Trial Decision

Invalidation No. 2017-800070

Demandant	B. Braun Aesculap Japan Co., Ltd.
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Demandant	B. Braun Medical SAS
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The case of trial regarding the invalidation of Japanese Patent No. 6018822, entitled "Access Port and Identification Method thereof" between the parties above has resulted in the following trial decision.

Conclusion

The patent for the invention according to Claims 1 to 6 of Japanese Patent No. 6018822 shall be invalidated.

The costs in connection with the trial shall be borne by the Demandee.

Reason

No. 1 History of the procedures

The application for the invention according to Japanese Patent No. 6018822 is a divisional application (Japanese Patent Application No. 2012-156976, hereinafter, referred to as the application of the Patent) filed on July 12, 2012 from Japanese Patent

Application No. 2007-558331 filed on March 6, 2006 (Priority claim: March 4, 2005 (hereinafter, referred to as "the priority date")) as an international filing date, and the establishment of patent right was registered on October 7, 2016.

Then, on May 22, 2017, a demand for invalidation trial of the case for the Patent was made by the Demandant, B. Braun AESCULAP Inc., and the Demandant B. Braun Medical SAS (hereinafter, referred to as the Demandants"), making the Demandee CR BARD INCORPORATED.

The subsequent history of the procedures relating to the demand for invalidation trial is as follows.

May 22, 2017	Demand for invalidation trial of the case
September 25, 2017	Submission of Written reply of trial case
December 21, 2017	Submission of Oral proceedings statement brief by the Demandants
January 15, 2018	Submission of Oral proceedings statement brief by the Demandee
January 23, 2018	Oral proceedings
January 30, 2018	Submission of Written statement by the Demandants
February 13, 2018	Submission of Written statement by the Demandee
April 5, 2018	Advance notice of trial decision

There was no response to the advance notice of trial decision from the Demandee.

In this trial decision, when the reference part is specified with lines, the number of lines does not include blank lines.

No. 2 The Patent Invention

The inventions according to Claims 1 to 6 of the Patent are as follows, as specified by the matters described in Claims 1 to 6 of the scope of claims of the Patent.
(Hereinafter, the inventions according to Claims 1 to 6 of the Patent are referred to as "Patent Invention 1" to "Patent Invention 6," respectively.)

"[Claim 1]

An automatically injectable access port for providing subcutaneous access to a patient, which is used for a computed tomographic scan process, comprising:

a body configured to hold a septum; and

an identifiable feature that is configured to identify the automatically injectable access port via an X-ray after subcutaneous implantation, is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port of at least one of the access port, and is visible by the X-ray,

wherein the automatically injectable access port can be injected and pressurized by mechanical assistance, and

wherein the septum is a septum for repeatedly inserting a needle into a cavity defined in the body through the septum.

[Claim 2]

The automatically injectable access port according to Claim 1, wherein the body is equipped with a housing,

the housing having a discharge port and a cap capable of being fixed to the housing,

the cap holding the septum in the body.

[Claim 3]

The automatically injectable access port according to Claim 2, wherein the housing is equipped with a housing base defining at least one container.

[Claim 4]

The automatically injectable access port according to Claim 1, wherein the body is equipped with a housing defining a cavity with the septum, and

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

[Claim 5]

The automatically injectable access port according to Claim 4, wherein the discharge stem is configured to couple with a catheter.

[Claim 6]

The automatically injectable access port according to Claim 1, wherein the body is equipped with a suture aperture".

No. 3 The allegation of the Demandants

The object of the demand alleged by the Demandants is to seek the trial decision that the patent for Patent Inventions 1 to 6 shall be invalidated.

Further, the object of the demand is as follows in view of the descriptions of the written demand for trial, the oral proceedings statement brief dated on December 21, 2017, and the written statement dated January 30, 2018.

1 Reasons for invalidation

(1) Reason for invalidation 1

Since the inventions according to Claims 1 to 6 of the Patent are not described in the detailed description of the invention of the application according to the Patent, the Appellant should not be granted a patent for the invention in accordance with the provisions of Article 36(6)(i) of the Patent Act, and the patent falls under Article 123(1)(iv) of the Patent Act and thus should be invalidated.

(2) Reason for invalidation 2

Since the inventions according to Claims 1 to 6 of the Patent are not clear, the Appellant should not be granted a patent for the invention in accordance with the provisions of Article 36(6)(ii) of the Patent Act, and the patent falls under Article 123(1)(iv) of the Patent Act and thus should be invalidated.

(3) Reason for invalidation 4

(3-1) Patent Invention 1

(A) Since the invention according to Claim 1 of the Patent could have been easily invented by a person skilled in the art based on the inventions described in Evidence A No. 9, Evidence A No. 10-1, Evidence A No. 11, and Evidence A No. 12, the Appellant should not be granted a patent for the invention in accordance with the provisions of Article 29(2) of the Patent Act, and the patent falls under Article 123(1)(ii) of the Patent Act and thus should be invalidated.

(B) Since the invention according to Claim 1 of the Patent could have been easily invented by a person skilled in the art based on the inventions or technical matters described in Evidence A No. 9, Evidence A No. 10-1, Evidence A No. 11, Evidence A No. 12, Evidence A No. 14, Evidence A No. 15, Evidence A No. 17, and Evidence A No. 18, the Appellant should not be granted a patent for the invention in accordance with the provisions of Article 29(2) of the Patent Act, and the patent falls under Article 123(1)(ii) of the Patent Act and thus should be invalidated.

(C) Since the invention according to Claim 1 of the Patent could have been easily invented by a person skilled in the art based on the inventions described in Evidence A No. 8, Evidence A No. 11, Evidence A No. 12, and Evidence A No. 15, the Appellant should not be granted a patent for the invention in accordance with the provisions of Article 29(2) of the Patent Act, and the patent falls under Article 123(1)(ii) of the Patent Act and thus should be invalidated.

(D) Since the invention according to Claim 1 of the Patent could have been easily invented by a person skilled in the art based on the inventions or technical matters described in Evidence A No. 8, Evidence A No. 9, Evidence A No. 11, Evidence A No. 12, Evidence

A No. 14, Evidence A No. 15, Evidence A No. 17, and Evidence A No. 18, the Appellant should not be granted a patent for the invention in accordance with the provisions of Article 29(2) of the Patent Act, and the patent falls under Article 123(1)(ii) of the Patent Act and thus should be invalidated.

(3-2) Patent Invention 2 to Patent Invention 5

Since the inventions according to Claims 2 to 5 of the Patent could have been easily invented by a person skilled in the art based on the invention described in Evidence A No. 8 in addition to the inventions or technical matters described in the evidences cited in the reasons for invalidation of above (3-1) (A) to (D), the Appellant should not be granted a patent for the invention in accordance with the provisions of Article 29(2) of the Patent Act, and the patent falls under Article 123(1)(ii) of the Patent Act and thus should be invalidated.

(3-3) Patent Invention 6

Since the invention according to Claim 6 of the Patent could have been easily invented by a person skilled in the art based on the inventions described in Evidence A No. 8, Evidence A No. 10-1, Evidence A No. 11, and Evidence A No. 19 in addition to the inventions or technical matters described in the evidences cited in the reasons for invalidation of above (3-1) (A) to (D), the Appellant should not be granted a patent for the invention in accordance with the provisions of Article 29(2) of the Patent Act, and the patent falls under Article 123(1)(ii) of the Patent Act and thus should be invalidated.

(4) Reason for invalidation 5

Since the inventions according to Claims 1 to 6 of the Patent does not utilize a law of nature, it does not fall under "the invention" of Article 2(1) of the Patent Act. The patent thereof violates the provisions of the main paragraph of Article 29(1) of the Patent Act, falls under Article 123(1)(ii) of the Patent Act, and should be invalidated.

Reason for invalidation 3 was withdrawn in the oral proceedings.

2 Means of proof

The Demandants submitted Evidence A No. 1 to Evidence A No. 19 attached to the written demand for trial, and submitted Evidence A No. 20 to Evidence A No. 22 attached to the oral proceedings statement brief.

Evidence A No. 1: Japanese Patent No. 60188228 (Patent publication of the case)

Evidence A No. 2: Japanese Unexamined Patent Application Publication No. 2012-236040

Evidence A No. 3: Written amendment dated October 28, 2013 of the patent application of the case
Evidence A No. 4: Written amendment dated March 3, 2016 of the patent application of the case
Evidence A No. 5: Written opinion dated March 3, 2016 of the patent application of the case
Evidence A No. 6: Written amendment dated July 13, 2016 of the patent application of the case
Evidence A No. 7: Notice of the reasons for refusal dated August 20, 2013 of the patent application of the case
Evidence A No. 8: Japanese Unexamined Patent Application Publication No. 2004-350937
Evidence A No. 9: TAKEUCHI, Shuhei, SAITO, Hiroya, HIRAMATSU, Kazuhide, HOKODATE, Hirofumi, TAKAMURA, Akio, and Jang Dae Jin
"Pressure resistance test in contrast-enhanced CT using an automatic injector from a central vein reservoir"
IVR INTERVENTIONAL RADIOLOGY, Volume 63, pages 27-30, Medical Education and Research Company, January 1, 2005, and Abstract
Evidence A No. 10-1: Attached document of P-UCELSITE PORT, made by TORAY INDUSTRIES, INC., TORAY MEDICAL CO, LTD. on July 1, 2002 (New style 1st Edition)
Evidence A No. 10-2: Attached document of P-UCELSITE PORT, made by TORAY INDUSTRIES, INC., TORAY MEDICAL CO, LTD. on August 1, 2002 (2nd Edition)
Evidence A No. 10-3: Attached document of P-UCELSITE PORT, made by TORAY INDUSTRIES, INC., TORAY MEDICAL CO, LTD. on March 1, 2003 (3rd Edition)
Evidence A No. 10-4: Attached document of P-UCELSITE PORT, made by TORAY INDUSTRIES, INC., TORAY MEDICAL CO, LTD. on February 1, 2004 (4th Edition)
Evidence A No. 10-5: Attached document of P-UCELSITE PORT, made by TORAY INDUSTRIES, INC., TORAY MEDICAL CO, LTD. on June 23, 2004 (5th Edition)
Evidence A No. 10-6: Attached document of P-UCELSITE PORT, made by TORAY INDUSTRIES, INC., TORAY MEDICAL CO, LTD. on July 1, 2005 (6th Edition)
Evidence A No. 11: Specification and abstracted translation of U.S. Patent No. 5851221
Evidence A No. 12: Explanatory document and translation of IsoMed
Evidence A No. 13: Written oath and complete translation by Hank LaForce
Evidence A No. 14: Specification and abstracted translation of U.S. Patent No. 4863470
Evidence A No. 15: Specification and abstracted translation of International Publication

