

DOCUMENT MADE AVAILABLE UNDER THE PATENT COOPERATION TREATY (PCT)

International application number:	PCT/US2022/044912
International filing date:	27 September 2022 (27.09.2022)
Document type:	Certified copy of priority document
Document details:	Country/Office: US
	Number: 63/250,009
	Filing date: 29 September 2021 (29.09.2021)
Date of receipt at the International Bureau:	16 October 2022 (16.10.2022)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a),(b) or (b-bis)

1231005

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

October 15, 2022

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 63/250,009

FILING DATE: *September 29, 2021*

RELATED PCT APPLICATION NUMBER: *PCT/US22/44912*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US63/250,009*



Certified by

Kathi

Performing the Functions and Duties of the
Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1052-002P1
		Application Number	
Title of Invention	HAIR LOSS THERAPY		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--------------------------	---

Inventor Information:

Inventor	1	<button>Remove</button>		
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Animesh		Sinha	
Residence Information (Select One) • US Residency Non US Residency Active US Military Service				
City	Amherst	State/Province	NY	Country of Residence
				US
Mailing Address of Inventor:				
Address 1	477 Lebrun Road			
Address 2				
City	Amherst	State/Province	NY	
Postal Code	14226	Country	US	
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.				

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence information of this application.			
Customer Number	112702		
Email Address	info@lianghennessy.com	<button>Add Email</button>	<button>Remove Email</button>

Application Information:

Title of the Invention	HAIR LOSS THERAPY		
Attorney Docket Number	1052-002P1	Small Entity Status Claimed	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1052-002P1
		Application Number	
Title of Invention	HAIR LOSS THERAPY		

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	112702		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button. Add			

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1052-002P1
		Application Number	
Title of Invention	HAIR LOSS THERAPY		

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)	Remove

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1052-002P1
		Application Number	
Title of Invention	HAIR LOSS THERAPY		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐

B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

☐

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1052-002P1
		Application Number	
Title of Invention	HAIR LOSS THERAPY		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant	1	Remove
------------------	---	------------------------

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

[Clear](#)

Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Applicant:

Address 1			
Address 2			
City		State/Province	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. [Add](#)

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1052-002P1
		Application Number	
Title of Invention	HAIR LOSS THERAPY		

Assignee	1
-----------------	---

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1				
Address 2				
City		State/Province		
Country i		Postal Code		
Phone Number		Fax Number		
Email Address				

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Stanley Liang/		Date (YYYY-MM-DD)	2021-09-29
First Name	Stanley	Last Name	Liang	Registration Number
				43753

Additional Signature may be generated within this form by selecting the Add button.

Add

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1052-002P1
		Application Number	
Title of Invention	HAIR LOSS THERAPY		

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 the Freedom of Information Act requires disclosure of these records.
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 inspections 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.

Provisional Application for Patent Cover Sheet This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)					
Inventor(s)					
Inventor 1					Remove
Given Name	Middle Name	Family Name	City	State	Country i
Animesh		Sinha	Amherst	NY	US
All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the Add button.					Add
Title of Invention		HAIR LOSS THERAPY			
Attorney Docket Number (if applicable)		1052-002P1			
Correspondence Address					
Direct all correspondence to (select one):					
☒ The address corresponding to Customer Number			☐ Firm or Individual Name		
Customer Number			112702		
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
☒ No.					
Yes, the invention was made by an agency of the United States Government. The U.S. Government agency name is:					
Yes, the invention was under a contract with an agency of the United States Government. The name of the U.S. Government agency and Government contract number are:					

Entity Status

Applicant asserts small entity status under 37 CFR 1.27 or applicant certifies micro entity status under 37 CFR 1.29

- ☒ Applicant asserts small entity status under 37 CFR 1.27
- ☐ Applicant certifies micro entity status under 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
- ☐ No

Warning

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Signature

Please see 37 CFR 1.4(d) for the form of the signature.

Signature	Stanley Liang/		Date (YYYY-MM-DD)	2021-09-29	
First Name	Stanley	Last Name	Liang	Registration Number (If appropriate)	43753

This collection of information is required by 37 CFR 1.51. 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 1.11 and 1.14. This collection is estimated to take 8 hours 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.**

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.

