

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) 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. PCT/EP2016/081701	International filing date (day/month/year) 19.12.2016	Priority date (day/month/year) 21.12.2015
International Patent Classification (IPC) or both national classification and IPC INV. A61K9/00 A61K47/34		
Applicant BAYER OY		

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 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 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:  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 Felder, Christian Telephone No. +49 89 2399-0
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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:
 - 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 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 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-14</u>
	No: Claims	<u>15</u>
Inventive step (IS)	Yes: Claims	<u>1-14</u>
	No: Claims	<u>15</u>
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	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

Reference is made to the following documents:

- | | |
|----|---|
| D1 | US 2009/202612 A1 (AHMED SALAH U [US] ET AL) 13 August 2009
(2009-08-13) |
| D2 | EP 2 062 569 A1 (BAYER SCHERING PHARMA OY [FI]) 27 May 2009
(2009-05-27) |
| D3 | US 2012/093911 A1 (MALCOLM KARL [IE] ET AL) 19 April 2012
(2012-04-19) |
| D4 | US 4 155 991 A (HARTMANN HEIDEMARIE [DE] ET AL) 22 May 1979
(1979-05-22) |

The present application claims a method of manufacturing a vaginal ring, wherein the vaginal ring comprises

- at least one therapeutically active agent and
- a body comprising a crosslinked siloxane elastomer, the method comprising
- manufacturing the body in the form of a rod having a first end and a second end,
- forming the body into a ring by
- arranging an attachment part between the first end of the body and the second end of the body, wherein the attachment part comprises a non-crosslinked siloxane elastomer having a weight average molecular weight of 650-850 g/mol and a cross-linking catalyst, and
- curing the attachment part for a period of time of 1-30 second using a temperature of 125-220°C.

Furthermore, a vaginal ring obtainable by said method is claimed.

1 Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 15 is not new in the sense of Article 33(2) PCT.

The present claims 1-14 discloses a method of manufacturing a vaginal ring, wherein the vaginal ring comprises

- at least one therapeutically active agent and
- a body comprising a crosslinked siloxane elastomer, the method comprising
- manufacturing the body in the form of a rod having a first end and a second end,
- forming the body into a ring by
- arranging an attachment part between the first end of the body and the second end of the body, wherein the attachment part comprises a non-crosslinked siloxane elastomer having a weight average molecular weight of 650-850 g/mol and a cross-linking catalyst, and
- curing the attachment part for a period of time of 1-30 second using a temperature of 125-220°C.

None of the cited documents discloses such a method. Therefore, the present claims 1-14 are novel over the prior art.

Claim 15 is defining a product in terms of a process and should therefore be formulated as a product by process.

Furthermore, the attention of the applicant is drawn to the fact that a product is not rendered novel merely by the fact that it is produced by means of a new process.

There is no hint in the description that a composition which is produced in a way as disclosed by the present application has different properties than the same composition obtained by a different process.

Therefore the present claim 15 is not novel in the light of the cited documents D1-D4 which already disclose a drug delivery device, e.g. a vaginal ring which has a body comprising a siloxane-based elastomer and at least one active agent.

2 Inventive step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 15 does not involve an inventive step in the sense of Article 33(3) PCT.

The present claims 1-14 seem to be inventive in the light of the cited prior art since none of said prior art documents discloses forming the body into a ring by

- arranging an attachment part between the first end of the body and the second end of the body, wherein the attachment part comprises a non-crosslinked siloxane elastomer having a weight average molecular weight of 650-850 g/mol and a cross-

linking catalyst, and

- curing the attachment part for a period of time of 1-30 second using a temperature of 125-220°C.

The present claim 15 is obvious in the light of documents D1-D4 since they disclose already a drug delivery device, e.g. a vaginal ring which has a body comprising a siloxane-based elastomer and at least one active agent.

3 Industrial applicability

The present claims 1-15 are industrially applicable.