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) 15 September 2017 (15-09-2017)

Applicant's or agent's file reference
2082.142

FOR FURTHER ACTION
See paragraph 2 below

International application No
PCT/CA2017/000042

International filing date (day/month/year) 06 March 2017 (06-03-2017)
Priority date (day/month/year) 04 March 2016 (04-03-2016)

International Patent Classification (IPC) or both national classification and IPC
IPC: G01N 27/62 (2006.01), A61B 5/08 (2006.01), A61B 5/097 (2006.01)

Applicant
CANNABIX TECHNOLOGIES INC.

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

- [X] 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
- [X] 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
- [ ] 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 ("IDPA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPA and the chosen IPEA has notified the International Bureau under Rule 66.1(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
15 September 2017 (15-09-2017)

Authorized officer
Dan Marinescu (819) 639-8202

Form PCT/ISA/237 (cover sheet) (January 2015)
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 43bis.1(a))

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

   a. ☒ forming part of the international application as filed:
       ☒ in the form of an Annex C/ST.25 text file.
       ☒ on paper or in the form of an image file.
   b. ☕ furnished together with the international application under PCT Rule 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 in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:
<table>
<thead>
<tr>
<th>Box No. V</th>
<th>Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Statement</td>
<td></td>
</tr>
<tr>
<td>Novelty (N)</td>
<td>Claims 1 - 19</td>
</tr>
<tr>
<td>Claims</td>
<td>NONE</td>
</tr>
<tr>
<td>Inventive step (IS)</td>
<td>Claims NONE</td>
</tr>
<tr>
<td>Claims</td>
<td>1 - 19</td>
</tr>
<tr>
<td>Industrial applicability (IA)</td>
<td>Claims 1 - 19</td>
</tr>
<tr>
<td>Claims</td>
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</tr>
</tbody>
</table>

2. Citations and explanations:

D1: CA2887841 (ATTARIWALA et al.) 16 April 2015 (16-04-2015)
D2: US8237118 (PROX et al.) 07 August 2012 (07-08-2012)

**ARTICLE 33(2) PCT - NOVELTY**

Claim 1 discloses a controlled substance detection system for detecting one or more controlled substances in the breath of a subject, comprising:

- a containment trap for removing interfering materials from the breath of the subject; and
- a collection component for sampling components of breath introduced into the system through the containment trap for analysis to determine the presence of one or more controlled substances in the breath.

In which components of the breath sampled by the collection component are analyzed using FAIMS.

D1 teaches a system for collecting cannabis and the psychoactive component tetrahydrocannabinol from a sample of exhaled breath, which comprises a containment trap and a collection component for sampling components of breath (see entire document). The patent document discloses the subject matter of claim 1 less the FAIMS analysis part. Therefore, claim 1 complies with Article 33(2) PCT having regard to D1.

Claim 11 is directed to a method of detecting cannabis or other controlled substances used by analyzing breath of a subject. D1 teaches the steps of the method less the step of analyzing the sample using FAIMS (see entire document). Therefore, claim 11 complies with Article 33(2) PCT having regard to D1.

Claim 15 is directed to a detection system for detecting one or more controlled substances in the breath of a subject. D1 teaches all the components of the system with the exception of the FAIMS analysis part (see entire document). Therefore, claim 15 complies with Article 33(2) PCT having regard to D1.

The dependent claims (2 – 10, 12 - 14 and 16 – 19) comply with Article 33(2) PCT having regard to D1.

**ARTICLE 33(3) PCT - INVENTIVE STEP**

As shown above, D1 discloses the subject matter of claim 1 less the FAIMS analysis part. However, at the claim date, a person skilled in the art was aware of FAIMS as a separation technique which allows continuous sample introduction, enabling real-time analysis. D2 is cited, as it teaches a partial ovoidal FAIMS apparatus for separating ions (see abstract and col. 3).

In view of the combined teachings of D1 and D2 it would have been obvious to a person skilled in the art to implement a detection system having the features disclosed by claim 1. Therefore, claim 1 does not comply with Article 33(3) PCT having regard to D1 and D2.

Similarly, claim 11 and claim 15 do not comply with Article 33(3) PCT having regard to D1 and D2.

Claims 2 – 10 depend from claim 1 and disclose additional features, which are taught by D1. These claims do not comply with Article 33(3) PCT having regard to D1 and D2.

Claims 12 – 14 depend from claim 11 and disclose additional features, which are taught by D1. These claims do not comply with Article 33(3) PCT having regard to D1 and D2.

(continued in Supplemental Box, page 4)
In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. V, page 3

Claims 16 – 19 depend from claim 15 and disclose additional features, which are taught by D1. These claims do not comply with Article 33(3) PCT having regard to D1 and D2.

ARTICLE 33(4) PCT - INDUSTRIAL APPLICABILITY

Claims 1 - 19 disclose systems and methods of detecting controlled substances in the breath of a subject. Therefore, the claims have industrial applicability and comply with Article 33(4) PCT.