Electronic Acknowledgement Receipt	
EFS ID:	43905746
Application Number:	63250009
International Application Number:	
Confirmation Number:	8862
Title of Invention:	HAIR LOSS THERAPY
First Named Inventor/Applicant Name:	Animesh Sinha
Customer Number:	112702
Filer:	Stanley D. Liang
Filer Authorized By:	
Attorney Docket Number:	1052-001P1
Receipt Date:	29-SEP-2021
Filing Date:	
Time Stamp:	18:07:49
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 150
RAM confirmation Number	E20219SI08313040
Deposit Account	600114
Authorized User	Stanley Liang
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 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	Specification	1052-002P1_application_final.pdf	223138	no	12
			ec60bacab3ade5f0c8667f31924819383788b63e		
Warnings:					
Information:					
2	Application Data Sheet	aia0014.pdf	1255609	no	8
			8c4875f3bfa3ec038f907118d70c99658df4a509		
Warnings:					
Information:					
3	Provisional Cover Sheet (SB16)	ProvisionalSB.pdf	2032202	no	3
			da043238c5166987ffebe785162de50cfbdc01f6		
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	36644	no	2
			07cbb0e354832f5131e8e5620d6dfc129a9a9bec		
Warnings:					
Information:					
Total Files Size (in bytes):			3547593		

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

HAIR LOSS THERAPY

TECHNICAL FIELD

[0001] This disclosure relates to therapy for hair loss.

BACKGROUND

[0002] Hair loss (alopecia) is a loss of hair from part of the head or body, though typically at least the head is involved. Hair loss can be quite severe and results in baldness. Hair loss in some people causes psychological distress. Hair loss is a common problem, especially in men, but also in women.

SUMMARY

[0003] In one aspect, this disclosure provides a single pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil and finasteride. This disclosure also relates to a method of treating or preventing hair loss in a male subject in need thereof comprising administering a pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil and finasteride, to the subject.

[0004] Numerous other aspects are provided in accordance with these and other aspects of the invention. Other features and aspects of the present invention will become more fully apparent from the following detailed description and the appended claims.

DETAILED DESCRIPTION

[0005] As used herein, unless otherwise indicated, the word “a” or “plurality” before a noun represents one or more of the particular noun.

[0006] The term “a single pharmaceutical composition” does not represent more than one composition.

[0007] For the terms “for example” and “such as,” and grammatical equivalences thereof, the phrase “and without limitation” is understood to follow unless explicitly stated otherwise. As used herein, the term “about” is meant to account for variations due to experimental error. All measurements reported herein are understood to be modified by the term “about,” whether or not the term is explicitly used, unless explicitly stated otherwise. As used herein, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise.

[0008] “Effective amount,” “prophylactically effective amount,” or “therapeutically effective amount” refers to an amount of an agent or composition that provides a beneficial effect or favorable result to a subject, or alternatively, an amount of an agent or composition that exhibits the desired *in vivo* or *in vitro* activity. “Effective amount,” “prophylactically effective amount,” or “therapeutically effective amount” refers to an amount of an agent or composition that provides the desired biological, therapeutic, and/or prophylactic result. That result can be reduction, amelioration, palliation, lessening, delaying, and/or alleviation of one or more of the signs, symptoms, or causes of a disease, disorder or condition in a patient/subject, or any other desired alteration of a biological system. “Effective amount,” “prophylactically effective amount,” or “therapeutically effective amount” can be an amount administered as more than one dose of a formulation/composition.

[0009] As used herein, a “patient” and a “subject” are interchangeable terms and may refer to a human patient/subject, a non-human primate, etc.

[0010] All ranges disclosed herein are to be understood to encompass any and all subranges subsumed therein. For example, a stated range of “1.0 to 10.0” should be considered to include any and all subranges beginning with a minimum value of 1.0 or more and ending with a maximum value of 10.0 or less, e.g., 1.0 to 5.3, or 4.7 to 10.0, or 3.6 to 7.9.

[0011] All ranges disclosed herein are also to be considered to include the end points of the range, unless expressly stated otherwise. For example, a range of “between 5 and 10” or “5 to 10” or “5-10” should be considered to include the end points 5 and 10.

[0012] It is further to be understood that the feature or features of one embodiment may generally be applied to other embodiments, even though not specifically described or illustrated in such other embodiments, unless expressly prohibited by this disclosure or the nature of the relevant embodiments. Likewise, compositions and methods described herein can include any combination of features and/or steps described herein not inconsistent with the objectives of the present disclosure. Numerous modifications and/or adaptations of the compositions and methods described herein will be readily apparent to those skilled in the art without departing from the present subject matter.

