

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

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

Applicant's or agent's file reference
P108941-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/AU2019/050699

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 25/36 (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 43 <i>bis</i> .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

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**

International application No.

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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/AU2019/050699									
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 11, 17 to 18, 21 to 28, 30 and 32 Claims 1 to 10, 12 to 16, 19 to 20, 29, 31 and 33 to 34 </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 34 </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 34 Claims NONE </td> <td style="text-align: center; vertical-align: top;"> YES NO </td> </tr> </table>			Novelty (N)	Claims 11, 17 to 18, 21 to 28, 30 and 32 Claims 1 to 10, 12 to 16, 19 to 20, 29, 31 and 33 to 34	YES NO	Inventive step (IS)	Claims NONE Claims 1 to 34	YES NO	Industrial applicability (IA)	Claims 1 to 34 Claims NONE	YES NO
Novelty (N)	Claims 11, 17 to 18, 21 to 28, 30 and 32 Claims 1 to 10, 12 to 16, 19 to 20, 29, 31 and 33 to 34	YES NO									
Inventive step (IS)	Claims NONE Claims 1 to 34	YES NO									
Industrial applicability (IA)	Claims 1 to 34 Claims NONE	YES NO									
The present invention relates to pharmaceutical compositions comprising 9-tetrahydrocannabinol (THC), cannabidiol (CBD) and a terpene fraction, and the use of these in a method of opioid sparing and for treating opioid dependence and/or addiction. 2. CITATIONS AND EXPLANATIONS: <u>CITATIONS</u> D1: US 2016/0106705 A1 (UNITED CANNABIS CORP.) 21 April 2016 <u>NOVELTY (N)</u> The invention as claimed in Claims 1 to 10, 12 to 16, 19 to 20, 29,31 and 33 to 34 is considered to fail to meet the criteria set out in PCT Article 33(2) as lacking novelty in light of the disclosure of document D1. The invention defined in Claims 1 to 10, 12 to 16, 19 to 20, 29,31 and 33 to 34 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 beta-myrcene or linalool), in the same ratios and amounts as presently claimed (see Claims 1 to 6; paragraphs [0005], [0012], [0016], [0067], [0078], Example 9). The composition may further comprise cannabichromene (see Claim 1; paragraph [0005]). This document further discloses the use of said composition for the treatment of opioid dependency (see Claims 40, 47; paragraphs [0019], [0082] to [0083], [0086]; Example 9), where the patient may have chronic non-cancer pain (see paragraphs [0082] to [0083]). Further, this document discloses a method of treating opioid dependency by reducing the amount of opiates used, which it is submitted reads upon the presently-claimed “method of opioid sparing” (see paragraph [0021]). As a result, said claims are considered to lack novelty. The invention as claimed in Claims 11, 17 to 18, 21 to 28, 30 and 32 is considered to meet the criteria set out in PCT Article 33(2) as possessing novelty in light of the disclosure of document D1, in that no prior art disclosure was found which provides a clear and enabled disclosure of the features defined in said claims. <u>INVENTIVE STEP (IS)</u> The present invention as claimed in Claims 1 to 10, 12 to 16, 19 to 20, 29,31 and 33 to 34 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 document D1, for the reasons discussed under <u>Novelty (N)</u> above. The invention as defined in Claims 11, 17 to 18, 21 to 28, 30 and 32 lacks an inventive step in light of the disclosure of document D1, 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 the co-administration of other active agents, and determine appropriate dosage amounts and administration											

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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 34 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 34 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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PCT/AU2019/050699

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)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International Application No.

Supplemental Box

PCT/AU2019/050699

Continuation of: **Box VI**

The invention defined in Claims 1 to 10, 13 to 15, 17, 19 to 20, 31 and 33 to 34 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], [0425] Embodiment 63). Said compositions may be extracted from Cannabis (see paragraphs [0199] to [0200]). Said compositions may be co-administered with an opioid (see paragraph [0393]). This document further discloses the use of said composition for the treatment of substance addiction such as opioid addiction (see paragraphs [0014], [0310], [0425] Embodiment 54) and opioid sparing (see paragraph [0010]), where the patient may have chronic non-cancer pain (see paragraphs [0313] to [0315]). As a result, said claims are considered to lack novelty.

The invention defined in Claims 1 to 10, 12 to 16, 20 31 and 33 to 34 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 myrcene, alpha-terpinene, linalool or alpha-phellandrene) (see page 8 line 17 to page 9 line 2), in the same ratios and amounts as presently claimed (see Claims 1 to 32). The composition may further comprise one or both of cannabichromene (see page 7 lines 3 to 5) and cannabigerol (see page 4 lines 7 to 8). Said compositions may be extracted from Cannabis (see page 4 lines 32 to 33). This document further discloses the use of said composition for the treatment of opioid dependence (see page 34 lines 5 to 15), where the patient may have chronic non-cancer pain (see page 34 lines 16 to 25). As a result, said claims are considered to lack novelty.