Patent Right	Date	February 17, 2021	Court	Intellectual Property High Court, First Division
	Case number	2020 (Gyo-Ke) 10011		
- A case in which, with regard to the invention titled "Catheter assembly," the court determined that the JPO decision that denied an inventive step in the invention contains an error in finding common features and overlooking differences.				

Case type: Rescission of Appeal Decision of Refusal
Results: Granted
References: Article 29, paragraph (2) of the Patent Act
Related rights, etc.: Patent Application No. 2015-242055
Decision of JPO: Appeal against Examiner's Decision of Refusal No. 2018-6969

Summary of the Judgment

1. The plaintiff filed an appeal against an examiner's decision that refused its patent application for an invention titled "Catheter assembly" (Patent Application No. 2015-242055; hereinafter, the "Application" and the "Invention"). The JPO rendered a decision to maintain the examiner's decision of refusal, on the grounds that a person skilled in the art could have easily made the Invention based on the cited invention and the matters stated in Cited Document 3, as well as well-known matters. The plaintiff filed this lawsuit to seek rescission of the JPO decision (the "JPO Decision").
2. The plaintiff alleged that the JPO Decision should be rescinded due to the error in the determination on an inventive step in the Invention. In this judgment, the court rescinded the JPO Decision, determining as follows with regard to the error in finding common features and overlooking differences.
(1) The JPO Decision determined that technical matters are indicated in Cited Document 1 as follows: "[i] the distal section of a septum is sealed when a needle is pulled out and prevents fluid from flowing into the proximal end of a catheter adapter or flowing out from the proximal end of a catheter adapter via the hollow section, and it has a slit that can open to allow the flow in and out."

However, in Cited Document 1, there are the following statements: "An integrated and low-resistance septum in the Invention provides a seal to surrounding areas of a needle during storage and use and is installed in a septum assembly so that it is sealed when a needle is withdrawn thereafter. The septum assembly has a septum housing and an integrated septum installed in it. The septum has a distal section, proximal section, cavity section, and longitudinal shaft. The cavity extends completely through the

proximal section of the septum. The septum has at least one flare area that extends towards the outside apart from the outer diameter of the proximal section. When this septum is inserted in the septum housing, the flare area is compressed, the cavity section that extends through the proximal section closes, and a seal is provided to the proximal end of the cavity."; "The proximal end of the catheter 22 has the integrated low-resistance septum 10 in the Invention in order to prevent fluid leakage from the proximal end of the catheter adapter 24.;" "Figures 23 through 25 are a series of figures of another integrated low-resistance septum 410 in the Invention where it is isolated first in a partial development perspective view of a catheter and an introducer needle assembly 420 and then shown in cross-sectional view."; and "The septum 410 has a proximal section 450, a distal section 460, and a cavity section 470. The distal section 460 is similar to the other embodiments of the septum 410 in the Invention mentioned above and can have a slit 462 so that an introducer needle (not shown in the Figure) can be easily inserted through it."

Based on the aforementioned statements, according to Cited Document 1, it is understood that the septum 410 that is installed in a septum assembly is installed to prevent fluid leakage from the proximal end of the catheter adapter 24 and that the distal section 460 of the septum 410 can have the slit 462 to make insertion of the introducer needle that goes through it easy.

And Figure 26 depicts the slit 462 that is installed around the approximate center in the thickness direction and in the longitudinal shaft direction from the proximal end to the distal end on the distal section 460 of the septum 410.

On the other hand, there is no statement on the fact that the slit 462 "can open to allow the flow in and out" of fluid in Cited Document 1.

In addition, in light of the shape of the slit 462 as shown in Figure 26, it cannot be immediately recognized from Figure 26 that the slit 462 "can open to allow the flow in and out" of fluid.

In addition, looking at overall statements (including drawings) in Cited Document 1, there is no statement suggesting that the slit 462 has a structure "that can open to allow the flow in and out" of fluid.

(2) Rather, based on the statements on the septum in Cited Document 1, it is understood that the septum stated in Cited Document 1 provides a seal around the needle during the storage and use of the needle, functions to prevent fluid leakage from the assembly 20 after insertion into a patient, and is installed in the septum assembly so that it is sealed when the needle is withdrawn from the patient. Based on the statements on the slit in Cited Document 1, it is understood that a slit that is installed at the distal section

of a septum is installed to determine the position of an introducer needle that goes through the distal section of the septum and to make insertion of the needle easy.

In addition, according to Figures 1, 23, and 25 through 27, it can be recognized that the distal end of the extension tube is connected to a hollow section that is between the proximal end and distal end of a catheter adapter and is open to the distal side of the distal end of the distal section of a septum. Therefore, in cases of the catheter and introducer needle assembly as stated in Cited Document 1, it is understood that fluid is infused into a patient and is removed from a patient's circulatory system through the extension tube via the aforementioned hollow section of a catheter adapter.

(3) Based on the above, the septum stated in Cited Document 1 is installed in the septum assembly in order to provide a seal around a needle during the storage and use of the needle and to seal the assembly when the needle is withdrawn; a slit installed on the distal section of a septum is installed to make insertion of an introducer needle that goes through it easy. Therefore, it cannot be found that the distal section of a septum "has a slit that can open to allow the flow in and out" of fluid.

Then, it cannot be said that the distal section of the "septum" as stated in Cited Document 1 corresponds to the structure of the Invention that "the second valve member is a two-way valve and can open so that fluid can flow in both the proximal direction and distal direction through the internal chamber of the catheter hub" (Structure) and the catheter and introducer needle assembly as stated in Cited Document 1 is different from the Invention on the point that it does not have the Structure. Therefore, in this regard, it is found that the JPO Decision contains an error in finding common features and an overlooking of differences.

Judgment rendered on February 17, 2021
2020 (Gyo-Ke) 10011, Case of seeking rescission of the JPO decision
Date of conclusion of oral argument: December 8, 2020

Judgment

Plaintiff: B. Braun Melsungen Aktiengesellschaft

Defendant: Commissioner of the Japan Patent Office

Main text

1. The decision made by the Japan Patent Office (JPO) on September 26, 2019, concerning the case of appeal against Examiner's Decision of Refusal No. 2018-6969 shall be rescinded.
2. The Defendant shall bear the court costs.

Facts and reasons

No. 1 Claim

Same as the main text.

No. 2 Outline of the case

1. Outline of procedures at the JPO

(1) The Plaintiff newly filed an application for a patent (Patent Application No. 2015-242055; hereinafter referred to as the "Application") on December 11, 2015, by dividing part of the patent application (Patent Application No. 2015-563128; Exhibit Ko 26) for which the international filing date is August 18, 2014 (priority date: August 21, 2013, August 29, 2013, and October 31, 2013 (hereinafter collectively referred to as the "Priority Date"); countries claiming priority: United Kingdom and China) concerning an invention tilted "catheter assembly."

The Plaintiff received a notice of grounds for refusal dated July 14, 2016 (Exhibit Ko 9) and amended the claim dated January 13, 2017 (Exhibit Ko 11). Subsequently, the Plaintiff received a notice of grounds for refusal dated April 13, 2017, and made an amendment to the claim, description, and drawings dated October 18, 2017 (Exhibit Ko 14); however, the Plaintiff received an examiner's decision of refusal on January 17, 2018 (Exhibit Ko 15).

(2) The Plaintiff filed an appeal against the examiner's decision of refusal (Appeal against

Examiner's Decision of Refusal No. 2018-6969) on May 22, 2018, and made an amendment to the claim and drawings (hereinafter referred to as the "Amendment"; Exhibit Ko 17).

Then, on September 26, 2019, the JPO made the decision to maintain the examiner's decision (hereinafter referred to as the "JPO Decision"), and the certified copy thereof was served to the Plaintiff on October 8, 2019.

(3) The Plaintiff filed this lawsuit to seek rescission of the JPO Decision on February 4, 2020.

2. Statement of the claim

The claim after the Amendment consists of Claims 1 through 34 and the statement of Claim 1 is written as follows (hereinafter the invention related to Claim 1 is referred to as the "Invention"; Exhibit Ko 17).

[Claim 1]

A catheter assembly that is characterized by having a catheter hub that has a distal end, proximal end, and internal chamber, wherein the proximal end of the catheter hub can be connected to a device to infuse fluid into the internal chamber or withdraw fluid from the internal chamber;

a hollow-tube catheter that has a proximal end and distal end, wherein the proximal end of the catheter is connected to the distal end of the catheter hub and wherein the hollow section of the catheter is open to the internal chamber of the catheter hub;

a needle that has a sharpened needle tip and needle shaft, wherein the needle extends through the internal chamber of the catheter hub and the catheter in the ready state and wherein the needle tip position is on the distal side of the distal end of the catheter;

a hollow extension tube that has a distal end and proximal end, wherein the distal end of the extension tube is connected to the catheter hub between the proximal end and distal end of the catheter hub, wherein the distal end of the extension tube is open to the internal chamber of the catheter hub, and wherein the proximal end of the extension tube can be connected to a device to infuse fluid into the internal chamber of the catheter hub; and

a valve assembly that is placed in the internal chamber of the catheter hub; and

the valve assembly has:

a first valve member that closes the distal end of the extension tube and can be opened by the action of pressurized fluid in the extension tube;

a second valve member that prevents fluid from flowing into the proximal end of the catheter hub or from flowing out of the proximal end of the catheter hub via the internal chamber; wherein

the second valve member is a two-way valve and can open so that fluid can flow

in both the proximal direction and distal direction through the internal chamber of the catheter hub;

and the catheter assembly also has:

a needle protection assembly that has a first arm, second arm, and proximal wall, wherein the first arm and second arm extend in the distal direction on both sides of the needle;

the needle protection assembly engages with the catheter hub wherein the assembly is removable in the ready state; and

the engagement of the needle protection assembly with the catheter hub is released by transferring to the protection state of the needle.

3. Summary of the grounds for the JPO Decision

(1) Grounds for the JPO Decision are as stated in the attached written decision (copy).

The summary is as follows: the Invention could have been invented by a person skilled in the art easily based on the invention stated in Cited Document 1 (Exhibit Ko 1) and matters stated in Cited Document 3 (Exhibit Ko 3), which are publications distributed before the Priority Date, and well-known matters stated in Cited Documents 4 through 7 (Exhibits Ko 4 through 7), and the Invention cannot obtain a patent pursuant to the provisions of Article 29, paragraph (2) of the Patent Act. Therefore, the Application should be refused without the need to examine inventions related to the remaining claims.

Cited Documents 1, and 3 through 7 are as stated below.

Cited Document 1: Japanese Unexamined Patent Application Publication (Translation of PCT Application) No. 2009-513267

Cited Document 3: Description of US Publication of Unexamined Patent Application No. 2013/0090609

Cited Document 4: Unexamined Patent Application Publication No. 2007-136246

Cited Document 5: Unexamined Patent Application Publication No. 2003-180833

Cited Document 6: Description of US Publication of Unexamined Patent Application No. 2013/0030370

Cited Document 7: International Publication No. WO 99/08742

(2) The invention stated in Cited Document 1 that is found by the JPO Decision (hereinafter referred to as "Cited Invention") and common features and differences between the Invention and Cited Invention are as stated below.

A. Cited Invention

An integrated catheter and introducer needle assembly that enables the infusion of fluid into a patient or the removal of fluid from the circulatory system of a patient by using a catheter and wherein a device can be installed on the catheter to remove or supply

fluid; wherein

the septum-embedded integrated catheter and introducer needle assembly has a catheter assembly, including a catheter that is installed on a catheter adapter, and a needle assembly that has an introducer needle with a shaft;

the catheter adapter has a distal end, proximal end, and hollow section, a septum is placed in the hollow section, a catheter with a proximal end and distal end is connected to the distal end of a catheter adapter at the proximal end, and the hollow section of the catheter is open to the hollow section of the catheter adapter;

a septum is installed at the proximal end of a catheter and has a proximal section, distal section, and cavity section, and the distal section is sealed when a needle is pulled out and prevents fluid from flowing into the proximal end of a catheter adapter or flowing out from the proximal end of a catheter adapter via the hollow section, and it has a slit that can open to allow the flow in and out;

a needle extends through the hollow section of the catheter adapter and catheter, the needle tip is located on the distal side of the distal end of the catheter, and the distal end of the needle has a sharp end to puncture a patient's skin;

wherein an extension tube has a distal end and proximal end and the distal end is connected to a catheter adapter between the proximal end and distal end of the catheter adapter.

