

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (*day/month/year*)
21 August 2019

Applicant's or agent's file reference
P108940-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/AU2019/050698

International filing date (*day/month/year*)

03 July 2019

Priority date (*day/month/year*)

03 July 2018

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

A61K 31/05 (2006.01) A61K 31/352 (2006.01) A61K 31/015 (2006.01) A61K 31/01 (2006.01) A61K 31/045 (2006.01) A61P 25/22 (2006.01)

Applicant

ZELDA THERAPEUTICS OPERATIONS PTY LTD

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 43bis.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 66.1bis(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

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606,
AUSTRALIA
Email address: pct@ipaustalia.gov.au

Date of completion of this opinion

21 August 2019

Authorised Officer

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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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 (under 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(b))
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 13ter.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 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.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		International Application No. PCT/AU2019/050698									
Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement										
1. Statement <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; vertical-align: top;"> Novelty (N) </td> <td style="width: 50%; vertical-align: top;"> Claims 9, 16 to 20 and 22 Claims 1 to 8, 10 to 15, 21 and 23 </td> <td style="width: 20%; text-align: center; vertical-align: top;"> YES NO </td> </tr> <tr> <td style="vertical-align: top;"> Inventive step (IS) </td> <td style="vertical-align: top;"> Claims NONE Claims 1 to 23 </td> <td style="text-align: center; vertical-align: top;"> YES NO </td> </tr> <tr> <td style="vertical-align: top;"> Industrial applicability (IA) </td> <td style="vertical-align: top;"> Claims 1 to 23 Claims NONE </td> <td style="text-align: center; vertical-align: top;"> YES NO </td> </tr> </table>			Novelty (N)	Claims 9, 16 to 20 and 22 Claims 1 to 8, 10 to 15, 21 and 23	YES NO	Inventive step (IS)	Claims NONE Claims 1 to 23	YES NO	Industrial applicability (IA)	Claims 1 to 23 Claims NONE	YES NO
Novelty (N)	Claims 9, 16 to 20 and 22 Claims 1 to 8, 10 to 15, 21 and 23	YES NO									
Inventive step (IS)	Claims NONE Claims 1 to 23	YES NO									
Industrial applicability (IA)	Claims 1 to 23 Claims NONE	YES NO									
The present invention relates to pharmaceutical compositions comprising delta-9-tetrahydrocannabinol (THC), cannabidiol (CBD) and a terpene fraction, and the use of these in a method of treating post-traumatic stress disorder (PTSD) and/or anxiety. 2. CITATIONS AND EXPLANATIONS: <u>CITATIONS</u> D1: US 2016/0106705 A1 (UNITED CANNABIS CORP.) 21 April 2016 D2: US 2015/0313868 A1 (KOTZKER CONSULTING LLC) 05 November 2015 D3: CA 2952335 A1 (DELTA 9 GARDENING B.V., CA) 19 June 2017 <u>NOVELTY (N)</u> The invention as claimed in Claims 1 to 8, 10 to 15, 21 and 23 is considered to fail to meet the criteria set out in PCT Article 33(2) as lacking novelty in light of the disclosure of documents D1 to D3. The invention defined in Claims 1 to 8, 10 to 15, 21 and 23 lacks novelty in light of the disclosure of document D1. This document discloses extracts of Cannabis (see paragraph [0027]) comprising delta-9-tetrahydrocannabinol (which is referred to as “THC”, see paragraph [0031]), cannabidiol and a terpene fraction (such as d-limonene, linalool, 1,8-cineole, alpha-pinene, beta-myrcene or beta-caryophyllene), in the same ratios and amounts as presently claimed (see Claims 1 to 6; paragraphs [0005], [0012], [0016], [0067], [0078], Example 7). Said compositions may be administered orally (see Claim 17; paragraphs [0013], [0063], [0068]). This document further discloses the use of said composition for the treatment of anxiety and PTSD (see Claims 40, 49; paragraphs [0023], [0082] to [0083]; Example 7). As a result, said claims are considered to lack novelty. The invention defined in Claims 1 to 8, 10 to 15, 21 and 23 lacks novelty in light of the disclosure of document D2. This document discloses extracts of Cannabis (see paragraphs [0068], [0095]) comprising delta-9-tetrahydrocannabinol (which is referred to as “9THC”), cannabidiol and a terpene fraction (such as limonene, myrcene, pinene, linalool or beta-caryophyllene), in the same ratios and amounts as presently claimed (see Claims 1, 2, 7, 16, 19, 23; paragraphs [0048], [0052], [0076], [0087], [0093], [0113], [0114], [0143]; Example 3). Said compositions may be administered orally or via inhalation (see Claim 8; paragraphs [0037], [0047], [0062], [0092], [0097], [0100], [0101], [0112], [0113]). This document further discloses the use of said composition for the treatment of anxiety and PTSD (see Claim 12; paragraphs [0041], [0061], [0081], [0088], [0115], [0156]). As a result, said claims are considered to lack novelty. The invention defined in Claims 1 to 5, 7, 10 to 15 and 23 lacks novelty in light of the disclosure of document D3. This document discloses extracts of Cannabis comprising delta-9-tetrahydrocannabinol, cannabidiol and a terpene fraction (such as D-limonene, beta-myrcene, beta-linalool or beta-caryophyllene), in the same ratios and amounts as presently claimed (see Examples 1 to 4, 7, 10,											

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11, 12, 14, 16 to 19). This document further discloses the use of said composition for the treatment of anxiety and PTSD (see paragraph [0058]). As a result, said claims are considered to lack novelty.

