair/PrivatePair>. 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.

Application/Control Number: 16/847,337

Page 7

Art Unit: 1656

/PAUL J HOLLAND/

Primary Examiner, Art Unit 1656

<i>Examiner-Initiated Interview Summary</i>	Application No. 16/847,337	Applicant(s) Pettit et al.		
	Examiner PAUL J HOLLAND	Art Unit 1656	AIA (First Inventor to File) Status No	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
PAUL J HOLLAND	Primary Examiner	Telephonic
Ms. Crissa Cook	Attorney of Record	

Date of Interview: 02 March 2021

Issues Discussed:

Proposed Amendment(s)

Examiner Holland contacted applicant's attorney of record, Ms. Crissa Cook, to discuss proposed amendments to the claims to place the application in condition for an allowance.

/PAUL J HOLLAND/ Primary Examiner, Art Unit 1656	
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	

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.



NOTICE OF ALLOWANCE AND FEE(S) DUE

23589 7590 03/10/2021
Hovey Williams LLP
10801 Mastin Blvd., Suite 1000
Overland Park, KS 66210

EXAMINER

HOLLAND, PAUL J

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 03/10/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/847,337	04/13/2020	Steven Clyde Pettit	50091-US-CNT2	7927

TITLE OF INVENTION: CELL CULTURE MEDIA CONTAINING COMBINATIONS OF PROTEINS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	06/10/2021

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.

23589 7590 03/10/2021
Hovey Williams LLP
10801 Mastin Blvd., Suite 1000
Overland Park, KS 66210

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.
16/847,337	04/13/2020	Steven Clyde Pettit	50091-US-CNT2	7927

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nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	06/10/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
HOLLAND, PAUL J	1656	435-326000

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,

(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.

1 _____
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. _____



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

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HOLLAND, PAUL J				
ART UNIT			PAPER NUMBER	
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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. 16/847,337	Applicant(s) Pettit et al.	
	Examiner PAUL J HOLLAND	Art Unit 1656	AIA (FITF) Status No

-- 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 amendment filed 12/01/2020.
☐ 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 1-26. 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>20210304</u> .	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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/PAUL J HOLLAND/
Primary Examiner, Art Unit 1656

DETAILED CORRESPONDENCE

Application Status

The present application is being examined under the pre-AIA first to invent provisions.

Applicant's amendment to the claims filed on 12/01/2020 in response to the Non-Final Rejection mailed on 09/01/2020 is acknowledged and entered into the record.

Applicant's remarks and rule 132 declaration filed on 12/01/2020 in response to the Non-Final Rejection mailed on 09/01/2020 have been fully considered and are deemed persuasive to overcome the prior rejections of record.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in the prior Office Action.

Withdrawn Drawings

The objection to the drawings is withdrawn in view of applicant's remarks filed on 12/01/2020.

Withdrawn Specification

The objection to the disclosure is withdrawn in view of applicant's amendment to the specification filed on 12/01/2020 to reflect the issuance of the 15/188,478 application as U.S. Patent No. 10,618,951.

Withdrawn Claim Rejections - 35 USC § 112(b), or Second Paragraph

The rejection of claims 4-5 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, for indefiniteness is withdrawn in view of applicant's amendment to the claims.

Withdrawn Claim Rejections - 35 USC § 102

The rejection of claims 1-6 and 9-12 under pre-AIA 35 U.S.C. 102(b) as being anticipated by Deeter et al. (**WO2007/002762 A2**; cited on IDS filed on 07/01/2020) as evidenced by Davies (**US Patent Application** 5,917,022; cited on IDS filed on 07/01/2020) is withdrawn in view of applicant's remarks and declaration filed on 12/01/2020.

Withdrawn Claim Rejections - 35 USC § 103

The rejection of claims 7-6 and 14-17 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Deeter et al. (**WO2007/002762 A2**; cited on IDS filed on 07/01/2020) as evidenced by Davies (**US Patent Application** 5,917,022; cited on IDS filed on 07/01/2020) in view of Luyten et al. (**US Patent** 6,617,161, 2003; cited on IDS filed on 07/01/2020) and Potter et al. (**US Patent** 5,985,289, 1999; cited on IDS filed on 07/01/2020) is withdrawn in view of applicant's remarks and declaration filed on 12/01/2020.