No. WO2004/012787
Evidence A No. 16: National Publication of International Patent Application No. 2006-500087
Evidence A No. 17: "IVP Special Think about future reservoirs" Rad Fan, Vol. 1, No. 3, Pages 40-43, Medical Eye Co., Ltd., July 25, 2003
Evidence A No. 18: KAWASAKI, Ryuta, MORITA, Sojiro, HISA, Nobuaki, TSUJI, Akihito, NODA, Yoshihiro "Examination of 389 cases of implantable central venous catheterization (IVH reservoir) of forearm placement," Cancer and chemotherapy, Vol. 26, No. 13, Pages 2055-2060, issued by Cancer and chemotherapy Company, November 16, 1999
Evidence A No. 19: National Publication of International Patent Application No. 2003-510136
Evidence A No. 20: Examination Guidelines for Patent and Utility Model "Volume II the specification and the scope of claims" "Chapter 3, section 3, requirements for clarity (Article 36(6)(ii) of the Patent Act)," page 1
Evidence A No. 21: Judgment by the Intellectual property high court of Japan January 22, 2015 (2014 (Gyo-ke) 10101)
Evidence A No. 22: Examination Guidelines for Patent and Utility Model "Volume III Requirements for patentability" "Chapter 1 The applicability of the patent and Industrial applicability (the main paragraph of Article 29(1) of the Patent Act)," Pages 1 to 4

No. 4 The Demandee's allegation

The Demandee requested the trial decision that the demand for trial of the case was groundless and the costs in connection with the trial shall be borne by the Demandants, and submitted Evidence B No. 1 to Evidence B No. 2 attached to the written reply of trial case.

Evidence B No. 1: KOJIEN, 6th edition 2nd printing, "Distinction," SHINMURA, Izuru, Iwanami Press, January 11, 2011
Evidence B No. 2: Examination Guidelines for Patent and Utility Model "Volume III Requirements for patentability" "Chapter 1 The applicability of the patent and Industrial applicability (the main paragraph of Article 29(1) of the Patent Act)," Pages 1 to 3

No. 5 Judgment by the body on Reason for invalidation 2 (clarity)

In view of the nature of the case, Reason for invalidation 2 is firstly considered.

The Demandants allege that "an identifiable feature that is configured to identify

the automatically injectable access port via an X-ray after subcutaneous implantation, is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port of at least one of the access ports, and is visible by the X-ray," of Claim 1 (hereinafter, referred to as "Constituent component 1C-1" following page 5 of the statement brief of the Demandants) is not clear in the point of the following (A) to (C) (Written demand for trial, pages 12 to 21, Oral proceedings statement brief, pages 5 to 6 and 8 to 18, and Written statement, Pages 2 to 4).

(A) Regarding the description of Constituent component 1C-1

In the description of "of the automatically injectable access port of at least one of the access port," (1) it is not clear whether or not "the access port" described later means an automatically injectable access port, and (2) if "the access port" described later means the automatically injectable access port, it is not clear why "of the auto-injectable access port" is mentioned in addition to "at least one of the access port".

Therefore, Constituent component 1C-1 cannot be understood as Japanese (Statement brief, pages 5 to 6).

(B) Regarding "Distinction"

Constituent component 1C-1 (1) cannot be interpreted to mean that "an identifiable is correlated with information that can distinguishes the automatically injectable access port from an access port that is not rated to be automatically injectable," and thus the significance of the "distinction" is unclear, and (2) even if it is interpreted to mean as above and the "distinction" is divided into the case based on subjective facts and the case based on objective facts, the significance thereof is unclear (Written demand for trial, pages 12 to 17, Oral proceedings statement brief, pages 6, and 8 to 13, and Written statement, pages 6 to 7).

(C) Regarding "automatically injectable"

(C-1) From the description of the Specification, it can be understood that "an automatically injectable access port" is an access port that has pressure resistance to withstand the injection pressure of an automatic injector, and "an access port that is not rated to be automatically injectable" is an access port that does not have pressure resistance to withstand the injection pressure of an automatic injector. However, considering common general technical knowledge, it is unclear how much pressure the pressure resistance withstanding the injection pressure of the automatic injector can

withstand, so that the significances of "an automatically injectable access port" and "an access port that is not rated to be automatically injectable" are unclear (Written demand for trial, pages 17 to 21).

(C-2) Although the Demandee alleges that "it is optional what kind of access port is defined as automatically injectable," and "whether or not it is 'automatically injectable' is not a characteristic specified by pressure resistance common to all access ports, but a relative characteristic determined in terms of whether or not an access port can withstand automatic injection under certain conditions," these cannot be read from the Specification, etc. (Oral proceedings statement brief, pages 13 to 14).

On the other hand, as alleged by the Demandee, if it is optional what kind of access port is defined as automatically injectable, a person skilled in the art cannot understand whether or not a specific object (access port) falls within the scope of the inventions according to claims, and if it is interpreted whether or not it is "automatically injectable" is a relative characteristic determined in terms of whether or not an access port can withstand automatic injection under certain conditions, it is unclear what kind of conditions are included in "certain conditions" (Oral proceedings statement brief, pages 14 to 15).

(C-3)

The Demandee alleges that model numbers or pressure resistance is not "correlated with information that can be distinguished from an access port that is not rated to be automatically injectable". However, a person who observes the model number via X-ray can confirm the instruction manual of the access port from the obtained model number, and can identify whether or not the access port is automatically injectable from the description of the instruction manual. Further, the pressure resistance of the access port is a major factor in determining whether or not it is automatically injectable, and is "correlated with information that can be distinguished from an access port that is not rated to be automatically injectable" (Oral proceedings statement brief, pages 16 to 17).

Then, the Demandee does not indicate at all what it means to be "correlated with information that can be distinguished from an access port that is not rated to be automatically injectable". Therefore, even if adopting the Demandee's allegation, it cannot be specifically recalled what is an identifiable feature that "is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable," and thus it is unclear (Oral proceedings statement brief, pages 17 to 18).

Then, it will be examined whether or not these (A) to (C) are clear.

1 (A) Regarding the description of Constituent component 1C-1

(1) Seeing the description before "the access port" of Claim 1, access ports other than "an automatically injectable access port" are not listed, so that it is obvious that "the access port" mean "an automatically injectable access port".

(2) From the description of Paragraph [0015] of the Specification that "the present disclosure relates to at least one access port that has at least one perceptible or identifiable feature, for identifying the access port," and "at least one identifiable feature of the access port can be correlated with the access port that is automatically injectable. In this method, once at least one identifiable feature of the access port has been observed or otherwise determined, the correlation of at least one such feature of the access port can be achieved. Then, information related to the access port can be obtained," the detailed description of the invention described "an automatically injectable access port" equipped with "at least one perceptible or identifiable feature" "correlated with the access port that is automatically injectable" for "obtaining information related to the access port".

Therefore, in the detailed description of the invention, it is described that (1) an automatically injectable access port is equipped with an identifiable feature, and (2) the feature of the automatically injectable access port is correlated with the information on the automatically injectable access port.

Then, considering the description of the detailed description of the invention, it is recognized that "of at least one of the access port" of Constituent component 1C-1 relates to "an identifiable feature," while "of the automatically injectable access port" relates to "information". Since "the access port" described later means an automatically access port, it cannot be said that the reason why "of the automatically injectable access port" is described in addition to "of at least one of the access port" is unclear.

Therefore, it cannot be said that Constituent component 1C-1 is unclear as Japanese.

2 (B) Regarding "distinction"

(1) In general, "distinction" means "dividing by difference" (see Evidence B No. 1), so that the meaning of "information that can be distinguished from an access port that is not rated to be automatically injectable" can be understood literally.

(2) Concerning "distinction" of the description "an identifiable feature that is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port, and is visible by the X-ray," if seeing "visible by the X-ray" described later, assuming that there is a person

who sees the identifiable feature via X-ray, it can be understood that it means that the person "distinguishes" the automatically injectable access port and the access port that is not rated to be automatically injectable, from the identifiable feature.

Therefore, the signification of "distinction" is clear.

3 (C) Regarding "automatically injectable"

(1) From the descriptions of Paragraph [0013] of the Specification that "... The access port can be injected manually (e.g. via a syringe containing a needle) or can be injected and pressurized by mechanical assistance (e.g. a so-called auto-injectable port)," and Paragraph [0014] that "the automatically injectable port can be used, among other processes, for example, in a computed tomographic ("CT") scan process. More specifically, so-called "automatic injector" systems can be used to inject contrast into a peripherally inserted venous (IV) line...," it can be understood that the automatically injectable port used in the computed tomographic scan process can be injected and pressurized by mechanical assistance.

Then, in Claim 1, it is described that "An automatically injectable access port for providing subcutaneous access to a patient, which is used for a computed tomographic scan process, ... wherein the automatically injectable access port can be injected and pressurized by mechanical assistance".

Accordingly, from the descriptions of the Specification and Claim 1, the phrase "automatically injectable" means that it "can be injected and pressurized by mechanical assistance" at best in the access port used in the computed tomographic scan process, so that it is recognized that it does not specify the pressure resistance and the like withstanding the injection pressure.

(2) Since the allegation of the Demandants is assuming that it is unclear how much the pressure resistance is for an "automatically injectable" access port, it is groundless in the assumption.

Therefore, since 1 to 3 alleged by the Demandants are groundless, it cannot be said that Patented Invention 1 is not clear.

