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**Datasheet for the decision
of 9 May 2022**

Case Number: T 1579/17 - 3.2.08

Application Number: 11835654.2

Publication Number: 2632399

IPC: A61F6/18

Language of the proceedings: EN

Title of invention:
INTRA-UTERINE INSERTION DEVICE

Patent Proprietor:
Odyssea Pharma S.p.r.l.

Opponent:
Bayer Oy/Bayer Intellectual Property GmbH

Relevant legal provisions:
EPC Art. 54(2), 123(2), 84
RPBA 2020 Art. 13(2), 12(4), 15(3)

Keyword:

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(no)

Amendments - auxiliary request 2 - allowable (no)

Amendment after summons - auxiliary request 3b - cogent
reasons (no)

Claims - auxiliary requests 7, 8 - support in the description
(no)

Decisions cited:

T 0986/00, T 0181/02, T 0109/02, T 0651/08, T 0776/05,
T 2294/08



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1579/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 9 May 2022

Appellant: Bayer Oy/Bayer Intellectual Property GmbH
(Opponent) Pansiontie 47/Alfred-Nobel-Str. 10
20101 Turku/40789 Monheim am Rhein (FI)

Representative: König, Gregor Sebastian
König-Szynka-Tilmann-von Renesse
Patentanwälte Partnerschaft mbB
Mönchenwerther Straße 11
40545 Düsseldorf (DE)

Respondent: Odyssea Pharma S.p.r.l.
(Patent Proprietor) Rue du Travail 16
4460 Grâce-Hollogne (BE)

Representative: Gyi, Jeffrey Ivan
De Clercq & Partners
Edgard Gevaertdreef 10 a
9830 Sint-Martens-Latem (BE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 31 May 2017
rejecting the opposition filed against European
patent No. 2632399 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: G. Buchmann
C. Schmidt

Summary of Facts and Submissions

- I. With the decision posted on 31 May 2017 the opposition division rejected the opposition against the European patent No. EP 2 632 399.
- II. The opponent filed an appeal against that decision.
- III. Oral proceedings took place via videoconference before the Board on 11 March 2022 and on 9 May 2022. The respondent (patent proprietor) did not attend the oral proceedings on 9 May 2022. In accordance with the provisions of Rule 115(2) EPC, the proceedings were continued without the patent proprietor.
- IV. The respondent (patent proprietor) requested that the appeal be rejected as inadmissible or be dismissed, i.e. that the patent be maintained as granted (main request), or that the patent be maintained on the basis of one of the following auxiliary requests:
 - auxiliary requests 1 and 2, re-filed on 20 February 2018 and originally filed on 26 April 2016,
 - auxiliary request 3, re-filed on 20 February 2018 and originally filed on 26 April 2016, corrected by letter dated 14 November 2018,
 - auxiliary requests 3a and 3b, filed on 10 February 2022,
 - auxiliary requests 4-6, filed on 20 February 2018,
 - auxiliary requests 7 and 8, re-filed on 20 February 2018 and originally filed as auxiliary requests 5 and 6 on 19 April 2017.

V. The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.

VI. In the present decision, reference is made to the following evidence:

D1-D1c

Technical drawing by Rexam Pharma GmbH showing "Mirena Inserter 190171.601-3" and several of its components

D10

Insertion Instructions for the Mirena 52 mg Intrauterine Delivery System

D13

Enlargement of the inserter in document D10

D18 US-A-4143656

D19 US-B-6588428

VII. Claim 1 of the **main request** reads as follows. The numbering of the features has been added by the Board.

a1

"An inserter (100),

a2

having a proximal (20) and distal (30) end,

a3

for inserting and positioning an intra-uterine device (IUD) (120) which is attached to a withdrawal string (130), said inserter (100) comprising:

b1

a plunger (102), having a central longitudinal axis,

b2

configured for slidable mounting of a hollow protective

tube (110),

b3

the distal (30) end of the plunger (102) being configured for dismountable connection with the IUD (120),

b4

which protective tube (110) is configured to slidably cover the IUD (120);

c1

a handle (104) attached to the proximal (20) end of the plunger (102); and

d1

a longitudinal member (150) which extends in the distal (30) direction with respect to the plunger (102),

d2

which longitudinal member (150) contains a friction contact surface (152) against which the protective tube (110) can frictionally engage, characterized in that,

d3

the longitudinal member forms part of the handle (104),

d4

wherein the frictional engagement of the friction contact surface (152) against the protective tube (110) is manually actuatable and

d5

wherein the frictional engagement of the friction contact surface (152) against the protective tube (110) increases resistance to sliding of the protective tube (110) relative to the plunger (102)."

VIII. **Auxiliary requests**

The auxiliary requests contain the following amendments.

(a) **Auxiliary request 1**

Claim 1 of auxiliary request 1 differs from claim 1 as granted in the addition (to Feature 4) of the feature according to which the frictional engagement is actuatable "in a radial direction relative to the longitudinal axis of the plunger (102)".

