From: BOIP-PATENT
Sent: Wednesday, March 3, 2021 1:26 AM
To: Tyler Eller
CC: Docketing WN; syin@boip.com.cn; John M. Guynn
Subject: 【Invoice】Filing report for Malaysian National Phase Application; your Ref.: 15257.20b.8; BOIP Ref.: BY21XM0291FGPC-MY
Attachments: BY21XM0291FGPC-MY_Preliminary Examination Report.pdf; BY21XM0291FGPC-MY_Invoice.pdf; BY21XM0291FGPC-MY_Official filing receipt.pdf; BY21XM0291FGPC-MY_Patent Application Filed.pdf

Dear Sirs,

This is further to our email below.

Please find attached the application documents as filed, official filing receipt, Preliminary Examination Report and our Invoice for services rendered.

Malaysian Application No.: PI2021000684

Official filing date: February 22, 2021

Deadline for response to Preliminary Examination Report: 22 May 2021 (to file the executed Form 17); 7 November 2022 (to file the request for Substantive Examination)

Thank you for entrusting these filings with us. Please do not hesitate to contact us if you have any questions.

Please acknowledge receipt of this email by return.

Sincerely yours,

DOCKETED
Atty JMG File# 15257.20B.8
By Jaclyn Boone On 03 Mar 2021
Action Instruct - Instruct - Response Due - Request Exam
Response Due 3/5/21 - 4/22/21 - 5/22/21 - 11/7/22
Submit IDR

Verified
By: DPeterson On: 03 Mar 2021

Huijuan QIE (Ms.)
For Larry Min (GM)
Filing Department
品源知识产权
BEYOND ATTORNEYS AT LAW
Beyond Attorneys at Law
F6, Xijin Centre, 39 Lianhuachi East Rd., Haidian District, Beijing 100036, China
Tel: +86-10-8292 4510 | Fax: +86-10-6337 7018
E-mail: patent@boip.com.cn | Website: www.boip.com.cn

发件人： BOIP-PATENT [mailto:patent@boip.com.cn]
发送时间： 2021年2月8日 14:54
收件人： 'Tyler Eller'
抄送： 'JGuynn'; 'Tyler Eller'; docketing@wnlaw.com; syin@boip.com.cn
主题： RE: Instructions for Malaysian National Phase Application Filing due February 7, 2021; Our Ref.: 15257.20b.8; BOIP Ref.: BY21XM0291FGPC-MY

Dear Colleagues,

This is further to our email below.

Enclosed please find the Form 17 to be signed by the applicant for the subject application. Please have it signed and the return the **original** documents to us as soon as possible.

As for the Form 22, please confirm whether the applicant acquired the rights of the invention from the inventor by virtue of assignment from the inventor's employer.

Thank you for your assistance in this matter. Should you have any question, please feel free to contact us.

Please acknowledge receipt of this email by return.

Sincerely yours,

Huijuan QIE (Ms.)
For Larry Min (GM)
Filing Department

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BEYOND ATTORNEYS AT LAW
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F6, Xijin Centre, 39 Lianhuachi East Rd., Haidian District, Beijing 100036, China
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E-mail: patent@boip.com.cn | Website: www.boip.com.cn

From: BOIP-PATENT [mailto:patent@boip.com.cn]
Sent: Monday, February 01, 2021 5:23 PM
To: 'Tyler Eller'
Cc: 'JGuynn'; 'Tyler Eller'; docketing@wnlaw.com; syin@boip.com.cn
Subject: Re: Instructions for Malaysian National Phase Application Filing due February 7, 2021; Our Ref.: 15257.20b.8; BOIP Ref.: BY21XM0291FGPC-MY

Dear Colleagues,

Thank you for entrusting us with this new Malaysian National Phase patent application.

Please note that our reference number for this case is BY21XM0291FGPC-MY. We would appreciate it if you would use it in the future correspondence.

Should you have any questions, please feel free to contact us.

Please acknowledge receipt of this email by return.

Sincerely yours,

Huijuan QIE (Ms.)
For Larry Min (GM)
Filing Department

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发件人： syin@boip.com.cn [mailto:syin@boip.com.cn]
发送时间： 2021年1月30日 8:19
收件人： 'Tyler Eller'; patent@boip.com.cn
抄送： JGuynn; 'Tyler Eller'; docketing@wnlaw.com
主题： Re: Instructions for Malaysian National Phase Application Filing due February 7, 2021; Our Ref.: 15257.20b.8

Dear John：

Thank you for your email today. Your instruction and the attachments have been received. We will take care of the case.

Best regards,

Shenmin

Shenmin Yin, Ph.D.
Patent Attorney/ Trademark Attorney/ Partner

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BEYOND ATTORNEYS AT LAW

Beyond Attorneys at Law
New York Representative Office
9213 51st Avenue, Elmhurst, NY11373
Tel: 347-935-8012 | Fax: 212-845-9516
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From: Tyler Eller
Date: 2021-01-29 15:44
To: syin@boip.com.cn; patent@boip.com.cn
CC: jguynn@wnlaw.com; teller@wnlaw.com; docketing@wnlaw.com
Subject: Instructions for Malaysian National Phase Application Filing due February 7, 2021; Our Ref.: 15257.20b.8

VIA E-MAIL ONLY

Beyond Attorneys at Law
F6 Xijin Centre
39 Lianhuachi East Rd.
Haidian District, Beijing 100036
China

Re: Malaysian Patent Application

Compositions and Methods for Treating Sexual Dysfunction and Enhancing Sexual Response and Pleasure
Serial No.: PCT/US2018/059712
Filed: November 7, 2018
WN Ref.: 15257.20b.8
Your Ref.: Please Advise

Dear Shenmin:

We represent ILYLT, LLC, a limited liability corporation organized and existing under the laws of the United States of America, which has a principal place of business at 6591 South Cottonwood Street, Murray, Utah 84107. Please see the attached 92bis and IB306 documents confirming the above listed applicant information.

Our client desires to proceed with entry into the national stage of the above-identified PCT international application. The 30 month deadline for entering the national stage is **February 7, 2021**. Please file the application on or prior to that date.

In connection with entry into the national stage with respect to the PCT application, we are sending the following documents to you by e-mail only:

1. a copy of the application in Word format;
2. a copy of the published international application;
3. a copy of the International Search Report & Written Opinion; and
4. an amended claim set for submission with the application filing.

You are authorized to proceed with the translations required for the application filing. If you require any further documentation in order to complete entry into the national stage, please notify us immediately.

Standing Instructions. In handling this matter, please take notice of and observe the following standing instructions:

1. Please note that no surcharges for expedited handling or translation work will be honored unless they are specifically identified to us and authorized in advance and, in any case, do not exceed 15% of the normal fee.
2. Please direct all correspondence concerning this matter to the attention of the undersigned.
3. All correspondence concerning this matter, including debit notes, should include reference to our file number, namely 15257.20b.8.
4. Please notify us immediately of any official communication. Please do not unduly delay its dispatch even if, for example, there is a delay in obtaining copies of the cited prior art. If you have not received instructions from us at least three (3) days prior to any *final* deadline, please contact the undersigned by telephone or facsimile for instructions. If you have not received instructions from us at least three (3) days prior to any *extendable* deadline, please apply for an extension of time and send us a reminder, which includes the new, extended deadline for responding.
5. Please forward one (1) copy of each prior art patent or publication cited.
6. In the absence of specific instruction from us, please take any action necessary to prevent abandonment during the application's pendency before the Patent Office.

Please note that responsibility for annuities other than those due at the time of filing will be handled by our annuities service, CPA.

Please immediately confirm receipt of these instructions by return e-mail.

We look forward to hearing from you. If you have any questions, please do not hesitate to contact us.

Sincerely,

John M. Guynn

Tyler Eller
Paralegal
Office-Direct: 801-321-8822
EMAIL: TELLER@WNLAW.COM

workman nydegger
Intellectual Property Law

60 East South Temple • Suite 1000
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Laman Web (Web) : www.myipo.gov.my

APPLICATION NO : PI2021000684
APPLICANT : ILYLT, LLC
APPLICANT'S/AGENT'S REF. : TFL/VL/346277/21/PTN
DATE OF MAILING : 22 FEBRUARY 2021

PRELIMINARY EXAMINATION - ADVERSE FORMALITIES REPORT

Please find attached a copy of the Preliminary examination report under Section 29 of the Patents Act, relating to the following deficiencies :

☒ **ANNEX A**: Deficiencies as to Regulation 5 to 11,50 and 51

☐ **ANNEX D**: Deficiencies as to Regulation 18.

You are invited to correct the deficiencies. Corrections should be received at the above Office or Branch Offices in Sabah or Sarawak within 3 months of the above date of mailing, otherwise the application may be refused.

Date : 22 FEBRUARY 2021

(ASMAWATI JUSOH)
For Registrar of Patents
asmawati@myipo.gov.my
03 – 22998811

To : TAI FOONG LAM
C/O GAN PARTNERSHIP
D-32-02, MENARA SUEZCAP 1, KL GATEWAY
2 JALAN KERINCHI, GERBANG KERINCHI LESTARI
59200 KUALA LUMPUR
MALAYSIA

ANNEX A

APPLICATION NO. : PI2021000684

ADVERSE PRELIMINARY EXAMINATION REPORT
[Section 29(1) of Patents Act 1983, Regulation 26(1)]
[Regulations 5, 6, 7(1), 8, 9, 11 and 51)]

- ☐ The application does not contain all the required documents (Reg. 5) i.e. Request, Description, Claim, Abstract
- ☐ The application does not contain the name and address of the inventor (Reg. 6)
- ☐ The Request is not made on Form 1 or 14. [Reg. 7(1)]
- ☐ Names and addresses are not given in full in the Request (Reg. 8)
- ☐ The applicant's nationality/residence is not/incorrectly stated in the Request (Reg.9)
- ☐ The application does not designate a common representative (Reg. 11)
- ☒ The Request is not accompanied by Form 17 (Reg. 10)
- ☐ The Request is not accompanied by Form 22 (Reg. 10)
- ☐ Address for service not provided (Reg. 51)
- ☐ Other

Further explanations/observation:

Date : 22 FEBRUARY 2021

(ASMAWATI JUSOH)
For Registrar of Patents
asmawati@myipo.gov.my
03 – 22998811

To : TAI FOONG LAM
C/O GAN PARTNERSHIP
D-32-02, MENARA SUEZCAP 1, KL GATEWAY
2 JALAN KERINCHI, GERBANG KERINCHI LESTARI
59200 KUALA LUMPUR
MALAYSIA

PERBADANAN HARTA INTELEK MALAYSIA
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Laman Web (Web) : www.myipo.gov.my

NOTICE OF ENTERING THE NATIONAL PHASE
[SECTION 780 OF PATENTS ACT 1983]

APPLICANT	:	ILYLT, LLC
APPLICATION NO.	:	PI2021000684
INTERNATIONAL APPLICATION NO.	:	PCT/US2018/059712
REQUEST RECEIVED ON	:	08 FEBRUARY 2021
INTERNATIONAL FILING DATE	:	07 NOVEMBER 2018
AGENT'S/APPLICANT'S FILE REF.	:	TFL/VL/346277/21/PTN

Please take note that upon entering the national phase, the applicant is required to comply with the requirement of the national phase in accordance with the requirements of the national phase in accordance with the Patents Act 1983.

Date : 22 February 2021

(ASMAWATI JUSOH)
For Registrar of Patents
asmawati@myipo.gov.my
03 – 22998811

To :

TAI FOONG LAM
C/O GAN PARTNERSHIP
D-32-02, MENARA SUEZCAP 1, KL GATEWAY
2 JALAN KERINCHI, GERBANG KERINCHI LESTARI
59200 KUALA LUMPUR
MALAYSIA

Annex A

***ADVICE TO APPLICANTS - TIME PERIODS/**
REQUEST FOR EXAMINATION
[PCT - National Phase]

During the prosecution of an application the applicant is required to take certain actions within specified time periods. If no action is taken then the application may be refused or considered withdrawn. The attention of applicants is drawn, in particular, to the following important action required of the applicant:

(a) A request for Substantive Examination should be made by the applicant on Form 5, together with the prescribed fee, **within 4 years from the international filing date of the application, failing which the application shall be deemed to be withdrawn.**

OR

(b) A request for Modified Substantive Examination should be made by the applicant on Form 5A, together with the prescribed fee, **within 4 years from the international filing date of the application, failing which the application shall be deemed to be withdrawn.**

In accordance with regulation 27, the request for substantive examination should be accompanied by information relating to any corresponding Australian, Japan, Korean, United Kingdom, United States, European Patent Office or PCT application and its search and examination results. Note that, under Section 56(2)(e) of the Patents Act 1983, a patent may be invalidated due to failure to provide the information. Information not available at the time of requesting substantive examination may be lodged at the Registry at a later date when it becomes available.

