

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

To: MBM INTELLECTUAL PROPERTY LAW LLP 275 SLATER ST 14TH FLOOR OTTAWA, Ontario Canada, K1P 5H9

Date of mailing (day/month/year)	16 December 2019 (16-12-2019)
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Applicant's or agent's file reference 3741-103PCT	FOR FURTHER ACTION See paragraph 2 below
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International application No. PCT/CA2019/051477	International filing date (day/month/year) 18 October 2019 (18-10-2019)	Priority date (day/month/year) 19 October 2018 (19-10-2018)
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International Patent Classification (IPC) or both national classification and IPC IPC: A61K 36/00 (2006.01), A61K 31/05 (2006.01), A61K 31/352 (2006.01), A61K 36/185 (2006.01), B01D 11/02 (2006.01), C07C 39/23 (2006.01) (more IPCs on the last page)
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Applicant FONG, SONNY ET AL

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 or 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<i>bis</i>(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/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Date of completion of this opinion 13 December 2019 (13-12-2019)	Authorized officer Henrietta Bor (819) 639-7761
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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 (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 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 in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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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

☐ claim Nos.

because:

☐ the said international application, or the said claim 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 claim Nos.
are so unclear that no meaningful opinion could be formed (*specify*):

☐ 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.

☐ 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.

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: 25%; vertical-align: top;">Novelty (N)</td> <td style="width: 10%; vertical-align: top;">Claims</td> <td style="width: 45%; vertical-align: top;">1 - 18</td> <td style="width: 20%; text-align: right; vertical-align: top;">YES</td> </tr> <tr> <td></td> <td style="vertical-align: top;">Claims</td> <td style="vertical-align: top;">none</td> <td style="text-align: right; vertical-align: top;">NO</td> </tr> <tr> <td colspan="4" style="height: 10px;"></td> </tr> <tr> <td style="vertical-align: top;">Inventive step (IS)</td> <td style="vertical-align: top;">Claims</td> <td style="vertical-align: top;">1 - 18</td> <td style="text-align: right; vertical-align: top;">YES</td> </tr> <tr> <td></td> <td style="vertical-align: top;">Claims</td> <td style="vertical-align: top;">none</td> <td style="text-align: right; vertical-align: top;">NO</td> </tr> <tr> <td colspan="4" style="height: 10px;"></td> </tr> <tr> <td style="vertical-align: top;">Industrial applicability (IA)</td> <td style="vertical-align: top;">Claims</td> <td style="vertical-align: top;">1 - 18</td> <td style="text-align: right; vertical-align: top;">YES</td> </tr> <tr> <td></td> <td style="vertical-align: top;">Claims</td> <td style="vertical-align: top;">none</td> <td style="text-align: right; vertical-align: top;">NO</td> </tr> </table>	Novelty (N)	Claims	1 - 18	YES		Claims	none	NO					Inventive step (IS)	Claims	1 - 18	YES		Claims	none	NO					Industrial applicability (IA)	Claims	1 - 18	YES		Claims	none	NO		
Novelty (N)	Claims	1 - 18	YES																																
	Claims	none	NO																																
Inventive step (IS)	Claims	1 - 18	YES																																
	Claims	none	NO																																
Industrial applicability (IA)	Claims	1 - 18	YES																																
	Claims	none	NO																																
2. Citations and explanations:	The instant application is directed to a process for preparing powdered cannabis extract comprising the steps: of combining liquid cannabis extract with molten methyl sulfonylmethane (MSM), dissolving the cannabis extract in the MSM into a single phase, cooling the mixture to a solid state and milling the solid mixture into a powder. Also claimed is the product in a dosage form or a topical form. The inventive feature appears to be the method of dissolving the extract in the MSM, solidifying the mixture and milling the solid into a powder which produces an evenly distributed dispersion of cannabis extract in a MSM matrix. Reference is made to the following documents: D1 US20180369191A1 (MUSCARELLA W.) 27 December 2018 (27-12-2018), D2 US20170348277A1 (RUIZ B.) 7 December 2017 (07-12-2017), D1 is directed to blended, processed cannabis compounds containing multiple additives <i>inter alia</i>, methyl sulfonylmethane, for use in pills, salves, syrups, drops and creams. D2 discloses a cannabis composition comprising MSM and at least one cannabinoid in a liquid form for the treatment of eye conditions in an animal. The cannabis extract is dissolved in MSM at 210° F and used in a liquid form. (Continued in Supplemental Box I)																																		

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 1 - 5, 7 and 10 do not comply with PCT Article 6. These claims are not fully supported by the description. Specifically, claims 1 – 5, 7 and 10 encompassing any botanical extract are broader in scope than what has been disclosed in the specification. The description only provides support for cannabis extracts.

Claim 1 does not comply with PCT Article 6. The claim shall be clear and concise. The acronym MSM must be defined upon its first use in the claims.

Claim 4 does not comply with PCT Article 6. The claim shall be clear and concise. Claim 4 lacks clarity as both roman numerals and letters are used to label the process steps.

Supplemental Box

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

Continuation of: Box V

Novelty:

Claims 1 - 18 are novel and therefore comply with PCT Article 33(2). Document D1 is considered to represent the closest prior art. Document D1 discloses blended, processed cannabis compounds containing multiple additives, *inter alia*, methyl sulfonylmethane, for use in pills, salves, syrups, drops and creams. D2 discloses a cannabis composition comprising MSM and at least one cannabinoid in a liquid form for the treatment of eye conditions in an animal. The cannabis extract is dissolved in MSM at 210° F and used in a liquid form. Although cannabis and/or cannabinoids are widely used in combination with MSM (a known anti-inflammatory, solvent, and pain reliever) in the production of ingestible and topical products, the prior art does not disclose solidification of a cannabis extract/MSM mixture, milling, or use of this mixture in a solid form. Specifically, neither D1 nor D2 disclose a process for preparing powdered cannabis extract comprising the steps: of combining liquid cannabis extract with molten methyl sulfonylmethane (MSM), dissolving the cannabis extract in the MSM into a single phase, cooling the mixture to a solid state and milling the solid mixture into a powder. Claims 1 - 18 are therefore novel.

Inventive Step:

Claims 1 - 18 involve an inventive step and therefore comply with PCT Article 33(3). Although cannabis and/or cannabinoids are widely used in combination with MSM (a known anti-inflammatory, solvent and pain reliever) in the production of ingestible and topical products, the prior art does not disclose solidification of a cannabis extract/MSM mixture, milling or use of this mixture in a solid form. It would not have been obvious to a person skilled in the art from the cited documents, when taken individually or in any combination that dissolving cannabis extract in molten MSM, solidifying the mixture and milling said mixture into a powdered form would produce a highly evenly distributed extract specifically suited for use in cannabis products. Claims 1 - 18 therefore involve an inventive step.

Industrial Applicability:

The subject matter of claims 1 - 18 is considered to be industrially applicable and thus complies with the requirements of PCT Article 33(4).

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Supplemental Box

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

Continuation of:

C07D 311/80 (2006.01)