

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/089,040		ATTY. DOCKET NO.: P1143.70000US04	
				FILING DATE: September 27, 2018		CONFIRMATION NO.: 8702	
				FIRST NAMED INVENTOR: Bruce D. Forrest			
				GROUP ART UNIT: 1645		EXAMINER: Not Yet Assigned	
Sheet	1	of	2				

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		4,221,906		Querry et al.	09-09-1980
		4,242,501		Cano et al.	12-30-1980
		4,686,102		Ritchey et al.	08-11-1987
		5,623,057		Marburg et al.	04-22-1997
		5,847,112		Kniskern et al.	12-08-1998
		8,753,645		Biemans et al.	06-17-2014
		8,808,707		Siber et al.	08-19-2014
		9,764,039		Thanos et al.	09-19-2017
		9,359,400		Usera et al.	06-07-2016
		2015-0374811	A1	Malley et al.	12-31-2015

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD- YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
		CN	104069488	A	Sinovac Res & Dev Co. Ltd.	10-01-2014	Y – Abstract Only
		EP	2865392	A1	SK Chemicals Co., Ltd.	04-29-2015	
		WO	2008/143709	A2	Wyeth	11-27-2008	
		WO	2011/100151	A1	Merck Sharp & Dohme Corp.	08-18-2011	
		WO	2016/207905	A2	Biological E Limited	12-19-2016	
		WO	2018/064444	A1	Biological E Limited	04-05-2018	
		WO	2019/070994	A1	Liffey Biotech Limited	04-11-2019	

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		Extended European Search Report, mailed November 4, 2019, in connection with Application No. EP 17776881 (P1143.70000EP00).	
		International Search Report and Written Opinion, mailed September 13, 2017, in connection with Application No. PCT/US2017/025621 (P1143.70000WO00).	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/089,040		ATTY. DOCKET NO.: P1143.70000US04	
				FILING DATE: September 27, 2018		CONFIRMATION NO.: 8702	
				FIRST NAMED INVENTOR: Bruce D. Forrest			
				GROUP ART UNIT: 1645		EXAMINER: Not Yet Assigned	
Sheet	2	of	2				

		International Preliminary Report on Patentability, mailed October 11, 2018, in connection with Application No. PCT/US2017/025621 (P1143.70000WO00).	
		BENTLEY et al., Genetic Analysis of the Capsular Biosynthetic Locus from All 90 Pneumococcal Serotypes. PLoS Genet. 2006 Mar; 2(3): e31. Epub 2006 Mar 10. doi: 10.1371/journal.pgen.0020031.	
		DURANDO et al., Experience with pneumococcal polysaccharide conjugate vaccine (conjugated to CRM197 carrier protein) in children and adults. Clin Microbiol Infect. 2013;19 Suppl 1:1–9. doi:10.1111/1469-0691.12320.	
		HU et al., Towards the next generation of biomedicines by site-selective conjugation. Chem Soc Rev. 2016;45(6):1691–1719. doi:10.1039/c4cs00388h.	
		JEFFERIES et al., 13-valent pneumococcal conjugate vaccine (PCV13). Hum Vaccin. 2011;7(10):1012–1018. doi:10.4161/hv.7.10.16794.	
		KOLKMAN et al., Functional analysis of glycosyltransferases encoded by the capsular polysaccharide biosynthesis locus of Streptococcus pneumoniae serotype 14. J Biol Chem. 1997;272(31):19502–19508. doi:10.1074/jbc.272.31.19502.	
		SKINNER et al., Pre-clinical evaluation of a 15-valent pneumococcal conjugate vaccine (PCV15-CRM197) in an infant-rhesus monkey immunogenicity model. Vaccine. 2011;29(48):8870–8876. doi:10.1016/j.vaccine.2011.09.078.	

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR § 1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR § 1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR § 1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. § 120.]

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Electronic Acknowledgement Receipt

EFS ID:	38826976
Application Number:	16089040
International Application Number:	
Confirmation Number:	8702
Title of Invention:	SACCHARIDE-POLYPEPTIDE CONJUGATE COMPOSITIONS AND METHODS OF USE THEREOF
First Named Inventor/Applicant Name:	Bruce D. FORREST
Customer Number:	23628
Filer:	Chelsea E. Witte-Garcia/Kristy Alaura
Filer Authorized By:	Chelsea E. Witte-Garcia
Attorney Docket Number:	P1143.70000US04
Receipt Date:	10-MAR-2020
Filing Date:	27-SEP-2018
Time Stamp:	19:09:15
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	P114370000US04-TRN-CEW.pdf	26190 d99803cfe3b5ab30f171b1654cd2499b34a b1dd0	no	1

Warnings:

Information:					
2	Transmittal Letter	P114370000US04-IDSBODY-CEW.pdf	31928 fe70356112900e3d2b8db5130a0901e6c8a83dc5	no	3
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	P114370000US04-IDS1449-CEW.pdf	29450 05b61b9adf1a57ab5c19306d6cf02a203c069f9d	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Other Reference-Patent/App/Search documents	P114370000EP00_EESR_mailed_11-04-2019.pdf	990833 0d411f634dc88d42570a3a3295d18035dfe8dd8ec	no	10
Warnings:					
Information:					
5	Other Reference-Patent/App/Search documents	P114370000WO00_ISR_mailed_09-13-2017.pdf	2007552 560ab03c99668b10c4c2b9f19fd71c6a752d5f1c	no	12
Warnings:					
Information:					
6	Other Reference-Patent/App/Search documents	P114370000WO00_IPRP_mailed_10-11-2018.pdf	1449928 abac10f92a9c09cb6693bfb1b75ce878d0373108	no	10
Warnings:					
Information:					
7	Foreign Reference	CN104069488A_Eng_Abst.pdf	1866836 becbd31e4c868812d2056c29ffa79c5145afae3a	no	11
Warnings:					
Information:					
8	Foreign Reference	EP2865392A1.pdf	3605501 c17c156345e89a06ae3db5139850121d904214e1	no	28
Warnings:					
Information:					

9	Foreign Reference	WO2008143709A2.pdf	6238467	no	59
			aeec22f91514a6ee45e130df5c702c3b645fc5db		
Warnings:					
Information:					
10	Foreign Reference	WO2011100151A1.pdf	4670735	no	37
			d60819c97ef3ac1695e35db39828d3ac5bd4b35d		
Warnings:					
Information:					
11	Foreign Reference	WO2016207905A2.pdf	3167581	no	24
			bf8ea041955ea441890ad1e85d6e0c0893c1f0f2		
Warnings:					
Information:					
12	Foreign Reference	WO2018064444A1.pdf	8884731	no	75
			bdf3bf677badb8a6cd6e0e0d6abb744fb5ff35a		
Warnings:					
Information:					
13	Foreign Reference	WO2019070994A1.pdf	25439884	no	195
			7fb62cbceef79096252e6367f70a87d2c4910732		
Warnings:					
Information:					
14	Non Patent Literature	Bentley_et_al_PLoS_Genet_2006_v2_pe31.pdf	13946128	no	8
			ab8b6af83e765ab9e5c2fae07927e05d3ccb0b1c		
Warnings:					
Information:					
15	Non Patent Literature	Durando_et_al_Clin_Mircrobiol_Infect_2013_v19_p1.pdf	249627	no	9
			14229e68fd85377391898dcb7a4b357e61dc0f4		
Warnings:					
Information:					

16	Non Patent Literature	Hu_et_al_Chem_Soc_Rev_2016_v45_p1969.pdf	4096266 15508251bc606109b7ba9df58f47c39c8425e1a	no	29
Warnings:					
Information:					
17	Non Patent Literature	Jefferies_et_al_Hum_Vaccin_2011_v7_p1012.pdf	1789475 9d458301086c296eda7b2d1c81e0eba45f5e0fb5	no	8
Warnings:					
Information:					
18	Non Patent Literature	Kolkman_et_al_J_Biol_Chem_1997_v272_p19502.pdf	3943190 7b119c218dd65bc42d09434e5439c24cb9600218	no	8
Warnings:					
Information:					
19	Non Patent Literature	Skinner_et_al_Vaccine_2011_v29_p8870.pdf	1540072 be7268865d0f6e17d89110ce10278d6dfcc316dc	no	7
Warnings:					
Information:					
Total Files Size (in bytes):			83974374		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



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.
16/089,040	09/27/2018	Bruce D. FORREST	P1143.70000US04	8702
23628	7590	06/29/2020		
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER BASKAR, PADMAVATHI	
			ART UNIT	PAPER NUMBER
			1645	
			NOTIFICATION DATE	DELIVERY MODE
			06/29/2020	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):

Patents_eOfficeAction@WolfGreenfield.com
WGS_eOfficeAction@WolfGreenfield.com

Office Action Summary

Applicant(s)
FORREST et al.

