

Date	April 11, 2002	Court	Tokyo High Court, 6th Civil Division
Case number	2000 (Gyo-Ke) 65		
– A case in which the court determined that the invention titled "process and device for optical and reproducible representation of surgical operations" relates to a medical act that is not recognized as patentable and it therefore does not fall within the category of "industrially applicable invention" referred to in the main paragraph of Article 29, paragraph (1) of the Patent Act.			

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

Summary of the Judgment

1. The plaintiff acquired the right to obtain a patent based on a patent application claiming an invention titled "process and device for optical and reproducible representation of surgical operations." In response to the plaintiff's request for a trial against an examiner's decision of refusal for its patent application, the JPO rendered a decision to dismiss the claim in the request. Accordingly, the plaintiff filed this suit to seek rescission of the JPO decision.

2. In this judgment, the court determined that the invention claimed in the patent application mentioned above relates to a medical act that is not recognized as patentable and it therefore does not fall within the category of "industrially applicable invention" referred to in the main paragraph of Article 29, paragraph (1) of the Patent Act, and dismissed the plaintiff's claim. In making this judgment, the court held as follows.

(1) Under the system that recognizes a medical act itself as patentable, there is, at least ideally, always the possibility that a medical act that a physician intends to perform is subject to a patent. In addition, in general, whether an act is subject to exercise of a patent right is not necessarily immediately and unambiguously clear, and there are many cases where a patent right is asserted against an act, which is eventually not deemed to constitute infringement of the patent right, in the form of a claim for an injunction, etc. This is obvious to this court. A physician could be required to engage in a medical act while being constantly concerned about whether an act he/she intends to perform is subject to a patent, whether he/she would be held responsible for infringement of a patent right due to his/her act, and for what he/she would be held responsible.

(2) A system that puts physicians who engage in medical acts in such circumstances should be considered to be significantly unjustifiable in consideration of the nature of medical acts. It should be considered reasonable to interpret that the Japanese patent

system does not approve such a result. If so, it is clear that the Patent Act does not recognize medical acts themselves as patentable unless it puts in place measures for preventing such a result. However, when the Patent Act made clear the addition of medicines and methods of preparation thereof to the subject matter of patent along with food and drink, etc. by excluding them from the category of unpatentable inventions, no measure was put in place in relation to patents pertaining to medical acts themselves, though a measure was put in place for patents pertaining to inventions for preparation of a medicine. Specifically, the provision to the effect that a patent pertaining to an invention for preparation of a medicine shall not be effective against the "act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist" (Article 69, paragraph (3) of the Patent Act) was established in the Patent Act.

In Article 1, the Patent Act provides that "The purpose of this Act is, through promoting the protection and the utilization of inventions, to encourage inventions, and thereby to contribute to the development of industry." In the main paragraph of Article 29, paragraph (1), the Patent Act provides that "An inventor of an invention that is industrially applicable may be entitled to obtain a patent for said invention, except for the following." However, the Patent Act gives no definition of what is included in "industry." Moreover, there is no specific provision that prescribes medical acts in general as being unpatentable. As long as this is the case, even if it should be generally said that there is originally no reason for narrowly interpreting the meaning of "industry," there is no other way but to understand that the Patent Act provides that an invention relating to a medical act, which is not recognized as patentable for the aforementioned reason, shall not fall within the category of "invention that is industrially applicable."

Judgment rendered on April 11, 2002

2000 (Gyo-Ke) 65 Case of Seeking Rescission of a JPO Decision

Date of conclusion of oral argument: February 28, 2002

Judgment

Plaintiff: Surgical Navigation Technologies, Inc. (An Affiliated
Company of Sofamor Danek Group, Inc.)

Defendant: Kozo Oikawa, Commissioner of the JPO

Main text

The plaintiff's claim shall be dismissed.

The plaintiff shall bear the court costs.

The additional period for filing the final appeal against this judgment
and a petition for acceptance of the final appeal shall be specified as 30
days.

Facts and reasons

No. 1 Judgment sought by the parties

1. Plaintiff

A JPO decision rendered regarding Trial No. 1998-18303 on October 8, 1999 shall
be rescinded.

The defendant shall bear the court costs.

2. Defendant

The plaintiff's claim shall be dismissed.

The plaintiff shall bear the court costs.

No. 2 Facts undisputed by the parties

1. Developments in procedures at the JPO

Georg Schlondorff filed an international patent application for an invention titled
"process and device for the reproducible optical display of a surgical operation" on May
21, 1988 with a priority claim based on a patent application filed in the Federal
Republic of Germany on May 27, 1987. On August 5, 1998, he received an examiner's
decision of refusal, so he filed a request for a trial against the examiner's decision of
refusal on November 24 of the same year. The JPO examined the case as Trial No.
1998-18303. Georg Schlondorff transferred the right to obtain a patent for the
aforementioned invention to the plaintiff on March 9, 1999, when the trial was pending.
The plaintiff submitted a notification of change of patent applicant on May 25, 1999.

After examining the aforementioned case, the JPO rendered a decision to the effect that "The request for a trial in question shall be dismissed" on October 8, 1999. The JPO served a certified copy of the JPO decision to the plaintiff on October 25 of the same year.

2. Scope of claims (Claim 1)

The scope of claims pertaining to the patent application consists of Claims 1 to 18. Of those claims, Claim 1 is as follows:

"A process for the reproducible optical display of a surgical operation performed by using surgical instrument (31), wherein information about the laminagram of a human body part that is subject to the surgical operation is stored in the data memory of data-processing device (21),

the positional data of the surgical site is specified based on the information about the laminagram, surgical instrument (31) is attached to support (16), which can flexibly move three-dimensionally, the positional data of surgical instrument (31) is decided by using the coordinate measuring position (1;50) and is sent to data-processing device (21), and the positional data of surgical instrument (31) is associated with the positional data of the surgical site, and surgical instrument (31) is directed to the surgical site based on this association, which is characterized by the following points:

- (a) at least three measuring points (42), which are easily accessible from outside, are specified or arranged on the human body part as reference points,
- (b) laminagram (41), including measuring points (42), is prepared from the human body part and filed in the data memory,
- (c) the space positions of measuring points (42) are detected by using the coordinate measuring position (1;50), and the measurement data is filed in the data memory,
- (d) data-processing device (21) seeks a relationship between the image data of measuring points (42) included in laminagram (41) and the data of measuring points (42) detected by the coordinate measuring position (1;50),
- (e) the space position of surgical instrument (31), which can flexibly move three-dimensionally, is continuously detected by using the coordinate measuring position (1;50), and the positional data is sent to data-processing device (21),
- (f) data-processing device (21) superimposes the positional data of surgical instrument (31) onto the image information of laminagram (41),
- (g) data-processing device (21) generates superimposed image (43) wherein the image content of laminagram (41) and the moment-to-moment position of surgical instrument (31) in the human body part are superimposed on each other,
- (h) the moment-to-moment position of surgical instrument (31) in the human body part

is displayed on output device (22) as superimposed image (43) along with laminagram (41) of the area where surgical instrument (31) is present, and

(i) when surgical instrument (31) gets away from the displayed laminagram (41) due to its displacement, the laminagram of the site to which surgical instrument (31) was displaced is generated in place of the laminagram that had been displayed up to then." (Hereinafter the invention claimed in Claim 1 is referred to as the "Claimed Invention.")

3. Reasons given in the JPO decision

The reasons given in the JPO decision are as stated in a copy of the written JPO decision attached to this judgment. In short, the JPO found that the Claimed Invention falls under a "method of diagnosis of human beings." On the premise of this finding, the JPO ruled as follows: A method of diagnosis of human beings is ordinarily a method whereby a physician or a person who has been directed by a physician diagnoses human beings, and it is so-called a "medical act"; therefore, it does not fall under "industry" mentioned in the main paragraph of Article 29, paragraph (1) of the Patent Act; consequently, the Claimed Invention does not fall under an "invention that is industrially applicable."

No. 3 Main points of the grounds for rescission of the JPO decision alleged by the plaintiff

The JPO erroneously interpreted that a "method of diagnosis of human beings" does not fall under "industry" mentioned in the main paragraph of Article 29, paragraph (1) of the Patent Act (Ground for Rescission 1). In addition, aside from this point, the JPO falsely recognized that the Claimed Invention falls under a "method of diagnosis of human beings" (Ground for Rescission 2). These errors contained in the JPO decision affect the conclusion of the JPO decision, respectively. Therefore, the JPO decision should be dismissed as an illegal one.

(omitted)

No. 5 Court decision

1. Regarding Ground for Rescission 1 (misinterpretation that a "method of diagnosis of human beings" (medical activities) does not fall under "industry")

(1) In Article 1, the Patent Act provides that "The purpose of this Act is, through promoting the protection and the utilization of inventions, to encourage inventions, and thereby to contribute to the development of industry." In the main paragraph of Article 29, paragraph (1), the Patent Act provides that "An inventor of an invention that is industrially applicable may be entitled to obtain a patent for said invention, except for

the following."

According to general terminology, "industry" mentioned here means a "work of engaging in production, that is, an economical act of creating the use value of a natural object by adding human power thereto or of changing the configuration of a natural object or transferring it for increasing the use value thereof; agriculture, stockbreeding, forestry, fishery, mining, manufacturing, commerce, trade, etc. " (Kojien, fourth edition). However, as mentioned above, generally speaking, it must be said that there was originally no reason for narrowly interpreting the meaning of "industry," taking into account that the purpose of the Patent Act is provided for as contributing to the development of industry by encouraging inventions. The defendant also acknowledges this point.

The Japanese patent system had long held the condition that medical acts, i.e. technologies that are deeply involved in human life and dignity and technologies closely related thereto, can be considered to express ideas that are not subject to protection under the Patent Act by providing for medicines and methods of preparation thereof as unpatentable inventions in the statutory form along with food and drink, etc. However, through the amendment by Act No. 46 of 1975, medicines and methods of preparation thereof were removed from unpatentable inventions along with food and drink, thereby having made clear that they are included in the subject matter of protection by patent (see Article 32 of the Patent Act before and after said amendment).

Under such circumstances, technologies relating to medicines and medical equipment have been considered to fall naturally under "inventions that are industrially applicable."

The argument that medical acts should be widely available for humankind without being included in the subject matter of protection under the Patent Act because they are deeply involved in human life or dignity, has been cited as a main ground for denying the patentability of medical acts in the past. However, this argument is not necessarily sufficiently convincing. Although it is clear that medical acts are deeply involved in human life or dignity, not only medical acts but also many other things that have come to be recognized as being patentable are deeply involved in human life or dignity. The development of medical acts should rather be promoted by including them in the subject matter of the patent because they are deeply involved in human life or dignity and are important technologies to the extent that they should be widely available for humankind, and this will eventually make a more significant contribution to the welfare of humankind. This way of thinking seems to more closely match the purpose of establishment of the patent system. It should be considered at least sufficiently

reasonable to think that it is inconsistent to deny the patentability of medical acts while recognizing the patentability of medicines and medical equipment.

Current medical acts, in particular, advanced medical care, depend significantly on medicines and medical equipment, and it is hardly deniable that a choice of a medical act is virtually dominated in part by patents for medicines and medical equipment, even if medical acts themselves are provided for as unpatentable. It should be said that there is some legitimacy to questions of significance in providing for only medical acts as unpatentable under such circumstances and of whether granting patents only for medicines and medical equipment while not granting them for medical acts will end up only promoting medical acts that significantly depend on medicines and medical equipment.

Considering these together, as long as it was chosen to recognize technologies pertaining to medicines and medical equipment as patentable, these technologies as well as technologies pertaining to medical acts should be recognized as patentable as those that fall under "inventions that are industrially applicable." The idea that it is impossible to find a reason for excluding technologies pertaining to medical acts in terms of interpretation of law may be worth considering.

(2) However, it should be said that there is a significant difference between medicines/medical equipment and medical acts, which cannot be overlooked in considering whether they are patentable.

Even if a medicine or medical equipment becomes subject to a patent, that fact does not preclude a physician from engaging in a medical act by taking advantage of all the abilities and means (medicines and medical equipment play a central role) that he/she has at that time. A physician can exert his/her abilities without any constraints. Even if there may be a situation where a physician could not use a medicine or medical equipment which he/she wants to use under normal circumstances as it is subject to a patent, the situation appears only in the manner that he/she cannot get the relevant medicine or medical equipment. Therefore, such situation does not preclude the physician from exerting the abilities and means that he/she has at the time of actually engaging in a medical act to the maximum extent. The physician can engage in a medical act without having to worry about whether an act that he/she is going to perform is subject to a patent.

However, the situation is different when a medical act itself is recognized as patentable. Under such system, there is, at least ideally, always the possibility that a medical act that a physician intends to perform is subject to a patent. In addition, in general, whether an act is subject to exercise of a patent right is not necessarily

immediately and unambiguously clear, and there are many cases where a patent right is asserted against an act, which is eventually not deemed to constitute infringement of the patent right, in the form of a claim for an injunction, etc. This is obvious to this court. A physician could be required to engage in a medical act while being constantly concerned about whether an act he/she intends to perform is subject to a patent, whether he/she would be examined about his/her own responsibility for infringement of a patent right due to his/her act, and for what responsibility he/she would be examined. Under a system where a medical act itself is subject to a patent, physicians would be required to engage in medical acts in such circumstances unless measures for preventing such circumstances are put in place.

A system that puts physicians who engage in medical acts in such circumstances should be considered to be significantly unjustifiable in consideration of the nature of medical acts. It should be considered reasonable to interpret that the Japanese patent system does not approve such a result. If so, it is clear that the Patent Act does not recognize medical acts themselves as patentable unless it puts in place measures for preventing such a result. However, when the Patent Act made clear the addition of medicines and methods of preparation thereof to the subject matter of patent along with food and drink, etc. by excluding them from the category of unpatentable inventions, no measure was put in place in relation to patents pertaining to medical acts themselves, though a measure was put in place for patents pertaining to inventions for preparation of a medicine. Specifically, the provision to the effect that a patent pertaining to an invention for preparation of a medicine shall not be effective against the "act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist" (Article 69, paragraph (3) of the Patent Act) was established in the Patent Act.

As mentioned above, in Article 1, the Patent Act provides that "The purpose of this Act is, through promoting the protection and the utilization of inventions, to encourage inventions, and thereby to contribute to the development of industry." In the main paragraph of Article 29, paragraph (1), the Patent Act provides that "An inventor of an invention that is industrially applicable may be entitled to obtain a patent for said invention, except for the following." However, the Patent Act gives no definition of those that are included in "industry." Moreover, there is no specific provision that prescribes medical acts in general as being unpatentable. As long as this is the case, even if it should be generally said that there is originally no reason for narrowly interpreting the meaning of "industry," there is no other way but to understand that the Patent Act provides that an invention relating to a medical act, which is not recognized

as patentable for the aforementioned reason, shall not fall under an "invention that is industrially applicable."

The plaintiff's allegation that a medical act itself should be recognized as patentable is worth considering in terms of lawmaking. However, it is unacceptable as an interpretation of the current Patent Act, in which measures that are prerequisites for recognizing the patentability of medical acts have not been put in place, as mentioned above.

2. Regarding Grounds for Rescission 2 (false recognition that the Claimed Invention falls under "methods of diagnosis of human beings" (medical acts))

The statement of the scope of claims that identifies the Claimed Invention is as mentioned above (No. 2, 2.). According to this, it should be obvious that the Claimed Invention falls under medical acts whose patentability should be denied for the aforementioned reason.

The plaintiff alleges that the Claimed Invention can probably be considered to be similar to a medical act because it serves as a method of supporting a surgery through measurement of the structure and conditions of a body if it is worked at the scene of a surgery, and thereby virtually recognizes that the Claimed Invention falls under a medical act as long as it is worked at the scene of a surgery. On the other hand, the plaintiff alleges as follows: The Claimed Invention is not to be worked only at the scene of a surgery; for example, if a surgery is optically displayed using the Claimed Invention, the optical display can be utilized as a training material for medical school students, interns, etc. or as a material for teachers' lectures; in addition, it can be repeated as needed, and is also applicable to assessment for an eligibility test, etc. However, this allegation is unreasonable.

Firstly, even if there is a method of using the Claimed Invention as alleged by the plaintiff, it is nothing more than recording the steps of the Claimed Invention, which were taken during a surgery (in the case of using the phrase "during a surgery" in the narrow sense, steps prior to the surgery are also included), by some means and using what was recorded by reproducing it after the surgery. As a matter of course, it is impossible to deny that the Claimed Invention falls under a medical act on the grounds of the existence of such method of use.

Secondly, leaving this point, even if the Claimed Invention were not the one that can be worked only at the scene of a surgery as alleged by the plaintiff, this fact conversely means that the Claimed Invention can at least be worked at the scene of a surgery. As long as this is the case, when considering the patentability of the Claimed Invention, it is needless to say that a conclusion must be drawn on the premise that the Claimed

Invention falls under a medical act.

On these bases, it can be said that the Claimed Invention obviously falls under a medical act, that is not recognized as patentable, without the need for questioning whether it is reasonable to call the Claimed Invention a "method of diagnosis of human beings." Therefore, it is concluded that there is no reason for the plaintiff's allegation of Ground for Rescission 2.

3. As mentioned above, there is no reason for any of the grounds for rescission alleged by the plaintiff, and the JPO decision does not contain any other defect for which it should be rescinded. Therefore, the claim in this action shall be dismissed. The judgment shall be rendered in the form of the main text by applying Article 7 of the Administrative Case Litigation Act and Article 61 and Article 96, paragraph (2) of the Code of Civil Procedure for the bearing of the court costs and the additional period for filing the final appeal and a petition for acceptance of the final appeal.

Tokyo High Court, 6th Civil Division

Presiding judge: YAMASHITA Kazuaki

Judge: ABE Masayuki

Judge SHISHIDO Mitsuru is not eligible to sign and seal this judgment due to transfer.

Presiding judge: YAMASHITA Kazuaki