In accordance with Section 29A(8) of the Patents Act 1983, the 4-year period cannot be extended under the provisions of Section 82. However, deferment of both examination and the provision of the information may be requested under Section 29A(6) but the request for deferment must be filed within the 4 year period.

With a view of expediting substantive examination the applicant is encouraged to lodge voluntary amendments at any time to take into account of the Malaysian legislation, to take into account of any search and examination results in order to bring the Malaysian application into substantial conformity with any Australian, Japan, Korean, United Kingdom, United States or European granted patent.

*Kindly take note that the advice provided herein is not exhaustive, and kindly refer to the Patents Act 1983 for further details.

ganpartnership
advocates & solicitors • arbitrators • adjudicators • mediators
registered patent agents • registered trade mark agents • registered industrial design agents

D-32-02, Menara SUEZCAP 1, KL Gateway
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59200 Kuala Lumpur, Malaysia

T +6 03 7931 7060
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E office@ganlaw.my
W www.ganlaw.my

8 February, 2021

Our Ref: TFL/VL/346277/21/PTN
Your Ref: Please advise

Intellectual Property Corporation of Malaysia **By Hand only**
Patent Unit
Mezzanine Level, 12 12A, 13, 15-19
Tower B, Menara UOA Bangsar
5 Jalan Bangsar Utama 1
59000 Kuala Lumpur

Dear Sirs,

Malaysia Entry into National Phase Entry Application

PCT Application No.	:	**PCT/US2018/059712**
International Filling Date.	:	**November 7, 2018**
Title	:	**Compositions and Methods for Treating Sexual Dysfunction and Enhancing Sexual Response and Pleasure**
Applicant	:	**ILYLT, LLC**

We refer to the above matter.

Please find enclosed the following documents in support of the above application:

(b) Two (2) copies of the Patent **Form No. 2A**;
(c) Two (2) copies of the Patent **Form No. 22**;
(d) Two (2) sets of **Specifications** comprising the:
(i) description;
(ii) claims; and
(iii) abstract;
(e) Two (2) copies of the signed **PCT Assignment**;
(f) Two (2) copies of the **published PCT Application** with publication number WO/2020/032988;
(g) Two (2) copies of the **PCT International Search Report and Written Opinion** of the International Searching Authority; and
(h) Our MBB cheque No. 166976 for the sum of **RM 470.00** as requisite filing fees for the Form No. 2A (RM290.00) with 15 claims (RM20.00 x 5) [RM100.00], Form No. 17 (RM80.00) and Form No. 22 (RM80.00).

Please note that we will file the Patent Form No. 17 in due course once our client has transmitted to us the duly executed Patent Form No. 17.

PI 2021000684-

Kindly acknowledge receipt of this letter and the enclosures by signing and returning to us the duplicate copy of this letter.

Thank you for your assistance in this matter.

Yours faithfully,
ganpartnership

Gan partnership

Vincent Liew
Associate
Email: vincent@ganlaw.my
Encls.

Patents Form No. 2A PATENTS ACT 1983 FEE FOR ENTERING THE NATIONAL PHASE (Regulations 25A) To : The Registrar of Patents Patents Registration Office Kuala Lumpur, Malaysia	For Official Use Fee received on: ..... Amount: ..... *Cheque / Postal Order / Money Order / Draft / Cash No: .....
Please submit this Form in duplicate together with the prescribed fee and/or reinstatement fee for international application.	Applicant's or Agent's file reference : TFL/VL/346277/21/PTN

I. APPLICANT(S):

Name : ILYLT, LLC
Address : 6591 South Cottonwood Street, Murray, Utah 84107, United States of America.

II. THE APPLICANT(S) REQUEST(S) ENTRY INTO THE NATIONAL PHASE IN ACCORDANCE WITH:

*SECTION 78O ☒
*SECTION 78OA ☐

INTERNATIONAL APPLICATION NO. : PCT/US2018/059712

III. AGENT :

Applicant has appointed a patent agent in the accompanying Patents Form No. 17

Yes ☒ No ☐

Agent's Registration No.: PA/2000/0102

SIGNATURE .....
** *(Applicant/Agent)*

05/02/2021
(Date)

If Agent, indicate Agent's Registration No. PA/2000/0102

For Official Use

Date application received: .....

PI 2021000684-

* Tick whichever is applicable
** Type name under signature and delete whichever does not apply

Patents Form No. 22 PATENTS ACT 1983 STATEMENT JUSTIFYING THE APPLICANT'S RIGHT TO A PATENT/CERTIFICATE (Regulations 10(2)) To: The Registrar of Patents Patent Registration Office Kuala Lumpur Malaysia	**For Official Use** APPLICATION NO.: Filing Date: Request received on : Fee Received on : Amount : *Cheque / Postal Order / Money Order / Draft / Cash No. Date of mailing:
Please submit this Form in duplicate together with the prescribed fee.	Applicant's or Agent's file reference

I. IN THE MATTER OF :

Patent Application No.: Filing Date :

Certificate Application No. Filing Date :

II. TITLE OF INVENTION: **COMPOSITIONS AND METHODS FOR TREATING SEXUAL DYSFUNCTION AND ENHANCING SEXUAL RESPONSE AND PLEASURE**

III. APPLICANT (S)

Name : **ILYLT, LLC**

Address : **6591 South Cottonwood Street, Murray, Utah 84107, United States of America.**

IV. I/WE BELIEVE THAT THE INVENTOR(S)/INNOVATOR(S) OF THE ABOVE MENTIONED APPLICATION IS AS FOLLOWS:

JENN, Dennis

V. STATEMENT JUSTIFYING THE APPLICANT'S RIGHT TO A PATENT/CERTIFICATE :

The applicant acquired the rights of the invention from the inventor by virtue of assignment from the inventor's employer.

VI. ADDITIONAL INFORMATION accompanies this Form :

Yes [✓] No [ ]

VII. SIGNATURE:

Tai Foong Lam

** *(Applicant / Agent)*

5 February 2021

(Date)

If Agent, indicate Agent's Registration No. **PA/2000/0102**

* Delete whichever does not apply.

**** Type name under signature and delete whichever does not apply

PI 2021000684

COMPOSITIONS AND METHODS FOR TREATING SEXUAL DYSFUNCTION AND ENHANCING SEXUAL RESPONSE AND PLEASURE

TECHNICAL FIELD

The invention is in the field of pharmaceutical preparations, particularly for sexual enhancement in men, women, the disabled, and the aged.

BACKGROUND ART

There are a variety of health issues that can impact the ability or desire to engage in intimate sexual relations, which form a healthy part of adult relationships. These include sexual dysfunction in men and women and a loss of sensitivity and pleasure. The inability to perform and/or lack of desire to engage in sexual relations can detrimentally impact a relationship and can lead to divorce, breakup, or long-term boredom. It can lead to loss of self-esteem or even mental illness.

Men are more likely than women to have threshold desire to have sex, which is both a physical and psychological need, and are therefore more likely to initiate sex with a partner. When a man is extremely stressed, anxious or insecure, however, his ability to perform can also be inhibited physically (temporary erectile dysfunction). Older or sick men can suffer chronic erectile dysfunction ("ED"), which can be completely incapacitating relative to ability to perform. Particularly as men age and/or if suffering from chronic illness, they can experience lack of threshold desire, loss of sensitivity, loss of pleasure (collectively "arousal disorder") and/or difficulty in climaxing ("orgasmic disorder"). At the opposite end of the

spectrum is premature ejaculation which can severely curtail duration and satisfaction for both participants.

In women, sexual dysfunction is more complex and difficult to define but can involve lack of threshold desire, loss of sensitivity, loss of pleasure (collectively "sexual arousal disorder") and/or inability to climax ("orgasmic disorder"). Emotional and psychological sexual dysfunction may be more common among women. There are many studies that show that women commonly have insecurities about body image and carry their stresses and anxieties of life with them into the bedroom. These insecurities and stresses greatly impact the mood-factor (emotional and psychological state) and inhibit physiological arousal, such as decreased blood flow to the clitoris and labia, often making orgasm unattainable.

Compared to men, women have more complex emotions that can be barriers to threshold desire. Women are more sensitive sexually to insecurities, stresses, and anxieties than men. Books and commentators have been known to say: "sex is much more emotional for women than men." Also, men often view sex as a way to release and reduce stress and tension. In contrast, women often identify sex with increased stress and anxiety, particularly women who both work outside the home and raise children. Examples of hypothetical stresses include: "I'm not in the mood." "I'm stressed or tired from work, the kids, play dates, managing the household, dirty dishes." "Really? We're doing this now, etc.?" So, sex can becomes another item on an already stressful checklist. Examples of hypothetical anxieties include: "I think I've put on a few pounds." "My butt doesn't look good." "I feel bloated and hormonal." "How do I compare?" "Will I be able to perform for my partner, act sufficiently interested, be interested, etc.?"

While there are drugs (*e.g.*, Viagra®, Cialis® and Levitra®) that can remedy the physiological condition of ED and permit men to perform sexually, they generally do not restore lost sensitivity, diminished enjoyment, or difficulty in climaxing. Such drugs are generally ineffective for women because they do not adequately address issues involving lack of threshold desire, loss of sensitivity, loss of pleasure, or inability to climax (*i.e.*, because they do virtually nothing to address powerful psychological forces affecting women).

In fact, the main reason physiological enhancers for women on the market today do not work is because they fail to address the mood-factor. Unlike men, who feel buildup of semen and equate it with sexual tension and need to find sexual release, the trigger for women to desire sex is typically not physical but psychological and strongly correlated with mood and self-image. Their emotional and psychological state can actually dictate physiological response, arousal and performance significantly more than in men. And while men are notorious finishers during sex, women are not so prone (50% reportedly never achieving orgasm during sex). This is generally not due to a lack of physical stimulation but rather emotional barriers or inhibitions. Only enhancing the physiological response in women does not adequately address the inability to reach climax.

Many of the foregoing problems are particularly acute in men and women who suffer from physical ailments and/or age-related conditions that cause sexual dysfunction and/or lack of desire and enjoyment. Again, it must be emphasized that performance does not necessarily coincide with normal enjoyment of sexual relations. Drugs that only address lack of performance but fail to address diminished desire, sensitivity, and pleasure are incomplete solutions.

While there are herbal supplements that purport to address some or all of the foregoing issues, there remains a long-felt but unmet need to find compositions that effectively and reliably addresses diminished performance while also increasing desire, sensitivity and enjoyment.

SUMMARY OF THE INVENTION

The present invention relates to pharmaceutical preparations and related methods of manufacture and use for enhancing various aspects of sexual activity, and treating sexual dysfunction in men and women. To accomplish these results the pharmaceutical preparations include a combination of: (1) one or more cannabinoid compounds derived from the plant genus *Cannabis*, which are included in an effective amount and/or in a ratio effective to enhance sexual pleasure (*e.g.*, threshold desire, sensitivity and/or enjoyment); and (2) one or more compounds that enhance blood flow to the genital region in order to enhance sexual response (*e.g.*, ability to perform and/or time to arousal). The combination results in increased ability to perform and enjoyment of intimate sexual activities by men and women, which treats one or more of arousal disorder, orgasmic disorder, and erectile dysfunction in both males and females.

According to several embodiments, the pharmaceutical preparations can be delivered in a manner so that the time of enhanced sexual response and sexual pleasure coincide or complement each other (*i.e.*, so that both are present at the same time at least some of the time). Methods of delivery include oral delivery, topical delivery, injection, inhalation, or combinations thereof. Advantageously, the components of the pharmaceutical preparations can be delivered together in a single mode of delivery for simplicity and proper dosage (*e.g.*,

in a combined oral preparation or a topical preparation). Alternatively, the components of the pharmaceutical preparations can be pre-packaged in a kit and delivered individually, whether simultaneously or sequentially.

