Patent Right	Date	December 4, 2019	Court	Intellectual Property High Court, First Division
	Case number	2018 (Gyo-ke) 10175		
- In finding of the "invention described in publication" (Article 29, paragraph (1), item (iii) of the Patent Act), to find the described matter of a specific publication and the described matter of a different independent publication in combination is equal to judgment on inventive step brought into the judgment on novelty, which contradicts the gist of the Patent Act employing a structure of judgment separately for the inventive step and the novelty and should not be allowed in principle.				

Case type: Rescission of Trial Decision of Invalidation

Result: Dismissed

References: Article 29, paragraph (1), item (iii), paragraph (2) of the Patent Act

Number of related rights, etc.: Patent No. 6018822, Invalidation Trial No. 2017-800070

Summary of the Judgment

1. Plaintiff is the patentee of the present patent according to the invention titled "access port and identification method thereof". The Japan Patent Office rendered the trial decision of invalidation for the request for trial for patent invalidation by Defendants, since the present patent lacks the support requirement and lacks inventive step. This case is a lawsuit seeking rescission of this JPO decision by Plaintiff.

As reasons for rescission, Plaintiff alleged error in judgment of the support requirement and error in judgment of inventive step.

2. This judgment held substantially as follows and dismissed Plaintiff's claim.

(1) Reason 1 for rescission (error in judgment on the support requirement)

The problem of Present Invention 1 is, after an access port capable of automatic injection is implanted, to enable identification on whether the access port is an access port capable of automatic injection, and as the solution thereof, "at least one identifiable feature of the access port configured to identify the access port capable of automatic injection through an X-ray after subcutaneous implantation, correlated with information of the access port capable of automatic injection distinguishable from an access port not rated as capable of the automatic injection and visible by an X-ray" is included.

It should be considered that a person ordinarily skilled in the art who got in touch with the description of the present Description can recognize that the "identifiable feature" can be perceived by exposing the access port employing the "identifiable feature" of Present Invention 1 to the X-ray, whereby the correlation with the "information distinguishable from an access port not rated as capable of automatic

injection" is achieved, the "information distinguishable from an access port not rated as capable of automatic injection" can be obtained, and as a result, it should be considered that the person ordinarily skilled in the art can recognize that it is identifiable as capable of automatic injection after the subcutaneous implantation. Thus, Present Invention 1 is within a range that a person ordinarily skilled in the art can recognize that the problem of Present Invention 1 can be solved by the description in the detailed description of the invention in the present Description.

(2) Reason 2 for rescission (error in judgment on inventive step)

A. Finding of the cited invention

Cited Document 1 is found to describe the "Toray port which is an access port for providing a subcutaneous access to a patient, used for contrast radiography CT and capable of injection of the contrast medium and pressurization by mechanical assistance by the automatic injector" (cited invention found by the decision).

Defendants allege that, in order to understand the contents of the configuration of the invention of the Toray port described in Cited Document 1, reference to Cited Document 2 which is an attached document to the Toray port is allowed, and the finding in this JPO decision of the Exhibit Ko 9 invention has no error.

However, in finding of the "invention described in publication" (Article 29, paragraph (1), item (iii) of the Patent Act), to find the described matter of a specific publication and the described matter of a different independent publication in combination is equal to judgment on inventive step brought into the judgment on novelty, which contradicts the gist of the Patent Act employing a structure of judgment separately for inventive step and novelty, and should not be allowed in principle.

Thus, the Exhibit Ko 9 invention found by this JPO decision cannot be found from the description in Cited Document 1 which is a paper describing an experiment result related to pressure resistance capability using the Toray port, and Cited Document 2, which is an attached document describing the specification and the use conditions of the Toray port with an author and a date both different from those of Cited Document 1. As described above, the finding of the Exhibit Ko 9 invention by this JPO decision is an error. Moreover, whether or not Present Invention 1 could have been easily conceived of will be judged on the basis of the correctly found cited invention.

B. Whether Different Feature 1 could be easily conceived of

At the time of the priority date of this case, in medical equipment used by being implanted in human bodies, to include a radiopaque identifier including information specifying the device after being implanted in the human body; that is, a feature

identifiable and visible by X-rays, is found to be a matter of well-known art which had been already employed at a clinical level.

Cited Invention belongs to the same technical field as that of the aforementioned well-known art, and there is no factor teaching away from the application of the aforementioned well-known art to Cited Invention and thus, it should be considered that to apply the aforementioned well-known art to Cited Invention so as to include the identifiable feature, visible by X-rays, including the information specifying the device after being implanted in the human body, could have been made by a person ordinarily skilled in the art as appropriate.

The information specifying Cited Invention is information which can distinguish the access port capable of automatic injection from an access port not rated as capable of the automatic injection. Then, since the aforementioned "information" can be identified by the identifiable feature, visible by X-rays, including the information specifying Cited Invention, it can be considered that the aforementioned "at least one" identifiable feature" of the access port" is "correlated" with the "information of the access port capable of automatic injection distinguishable from an access port not rated as capable of automatic injection". Thus, to apply the aforementioned well-known art to Cited Invention so as to have the configuration according to Different Feature 1 could have been conceived by a person ordinarily skilled in the art as appropriate.

Thus, Present Invention 1 could have been easily made by applying the well-known art and the like to Cited Invention.

Judgment rendered on December 4, 2019
2018 (Gyo-Ke) 10175 A case of seeking rescission of the JPO decision
Date of conclusion of oral argument: October 9, 2019

Judgment

Plaintiff: C. R. Bard Incorporated

Defendant: B. Braun Aesculap Co., Ltd.
Defendant: B. Braun Medical

Main text

1. The Plaintiff's claim shall be dismissed.
2. Plaintiff shall bear the court costs.
3. The additional period for filing a final appeal and a petition for acceptance of final appeal against this judgment for Plaintiff shall be 30 days.

Facts and reasons

No. 1 Claim

The trial decision for Invalidation Trial No. 2017-800070 case rendered by the Japan Patent Office on August 8, 2018 shall be rescinded.

No. 2 Outline of the case

1. Outline of procedures, etc. at the JPO

(1) Plaintiff filed a patent application (Division of application of Patent Application No. 2007-558331 with an International filing date of March 6, 2006 and a priority date of March 4, 2005) for the invention titled "ACCESS PORT AND IDENTIFICATION METHOD THEREOF" on July 12, 2012 and was granted registration of establishment on October 7, 2016 (Patent No. 6018822, Exhibit Ko 1, Number of claims: 6, hereinafter referred to as "Present Patent").

(2) Defendants claimed an invalidation trial against it on May 22, 2017, which was pending as Invalidation Trial No. 2017-800070 case.

(3) The JPO made the JPO decision described in the written decision (copy) in the attachment that "the patent for the inventions according to Claims 1 to 6 of Patent No. 6018822 shall be invalidated." on August 8, 2018, and a certified copy was

delivered to Plaintiff on the 16th day of the month.

(4) Plaintiff instituted this lawsuit seeking rescission of this JPO decision on December 12, 2018.

2. Description of scope of claims

The description in Claims 1 to 6 in the scope of claims of Present Patent is as follows (Exhibit Ko 1). The symbol in the sentences "/" indicates a new paragraph in the original text (the same applies to the following.). Hereinafter, the inventions according to the respective claims are referred to as "Present Invention 1" and the like.

[Claim 1]

An access port capable of automatic injection for providing subcutaneous access to a patient, used for a computer tomographic scanning process, comprising /

a main body configured to hold a diaphragm; and /

at least one identifiable feature of the access port configured to identify the access port capable of automatic injection through X-ray after subcutaneous implantation, correlated with information of the access port capable of automatic injection distinguishable from an access port not rated as capable of the automatic injection and visible by X-ray, wherein /

the access port capable of automatic injection is capable of injection by mechanical assistance and is capable of pressurization, and /

the diaphragm is a diaphragm for repeated insertion of a needle through the diaphragm into a cavity defined in the main body.

[Claim 2] The access port capable of automatic injection according to Claim 1, wherein /

the main body includes a housing /

the housing has a discharge port and a cap which can be fixed to the housing, and /

the cap holds the diaphragm in the main body.

