### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Hansen; Bjorn Erik Confirmation No.:

Serial No.: 17/525248 Group No.:

Filing or 371(c) Date: November 12, 2021 Examiner:

Entitled: SEXUAL THERAPY FORMULATION AND METHOD OF TREATMENT

## THIRD-PARTY PRE-ISSUANCE SUBMISSION

### Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application:

- 1. HALKITIS (2007) "Sildenafil (Viagra) and Club Drug Use in Gay and Bisexual Men: The Role of Drug Combinations and Context" Vol. 1(2): 139-147. American Journal of Men's Health.
- 2. McMURRAY (2007) "Long-term safety and effectiveness of sildenafil citrate in men with erectile dysfunction" Vol. 3(6): 975–981. Therapeutics and Clinical Risk Management.
- 3. SMITH (2005) "Recreational Use and Misuse of Phosphodiesterase 5 Inhibitors" Vol. 45(1): 63-75. Journal of the American Pharmacists Association.
- 4. BAHJI (2019) "Efficacy of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for posttraumatic stress disorder: A systematic review and meta-analysis" Vol. 96: 1-15. Progress in Neuropsychopharmacology & Biological Psychiatry.
- 5. OBLIVION (2003) "Viagra with MDMA for Erections" Retrieved 4 May 2014. https://web.archive.org/web/20140504015737/https://erowid.org/experiences/exp.php?ID=27174
- VSJOE (2018) "Finally, I Was Also Able to Orgasm" Retrieved 8 February 2019. <a href="https://web.archive.org/web/20190208014713/https://erowid.org/experiences/exp.php?ID=112151">https://erowid.org/experiences/exp.php?ID=112151</a>
- 7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experiences/exp.php?ID=21223
- 8. MOONDO (2014) "To Treat Premature Ejaculation" Retrieved 22 February 2019. https://web.archive.org/web/20190222023609/https://erowid.org/experiences/exp.php?ID=104048
- 9. Int'l Pat. App. Pub. No. WO/2020/006606 "A PHARMACEUTICAL COMPOSITION AND METHOD OF USE OF SAME" (Published January 9, 2020)

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

U.S.S.N. 17/525248	References
Pending Claims	1 HALLWEIG (2008) (GT11 GT (V) ) 1 GT 1 D H 1 G 1
<b>1.</b> A sexual therapy formulation for	1. HALKITIS (2007) "Sildenafil (Viagra) and Club Drug Use in Gay and
	Bisexual Men: The Role of Drug Combinations and Context" Vol. 1(2): 139-147. American Journal of Men's Health.
treatment of a patient suffering from some	139-147. American Journal of Men's Health.
degree of erectile	From <b>page 139</b> "Data ascertained in a study of club drug use among 450
dysfunction as well as	gay and bisexual men indicate that at least one class of PDE-5
low or reduced libido,	(phosphodiesterase type 5 inhibitor, <b>sildenafil [Viagra]</b> ) is used frequently
said formulation	in combination with club drugs such as methamphetamine, MDMA (3,4
comprising: an erection	methylenedioxymethamphetamine [ecstasy]), ketamine, cocaine, and GHB
enhancement	(gamma hydroxy butyrate)."
component comprising	(Summa hydroxy outyrate).
one or more of	From page 139 "Of particular importance is the fact that use of club drugs
sildenafil citrate,	in combination with sildenafil is strongly associated with circuit and sex
vardenafil	<b>parties</b> , where a centerpiece of these environments focuses on sexual
hydrochloride, tadalafil,	exchange."
and avanafil; a libido	
stimulation component	From page 144 "Specifically, the recreational use of sildenafil in
comprising one or more	combination with the club drugs included in this study (cocaine, GHB,
of	ketamine, <b>MDMA</b> , methamphetamine) is less likely to occur among men of
dehydroepiandrosteron	color, especially Black men. Furthermore, age is strongly related to the
e, testosterone,	behavior of combining sildenafil with certain club drugs, with older men
dihydrotestosterone, L-	in our sample more likely to engage in this behavior than their younger
arginine, L-citrulline,	counterparts. The fact that age and race were identified to be significant
Vitamin E, fenugreek,	factors for the prediction of sildenafil use may be influenced by two
ginseng, maca,	conditions: (a) increasing rates of erectile dysfunction associated with
yohimbine, 3,4-	age and (b) limited access to health care and medications for minorities in
methylenedioxymetha	general."
mphetamine, an R(-) isomer of 3,4-	
methylenedioxymetha	2. McMURRAY (2007) "Long-term safety and effectiveness of sildenafil
mphetamine, an S(+)	citrate in men with erectile dysfunction" Vol. 3(6): 975–981. Therapeutics
isomer of 3,4-	and Clinical Risk Management.
methylenedioxymetha	and Omnour Rusk Pranagomont
mphetamine, and a	From <b>page 975</b> "In March 1998, the US Food and Drug Administration
racemic mixture of 3,4-	(FDA) approved <b>sildenafil citrate</b> ( <b>Viagra</b> ®, Pfizer Inc, New York, NY,
methylenedioxymetha	USA) for the treatment of erectile dysfunction (ED) (FDA 1998)."
mphetamine; and a	
synergistic effect	
produced from said	4. BAHJI (2019) "Efficacy of 3,4-methylenedioxymethamphetamine
erection enhancement	(MDMA)-assisted psychotherapy for posttraumatic stress disorder: A
component combined	systematic review and meta-analysis" Vol. 96: 1-15. Progress in
with said libido	Neuropsychopharmacology & Biological Psychiatry.
stimulation component	
allows the patient to	From page 12
obtain and maintain an	