Art Unit
1645

AIA (FITF) Status
Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 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 03/10/2020.
☐ 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) 1,29,62,67,71,73-75,78,81,97,106,109,112-114,154,157,163 and 256 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) _____ is/are rejected.
- 8) ☐ Claim(s) _____ is/are objected to.
- 9) ☒ Claim(s) 1,29,62,67,71,73-75,78,81,97,106,109,112-114,154,157,163 and 256 are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

1. The preliminary amendment filed on 03/10/2020 is entered. Claims 1, 29, 62, 67, 71, 73-75, 78, 81, 97, 106, 109, 112-114, 154, 157, 163 and 256 are pending.

REQUIREMENT FOR UNITY OF INVENTION

2. As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 (in part), 71, 73, 74, 75, 78, 81, 97, 106, 109 and 256 drawn to a pharmaceutical composition and a method of making composition,

(See paragraph # 5).

Group 2-4, Claims 29 or 62 or 67 drawn to a pharmaceutical composition comprising at least two immunogenic polypeptide conjugates

(See paragraph # 5).

Group 5 or 6 claims 112-114, 154, 157 or 163 drawn to a method comprising administering a pharmaceutical composition.

(See paragraph # 5).

4. The groups of inventions 1-6 listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to polysaccharides. However, US 2015/0374811 A1 teaches a pharmaceutical composition (pharmaceutical immunogenic composition; paragraph [0136]) comprising a plurality of at least eight unique immunogenic saccharide-polypeptide conjugates each comprising individually a capsular polysaccharide conjugated to a polypeptide (plurality of at least eight unique immunogenic saccharide-polypeptide conjugates each comprising individually a capsular polysaccharide conjugated to a pneumococcal antigen polypeptide; paragraph # 0134, wherein the capsular polysaccharide (capsular polysaccharide; paragraph # 0134 is from a unique *Streptococcus pneumoniae* serotype selected from a group consisting of 2 (paragraph # 0134), 8 (paragraph # 0134), 9N (paragraph # 0134), 10A (paragraph # 0134), 11A (paragraph # 0134), 12F (paragraph # 0134), 15B (paragraph # 0134), 17F (paragraph # 0134), 22F (paragraph # 0134), 23A (paragraph # 0134), 24F (paragraph # 0134), 33F (paragraph # 0134) and 34 (paragraph # 0134). Therefore, the technical feature of linking groups 1-5 does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

5. This application contains claims directed to more than one invention. These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 as indicated above.

The inventions are as follows:

Claim 1 Or claim 112, please select at least eight or more or any one combination of eight or more capsular polysaccharide conjugated to a polypeptide from serotype 2, 6C, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 20A, 20B, 22F, 23A, 23B, 24F, 24B, 31, 33F, 34, 35B, 35F, and 38.

Claim 2, please select at least two or more or any one combination of two or more capsular polysaccharide conjugated to a polypeptide from serotype 6C and at least one additional serotype is selected from the group consisting of 1, 2, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 20A, 20B, 22F, 23A, 23B, 24F, 31, 33F, 34, 35B, and 38.

Claim 3, please select at least two or more or any one combination of two or more capsular polysaccharide conjugated to a polypeptide from serotype 20B and at least one additional serotype is selected from the group consisting of 1, 2, 3, 4, 5, 6A, 6B, 6C, 7F, 9V, 14, 18C, 19A, 19F, 23F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 20A, 22F, 23A, 23B, 24F, 31, 33F, 34, 35B, and 38.

Claim 67, please select at least two or more or any one combination of two or more capsular polysaccharide conjugated to a polypeptide from serotype 1, 2, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 6C, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 20A, 20B, 22F, 23A, 23B, 24F, 24B, 31, 33F, 34, 35F, 35B, and 38.

Applicant is required, in reply to this action, to elect a single combination of serotype and indicate clearly what are the serotypes selected for prosecution to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable is considered non-responsive unless accompanied by an election.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi Baskar whose telephone number is (571)272-0853. The examiner can normally be reached on Mon-Fri 9-5:30pm.

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, Gary Nickol can be reached on 571-272-0835. 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.

Respectfully,

/Padmavathi Baskar/
Primary Examiner, Art Unit 1645
Padmavathi Baskar, Ph.D. (Microbiology and Immunology)



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

23628 7590 03/10/2021
WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/10/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/089,040	09/27/2018	Bruce D. FORREST	P1143.70000US04	8702

TITLE OF INVENTION: SACCHARIDE-POLYPEPTIDE CONJUGATE COMPOSITIONS AND METHODS OF USE THEREOF

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.

23628 7590 03/10/2021
WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

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.
16/089,040	09/27/2018	Bruce D. FORREST	P1143.70000US04	8702

TITLE OF INVENTION: SACCHARIDE-POLYPEPTIDE CONJUGATE COMPOSITIONS AND METHODS OF USE THEREOF

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
BASKAR, PADMAVATHI	1645	424-244100

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. _____



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.
16/089,040	09/27/2018	Bruce D. FORREST	P1143.70000US04	8702
23628	7590	03/10/2021	EXAMINER	
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			BASKAR, PADMAVATHI	
			ART UNIT	PAPER NUMBER
			1645	
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. 16/089,040	Applicant(s) FORREST et al.	
	Examiner Padmavathi Baskar	Art Unit 1645	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 12/28/2020.
☐ 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 See Continuation Sheet. 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 <u>03/10/2020 and 12/28/2020</u> . 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☒ Interview Summary (PTO-413), Paper No./Mail Date. <u>03/04/2021</u> .	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
---	---

/Padmavathi Baskar/
Primary Examiner, Art Unit 1645

Continuation of 3. The allowed claim(s) is/are: 67,74-75,78,81,97,106,109,112-114,154,256,297 and 299-303

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Restriction Requirement

2. Applicant's response 12/28/2020 to election is acknowledged. Applicant elected Applicant hereby elects Group 4 (claim 67), drawn to a pharmaceutical composition comprising at least two immunogenic polypeptide conjugates, 35B and 23A and 23B.

Status of claims

3. Claims 67, 71, 73-75, 78, 81, 97, 106, 109, 112-114, 154, 256, and 296-300 are pending.
Claims 1, 29, 62, 157, 163, and 256 have been canceled.
Claims 71, 74, 75, 68, 81, 97, 106, 109, 112, 113, and 256 have been amended
New claims 296-300 have been added.
Claims 67, 71, 73-75, 78, 81, 97, 106, 109 and 296-300 are under examination with respect to 35B, 23A and 23B.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 03/10/2020 and 12/28/2020 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner and a signed copy of each is attached to this office action.

Examiner's amendment

5. 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 a telephone interview with Chelsea E. Witte-Garcia, on 03/04/2021 and the application has been amended as follows:

Claims 71, 73, 296 and 298 are cancelled.