[Claim 3] The access port capable of automatic injection according to Claim 2, wherein the housing includes a base for the housing which defines at least one container.

[Claim 4] The access port capable of automatic injection according to Claim 1, wherein /

the main body includes a housing defining a cavity together with the diaphragm; and /

the cavity is in fluid communication with a lumen of a discharge stem.

[Claim 5] The access port capable of automatic injection according to Claim 4, wherein the discharge stem is configured to be connected to a catheter.

[Claim 6] The access port capable of automatic injection according to Claim 1, wherein the main body includes a suture opening.

3. Gist of the reasons given in this JPO decision

(1) The reasons for this JPO decision are as described in the written JPO decision (copy) in the attachment. In brief, [i] Present Invention 1 does not conform to the requirement provided for in Article 36, paragraph (6), item (i) of the Patent Act and violates the support requirement; and [ii] Present Inventions 1 to 6 could have been easily made on the basis of the invention described in Cited Document 1 in the following A and Cited Document 2 in the following B.

A. Cited Document 1: Paper titled "Pressure Test in contrast radiography CT using automatic injector from central venous reservoir" by TAKEUCHI Shuhei et al. (IVR INTERVENTIONAL RADIOLOGY, Vol. 20, No. 1, pp 27 to 30, issued on January 1, 2005, Exhibit Ko 9.)

B. Cited Document 2: The first to sixth editions of the document attached to "P-U Celsite Port" (Toray Industries, Inc., Toray Medical Co., Ltd. Prepared from July 1, 2002 to July 1, 2005, Exhibit Ko 10.)

(2) This JPO decision found common features and different features between the invention described in Cited Document 1 and Present Invention 1 as follows.

A. Invention described in Cited Document 1

An access port capable of injection of a contrast medium used for contrast radiography by an automatic injector for providing subcutaneous access to a patient, including /

a main body configured to hold a diaphragm, wherein /

the access port is used so as not to apply pressure not smaller than a maximum injection pressure indicated on a product specification; and /

the diaphragm is a diaphragm for repeated insertion of a needle through the diaphragm into a cavity defined in the main body (hereinafter referred to as the "Exhibit Ko 9 invention").

B. Common feature

An access port used in a computer tomographic scanning process for providing a subcutaneous access to a patient, including /

a main body configured to hold a diaphragm, wherein /

the access port is capable of injection by mechanical assistance and pressurization; / and /

the diaphragm is a diaphragm for repeated insertion of a needle through the diaphragm into a cavity defined in the main body.

C. Different features

(Different Feature 1) Present Invention 1 includes at least one identifiable feature of the access port configured to identify the access port capable of automatic injection through X-ray after subcutaneous implantation, correlated with information of the access port capable of automatic injection distinguishable from an access port not rated as capable of the automatic injection and visible by X-ray, while it is not clear whether the Exhibit Ko 9 invention includes such feature.

(3) The different feature between Present Invention 2 and the Exhibit Ko 9 invention found in this JPO decision other than Different Feature 1 is as follows.

(Different Feature 2) The main body of Present Invention 2 includes a housing, the housing has a discharge port and a cap which can be fixed to the housing, and the cap holds the diaphragm in the main body, while it is not clear whether the Exhibit Ko 9 invention is configured as such.

(4) The different feature between Present Invention 3 and the Exhibit Ko 9 invention found in this JPO decision other than Different Features 1 and 2 is as follows.

(Different Feature 3) The housing of Present Invention 3 includes the base for the housing which defines at least one container, while it is not clear whether the Exhibit Ko 9 invention is configured as such.

(5) The different feature between Present Invention 4 and the Exhibit Ko 9 invention found in this JPO decision other than Different Feature 1 is as follows.

(Different Feature 4) The main body of Present Invention 4 includes the housing which defines the cavity together with the diaphragm, and the cavity in fluid communication with the lumen of the discharge stem, while it is not clear whether the Exhibit Ko 9 invention is configured as such.

(6) The different feature between Present Invention 5 and the Exhibit Ko 9 invention found in this JPO decision other than Different Features 1 and 4 is as follows.

(Different Feature 5) The discharge stem of Present Invention 5 is configured to be connected to the catheter, while it is not clear whether the Exhibit Ko 9 invention

is configured as such.

(7) The different feature between Present Invention 6 and the Exhibit Ko 9 invention found in this JPO decision other than Different Feature 1 is as follows

(Different Feature 6) The main body of Present Invention 6 includes a suture opening, while it is not clear whether the Exhibit Ko 9 invention is configured as such.

4. Reasons for rescission

(1) Error in judgment on the support requirement (reason 1 for rescission)

(2) Error in judgment on inventive step of Present Invention 1 (reason 2 for rescission)

(3) Error in judgment on inventive step of Present Inventions 2 to 6 (reason 3 for rescission)

(omitted)

No. 4 Judgment of this court

1. Each of Present Inventions

(1) Description in Present Description

The scope of claims according to each of Present Inventions is as described in the aforementioned No. 2, 2, and the Detailed Description of the Invention in Present Description has the following description (for Figures 1A and 1B cited in the following description, see the list of drawings of Present Description in the attachment).

A. Background Art

[0003] An access port provides a convenient method for repeatedly sending out a substance to a remote region in a body without using a surgical operation. The port can be implanted as a whole in the main body (that is, subcutaneously) and enables infusion of a drug, drip pharmaceuticals, blood products, and other fluids. In addition, the port can be also used for blood sampling.

[0004] A typical port typically includes a housing assembly, a diaphragm, and a discharge port. The housing assembly and the diaphragm define a container to which an access can be made through the diaphragm. The discharge port of the housing can be made to communicate with a catheter accessing to a vein (blood vessel). As described above, the catheter can be used for sending a fluid to a remote

position in the body from the port or the ascending aorta, for example.

[0005] In ordinary working, the port is implanted in the body, and the catheter has its path determined to a remote region where sending-out of the fluid is desired. In order to send out the fluid, a caregiver checks the position of the diaphragm of the port by palpation of the patient's skin. A port access is achieved by a needle or typically a needle for subcutaneously inserting a non-coring needle into the container through the diaphragm of the port. Subsequently, the fluid such as a drug or other useful substance can be administered by a bolus injection or continuous infusion into the container. As described above, the fluid can flow into the catheter through the container and can finally flow to a portion where the fluid is desired.

B. Problems to be Solved by the Invention

[0007] In general, conventional access ports of various manufacturers or of various models can typically show substantially similar outer shapes that cannot be distinguished from each other. Therefore, once the access port is implanted, it might become difficult to find a model, format, or design of the access port. Particularly, if identification of the implanted access port cannot be found easily by another method, such uncertainty might not be desirable, at least for the purpose of replacement timing among other reasons.

[0008] It would be advantageous to provide an access port having at least one identifiable feature that can be detected after subcutaneous implantation of the access port or can be found by another method as described above.

C. Means for Solving the Problem

[0009] An aspect assumed by this disclosure relates to an access port for providing subcutaneous access to a patient. The access port capable of automatic injection according to the aspect of the present invention is used for a computer tomographic scanning process and includes a main body configured to hold a diaphragm and at least one identifiable feature of the access port configured to identify the access port capable of automatic injection through X-ray after subcutaneous implantation, correlated with information of the access port capable of automatic injection distinguishable from an access port not rated as capable of the automatic injection and visible by X-ray, the access port capable of automatic injection is capable of injection by mechanical assistance and of pressurization, and the diaphragm is a diaphragm for repeated insertion of a needle through the diaphragm into a cavity defined in the main body.

[0011] Another aspect of this disclosure relates to an access port for providing a subcutaneous access to a patient. Particularly, such access port can include a main body configured to hold a diaphragm, and the diaphragm is a diaphragm for repeated insertion of a needle through the diaphragm into a cavity defined in the main body. Moreover, the access port can include at least one feature configured to identify the access port so that automatic injection can be conducted after the subcutaneous implantation.

