Trial Decision

Correction No. 2020-390073

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The case of trial for correction for Japanese Patent No. 6566159 has resulted in the following trial decision.

Conclusion

The correction of the scope of claims of Japanese Patent No. 6566159 shall be approved as the corrected scope of claims attached to the written demand for trial of the case, concerning Claims 2 and 3 after the correction.

Reason

No. 1 History of the procedures

Japanese Patent No. 6566159 regarding the trial for correction of the case (hereinafter, referred to as "the Patent) is a divisional application (Japanese Patent Application No. 2019-86613) filed on April 26, 2019 from Japanese Patent Application No. 2018-521150 filed on June 2, 2017 (Priority date, June 3, 2016), as an international filing date. Then, the establishment of patent right was registered on August 9, 2019 (the publication date of the Gazette containing the Patent: August 28, 2019), a trial for correction of the case was demanded on August 19, 2020, and a written statement was submitted on October 29, 2020.

No. 2 Object of the demand

The object of the demand for trial of the case is to seek the trial decision that the correction of the scope of claims of the Patent is approved as the corrected scope of claims attached to the written demand for trial of the case (hereinafter, referred to as "the written demand"), concerning Claims 2 and 3 after the correction, and the contents of correction of the trial of the case (hereafter, referred to as "the Correction") are as follows. Further, the underlined parts show the corrected parts.

1. Correction A

"The detent pieces have inner surfaces inclined toward the needle hub" in Claim 2 of the scope of claims is corrected to "the detent pieces are elastically deformable, and have inner surfaces inclined toward the needle hub".

2. Correction B

"The detent pieces have inner surfaces inclined toward the needle hub, and are integrally formed with the cylindrical portion on the large-diameter part side" in Claim 3 of the scope of claims is corrected to "the detent pieces are elastically deformable, have inner surfaces inclined toward the needle hub, are located inside the expansion part, and is integrally formed with the cylindrical portion on the large-diameter part side"

No. 3 Judgment by the body

1 Purpose of correction

(1) Regarding Correction A

Since Correction A limits "the detent pieces" in Claim 2 before the Correction to those that "are elastically deformable," it falls under the restriction of the scope of claims in accordance with Article 126(1)(i) of the Patent Act.

(2) Regarding Correction B

Since Correction B limits "the detent pieces" in Claim 3 before the Correction to ones that "are elastically deformable" and "is provided inside the expansion part," it falls under the restriction of the scope of claims in accordance with Article 126(1)(i) of the Patent Act.

2. Correction that is within the matters described in the description, scope of claims, or drawings attached to the application

(1) Regarding Correction A

The description attached to the application describes the following matters. Additionally, the underlines are applied by the body (The same applies hereafter.).

A "The detent pieces 74, 74 are pressed to the radially outer side by the tapered surface 34 of the needle hub main body 26 while the detent claws 78, 78 are caused to slide with respect to the tapered surface 34. As a result, an elastic recovery force toward the radially inner side is exerted on the detent pieces 74, 74 as an urging force".([0069])

B "The detent claws 78, 78 of the detent pieces 74, 74 climb over the tapered surface 34 of the needle hub main body 26 and elastically recover to enter the detaining recess 36". ([0070])

C "May be provided so as to protrude toward the radially outer side of the detents (detent pieces 74, 74), for example. Further, the deformation amount limiter is not limited to the mode of being provided on the radially inner surface of the expansion part. For example, the deformation amount limiter may be provided on the radially outer surface of the detent, and when the detent elastically deforms toward the radially outer side, the deformation may be restricted by the deformation amount limiter abutting against the radially inner surface of the expansion part". ([0104])

As described above, since the description attached to the application describes that the detent pieces are elastically deformable, the correction according to Correction A is within the scope of the matters described in the description, scope of claims, or drawings attached to the application, and falls under the provisions of Article 126(5) of the Patent Act.

(2) Regarding Correction B

The correction that makes "the detent pieces" "elastically deformable" in Correction B, as examined in (1) above, is within the scope of the matters described in the description, scope of claims, or drawings attached to the application.

Further, the description attached to the application describes the following matters.

A "The expansion part has a roughly oval tube shape including a small-diameter part and a large-diameter part that are orthogonal to each other, the detent is provided in an inside covered with a peripheral wall of the large-diameter part" ([0023])

B "An expanded part 64 serving as an expansion part" ([0054])

"In the inside of the expanded part 64, there is formed an internal space 70 on the proximal end side of the inner hole 60 penetrating the needle tip protector 10, and the cross section of the internal space 70 has a substantially elliptical shape in which the vertical dimensions in FIG. 6 are larger than the lateral dimensions in FIG. 6 and the vertical dimensions in FIG. 6 gradually increase toward the proximal end side". ([0056])

"Inside the internal space 70, detent pieces 74, 74 serving as a pair of detents

projecting inward are integrally formed with the radially inner surface 65 of the peripheral wall 58". ([0058])

C "The detent pieces 74, 74 are provided inside the large-diameter parts 68, 68 constituting the substantially oval-shaped expanded part 64" ([0078])

As described above, since the description attached to the application describes that the detent pieces are provided in the expansion part, the correction that "the detent pieces" "are provided inside the expansion part" in Correction B is within the scope of the matters described in the description, scope of claims, or drawings attached to the application.

Therefore, the correction according to Correction B is within the scope of the matters described in the description, scope of claims, or drawings attached to the application, and falls under the provisions of Article 126(5) of the Patent Act.

3 Correction that substantially does not enlarge or alter the scope of claims
(1) Regarding Correction A

Correction A, as examined in 1 (1) above, limits "the detent pieces" in Claim 2 in the scope of claims before correction, and does not replace the matters specifying the invention and change the target and category of the invention.

Therefore, the correction by Correction A does not substantially enlarge or alter the scope of claims, and falls under Article 126(6) of the Patent Act.

(2) Regarding Correction B

Correction B, as examined in 1 (1) above, limits "the detent pieces" in Claim 3 in the scope of claims before correction, and does not replace the matters specifying the invention and change the target and category of the invention.

Therefore, the correction by Correction B does not substantially enlarge or alter the scope of claims, and falls under Article 126(6) of the Patent Act.

4 The Demandant should be granted a patent for the inventions after correction independently at the time of filing of the patent application

As examined in 1 above, since the corrections according to Corrections A and B aim at the restriction of the scope of claims in accordance with Article 126(1)(i) of the Patent Act, it will be examined below whether or not the Appellant should be granted a

patent for the invention specified by the matters described in the scope of claims after correction independently at the time of filing of the patent application (whether or not it falls under the provisions of Article 126(7) of the Patent Act).

4-1 Inventions after correction

The inventions according to Claims 2 and 3 after correction (hereinafter, referred to as "Corrected Invention 2" and "Corrected Invention 3") are as follows.

[Claim 2]

An indwelling needle assembly comprising:

a metallic indwelling needle having a needle tip;

a needle hub provided on a proximal end side of the indwelling needle; and

a needle tip protector that has a tubular peripheral wall and covers the needle tip of the indwelling needle by being externally mounted to the needle hub and by being moved to the needle tip side,

wherein at a predetermined position where the needle tip protector is moved to the needle tip side of the indwelling needle, detent pieces provided at the needle tip protector are detained to the needle hub to prevent the needle tip of the dwelling needle from being re-exposed,

wherein a) the needle tip protector:

has a cylindrical part extending in a needle axis direction;

is provided with the detent pieces, and an expansion part having a larger diameter than the cylindrical part, located on the radially outer side in relation to the detent pieces, and equipped with a small-diameter part and a large-diameter part, on a proximal end side of the cylindrical part; and

is provided with a needle hub engager engaged with the needle hub and holding the needle tip of the indwelling needle in a protruding state, on a peripheral wall of the large-diameter part, and

the detent pieces are elastically deformable, have inner surfaces inclined toward the needle hub, and are integrally formed with the cylindrical part on the large-diameter part side, but are not provided on the small-diameter part side, and

wherein b) the needle hub has

engaging arms engaged with the needle hub engager of the needle tip protector to hold the needle tip of the indwelling needle in a protruding state, and

a connecting tube connected to an external conduit to form a fluid flow path extending from the external conduit to the indwelling needle, and

at least a part of the connecting tube protrudes to the proximal end side from a proximal end portion of the engaging arms serving as elastically deforming fulcrums of the engaging arms.

[Claim 3]

An indwelling needle assembly comprising:

an indwelling needle having a needle tip;

a needle hub provided on a proximal end side of the indwelling needle; and

a needle tip protector that has a tubular peripheral wall and covers the needle tip of the indwelling needle by being externally mounted to the needle hub and by being moved to the needle tip side,

wherein at a predetermined position where the needle tip protector is moved to the needle tip side of the indwelling needle, detent pieces provided at the needle tip protector are detained to the needle hub to prevent the needle tip of the dwelling needle from being re-exposed,

wherein a) the needle tip protector:

has a wind-like part at a distal end portion thereof;

has a cylindrical part extending in a needle axis direction;

is provided with the detent pieces, and an expansion part having a larger diameter than the cylindrical part, located on the radially outer side in relation to the detent pieces, and equipped with a small-diameter part and a large-diameter part, on a proximal end side of the cylindrical part; and

is provided with a needle hub engager engaged with the needle hub and holding the needle tip of the indwelling needle in a protruding state, on a peripheral wall of the large-diameter part, and

the detent pieces are elastically deformable, have inner surfaces inclined toward the needle hub, are provided inside the expansion part, and are integrally formed with the cylindrical part on the large-diameter part side, but are not provided on the small-diameter part side, and

wherein b) the needle hub has

engaging arms engaged with the needle hub engager of the needle tip protector to hold the needle tip of the indwelling needle in a protruding state, and

a connecting tube connected to an external conduit to form a fluid flow path extending from the external conduit to the indwelling needle, and

at least a part of the connecting tube protrudes to the proximal end side from a proximal end portion of the engaging arms serving as elastically deforming fulcrums of

the engaging arms.

