4 Research and Study on Patent Protection in Medical Field

The recent rapid progress in life science related technologies has led to an increase of patent applications in such medical fields as gene therapy and regeneration medicine. Also, patent applications for embryonic stem cell, cloning and organ transplant have been filed, and they are required to be considered from the viewpoint of bioethics. Under such circumstances, in this research and study, we examined patent protection for medical field concerning the relationship between medical therapy or diagnosis performed by medical practitioners and patent rights, and that between bioethics and patent rights, based on the actual situation, problems and future trends in Japan and overseas.

I Introduction

There are a few fields in the world of patents in which ethics is at issue. These fields encompass medical procedures involving the human body and life. When dealing with the issue of medical procedures within the framework of the Patent Law, ethical issues further enter the realm of public order resulting in an even more complex situation.

In the past, medical care was considered to be a form of philanthropy, and the monopoly of medical procedures itself was not considered to be desirable. In the patent prosecution practice in Japan, patent applications relating to medical procedures have been rejected on the grounds of a lack of industrial applicability.

However, due to the progress of gene therapy in recent years, the concept of medical care has undergone a considerable change, and it has become necessary to reexamine whether or not conventional prosecution practices are reasonable.

Further, international harmonization is important in the Patent Law, and medical fields, especially advanced medical field, are no exception. It is therefore necessary to investigate the situations in foreign countries. Moreover, it is necessary to conduct a fact-finding survey pertaining to advanced technology before engaging in legal discussions.

Next, the discussion shifts to the matter of how medical procedures should be evaluated under the Patent Law. The evaluation must inevitably be from multiple perspectives. Since a legal evaluation according to the Patent Law becomes the issues, it is necessary to examine in view of two aspects if a patent application of medical procedure is granted. One aspect is if incentives are available for the development of medical technology, and conversely, other aspect is what harm point is. In addition to the above considerations, ultimately a comprehensive discussion must be made to examine the issue from the viewpoint of ethics.

II Present Situation of Patent Protection in Medical Fields

1 Medical Procedures in Patent Field

Accompanying the progress of biotechnology in recent years, research has been actively conducted on genome analysis and ES cells (embryonic stem cell), and the application of those results has led to the achievement of remarkable progress in medical technology, including gene therapy and regenerative medical treatment. As the objective of the Japanese Patent Law is to encourage inventions by protecting and using those inventions in order to contribute to the development of industry, the protection of rapidly progressing medical technology by patents may also be considered. However, since practices such as the treatment and surgeries performed by medical practitioners are involved with human life and death, it has been somewhat difficult to become accustomed to protection through patents as has been done in the past. Therefore, the Japan Patent Office (JPO) currently handles medical procedures in the manner described below. It is stipulated in the main body of Article 29(1) of the Japanese Patent Law that, "Any person who has made an invention which is industrially applicable may obtain a patent therefor, except in the case of the following inventions:……". The JPO lists those inventions that do not apply to "industrially applicable inventions" in the "Examination Guidelines for Patent and Utility Model (*Tokkyo jitsuyoushinan shinsa kijun*)" as being "method of treatment of human body by an operative, a therapeutic, or a diagnostic method practiced on the human body". Namely, since methods involving an operation, a treatment or a diagnosis of human are one in which a medical practitioner (or person being instructed by a medical practitioner) performs an operation, a treatment

or a diagnosis on a human , and are considered to be "medical procedures". Since "medical procedure" does not fall within the classification of "industrially applicable inventions", they are treated as not satisfying the requirements of the main body of Article 29(1) of the Japanese Patent Law.

On the other hand, in view of the objective of the Japanese Patent Law, in special cases in which rather than recognizing the effect of patent rights, the addition of restrictions on those rights is on the contrary considered to be reasonable in terms of the development of industry and the promotion of the public interest, based on the way of thinking that it is necessary to proceed with the addition of such restrictions(*1), the scope over which patent rights do not extend is stipulated in Article 69 of the Japanese Patent Law.

With respect to this implementation and stipulation, the following problems have been pointed out. With respect to the "implementation of industrially applicable inventions", since methods that can be performed by medical practitioners as well as persons other than medical practitioners, such as hair transplants or non-destructive testing, include cases of being performed by medical practitioners, a patent application for those methods ends up being rejected as unpatentable, and is unable to receive protection even if they are performed by persons other than medical practitioners. With respect to methods involving the insertion of a vector into cells, in case they are recognized as being used only for gene therapy performed by medical practitioners, even if they were to be performed by a person other than medical practitioners in the future, they are unable to receive protection by patents. On the other hand, with respect to the "scope over which patent rights do not extend", since numerous patents are involved when gene therapy is performed by a medical practitioner, and there are cases in which it is not possible to license a gene and so forth, there are cases in which gene therapy cannot be performed even when there is a desire to perform it.

Moreover, since there are differences in patent protection of medical procedures between Japan and foreign countries, the potential risk to the applicants has also been pointed out.

In this manner, the current treatment on medical procedures by the JPO not only has problems with domestic implications, but also contains problems from the viewpoint of international harmonization. In consideration of this situation, it is believed to be important to not only more accurately identify those problems as described above, but also to seek ways to resolve those problems.