D. Description of Embodiments

[0013] This disclosure roughly relates to a subcutaneous access and more specifically to a method and a device related to the subcutaneous access. In general, this disclosure relates to an access port for subcutaneous implantation. In one embodiment, the access port enables doctors or other medical personnel to obtain the subcutaneous access for a long time to an interior of the body of a patient. By using the subcutaneous access port, a chance of contagion can be reduced by suppressing fluid connection from the skin of the patient or an external environment (spreading into the interior of the body of the patient). The access device enables an access to the inside of the patient without requiring a needle for inserting the skin. Moreover, an internal configuration component such as a catheter or a valve can be replaced without a surgical treatment. Various features or aspects of this disclosure can be applied to any such port for subcutaneous access to a patient without limitation. The access port is capable of manual injection (through a syringe including a needle, for example) and is capable of injection and pressurization by mechanical assistance (a so-called automatic injectable port, for example).

[0014] The automatic injectable port can be used in a computer tomographic ("CT") scanning process, for example, among other processes. More specifically, the so-called "automatic injector" system can be used for injecting a contrast medium into a venous (IV) line peripherally inserted. ...

[0015] More specifically, this disclosure relates to an access port having at least one feature perceivable or identifiable for identifying the access port, and the identifiable feature can be perceived after the access port is implanted in the patient. For example, at least one or a plurality of, depending on the case, identifiable features of the access port assumed by this disclosure can have a correlation with information related to the access port (a model or a design of the manufacturer, for example). As described above, the feature identifiable from a specific model of the access port is unique with respect to not all of but most of the other identifiable features of another

access port of a different model or design. Needless to say, at least one identifiable feature of the access port assumed by this disclosure can have a correlation with information of any aspect of interest such as a model of the port, the model of the catheter, date of manufacture, a material lot, a component number, and the like. In one working example, at least one identifiable feature of the access port can have a correlation with the access port capable of automatic injection. In this method, once at least one identifiable feature of the access port is observed or determined by another method, the correlation of the at least one feature of the access port can be achieved, and the information related to the access port can be obtained.

[0016] In one embodiment, the at least one feature can be perceived by palpation (that is, medical examination by touching), via other physical interactions or visual observation. Therefore, those concerned can touch or feel the access port through the skin in order to perceive at least one characteristic to be identified of the access port. In another embodiment, the at least one identifiable feature can be perceived through imaging of X-rays or ultrasonic waves. In still another embodiment, with regard to the at least one identifiable feature, interaction or communication with the access port can be perceived through magnetic energy, optical energy, or electric wave energy.

[0017] Here, in view of the embodiment in which the at least one feature can be perceived by palpation, other physical interactions, or visual observation, topography or an outer surface feature of the access port assumed by this disclosure can be formed for perception. For example, by reference to Figures 1A and 1B, a typical access port assumed by this disclosure is illustrated. Figures 1A and 1B illustrate a perspective view and a schematic side sectional view of the access port 10 which enables an internal access into the body of a patient by a subcutaneous access or other methods, respectively. The access port 10 includes a housing or a main body 20 defined by one cap 14 and one base 16. The cap 14 and the base 16 can be configured to hold a diaphragm 18 between them as is technically known. As illustrated in Figure 1A, the cap 14 and the base 16 can be mated and engaged with each other along a mating line 15. The cap 14 and the base 16 may be fixed or mounted to each other by a mechanical fastening tool such as a screw or other fastening device or may be bonded/fixed to each other, or as is technically known, they may be fixed to each other. Moreover, the cap 14, the base 16, and the diaphragm 18 can collectively define a cavity 36 in fluid communication with a lumen 29 of a discharge stem 31.

[0018] In order to arrange the cavity 36 subcutaneously in a patient 7, as illustrated in

Figure 1B, the main body 20 can be implanted in the patient 7. Moreover, a suture opening 66 (Figure 1A) can be used for fixing the access port 10 in the patient 7 as necessary. After the main body 20 is implanted in the patient 7, an upper surface of the diaphragm 18 can be substantially the same plane as a surface of the skin 6 of the patient 7, and in order to create a transcutaneous passage in the cavity 36 from an outside of the skin of the patient, a hole can be made repeatedly. The discharge stem 31 passes through the discharge stem 31 from the cavity 36 and can create a fluid-communication passage in the body of the patient 7. The catheter can be connected to the discharge stem 31 for fluid communication with the cavity 36 and for transferring the fluid from the cavity 36 to a desired separated position from the cavity 36 and in the patient 7.

[0020] According to this disclosure, the access port 10 can include the main body 20 indicating at least one identifiable feature. In more detail, as illustrated in Figure 1A, the main body 20 can indicate a partially approximately pyramid shape (that is, a base part of a polygon having a surface with respect to each side of a polygon extending to a common apex, also known as a frustum). In general, the main body 20 of the access port 10 can indicate a partially pyramid shape extending between a lower-side base of an approximately quadrilateral shape positioned on a reference surface 11 and an upper side base of an approximately quadrilateral shape positioned on the reference surface 9. For clarity, the reference surface 9 and the reference surface 11 are not illustrated in Figures 2 to 21. However, as used here, reference to the reference surface 9 or the reference surface 11 in relation with Figures 2 to 21 refers to a corresponding reference surface similar to the reference surface 9 and the reference surface 11 as illustrated in Figures 1A and 1B.

[0021] As illustrated in Figure 1A, an outer surface of the access port 10 is substantially defined by four substantially planar side surfaces 50 connected to each other by a plurality of radiuses 32. In addition, an upper-side outer shape portion 61 of the access port 10 is defined by an upper surface 60 connected to chamfered portions 46A and 46B and further defined by an upper surface of the diaphragm 18. By way of further explanation, an outer periphery of the upper-side outer shape portion 61 can be depicted as an outer surface of an approximately quadrilateral shape formed by four side regions 54 and having four rounded corner regions 30 adjacent to these side regions 54. Such a form can provide an access port having at least one feature which can be perceived by palpation.

[0046] This disclosure also specifies that the at least one feature of the access port assumed by this disclosure cannot be observed visually or by palpation or rather can

be observed by a method other than that. For example, this disclosure also specifies that at least one feature of the access port can be observed through an interaction with photographic arts such as X-ray or ultrasonic waves. For example, in one embodiment, metal features (a plate or other metal shapes, for example) can be included in the access port assumed by this disclosure. As can be understood, such metal features can be indicated by the X-ray generated by exposing an X-ray sensitive film to X-ray energy passing through the access port and by exposing the access port to the X-ray energy. Moreover, this disclosure also specifies that a size and a shape or both the size and the shape of the metal features of the access port are configured to improve identification of the access port. For example, assuming that the metal feature has a metal plate, the size, the shape, or both are selectively adjusted for identification of the access port. ...

(2) According to the aforementioned (1), the features of Present Invention are as follows.

Conventional access ports have substantially similar outer shape that in some cases cannot be distinguished from each other even if their manufacturers or models are different, and once the access port is implanted, it becomes difficult to find the model, format, or design of the access port, which is not preferable for a purpose of replacement timing or the like and thus, provision of an access port having at least one identifiable feature which is detected after subcutaneous implantation would be advantageous ([0007], [0008]).

Thus, Present Invention provides an access port capable of automatic injection [i] used for a computer tomographic scanning process and including a main body configured to hold a diaphragm, and [ii] at least one identifiable feature of the access port configured to identify the access port capable of the automatic injection through X-ray after subcutaneous implantation, correlated with information of the access port capable of automatic injection distinguishable from an access port not rated as capable of the automatic injection and visible by X-ray, [iii] capable of injection by mechanical assistance and of pressurization, and [iv] the diaphragm is a diaphragm for repeated insertion of a needle through the diaphragm into a cavity defined in the main body ([0009]).

2. Reason 1 for rescission (error in judgment on support requirement)

(1) Whether or not the description of the scope of claims conforms to the support requirement should be decided by comparing the description of the scope of claims

with the Detailed Description of the Invention and by examining whether the invention described in the scope of claims is the invention described in the Detailed Description of the Invention and whether it is within such a range that a person ordinarily skilled in the art could have recognized that the problem of the invention could be solved by the description in the Detailed Description of the Invention or whether a person ordinarily skilled in the art could have recognized that the problem of the invention could be solved in view of the general common technical knowledge as of the filing without the description or suggestion.

