

From: dregel@dcc.com on behalf of Claire Gregg [cgregg@dcc.com]
Sent: Wednesday, March 10, 2021 9:48 PM
To: Docketing WN; John M. Guynn
CC: Tyler Eller; mroberts@dcc.com; cgregg@dcc.com
Subject: Australian Patent Application No. 2018436267 - Your Ref: 15257.20b.2 - DCC Ref: 35555559/MKR/CZG [ITUSEONLY-DCC.FID1192276]
Attachments: Invoice No 100483367 - 35555559 (35555559).pdf; AU 2018436267 Preliminary Amendment - 35555559.pdf

Via E-mail Only

DOCKETED

Attention: John Guynn
Your Ref: 15257.20b.2
DCC Ref: 35555559/MKR/CZG/DAR

Atty JMG File# 15257.20B.2
By kplatt On 12 Mar 2021
Action Request Examination
Response Due 07-Nov-2023
Submit IDR

Dear John,

Verified

By: Jaclyn Boone On: 12 Mar 2021

ILYLT, LLC

Australian Patent Application No. 2018436267

"Compositions and methods for treating sexual dysfunction and enhancing sexual response and pleasure"

We refer to your instructions of 23 February 2021 and 11 March 2021 and confirm that we have prepared and filed a preliminary amendment to replace the claims on file with the claims attached to your email of 11 March 2021.

We also made some amendments to bring the specification into better conformity with Australian practice. In this regard, we have added two paragraphs to the description to clarify the meaning of the word "comprising" as used in the specification and to clarify that the prior art referred to in the specification should not be considered to represent part of the common general knowledge in the art.

A copy of our submission as filed is **attached**.

Further progress of the application will be reported to you in due course.

Our invoice is **attached**.

Yours faithfully,
Claire and Mark

Claire Gregg
Associate

Mark Roberts
Principal



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DCC Ref: 35555559/MKR/CZG

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Amendment – Amendment in Anticipation of Examination

11 March 2021

Contact: Claire Gregg
CGregg@dcc.com

The Commissioner of Patents
WODEN ACT 2606

Mark Roberts
MRoberts@dcc.com

Dear Commissioner,

ILYLT, LLC

Australian Patent Application No. 2018436267

"Compositions and methods for treating sexual dysfunction and enhancing sexual response and pleasure"

We request leave to amend the complete specification in accordance with the accompanying Statement of Proposed Amendments. The amendments do not result in the specification claiming or disclosing matter beyond that disclosed in the application as filed.

The nature and location of the proposed amendments are believed to be clear from the marked up pages provided.

We request that these amendments be taken into consideration during examination.

Yours respectfully,

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Principal

MRoberts@davies.com.au

AUSTRALIAN PATENT APPLICATION NO. 2018436267

ILYLT, LLC

FIRST STATEMENT OF PROPOSED AMENDMENTS

1. Cancel page 22 currently on file and substitute with new page 22 (as enclosed with a copy of the original page(s) showing the nature/location of the proposed amendments).
2. Cancel claim pages 23-27 currently on file and substitute with new claim pages 23-25 (as enclosed with a copy of the original claim pages showing the nature/location of the proposed amendments).

11 March 2021

year old subject of Examples 2 and 4, benefit more from an edible having a higher THC:CBD ratio.

EXAMPLE 12

Any of the foregoing examples is modified by providing at least one of the components (*e.g.*, pleasure-enhancing component) in a preparation that can delivered by inhalation. Examples include, for example, vaporizers that heat one or more components of the pharmaceutical preparation with water or “vape juice” (*e.g.*, glycerin and/or propylene glycol) to provide a vapor that carries the components of interest and can be inhaled. The temperature and/or selection of vaporizing liquids can affect the concentration and/or ratio of cannabinoids delivered to the user.

EXAMPLE 13

Any of the foregoing examples is modified by providing at least one of the components (*e.g.*, pleasure-enhancing component) in a topical preparation that can be applied to any region of the body able to rapidly absorb the active components. Examples include, for example, the genital and/or anal regions of men and women.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

Throughout this specification and the claims that follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

The claims defining the invention are as follows:

1. A method for treating at least one of sexual arousal disorder and orgasmic disorder in a human comprising administering a composition comprising a sexual pleasure enhancing component and a sexual response-enhancing component to the human, wherein the sexual pleasure enhancing component comprises a therapeutically effective amount of one or more cannabinoid compounds, and wherein the sexual response enhancing component comprises a therapeutically effective amount of one or more components, which are not cannabinoids, that raise blood level of nitric oxide (NO) and increase blood flow to the genital region of the human, with the proviso that the sexual arousal disorder is not erectile dysfunction in a male.
2. The method of claim 1, wherein the treating comprises increasing at least one of threshold sexual desire, sexual sensitivity, sexual pleasure, ability to orgasm, and strength of orgasm.
3. The method of claim 1 or 2, wherein the human is female.
4. The method of claim 1 or 2 wherein the human is male.
5. The method of any one of claims 1-4, wherein the one or more cannabinoid compounds comprise at least one of tetrahydrocannabinol (THC) and cannabidiol (CBD).
6. The method of claim 5, wherein the composition comprises THC and CBD in a ratio of THC/CBD of at least 2:1, or 3:1 to 20:1, or 4:1 to 15:1, or in a ratio of CBD/THC of at least 2:1, or 3:1 to 20:1, or 4:1 to 15:1.
7. The method of claim 6, wherein the composition comprises THC and CBD in a ratio of THC/CBD of 0.5:1 to 2:1.
8. The method of any one of claims 5-7, wherein the composition is a fixed unit dosage form that provides at least one of the THC or CBD in a range of 5 mg to 500 mg, or 7.5 mg to 450 mg, or 10 mg to 400 mg, or 15 mg to 350 mg, or 20 mg to 300, or 25 mg to 250 mg, or 35 mg to 200 mg.

9. The method of any one of claims 1-8, wherein the one or more cannabinoid compounds comprise at least one of cannabinal (CBN), tetrahydrocannabivarin (THCV), cannabigerol (CBG), dronabinol, nabilone, derivative of THC, and derivative of CBD.
10. The method of any one of claims 1-9, wherein the one or more cannabinoid compounds are obtained from plant parts of one or more plants selected from *Cannabis sativa*, *Cannabis indica*, and hybrids thereof.
11. The method of any one of claims 1-10, wherein the sexual response enhancing component is selected from sildenafil, tadalafil, vardenafil, L-arginine, L-citrulline, and herbal supplement.
12. The method of claim 11, wherein the herbal supplement comprising at least one of yohimbe root, ginseng, ginkgo biloba, horny goat weed, goosefoot, *Chenopodium ambrosioides*, *Chlorophytum borivilianum*, *Desmodium gangeticum*, garlic combined with vitamin C, and damiana.
13. The method of any one of claims 1 to 12, wherein the composition is a pharmaceutical composition, and wherein the sexual pleasure enhancing component comprises at least one of 5 mg to 500 mg of tetrahydrocannabinol (THC) in a fixed unit dosage and 5 mg to 500 mg of cannabidiol (CBD) in a fixed unit dosage.
14. The method of any one of claims 1-13, wherein the composition is in the form of a tablet or capsule.
15. The method of any one of claims 1-13, wherein the composition is in the form of a vaginal suppository, anal suppository, sexual lubricant, massage oil, genital spray, or patch.
16. The method of any one of claims 1-13, wherein the composition is formulated for vaporization and inhalation without smoking using a heat vaporizer or a nebulizer.
17. The method of any one of claims 1-13, wherein the composition is in the form of an infused edible.

18. The method of claim 17, wherein the infused edible is selected from an oral drop, lozenge, lollipop, food preparation, brownie, cookie, chocolate, chew, gum drop, soft candy, hard candy, and liquid shot.

19. Use of a composition comprising a sexual pleasure enhancing component and a sexual response-enhancing component in the manufacture of a medicament for treating at least one of sexual arousal disorder and orgasmic disorder in a human, with the proviso that the sexual arousal disorder is not erectile dysfunction in a male, wherein the sexual pleasure enhancing component comprises a therapeutically effective amount of one or more cannabinoid compounds, and wherein the sexual response enhancing component comprises a therapeutically effective amount of one or more components, which are not cannabinoids, that raise blood level of nitric oxide (NO) and increase blood flow to the genital region of the human.

20. The use of claim 19, wherein the sexual pleasure enhancing component comprises at least one of tetrahydrocannabinol (THC) or cannabidiol (CBD), and wherein the sexual response enhancing component is selected from sildenafil, tadalafil, vardenafil, L-arginine, L-citrulline, and herbal supplement.

year old subject of Examples 2 and 4, benefit more from an edible having a higher THC:CBD ratio.

EXAMPLE 12

Any of the foregoing examples is modified by providing at least one of the components (*e.g.*, pleasure-enhancing component) in a preparation that can delivered by inhalation. Examples include, for example, vaporizers that heat one or more components of the pharmaceutical preparation with water or “vape juice” (*e.g.*, glycerin and/or propylene glycol) to provide a vapor that carries the components of interest and can be inhaled. The temperature and/or selection of vaporizing liquids can affect the concentration and/or ratio of cannabinoids delivered to the user.