erection thus permitting the patient to engage in intimate sexual activity as well providing the patient with the desire to engage in intimate sexual activity.

Category	MDMA-Induced state
Mood/Affect	Mild euphoria; anxiolytic; fear extinction; enhanced perception of feelings; increased tolerance of affect
Cognition/Memory	Boosted creativity and imagination; increased contem- plativeness; enhanced recall and tolerance of traumatic memory
Attachment & in- terpersonal b- ehaviour	Reduced social fears and defensiveness; improved social approach behaviours; enhanced empathy, open- ness, trust, feelings of connection; increased need for touch
Self	Boosted self-esteem and self-acceptance
Body	Analgesia; muscle relaxation; enhanced libido and sensuality

9. Int'l Pat. App. Pub. No. WO/2020/006606 "A PHARMACEUTICAL COMPOSITION AND METHOD OF USE OF SAME" (Published January 9, 2020)

From **Abstract** "The present disclosure relates to a pharmaceutical composition in a pharmaceutically acceptable vehicle. The pharmaceutical composition includes a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof. **The disclosed pharmaceutical composition may be useful in the treatment of erectile dysfunction** and premature ejaculation."

From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

- 2. The sexual therapy formulation as recited in claim 1, wherein said erection enhancement component comprises an amount of sildenafil citrate.
- 1. HALKITIS (2007) "Sildenafil (Viagra) and Club Drug Use in Gay and Bisexual Men: The Role of Drug Combinations and Context" Vol. 1(2): 139-147. American Journal of Men's Health.

From **page 139** "Data ascertained in a study of club drug use among 450 gay and bisexual men indicate that at least one class of PDE-5 (phosphodiesterase type 5 inhibitor, **sildenafil [Viagra]**) is used frequently in combination with club drugs such as methamphetamine, MDMA (3,4 methylenedioxymethamphetamine [ecstasy]), ketamine, cocaine, and GHB (gamma hydroxy butyrate)."

From page 139 "Of particular importance is the fact that use of club drugs in combination with sildenafil is strongly associated with circuit and sex parties, where a centerpiece of these environments focuses on sexual exchange."

From page 144 "Specifically, the recreational use of sildenafil in combination with the club drugs included in this study (cocaine, GHB, ketamine, MDMA, methamphetamine) is less likely to occur among men of color, especially Black men. Furthermore, age is strongly related to the behavior of combining sildenafil with certain club drugs, with older men in our sample more likely to engage in this behavior than their younger counterparts. The fact that age and race were identified to be significant factors for the prediction of sildenafil use may be influenced by two conditions: (a) increasing rates of erectile dysfunction associated with age and (b) limited access to health care and medications for minorities in general."

2. McMURRAY (2007) "Long-term safety and effectiveness of sildenafil citrate in men with erectile dysfunction" Vol. 3(6): 975–981. Therapeutics and Clinical Risk Management.

From **page 975** "In March 1998, the US Food and Drug Administration (FDA) approved **sildenafil citrate** (**Viagra**®, Pfizer Inc, New York, NY, USA) for the treatment of erectile dysfunction (ED) (FDA 1998)."

9. Int'l Pat. App. Pub. No. WO/2020/006606 "A PHARMACEUTICAL COMPOSITION AND METHOD OF USE OF SAME" (Published January 9, 2020)

From **Abstract** "The present disclosure relates to a pharmaceutical composition in a pharmaceutically acceptable vehicle. The pharmaceutical composition includes a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof. **The disclosed pharmaceutical composition may be useful in the treatment of erectile dysfunction** and premature ejaculation."