67. (Currently Amended) A pharmaceutical composition comprising a plurality of at least two unique ~~an~~ immunogenic saccharide-polypeptide conjugates, each comprising, individually ~~a, at least two~~ unique capsular polysaccharides, ~~fragments thereof, or combinations thereof,~~ conjugated to a polypeptide, wherein each of the ~~at least two~~ unique capsular polysaccharides, ~~or fragments thereof,~~ is from a *Streptococcus pneumoniae* serotype selected from a group consisting of 1, 2, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 6C, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 20A, 20B, 22F, 23A, 23B, 24F, 24B, 31, 33F, 34, 35F, and 35B, and 38.

74. (Currently Amended) The pharmaceutical composition of claim 67, wherein ~~at least one polypeptide of the plurality is an oligopeptide and/or~~ at least one polypeptide comprises a mixture of polypeptides.

78. (Currently Amended) The pharmaceutical composition of claim 67, further comprising an adjuvant; a chelating agent; a surfactant; , an emulsifier, ~~or a combination thereof;~~ a buffering agent; a preservative; a salt; ~~and/or~~ an anti-fungal compound; or a combination ~~or a salt~~ thereof.

97. (Currently Amended) The pharmaceutical composition of claim 67, wherein at least one of the unique immunogenic saccharide-polypeptide conjugate elicits an opsonophagocytic response.

106. (Currently Amended) The pharmaceutical composition of claim 67, wherein the immunogenic saccharide-polypeptide conjugates ~~conjugate(s)~~ are individually, ~~respectively,~~ or collectively present in an amount of at least ~~about~~ 0.001%, by weight, based on the weight of the pharmaceutical composition.

114. (Currently Amended) The method of claim 113, wherein the second composition comprises an immunogenic saccharide-polypeptide conjugate comprising a capsular polysaccharide ~~or fragment of~~

~~the capsular polysaccharide~~ from a serotype of *Streptococcus pneumoniae* conjugated to the a second polypeptide.

154. (Currently Amended) The method of claim 112 ~~143~~ wherein the subject is a human.

299. (Currently Amended) The pharmaceutical composition of claim 67, wherein each of the immunogenic saccharide-polypeptide conjugates is present in an amount of ~~about~~ at least 0.001%, by weight, based on the weight of the pharmaceutical composition.

301. (New) The pharmaceutical composition of claim 67, further comprising at least one additional immunogenic saccharide-polypeptide conjugate comprising a capsular polysaccharide from a unique *Streptococcus pneumoniae* serotype selected from the group consisting of 6C, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 20A, 20B, 22F, and 34.

302. (New) The pharmaceutical composition of claim 67, wherein plurality of unique immunogenic saccharide-polypeptide conjugate comprises individually *Streptococcus pneumoniae* serotype comprising 6C, 9N, 15A, 15C, 16F, 23A, 23B, and 35B.

303. (New) The pharmaceutical composition of claim 67, wherein plurality of unique immunogenic saccharide-polypeptide conjugate comprises individually *Streptococcus pneumoniae* serotype consisting of 6C, 9N, 15A, 15C, 16F, 23A, 23B, and 35B.

Reasons for Allowance

6. The following is an examiner's statement of reasons for allowance:

The claimed pharmaceutical composition comprising capsular polysaccharides from a *Streptococcus pneumoniae* serotype 23A, 23B and 35B of the instant application is novel and nonobvious. The specification teaches (Table 2 and examples) the capsular conjugates and therefore induce an immune response when administered. The claimed composition has not been disclosed or

studied in the prior art and the specification meets 35 U.S.C. 112, first paragraph, requirements because it contains an adequate written description of the invention that enables one of ordinary skill in the art to make and use the invention. The specification also sets forth the best mode to carry out the invention. The claims also meet 35 U.S.C. 112, second paragraph, requirements because the claims point out and distinctly claim the invention.

7. Claims 67, 74-75, 78, 81, 97, 106, 109, 297 and 299-303 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 112-114, 154 and 256 (group 5), directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, 06/29/2020 hereby rejoined and fully examined for patentability under 37 CFR 1.104. Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Conclusion

8. Claims 67, 74-75, 78, 81, 97, 106, 109, 297, 299-303, 112-114, 154 and 256 are allowed and are numbered as 1-19 respectively.

Correspondence

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi Baskar whose telephone number is (571)272-0853. The examiner can normally be reached on Mon-Fri 9-5:30

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, Gary Nickol can be reached on 571-272-0835. 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.

Respectfully,

/Padmavathi Baskar/
Primary Examiner, Art Unit 1645
Padmavathi Baskar, Ph.D. (Microbiology and Immunology)

<i>Examiner-Initiated Interview Summary</i>	Application No. 16/089,040	Applicant(s) FORREST et al.		
	Examiner Padmavathi Baskar	Art Unit 1645	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
Padmavathi Baskar	Primary Examiner	Telephonic
Chelsea E. Witte-Garcia	Attorney of Record	

Date of Interview: 04 March 2021

Issues Discussed:

Other

The examine and the attorney discussed the allowable subject matter of pharmaceutical composition comprising polysaccharide conjugates 35B, 23A and 23B from Streptococcus pneumoniae. These serotypes along with 6C, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 20A, 20B, 22F, and 34 or 6C, 9N, 15A, 15C, 16F, 23A, 23B, and 35B appear to be free of prior art and the specification table 2 has support doe said composition. The applicant agreed to the examiner's amendment as set forth in the attached office action.

/Padmavathi Baskar/ Primary Examiner, Art Unit 1645	
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.

Issue Classification 	Application/Control No. 16/089,040	Applicant(s)/Patent Under Reexamination FORREST et al.	
	Examiner Padmavathi Baskar	Art Unit 1645	

CPC						
Symbol					Type	Version
A61K	/	39	/	092	F	2013-01-01
A61K	/	47	/	646	I	2017-08-01
A61K	/	2039	/	55505	A	2013-01-01
A61K	/	2039	/	6037	A	2013-01-01
A61K	/	2039	/	70	A	2013-01-01

CPC Combination Sets							
Symbol				Type	Set	Ranking	Version
	/		/				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	19	
/Padmavathi Baskar/ Primary Examiner, Art Unit 1645	04 March 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	-----

Issue Classification 	Application/Control No. 16/089,040	Applicant(s)/Patent Under Reexamination FORREST et al.
	Examiner Padmavathi Baskar	Art Unit 1645

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61K39/09	/	39	/ 09
A61K47/64	/	47	/ 64
NON-CLAIMED			
A61K39/00	/	39	/ 00

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	19	
/Padmavathi Baskar/ Primary Examiner, Art Unit 1645	04 March 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	-----

Issue Classification 	Application/Control No. 16/089,040	Applicant(s)/Patent Under Reexamination FORREST et al.
	Examiner Padmavathi Baskar	Art Unit 1645

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	67	10	299	19	256										
2	74	11	300												
3	75	12	301												
4	78	13	302												
5	81	14	303												
6	97	15	112												
7	106	16	113												
8	109	17	114												
9	297	18	154												

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 19	
/Padmavathi Baskar/ Primary Examiner, Art Unit 1645 (Primary Examiner) _____ (Date) 04 March 2021		O.G. Print Claim(s) 1	O.G. Print Figure -----

<i>Search Notes</i> 	Application/Control No. 16/089,040	Applicant(s)/Patent Under Reexamination FORREST et al.
	Examiner Padmavathi Baskar	Art Unit 1645

CPC - Searched*		
Symbol	Date	Examiner
SEE ATTACHED WEST SEARCH HISTORY.	03/04/2021	PB

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
INVENTORS NAME SEARCH IS PERFORMED IN PALM/PE2E.	03/04/2021	PB
CONTINUATION DOCUMENTS WERE REVIEWED AND SIGNED. SEE ATTACHED BIB SHEET.	03/04/2021	PB
TEXT AND INVENTORS NAME SEARCH PERFORMED ON WEST USING DATABASES, USPAT, US PUBLICATIONS, JPO, EPO, AND DERWENT. SEE ATTACHED WEST SEARCH HISTORY.	03/04/2021	PB
TEXT AND INVENTORS NAME SEARCH PERFORMED ON STN USING DATABASES MED LINE, BIOSIS, CAPLUS, HCAPLUS, EMBASE, WPIX, JAPIO, PASCAL, DISSABS. SEE ATTACHED STN SEARCH HISTORY.	03/04/2021	PB

