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.
17/525,248	11/12/2021	Bjorn Erik Hansen	7782.0200	3168

106452 7590 12/14/2022

John Rizvi, P. A.
10394 W. Sample Road, Suite 201
Coral Springs, FL 33065

EXAMINER	
KUCHARCZK, JED A	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
12/14/2022	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):

Docketing@thepatentprofessor.com
John@thepatentprofessor.com
PPDPair@thepatentprofessor.com

Office Action Summary	Application No. 17/525,248	Applicant(s) Hansen et al.	
	Examiner JED A KUCHARCZK	Art Unit 4182	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 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 11/12/2021.

☐ 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 _____ 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: _____.

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.

Status of the Claims

2. Claims 1-20 are pending as filed on 11/12/2021. Claims 1-20 are rejected.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 05/24/2022 was properly filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Additionally, the third-party submission submitted on 07/22/2022 is being considered by the examiner.

4. The information disclosure statement filed on 04/21/2021 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

6. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

7. The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely

online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

8. **Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of copending Application No. 17/745048 (reference application).** Although the claims at issue are not identical, they are not patentably distinct from each other because of the following:

9. Claims 1 and 11 of '048 teach a sexual therapy formulation for treating a patient with a sexual disorder or a hypoactive sexual disorder, said formulation comprising: an erection enhancement that is sildenafil citrate, vardenafil hydrochloride, tadalafil, avanafil, and/or an alternate phosphodiesterase-5 inhibitor; and a libido stimulation component. Compared to the claimed invention, there are only two differences. The intended use for treating a (hypoactive) sexual disorder is broader than the intended use for treating "erectile dysfunction as well as low or reduced libido" in instant claims 1 and 11. Also, the erection enhancement component contains the option of "an alternate phosphodiesterase-5 inhibitor" which is not recited by instant claims 1 and 11.

10. Regarding the different intended uses, erectile dysfunction and low/reduced libido are species fully encompassed by the genus (hypoactive) sexual disorders. A POSITA would have recognized that the '048 formulation could treat erectile dysfunction and low/reduced libido, because the formulation contains an erection enhancement component and a libido stimulation component. The formulation would have been reasonably expected to provide a therapeutic benefit to a patient suffering from erectile dysfunction and low/reduced libido.

11. Regarding the different erection enhancement component options, the limitation "an alternate phosphodiesterase-5 inhibitor" is embraced by the instant erection enhancement component of claim 1 because the term "comprising" creates an open Markush group. The erection enhancement component of claim 11 is "selected from the group consisting of sildenafil citrate, vardenafil hydrochloride, tadalafil, and avanafil", which excludes an alternate phosphodiesterase-5 inhibitor. However, claims 2-4 of '048 require an amount of sildenafil citrate, for example a therapeutically effective amount, such as about 20 mg to about 100 mg. This renders unpatentable the dependent claims as follows:

12. Claims 2-4 and 12-14, wherein the sexual therapy formulation comprises an erection enhancement component, such as about 20 mg to about 100 mg of sildenafil citrate, and a libido enhancement component as claimed.

13. Claims 5-7 and 15-17, wherein the libido stimulation component is 3,4-methylenedioxymethamphetamine, R(-) isomer of 3,4- methylenedioxymethamphetamine, S(+) isomer of 3,4-methylenedioxymethamphetamine, and/or a racemic mixture of 3,4-methylenedioxymethamphetamine, and per claim 7 and 17 the amount is about 30 mg to about 125 mg.

14. Claims 8, 9, and 10, which depend from claims 4, 8, and 9, respectively, require a libido stimulation component of 3,4-methylenedioxymethamphetamine, R(-) isomer of 3,4-methylenedioxymethamphetamine, S(+) isomer of 3,4-methylenedioxymethamphetamine, and/or a racemic mixture of 3,4-methylenedioxymethamphetamine, and per claim 10, wherein the amount is about 30 mg to about 125 mg.

15. Claims 18, 19, and 20, which depend from claims 14, 18, and 19, respectively, require a libido stimulation component of 3,4-methylenedioxymethamphetamine, R(-) isomer of 3,4-methylenedioxymethamphetamine, S(+) isomer of 3,4-methylenedioxymethamphetamine, and/or a racemic mixture of 3,4-methylenedioxymethamphetamine, and per claim 20, wherein the amount is about 30 mg to about 125 mg.

16. Regarding claims 7, 10, 17, and 20, these claims recite the limitation "about 30 mg to about 125 mg" of the libido stimulation component. This is fully encompassed by the range "about 30 mg to about 200 mg" of the same component according to claims 7, 10, 17, and 20 of '048. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art", a *prima facie* case of obviousness exists. See MPEP 2144.05(I). A POSITA would have found the claimed range obvious from optimizing the amount of the libido stimulation component in search of improved therapeutic properties of the formulation.