From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non- priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: avanafil, iodenafil, mirodenafil, **sildenafil**, tadalafil, vardenafil, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From **page 2** "According to an embodiment of the invention, there is provided **a pharmaceutical composition** in a pharmaceutically acceptable

vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof." **3.** The sexual therapy 1. HALKITIS (2007) "Sildenafil (Viagra) and Club Drug Use in Gay and formulation as recited Bisexual Men: The Role of Drug Combinations and Context" Vol. 1(2): 139-147. American Journal of Men's Health. in claim 2, wherein a unit dosage of said formulation comprises From page 139 "Data ascertained in a study of club drug use among 450 a therapeutically gay and bisexual men indicate that at least one class of PDE-5 effective amount of (phosphodiesterase type 5 inhibitor, **sildenafil [Viagra]**) is used frequently said erection in combination with club drugs such as methamphetamine, MDMA (3,4 methylenedioxymethamphetamine [ecstasy]), ketamine, cocaine, and GHB enhancement component comprising (gamma hydroxy butyrate)." sildenafil citrate. From page 139 "Of particular importance is the fact that use of club drugs in combination with sildenafil is strongly associated with circuit and sex parties, where a centerpiece of these environments focuses on sexual exchange." From page 144 "Specifically, the recreational use of sildenafil in combination with the club drugs included in this study (cocaine, GHB, ketamine, MDMA, methamphetamine) is less likely to occur among men of color, especially Black men. Furthermore, age is strongly related to the behavior of combining sildenafil with certain club drugs, with older men in our sample more likely to engage in this behavior than their younger counterparts. The fact that age and race were identified to be significant factors for the prediction of sildenafil use may be influenced by two conditions: (a) increasing rates of erectile dysfunction associated with age and (b) limited access to health care and medications for minorities in general." 2. McMURRAY (2007) "Long-term safety and effectiveness of sildenafil citrate in men with erectile dysfunction" Vol. 3(6): 975–981. Therapeutics and Clinical Risk Management. From page 975 "In March 1998, the US Food and Drug Administration (FDA) approved sildenafil citrate (Viagra®, Pfizer Inc, New York, NY, USA) for the treatment of erectile dysfunction (ED) (FDA 1998)." 9. Int'l Pat. App. Pub. No. WO/2020/006606 "A PHARMACEUTICAL" COMPOSITION AND METHOD OF USE OF SAME" (Published January

9, 2020)

From **Abstract** "The present disclosure relates to a pharmaceutical composition in a pharmaceutically acceptable vehicle. The pharmaceutical composition includes a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof. **The disclosed pharmaceutical composition may be useful in the treatment of erectile dysfunction** and premature ejaculation."

From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: avanafil, iodenafil, mirodenafil, **sildenafil**, tadalafil, vardenafil, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

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- **4.** The sexual therapy formulation as recited in claim 3, wherein said therapeutically effective amount of sildenafil citrate is
- 3. SMITH (2005) "Recreational Use and Misuse of Phosphodiesterase 5 Inhibitors" Vol. 45(1): 63-75. Journal of the American Pharmacists Association.

From page 66 "Sildenafil citrate is marketed in the United States as 25, 50, and 100 mg tablets.11 The drug is sometimes referred to as "vitamin V,"

about 20 milligrams to about 100 milligrams.

and slang terms pertaining to its recreational use include "hammerheading" and "sextasy" (use in conjunction with

methylenedioxymethamphetamine [MDMA], ecstasy); and "tina," (use in conjunction with methamphetamine).16 Also known as a "thrill pill," sildenafil has been sold on school and college campuses and at parks, with subsequent consumption at clubs and raves.17 It is often purchased for \$25–\$30 on the black market."

5. OBLIVION (2003) "Viagra with MDMA for Erections" Retrieved 4 May 2014.

https://web.archive.org/web/20140504015737/https://erowid.org/experiences/exp.php?ID=27174

"Ultimately, the dosage which you will require for your body is largely dependent on your health and your age. It is best to initially **start off with a dose of around 10 to 25 mgs. of Viagra**, and **then add an additional 10 to 25 mgs. for each roll** until you have found your ideal dosage."

**5.** The sexual therapy formulation as recited in claim 1, wherein said libido stimulation component comprises an amount of 3,4methylenedioxymetha mphetamine, said R(-) isomer of 3,4methylenedioxymetha mphetamine, said S(-)isomer of 3.4methylenedioxymetha mphetamine, and/or said racemic mixture of 3.4methylenedioxymetha

mphetamine.

1. HALKITIS (2007) "Sildenafil (Viagra) and Club Drug Use in Gay and Bisexual Men: The Role of Drug Combinations and Context" Vol. 1(2): 139-147. American Journal of Men's Health.

From **page 139** "Data ascertained in a study of club drug use among 450 gay and bisexual men indicate that at least one class of PDE-5 (phosphodiesterase type 5 inhibitor, **sildenafil [Viagra]**) is used frequently in combination with club drugs such as methamphetamine, MDMA (3,4 methylenedioxymethamphetamine [ecstasy]), ketamine, cocaine, and GHB (gamma hydroxy butyrate)."