--	--

<i>Search Notes</i> 	Application/Control No. 16/089,040	Applicant(s)/Patent Under Reexamination FORREST et al.
	Examiner Padmavathi Baskar	Art Unit 1645

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
-	SEE ATTACHED WEST SEARCH HISTORY.	03/04/2021	PB

--	--

Bibliographic Data

Application No: 16/089,040

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /Padmavathi Baskar/

Examiner's Signature

Initials

Title:

SACCHARIDE-POLYPEPTIDE CONJUGATE COMPOSITIONS
AND METHODS OF USE THEREOF

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/27/2018	424	1645	P1143.70000US04
RULE			

APPLICANTS

Pogona, LLC, South Nyack, NY, UNITED STATES

INVENTORS

Bruce D. FORREST, South Nyack, NY, UNITED STATES

Jack D. LOVE, Tampa, FL, UNITED STATES

CONTINUING DATA

This application is a 371 of PCT/US17/25621 03/31/2017

PCT/US17/25621 has PRO of 62373807 08/11/2016

PCT/US17/25621 has PRO of 62372263 08/08/2016

PCT/US17/25621 has PRO of 62330245 05/02/2016

PCT/US17/25621 has PRO of 62316555 03/31/2016

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

01/08/2020

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

WOLF GREENFIELD & SACKS, P.C.

600 ATLANTIC AVENUE

BOSTON, MA 02210-2206

UNITED STATES

FILING FEE RECEIVED

\$600

WEST Search History for Application 16089040

Creation Date: 2021030417:30

Prior Art Searches

Query	DB	Hits	Op.	Plur.	Thes.	Date
capsular polysaccharides from serotypes 35B 23A 23B	USPT	0	ADJ	YES		03-04-2021
polysaccharides 35B 23A 23B	USPT	0	ADJ	YES		03-04-2021
FORREST BRUCE D.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	10	ADJ	YES		03-04-2021
LOVE, JACK D.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	29	ADJ	YES		03-04-2021
6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 35B	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	2	ADJ	YES		03-04-2021
35B 23A 23B	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	4	ADJ	YES		03-04-2021
6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 34	PGPB, USPT,	2	ADJ	YES		03-04-2021

	USOC, EPAB, JPAB, DWPI, TDBD, FPRS					
(35B 23A 23B) and (6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 34)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
(35B 23A 23B) and (6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 35B)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
(LOVE, JACK D.in.) and (35B 23A 23B)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
(LOVE, JACK D.in.) and (35B 23A 23B)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
35B 23A 23B 6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 34	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021

35B 23A 23B 6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 35B	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
35B 23A 23B 6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, 35B	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
capsular polysaccharides from serotypes 35B 23A 23B	USPT	0	ADJ	YES		03-04-2021
polysaccharides 35B 23A 23B	USPT	0	ADJ	YES		03-04-2021
FORREST BRUCE D.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	10	ADJ	YES		03-04-2021
LOVE, JACK D.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	29	ADJ	YES		03-04-2021
6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 35B	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	2	ADJ	YES		03-04-2021
35B 23A 23B	PGPB, USPT, USOC,	4	ADJ	YES		03-04-2021

	EPAB, JPAB, DWPI, TDBD, FPRS					
6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 34	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	2	ADJ	YES		03-04-2021
(35B 23A 23B) and (6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 34)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
(35B 23A 23B) and (6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 35B)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
(LOVE, JACK D.in.) and (35B 23A 23B)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
(LOVE, JACK D.in.) and (35B 23A 23B)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
35B 23A 23B 6C, 8, 9N, 10A, 11A, 12F, 15A,	PGPB,	0	ADJ	YES		03-04-2021

22F, 23A, 23B, 24F, 33F, and 34	USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS					
35B 23A 23B 6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 35B	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
35B 23A 23B 6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, 35B	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
35B 23A 23B 6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 24F, 33F, 35B	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
35B 23A 23B 6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 24F, 33F, and 34	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	ADJ	YES		03-04-2021
(6C, 8, 9N, 10A, 11A, 12F, 15A, 22F, 23A, 23B, 24F, 33F, and 34) and ((A61K2039/55505 A61K2039/6037 A61K39/092 A61K2039/54 A61K2039/545 A61K2039/70 A61K39/39 A61K45/06 A61K47/10 A61K47/183 A61K47/26 A61K47/646 A61K9/08 A61P31/04 A61P37/04 A61P43/00).CPC. or (1/1).CCLS. or (A61K39/09 A61K39/39 	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	2	ADJ	YES		03-04-2021

A61K47/10 A61K47/18 A61K47/26 A61K47/64 A61K9/08).IPCR.)						
--	--	--	--	--	--	--

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/089,040		ATTY. DOCKET NO.: P1143.70000US014	
				FILING DATE: September 27, 2018		CONFIRMATION NO.: 8702	
				FIRST NAMED INVENTOR: Bruce D. Forrest			
				GROUP ART UNIT: 1645		EXAMINER: Padmavathi Baskar	
Sheet	1	of	1				

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
/P.B./		2017-0021006	A1	Watson et al.	01-26-2017

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD- YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
/P.B./		WO	2016/149771	A1	Gamma Vaccines Pty Limited	09-29-2016	
/P.B./		WO	2017/067962	A1	Glaxosmithkline Biologicals S.A.	04-27-2017	

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
/P.B./		International Search Report and Written Opinion, mailed February 11, 2019, in connection with Application No. PCT/US2018/054391 (P1143.70001WO00).	
/P.B./		International Preliminary Report on Patentability, mailed April 16, 2020, in connection with Application No. PCT/US2018/054391 (P1143.70001WO00).	

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR § 1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR § 1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR § 1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. § 120.]

EXAMINER: /Padmavathi Baskar/	DATE CONSIDERED: 01/28/2021
--------------------------------------	------------------------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