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

Claim Rejections - 35 USC § 102

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

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

19. **Claim(s) 1-20 is/are rejected under 35 U.S.C. 102(a)(1)** as being anticipated by Lingamyoni "Foxy Sextasy" 07 Jun 2007 [online]: Erowid [retrieved 01 December 2022],

retrieved from

<https://web.archive.org/web/20190208014713/https://erowid.org/experiences/exp.php?ID=112151>), as evidenced by:

"Sildenafil" 06 Jun 2007 [online]: Erowid [retrieved 01 December 2022], retrieved from <https://web.archive.org/web/20070606233746/http://erowid.org/pharms/sildenafil/>

and by

"MDMA" 07 Jun 2007 [online]: Erowid [retrieved 01 December 2022], retrieved from <https://web.archive.org/web/20070607190810/http://www.erowid.org/chemicals/mdma>.

20. Lingamyoni teaches a formulation comprising a therapeutically effective amount of sildenafil and 3,4-methylenedioxymethamphetamine (MDMA) in dosage amounts of 125 mg and 50 mg, respectively, as shown in Image A below:

DOSE : T+ 0:00	125 mg	oral	MDMA (Ecstasy)	(powder / crystals)
T+ 0:00	50 mg	oral	Pharms - Sildenafil	(pill / tablet)

"MDMA (Ecstasy)" and "Pharms - Sildenafil" in Image A refer to 3,4-methylenedioxymethamphetamine and sildenafil citrate, respectively, as evidenced by the hyperlinked references MDMA and Sildenafil. The MDMA reference teaches that the chemical name of MDMA is 3,4-methylenedioxymethamphetamine. See page 1. The Sildenafil reference refers to "sildenafil citrate" in the description, indicating that "sildenafil" in Image A is shorthand for sildenafil citrate. See page 1. This anticipates the claims as follows:

21. Claim 1 recites "A sexual therapy formulation for the treatment of a patient suffering from some degree of erectile dysfunction as well as low or reduced libido, said formulation

comprising: an erection-enhancing component comprising one or more of … sildenafil citrate … and a libido-stimulation component comprising one or more of … 3,4-methylenedioxymethamphetamine…", wherein there is synergy between the two components. Lingamyoni's formulation comprising sildenafil citrate and MDMA is capable of treating erectile dysfunction and low/reduced libido—the intended use recited in the preamble of claim 1—because it contains the same components as the claimed combination. The synergistic properties are inherent in the formulation taught by Lingamyoni.

22. Claims 2-4 further limit the erection enhancement component of the formulation by requiring an amount of sildenafil citrate (claim 2); wherein a unit dosage of the formulation comprises a therapeutically effective amount of the erection enhancement component comprising sildenafil citrate (claim 3); and wherein the sildenafil citrate is about 20 mg to about 100 mg (claim 4). Lingamyoni's formulation contains 50 mg of sildenafil citrate, which is within the claimed range of about 20 mg to about 100 mg.

23. Claims 5-7 further limit the libido stimulation component by requiring an amount of 3,4-methylenedioxymethamphetamine (claim 5); wherein a unit dosage of said formulation comprises a therapeutically effective amount of the libido stimulation component comprising 3,4-methylenedioxymethamphetamine (claim 6); and wherein the 3,4-methylenedioxymethamphetamine is about 30 mg to about 125 mg (claim 7). Lingamyoni's formulation contains 125 mg of MDMA, which is within the claimed range of about 30 mg to 125 mg.

24. Claims 8-10 further limit the libido stimulation component by requiring an amount of 3,4-methylenedioxymethamphetamine (claim 8); wherein a unit dosage of said formulation

comprises a therapeutically effective amount of the libido stimulation component comprising 3,4-methylenedioxymethamphetamine (claim 9); and wherein the 3,4-methylenedioxymethamphetamine is about 30 mg to about 125 mg (claim 10). Lingamyoni's formulation contains 125 mg of MDMA, which is within the range of about 30 mg to 125 mg.

25. Claim 11 recites "A sexual therapy formulation for the treatment of a patient suffering from some degree of erectile dysfunction as well as low or reduced libido, said formulation comprising: an erection-enhancing component selected from the group consisting of … sildenafil citrate … and a libido-stimulation component selected from the group consisting of… 3,4-methylenedioxymethamphetamine…", wherein there is synergy between the two components. Lingamyoni's formulation comprising sildenafil and MDMA is capable of treating erectile dysfunction and low/reduced libido—the intended use recited in the preamble of claim 11— because it contains the same components as the claimed combination. The synergistic properties are inherent in the formulation taught by Lingamyoni.

26. Claims 12-14 further limit the erection enhancement component of the formulation by requiring an amount of sildenafil citrate (claim 12); wherein a unit dosage of the formulation comprises a therapeutically effective amount of the erection enhancement component consisting of sildenafil citrate (claim 13); and wherein the sildenafil citrate is about 20 mg to about 100 mg (claim 14). Lingamyoni's formulation contains 50 mg of sildenafil citrate, which is within the range of about 20 mg to about 100 mg.