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4. BAHJI (2019) "Efficacy of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for posttraumatic stress disorder: A systematic review and meta-analysis" Vol. 96: 1-15. Progress in Neuropsychopharmacology & Biological Psychiatry.

From page 12
Appendix 8. Properties of MDMA table

Category	MDMA-Induced state
Mood/Affect	Mild euphoria; anxiolytic; fear extinction; enhanced perception of feelings; increased tolerance of affect
Cognition/Memory	Boosted creativity and imagination; increased contem- plativeness; enhanced recall and tolerance of traumatic memory
Attachment & in- terpersonal b- ehaviour	Reduced social fears and defensiveness; improved social approach behaviours; enhanced empathy, open- ness, trust, feelings of connection; increased need for touch
Self	Boosted self-esteem and self-acceptance
Body	Analgesia; muscle relaxation; enhanced libido and sensuality

**6.** The sexual therapy formulation as recited in claim 5, wherein a unit dosage of said formulation comprises a therapeutically effective amount of said libido stimulation component comprising 3,4methylenedioxymetha mphetamine, said R(-) isomer of 3,4methylenedioxymetha mphetamine, said S(+)isomer of 3,4methylenedioxymetha mphetamine, and/or said racemic mixture of 3.4methylenedioxymetha

mphetamine.

4. BAHJI (2019) "Efficacy of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for posttraumatic stress disorder: A systematic review and meta-analysis" Vol. 96: 1-15. Progress in Neuropsychopharmacology & Biological Psychiatry.

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Attachment & in- terpersonal b- ehaviour	Reduced social fears and defensiveness; improved social approach behaviours; enhanced empathy, open- ness, trust, feelings of connection; increased need for touch
Self	Boosted self-esteem and self-acceptance
Body	Analgesia; muscle relaxation; enhanced libido and sensuality

9. Int'l Pat. App. Pub. No. WO/2020/006606 "A PHARMACEUTICAL COMPOSITION AND METHOD OF USE OF SAME" (Published January 9, 2020)

From **Abstract** "The present disclosure relates to a pharmaceutical composition in a pharmaceutically acceptable vehicle. The pharmaceutical composition includes a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof. **The disclosed pharmaceutical composition may be useful in the treatment of erectile dysfunction** and premature ejaculation."

From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

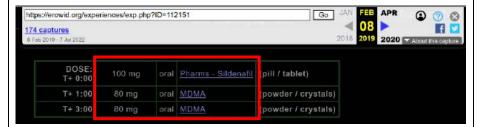
From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

# **7.** The sexual therapy formulation as recited

6. VSJOE (2018) "Finally, I Was Also Able to Orgasm" Retrieved 8 February 2019.

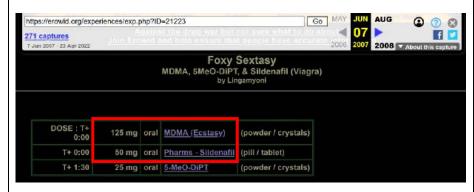
in claim 6, wherein said therapeutically effective amount of 3,4methylenedioxymetha mphetamine, said R(-) isomer of 3,4methylenedioxymetha mphetamine, said S(+)isomer of 3,4methylenedioxymetha mphetamine, and/or said racemic mixture of 3.4methylenedioxymetha mphetamine, is about 30 milligrams to about 125 milligrams.

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7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experie

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8. MOONDO (2014) "To Treat Premature Ejaculation" Retrieved 22 February 2019.

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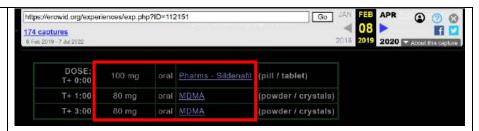


8. The sexual therapy formulation as recited in claim 4, wherein said libido stimulation component comprises an amount of 3,4-methylenedioxymetha mphetamine, said R(-)

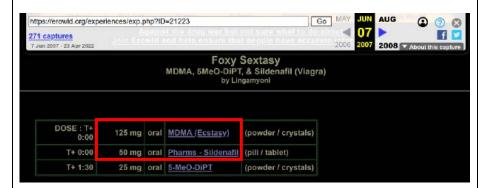
6. VSJOE (2018) "Finally, I Was Also Able to Orgasm" Retrieved 8 February 2019.

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isomer of 3,4-methylenedioxymetha mphetamine, said S(+) isomer of 3,4-methylenedioxymetha mphetamine, and/or said racemic mixture of 3,4-methylenedioxymetha mphetamine.