2 Patents and Bioethics

The biotechnology is progressing day by day, and recently the animalclones are made in the natural of things. Technologies are being created one after the other that hold the potential for creating human organs and human individuals as is evidenced by the differentiation of nerve cells from ES cells. However, discussions relating to ethics are being actively held overseas, and particularly in Europe, with respect to such technologies. On the other hand, the concept of bioethics has not yet permeated a significant portion of Japanese society, and is still not considered to be a prominent issue at present. However, the "Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques"(*2) was enacted in November 2000 in order to control research and development corresponding to the progress of technology, and guidelines pertaining to human ES cells are currently being drafted. In this manner, a situation is arising in Japan as well, in which it is necessary to make a consideration for biotechnological research and technology development from the viewpoint of bioethics. It is believed that a substantial guideline will be required for patents that protect the results of such research and development. Article 32 of the Japanese Patent Law contains stipulations about unpatentability relating to public order and morality. With respect to technologies relating to bioethics, it is indicated in the Implementing Guidelines for Inventions in Specific Fields (Biological Inventions) thatwhen working of an invention inventably contravenes public order, morality, or public health, the invention falls under the invention as provided in Article 32 of Japanese Patent Law.

On the other hand, in Europe, Rule 23d of Implementing Regulations to the European Patent Convention (EPC) contains the stipulation indicated below:

Under Article 53(a) of EPC, European patents shall not be granted in respect of biotechnological inventions which, in particular concern the following:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings; and
(c) Uses of human embryos for industrial or

(*1) Kosaku Yoshihuji, Tokkyoho gaisetsu, 441, (Yuhikaku, 13th ed. 1998).
(*2) Law No. 146, 2000 (established on November 30, 2000, issued on December 6, 2000) *"Hito ni kansuru Clone gijutsu-tou no kisei ni kansuru houritsu"*.

commercial purposes.

This was introduced on the basis of Article 6 of the Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions (the EU Biotechnology Directive).

In Japan, there are currently no concrete guidelines for the manner in which technology relating to bioethics is to be handled under the Patent Law. However, in order to accommodate the progress of technology, in addition to understanding the present situation of technology, it is also necessary to gather information on the situations in foreign countries and put that information to use in the drafting of guidelines .

III Medical Procedures

1 Problems Surrounding Patents

(1) Gene Therapy and Cell Therapy

(i) Introduction

Following the announcement of detailed analysis of the human genome sequence working draft by the Human Genome Project and Celera Genomics in June 2000, revolutionary treatment for new drug discovery using genome sequences has finally moved closer to reality. Two typical examples of this are gene therapy and cell therapy. Gene therapy involves the administration of a gene having an inherently normal function against diseases caused by a gene deficiency that should inherently be present or a gene being in an abnormal state for the purpose of correcting or enhancing cell function and treating the disease. The world's first gene therapy was performed in 1990 in the US on a patient who has a gene deficiency for an enzyme known as adenosine deaminase. The treatment was successful and the patient is in good health today. A similar treatment was performed in Japan for the first time at Hokkaido University, and the treatment was also successful.

Later, gene therapy has been performed for the treatment of deadly diseases such as cancer and AIDS, and nearly 10 years have passed since such treatment was first performed. There are currently more than 300 clinical research protocols for gene therapy being conducted around the world, and the number of patients that have received gene therapy as of June 1999 reached 3,200 (and is estimated to reach 4,000 in the year 2000). Numerous gene therapy clinical researches has been conducted in Japan as well, and 17 patients are actually receiving treatment as of the end of 2000.

(ii) From first generation to second generation

Gene therapy that treats a disease caused by a single gene deficiency is referred to as first generation. It was clearly determined from first generation gene therapy that gene therapy is safe. Thus, therapy was started for diseases for which there are greater possibility of treatment, namely diseases that can be treated by inserting a gene even if their causes are unknown. A typical example of such diseases is circulatory disease, and gene therapy moved to the second generation.

A clinical study was successfully conducted at Tufts University in the US that was started in 1994 involving gene therapy for arteriosclerosis obliterans using endothelial growth factor gene which produces blood vessels. It is scheduled for this gene to be launched in the first part of the 21st century as the first gene pharmaceutical. Patent issues surrounding gene therapy and cell therapy have thus come under close scrutiny as the practical application of such gene pharmaceuticals moves closer to reality.

(iii) Patent issues surrounding gene therapy and cell therapy

Gene therapy is quite different from therapy performed by conventional pharmaceuticals. It involves a complex technology comprised of numerous patents, and examples of important patents alone include patents concerning the vectors themselves, methods of producing a vector, methods of administrating a vector and methods of treating a human. In order to deploy this therapy as a business, it is necessary to acquire licenses of these patents irrespective of whether they are exclusive or non-exclusive.

The largest difference between the US and Japan in terms of patents relating to gene therapy is whether or not administration methods and therapeutic methods are patentable. The policy of not granting any patents of therapeutic methods as observed in the current Japanese Patent Law inhibits the creation of biotechnological venture business and the development of promising industries, and is considered to make it difficult for Japan to win out in biotechnological competition with the US and Europe. Consequently, the grant of patents of therapeutic methods as in the US should be considered.

(2) Medical Equipment

Medical equipments are diagnostic and therapeutic tools in the medical field along with pharmaceuticals, and are essential for maintaining and improving the national health and welfare.

Medical equipments can be said to embody the methods and techniques of diagnosis or therapy in instruments, devices and systems based on the principles of physics, chemistry and physiology. Thus, medical equipment in line with a specific objective is proposed and invented only when either a method of diagnosis or therapy is known or has been newly discovered. In general,

when a creative or innovative method of diagnosis or therapy is discovered, if the method itself can be patented, compared to the patents obtained as inventions of various equipment and systems based on that method, the scope of patent protection becomes broader, which in turn leads to greater incentive for the inventor as well as persons working that invention as a business.

