

# PATENT COOPERATION TREATY

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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/EP2022/059213

International filing date (day/month/year)  
07.04.2022

Priority date (day/month/year)  
14.04.2021

International Patent Classification (IPC) or both national classification and IPC  
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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.

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Date of completion of  
this opinion

see form  
PCT/ISA/210

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**Box No. I Basis of the opinion**

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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:

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**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**

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1. Statement

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

2. Citations and explanations

see separate sheet

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**Box No. VII Certain defects in the international application**

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

see separate sheet

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**Box No. VIII Certain observations on the international application**

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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

item V

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

1 Reference is made to the following documents:

- D1 EP 1 009 288 A1 (AXYA MEDICAL INC [US]) 21 June 2000 (2000-06-21)
- D2 JP H03 132334 A (FUJI DENSAN KK) 5 June 1991 (1991-06-05)
- D3 US 4 075 046 A (MACDONALD HAROLD B) 21 February 1978 (1978-02-21)
- D4 US 3 386 870 A (MORIN LOUIS H) 4 June 1968 (1968-06-04)
- D5 EP 2 673 230 A1 (ODYSSEA PHARMA S A [BE]) 18 December 2013 (2013-12-18)
- D6 FR 2 729 940 A1 (FYLTIS SA [FR]) 2 August 1996 (1996-08-02)

2 **Novelty and inventive step**

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

2.1 **Independent claims**

2.1.1 Claim 1 - Inventive step in view of D1 and D1-D4

D1 is considered to be the prior art closest to the subject-matter of claim 1 and discloses (the references in brackets refer to this document):

An apparatus for ultrasonic welding (**claim 1: "Ultrasonic welding apparatus"**) of a removal thread of an intrauterine system (**the apparatus in D1 is suitable for welding such removal thread**), comprising

- a welding jig (**"second member 32" in fig. 15A**) comprising a welding groove (**see groove formed by 32 in fig. 15A**), the welding groove having a length Lg, a width Wg and a depth Dg and a bottom,
- a sonotrode (**para. [0045]: "first member 30 is capable of vibrating and delivering mechanical energy at ultrasonic frequencies"**), a width Ws of a weldingtip (**"suture-contacting surface 30A" in fig. 15A**) of the sonotrode that

is 80-98 % of  $W_g$  (*the ratio of the widths in fig. 15A appear to be in that range*) and a depth  $D_s$ , wherein the welding tip of the sonotrode has a concave shape (*see 30A in fig. 15A; para. [0051]: "the concave suture-contacting surface 30A"*).

The subject-matter of claim 1 therefore differs from this known D1 in that:

- A) the bottom has a concave shape; and
- B) the length of the sonotrode  $L_s$  is 150-220 % of  $L_g$ .

The subject-matter of claim 1 is therefore new in view of D1 (Article 33(2) PCT).

The differentiating feature B) is not considered to be a technical feature as no technical effect around this particular threshold is mentioned in the application. Furthermore, the regions not overlapping ( $L_s > 100\%$  of  $L_g$ ) cannot contribute to a technical effect. As this feature is not considered to contribute to producing a technical effect serving a technical purpose, it cannot be inventive in the sense of Article 33(3) PCT.

The technical effect of the concave shaped bottom (differentiating feature A) is described on p. 3, l. 16-20 of the original description as to "*ensure correct positioning*" of the thread as "*the bottom of the welding groove has a concave shape, having preferably essentially a shape such that a lower part of a first removal thread fits therein snugly, i.e. that it does not slide away when pressure is applied to it*".

Taking into account the disclosure of the closest prior art D1, the technical problem to be solved may therefore be regarded as how to modify the apparatus of D1 to improve the positioning of the thread.

D1 (para. [0047]: "*if the material is a filament having a substantially circular cross-section, at least one of the suture-contacting surfaces should preferably have a rounded contour to match the contour of the filament in contact with it*") disclose the benefits of a concave bottom in the welding groove. Providing the embodiment depicted in fig. 15A with a concave shaped bottom is firstly

considered to come with the set of skills of a person skilled in the art. Secondly, this slight constructional change is considered obvious in view of the cited passage in para. [0047] of D1.

