

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: TIMOTHY H. VAN DYKE
BEUSSE, WOLTER, SANKS & MARIE PLLC
390 N. ORANGE AVE., SUITE 2500
ORLANDO, FL 32801

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

03 MAR 2020

Applicant's or agent's file reference
10462-113PC0

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 19/64066

International filing date (day/month/year)

02 December 2019 (02.12.2019)

Priority date (day/month/year)

30 November 2018 (30.11.2018)

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

IPC - A61M 15/00; G09B 9/00 (2020.01)

CPC - A61M 15/00, A61M 15/0001, A61M 15/0005, A61M 15/009; G09B 9/00

Applicant

NOBLE INTERNATIONAL, INC.

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/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

10 February 2020

Authorized officer

Lee Young

PCT Help Desk

Telephone No. 571-272-4300

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Box No. 1 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 forming part of 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.

claims Nos. 7-10, 15

because:

the said international application, or the said claims 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 claims Nos. 7-10, 15 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 7-10 and 15 are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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. 7-10, 15

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 13ter.1(a) or (b).

See Supplemental Box for further details.

**WRITTEN OPINION OF THE
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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

1. Statement

Novelty (N)	Claims	1-6, 11-14, 16-20	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-6, 11-14, 16-20	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-6, 11-14, 16-20	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-6, 11-14, and 16-20 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the subject matter claimed.

The prior art is exemplified by EP 0667168 A1 to CIRCADIAN, INC. (hereinafter Circadian), US 2015/0320947 A1 to BOEHRINGER INGELHEIM INTERNATIONAL GMBH) (hereinafter Boehringer).

Claim 1; Circadian discloses a resettable respiratory inhaler training device, (pg. 14, ln 10-15, 39-41) comprising; a device housing (104), the housing comprising a chamber (Figs 1A-1B; pg 8, lns 52-58); a cartridge (106) for placement into the chamber, the cartridge comprising a body and a base, wherein the body is receivable within the chamber (Figs 1a, 1b; pg 8, lns 52-58).

Circadian does not disclose the housing comprising an unlocked position and a locked position; said cartridge comprises a status indicator window to indicate a new or used status of the cartridge, an aperture in the base of the cartridge, and a shutter to selectively open or close the aperture; a reset cap comprising a protrusion for interfacing with the aperture during reset of the device; and wherein removal of the cartridge from the device housing changes the status in the indicator window from the used status to the new status and resets the cartridge for a subsequent use.

Boehringer discloses a housing comprising an unlocked position and a locked position (paras [0083], [0212]); said cartridge comprises a status indicator window to indicate a new or used status of the cartridge (paras [0107]-[0108]), an aperture (23) in the base of the cartridge (Fig 1; para [0082]); and wherein removal of the cartridge from the device housing changes the status in the indicator window from the used status to the new status and resets the cartridge for a subsequent use (para [0246]). However, Boehringer otherwise fails to remedy the deficiencies of Circadian.

Therefore the prior art of record does not teach or fairly suggest the subject matter claimed. Specifically, none of the prior art, alone or in combination, discloses or fairly suggests a shutter to selectively open or close the aperture and a reset cap comprising a protrusion for interfacing with the aperture during reset of the device.

Claims 2-6, 11-14, and 16-20 meet the criteria set out in PCT Article 33(2)-(3) as depending from claim 1.

Claims 1-6, 11-14, and 16-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.