However, there are normally many cases in which it is possible to file an invention of a device or system in place of a therapeutic method. Although this actually results in few problems, it is logically impossible to replace all concepts included in an invention of a therapeutic method into the form of a device or system.

(3) Medical Procedures

If an invention or technology is considered to fall within the category of being a "method of human therapy or diagnosis", any patent relating to the invention on that technology cannot be granted in Japan at present no matter how superior its effects. Even in the case of developing a superior therapeutic method using existing pharmaceuticals or developing a superior gene therapy method that uses a gene, and those methods are recognized as having clear superiority over the existing art, according to current implementation of the Japanese Patent Law, patents are only granted for inventions classified in prescribed categories such as pharmaceutical compositions, pharmaceutical kits, genes themselves or vectors, while the therapeutic method itself cannot be granted a patent.

However, the fact that these technologies were created as a result of the accumulation of persistent research activities by medical practitioners is not different from inventions in other field. In addition, therapeutic methods-relating technologies such as medical procedures and so forth obtained as a result of those research activities should be considered to be essentially the creation of new technical ideas resulting from intellectual activities in the same manner as the case of, for example, genetic recombination methods or pharmaceutical production methods.

The promotion of research and development in these fields is considered to be extremely important in terms of improving public welfare, including the improvement of the quality of health care and the quality of life of patients. In this case, if there is no suitable protection, the opportunity to recover capital invested in research is lost, thereby making it extremely difficult to promote research and development.

2 Situation in the US

35 U.S.C. Sec. 287(c) (the US Patent Law), which stipulates the exception for medical procedures, was added by a revision in 1996. To begin with, the stipulations of 35 U.S.C. Sections 281, 283, 284 and 295 that are cited in 35 U.S.C. Sec. 287(c)(1) are stipulations providing for remedy in the form of injection, damages and so forth. Thus, the provisions of 35 U.S.C. Sec. 287(c)(1) stipulates the general rule that, even in case medical procedures performed by a medical practitioner infringes a patent right, remedy provisions for patent infringement do not apply to the medical practitioner, namely that damages and injection are not granted. Furthermore, according to the defining provisions (35 U.S.C. Sec. 287(c)(2)), a related health care entity means an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity. These typically are considered to be hospitals, universities and so forth, and remedy provisions are also not applied to hospitals at which medical practitioners who perform medical procedures.

However, the term "medical procedures" in the text of 35 U.S.C. Sec. 287(c) is defined in Section (2)(A).

What should be noted here is that, along with "(i) the use of patented machine, manufacture, or composition of matter in violation of such patent" and "(ii) the practice of a patented use of a composition of matter in violation of such patent", "(iii) the practice of a process in violation of a biotechnology patent" is excepted from "medical procedures". Thus, gene therapy using biotechnology, for which there is the greatest desire for research and development in the future and which is actually thought to be conducted, do not fall under the medical procedures as defined in 35 U.S.C. Sec. 287(c), and are not excepted from remedy. In other words, even if gene therapy using biotechnology is a procedure performed by a medical practitioner, it is applicable for damages and injunction due to patent infringement.

3 Situation in Europe

Article 52(4) of EPC(*3) did not exist prior to the Strasbourg Conference of 1963, and the first discussions relating to this provision were contained in a document of the Committee of the European Community of 1964. Agreement in the Patent Cooperation Treaty (PCT) of 1970 had an important effect on this provision. Namely, in PCT

(*3) Since this provision was incorporated to Article 53(c) of EPC in the time of recent reversed EPC, it composes the exceptions to patentability.

Rule 39.1, "methods for treatment of the human or animal body by operation or the therapy, as well as diagnostic methods" were included in a list of its subject matter for which International Searching Authority are not to be required to search.

Finally, inventions relating to medical procedures were recognized as constituting inventions, but were deemed to lack industrial applicability, after which the above provisions were newly established by the Diplomatic Conference in Munich.

Although these EPC provisions had a considerable effect on the national laws of Contracting States, there are some Contracting states that deny the inventiveness of such inventions or treat them in the form of legal exceptions regardless of their industrial applicability (*4).

Traditional term interpretations and interpretive decisions relating to industrial applicability maintain their effect in decisions relating to medical procedures in Europe, and no particular new interpretations, theories or developments can be seen. However, the possibility cannot be denied that even the situation surrounding medical procedures in Europe that appears comparatively conservative will eventually be subjected to changes in corporate activities surrounding the progress of advanced medical care and medical procedures, and transformations in, for example, the necessity for new investment as witnessed in the US and other countries. It will be necessary to constantly pay close attention to what types of accommodations are made by the European Patent Office (EPO) in such a case.

According to the recent decisions(*5), it arise question about "question of how far patent protection should cover medical procedures also arise". In response to this, "the answer has a substantial bearing on the overall economic and legal risks and restraints to which medical activity is subject". In addition, "the appropriate legislative answer to these questions is a matter of policy, which will always be determined by a variety of medical, legal, social and other aspects, even cultural and ethical ones". Moreover, it has also been indicated in the decisions that "it is therefore understandable that the rules governing the patentability of inventions relating to medical activities may differ, even considerably, from one patent system to another, and the EPC has selected a policy judgment so that persons engaging in medical procedures are not obstructed by patents".