According to several embodiments, the one or more cannabinoid compounds derived from the plant genus *Cannabis* include at least two cannabinoid compounds that are included in amounts and/or ratios in order to address a particular condition being treated. By way of example, it has been found that persons (men or women) suffering from lack of threshold desire, sensitivity, pleasure and/or ability to climax can benefit from preparations that have a relatively higher quantity or ratio of tetrahydrocannabinol (THC) as compared to cannabidiol (CBD) (*e.g.*, more than 2:1 THC/CBD). Alternatively, persons suffering from premature ejaculation (men) or who are prone to nervousness or anxiety when engaging in sexual activity (men or women) can benefit from preparations that have a relatively lower quantity THC/CBD ratio (*e.g.*, less than 0.5:1 THC/CBD). Persons with normal sexual response can benefit from an intermediate THC/CBD ratio (*e.g.*, between 0.5:1 to 2:1 THC/CBD).

As discussed above, women can have very real insecurities about body image and carry stresses and anxieties into the bedroom. Similarly, when a man is extremely stressed, anxious or insecure, his ability to perform sexually can also be inhibited. Insecurities and stresses can greatly impact emotional and psychological state and inhibit physiological arousal, often making sex impossible for the man and/or orgasm unattainable for the woman. However, by addressing both the mood-factor (emotional and psychological state) and blood flow to the genitalia, physical arousal occurs easier and more naturally, which permits awareness and focus to shift to sensuality, sexual sensitivity, and sexual stimulation, enhancing sexual pleasure for both men and women, and promoting orgasms and sometimes multiple orgasms.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Disclosed herein are pharmaceutical preparations that include at least one compound that enhances sexual pleasure and at least one other compound that enhances sexual response. Also disclosed are methods of manufacturing and using such pharmaceutical preparations.

The term "sexual pleasure" can include a variety of physiological and/or psychological aspects or conditions that affect the amount of enjoyment of sexual activity. Examples include, but are not limited to, threshold desire to commence sexual activity, physical sensitivity during sexual activity, psychological pleasure or awareness during sexual activity, ability to reach climax, amount of pleasure leading up to climax, quality of climax, duration of climax, and the like.

The term "sexual response" can include a variety of physiological and/or psychological aspects that affect the ability to perform sexual activities. In men, the most common condition is the inability to achieve or maintain an erection. In women, conditions that inhibit sexual response are more varied and complex but include, for example, inability or delay in becoming aroused while being kissed or touched in erogenous zones. In many cases such inability can be more psychological than physiological.

The term "sexual arousal disorder" can apply to men and women and is where a person has difficulty with arousal or are unable to become aroused or maintain arousal during sexual activity.

The term "orgasmic disorder" can apply to men and women and is where a person has persistent or recurrent difficulty in achieving orgasm after sufficient sexual arousal and ongoing stimulation.

The term "low sexual desire" can apply to men and women and is where the person has lack of sexual interest and willingness to be sexual.

According to several embodiments, the one or more compounds that enhance sexual pleasure ("pleasure-enhancing component") include one or more cannabinoid compounds from the plant genus *Cannabis*. Examples of cannabinoid compounds include tetrahydrocannabinol ("THC"), which is a subgenus of several different isomers having different chiral centers and is the main psychoactive constituent of *Cannabis*; cannabidiol ("CBD"), which is less or perhaps even non-psychoactive but may modulate certain effects of THC in the nervous system, cannabinol ("CBN"), tetrahydrocannabivarin ("THCV"), and cannabigerol ("CBG"). Examples of synthesized cannabinoid compounds include dronabinol (Marinol) (a pure isomer of THC, (–)-trans-Δ9-tetrahydrocannabinol, which is the main isomer found in cannabis) and nabilone (a synthetic racemic mixture consisting of the (S,S) and the (R,R) isomers of THC). Synthetic forms of THC and CBD can function the same as plant-based THC and CBD, respectively, and are therefore "cannabis extracts" unless expressly excluded.

Without being bound to any particular theory, it is postulated that pharmaceutical preparations that have higher quantities of THC have a more excitatory effect on the central nervous system while pharmaceutical preparations that have lower quantities of THC and/or higher quantities of CBD can have a more calming effect. Selecting the optimal combination

of excitatory and calming effects can be advantageous in treating a particular sexual dysfunction.

In some embodiments, optimal results can be achieved when the pharmaceutical preparation includes at least two cannabinoid compounds that are included in amounts and/or ratios in order to address a particular condition being treated. It should be understood that *Cannabis* plants typically have dozens of cannabinoids and that the THC/CBD ratios expressed herein may work best when a substantial quantity (*e.g.*, most or all) of the minor cannabinoid compounds found in *Cannabis* plants are included. In fact, the THC/CBD ratios may, in at least some cases, be a proxy for the ratio of other cannabinoid compounds found in a particular *Cannabis* species. Thus, the term "consisting essentially of" does not exclude any of the minor cannabinoid compounds—any or all may be present—so long as they do not deactivate or so substantially alter the effects of TCH and/or CBD that it/they can no longer be recognized.

By way of illustration, it has been found that persons (men or women) suffering from lack of threshold desire, sensitivity, pleasure and/or ability to climax (arousal disorder and/or orgasmic disorder) can benefit from preparations that have a relatively higher quantity or ratio of tetrahydrocannabinol (THC) as compared to cannabidiol (CBD). Such preparations may be euphemistically called "high excitement preparations" or "amplifying preparations". Amplifying preparations may, in some cases, include THC and no CBD.

Alternatively, persons suffering from premature ejaculation (men) or who are prone to nervousness or anxiety when engaging in sexual activity (men or women) can benefit from preparations that have a relatively lower quantity or ratio of THC as compared to CBD (or

higher ratio of CBD to THC). Such preparations may be euphemistically called "calming preparations" or "stabilizing preparations". Calming preparations may, in some cases, include CBD and no THC.

In yet other cases, people who do not suffer from any particular condition but nevertheless wish to enhance sexual experience can benefit from preparations that have a balanced quantity or ratio of THC as compared to CBD. Such preparations may be euphemistically called "intermediate preparations" or "balanced preparations". Such preparations will typically include both THC and CBD.

According to several embodiments, the quantity of THC in amplifying preparations can be in a range of about 50 mg to about 500 mg per dose, or about 75 mg to about 400 mg per dose, or about 100 mg to about 300 mg per dose. To complement the THC, the quantity of CBD in amplifying preparations can be in a range of about 10 mg to about 250 mg per dose, or about 15 mg to about 200 mg per dose, or about 25 mg to about 150 mg per dose. The ratio of THC to CDB in amplifying preparations can be at least about 2:1 THC/CBD, or in a range of about 2:1 to about 25:1 THC/CBD, or about 3:1 to about 20:1 THC/CBD, or about 4:1 to about 15:1 THC/CBD.

According to several embodiments, the quantity of THC in stabilizing preparations can be in a range of about 10 mg to about 250 mg per dose, or about 15 mg to about 200 mg per dose, or about 25 mg to about 150 mg per dose. To complement the THC, the quantity of CBD in stabilizing preparations can be in a range of about 50 mg to about 500 mg per dose, or about 75 mg to about 400 mg per dose, or about 100 mg to about 300 mg per dose. The ratio of THC to CDB in stabilizing preparations can be less than or equal to about 0.5:1 THC/CBD.

Stated another way, the ratio of CBD to THC can be at least about 2:1 CBD/THC, or in a range of about 0.5:1 to about 25:1 CBD/THC, or about 3:1 to about 20:1 CBD/THC, or about 4:1 to about 15:1 CBD/THC.

According to several embodiments, the quantity of THC in balanced preparations can be in a range of about 25 mg to about 400 mg per dose, or about 50 mg to about 300 mg per dose, or about 75 mg to about 250 mg per dose. To complement the THC, the quantity of CBD in balanced preparations can be in a range of 25 mg to about 400 mg per dose, or about 50 mg to about 300 mg per dose, or about 75 mg to about 250 mg per dose. The ratio of THC to CDB in balanced preparations can be in a range of about 0.1:1 to about 10:1 THC/CBD, or about 0.25:1 to about 5:1 THC/CBD, or about 0.5:1 to about 2:1 THC/CBD.

While pharmaceutical preparations can fall within the meaning of an amplifying preparation, stabilizing preparation, or balanced preparation, it will be understood that these are merely euphemistic or arbitrary categories created for the purpose of teaching general principles regarding how to manufacture a preparation designed to treat one or more particular conditions. Nevertheless, preparations may include amounts and/or ratios of cannabinoid compounds in order to have a desired balance between excitement and stabilization. In many cases the preparations may be formulated to both excite and stabilize. The relative degrees of excitement and stabilization can be selected for a specific condition or gender.

In view of this, compositions containing THC, alone or in combination with CBD, may include THC in a range of about 10 mg to about 500 mg per dose, or about 15 mg to about 400 mg per dose, or about 25 mg to about 300 mg per dose, or about 50 mg to about 250 mg per dose, or about 75 mg to about 150 mg per dose. The amount of THC can be at least 5 mg,

7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 50 mg, 60 mg, 75 mg, or 100 mg (lower values) and up to 750 mg, 500 mg, 450 mg, 400 mg, 350 mg, 300 mg, 250 mg, 200 mg, 175 mg, 150 mg, 120 mg, or 100 mg (upper values) of THC per dose, and a ranges bounded by a lower and upper value.

Similarly, compositions containing CBD, alone or in combination with THC, may include CBD in a range of about 10 mg to about 500 mg per dose, or about 15 mg to about 400 mg per dose, or about 25 mg to about 300 mg per dose, or about 50 mg to about 250 mg per dose, or about 75 mg to about 150 mg per dose. The amount of CBD can be at least 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 50 mg, 60 mg, 75 mg, or 100 mg (lower values) and up to 750 mg, 500 mg, 450 mg, 400 mg, 350 mg, 300 mg, 250 mg, 200 mg, 175 mg, 150 mg, 120 mg, or 100 mg (upper values) of CBD per dose, and a ranges bounded by a lower and upper value.

It turns out there are different strains of *Cannabis* which include differing amounts and/or ratios of the various cannabinoid compounds. For example, *Cannabis sativa* typically has a relatively high THC/CBD ratio. Conversely, *Cannabis indica* has a relative low THC/CBD ratio compared to *Cannabis sativa* (although the absolute amount of THC can be higher in *Cannabis indica* than in *Cannabis sativa*). There are also several hybrid varieties or strains of *Cannabis sativa* and *Cannabis indica* that have intermediate amounts and/or ratios of cannabinoid compounds. The amounts and/or ratios of cannabinoid compounds can change depending on the maturity of the plant, how the plant was grown, amount of artificial or natural light, climate, nutrients, and plant parts being used. In general, the buds and leaves have the highest quantities of cannabinoid compounds, while the stems and seeds have the

lowest. In addition, the leaves, stems and seeds can have lower THC/CBD ratio than the buds of the same plant.

According to several embodiments, a single strain or variety of *Cannabis* can be used as the source of cannabinoid compounds in a given pharmaceutical preparation. By way of example, amplifying preparations can be made by extracting cannabinoid compounds from *Cannabis sativa* or hybrids of *Cannabis sativa* and *Cannabis indica* which are dominant toward *Cannabis sativa*. Conversely, stabilizing preparations can be made by extracting cannabinoid compounds from *Cannabis indica* or hybrids of *Cannabis sativa* and *Cannabis indica* which are more dominant toward *Cannabis indica*. Balanced preparations can be made by extracting cannabinoid compounds from hybrids of *Cannabis sativa* and *Cannabis indica* which are more balanced between THC and CBD (*i.e.*, there is less dominance of one over the other as compared to hybrids used to make either amplifying or stabilizing preparations).

According to other embodiments, multiple strains or varieties of *Cannabis* can be used as sources of the cannabinoid compounds in a given pharmaceutical preparation. By way of example, amplifying preparations can be made by extracting cannabinoid compounds from both *Cannabis sativa* and *Cannabis indica*, wherein the quantity of *Cannabis sativa* is substantially higher. Alternatively, amplifying preparations can be made by extracting cannabinoid compounds from *Cannabis sativa* and one or more hybrids of *Cannabis sativa* and *Cannabis indica*, such as those which are dominant toward *Cannabis sativa*. Amplifying preparations may contain plant-derived and/or synthetic THC and/or CBD.

Similarly, stabilizing preparations can be made by extracting cannabinoid compounds from both *Cannabis sativa* and *Cannabis indica*, wherein the quantity of *Cannabis indica* is

higher. Alternatively, amplifying preparations can be made by extracting cannabinoid compounds from *Cannabis indica* and one or more hybrids of *Cannabis sativa* and *Cannabis indica*, such as those which are dominant toward *Cannabis indica*. In addition, leaves, stems and seeds of *Cannabis sativa* can naturally have a lower THC/CBD than buds of the same plant. Amplifying preparations may contain plant-derived and/or synthetic CBD and/or THC.