(b) **Auxiliary request 2**

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 in that Feature **d5** has been amended so that the frictional engagement does not "increase resistance to" but "prevents" sliding of the protective tube relative to the plunger.

(c) **Auxiliary request 3**

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 1 in the addition of the following alternative features:

"either

- [first alternative]

the longitudinal member (150) is in essentially fixed relation to the plunger (102), and is configured to receive a force in an essentially radial direction relative to the central longitudinal axis of the plunger (102), wherein the force is applied by the protective tube (110) upon manual actuation of the protective tube (110),

or

- [second alternative]

the longitudinal member (150) is configured for radial movement relative to the central longitudinal axis of the plunger (102) and for the application of a force to the protective tube (110) upon manual actuation of the longitudinal member (150)".

(d) **Auxiliary request 3a**

Claim 1 of auxiliary request 3a has been restricted to the first alternative of auxiliary request 3.

(e) **Auxiliary request 3b**

Claim 1 of auxiliary request 3b differs from claim 1 of auxiliary request 3a in that the feature has been added according to which "the protective tube (110) can be prevented from sliding relative to the plunger (102) at any desired position".

(f) **Auxiliary request 4**

Claim 1 of auxiliary request 4 reads as follows. Differences with respect to claim 1 of auxiliary request 3 have been underlined.

a1

"An inserter (100),

a2

having a proximal (20) and distal (30) end,

a3

for inserting and positioning an intra-uterine device (IUD) (120) which is attached to a

withdrawal string (130), said inserter (100) comprising:

b1

a plunger (102), having a central longitudinal axis,

b2

configured for slidable mounting of a hollow protective tube (110),

b3

the distal (30) end of the plunger (102) being configured for dismountable connection with the IUD (120),

b4

which protective tube (110) is configured to slidably cover the IUD (120);

c1

a handle (104) attached to the proximal (20) end of the plunger (102); and

d1

a longitudinal member (150) which extends in the distal (30) direction with respect to the plunger (102),

d2

which longitudinal member (150) contains a friction contact surface (152) against which the protective tube (110) can frictionally engage,

c2

the protective tube (110) having a central lumen, through which the plunger (102) is disposed, wherein the distal (30) end of the protective tube (110) is configured for receiving the intra-uterine device (IUD) (120)

characterized in that,

d3

the longitudinal member forms part of the handle (104),

d4

wherein the frictional engagement of the friction contact surface (152) against the protective tube (110) is manually actuatable in a radial direction relative to the longitudinal axis of the plunger (102) and

d5

wherein the frictional engagement of the friction contact surface (152) against the protective tube (110) increases resistance to sliding of the protective tube (110) relative to the plunger (102), and in that either

c3 [first alternative]

the protective tube further comprises a cuff (116) disposed and fixed at a point along the outside surface of the protective tube (110), and the longitudinal member (150) is in essentially fixed relation to the plunger (102), and is configured to receive a force in an essentially radial direction relative to the central longitudinal axis of the plunger (102), wherein the force is applied by the cuff (116) upon manual actuation of the cuff (116),

or

c4 [second alternative]

the longitudinal member (150) is configured for radial movement relative to the central longitudinal axis of the plunger (102) and for the application of a force to the protective tube (110) upon manual actuation of the longitudinal member (150)."

(g) **Auxiliary request 5**

Claim 1 of auxiliary request 5 has been restricted to the second alternative of auxiliary request 4.

(h) **Auxiliary request 6**

Claim 1 of auxiliary request 6 has been restricted to the first alternative of auxiliary request 4.

(i) **Auxiliary request 7**

The product claim has been deleted.

Claim 1:

Independent method claim 1 is a combination of granted claims 1, 5, 7, 14 and 15 and reads as follows:

"A method for priming for insertion into the cervical canal (222) an inserter assembly which inserter assembly comprises:

a1-a3

- an inserter having a proximal (20) and distal (30) end, for inserting and positioning an intra-uterine device (IUD) (120) which is attached to a withdrawal string (130), said inserter (100) comprising:

b1-b4

a) a plunger (102), having a central longitudinal axis, configured for slidable mounting of a hollow protective tube (110), the distal (30) end of the plunger (102) being configured for dismountable connection with the IUD (120), which protective

tube (110) is configured to slidably cover the IUD (120);

c1

b) a handle (104) attached to the proximal (20) end of the plunger (102); and

d1-d5

c) a longitudinal member (150) which extends in the distal (30) direction with respect to the plunger (102), which longitudinal member (150) contains a friction contact surface (152) against which the protective tube (110) can fictionally engage, wherein the longitudinal member forms part of the handle (104), wherein the frictional engagement of the friction contact surface (152) against the protective tube (110) is manually actuatable and wherein the frictional engagement of the friction contact surface (152) against the protective tube (110) increases resistance to sliding of the protective tube (110) relative to the plunger (102),

c4

wherein the plunger (102) is disposed with a longitudinal groove for receiving the withdrawal string (130),

c2

further comprising the protective tube (110) having a central lumen, through which the plunger (102) is disposed, wherein the distal (30) end of the protective tube (110) is configured for receiving the intra-uterine device (IUD) (120), and