D2 (translation of para. [0001]: "*the bottom of the groove 21 has a curvature  $r$  along the periphery of the nylon thread  $N_y$  so that the nylon thread  $N_{31}$  to be fused can be sufficiently held*"; fig. 3, 5, 6) also disclose a concave bottom in the welding groove thereby solving the problem of correct positioning.

Further, also D3 (fig. 6A) and D4 (fig. 5) disclose a concave bottom in the welding groove for an improved positioning.

Feature "concave shaped bottom" is described in documents D2-D4 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal design option to include this feature in the apparatus (embodiment depicted in fig. 15A) described in D1 in order to solve the problem posed.

The subject-matter of claim 1 does therefore not involve an inventive step within the meaning of Article 33(3) PCT.

#### 2.1.2 Claim 1 - Inventive step in view of D2-D4

If D2 is considered to be the prior art closest to the subject-matter of claim 1, it discloses (the references in brackets refer to the translation of this document):

An apparatus for ultrasonic welding (***para. [0001]: "ultrasonic fusing apparatus of string-like synthetic resin such as nylon monofilament"***) of a removal thread of an intrauterine system (***suitable for welding such a thread***), comprising

- a welding jig (***"cradle 2" in fig. 5***) comprising a welding groove (see fig. 5), the welding groove having a length  $L_g$ , a width  $W_g$  and a depth  $D_g$  and a bottom with concave shape (***para. [0001]: "the bottom of the groove 21 has a curvature  $r$  along the periphery of the nylon thread  $N_y$  so that the nylon thread  $N_{31}$  to be fused can be sufficiently held"***; fig. 3, 5, 6),
- a sonotrode (***"ultrasonic welding horn 1"***), a width  $W_s$  of a weldingtip (***para. [0001]: "groove 12 is formed in the tip portion 11"***) of the sonotrode that is

80-98 % of  $W_g$  (***see fig. 6 in combination with the obvious width a person skilled in the art would use***) and a depth  $D_s$ , wherein the welding tip of the sonotrode has a concave shape (***para. [0001]: "the groove 12 has a substantially semicircular cross section"; fig. 5, 6***).

The subject-matter of claim 1 therefore differs from this known D2 in that:

- the sonotrode having a length  $L_s$  that is 150-220 % of  $L_g$ .

The differentiating feature is not considered to be a technical feature as no technical effect around this particular threshold is mentioned in the application. Further, the regions not overlapping ( $L_s > 100\%$  of  $L_g$ ) cannot contribute to a technical effect. This feature is therefore not considered to contribute to producing a technical effect serving a technical purpose. The subject-matter of a claim cannot be inventive if there is no technical contribution to the prior art.

The subject-matter of claim 1 does therefore not involve an inventive step within the meaning of Article 33(3) PCT.

#### 2.1.3 Claim 12 - Inventive step in view of D5 - D1

It is commonly known to fix a removal thread of an intrauterine system, comprising a first and a second string of threads, with a knot, as for example disclosed in D5 (***para. [0002-0007, 0036]***).

The subject-matter of claim 12 therefore differs from this known D5 in that:

A method for ultrasonic welding of the removal thread of an intrauterine system, comprising:

- arranging a first string of thread at the bottom of the welding groove, along its length;
- arranging a second string of thread on top of the first string of thread in the welding groove, along its length;
- arranging the welding tip on top of the second string of thread in the welding groove, along its length; and
- welding the first and second string of threads together

is not disclosed in D5.

Taking into account the disclosure of the closest prior art D5, the technical problem to be solved may therefore be regarded as to provide an alternative joining method to the knotting of the threads.