Balanced preparations can be made by extracting cannabinoid compounds from both *Cannabis sativa* and *Cannabis indica*, wherein the quantities of *Cannabis indica* and *Cannabis indica* are similar. Alternatively, balanced preparations can be made by extracting cannabinoid compounds from hybrids of *Cannabis sativa* and *Cannabis indica*, such as one or more that is dominant toward *Cannabis sativa* and one or more that is dominant toward *Cannabis indica*. Balanced preparations may contain plant-derived and/or synthetic CBD and/or THC.

Examples of *Cannabis sativa* dominant strains include Santa Maria, AK-47, Malawi gold, Bazooka, Durban Poison, Maui Waui, Early Bud, Early Pearl, Early Skunk Plant, Great White Shark, Green Spirit, Haze, Haze Skunk, Hempstar, Jack Herer, Kali Mist, Ice, LamsBread x Skunk, Leda Uno, Malawi gold, Niagra x Shiva, Night Queen, Northern Lights x Haze, Power Plant, Purple Haze, Purple Skunk, Smokey Bear, Silver Haze, Shaman, Strawberry Cough, Sweet Island Skunk, Super Silver Haze, Swazi x Skunk, Thai, Voodoo, and White Cloud.

Examples of *Cannabis indica* dominant strains include Afghani#1, Amstel Gold, Bella Caio, Big Bud, Black Domina, Black African, Black Jack, Chitral, Celtic Cross, Celtic Stone, Chronic, DoubleGum, Early Girl, Early Skunk, Eclipse, Euforia, Green Spirit, G-13,

Granddaddy Purple, Hawaiian Skunk, Hindu Kush, Holland's Hope, Hypno, HashPlant, Jack Flash, K2, Lemon Stinky, Mango, Master Kush, Mazar, Mighty Might, Niagra, Northern Lights, Romulan, Pink Indica, Purple High, Purple Urkel, Purple Star, Ruderalis Indica, Shiva, Sour Bubble, Southern Afghani, Super Chrystal, and Twilight.

Examples of more balanced *sativa-indica* hybrid strains include Blueberry kush, Rainbow Kashmiri, Blue Velvet, Blueberry, BubbleBerry, Bubblegum, Buddha Plant, Cali Orange Plant, Durban Poison x Mighty Might, Flo, First Mature, Fourway#1, Fruity Pebbles, Full Moon, Jamaican Pearl, Juicy Fruit, GrapeFruit Haze, Himalayan Gold, Island Lady, KC-33, Kerala x Skunk, Kushage, Northern Berry, NYC Diesel, Purple#1, Purple Kush, Romberry, Shiva Shanti, Skunk Red Hair, Skunk Passion, Skunk Haze, Swiss Miss, Turtle Power, and White Widow.

The cannabinoid compounds can be extracted from one or more *Cannabis* plants using known methods, including organic solvent extraction, water extraction using hot or boiling water, mixed solvents using both an organic solvent and water, heat vaporization, fractional distillation, and the like. Depending on the method of extraction, the identifies and/or ratios of cannabinoid compounds can be altered or selected as desired. In general, extraction is able to provide a better approximation of the actual ratios of cannabinoid compounds found in a particular *Cannabis* plant as compared to combustion (*i.e.*, smoking). Combustion causes significant destruction of some of the cannabinoid compounds and can change the THC/CBD ratio.

According to several embodiments, the at least one compound that enhances sexual response ("response-enhancing component") includes one or more compounds that enhance blood flow

to the genital region. Examples of response-enhancing components include compounds that dilate blood vessels, such as compounds that increase the amount of nitric oxide (NO) in the blood. These include known pharmaceutical drugs as well as herbal supplements that have been shown to enhance sexual response and improve performance. The response-enhancing component can address ED in men and/or physical problems in women that can inhibit or delay performance, whether from a physical or psychological standpoint.

Specific examples of response-enhancing components include sildenafil (Viagra®), tadalafil (Cialis®), and vardenafil (Levitra®), which are pharmaceuticals, and their precursors and metabolites. Compositions within the scope of the invention may include a pharmaceutically acceptable dose of one or more of the foregoing. A pharmaceutically acceptable dose may depend on the gender, weight and/or age of the recipient and will be within known guidelines for these well-known compounds.

Herbal supplements can also increase NO levels in the blood to enhance sexual response and improve performance. They include at least 500 mg, 1 g, 1.5 g, 2 g, 2.5 g, 3 g, 4 g, 5 g, or 6 g and up to 20 g, 15 g, 12 g, 10 g, 9 g, or 8 g, or any range between lower and upper values of: L-arginine, L-citrulline, yahimbe root, ginseng (*e.g.*, Korean red ginsing), ginkgo biloba, horny goat weed, goosefoot, Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, and/or damiana. Compositions within the scope of the invention may include a pharmaceutically acceptable dose (or dose that is effective to raise blood NO levels) of one or more of the foregoing in order to enhance sexual response and improve performance. A pharmaceutically acceptable (or effective) dose may depend on the gender, weight and/or age of the recipient and will be within known guidelines for these compounds and compositions.

Others herbal supplemental are sold under various tradenames and include Zytenz, Vydexafil, Oxysurge, Testosyn, KOR Test Booster, Virility Ex, Natural Gain Plus, ExtenZe, Alpha T1, Happy Endings, Libido Boost Plus, Virectin, Male Extra, Climadex, Vendexafil Ultra, TestoRev, Magnum Pump XR, VigRX Plus, Ageless Male, Nugenix, Vigorplex®, Libidus, Maxidus, Xzen XPress, Xzen Gold, Xzen Platinum, Xzen 1200, Vydexafil, AI Sports Perform, VitalKoR, Athletic Edge APE, Axcite Magnum, VirMax, Virilis Pro, Virility-X, XZone, Reload, Mojo Risen, Zoom-Zooma-Zoom, Love Rider, Ninja Mojo, Mojo Nights, EreXite, VMaxx Rx, Firminite, ZenMaxx, Black Ant, RigiRx Plus, France T253, ViaXtreme, Man Up, Herbal Vigor Quick Fix, Miraculous Evil Root, Zhen Gong Fu, GoldReallas, Liu Bian Li, MV5 Days, S.W.A.G., Weekend Warrior, Bali Mojo, Vimax, Tiger King, Alpha Male, Vitalikor Fast Acting, MVP Mega, MaxTreme Zen, Vicerex, Affirm XL, Kaboom Action Strips, and X-Rock. Compositions within the scope of the invention may include a pharmaceutically acceptable dose (or dose that is effective to raise blood NO levels) of one or more of the foregoing in order to enhance sexual response and improve performance. A pharmaceutically acceptable (or effective) dose may depend on the gender, weight and/or age of the recipient and will be within known guidelines for these compounds and compositions.

The amount of the foregoing compounds or compositions can vary depending on the potency and mode of action. In general, such compounds or compositions enable men to achieve and maintain an erection by increasing blood flow to the genital region, such as by causing the body to produce nitric oxide. For reasons that may not be well-understood, they also aid women when combined with one or more cannabinoid compounds as disclosed herein, which is surprising and unexpected since they typically have no effect on women when used alone.

While enabling sexual activity can, by itself, increase sexual pleasure, response-enhancing components do not enhance sexual pleasure *per se* (*e.g.*, in a perfectly healthy man who does not suffer from erectile dysfunction, the use of response-enhancing drugs may not significantly affect the pleasure of the sexual act, including climax). They may simply provide the fun and novelty of longer-lasting and/or quicker threshold erections. Similarly, while cannabinoids can make a person "high" and therefore more relaxed and uninhibited, they are also known to diminish sexual response and performance, particularly in men. In some cases, they can prevent achieving or maintaining an erection. In other cases, they can unnecessarily prolong or prevent climax. Unexpectedly, however, it has now been found that combining one or more response-enhancing components with one or more pleasure-enhancing components optimizes the beneficial effects of both while offsetting or eliminating the negative effects. This greatly enhances the overall sexual experience.

Even more unexpectedly, combining one or more response-enhancing components with one or more pleasure-enhancing components can provide the elusive aphrodisiac (or "Spanish fly") that has been the subject of myth and lore but not actually achieved in reality. Unlike men, in which sexual activity is predominately (and logistically) physical and secondarily psychological, women can technically engage in sexual activity whether or not they care to or are aroused. As such, sexual pleasure is more complicated in women and is as much or more psychological as it is physical. For this reason, in both humans and animals, sexual activity is typically initiated by males rather than females. The pharmaceutical preparations disclosed herein can shift this balance and give women more initial threshold desire as well as actual sexual pleasure, which inure to the benefit of both women and their sexual partners. Without being bound to any particular theory, it is postulated that increasing blood flow to the genital region of women, while not itself having been proven to increase sexual pleasure or sexual

response, increases the effects of the cannabinoid compounds, both physically and psychologically so that, when used together, they synergistically act together to provide increased sexual pleasure and response as compared to when using either alone.

The pharmaceutical preparations can have a variety of different modes of delivery, which can be gender-specific or otherwise tailored for the specific needs or desires of the patient. According to an embodiment, the pharmaceutical preparation can be designed as a topical (external or internal, including body cavity, but excluding oral and nasal), *e.g.*, massage oils, lotions, gels, creams, lubricants, genital sprays, vaginal patch, vaginal suppository, or anal suppository. Alternatively or in addition, they can be formulated for ingestion, *e.g.*, capsules, tablets, oral drops, lozenges, lollipops, and food preparations, *i.e.*, "edibles" (aka ingestible, in contrast to sublingual or buccal absorption), such as brownies, cookies, chocolates, chews, gum drops, soft candies, hard candies, liquid shots, and the like). Alternatively, they can be formulated for inhalation into the lungs (*e.g.*, by a heat vaporizer ("vape") or nebulizer).

Capsules include any delivery form that includes an outer covering enclosing the actives. The outer covering can be any suitable material known in the art, such as gelatin, starch, cellulose ether, gum, protein, or polysaccharide. Tablets include actives compressed into a solid form, sometimes with a binder or inert component. While many capsules and tablets are configured to be swallowed whole, they may also be divided into pieces and swallowed, in some cases chewed and swallowed, sometimes crushed by the teeth to release a liquid, gel or solid that is swallowed. Some tablets or capsules can be used vaginally or anally as suppositories. Or they may be used buccally or sublingually.

A "solid ingestible" includes dosage forms that can be swallowed with no or minimal chewing (*e.g.*, some types of capsules and tablets); dosage forms that are chewed and swallowed, such as food preparations and other edibles (*e.g.*, brownies, cookies, desserts, chocolates, chews, gum drops, soft candies, and some types of capsules and tablets); dosage forms that dissolve in the mouth and are swallowed (*e.g.*, hard candies, lollipops, lozenges, some types of capsules and tablets). A characteristic of a solid ingestible is that the active is intended to be absorbed in the stomach, gut and/or small intestine, as opposed to being primarily absorbed buccally or sublingually.

A "liquid ingestible" includes a liquid or gel that can be swallowed with little or no chewing. A characteristic of a solid ingestible is that the active is intended to be absorbed in the stomach, gut and/or small intestine, as opposed to being primarily absorbed buccally or sublingually. A liquid ingestible can be a shot, a drink, gel pack, oral drops, and the like.

"Dual delivery" compositions can be applied and absorbed in more than one way. Examples include flavored body oils, creams, lotions, liquids, gels, and lubricants, which can be placed on areas of the body where they can be readily absorbed, such as on the skin, especially on or in the genital region, anal region, or armpits of a man or woman, and optionally licked or ingested by the other partner during application and sex play. In some cases, a composition can be placed on or in the genital (or anal) region of one partner and transferred to the genital (or anal) region of the other partner during sex play and intercourse. Such compositions can be placed on or in sex toys, vibrators, dildos, condoms, other prophylactic devices, props, and the like.

In general, extraction of cannabinoids and then delivery without combustion provides superior results compared to smoking weed and ingesting an ED drug. Combustion destroys a significant quantity of cannabinoid compounds and can change their ratios, which makes proper dosing difficult. Smoking weed and ingesting an ED drug also suffers from the inability to control the timing of each, since smoking causes almost instantaneous high while ingesting an ED drug takes time for the body to metabolize. The result can be premature cannabinoid effect, with delayed blood-flow increasing effect coupled with reduced cannabinoid effect when it is desirable for both to be maximized. Delivering both the pleasure-enhancing and performance-enhancing components in a single preparation and/or in the same manner can better control dosing and timing.