B. Common features and differences between the Invention and Cited Invention

(Common features)

The following point: "A catheter assembly that is characterized by having a catheter hub that has a distal end, proximal end, and internal chamber, wherein the proximal end of the catheter hub can be connected to a device to infuse fluid into the internal chamber or withdraw fluid from the internal chamber;

a hollow-tube catheter that has a proximal end and distal end, wherein the proximal end of the catheter is connected to the distal end of the catheter hub and wherein the hollow section of the catheter is open to the internal chamber of the catheter hub;

a needle that has a sharpened needle tip and needle shaft, wherein the needle extends through the internal chamber of the catheter hub and the catheter in the ready state and wherein the needle tip position is on the distal side of the distal end of the catheter;

a hollow extension tube that has a distal end and proximal end, wherein the distal end of the extension tube is connected to the catheter hub between the proximal end and distal end of the catheter hub, wherein the distal end of the extension tube opens to the internal chamber of the catheter hub, and wherein the proximal end of the extension tube can be connected to a device to infuse fluid into the internal chamber of the catheter hub; and

a valve assembly that is placed in the internal chamber of the catheter hub; and

the valve assembly has:

a second valve member that prevents fluid from flowing into the proximal end of the catheter hub or from flowing out of the proximal end of the catheter hub via the internal chamber; wherein

the second valve member is a two-way valve and can open so that fluid can flow in both the proximal direction and distal direction through the internal chamber of the catheter hub."

(Difference 1)

Concerning "valve assembly," the Invention has "a first valve member that closes the distal end of the extension tube and can be opened by the action of pressurized fluid in the extension tube," while the Cited Invention does not have that structure.

(Difference 2)

The Invention has "a needle protection assembly that has a first arm, second arm, and proximal wall and the first arm and second arm extend in the distal direction on both sides of the needle; wherein the needle protection assembly engages with the catheter hub wherein the assembly is removable in the ready state; and the engagement of the needle protection assembly with the catheter hub is released by transferring to the protection state of the needle," while the Cited Invention does not have these structures.

4. Grounds for rescission

Error in determination on an inventive step of the Invention

(omitted)

No. 4 Judgment of this Court

1. Statement in the Description

(1) There are following statements in the description after the Amendment (hereinafter referred to as the "Description," including drawings; Exhibits Ko 8, 14, and 17) (for Figures 1 through 3, 7a, 7b, and 7c that are cited in the following statements, see Attachment 1).

A. [Technical field]

[0001]

The Invention is related to a catheter assembly, in particular, an intravenous catheter assembly.

[Background art]

[0002]

An intravenous (IV) catheter is used to access a patient's vein and, in particular, it is used to supply fluid to a patient or to remove fluid: in particular, blood, from a patient. An IV catheter can be primed with a sterile solution to remove air from the device before puncturing a patient's skin. It reduces the risk of an air embolism in a patient.

[0003]

The IV catheter assembly has a catheter that extends from the distal end of a catheter hub. A needle extends through the catheter hub and the catheter and a sharpened needle tip are located on the distal side of the distal end of the catheter. In typical procedures for inserting a catheter into the vein of a patient, a healthcare professional must insert a sharpened needle tip and catheter into a patient and place them in the patient's vein. After the needle tip is placed in a vein, the healthcare professional manually slides the catheter smoothly in the distal direction along the needle shaft and inserts the catheter into the vein. After the catheter is placed appropriately in the vein, the needle is withdrawn. The catheter hub is fastened by tape and in that way, the catheter is anchored to the patient's skin. After these procedures, infusion or removal of fluid to and from a vein through the catheter hub and catheter, as well as other types of access, can be performed.

[0004]

In order to control (adjust) the flow of fluid through the catheter and catheter hub, in particular, in order to prevent blood from flowing out from a vein via the catheter, there is known technology for installing a valve in the catheter hub.

[0005]

Patent Document 1 discloses the device to infuse liquid into or discharge liquid from a patient. According to one of the embodiments, the device has a catheter hub with a catheter and the catheter extends from the catheter hub. Inside the catheter hub, a flexible valve is installed to control the flow of fluid via the catheter. A valve opener is installed to open the valve when fluid is infused or discharged via the proximal end of the catheter hub. Patent Document 1 discloses technology to install a port that extends in the lateral direction on the catheter hub. A flexible column or cylindrical seal extends in the circumferential direction along a port around the inside of the catheter.

[0006]

Patent Document 2 is a document related to a catheter adapter that has an integrated single connection valve (valve assembly) and side port. This connection valve is placed in a hub of the catheter adapter in a manner to close the bore and side port of the catheter adapter. In addition, the connection valve has a main body, which has the overall shape of a cylinder and extends in the circumferential direction along a port circling the inside of the catheter. In addition, the connection valve has a conical valve member that allows

fluid to flow from the proximal end of a hub into the catheter. The device disclosed in Patent Document 2 cannot remove fluid from a patient, and it can only infuse fluid into a patient through a port or the proximal end of an adapter hub.

[0007]

Patent Document 3 depicts and discloses a medical connector. This connector has a main body with a main passage and a port and the main passage extends through the connector. A valve that has the overall shape of a cylinder is placed along the port within the main body. A tab extends from the valve into the port. The valve is usually open and allows the flow of fluid along the main passage. When a tab is pushed down in the port, a valve intersecting the main passage is closed, the flow of fluid along the main passage is blocked, and fluid can be infused into a connector via the port or can be withdrawn from the connector.

[0008]

Patent Document 4, which is more closely associated with the Invention, discloses a catheter device that has an infusion port and valve. This device has a hollow catheter extension unit and the distal end can be connected to a catheter. The connection device is installed at the proximal end of the extension section. A port extends from the extension section in the radial direction and opens in a bore of the extension section. A valve assembly is placed along the port in the extension section and has a first valve member of which the overall shape is a cylinder, and which closes the port. A second valve member prevents blood from leaking in the proximal direction from the extension unit via a bore. The second valve member is formed as a two-way valve and allows fluid to flow in either the distal or proximal direction.

[0009]

More recently, Patent Document 5 discloses a catheter assembly and its components. The catheter assembly has a valve and valve opener that are placed in a catheter hub. A valve opener opens a valve by depressing an IV set Luer connector and allows fluid to flow through the catheter. When a needle is withdrawn from a catheter through a catheter hub, a needle tip protection device, which acts to cover the needle tip, can be installed in the valve opener.

B. [Problem to be solved by the invention]

[0018]

Thus, an improved catheter assembly that can perform advanced control (adjustment) of infusing fluid into a patient and withdrawing fluid from a patient via catheter, is required.

C. [Means to solve the problem]

[0019]
(1) The Invention provides a catheter assembly that has the following constituent features.
- A catheter hub that has a distal end and proximal end, as well as an internal chamber. The proximal end of the catheter hub can be connected to a device to infuse fluid into the internal chamber or withdraw fluid from the internal chamber.
- A hollow-tube catheter that has a distal end and proximal end. The proximal end of the catheter is connected to the distal end of the catheter hub and the hollow section of the catheter is open to the internal chamber of the catheter hub.
- A needle with a sharpened needle tip. When it is in the ready state, the needle extends through the internal chamber of the catheter hub and catheter and the needle tip is located on the distal side of the distal end of the catheter.
- A hollow extension tube that has a distal end and proximal end. The distal end of the extension tube is connected to the catheter hub between the proximal end and distal end of the catheter hub, the distal end of the extension tube opens to the internal chamber of the catheter hub, and the proximal end of the extension tube can be connected to a device to infuse fluid into the internal chamber of the catheter hub.
- A valve assembly that is placed in the internal chamber of the catheter hub.
(2) A valve assembly has the following constituent features.
- A first valve member that closes the distal end of the extension tube and can be opened by the action of pressurized fluid in the extension tube.
- A second valve member that prevents fluid from flowing into the proximal end of the catheter hub or from flowing out of the proximal end of the catheter hub via the internal chamber. The second valve member is a two-way valve and can open so that fluid can flow in both the proximal direction and distal direction through the internal chamber of the catheter hub.
[0020]
The device related to the Invention has a catheter hub. The catheter hub is hollow and has an internal chamber inside it. An internal chamber opens onto both the proximal end and the distal end of the catheter hub. The catheter hub may be formed as a single piece. Or the catheter hub may be formed as two pieces that are connected to each other or as separate pieces consisting of more than two pieces.
[0021]
The catheter hub is formed so that its proximal end can connect to a syringe and other devices to infuse fluid into or remove fluid from a patient. These devices are well-known in this technology field and familiar to persons skilled in the art. In particular, an internal Luer taper, which is a female Luer taper, is installed on the internal wall of the proximal

end of a catheter hub that demarcates the internal chamber, which enables the use of the standard fitting that has a standard male Luer taper that is connected to the proximal end of a catheter hub. Luer taper standards and requirements therefor are familiar to persons skilled in the art.

[0023]

A hollow-tube catheter is connected to the catheter hub and the catheter extends on the distal side from the distal end of the catheter hub.

[0024]

The catheter assembly has a needle that has a sharpened needle tip and a bore that penetrates through the needle. In the ready state, a needle is connected to the needle hub at the proximal end, as is well-known in this technology field, and the needle extends through the catheter hub and catheter in the ready state. In the ready state, a sharpened needle tip is located on the distal side of the distal end of the catheter, and the needle and the catheter can be inserted in a patient's vein using a known method. It is preferable for a needle hub to have an internal chamber that communicates with the bore in the needle shaft. In this case, if blood flashback is observed in the internal chamber of the needle hub by a user using a known method, it means that the needle is appropriately placed in a vein. In typical cases, the internal chamber of the needle hub can discharge air from the internal chamber at its proximal end; however, it is clogged with a vented plug that does not pass blood.

[0028]

The catheter assembly related to the Invention has a hollow extension tube that has a distal end and proximal end. The extension tube is flexible. The distal end of the extension tube is connected to the catheter hub between the proximal end and distal end of the catheter hub. It is preferable that the distal end of the extension tube be connected to the distal end of the catheter hub. The distal end of the extension tube is open to the internal chamber of the catheter hub and allows fluid to flow between the extension tube and the internal chamber. The proximal end of the extension tube can be connected to a syringe and other devices to infuse fluid into the internal chamber of the catheter hub. For example, a connection hub, or optimally, a hub with a female Luer taper, may be installed at the proximal end of an extension tube.

[0029]

When using a catheter assembly, fluid can be introduced into the catheter hub and catheter using an extension tube. When connecting a device to introduce fluid into the proximal end of an extension tube, the device can be placed in a position that is separated from a catheter and catheter hub placed in the vein of a patient. Use of a flexible extension

tube can reduce or prevent sliding and displacement of the catheter hub and catheter that occurs as a result of connection or removal of a device to supply fluid at the proximal end of an extension tube. This can reduce the occurrence of phlebitis in the area where a catheter is installed.