This decision provides an intrinsic opinion regarding the issue of medical procedures and patent rights, and is considered to be extremely significant. Ultimately, there is no absolute solution regarding this matter, and it is necessary to select the most appropriate policies while constantly taking into consideration social and various other factors.

4 Arguments in the Patent Law Regarding Therapeutic Method Inventions

The following are presumed to be the reasons for the Japanese Patent Law excluding therapeutic methods from the subject matters for patent protection(*6).

Firstly, the driving force behind technical innovations in medical fields has primarily been universities and other public institutions. As a result, economic incentives have been provided in the form of public assistance for research fund and so forth, thereby eliminating the need for patenting the results of that research.

Secondly, since the incentive for research should be academic evaluations and so forth resulting from the discovery of a new therapeutic method instead of economic incentives, such therapeutic methods should be excepted from the subject matters for patentability.

Thirdly, since pharmaceuticals and medical equipment for the purpose of treatment can be patented under the current system, adequate incentives are ensured.

Fourthly, since medical care is considered to be a form of philanthropy, procedures of saving patients' lives should not be impaired for reasons such as problems in license negotiations. An example of a provision of the Japanese Patent Law that indicates similar considerations is Article 69(3) which prevents patenting of acts of preparing pharmaceuticals but allows pharmaceuticals for patentability.

On the other hand, there are some aspects of these premises that require reconsideration. Firstly, in new medical fields, an increasing amount of attention has been focused on the role of biotechnological venture businesses together with universities and other public institutions in serving as the driving force behind traditional medical procedures research. Due in part to therapeutic methods being clearly indicated as being patentable by a revision of the Patent Law in 1996 in the US, a large number of patents relating to gene therapy and regenerative

(*4) Rainer Moufang, Methods of Medical Treatment Under Patent Law, IIC Vol.24, pp.27-30 (1993).
(*5) T35/99 (OJ EPO, 443, (2000)).
(*6) Nobuhiro Nakayama, Kogyoshoyukenhou jo tokkyohou, pp.116-7, (Kobundo, 1993).

medicine have been granted, and the number of cases of clinical treatment far exceed the number in Japan.

Indeed, the present situation is such that there is a considerable discrepancy in the degree of technological advances between the US and Japan. The concerns have been pointed out over the fact that, even if a patent is granted in Japan, it only ends up benefiting foreign applicants. However, at least for these reasons alone, it is difficult to maintain the medical procedure that differs from that of other fields.

Secondly, since to publish the results of researchers' work in papers and to obtain additional incentive for research by acquiring patents are not a matter to be considered if one of these is obtained, the other becomes unnecessary. In Japan, the utilization of research results from universities is finally starting to be widely recommended.

Thirdly, since new devices, systems, pharmaceuticals and factors are not necessarily required in processes involving gene therapy and regenerative medicine, the need has arisen to discuss the patentability of medical procedures themselves.

The fourth reason requires careful consideration. It is certainly true that the image of a medical practitioner applying for a temporary injunction to suspend an operation in front of a patient on the verge of dying would definitely be a nightmare. However, the following arguments are predicted with respect to policies indicating that medical procedures cannot be patented for reason of their emergency nature.

① Since it is realistically unlikely that anyone would attempt to exercise the right to demand injunction for medical procedures performed by a medical practitioner, it is possible to adopt an optimistic view that there would not cause any actual damage from allowing such medical procedures to be patented. With respect to sensibleness, since persons developing therapeutic methods are no longer limited to medical practitioners, the argument can be made that the actual exercising of such rights is not completely out of the question.

② As a similar argument to that of ①, even if a person actually took legal actions to exercise the right to demand injunction, a court would probably not admit exercising of such rights by taking advantage of legal techniques such as the misuse of rights, and since a court should do so, it is possible to argue this by saying that actual damage resulting from allowing therapeutic methods to be patentable would not occur. However, there is also no guarantee that a patient's life may be threatened as a result of having to wait for a court decision. More to the point, the counter-argument would probably be made that it should not be socially acceptable that the decision to allow treatment is left to the discretion of a court while a patient requiring that treatment and a medical practitioner having the skill to perform that treatment are kept waiting.

③ Since the boundary of medical procedures is not always clear-cut as in the case of hair transplants and computer diagnosis, and medical procedures are not always performed by medical practitioners, it is anticipated that a counter-argument will be made stating that the argument based on the ethics of medical practitioners is not persuasive.

④ Even today when medical procedures are not to be patentable, it has been regrettable to learn from experience that there are in fact patients who are unable to be saved as a result of not receiving a certain level of treatment for economic or geographical reasons. Since a patient cannot be saved due to being unable to pay a license fee is essentially the same situation, it is possible to make the somewhat defiant argument that patents of medical procedures should be allowed. Since the costs of research for sustaining advanced medical care of today are huge, the argument can be made that their complete exception from patentablity prevents venture businesses and so forth from entering this field. Taking this argument further, as long as medical procedures are eligible for patents, providing the exceptional provisions like for acts of preparing pharmaceuticals to exclude medical procedures of medical practitioners from the scope of protection causes protection to exist in name only and is unreasonable.

Although these arguments may seem drastic, their true intention is not to prohibit unauthorized medical procedures, but is limited to only the securing of a certain degree of license fees, and it is believed that the time has come to be worth considering the patentability of medical procedures after ensuring its significance through the establishment of rules for exercising rights(*7).