IUD1

- a T-shaped intra-uterine device (IUD) (120) comprising a pair of wings (122) each having a rounded wing tip, which wings fixed to a central rod (124), said IUD (120) positioned at the distal (30) end of the plunger (102),

IUD2

wherein the IUD further comprises a withdrawal string (130) attached at one end, preferably to the rod (124), wherein the withdrawal string (130) passes along the longitudinal groove for receiving the withdrawal string (130),

IUD3

wherein the IUD (120) is positioned with the wings (122) outside the protective tube (110)

which method comprises the steps:

A1)

keeping the withdrawal string (130) relaxed;

B1)

advancing partially the protective tube (110) distally over the plunger (102) until the protective tube (110) is positioned such that the wing tips of the IUD (120) would partially protrude from the protective tube (110) but are touching when the central rod of the IUD (120) is engaged with the distal (30) end of the plunger (102);

C1)

activating frictional engagement of the friction contact surface (152) against the protective tube (110), so as to fix the position of the protective tube (110) relative to the plunger (102); and

D1)

providing tension to the withdrawal string (130), wherein the IUD (120) enters inside the central lumen of the protective tube until the wings (122) of the IUD are covered by the protective tube (110) and the wing tips (126) of the IUD (120) partially protrude (preferably are half out) from the protective tube (110) but are touching, and the proximal (20) end of the IUD (120) is engaged with the distal (30) end of the plunger (102);

E1)

thereby priming the inserter assembly."

Claim 2:

Independent method claim 2 is a combination of granted claims 1, 5, 7, 14 and 16 and reads as follows:

"Method for priming for insertion into the cervical canal (222) an inserter assembly which inserter assembly comprises:

a1-a3

- an inserter having a proximal (20) and distal (30) end, for inserting and positioning an intra-uterine device (IUD) (120) which is attached to a withdrawal string (130), said inserter (100) comprising:

b1-b4

a) a plunger (102), having a central longitudinal axis, configured for slidable mounting of a hollow protective tube (110), the distal (30) end of the plunger (102) being configured for dismountable connection with the IUD (120), which protective tube (110) is configured to slidably cover the IUD (120);

c1

b) a handle (104) attached to the proximal (20) end of the plunger (102); and

d1-d5

c) a longitudinal member (150) which extends in the distal (30) direction with respect to the plunger (102), which longitudinal member (150) contains a friction contact surface (152) against which the protective tube (110) can fictionally engage, wherein the longitudinal member forms part of the

handle (104), wherein the frictional engagement of the friction contact surface (152) against the protective tube (110) is manually actuatable and wherein the frictional engagement of the friction contact surface (152) against the protective tube (110) increases resistance to sliding of the protective tube (110) relative to the plunger (102),

c4

wherein the plunger (102) is disposed with a longitudinal groove for receiving the withdrawal string (130),

c2

further comprising the protective tube (110) having a central lumen, through which the plunger (102) is disposed, wherein the distal (30) end of the protective tube (110) is configured for receiving the intra-uterine device (IUD) (120), and

IUD1

- a T-shaped intra-uterine device (IUD) (120) comprising a pair of wings (122) each having a rounded wing tip, which wings fixed to a central rod (124), said IUD (120) positioned at the distal (30) end of the plunger (102),

IUD2

wherein the IUD further comprises a withdrawal string (130) attached at one end, preferably to the rod (124), wherein the withdrawal string (130) passes along the longitudinal groove for receiving the withdrawal string (130),

IUD3

wherein the IUD (120) is positioned with the wings (122) outside the protective tube (110)

which method comprises the steps:

A2)

placing the withdrawal string (130) under tension so that the proximal (20) end of the IUD (120) is engaged with the distal (30) end of the plunger (102); and

B2)

partially advancing the protective tube (110) distally over the plunger (102) until the wings (122) of the IUD are covered by the protective tube (110) and the wing tips (126) of the IUD (120) partially protrude from the protective tube (110) but are touching;

C2)

thereby priming the inserter assembly."

(j) **Auxiliary request 8**

Claim 1 of auxiliary request 7 has been deleted.

IX. **The respondent's arguments, as far as relevant for the present decision, can be summarised as follows:**

Admissibility of the appeal

The appeal was inadmissible because it presented an entirely new case rather than dealing with the reasons for the opposition division's decision.

Admittance of documents D18 and D19

These documents should not be admitted because they were late-filed and could have been filed earlier, in particular within the opposition period.

Main request - Article 54(2) EPC

The function of the inserter in D19 was based not on frictional engagement but on a form fit of the projections (11) in the openings (17, 17'). The frictional engagement as claimed could not be derived from D19 without hindsight because it was in contrast to the function as described in D19, column 3, lines 34-39.