D. [0030]

The catheter assembly has a valve assembly that is placed in the internal chamber of the catheter hub. When the valve assembly is closed, the valve assembly prevents fluid from flowing between the extension tube and internal chamber of the catheter hub and prevents fluid from flowing in the proximal direction or distal direction via the internal chamber. The valve assembly has a first valve member. When the first valve member is open, fluid can flow into the internal chamber of the catheter hub from an extension tube. In this case, the valve assembly may be a one-way valve that is placed between the extension tube and the internal chamber of the catheter hub. In addition, the valve assembly has a second valve member. When the second valve member is open, it allows fluid to be supplied in the distal direction towards a catheter from the proximal end of a catheter hub or for fluid to be withdrawn in the proximal direction towards the proximal end of a catheter hub from a catheter. In this way, the valve assembly can function as a two-way valve to control (adjust) the flow of fluid to or from the proximal end of a catheter hub via the catheter hub.

[0031]

The first valve member controls (adjusts) the flow of fluid between an extension tube and the internal chamber of the catheter hub. In the preferred embodiment, the first valve member has a flexible and resilient valve body. Due to an increase in pressure by fluid in an extension tube, the valve body opens the distal end of an extension tube and allows fluid to flow into a catheter hub. It is preferable that a valve body is tube-shaped and, especially in the internal chamber of the catheter hub, it is preferable to place the valve body so that it abuts the internal surface of a wall of the catheter hub. In one of embodiments, the cross-section of the valve body and part of the internal chamber of the catheter hub where the valve body is placed may be a circle or oval figure.

[0033]

The valve assembly has a second valve member. As mentioned above, the second valve member controls (adjusts) the flow of fluid which flows into a catheter hub or flows out of a catheter hub, via the internal chamber of the catheter hub. The second valve member is placed in a position closer to the proximal side than the distal opening of an extension tube and the first valve member, in the internal chamber of the catheter hub. According to one of the embodiments, the second valve member has a flexible and

resilient valve disc that extends (spreads) laterally by intersecting the internal chamber of the catheter hub. One or multiple openings that can be closed, such as a slit, etc.: in particular one or multiple slits that extend in the radial direction, are installed on this valve disc.

[0035]

In the ready state, a needle shaft extends through the valve assembly. In the ready state, it is preferable that the second valve member seals the surrounding area of a needle shaft. While air can flow out in the proximal direction through the second valve member, it is preferable to have a structure with a form where blood is prevented from going through the second valve member. In the embodiment where the second valve member has a valve disc that has one or multiple slits, this structure can be achieved by maintaining a specific slit or each slit in an appropriate mode where: under the ready state, the specific slit or each slit is held sufficiently open by a needle shaft and where air can go through, but blood is prevented from going through.

[0036]

The second valve member may be composed in a way that it opens by the action of differences in fluid pressure in the direction intersecting the second valve member. In particular, the second valve member may be composed in a way that it is opened by having high fluid pressure on the proximal side of the second valve member and fluid can be infused into a catheter and a patient's vein. In the same way, the second valve member may be composed in a way that it is opened by having low fluid pressure on the proximal side of the second valve member and fluid can be withdrawn from a catheter and a patient's vein.

E. [Embodiment of the invention]

[0064]

Figure 1 and Figure 2 show devices related to the first embodiment of the Invention for which Reference No. 2 is provided comprehensively. Device 2 shown in Figure 1 and Figure 2 is in a ready state or ready position. Device 2 shown in Figure 3 is in a retracted state or retracted position where a needle is retracted in the proximal direction.

[0065]

Device 2 has a Catheter Hub 4 that has a Distal End 6 and a Proximal End 8. And an elongated hollow-tube Catheter 10 is connected to the Catheter Hub 4 in known specifications and extends from the Distal End 6 of the Catheter Hub 4. The Catheter Hub 4 has an Internal Chamber 12. The Internal Chamber 12 is open at the Proximal End 8 of the Catheter Hub 4 and communicates with the hollow-tube Catheter 10 at the Distal End 6 of the Catheter Hub 4. The structure of the Catheter Hub 4 is explained in detail below.

[0066]

A generally cylindrical Needle Hub 20 has a Distal End 22 and a Proximal End 24. The Needle Hub 20 is formed in a mode with an Internal Chamber 26 and the open Proximal End 24 is closed by a Vented Flashback Plug 28. When using the device, the Internal Chamber 26 of the Needle Hub 20 functions as a flashback chamber for users to observe blood flashback in a known mode.

[0067]

A Proximal End 32 of a Needle 30 is connected to the Distal End 22 of the Needle Hub 20. The Needle 30 has a bore and a Needle Shaft 34 that has a Sharpened Needle Tip 36 at the distal end. In the ready state as shown in Figure 1 and Figure 2, the Needle 30 penetrates through the Internal Chamber 12 of the Catheter Hub 4 and through the Catheter 10 in a mode where the sharpened Needle Tip 36 extends on the distal side of the distal end of the Catheter 10.

[0068]

The Needle 30 can install a Slot 38 separated from the sharpened Needle Tip 36 at the distal end portion. Under the ready state, the Slot 38 is positioned in the Catheter 10. When using a device, blood that flows in a bore in the Needle Shaft 34 flows out between the Needle Shaft 34 and the inner surface of the Catheter 10 via the Slot 38. This serves as a flashback indication to show users that the Needle Tip 36 is appropriately placed in a patient's vein. Blood that flows in the bore in the Needle Shaft 34 flows into the Internal Chamber 26 of the Needle Hub 20 and serves as a primary flashback indication for users as mentioned above.

[0069]

As mentioned above, Device 2 has the Catheter Hub 4 that has the Internal Chamber 12. The Catheter Hub 4 has a Proximal Section 40 and a Distal Section 42. The Internal Chamber 12 is opened at the Proximal End 8 of the Catheter Hub 4 and communicates with the hollow-tube Catheter 10 by extending through both the Proximal Unit 40 and the Distal Unit 42 of the Catheter Hub 4. The overall shape of the Proximal Unit 40 of the Catheter Hub 4 is conical and a Taper 44: in particular, female Luer taper of standard form, is formed inside it. A Protrusion 46 that extends in the Internal Chamber 12 that is placed on the distal side of the Luer taper is installed at the Proximal Section 40 of the Catheter Hub 4. Under the embodiment that is shown in Figure 1 and Figure 2, the Protrusion 46 is a circumferentially extending ring.

[0070]

A Valve Opener 50 is installed at the Proximal Section 40 of the Catheter Hub 4. The Valve Opener 50 has an elongated Stem 52 and a conical Head 54 that is arranged at the

distal end of the Stem 52 or a shaft. As shown in Figure 1 and Figure 2, a bore that extends through the Valve Opener 50 in the longitudinal direction is installed and the bore accepts a Needle Shaft 24 of the Needle 30 that is in a ready state. The Valve Opener 50 is maintained in the Internal Chamber 12 of the Catheter Hub 4 and its sliding in the proximal direction is limited by the Protrusion 46. The Valve Opener 50 can freely slide in the distal direction in association with the action of a male fitting, such as a syringe that is inserted in the Proximal End 8 of the Catheter Hub 4.

[0073]

A flexible Extension Tube 62 extends from the Distal Section 42 of the Catheter Hub 4. The distal end of the Extension Tube 62 opens in the Internal Chamber 12 of the Catheter Hub 4. At the proximal end of the Extension Tube 62, a hollow Connection Hub 64 that has an opening on that proximal end is installed. An internal taper, in particular, a standard female Luer taper, is installed on the Connection Hub 62 to accept a syringe and other fittings in a known mode. As shown in Figure 1, in order to maintain aseptic conditions, a Vented Plug 66 is installed at the proximal end of the Connection Hub 64. As shown in Figure 3, for example, the Connection Hub 64 can be used for introducing fluid into the Extension Tube 62 and Device 2 (catheter assembly) by using a Syringe 68.

F. [0074]

A Valve Assembly 70 is also installed in the Distal Section 42 of the Catheter Hub 4. The Valve Assembly 70 is placed in the Internal Chamber 12 of the Catheter Hub 4 and has a First Valve Portion 72 placed in the Internal Chamber 12 on the distal side from the Valve Opener 50 and a Second Valve Portion 74 placed on the distal side from the First Valve Portion 72.

[0075]

The function of the First Valve Portion 72 is to seal the Internal Chamber 12 in the Catheter Hub 4, and to prevent fluid from flowing in the proximal or distal direction when the First Valve Portion 72 is closed. The First Valve Portion 72 has a flexible Valve Disc 76 that extends laterally across the Internal Chamber 12 of the Catheter Hub 4. The Valve Disc 76 consists of flexible and resilient materials. One or multiple slits that extend in the radial direction are installed in the Valve Disc 76. Thus, as shown in Figure 1 and Figure 2, in the ready state, the Needle Shaft 34 of the Needle 30 extends through the Valve Disc 76. Detailed embodiment examples of the Valve Assembly 70 are shown in Figure 7a through Figure 7c and the details will be explained later.

[0077]

The First Valve Portion 72 is a two-way valve. When the Needle 30 is retracted and the Valve Disc 76 is closed, the flow of fluid in the Catheter Hub 4 is prevented in the

distal direction or a proximal direction. If there is no Valve Opener 50, the Valve Disc 76 opens on the proximal side of the Valve Disc 76, for example, by the action of fluid pressure that decreases by causing vacuum conditions (reduced pressure) at the Proximal End 8 of the Catheter Hub 4 using a syringe that engages with the Proximal End 8 of the Catheter Hub 4. In this way, fluid can be withdrawn in the proximal direction from the Catheter 10 to the Proximal End 8 of the Catheter Hub 4 through the Catheter Hub 4. For example, when high fluid pressure affects the proximal side of the Valve Disc 76 by using a syringe that engages with the Proximal End 8 of the Catheter Hub 4, the Valve Disc 76 opens and it allows fluid to flow in the distal direction through the Catheter Hub 4. In this way, fluid can be infused in a patient through the Catheter Hub 4 and the Catheter 10.
[0078]

The Valve Opener 50 can be slid in the distal direction by engaging a fitting, such as a syringe, etc., that has a male taper, in particular, a standard male Luer taper, with the Proximal End 8 of the Catheter Hub 4. Sliding the Valve Opener 50 in the distal direction abuts the Head 54 of the Valve Opener 50 against the Valve Disc 76 and opens the slit of the Valve Disc 76. Fluid can be thus withdrawn from or infused into a patient by opening the Valve Disc 76 as mentioned above. The Valve Disc 76 consists of resilient materials. When the male fitting that engages with the Proximal End 8 of the Catheter Hub 4 is removed, the Valve Opener 50 is slid in the proximal direction by the Valve Disc 76 until the slit of the Valve Disc 76 is closed. As mentioned above, further sliding of the Valve Opener 50 in the proximal direction is prevented by the Protrusion 46 of the Proximal Portion 40 of the Catheter Hub 4.
[0079]

The Second Valve Portion 74 is placed on the distal side of the First Valve Portion 72 and in the Internal Chamber 12 of the Catheter Hub 4. The function of the Second Valve Portion 74 is to seal the opening of the distal end of the Extension Tube 62. The Second Valve Portion 74 has the shape of a Tube 80 which consists of flexible and resilient materials and it extends along the surroundings of the Internal Chamber 12 of the Catheter Hub 4. The Tube 80 has a form conforming to the inner surface of the Distal Portion 42 of the Catheter Hub 4 and generates a fluid-tight seal for the inner surface. The overall shape of the Internal Chamber 12 in the Distal Portion 42 of the Catheter Hub 4 is a cylinder and therefore the overall shape of the Tube 80 is also a cylinder. Despite the aforementioned method, the Internal Chamber 12 in the Distal Portion 42 of the Catheter Hub 4 may be formed so that a cross-section becomes an oval figure. In cases when this structure is used, the Tube 80 is also formed so that its cross-section becomes an oval figure. Figure 7 (a) through Figure 7 (c) indicate embodiment examples of a valve

assembly and the details of the valve assembly are explained below.
[0080]