7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experiences/exp.php?ID=21223



8. MOONDO (2014) "To Treat Premature Ejaculation" Retrieved 22 February 2019.

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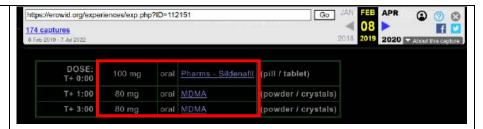


9. The sexual therapy formulation as recited in claim 8, wherein a unit dosage of said formulation comprises a therapeutically effective amount of said libido stimulation

6. VSJOE (2018) "Finally, I Was Also Able to Orgasm" Retrieved 8 February 2019.

 $\frac{https://web.archive.org/web/20190208014713/https://erowid.org/experiences/exp.php?ID=112151}{s/exp.php?ID=112151}$ 

component comprising 3,4methylenedioxymetha
mphetamine, said R(-)
isomer of 3,4methylenedioxymetha
mphetamine, said S(+)
isomer of 3,4methylenedioxymetha
mphetamine, and/or
said racemic mixture of
3,4methylenedioxymetha
mphetamine.



7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experiences/exp.php?ID=21223



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salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof. **The disclosed pharmaceutical composition may be useful in the treatment of erectile dysfunction** and premature ejaculation."

From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non- priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

10. The sexual therapy formulation as recited in claim 9, wherein said therapeutically effective amount of 3,4-methylenedioxymetha mphetamine, said R(-) isomer of 3,4-methylenedioxymetha mphetamine, said S(+)

6. VSJOE (2018) "Finally, I Was Also Able to Orgasm" Retrieved 8 February 2019.

 $\underline{\text{https://web.archive.org/web/20190208014713/https://erowid.org/experience}} \\ \underline{\text{s/exp.php?ID=}112151}$ 



isomer of 3,4-methylenedioxymetha mphetamine, and/or said racemic mixture of 3,4-methylenedioxymetha mphetamine, is about 30 milligrams to about 125 milligrams.

7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experiences/exp.php?ID=21223



8. MOONDO (2014) "To Treat Premature Ejaculation" Retrieved 22 February 2019.

https://web.archive.org/web/20190222023609/https://erowid.org/experiences/exp.php?ID=104048



9. Int'l Pat. App. Pub. No. WO/2020/006606 "A PHARMACEUTICAL COMPOSITION AND METHOD OF USE OF SAME" (Published January 9, 2020)

From **Abstract** "The present disclosure relates to a pharmaceutical composition in a pharmaceutically acceptable vehicle. The pharmaceutical composition includes a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof. The disclosed pharmaceutical composition may be useful in the treatment of erectile dysfunction and premature ejaculation."

From **claim 1** "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non- priapismic, **dose of a penile-erection-**

inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

11. A sexual therapy formulation for treatment of a patient suffering from some degree of erectile dysfunction as well as low or reduced libido. said formulation comprising: an erection enhancement component selected from the group consisting of sildenafil citrate, vardenafil hydrochloride, tadalafil, and avanafil; a libido stimulation component selected from the group consisting of

1. HALKITIS (2007) "Sildenafil (Viagra) and Club Drug Use in Gay and Bisexual Men: The Role of Drug Combinations and Context" Vol. 1(2): 139-147. American Journal of Men's Health.

From **page 139** "Data ascertained in a study of club drug use among 450 gay and bisexual men indicate that at least one class of PDE-5 (phosphodiesterase type 5 inhibitor, **sildenafil [Viagra]**) is used frequently in combination with club drugs such as methamphetamine, MDMA (3,4 methylenedioxymethamphetamine [ecstasy]), ketamine, cocaine, and GHB (gamma hydroxy butyrate)."

From page 139 "Of particular importance is the fact that use of club drugs in combination with sildenafil is strongly associated with circuit and sex parties, where a centerpiece of these environments focuses on sexual exchange."

From **page 144** "Specifically, the recreational **use of sildenafil in combination with the club drugs** included in this study (cocaine, GHB, ketamine, **MDMA**, methamphetamine) is less likely to occur among men of

dehydroepiandrosteron e, testosterone, dihydrotestosterone, Larginine, L-citruline, Vitamin E, fenugreek, ginseng, maca, vohimbine, 3,4methylenedioxymetha mphetamine, an R(-) isomer of 3,4methylenedioxymetha mphetamine, an S(+)isomer of 3.4methylenedioxymetha mphetamine, and a racemic mixture of 3,4methylenedioxymetha mphetamine; and a synergistic effect produced from said erection enhancement component combined with said libido stimulation component allows the patient to obtain and maintain an erection thus permitting the patient to engage in intimate sexual activity as well providing the patient with the desire to engage in intimate sexual activity.

color, especially Black men. Furthermore, **age is strongly related to the behavior of combining sildenafil with certain club drugs**, with older men in our sample more likely to engage in this behavior than their younger counterparts. The fact that age and race were identified to be significant factors for the prediction of sildenafil use may be influenced by two conditions: (a) **increasing rates of erectile dysfunction associated with age** and (b) limited access to health care and medications for minorities in general."