8486076.1

=> d his ful

```
FILE 'REGISTRY' ENTERED AT 07:54:24 ON 08 JAN 2021
E CRM197/CN
L1      1 SEA ABB=ON  PLU=ON  "CRM197 PROTEIN"/CN
E CRM 197/CN
L2      5 SEA ABB=ON  PLU=ON  ("CRM 197"/CN OR "CRM 197 (173-LYSINE) (
SYNTHETIC CATALYTICALLY INACTIVATED DIPHTHERIA TOXIN
PRECURSOR)"/CN OR "CRM 197 (CORYNEBACTERIUM DIPHTHERIAE
INACTIVE DIPHTHERIA TOXIN CRM197 GENE)"/CN OR "CRM 197
(CORYNEBACTERIUM DIPHTHERIAE INACTIVE DIPHTHERIA TOXIN
CRM197 PRECURSOR)"/CN OR "CRM 197 (CORYNEBACTERIUM
DIPHTHERIAE)"/CN OR "CRM 197 (SYNTHETIC CATALYTICALLY
INACTIVATED DIPHTHERIA TOXIN PRECURSOR)"/CN)
L3      34 SEA ABB=ON  PLU=ON  TETANUS TOXOID?/CN
E TETANUS TOXIN/CN
L4      1 SEA ABB=ON  PLU=ON  "TETANUS TOXIN"/CN
E DIPHTHERIA TOXOID/CN
L5      2 SEA ABB=ON  PLU=ON  ("DIPHTHERIA TOXOID"/CN OR "DIPHTHERIA
TOXOID (CORYNEBACTERIUM DIPHTHERIAE)"/CN OR "DIPHTHERIA
TOXOIDS"/CN)
E DIPHTHERIA TOXIN/CN
L6      1 SEA ABB=ON  PLU=ON  "DIPHTHERIA TOXIN"/CN
E PERTUSSIS TOXOID/CN
L7      1 SEA ABB=ON  PLU=ON  ("PERTUSSIS TOXOID"/CN OR "PERTUSSIS
TOXOIDS"/CN)
E PERTUSSIS TOXIN/CN
L8      1 SEA ABB=ON  PLU=ON  "PERTUSSIS TOXIN"/CN
E CHOLERA TOXOID/CN
L9      2 SEA ABB=ON  PLU=ON  ("CHOLERA TOXOID (METHIONYL,41-TYROSINE
) (VIBRIO CHOLERAEE GENE CTXA SUBUNIT A FRAGMENT)"/CN OR
"CHOLERA TOXOID (METHIONYL,63-TYROSINE) (VIBRIO CHOLERAEE
GENE CTXA SUBUNIT A FRAGMENT)"/CN)
E CHOLERA TOXIN/CN
L10     1 SEA ABB=ON  PLU=ON  "CHOLERA TOXIN"/CN
L11     5 SEA ABB=ON  PLU=ON  PNEUMOCOCCAL SURFACE PROTEIN A ?/CN
E PNEUMOCOCCAL PNEUMOLYSIN/CN
L12     3 SEA ABB=ON  PLU=ON  ("PNEUMOCOCCAL SURFACE ADHESIN A
(STREPTOCOCCUS PNEUMONIAE GENE PSAA FRAGMENT)"/CN OR
"PNEUMOCOCCAL SURFACE ADHESIN A (STREPTOCOCCUS PNEUMONIAE
GENE PSAA PRECURSOR)"/CN)
L13     7 SEA ABB=ON  PLU=ON  KEYHOLE LIMPET HEMOCYANIN?/CN
L14     19 SEA ABB=ON  PLU=ON  C5A PEPTIDASE ?/CN
L15     6 SEA ABB=ON  PLU=ON  TUBERCULIN ?/CN
L16     88 SEA ABB=ON  PLU=ON  (L1 OR L2 OR L3 OR L4 OR L5 OR L6 OR
L7 OR L8 OR L9 OR L10 OR L11 OR L12 OR L13 OR L14 OR L15)
```

```
FILE 'HCAPLUS' ENTERED AT 07:59:27 ON 08 JAN 2021
L17     216410 SEA ABB=ON  PLU=ON  (?SACCHARIDE? OR CPS OR CP) AND
(PROTEIN OR PEPTIDE OR OLIGOPEPTIDE OR POLYPEPTIDE OR
POLYPROTEIN)
L18     42375 SEA ABB=ON  PLU=ON  L17 AND (CONJUGAT? OR ?LINK? OR
COUPL?)
L19     1513 SEA ABB=ON  PLU=ON  L18 AND ((STREPTOCOCC? OR S OR D OR
DIPLOCOCCI?) (W) PNEUMON? OR PNEUMOCOCC?)
L20     9 SEA ABB=ON  PLU=ON  L19 AND (23A OR 23B OR 35B)
L22     27442 SEA ABB=ON  PLU=ON  "STREPTOCOCCUS PNEUMONIAE"+OLD, PFT/CT
```

L23 4159 SEA ABB=ON PLU=ON L22 AND (OLIGOPEPTIDES+OLD,PFT OR
 PEPTIDES OR PROTEINS)/CT
 L24 945 SEA ABB=ON PLU=ON L23 AND (MONOSACCHARIDES+OLD,PFT OR
 OLIGOSACCHARIDES+OLD,PFT OR POLYSACCHARIDES+OLD,PFT OR
 CAPSULAR POLYSACCHARIDES+OLD,PFT OR SACCHARIDES OR
 CARBOHYDRATES)/CT
 L25 7 SEA ABB=ON PLU=ON L24 AND (23A OR 23B OR 35B)
 L26 10 SEA ABB=ON PLU=ON L20 OR L25

 FILE 'REGISTRY' ENTERED AT 08:09:35 ON 08 JAN 2021
 L31 1 SEA ABB=ON PLU=ON 100179-39-3/RN

 FILE 'HCAPLUS' ENTERED AT 08:10:33 ON 08 JAN 2021
 L33 85765 SEA ABB=ON PLU=ON (?SACCHARIDE? OR CPS OR CP) (10A) (PROTE
 IN OR PEPTIDE OR OLIGOPEPTIDE OR POLYPEPTIDE OR POLYPROTEIN
)
 L34 6964 SEA ABB=ON PLU=ON L33(10A) (CONJUGAT? OR ?LINK? OR
 COUPL?)
 L35 643 SEA ABB=ON PLU=ON L34(S) (L16 OR CRM197 OR (CROSS REACT?
 OR CRM) (2W) 197 OR TT OR DT OR CT OR ?TOXOID? OR PT OR
 ?TOXIN? OR PNEUMOCOCCAL PNEUMOLYSIN OR PNEUMOCOCC? (5W) (SPA
 OR PROTEIN A) OR PSPA OR (PSA OR PSP) (W) A OR PSSA OR
 C5A(S) PEPTIDASE OR NTHI OR INFLUENZA OR USPA OR USP A OR
 KLH)
 L36 289 SEA ABB=ON PLU=ON L34(S) (L31 OR KEYHOLE LIMPET OR OMPC
 OR OUTER MEMBRANE? OR PPD OR TUBERCULIN OR PROTEIN D)
 L40 285 SEA ABB=ON PLU=ON (L35 OR L36) AND (?ADJUVANT? OR
 CHELAT? OR SURFACTANT OR SURFACE(2A) ACTIVE OR EMULSIF? OR
 EMULSION OR BUFFER? OR PRESERVATIVE OR ANTIFUNG## OR
 FUNGICID? OR ANTI FUNG##)
 L42 18 SEA ABB=ON PLU=ON L40 AND OPSONOPHAGOCY?
 L43 96 SEA ABB=ON PLU=ON L19 AND OPSONOPHAGOCY?
 L44 57 SEA ABB=ON PLU=ON L43 AND (L16 OR CRM197 OR (CROSS
 REACT? OR CRM) (2W) 197 OR TT OR DT OR CT OR ?TOXOID? OR PT
 OR ?TOXIN? OR PNEUMOCOCCAL PNEUMOLYSIN OR PNEUMOCOCC? (5W) (S
 PA OR PROTEIN A) OR PSPA OR (PSA OR PSP) (W) A OR PSSA OR
 C5A(S) PEPTIDASE OR NTHI OR INFLUENZA OR USPA OR USP A OR
 KLH)
 L45 24 SEA ABB=ON PLU=ON L43 AND (L31 OR KEYHOLE LIMPET OR OMPC
 OR OUTER MEMBRANE? OR PPD OR TUBERCULIN OR PROTEIN D)
 L46 28 SEA ABB=ON PLU=ON (L44 OR L45) AND (?ADJUVANT? OR
 CHELAT? OR SURFACTANT OR SURFACE(2A) ACTIVE OR EMULSIF? OR
 EMULSION OR BUFFER? OR PRESERVATIVE OR ANTIFUNG## OR
 FUNGICID? OR ANTI FUNG##)
 E OPSONOPHAGOCYOSIS+ALL/CT
 E E4+ALL
 L47 1186 SEA ABB=ON PLU=ON OPSONOPHAGOCYTOSIS+OLD,PFT/CT
 L48 24 SEA ABB=ON PLU=ON L24 AND L47

 FILE 'MEDLINE, BIOSIS, EMBASE, WPIX, JAPIO, PQSCITECH' ENTERED AT
 08:22:02 ON 08 JAN 2021
 L51 55 SEA ABB=ON PLU=ON L20

 FILE 'WPIX, PQSCITECH' ENTERED AT 08:22:33 ON 08 JAN 2021
 L54 43 SEA ABB=ON PLU=ON L20
 L55 25 SEA ABB=ON PLU=ON L54 AND PER/PHP