As mentioned above, the Tube 80 seals the distal end of the Extension Tube 62 at the opening to the Internal Chamber 12 of the Catheter Hub 4. An interference fitting between the Tube 80 and the Catheter Hub 4 abuts the outer surface of the Tube 80 against the inner surface of the Distal Portion 72 of the Catheter Hub 4 and generates a fluid-tight seal. When the fluid pressure in the Extension Tube 62 increases, it allows a part of the Tube 80 to separate from the inner surface of the Internal Chamber 12, and fluid flows into the Internal Chamber 12 from the Extension Tube 62 and then flows in the distal direction in Catheter 10. In this way, as shown in Figure 3, for example, fluid can be infused into the Catheter 10 from the Syringe 68 that is connected to the Connection Hub 64 via the Extension Tube 62.
G. [0096]

The embodiment of a valve assembly that is used at the Distal Portion 42 of the Catheter Hub 4 is explained below in reference to Figure 7a through Figure 7c.
[0097]

Figure 7a shows a longitudinal cross-sectional view of a valve assembly to be used with a device (catheter assembly) related to the Invention. The valve assembly to which Reference No. 702 is comprehensively assigned is formed by flexible liquid- and air-proof materials. A Valve Assembly 702 has a First Valve Portion 704 whose overall shape is a tube and a second valve portion in the shape of a Valve Disc 706 that is installed at the proximal end of the First Valve Portion 704.
[0098]

Figure 7b and Figure 7c are figures that show the embodiment of the Valve Disc 706 of the Valve Assembly 702. As shown in Figure 7b, the Valve Assembly 702 may have a cross-section whose overall shape is a circle. In addition, despite the aforementioned shape, as shown in Figure 7c, the Valve Assembly 702 may have a flattened overall shape and an elliptical cross-section. The Internal Chamber 12 in the Distal Portion 42 of the Catheter Hub 4 is formed in a form conforming to the Valve Assembly 702. In concrete terms, it is formed so that the Valve Assembly 702 fits tightly in the Internal Chamber 12, the First Valve Portion 704 comes closely into contact with the inner surface of the Internal Chamber 12, and a fluid-tight seal is generated between the Valve Assembly 702 and the inner surface of the Catheter Hub 4.
[0099]

Multiple Slits 708 are installed in the Valve Disc 706. In the embodiment shown in Figure 7b and Figure 7c, three slit arrays that extend from the center of the Valve Disc

706 outward in the radial direction are installed. It is possible to install a Slit 708 that has a form different from the aforementioned shape on the Valve Disc 706. For example, it is also possible to install a single slit.

[0100]

Under the ready state, the Needle Shaft 34 extends through the Valve Disc 706. The Needle Shaft 34 maintains Slit 708 in fully-opened conditions and this enables air to flow, in particular, in the proximal direction through the valve disc; however, this open state is insufficient for blood to go through the Valve Disc 706. Thus, as mentioned above, a flashback indication is provided to users.

(2) According to the statement in (1) above, it is found that there are the following disclosures in relation to the Invention in the Description.

A. Concerning the catheter assembly, it has been known that, in order to control (adjust) the flow of fluid via a catheter and catheter hub, in particular, in order to prevent blood from flowing out from a vein via the catheter, technology to install a valve in the catheter hub had been known ([0001] and [0004]); however, the "Invention" aims to provide an improved catheter assembly that can perform advanced control (adjustment) by infusing fluid into a patient and withdrawing fluid from a patient via a catheter ([0018]).

B. A valve assembly of the catheter assembly of the Invention has a first valve member that closes the distal end of the extension tube and can be opened by the action of pressurized fluid in the extension tube and a second valve member that prevents fluid from flowing into the proximal end of the catheter hub or from flowing out of the proximal end of the catheter hub via the internal chamber. When the first valve member is open, fluid can flow into the internal chamber of the catheter hub from an extension tube. When the second valve member is opened, it allows fluid to be supplied in the distal direction towards a catheter from the proximal end of a catheter hub or to withdraw fluid in the proximal direction towards the proximal end of a catheter hub from a catheter. In this way, the second valve member can function as a two-way valve to control (adjust) the flow of fluid to or from the proximal end of a catheter hub ([0019] and [0030]).

2. Statement in the Cited Documents

There are the following statements in Cited Document 1 (Exhibit Ko 1) (for Figures 1 through 3, 10 through 12, 16 through 18, 20, and 23 through 27 that are cited in the following statements, see Attachment 2).

(1) [Technical field]

[0001]

The Invention is related to a catheter and an introducer needle assembly.

[Background art]

[0002]

In medical treatment, these catheters and the introducer needle assemblies are used to place a catheter appropriately in a patient's vascular system. When they are placed in a fixed position, an intravenous (or "IV") catheter or other catheter can be used to infuse saline, medical compounds, and/or fluid containing nutritional compounds (including total parenteral nutrition or "TPN") to a patient requiring these treatments. In addition, a catheter can remove fluid from the circulatory system and monitor conditions in a patient's vascular system.

[0004]

A peripheral IV catheter is often provided as an "over the needle" catheter that is installed on the introducer needle, which has a sharpened distal tip. The sharpened tip often has a chamfered tip section intended to separate from a patient's skin when puncturing the skin. Part of the catheter containing at least the distal tip of the catheter firmly holds the outside of the needle in order to prevent peeling of the catheter when inserting the catheter in a patient's circulatory system. Several technologies that place these catheters are implemented in the technology field; however, most of them usually include a step to insert at least part of a needle into the target blood vessel and then slide the catheter on the needle into the fixed position.

[0006]

When it is confirmed that a needle is properly fixed, the user can block the flow in a blood vessel temporarily using the tip of the catheter, remove the needle and leave the catheter in the fixed position, and install a device on the catheter to remove or supply fluid or seal the catheter. However, this method is actually somewhat difficult. This is because the target blood vessel cannot be blocked easily in many sections where a needle is to be fixed. In addition, even if the target blood vessel is blocked, the blockage may be incomplete and it can result in blood leakage from the catheter and may place healthcare professionals using the catheter in danger.

[0007]

Therefore, catheters and introducer needle assemblies have been developed in this technical field to provide various seals or "septa" to prevent the outflow of fluid during and after removal of an introducer needle. These structural formulas are usually elastomer plates that are designed to fit the shape of the needle tightly during storage and use in order to prevent leakage and to seal when removing the needle thereafter. These septa need to be extended in a needle that has a flashback notch to prevent undesirable leakage of blood and to enclose the notch and needle tip during removal of the needle. When septa are extended as mentioned above, the amount of friction that is attached to the needle and

the amount of labor required to remove it are increased. In order to avoid this, a septum with an internal cavity that has a slightly larger inner diameter than the needle to be used was developed. As a result, the needle comes into contact with the septum only in the outer area of the cavity and the surface area that comes into contact with the septum is decreased.

[0008]

These septa are provided as two-part constituent components to provide the necessary functions, at this time. They usually contain at least two components that are assembled to form a septum that has a distal section, proximal section, and compound cavity. However, it was proved that assembly of these septa is often difficult and requires considerable work. Therefore, improvement to be made in this industry is provision of a septum that has fewer components in order to provide easy installment and excellent functionality.

[Problem to be solved by the invention]

[0009]

Therefore, the Invention provides an integrated septum to be used in a catheter and an introducer needle assembly.

(2) [Means to solve the problem]

[0010]

The septum in the Invention provides a seal around the introducer needle during the storage and use of a needle, and when a needle is withdrawn, it seals the assembly in order to prevent fluid leakage.

The septum in the Invention usually has a distal section, proximal section, cavity section, and longitudinal shaft. The distal section is the most distant from the device user, positioned the closest to a patient, and works as a primary seal to prevent blood leakage from a catheter. A septum has a cavity section that is placed between the distal section and proximal section to reduce friction on the needle. The cavity section usually has an inner diameter larger than or equivalent to the outer diameter of the needle to be used with the septum in order to reduce friction during removal of the needle. Therefore, in some structures, a septum comes into contact with a needle only at the distal section and proximal section, and in other structures, it comes into contact with a needle along its length. The proximal section of the septum functions as the secondary seal to prevent leakage of materials from the cavity. It seals the cavity and cleans a needle when it is taken out.

[0011]

The septum in the Invention is usually placed in the septum housing that can compress

the septum. The housing may be another constituent component or the catheter adapter area instead. The septum housing may also be a canister that implements compression in the radial direction. The compression in the radial direction from the housing helps to ensure the consistency of the septum with the form of the needle to be inserted through the housing and the seal when withdrawing the needle. The septum can be maintained in a fixed position only by compression, by mechanical installation or connection, and/or by adhesive that is known to persons skilled in the art. The compression may be from a single radial direction, a counterpart radial direction, or multiple radial directions.

[0012]

An integrated and low-resistance septum in the Invention provides a seal to surrounding areas of a needle during the storage and use and is installed in a septum assembly so that it is sealed when a needle is withdrawn thereafter. The septum assembly has a septum housing, and an integrated septum installed in it. The septum has a distal section, proximal section, cavity section, and longitudinal shaft. The cavity extends completely through the proximal section of the septum. The septum has at least one flare area that extends towards the outside apart from the outer diameter of the proximal section. When this septum is inserted in the septum housing, the flare area is compressed, the cavity section that extends through the proximal section closes, and a seal is provided to the proximal end of the cavity.

[0013]

In another method, the proximal section of the septum may have two flare areas that are positioned on the outer diameter of the proximal section almost by facing each other. When the septum is installed in the septum housing, compression in the radial direction is implemented from the directions of the two flare areas, respectively. In the method where many additional flares can be installed or another method, additional compression in the radial direction can be implemented by using a circumferential ridge.

[0014]

The cavity can extend completely through the proximal section of a septum in alternative mode. In this case, the proximal section of a septum may have an elongated sheath that surrounds the proximal section of the cavity. The proximal section of the cavity holds a needle, functions as a seal, and has an inner diameter equivalent to or slightly smaller than the outer diameter of the needle in order to clean the needle when it is withdrawn.

[0017]

The Invention contains a catheter and introducer needle assembly that uses the integrated septum in the Invention. This assembly has a septum assembly and introducer

needle. In some assemblies, an introducer needle contains a flashback notch that allows it to confirm the appropriate fixed position of the needle. In these assemblies, the septum is designed to be longer than or equivalent to the distance between the proximal end of the notch and the distal end of the opening of the needle tip so that it ensures an appropriate seal for a needle when it is withdrawn.

(3) [Best mode for working the invention]

[0019]

The preferable embodiment of the Invention at this time is most easily understood by referring to drawings. Identical components are indicated with identical numbers throughout the drawings. As wholly indicated or depicted in the figures of the Description, it is immediately apparent that the constituent components of the Invention can be placed and designed with widely different structures. Therefore, as shown in Figures 1 through 7, the following more detailed explanation of the embodiment of the integrated and low-resistance septum in the Invention is not intended to limit the scope of the Invention but to simply show a preferable embodiment of the Invention as it is claimed.

[0020]

The term "proximal" is used to indicate the part of a device that is the closest to the user and the most distant from the patient during normal use. The term "distal" is used to indicate the part of a device that is the most distant from the user who uses the device and the closest to the patient during normal use.

[0021]

In the following detailed explanation, the Invention is indicated in relation to a peripheral IV catheter that has an integrated dilatation tube (integrated catheter). It should be understood that the integrated and low-resistance septum in the Invention can be used with other catheter systems. The Invention can be applied to a standard peripheral IV catheter, dilatation indwelling catheter that requires the connection of a needle to a needle hub by a probe needle, and other medical devices that are preferred to have a septum adjust fluid flow into or away from a space.