Where it is desired to inhale a cannabinoid infused material, such as a liquid, gel or paste, vaporizing apparatus known in the art for delivering nicotine can be used. The concentration of cannabinoids in the vape juice or oil can be adjusted, similar to how it is done when delivering nicotine using a vape stick, hookah, or mod box, so that a predetermined number of puffs will deliver a predetermined amount of the one or more cannabinoids of interest.

Nebulizers known in the art used in hospitals, for hospice or for home care can be used to deliver a predetermined amount of cannabinoids.

In addition to the cannabinoids, the other active for increasing blood flow can be delivered by any suitable means to provide a predetermined quantity of the active. These include oral ingestion, topical delivery, and inhalation, although oral ingestion by capsule or table is currently the most prescribed delivery method.

EXAMPLES

For purposes of the following examples, sexual pleasure and sexual response are assigned a value on a scale of 1 to 10, with 1 being the lowest and 10 being the highest. Three categories in men were measured: hardness of erection on a scale of 1 to 10; sensitivity on a scale of 1 to 10; and strength of orgasm on a scale of 1 to 10. Three categories in women are measured: threshold desire on a scale of 1 to 10; sensitivity on a scale of 1 to 10; and strength of orgasm on a scale of 1 to 10.

EXAMPLE 1A

The subject was a 41 year old male. The marijuana strain used to provide the cannabinoid compounds was AK-47 hybrid strain. The cannabinoid compounds from marijuana were delivered orally usable an edible. Marijuana plant parts (mostly leaves and buds) were ground up and simmered in vegetable oil for 3 hours to extract cannabinoid compounds (primarily THC and CBD) and then strained. The cannabinoid infused oil was assumed to contain roughly the same ratio of THC to CBD in the plant parts (as well as other cannabinoids in the plant parts). The minor cannabinoids did not negate or substantially alter the predominating effects of the THC and CBD.

The infused oil was used in place of the oil called for in normal preparation of brownies per instructions. The cannabinoid infused oil was blended in an amount of 1/4 ounce per 18 ounce fudge brownie mix. Brownies containing the extracted cannabinoid compounds were prepared from the mixed batter by placing into a small cake pan (6 in^2) and baked in the over according to instructions. A small pan of brownies was cut up into 3 inch squares.

The subject ingested two brownies and one XZEN pill. [Note: it was later discovered that XZEN used in this and other examples herein may have been tainted with a pharmaceutical, such as sildenafil, tadalafil, or vardenafil, or biosimilar compound, because it was pulled from the market and modified.] The subject started noticing the effects of both after about 1 hour and commenced sexual activity with a female partner shortly thereafter. The subject was able to obtain and maintain a hard erection and sensitivity and pleasure during sex were increased. The subject was able to last longer than usual and, in this case, sex lasted about 30 minutes. At the culmination, ejaculation was very intense. The statistics were (on a scale of 1 to 10): hardness of erection: 9; sensitivity: 8; strength of orgasm: 10.

EXAMPLE 1B

The female partner in Example 1A weighed less than the male subject in Example 1A and ingested one cannabinoid infused brownie square and also experienced heightened sensitivity (8) and pleasure during the sexual activity, which was attributed to reduced anxiety and inhibition and increased threshold desire. The female did not ingest any blood flow enhancements. It is postulated that the female partner would further benefit from combining ingestion of the cannabinoid edible with a component that increases blood flow to the female genital region in order to increase threshold desire (*e.g.*, 8 as a result of swelling and thickening of the clitoris and labia), as well as more intense orgasm (*e.g.*, 8) as a result of the combined psychological and physiological effects of ingesting both the pleasure-enhancing and performance-enhancing component.

EXAMPLE 1C

The female partner ingests the cannabinoid edible with a component that increases blood flow to the female genital region. The combination increases threshold desire (*e.g.*, 8 as a result of swelling and thickening of the clitoris and labia), as well as more intense orgasm (*e.g.*, 8) as a result of the combined psychological and physiological effects of ingesting both the pleasure-enhancing and performance-enhancing component.

EXAMPLE 2A

The subject was a 70 year old male. The marijuana strain used to provide the cannabinoid compounds was AK-47. The cannabinoid compounds were extracted by simmering 1/4 ounce of marijuana in 1 cup avocado oil to make butter. The subject spread approximately 1 tablespoon of the butter onto toast and then ingested the toast and one XZEN pill on an empty stomach. After 45 minutes the subject felt some flushing and effects of the cannabinoid compounds.

After one hour the subject had a hard erection and proceeded to have sex with a female partner of similar age. The sex lasted an amazing 2 hours and the subject was able to ejaculate 5 times within that time span, which would be remarkable for a young man, but in this case the subject was a 70 year old man. The statistics were (on a scale of 1 to 10): hardness of erection: 10; sensitivity: 9; strength of orgasm: 9. This example exemplifies the benefit to an older man of using cannabinoids with a higher ratio of THC:CBD (at least 2:1). The subject's opinion was that the sex was like being a young man all over again ("21

again"), and his overall mood in general improved dramatically (demeanor and disposition), which was another unexpected benefit.

The female partner in Example 2A did not ingest any enhancements. However, it is postulated that the female partner would benefit from ingesting the preparations disclosed herein and experience increased threshold desire (8), heightened sensitivity and pleasure (8), and more powerful orgasm (8).

EXAMPLE 2B

This example is repeated but with the man ingesting Viagra® instead of XZEN with similar results. The example is modified by substituting Viagra® or XZEN with any other known male enhancement, such as Cialis®, Levitra®, L-arginine, horny goat weed, and the like.

EXAMPLE 3A

The subject was a 41 year old male. The marijuana strain used to provide the cannabinoid compounds was Blueberry Kush. The cannabinoid compounds were delivered orally using an edible. The marijuana plant parts (mostly leaves and buds) were ground up and simmered in vegetable oil for 3 hours to extract cannabinoid compounds and then strained. The cannabinoid infused oil was assumed to contain roughly the same ratio of THC to CBD in the plant parts (as well as other cannabinoids in the plant parts). The minor cannabinoids did not negate or substantially alter the predominating effects of the THC and CBD.

The infused oil was used in place of the oil called for in normal preparation of brownies per instructions. The cannabinoid infused oil was blended in an amount of 1/4 ounce per 18 ounce fudge brownie mix. Brownies containing the extracted cannabinoid compounds were prepared from the mixed batter by placing into a small cake pan (6 in^2) and baked in the over according to instructions. A small pan of brownies was cut up into 3 inch squares.

The subject ingested two brownies and one XZen pill. The subject started noticing the effects of both after about 1 hour and commenced sexual activity shortly thereafter. The subject was able to maintain a hard erection and sensitivity was increased. The subject was able to last longer and sex lasted about 45 minutes with a female partner. Ejaculation was very intense. The subject was thereafter able to achieve another erection after 30 minutes and commenced sexual activity again, which lasted about 30 minutes, and able to achieve a second orgasm. The statistics were (on a scale of 1 to 10): hardness of erection: 9; sensitivity: 8; strength of orgasm: 9. This example, as compared to Examples 1 and 2, demonstrates the beneficial effects for a relatively young, healthy man when using a cannabinoid having a more balanced ratio of THC to CBD (which was closer to 1:1 than in Example 1 and possibly less 1:1), relative to the ability to last longer.

EXAMPLE 3B

The female partner in Example 3A ingested one cannabinoid infused brownie square and also experienced heightened sensitivity and pleasure (8) during the sexual activity, which was attributed to reduced anxiety and inhibition and increased threshold desire. The female did not ingest any blood flow enhancements. It is postulated that the female partner would further benefit from combining ingestion of the cannabinoid edible with a component that increases

blood flow to the female genital region in order to increase threshold desire (*e.g.*, 8 as a result of swelling and thickening of the clitoris and labia), as well as more intense orgasm (8) as a result of the combined psychological and physiological effects of ingesting both the pleasure-enhancing and performance-enhancing component.

EXAMPLE 4A

The subject was a 70 year old male. The marijuana strain used to provide the cannabinoid compounds was Blueberry Kush. The cannabinoid compounds were extracted by simmering 1/4 ounce of marijuana in 1 cup avocado oil to make butter. The subject spread approximately 1 tablespoon of the butter onto toast and then ingested the toast and one XZEN pill on an empty stomach. After 45 minutes the subject felt some flushing and effects of the cannabinoid compounds.

After one hour the subject had a hard erection and proceeded to have sex with a female partner of similar age. The sex lasted 2 hours and the subject was able to ejaculate 3 times within that time span. The statistics were (on a scale of 1 to 10): hardness of erection: 10; sensitivity: 9; strength of orgasm: 9. This example demonstrated that while a clear benefit was obtained by the subject ingesting a balanced ratio of THC:CBD, the results were not quite as dramatic as Example 2, in which the subject ingested a higher ratio of THC:CBD and was able to achieve 5 orgasms instead of 3.

The female partner did not ingest any enhancements. However, it is postulated that the female partner would benefit from ingesting the preparations disclosed herein and experience

increased threshold desire (8), heightened sensitivity and pleasure (8), and more powerful orgasm (8).

EXAMPLE 5

A 50 year old male ingested a single brownie prepared according to Example 3 and one XZen pill. The subject felt the effects of both components and was able to achieve an erection more quickly and maintain it longer. The subject engaged in sexual activities with a female partner within about 1-2 hours of ingestion lasting about 30 minutes. The subject had an erection of about an 8, heightened sensitivity of about 8; and a more intense orgasm of about 8. It is postulated that the male subject might have benefitted more using the higher THC:CBD preparation and/or ingesting an increased quantity of the edible.

The female partner did not ingest any enhancements. However, it is postulated that the female partner would benefit from ingesting the preparations disclosed herein and experience increased threshold desire (8), heightened sensitivity and pleasure (8), and more powerful orgasm (8).

EXAMPLE 6

The subject is a 22 year old male who is provided with an infused edible made according to any of the foregoing Examples. The subject is strong and virile but prone to premature ejaculation. The subject ingests the infused edible together with a component that increases blood flow to the genital region (*e.g.*, XZen or part of a Viagra®). After 20-30 minutes the subject has a hard erection and proceeds to have sex with a partner. When using an edible

with high THC:CBD ratio, the sex is brief (about 1-3 minutes) but intense. The statistics are (on a scale of 1 to 10): hardness of erection: 10; sensitivity: 8; strength of orgasm: 8.

Alternatively, the subject ingests a cannabinoid infused edible having a higher ratio of CBD:THC and experiences the same quality of erection, sensitivity, and strength of orgasm but is able to last much longer than usual (*e.g.*, 15-45 minutes), which greatly boosts the subject's confidence when engaging in sexual activities with others. Due to the subject's age, he is able to achieve multiple orgasms with fast or immediate recovery between ejaculations.

This example demonstrates that, while a clear benefit is obtained by the subject ingesting a high ratio of THC:CBD, the results are objectively much better when the subject ingests a much lower ratio of THC:CBD (or higher ratio of CBD:THC). It is postulated that a more balanced ratio of THC:CBD would provide an intermediate benefit between the extremes described herein.

EXAMPLE 7

The subject is a 21 year old female who is provided with an infused edible made according to any of the foregoing Examples. The subject is healthy but inexperienced and nervous when engaging in sexual activity, which decreases threshold desire, pleasure and fulfillment, and makes it difficult or impossible for the subject to achieve orgasm. The subject ingests the infused edible together with a component that increases blood flow to the genital region (*e.g.*, XZen for Women or part of a Viagra®). After about 1 hour the subject feels flushing and the effects of the cannabinoid compounds and the blood flow enhancer, including increased swelling of the vulva and nipples which, although largely physiological, combine with the

enhanced psychological effects of excitement and decreased anxiety provided by the infused edible to increase threshold desire (*e.g.*, 9).

When the subject ingests an edible containing a high THC:CBD ratio, the subject may be more physically aggressive but might still have difficulty achieving orgasm regularly. It is postulated that a higher CBD:THC ratio would provide a calming effect that permits deeper psychological appreciation and enjoyment of sexual activity, leading to more reliable and fulfilling orgasms. Depending on the woman, an intermediate TCD:CBD ratio may be sufficiently calming, yet more excitatory so as to promote quicker and/or multiple orgasms.