No. 6 Judgment by the body on Reason for invalidation 1 (requirements for support)

The Demandants allege that Patent Invention 1 is not described in the detailed description of the invention. (Written demand for trial, page 7, line 1 to page 12, line 15)

1 Requirements for support of the Specification

Whether or not the description of the scope of claims conform to requirements for support of the Specification should be determined by examining whether or not the invention described in the scope of claims is the invention described in the detailed description of the invention and is within the range such that a person skilled in the art can recognize that the problem of the invention can be solved based on the detailed description of the invention, or whether or not, even in the absence of such description or suggestion, the invention is within the range such that a person skilled in the art can recognize that the problem of the invention can be solved in light of the common general technical knowledge at the time of filing, by means of comparing the description of the scope of claims and the detailed description of the invention.

Then, it will be examined as follows.

2 Regarding the description of the scope of claims

In Claim 1 of the scope of claims according to Patent Invention 1, it is described that "An automatically injectable access port for providing subcutaneous access to a patient, which is used for a computed tomographic scan process comprises" "an identifiable feature that is configured to identify the automatically injectable access port via an X-ray after subcutaneous implantation, is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port of at least one of the access port, and is visible by the X-ray," "wherein the automatically injectable access port can be injected and pressurized by mechanical assistance".

3 Regarding the detailed description of the invention

The Specification describes the following matters.

A "[Problem to be solved by the invention]

[0007]

In general, conventional access ports of different manufacturers or models can typically exhibit substantially similar contours that are indistinguishable from each other. Therefore, once the access port is implanted, it may be difficult to find the model, style, or design of the access port. Especially if the identification of the implanted access port is difficult to find by other methods, such uncertainty may be unfavorable, at least for replacement timing purposes, among other reasons.

[0008]

In this way, it would be advantageous to provide an access port with at least one

identifiable feature that can be detected or found by other methods after subcutaneous implantation of the access port".

B "[Means for solving the problem]

[0009]

One aspect envisioned by the present disclosure relates to an access port for providing subcutaneous access to a patient. An automatically injectable access port of one embodiment of the present invention includes a body that is used for a computed tomographic scan process and is configured to hold a septum, and an identifiable feature that is configured to identify the automatically injectable access port via an X-ray after subcutaneous implantation, is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port of at least one of the access port, and is visible by the X-ray. The automatically injectable access port can be injected and pressurized by mechanical assistance, and the septum is a septum for repeatedly inserting a needle into a cavity defined in the body through the septum.

[0010]

Another aspect envisioned by the present disclosure relates to a method of identifying an access port implanted subcutaneously. More specifically, a subcutaneously implanted access port can be provided and at least one feature of the subcutaneously implanted access port can be perceived. In addition, the subcutaneously implanted access port can be identified by perceiving the at least one feature".

C "[0013]

The present disclosure relates generally to subcutaneous access, and more specifically to methods and devices related to subcutaneous access. In general, the present disclosure relates to access ports for subcutaneous implantation. In one embodiment, the access port can allow a physician or other healthcare professional to gain long-term subcutaneous access to the interior of the patient's body. The use of access ports for subcutaneous access can reduce the chance of infection by suppressing fluid connections (spreading into the patient's body) from the patient's skin and external environment. The access device allows access to the patient's interior without the need for a needle to pierce the skin. In addition, internal components such as catheters and valves can be replaced without surgical intervention. The various features or aspects of the disclosure can be applied to any such port for subcutaneous access to a patient without limitation. The access port can be injected manually (e.g. via a syringe containing a needle) or can be injected and pressurized by mechanical assistance (e.g. a so-called automatically injectable port).

[0014]

The automatically injectable port can be used, among other processes, for example, in a computed tomographic ("CT") scan process. More specifically, so-called "automatic injector" systems can be used to inject a contrast agent into a peripherally inserted venous (IV) line. For example, such automatic injectors or injection systems are commercially available from Medrad (a subsidiary of Schering AG, Germany) and are also marketed under the name STELLANT (Registered Trademark). Such automated injection systems are generally controllable by selecting the desired flow rate, as infusion treatments are often limited with respect to the desired flow rate of the contrast agent".

D "[0015]

More specifically, the present disclosure relates to an access port having at least one perceptible or identifiable feature for identifying the access port, wherein the identifiable feature can be perceived after the access port is implanted inside a patient. For example, at least one, or possibly a plurality of, identifiable features of the access port envisioned by the present disclosure can be correlated with information related to the access port (e.g. manufacturer's model or design). Thus, identifiable features from a particular type of access port are unique, if not all, of other identifiable features of another access port of a different type or design. Of course, at least one identifiable feature of the access port envisioned by the present disclosure may be correlated with any interest information such as port type, catheter type, date of manufacture, material lot, and part number. In one embodiment, at least one identifiable feature of the access port can be correlated with the access port that is automatically injectable. In this method, once at least one identifiable feature of the access port has been observed or determined by other methods, the correlation of at least one such feature of the access port can be achieved, and then information related to the access port can be obtained.

[0016]

In one embodiment, at least one feature can be perceived by palpation (i.e. consultation by touching), via other physical interactions, or by visual observation. Thus, parties can touch or feel the access port through their skin to perceive at least one identifiable feature of the access port. In another embodiment, at least one identifiable feature can be perceived via x-ray or ultrasound imaging. In a further embodiment, at least one identifiable feature can perceive interaction or communication with the access port via magnetic energy, light energy, or radio energy".

E "[0020]

According to the present disclosure, the access port 10 may include a body 20

showing at least one identifiable feature. More specifically, as shown in FIG. 1A, the body 20 shows a partially pyramidal shape (i.e., also known as a truncated body, a polygonal base having surfaces to the respective sides extending toward a common vertex). Generally, the body 20 of the access port 10 can show a partial pyramid-like shape that extends between a substantially quadrilateral lower base positioned on the reference surface 11 and a substantially quadrilateral upper base positioned on the reference surface 9. For clarity, the reference surface 9 and the reference surface 11 will not be shown in FIGS. 2-21. However, as used herein, reference to the reference surface 9 or the reference surface 11 with respect to FIGS. 2 to 21 refers to a corresponding reference similar to the reference surface 9 and the reference surface 11 as shown in FIGS. 1A and 1B.

[0021]

As shown in FIG. 1A, the 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 rounded corners (radiuses) 32. In addition, the upper outer shape portion 61 of the access port 10 is defined by the upper surface 60 coupled to the chamfered portions 46A and 46B, and further defined by the upper surface of the septum 18. More specifically, the outer circumference of the upper outer shape portion 61 may be depicted as a substantially quadrilateral outer surface formed by four side regions 54 and having four rounded corner regions 30 adjacent to these side regions 54. Such a form may provide an access port having at least one feature that can be perceived by palpation".

F "[0024]

In another embodiment, in another aspect envisioned by the present disclosure, templates can be used to perceive at least one feature of the access port. For example, the complementary shaped template is positioned above the access port assumed by the present disclosure and collided with the access port so as to determine whether or not the access port matches or substantially corresponds to the shape of the template. Such a process can reliably display or perceive at least one feature of the access port envisioned by the present disclosure. Of course, the plurality of templates corresponding to various types of access ports can be sequentially engaged with unknown access ports in order to perceive at least one feature thereof. Such a process can allow identification (e.g. of model or manufacturer) of the access port envisioned by the present disclosure".

G "[0046]

It is also included in the disclosure that at least one feature of the access port envisioned by the present disclosure cannot be observed visually or by palpation, but rather can be observed in other methods. For example, it is included in the disclosure

that at least one feature of an access port can be observed through interaction with imaging techniques such as X-rays or ultrasound. For example, in one embodiment, metallic features (e.g., plates or other metallic shapes) can be included by the access ports envisioned by the present disclosure. As can be understood, such metallic features are shown by X-rays produced by the exposure of an X-ray photosensitive film to X-ray energy passing through the access port and, at the same time, the exposure of the access port to the X-ray energy. Further, the present disclosure includes that the size, shape, or both size and shape of the metallic features of the access port are configured to improve the identification of the access port. For example, assuming that a metallic feature has a metal plate, the size, shape, or both are selectively adjusted to identify the access port. Similarly, the access port features envisioned by the present disclosure can be adjusted for detection via ultrasonic interactions. Such features can include outer surface shape features. In other embodiments, such features can comprise a composite structure including a plurality of materials forming a boundary surface that can be identified by ultrasound imaging".

(1) Regarding the object of the invention

In the descriptions A and D above, it is described that conventionally, once an access port is implanted, it has been difficult to identify the model number of the implanted access port, and the inability to identify the model number of the implanted access port is not desirable due to replacement timing or other reasons, so that it is advantageous to provide an access port with identifiable features that can be perceived through palpation, visual observation, X-ray or ultrasound imaging, etc. after subcutaneous implantation of the access port.

Furthermore, in the descriptions C and D above, it is described that the access port that can be injected and pressurized by mechanical assistance, that is the automatically injectable port, can be used to inject a contrast agent into a venous line by using automatic injector systems, in a computed tomographic scan process, and it is described that in the access port according to the Patent, the at least one identifiable feature is correlated with the access port that can be automatically infused. Here, it is recognized that "can be automatically injected" and "automatically injectable" are synonymous from the descriptions of [0009], [0013], and [0014].

Therefore, on the basis of the detailed description of the invention, it is recognized that one of the objects of the present invention is to provide an access port comprising an identifiable feature that is correlated with an automatically injectable access port, and can

be perceived after subcutaneous implantation, which can identify that it is automatically injected after subcutaneous implantation, regarding the automatically injectable access port that can be injected and pressurized by mechanical assistance, and can be used to inject a contrast agent into a venous line by using automatic injector systems in a computed tomographic scan process, even though once the access port is implanted, it may be difficult to find the model number, etc.

(2) Regarding means for solving the problem

In the description B above, the means for solving the problem of the patent invention is described as "an automatically injectable access port of one embodiment of the present invention includes a body that is used for a computed tomographic scan process and is configured to hold a septum, and an identifiable feature that is configured to identify the automatically injectable access port via an X-ray after subcutaneous implantation, is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port of at least one of the access port, and is visible by the X-ray. The automatically injectable access port can be injected and pressurized by mechanical assistance, and the septum is a septum for repeatedly inserting a needle into a cavity defined in the body through the septum".