The invention as claimed in Claims 9, 16 to 20 and 22 is considered to meet the criteria set out in PCT Article 33(2) as possessing novelty in light of the disclosure of documents D1 to D3, in that no prior art disclosure was found which provides a clear and enabled disclosure of the features defined in said claims.

INVENTIVE STEP (IS)

The present invention as claimed in Claims 1 to 8, 10 to 15, 21 and 23 is considered to fail to meet the criteria set out in PCT Article 33(3) as lacking an inventive step in light of the disclosure of documents D1 to D3, for the reasons discussed under Novelty (N) above.

The invention as defined in Claims 9, 16 to 20 and 22 lacks an inventive step in light of the disclosure of documents D1 and D2, each when taken alone. It is submitted that it would be a matter of routine in the pharmaceutical arts for a Person Skilled in the Art (P.S.A.) to consider whether one or more of the composition active ingredients should be enriched, as well as determine appropriate administration regimes and forms thereof, without the use of an inventive step, and which therefore cannot be considered as contributing to providing a patentable invention.

The invention as defined in Claims 6, 8 to 9, 16 to 20 and 21 to 22 lacks an inventive step in light of the disclosure of document D3, when taken alone. It is submitted that it would be a matter of routine in the pharmaceutical arts for a Person Skilled in the Art (P.S.A.) to consider whether one or more of the composition active ingredients should be enriched, as well as determine appropriate composition component amounts, and administration regimes and forms thereof, without the use of an inventive step, and which therefore cannot be considered as contributing to providing a patentable invention.

In light of the above, the invention as claimed in Claims 1 to 23 is considered to fail to meet the criteria set out in PCT Article 33(3) as lacking an inventive step in light of the prior art.

INDUSTRIAL APPLICABILITY (IA)

The invention as claimed in Claims 1 to 23 is considered to meet the requirements of Industrial Applicability because it can be made by, or used in, industry.

P Category Document/s listed in Box VI:

There is a document(s) listed as a P category document in Box VI because it:

- discloses subject matter that is of particular relevance to this application and
- is published before the international filing date but after the priority date of this application.

Under the PCT, only documents published before the priority date of the instant application can deprive the claims of that application of novelty or inventive step.

However, the relevance of a document published after the priority date of the application under consideration is dependent on national law in individual countries.

P category document/s may become significant in the National Phase.

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Priority date (valid claim)
(day/month/year)

31 May 2017

30 October 2017

See Supplemental Box for Details

Date of written disclosure
referring to non-written disclosure
(day/month/year)

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Supplemental Box

PCT/AU2019/050698

Continuation of: **Box VI**

The invention defined in Claims 1 to 8, 10 to 15, 21 and 23 lacks novelty in light of the disclosure of WO 2018/222923 A1.

This document discloses pharmaceutical compositions comprising delta-9-tetrahydrocannabinol (which is referred to as “THC”, see paragraphs [0214], [0223]), cannabidiol and a terpene fraction which is (E)-beta-caryophyllene, in the same ratios and amounts as presently claimed (see paragraphs [0008], [0024] to [0030], [0084], [0239], [0253]). Said compositions may be extracted from Cannabis (see paragraphs [0199] to [0200]) and may be administered orally or via inhalation (see paragraph [0261]). This document further discloses the use of said composition for the treatment of anxiety (see paragraphs [0301], [0425] Embodiments 45, 46, 85). As a result, said claims are considered to lack novelty.

The invention defined in Claims 1 to 8, 10 to 15, 21 and 23 lacks novelty in light of the disclosure of WO 2019/089583 A1.

This document discloses pharmaceutical compositions comprising delta-9-tetrahydrocannabinol (which is referred to as “THC”, see page 8 lines 5 to 8), cannabidiol and a terpene fraction (such as limonene, pinene, linalool or beta-caryophyllene) (see page 8 line 17 to page 9 line 2), in the same ratios and amounts as presently claimed (see Claims 1 to 32). Said compositions may be extracted from Cannabis (see page 4 lines 32 to 33) and may be administered orally or via inhalation (see page 26 lines 29 to 34). This document further discloses the use of said composition for the treatment of anxiety and PTSD (see Claim 41; page 4 lines 15 to 16, page 15 lines 25 to 29, page 28 line 28 to page 30 line 22). As a result, said claims are considered to lack novelty.