EXAMPLE 8

A 25 year old female subject is provided with an infused edible made according to any of the foregoing Examples. The subject ingests the infused edible together with a component that increases blood flow to the genital region (*e.g.*, XZen for Women or part of a Viagra®). After about 1 hour the subject feels flushing and the effects of the cannabinoid compounds, including increased swelling of the vulva and nipples which, although largely physiological, combine with the enhanced psychological effects of excitement and decreased anxiety provided by the infused edible to increase threshold desire.

After one hour the subject commences sexual activity with a 41 year old male partner. The subject experiences heightened sensitivity (9) and pleasure and is able to climax more quickly and more powerfully (9) than usual. Depending on the endurance of her male sex partner, the female subject is able to achieve multiple orgasms as a result of the increased physiological and psychological awareness and sensitivities provided by the combined use of pleasure-

enhancing and performance-enhancing components. Because of the female subject's age (25) and sexual confidence, it is postulated that the subject would, like the 41 year old subject of Examples 1 and 3, benefit from an edible having a balanced THC:CBD ratio.

EXAMPLE 9

A 68 year old female subject of normal sexual experience and activity for her age is provided with an infused edible made according to any of the foregoing Examples. The subject ingests the infused edible together with a component that increases blood flow to the genital region (*e.g.*, XZen for Women or part of a Viagra®). After about 1 hour the subject feels flushing and the effects of the cannabinoid compounds and blood flow enhancer, including increased swelling of the vulva and nipples which, although largely physiological, combine with the enhanced psychological effects of excitement and decreased anxiety provided by the infused edible to increase threshold desire.

After one hour the subject commences sexual activity with a male partner of similar age. The subject experiences high threshold desire (7), heightened sensitivity (9) and is able to climax more quickly and more powerfully (9) than usual. Depending on the endurance of her male sex partner, the female subject is able to achieve multiple orgasms as a result of the increased physiological and psychological awareness and sensitivities provided by the combined use of pleasure-enhancing and performance-enhancing components. Because of the female subject's age (68), it is postulated that the subject would, like the 70 year old subject of Examples 2 and 4, benefit more from an edible having a higher THC:CBD ratio.

EXAMPLE 10

A 45 year old female subject is provided with an infused edible made according to any of the foregoing Examples. The subject ingests the infused edible together with a component that increases blood flow to the genital region (*e.g.*, XZen for Women or part of a Viagra®). After about 1 hour the subject feels flushing and the effects of the cannabinoid compounds and blood flow enhancer, including increased swelling of the vulva and nipples which, although largely physiological, combine with the enhanced psychological effects of excitement and decreased anxiety provided by the infused edible to increase threshold desire (9).

After one hour the subject commences sexual activity with a male partner of similar age. The subject experiences heightened sensitivity (9) and pleasure and is able to climax more quickly and more powerfully (9) than usual. Depending on the endurance of her male sex partner, the female subject is able to achieve multiple orgasms as a result of the increased physiological and psychological awareness and sensitivities provided by the combined use of pleasure-enhancing and performance-enhancing components. Because of the female subject's age (45), it is postulated that the subject would, like the 50 year old subject of Example 5, benefit more from an edible having a higher THC:CBD ratio and/or ingesting a higher quantity of edible having a balanced THC:CBD ratio.

EXAMPLE 11

A 70 year old female subject who rarely engages in sexual activity because of lost desire and pleasure is provided with an infused edible made according to any of the foregoing Examples. The subject ingests the infused edible together with a component that increases

blood flow to the genital region (*e.g.*, XZen for Women or part of a Viagra®). After about 1 hour the subject feels flushing and the effects of the cannabinoid compounds and blood flow enhancer, including increased swelling of the vulva and nipples which, although largely physiological, combine with the enhanced psychological effects of excitement and decreased anxiety provided by the infused edible to increase threshold desire (7 or 8).

After one hour the subject commences sexual activity with a male partner of similar age. The subject experiences heightened sensitivity (7 or 8) and pleasure and is able to achieve climax (6 or 7), perhaps for the first time in a long time or ever. Depending on the endurance of her male sex partner, the female subject is able to achieve multiple orgasms as a result of the increased physiological and psychological awareness and sensitivities provided by the combined use of pleasure-enhancing and performance-enhancing components. Because of the female subject's age (70), it is postulated that the subject might, like the 70 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.

CLAIMS

1. A pharmaceutical composition for treating sexual dysfunction in a human, comprising one or more dosage forms configured to deliver:

a cannabinoid component comprised of at least one of 5 mg to 500 mg of tetrahydrocannabinol (THC) or 5 mg to 500 mg of cannabidiol (CBD); and

a therapeutically effective amount of a sexual response enhancing component selected from the group consisting of sildenafil, tadalafil, and vardenafil.

2. The pharmaceutical composition of claim 1, wherein the one or more dosage forms comprise a tablet, capsule, or suppository.

3. An ingestible dosage form for enhancing sexual response and sensitivity in a human, comprising:

an ingestible cannabinoid component comprising at least one of 5 mg to 500 mg of tetrahydrocannabinol (THC) or 5 mg to 500 mg of cannabidiol (CBD); and

a tablet or capsule that contains a sexual response enhancing component selected from a therapeutically effective amount of sildenafil, tadalafil, or vardenafil and/or at least 1 g, such as at least 2 g, of an herbal supplement comprising one or more of L-arginine, L-citrulline, yahimbe root, ginseng (*e.g.*, Korean red ginsing), ginkgo biloba, horny goat weed, goosefoot,

Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, and/or damiana.

4. The ingestible dosage form of claim 3, wherein the ingestible cannabinoid component is selected from the group consisting of tablet, capsule, oral drops, lozenges, lollipops, food preparations, such as brownies, cookies, or chocolates, chews, gum drops, soft candies, hard candies, and liquid shots.

5. A composition for enhancing sexual response and sensitivity in a human, comprising:

a topical cannabinoid dosage form comprising at least one 5 mg to 500 mg of tetrahydrocannabinol (THC) or 5 mg to about 500 mg of cannabidiol (CBD); and

a tablet or capsule that contains a sexual response enhancing component selected from a therapeutically effective amount of sildenafil, tadalafil, or vardenafil in and/or at least 1 g, such as at least 2 g, of an herbal supplement comprising one or more of L-arginine, L-citrulline, yahimbe root, ginseng (*e.g.*, Korean red ginsing), ginkgo biloba, horny goat weed, goosefoot, Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, and/or damiana.

6. The composition of claim 5, wherein the topical cannabinoid dosage form is selected from the group consisting of massage oils, lotions, gels, creams, lubricants, genital sprays, vaginal patch, vaginal suppository, and anal suppository.

7. A composition for enhancing sexual response and sensitivity in a human, comprising:

a vaporizable and inhalable cannabinoid dosage form configured to provide at least one of a dose of 5 mg to 500 mg of tetrahydrocannabinol (THC) or a dose of 5 mg to 500 mg of cannabidiol (CBD); and

a tablet, capsule, or topical dosage form that contains a sexual response enhancing component selected from a therapeutically effective amount of sildenafil, tadalafil, or vardenafil in and/or at least 1 g, such as at least 2 g, of an herbal supplement comprising one or more of L-arginine, L-citrulline, yahimbe root, ginseng (*e.g.*, Korean red ginsing), ginkgo biloba, horny goat weed, goosefoot, Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, and/or damiana.

8. The composition of claim 7, wherein the vaporizable and inhalable cannabinoid dosage form is formulated for vaporization and inhalation using a heat vaporizer or a nebulizer.

9. A composition for treating sexual dysfunction and/or enhancing sexual response and sensitivity in a human, comprising:

a cannabinoid configured to be administered by ingestion, inhalation, or topically, the cannabinoid comprising at least one of tetrahydrocannabinol (THC) or cannabidiol (CBD); and

a sexual response component configured to be administered by ingestion and including an effective amount of a sexual response component selected from the group consisting of sildenafil, tadalafil, vardenafil, herbal supplement, and combinations thereof.

10. The composition of claim 9, wherein the cannabinoid comprises 5-500 mg, or 7.5-450 mg, or 10-400 mg, or 15-350 mg, or 20-300 mg, or 25-250 mg of THC and/or 5-500 mg, or 7.5-450 mg, or 10-400 mg, or 15-350 mg, or 20-300 mg, or 25-250 mg of CBD.

11. The composition of claim 9 or 10 at least one of claims 19 to 22, wherein the cannabinoid is configured to be administered as an infused edible, oral drop, liquid shot, capsule, or tablet.

12. The composition of claim 9 or 10, wherein the cannabinoid is configured to be administered by inhalation of a heat vaporized cannabis extract.

13. The composition of claim 9 or 10, wherein the cannabinoid is administered topically as an oil, lotion, gel, cream, lubricant, genital spray, vaginal patch, vaginal suppository, or anal suppository.

14. The composition of any one of claims 9 to 13, wherein the sexual response component is an herbal supplement selected from the group consisting of L-arginine, L-citrulline, yahimbe root, ginseng (*e.g.*, Korean red ginsing), ginkgo biloba, horny goat weed, goosefoot, Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, damiana, and combinations thereof.

15. A composition for treating sexual dysfunction and/or enhancing sexual response and sensitivity in a human, comprising:

a tablet or capsule comprising at least one of tetrahydrocannabinol (THC) or cannabidiol (CBD); and

a tablet or capsule comprising an effective amount of a sexual response component selected from the group consisting of sildenafil, tadalafil, vardenafil, L-arginine, herbal supplement, and combinations thereof.

ABSTRACT

COMPOSITIONS AND METHODS FOR TREATING SEXUAL DYSFUNCTION AND ENHANCING SEXUAL RESPONSE AND PLEASURE

Pharmaceutical preparations include at least one component that enhances sexual response and at least one other compound that enhances sexual sensitivity and pleasure. The component that enhances sexual response enhances blood flow to the genital region. Examples include compounds that dilate blood vessels, such as compounds that increase the amount of nitric oxide (NO) in the blood. The component that enhances sexual sensitivity and pleasure includes one or more cannabinoid compounds from the plant genus *Cannabis*, including extracted compounds, synthetic forms, and derivatives thereof. Examples include tetrahydrocannabinol (THC), the main psychoactive constituent of *Cannabis*, and cannabidiol (CBD), which is less or non-psychoactive and modulates THC activity. The ratio of THC/CBD can be selected depending on age, gender, physical health, and/or psychological condition of the user.

ASSIGNMENT

WHEREAS, Assignor, ILYSM, LLC, a limited liability company organized and existing under the laws of the State of Utah, with a principal place of business at 6591 South Cottonwood Street, Murray, Utah 84107, is the assignee of record of the entire right, title and interest in and to the following patent applications and the inventions disclosed therein:

United States Patent Application No. 16/056,726, filed August 7, 2018
United States Patent Application No. 16/170,446, filed October 25, 2018
International Patent Application No. PCT/US2018/0597, filed November 17, 2018; and
Canadian Patent Application No. 3,049,874, filed July 19, 2019.

WHEREAS, Assignor, ILYSM, LLC wishes to assign the entire right, title, and interest in and to the said patent applications and the inventions disclosed therein to ILYLT, LLC, a limited liability company organized and existing under the laws of Utah and having a principal place of business at 6591 South Cottonwood Street, Murray, Utah 84107.

WHEREAS, Assignee, ILYLT, LLC, desires to secure the entire right, title, and interest in and to said patent applications and the inventions disclosed therein.

NOW THEREFORE, in exchange for good and valuable consideration paid to Assignor by Assignee, the receipt and sufficiency of which is hereby acknowledged,

ASSIGNOR HEREBY ASSIGNS TO ASSIGNEE:

The entire right, title, and interest in and to said patent applications and the inventions disclosed therein, and in all divisions, continuations and continuations-in-part thereof, and in any reissues or extensions of Letters Patent or Patents granted thereon, and in all corresponding applications which may be filed in the United States and countries foreign to the United States, and in all patents issuing thereon in the United States and foreign countries, as well as the right to sue for past infringement and damages under any and all such patents.

The right to file foreign patent applications on said invention in its own name, wherever such right may be legally exercised, including the right to claim the benefits of the International convention for such applications.

Assignor hereby authorizes and requests the United States Commissioner of Patents and Trademarks and such Patent Office officials in foreign countries as are duly authorized by their patent laws to issue patents to issue any and all patents on said invention to the Assignee as the

owner of the entire interest, for the sole use of Assignee, its successors, assigns, and legal representatives.