4 Examination

In comparison of the description of the scope of claims and the detailed description of the invention, from 2 and 3 (2) above, Patent Invention 1 can be considered to be the invention described in the detailed description of the invention formally.

Next, it will be examined whether or not Patent Invention 1 is within the range such that a person skilled in the art can recognize that the problem of the invention can be solved based on the detailed description of the invention, or whether or not, even in the absence of such description or suggestion, the invention is within the range such that a person skilled in the art can recognize that the problem of the invention can be solved in light of the common general technical knowledge at the time of filing.

In the first place, the access port "can allow a physician or other healthcare professional to gain long-term subcutaneous access to the interior of the patient's body" (the description C above), and it is obvious that a person identifying whether or not the access port is automatically injectable in a computed tomographic scan process is "a physician or other healthcare professional" (hereinafter, referred to as the physician, etc.). Patent Invention 1 includes an identifiable feature that is visible by the X-ray, as a feature

that can be perceived after subcutaneous implantation so as to enable the physician, etc. to identify that the subcutaneously implanted access port is automatically injectable.

Therefore, in order to recognize that Patent Invention 1 can solve the problem of the invention, it is necessary for physicians, etc. who perceive an identifiable feature visible by X-ray to be able to identify from the feature that the access port having the feature is automatically injectable.

Regarding the feature that can be perceived by palpation or visual observation (the description E above), in the description F above, it is described that it is possible to identify the access port by checking whether or not the access port matches the shape of the template.

On the other hand, regarding the feature that is visible by the X-ray, even referring to the related descriptions (the descriptions C, D, and G above), there is no explicit description of identifying access ports from features perceived through X-ray imaging. However, similar to features that can be perceived by palpation or visual observation, since it is common general technical knowledge that access ports can be identified by whether the features perceived through X-ray imaging match the shape of the template, it can be sufficiently assumed by a person skilled in the art.

However, the access port identified by matching the shape of the template with the feature perceived through X-ray imaging does not indicate that the perceived feature itself is automatically injectable. That is, just because the features perceived through X-ray imaging match the shape of the template, physicians, etc. cannot immediately identify that the access port is automatically injectable.

The Demandee alleges, about this point, that "whether or not it is 'automatically injectable'... is a relative characteristic determined in terms of whether or not an access port can withstand automatic injection under given usage conditions. The given usage conditions here are, for example, conditions relating to the use of an accessory device (for example, a catheter, a needle, etc.) used with the access port for each access port, allowable injection pressure,...which is set appropriately by the manufacturer of the access port and specified in the attached document attached at the time of selling or the like" (Oral proceedings statement brief, page 5), "the access port is a medical device, and the manufacturer of the access port encloses the attached document (...) and sells it. The attached document...is a document that is required by law to be attached when selling medical devices....

Then, the manufacturer of the access port can appropriately set which access port is automatically injectable in their product according to the specifications of each access

port and the restriction conditions for its use. That is, the manufacturer of the access port can position the access port capable of automatically injecting as 'the automatically injectable access port' within the range satisfying the usage conditions described in the attached document. Although this is not described in the specification of the Patent, regarding the specifications of medical devices called access ports, it is unlikely that the provider of the access port does not impose any restrictions on the accessories and usage conditions, and it is a matter that is obvious to a person skilled in the art" (Oral proceedings statement brief, pages 5 to 6), and "if the meaning of the mark is described in the attached document, the practitioner can specify the meaning of the mark in the attached document.... From the viewpoint of solving the problems of the invention, it is sufficient if each company that performs 'production' and 'transfer' optionally sets what kind of mark is used as the reference for distinction at the implementation stage, and the practitioner who performs 'use' can confirm the meaning thereof in the attached document" (Oral proceedings statement brief, page 8).

However, even if it is obvious that the usage conditions should be attached when using the access port, and that it is automatically injectable within the range of the usage conditions described in the attached document, and even if the attached document states that the meaning of the identifiable feature is an automatically injectable access port, practitioners such as physicians, etc. cannot identify whether or not it is automatically injectable without checking the attached document. Hence, it is not self-evident that it can be immediately identified as automatically injectable from the feature perceived through X-ray imaging.

Further, in the Specification, there is no description and suggestion about the attached document of the access port.

Therefore, the Demandee's allegation is groundless.

Accordingly, Patent Invention 1 exceeds the range that can be recognized as being able to solve the problem of the invention. Further, in light of the common general technical knowledge at the time of filing, it cannot be said that the contents disclosed in the detailed description of the invention can be extended or generalized to those without the attached document.

Therefore, since Patent Invention 1 is described in the detailed description of the invention, the Patent was granted to a patent application that does not comply with the requirements stipulated in Article 36(6)(i) of the Patent Act.

No. 7 Judgment by the body on Reasons for invalidation 4 (inventive step)

First

As described No. 6 above, Patent Invention 1 does not comply with requirements for support.

However, in view of the case, Patent Invention 1 is considered as "an attached document is attached, the attached document contains a description that the practitioner can identify as an access port that is automatically injectable within the range of usage conditions, which is appropriately set by the manufacturer, and further an identifiable feature that is visible by the X-ray of the access port associates the access port and the description of the attached document," it will be further examined whether or not such Patent Invention 1 has inventive step.

Specifically, Evidence A No. 10-1 will be examined as an attached document of "P-UCELSITE PORT made by TORAY" of Evidence A No. 9 which will be described later.

No. 7- 1 Reason for invalidation 4-A

1 Regarding the respective items of Evidence A

(1) Evidence A No. 9

(1-1) Described matters of Evidence A No. 9

Evidence A No. 9 that is a publication distributed before the priority date of the Patent describes the following matters with the drawings.

A "Purpose

Implantable central venous catheterization (CV reservoir) is widely used for home anticancer drug therapy and central venous nutrition 1, 2). It may be indwelled for the purpose of securing a vein, and in these cases, it is sometimes necessary to inject a contrast agent from a CV reservoir during contrast CT.

However, although the pressure resistance of a port alone or a catheter alone is described in the attached document of each company, evaluation as a system that integrates the catheter and the port has hardly been examined 3). Therefore, we performed the examination on pressure resistance as to whether or not the CV reservoir indwelled in a subclavian vein can be used as a contrast agent administration route without damage, and thus will report it". (Page 27, line 1 of the lower left column to line 3 of the lower right column)

B "Method

The equipment used was an automatic injector (Auto Enhance A-50; Nemoto Kyorindo Co., Ltd.), an extension tube (extension tube for injector LX1 1OOcm; TOP), and an injection needle (20G/22G without coreless needle side tube; Nipro). Table 1

shows the ports and catheters used in the experiment. As an experimental system, the tip of a catheter with a length of 20 cm was immersed in a container filled with physiological saline (Fig. 1), and then in that state, an automatic injector is used to inject Iopamidol (Iopamiron 300 syringe; Nihon Schering K.K.) with an iodine concentration of 300 mgI/ml under the same conditions as the actual contrast (1.5 ml/sec, 3.0 ml/sec, 5.0 ml/sec).

Injection pressure at each injection rate was measured when pressure became constant on a pressure monitor of the automatic injector, and the average value of the three measurements was used. The observation items were catheter breakage, boat breakage, and catheter deviation.

Furthermore, the injection pressure was measured in the same manner by changing the thickness of a puncture needle and the length of the catheter. The pressure limit is usually set to 10 kg/cm^2 or less, which is the actual measured injection pressure recommended in the attached document of Iopamiron syringe, but in this experiment, it was set to 15 kg/cm^2 or less".
(Page 27, line 4 of the lower right column to page 28, line 9 of the upper left column)

表１　カテーテルおよび埋め込みポートの物理的特性

		直径	製造者	最大耐圧
カテーテルを備える埋め込みポート				
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	(VTI)	5 Fr (16G)	COOK	40psi
CLINY Port System	(CLI)	5 Fr (16G)	CREATE MEDIC	21.7psi
埋め込みポート				
SEPTUM-PORT	(SEP)	6 Fr	SUMITOMO BAKELITE	42.7psi
SOPH-A-PORT	(SOP)	6 Fr	SOPHYSA	
埋め込みカテーテル				
BIOLINE	(BIO)	14 G (5.7Fr)	NIPRO	
MU catheter kit	(MU)	14 G (5.7Fr)	MEDIKIT	

表１　カテーテルおよび埋め込みポートの物理的特性　Table 1 Physical characteristics of catheters and implanted ports
カテーテルを備える埋め込みポート　Implanted ports equipped with catheters
埋め込みポート　Implanted ports
埋め込みカテーテル　Implanted catheters
直径　Diameter
製造者　Manufacturers

最大耐圧　　Maximum pressure resistance

C "Result

Table 2 shows each injection rate, injection pressure, and system status.