EXAMPLE 13

Any of the foregoing examples is modified by providing at least one of the components (*e.g.*, pleasure-enhancing component) in a topical preparation that can be applied to any region of the body able to rapidly absorb the active components. Examples include, for example, the genital and/or anal regions of men and women.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

Throughout this specification and the claims that follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

CLAIMS The claims defining the invention are as follows:

ORIGINAL CLAIMS 1-36 DELETED

1. A method for treating at least one of sexual arousal disorder and orgasmic disorder in a human comprising administering a composition comprising a sexual pleasure enhancing component and a sexual response-enhancing component to the human, wherein the sexual pleasure enhancing component comprises a therapeutically effective amount of one or more cannabinoid compounds, and wherein the sexual response enhancing component comprises a therapeutically effective amount of one or more components, which are not cannabinoids, that raise blood level of nitric oxide (NO) and increase blood flow to the genital region of the human, with the proviso that the sexual arousal disorder is not erectile dysfunction in a male.
2. The method of claim 1, wherein the treating comprises increasing at least one of threshold sexual desire, sexual sensitivity, sexual pleasure, ability to orgasm, and strength of orgasm.
3. The method of claim 1 or 2, wherein the human is female.
4. The method of claim 1 or 2 wherein the human is male.
5. The method of any one of claims 1-4, wherein the one or more cannabinoid compounds comprise at least one of tetrahydrocannabinol (THC) and cannabidiol (CBD).
6. The method of claim 5, wherein the composition comprises THC and CBD in a ratio of THC/CBD of at least 2:1, or 3:1 to 20:1, or 4:1 to 15:1, or in a ratio of CBD/THC of at least 2:1, or 3:1 to 20:1, or 4:1 to 15:1.
7. The method of claim 6, wherein the composition comprises THC and CBD in a ratio of THC/CBD of 0.5:1 to 2:1.
8. The method of any one of claims 5-7, wherein the composition is a fixed unit dosage form that provides at least one of the THC or CBD in a range of 5 mg to 500 mg, or 7.5 mg to 450 mg, or 10 mg to 400 mg, or 15 mg to 350 mg, or 20 mg to 300, or 25 mg to 250 mg, or 35 mg to 200 mg.

9. The method of any one of claims 1-8, wherein the one or more cannabinoid compounds comprise at least one of cannabinal (CBN), tetrahydrocannabivarin (THCV), cannabigerol (CBG), dronabinol, nabilone, derivative of THC, and derivative of CBD.

10. The method of any one of claims 1-9, wherein the one or more cannabinoid compounds are obtained from plant parts of one or more plants selected from Cannabis sativa, Cannabis indica, and hybrids thereof.

11. The method of any one of claims 1-10, wherein the sexual response enhancing component is selected from sildenafil, tadalafil, vardenafil, L-arginine, L-citrulline, and herbal supplement.

12. The method of claim 11, wherein the herbal supplement comprising at least one of yohimbe root, ginseng, ginkgo biloba, horny goat weed, goosefoot, Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, and damiana.

13. The method of any one of claims 1 to 12, wherein the composition is a pharmaceutical composition, and wherein the sexual pleasure enhancing component comprises at least one of 5 mg to 500 mg of tetrahydrocannabinol (THC) in a fixed unit dosage and 5 mg to 500 mg of cannabidiol (CBD) in a fixed unit dosage.

14. The method of any one of claims 1-13, wherein the composition is in the form of a tablet or capsule.

15. The method of any one of claims 1-13, wherein the composition is in the form of a vaginal suppository, anal suppository, sexual lubricant, massage oil, genital spray, or patch.

16. The method of any one of claims 1-13, wherein the composition is formulated for vaporization and inhalation without smoking using a heat vaporizer or a nebulizer.

17. The method of any one of claims 1-13, wherein the composition is in the form of an infused edible.

18. The method of claim 17, wherein the infused edible is selected from an oral drop, lozenge, lollipop, food preparation, brownie, cookie, chocolate, chew, gum drop, soft candy, hard candy, and liquid shot.

19. Use of a composition comprising a sexual pleasure enhancing component and a sexual response-enhancing component in the manufacture of a medicament for treating at least one of sexual arousal disorder and orgasmic disorder in a human, with the proviso that the sexual arousal disorder is not erectile dysfunction in a male, wherein the sexual pleasure enhancing component comprises a therapeutically effective amount of one or more cannabinoid compounds, and wherein the sexual response enhancing component comprises a therapeutically effective amount of one or more components, which are not cannabinoids, that raise blood level of nitric oxide (NO) and increase blood flow to the genital region of the human.

20. The use of claim 19, wherein the sexual pleasure enhancing component comprises at least one of tetrahydrocannabinol (THC) or cannabidiol (CBD), and wherein the sexual response enhancing component is selected from sildenafil, tadalafil, vardenafil, L-arginine, L-citrulline, and herbal supplement.