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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
19/094,703	03/28/2025	Reid WALDMAN	135091-0001CT03	3228
27189	7590	03/16/2026	EXAMINER	
PROCOPIO, CORY, HARGREAVES & SAVITCH LLP			HENLEY III, RAYMOND J	
525 B STREET				
SUITE 2200				
SAN DIEGO, CA 92101				
			ART UNIT	PAPER NUMBER
			1629	
			NOTIFICATION DATE	DELIVERY MODE
			03/16/2026	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):

PTONotifications@procopio.com
docketing@procopio.com

Office Action Summary

Application No.

19/094,703

Applicant(s)

WALDMAN, Reid

Examiner

RAYMOND J HENLEY III

Art Unit

1629

AIA (First Inventor to File) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on the RCE papers filed February 04, 2026.

☐ 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) 1-20 is/are pending in the application.

5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

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

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on March 28 2025 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

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

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

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

4) ☐ Other: ____.

Paper No(s)/Mail Date 02/04/2026.

CLAIMS 1-20 ARE PRESENTED FOR EXAMINATION

Notice of Pre-AIA or AIA Status

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

Applicant's RCE and Information Disclosure Statement filed February 04, 2026 have been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08, the cited references have been considered by the Examiner.

The following are new rejections being made on the record.

Claim Rejection - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103 as being unpatentable over Sinha, (U.S. 2024/0474594, (effective 09/29/21 via Prov. Application 63/250,009), in view of Reynolds et al.,

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"Investigation of the Effect of Tablet Surface Area/Volume on Drug Release from Hydroxypropylmethylcellulose Controlled-Release Matrix Tablets", Drug Development and Industrial Pharmacy, 28(4), 457-466 (2002), (hereinafter "Reynolds", cited by Applicant).

Sinha teaches a method of treating hair loss, comprising orally administering a dosage form to a human patient experiencing hair loss, wherein the dosage form comprises "about 5 mg to about 10 mg" of minoxidil, which would include a range of 4.7 to 10.0, (i.e., the claimed "about 8.5 mg.", (see at least the abstract, [0013], [0012]-[0014], (claims 10 and 16). The dosage form may provide delayed, sustained or enteric release, [0043], and contain one or more diluents, carriers, excipients, fillers, disintegrants, solubilizing agents, dispersing agents, lubricants, release aids, binders etc., [0046]-[0047].

The differences between the above and the claimed subject matter lie in that Sinha fails to teach (a) hydroxypropyl methylcellulose as being present in the oral dosage form; (b) a dosage frequency of once or twice daily, (c) the pharmacokinetic parameters of present claims 1, 2 and 12-16; (d) the types of hair loss as in present claims 5-10 and (e) the lack of symptomology as in present claims 19-20).

However, the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains because (a) Sinha explicitly teaches; extended release dosage forms, [0043]; that among the auxiliary agents present, carriers/excipients may be used, (e.g., [0046]); that the compositions he teaches may be produced in accordance with general practice in the pharmaceutical industry, ([0045]); and that large macromolecules such as polysaccharides can be used as carrier compounds for the compositions, ([0049]). One of ordinary skill in the art would have been

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motivated to employ hydroxypropyl methylcellulose as an extended release carrier in the compositions of Sinha because Reynolds teaches that “hydrophilic polymers, such as hydroxypropyl methylcellulose (HPMC), are commonly used as rate-controlling polymers for controlled drug release from matrix-type dosage forms”. It is further believed that, in the absence of evidence to the contrary, the determination of the optimum HPMC percentage to employ would have been a routine determination of the skilled artisan. This is also true for active ingredient dosage frequency in regards to difference (b) above because the optimization of the dosing of active agents in the pharmaceutical/medical arts is a primary concern when considering an effective therapeutic regimen for a given patient or patient group.

Regarding differences (c) and (e), because the reference teaches the presently claimed dosage amounts, it must be true that the pharmacokinetic parameters and non-symptomology associated with such amounts after administration would be present in the prior art whether reported or not or else recognized by one of ordinary skill in the art.

Regarding difference (d), at least present claim 1 encompasses “hair loss” in general and thus would have readily suggested to one of ordinary skill in the art the specific types of hair loss known in the art at the time of the invention.

Accordingly, for the above reasons, the claims are deemed properly rejected.

Double Patenting

Provisional

Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20, (unless otherwise specified), of copending Application Nos. (reference applications). 19/094,716; 19/253,703; 19/253,708; 19/255,878; 19/230,047,

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(claims 1-21); 19/230,054, (claims 1-21); 19/258,817; 19/260,035; 19/267,447; 19/267,464; 19/308,124; 19/315,454, (claims 1-19); 19/328,077, (claims 1-19); or 19/329,494, (claims 1-19).

Although the claims at issue are not identical, they are not patentably distinct from each other because the co-pending claims in each application are directed to either treating hair loss in general or to specific types of hair loss as is presently claimed or else encompassed by present claim 1. Also, overlapping or the same percentages of hydroxypropyl methylcellulose appears in the either the independent or dependent copending claims. The presently claimed dosage amount of “about 8.5 mg” of minoxidil, dosage frequency, other non-active agents and symptomology resulting from the administration are either recited in or else encompassed by the copending claims as are the pharmacokinetic parameters required by the present claims.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Accordingly, the claims are deemed properly rejected and none are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND J HENLEY III whose telephone number is (571)272-0575. The examiner can normally be reached M-F 6-2:30pm EST.

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, Jeffrey S Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/RAYMOND J HENLEY III/
Primary Examiner, Art Unit 1629
March 12, 2026