2. McMURRAY (2007) "Long-term safety and effectiveness of sildenafil citrate in men with erectile dysfunction" Vol. 3(6): 975–981. Therapeutics and Clinical Risk Management.

From **page 975** "In March 1998, the US Food and Drug Administration (FDA) approved **sildenafil citrate (Viagra®**, Pfizer Inc, New York, NY, USA) for the treatment of erectile dysfunction (ED) (FDA 1998)."

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From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

12. The sexual therapy formulation as recited in claim 11, wherein said erection enhancement component consists of an amount of sildenafil citrate.

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From **page 139** "Data ascertained in a study of club drug use among 450 gay and bisexual men indicate that at least one class of PDE-5 (phosphodiesterase type 5 inhibitor, **sildenafil [Viagra]**) is used frequently in combination with club drugs such as methamphetamine, MDMA (3,4 methylenedioxymethamphetamine [ecstasy]), ketamine, cocaine, and GHB (gamma hydroxy butyrate)."

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From **page 975** "In March 1998, the US Food and Drug Administration (FDA) approved **sildenafil citrate (Viagra®**, Pfizer Inc, New York, NY, USA) for the treatment of erectile dysfunction (ED) (FDA 1998)."

13. The sexual therapy formulation as recited in claim 12, wherein a unit dosage of said formulation comprises a therapeutically effective amount of said erection enhancement component consisting of sildenafil citrate.

1. HALKITIS (2007) "Sildenafil (Viagra) and Club Drug Use in Gay and Bisexual Men: The Role of Drug Combinations and Context" Vol. 1(2): 139-147. American Journal of Men's Health.

From **page 139** "Data ascertained in a study of club drug use among 450 gay and bisexual men indicate that at least one class of PDE-5 (phosphodiesterase type 5 inhibitor, **sildenafil [Viagra]**) is used frequently in combination with club drugs such as methamphetamine, MDMA (3,4 methylenedioxymethamphetamine [ecstasy]), ketamine, cocaine, and GHB (gamma hydroxy butyrate)."

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From **Abstract** "The present disclosure relates to a pharmaceutical composition in a pharmaceutically acceptable vehicle. The pharmaceutical composition includes a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof. **The disclosed pharmaceutical composition may be useful in the treatment of erectile dysfunction** and premature ejaculation."

From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non- priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

**14.** The sexual therapy formulation as recited in claim 13, wherein

3. SMITH (2005) "Recreational Use and Misuse of Phosphodiesterase 5 Inhibitors" Vol. 45(1): 63-75. Journal of the American Pharmacists Association.

said therapeutically effective amount of sildenafil citrate is about 20 milligrams to about 100 milligrams.

From page 66 "Sildenafil citrate is marketed in the United States as 25, 50, and 100 mg tablets.11 The drug is sometimes referred to as "vitamin V," and slang terms pertaining to its recreational use include "hammerheading" and "sextasy" (use in conjunction with

methylenedioxymethamphetamine [MDMA], ecstasy); and "tina," (use in conjunction with methamphetamine).16 Also known as a "thrill pill," sildenafil has been sold on school and college campuses and at parks, with subsequent consumption at clubs and raves.17 It is often purchased for \$25–\$30 on the black market."

5. OBLIVION (2003) "Viagra with MDMA for Erections" Retrieved 4 May 2014.

 $\frac{https://web.archive.org/web/20140504015737/https://erowid.org/experiences/exp.php?ID=27174}{s/exp.php?ID=27174}$ 

"Ultimately, the dosage which you will require for your body is largely dependent on your health and your age. It is best to initially **start off with a dose of around 10 to 25 mgs. of Viagra**, and **then add an additional 10 to 25 mgs. for each roll** until you have found your ideal dosage."

15. The sexual therapy formulation as recited in claim 11, wherein said libido stimulation component consists of an amount of 3,4methylenedioxymetha mphetamine, said R(-) isomer of 3.4methylenedioxymetha mphetamine, said S(+)isomer of 3.4methylenedioxymetha mphetamine, or said racemic mixture of 3,4methylenedioxymetha mphetamine.

1. HALKITIS (2007) "Sildenafil (Viagra) and Club Drug Use in Gay and Bisexual Men: The Role of Drug Combinations and Context" Vol. 1(2): 139-147. American Journal of Men's Health.