[0022]

An integrated catheter and an Introducer Needle Assembly 20 in which an Integrated Low-Resistance Septum 10 in the Invention is embedded is wholly depicted in Figure 1. The catheter and the Introducer Needle Assembly 20 have a Catheter Assembly 18, including a Catheter 22 that is installed on a Catheter Adapter 24, and a Needle Assembly 16 that has an Introducer Needle 30 with a Shaft 12. The Catheter 22 can consist of materials containing fluorinated ethylene propylene (FEP), polytetrafluoroethylene (PTFE), polyurethane, and other thermoplastic resins, but not limited to these. In some

embodiments, the Catheter 22 can be manufactured using thermoplastic hydrophilic polyurethane that softens when it is exposed to physiological conditions existing in a patient's body. In addition, it may be helpful to provide a transparent or translucent Catheter 22. Given the above, if the Introducer Needle 30 has a notch or opening adjacent to the distal end to allow blood flow when it is successfully fixed in a blood vessel, it becomes possible to observe reflux of blood in an annular space between the Introducer Needle 30 and the Catheter 22. The Catheter Adapter 24 can be manufactured with materials containing polycarbonate, polystyrene, polypropylene, and other thermoplastic polymer resins, but is not limited to these.

[0023]

The Catheter Adapter 24 as shown in Figure 1 has a Wing 26 that extends from either side of the Catheter Adapter 24 in the outer radial direction. The Wing 26 simplifies the processes of the catheter and the Introducer Needle Assembly 20 and provides a large surface area for installing the Catheter 22 on a patient. The Wing 26 can include a Suture Bore 28 optionally. The proximal end of the Catheter 22 has the Integrated Low-Resistance Septum 10 in the Invention in order to prevent fluid leakage from the proximal end of the Catheter Adapter 24. The Catheter 22 and the Introducer Needle Assembly 20 also have the Introducer Needle 30. The proximal end of the Needle 30 is stored in a Needle Hub 32. The distal end of the Needle 30 has a Sharpened Tip 34 that punctures a patient's skin and a Notch 36 to reflux blood when a Distal Tip 34 is successfully fixed in a patient's blood vessel. When used, the Needle 30 and the Catheter 22 are inserted into a patient's blood vessel, appropriate insertion is confirmed, the Needle 30 is removed, and the Catheter 22 remains in the fixed position.

[0024]

Figure 2 is a partial development view of the Catheter Assembly 18 that has a Septum 10 and that is indicated separately from the Catheter Assembly 18. When it is assembled, the Septum 10 seals the proximal end of the Catheter Adapter 24 and prevents fluid leakage from the proximal end of the Catheter Adapter 24.

[0025]

The Septum 10 in the Invention is an integrated device that fits in the Catheter Adapter 24. In some embodiments, the Septum 10 is fixed in a Septum Housing 40 first. The Septum Housing 40 extends through the proximal end of the Housing 40 and has a proximal end with a Passage 42 that opens to a Lumen 44 of the housing. The distal end of the Housing 40 is widely open to accept the Septum 10. However, in other embodiments, another septum housing constituent component is not necessary. In these embodiments, the Catheter Adapter 24 takes the place of the septum housing and holds

and provides compressing force for the Septum 10. When using the Assembly 20, the Septum 10 functions to prevent fluid leakage from the Assembly 20 after insertion into a patient, and later it continues to prevent fluid leakage when the Needle 30 is withdrawn from the patient and the Catheter 22 remains in the fixed position.

[0026]

Figures 3 through 7 show isolated images, looking from the end section, or cross-sections of the Septum 10 of Figures 1 and 2 (and their minor changes), as discussed in detail below. In reference to Figure 3 first, the Septum 10 in Figures 1 and 2 is shown in an isolated perspective view. The Septum 10 includes three areas, a Proximal Section 50, a Distal Section 60, and a Cavity Section 70, in total. In some embodiments, either or both the Proximal Section 50 and the Distal Section 60 may have slits in advance to simplify positioning of an introducer needle (not shown in the Figure) in the Assembly 20. The Distal Section 60 has a Slit 62 in the Figure. The Cavity Section 70 is usually placed in the center between the Proximal Section 50 and the Distal Section 60. The Cavity 70 usually functions to provide a small friction area that is placed on the needle. In the embodiment of the Septum 10 in the Invention, the Cavity Section 70 extends completely through the Proximal Section 50 and comes out of the Proximal Section 50 of the Septum 10 at a Proximal Exit 72.

[0027]

In the Septum 10 as shown in Figure 2 and Figures 3 through 7, the Proximal Section 50 of the Septum 10 has at least one Flare Area 52. In reference to Figure 3, the Septum 10 in these figures has a pair of the Flare Areas 52 that are placed almost facing each other on the Proximal Section 50 of the Septum 10. The end views of the Septum 10 shown in Figures 4 and 6 indicate the relative forms and dimensions of the Proximal End 50 of the Septum 10 against the Distal End 60 before installing the Septum 10. In particular, the Flare Areas 52 have dimensions where the outer diameter of the Septum 10 is larger than the inner diameter of the Septum Housing 40 or the Catheter Adapter 24, even if either of the Flare Areas 52 are used to close the Septum 10. During manufacturing of the Catheter Assembly 18, the Septum 10 is pressed into the fixed position in either of the Septum Housing 40 and/or the Catheter Adapter 24. The Flare Area 52 is compressed by installing the Septum 10 in the Septum Housing 40 or the Catheter Adapter 24. When the Flare Areas 52 are compressed, the Proximal Exit 72 closes and can function as a seal. Figures 6 and 7 provide an end view and cross-sectional view of the Septum 10 in Figures 3 through 5 by rotating the figures in Figures 4 and 5 by 90 degrees. They also show the shape of the Flare Area 52.

[0029]

Next, in reference to Figures 10 and 11, the Septum 10 is installed in the Septum Housing 40 and the housing is then placed in the Catheter Adapter 24 and indicated. As mentioned above, a catheter adapter can be configured in a different way so that it can directly receive the Septum 10 without involving the Septum Housing 40. The Proximal Section 50 of the Septum 10 is deformed in the Figures so that it seals the Proximal Exit 72 and the Cavity Section 70. In the Septum 10, the Distal Section 60 of the Septum 10 as a whole is composed to function as a primary seal for the Assembly 20 by mainly firmly compressing the introducer needle when the needle is withdrawn during storage and thereafter, and it closes firmly in the radial direction primarily on the needle to prevent fluid leakage. The Proximal Section 50 of the Septum 10 functions as the secondary seal to close the Cavity Section 70 of the Septum 10. In some embodiments, the Proximal Section 50 of the Septum 10 can function as a squeegee to clean fluid from the needle when it is withdrawn through the Septum 10. The Septum 10 can be made of various and appropriate materials containing polyisoprene and other thermoplastic elastomers, or silicon and other thermosetting elastomers, but is not limited to these.

[0030]

The Septum Housing 40 as shown in Figure 11 has a proximal opening end and distal opening end. The Housing 40 can surround the Distal Section 60 of the Septum 10 by conducting an interference-fit so that it surrounds at least part of the Proximal Section 50 of the Septum 10 and holds the Septum 10 in the fixed position in the Catheter Adapter 24. Using another method, the Septum 10 can be placed in the Catheter Adapter 24 without using the Housing 40. In some cases, the use of the Septum Housing 40 can make installation of the Septum 10 in the Catheter Adapter 24 easier. As shown in Figure 11, the Septum Housing 40 extends only along with part of the Distal Section 60 of the Septum 10. Using another method, the Housing 40 can extend completely along the length of the Septum 10 or simply along with the Distal Section 60 of the Septum 10. In this substitute structure, as mentioned below, it is obvious that the Housing 40 adds compressing force to the Septum 10 in lieu of the Catheter Adapter 24. An introducer needle (not shown in the Figure) can extend through the Septum 10 and through the Housing 40 thanks to the proximal opening end and distal end of the Septum Housing 40. In some embodiments, it may be helpful to provide a Lip 46 to the proximal end of the Housing 40 so that it extends partially over the surface of the Proximal End 50 of the Septum 10. This can prevent another medical device from being installed on the Proximal End 50 of the Catheter Adapter 24.

(4) [0034]

In the same way as in the aforementioned embodiment of the septum in the Invention,

a slit may be provided in advance to a Septum 210 in Figure 12 so that an introducer needle (not shown in the Figure) can be inserted easily through the Septum 210. This preparation is known to persons skilled in the art.

[0036]

Next, in reference to Figure 16, a partially cutaway view of another embodiment of an Integrated Low-Resistance Septum 110 in the Invention is shown. In the same way, the Septum 110 has a Proximal Section 150, a Distal Section 160, and a cavity section. In this case, a Cavity 170 potentially extends into the Proximal Section 150 and the Distal Section 160 in the Figure; however, it does not extend through them. As a result, a slit may be provided in advance in the Proximal Section 150 and the Distal Section 160 so that an introducer needle (not shown in the Figure) can be inserted easily through them or the needle can be inserted easily through the materials of the Septum 110. The Septum 110 can be created using gas-assist injection molding and other injection molding technology, but not limited thereto.

[0039]

In the same way as the aforementioned embodiment of the septum in the Invention, as shown in Figure 17, when a Needle 130 extends through both the Proximal Section 150 and the Distal Section 160 of the Septum 110, the Septum 110 matches with the Needle 130. In the same way, when the Needle 130 is withdrawn, as shown partially in Figure 18, the Septum 110 is sealed as seen on the Distal Section 160 of the Septum 110.

[0041]

A Septum 310 can be assembled around the Introducer Needle 30, as shown in Figure 20. In another method, the Septum 310 can be folded first and a needle can be inserted through the Septum 310 thereafter. The Septum 310 simplifies assembly by installing slits in a Proximal Section 350 and a Distal Section 360 and by avoiding the necessity of allowing insertion of a needle to go through the Septum 310.

(5) [0044]

Figures 23 through 25 are a series of figures of another Integrated Low-Resistance Septum 410 in the Invention where it is isolated first in a partial development perspective view of a catheter and an Introducer Needle Assembly 420 and then shown in cross-sectional view. In Figure 23, the Septum 410 is shown in an isolated perspective view that is developed from the position inside the catheter and the Introducer Needle Assembly 420. The Septum 410 has a Proximal Section 450, a Distal Section 460, and a Cavity Section 470. The Distal Section 460 is similar to the other embodiments of the Septum 410 in the Invention mentioned above and can have a Slit 462 so that an introducer needle (not shown in the Figure) can be easily inserted through it. The Proximal Section 450 has

an elongated sheath that extends from the Distal Section 460 by surrounding an introducer needle (not shown in the Figure) that moves forward through it. The sheath is actually an extension of a Cavity Wall Surface 474.

[0045]

Figure 24 shows that the Cavity Section 470 of the Septum 410 is different from what has been disclosed before. In the same way as shown for the Septum 10 in Figures 2 through 11, the Cavity Section 470 of the Septum 410 as shown in Figure 24 extends completely through the Proximal Section 450 of the Septum 410, which opens to the environment at a Proximal Exit 472. However, apart from this embodiment, as is obvious from Figures 25 through 27, the Cavity Section 470 has a Distal Cavity 476b and a Proximal Cavity 476a. The Distal Cavity 476b is placed near the Distal Section 460 of the Septum 410. The Distal Cavity 476b has a Distal Inner Diameter 478b and the Proximal Cavity 476a has a Proximal Inner Diameter 478a. In the Septum 410, the Distal Inner Diameter 478b of the Distal Cavity 476b is smaller than the outer diameter of the introducer needle that is used in an Assembly 420. The Proximal Inner Diameter 478a of the Proximal Cavity 476a is larger than the Distal Inner Diameter 478b; however, it is slightly smaller than outer diameter of the introducer needle (not shown in the Figure).

[0046]

The Proximal Cavity 476a and the Distal Cavity 476b add different force to a needle that moves forward through them thanks to the Inner Diameters 478a and 478b. A Small Diameter 478b of the Distal Cavity 476b allows the addition of strong force to the needle, almost as if cleaning the needle when the needle comes out of the Distal Section 460 of the septum. A Larger Diameter 478a of the Proximal Cavity 476a reduces the force to be added on the needle by the Septum 410 and it reduces the resistance to the needle; however, it continues to function as a squeegee and to clean the needle when it comes out. In the same way as the septum indicated above, the Septum 410 is sealed when a needle is withdrawn.