FILE 'HCAPLUS' ENTERED AT 08:25:23 ON 08 JAN 2021
D QUE L20
D QUE L25
D L26 1-10

FILE 'MEDLINE, BIOSIS, EMBASE, WPIX, JAPIO, PQSCITECH' ENTERED AT
08:25:25 ON 08 JAN 2021
L56 48 DUP REM L55 L51 (32 DUPLICATES REMOVED)
D L56 1-48

FILE 'HCAPLUS' ENTERED AT 08:26:10 ON 08 JAN 2021
L57 44 SEA ABB=ON PLU=ON (L42 OR L46 OR L48) NOT L26
D QUE L42
D QUE L46
D QUE L48
D L57 1-44

FILE 'MEDLINE, BIOSIS, EMBASE, WPIX, JAPIO, PQSCITECH' ENTERED AT
08:27:33 ON 08 JAN 2021
L58 14 SEA ABB=ON PLU=ON L42
L59 26 SEA ABB=ON PLU=ON L46
L60 29 SEA ABB=ON PLU=ON (L58 OR L59) NOT L51

FILE 'WPIX, PQSCITECH' ENTERED AT 08:31:23 ON 08 JAN 2021
L61 10 SEA ABB=ON PLU=ON L42
L62 10 SEA ABB=ON PLU=ON L46
L63 9 SEA ABB=ON PLU=ON (L61 OR L62) AND PER/PHP
L64 8 SEA ABB=ON PLU=ON L63 NOT L55

FILE 'WPIX, MEDLINE, BIOSIS, EMBASE, PQSCITECH' ENTERED AT 08:32:42
ON 08 JAN 2021
L65 23 DUP REM L64 L60 (14 DUPLICATES REMOVED)
D L65 1-23

FILE 'MEDLINE' ENTERED AT 08:33:20 ON 08 JAN 2021
L66 22959 SEA ABB=ON PLU=ON ("STREPTOCOCCUS PNEUMONIAE"/CT OR
B3.353.750.737.872.550./CT OR B3.510.400.800.872.550./CT
OR B3.510.550.737.872.550./CT)
L67 216 SEA ABB=ON PLU=ON L66 AND (23A OR 23B OR 35B)
L68 572648 SEA ABB=ON PLU=ON (POLYSACCHARIDES/CT OR D9.698./CT)
L69 8 SEA ABB=ON PLU=ON L67 AND (L68 OR D9./CT)
L70 3366 SEA ABB=ON PLU=ON L66 AND (L68 OR D9./CT)
L71 560 SEA ABB=ON PLU=ON L70 AND (CS OR BI)/CT
L72 300739 SEA ABB=ON PLU=ON (OLIGOPEPTIDES/CT OR D12.644.456./CT)
E PEPTIDES+ALL/CT
L73 2752045 SEA ABB=ON PLU=ON (PEPTIDES/CT OR D12.644./CT)
L74 423 SEA ABB=ON PLU=ON L71 AND (D12.776./CT OR L72 OR L73)
L75 153 SEA ABB=ON PLU=ON L74 AND (CONJUGAT? OR ?LINK? OR
COUPL?)
L76 50066 SEA ABB=ON PLU=ON (PHAGOCYTOSIS/CT OR G12.450.564.809./CT
OR G12.688./CT OR G4.417.350./CT OR G9.188.665./CT)
L77 4161 SEA ABB=ON PLU=ON ("OPSONIN PROTEINS"/CT OR D12.776.124.4
86.485.114.767./CT OR D12.776.124.486.657./CT OR D12.776.12
4.790.651.114.767./CT OR D12.776.377.715.548.114.767./CT)
L78 7 SEA ABB=ON PLU=ON L75 AND L76
L79 4 SEA ABB=ON PLU=ON L75 AND L77
L80 16 SEA ABB=ON PLU=ON L69 OR L78 OR L79

D QUE L69
D QUE L78
D QUE L79
D L80 1-16

FILE 'HCAPLUS, MEDLINE, BIOSIS, EMBASE, WPIX, JAPIO, PQSCITECH'
ENTERED AT 08:42:16 ON 08 JAN 2021

L81 862 SEA ABB=ON PLU=ON "FORREST B"?/AU
L82 6550 SEA ABB=ON PLU=ON "LOVE J"?/AU
L83 4 SEA ABB=ON PLU=ON L81 AND L82
L84 11 SEA ABB=ON PLU=ON (L81 OR L82) AND L19
L85 2 SEA ABB=ON PLU=ON (L81 OR L82) AND L24
L86 5 SEA ABB=ON PLU=ON (L81 OR L82) AND L36
L87 11 SEA ABB=ON PLU=ON (L83 OR L84 OR L85 OR L86)
L88 4 DUP REM L87 (7 DUPLICATES REMOVED)
D L88 1-4

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/089,040		ATTY. DOCKET NO.: P1143.70000US04	
				FILING DATE: September 27, 2018		CONFIRMATION NO.: 8702	
				FIRST NAMED INVENTOR: Bruce D. Forrest			
				GROUP ART UNIT: 1645		EXAMINER: Not Yet Assigned	
Sheet	1	of	2				

**ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.B/
U.S. PATENT DOCUMENTS**

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		4,221,906		Querry et al.	09-09-1980
		4,242,501		Cano et al.	12-30-1980
		4,686,102		Ritchey et al.	08-11-1987
		5,623,057		Marburg et al.	04-22-1997
		5,847,112		Kniskern et al.	12-08-1998
		8,753,645		Biemans et al.	06-17-2014
		8,808,707		Siber et al.	08-19-2014
		9,764,039		Thanos et al.	09-19-2017
		9,359,400		Usera et al.	06-07-2016
		2015-0374811	A1	Malley et al.	12-31-2015

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD- YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
		CN	104069488	A	Sinovac Res & Dev Co. Ltd.	10-01-2014	Y – Abstract Only
		EP	2865392	A1	SK Chemicals Co., Ltd.	04-29-2015	
		WO	2008/143709	A2	Wyeth	11-27-2008	
		WO	2011/100151	A1	Merck Sharp & Dohme Corp.	08-18-2011	
		WO	2016/207905	A2	Biological E Limited	12-19-2016	
		WO	2018/064444	A1	Biological E Limited	04-05-2018	
		WO	2019/070994	A1	Liffey Biotech Limited	04-11-2019	

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		Extended European Search Report, mailed November 4, 2019, in connection with Application No. EP 17776881 (P1143.70000EP00).	
		International Search Report and Written Opinion, mailed September 13, 2017, in connection with Application No. PCT/US2017/025621 (P1143.70000WO00).	

EXAMINER: /Padmavathi Baskar/	DATE CONSIDERED: 02/01/2021
-------------------------------	--------------------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/089,040		ATTY. DOCKET NO.: P1143.70000US04	
				FILING DATE: September 27, 2018		CONFIRMATION NO.: 8702	
				FIRST NAMED INVENTOR: Bruce D. Forrest			
				GROUP ART UNIT: 1645		EXAMINER: Not Yet Assigned	
Sheet	2	of	2				

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.B/

		International Preliminary Report on Patentability, mailed October 11, 2018, in connection with Application No. PCT/US2017/025621 (P1143.70000WO00).	
		BENTLEY et al., Genetic Analysis of the Capsular Biosynthetic Locus from All 90 Pneumococcal Serotypes. PLoS Genet. 2006 Mar; 2(3): e31. Epub 2006 Mar 10. doi: 10.1371/journal.pgen.0020031.	
		DURANDO et al., Experience with pneumococcal polysaccharide conjugate vaccine (conjugated to CRM197 carrier protein) in children and adults. Clin Microbiol Infect. 2013;19 Suppl 1:1–9. doi:10.1111/1469-0691.12320.	
		HU et al., Towards the next generation of biomedicines by site-selective conjugation. Chem Soc Rev. 2016;45(6):1691–1719. doi:10.1039/c4cs00388h.	
		JEFFERIES et al., 13-valent pneumococcal conjugate vaccine (PCV13). Hum Vaccin. 2011;7(10):1012–1018. doi:10.4161/hv.7.10.16794.	
		KOLKMAN et al., Functional analysis of glycosyltransferases encoded by the capsular polysaccharide biosynthesis locus of Streptococcus pneumoniae serotype 14. J Biol Chem. 1997;272(31):19502–19508. doi:10.1074/jbc.272.31.19502.	
		SKINNER et al., Pre-clinical evaluation of a 15-valent pneumococcal conjugate vaccine (PCV15-CRM197) in an infant-rhesus monkey immunogenicity model. Vaccine. 2011;29(48):8870–8876. doi:10.1016/j.vaccine.2011.09.078.	