From **page 139** "Data ascertained in a study of club drug use among 450 gay and bisexual men indicate that at least one class of PDE-5 (phosphodiesterase type 5 inhibitor, **sildenafil [Viagra]**) is used frequently in combination with club drugs such as methamphetamine, MDMA (3,4 methylenedioxymethamphetamine [ecstasy]), ketamine, cocaine, and GHB (gamma hydroxy butyrate)."

From page 139 "Of particular importance is the fact that use of club drugs in combination with sildenafil is strongly associated with circuit and sex parties, where a centerpiece of these environments focuses on sexual exchange."

From page 144 "Specifically, the recreational use of sildenafil in combination with the club drugs included in this study (cocaine, GHB, ketamine, MDMA, methamphetamine) is less likely to occur among men of color, especially Black men. Furthermore, age is strongly related to the behavior of combining sildenafil with certain club drugs, with older men in our sample more likely to engage in this behavior than their younger counterparts. The fact that age and race were identified to be significant factors for the prediction of sildenafil use may be influenced by two conditions: (a) increasing rates of erectile dysfunction associated with

**age** and (b) limited access to health care and medications for minorities in general."

4. BAHJI (2019) "Efficacy of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for posttraumatic stress disorder: A systematic review and meta-analysis" Vol. 96: 1-15. Progress in Neuropsychopharmacology & Biological Psychiatry.

From page 12
Appendix 8. Properties of MDMA table

Category	MDMA-Induced state
Mood/Affect	Mild euphoria; anxiolytic; fear extinction; enhanced perception of feelings; increased tolerance of affect
Cognition/Memory	Boosted creativity and imagination; increased contem- plativeness; enhanced recall and tolerance of traumatic memory
Attachment & in- terpersonal b- ehaviour	Reduced social fears and defensiveness; improved social approach behaviours; enhanced empathy, open- ness, trust, feelings of connection; increased need for touch
Self	Boosted self-esteem and self-acceptance
Body	Analgesia; muscle relaxation; enhanced libido and sensuality

9. Int'l Pat. App. Pub. No. WO/2020/006606 "A PHARMACEUTICAL COMPOSITION AND METHOD OF USE OF SAME" (Published January 9, 2020)

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From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non- priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

**16.** The sexual therapy formulation as recited in claim 15, wherein a unit dosage of said formulation comprises a therapeutically effective amount of said libido stimulation component consisting of 3,4methylenedioxymetha mphetamine, said R(-) isomer of 3,4methylenedioxymetha mphetamine, said S(+)isomer of 3,4methylenedioxymetha mphetamine, or said racemic mixture of 3.4methylenedioxymetha mphetamine.

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From **claim 1** "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a

physiologically effective, non- priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

**17.** The sexual therapy formulation as recited in claim 16, wherein said therapeutically effective amount of 3.4methylenedioxymetha mphetamine, said R(-) isomer of 3,4methylenedioxymetha mphetamine, said S(-)isomer of 3,4methylenedioxymetha mphetamine, or said racemic mixture of 3,4methylenedioxymetha mphetamine is about 30 6. VSJOE (2018) "Finally, I Was Also Able to Orgasm" Retrieved 8 February 2019.

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7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experiences/exp.php?ID=21223 milligrams to about 125 milligrams.



8. MOONDO (2014) "To Treat Premature Ejaculation" Retrieved 22 February 2019.

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From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non- priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

**18.** The sexual therapy formulation as recited in claim 14, wherein said libido stimulation component consists of an amount of 3,4methylenedioxymetha mphetamine, said R(-) isomer of 3,4methylenedioxymetha mphetamine, said S(+)isomer of 3,4methylenedioxymetha mphetamine, or said racemic mixture of 3,4methylenedioxymetha mphetamine.

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https://web.archive.org/web/20190208014713/https://erowid.org/experiences/exp.php?ID=112151

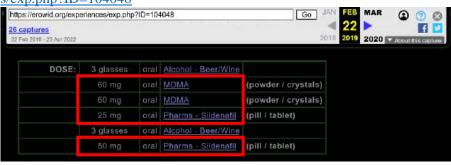


7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experiences/exp.php?ID=21223



8. MOONDO (2014) "To Treat Premature Ejaculation" Retrieved 22 February 2019.

 $\underline{https://web.archive.org/web/20190222023609/https://erowid.org/experience} \\ \underline{s/exp.php?ID=104048}$ 



**19.** The sexual therapy formulation as recited in claim 18, wherein a unit dosage of said formulation comprises a therapeutically effective amount of said libido stimulation component consisting of 3,4methylenedioxymetha mphetamine, said R(-) isomer of 3,4methylenedioxymetha mphetamine, said S(+)isomer of 3,4methylenedioxymetha mphetamine, or said racemic mixture of 3,4methylenedioxymetha mphetamine.