Assignor hereby agrees, without further consideration and without expense, to sign all lawful papers and to perform all other lawful acts which Assignee may request of Assignor to make this Assignment fully effective, including, by way of example but not of limitation, the following:

Prompt execution of all original, divisional, substitute, reissue and other United States and foreign patent applications on the invention, and all lawful documents requested by Assignee to further the prosecution of any of such patent applications.

Cooperation to the best of Assignor's ability in the execution of all lawful documents, the production of evidence, nullification, reissue, extension or infringement proceedings involving the invention.

DATED Jan. 22, 2021

ASSIGNOR
ILYSM, LLC

By: _____
Dennis M. Jenn
Manager and Member

By: _____
John M. Guynn
Manager and Member

ACCEPTED Jan. 22, 2021

ASSIGNEE
ILYLT, LLC

By: _____
Dennis M. Jenn
Manager and Member

By: _____
John M. Guynn
Manager and Member

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059712

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61K 31/352; A61K 31/05; A61K 36/185; A61P 15/00 (2018.01)
CPC - A61K 31/352; A61K 31/05; A61K 36/185 (2018.08)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 424/725; 514/453; 514/454 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/0161284 A1 (CAPRIO) 14 June 2018 (14.06.2018) entire document	1, 2, 11, 12, 14-16, 19-21, 31-36
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Y		3, 13, 17, 18
Y	US 2014/0287068 A1 (BIOTECH INSTITUTE LLC) 25 September 2014 (25.09.2014) entire document	3, 13, 17, 18
P, X	US 10,064,905 B1 (ILYSM LLC) 04 September 2018 (04.09.2018) entire document	1-3, 11-21, 31-36

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 December 2018	16 JAN 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

PI 2021000684

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059712

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-10, 22-30
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Verified

By: kplatt On: 18 Jan 2019

DOCKETED

Atty JMG File# 15257.20B
By DAnderson On 18 Jan 2019
Action Article 19 Amendments
Response Due 12/7/19
Submit IDR

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: JOHN M. GUYNN
WORKMAN NYDEGGER
60 EAST SOUTH TEMPLE
SUITE 1000
SALT LAKE CTIY, UT 84111

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 16 JAN 2019
Applicant's or agent's file reference 15257-20B	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US2018/059712	International filing date *(day/month/year)* 07 November 2018
Applicant ILYSM, LLC	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau of WIPO preferably through ePCT or on paper to, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 Telephone No. PCT OSP: 571-272-7774

Form PCT/ISA/220 (July 2017)

PI 20210006 84-

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 15257-20B	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2018/059712	International filing date *(day/month/year)* 07 November 2018	(Earliest) Priority Date *(day/month/year)* 07 August 2018
Applicant ILYSM, LLC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the language, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed.
      ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
   b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,
   a. the figure of the drawings to be published with the abstract is Figure No. _____
      ☐ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059712

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-10, 22-30
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059712

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61K 31/352; A61K 31/05; A61K 36/185; A61P 15/00 (2018.01)
CPC - A61K 31/352; A61K 31/05; A61K 36/185 (2018.08)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 424/725; 514/453; 514/454 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/0161284 A1 (CAPRIO) 14 June 2018 (14.06.2018) entire document	1, 2, 11, 12, 14-16, 19-21, 31-36
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Y		3, 13, 17, 18
Y	US 2014/0287068 A1 (BIOTECH INSTITUTE LLC) 25 September 2014 (25.09.2014) entire document	3, 13, 17, 18
P, X	US 10,064,905 B1 (ILYSM LLC) 04 September 2018 (04.09.2018) entire document	1-3, 11-21, 31-36

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 December 2018	16 JAN 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

Verified

By: kplatt On: 18 Jan 2019

DOCKETED

Atty JMG File# 15257.20B

By DAnderson On 18 Jan 2019

Action Written Opinion

Response Due 3/16/19

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: JOHN M. GUYNN
WORKMAN NYDEGGER
60 EAST SOUTH TEMPLE
SUITE 1000
SALT LAKE CTIY, UT 84111

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	16 JAN 2019
Applicant's or agent's file reference 15257-20B	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2018/059712	07 November 2018	07 August 2018

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61K 31/352; A61K 31/05; A61K 36/185; A61P 15/00 (2018.01)
CPC - A61K 31/352; A61K 31/05; A61K 36/185 (2018.08)

Applicant ILYSM, LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	20 December 2018	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (January 2015)

PI 2021000684-

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2018/059712

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 4-10, 22-30

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 4-10, 22-30 are so unclear that no meaningful opinion could be formed *(specify)*:

Claim 4-10 and 22-30 are multiple dependent claims not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claims Nos. 4-10, 22-30

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2018/059712

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	3, 13, 17, 18	YES
	Claims	1, 2, 11, 12, 14-16, 19-21, 31-36	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-3, 11-21, 31-36	NO
Industrial applicability (IA)	Claims	1-3, 11-21, 31-36	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 2, 11, 12, 14-16, 19-21, and 31-36 lack novelty under PCT Article 33(2) as being anticipated by Caprio.

Regarding Claim 1, Caprio discloses a pharmaceutical composition for treating sexual dysfunction (Abstract, compositions for the treatment of erectile dysfunction) in a human (Para. [0017], "subject" includes...human), comprising one or more dosage forms configured to deliver (Para. [0023], administration...components of the composition are supplied either separately or mixed together in unit dosage form): a cannabinoid component comprised of at least one of 5 mg to 500 mg of tetrahydrocannabinol (THC) (Paras. [0005]-[0008], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg...In some embodiments, the cannabis extract comprises cannabinoid tetrahydrocannabinol (THC)) or 5 mg to 500 mg of cannabidiol (CBD); and a therapeutically effective amount of a sexual response enhancing component selected from the group consisting of sildenafil, tadalafil, and vardenafil (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil).

Regarding Claim 2, Caprio discloses the pharmaceutical composition of claim 1, wherein the cannabinoid component further comprises at least one of cannabinol (CBN), tetrahydrocannabivarin (THCV), cannabigerol (CBG), dronabinol, nabilone, a derivative of THC, or a derivative of CBD (Para. [0025], comprise one or more cannabinoid selected from...cannabidiolic acid (CBDA), cannabidivarin (CBDV), and cannabidivarinic acid (CBDVA)).

Regarding Claim 11, Caprio discloses an ingestible dosage form for enhancing sexual response (Abstract, compositions for the treatment of erectile dysfunction; Para. [0032], Administration may also be orally...capsules; Para. [0023], administration...components of the composition are supplied either separately or mixed together in unit dosage form) and sensitivity (Paras. [0005]-[0007], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg...composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil; i.e., this composition is the claimed composition; thus, the composition must inherently exhibit the same properties, such as enhancing sexual sensitivity) in a human (Para. [0017], "subject" includes...human), comprising: an ingestible cannabinoid component comprising at least one of 5 mg to 500 mg of tetrahydrocannabinol (THC) (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally... capsules; Paras. [0005]-[0008], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg...In some embodiments, the cannabis extract comprises cannabinoid tetrahydrocannabinol (THC)) or 5 mg to 500 mg of cannabidiol (CBD); and a tablet or capsule (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules) that contains a sexual response enhancing component selected from a therapeutically effective amount of sildenafil, tadalafil, or vardenafil in (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil) and/or at least 1 g, such as at least 2 g, of an herbal supplement comprising one or more of L-arginine, L-citrulline, yahimbe root, ginseng (e.g., Korean red ginsing), ginkgo biloba, horny goat weed, goosefoot, Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, and/or damiana.

Regarding Claim 12, Caprio discloses the ingestible dosage form of claim 11, wherein the ingestible cannabinoid component (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules; Paras. [0005]-[0008], cannabis, or extract thereof, is administered...cannabis extract comprises at least one cannabinoid) is a tablet or capsule (Para. [0032], capsule).

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 31 and 33 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 31 and 33 are indefinite for the following reasons:

Regarding claims 31 and 33, the claims fail to provide sufficient antecedent basis for "the cannabis extract." For purposes of the Written Opinion proposed, claims 31 and 33 have been analyzed as "a cannabis extract" to provide sufficient antecedent basis for "the cannabis extract," as best interpreted.

WRITTEN OPINION OF THE
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International application No.
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding Claim 14, Caprio discloses a composition for enhancing sexual response and sensitivity (Abstract, compositions for the treatment of erectile dysfunction; Paras. [0005]-[0007], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg...composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil; i.e., this composition is the claimed composition; thus, the composition must inherently exhibit the same properties, such as enhancing sexual sensitivity) in a human (Para. [0017], "subject" includes...human), comprising: a topical cannabinoid dosage form (Para. [0023], components of the composition are supplied either separately; Para. [0032], administer the cannabis extract or cannabinoid/anti-ED agent combination, or pharmaceutical compositions comprising same, locally to the area in need of treatment, such as the groin rejoin or penis. This method of administration may be achieved by, for example, and not by way of limitation, local infusion, topical application) comprising at least one 5 mg to 500 mg of tetrahydrocannabinol (THC) (Paras. [0005]-[0008], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg...In some embodiments, the cannabis extract comprises cannabinoid tetrahydrocannabinol (THC)) or 5 mg to about 500 mg of cannabidiol (CBD); and a tablet or capsule (Para. [0023], components of the composition are supplied either separately; Para. [0032], Administration may also be orally...capsules) that contains a sexual response enhancing component selected from a therapeutically effective amount of sildenafil, tadalafil, or vardenafil in (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil) and/or at least 1 g, such as at least 2 g, of an herbal supplement comprising one or more of L-arginine, L-citrulline, yahimbe root, ginseng (e.g., Korean red ginsing), ginkgo biloba, horny goat weed, goosefoot, Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, and/or damiana.

Regarding Claim 15, Caprio discloses the composition of claim 14, wherein the topical cannabinoid dosage form (Para. [0032], administer the cannabis extract or cannabinoid/anti-ED agent combination, or pharmaceutical compositions comprising same, locally to the area in need of treatment, such as the groin rejoin or penis. This method of administration may be achieved by, for example, and not by way of limitation, local infusion, topical application) is selected from the group consisting of massage oils, lotions, gels, creams (Para. [0022], gels, creams), lubricants, genital sprays, vaginal patch, vaginal suppository, and anal suppository.

Regarding Claim 16, Caprio discloses a composition for enhancing sexual response and sensitivity (Abstract, compositions for the treatment of erectile dysfunction; Paras. [0005]-[0007], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg...composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil; i.e., this composition is the claimed composition; thus, the composition must inherently exhibit the same properties, such as enhancing sexual sensitivity) in a human (Para. [0017], "subject" includes...human), comprising: a vaporizable and inhalable cannabinoid dosage form (Para. [0032], administer the cannabis extract or cannabinoid/anti-ED agent combination, or pharmaceutical compositions comprising same... Administration may also be...vapors; Para. [0023], administration...components of the composition are supplied either separately or mixed together in unit dosage form; Please See Applicants Specification, PCT/US/2018/059712, Para. [0089], stating "vapor that carries the components of interest and can be inhaled;" i.e., vapor dosage form is inhalable) configured to provide at least one of a dose of 5 mg to 500 mg of tetrahydrocannabinol (THC) (Paras. [0005]-[0008], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg...In some embodiments, the cannabis extract comprises cannabinoid tetrahydrocannabinol (THC)) or a dose of 5 mg to 500 mg of cannabidiol (CBD); and a tablet, capsule, or topical dosage form (Para. [0023], administration...components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally... capsules) that contains a sexual response enhancing component selected from a therapeutically effective amount of sildenafil, tadalafil, or vardenafil in (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil) and/or at least 1 g, such as at least 2 g, of an herbal supplement comprising one or more of L-arginine, L-citrulline, yahimbe root, ginseng (e.g., Korean red ginsing), ginkgo biloba, horny goat weed, goosefoot, Chenopodium ambrosioides, Chlorophytum borivilianum, Desmodium gangeticum, garlic combined with vitamin C, and/or damiana.