4-2 The Demandant's allegation

(1) Although the Demandant filed a patent infringement lawsuit based on the Patent (Tokyo District Court 2019 (WA) No. 27053 a case of patent right infringement injunction), the defense of invalidation (A-4, A-5, and A-11) alleged by the Defendant is groundless, and the Demandant should be granted a patent for the inventions according to Claims 2 and 3 after correction independently at the time of filing of the patent application.

(2) Outline of the defense of invalidation

Reasons for invalidation according to the defense of invalidation (A-4, A-5, and A-11) are as follows.

Reason 1: The Patent violates the provisions of prior art effect (Article 29-2 of the Patent Act) based on Evidence A No. 2 and should be invalidated.

Reason 2: Since the inventions according to Claims 1 to 3 of the Patent are identical to the invention described in Evidence A No. 3 and fall under Article 29(1)(iii) of the Patent Act, the Patent violates the provisions of Article 29(1) of the Patent Act and should be invalidated.

Reason 3: Since Corrected Inventions 2 and 3 could have been easily invented by a person skilled in the art based on the invention described in Evidence A No. 3, the technology described in Evidence A No. 12, and the technology described in Evidence A No. 13, the Patent violates the provisions of Article 29(2) of the Patent Act and should be invalidated.

Evidence A No. 1: Tokyo District Court 2019 (WA) No. 27053 the written brief of the case of patent right infringement injunction (Plaintiff Part 2)
Evidence A No. 2: Japanese Unexamined Patent Application Publication No. 2017-196060 (the same lawsuit B-2)
Evidence A No. 3-1: The description of Chinese Utility Model Registration 204219517 (the same lawsuit B-3)
Evidence A No. 3-2: The abstract translation of the description of Chinese Utility Model Registration 204219517 (the same lawsuit B-23 abstract translation)

Evidence A No. 4: The same lawsuit, the defendant's second brief, abstract (front cover (Page 1), contents (Pages 2 to 3), detailed contents (Pages 4 to 6), No. 5 Invalidation theory (violation of prior art effect) (Pages 34 to 39))
Evidence A No. 5: The same lawsuit, the Defendant's third brief
Evidence A No. 6: Japanese Patent No. 3134920 (the same lawsuit B-1)
Evidence A No. 7: United States Patent Application Publication No. 2004/0236287 (the same lawsuit B-16, A-11)
Evidence A no. 7-2: The abstract translation of United States Patent Application Publication No. 2004/0236287 (the same lawsuit, abstract translation of B-16, A-11)
Evidence A No. 8: Domestic Re-Publication of PCT international Publication for Patent Application No. 2006/123645 (the same lawsuit B-17)
Evidence A No. 9: Domestic Re-Publication of PCT international Publication for Patent Application No. 2007/083770 (the same lawsuit B-18)
Evidence A No. 10: International Publication No. 2009/021263 (the same lawsuit B-19)
Evidence A No. 10-2: The abstract translation of International Publication No. 2009/021263
Evidence A No. 11: The same lawsuit, the Defendant's fifth brief
Evidence A No. 12: United States Patent Application Publication No. 2007/0260190 (the same lawsuit B-36)
Evidence A No. 13: The description of Chinese Utility Model Registration 200951238 (the same lawsuit B-37)

Hereinafter, Evidence A No. 2 will be referred to as "A-2" and the invention described in A-2 will be referred to as "Invention A-2". The same applies to other Evidences A.

4-3 Regarding described matters of Evidences A and inventions described in Evidences A

A Regarding described matters of A-2 and Invention A-2

A-2(Japanese Patent Application No. 2016-88440 (Japanese Unexamined Patent Application Publication No. 2017-196060)) was filed (April 26, 2016) before the priority date (June 3, 2016) of the Patent, and was published (November 2, 2017) after the priority date of the Patent. The applicant (TOP Corporation) is different from the applicant (Nipro Corporation) of the application according to the Patent.

A-2 describes the following.

(A) "[0030]

As illustrated in FIG. 1, a medical needle 1 with a protector of the present embodiment includes a hub 3 that supports a needle tube 2 with a sharpened front end, a cylindrical protector 4 into which the hub 3 is assembled, and a pair of wing-like members 5 externally fitted to the protector 4.

[0031]

The protector 4 is formed by injection molding of a polypropylene resin or the like and is capable of storing the needle tube 2. The wing-like members 5 are formed by injection molding of a soft resin such as a vinyl chloride resin.

[0032]

As illustrated in FIG. 2A, the hub 3 is formed from a hub base portion 7 with the rear end connected to a flexible tube 6 and a small cylindrical portion 71 extending from the front end of the hub base portion 7 in the front-end direction. The rear end of the needle tube 2 is supported by the front end of the small cylindrical portion 71".

(B) "[0034]

As illustrated in FIGS. 2B and 2C, the small cylindrical portion 71 includes a needle tube support portion 72 in which the needle tube 2 is inserted and supported at the front end side. The hub base portion 7 includes a connection tube portion 72 connected to the flexible tube 6 at the rear end side. The needle tube support portion 72a and the connection tube portion 72c communicate with each other via a hollow portion 72c provided in the middle thereof.

[0035]

The rear end of the hub base portion 7 has a pair of arms 73, 73 in symmetry with respect to the central axis of the small cylindrical portion 71 as illustrated in FIGS. 2A and 2C. The arms 73, 73 are provided along the length of the small cylindrical portion 71 with a space from the hub base portion 7. At the front end of each of the arms 73, a hook 73b is provided via a neck portion 73a, and at the front end of the hook 73b, an inclination surface 73c is formed from the front end side to the rear end side such that the side of the surface in proximity to the small cylindrical portion 71 is sharpened".

(C) "[0037]

As illustrated in FIGS. 2A to 2C, a first protrusion portion 74 and a second protrusion portion 75 are provided on the outer peripheral surface of the front end of the small cylindrical portion 71. The first protrusion portion 74 is provided on the front

end of the small cylindrical portion 71, and the second protrusion portion 75 is provided closer to the rear end side than the first protrusion portion 74 with a first predetermined space from the first protrusion portion 74.

[0038]

The first protrusion portions 74 protrude along a line orthogonal to a line connecting the arms 73 and 73 (corresponding to a first axial line of the present invention) as seen from the front end side. The second protrusion portions 75 protrude along the line connecting the arms 73, 73 (corresponding to a second axial line of the present invention) as seen from the front end side.

[0039]

A pair of first protrusion portions 74 are provided with a slope 74a at the front end in a vertically symmetrical manner (see FIG. 2A). The slopes 74a are formed to be gradually higher from the front end to the rear end. A pair of second protrusion portions 75 are provided with a slope 75a at the rear end in a horizontally symmetrical manner (see FIG. 2A). The slopes 75a are formed to be gradually lower from the front end to the rear end".

(D) "[0043]

As illustrated in FIGS. 3A to 3C, the protector 4 includes a width-increased portion 42 that gradually increases in width from the front end side to the rear end side in a planar view (see FIG. 3B) at the rear end of a large cylindrical portion 41. The internal space in the large cylindrical portion 41 is set such that the small cylindrical portion 71 (including the protrusion portions 74 and 75) is slidable therein.

[0044]

The rear end of the width-increased portion 42 includes insertion portions 42a, 42a into which the arms 73, 73 are inserted. Each of the insertion portions 42a includes a window 42b on a lateral side such that the hook 73b of the arm 73 inserted into the insertion portion 42a is locked at the window 42b. That is, the arms 73 and the hooks 73b of the hub base portion 7 and the insertion portions 42a and windows 42b of the protector 4 constitute a first lock unit.

[0045]

As illustrated in FIGS. 3A to 3C, the rear end of the protector 4 has protrusion pieces 43, 43 and side wall portions 44, 44.

[0046]

As illustrated in FIGS. 3A and 3B, the protrusion pieces 43, 43 are plate-like members that extend to the rear end side while inclining toward the axial line of the

protector 4. The pair of protrusion pieces 43, 43 are provided continuously from the rear end of the large cylindrical portion 41 in a horizontally symmetrical manner (see FIG. 3A). The lateral direction corresponds to a third axial line orthogonal to the axial line of the protector 4 in the present invention.

[0047]

The protrusion pieces 43 are curved in a convex form outward from the axial line of the protector 4. The distance between the protrusion ends of the pair of protrusion pieces 43, 43 is set to be equal to or shorter than the height of the second protrusion portions 75, 75. In the present embodiment, the distance between the protrusion ends of the pair of protrusion pieces 43 and 43 is set to be substantially equal to the diameter of the small cylindrical portion 71.

[0048]

Since the protector 4 is formed from a polypropylene resin as described above, the protrusion pieces 43 are elastically deformable in the direction away from the axial line of the large cylindrical portion 41 (the horizontal direction illustrated in FIG. 3A)".

(E) "[0055]

When the needle tube 2 is inserted into a blood vessel or the like, as illustrated in FIG. 4A, the hooks 73b at the front ends of the arms 73 in the hub base portion 7 are locked in the windows 42b of the protector 4 so that the needle tube 2 is protruded from the protector 4".

(F) "[0059]

After that, as illustrated in FIG. 5B, when the hub 3 is further moved backward and the needle tube 2 not illustrated in the drawing is stored in the large cylindrical portion 41, the protrusion pieces 43, 43 go over the second protrusion portions 75, 75 and return to the original state by their elasticity, and are fitted into clearances between the first protrusion portions 74 and the second protrusion portions 75. Accordingly, in a planar view (see FIG. 5B), the rear ends of the protrusion pieces 43, 43 are locked by the front ends of the second protrusion portions 75, 75".

(G) "[0062]

As a result, the protrusion pieces 43, the side wall portions 44, and the protrusion portions 74 and 75 cannot be unlocked unless the protrusion pieces 43 are deformed outward, and thus the needle tube 2 stored in the large cylindrical portion 41 will not be protruded again. This makes it possible to prevent incorrect insertion".