Auxiliary request 1 - Article 54(2) EPC

The subject-matter of claim 1 was novel because the prior art did not disclose manual radial actuation of the frictional engagement.

Auxiliary request 2 - Article 123(2) EPC

The added feature of auxiliary request 2 was based on page 15, lines 1-8 of the application as originally filed.

Auxiliary request 3 - Article 54(2) EPC

Second alternative

The subject-matter of claim 1 was novel because in D19 the force of the arm (10) was applied to the base (16) only when the arm was released, not when it was actuated.

First alternative

The function of the inserter in D18 was based not on frictional engagement but on the interlocking function of the edges (20) and (37). The frictional engagement as claimed could not be derived from D19.

Auxiliary request 3a - Article 54(2) EPC

Regarding novelty, the arguments presented in relation to the first alternative of auxiliary request 3 applied.

Auxiliary request 3b - admittance

The amendment filed with auxiliary request 3b was a reaction to the Board's preliminary opinion, so this request should be admitted into the proceedings.

Auxiliary request 4 - Article 54(2) EPC

Second alternative

The prior art did not disclose the claimed arrangement of the longitudinal member.

Furthermore, the handle (15) in D18 did not represent a cuff.

First alternative

There was no disclosure in the prior art of the claimed arrangement of the longitudinal member.

Auxiliary request 5 - Article 54(2) EPC

The arguments provided in relation to the second alternative of auxiliary request 4 applied.

Auxiliary request 6 - Article 54(2) EPC

The arguments provided in relation to the first alternative of auxiliary request 4 applied.

Auxiliary requests 7 and 8 - Article 84 EPC

None of the arguments presented by the respondent regarding auxiliary requests 7 and 8 was relevant for this point of the present decision.

X. **The appellant's arguments, as far as relevant for the present decision, can be summarised as follows:**

Admissibility of the appeal

The appeal met the requirements of Rule 99(2) EPC and Article 12(2) RPBA 2007.

Admittance of documents D18 and D19

Both documents were *prima facie* highly relevant for the novelty of the opposed patent. They were filed as a reaction to how the claims had been interpreted in the opposition decision, so they should be admitted.

Main request - Article 54(2) EPC

Claim 1 lacked novelty over D19 (column 2, line 23 - column 3, line 50). In particular, the longitudinal member (10) had a projection (11) for locking into openings (17, 17'). Between the openings, the projection 11 slid along the inner surface of the base (16) and was biased towards the inner surface by the elastic loop (8), so it contained a friction contact surface against which the protective tube (inner surface of the base 16) was frictionally engaged.

When the thruster (9) was pressed, the friction was released. It was within the scope of claim 1 of the patent that the manual actuation of the frictional

engagement corresponded to a release of the friction. Therefore, in D19 the frictional engagement of the friction contact surface against the protective tube (base 16) was manually actuatable as required by Feature d4.

Auxiliary request 1 - Article 54(2) EPC

The added feature did not contribute to novelty because the arm (10) in D19 was moved radially with respect to the axis of the needle (1).

Auxiliary request 2 - Article 123(2) EPC

The amendment was allegedly based on page 15, lines 1-8 of the description as originally filed. According to this passage "the protective tube (110) can be prevented from sliding relative to the plunger (102) at any desired position". The fact that the protective tube can be prevented from sliding at any desired position had been unallowably omitted from the claim.

Auxiliary request 3 - Article 54(2) EPC

Second alternative

Upon release of the force (26) shown in Figure 3 of D19, the arm moved radially outwards and engaged the inner surface of the base (16) (Figure 4), thereby applying a force to the protective tube. Since the release of the manually applied force represented one form of actuating the arm (10), this function fell under the definition of the second alternative added to auxiliary request 3.

First alternative

The first alternative of claim 1 lacked novelty over

D18 (see columns 5-8 and Figures 7-10). In particular, to release the IUD in D18, the stems (17) of the outer tube were compressed in a radial direction relative to the axis of the plunger (rod 31) (Figures 7-10), so that they could enter the cut-out area (34) between the stems (35). Even though no friction was described between the stems (17) on one side and the stems (35) on the other side, it was inevitably present between the surfaces of these components when the stems (17) were manually released.

Auxiliary requests 3a - Article 54(2) EPC

Regarding the novelty of auxiliary request 3a, the arguments concerning auxiliary request 3 applied.

Auxiliary request 3b - admittance

Auxiliary request 3b was filed after the summons to oral proceedings. Since the respondent did not give any cogent reasons for the late submission, this request should not be admitted under Article 13(2) RPBA 2020.

Auxiliary request 4 - Article 54(2) EPC

Second alternative

The added features were disclosed by D19, column 2, lines 37-40.

First alternative

The added features were disclosed by D18, column 5, lines 20-23 and Figures 7 and 8.