27. Claims 15-17 further limit the libido stimulation component of the formulation by requiring an amount of 3,4-methylenedioxymethamphetamine (claim 15); wherein a unit dosage of said formulation comprises a therapeutically effective amount of said libido

stimulation component consisting of 3,4-methylenedioxymethamphetamine (claim 16); and wherein the 3,4-methylenedioxymethamphetamine is about 30 mg to about 125 mg (claim 17). Lingamyoni's formulation contains 125 mg of MDMA, which is within the range of about 30 mg to 125 mg.

28. Claims 18-20 further limit the libido stimulation component of the formulation by requiring an amount of 3,4-methylenedioxymethamphetamine (claim 18); wherein a unit dosage of said formulation comprises a therapeutically effective amount of said libido stimulation component consisting of 3,4-methylenedioxymethamphetamine (claim 19); and wherein the 3,4-methylenedioxymethamphetamine is about 30 mg to about 125 mg (claim 20). Lingamyoni's formulation contains 125 mg of MDMA, which is within the range of about 30 mg to 125 mg.

Claim Rejections - 35 USC § 112

29. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

30. **Claims 4, 7-10, 14, and 17-20 are rejected under 35 U.S.C. 112(b)** as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention.

31. The term "about" in claims 4, 7, 10, 14, 17 and 20 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art

would not be reasonably apprised of the scope of the invention. The term "about" is used to describe the upper and lower limits of amounts of compounds; for example, claim 4 states "about 20 milligrams to about 100 milligrams." One of ordinary skill in the art would not know if 19.5 milligrams, 19 milligrams, or 18 milligrams, for example, is encompassed by the claim. Likewise, it is unclear if 20.5 mg, 21 mg, or 21.5 mg is embraced by the claim. Since the precise upper and lower boundaries of claimed ranges are unclear, this renders the claim indefinite. See MPEP 2173.05(b). Claims 8, 9, 18, and 19 are dependent on claims with the indefinite term "about," rendering them indefinite.

Claim Objections

32. **Claims 1, 3 , 5-11, 13, and 15-20 are objected to** because of the following informalities:

33. Claim 1, lines 1-2, and claim 11, lines 1-2, recites "from some degree of erectile dysfunction", which would be clearer if rephrased as "from erectile dysfunction".

34. Claims 1, 5-11 and 15-20 recite the limitation "3,4-methylenedioxymethamphetamine" as well as "racemic mixture of 3,4-methylenedioxymethamphetamine". In light of the specification paragraph [0063], it appears the limitation "3,4-methylenedioxymethamphetamine" is intended to represent a non-racemic (enantio-enriched) mixture of 3,4-methylenedioxymethamphetamine. To improve clarity, the term "3,4-methylenedioxymethamphetamine" should be replaced with "non-racemic mixture of 3,4-methylenedioxymethamphetamine" or with "enantiomeric mixture of 3,4-methylenedioxymethamphetamine", for example.

35. Claims 1 and 11 contain improper grammar. At the end of line 4 of each claim (after "avanafil;"), the conjunction "and" should be inserted; at the beginning of line 10 (before "a synergistic effect)", "wherein" should be added; and in line 11 (after "erection") a comma should be inserted.

36. Claims 5-10 and 15-20 use the term "said" unnecessarily. For example, claim 5 recites "said libido stimulation component comprises an amount of 3,4-methylenedioxymethamphetamine, said R(-) isomer of 3,4 methylenedioxymethamphetamine, said S(+) isomer of 3,4-methylenedioxymethamphetamine, and/or said racemic mixture of 3,4-methylemedioxymethamphetamine." While "said libido stimulation component" is acceptable, the additional usage of "said" (see underlined) when referring to specific libido stimulation components is unnecessary. Additionally, the use of "said" when referring to some but not all components; for example, "said" is not used when referring to "an amount of 3,4-methylenedioxymethamphetamine"; leads to a lack of clarity. It is suggested to remove "said" preceding the specific libido stimulation components.

37. Claims 3, 6, 9, 13, 16, and 19 recite "wherein a unit dosage of said formulation comprises", which could be written more clearly. It is suggested that the preamble be rewritten in the following format example: "The sexual therapy formulation as recited in claim [2] as a unit dosage comprising a therapeutically effective amount of []."

38. Appropriate correction is required.

Conclusion

39. Claims 1-20 are pending and rejected.

40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JED A KUCHARCZK whose telephone number is (571)270-5206. The examiner can normally be reached Mon-Fri 7:30 to 5.

41. 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.

42. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karlheinz Skowronek can be reached on (571) 272-9047. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

43. 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.

/J.A.K./
Examiner, Art Unit 4182

/Amanda L. Aguirre/
Primary Examiner, Art Unit 1626