(H) From FIG. 1 and FIG. 3, it can be seen that the large cylindrical portion 41 extends in an axial direction of the needle tube 2.

(I) From FIG. 3, it can be seen that the width-increased portion 42 has a larger diameter than the large cylindrical portion 41, is located on the radially outer side in relation to the protrusion piece 43, and is equipped with a small diameter portion and a large diameter portion.

(J) From FIG. 1 and FIG. 3, it can be seen that the window 42b is provided on a peripheral wall of the large diameter portion of the width-increased portion 42.

(K) From FIG. 3 and the description of [0046], it can be seen that the protrusion pieces 43 have inner surfaces inclining toward the axial line of the protector 4, are in the width-increased portion 42, and are integrally formed with the large cylindrical portion 41, but are not provided on the small diameter portion side.

(L) From FIG. 6, it can be seen that the flexible tube 6 is inserted in and connected to the connection tube portion 72b.

(M) From FIG. 4, it can be seen that the connection tube portion 72b does not protrude to a proximal end side from a proximal end part of the arm 73 serving as an elastically deforming fulcrum of the arm 73.

Summarizing the described matters of (A) to (M) above, A-2 describes the following Invention A-2.

"A medical needle 1 with a protector comprising:

a needle tube 2 with a sharpened front end;

a hub 3 that supports a rear end of the needle tube 2; and

a cylindrical protector 4 which is assembled to the hub 3 and can store the needle tube 2,

wherein at a predetermined position where the protector 4 is moved to the front end side of the needle tube 2, protrusion pieces 43 provided on the protector 4 are locked to the hub 3 to prevent the needle tube 2 from protruding again, and incorrect insertion,

wherein the protector 4

has wing-like members 5;

has a large cylindrical portion 41 extending in an axial direction of the needle tube 2;

is provided with protrusion pieces 43, and a width-increased portion 42 with a diameter larger than the large cylindrical portion 41, located on the radially outer side in relation to the protrusion pieces 43, and equipped with a small diameter portion and a large diameter portion, at a rear end of the large cylindrical portion 41; and

is provided with a window 42b to which the hub 3 is locked to hold the needle tube 2 in a protruding state, and

the protrusion pieces 43 can elastically deform, and have inner surfaces inclining toward the axial line of the protector 4, are in the width-increased portion 42, and are integrally formed with the large cylindrical portion 41, but are not provided on the small diameter portion side, and

wherein the hub 3 has

arms 73 locked to the window 42b of the protector to hold the needle tube 2 in a protruding state, and

a connection tube portion 72b into which a flexible tube 6 is inserted and connected, and

the connection tube portion 72b does not protrude to a proximal end side from a proximal end part of the arms 73 serving as elastically deforming fulcrums of the arms 73.

B Regarding the described matters of A-3-1 and Invention A-3

A-3-1 describes the following.

(A) "

[0020] 实施例：如图 1-4 所示，本实用新型提供了一种自毁式安全医用针的具体实施例，其包括：具有内腔 12 的套筒 10、可在内腔 12 中往复运动并具有针头 22 的针座 20、与针座 20 相互扣合的锁扣头 28、以及与锁扣头 28 内部相连通的导管 30，其中套筒 10 在内腔 12 设置有阻挡块 120 和锁扣块 122，而针座 20 相应设置有与阻挡块 120 抵靠配合的限位部 24、以及与锁扣块 122 互锁配合且可弹性变形的锁紧部 26。其中阻挡块 120 阻止针座 20 继续运动，而锁扣块 122 则阻止针座 20 反向运动。锁紧部 26 优选为一对可弹性张开的扩张臂，其中扩张臂的末端与锁扣块 122 平面抵靠接触，而阻挡块 120 与限位部 24 之间是平面抵靠接触。

[0021] 套筒 10 为一端开口而另一端半开放的中空椭圆形筒，其进一步包括设置在一端且相对设置的一对锁扣窗 14、和设置在另一端且与针头 22 相邻的蝴蝶翼 16。其中开口允许针头 22 的出入，阻挡块 120 位于开口和锁扣块 122 之间，且阻挡块 120 和锁扣块 122 之间设置有允许扩张臂通过且具有使扩张臂逐渐收缩的斜面。

[0022] 针座 20 形状与套筒 10 相匹配，其进一步包括与针头 22 和锁扣头 28 均内部相连通的通道 21、可与锁扣窗 14 相扣合的锁扣头 28，且该锁扣头 28 包括一对与相应锁扣窗 14 扣合且可弹性变形的扣合臂 280、以及与导管 30 相连通的通孔 282。限位部 24 位于针头 22 和锁紧部 26 之间，同时能防止针座 20 脱离套筒 10。扣合臂 280 的末端设有向外延伸的凸部，且在受压变形时锁扣至锁扣窗 14 内壁上。扣合臂 280 与锁扣头 28 之间有允许弹性变形的间隙。由于针座 20 和套筒 10 之间是椭圆柱、孔配合，也可以采取其他形状的配合，能有效防止针座 20 在套筒 10 内旋转，而且针头 22 和针座 20 是固定连接，针头 22 在使用回抽时需捏住锁扣头 28，使扣合臂 280 弹性变形来脱离锁扣窗 14 的配合以释放锁扣头 28，带动针座 20 和针头 22 向后回抽，且因针座 20 和套筒 10 之间是椭圆柱、孔配合，防止了操作时人为造成的转动。

"

([0020] As described in FIGS. 1 to 4, the present device provides a concrete embodiment of a safety self-destruction type medical needle which includes an outer cylinder 10 having a lumen 12, a needle hub 20 reciprocating in the lumen 12 and having a needle 22, an engaging end portion 28 engaged with the needle hub 20, and a tube 30 communicated with the inside of the engaging end portion 28, and in which the lumen 12 of the outer cylinder 10 is provided with a limiting receiving portion 120 and a locking receiving portion 122, and the needle hub 20 is correspondingly provided with a limiting portion 24 abutting on and engaging with the limiting receiving portion 120 and a locking portion 26 locking and engaging with the locking receiving portion 122 and capable of elastically deforming. The limiting receiving portion 120 prevents the continuous movement of the needle hub 20, and the locking receiving portion 122 prevents the movement in the opposite direction of the needle hub 20. The locking portion 26, preferably, is a pair of extension arms capable of elastically opening. Terminals of the extension arms and the locking receiving portion 122 abut each other in a plane, and the limiting receiving portion 120 and the limiting portion 24 abut each other in a plane.

[0021] The outer cylinder 10 is a hollow elliptical cylinder opening at one end and semi-opening at the other end, and further includes a pair of engaging windows 13 provided at one end and provided so as to oppose to each other, and a butterfly-shaped wing 16 provided at the other end and adjacent to the needle 22. The opening accepts taking in/out of the needle 22, and the limiting receiving portion 120 is located between the opening and the locking receiving portion 122. Between the limiting receiving portion 120 and the locking receiving portion 122, an inclined surface is provided, which allows the expansion arms to pass through and gradually contracts the expansion arms.

[0022] A shape of the needle hub 30 further includes a passage 21 communicating with the inside of the needle 22, and an engaging end portion 28 according to the outer cylinder 10, and the engaging end portion 28 engaged with the engaging window 14. The engaging end portion 28 includes a pair of engaging arms 280 engaged with the corresponding engaging window 14 and capable of elastically deforming, and a through-hole 282 communicating with a tube 30. The limiting portion 24 is located between the needle 22 and the locking portion 26, and can prevent the needle hub 20 from coming off from the outer cylinder 10. At the terminal of the engaging arm 280, there is provided a projecting portion extending outward and locked to an inner wall of the engaging window 14 during pressure receiving deformation. There is a clearance accepting elastic deformation between the engaging arm 280 and the engaging end portion 28. Since a space between the needle hub 20 and the outer cylinder 10 uses engagement of an elliptical column and the hole and may use engagement of other shapes, the needle hub 20 can be effectively prevented from rotating in the outer cylinder 10, and the needle 22 and the needle hub 20 are fixedly connected. When the needle 22 is used and pulled back, it is necessary to pull the needle hub 20 and the needle 22 backward by gripping the engaging end portion 28, elastically deforming the engaging arm 280 to remove it from the engaging window 14, and releasing the engaging end portion 28. Also, since the space between the needle hub 20 and the outer cylinder 10 uses the engagement of the elliptical column and the hole, artificial rotations during operation are prevented.) (See A-3-2.)

(B) From FIG. 2, it can be seen that the needle hub 20 is provided on the proximal end side of the needle.

(C) From FIG. 2, FIG. 4, and the descriptions of [0020] and [0022], it can be seen that the outer cylinder 10 is externally equipped to the needle hub 20 and pulls the needle 22

backward to cover the needle 22, and at a predetermined position where the needle 22 is pulled backward with respect to the outer cylinder 10, the locking receiving portion 122 provided on the outer cylinder is engaged with the locking portion 26 of the needle hub 20 to prevent the needle 22 from being re-exposed. Furthermore, it can be seen that at the same predetermined position, the limiting receiving portion 120 provided on the outer cylinder is engaged with the limiting portion 24 of the needle hub 20 to prevent the needle hub 20 from coming off from the outer cylinder 10.

(D) From FIG. 1 to FIG. 4 and the description of [0021], it can be seen that the outer cylinder 10 has the elliptical cylinder portion extending in the axial direction of the needle 22.

(E) From FIG. 1 to FIG. 4, it can be seen that on the proximal end side of the elliptical cylinder portion, there are provided the locking receiving portion 122, and an enlarged portion with a diameter larger than the elliptical cylinder portion, located on the radially outer side in relation to locking receiving portion 122, and equipped with a small diameter portion and a large diameter portion.

