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/IB2016/051060	26.02.2016	10.03.2015

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

Applicant
RATHORE, JAI HIND

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:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Diamantouros, S Telephone No. +49 89 2399-0

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB2016/051060

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. 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. 49-68

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. 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 the whole application or for said claims Nos. 49-68

☐ 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. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-48

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	1-48
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-48
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-48
	No:	Claims	

2. Citations and explanations

   see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 57-68 are not treated in this opinion, because they disclose a method for the treatment of the human or animal body by therapy (Rule 39.1(iv) PCT). More specifically, claim 57 discloses a "fluid injecting method". Even though this formulation does not specifically mention that a medicament will be injected into a patient, it is broad enough and it does not exclude it, while from the description it is clear that the device is supposed to administer a drug into a patient (see "object of the invention" in the description and also the section "background of the invention"). Similarly, claim 63 discloses a fluid collecting method, wherein a needle is inserted into a "target fluid source", collecting a fluid. It is clear that also this claim refers to the collection of fluids from a patient.

In order for these and their dependent claims to be deemed as fulfilling the requirements of Rule 39.1(iv) PCT, the use of the invention for the treatment of patients will have to be excluded.

Care should be taken not to introduce subject-matter which extends beyond the content of the application as filed, according to Article 19(2) PCT.

Re Item IV

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are 2 inventions covered by the claims indicated as follows:

1 Fluid injecting system (claims 1-48)

Features:

a) Injector
b) Plunger assembly
c) Fluid container
d) Needle retraction mechanism

2 Fluid collector (claims 49-56)

Features:

a) Fluid container
b) Piston assembly
c) Container cover
d) Fluid suction mechanism

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

(a) The common feature of the two inventions is that they are directed towards a plunger carrying system with a fluid container. This is a well-known feature in the art and does not from a single general inventive concept.

(b) The technical effects of the remaining features is:

Invention 1: The vacuum created by the double plunger is used to retract the needle.
Invention 2: The vacuum created by the double plunger is used for the suction of a fluid.

It is obvious that these 2 inventions solve different technical problems and that the technical relationship between the subject-matter of the groups of claims referring to the inventions required by Rule 13.1 PCT is lacking.

Re Item V

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

Reference is made to the following documents:

D1 WO 2014/080420 A2 (RATHORE JAI HIND [IN]; RATHORE BHARATI [IN]; RATHORE PRATIBHA [IN]; RA) 30 May 2014 (2014-05-30)

D2 WO 03/030961 A2 (MAXXON INC [US]) 17 April 2003 (2003-04-17)

Document D1 seems to be the prior art closest to the subject-matter of claim 1. Claim 1 differs from it in that:

(a) A united plunger barrel is formed by the engagement of an outer and an inner barrel.
(b) The fluid cartridge can be disengaged from the injector so that the injector can be reused.

The technical effect of these features is that the injector is reusable while the only parts to be discarded are the needle hub and the medicament cartridge. As a result a cheaper and friendlier to the environment system is achieved without an increased risk of needle injuries.

Document D1 does not contain any hints towards making a reusable injector with a vacuum driven retractable needle. It indeed stresses the fact that the device should be single-use for safety reasons. Therefore, it appears that claim 1 is novel and inventive according to Articles 33(2) and 33(3) PCT.

The dependent to it claims will also be novel and inventive.

Re Item VII

Certain defects in the international application

1 Independent claims should be in the two-part form (Rule 6.3(b) PCT).

2 The description should be brought in conformity with any amended claims (Rule 5.1(a)(iii) PCT).

3 The basis for any amendments should be identified in the application as filed (Article 19.1 PCT).

Re Item VIII

Certain observations on the international application

The application does not meet the requirements of Article 6 PCT, because claim 1 is not clear.

1 The term "injector having an injector body" is vague and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.

2 The creation of the vacuum between the outer and inner plunger barrel is defined in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

3 In addition, the retraction of the hypodermic needle within the fluid cartridge is also defined in terms of result to be achieved.

4 It is mentioned that the movement of the outer plunger barrel is restricted in the forward direction, which leads to the creation of the vacuum, but also that the device is reusable. It is not clear how these two features are compatible.

5 It is clear from the description that the following features are essential to the definition of the invention:

(a) Plunger head 31 and cavity 66. Without these features the barrel plunger cannot connect to the cartridge plunger to form a single plunger unit 67.
(b) needle catch projection 65 and conical cavity 75. These features make the connection between plunger and needle hub possible.
(c) U clip locking means 35 with conical lock-notch 34 and partition ring 11. This feature locks the two plunger barrels together and keeps them locked until the end of the injection, when the needle retraction starts.
(d) the geometry of inner and outer plunger, the seal holder 25 and the seal 26. These features make the creation of the single barrel and of the vacuum possible.

Since independent claim 1 does not contain these features it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.