Examiner's Amendment to the Claims

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

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Authorization for this examiner's amendment was given in a telephone interview with Ms. Crissa Cook, Reg. No. 64,054, on 03/02/2021.

Please replace claims 1 and 26 in the claim set filed on 12/01/2020 with the following re-written claims 1 and 26.

1. (Currently Amended) A method for enhancing cell growth in culture, said method comprising:
a) culturing cells in a cell culture media supplemented with a plant-produced recombinant mammalian albumin supplement, wherein said plant-produced recombinant mammalian albumin has less than 1 EU of endotoxin/mg of albumin and less than 2% aggregated albumin, wherein said cell growth in culture is enhanced relative to a culture without said plant-produced recombinant mammalian albumin supplement.

26. (Currently Amended) The method of claim 1, ~~wherein cell growth in said culture is enhanced~~ further comprising culturing said cells having enhanced growth for *in vitro* fertilization, testing an effect of a compound or drug on said cells, synthesizing biologics, propagation and differentiation of stem cells, vaccine production, or tissue engineering.

Examiner's Statement of Reasons for Allowance

The following is an examiner's statement of reasons for allowance. Claims 1-26 are drawn to methods for enhancing cell growth in culture, said method comprising: a) culturing cells in a cell culture media supplemented with a plant-produced recombinant mammalian albumin supplement, wherein said plant-produced recombinant mammalian albumin has less than 1 EU of endotoxin/mg of albumin and less than 2% aggregated albumin, wherein said cell growth in culture is enhanced relative to a culture without said plant-produced recombinant mammalian albumin supplement. The closest prior art of record is the reference of Deeter et al. (WO 2007/002762 A2; cited on IDS filed on 07/01/2020) [see prior Office Actions]. However, applicant's declaration filed under Rule 1.132 which demonstrates that the compositions of Deeter et al. are incapable of achieving the claimed less than 1 EU of endotoxin/mg of albumin [see Table E3 and Table E4] and that the levels of endotoxins in the culture medium were not

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appreciated at the time of Deeter's invention is found to be persuasive. Furthermore, Example 7 in the specification demonstrates that the mammalian albumin produced in a transgenic plant has differential effects on the cultured cells in comparison to other expression systems, which the disclosure attributes to heat shock proteins found in plants. Accordingly, the methods of claims 1-26 are allowable over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee, and to avoid processing delays, should preferably accompany the issue fee. Such admissions should be clearly labeled "Comments on Statement of Reasons of Allowance".

Quick Path Information Disclosure Statement

For situations when the applicant needs to file an IDS *after issue fee has been paid*, The United States Patent and Trademark Office (USPTO) has implemented a Quick Path Information Disclosure Statement (QPIDS) program intended to reduce pendency and applicant costs. This pilot program will permit an examiner to consider an IDS after payment of the issue fee without the need to reopen prosecution, effectively obviating the need to pursue a Request for Continued Examination (RCE). Where the examiner determines that no item of information in the IDS necessitates reopening prosecution, the Office will issue a corrected notice of allowability. In addition to reducing pendency, this program will promote efficiency in the examination process. There will be no fee required to use this program, beyond existing fees, e.g., fees for IDS submission. More information on this and other new initiatives at the Patent Office can be found at http://www.uspto.gov/patents/init_events/patapp-initiatives-timeline.jsp or by calling the examiner or his/her supervisor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL J HOLLAND whose telephone number is (571)270-3537.

The examiner can normally be reached on Monday to Friday from 8AM to 5PM.

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, Manjunath Rao can be reached on 571-272-0939. 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 <https://ppair-my.uspto.gov/pair/PrivatePair>. 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.

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/PAUL J HOLLAND/

Primary Examiner, Art Unit 1656

<i>Examiner-Initiated Interview Summary</i>	Application No. 16/847,337	Applicant(s) Pettit et al.		
	Examiner PAUL J HOLLAND	Art Unit 1656	AIA (First Inventor to File) Status No	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
PAUL J HOLLAND	Primary Examiner	Telephonic
Ms. Crissa Cook	Attorney of Record	

Date of Interview: 02 March 2021

Issues Discussed:

Proposed Amendment(s)

Examiner Holland contacted applicant's attorney of record, Ms. Crissa Cook, to discuss proposed amendments to the claims to place the application in condition for an allowance.

/PAUL J HOLLAND/ Primary Examiner, Art Unit 1656	
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	

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.