(F) From FIG. 1 to FIG. 3 and the description of [0022], it can be seen that the engaging window 14 is provided on a peripheral wall of the large diameter portion, and the needle hub 20 is engaged to hold the needle 22 in a protruding state.

(G) From FIG. 2 and FIG. 4, it can be seen that the locking receiving portions 122 have inner surfaces inclining toward the needle hub 20, and are integrally formed with the elliptical cylinder portion on the large diameter portion side.

(H) From FIG. 2, it can be seen that the tube 30 is inserted in and connected to the through-hole 282.

Summarizing the described matters of (A) to (H) above, A-3 describes the following Invention A-3.

"A self-destruction type medical needle comprising:

a needle 22;

a needle hub 20 provided on the proximal end side of the needle 22; and

an outer cylinder 10 that is a hollow elliptical cylinder, is externally equipped to

the needle hub 20 and pulls the needle 22 backward to cover the needle 22,

wherein at a predetermined position where the needle 22 is pulled backward with respect to the outer cylinder 10, a locking receiving portion 122 provided on the outer cylinder is engaged with a locking portion 26 of the needle hub 20 to prevent the needle 22 from being re-exposed, and a limiting receiving portion 120 provided on the outer cylinder is engaged with a limiting portion 24 of the needle hub 20 to prevent the needle hub 20 from coming off from the outer cylinder 10,

wherein the locking portion 26 is elastically deformable,

wherein the outer cylinder 10

has a butterfly-shaped wing adjacent to the needle 22;

has an elliptical cylinder portion extending in an axial direction of the needle 22;

is provided with the locking receiving portion 122, and an enlarged portion with a diameter larger than the elliptical cylinder portion, located on the radially outer side in relation to the locking receiving portion 122, and equipped with a small diameter portion and a large diameter portion, on the proximal end side of the elliptical cylinder portion; and

is provided with an engaging window 14 to which the needle hub 20 is engaged to hold the needle 22 in a protruding state, on a peripheral wall of the large diameter portion, and

wherein the locking receiving portions 122 have inner surfaces inclining toward the needle hub 20, and are integrally formed with the elliptical cylinder portion on the large diameter portion side; and

has engaging arms 280 engaged with the engaging window 14 of the outer cylinder 20 to hold the needle 22 in a protruding state, and

a through-hole 282 into which a tube 30 is inserted and communicated".

C Described matters of A-6

A-6 describes the following.

(A) "[0001] The present invention relates to an indwelling winged needle and, more particularly, to a winged indwelling needle giving a protector function to a winged cylindrical holder for preventing sticking accidents that could otherwise take place when restoring the indwelling needle into a protector after use, and capable of protecting an edge of the indwelling needle by merely sliding the needle".

(B) "[0010]...At the proximal end of the hub 2, there are provided a connecting portion

24 for the tube 3 and a pair of flexible locking arms 21 extending from the connecting portion 24 toward the distal end of the hub 2. As each of the pair of locking arms 21, there is employed an arm having a hook 211 at the distal end and capable of flexing in the direction of the axis of the hub 2 by means of a slit 212 as shown in FIGS. 2 through 5",

(C) "[0012] On the inner wall of the cylindrical holder 4, there is provided a flange 42 on the distal end in the proximity of the locking holes 41. This flange 42 has a flexible abutment branch 43 extending toward the proximal end of the cylindrical holder 4. The flexible abutment branch 43 has a length about equal to the width of the annular groove 23 of the hub 2. The second locking means comprises the flexible abutment branch 43 and the flange 42 of the cylindrical holder 4 as a locking portion and the annular projection 22 and the annular groove 23 of the hub 2 as a locked portion. Thus, due to the provision of the second locking means, when the hub 2 is at the second position of the cylindrical holder 4, the end surface of the annular projection 22 on the annular groove 23 side abuts against the flange 42, thereby preventing the backward movement of the hub 2 and at the same time, an end surface 231 of the annular groove 23 on the proximal end side abuts against the distal end of the flexible abutment branch 43, thereby preventing the forward movement of the hub 2. By this structure the hub 2 is substantially unreleasably locked at the second position of the cylindrical holder 4".

(D) "[0013]...In the first position, the hub 2 and the cylindrical holder 4 are held in engagement with each other by the first locking means comprising the locking arms 21 of the hub 2 (more accurately, the hooks 211 of the locking arms 21) and the locking holes 41 of the cylindrical holder 4. Thus, when the winged indwelling needle is stuck to the skin of a patient, the hub 2 is prevented from moving backward; i.e., toward the proximal end of the cylindrical holder 4".

(E) "[0014]...the end surface 231 of the annular groove 23 on the proximal end side of the hub 2 and the tip of the flexible abutment branch 43 abut against each other, thereby preventing the hub 2 from moving forward (see FIGS. 4 and 5). In this case, the edge 11 of the cannula 1 is completely received in the cylindrical holder 4".

(F) From FIG. 2, it can be seen that the connecting portion 24 protrudes to the proximal end side from the proximal end part of the engaging arms 21 serving as bending fulcrums of the engaging arms 21.

(G) From FIG. 3 and FIG. 5, it can be seen that a flexible abutment branch 43 has an inner surface inclined toward the hub 2.

(H) From FIG. 2, it can be seen that the connecting portion 24 is connected by being inserted in the tube 3.

Summarizing the described matters of (A) to (H) above, A-6 describes the following Technology A-6.

"A winged indwelling needle wherein a flexible abutment branch 43 provided in a cylindrical holder 4 is locked to a hub 2 to completely store an edge 11 of a cannula 1,

the flexible abutment branch 43 being flexible and having an inner surface inclined toward the hub 2,

the hub 2 having engaging arms 21 engaged with locking holes 41 of the cylindrical holder 4 and preventing the hub 2 from moving toward the proximal end of the cylindrical holder 4 when the winged indwelling needle is stuck to a skin of a patient, and

a connecting portion 24 connected by being inserted in a tube 3,

the connecting portion 24 protruding to the proximal end side from the proximal end part of the engaging arms 21 serving as bending fulcrums of the engaging arms 21".

D Described matters of A-7

A-7 describes the following.

(A) "[0032] Referring to FIGS.1 and 2, a first embodiment of the medical device 10 is shown. The medical device 10 generally includes a needle cannula 12, a hub 22, a needle shield 40, a release element 60 releasably connecting the hub 22 and the needle shield 40 and a biasing member 80, for actuating (i.e., moving) the needle shield 40 to the safety, needle-enclosing position or configuration. The hub 22 is adapted for connection to a receptacle (not shown) of, for example, a blood collection set by way of a flexible tube 98 by means and procedures known in the art."

(B) "[0034] The hub 22 is preferably of a unitary structure, which is desirably molded from a thermoplastic material. The hub 22 has a generally tubular-shaped body 24 with a proximal end 26 and a distal end 28. The body 24 has an outer surface 30 and defines an internal passageway or lumen 32 extending from the proximal end 26 to the

distal end 28. The passageway 32 communicates with the lumen 18 defined in the needle cannula 12 to enable fluid, such as blood, to pass through the medical device 10 and to the tube 98 connecting the medical device 10 to the blood collection receptacle.
[0035] The proximal end 14 of needle cannula 12 is received within and supported by the distal end 28 of the body 24. Particularly, the proximal end 14 of the needle cannula 12 is disposed in the passageway 32, with the distal end 16 of needle cannula 12 projecting outward from the distal end 28 of the body 24. The needle cannula 12 is preferably secured to the hub 22 through the use of an appropriate medical grade adhesive, mechanical means, or the like. In particular, the proximal end 14 of the needle cannula 12 may be secured adhesively within the passageway 32 at the distal end 28 of the body 24 of the hub 22. The proximal end 26 of the body 24 may include a tapered or reduced diameter portion 34 having a shoulder 36, whose function will be discussed hereinafter. The proximal end 26 of the body 24 is generally adapted to cooperate with the tube 98 used to connect the medical device 10 to, for example, a blood collection receptacle. The passageway 32 at the distal end 28 of the body 24 preferably includes a reduced diameter portion or area 38 sized to accept and support the proximal end 14 of the needle cannula 12."

(C) "[0039] The needle shield 40 is secured releasably in the first position by a release element 60. The release element 60 is preferably fixed to the hub 22, for example, by a medical grade adhesive or by mechanical methods. The release element 60 has a body 62 with a first or proximal end 64 and a second or distal end 66. The body 62 defines an internal bore or passageway 68 adapted to receive the hub 22. The body 62 of the release element 60 generally comprises an annular-shaped inner member 70 defining the passageway 68, and one or more locking arms 72 located about the inner member 70. An annular groove or pocket 74 is formed or defined by the inner member 70, the locking arms 72, and the outer surface 30 of the hub 22. The function of the annular groove or pocket 74 will be described hereinafter. While illustrated as a separate structure from the hub 22, the release element 60 may be integrally formed as part of the hub 22. The release element 60 is desirably molded from a thermoplastic material, either separate from or integrally with the hub 22 as indicated. Thus, the release element 60 may be considered to be part of the hub 22 in accordance with the present invention and generally forms a "grippable" or "graspable" portion of the hub 22, which extends proximally out from the needle shield 40. The release element 60 thus forms a convenient handle means for manipulating the medical device 10. An outer surface 75 of the body 62 of the release element 60 and, more particularly, the locking

arms 72 may be textured, thereby providing a surface grip for ease in grasping and manipulating the medical device 10 during a fluid collection procedure. When formed as a separate structure, the release element 60 in this embodiment of the medical device 10 is preferably fixedly connected to the hub 22, for example, by a medical grade adhesive or by mechanical methods, so that the locking arms 72 are positioned at fixed locations around the hub 22.