(2) The invention is described in Detailed Description of the Invention

According to the aforementioned 1(1), Present Description has description as "means for solving the problem" that "the access port capable of automatic injection according to the aspect of Present Invention is used for a computer tomographic scanning process and includes a main body configured to hold a diaphragm and at least one identifiable feature of the access port configured to identify the access port capable of automatic injection through X-ray after subcutaneous implantation, correlated with information of the access port capable of automatic injection distinguishable from an access port not rated as capable of the automatic injection and visible by X-ray, the access port capable of automatic injection is capable of injection by mechanical assistance and of pressurization, and the diaphragm is a diaphragm for repeated insertion of a needle through the diaphragm into a cavity defined in the main body." ([0009]) and in addition, the access port is capable of injection by mechanical assistance (port capable of automatic injection) and pressurization ([0013]), the port capable of automatic injection can be used in the computer tomographic ("CT") scanning process ([0014]), the typical access port 10 can be configured to hold the diaphragm 18 between the cap 14 and the base 16, they can collectively define the cavity 36 in fluid communication with the lumen 29 of the discharge stem 31 in the main body 20 ([0017], [0018], Figure 1A, Figure 1B), the identifiable feature can be perceived after the access port is implanted in the patient and can have the correlation with the access port capable of automatic injection ([0015]), and the identifiable feature can be one that can be perceived through imaging of X-ray such as a size, a shape, and the like of the metal plate ([0016], [0046]).

According to these descriptions, Present Invention 1 described in Claim 1 of the scope of claims is the invention described in the Detailed Description of the Invention in Present Description.

(3) Within such a range that person ordinarily skilled in the art can recognize that the problem of the invention can be solved

As described in the aforementioned 1(1), the "problem to be solved by the invention" in Present Description has the description that conventional access ports even of other manufacturers or of other models can have substantially similar outer shapes such that they cannot be distinguished from each other, and once the access port is implanted, it might become difficult to identify a model, format, or design of the access port, which leads to a problem that is not desirable for the purpose of replacement timing ([0007]), and provision of an access port having at least one identifiable feature which is detected after the subcutaneous implantation would be advantageous ([0008]).

Moreover, the "means for solving the problem" has such description that the access port is capable of manual injection (through a syringe including a needle, for example) or is capable of injection by mechanical assistance (so-called port capable of automatic injection, for example) and of pressurization ([0013], [0014]), and the identifiable feature of the access port can have a correlation with the information related to the access port (a model or a design of the manufacturer, for example) and can have a correlation with the access port capable of automatic injection ([0015]).

According to the description above, the solution to the problem of Present Invention 1 is found to be such that the access port is made identifiable as the access port capable of automatic injection after implantation of the access port capable of automatic injection and has "at least one identifiable feature of the access port configured to identify the access port capable of automatic injection through X-ray after subcutaneous implantation, correlated with information of the access port capable of automatic injection distinguishable from an access port not rated as capable of the automatic injection and visible by X-ray".

Moreover, Present Description has the description related to the "identifiable feature" that, other than those that can be perceived by palpation or visual observation, it may be one that can be perceived through imaging of X-ray such as the metal feature of a plate or other metal shapes, and the metal feature is indicated by the X-ray generated by exposing X-ray sensitive film to X-ray energy passing through the access port and by exposing the access port to the X-ray energy ([0016], [0046]), once the identifiable feature is observed or determined by another method, the correlation of at least one such feature of the access port can be achieved, and the information related to the access port can be obtained ([0015]).

It should be considered that a person ordinarily skilled in the art who contacted these descriptions can recognize that the "identifiable feature" can be perceived by exposing the access port employing the "identifiable feature" of Present Invention 1 to

X-ray, whereby the correlation with the "information distinguishable from an access port not rated as capable of the automatic injection" can be achieved, and the "information distinguishable from an access port not rated as capable of the automatic injection" can be obtained and as a result, it can be identified as capable of automatic injection after the subcutaneous implantation.

Thus, a person of ordinary skill in the art can recognize that Present Invention 1 described in Claim 1 of the scope of claims is within a range that can solve the problem of Present Invention 1 by the description in the Detailed Description of the Invention in Present Description.

(4) Defendants' allegation

Defendants allege that Present Description does not have any description or suggestion on how the "identifiable feature, visible by X-ray" and "the information of the access port capable of automatic injection distinguishable from the access port not rated as capable of automatic injection" are "correlated" with each other and thus, Present Invention 1 fails to satisfy the support requirement.

However, Present Description has the description that "the identifiable feature can have a correlation ... with the information related to the access port" and the "the feature identifiable from the access port is unique with respect to not all of the other identifiable features of another access port but most of them of a different model or design" ([0015]) and describes, as an example of the identifiable feature that can be perceived by palpation, the main body has a partially approximately pyramid shape ([0020], [0021], Figure 1A, Figure 1B) and as an example of the identifiable feature that can be perceived through imaging with X-ray, a size, a shape, or both the size and shape of the metal feature of the access port is selectively adjusted for identification of the access port ([0046]).

According to these descriptions, it is disclosed that the access port is made specifiable by making the "identifiable feature" a shape or a size specific to the access port and thus, "can have a correlation ... with the information related to the access port". Moreover, the "information of the access port capable of automatic injection distinguishable from the access port not rated as capable of the automatic injection" of the Present Invention 1 is the "information related to the access port" and thus, it should be considered that the aforementioned description can be understood as one of specific aspects of the "correlation" between the "information of the access port capable of automatic injection distinguishable from the access port not rated as capable of the automatic injection" and the "identifiable feature, visible by X-ray".

Thus, the allegation by Defendants cannot be employed.

(5) Summary

According to the above, Present Invention 1 does not violate the support requirement, and the reason 1 for rescission alleged by Plaintiff has reasons.

However, even if the judgment on compatibility of the support requirement has an error, if the other reasons for invalidation judged by this JPO decision have reasons, they do not influence the conclusion of this JPO decision and thus, the other reasons for rescission will be further examined below.

3. Reason 2 for rescission (error in judgment on inventive step of Present Invention 1)

(1) Invention described in Cited Document 1

A. Cited Document 1 has the following description (for Table 1 and Table 2 in the following sentences, see the list of drawings of Cited Document 1 in the attachment).

(A) Purpose (page 27, lower left column, line 1 to lower right column, line 3)

The implant-type central vein catheter method (CV reservoir) has widely spread for the purpose of anticancer therapy/central vein nutrition at home. In some cases it is indwelled for the purpose of maintaining veins, and, among these cases, a case where the contrast medium injection should be infused from the CV reservoir at the contrast CT is experienced.

However, though pressure resistance capability of a single port or a single catheter is described in an attached document, evaluation as a system integrating the catheter and the port has hardly been examined. Thus, at this time we examined the pressure resistance capability to see whether the CV reservoir indwelled in the subclavian vein can be used as a contrast medium administration path without incurring damage, and will report the result.

(B) Method (page 27, lower right column, line 4 to page 28, upper left column, line 9)

Used devices are an automatic injector (Auto Enhance A-50; Nemoto Kyorindo), an extension tube (extension tube for injector LX1 100 cm; TOP), and an injection needle (Coreless needle without side tube 20G/22G; Nipro). The port and the catheter used in the experiment are shown in Table 1 (note by the court: Table 1).

As an experiment system, a distal end of a catheter having a length of 20 cm was immersed in a container filled with a physiological saline solution (Fig. 1), and iopamidol (Iopamiron 300 syringe; Nihon Schering K.K.) with iodine concentration of

300 mgI/ml was injected by using the automatic injector in that state under the same conditions as in actual contrast imaging (1.5 ml/sec, 3.0 ml/sec, 5.0 ml/sec).

An injection pressure at respective injection speeds was measured when the pressure became constant on a pressure monitor of the automatic injector, and an average value of three sessions of the measurement was used. Observation items were catheter breakage/port breakage/catheter deviation.

Moreover, the injection pressure was measured similarly by changing a thickness of a puncture needle and the length of the catheter. A pressure limit is usually set to an actual measurement injection pressure of 10 kg/cm^2 or less recommended in the document attached to Iopamiron syringe, but in this experiment it was set to 15 kg/cm^2 or less.