[0047]

Figure 25 is a cross-sectional view of the Septum 410 that is installed in the catheter and the Introducer Needle Assembly 420. The Assembly 420 also has an Introducer Needle 430 that goes through the Septum 410. A Needle 430 has a Reflux Notch 436a and a Distal Tip 434 that has a Locking Notch 436b. The Needle 430 can also have a Ridge 438 that interacts with a Needle Shielding Device 496. In addition, the Assembly 420 can have a Closure 498 that prevents the Needle 430 from re-entering the Assembly 420 after single removal.

[0048]

In the Septum 410 as shown in Figure 25, the Cavity Wall Surface 474 can optionally have various additional features on an Outer Surface 490. As shown in Figure 25, one of these features is a Groove 492 that makes it easy to install the Septum 410 on a Catheter Adapter 424. Another feature is a Connected Feature 494 that is useful in the embodiment of the Septum 410 as shown in Figures 25 through 27, where the Needle Shielding Device 496 and a Retainer 497 are installed as shown in the Figures. When the Needle Shielding Device 496 is taken out from the Septum 410, it interacts with the Retainer 497 so that it covers the Distal Tip 434 of the Needle 430.

[0049]

Figure 26 shows the Needle 430 that is partially removed from the Assembly 420. In more detail, in Figure 20, tip of the Needle 430 goes through the Distal Section 460 of the Septum 410. As mentioned above, please note that the length of the Septum 410 is designed so that the Reflux Notch 436a of the Needle 430 does not come out from the Septum 410 and thereby fluid leakage is prevented. At the removal stage, the Ridge 438 of the Needle 430 engages with the Needle Shielding Device 496 that is installed around the Septum 410, takes out the Device 496 from the septum, and moves it forward along with the Needle 430 when it is taken out. Figure 27 shows that when the Needle 430 is taken out completely from the Assembly 420, the Shielding Device 496 surrounds the Distal Tip 434 of the Needle 430 and protects users from injury due to potential needle puncture. At the same time, the Closure 498 closes at the opening in the Assembly 420 and the Needle 430 moves forward in the Septum 410 through it. This prevents re-insertion of a needle and thereby prevents re-use of the device.

[0050]

The Invention provides a seal mainly to a needle that is used in a catheter and introducer needle assembly during the storage and use, and thereby provides an integrated septum that seals the assembly when taking out a used needle. All of the various embodiments of the septum in the Invention can be easily created by using rapid injection molding technology. It has a distal section that functions as a primary seal against fluid flow from a patient, a distal seal that functions as the secondary seal and needle cleaner in some cases, and a cavity. The septum in the Invention has an internal cavity that is long enough to appropriately surround a needle, which has a notch functioning to check that it enters in a blood vessel; however, it reduces the amount of resistance to be added to the needle by the septum.

[0051]

As it is generally stated in the Description and claimed at the beginning, the Invention can be worked in other specific forms without deviating from its structure, method, or

other basic features. The indicated embodiments are considered to be examples only for all modes and they are not restrictive. Therefore, the scope of the Invention is shown not by the aforementioned statements, but by the patent claim stated at the beginning. The meaning of equivalent articles in the patent claim and all changes within the scope are considered to be included in the scope of the Invention.

3. Error in finding common features and overlooking of differences

(1) The Plaintiff alleged as follows: the JPO Decision cited [0012], [0023], [0044], and Figure 26 as indicated in Cited Document 1 as basis and determined that the Cited Invention "has a slit that can open to allow the flow in and out" at the "distal section" of a "septum," and then determined that the fact that the Cited Invention has "a slit that can open to allow the flow in and out" at the distal section of the "septum" corresponds to the structure (Structure) of the Invention that "the second valve member is a two-way valve and can open so that fluid can flow in both the proximal direction and distal direction through the internal chamber of the catheter hub" and that the Structure is a common feature of the Invention and Cited Invention. Then, the Plaintiff alleged that the JPO Decision contains an error in the determination of common features and an overlooking of differences as there is no indication in Cited Document 1 related to the fact that the distal section of the "septum" has "a slit that can open to allow the flow in and out" and the catheter and introducer needle assembly as indicated in Cited Document 1 is different from the Invention in that it does not have the Structure.

A. When examining these points, the JPO Decision determined that technical matters are indicated in Cited Document 1 as follows: "[i] the distal section of a septum is sealed when a needle is pulled out and prevents fluid from flowing into the proximal end of a catheter adapter or flowing out from the proximal end of a catheter adapter via the hollow section, and it has a slit that can open to allow the flow in and out ([0012], [0023], [0044], and Figure 26)." (page 6)

However, in [0012] of Cited Document 1, there are the following statements: "An integrated and low-resistance septum in the Invention provides a seal to surrounding areas of a needle during storage and use and is installed in a septum assembly so that it is sealed when a needle is withdrawn thereafter. The septum assembly has a septum housing and an integrated septum installed in it. The septum has a distal section, proximal section, cavity section, and longitudinal shaft. The cavity extends completely through the proximal section of the septum. The septum has at least one flare area that extends towards the outside apart from the outer diameter of the proximal section. When this septum is inserted in the septum housing, the flare area is compressed, the cavity section that extends through the proximal section closes, and a seal is provided to the proximal end

of the cavity."; in [0023], "The proximal end of the Catheter 22 has the Integrated Low-Resistance Septum 10 in the Invention in order to prevent fluid leakage from the proximal end of the Catheter Adapter 24.;" in [0044], "Figures 23 through 25 are a series of figures of another Integrated Low-Resistance Septum 410 in the Invention where it is isolated first in a partial development perspective view of a catheter and an Introducer Needle Assembly 420 and then shown in cross-sectional view." and "The Septum 410 has a Proximal Section 450, a Distal Section 460, and a Cavity Section 470. The Distal Section 460 is similar to the other embodiments of the Septum 410 in the Invention mentioned above and can have a Slit 462 so that an introducer needle (not shown in the Figure) can be easily inserted through it."

Based on the aforementioned statements, according to Cited Document 1, it is understood that the Septum 410 that is installed in a septum assembly is installed to prevent fluid leakage from the proximal end of the Catheter Adapter 24 and that the Distal Section 460 of the Septum 410 can have the Slit 462 to make insertion of the introducer needle that goes through it easy.

And Figure 26 (see Attachment 2) depicts the Slit 462 that is installed around the approximate center in the thickness direction and in the longitudinal shaft direction from the proximal end to the distal end on the Distal Section 460 of the Septum 410.

On the other hand, there is no statement on the fact that the Slit 462 "can open to allow the flow in and out" of fluid in [0012], [0023], and [0044] of Cited Document 1.

In addition, in light of the shape of the Slit 462 as shown in Figure 26, it cannot be immediately recognized that the Slit 462 "can open to allow the flow in and out" of fluid from Figure 26.

In addition, looking at overall statements (including drawings) in Cited Document 1, there is no statement suggesting that the Slit 462 has a structure "that can open to allow the flow in and out" of fluid.

B. Instead, Cited Document 1 has the following statements concerning a septum, in addition to [0012] above: "The septum in the Invention provides a seal around the introducer needle during the storage and use of a needle and then, when a needle is withdrawn, it seals the assembly in order to prevent fluid leakage."; "The distal section is the most distant from the device user, positioned the closest to a patient, and works as a primary seal to prevent blood leakage from a catheter."; "The proximal section of the septum functions as the secondary seal to prevent leakage of materials from the cavity. It seals the cavity and cleans a needle when it is taken out." ([0010]); "When it is assembled, the Septum 10 seals the proximal end of the Catheter Adapter 24 and prevents fluid leakage from the proximal end of the Catheter Adapter 24." ([0024]); "The Septum 10 in

the Invention is an integrated device that fits in the Catheter Adapter 24.": and "When using the Assembly 20, the Septum 10 functions to prevent fluid leakage from the Assembly 20 after insertion into a patient, and later it continues to prevent fluid leakage when the Needle 30 is withdrawn from the patient and the Catheter 22 remains in the fixed position." ([0025]).

Based on the aforementioned statements, it is understood that the septum stated in Cited Document 1 provides a seal around the needle during the storage and use of the needle, functions to prevent fluid leakage from the Assembly 20 after insertion into a patient, and is installed in the septum assembly so that it is sealed when the needle is withdrawn from the patient.

In addition, Cited Document 1 has the following statements related to "slit"; "In some embodiments, either or both the Proximal Section 50 and the Distal Section 60 may have slits in advance to simplify positioning of an introducer needle (not shown in the Figure) in the Assembly 20. The Distal Section 60 has a Slit 62 in the Figure." ([0026]); "a slit may be provided in advance to a Septum 210 in Figure 12 so that an introducer needle (not shown in the Figure) can be inserted easily through the Septum 210." ([0034]); "a Cavity 170 potentially extends into the Proximal Section 150 and the Distal Section 160 in the Figure; however, it does not extend through them. As a result, a slit may be provided in advance in the Proximal Section 150 and the Distal Section 160 so that an introducer needle (not shown in the Figure) can be inserted easily through them or the needle can be inserted easily through the materials of the Septum 110." ([0036]); "In another method, the Septum 310 can be folded first and a needle can be inserted through the Septum 310 thereafter. The Septum 310 simplifies assembly by installing slits in a Proximal Section 350 and a Distal Section 360 and by avoiding the needle going through the Septum 310." ([0041]); "Figures 23 through 25 are a series of figures of another Integrated Low-Resistance Septum 410 in the Invention where it is isolated first in a partial development perspective view of a catheter and an Introducer Needle Assembly 420 and then shown in cross-sectional view."; and "The Distal Section 460 is similar to the other aforementioned embodiments of the Septum 410 in the Invention mentioned above and can have a Slit 462 so that an introducer needle (not shown in the Figure) can be easily inserted through it." ([0044]).

Based on the aforementioned statements, it is understood that a slit that is installed at the distal section of a septum is installed to determine the position of an introducer needle that goes through the distal section of the septum and to make insertion of the needle easy.

In addition, according to Figures 1, 23, and 25 through 27, it can be recognized that the distal end of the extension tube is connected to a hollow section that is between the

proximal end and distal end of a catheter adapter and is open to the distal side of the distal end of the distal section of a septum. Therefore, in cases of the catheter and introducer needle assembly as stated in Cited Document 1, it is understood that fluid is infused into a patient and is removed from a patient's circulatory system through the extension tube via the aforementioned hollow section of a catheter adapter.

C. Based on the above, the septum stated in Cited Document 1 is installed in the septum assembly in order to provide a seal around a needle during the storage and use of the needle and to seal the assembly when the needle is withdrawn; a slit installed on the distal section of a septum is installed to make insertion of an introducer needle that goes through it easy. Therefore, it is not recognized that the distal section of a septum "has a slit that can open to allow the flow in and out" of fluid.

Then, it cannot be said that the distal section of the "septum" as stated in Cited Document 1 corresponds to the structure of the Invention that "the second valve member is a two-way valve and can open so that fluid can flow in both the proximal direction and distal direction through the internal chamber of the catheter hub" (Structure) and the catheter and introducer needle assembly as stated in Cited Document 1 is different from the Invention on the point that it does not have the Structure. Therefore, in this regard, it is recognized that the JPO Decision contains an error in the determination of common features and an overlooking of differences.

(2) On the contrary, the Defendant alleged as follows: [i] it is indicated in Cited Document 1 that a catheter and introducer needle assembly has already been able to infuse fluid into a patient and to remove fluid from a patient's circulatory system ([0002]); [ii] it is common general technical knowledge that fluid is infused into a patient and removed from a patient's circulatory system through a "septum that has a slit" that is placed in the hollow section of a catheter hub and functions as a "two-way valve" (for example, Exhibit Ko 3 and Exhibit Otsu 6). Based on this fact, the Defendant alleges that a person skilled in the art naturally considers that the distal section of the "septum" of a catheter and introducer needle assembly as stated in Cited Document 1 corresponds to the Structure and therefore there is no error in the determination of common features in the JPO Decision.