[0040] The body 62 of the release element 60 generally coaxially receives the proximal end 26 of the body 24 of the hub 22, as illustrated in FIGS. 1 and 2. In particular, the reduced diameter portion 34 at the proximal end 26 of the body 24 of the hub 22 is received in the annular-shaped inner member 70, and preferably extends proximally outward from the proximal end 64 of the body 62 of the release element 60 to cooperate with the tube 98. The inner member 70 defines a distal recess 76 opening to the internal passageway 68. The distal recess 76 has a larger diameter than that of the internal passageway 68. The distal recess 76 is adapted to cooperate with the reduced diameter or tapered portion 34 defined by the body 24 of the hub 22. The shoulder 36 of the reduced diameter portion 34 engages the distal recess 76 in the first position of the needle shield 40 and prevents axial movement of the release element 60 along the body 24 of the hub 22 in the distal direction, as is most apparent in FIG. 2.

[0041] The locking arms 72 extend distally along the inner member 70 and terminate in integrally formed barbs or hooks 78 adapted to mate with the detents 58 provided at the proximal end 44 of the needle shield 40. In particular, as indicated previously, the detents 58 are formed in the outwardly bulged portion 56 at the proximal end 44 of the body 42 of the needle shield 40. The detents 58 and locking arms 72 form a locking element of the medical device 10. The engagement of the hooks 78 with the detents 58 secures the needle shield 40 in the first or retracted position. As indicated previously, the release element 60 is preferably fixedly connected to or integrally formed with the hub 22. Thus, the locking arms 72 and, more particularly, the hooks 78 are positioned at fixed locations around the hub 22 opposite the detents 58 to properly engage the detents 58 and secure the needle shield 40 in the first or retracted position."

(D) From FIG. 1, it can be seen that the reduced diameter portion 34 is inserted in the tube 98 to cooperate with it.

Summarizing the described matters of (A) to (D) above, A-7 describes the following Technology A-7.

"A medical device 10 taking a safety needle-enclosing position by moving a needle shield 40,

wherein a hub 22 has

locking arms 72 that mate with detents 58 of the needle shield 40 to hold the needle shield 40 at a retracted position, and

a reduced diameter portion 34 inserted in a tube 98 to cooperate with it,

the reduced diameter portion 34 extending proximally outward from a proximal end 64 of a release element 60 comprising the locking arms 72".

E Described matters of A-8

A-8 describes the following.

(A) "[0001]

This invention relates to a winged needle assembly provided with a mechanism which is capable of accommodating a used winged needle in a protector with a simple operation in order to prevent an accident of erroneously sticking the winged needle after it is used"

(B) "[0019]

Referring to FIG. 4, the needle hub 2 comprises three members of a distal end 21 for holding the proximal end of the needle cannula 1, a proximal end 23 to which the tube 6 is connected, and an intermediate portion 22 for connecting the distal end 21 and the proximal end 23 together. The needle hub 2 may be one in which the distal end 21, the intermediate portion 22, and the proximal end 23 are integrally fixed together by such a method as adhesion, or may be one which as a whole is integrally formed by a conventional method such as injection-molding".

(C) "[0027]

As the first engaging means, the means comprising, for example, a first engaging portion provided at the proximal end 23 of the needle hub 2 and a first engaged portion provided at the proximal end of the protector 3 can be used. Concretely as shown in FIGS. 1 and 4, the proximal end 23 of the needle hub 2 is provided with a flexible arm 232 that extends toward the distal end side from the outer peripheral surface of the proximal end 23 and, further, the distal end of the arm 232 is provided with a projection 233 protruding outward as the first engaging portion. Further, the proximal end of the protector 3 is provided with a through hole 31 or a recessed portion which is opening inward as the first engaged portion. The arm 232 is so formed as to be urged outward,

and the needle hub 2 is brought into engagement with the protector 3 as the projection 233 protrudes into the hole 31 from the inside of the protector 3".

(D) "[0030]

As the second engaging means, there is used means comprising, for example, a second engaging portion provided at the proximal end of the protector 3 and a second engaged portion provided at the distal end 21 of the needle hub 2. Concretely, as shown in FIGS. 3 and 5, the proximal end of the protector 3 is provided with a flexible flange 32 that protrudes inward as the second engaging portion. Further, the distal end 21 of the needle hub 2 is provided with a protruding portion 211 protruding outward and with a groove portion 212 arranged on the proximal end side of the protruding portion 211 as the second engaged portion. The groove portion 212 is designed to have a length equal to the length in the axial direction of the flange 32 or is slightly greater than the length thereof in the axial direction. The flange 32 is formed so as to be biased inward. By fitting into the groove portion 212, the end portion of the distal end side comes in contact with the protruding portion 211 and the end portion of the proximal end side comes in contact with the edge on the proximal end side of the groove portion 212, and thus, the needle hub 2 engages with the protector 3. The groove portion 212 may be provided in the distal end 21 of the needle hub 2, or may be formed by fixing together the distal end 21 and the intermediate portion 22 of the needle hub 2 as shown in FIGS. 3 and 5".

(E) "[0036]

Next, how to use the winged needle assembly of the present invention is described below with reference to the drawings. First, the cap fitted with the needle cannula 1 of the winged needle assembly is removed, and the blade tip 11 of the needle cannula 1 is sticked into the patient in a state where the needle hub 2 is engaged by the first engaging means at the first position at which the distal end of the needle cannula 1 protrudes from the distal end side of the protector 4. After the medical treatment has been finished, the arms 232 provided at the proximal end 23 of needle hub 2 of the winged needle assembly are pushed from the outer sides to release the first engaging means, whereby the needle hub 2 slides toward the proximal end side due to the spring 4, and the needle cannula 1 is accommodated in the protector 3. When the needle hub 2 slides up to the second position where the needle cannula 1 is completely accommodated in the protector, the needle hub 2 is engaged by the second engaging means in a manner that it is not disengaged, and the needle cannula 1 is prevented from

being exposed again from the protector 3".

(F) From FIG. 1, FIG. 4 and the description of [0027], it can be seen that the proximal end 23 protrudes to the proximal end side from the proximal end part of the arm 232 serving as a bending fulcrum of the arm 232.

(G) From FIG. 3 and FIG. 6, it can be seen that the flange 32 has an inner surface inclined toward the needle hub 2.

(H) From FIG. 3, it can be seen that the tube 6 is inserted in and connected to the proximal end 23.

Summarizing the described matters of (A) to (H) above, A-8 describes the following Technology A-8.

"A winged needle assembly that prevents a needle cannula 1 from being exposed again by locking a flange 32 provided on a protector 4 to a needle hub 2,

the flange 32 being flexible and having an inner surface inclined toward the needle hub 2,

the needle hub 2 having

an arm portion 232 being engaged with a hole 31 of the protector 3 and locked at a first position at which a distal end of the needle cannula 1 protrudes, and

a proximal end 23 into which a tube 6 is inserted and connected,

the proximal end 23 protruding to the proximal end side from the proximal end part of the arm 232 serving as a bending fulcrum of the arm portion 232".

F Described matters of A-9

A-9 describes the following.

(A) "[0006]

FIGS. 19 to 20B show another example of the conventional medical needle device. The medical needle device shown in FIGS. 19 to 20B is constituted by a rigid needle 100, a hub 200, a tube 300, and a shield tube 400 that stores the hub 200 therein such that it can hold the hub 200. The shield tube 400 is provided with a wing 500 on its front end side. The hub 200 can slide in an axial direction inside the shield tube 400. As shown in FIG. 19, when a predetermined length of the rigid needle 100 protrudes from a front end of the shield tube 400, if a hook 222 of an engagement arm

211 is engaged with an engagement hole 410 of the shield tube 400, the sliding of the hub 200 toward a rear end side of the shield tube 400 is inhibited. After use, by pinching the engagement arm 211 with the fingers, the engagement is released, and the hub 200 is allowed to slide toward the rear end side of the shield tube 400. As shown in FIGS. 20A and 20B, an annular convex portion 220 collides with a step portion 420, thereby inhibiting the movement of the hub 200 toward the rear end side of the shield tube 400. At the same time, a base end side surface 231 of the annular groove 230 and a front end of a flexible abutment branch 430 collide with each other, whereby the movement of the hub 200 toward the front end side of the shield tube 400 also is prevented. At this time, a cutting edge 111 of the rigid needle 100 is stored completely in the shield tube 400 (see, for example, Patent Document 2)".

(B) From FIG. 19, FIG. 20A and the description of [0006], it can be seen that the hub 200 has the engagement arm 211 and a part inserted and connected in a tube 300, and the part connected to the tube 300 protrudes to a rear end side from a rear end part of the engagement arm 211 serving as a bending fulcrum of the engagement arm 211.

(C) From FIG. 20A, FIG. 20B, and the description of [0006], it can be seen that the base end side surface 231 of the annular groove 230 is provided on the hub 200.

(D) From FIG. 20B and the description of [0006], it can be seen that the flexible abutting member 430 is provided on the shield tube 400 and has an inner surface inclined toward the hub 200.

Summarizing the described matters of (A) to (D) above, A-9 describes the following Technology A-9.

"A medical needle device wherein a flexible abutment branch 430 provided on a shield tube 400 collides with a hub 200, whereby the movement is prevented while a cutting edge 111 of a rigid needle 100 is stored in the shield tube 400,

the flexible abutment branch 430 being flexible and having an inner surface inclined toward the hub 200,

the hub 200 having

an engagement arm 211 engaged with an engagement hole 410 of the shield tube 400 to prevent the movement while the rigid needle 100 protrudes, and

a part inserted in and connected to a tube 300,

the part connected to the tube 300 protruding to a rear end side from a rear end part of the engagement arm 211 serving as a bending fulcrum of the engagement arm 211".

G Described matters of A-10

A-10 describes the following.