(C) Result (page 28, left column, line 10 to right column, last line)

Each of the injection speeds and injection pressures and a situation of the system are illustrated in Table 2 (note by the court: Table 2).

1. Injection speed 1.5 ml/sec

When a 22G Huber-pointed needle and an extension tube were used, the injection pressure was 6.3 ± 1.83 kg/cm^2 (average: 6.3 kg/cm^2), and when a 20G Huber-pointed needle was used, the injection pressure was 4.7 ± 1.45 kg/cm^2 (average: 4.7 kg/cm^2). Breakage of the system was not found in either case.

2. Injection speed 3.0 ml/sec

When a 22G Huber-pointed needle and an extension tube were used, the injection pressure was 13.3 ± 1.09 kg/cm^2 (average: 13.3 kg/cm^2), and when a 20G Huber-pointed needle was used, the injection pressure was 10.6 ± 4.13 kg/cm^2 (average: 10.6 kg/cm^2). Breakage of the system was not found in either case.

In Ark port, Cliny reservoir system, pressure limit was applied at the injection pressure limit of 15 kg/cm^2. Breakage of the system was not found.

3. Injection speed 5.0 ml/sec

The pressure limit was applied at the injection pressure limit of 15 kg/cm^2 in all of eight types of combinations used at this time, but breakage of the system was not found.

(D) Consideration

a. With spread of the CV reservoir, adaptation has been expanded for the cases in

which peripheral veins cannot be maintained easily. However, when contrast CT is to be carried out for such a case, the peripheral vein on the side opposite to the indwelling has been maintained. Contribution could be made to improvement of the patient QOL if administration from the CV reservoir can be realized, but a concern of incurring system breakage cannot be ignored and in practice it has not been used.

The pressure resistance capability of a single port or a single catheter is described in the attached document of each manufacturer, but evaluation as the CV reservoir system including matching between the port and the catheter has not yet been established. Thus, actual measurement injection pressure was measured under a plurality of contrast conditions, and in this experiment possibility of system breakage was also evaluated to see whether or not the CV reservoir indwelled in the subclavian vein is usable as a contrast medium administration path without incurring system breakage. (the above for page 29, left column, lines 13 to 27).

b. In the experiment circuit employed this time, a pressure monitor of an injector was used as simple monitoring at a usual treatment scene. Moreover, when a vein system is assumed, ...it is thought that, by immersing the catheter distal end in a physiological saline solution still in an open system, the state would be closer to a physiological state.

John and others stated that the pressure at the injection applied to a catheter connection portion can be acquired by subtraction of the injection pressure when the catheter is connected from that without connection. Thus, in the present experiment, the pressure applied into the port and the catheter was acquired by calculation by subtracting the pressure when only the Huber needle 20G and the extension tube were connected and injection was performed, from the injection pressure of the entire system. When only the Huber needle 20G and the extension tube were connected and injection was performed at 1.5 ml/sec, the result of 3.3 kg/cm^2 was obtained and thus, the pressure of 1.5 to 2.3 kg/cm^2 is mathematically applied in the periphery from the Huber needle, but this value was a value not larger than the pressure resistance performances of 20 to 42.7 psi (1.4 to 3 kg/cm^2) described in the attached document of each port manufacturer.

From the examination conducted this time, it was considered that when iopamidol (Iopamiron 300 syringe; Nihon Schering K.K.) with iodine concentration of 300 mgI/ml was used at actual injection, injection at 3.0 ml/sec is possible by using Huber needle 20G without a side tube from the CV reservoir. The Huber needle 22G can also be used, but since the injection pressure of the entire system is raised,

approximately 1.5 ml/sec was considered to be appropriate as a speed for safe injection (the above for page 29, left column, line 35 to right column, line 28).

c. In the experiment circuit employed this time, evaluation was made in a state different from a perfect physiological condition and where the port was not deteriorated at all. Therefore, to see whether the result can be fully applied to clinical examples, accumulation of future cases is needed, but as one of targets of contrast radiography from the CV reservoir, it was considered that injection in an injection amount of approximately 1.5 ml/sec can be conducted safely without incurring breakage of the system, and by using 20G, injection at 3.0 ml/sec is also possible (the above for page 29, right column, line 2 from the bottom to page 30, left column, line 6).

(E) Summary (page 30, left column, lines 7 to 15)

Examination on the pressure resistance capability was conducted in terms of on whether the CV reservoir indwelled in the subclavian vein can be used as a contrast medium administration path without incurring breakage. It was considered that the contrast radiography from the CV reservoir can be performed safely without incurring breakage of the system with the injection speed of 1.5 ml/sec when the 21G puncture needle was used and with the injection speed of approximately 3.0 ml/sec when the 20G puncture needle is used. Evaluation of the pressure resistance capability and evaluation of durability by each manufacturer is desired in the future, including matching between the catheter and the port.

B. According to the above, Cited Document 1 discloses the following matters.

The CV reservoir has widely prevailed for the purpose of anticancer therapy / central venous nutrition at home. In some cases they are indwelled for the purpose of ensuring the veins, and in some of these cases the contrast medium should be injected from the CV reservoir at the contrast radiography CT. However, although the pressure resistance capability of the single port or the single catheter is described in the attached document of each manufacturer, the evaluation as the CV reservoir system has not been established, including matching between the port and the catheter. Thus, actual measurement injection pressures were measured under a plurality of contrast radiography conditions in order to determine whether the CV reservoir indwelled in the subclavian vein can be used as a contrast medium administration path without incurring breakage of the system, and evaluation was made also for

possibility of the system breakage (aforementioned A(A), (D)a).

Used equipment was an automatic injector (Auto Enhance A-50; Nemoto Kyorindo), an extension tube (extension tube for injector LX1 100cm; TOP), and an injection needle (Coreless needle without side tube 20G/22G; Nipro), and eight types of the port and the catheter were used, including "P-U CELSITE PORT (P-U) by "Toray" (aforementioned A(B) and Table 1).

Assuming a venous system, it was considered that, by immersing the catheter distal end in a physiological saline solution remaining in an open system, the state would get closer to a physiological state, and as an experiment system, the catheter distal end with a length of 20 cm was immersed in a container filled with the physiological saline solution, and Iopamidol with iodine concentration of 300 mgI/ml was injected under the same condition (1.5 ml/sec, 3.0 ml/sec, 5.0 ml/sec) as that in actual contrast radiography by using the automatic injector in that state (aforementioned A(B), (D)b).

As the result of the experiment, no breakage of the system was found in any of the combinations of the eight types of ports and catheters including the Toray port, and when the pressure applied into the port and the catheter was calculated for the case in which the Huber needle 20G was used at the injection speed of 1.5 ml/sec, the value was not larger than the pressure resistance capability described in the attached document of each port manufacturer. With regard to whether the result can be fully applied to clinical examples, accumulation of future cases is needed, but as one of targets of contrast radiography from the CV reservoir, it is considered that injection at an injection speed of approximately 1.5 ml/sec can be conducted safely without incurring breakage of the system (aforementioned A(C), (D)b, c, (E), Table 2)

C. According to the aforementioned description, the Toray port is [i] a CV reservoir (access port) indwelled in a patient for the purpose of maintaining the vein; and [ii] when the catheter distal end is immersed in the physiological saline solution assuming the venous system and by injecting the contrast medium (Iopamidol) under the same conditions as those for the actual contrast radiography using the automatic injector, system breakage is not found, and [iii] it is understood that the injection speed of approximately 1.5 ml/sec can be used as a contrast medium administration path of the contrast radiography CT.

Then, it is found that the Cited Document 1 describes the "Toray port which is an access port for providing a subcutaneous access to a patient, used for contrast radiography CT and capable of injection of the contrast medium and pressurization by

mechanical assistance by the automatic injector" (hereinafter referred to as "Cited Invention").

D. Allegation by the parties

(A) Allegation by defendants

Defendants allege that in order to understand the contents of the configuration of the invention of the Toray port described in Cited Document 1, referring to Cited Document 2 which is an attached document to the Toray port is allowed, and the finding in this JPO decision of the Exhibit Ko 9 invention from both Cited Document 1 and Cited Document 2 has no error.