Auxiliary requests 5 and 6 - Article 54(2) EPC

These requests were restricted to the first and second

alternative of auxiliary request 4, respectively, so the respective arguments applied.

Auxiliary requests 7 and 8 - Article 84 EPC

The claims of auxiliary requests 7 and 8 were not supported by the description as required by Article 84 EPC.

Reasons for the Decision

1. Admissibility of the appeal

The respondent argued that the appeal was inadmissible because it presented a new case rather than setting out the reasons why the impugned decision should be reversed.

In the statement setting out the grounds of appeal, however, the appellant discusses the opposition division's interpretation of the claim. This interpretation was decisive for the decision to reject the opposition. The corresponding novelty objection based on documents D1a-c, D10 and D13 was raised in the statement setting out the grounds of appeal. This is sufficient for the appeal to be admissible, irrespective of the fact that the appellant filed additional documents and objections.

Moreover, the fact that the appellant presents a new interpretation of details of the Mirena inserter does not *per se* run counter to the admissibility of the appeal.

Therefore, the statement setting out the grounds of

appeal fulfils the requirements of Rule 99(2) EPC and the appeal is considered admissible.

2. **Admittance of D18 and D19**

Documents D18 and D19 were filed with the statement setting out the grounds of appeal. The respondent requested that these documents not be admitted because they were late-filed and could have been filed earlier, in particular within the opposition period.

However, as set out clearly below, these documents are highly relevant for the outcome of the appeal. Therefore, the board has admitted them under Article 12(4) RPBA 2007.

3. **Main Request - novelty**

Document D19 discloses (see column 2, line 23 - column 3, line 50):

a1

An inserter,

a2

having a proximal and distal end,

a3

for inserting and positioning an intra-uterine device (IUD) (15) which is attached to a withdrawal string (22), said inserter comprising:

b1

a plunger (needle 1), having a central longitudinal axis,

b2

configured for slidable mounting of a hollow protective tube (sheath 4 with base 16),

b3

the distal end of the plunger being configured for

dismountable connection with the IUD,

b4

which protective tube is configured to slidably cover the IUD;

c1

a handle (thumb piece 3) attached to the proximal end of the plunger (1); and

d1

a longitudinal member (moving arm 10) which extends in the distal direction with respect to the plunger,

d3

and the longitudinal member (10) forms part of the handle (3).

Furthermore, D19 discloses the following features:

d2

The longitudinal member (10) of D19 has a projection (11) for locking into openings (17, 17'). When moved between the openings, the projection 11 slides along the inner surface of the base and is biased towards the inner surface by the elastic loop (8). The longitudinal member (10) thus has a friction contact surface at the end of the projection (11) against which the protective tube (inner surface of the base 16) can frictionally engage, as required by Feature d2.

The respondent argued that in D19 the resistance to sliding of the needle relative to the sheath was described as being achieved by the projection (11), which engages by form fit with the openings (17, 17') in order to immobilise the needle in the sheath (column 2, line 54 - column 3, line 18).

However, D19 implicitly discloses that as long as the projection (11) is not engaged in the openings (17,

17') there is some friction between the projection (11) and the inner surface of the base (16) because the loop (8) biases the arm against the inner surface of the base when the thruster (9) of the thumb piece is not pressed.

d4

When the thruster is pressed, the friction is released. It is within the scope of claim 1 of the patent that the manual actuation of the frictional engagement corresponds to a release of the friction (see e.g. the embodiment shown in Figure 3 of the patent). Therefore, in D19 the frictional engagement of the friction contact surface against the protective tube (base 16) is manually actuatable (releasable) as required by Feature d4.

d5

The frictional engagement of the friction contact surface against the protective tube increases the resistance to sliding of the protective tube relative to the plunger (due to the very nature of a frictional force).

The respondent argued that the claimed function could only be derived from D19 using hindsight. The button (9) was only actuated in the situation shown in Figure 3 of D19 when the projection (11) was being released from the opening (17). In the situation shown in Figure 4, there might be some frictional engagement but there was no manual actuation of the button (9). On the contrary, pressing the button in that situation would prevent the projection (11) from entering the opening (17'), thereby preventing the device from functioning as described in column 3, lines 34-39.

However, claim 1 does not define a method of using the inserter. The claim specifies the technical feature according to which "the frictional engagement of the friction contact surface against the protective tube (base 16) is manually actuatable" (Feature d4). This feature is intrinsically present in the inserter disclosed in D19, even if no frictional engagement is intended to be used when employing the inserter.

Therefore, the subject-matter of claim 1 of the main request lacks novelty over D19.

4. **Auxiliary request 1 - novelty**

In claim 1 of auxiliary request 1, the feature has been added according to which the frictional engagement is actuatable "in a radial direction relative to the longitudinal axis of the plunger (102)".

The arm (10) in D19 is moved in a radial direction relative to both the complete inserter and the axis of the needle (1) (see Figures 1-4).