(A) "Referring to Figures 1 to 14 there is shown a first example of a retractable infusion or transfusion needle assembly 10 according to a first example of the invention. The retractable needle assembly 10 has an elongated housing 12 in which a needle sub assembly 14 is movable between an extended position, shown in Figure 1, and a retracted position, shown in Figure 11. The needle sub assembly (see Figure 2) comprises a hollow shaft 16 having a cannula 18 mounted at a front end 20. A plastic tube 22 may be mounted at the other end 24. Fluid may thus be supplied via the plastic tube 22 and a bore 17 of the hollow shaft 16 to the cannula 18 or vice versa. In the extended position, the point 26 of the cannula 18 extends out of housing 12 and may be inserted into a patient's vein. In the retracted position, the cannula, and in particular its point 26, is located within the housing 12 and is not exposed to the user." (Page 8, lines 21 to 32)

(B) "The shaft 16 has an annular flange 28 located between its ends. The length of the shaft 16 and the location of the flange 28 depend on the length of the housing 12.
Located toward the upper end 24 of the shaft 16 are two resilient legs 30. These legs 30 extend backwards and away from the axis of the shaft 16, and (as seen in Figure 8) at their free ends 32 have a surface 34 extending generally perpendicular to the axis of the shaft 16. A small protrusion 36 extends backwards beyond the surface 34. The legs 30 are flexible and may be bent toward the shaft 16 upon application of an inwardly directed force, springing back when the force is released.
The housing 12 comprises a main body 40 and an end body 42. The main body 12 is elongated and has a generally cylindrical bore 44 within which the cannula 18 and a front portion of shaft 16 are located." (Page 9, lines 6 to 18)

(C) "The end body 42 has a first pair of diametrically opposed resilient legs 66 that extend rearward and inward toward the longitudinal axis. When assembled, the legs 66 extend into the slots 58. The free ends 68 of these legs 66 extend inwards further than the outer diameter of the central annular flange 28 on the shaft 16 and preferably engage with and are biased against the surface of the shaft 16. In the extended position,

the flange 28 is located between the legs 66 and the front end 46." (Page 10, lines 11 to 17)

(D) "In the extended state, the spring 52 is compressed and biases the needle sub assembly 14 toward the rear end. However, this is prevented by the legs 30, and in particular surfaces 34, engaging the surfaces 35 on the end of the end body 42, as seen in Figure 8." (Page 11, lines 19 to 22)

(E) "The spring 52 pushes the shaft 16 rearwards until the flange 28 contacts the ends 68 of the legs 66 of the end body 42. As the shaft moves backwards, the flange 28 pushes the legs 66 outwards, continues its backwards motion, and passes the legs 66, which then snap back towards their undeflected state against the shaft 16. Movement continues until the flange 28 contacts the end of the end body 42. In this position the cannula point 26 is located wholly within the housing 14, as seen in Figures 12 & 14 and the flange is located between the end of the end body 42 and the ends of the legs 66. The legs 66 may engage the spring, but because the flange 28 extends radially further than the spring, there will be an outer portion of the flange 28 that extends radially beyond the position of the legs 66. Attempting to extend the cannula 18 will result in the flange 28 contacting the ends 68 of the legs 66. The legs 66 are sized so that normal "accidental" force will be resisted, thereby preventing any significant movement. If a user deliberately attempts to extend the cannula by application of excessive force, the angle of the legs will cause the legs to deflect inwards rather than deflect outwards. Thus, once the cannula has been retracted, it cannot be accidentally or easily extended again and either reused or merely exposed." (Page 13, lines 6 to 23)

(F) From FIG. 2 and FIG. 7, it can be seen that the other end 24 connected to the plastic tube 22 protrudes to a rear end side from a part serving as a bending fulcrum of the leg 30 and a rear end part of the leg 30.

(G) From FIG. 5 and FIG. 13, it can be seen that the legs 66 have inner surfaces inclined toward the shaft 16.

(H) From FIG. 7, it can be seen that the other end 24 is inserted in and connected to the plastic tube 22.

Summarizing the described matters of (A) to (H) above, A-10 describes the

following Technology A-10.

"A retractable needle assembly 10 wherein once a cannula 18 has been retracted, it cannot be easily extended again with legs 66 contacted with a shaft 16,

the legs 66 being resilient legs and having inner surfaces inclined toward the shaft 16,

the shaft 16 having

legs 30 engaging surfaces 35 of the housing 12 and preventing the cannula 18 from moving toward a rear end side, and

the other end 24 inserted in and connected to a plastic tube 22,

the other end 24 protruding to a rear end side from parts serving as bending fulcrums of the legs 30 and a rear end part of the legs 30".

H Described matters of A-12

A-12 describes the following.

(A) "[0016] Referring to FIGS. 1 to 3, the intravenous injection unit of the present invention comprises a needle set 10 including a connection end on a first end thereof so as to be connected with an end of a hose 13, and a needle 12 is connected to a second end of the needle set 10. A protrusion 14 and a wing 11 extend from an outer periphery of the needle set 10 at a distance. A connector 15 is connected to the other end of the hose 13 so that medicine can be supplied to the hose 13 via the connector 15.

[0017] A sleeve 20 has a slot 21 longitudinally defined through a wall thereof and a head 23 is connected to a first end of the sleeve 20. The slot 21 is terminated before the head 23 and communicates with a second end of the sleeve 20. A plurality of stop plates 22 extend from an inner periphery of the first end of the sleeve 20 inclinedly and inward. Each of the stop plates 22 is a thin and flexible plate and can be pushed outward slightly.

[0018] The wing 11 and the protrusion 14 are movably engaged with the slot 21 and the hose 13 extends out from the first end of the sleeve 20. A cover 16 is removably connected to the needle set 10 and the needle 12 is received in the cover 16. When in use, the cover 16 is first removed and the wing 11 is taped to the patient's limb. Medicine is supplied via the hose 13 and enters the patient's vein via
the needle 12.

[0019] After use, as shown in FIG. 4, the sleeve 20 is moved toward the needle set 10 until the protrusion 14 moves over and is engaged with the stop plates 22. By the engagement of the stop plates 22 and the protrusion 14, the sleeve 20 cannot be pulled

backward so as to ensure that the needle 12 is received in the sleeve 20."

(B) From FIG. 4, it can be seen that the stop plates 22 have inner surfaces inclined toward the needle set 10.

Summarizing the described matters of (A) to (B) above, A-12 describes the following Technology A-12.

"An intravenous injection unit that makes a plurality of stop plates 22 extending from a sleeve 20 engage with a protrusion 14 to ensure that the needle 12 is received in the sleeve 20,

wherein the stop plates 22 are thin and flexible plates, can be pushed outward slightly, and have inner surfaces inclined toward the needle set 10".

I Described matters of A-13

A-13 describes the following.

(A) "

本实用新型涉及医疗器械技术领域，确切地说，它是一种一次性使用安全静脉输液针。

" (Page 3, lines 3 to 4)

(The present invention relates to a technical field of medical equipment, and specifically relates to a disposable and safety intravenous infusion needle.)

(B) "

本实用新型除针头 11 外，均可采用塑料制成，针头护套 12、软管 19 和针座 20 与现有技术相同，针座 20 与输液管的连接方式亦与现有技术相同。如附图 1 所示，针头护套 12 套在针头 11 上，软管 19 经针座 20 连接至输液管，再至输液瓶。针头 11 可用注塑工艺安装在针杆 14 的前端，针杆 14 的后端设有拔针手柄 18，两者粘接成一体。滑动护套 16 套在针杆 14 上，针杆 14 的尾端连接软管 19。针杆 14 的前部设有外卡槽 13，拔针手柄 18 上设有外卡块 17，滑动护套 16 的内部设有内卡块 22，后部内圈上设有内卡槽 21。使用前，拔针手柄 18 上的外卡块 17 卡在滑动护套 16 的内卡

槽 21 内；输液结束后，不必分离双翼 15 与人体皮肤之间的固定，按下拔针手柄 18 上的外卡块 17，再将针杆 14 沿滑动护套 16 向后抽动，如附图 2 所示，直至针头 11 从患者血管中拔出、滑动护套 16 的内卡块 22 卡在针杆 14 前部的外卡槽 13 内、滑动护套 16 护住针头 11，最后将双翼 15 从人体皮肤上取下。内卡块 22 卡在外卡槽 13 内后，滑动护套 16 就再也无法后退或重新套装在针杆 14 上，即产生自毁功能；滑动护套 16 护住针头 11，以方便医疗垃圾的处理、防止医疗污物对环境造成污染。双翼 15 可以采用注塑工艺固定在滑动护套 16 的前端。

" (Page 4, line 23 to page 5, line 8)

(The present invention is made of plastic except for the needle 11. The needle cap 12, the hose 19, and the needle base 20 are the same as those in the prior art, and the connection method between the needle base 20 and the infusion tube is also the same as in the prior art. As described in FIG. 1, the needle cap 12 is covered with the needle 11, and the hose 19 is connected to an infusion tube by the needle base 20 and then to an infusion bottle. The needle 11 can be attached to the front end of the needle rod 14 by an injection molding process, the needle removal handle 18 is provided at the rear end of the needle rod 14, and the two are integrally adhered to each other. The slide sleeve 16 is covered with the needle rod 14, and the terminal end of the needle rod 14 is connected to the hose 19. An external locking groove 13 is provided on the front portion of the needle rod 14, an external locking block 17 is provided on the needle removal handle 18, an internal locking block 22 is provided inside the slide sleeve 16, and an internal locking groove 21 is provided on the inner periphery of the rear portion. Before use, the external locking block 17 of the needle removal handle 18 is locked in the internal locking groove 21 of the slide sleeve 16, after the infusion is complete, there is no need to separate the fixation between both wings 15 and a human skin, and after pushing the external locking block 17 of the needle removal handle 18, the needle rod 14 is pulled backward along the slide sleeve 16. As described in FIG. 2, the needle 11 is pulled out of a patient's blood vessel, the internal locking block 22 of the slide sleeve 16 is locked in the external locking groove 13 at the front of the needle rod 14, and finally, both wings 15 are removed from the human skin until the slide sleeve 16 protects the needle 11. After the internal locking block 22 is locked in the external locking groove 13, the slide sleeve 16 moves backwards or cannot be reattached to the needle rod 14; that is, a self-destructive function occurs, and the slide sleeve 16 protects the needle 11 to facilitate the treatment of medical waste and prevent environmental pollution by the medical waste. Both wings 15 can be fixed to the front end of the

slide sleeve 16 in an injection molding process.)

