

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

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/US2019/065099

International filing date (day/month/year)
06.12.2019

Priority date (day/month/year)
07.12.2018

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/315 C08J7/12 B23K26/364

Applicant
ABRAMS, ROBERT S.

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

Knaus-Reinbold, S

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:
 - 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. 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. 46

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. 46

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

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>5, 6, 13-20, 28, 30, 32-38, 43, 44</u>
	No: Claims	<u>1-4, 7-12, 21-27, 29, 31, 39-42, 45</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-45</u>
Industrial applicability (IA)	Yes: Claims	<u>1-45</u>
	No: Claims	

2. Citations and explanations

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

- 1 The present application contains 46 claims. There are so many dependent claims (1,29,46), and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as they create a smoke screen in front of the skilled reader when assessing what should be the subject-matter to search. The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCT Guidelines 9.19).
- 2 The extent of the search was consequently limited to **claim 1 to 45**, which appears to comprise a reasonable definition of what is understood to be the invention for which protection is sought.

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 2017/281873 A1 (KANEKO HIROYUKI [JP] ET AL) 5 October 2017 (2017-10-05) |
| D2 | WO 2015/118958 A1 (SUMITOMO RUBBER IND [JP]) 13 August 2015 (2015-08-13) |
| D3 | EP 3 058 975 A1 (SUMITOMO RUBBER IND [JP]) 24 August 2016 (2016-08-24) |
| D4 | EP 3 409 311 A1 (SUMITOMO RUBBER IND [JP]) 5 December 2018 (2018-12-05) |

Novelty Article 33(2) PCT

- 3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-4,7,9-12,21-27,29, 31,39-42 and 45** does not seem to be new in the sense of Article 33(2) PCT.
- 3.1 The document D1 discloses a process (figure 4) for making one or more continuous channels in a film (15) residing on at least a circumferential outer surface portion of a gasket (13), the gasket (13) comprising a main body made of an elastic material (paragraph 39), the main body having a circumferential

surface portion and an internal cavity in its center, the cavity being defined by an inner surface portion of the gasket and being open at one end, the process comprising the following steps:

- (a) inserting a portion of one end of a mandrel into the open end of the cavity;
- (b) securing the gasket to the mandrel;
- (c) positioning the mandrel and secured gasket in proximity to a laser; and
- (d) applying a laser beam emitted from the laser to one or more selected locations on a surface portion of the film residing on the circumferential outer surface portion of the gasket while rotating the mandrel and the secured gasket along the mandrel's longitudinal axis to produce one or more continuous channels in the film, the channels extending around the entire circumference of a circumferential outer surface of the gasket. (see paragraph 71-76)

Therefore the subject matter of claim 1 is not novel over document D1.

3.2 Document D1 also describes the technical features of claims 1-4, 7, 9-12, 21-27, 29, 31, 39-42 and 45. (Thickness (paragraph 51), slidability (paragraph 45), axially spaced (paragraph 48), width (paragraph 53), depth (paragraph 52).

3.3 Furthermore Documents D2 to D4 disclose the technical feature of claims 1-4, 9-12, 21-26, 29, 31, 39-42 and 45.

Document D2: figure 1 to 3, a process for making one or more continuous channels in a film (15), the gasket, the process comprising the following steps:

- (a) inserting a portion
- (b) securing the gasket to the mandrel;
- (c) positioning the mandrel and secured gasket in proximity to a laser; and
- (d) applying a laser beam (see description)

Document D3: figure 1 to 3, a process for making one or more continuous channels in a film (15), the gasket, the process comprising the following steps:

- (a) inserting a portion
- (b) securing the gasket to the mandrel;
- (c) positioning the mandrel and secured gasket in proximity to a laser; and
- (d) applying a laser beam (see paragraph 47-76)

Document D4: figure 1 , a process for making one or more continuous channels in a film (3), the gasket (1), the process comprising the following steps:

- (a) inserting a portion
- (b) securing the gasket to the mandrel;
- (c) positioning the mandrel and secured gasket in proximity to a laser; and
- (d) applying a laser beam (see paragraph 39-40)

Inventive Step Article 33(3) PCT

- 4 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 5,6,8,13-20,28,30,32-38,43 and 44** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D1 is the closest prior art.
- 5 In **claims 5,6,8,13-20 and 28** a slight constructional change in the process of claim 1 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.
- 6 In **claims 30,32-38,43 and 44** a slight constructional change in the matched syringe and plunger system of claim 29 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.

Further comments

- 7 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in **documents D1 to D4** are not mentioned in the description, nor are these documents identified therein.
- 8 Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 9 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 10 Claim 29 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

Re Item VIII

Certain observations on the international application

Clarity Article 6 PCT

11 The application does not meet the requirements of Article 6 PCT, because **claims 1 and 29** are not clear.

12 Claims 1 and 29 do not meet the requirements of Article 6 PCT because the matter for which protection is sought is not clearly defined:

- (a) inserting a portion of one end of a mandrel into the open end of the cavity;
- (b) securing the gasket to the mandrel;
- (c) positioning the mandrel and secured gasket in proximity to a laser; and
- (d) applying a laser beam emitted from the laser to one or more selected locations on a surface portion of the film residing on the circumferential outer surface portion of the gasket **while rotating the mandrel and the secured gasket** along the mandrel's longitudinal axis to produce one or more continuous channels in the film, the channels extending around the entire circumference of a circumferential outer surface of the gasket.

The claim attempts to define the subject-matter 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.

The applicant has to be more precise how to insert the mandrel, how to secure the gasket, how to position the mandrel and gasket and how to apply a laser beam.

13 It is clear from the description, claim 5 and 20 and figure 1 to 5 that features:

- the gasket is secured to the mandrel by press-fit assembly.
- wherein the position of the laser relative to the mandrel and secured gasket is controlled by a servo-motor.

are essential to the definition of the invention.

The combination of the features above seem to be at least necessary to perform the function described and to achieve the result claimed by the applicant. If any of the features was missing, the process would not work, and there are no other possibilities disclosed in the description.

Since independent claim 1 does not contain this feature 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.

14 It is clear from the description, claim 30 and 45 and figure 1 to 5 that features:

- the gasket is secured to the mandrel by press-fit assembly.
- the syringe barrel has a wall including an inner surface defining a generally cylindrical lumen, the barrel having an inner diameter; the gasket having a leading face, a side surface, a trailing portion, and an outer diameter; the gasket configured to be received within any the barrel with the gasket outer diameter located within and movable with respect to the barrel inner diameter; and

the barrel and gasket of the system respectively sized to provide spacing between the smallest barrel inner diameter and largest gasket outer diameter, when assembled, deviating from the nominal spacing by no more than: ± 100 microns, ± 50 microns, ± 35 microns, ± 25 microns, ± 20 microns, ± 15 microns, ± 10 microns, ± 5 microns or ± 2 microns

are essential to the definition of the invention.

The combination of the features above seem to be at least necessary to perform the function described and to achieve the result claimed by the applicant. If any of the features was missing, the system would not work, and there are no other possibilities disclosed in the description.

Since independent claim 29 does not contain this feature 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.