Therefore, the subject-matter of claim 1 of auxiliary request 1 is not novel in view of D19 (Article 54(2) EPC).

5. **Auxiliary request 2 - amendments**

In auxiliary request 2, Feature d5 has been amended to state that the frictional engagement "prevents" sliding of the protective tube relative to the plunger instead of "increas[ing] the resistance".

As a basis for the added feature the respondent cited page 15, lines 1-8 of the application as originally

filed.

This passage describes the advantages of the invention. Among other things it states that "since the invention uses frictional engagement rather than discrete stops, the protective tube (110) can be prevented from sliding relative to the plunger (102) at any desired position".

The fact that the protective tube can be prevented from sliding at any desired position has been omitted when introducing the amendment into claim 1 of auxiliary request 2. The amended claim therefore includes embodiments where the protective tube is prevented from sliding at discrete stops only and not at any desired position. This, however, is explicitly excluded by the cited passage of the description.

Therefore, the subject-matter of claim 1 of auxiliary request 2 extends beyond the content of the application as filed and contravenes Article 123(2) EPC.

6. Auxiliary request 3 - novelty

6.1 Claim 1 of auxiliary request 3 contains two alternative embodiments of the longitudinal members, which formally represent two independent claims. Neither of them is novel (Article 54(2) EPC).

6.2 Second alternative- movable longitudinal member

Compared with auxiliary request 1, the second alternative of claim 1 comprises the additional features according to which "the longitudinal member (150) is configured for radial movement relative to the central longitudinal axis of the plunger (102) and for

the application of a force to the protective tube (110) upon manual actuation of the longitudinal member (150)".

In D19, the arm (10) which provides the frictional engagement with the inner surface of the base (16) is configured for radial movement relative to the central longitudinal axis of the needle 1 (Figure 3). Upon release of the force (26) shown in Figure 3 of D19, the arm moves radially outwards and engages the inner surface of the base (16) (Figure 4). Since the base is part of the protective tube, this corresponds to a force being applied to the protective tube. As the release of the manually applied force represents a form of actuating the arm (10), this function falls under the definition of the second alternative of claim 1 of auxiliary request 3.

The respondent argued that in D19 the force was applied only when the arm was released, not when it was actuated.

The term "actuatable" is, however, already used in feature 4d of claim 1, where its meaning includes both the application and release of the frictional engagement (see the discussion regarding the main request). There is no reason to construe the "actuation" of the longitudinal member in the feature added to auxiliary request 3 any differently. Hence "actuation" of the longitudinal member includes the application and the release of a force to the longitudinal member.

Therefore, the second alternative of auxiliary request 3 is not novel in view of D19.

6.3 **First alternative - fixed longitudinal member**

Compared with auxiliary request 1, the first alternative of claim 1 of auxiliary request 3 comprises the feature according to which "the longitudinal member (150) is in essentially fixed relation to the plunger (102), and is configured to receive a force in an essentially radial direction relative to the central longitudinal axis of the plunger (102), wherein the force is applied by the protective tube (110) upon manual actuation of the protective tube (110)".

Document D18 discloses (see columns 5-8 and Figures 7-10):

a1

an inserter (10),

a2

having a proximal and distal end,

a3

for inserting and positioning an intra-uterine device (IUD) (50) which is attached to a withdrawal string (column 7, line 15), said inserter comprising:

b1

a plunger (rod 31), having a central longitudinal axis,

b2

configured for slidable mounting of a hollow protective tube (11),

b3

the distal end of the plunger being configured for dismountable connection with the IUD (receptacle section 32),

b4

which protective tube is configured to slidably cover the IUD (Figures 9-10);

c1

a handle (33) attached to the proximal end of the plunger; and

d1

a longitudinal member (stems 35) which extends in the distal direction with respect to the plunger and

d3

the longitudinal member (stems 35) forms part of the handle (33).

To release the IUD in D18, the stems (17) of the outer tube are pressed together in a radial direction towards the axis of the plunger (rod 31) (Figures 7-10).

Therefore, they can enter the cut-out area (34) between the stems (35), and the tube slides proximally relative to the plunger. The stems (17) are moved from one abutment (36) to another abutment (the bottom of the cut-out area 34). Even though no friction is described between the stems (17) with edges (20) on one side and the stems (35) with edges (37) on the other side, it is inevitably present between the surfaces of these components when the stems (17) are released.

Therefore, D18 also discloses that:

d2

the longitudinal member (stem 35) contains a friction contact surface against which the protective tube (via the stems 17) can frictionally engage, and that,

d4

the frictional engagement of the friction contact surface against the protective tube (11) is manually actuatable (releasable) in a radial direction relative to the longitudinal axis of the plunger (31) and

d5

wherein the frictional engagement of the friction

contact surface against the protective tube (11) increases resistance to sliding of the protective tube (11) relative to the plunger (31).