(C) From FIG. 2 and FIG. 3, it can be seen that the internal locking block 22 is elastically deformable, has an inner surface inclined toward the needle rod 14, and is formed on the same plane as the internal locking groove 21 to which the needle removal handle 18 provided on the needle rod 14 is locked.

Summarizing the described matters of (A) to (C) above, A-13 describes the following Technology A-13.

"An intravenous infusion needle that pulls a needle rod 14 backward along a slide sleeve 16 and prevents the slide sleeve 16 from moving backward after an internal locking block 22 provided on the slide sleeve 16 is locked in an external locking groove 13 of a needle rod 14 to make the slide sleeve 15 protect the needle 11,

wherein the internal locking block 22 is elastically deformable, has an inner surface inclined toward the needle rod 14, and is formed on the same plane as an internal locking groove 21 to which a needle removal handle 18 provided on the needle rod 14 is locked, and

wherein the needle rod 14 has the needle removal handle 18 locked to the internal locking groove 21 of the slide sleeve 16".

4-4 Judgment

(1) Regarding prior art effect based on Invention A-2

A Regarding Corrected Invention 2

(A) Comparison

"A needle tube 2 with a sharpened front end" of Invention A-2 and "a metallic indwelling needle having a needle tip" of Corrected Invention 2 are identical to the extent that each is "an indwelling needle having a needle tip". Then, "a needle tube 2" of Invention A-2 corresponds to "an indwelling needle" of the Corrected Invention, and subsequently likewise, "a hub 3 that supports a rear end of the needle tube 2" corresponds to "a needle hub provided on a proximal end side of the indwelling needle," "a hub 3" corresponds to "a needle hub," "a cylindrical protector 4 which is assembled to the hub 3 and can store the needle tube 2" corresponds to "a needle tip protector that has a tubular peripheral wall and covers the needle tip of the indwelling needle by being externally mounted to the needle hub and by being moved to the needle tip side," "a protector 4" corresponds to "a needle tip protector," "a front end side" corresponds to "a

needle tip side," "protrusion pieces 43" correspond to "detent pieces," "the protruding again of the needle tube 2 and incorrect insertion" corresponds to "the needle tip from being re-exposed," "a medical needle 1 with a protector" corresponds to "an indwelling needle assembly," "an axial direction of the needle tube 2" corresponds to "a needle axis direction," "a large cylindrical portion 41" corresponds to "a cylindrical part," "a rear end" corresponds to "a proximal end side," "a width-increased portion 42" corresponds to "an expansion part," "lock" corresponds to "detain," "the needle tube 2 in a protruding state" corresponds to "the needle tip of the indwelling needle in a protruding state," "a window 42b" corresponds to "a needle hub engager," "can elastically deform" corresponds to "are elastically deformable," "inner surfaces inclining toward the axial line of the protector 4" correspond to "inner surfaces inclined toward the needle hub," "the needle tube 2 in a protruding state" corresponds to "the needle tip of the indwelling needle in a protruding state," "arms 73" correspond to "engaging arms," and "a flexible tube 6" corresponds to "an external conduit," respectively. Further, since it can be said that Invention A-2 connects the flexible tube 6 to the connection tube portion 72b to form a fluid flow path from the flexible tube 6 to the needle tube 2, "a connection tube portion 72b into which a flexible tube 6 is connected" of Invention A-2 corresponds to "a connecting tube connected to an external conduit to form a fluid flow path extending from the external conduit to the indwelling needle" of Corrected Invention 2, and similarly, "a connection tube portion 72b" corresponds to "a connecting tube".

Accordingly, Corrected Invention 2 and Invention A-2 are identical in the point of

"An indwelling needle assembly comprising:

an indwelling needle having a needle tip;

a needle hub provided on a proximal end side of the indwelling needle; and

a needle tip protector that has a tubular peripheral wall and covers the needle tip of the indwelling needle by being externally mounted to the needle hub and by being moved to the needle tip side,

wherein at a predetermined position where the needle tip protector is moved to the needle tip side of the indwelling needle, detent pieces provided at the needle tip protector are detained to the needle hub to prevent the needle tip of the dwelling needle from being re-exposed,

wherein the needle tip protector:

has a cylindrical part extending in a needle axis direction;

is provided with the detent pieces, and an expansion part having a larger

diameter than the cylindrical part, located on the radially outer side in relation to the detent pieces, and equipped with a small-diameter part and a large-diameter part, on a proximal end side of the cylindrical part; and

is provided with a needle hub engager engaged with the needle hub and holding the needle tip of the indwelling needle in a protruding state, on a peripheral wall of the large-diameter part, and

the detent pieces are elastically deformable, have inner surfaces inclined toward the needle hub, and are integrally formed with the cylindrical part on the large-diameter part side, but are not provided on the small-diameter part side, and

wherein the needle hub has

engaging arms engaged with the needle hub engager of the needle tip protector to hold the needle tip of the indwelling needle in a protruding state, and

a connecting tube connected to an external conduit to form a fluid flow path extending from the external conduit to the indwelling needle,"
and are different in the following points.

[Different Feature 1]

The indwelling needle of Corrected Invention 2 is metallic, whereas in Invention A-2, it is not specified as such.

[Different Feature 2]

Concerning the connecting tube, in Corrected Invention 2, at least a part of the connecting tube protrudes to the proximal end side from a proximal end portion of the engaging arms serving as elastically deforming fulcrums of the engaging arms, whereas in Invention A-2, the connection tube portion 72b does not protrude to a proximal end side from a proximal end part of the arms 73 serving as elastically deforming fulcrums of the arms 73.

(B) Regarding Different Features

a Regarding [Different Feature 1]

In an indwelling needle assembly, making an indwelling metallic is well-known prior art without mentioning literature. Although Invention A-2 does not specifically illustrate a material of the needle tube 2, in light of the above-mentioned well-known prior art, it is merely a design matter to make the material of the needle tube concretely metallic when implementing the invention. Therefore, [Different Feature 1] above merely adds the well-known prior art, and it cannot be said that any new effects are

caused thereby, so that it cannot be said to be substantial.

b Regarding [Different Feature 2]

"The connection tube portion 72b" of Invention A-2 corresponding to "the connecting tube" of Corrected Invention 2 is connected by inserting a flexible tube 6 that is an external conduit.

There is only one example of Technology A-8 that is a connecting tube of a structure connected by inserting the external conduit, which at least partially protrudes to the proximal end side from a proximal end portion of the engaging arms serving as elastically deforming fulcrums of the engaging arms, and it cannot be said that it is a well-known art immediately.

Each of those in Technology A-6, Technology A-7, and Technology A-9 is a connecting tube of a structure connected by being inserted in an external conduit, so that the connection structures of the connecting tube and the external conduit are different from Invention A-2. Therefore, it may be necessary to transform the "a flexible tube 6," so that regarding Different Feature 2 above, these cannot be positioned as well-known art that can be immediately transformed into "the connection tube portion 72b" of Invention A-2.

On the other hand, it is recognized that in Invention A-3, as described in 4-3 B above, similarly to Invention A-2, at least a part of a through-hole 282 into which a tube 30 is inserted and communicated does not protrude to a proximal end side from a proximal end part of the engaging arms 280 serving as elastically deforming fulcrums of the engaging arms 280.

Therefore, even if the connecting tube structure similar to that of Invention A-2 is well-known, it cannot be said that the structure of Corrected Invention 2 according to Different Feature 2 is merely an addition or conversion of well-known art, and it cannot be said that it falls under very minor difference in the means for solving the problem of Corrected Invention 2.

Furthermore, if it is recognized that at least a part of the through-hole 282 of Invention A-3 protrudes to a proximal end side from a proximal end part of the engaging arms 280 serving as elastically deforming fulcrums of the engaging arms 280, it can be said that the point that the connecting tube of a structure connected by inserting the external conduit, which at least partially protrudes to the proximal end side from a proximal end portion of the engaging arms serving as elastically deforming fulcrums of the engaging arms, is a well-known art, from Invention A-3 and Technology A-8.

However, in that case, those of the structure that "in a connection tube portion of the structure connected by inserting the external conduit, the connection tube portion 72b does not protrude to a proximal end side from a proximal end part of the arm 73 serving as an elastically deforming fulcrum of the arm 73" of Invention A-2 are considered as a characteristic structure like no other, so that it cannot be simply converted to other well-known arts.

Therefore, Different Feature 2 above is substantial.

(C) Summary

From the above, it cannot be said that Corrected Invention 2 is identical or substantially identical to Invention A-2.

Therefore, Reason 1 for Corrected Invention 2 is groundless.

B Regarding Corrected Invention 3

In comparison of Corrected invention 3 and Invention A-2, the two are different at least in Different Feature 2 of A (A) above.

The judgment on Different Feature 2 is as described in A (B), so that it cannot be said that Corrected Invention 3 is identical to Invention A-2.

Therefore, Reason 1 for Corrected Invention 3 is groundless.

C Summary

It cannot be said that the Correction does not fall under Article 126(7) of the Patent Act, for Reason 1 above.

