PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2018/051436	25.05.2018	07.06.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/24 A61M5/32

Applicant
NDM TECHNOLOGIES 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*bis*.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 usually 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 notifed 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:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Date of completion of this opinion
see form PCT/ISA/210

Authorized Officer
Daintith, Nichola
Telephone No. +49 89 2399-0

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2018/051436

Box No. I Basis of the 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(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 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:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-13
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-13
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-13
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 None of the prior art discloses all the features of independent claims 1 or 11 in their entirety and hence the requirement of novelty of Article 33(2) PCT appears to be met.

2 The closest prior art appears to be disclosed within WO2017/060394 (D1) which discloses the following features of claim 1:

> An injector device comprising:
> a needle 90 having a proximal end 91 for insertion into the skin of a patient and a distal end 92 for insertion through a septum in the neck of a drug cartridge 910, the alignment of the distal end 92 defining an axis (z-axis);
> a collar region 20 for receiving the neck of the drug cartridge 910; and
> a needle support member 48, which supports the needle 90

The features of claim 1 not known from D1 are:

> that the needle support member supports the needle at a rest position close to the distal end before the neck of the drug cartridge is received in the collar region, and
>
> that the needle support member is displaceable by the neck of the drug cartridge relative to the needle, such that the needle support member moves away from the rest position as the neck moves into the collar region.

2.1 The problem of the prior art lies in that a thin gauge needle may buckle and bend when pressed into the septum. The solution lies in the provision means for preventing bucking by supporting and controlling the needle during insertion into the septum. The invention of the application is the provision of a support member which supports the needle at the distal end where is is most vulnerable, but which does not prevent the needle from passing through the septum in that the needle support member moves away from the rest position as the collar moves over the neck of the device and the septum. The requirement of inventive activity of Article 33(3)PCT appears to be met by independent claim 1.

2.2 Independent claim 11 concerns the method of coupling a drug cartridge to a needle device such as in claim 1 and is mutatis mutandis novel and inventive.

3 The dependent claims 2 to 10, 12 and 13 concern further embodiments of the device of claim 1 and method of claim 11 and are hence formally also novel and inventive.