However, in finding of the "invention described in publication" (Article 29, paragraph (1), item (iii) of the Patent Act), to find the described matter of a specific publication and the described matter of a different independent publication in combination is equal to judgment on inventive step brought into the judgment on novelty, which contradicts the gist of the Patent Act employing a structure of judgment separately for the inventive step and novelty and should not be allowed in principle.

Thus, the Exhibit Ko 9 invention cannot be found from the description in Cited Document 1 which is a paper describing the experiment result related to the pressure resistance capability using the Toray port and Cited Document 2 which is an attached document describing the specification and the use conditions of the Toray port with an author and a date both different from those of Cited Document 1. Cited Document 1 does not have description on a specific configuration of the Toray port, and it cannot be found that the specific configuration of the Toray port was general common technical knowledge at the time of the priority date of the present application and thus, it cannot be considered that the Exhibit Ko 9 invention is substantially disclosed in Cited Document 1.

Thus, the aforementioned allegation by Defendants cannot be employed.

(B) Allegation by Plaintiff

Plaintiff alleges that the disclosure in Cited Document 1 is only an experiment result under specific conditions, and whether it can be fully adapted clinically is reserved and thus, the configuration "capable of injection of the contrast medium by mechanical assistance by the automatic injector and of pressurization" is not disclosed.

However, since Cited Document 1 discloses that "no breakage was found in any of

the experiments in which Iopamidol with iodine concentration of 300 mgI/ml was injected at each of the injection speeds of 1.5 ml/sec, 3.0 ml/sec, and 5.0 ml/sec with maximum pressurization of 15 kg/cm^2 as a limit by mechanical assistance by the automatic injector" in the Toray port, it is obvious that the Toray port is "capable of injection of the contrast medium and pressurization by mechanical assistance by the automatic injector". It should be considered that the description in Cited Document 1 that "with regard to whether the result can be fully applied to clinical examples, accumulation of future cases is needed" points out that accumulation of cases is needed to fully apply the system combining the Toray port and the catheter as an input path of the contrast medium and does not deny that the Toray port itself is capable of injecting the contrast medium by the automatic injector.

Thus, the aforementioned allegation by Plaintiff cannot be employed.

E. As described above, the finding of the Exhibit Ko 9 invention in this JPO decision is an error. Moreover, whether Present Invention 1 could have been easily conceived of on the basis of the correctly found Cited Invention will be judged.

(2) Common Feature and Different Feature between Present Invention 1 and Cited Invention

Common Feature and Different Feature between Present Invention 1 and the Cited Invention are as follows.

A. Common Feature

An access port for providing subcutaneous access to a patient, used in a computer tomographic scanning process, the access port being capable of injection and pressurization by mechanical assistance by an automatic injector.

B. Different Features

(A) Same as Different Feature 1 between Present Invention 1 and the Exhibit Ko 9 invention

(B) Present Invention 1 includes the main body configured to hold the diaphragm, and the diaphragm is a diaphragm for repeated insertion of a needle through the diaphragm into a cavity defined in the main body, while it is not clear whether the Cited Invention has such configuration (Different Feature X)

(3) Whether Different Feature X could be easily conceived of

A. Described matters of Cited Document 2

Cited Document 2 "prepared on July 1, 2002 (new format, first edition)" has the

following description (the similar contents are described also in "Revised on August 1, 2002 (second edition)", "Revised on March 1, 2003 (third edition)", "Revised on February 1, 2004 (fourth edition)", "Revised on June 23, 2004 (fifth edition)", and "Revised on July 1, 2005 (sixth edition)").

(A) Page 1, upper column

Medical device authorization number: 20900BZZ00772000

Device/instrument 74 drug injector implant-type drug injector

P-U Celsite port (single item type)

(B) Page 1, left column

[Warning] This product is designed exclusively for Anthron ® P-U catheter. Connect to Anthron ® P-U catheter. If connected to those other than it, the port and the catheter are not reliably connected to each other, and nonconformity such as removal of the catheter and the like can occur.

[Contraindication/prohibition]

Comply with the following matters on contraindication/prohibition.

1) Re-use prohibited.
2) No pressurization higher than the maximum injection pressure which will be described later. ...

[Contraindication for coadministration]

At port puncture, do not use those other than a non-coring needle. If a puncture needle other than the non-coring needle is used, there is a concern that durability of the septum can be drastically deteriorated.

(C) Page 1, right column

Product specification

1) Port

(Table in the list of drawings and tables of Cited Document 2 in the attachment)

2) Non-coring needle 22G x 30 mm (straight)

[Performance, intended use, efficacy or effect]

This product is intended to be installed in the body as a subcutaneous implant type catheter access system and for administering a drug solution into a blood vessel transcutaneously.

(D) Page 2, left column

Implantation of the port
[v] Inject a physiological saline solution by using a 22G no-coring needle and a syringe, and check that there is no catheter obstruction, liquid leakage, or the like. Check the position of a catheter distal end as necessary.
(Figure in the list of drawings and tables of Cited Document 2 in the attachment)

(F) Page 3, left column
[Name, address, and the like of manufacturer]
'TORAY'
[Manufactured by]
Toray Industries Inc.

B. As described in the aforementioned A, Cited Document 2 describes that the Toray port includes a main body and a diaphragm for repeated insertion of a needle into a cavity of the main body.

Moreover, there is motivation to combine the Toray port described in Cited Document 1 with the matters described in Cited Document 2 which is the attached document of the Toray port, and Plaintiff does not argue that the configuration of Different Feature X could have been easily conceived of.

Thus, Different Feature X could have been easily conceived of by combining the described matters of Cited Document 2 with Cited Invention.

(4) Whether Different Feature 1 could be easily conceived of
A. Described matter in each document

The documents at the time of priority date of the present application have the following respective descriptions (Exhibit Ko 11 Figure 10, Exhibit Ko 12 Figures 2-1, 2-3, 2-4 in the following description are as in the list of drawings of the well-known examples in the attachment).
(A) The Description of U.S. Patent No. 5851221 (Exhibit Ko 11) discloses [i] in an implant type medical device manufactured by attaching a header module 12 formed in advance to a hermitic sealed housing 14, a housing 20 of the header module 12 includes a radiopaque ID plate 60 (eighth column, lines 23 to 34, Figure 10); [ii] the implant type medical device includes an implantable drug supplying device, an IPG (a cardiac pacemaker, a pacemaker, a cardioverter, a stimulator for nerves, muscles, and a nerve stimulator, a cardiac muscle stimulator, and the like), an implant type cardiac signal monitor and recorder, and the like (sixth column, lines 39 to 54).

(B) The manual of IsoMed (Exhibit Ko 12) is a clinical reference guide for injection treatment of a hepatic artery and discloses [i] the IsoMed injection system includes an IsoMed constant rate pump and a Medtronic blood-vessel catheter, and when it is used for hepatic artery injection of a chemotherapeutic drug, first, the catheter is connected to the pump, the pump is arranged in a subcutaneous hole in an abdomen part, the catheter is passed in the abdominal wall, and an end portion thereof is arranged in the gastroduodenal artery or the like (page 2-2, lines 1 to 8, Figure 2-1); [ii] The IsoMed constant rate pump has a reservoir for storing a chemotherapeutic drug or a heparinization liquid drug, and a self-sealing diaphragm and includes a center reservoir fill port capable of accessing the reservoir by a refill needle (page 2-3, lines 14 to 18, page 2-4, lines 1 to 6, Figure 2-3); and [iii] the IsoMed constant rate pump further includes an X-ray identification tag or the like, and the X-ray identification tag records a Medtronic identifier, a pump model number, and a volume and a flowrate of the reservoir (page 2-4, lines 10 to 14, Figure 2-4).

(C) The paper titled "The radiology of cardiac pacemakers" by Robert M. Steiner et al. (RadioGraphics, Vol, 6, No. 3, pp 373 to 399, Exhibit Otsu 1) discloses that an X-ray image of a generator is useful for identification of a manufacturer, a type, and an operation mechanism of the pacemaker, but since several tens of manufacturers manufacture several hundreds of models, and there is no doctor who is familiar with all the pacemakers in distribution, and therefore a reference chart indicating an appearance on the X-ray image or a radiopaque code usually provided from the manufacturer is usable (page 379).