D1 (*para. [0007, 0008, 0010, 0029, 0030]; fig. 2A, 10-19*) teaches to use a method of ultrasonic welding of a thread instead of a knot as a surgical suture.

D1 thereby discloses:

- arranging a first string of thread (*"second portion 18" in fig. 15A*) at the bottom of the welding groove, along its length (*see 18 in fig. 15A*);
- arranging a second string of thread (*para. [0035]: "a first portion 16 of elongated material"*) on top of the first string of thread in the welding groove, along its length (*see 18 in fig. 15A*);
- arranging the welding tip (*"suture-contacting surface 30A" in fig. 15A*) on top of the second string of thread in the welding groove, along its length; and
- welding the first and second string of threads together (*para. [0053]: "...after the welding process to release the joined material"*).

Feature "ultrasonic welding method" is described in document D1 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal design option to include this feature in the fixing method of the removal thread of an intrauterine system described in D5 in order to solve the problem posed.

The subject-matter of claim 12 does therefore not involve an inventive step within the meaning of Article 33(3) PCT.

#### 2.1.4 Claim 15

The same reasoning (under 2.1.3) applies mutatis-mutandis to the subject-matter of the independent product claim 15, which neither fulfils the requirements of inventive step.

## 2.2 Dependent claims

Dependent claims 2-11, 13 and 14 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step.

**2.2.1 Claims 2 and 3**

A radius of curvature of 0.1-0.2 mm is common for the concave shape of the bottom of a welding groove and/or welding tip as this range corresponds to a common thread diameter.

Further, such a radius of curvature is disclosed in D6 (p. 9, l. 10-13; fig. 2, 4).

**2.2.2 Claim 4**

A welding groove having a length  $L_g$  in the broad range of 2.5-20 mm is common in ultrasonic welding. The examining division can therefore not recognize any surprising effect due to this additional technical feature, which would indicate or hint towards an inventive step.

**2.2.3 Claim 5**

D1 (fig. 15A), D2 (fig. 6), D3 (fig. 4) and D4 (fig. 5) disclose welding groove having a width being essentially identical to a largest cross-sectional dimension of the thread to be welded.

**2.2.4 Claim 6**

A width between 0.25-0.5 mm is common as this range corresponds to a common thread diameter.

**2.2.5 Claim 7**

D1 (fig. 15A), D2 (fig. 6), D3 (fig. 4) and D4 (fig. 5) disclose a depth of a welding groove being larger than twice the largest cross-sectional dimension of the thread to be welded.

**2.2.6 Claim 8**

A depth between 0.5-1.5 mm is common as this range corresponds to a common thread diameter.

**2.2.7 Claim 9**

The length  $L_s$  being 180-210 % of  $L_g$  is not considered to be a technical feature as no technical effect around this particular threshold is mentioned in the application, see reasoning in item 2.1.1.

**2.2.8 Claim 10**

The width  $W_s$  being in the range of 84-98 % of width  $W_g$  is considered obvious in view of D1 (the ratio of the widths in fig. 15A appear to be in that range) and D2 (see fig. 6).

**2.2.9 Claim 11**

Sonotrodes being made of titanium or precipitation hardened aluminium are common in the field of ultrasonic welding. A surprising effect due to this additional technical feature can therefore not be recognized.

**2.2.10 Claim 13**

A system pressure of 1.6 to 2.4 bar is common in US welding.

It is further noted, that no technical effect around this particular threshold is mentioned in the application.

**2.2.11 Claim 14**

(Setting the US-generator to) an ultrasound energy of 0.5 - 1.5  $W_s$  is common. A surprising effect can therefore not be seen.

**item VII**

**3 Certain defects in the international application**

- 3.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1-D4 is not mentioned in the description, nor are these documents identified therein.
- 3.2 Independent claims 1 and 12 are 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 being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

**item VIII**

- 4 The application does not meet the requirements of Article 6 PCT, because claim 13 is not clear.
- 4.1 Claim 13
- It remains unclear what pressure is meant and how and where and when it is measured.