1. Injection rate 1.5 ml/sec

When using a 22 G Huber needle and extension tube, the injection pressure was 6.3 ± 1.83 kg/cm^2 (average 6.3 kg/cm^2), and when a 20 G Huber needle was used, the injection pressure was 4.7 ± 1.45 (average 4.7 kg/cm^2). No system damage was found in either case". (Page 28, line 10 of the upper left column to line 3 of the upper right column)

D "Discussion

With the spread of CV reservoirs, the adaptation has been expanded to cases where it is difficult to secure peripheral veins. However, when performing contrast CT in such cases, there is a history of securing the peripheral vein on the opposite side of the indwelling. If it can be administered from the CV reservoir, it will contribute to improving the patient's QOL, but the current situation is that the system has not been used because there is a risk of system damage. Although the pressure resistance of the port alone or the catheter alone is described in the attached document of each company, evaluation as a CV reservoir system, including port-catheter matching, has not yet been established. Therefore, this time, we measured the actual injection pressure under a plurality of contrast conditions to see whether or not the CV reservoir indwelled in a subclavian vein can be used as a contrast agent administration route without causing system damage, and evaluated the possibility of system damage". (Page 29, lines 13 to 28 of the left column)

E "In this experimental circuit, ...an injector pressure monitor was used as a simple means of monitoring in the field of daily medical care. In addition, assuming a venous system, ...it was thought that by immersing the tip of the catheter in physiological saline with the open system, it would be closer to a physiological state". (Page 29, line 36 of the left column to line 7 of the right column)

F "In this experimental circuit, the evaluation was performed, unlike full physiological conditions, under the condition that the port was not deteriorated at all. Therefore, although it is necessary to accumulate future cases to determine whether or not the results are completely applicable to clinical cases, as a guideline for contrast from the CV reservoir, if the injection amount is about 1.5 ml/sec, it can be safely performed without causing system damage, and it is considered possible to inject at 3.0 ml/sec by using 20 G". (Page 29, line 2 from the bottom of the right column to page 30, line 6 of the left

column)

G "Summary

We examined the pressure resistance to see whether or not the CV reservoir indwelled in a subclavian vein can be used as a contrast agent administration route without causing damage. If the injection amount is 1.5 ml/sec when using the 21 G puncture needle, and if the injection is about 3.0 ml/sec when using a 20 G puncture needle, contrast from the CV reservoir was considered to be safely performed without causing system damage...." (Page 30, lines 7 to 13 of the left column)

H From the descriptions of "Implantable central venous catheterization (CV reservoir) is widely used for home anticancer drug therapy and central venous nutrition 1, 2). It may be indwelled for the purpose of securing a vein, and in these cases, it is sometimes necessary to inject a contrast agent from a CV reservoir during contrast CT.... Therefore, we performed the examination on pressure resistance whether or not the CV reservoir indwelled in a subclavian vein can be used as a contrast agent administration route without damage, and thus will report it" of the summarized matters A above, "the equipment used was an automatic injector (Auto Enhance A-50; Nemoto Kyorindo Co., Ltd.), an extension tube (extension tube for injector LX1 1OOcm; TOP), and an injection needle (20G/22G without coreless needle side tube; Nipro). Table 1 shows the ports and catheters used in the experiment. As an experimental system, the tip of a catheter with a length of 20 cm was immersed in a container filled with physiological saline (Fig. 1), and then in that state, an automatic injector was used to inject Iopamidol (Iopamiron 300 syringe; Nihon Schering K.K.) with an iodine concentration of 300 mgI/ml under the same conditions as the actual contrast (1.5 ml/sec, 3.0 ml/sec, 5.0 ml/sec)" of the summarized matter B above, "Implanted ports equipped with catheters...P-UCELSITE PORT (P-U)...Manufacturer...TORAY" of Table 1 that is an abstracted translation of Table 1, and "assuming a venous system, ...it was thought that by immersing the tip of the catheter in physiological saline with the open system, it would be closer to a physiological state" of the summarized matter E above, it can be understood that an experiment had been done, in which P-UCELSITE PORT made by TORAY was immersed in physiological saline assuming a venous system as a contrast agent administration route for contrast CT and iopamidol was injected as a contrast agent under the same conditions as the actual contrast, by using an automatic injector.

I From the descriptions of the recognized matter H above and the summarized matter C above, in the experiment related to the recognized matter H above, it can be understood that at an injection rate of 1.5 ml/sec, no damage was observed in the system using P-

UCELSITE PORT made by TORAY.
J From the recognized matters H and I above, it can be understood that the P-UCELSITE PORT made by TORAY can inject a contrast agent by the automatic injector as a contrast agent administration route for contrast CT.

Summarizing the summarized matters A to G above and the recognized matters H to J above in light of the common general technical knowledge, it can be said that Evidence A No. 9 describes
"A P-UCELSITE PORT made by TORAY that can inject iopamidol that is a contrast agent by an automatic injector indwelled in a patient for the purpose of securing veins, which is used for contrast CT".

(1-2) Described matters of Evidence A No. 10-1
Evidence A No. 10-1 that is a publication distributed before the priority date of the Patent describes the following matters with the drawings.

A "Instrument Device 74 Drug Injector Implantable drug injector P-UCELSITE PORT (single item type)" (page 1/3)
B "[Warning]
This product is designed exclusively for Anthrone @ P-U catheters. Please connect with Anthrone @ P-U catheter. If you connect to other than these, the port and catheter may not be connected securely, and problems such as the coming off of the catheter may occur". (page 1/3)
C "[Contraindications/Prohibitions]
Observe the following contraindications and prohibitions....
2) Do not pressurize above the maximum injection pressure described later...." (page 1/3)
D "[Contraindications for concomitant use]
When puncturing a poat, do not use anything other than a non-coring needle.
The use of puncture needles other than non-coring needles may significantly reduce the durability of a septum". (page 1/3)
E "Product specifications

■製品スペック

1）ポート

	ラージ	スモール	フラキアル
穿刺耐用回数	2000回	2000回	1000回
底部の長さ	31mm	26mm	22mm
底部の幅	27mm	22mm	18mm
重量	8g	5g	2.5g
プライミング容量	0.5mL	0.3mL	0.2mL
セプタム直径	12.5mm	9.5mm	7.6mL
セプタムから底面までの高さ	12.2mm	9.7mm	8.7mm
耐圧 MPa (psi)	2.10(300)	2.10(300)	2.10(300)

2）ノンコアリングニードル　22G×30mm（ストレート）

製品スペック	Product specifications
１）ポート	1) Port
穿刺耐用回数	Number of puncture durability
底部の長さ	Length of bottom portion
底部の幅	Width of bottom portion
重量	Weight
プライミング容量	Priming capacity
セプタム直径	Septum diameter
セプタムから底面までの高さ	Height from septum to bottom surface
耐圧	Pressure resistance
ラージ	Large
スモール	Small
フラキアル	Brachial

２）ノンコアリングニードル２２Ｇ×３０ｍｍ（ストレート） 2) Non-coring needle 22 G × 30 mm (straight)

" (page 1/3)

F "[Performance, purpose of use, efficacy or effect]

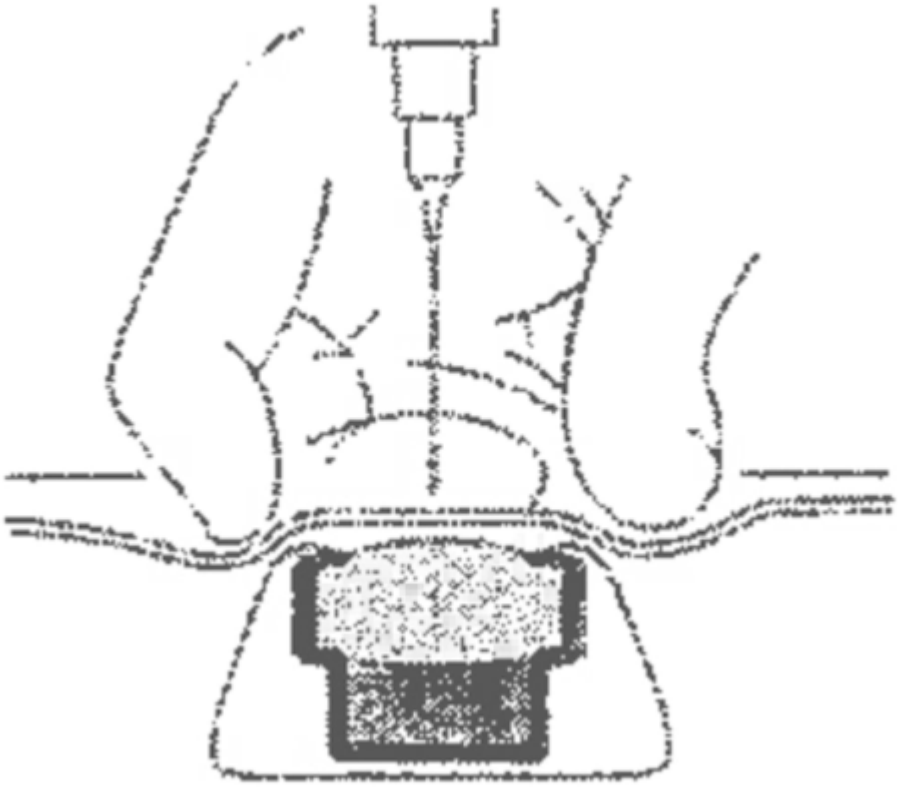
The object of this product is to be installed in a body as a subcutaneous implantable catheter access system, and to percutaneously administer a drug solution into a blood

vessel". (page 1/3)

G "[Manufacturer's name and address, etc.]

'TORAY'" (page 3/3)

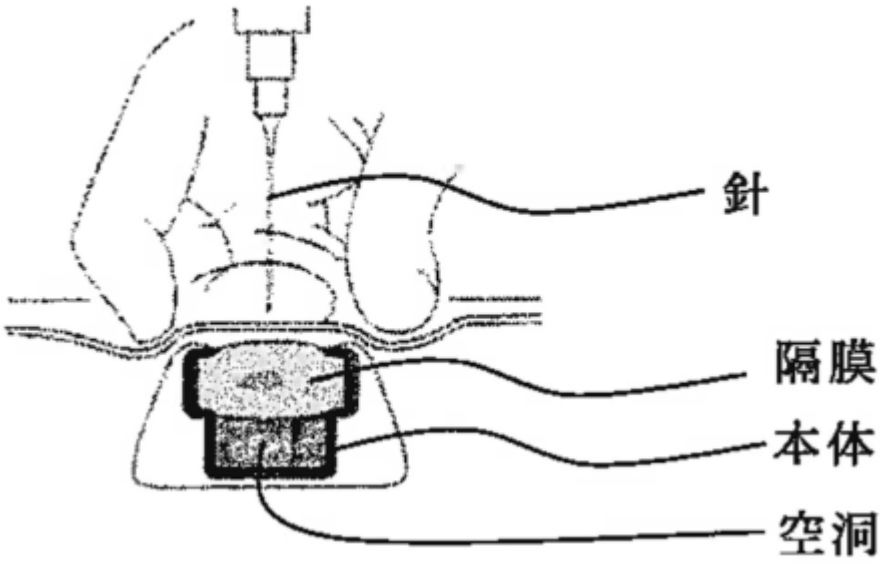
H The following figure is described. (page 2/3)



I From the summarized matters A and G above, it can be understood that Evidence A No. 10 is the attached document of P-UCELSITE PORT made by TORAY.

J From the summarized matter F above, it can be understood that P-UCELSITE PORT made by TORAY is a subcutaneous implantable catheter access system, which is installed inside the body to percutaneously administer a drug solution into a blood vessel, that is an access port for providing subcutaneous access to a patient.

K In Illustrated contents H, considering common general technical knowledge, it is recognized that a needle, a septum, a body, and a cavity are shown as follows. Also, it can be seen that the body holds the septum and that the septum is for inserting the needle through the septum the cavity defined in the body.



針　Needle
隔膜　Septum
本体　Body
空洞　Cavity

L　From the summarized matters B to E above, it can be understood that the P-UCELSITE PORT uses Anthrone @ P-U catheter and a non-coring needle so as not to pressurize above the maximum injection pressure indicated in the product specifications.
M　From the number of the number of puncture durability of the summarized matter E and the illustrated contents K, it can be understood that the septum is for repeatedly inserting the needle.

Summarizing the summarized matter G above, the illustrated content H, and the recognized matters I to M above in light of the common general technical knowledge, Evidence A No. 10-1 describes the following invention.
"An access port for providing subcutaneous access to a patient comprising:
a body configured to hold a septum,
wherein the access port is used so as not to pressurize above the maximum injection pressure indicated in product specifications, and
wherein the septum is a septum for repeatedly inserting a needle into a cavity defined in the body through the septum" (hereinafter, referred to as Invention A-10).

Further, from the summarized matters A to E above, the following can be said.

"Evidence A No. 10-1 describes usage conditions such as the maximum injection pressure" (hereinafter, referred to as Matter A-10).

(1-3) Invention A-9

Since P-UCELSITE PORT made by TORAY described in Evidence A No. 9 is Invention A-10, it has the configuration of Invention A-10.

Therefore, Evidence A No. 9 describes the following invention (hereinafter, referred to as Invention A-9).

"An access port for providing subcutaneous access to a patient, which is used for contrast CT and through which can be injected a contrast agent by an automatic injector, comprising:

a body configured to hold a septum,

wherein the access port is used so as not to pressurize above the maximum injection pressure indicated in product specifications, and

wherein the septum is a septum for repeatedly inserting a needle into a cavity defined in the body through the septum".

(2) Evidence A No. 11

Evidence A No. 11 that is a publication distributed before the priority date of the Patent describes the following matters with the drawings. Further, the translation was based on the abstracted translation from the Demandants, and the part without the abstracted translation was prepared by the body (the same applies hereinafter).

A "FIELD OF THE INVENTION

The present invention generally relates to implantable medical devices and particularly to the attachment of a pre-formed header module, e.g., a lead or catheter connector header module or an electrode bearing header module, etc., to a hermetically sealed enclosure of the implantable medical device, typically including electronic integrated circuits, batteries, electromechanical pumps, or the like." (Column 1, lines 16 to 23)

B "The preferred embodiments relate to use of the mechanism and method summarized above to attach a pre-formed header module attachment surface with a hermetically sealed enclosure attachment surface in the manufacture of an implantable medical device. Such implantable medical devices include implantable drug dispensers, IPGs (including cardiac pacemakers, pacemaker-cardioverterdefibrillators, nerve, muscle, and neurological stimulators, cardiomyostimulators, etc.), implantable cardiac signal

monitors and recorders, and the like. Virtually all MEDTRONIC.RTM. electronic implantable medical devices that require attachment of a hermetically sealed power supply and circuitry with an interchangeable catheter or electrical lead or the like employ such a general configuration of a hermetically sealed enclosure and a pre-formed header module thereto." (Column 6, lines 36 to 51)

C "The attachment method and mechanism may also be used to attach an implantable drug pump catheter connector, a header module to the hermetically sealed enclosure for the pump mechanism, battery, and ICs controlling the pumping operation. However, those of skill in the art will be readily able to adapt the teachings found herein to other implantable medical devices." (Column 6, line 63 to Column 7, line 5)

D "The header module 12 is molded of a rigid thermoplastic, e.g., a medical grade polyurethane, a housing 20 having an exposed module surface 26, and a number of receptacles and channels shown in greater detail in FIGS. 6-9. Components including a header electrode 70 and a radiopaque ID plate 60 fitted within a respective electrode channel 28 and a plate channel 50 of the housing 20 are shown in FIGS. 2, 5, and 10. FIGS. 10-14 show how the header module 12 is attached to the hermetically sealed enclosure 14 employing the upstanding tabs 52 and 54 and show a mass of adhesive 76 filling the space between the respective attachment surfaces and the channels leading thereto in the final assembly step." (Column 8, lines 23 to 34)

E "The header module housing 20 is molded to have a pair of transversely extending suture bores or holes 22 and 24 extending across the width thereof through which sutures are passed into adjacent subcutaneous tissue when the cardiac signal monitor 10 is implanted as shown in FIG. 1. The suture holes 22 and 24 allow the electrodes 70 and 30 of the cardiac signal monitor 10 to be oriented at any desired angle to the heart." (Column 8, lines 35 to 42)

F "FIGS. 11-14 depict the manufacturing steps of attaching the preformed header module 12 to the enclosure attachment surface 38 of the hermetically sealed enclosure 14. The depicted attachment steps follow the assembly and welding of the hermetically sealed enclosure 12 (Note by the body: seems to be a mistake for 14) to its lid and the attachment of the tab base 56 to the lid to form the enclosure attachment surface 38 as described above. Moreover, the radiopaque ID plate 60 is fitted into the plate channel 50, and the header electrode 70 is fitted into the position 70' of the electrode channel 28. The

illustrated attachment steps can either follow or precede the attachment of the terminus of the feedthrough pin 40 to the interior surface of the header electrode 70." (Column 9, lines 41 to 53)

G "The radiopaque ID plate" of the summarized matters D and F above indicates an ID so that it can be seen by an X-ray. The ID usually means a code for identifying a device, and can be rephrased as a model number. Therefore, it can be said that "the radiopaque ID plate" is a feature visible by an X-ray, which represents information indicating a model number of a device equipped with the plate.

Summarizing the summarized matters A to D and F above and the recognized matter G above in light of the common technical knowledge, it can be said that Evidence A No. 11 describes the following matters (hereinafter, referred to as Matter A-11-1).
"An implantable medical device comprises a feature that represents information indicating a model number of the device and is visible by an X-ray".

Further, summarizing the summarized matter E above in light of the common technical knowledge, it can be said that Evidence A No. 11 describes the following matter (hereinafter, referred to as Matter A-11-2).
"An implantable medical device is provided with a suture bore".

(3) Evidence A No. 12

Evidence A No. 12 that is a publication distributed before the priority date of the Patent describes the following matters with the drawings.

A "Medtronic IsoMed Constant-Flow Infusion System
Clinical Reference Guide for Hepatic Arterial Infusion Therapy" (page 1)

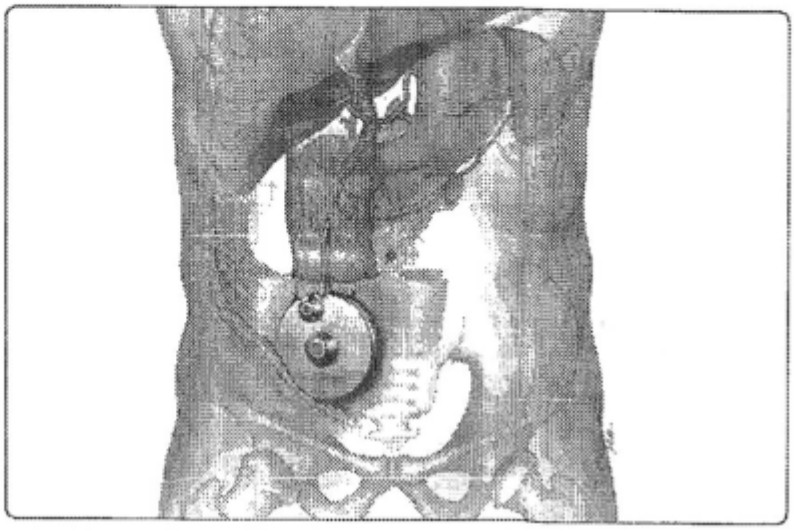
B "

The IsoMed Constant-Flow Infusion System

When used for hepatic arterial infusion of chemotherapeutic agents, the IsoMed Infusion System includes the IsoMed Constant-Flow pump and a Medtronic vascular catheter.

To assemble and implant the system, the catheter is first connected to the pump. The pump is placed in a subcutaneous pocket in the abdomen and anchored to the abdominal fascia. The catheter is then tunneled through the abdominal wall. The catheter tip is placed in the gastroduodenal or other suitable artery for delivery of chemotherapy to the liver (**Figure 2-1**).

Figure 2-1
Pump Placement for Hepatic Arterial Infusion Therapy



" (Page 2-2 (Section 10))

C "

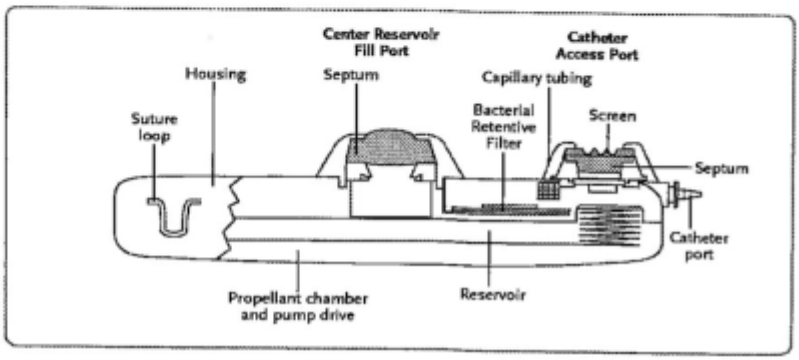
Pump Components

Refer to **Figure 2-3** for a detailed diagram showing components of the IsoMed pump. A description of each component is given below.

The pump has the following components:

- Titanium reservoir (20 ml, 35 ml or 60 ml)
- Propellant chamber and pump drive
- Center reservoir fill port with self-sealing septum
- Bacterial-retentive filter
- X-ray identification tag (**Figure 2-4**)
- Catheter access port with titanium screen and self-sealing septum
- Capillary tubing
- Catheter port
- Titanium suture loops
- Titanium housing.

Figure 2-3
Cutaway View of the IsoMed Pump



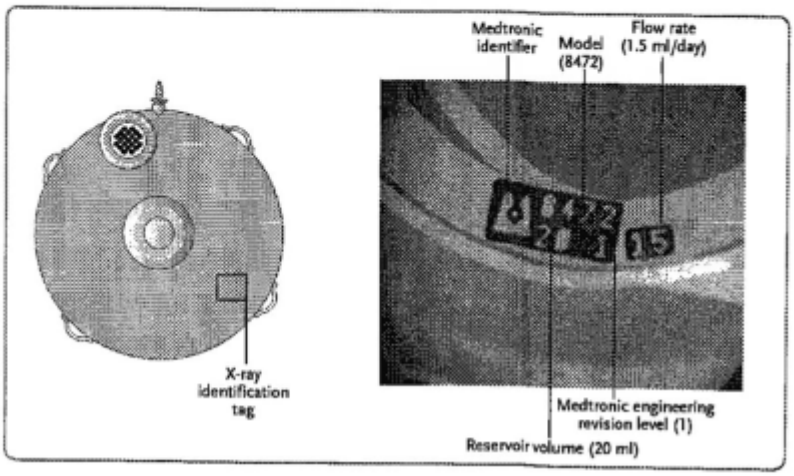
" (Page 2-3 (Section 11))

D "

X-RAY IDENTIFICATION TAG

The Medtronic identifier, pump model, reservoir volume and flow rate have been recorded on a small radiographic tag located inside the pump housing. This tag can be seen using standard x-ray procedures. When viewed on x-ray it will look like the sample in **Figure 2-4**.

Figure 2-4
IsoMed Identification Tag



" (Page 2-4 (Section 12))

E According to the summarized matter B above, the IsoMed constant-flow infusion system is a medical device that is implanted and used in a human body.
F According to the summarized matter C above, the IsoMed constant-flow infusion system has an X-ray identification tag.
G According to the summarized matter D above, the IsoMed constant-flow infusion system indicates a model number. It is obvious that the X-ray identification tag representing the model number is a feature that is visible by an X-ray.

Summarizing the summarized matters A to D above and the recognized matters E to G above in light of the common general technical knowledge, it can be said that Evidence A No. 12 describes the following matter (hereinafter, referred to as Matter A-12)
"An implantable medical device comprises a feature that represents a model number of the device and is visible by an X-ray".

(4) Evidence A No. 8

Evidence A No. 8 published before the priority date of the Patent describes the following matters with the drawings.

A "[0001]
[Field of the Invention]
The present invention relates to a drug solution injection device which is an instrument for injecting a drug solution into a patient's body, and more particularly to a subcutaneous implantable drug solution injection device used for treatment such as chemotherapy"
B "[0013]
As shown in FIGS. 1 to 3, the drug solution injection device 11 includes a housing main body 12, a puncture member 13, and a cylindrical connector 14 (see FIG. 2)....
[0014]
As shown in FIG. 2, the housing main body 12 includes a liquid storage portion 20 having a liquid storage recess 20a and a substantially bottomed cylindrical shape, and a cover portion 21 having a storage recess 18.
[0015]
The liquid reservoir 20 has an opening 19 formed on one side surface thereof by forming the liquid storage recess 20a on one side surface thereof. The puncture member 13 is arranged so as to close the opening 19. The storage recess 18 is formed on one side surface of the cover portion 21. The puncture member 13 and the liquid storage portion

20 are housed in the storage recess 18 of the cover portion 21, and the cover portion 21 and the liquid storage portion 20 are fixed to each other. An exposure hole 21a is formed in the cover portion 21 on the side surface opposite to the side surface on which the storage recess 18 is formed so that the central part of the upper surface of the puncture member 13 can be exposed. The exposure hole 21a exposes the central part of the upper surface of the puncture member 13. The puncture member 13 cannot be detached from the cover portion 21. A liquid pool space S is formed between the liquid storage portion 20 having the liquid storage recess 20a and the puncture member 13".

C "[0017]

As shown in FIG. 4, a retaining protrusion 14a is formed on the outer periphery of the axially central part of the connector 14 (a part on the tip end side of the connector 14). The retaining protrusion 14a has a tapered shape that increases in diameter from the tip end side to the base end side. The part of the connector 14 on the tip end side in relation to the retaining protrusion 14a is the tip end portion 14b. Therefore, when connecting to the connector 14 a small-diameter catheter C1 and a large-diameter catheter C2 having the catheter C1 inside, the tip of the catheter C1 does not get over the retaining protrusion 14a, and can be inserted up to the vicinity of the boundary between the retaining protrusion 14a and the tip end portion 14b. Further, the tip of the catheter C2 can be inserted to the base end side of the connector 14 over the retaining protrusion 14a. The catheter C2 and the catheter C1 arranged in the catheter C2 are branched and used on the base end side, respectively.

D "[0018]

Next, a characteristic part of the drug solution injection device 11 will be described.

As shown in the enlarged circle of FIG. 2, a locking ridge 25 having a substantially ring shape is formed at the upper end of the liquid storage portion 20. A locking claw 25a is formed on the outer periphery of the tip of the locking ridge 25. As shown in FIG. 2, the puncture member 13 is arranged in the locking ridge 25. A biting ridge 26 having a sharp cross section is formed at the upper end of the liquid storage portion 20 and inside the locking ridge 25. The biting ridge 26 corresponds to a coming-off prevention means and a biting means. Then, the biting ridge 26 bites into the lower end portion of the outer peripheral portion 13a of the puncture member 13".

E "[0019]

An edging ring 28 as a puncture-possible portion teaching member having a substantially inverted coronal shape is arranged between the locking ridge 25 and the cover portion 21. The edging ring 28 has a ring shape forming a circular shape without a break. In this embodiment, the edging ring 28 is made of a radiopaque material and titanium (Ti) as a

non-magnetic metal.
[0020]
The edging ring 28 is arranged at a part on the puncture member 13 side with respect to the liquid pool space S in the housing main body 12. The edging ring 28 includes a first ring portion 28a located on the outer periphery of the locking ridge 25, a second ring portion 28b that abuts on the outer peripheral portion 13a of the puncture member 13, and a third ring portion 28c that couples the first ring portion 28a and the first ring portion 28a. As shown in the enlarged circle of FIG. 2, the first ring portion 28a is formed with a locking claw 29 that engages with the locking claw 25a of the locking ridge 25, and the locking claw 25a and the locking claw 29 are locked"
F "[0022]
A biting ridge 30 having a sharp cross section is formed on the lower surface of the second ring portion 28b. The biting ridge 30 corresponds to a coming-off prevention mechanism and a biting mechanism. Then, the biting ridge 30 bites into the upper end portion of the outer peripheral portion 13a of the puncture member 13. That is, when the locking claw 25a and the locking claw 29 are locked, the biting ridges 26 and 30 are in a state of being bitten into the upper and lower sides of the outer peripheral portion 13a of the puncture member 13, thereby fixing the puncture member 13 so as not to come off from the exposure hole 21a of the housing main body 12".
G From FIG. 2, it can be seen that the housing main body 12 has the connector 14.
H From FIG. 2, it can be seen that the space S is fluid communicated with a lumen of the connector 14.
I From FIG. 2, it can be seen that the second ring portion 28b, the locking ridge 25, and the upper end portion of the liquid storage portion 20 maintain the outer peripheral portion 13a of the puncture member 13.

J From the summarized matter D above, the descriptions of the summarized matter E of "The edging ring 28 includes a first ring portion 28a located on the outer periphery of the locking ridge 25, a second ring portion 28b that abuts on the outer peripheral portion 13a of the puncture member 13, and a third ring portion 28c that couples the first ring portion 28a and the first ring portion 28a. As shown in the enlarged circle of FIG. 2, the first ring portion 28a is formed with a locking claw 29 that engages with the locking claw 25a of the locking ridge 25, and the locking claw 25a and the locking claw 29 are locked," the summarized matter F above, and the illustrated content I above, it can be said that concerning the puncture member 13, the locking claw 25a of the liquid storage portion 20, and the locking claw 29 of the edging ring 28 are locked to maintain the puncture

member 13 with the biting ridge of the liquid storage portion 20 and the biting ridge 30 of the edging ring 28. That is, the edging ring 28 maintains the puncture member 13.
K From the summarized matters B and D above, the illustrated content I above, and the recognized matter J above, it can be said that the drug solution injection device 11 is equipped with the housing main body 12, the housing main body 12 has the connector 14 and the edging ring 28 arranged in the housing main body 12, and the edging ring 28 maintains a puncture member in the drug solution injection device 11.
L From the description of the summarized matter B of "As shown in FIG. 2, the housing main body 12 includes a liquid storage portion 20 having a liquid storage recess 20a and a substantially bottomed cylindrical shape, and a cover portion 21 having a storage recess 18," and "a liquid pool space S is formed between the liquid storage portion 20 and the puncture member 13," and the illustrated content H above, it can be understood that the housing main body 12 is equipped with the liquid storage portion 20, the liquid storage portion 20 defines the space S with the puncture member 13, and the space S is fluid communicated with the lumen of the connector.
M From the summarized matter C above, it can be understood that the connector 14 is configured to connect with the catheter.

Summarizing the summarized matters A to F, the illustrated contents G to I, and the recognized matters J to M above in light of the common general technical knowledge, it can be said that Evidence A No. 8 described the following matters.
"A subcutaneous implantable drug solution injection device includes a housing main body 12, the housing main body 12 has a connector 14 and an edging ring 28 arranged in the housing main body 12, and the edging ring 28 maintains a puncture member 13 in the drug solution injection device" (hereinafter, referred to as Matter A-8-1).
"In the subcutaneous implantable drug solution injection device, the housing main body 12 is equipped with a liquid storage portion 20" (hereinafter, referred to as Matter A-8-2).
"The subcutaneous implantable drug solution injection device includes the liquid storage portion 20 defining a space S with the puncture member 13, and the space S is fluid communicated with a lumen of the connector" (hereinafter, referred to as Matter A-8-3).
"In the subcutaneous implantable drug solution injection device, the connector 14 is configured to connect with a catheter" (hereinafter, referred to as Matter A-8-4).

2 Regarding Patent Invention 1

If comparing Patent Invention 1 and Invention A-9 in light of the common general

technical knowledge, "used for contrast CT" of Invention A-9 corresponds to "used for a computed tomographic scan process" of Patent Invention 1.

Further, "can be injected a contrast agent by an automatic injector" of Invention A-9 has the same meaning as a contrast agent can be injected by a machine that is an automatic injector, and "the access port is used so as not to pressurize above the maximum injection pressure indicated in product specifications" of Invention A-9 suggests that it can be pressurized within a range below the maximum injection pressure, so that Patent Invention 1 and Invention A-9 are identical at least in the point that "can be injected and pressurized by mechanical assistance".

Therefore, Patent Invention and Invention A-9 are identical in the following feature.

<Corresponding Feature>

"An access port for providing subcutaneous access to a patient, which is used for a computed tomographic scan process, comprising:

a body configured to hold a septum,

wherein the access port can be injected and pressurized by mechanical assistance, and

wherein the septum is a septum for repeatedly inserting a needle into a cavity defined in the body through the septum".

Then, the two are different in the following features.

<Different Feature 1>

Patent Invention 1 comprises an identifiable feature that is configured to identify the automatically injectable access port via an X-ray after subcutaneous implantation, is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port of at least one of the access port, and is visible by the X-ray, whereas it is unclear whether or not Intention A-9 comprises such a feature.

Different Feature 1 above will be examined.

As shown in Matter A-11-1 and Matter A-12, it is a matter of well-known art that a medical device implanted and used in a human body includes a feature representing a model number of the device and visible by an X-ray (hereinafter, referred to as Well-known art A)

Therefore, it is easy for a person skilled in the art to apply Well-known art A to an

access port that is a similar medical device implanted and used in a human body.

Invention A-9 to which Well-known art A is applied includes an identifiable feature that is a model number visible by an X-ray, and has the attached document of Evidence A No. 10-1. As described in Matter A-10, the attached document describes usage conditions such as the maximum injection pressure, and from the usage conditions, physicians, etc. can identify that it is automatically injectable within the range of usage conditions set appropriately by the manufacturer. Also, since physicians etc. who perceive a model number by the X-ray can confirm the description of the attached document corresponding to the model number, the model number visible by the X-ray associates the access port with the description of the attached document.

Therefore, Intention A-9 to which Well-known art A is applied is attached with the attached document, and in the attached document, there is a description that the practitioner can specify that the access port is automatically injectable within the range of usage condition set appropriately by the manufacturer. Furthermore, the identifiable feature that is visible by the X-ray of the access port associates the access port and the description of the attached document, so that it is one of aspects of Patent Invention 1 premised in "First" above.

Then, in Different Feature 1, the usage conditions described in the attached document corresponds to "information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port," and the model number visible by the X-ray corresponds to "an identifiable feature that is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port, and is visible by the X-ray".

Therefore, Patent Invention 1 could have been easily made by a person skilled in the art by applying Well-known art A to Invention A-9.

3 Regarding Patent Invention 2

Patent Invention 2 further has the matters specifying the invention that "the body is equipped with a housing, the housing having a discharge port and a cap capable of being fixed to the housing, the cap holding the septum in the body" in Patent Invention 1.

Therefore, in comparison of Patent Invention 2 and Invention A-9, the two are different in the following feature in addition to Different Feature 1 above.

<Different Feature 2>

The body of Patent Invention 2 is equipped with a housing, the housing having a discharge port and a cap capable of being fixed to the housing, the cap holding the septum

in the body, whereas it is unclear whether or not Invention A-9 is so equipped.

Different Feature 2 above will be examined.

It could have been easily conceived by a person skilled in the art to apply Matter A-8-1 in the same technical field to the access port of Invention A-9.

Therefore, Patent Invention 2 could have been easily invented by applying Matter A-8-1 and Well-known art A to Invention A-9.

4 Regarding Patent Invention 3

Patent Invention 3 further has the matters specifying the invention that "the housing is equipped with a housing base defining at least one container" in Patent Invention 2.

Therefore, in comparison of Patent Invention 3 and Invention A-9, the two are different in the following feature in addition to Different Features 1 and 2.

<Different Feature 3>

The housing of Patent Invention 3 is equipped with a housing base defining at least one container, whereas it is unclear whether or not Invention A-9 is so equipped.

Different Feature 3 above will be examined.

It could have been easily made by a person skilled in the art to apply Matter A-8-2 in the same technical field to the access port of Invention A-9.

Therefore, Patent Invention 3 could have been easily invented by a person skilled in the art by applying Matter A-8-1, Matter A-8-2, and Well-known art A to Invention A-9.

5 Regarding Patent Invention 4

Patent Invention 4 further has the matters specifying the invention that "the body is equipped with a housing defining a cavity with the septum, and the cavity is in fluid communication with a lumen of a discharge stem" in Patent Invention 1.

Therefore, in comparison of Patent Invention 4 and Invention A-9, the two are different in the following feature in addition to Different Feature 1.

<Different Feature 4>

The body of Patent Invention 4 is equipped with a housing defining a cavity with the septum, and the cavity is in fluid communication with a lumen of a discharge stem, whereas it is unclear whether or not Invention A-9 is so equipped.

Different Feature 4 above will be examined.

It could have been easily conceived by a person skilled in the art to apply Matter A-8-3 in the same technical field to the access port of Invention A-9.

Therefore, Patent Invention 4 could have been easily invented by a person skilled in the art by applying Matter A-8-3 and Well-known art A to Invention A-9.

6 Regarding Patent Invention 5

Patent Invention 5 further has the matters specifying the invention that "the discharge stem is configured to couple with a catheter" in Patent Invention 4.

Therefore, in comparison of Patent Invention 4 and Invention A-9, the two are different in the following feature in addition of Different Features 1 and 4 above.

<Different Feature 5>

The discharge stem of Patent Invention 5 is configured to couple with a catheter, whereas it is unclear whether or not Invention A-9 is so configured.

Different Feature 5 above will be examined.

It could have seen easily made by a person skilled in the art to apply Matter A-8-4 in the same technical field to the access port of Invention A-9.

Therefore, Patent Invention 5 could have been easily invented by a person skilled in the art by applying Matter A-8-3, Matter A-8-4, and Well-known art A to Invention A-9.

7 Regarding Patent Invention 6

Patent Invention 6 further has the matters specifying the invention that "the body is equipped with a suture aperture" in Patent Invention 1.

Therefore, in comparison of Patent Invention 6 and Invention A-9, the two are different in the following feature in addition to Different Feature 1 above.

<Different Feature 6>

The body of Patent Invention 6 is equipped with a suture aperture, whereas it is unclear whether or not Invention A-9 is so equipped.

Different Feature 6 above will be examined.

Since it is a well-known art that a subcutaneous implantable medical device is equipped with a suture aperture (see Matter A-11-2. Hereinafter, referred to as Well-known art B.), it could have been easily conceived by a person skilled in the art to provide

a suture aperture in Invention A-9.

Therefore, Patent Invention 6 could have been easily invented by a person skilled in the art by applying Well-known art A and Well-known art B to Invention A-9.

8 Summary

Therefore, since Patent Inventions 1 to 6 could have been easily invented by a person skilled in the art based on Invention A-9, Matters A-8-1 to A-8-4, Well-known art A and Well-known art B, it should be invalidated for Reason for invalidation 4-A.

No. 7-2 Reason for invalidation 4-B to D

As described in No. 7-1, Patent Inventions 1 to 6 could have been easily invented by a person skilled in the art based on Invention A-9, Matters A-8-1 to A-8-4, and Well-known arts.

No. 8 Reason for invalidation 5 (applicability of patent)

The Demandants allege that since the essence of Patent Invention 1 is "arranged to mean that a specific identifiable feature is automatically injectable," Patent Invention 1 is merely an arbitrary arrangement and does not utilize a law of nature as a whole (Written demand for trial, page 46, line 24 to page 48, line 10).

Then, it will be examined whether or not Patent Invention 1 falls under creation of a technical idea utilizing a law of nature as a whole.

The technical problem premised in Patent Invention 1, according to [0007], [0008], and [0013] to [0016], is that once the access port is implanted, it may be difficult to find the model, but it makes it possible to identify that the implanted access port is automatically injectable via an X-ray after subcutaneous implantation.

Then, the configuration of the technical means for solving the problem is to include an identifiable feature that is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, of the automatically injectable access port, and is visible by an X-ray, and the configuration exerts the effect that it is possible to identify that the implanted access port is automatically injectable after subcutaneous implantation.

Therefore, it can be said that the technical significance of Patent Invention 1 is to provide an identifiable feature that is correlated with information that can be distinguished from an access port that is not rated to be automatically injectable, and is visible by an X-ray, in a subcutaneously implanted access port. Therefore, Patent Invention 1 cannot be

said to be an arbitrary arrangement, and falls under creation of a technical idea utilizing a law of nature as a whole.

No. 9 Closing

As described above, since the application according to the Patent does not meet the requirements stipulated in Article 36(6)(i) of the Patent Act, the Patent falls under Article 123(1)(iv) of the Patent Act.

Even if considering that the application according to the Patent meets the requirements stipulated in Article 36(6)(i) of the Patent Act, the patent regarding Patent Inventions 1 to 6 violates the provisions of Article 29(2) of the Patent Act, and thus falls under Article 123(1)(ii) of the Patent Act.

Therefore, the patent regarding Patent Invention 1 to 6 should be invalidated for Reasons for invalidation 1 and 4.

The costs in connection with the trial shall be borne by the Demandee under the provisions of Article 61 of the Code of Civil Procedure which is applied mutatis mutandis in the provisions of Article 169(2) of the Patent Act.

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

August 8, 2018

Chief administrative judge: NAITO, Shintoku

Administrative judge: TAKAGI, Akira

Administrative judge: KUMAKURA, Tsuyoshi