(D) The paper titled "Implantable Cardioverter-Defibrillators: Implications for the Nonelectrophysiologist" by Sergio L. Pinski et al. (Annals of Internal Medicine Vol. 122, No. 10, pp 770 to 777, Exhibit Otsu 2) discloses that, since the implantable defibrillators by all the manufacturers have radiopaque identifiers, the device can be identifiable in emergency by transmitting X-rays (page 771, left column, lines 14 to 26).

(E) The paper titled "Cardiac Rhythm Management Devices (Part II) Perioperative Management" by John L. Atlee et al. (Anesthesiology, Vol. 95, No. 6, pp 1492 to 1506, Exhibit Otsu 3) discloses that most of existing pacemakers and ICDs have unique radiopaque codes (signatures by X-ray or on an X-ray image) which can identify the manufacturer and the model of the device engraved by seeing chest X-ray photographs of regions where these devices are implanted (page 1502, left column, line 11 to right column, line 15).

(F) U.S. Patent No. 4863470 Description (Exhibit Ko 14) discloses that [i]

implants for breasts, penises, bladders, devices for incontinence, and the like are preferably easily identifiable both before and after the implantation in the body (first column, lines 14 to 35); [ii] by having a radiolucent portion surrounding a radiopaque identification marker included in the implant for subcutaneous implantation, the identification marker can be visually recognized before the implantation and can be read by X-ray photographing after the implantation (first column, lines 49 to 57); and [iii] the identification marker can indicate a manufacturer, a year of manufacture, a type, and the like in addition to a size of the implant (second column, lines 30 to 46).

B. Finding of well-known arts

(A) According to the described matters in the aforementioned A, in medical equipment used by being implanted in human bodies such as a medical device for the heart (Exhibit Ko 11, Exhibits Otsu 1 to 3), a subcutaneous implant type drug solution injector (Exhibit Ko 12), an artificial breast (Exhibit Ko 14), and the like, inclusion of the radiopaque identifier including information specifying the device after being implanted in the human body; that is, a feature identifiable and visible by X-ray, is found to be a well-known art which had been already employed at a clinical level at the time of priority date of this case.

(B) Allegation by Plaintiff

Plaintiff alleges that to inclusion of the X-ray visible feature cannot be found to be a well-known art in medical equipment in general used by being implanted in the human body, on the basis of only two cases of the inventions described in the documents of Exhibits Ko 11 and 12, and even if the descriptions in each of the documents of Exhibits Otsu 1 to 3 and Exhibit Ko 14 are considered, the matters disclosed in them are medical equipment for the heart used by being implanted in the human body and thus, cutaneous implant type medical equipment in general including the access port cannot be found to be a well-known art.

However, inclusion of a feature indicating a model number of the device visible by X-ray had been performed in a variety of medical devices used by being implanted in the human body not only as medical equipment for the heart but also as a pump for inputting an anticancer drug to an artificial breast and the hepatic artery is as described in the aforementioned A.

By considering that Exhibit Ko 12 describes that a hepatic-artery injection pump of chemical therapy drug solution is arranged in a subcutaneous hole in the abdomen part, and a drug solution is injected from outside the body, and that Exhibit Ko 11 cites a drug solution supply device other than a cardiac pacemaker, an implantable

defibrillator, and the like as examples of medical equipment including a radiopaque ID plate 60 as a feature visible by X-ray and suggests the application of drug solution supply, inclusion of the feature visible by X-ray indicating the model number of the device is found to be a well-known art also in the cutaneous implant type medical equipment including the access port, and Plaintiff's aforementioned allegation cannot be employed.

C. Judgment on whether it could have been easily conceived of

(A) Cited Invention is a subcutaneous implant type access port used for injecting a contrast medium in contrast radiography CT and belongs to the same technical field as that of the well-known art in the aforementioned B in the field of medical equipment used by being implanted in the human body. Moreover, there is no factor teaching away from the application of the aforementioned well-known art to Cited Invention. Then, application of the aforementioned well-known art to the Cited Invention so as to include the identifiable feature, visible by X-ray, including the information specifying the device after being implanted in the human body could have been easily conceived of by a person ordinarily skilled in the art.

The information specifying the "access port capable of automatic injection" which is the Cited Invention is information which can distinguish the access port capable of automatic injection from an access port not rated as capable of the automatic injection. Then, since the aforementioned "information" can be identified by the identifiable feature, visible by X-ray, including the information specifying the Cited Invention, it can be considered that the aforementioned "at least one" identifiable feature" of the access port" is "correlated" with the "information of the access port capable of automatic injection distinguishable from the access port not rated as capable of automatic injection".

Thus, application of the aforementioned well-known art to the Cited Invention so as to have the configuration according to Different Feature 1 could have been conceived of by a person ordinarily skilled in the art as appropriate.

(B) Plaintiff's allegation

Plaintiff alleges that the "correlation" of Present Invention needs to be such that the "identifiable feature" is directly given the meaning indicating "capable of automatic injection" on the basis of the information described in the attached document, and doctors and the like are required to understand the meaning of the "identifiable feature" on the basis of the attached document, and indication of only the

"port model" does not have the direct meaning of whether or not it is "capable of automatic injection" and there cannot be the "correlation with the access port capable of automatic injection", and thus it is not applicable to the "identifiable feature correlated with the information of the access port capable of automatic injection distinguishable from an access port not rated as capable of automatic injection and visible by X-ray".

However, the scope of claims of Present Invention 1 does not limit a specific aspect of the "correlation", and Present Description does not have any description or suggestion, either, on the "correlation" that the "identifiable feature" needs to be directly given the meaning indicating "capable of automatic injection" on the basis of the information described in the attached document, and doctors and the like are required to understand the meaning of the "identifiable feature" on the basis of the attached document and the like.

Moreover, according to the description in Present Description of this case that "once at least one identifiable feature of the access port is observed or determined by another method, the correlation of the at least one feature of the access port can be achieved, and the information related to the access port can be obtained" ([0015]), it can be understood that, when the "correlation" between the "identifiable feature" and the "information related to the access port" is achieved, the "information related to the access port can be obtained" from the "identifiable feature" and thus, the access port can be specified, but it is interpreted that a person ordinarily skilled in the art can set the specific aspect as appropriate.

Thus, Plaintiff's aforementioned allegation cannot be employed.

(5) Summary

According to the above, since Present Invention 1 could have been easily made by applying the described matters of Cited Document 2 and the well-known art to the Cited Invention and thus, the reason 2 for rescission is not grounded.

4. Reason 3 for rescission (error in judgment on inventive step of Present Inventions 2 to 6)

Present Inventions 2 to 6 all cite the invention specifying matters of Present Invention 1 directly or indirectly, and Different Feature 1 could have been easily conceived of as described in the aforementioned 3. Moreover, Plaintiff does not allege/prove that Different Features 2 to 6 could not have been easily conceived of.

Thus, since inventive step is found lacking also in Present Inventions 2 to 6, the

reason 3 for rescission is not grounded.

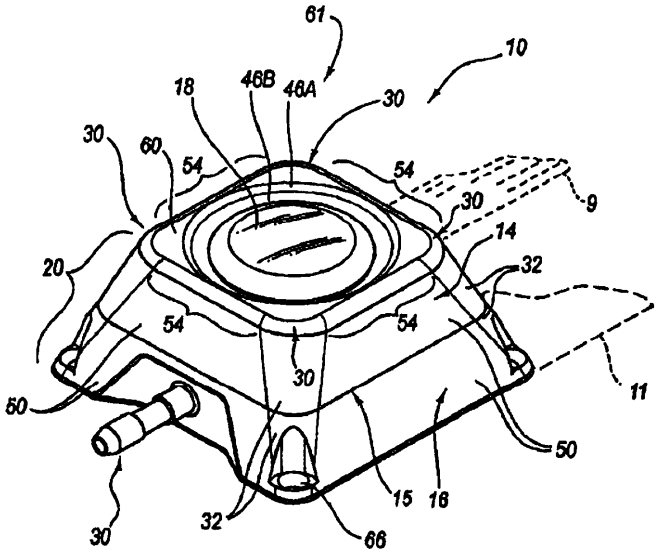
5. Conclusion

According to the above, this JPO decision is reasonable in the conclusion, and Plaintiff's request is not grounded and thus, it shall be dismissed, and the judgment is made as in main text.