Ⅳ Bioethics

1 Bioscience Policies and Ethical Rules in Europe

The concept of human dignity or human rights with respect to the human body are brought

(*7) organization of system of dealing with disputes for license fee, compulsory license system, contracting claim of quid pro quo, and so on.

up as ethical and legal bases for restricting the use of parts of the human body or its products for the purpose of medical research and development. However, there is not necessarily a well-defined norm or agreement with respect to its substantial contents or manner of implementation. In analyzing the accommodations made by developed countries thus far, there can be found two types of approaches to human rights and human dignity surrounding the use of the human body, namely the US approach and the European approach.

The US approach is based on the concept that human rights, in their original meaning, refer to the freedom and rights of the individual. In other words, this approach is based on a person being free to decide to use a part of his or her own body, and that a person is recognized to have broad-ranging disposition rights to his or her body or a portion of it. How a person uses a portion of his or her body or its product is composed as the right of privacy of that individual. The primary ethical and legal problems involved here consist of matters such as how to ensure the disclosure of information required to make a decision and the right to receive an adequate explanation(*8), and what extent personal information should be concealed to protect right of privacy.

In contrast, the European approach emphasizes the aspect of public order that goes beyond the individual intentions of human rights. This is based on the perception that personal freedoms and rights cannot be protected if social order is not maintained. In contrast to the contractual Weltanschauung of the US approach in which society is composed of the respective intentions of free individuals, a communal Weltanschauung in which society has an independent existence that goes beyond the individual and people are born and raised within that society lies in the background of the European approach.

When this European approach to human rights is applied to use of the human body, even if that body is one's own body or its product, there is the premise that disposition rights of the individual are subjected to certain restrictions. If this is applied to contract law, it becomes the principle of "public order and morality". In addition, in medical law, both individuals as well as corporations are subject to public control in the form of approval and authorization systems with respect to use of the human body.

In addition, in contrast to "persons" referring to individuals and individuals only in the US approach, in the European approach, they occasionally refer to a member of the entire population that is eligible for legal protection. This is particularly true in the accommodation of gene-related technologies. Thus, the range of public order and morality surrounding the human body includes not only organs, tissues and cells, but also genes and genetic character(*9).

2 UNESCO "Universal Declaration on Human Genome and Human Rights"

(1) Features of the Human Genome Declaration

The basic concept of the Human Genome Declaration(*10) adopted byUNESCO in November 1997 is to prevent the infringement of the human dignity and human rights in the human genome research, its applications and use of genetic information. Consequently, the Human Genome Declaration is composed of the two main pillars described below. The first pillar stipulates general rules while respectively considering the two standpoints of persons engaged in research and application, and persons who are the subjects of that research and application. The second pillar is the protection of the genetic information of individuals. Although the genetic characteristics of each individual are revealed in detail by human genome analysis, since there is the potential for those genetic characteristics to induce discrimination, the confidentiality of that genetic information must be protected.

UNESCO held an international symposium in January 1995 relating to legislation for protecting the results of genetic research (*11). Although a wide range of subjects were discussed there, with respect to the application of the patent system in particular, all of the countries expressed strong hesitation to granting biological patents for ethical reasons. An agreement was reached at the symposium that simply indicating a DNA sequence lacks novelty and thus there is no patentability; however if the function of that sequence is clearly demonstrated, then there is creativity and it is patentable.

The International Bioethics Committee conducted an international survey regarding the outline of the Human Genome Protection Declaration from May 1995 to January 1996. According to the report on the results(*12), with respect to the patentability of the human genome

(*8) It is said that informed consent is the achieved result of these rights.
(*9) In US approach, a gene is a part of privacy rights of individuals, and only protected to that extent.
(*10) 29 C/Resolution 17: Universal Declaration on Human Genome and Human Rights.
(*11) International Workshop on Legal System for the Protection of the Results of Genetic Research, 30-31 Jan. 1995.
(*12) International Consultation on the Outlines of UNESCO Declaration on the Human Genome, 5 April 1996.

within the framework of the human genome concept as a mankind's common heritage, it was indicated that, although this concept should guarantee free access to the results of human genome research, at the same time it should not exclude the patentability of those results. It was also stated that the distinction between discoveries and inventions in genome research is becoming increasingly difficult, that the general rule of being impossible to possess the human body, any part of it or its products conflicts with patentability from an ethical viewpoint, that the important issue actually is how to secure the benefits to mankind in this field, and that the concept of mankind's common heritage does not always exclude patents with respect to human genome research.

Now, what is the meaning of Article 1 of the UNESCO Declaration with respect to intellectual property rights? The phrase of "in a symbolic sense, the human genome is the heritage of humanity" contained in that declaration refers to a product of compromise, and clearly indicates the general rule of the human genome not being subject to ownership. Thus, on the basis of this phrase, it can be said that this entrusts free access to research results for the sake of future research advances.

In contrast, Article 4 of the declaration does not provide an adequate explanation of what is meant by "the human genome in its natural state". However, this can probably be interpreted as meaning that simply acquiring knowledge of DNA, genes or a partial genome sequence is not patentable, and that the raw genetic information obtained from those should guarantee free access by researchers.

In this manner, the declaration does not reach a conclusion regarding patentability of the human genome directly. However, the North-South problem of genome-related patents should also be pointed out. Articles 18 and 19 of the declaration respectively set up the importance of international dissemination of scientific knowledge concerning the human genome, and to benefit from the achievements of scientific and technological research as well as to promote the free exchange of scientific knowledge and information.

