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/203

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/IB2015/050737	30.01.2015	03.02.2014

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/165 A61M5/142

Applicant
NOVARTIS AG

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/203	Telephone No. +49 89 2399-0

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 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 filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

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:

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.

because:

☒ the said international application, or the said claims Nos. 1-20 relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ 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. ___

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper 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 a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form 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 a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

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

Re Item III

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

1 **Claims 1-19**

1.1 Independent method **claim 1** and the respective dependent **claims 2-19** are directed to methods for **treatment of the human or animal body by therapy**, which is excluded from patentability, Rule 39.1(iv) PCT. In particular, claims 1-19 are directed to administering a therapeutic to a patient, i.e. a human or animal body, by means of a peripheral intravenous line (cf. also e.g. paragraphs [0008]-[0021] in the description), which is used in the pertinent art for treating diseases, analgesic applications, etc.

1.2 Inherently, claims 1-19 are also directed to methods for **treatment of the human or animal body by surgery** (Rule 39.1(iv) PCT), as it is inherently taught that the therapeutic is dispensed from outside of the body via an IV line into the blood circuit of a human or animal body via a respective access port or needle.

2 **Claim 20**

Independent method **claim 20** does not comprise any technical features in the sense of actually technical method steps, which would go beyond an undefined *preparing* of an infusion set and a step of *choosing* a filter from a list of identified entries. Claim 20 does not define any definition of the infusion set being specially adapted for the mentioned filters (or vice versa), which would define any particular step of e.g. embedding the filter into the infusion set. Consequently, and also in the light of preceding claims 1-19 as well as the description (see e.g. paragraph [0022] apparently associated with claim 20) and figures, which are actually directed to the actual *use* of the mentioned filters in an infusion set, the *preparing* method of claim 20 is also regarded as actually being directed to a *use* of the mentioned filters in a generic infusion set, i.e. eventually in an administering method.

As a consequence, claim 20, as far as it can be construed in a technical manner, is also directed to a method for **treatment of the human or animal body by therapy**, which is excluded from patentability, Rule 39.1(iv) PCT. Inherently, claim 20 is also directed to a method for **treatment of the human or animal body by surgery** (Rule 39.1(iv) PCT).

Re Item VII

Certain defects in the international application

3 Notwithstanding the above explained non-establishment of opinion, it is noted that the application is also defective in various further aspects, particularly concerning claims 1 and 20, e.g. **lack of clarity** due to the mentioned filters appearing to be **registered trade marks** having no precise meaning as they are not internationally accepted as standard descriptive terms (Article 6 PCT), **lack of conciseness** due to the use of multiple independent claims in the same category (i.e. method) (Article 6 PCT), **lack of two-part form** of the independent claims (Rule 6.3(b) PCT). Moreover, it appears to lack novelty (Article 33(2) PCT) or at least not involve an inventive step (Article 33(3) PCT) to employ dedicated filters for filtering in an infusion set.