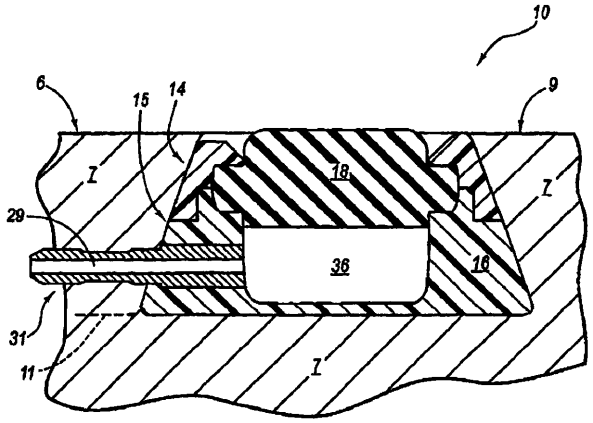
Intellectual Property High Court, First Division
Presiding judge: TAKABE Makiko
Judge: KOBAYASHI Yasuhiko
Judge: SEKINE Sumiko

Attachment: List of drawings in Present Description of this case

[Figure 1A]



[Figure 1B]



Attachment: List of drawings and tables in Cited Document 1

Table 1 Physical characteristics of catheter and implant port

implant port including catheter		diameter	manufacturer	maximum withstand pressure
Groshong M.R.I. Plastic Port (MRI-G)		8 Fr (12G)	BARD	25psi
Open-Ended M.R.I. Plastic Port (MRI)		6.6 Fr (14.5G)	BARD	25psi
ARCPORT	(ARC)	6 Fr (14G)	CLINICAL SUPPLY	40psi
P-UCELSITE PORT	(P-U)	6 Fr (14G)	TORAY	
VITAL-PORT	(VIT)	5 Fr (16G)	COOK	40psi
CLINY Port System	(CLI)	5 Fr (16G)	CREATE MEDIC	21.7psi
implant port				
SEPTUM-PORT	(SEP)	6 Fr	SUMITOMO BAKELITE	42.7psi
SOPH-A-PORT	(SOP)	6 Fr	SOPHYSA	
implant catheter				
BIOLINE	(BIO)	14 G (5.7Fr)	NIPRO	
MU catheter kit	(MU)	14 G (5.7Fr)	MEDIKIT	

Table 2 Injection pressure of Iopamiron 300

needle size		20G	20G	22G	22G
flowrate (ml/second)		3.0	1.5	3.0	1.5
SEP+BIO	14G	8.4	4.0	13.1	6.0
SOP+MU	14G	8.2	3.8	12.9	5.8
MRI−G	12G	8.9	4.0	12.8	5.4
MRI	14.5G	11.2	5.0	13.1	5.4
P-U	14G	11.5	4.6	13.3	5.5
VIT	14G	10.4	4.7	14.3	6.7
ARC	16G	12.1	5.3	*	7.6
CLI	16G	14.2	5.9	*	7.6

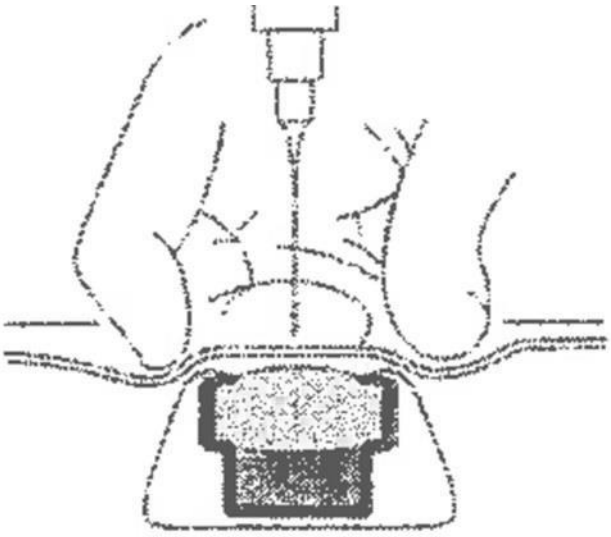
* Since injection pressure exceeds 15.0 kg/cm^2, injection at this rate was impossible.

Attachment: List of drawings and tables in Cited Document 2

Table

	large	small	brachial
durable number of times of puncture	2000	2000	1000
length of bottom part	31 mm	26 mm	22 mm
width of bottom part	27 mm	22 mm	18 mm
weight	8 g	5 g	2.5 g
priming capacity	0.5 mL	0.3 mL	0.2 mL
septum diameter	12.5 mm	9.5 mm	7.6 mL
height from septum to bottom surface	12.2 mm	9.7 mm	8.7 mm
withstand pressure MPa (psi)	2.10 (300)	2.10 (300)	2.10 (300)

Figure



Attachment: List of drawings in well-known examples

Exhibit Ko 11, Figure 10

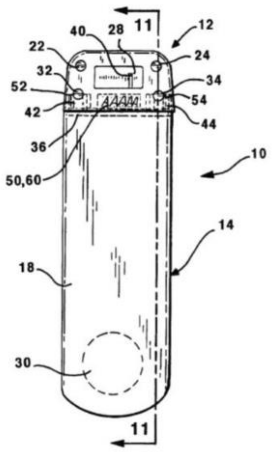


Exhibit Ko 12, Figure 2-1 (arrangement position of pump at hepatic artery injection treatment)

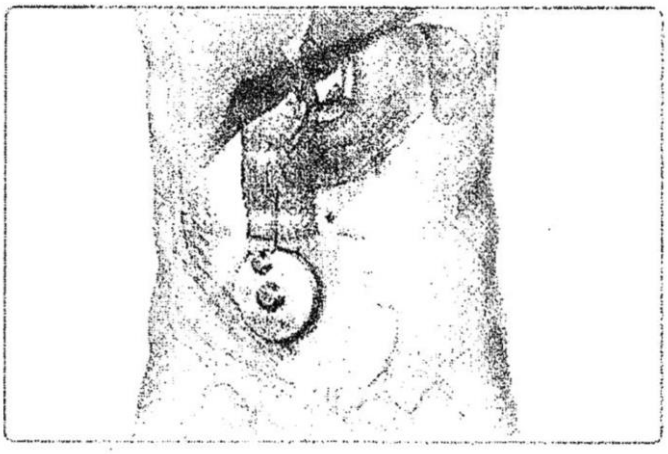


Exhibit Ko 12, Figure 2-3 (sectional view of IsoMed pump)

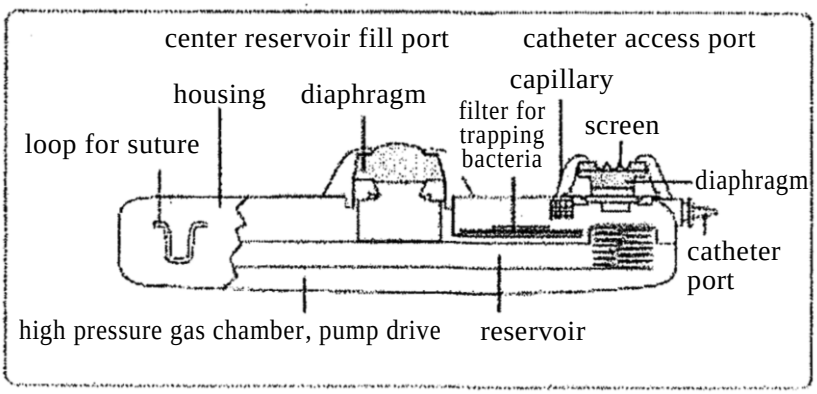


Exhibit Ko 12, Figure 2-4 (IsoMed identification tag)