(2) Human Genome Declaration and Intellectual Property Rights

In Japan until now, ideals and framework acceptable to the general public in the fields of life science and bioethics have unfortunately yet to be established. Human genome research is inherently unrestricted and contributes to the progress of science and human welfare. The problem lies in the application of research methods and research results in that process. Taking advantage of the opportunity offered by the UNESCO Declaration, it is necessary to have discussions from various perspectives regarding human genome research and its application and to obtain substantial results.

The issue of intellectual property rights pertaining to the human genome is one offshoot of this. Although this declaration is centrally targeted on human genome "research", since human genome research leads to clinical research and applications to medical care, the issue of intellectual property rights of the human genome will play an extremely important role in the realization of so-called order-made medical care. Although this does not mean that this declaration itself is useful, the ideals of human dignity and respect for human rights embodied in the various rules of this declaration should be considered to have the potential to be used as standards for granting intellectual property rights. In the case of the human genome, distinguishing between discoveries and inventions in patents is already difficult. In addition, the standard of public order and morality will likely be complemented and clarified by incorporating human dignity and human rights that serve as the core concepts of bioethics into the standards.

3 Bioethics and Patent Laws in the US and Europe

(1) Historical Trends of the European Patent Office

The issue of bioethics has been traditionally treated exclusively as "an issue of public order and morality" by the EPO.

Article 53(a) of EPC stipulates that even an invention satisfies patentability requirements such as novelty, inventive step and industrial applicability, if that invention violates public order and morality, it is not to be patented. The issue of bioethics at the EPO has become a controversial issue as to whether or not a biological invention subject to the EPC violates the provisions of this article.

Together with Article 52(1) of EPC stipulating the basic principle of the European patent system which states that "patents shall be granted for any inventions which are susceptible of industrial application, which are new, which involve an inventive step", it should be noted that Articles 53(a) and 53(b) of EPC are composed such that even among inventions that satisfy such patentability requirements, there exist inventions that deviate from the basic principle and cannot be patented. If one were to follow this composition, the provisions of Article 52(1) of EPC serve as the basis of the patent system, while Articles 53(a) and 53(b) of EPC that define deviation from

that basic principle must contain a considerably constructive significance. In conventional EPO decisions from Boards of Appeal, the reason of repeatedly employing an interpretation method to interpret as narrow as possible is precisely in consideration of this point since Articles 53(a) and 53(b) of EPC are exceptional provisions of Article 52(1) of EPC.

Moreover, attention should also be focused on Article 53(a), the second sentence of EPC, which states "provided that such exploitation shall not be deemed to be so contrary merely because public order or morality is prohibited by law or regulation in some or all of the Contracting States". In interpreting the "public order or morality" of this provision, although the norms stipulated in other laws or other government regulations may be referred to, dependence on those norms alone is strictly admonished, and whether the norms are referred to or not, it can be understood to be stipulated that an interpretation must be made in accordance with the legal system of the EPC. With respect to bioethics, although there are various provisions in other laws as well, it must be strongly emphasized that "public order and morality" under the EPC is a concept that should foremost be interpreted in line with the objectives of the EPC.

(2) Related Laws

Article 27(1) and (2) of the TRIPs Agreement that went into effect on January 1, 1995 confirm the legal relationship between Article 52(1) and Article 53(a) of EPC, and can be understood to ultimately have been provided for EPC to reasonably observe the TRIPs Agreement.

Moreover, the EU Biotechnology Directive went into effect on July 30, 1998 for the objectives consisting of ① improvement of inadequate patent protection as compared with the US and Japan, ② promotion of research and development as well as product distribution, and ③ equalization of national legislations within the region.

The Member States of the European Union (EU) must implement national laws, regulations and administrative provisions that comply with this Directive no later than 2 years from the effective date of this Directive in the official gazette of the EU (Article 15). Those Member States that make such legal revisions are simultaneously Members of the TRIPs Agreement and thus, laws following revision must simultaneously observe the TRIPs Agreement. As a result of such requirements, the composition of Article 6(1) of the EU Biotechnology Directive is composed so as to comply with Article 27(2) of the TRIPs Agreement.

A list of examples of such violation of public order and morality is given in Article 6(2) of the Directive. As was previously mentioned, EU Member States are bound such that the granting of patents to the inventions listed the Article is not allowed due to the violation of public order and morality.

(3) Situation in the US

Although there has essentially been no discussion regarding the relationship between the Patent Law and bioethics in the US, the situation remains unchanged until now without serious legal development. Currently, the US Patent and Trademark Office (USPTO) is aggressively issuing patents to biological inventions, including regenerative medicine and gene therapy.

4 Accommodations by Various Countries of Controls on Human Cloning Techniques

(1) Situation in Japan - "The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques"

(i) Birth of the Cloned Sheep "Dolly"

A group at the Roslin Institute in the UK announced in February 1997 that they had succeeded in producing a cloning of sheep by transplanting the nuclei of somatic cells of an adult sheep (mammary gland cells) to a denucleated ovum. The birth of this cloning of sheep, named Dolly, attracted the attention of the entire world as the first such revolutionary breakthrough in mammals.

The technology that resulted in the birth of Dolly (somatic cell cloning technology) is assumed to be advantageously used to make it considerably easier to produce animals that secrete pharmaceuticals into mother's milk, to accurately test the quality of breeding cattle meat and to reduce the amount of time required for that testing by using this technology in the livestock industry.