A. Concerning [i]

There are statements in [0002] of Cited Document 1: "In medical treatment, these catheters and the introducer needle assemblies are used to place a catheter appropriately in a patient's vascular system. When they are placed in a fixed position, an intravenous (or "IV") catheter and other catheter can be used to infuse saline, medical compounds, and/or fluid containing nutritional compounds (including total parenteral nutrition or "TPN") to a patient requiring these treatments. In addition, a catheter can remove fluid

from the circulatory system and monitor conditions in a patient's vascular system."

According to the aforementioned statements, it can be understood that a catheter and a catheter of an introducer needle assembly make it possible to "remove fluid from the circulatory system and to monitor conditions in a patient's vascular system"; however, it cannot be said that the aforementioned statements suggest that the distal section of a septum or a slit that is installed in the distal section has a structure "that can open to allow the flow in and out" of fluid.

B. Concerning [ii]

There are statements on Valve Disc 6 in Exhibit Otsu 6 (International Publication No. 2008/052791) that it is a valve that is placed along the port on the side and closes the port as a specific structure of a valve assembly and that has a first valve element that can be opened by the action of pressurized fluid in the port (Tube Element 5) and a Slot 6a that is formed as a two-way valve that allows fluid to flow either in the distal or proximal direction (line 7 on page 4 through line 3 on page 5 of the original text (page 5 of translation), line 17 through line 20 on page 5 of the original text (page 6 of translation), Figures 1 and 2, etc.).

There are statements in Cited Document 3 (Exhibit Ko 3 and Translation Otsu 5) that [i] a blood control valve that includes a septum that has a slit and a septum effector and that forms a fluid passage through the septum by the septum effector moving forward through a slit of the septum during use, and a port valve that can prevent fluid in the catheter assembly from leaking from the side port ([0002] and [0003]); [ii] "A catheter adapter stores a blood control valve that includes a septum effector and a septum. A septum seals part of a lumen. One or more slits penetrates a septum and extends and this allows alternative access that goes through the septum. Therefore, a port valve can provide unilateral and alternative access to the internal lumen of a catheter adapter via a port." ([0005]).

Based on the aforementioned statements, it is recognized concerning a catheter assembly that a technology where fluid can be infused into a patient and removed from a patient's circulatory system via a "septum that has a slit" that is placed in a hollow section of a catheter hub and that functions as a "two-way valve" was known to public at the time of the Priority Date.

On the other hand, according to the aforementioned statements, it cannot be recognized to the extent that a "septum that has a slit" that is placed in the hollow section of a catheter hub always functions as a "two-way valve." Therefore, even in consideration of the fact that the aforementioned technology was known to the public, it does not affect the determination in (1) C. above and it cannot be found that a person skilled in the art

naturally understands that the distal section of the "septum" of the catheter and introducer needle assembly as stated in Cited Document 1 corresponds to the Structure.

C. Summary

According to A. and B. above, the allegation of the Defendant that the JPO Decision contains no error in the determination of common features is groundless.

4. Summary

Based on the above, the JPO erred in determining the common features, overlooked the differences, and erroneously made a judgment to deny an inventive step of the Invention without making a determination as to whether a person ordinarily skilled in the art could have easily conceived of the differences. It is obvious that this error affects the conclusion of the JPO Decision.

Consequently, the grounds for rescission alleged by the Plaintiff are well-founded without the need to make judgment on other points.

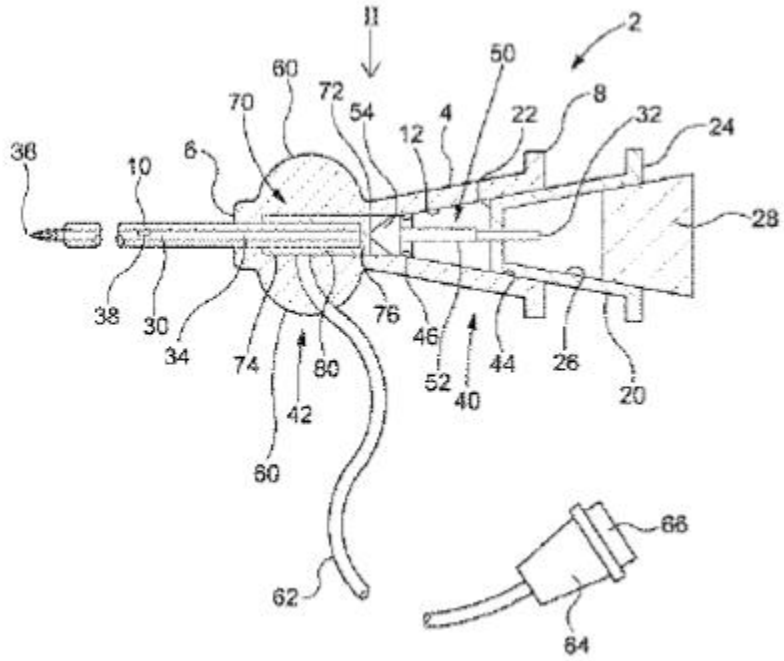
No. 5 Conclusion

As mentioned above, the grounds for rescission alleged by the Plaintiff are well-founded and therefore, the JPO Decision should be rescinded.

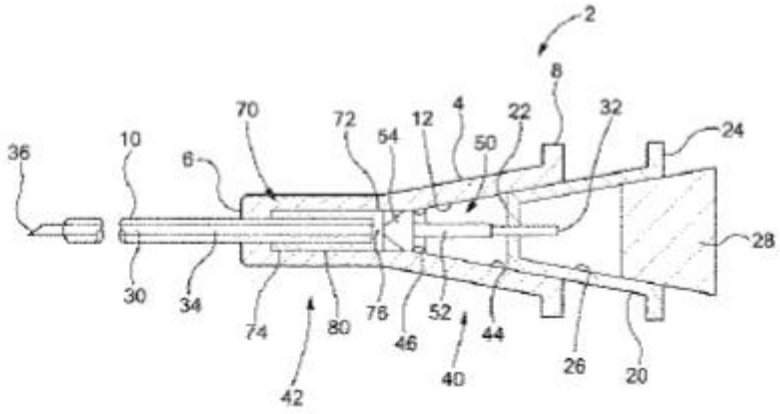
Intellectual Property High Court, First Division
Presiding judge: OTAKA Ichiro
Judge: KOBAYASHI Yasuhiko
Judge: TAKAHASHI Aya

(Attachment 1)

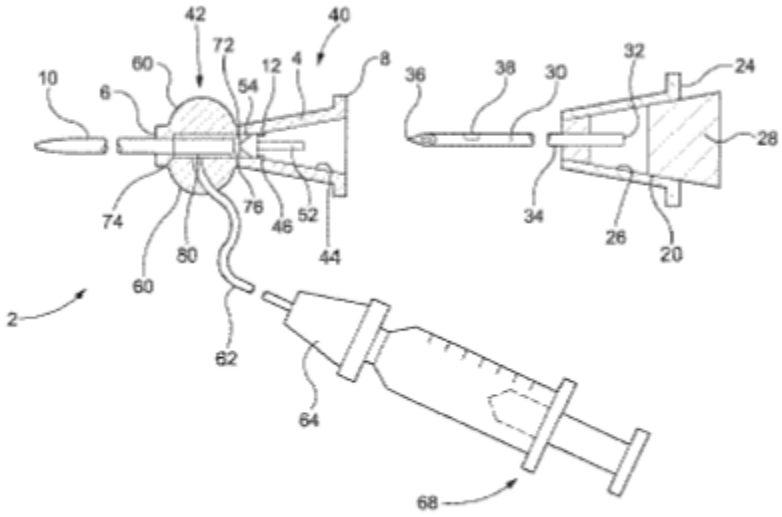
[Figure 1]



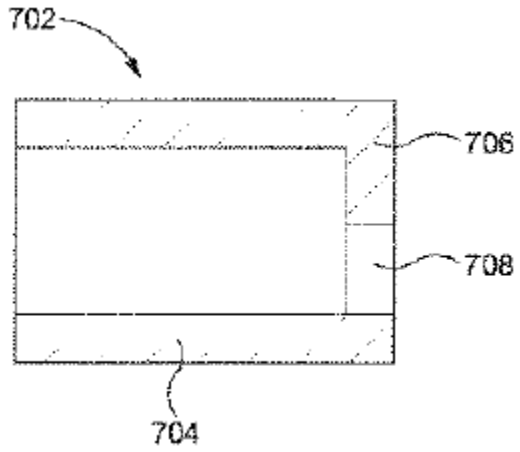
[Figure 2]



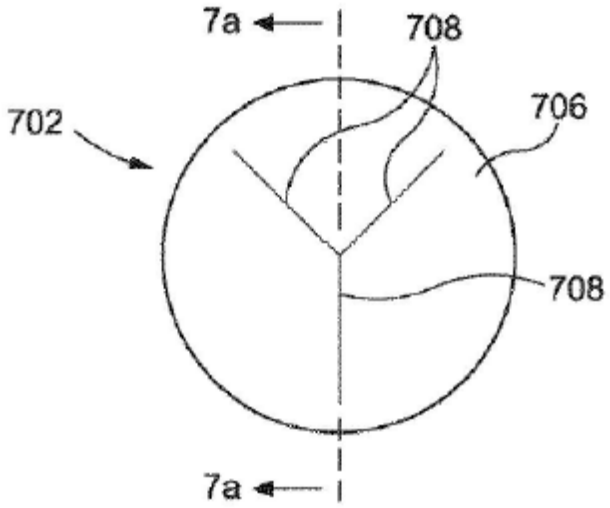
[Figure 3]



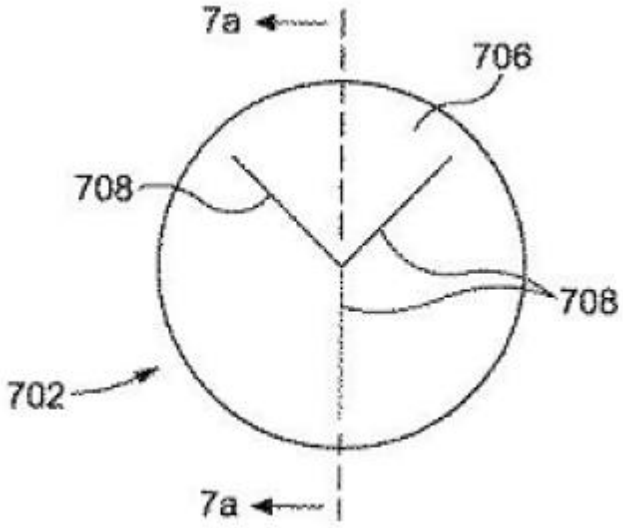
[Figure 7a]



[Figure 7b]

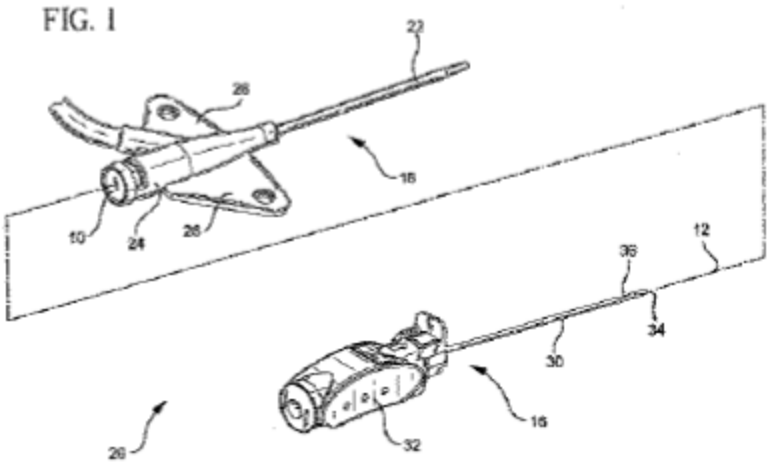


[Figure 7c]