(2) Regarding novelty and inventive step based on Invention A-3 (Reasons 2 and 3 in the defense of invalidation)

A Regarding Corrected Invention 2 of the case

(A) Comparison

"A needle 22" of Invention A-3 and "a metallic indwelling needle having a needle tip" of Corrected Invention 2 are identical to the extent that each is "an indwelling needle having a needle tip". Then, "a needle 22" of Invention A-3 corresponds to "an indwelling needle" of the Corrected Invention, and subsequently likewise, "a needle hub 20" corresponds to "a needle hub," "an outer cylinder 10 that is a hollow elliptical cylinder, is externally equipped to the needle hub 20 and pulls the needle 22 backward to cover the needle 22" corresponds to "a needle tip protector that

has a tubular peripheral wall and covers the needle tip of the indwelling needle by being externally mounted to the needle hub and by being moved to the needle tip side," "an outer cylinder 10" corresponds to "a needle tip protector," "a predetermined position where the needle 22 is pulled backward with respect to the outer cylinder 10" corresponds to "a predetermined position where the needle tip protector is moved to the needle tip side of the indwelling needle," "a locking receiving portion 122" corresponds to "detent pieces," "engage" corresponds to "detain," "prevent the needle 22 from being re-exposed" corresponds to "prevent the needle tip of the dwelling needle from being re-exposed," "a self-destruction type medical needle" corresponds to "an indwelling needle assembly," "an axial direction of the needle 22" corresponds to "a needle axis direction," "an elliptical cylinder portion" corresponds to "a cylindrical portion," "the needle 22 in a protruding state" corresponds to "the needle tip of the indwelling needle in a protruding state," "an engaging window 14" corresponds to "a needle hub engager," "the needle 22 in a protruding state" corresponds to "the needle tip of the indwelling needle in a protruding state," "engaging arms 280" correspond to "engaging arms," and "a tube 30" corresponds to "an external conduit," respectively. Since it can be said that Invention A-3 forms a fluid flow path from the tube 30 to the needle 20 by connecting the tube 30 and the through-hole 282, "a through-hole 282 into which a tube 30 is communicated" of Invention A-3 corresponds to "a connecting tube connected to an external conduit to form a fluid flow path extending from the external conduit to the indwelling needle" of Corrected Invention 2, and similarly, "a through-hole 282" corresponds to "a connecting tube".

Therefore, Corrected Invention 2 and Invention A-3 are identical in the point of "An indwelling needle assembly comprising:

an indwelling needle having a needle tip;

a needle hub provided on a proximal end side of the indwelling needle; and

a needle tip protector that has a tubular peripheral wall and covers the needle tip of the indwelling needle by being externally mounted to the needle hub and by being moved to the needle tip side,

wherein at a predetermined position where the needle tip protector is moved to the needle tip side of the indwelling needle, detent pieces provided at the needle tip protector are detained to the needle hub to prevent the needle tip of the dwelling needle from being re-exposed,

wherein the needle tip protector:

has a cylindrical part extending in a needle axis direction;

is provided with the detent pieces, and an expansion part having a larger diameter than the cylindrical part, located on the radially outer side in relation to the detent pieces, and equipped with a small-diameter part and a large-diameter part, on a proximal end side of the cylindrical part; and

is provided with a needle hub engager engaged with the needle hub and holding the needle tip of the indwelling needle in a protruding state, on a peripheral wall of the large-diameter part, and

the detent pieces have inner surfaces inclined toward the needle hub, and are integrally formed with the cylindrical part on the large-diameter part side, and

wherein the needle hub has

engaging arms engaged with the needle hub engager of the needle tip protector to hold the needle tip of the indwelling needle in a protruding state, and

a connecting tube connected to an external conduit to form a fluid flow path extending from the external conduit to the indwelling needle,"

are different in the following points.

[Different Feature 1]

The indwelling needle of Corrected Invention 2 is metallic, whereas in Invention A-3, it is not specified as such.

[Different Feature 2]

The detent pieces of Corrected Invention 2 are elastically deformable, whereas in Invention A-3, it is not configured as such.

[Different Feature 3]

The detent pieces of Corrected Invention 2 are not provided on the small diameter portion side, whereas in Invention A-3, it is unclear whether or not it is configured as such.

[Different Feature 4]

Concerning the connecting tube, in Corrected Invention 2, at least a part of the connecting tube protrudes to the proximal end side from a proximal end portion of the engaging arms serving as elastically deforming fulcrums of the engaging arms, whereas in Invention A-3, it is not configured as such.

(B) Regarding Different Features

Regarding [Different Feature 2]

In view of the matters, Different Feature 2 will be examined first.

Elastically deformable detent pieces are well known art as seen in Technology A-6, Technology A-8 to Technology A-10, Technology A-12, and Technology A-13.

However, in Invention A-3, the locking portion 26 to which the locking receiving portion 122 is engaged is elastically deformable, so that it cannot be said that it is meaningful to adopt the above-mentioned well-known art for the locking receiving portion 122 to make it elastically deformable, and it can be said that the manufacturing cost increases and the possibility that the locking receiving portion 122 and the locking portion 26 are broken only increases.

Therefore, it cannot be said that there is a motivation to adopt the above-mentioned well-known art to Invention A-3.

Further, it will be examined whether to adopt a well-known constitution of locking between a needle hub and a needle tip protector, which are common in Technology A-6, Technology A-8 to Technology A-10, and Technology A-12, that is the locking portion of the needle hub and the detent pieces of the needle tip protector, to Invention A-3.

However, A-6, A-8 to A-10, and A-12 do not describe the detent pieces formed on the large diameter portion side of an expansion part or the detent pieces formed on the side on which the needle hub engaging portion is provided.

Therefore, even if adopting the constitution of locking between a needle hub and a needle tip protector to Invention A-3, it does not lead to Corrected Invention 2.

In this point, it can be said that in Technology A-13, the locking block is formed on the side on which the needle hub engaging portion engaged with the engaging arm is provided.

However, in Invention A-3, the locking portion 26 of the needle hub 20 and the locking receiving portion 122 of the outer cylinder 10 are engaged, or the limiting portion 24 of the needle hub 20 and the limiting receiving portion 120 of the outer cylinder are engaged, respectively, thereby preventing the needle 22 from being re-exposed and preventing the needle hub 20 from coming off from the outer cylinder 10, whereas in Technology 13, although the external locking groove 13 of the needle rod 14 and the internal locking block 22 of the slide sleeve 16 are locked, thereby preventing the slide sleeve 16 from moving backward; that is, preventing the needle 11 from being re-exposed, it is unclear whether or not it prevents the needle rod 14 from coming off

from the slide sleeve 16.

Therefore, it can be said that the constitution of the engagement of the needle hub 20 and the outer cylinder 10 of Invention A-3, and the constitution of the locking of the needle rod 14 and the slide sleeve 16 of Technology A-13 are different in their problems, function, and effects, so that it cannot be said that there is a motivation to apply Technology A-13 to Invention A-3.

Therefore, Corrected invention 2 is not Invention A-3, and it cannot be said that it could have been easily invented by a person skilled in the art based on Invention A-3.

(C) Summary

Therefore, Reasons 2 and 3 for Corrected Invention 2 are groundless.

B Regarding Corrected Invention 3

In comparison of Corrected Invention 3 and Invention A-3, the two are different at least in Different Feature 2 of A (A) above.

Then, since the judgment on Different Feature 2 is as described in A (B) above, Corrected invention 3 is not Invention A-3, and it could not have been easily invented by a person skilled in the art based on Invention A-3.

C Summary

As described above, Reasons 2 and 3 for Corrected Inventions 2 and 3 are groundless.

Therefore, it cannot be said that the Correction does not fall under Article 126 (7) of the Patent Act for Reasons 2 and 3.

(3) Regarding novelty and inventive step when any one of the inventions described in A-6 to A-10, A-12, and A-13 is used as a main cited invention

Hereinafter, novelty and inventive step in relation to any one of the inventions described in A-6 to A-10, A-12, and A-13 will be considered by way of caution.

A In comparison of Corrected Invention 2 and Invention A-6, the two are different in at least the following points.

[Different Feature]

The detent pieces of Corrected Invention 2 are formed on the large diameter portion side, but are not provided on the small diameter side, whereas, in Invention A-6, it is not configured as such.

The above-mentioned Different Feature is examined.

The configuration that the detent pieces are formed on the large diameter portion side, but not provided on the small diameter side is not described in any of A-3, A-7 to A-10, A-12 and A-13. There is no evidence sufficient to be the common general technical knowledge as of the priority date of the Patent. The configuration according to Corrected Invention 2 in the above-mentioned different feature exerts effects that "it is also avoided that the large diameter portions 68 and 68 become thick, and the occurrence of dimensional errors and deterioration of quality accuracy due to air bubbles mixed in the member during molding can be suppressed" ([0078]). Accordingly, it cannot be said that forming the detent pieces on the large diameter portion side while not providing them on the small diameter portion side is merely a design change that can be appropriately made by a person skilled in the art.

Therefore, the above-mentioned Different Feature is substantial, and it cannot be easily conceived by a person skilled in the art.

B Then, also in comparison of Corrected Invention 2 and any one of Inventions A-7 to A-10, A-12, and A-13, and in comparison of Corrected Invention 3 and any one of Inventions A-6 to A-10, A-12, and A-13, they are different in the above-mentioned Different Feature, so that Corrected Inventions 2 and 3 are not any one of Inventions A-6 to A-10, A-12, and A-13, and could not have been easily invented by a person skilled in the art, based on these.

4-5 Summary

As described in (1)-(3) above, prior art effect based on Invention A-2 submitted as evidence, and novelty and inventive step based on A-3, A-6 to A-10, A-12, and A-13 are groundless.

No additional reasons for why the Demandant should not be granted a patent independently at the time of patent application are found.

Therefore, the Correction falls under the provisions of Article 126 (7) of the Patent Act.

No. 4 Closing

As described above, the request for trial for correction aims at matters prescribed in Article 126(1)(i) of the Patent Act and conforms to the provisions of Article 126(5) to

Article 126(7) of the Patent Act.

Therefore, the trial decision shall be made as described in the conclusion.

January 7, 2021

Chief administrative judge: SENJU, Akio

Administrative judge: KURAHASHI, Norio

Administrative judge: MIYAZAKI, Motoki