However, this also means that it has actually become possible to apply this technology to humans and produce a cloning of human being having a genetic structure identical to a person who already exists, and the validity of this application has resulted in significant international ethical concerns.

(ii) Accommodations by Japan

In Japan, the policy committee of the Council for Science and Technology, an advisory panel to the prime minister, made a decision in March 1997 to the effect that the distribution of government funds for research on cloning of human beings should be withheld.

Later, in order to hold discussions on the validity of application of Japanese cloning

technology to humans, the Bioethics Panel was established within the Council for Science and Technology in the form of a permanent deliberative organ for considering a wide range of issues pertaining to bioethics, gathering a various sense of values extensively and holding discussions from a broad perspective, including the viewpoint of anthro-sociology, and this committee has been proceeding with deliberations pertaining to this issue.

The Bioethics Panel promoted discussions by establishing the Clone Subcommittee in January 1998, after which the Clone Subcommittee released a report in November 1999 entitled, "Legal Regulations of Production of Humans by Cloning Technology". A decision was then made in December of the same year known as "Production of Humans by Cloning Technology", which adopted the course that the production of cloning of humans should be controlled by law, including punitive provisions.

Based on these discussions in the Bioethics Panel, the government drafted a bill and enacted the "The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques" in November 2000.

(2) Situation in Foreign Countries

With the announcement of the birth of Dolly, discussions and controls regarding the control of the application of cloning technology to humans were implemented in various countries and international organizations, including the US and Europe.

In France, this can be interpreted as being prohibited in the "Bioethics Acts" (1994). More specifically, this law states that the production of cloning of human beings falls under prohibition of eugenic treatment for the purpose of screening humans, while the production of cloning of human embryos falls under prohibition of production for the purpose of research on human embryos.

In the UK, the production of cloning of human embryos was confirmed not to be permitted by the "Human Fertilization and Embryology Act"(1990). The "Human Fertilization and Embryology Act"was revised in January 2001 so as to allow the use of some research on cloning of human embryos. Following this revision as well, the production of embryos for the purpose of producing cloning of human beings is expected to continue not to be permitted.

In Germany, the production of cloning of human embryos and their transplantation into a mother body are both clearly prohibited in the Embryo Protection Law (1990).

In the US, there are currently no laws at the federal level that prohibit the production of cloning of human beings.

In the Council of Europe, in addition to the signing of the "Convention on Human Rights and Biomedicine" containing provisions that prohibit the production of human embryos for research purposes in April 1997, the "Supplemental Protocol to the Convention on Human Rights and Biomedicine" was signed in January 1998 as a supplemental agreement to the above convention relating to the prohibition of the use of all cloning technology used for the purpose of creating genetically identical human beings.

Further, the World Health Organization adopted a resolution in May 1997 indicating that the application to humans of cloning technology for artificially producing living beings having the same genetic information cannot be allowed.

Furthermore, in a declaration made by the leaders of 8 nations at the Denver Summit in June 1997, it was clearly stated to the effect that suitable domestic measures and close international cooperation are required to prohibit the transplantation of somatic cell nuclei for the purpose of creating offspring.

Moreover, UNESCO also adopted the "Universal Declaration on Human Genome and Human Rights" in November 1997, indicating the production of cloning of human beings as being one example of an act that cannot be allowed as contrary to human dignity.

As has been mentioned above, following the birth of a cloned sheep by transplanting nuclei originating in somatic cells, the worldwide trend at least for the time being appears to be sweeping prohibition of the production of cloning of human beings.

V Summary

1 Perception of the Patent System

Due to the fact that the current Japanese Patent Law is implemented not to grant patents to medical procedures such as human surgical methods and diagnostic methods, in order to discuss the issue of patent protection in the medical field, it will be more important for parties concerned to share their perception of the current patent system compared to those in other fields.

For example, even if the current patent system were revised and its implementation was changed so that inventions relating to medical procedures were able to be granted patents, it goes without saying that patents are only granted to inventions that satisfy patentability requirements such as novelty and an inventive step. Thus, it is the major premise for holding discussions to share the perception that not all inventions relating to medical procedures will be granted patents.

Namely, even if inventions relating to medical procedures were granted patents as a result of revision of the patent law or changes in its implementation, patents would not be granted to inventions that were already known at the time of filing. Not only would this mean that the granting of patent to a third party might be inhibited by the publication of scientific reports and so forth by an inventor, but it would also mean that patents would not be granted to inventions relating to medical procedures that have already been disclosed.

However, among those opinions that point out the danger in granting patents to inventions relating to medical procedures, there are some fears that medical technologies used until now will no longer be able to work since patents are granted to all medical technologies. It is important to hold discussions while sharing a common perception of the patent system and on the basis of a common awareness that such fears are based on misunderstandings.

In addition, it is necessary to have a shared perception that if the patent system were a system for the purpose of promoting further advances in technology through public disclosure of technology, granting patents to inventions relating to medical technology leads to promotion of public disclosure of large-scale research results such as the Human Genome Project and also to promote research in medical fields such as genetic diagnosis and gene therapy. Granting patents to inventions relating to medical procedures would also have the effect of promoting the advancement of research in medical fields as well as promoting the progress of medical technology.