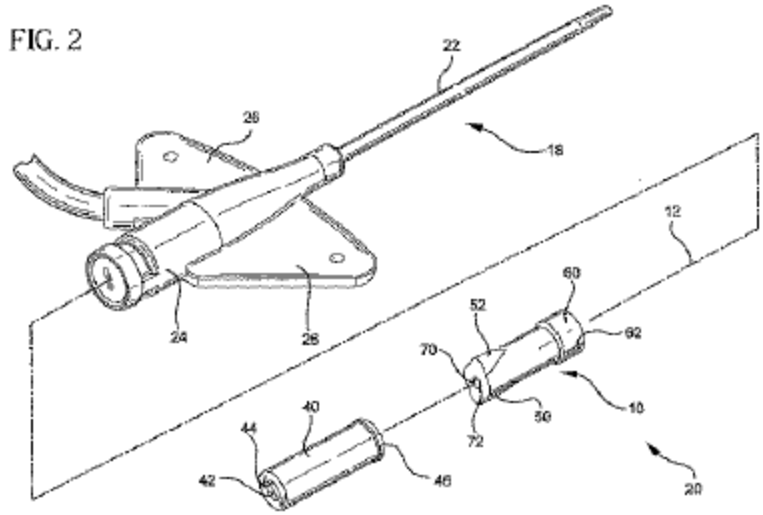


(Attachment 2)

[Figure 1]

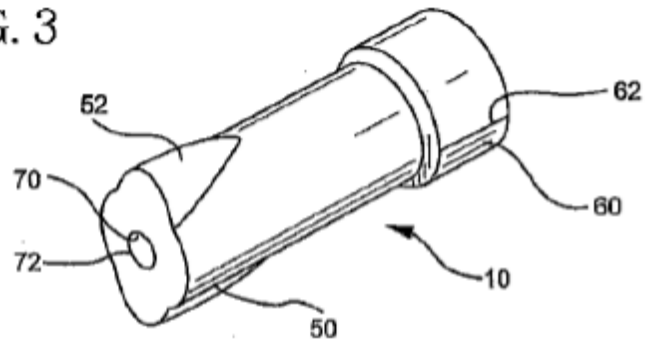


[Figure 2]



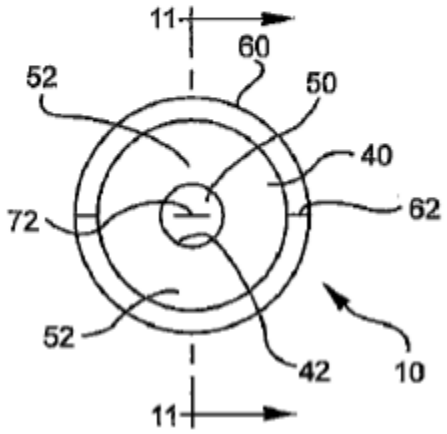
[Figure 3]

FIG. 3



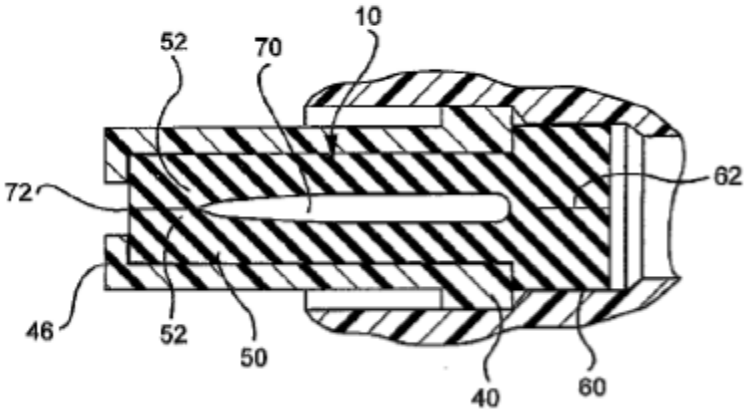
[Figure 10]

FIG. 10



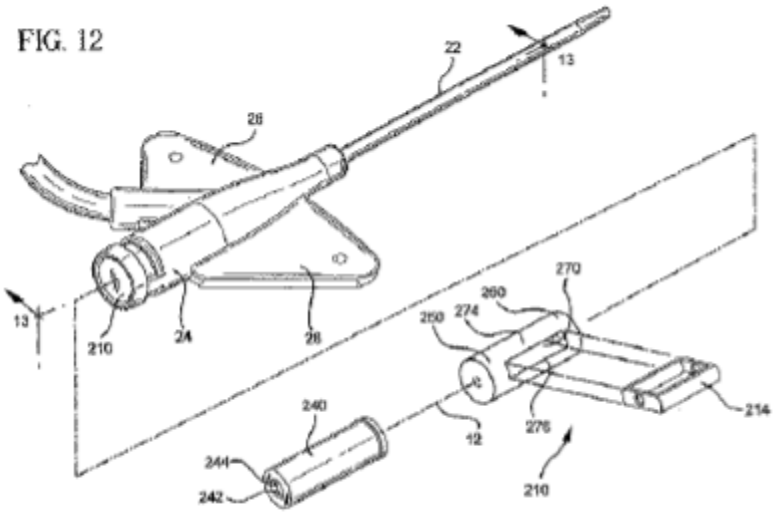
[Figure 11]

FIG. 11

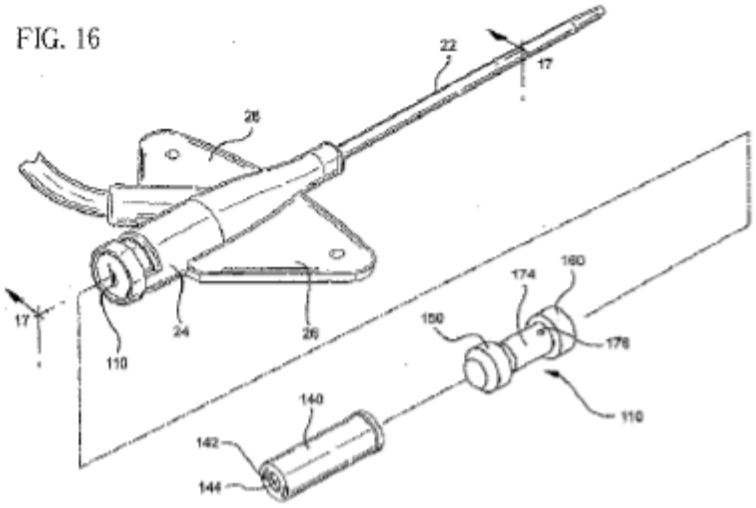


[Figure 12]

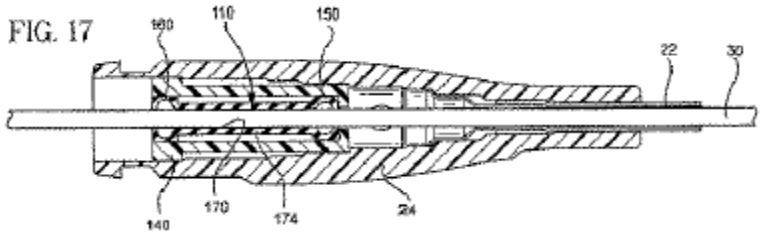
FIG. 12



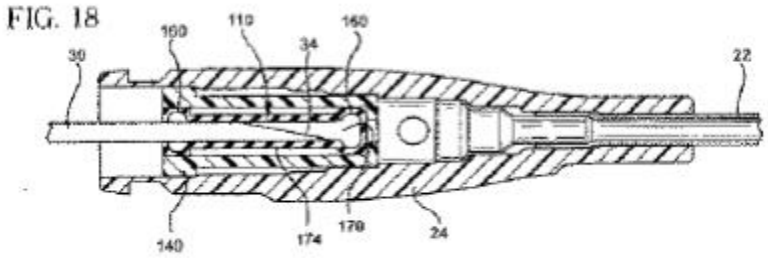
[Figure 16]



[Figure 17]

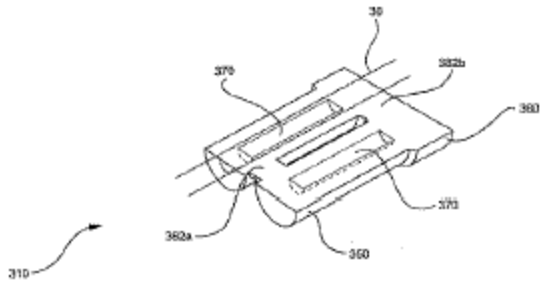


[Figure 18]



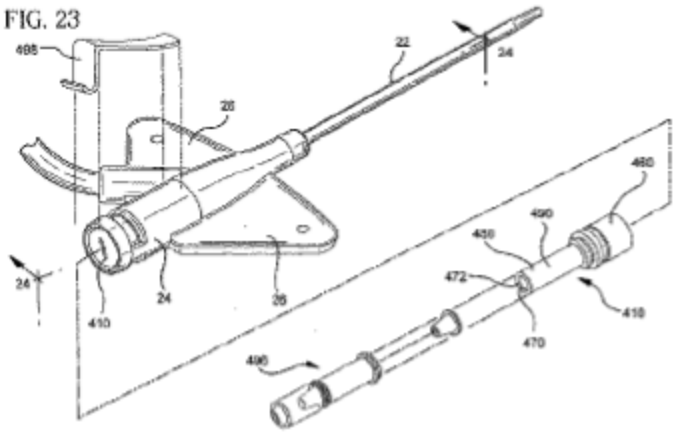
[Figure 20]

FIG. 20



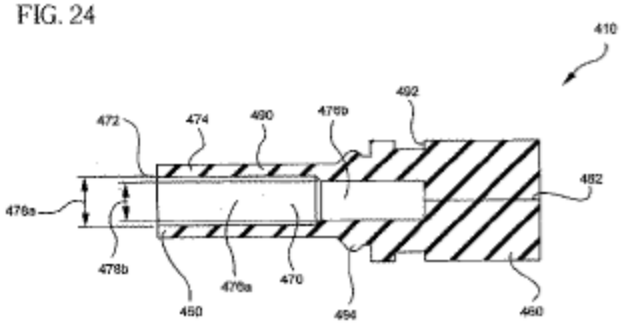
[Figure 23]

FIG. 23



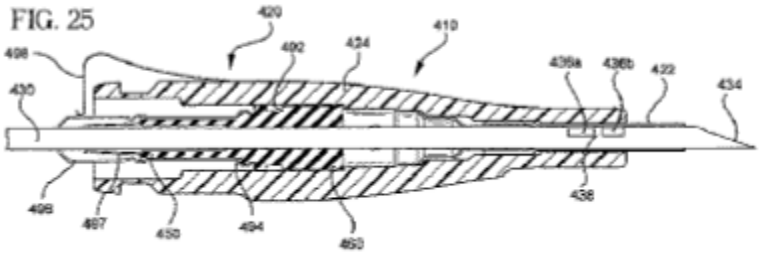
[Figure 24]

FIG. 24



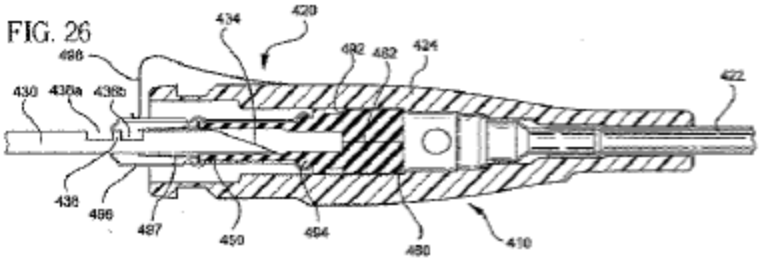
[Figure 25]

FIG. 25



[Figure 26]

FIG. 26



[Figure 27]

FIG. 27