6. VSJOE (2018) "Finally, I Was Also Able to Orgasm" Retrieved 8 February 2019.

 $\underline{\text{https://web.archive.org/web/20190208014713/https://erowid.org/experience}}_{s/exp.php?ID=112151}$ 

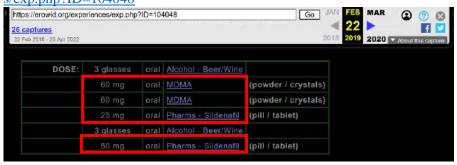


7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experiences/exp.php?ID=21223



8. MOONDO (2014) "To Treat Premature Ejaculation" Retrieved 22 February 2019.

 $\underline{\text{https://web.archive.org/web/20190222023609/https://erowid.org/experiences/exp.php?ID=104048}$ 



9. Int'l Pat. App. Pub. No. WO/2020/006606 "A PHARMACEUTICAL COMPOSITION AND METHOD OF USE OF SAME" (Published January 9, 2020)

From **Abstract** "The present disclosure relates to a pharmaceutical composition in a pharmaceutically acceptable vehicle. The pharmaceutical composition includes a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof. **The disclosed pharmaceutical composition may be useful in the treatment of erectile dysfunction** and premature ejaculation."

From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non- priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

From **claim 3** "The composition of claim 2, wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of: **avanafil**, iodenafil, mirodenafil, **sildenafil**, **tadalafil**, **vardenafil**, udenafil, zaprinast, icariin, benzamidenafil, and dasantafil."

From **claim 4** "The composition according to any one of claims 1 to 3, wherein the orgasm delaying agent is selected from the group consisting of: anaesthetics, analgesics, antidepressants, sedatives, and stimulants."

From **claim 10** "The composition according to claim 4, wherein the stimulant is selected from the group consisting of: **3,4-methylenedioxymethamphetamine**, amphetamine, caffeine, ephedrine, mephedrone, methylenedioxypyrovalerone, methylphenidate, nicotine, /V-methyl-alpha-methylphenethylamine, phenylpropanolamine, propylhexedrine, and pseudoephedrine."

From page 2 "According to an embodiment of the invention, there is provided a pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non-priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

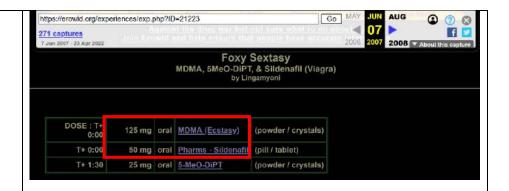
**20.** The sexual therapy formulation as recited in claim 19, wherein said therapeutically effective amount of 3.4methylenedioxymetha mphetamine, said R(-) isomer of 3,4methylenedioxymetha mphetamine, said S(+)isomer of 3,4methylenedioxymetha mphetamine, or said racemic mixture of 3,4methylenedioxymetha mphetamine is about 30 milligrams to about 125 milligrams.

6. VSJOE (2018) "Finally, I Was Also Able to Orgasm" Retrieved 8 February 2019.

https://web.archive.org/web/20190208014713/https://erowid.org/experiences/exp.php?ID=112151

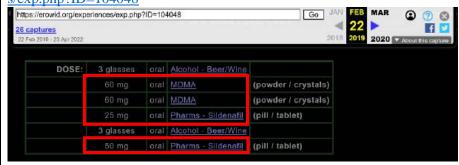


7. LINGAMYONI (2003) "Foxy Sextasy" Retrieved 7 June 2007. https://web.archive.org/web/20070607024945/https://erowid.org/experiences/exp.php?ID=21223



8. MOONDO (2014) "To Treat Premature Ejaculation" Retrieved 22 February 2019.

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From claim 1 "A pharmaceutical composition in a pharmaceutically acceptable vehicle, the pharmaceutical composition comprising a physiologically effective, non- priapismic, dose of a penile-erection-inducing agent or a pharmaceutically acceptable addition salt thereof and a physiologically effective dose of an orgasm-delaying agent or a pharmaceutically acceptable addition salt thereof."

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Electronic Acknowledgement Receipt				
EFS ID:	46251714			
Application Number:	17525248			
International Application Number:				
Confirmation Number:	3168			
Title of Invention:	SEXUAL THERAPY FORMULATION AND METHOD OF TREATMENT			
First Named Inventor/Applicant Name:	Bjorn Erik Hansen			
Customer Number:	106452			
Filer:	Shahin Shams			
Filer Authorized By:				
Attorney Docket Number:	7782.0200			
Receipt Date:	22-JUL-2022			
Filing Date:	12-NOV-2021			
Time Stamp:	13:53:45			
Application Type:				

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. New International Application Filed with the USPTO as a Receiving Office

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