2 Implementation Regarding Medical procedures in the Current Japanese Patent Law

In the current Japanese Patent Law, although inventions of methods relating to medical procedures such as human surgical methods and therapeutic methods are treated as not satisfying the requirement of "industrial applicability" as stipulated in the main body of Article 29(1) of the Japanese Patent Law, it is necessary to adequately discuss the validity of this implementation.

The EPO has revised provisions similar to the implementation used in Japan such that medical procedures do not fall within the category of "industrially applicable inventions" as stipulated in Article 52(4) of EPC, and the medical procedures were excluded from patentability according to the "Exception of Patentability" stipulated in Article 53(c) of EPC. This revision of EPC was implemented with the aim of conforming to the TRIPs Agreement.

Namely, although Article 27 of the TRIPs Agreement stipulates patentability, in paragraph 1 of that article it is stated that the general rule that patent shall be available for any inventions in all fields of technology, provided that they "are new, involve an inventive step and are capable of industrial application" and those inventions that may be excluded from patentability invention by Members are stipulated in paragraphs 2 and 3 of that article. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals are stipulated in paragraph 3(a) that they may be excluded from patentability. It is therefore necessary to further examine the interpretation of Article 27 of the TRIPs Agreement, namely the relationship between paragraphs 1 and 3.

In addition, in the current Japanese Patent Law, only those inventions of methods relating to human medical procedures are treated as not having industrial applicability, namely that medical practice is not an industry. At present however, since there is a number of opinions that it is no longer possible to state, "medical practice is not an industry", it is also necessary to carefully examine the validity of this examination guideline.

In other words, although the current Japanese Patent Law is such that diagnostic, therapeutic and surgical methods for the treatment of animals are recognized as having industrial applicability and are therefore patentable, similar methods used on humans are not recognized as having industrial applicability. It is therefore necessary to examine this point not only from the viewpoint of international harmonization of the patent system, but also from the viewpoint of international harmonization with respect to the implementation of examinations and the examination process.

In addition, even in the case of allowing patents to be granted to medical procedures as in the US, it is necessary to examine this matter while clearly defining the scope of medical procedures and acts by medical practitioners, such that patent rights do not extend to therapeutic procedures performed by medical practitioners.

It should be noticed here that changing the current implementation of the patent law does not necessarily admit that the current implementation is incorrect, but rather that, after having patents to be granted to inventions relating to medical procedures, the implementation can be carried out such that individual inventions are judged for industrial applicability and patents are not granted for reasons of not satisfying the requirement.

3 Definition of Medical Procedures and Acts by Medical practitioners

It should be noted that all inventions relating

to medical procedures are not excluded from patentability in the current Japanese Patent Law and also it is necessary to organize their relationship with infringements.

Namely, since patents are granted to instruments, pharmaceuticals and so forth required for medical procedures even under the current Japanese Patent Law, it is necessary to verify the relationship between these inventions and inventions relating to medical procedures.

For example, the use of patented instruments or pharmaceuticals by a medical practitioner in medical procedures undoubtedly constitutes patent infringement even under the current Japanese Patent Law. Consequently, not only is it necessary to verify specific effects resulting from granting patents to medical procedures, it is also necessary to further consider what is meant by medical procedures themselves.

At that time, since the scope of medical procedures is expanding and the nature of medical procedures is undergoing changes due to the progress of medical technology, it is neither very beneficial nor constructive to comprehensively discuss the merits and demerits of granting patents to all medical procedures. Thus, it is necessary to make a concrete and detailed assessment of those merits and demerits resulting from granting patents for each class of medical procedures.

Further, under the current Japanese Patent Law, in the case a medical practitioner uses a patented gene when performing gene therapy, since there are no provisions provided that restrict effect, it is reasonable to assume that the medical practitioner is required to obtain the license of the patentee of the gene. Although a similar approach is considered to be adopted in the US and Europe as well, it is also necessary to verify the balance and relationship with effect restricting provisions with respect to acts of preparing pharmaceuticals performed by medical practitioners as stipulated in Article 69(3) of the current Japanese Patent Law.

4 Conclusion

When considering granting patents to medical procedures, typical examples of opposition are the effect on economic activities, etc. and problems in terms of bioethics.

With respect to the effect on economic activities in the case of granting patents to medical procedures, as was previously stated, it is necessary to verify detrimental effects on economic activities for each type of inventions relating to medical procedures.

Further, when granting patents to inventions relating to medical procedures, it is necessary to consider separately the distinction of inventions relating to medical procedures from inventions in other fields, and restrictions on the effect of inventions relating to medical procedures after patents have been granted.

In particular, the distinction of inventions relating to medical procedures from inventions in other fields based solely on the assumption that medical practice is not an industry requires examination not only from the viewpoint of compatibility with the TRIPs Agreement, but also from numerous other viewpoints, including the actual state of research and development in the medical field and the actual health care setting.

Furthermore, although there are relevant issues relating to bioethics, and it is necessary to establish judgment standards for public order and morality in the light of bioethics, it is clear that the scope of problems from the viewpoint of bioethics and that of public order and morality overlap.

Consequently, it is preferable that a general framework from the viewpoint of "human dignity" and "basic human rights" be established with respect to guidelines relating to public order and morality, incorporating the viewpoint of bioethics while taking into consideration the advance of technology and so forth, and more specifically, that judgments be made on case by case. Further, with respect to the guidelines themselves, it is necessary to accumulate individual cases and revise continuously based on the formation of a social consensus, including the enactment of various laws and regulations, and it is required to promptly and effectively accommodate the progress of technology.

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