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR § 1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR § 1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR § 1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. § 120.]

EXAMINER: /Padmavathi Baskar/	DATE CONSIDERED: 02/01/2021
--------------------------------------	------------------------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/089,040		ATTY. DOCKET NO.: P1143.70000US04	
				FILING DATE: September 27, 2018		CONFIRMATION NO.: 8702	
				FIRST NAMED INVENTOR: Bruce D. Forrest			
				GROUP ART UNIT: 1645		EXAMINER: Padmavathi Baskar	
Sheet	1	of	1				

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD- YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		GUO et al., Genetic diversity of fluoroquinolone-nonsusceptible Streptococcus pneumoniae clinical isolates and the first identification of serotype 20B in China. Eur J Clin Microbiol Infect Dis. 2014 Mar;33(3):465-70. doi: 10.1007/s10096-013-1979-5. Epub 2013 Oct 4.	
		NUNES et al., The impact of private use of PCV7 in 2009 and 2010 on serotypes and antimicrobial resistance of Streptococcus pneumoniae carried by young children in Portugal: Comparison with data obtained since 1996 generating a 15-year study prior to PCV13 introduction. Vaccine. 2016 Mar 29;34(14):1648-56. doi: 10.1016/j.vaccine.2016.02.045. Epub 2016 Feb 23.	

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR § 1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR § 1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR § 1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. § 120.]

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Electronic Patent Application Fee Transmittal				
Application Number:		16089040		
Filing Date:		27-Sep-2018		
Title of Invention:		SACCHARIDE-POLYPEPTIDE CONJUGATE COMPOSITIONS AND METHODS OF USE THEREOF		
First Named Inventor/Applicant Name:		Bruce D. FORREST		
Filer:		Chelsea E. Witte-Garcia/Luke Brand		
Attorney Docket Number:		P1143.70000US04		
Filed as Small Entity				
Filing Fees for U.S. National Stage under 35 USC 371				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
Total in USD (\$)				130

Electronic Acknowledgement Receipt

EFS ID:	42727769
Application Number:	16089040
International Application Number:	
Confirmation Number:	8702
Title of Invention:	SACCHARIDE-POLYPEPTIDE CONJUGATE COMPOSITIONS AND METHODS OF USE THEREOF
First Named Inventor/Applicant Name:	Bruce D. FORREST
Customer Number:	23628
Filer:	Chelsea E. Witte-Garcia/Luke Brand
Filer Authorized By:	Chelsea E. Witte-Garcia
Attorney Docket Number:	P1143.70000US04
Receipt Date:	14-MAY-2021
Filing Date:	27-SEP-2018
Time Stamp:	15:24:03
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 130
RAM confirmation Number	E20215DF27170065
Deposit Account	232825
Authorized User	Luke Brand

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:
37 CFR 1.17 (Patent application and reexamination processing fees)

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	P114370000US04-TRN-CEW.pdf	26170	no	1
			cde58c62d43e0956ff1a3899f43fdb4e5cb04883		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	P114370000US04-FEE-CEW.pdf	32711	no	1
			1e1f0fe88d0ec81b3eee61fae9f16c71208f079d		
Warnings:					
Information:					
3	Transmittal Letter	P114370000US04-IDSBODY-CEW.pdf	29549	no	3
			ffe120f35b7ec19a4b879ba58ac1c27311c6a001		
Warnings:					
Information:					
4	Non Patent Literature	Guo_et_al_Eur_J_Clin_Microbiol_Infec_Dis_2014_v33_p465.pdf	11162095	no	6
			96d39f011d9f728bc00ac6ac869a6431226a112a		
Warnings:					
Information:					
5	Non Patent Literature	Nunes_et_al_Vaccine_2016_v34_p1648.pdf	19399035	no	9
			dede76ab14285ff6ad09ee58b2e93e655489edcf		
Warnings:					
Information:					
6	Information Disclosure Statement (IDS) Form (SB08)	P114370000US04-IDS1449-CEW.pdf	76952	no	1
			caca7b3baf2c09104dc6a9eaf7a7d6ab9a54669b		
Warnings:					
Information:					

This is not an USPTO supplied IDS fillable form					
7	Fee Worksheet (SB06)	fee-info.pdf	30544	no	2
			e0ea6766a88e39eb99ab5559eb28a1b5659cd390b		
Warnings:					
Information:					
Total Files Size (in bytes):				30757056	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Bruce D. Forrest
Application No.: 16/089,040
Confirmation No.: 8702
Filed: September 27, 2018
For: SACCHARIDE-POLYPEPTIDE CONJUGATE
COMPOSITIONS AND METHODS OF USE THEREOF
Examiner: Padmavathi Baskar
Art Unit: 1645

Certificate of Electronic Filing under 37 C.F.R. § 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).

Dated: May 14, 2021

Electronic Signature for Luke B. Brand: /Luke B. Brand/

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

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Commissioner:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, the undersigned requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. § 1.97

This Information Disclosure Statement has been filed after the mailing date of either a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 and is being filed on or before payment of an Issue Fee.

The undersigned hereby states, as specified in 37 C.F.R. § 1.97(e), that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart for the present Application not more than three months prior to the filing of this Statement. Therefore, please charge our credit card in the amount of \$130.00 to cover the fee set forth in 37 C.F.R. § 1.17(p).

PART II: Information Cited

The undersigned hereby makes of record in the present Application the information listed on the attached Form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed Form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the United States Patent and Trademark Office during the examination of the present Application; and
3. The citations for the information be printed on any patent which issues from the present Application.

By submitting this Information Disclosure Statement, the undersigned makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the undersigned makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

By submitting this Information Disclosure Statement, the undersigned makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. § 102.

Notwithstanding any statements by the undersigned, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

The Director is hereby authorized to charge any deficiency in the fees due, or credit any overpayment, by the filing of this Information Disclosure Statement to our Deposit Account No. 23/2825, under Docket No. P1143.70000US04, from which the undersigned is authorized to draw.

Respectfully submitted,

Electronic signature: /Chelsea E. Witte-Garcia/
Chelsea E. Witte-Garcia, Ph.D.