The longitudinal members (35) in D18 are not movable when the inserter is in use, so they are "in an essentially fixed relation to the plunger 31". Furthermore, the force of the arms (17) is applied to the longitudinal members (35) radially outwardly, so the longitudinal members are "configured to receive a force in an essentially radial direction relative to the longitudinal axis of the plunger". Moreover, when the arms (17) are released, i.e. when the arms forming part of the protective tube are manually actuated, the arms (17) apply the force to the longitudinal members (35).

The respondent referred to the interlocking function of the edges (20) and (37) which carried out the main control function in the inserter in D18. However, this does not exclude the presence of the friction between the components.

Therefore, the subject-matter of the first alternative of claim 1 of auxiliary request 3 is not novel in view of D18.

7. **Auxiliary request 3a - novelty**

Claim 1 of auxiliary request 3a is identical to the first alternative of claim 1 of auxiliary request 3, which lacks novelty over D18 (see above).

Therefore, the subject-matter of claim 1 of auxiliary request 3a is not novel (Article 54(2) EPC).

8. **Auxiliary request 3b - admittance**

Auxiliary request 3b was filed on 10 February 2022, i.e. after the summons to oral proceedings.

Compared with claim 1 of auxiliary request 3, the feature has been added according to which "the protective tube (110) can be prevented from sliding relative to the plunger (102) at any desired position".

These additional features represent an amendment to the appellant's case, so the admission of this request is subject to Article 13(2) RPBA 2020. Any such amendments may only be taken into consideration if there are exceptional circumstances, which have been justified with cogent reasons.

According to the respondent, the amendment was a reaction to the Board's preliminary opinion. However, since the Board did not raise any new issues in its preliminary opinion, the opinion did not create any exceptional circumstances which might justify an amendment at this late stage of the proceedings.

Therefore, auxiliary request 3b was not admitted into the proceedings pursuant to Article 13(2) RPBA 2020.

9. **Auxiliary request 4 - novelty**

9.1 **Second alternative**

The second alternative of claim 1 of auxiliary request 4 differs from the second alternative of claim 1 of auxiliary request 3 in that it comprises the feature according to which

"the protective tube (110) [has] a central lumen, through which the plunger (102) is disposed, wherein the distal (30) end of the protective tube (110) is configured for receiving the intra-uterine device (IUD) (120)".

This feature is disclosed in D19 where the protective tube (sheath 4) has a central lumen (Figure 1) and the plunger (needle 1) is introduced into the sheath. The distal end (14) of the sheath (4) receives the IUD (15) (column 2, lines 37-40).

The respondent did not provide any concrete arguments to support its assertion that the prior art did not disclose any alternative arrangements for the longitudinal member.

Therefore, the subject-matter of the second alternative of claim 1 of auxiliary request 4 is not novel in view of D19 (Article 54(2) EPC).

9.2 **First alternative**

The first alternative of claim 1 of auxiliary request 4 differs from the first alternative of claim 1 of auxiliary request 3 in that it comprises the features according to which

a) "the protective tube (110) [has] a central lumen, through which the plunger (102) is disposed, wherein the distal (30) end of the protective tube (110) is configured for receiving the intra-uterine device (IUD) (120)" and

b) "the protective tube further comprises a cuff (116) disposed and fixed at a point along the outside surface of the protective tube (110)".

D18, which discloses all the features of the first alternative of auxiliary request 3, further describes in column 5, lines 20-23 that the instrument "comprises an inserter tube (11) and a coating rod (31) telescopically positioned in the tube and having mounted therein an intrauterine device (50)" (as shown in Figure 9). This corresponds to the added feature a).

D18 further discloses a "handle (15)" which is disposed and fixed outside the surface of the protective tube (11) (Figures 7 and 8) and therefore corresponds to the cuff as described in feature b).

According to the respondent, the "handle (15)" was only a handle, not a cuff. Technically, however, the "handle (15)" corresponds to the cuff according to claim 1 of auxiliary request 4, which is fixed at a point along the outside surface of the tube.

The respondent did not provide any concrete arguments to support its assertion that the prior art did not disclose any alternative arrangements for the longitudinal member.

Therefore, the subject-matter of the first alternative of claim 1 of auxiliary request 4 is not novel in view of D18 (Article 54(2) EPC).

10. **Auxiliary request 5 - novelty**

Claim 1 of auxiliary request 5 has been restricted to the second alternative of claim 1 of auxiliary request 4.

Therefore, the subject-matter of claim 1 of auxiliary

request 5 is not novel in view of D19 (Article 54(2) EPC).

11. **Auxiliary request 6 - novelty**

Claim 1 of auxiliary request 6 has been restricted to the first alternative of claim 1 of auxiliary request 4.

Therefore, the subject-matter of claim 1 of auxiliary request 6 is not novel in view of D18 (Article 54(2) EPC).