[0013] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Methods and materials are described herein for use in the present invention; other,

suitable methods and materials known in the art can also be used. The materials, methods, and examples are illustrative only and not intended to be limiting. All publications, patent applications, patents, sequences, database entries, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control.

[0014] HAIR LOSS

[0015] Hair loss (alopecia) is a loss of hair from part of the head or body, though typically at least the head is involved. Hair loss can be quite severe and results in baldness. Hair loss in some people causes psychological distress. Hair loss is a common problem, especially in men, but also in women.

[0016] Finasteride ($C_{23}H_{36}N_2O_2$) is usually prescribed as a 1 mg pill for oral administration to treat hair loss in a subject, but a topical formulation does exist although not commonly used.

[0017] Results of phase III clinical studies in 1,879 men have shown that oral finasteride at 1 mg/day promotes hair growth and prevents further hair loss in a significant proportion of men with male pattern hair loss. Evidence suggests that the improvement in hair count reported after 1 year is maintained during 2 years of treatment. In men with vertex hair loss, global photographs showed improvement in hair growth in 48% of finasteride recipients at 1 year and in 66% at 2 years compared with 7% of placebo recipients at each time point. Furthermore, hair counts in these men showed that 83% of finasteride versus 28% of placebo recipients had no further hair loss compared with baseline after 2 years.

[0018] Minoxidil ($C_9H_{13}N_3O$) is relatively successful for hair treatment, applied topically on to scalp of a subject/patient as a scalp tonic or foam. This is the preferred and first choice of minoxidil treatment as topical minoxidil products are well established for their safety and effectiveness.

[0019] There are certain circumstances that minoxidil can be taken orally as a tablet. Oral minoxidil can be considered for hair loss if: topical minoxidil preparations cause a rash, irritation, or allergy; there is a lack of any benefit from topical minoxidil after 6 months of diligent use; topical minoxidil causes poor hair texture – sometimes minoxidil can cause dry, tangled hair that is prone to breakage; and other difficulties using topical minoxidil, causing compliance problems.

[0020] Oral minoxidil is mainly used for male and female pattern hair loss. However, there can be benefit with other types of hair loss too including telogen effluvium, traction alopecia and loose anagen syndrome.

[0021] The studies with oral minoxidil are very small but indicate that about one third of patients will notice a reduction in shedding, and a third will notice improved growth in 6 months or more. This means that up to 2 in 3 people out of 10 will benefit from oral minoxidil at 6 months. It is best to take treatment for 6 to 12 months to give it enough time to work.

[0022] The only head to head study comparing oral minoxidil to topical minoxidil in women with Female Pattern Hair Loss showed that 1mg of minoxidil gave comparable effects to 5% solution (1ml) once a day. Ramos, P. M. et al., *J Am Acad Dermatol* 2020; 82: 252–253. In this study, 26 women received oral minoxidil and 26 women received topical minoxidil. After 24 weeks of treatment, there was a 12% increase in hair density for women on oral minoxidil and 7.2% increase for women applying topical minoxidil. The difference was not statistically significant but the oral minoxidil group also had less hair shedding.

[0023] Minoxidil is available in 2.5mg, 5mg and 10mg tablets. A common starting dose is 0.625mg per day. The optimum dose for hair loss is not entirely clear. It may be in the region of 0.625mg to 2.5 mg per day. For men, a slightly higher dose may sometimes be required.

[0024] Doses of minoxidil for hair loss are considered ‘low dose’. This is because the doses used for hair loss are a lot lower than the doses which are used for conditions such as hypertension. The doses used for hypertension are 10-40 mg per day.

[0025] Side effects are very uncommon at the low doses which are used to treat hair loss. The largest study looking at side effects (Vaño-Galván S. et al., *J Am Acad Dermatol* 2021; 84: 1644–1651) showed that in 943 women and 461 men, 2.5% of women and 0.5% of men had to stop treatment because of a side effect.

[0026] The most common side effect is hypertrichosis (excessive hair) for both men and women—excess hair growth elsewhere on the face and body. Excess growth is more likely to occur at higher doses. While this side effect is bothersome, it can usually be managed with hair removal methods and is not a common reason for someone to stop. Hypertrichosis may affect 10-25% of those on low doses (<4mg) and up to 50% of those on higher doses (>5mg). Vaño-Galván S. et al., *J Am Acad Dermatol* 2021; 84: 1644–1651 showed that 20% of women and 6% of men

experienced hypertrichosis. Of those that experience this side effect, only 5% of women and 0% of men find it necessary to stop treatment.

[0027] Temporary shedding is a side effect that is very common at the onset of starting oral or topical minoxidil. This side effect occurs within the first 6 weeks and can be of significant concern. But it is important to continue with the medication as this will stop after 4 weeks.

[0028] Ankle swelling and fluid retention are also side effects. Swelling of the lower legs can occur in up to 3% people, but usually at higher doses. Fluid retention can also sometimes show up around the eyes as puffy eyes, which are worse in the morning. Vañó-Galván S. et al., *J Am Acad Dermatol* 2021; 84: 1644–1651 showed that 1.3% get ankle swelling (25% of these individuals stop treatment) and 0.3% experience swelling around the eyes (0% need to stop treatment for this).

[0029] Low blood pressure and feeling light-headed are also side effects. Minoxidil is also used to control high blood pressure, usually at doses of 10-40mg per day – much higher than the doses used for hair loss. However even lower doses can sometimes cause a reduction in blood pressure. 2% of people may get postural hypotension with low doses of minoxidil. 8% may have general symptoms of lightheadedness. This leads to dizziness when getting up quickly. 1.7% of those on low dose minoxidil experience light headedness and of these, only 11% need to stop treatment.

[0030] Minoxidil can also cause a fast heart rate, but usually at higher doses. 0.9% of those on low dose oral minoxidil appear to experience this side effect, and of these 33% need to stop treatment.

[0031] Headaches as a side effect may occur in as many as 9% of people but again this seems to improve with time. 0.4% experience this side effect and of these 44% need to stop treatment.

[0032] Uncommon side effects include nightmares, insomnia, pericarditis, skin rashes, nausea, vomiting, breast tenderness.

[0033] METHODS AND COMPOSITIONS

[0034] In one aspect, this disclosure provides a single pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of both minoxidil and finasteride. The composition is administered orally to a male subject or patient.

[0035] In another aspect, this disclosure relates to a method of treating or preventing hair loss in a male subject in need thereof comprising administering by oral administration a pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of

minoxidil and finasteride, to the subject. In some embodiments, the composition is a disclosed single pharmaceutical composition comprising both finasteride and minoxidil. In some embodiments, the method further comprises administering by topical administration a topical pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil and/or a therapeutically effective or prophylactically effective amount of finasteride.

[0036] This disclosure also provides a method of treating or preventing hair loss in a subject comprising administering by oral administration a pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil or a therapeutically effective or prophylactically effective amount of finasteride, to a subject in need thereof; and administering by topical administration a topical pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil or a therapeutically effective or prophylactically effective amount of finasteride to said subject. The subject can be male or female.

[0037] In some embodiments, the disclosed composition comprises about 1 to about 3 mg finasteride. In some embodiments, the disclosed composition comprises about 1 or about 3 mg finasteride. In some embodiments, the disclosed composition comprises about 0.625 to about 10 mg minoxidil. In further embodiments, the disclosed composition comprises about 0.625mg, about 2.5 mg, about 5 mg minoxidil, or about 10 mg minoxidil.

[0038] In some embodiments, the disclosed composition comprises about 1 or about 3 mg finasteride and about 0.625 to about 5 mg minoxidil. In further embodiments, the disclosed composition comprises about 1 mg or about 3 mg finasteride and about 0.625 mg, about 2.5 mg, about 5 mg or about 10 mg minoxidil.

[0039] FORMULATING AND ADMINISTERING COMPOSITIONS

[0040] The disclosed composition may be administered to a subject in need thereof at any suitable frequency, and at any suitable, effective dosage.

[0041] The disclosed composition for oral administration is provided in a form suitable for oral administration, such as a tablet, pill, lozenge, capsule, liquid suspension, liquid solution, or any other conventional oral dosage form. The oral dosage forms may provide immediate release, delayed release, sustained release, or enteric release, and, if appropriate, comprise one or more coating.

[0042] The topical composition is for topical administration and is provided in a form suitable for topical administration, such as a gel, foam, solution, or any other conventional topical formulation.

[0043] The composition can be produced by methods employed in accordance with general practice in the pharmaceutical industry, such as, for example, the methods illustrated in Remington: The Science and Practice of Pharmacy (Pharmaceutical Press; 21st revised ed. (2011) (hereinafter “Remington”).

[0044] In some embodiments, the composition comprises at least one pharmaceutically acceptable vehicle or excipient. These include, for example, diluents, carriers, excipients, fillers, disintegrants, solubilizing agents, dispersing agents, preservatives, wetting agents, preservatives, stabilizers, buffering agents (e.g. phosphate, citrate, acetate, tartrate), suspending agents, emulsifiers, and penetration enhancing agents such as DMSO, as appropriate. The composition can also comprise suitable auxiliary substances, for example, solubilizing agents, dispersing agents, suspending agents and emulsifiers.

[0045] In certain embodiments, the composition further comprises suitable diluents, glidants, lubricants, acidulants, stabilizers, fillers, binders, plasticizers or release aids and other pharmaceutically acceptable excipients.

[0046] A complete description of pharmaceutically acceptable excipients can be found, for example, in Remington's Pharmaceutical Sciences (Mack Pub., Co., N.J. 1991) or other standard pharmaceutical science texts, such as the Handbook of Pharmaceutical Excipients (Shesky *et al.* eds., 8th ed. 2017).

[0047] Large macromolecules that are slowly metabolized, such as proteins, polysaccharides, polylactic acids, polyglycolic acids, polymeric amino acids, copolymers of amino acids, can also be used as carrier compounds for the composition. Pharmaceutically acceptable carriers in therapeutic compositions may additionally contain liquids, such as water, saline, glycerol or ethanol. Moreover, the said compositions may further comprise excipients, such as wetting agents or emulsifiers, buffering substances, and the like. Such excipients include, among others, diluents and carriers conventional in the art, and/or substances that promote penetration of the active compound into the cell, for example, DMSO, as well as preservatives and stabilizers.

[0048] It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the

scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the appended claims. Thus, while only certain features of the invention have been illustrated and described, many modifications and changes will occur to those skilled in the art. It is therefore to be understood that the appended claims are intended to cover all such modifications and changes as fall within the true spirit of the invention.

CLAIMS

What is claimed is:

1. A single pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of both minoxidil and finasteride.
2. The composition of claim 1, wherein the composition comprises about 1 mg to about 3 mg finasteride.
3. The composition of claim 2, wherein composition comprises about 1 mg or about 3 mg finasteride.
4. The composition of any of claims 1-3, wherein the composition comprises about 0.625 mg to about 10 mg minoxidil.
5. The composition of claim 4, wherein the composition comprises about 0.625 mg, about 2.5 mg, about 5 mg minoxidil, or about 10 mg minoxidil.
6. A method of treating or preventing hair loss in a male subject in need thereof comprising administering by oral administration a pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil and finasteride, to the male subject.
7. The method of claim 6, wherein the pharmaceutical composition is a single pharmaceutical composition of any of claims 1-5.
8. The method of claim 6 or claim 7, wherein the composition comprises about 1 mg to about 3 mg finasteride.
9. The method of claim 8, wherein composition comprises about 1 mg or about 3 mg finasteride.

10. The method of any of claims 6-9, wherein the composition comprises about 0.625 mg to about 10 mg minoxidil.

11. The method of claim 10, wherein the composition comprises about 0.625 mg, about 2.5 mg, about 5 mg minoxidil, or about 10 mg minoxidil.

12. The method of any of claims 6-11, further comprising administering to the subject by topical administration a topical pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil and/or a therapeutically effective or prophylactically effective amount of finasteride.

13. A method of treating or preventing hair loss in a subject in need thereof comprising administering by oral administration a pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil or a therapeutically effective or prophylactically effective amount of finasteride, to a subject in need thereof; and administering by topical administration a topical pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil or a therapeutically effective or prophylactically effective amount of finasteride to said subject.

14. The method of claim 13, wherein the composition comprises about 1 mg to about 3 mg finasteride.

15. The method of claim 14, wherein composition comprises about 1 mg or about 3 mg finasteride.

16. The method of claim 13, wherein the composition comprises about 0.625 mg to about 10 mg minoxidil.

17. The method of claim 16, wherein the composition comprises about 0.625 mg, about 2.5 mg, about 5 mg minoxidil, or about 10 mg minoxidil.

18. The method of any of claims 13-17, wherein the subject is a female subject.

ABSTRACT

Disclosed is a single pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of both minoxidil and finasteride. Also disclosed is a method of treating or preventing hair loss in a male subject in need thereof comprising administering a pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil and finasteride, to the subject. The method can further comprise administering to the subject by topical administration a topical pharmaceutical composition comprising a therapeutically effective or prophylactically effective amount of minoxidil and/or a therapeutically effective or prophylactically effective amount of finasteride.