Regarding Claim 19, Caprio discloses a method of treating sexual dysfunction (Abstract, methods and compositions for the treatment of erectile dysfunction) and/or enhancing sexual response and sensitivity in a human (Para. [0017], "subject" includes...human), comprising: administering by ingestion (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules), inhalation, or topically a cannabinoid comprising at least one of tetrahydrocannabinol (THC) or cannabidiol (CBD) (Para. [0008], In some embodiments, the cannabis extract comprises cannabidiol (CBD). In some embodiments, the cannabis extract comprises cannabinoid tetrahydrocannabinol (THC)); and administering by ingestion (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules) an effective amount of a sexual response component selected from the group consisting of sildenafil, tadalafil, vardenafil (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil), herbal supplement, and combinations thereof.

Regarding Claim 20, Caprio discloses the method of claim 19, wherein the cannabinoid comprises 5-500 mg, or 7.5- 450 mg, or 10-400 mg, or 15-350 mg, or 20-300 mg, or 25-250 mg of THC (Paras. [0005]-[0008], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg... cannabis extract comprises cannabinoid tetrahydrocannabinol (THC)).

Regarding Claim 21, Caprio discloses the method of claim 19, wherein the cannabinoid comprises 5-500 mg, or 7.5-450 mg, or 10-400 mg, or 15-350 mg, or 20-300 mg, or 25-250 mg of CBD (Paras. [0005]-[0008], cannabis, or extract thereof, is administered in an amount from about 5 mg to about 50 mg...cannabis extract comprises cannabidiol (CBD)).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2018/059712

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding Claim 31 (as best interpreted), Caprio discloses a method of treating sexual dysfunction (Abstract, methods and compositions for the treatment of erectile dysfunction) and/or enhancing sexual response and sensitivity in a human (Para. [0017], "subject" includes... human), comprising: administering a cannabinoid via tablet or capsule, a cannabis extract comprising at least one of tetrahydrocannabinol (THC) (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules; Para. [0008], In some embodiments, the cannabis extract comprises cannabinoid tetrahydrocannabinol (THC)) or cannabidiol (CBD); and administering via tablet or capsule (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules) an effective amount of a sexual response component selected from the group consisting of sildenafil, tadalafil, vardenafil (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil), L-arginine, herbal supplement, and combinations thereof.

Regarding Claim 32, Caprio discloses the method of claim 31, wherein the sexual response component (Para. [0006], composition may comprise...an anti-erectile dysfunction drug (AED)), is selected from the group consisting of sildenafil, tadalafil, and vardenafil (Para. [0007], AED may comprise vardenafil, avanafil, sildenafil, tadalafil).

Regarding Claim 33 (as best interpreted), Caprio discloses a method of treating sexual dysfunction (Abstract, methods and compositions for the treatment of erectile dysfunction) and/or enhancing sexual response and sensitivity in a human (Para. [0017], "subject" includes... human), comprising: administering a cannabinoid by ingestion of a tablet, a capsule, an infused edible, or liquid shot, a cannabis extract comprising at least one of tetrahydrocannabinol (THC) (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules; Para. [0008], In some embodiments, the cannabis extract comprises cannabinoid tetrahydrocannabinol (THC)) or cannabidiol (CBD); and administering by ingestion (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules) an effective amount of a pharmaceutical selected from the group consisting of sildenafil, tadalafil, and vardenafil (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED), or pharmaceutically acceptable salt thereof; and cannabis...AED may comprise vardenafil, avanafil, sildenafil, tadalafil).

Regarding Claim 34, Caprio discloses the method of claim 33, wherein the pharmaceutical comprises sildenafil (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED)...AED may comprise vardenafil, avanafil, sildenafil).

Regarding Claim 35, Caprio discloses the method of claim 33, wherein the pharmaceutical comprises tadalafil (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED)...AED may comprise vardenafil, avanafil, sildenafil, tadalafil).

Regarding Claim 36, Caprio discloses the method of claim 33, wherein the pharmaceutical comprises vardenafil (Paras. [0006]-[0007], composition may comprise a therapeutically effective amount of an anti-erectile dysfunction drug (AED)...AED may comprise vardenafil).

Claims 3, 13, 17, and 18 lack an inventive step under PCT Article 33(3) as being obvious over Caprio in view of Biotech Institute LLC (hereinafter Biotech).

Regarding Claim 3, Caprio discloses the pharmaceutical composition of claim 1, wherein at least a portion of the cannabinoid component is obtained from plant parts of one or more plants (Para. [0025], from the bud of a marijuana plant...extract may comprise one or more cannabinoid), but fails to explicitly disclose plants selected from Cannabis sativa, Cannabis indica, and hybrids thereof. Biotech is in the field of compositions for the use of cannabis (Abstract), including medically (Para. [0200]) and teaches plants selected from Cannabis sativa, Cannabis indica (Para. [0211], cannabinoid found in Cannabis sativa and Cannabis indica), and hybrids thereof. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Caprio with the teaching of Biotech to detail plants selected from Cannabis sativa, Cannabis indica. The motivation for doing so would have been to detail plants that contain cannabinoid (Biotech, Para. [0211]) and thereby use it to treat erectile dysfunction (Caprio, Paras. [0006]-[0008]).

Regarding Claim 13, Caprio discloses the ingestible dosage form of claim 11, wherein the ingestible cannabinoid component (Para. [0023], components of the composition are supplied either separately or mixed together in unit dosage form; Para. [0032], Administration may also be orally...capsules; Para. [0008], cannabis extract comprises at least one cannabinoid), but fails to explicitly disclose component is selected from the group consisting of oral drops, lozenges, lollipops, food preparations, such as brownies, cookies, or chocolates, chews, gum drops, soft candies, hard candies, and liquid shots. Biotech is in the field of compositions for the use of cannabis (Abstract), including medically (Para. [0200]) and teaches component is selected from the group consisting of oral drops, lozenges, lollipops, food preparations, such as brownies (Para. [0813], Cannabis edibles such as candy, brownies, and other foods are a popular method of consuming cannabis), cookies, or chocolates, chews, gum drops, soft candies, hard candies, and liquid shots. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Caprio with the teaching of Biotech to detail component is selected from the group consisting of food preparations, such as brownies. The motivation for doing so would have been to detail a popular method for consuming cannabis for medicinal purposes (Biotech, Para. [0813]) and thereby use it to treat erectile dysfunction (Caprio, Paras. [0006]-[0008]).

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2018/059712

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding Claim 17, Caprio discloses the composition of claim 16, wherein the vaporizable and inhalable cannabinoid dosage form (Para. [0032], administer the cannabis extract or cannabinoid/anti-ED agent combination…Administration may also be…vapors; Para. [0023], administration…components of the composition are supplied either separately or mixed together in unit dosage form; Please See Applicants Specification, PCT/US2018/059712, Para. [0089], stating "vapor that carries the components of interest and can be inhaled;" i.e., vapor dosage form is inhalable), but fails to explicitly disclose dosage is formulated for vaporization and inhalation using a heat vaporizer. Biotech is in the field of compositions for the use of cannabis (Abstract), including medically (Para. [0200]) and teaches dosage is formulated for vaporization and inhalation using a heat vaporizer (Paras. [0871]-[0872], Vaporization is the process of heating a substance to its boiling point to release vapor containing the active constituents in a gaseous state. This vapor can be inhaled to deliver the active agents in the drug…vaporization device requires, at its most basic, a source of heat). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Caprio with the teaching of Biotech to detail dosage is formulated for vaporization and inhalation using a heat vaporizer. The motivation for doing so would have been to detail how to inhale active agents without harmful irritants and carcinogens (Biotech, Para. [0871]) and thereby use it to treat erectile dysfunction (Caprio, Paras. [0006]-[0008]).

Regarding Claim 18, Caprio discloses the composition of claim 16, wherein the vaporizable and inhalable cannabinoid dosage form (Para. [0032], administer the cannabis extract or cannabinoid/anti-ED agent combination…Administration may also be…vapors; Para. [0023], administration…components of the composition are supplied either separately or mixed together in unit dosage form; Please See Applicants Specification, PCT/US2018/059712, Para. [0089], stating "vapor that carries the components of interest and can be inhaled;" i.e., vapor dosage form is inhalable), but fails to explicitly disclose dosage is formulated for vaporization and inhalation using a nebulizer. Biotech is in the field of compositions for the use of cannabis (Abstract), including medically (Para. [0200]) and teaches dosage is formulated for vaporization (Para. [0871], Vaporization is the process of heating a substance to its boiling point to release vapor containing the active constituents in a gaseous state. This vapor can be inhaled to deliver the active agents in the drug) and inhalation using a nebulizer (Para. [0811], extracts of the present invention are designed to produce products for human or animal consumption via inhalation (via…nebulization)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Caprio with the teaching of Biotech to detail dosage is formulated for vaporization and inhalation using a nebulizer. The motivation for doing so would have been to detail how to inhale active agents (Biotech, Para. [0811]) and thereby use it to treat erectile dysfunction (Caprio, Paras. [0006]-[0008]).

Claims 1-3, 11-21, and 31-36 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Verified

By: kplatt On: 18 Jan 2019

DOCKETED

Atty JMG File# 15257.20B
By DAnderson On 18 Jan 2019
Action Article 19 Amendments
Response Due 12/7/19
Submit IDR

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: JOHN M. GUYNN
WORKMAN NYDEGGER
60 EAST SOUTH TEMPLE
SUITE 1000
SALT LAKE CTIY, UT 84111

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 16 JAN 2019
Applicant's or agent's file reference 15257-20B	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2018/059712	International filing date *(day/month/year)* 07 November 2018
Applicant ILYSM, LLC	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau of WIPO preferably through ePCT or on paper to, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 Telephone No. PCT OSP: 571-272-7774

Form PCT/ISA/220 (July 2017)

PI 2021000684-

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 15257-20B	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2018/059712	International filing date *(day/month/year)* 07 November 2018	(Earliest) Priority Date *(day/month/year)* 07 August 2018
Applicant ILYSM, LLC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the language, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

   a. the figure of the drawings to be published with the abstract is Figure No. _____

   ☐ as suggested by the applicant.

   ☐ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059712

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-10, 22-30
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 February 2020 (13.02.2020)

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(21) International Application Number:
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07 November 2018 (07.11.2018)

(25) Filing Language: English

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(74) Agent: **GUYNN, John M.**; Workman Nydegger, 60 East SouthTemple, Suite 1000, SaltLake City, Utah 84111 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

WO 2020/032988 A1

(54) Title: COMPOSITIONS AND METHODS FOR TREATING SEXUAL DYSFUNCTION AND ENHANCING SEXUAL RESPONSE AND PLEASURE

(57) Abstract: Pharmaceutical preparations include at least one component that enhances sexual response and at least one other compound that enhances sexual sensitivity and pleasure. The component that enhances sexual response enhances blood flow to the genital region. Examples include compounds that dilate blood vessels, such as compounds that increase the amount of nitric oxide (NO) in the blood. The component that enhances sexual sensitivity and pleasure includes one or more cannabinoid compounds from the plant genus *Cannabis*, including extracted compounds, synthetic forms, and derivatives thereof. Examples include tetrahydrocannabinol (THC), the main psychoactive constituent of *Cannabis*, and cannabidiol (CBD), which is less or non-psychoactive and modulates THC activity. The ratio of THC/CBD can be selected depending on age, gender, physical health, and/or psychological condition of the user.

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RESIT RASMI

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Rujukan			**Butiran Bayaran**			
Pusat Bayaran	:	IBU PEJABAT-	Cara Bayaran	No Doc	Tarikh Doc	Amaun (RM)
No. Invois	:	2082964	CEK TEMPATAN MBB	MBB166976	08/02/2021	470.00
Catatan	:					

Keterangan	No pendaftaran	Kuantiti	Kos Per Unit	GST	Jumlah
PM2A(a)	PI2021000684	1.00	290.00	0.00	290.00
PM2A(b)	PI2021000684	1.00	100.00	0.00	100.00
PM22	PI2021000684	1.00	80.00	0.00	80.00

Cetakan Berkomputer Tidak Perlu Tandatangan

MUHAMMAD FIRDAUS BIN NONG CHIK

*Resit ini akan dianggap batal sekiranya cek tidak dapat ditunaikan.
Pelepasan di bawah Seksyen 56(3)(b) Akta Cukai Barangan dan Perkhidmatan 2014

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Catatan	:					

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PM2A(b)	PI2021000684	1.00	100.00	0.00	100.00
PM22	PI2021000684	1.00	80.00	0.00	80.00

Cetakan Berkomputer Tidak Perlu Tandatangan

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Pelepasan di bawah Seksyen 56(3)(b) Akta Cukai Barangan dan Perkhidmatan 2014

SALINAN BAHAGIAN