12. **Auxiliary requests 7 and 8 - support by the description**

12.1 The independent claims of auxiliary requests 7 and 8 are directed to "method[s] for priming for insertion into the cervical canal an inserter assembly". They include the features of granted dependent claims 5, 7 and 14 as well as 15 or 16, respectively.

Since the respondent did not file an adapted description, the Board had to use the description as granted when deciding whether the the patent could be maintained in amended form.

The description as granted defines the invention as an inserter assembly and it mentions features as being optional, which are present in the independent claims of auxiliary requests 7 and 8.

In detail, paragraph [0011] states that "the present invention relates to an inserter (100) ..." according to claim 1 as granted. This is in contrast with the claims of auxiliary requests 7 and 8, which are directed to a method of priming an inserter. Paragraphs

[0019] and [0020] describe the features of a longitudinal groove in the plunger, and of the tube having a central lumen, as being optional. However, these features form part of the invention according to auxiliary requests 7 and 8. Furthermore, paragraph [0025] describes the T-shaped IUD as being optional, and paragraphs [0053] and [0106] state that the inserter of the invention may be used for a wide range of IUDs.

Yet the independent claims identify a specific (T-shaped) IUD as forming part of the invention.

Due to these contradictions between the claims and the description, the claims of auxiliary requests 7 and 8 are not supported by the description as required by Article 84 EPC.

12.2 Under Article 15(3) RPBA 2020, the Board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of a duly summoned party, who may then be treated as relying only on its written case.

12.3 The Board also refers to the Headnote of T 986/00, published in the Official Journal 2003, page 554:

"According to Article 113(2) EPC, the European Patent Office shall consider and decide upon a European patent only in the text submitted to it, or agreed, by the proprietor of the patent. A proprietor who chooses not to be represented at oral proceedings should ensure that he has filed all amendments he wishes to be considered before the oral proceedings."

Furthermore, according to established case law

summarised in CLB V.A.4.5.3(a): "A patent proprietor who prior to oral proceedings files amended claims but no description adapted thereto, and who is not represented at the oral proceedings, cannot 'rely on' the proceedings being continued in writing or the case being remitted to the department of first instance for adaptation of the description (T 181/02, T 109/02, T 651/08, T 776/05, T 2294/08). Hence, a patent proprietor should make sure, that all the required documents, including a description adapted to the claims, on the basis of which the maintenance of the patent could be ordered are on file, so that a decision can be taken by the board at the end of the oral proceedings if a given request is found allowable (T 986/00, OJ 2003, 554; T 181/02; T 109/02; T 776/05; T 651/08)." The Board agrees with this statement.

- 12.4 In the case in hand, the independent claims of auxiliary requests 7 and 8 contained substantial amendments compared with the claims as granted. Additionally, the parties knew that at the oral proceedings of 9 May 2022 - which the respondent did not attend - only auxiliary requests 7 and 8 would be dealt with.
- It can therefore be assumed that the respondent was aware of the fact that the description would have to be adapted to the amended claims if one of these requests were found to be allowable.

However, the respondent did not file an adapted description for auxiliary requests 7 and 8.

- 12.5 Since no description was filed in support of the independent claims of auxiliary requests 7 and 8 (Article 84 EPC), the patent cannot be maintained on

the basis of the these requests.

12.6 Article 13(2) RPBA 2020

The objection concerning the lack of an adapted description was raised for the first time at the oral proceedings. The objection represents an amendment to the appellant's case, so its admission is governed by Article 13(2) RPBA 2020. Any such amendments may only be taken into account if there are exceptional circumstances, which have been justified with cogent reasons.

12.7 In this respect the Board notes that, according to established practice, if an auxiliary request turns out to be allowable during the oral proceedings before the Boards of appeal, its description is normally amended during the oral proceedings before the Board or in separate proceedings once the case has been remitted to the department of first instance. Furthermore, when amended descriptions for auxiliary requests are filed in advance of oral proceedings, they are usually not discussed until the claims of a specific request are found to be allowable during the oral proceedings.

Thus, in this case, the appellant had no reason to comment on the description on file before the oral proceedings.

12.8 This applies even though the respondent was not present at the oral proceedings before the Board.

The respondent informed the Board that it would not be attending oral proceedings shortly before the scheduled date. Nevertheless, since the respondent did not withdraw its request for oral proceedings, it could

still have attended. The appellant did not know for sure that the maintenance of the patent would have to be decided on the basis of one of auxiliary requests 7 or 8 in conjunction with the description of the patent as granted until the very day of the oral proceedings when the respondent was not present. It was under these circumstances that the objection of lack of support in the description was raised.

- 12.9 The appellant cannot be expected to anticipate this course of proceedings and to react by raising objections in advance. Instead, this represents an exceptional circumstance as per Article 13(2) RPBA 2020 and thus allows for objections on that basis.

Therefore, the Board admitted the appellant's objection under Article 84 EPC into the proceedings.

Order

For these reasons it is decided that:

The decision under appeal is set aside. The patent is revoked.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated