Application of Methods related to Medical Activity to the Patent Law

1. Current application of medical inventions to the Patent Law

(1) Request for granting patents to methods including regenerative medicine and gene therapy

The Intellectual Property Policy Outline presented by the Strategic Council on Intellectual Property issued the following instruction on July 3, 2002 regarding the clarification of application of technology related to regenerative medicine and gene therapy to the Patent Law.

> In the field of regenerative medicine and gene therapy, which has made significant progress in recent years, new technology such as methods of cultivating skin and processing cells have been created. In order to clarify how to handle new technology under the Patent Law for the purpose of further promotion of inventions employing such technical developments, the Government of Japan will consider the necessity of revising the Patent Law and the Examination Guidelines and draw a conclusion by the end of FY 2002. When considering this issue, sufficient caution is required to prevent influence on medical activities carried out by doctors.

Discussions on the necessity for revising the Patent Law and the Examination Guidelines were therefore started in this working group in October 2002.

(2) Present conditions and circumstances of granting patents to medical inventions

A medical equipment or a medicine may be granted a patent as an “invention of a product” in itself, and a process of manufacturing it may be considered as an “invention of a process”.[1]

On the other hand, "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans” cannot be granted a patent. Specifically, "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans” are excluded from the scope of granting patents

on the understanding that it cannot be an “invention that is capable of industrial application”. The basis for this judgment includes the fact that there is no strong need to provide incentives under the patent system because such inventions are made at universities and large hospitals. Furthermore, a political reason is that research and development competition is not suitable in medical research, and a humanistic reason is that it would be inappropriate to require approval of the patent holder when urgent treatment is necessary. Another possible reason is that as medical research is conducted on humans, it cannot ultimately be conducted without the cooperation of the patients, and thus requires a high level of ethical awareness on the part of the researchers.

For example, during examinations in the late 1960s to early 1970s, the possibility of industrial application was denied for inventions that required humans and human body parts, not only in medical activity but also such in actions as permanent waves in the hair, methods for surgery, therapy and diagnosis, with the argument that “inventions that require human bodies as a component do not fall in the category of inventions in Article 29(1) , the main paragraph of the Patent Law, because those inventions have no possibility of industrial application”[2]. In the late 1970s and early 1980s, this clause was amended as “among inventions that require human bodies as a component, inventions pertaining to diagnostic and therapeutic methods, etc. have no patentability because they have no capability of industrial application as provided in Article 29 of the Patent Law.”[3] Thus the aforesaid permanent wave and similar methods could be granted a patent. When examination standards were amended in 1993, the phrase “require human bodies as a component” was deleted, and the provision was amended to "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans” are “not inventions capable of industrial application”. The current examination standard after amendment in 2000 provides the same definition.

The examination standard stipulates that in addition to the methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans, among the “methods to process parts extracted from a human body”, the “method to process parts extracted from a human body with the assumption that the extracted part is to be returned to the same person for therapy” falls under the "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans ” and so cannot be granted a patent[4]. In compliance with this provision, artificial dialysis, for example, falls under the category of "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human”, and is not eligible for patent

rights, and the culture of skin cells and cell processing methods are also not eligible for patents if the cultured or processed skin or cells are to be returned to the same person (in the case of autograft). As a result, patents may be granted for the same method if it is heterograft but not if it is autograft.

Although the phrase "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans" denotes several similar types of action, which includes not only medical activity but also culture of skin cells for autograft transplant, we shall refer to them as "methods related to medical activity" for convenience.

(3) Request for patent rights for inventions for methods related to medical activity

There have been requests to review the practice as described above and to amend it to allow patents to be granted for methods related to medical activity.

① Viewpoints on research and development promotion and industrial promotion

Skin culture, cell processing and some other techniques related to regenerative medicine and gene therapy can be carried out not only by physicians but also by those without medical license. These methods are used not only at medical institutions but are expected to develop into a new industry, with the establishment of consignment companies. If, however, the methods are used for autograft transplant, they are not eligible for patent rights as methods related to medical activity even if they do not involve extraction or inoculation procedures.

Despite such practice, researchers and research companies in these fields are requesting protection of these techniques by patent rights in order to encourage the industrial application of new technology and facilitate access for physicians and patients to medical products made with the new technology.

② Legal viewpoints

The Tokyo High Court supported the appeal decision by the Japan Patent Office (JPO) that patent applications for a medical activity should be rejected on April 11, 2002 (Tokyo High Court, 2002, (gyo ke) No. 65).

The decision by the Tokyo High Court stated that there are no grounds to interpret

the terms “medical activity” and “industries” in a narrow sense, and that although the plaintiff’s plea that medical activity may have industrial applicability in the interpretation of the current Patent Law is worth considering, there is a significant difference that cannot be ignored between medicines/medical equipment and medical activity when deciding whether they have patentability or not. Furthermore, a patent system that might force physicians to fear possible infringement of patents would be inappropriate, considering the fundamental nature of medical activity. Therefore, as long as there are no special provisions in the Patent Law, there is no choice but to decide that inventions in medical activity do not fall under the scope of inventions capable of industrial application.

③ Indications from governmental forums

Several requests have been made at various governmental forums on the treatment of technology, mostly those indicated in paragraph ① above, in addition to the Intellectual Property Strategy Guideline in fiscal 2003.

(a) Biotechnology (BT) Policy Outline

The BT Policy Outline presented by the Strategic Council on BT on December 6, 2002 states that it is necessary to review the “clarification of the handling of technology related to medical activity (regenerative medicine, etc.) under the Patent Law” and to reach an early conclusion.

(b) Intellectual Property Strategy by the Council for Science and Technology Policy

In the Intellectual Property Strategy presented by the Council for Science and Technology Policy on December 25, 2002, it is stated that patents should be granted for inventions, “particularly inventions on the processing, treatment, manufacture, etc. of products derived with biotechnology, including those of autograft, and others based on advanced medical technologies”, and that amendment of the examination standard, preparation for amendment of the Law and other specific measures should be taken immediately. As the basis for this assertion, it was noted that the earlier Intellectual Property Strategy: Interim Report issued by the Council (June 19, 2002) stated as follows. There is a tendency for the manufacture, etc. of products derived from biotechnology to be conducted by those other than physicians, and applications for manufacturing approval by the authorities are expected to increase for processed or treated products derived from biotechnology as medicines or medical equipment. Under such changing circumstances,

patents should be granted for inventions in medical services that concern the processing treatment and manufacture of products derived from biotechnology.

(4) Conditions in foreign countries concerning patent granting for inventions in medical services

Whereas patents are not granted for inventions in methods related to medical activity in Japan, the situation in foreign countries is as follows.

① Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

In TRIPS, the participating countries (Members) must grant patents for any inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (Paragraph 1, Article 27). However, it is stipulated that "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" may be excluded from patentability (Paragraph 3 (a), Article 27).

While Members may grant a certain exclusive right to the patent owners (Article 28), Members may provide limited exceptions to the exclusive rights conferred by a patent, taking account of the legitimate interests of third parties (Article 30)[5].

② European Patent Convention (EPC)

Europe has clearly stipulated that inventions of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as industrially applicapble (Article 52(4))[6].

This stipulation was amended to be compatible with TRIPS in 2000, and it is now clearly stated that the methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body fall under the category of unpatentable inventions, whether they are industrially applicable or not, and the conclusion has not been changed (Article 53(c). However, it has not yet been enforced and the Article before the amendment is still applied).

However, among the various inventions on methods related to medical activity, culture of skin and cell processing are not interpreted as medical activity and patents are granted.

③ **United Kingdom (UK)**

A requirement for a patent is that an invention be industrially applicable (Article 1 (1) (c)) in the UK, but it is clearly stated that a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body is not industrially applicable (Article 4 (2)).

④ **Germany**

A requirement for a patent is that an invention be industrially applicable (Article 1 (1)) in Germany, and it is clearly stated that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not industrially applicable (Article 5 (2)).

⑤ **France**

A requirement for a patent is that the invention is that an invention be industrially applicable (Article 611 -10. 1), and it is clearly stated that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not industrially applicable (Article 611-16).

⑥ **United States of America**

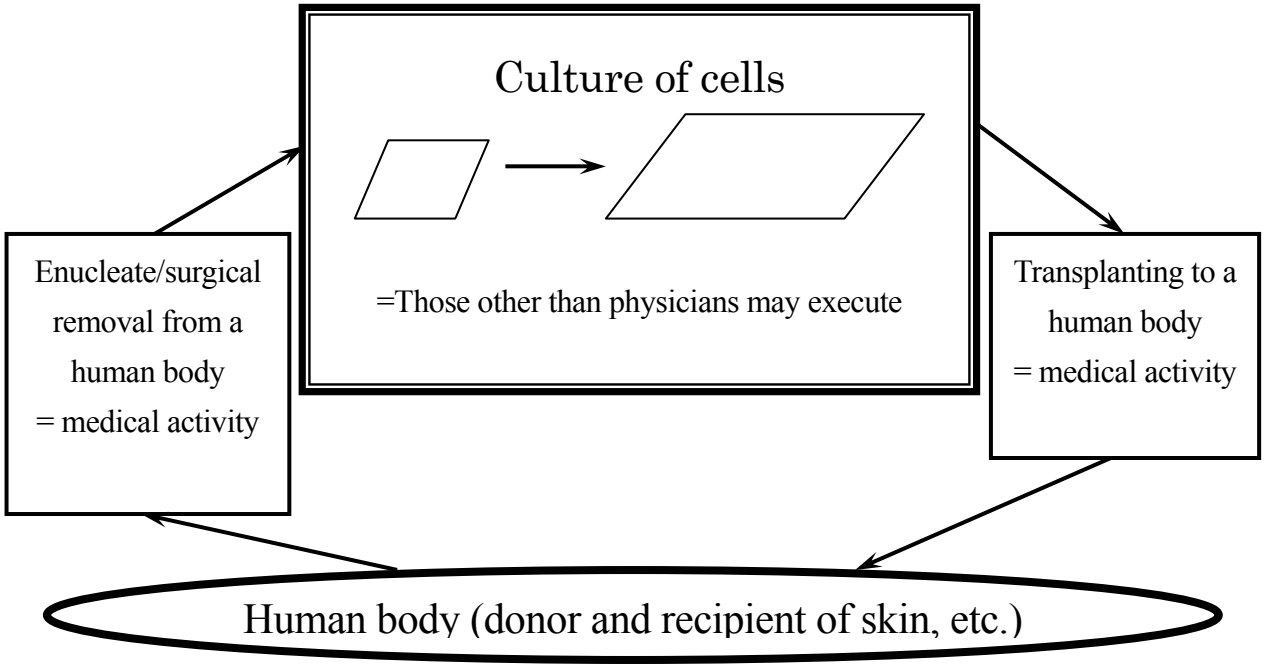
There is no provision regarding unpatentable inventions in the Patent Act (35 USC). Therefore, applications for patents for inventions of methods related to medical activity are judged by whether they meet the patent requirements such as novelty, and patents may be granted unless grounds for objections are found.

However, in 1993, a physician who held the patent right on a surgical method for cataracts filed a law suit against another physician employing a similar method and the hospital in which the surgery was conducted[7]. The Patent Act was therefore amended in 1996 such that in principle patent rights do not apply to medical activity by physicians, etc. (35 USC 287 (c) (1)). For biotechnology patents, however, an injunction or damage compensation demand rights may be excercised in case of infringement of patent rights, even if they fall under medical activity (35 USC 287 (c) (2) (A))[8].

2. Application of processing methods of regenerative medicine

As described above, in regard to the methods of manufacturing medicines or medical equipment (e.g. cultured epidermal sheets) from material extracted from a human body (e.g. cells), criteria for granting a patent differs for those in which the manufactured

medical equipment is transplanted in another (allograft) and for those in which it is transplanted in the same body (autograft). The basis for this is that the latter applies to the "method to process the parts extracted from a human body with the assumption that the extracted part is to be returned to the same person for therapy".



However, in view of the current situation that these actions are conducted within industries away from medical institutions as described in Section 1 (3) ①, at least this technology/methods may be interpreted as being industrially applicable.

Furthermore, as will be discussed later, there have been opinions that it is necessary to ensure the safety of the method at the time of judging whether it is within the scope of patent granting. The methods for manufacturing medicines or medical equipment using parts extracted from humans, whether it is for autograft transplant or that of allograft, fall under the provision on manufacturing methods in the Pharmaceutical Affairs Law. Therefore, it is mandatory to obtain approval provided in the Pharmaceutical Affairs Law to manufacture these medicines and medical equipment for sale in the market, and any breach would be subject to legal penalty. In other words, the feasibility of industrial application other than in medical institutions is verified by the fact that safety is ensured upon manufacture in accordance with the Pharmaceutical Affairs Law.

Allowing such techniques to be within the scope of patent granting therefore also implies that demands for careful review must be met in order to assure safety.

3. Handling of general methods related to medical activity

We have discussed whether the provision that methods related to medical activity in general including methods of surgery, therapy and diagnosis given directly to patients are not within the scope of patent granting should be amended. However, we have a wide range of opinions and there is still much room for debate.

(1) Political necessity to meet current needs

* If we decide whether methods related to medical activity are within the scope of patent granting or not, we need to ascertain whether granted patents make some contribute to the development of industry on the basis of Article 1 of the Patent Law.
* Patents are granted for inventions of medicines and medical equipment used in methods related to medical activity, and there are the same needs concerning methods related to medical activity in general, except methods of processing used for regenerative medicine, so patents should be granted for the latter as well.
* When a patent is granted, it becomes easier to supply or recoup costs, thus promoting investment for research and development.
* Cases in which the rejection of patents for medical activity has hindered the execution of business have not appeared.
* The present situation where only the provision on the indirect infringement of rights is applied to patent granting criteria seems to be against the principle of the Patent Law.

(2) Ensuring safety

* To be eligible for a patent, safety in the subject area must be ensured. A judgement of the Supreme Court shows that prevention of danger and safe operation are required for completion of an invention[9].
* When a patent is granted for a certain method, it could create misunderstanding that the particular method has been proven to be safe.
* Since the Patent Law does not ensure the safety of the subject invention, safety in methods related to medical activity should be ensured by means other than the Patent Law.

(3) Particularity of medical research

* As stated in the Declaration of Helsinki, we regard parts from human bodies (e.g. tussue or cells) as human themselves in medical research and need to keep advanced safety and ethics.
* With the development of TLO (Technology Licensing Offices) in university faculties in recent years, young researchers have become actively involved in obtaining patents.
* When a researcher has trouble obtaining patient consent for clinical tests or passing the institutional review board screening, and a third party conducts the same tests without going through such formalities and achieves results, there is a possibility that the patent will be granted to the third party. Granting a patent to such achievements in technological development could constitute a problem.

Under the above circumstances, we consider it necessary to continue reviewing the political necessity, actual consequences, etc. of deciding whether methods related to medical activity in general should fall under the scope of patents, as we did not reach an agreement at this stage.

4. Establishment of execution limit provision on patent rights

In this working group, it was pointed out that a provision should be made to limit the execution of the right to patents granted for methods related to medical activity as a necessary measure in view of granting patents for medical activity in general. However, since we have not reached an agreement on whether to allow medical activity in general to fall under the scope of patent granting as described in Section 3, we did not reach a conclusion on this question as well, and we should continue reviewing it while monitoring future applications concerning regenerative medicine.

5 Specific measures

Based on the above discussions, in regard to the current practice in patent examination standards of excluding the “method of processing of the extracted part with the purpose of returning it to the same person (e.g. hemodialysis)” from the scope of patent granting on the basis that it falls under the “methods of surgery, therapy or diagnosis of humans”, we believe it is appropriate to promptly amend the standard to define that

"manufacturing methods for medicines or medical equipment made from human parts (e.g. cultured epidermal sheets and artificial bones)" are within the scope of patent granting. It may be appropriate to continue monitoring possible influences in application trends, research and development activities, and magnitude of enforcement regarding patents granted in the future resulting from such amendments concerning the handling of methods related to medical activity under the Patent Law, including the necessity of future discussion.

Footnotes

1 Unpatentable grounds for medicines were deleted by the amendment of the Patent Law in 1975; medicines are now within the scope of patent granting.

2 Examination Manual (March 1968) 42.02P

3 Examination Manual (1981) 41.02A

4 In the amendment of 1993, this clause was clearly stipulated in the Examination Standards.

5 However, it is required that such right must not unfairly obstruct standard execution and must not unfairly damage the profits of the patent owner.

6 In Europe, medical activity for animals is regulated in the same manner as for humans.

7 The defendant pleaded that the patent is void and a decision should be given without deliberation, but was overruled (*Pallin v. Singer*, 36 USPQ2d 1050 (Va. 1995)). Later, the case was settled by consent judgement, which is equivalent to a compromise before the court in Japan, before the decision through deliberation.

8 A bill to delete this exception (107 H.R. 3967) was recently proposed.

9 Commissarie a la energie atomique v. Commissioner of JPO, 23 MINSHU 54 (Sup. Ct., Jan. 28, 1969); patent application for atomic energy.

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Professor, Tokai University

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Attorney at Law and Patent Attorney, Abe Ikubo & Katayama

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Rintaro Sawa

Executive Member Board of Trustees, Japan Medical Association

Masashi Suganuma

M.D.,Ph.D.COO,CanBas Co.,Ltd.

Minoru Takeda

Attorney at Law and Patent Attorney, Takeda Law Office

Hajime Tsukuni

Patent Attorney, Tsukuni Patent Office

Shozo Nagai

Patent Attorney, Director Patent Department, Yamanouchi Pharmaceutical Co., Ltd.

Toshiharu Furukawa

Chief Executive officer of Institute of Gene and Brain Science

Ryuichi Morishita

Professor, Division of Clinical Gene Therapy, Osaka University

Patent System Subcommittee of the Industrial Structure Council Intellectual Property Committee

(Chairperson)

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Professor, University of Tokyo

(Members)

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Professor, Waseda University

Naoki Asami

Editor-in-Chief, Nikkei, Electronics, Nikkei Business Publications, Inc.

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Yoshihiro Ichii

Managing Patent Attorney Intellectual Property Department, IBM Japan, Ltd.

Masahiro Ezaki

General Manager Intellectual Property Div., TOYOTA Motor Corporation

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Vice President Japan Patent Attorneys Association

Kazuhiro Okada

President WACOH Corporation

Yukitaka Kitamura

Editional Writer, Yomiuri Shimbun

Isamu Shimura

Director Intellectual Property Rights Operations Company, Matsushita Electric Industrial Co., Ltd.

Yasutaka Suga

Director Economic Policy Division Department of Economic and Social Policy Japanese Trade Union Confederation

Minoru Takeda

Attorney at Law and Patent Attorney, Takeda Law Office

Nobuyoshi Tanaka

Managing Director Group Executive Corporate Intellectual Property & Legal Headquarters, Canon Inc.

Tsuneshichi Tanaka

Executive Vice President , Ritsumeikan University

Michio Tsuchida

Professor, Doshisya University

Sadao Nagaoka

Professor, Hitotsubashi University

Yoshikazu Nishide

Director Intellectual Property, Fujisawa Pharmaceutical Co., Ltd

Kazuko Matsuo

Attorney at Law and Patent Attorney, Nakamura and Partners

Giichi Marushima

Chairman, Subcommittee on Intellectual Property, Committee on Industrial Technology, Keidanren

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RIKEN Frontier Research System Director

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Toshiya Watanabe

Professor, University of Tokyo

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[Examination Standards Office]
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