Registration No.: 75,713

WOLF, GREENFIELD & SACKS, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

617.646.8000

Docket No.: P1143.70000US04

Date: May 14, 2021

TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	16/089,040-Conf. #8702	
	Filing Date	September 27, 2018	
	First Named Inventor	Bruce D. Forrest	
	Art Unit	1645	
	Examiner Name	Padmavathi Baskar	
Total Number of Pages in This Submission		Attorney Docket Number	P1143.70000US04

ENCLOSURES (Check all that apply)			
☒ Fee Transmittal Form ☐ Fee Attached ☐ Amendment/Reply ☐ After Final ☐ Affidavits/declaration(s) ☐ Extension of Time Request ☐ Express Abandonment Request ☒ Information Disclosure Statement ☐ Certified Copy of Priority Document(s) ☐ Reply to Missing Parts/ Incomplete Application ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53	☐ Drawing(s) ☐ Licensing-related Papers ☐ Petition ☐ Petition to Convert to a Provisional Application ☐ Power of Attorney, Revocation Change of Correspondence Address ☐ Terminal Disclaimer ☐ Request for Refund ☐ CD, Number of CD(s) _____ ☐ Landscape Table on CD	☐ After Allowance Communication to TC ☐ Appeal Communication to Board of Appeals and Interferences ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) ☐ Proprietary Information ☐ Status Letter ☒ Other Enclosure(s) (please Identify below): Form PTO-1449 Copies of cited references	
<table border="1"><tr><td>Remarks</td></tr></table>			Remarks
Remarks			

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	WOLF, GREENFIELD & SACKS, P.C.		
Signature	/Chelsea E. Witte-Garcia/		
Printed name	Chelsea E. Witte-Garcia, Ph.D.		
Date	May 14, 2021	Reg. No.	75,713

Certificate of Electronic Filing under 37 C.F.R. § 1.8	
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).	
Dated: May 14, 2021	Electronic Signature for Luke B. Brand: /Luke B. Brand/

FEE TRANSMITTAL		Complete if known	
		Application Number	16/089,040-Conf. #8702
		Filing Date	September 27, 2018
☒	Applicant asserts small entity status. See 37 CFR 1.27.	First Named Inventor	Bruce D. Forrest
☐	Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.	Examiner Name	Padmavathi Baskar
		Art Unit	1645
TOTAL AMOUNT OF PAYMENT		Practitioner Docket No.	P1143.70000US04

METHOD OF PAYMENT (check all that apply)

☐ Check
☒ Credit Card
☐ Money Order
☐ None
☐ Other (please identify): _____

☒ Deposit Account
Deposit Account Number: 23/2825
Deposit Account Name: Wolf, Greenfield & Sacks, P.C.

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☐ Charge fee(s) indicated below
☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17, **except for any excess claims fees or multiple dependent claim fee**
☐ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17

☒ Credit any overpayment of fee(s)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION
1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)

Application Type	FILING FEES			SEARCH FEES			EXAMINATION FEES			Fees Paid (\$)
	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	
Utility	320	160*	80	700	350	175	800	400	200	
Design	220	110	55	160	80	40	640	320	160	
Plant	220	110	55	440	220	110	660	330	165	
Reissue	320	160	80	700	350	175	2,320	1,160	580	
Provisional	300	150	75	0	0	0	0	0	0	

* The \$160 small entity status filing fee for a utility application is further reduced to \$80 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	Undiscounted Fee (\$)	Small Entity Fee (\$)	Micro Entity Fee (\$)
Each claim over 20 (including Reissues)	100	50	25
Each independent claim over 3 (including Reissues)	480	240	120
Multiple dependent claims	860	430	215

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
- 20 or HP = _____ x _____ = _____						

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 5 or HP = _____ x _____ = _____			

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$420 (\$210 for small entity) (\$105 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____ - 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____				

4. OTHER FEE(S)

Non-English specification, \$130 fee (no small or micro entity discount)

Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, \$400 fee (\$200 small or micro entity)

Other (e.g., late filing surcharge): 2806 Submission of an Information Disclosure Statement 130.00
SUBMITTED BY

Signature	/Chelsea E. Witte-Garcia/	Registration No. (Attorney/Agent)	75,713	Telephone	617.646.8000
Name (Print/Type)	Chelsea E. Witte-Garcia, Ph.D.			Date	May 14, 2021

Certificate of Electronic Filing under 37 C.F.R. § 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).

Dated: May 14, 2021

Electronic Signature for Luke B. Brand: /Luke B. Brand/

9238750.1



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.
16/089,040	09/27/2018	Bruce D. FORREST	P1143.70000US04	8702
23628	7590	05/21/2021		
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER BASKAR, PADMAVATHI	
			ART UNIT	PAPER NUMBER
			1645	
			NOTIFICATION DATE	DELIVERY MODE
			05/21/2021	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):

Patents_eOfficeAction@WolfGreenfield.com

WGS_eOfficeAction@WolfGreenfield.com

Notice of Allowability	Application No. 16/089,040		Applicant(s) FORREST et al.	
	Examiner Padmavathi Baskar		Art Unit 1645	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 05/14/2021.
☐ 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 See Continuation Sheet. 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 05/14/2021.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. ____.

5. ☒ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Padmavathi Baskar/ Primary Examiner, Art Unit 1645	
--	--

Continuation of 3. The allowed claim(s) is/are: 67,74-75,78,81,97,106,109,112-114,154,256,297 and 299-303

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/14/2021 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner and a signed copy of each is attached to this office action.

Conclusion

3. Claims 67, 74-75, 78, 81, 97, 106, 109, 297, 299-303, 112-114, 154 and 256 are allowed and are numbered as 1-19 respectively.

Correspondence

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi Baskar whose telephone number is (571)272-0853. The examiner can normally be reached on Mon-Fri 9-5:30

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, Gary Nickol can be reached on 571-272-0835. 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.

Respectfully,

/Padmavathi Baskar/
Primary Examiner, Art Unit 1645
Padmavathi Baskar, Ph.D. (Microbiology and Immunology)

Issue Classification 	Application/Control No. 16/089,040	Applicant(s)/Patent Under Reexamination FORREST et al.	
	Examiner Padmavathi Baskar	Art Unit 1645	

CPC						
Symbol					Type	Version
A61K	/	39	/	092	F	2013-01-01
A61K	/	47	/	646	I	2017-08-01
A61K	/	2039	/	55505	A	2013-01-01
A61K	/	2039	/	6037	A	2013-01-01
A61K	/	2039	/	70	A	2013-01-01

CPC Combination Sets							
Symbol				Type	Set	Ranking	Version
	/		/				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	19	
/Padmavathi Baskar/ Primary Examiner, Art Unit 1645	18 May 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	-----

<i>Issue Classification</i> 	Application/Control No. 16/089,040	Applicant(s)/Patent Under Reexamination FORREST et al.
	Examiner Padmavathi Baskar	Art Unit 1645

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61K39/09	/	39	/ 09
A61K47/64	/	47	/ 64

NON-CLAIMED			
A61K39/00	/	39	/ 00

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	19	
/Padmavathi Baskar/ Primary Examiner, Art Unit 1645	18 May 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	-----

Issue Classification 	Application/Control No. 16/089,040	Applicant(s)/Patent Under Reexamination FORREST et al.
	Examiner Padmavathi Baskar	Art Unit 1645

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	67	10	299	19	256										
2	74	11	300												
3	75	12	301												
4	78	13	302												
5	81	14	303												
6	97	15	112												
7	106	16	113												
8	109	17	114												
9	297	18	154												

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 19	
/Padmavathi Baskar/ Primary Examiner, Art Unit 1645 (Primary Examiner) _____ (Date) 18 May 2021		O.G. Print Claim(s) 1	O.G. Print Figure -----

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/089,040		ATTY. DOCKET NO.: P1143.70000US04	
				FILING DATE: September 27, 2018		CONFIRMATION NO.: 8702	
				FIRST NAMED INVENTOR: Bruce D. Forrest			
				GROUP ART UNIT: 1645		EXAMINER: Padmavathi Baskar	
Sheet	1	of	1				

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD- YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
/P.B./		GUO et al., Genetic diversity of fluoroquinolone-nonsusceptible Streptococcus pneumoniae clinical isolates and the first identification of serotype 20B in China. Eur J Clin Microbiol Infect Dis. 2014 Mar;33(3):465-70. doi: 10.1007/s10096-013-1979-5. Epub 2013 Oct 4.	
/P.B./		NUNES et al., The impact of private use of PCV7 in 2009 and 2010 on serotypes and antimicrobial resistance of Streptococcus pneumoniae carried by young children in Portugal: Comparison with data obtained since 1996 generating a 15-year study prior to PCV13 introduction. Vaccine. 2016 Mar 29;34(14):1648-56. doi: 10.1016/j.vaccine.2016.02.045. Epub 2016 Feb 23.	

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR § 1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR § 1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR § 1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. § 120.]

EXAMINER: /Padmavathi Baskar/	DATE CONSIDERED: 05/18/2021
--------------------------------------	------------------------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.