3 Research and Study on Protection of Results of Genome Research

Due to rapid progress in genetic analysis peripheral technologies in recent years, genome research has brought about a significant revolution in conventional research and development techniques. In addition, the creation of new research and development techniques has led to the generation of various results incidental to genome research including DNA sequences and genes. Under such circumstances, patent applications relating to the results of genome research are being made in various forms unlike those in the past, and there is considerable discussion regarding the relationship of rights relating to these results.

In this research and study, a study was made of the future state of suitable protection of the results of genome research while taking into consideration the existence of problems characteristic to the present stage of genome research from technical, legal and practical viewpoints.

I Gene - Related Technology and Patents

1 The Patent Law and Genes

Under the Japanese Patent Law (JPL), the number of subjects protected by patents is increasing each year, and in the field of biotechnology as well, the targets of protection are changing along with the progress of technology. During the period from around 1950 to around 1955, applications describing technologies for creating effective substances such as antibiotics using microorganisms began to be filed. Accompanying the introduction of the substance patent system in 1975, it became possible to file and patent microorganisms themselves, chemical substances and so forth that had previously been outside the application scope of patents. In addition, the number of cases recognizing patents on plants and animals has also increased. On the other hand, following the proliferation of gene recombinat technology in the 1980's, applications began to be filed for proteins and so forth obtained by gene recombinat technology. In this manner, chemical substances obtained artificially instead of from nature as in the past are becoming the subjects of patent protection, and genes will also become subjects of patent protection as a result of acquiring specific genes in their pure form using artificial techniques and elucidating their useful functions (uses) in the same manner as other chemical substances.

2 Implementation Regarding Gene-Related Inventions

Genes originally came to be positioned as substance inventions. Later in the 1980's, a considerable number of gene-related applications were filed. In consideration of this situation, "Examination Standards for Specific Technical Fields (Biological Inventions)" were announced in 1993 by the Japanese Patent Office (JPO), and standards in the field of biotechnology, including inventions relating to genes, were clarified. These standards clearly describe judgment of the respective patentability requirements and specification description requirements for microorganisms, plants, animals and genetic engineering. Moreover, "Specification Examples Relating to Biological Inventions" was produced in 1994 for the purpose of enhancing understanding.

On the other hand, the trilateral patent offices of Japan, the U.S. and Europe conducted a comparative study starting in 1995 of the implementation of patent examinations regarding biotechnological inventions, and particularly inventions relating to genetic engineering, for the purpose of international harmonization in biotechnological fields. Upon completion of that study, the JPO produced "Implementation Guidelines Relating to Biological Inventions" in 1997.

In addition, amidst the progress made in the field of genome analysis by the Human Genome Project that began in 1990, inventions relating to gene fragments (ESTs: Expressed Sequence Tags) have begun to be filed in the U.S., and since statements have been issued to the effect that gene fragments can be patented in the U.S., it was agreed at a meeting of the commissioners of the patent offices of Japan, the U.S. and Europe held in Miami in 1998 to conduct a comparative study in Japan, the U.S. and Europe on the patentability of DNA fragments. In May of the following year of 1999, it was agreed at a meeting of persons in charge of biotechnological fields of the patent offices of Japan, the U.S. and Europe held in Hague to adopt and announce a report of the comparative study, which was later publicly disclosed throughout the world on the

Internet in June(*1). In this report, the trilateral patent offices of Japan, the U.S. and Europe agreed on the interpretation that, "DNA fragments not having function or extraordinary utility are not inventions that can be granted a patent." Moreover, on the basis of this comparative study of the patent offices of Japan, the U.S. and Europe, the JPO produced and publicly announced the "Examples of examination on the inventions related to genes"(*2). In addition to DNA fragments, these examples contain ones relating to full-length complementary DNA (cDNA) and single nucleotide polymorphism (SNP).

3 Genome Drug Development

The current flow of drug development is changing towards the direction of analyzing a DNA sequence with a sequencer, clarifying function from the resulting DNA sequence using a computer, searching for substances that inhibit or activate that function after analyzing that function and the mechanism of disease, and then using those substances in pharmaceuticals. Accompanying these changes in the flow of drug development, the form of patent applications is also changing. When a large number of novel gene fragments are obtained, applications are filed for computer readable media on which their sequence information is stored and databases containing their sequence information, or applications are filed for novel genes and proteins coded for by genes for which the functions of certain sequences have been elucidated by computer using bioinformatics based on the above sequence information. Moreover, applications are also filed for methods for screening chemical substances that inhibit or activate a protein having that function by using such protein, as well as applications relating to the resulting chemical substances or pharmaceuticals containing the chemical substances as their active ingredients. In this manner, accompanying changes in the flow of drug development, the form of applications is also changing, and applications are being filed such that a single application is filed for a series of research results extending from the discovery of a novel gene to pharmaceutical development.

II Present State of Genome Research

1 Status of Technology Development

1-1 Genome and Gene Analysis Technologies

Many of the gene analysis technologies that are widely used at present, including PCR (Polymerase Chain Reaction) technology, DNA synthesizers, DNA sequencers, DNA microarrays, DNA chip technology, gene-destroyed mice (knockout mice) production technology and viral vectors for gene therapy, were developed after 1980.

1-2 DNA Microarray and DNA Chip Technology

Although computer microchips are developed to function as tools capable of rapidly processing large amounts of information, DNA microarrays and DNA chips are similarly developed for the purpose of acquiring large amounts of genetic information using a small substrate (for example, measuring about 1 cm x 1 cm in the case of DNA chips or several cm x several cm in the case of DNA microarrays). Considerable attention has been focused on these DNA chips and DNA microarrays recently, and research is being conducted on the application of chip technology, including research in the interaction between DNA sequences and proteins. In addition, important use for DNA microarray and DNA chip technology include its application of gene polymorphism information analysis involving investigating congenital differences or changes in genetic code, or changes in genetic code accompanying illness, as well as gene expression information analysis involving investigating the functions of gene codes.

The term "systematic" best expresses the approach applied by genome research as compared with the approach of conventional biological research. It is not possible to understand complex life phenomena and disease states simply in terms of the function of a single or small number of genes. By systematically investigating the amount of expression and polymorphism of a large number of genes using DNA microarrays and DNA chips, it becomes possible to identify those mechanisms that bring about changes in life phenomena and disease states due to differences in the quality and quantity of genes. As a result, it is possible to achieve significant enhancement of the

(*1) Trilateral Project B3b, "Comparative study on biotechnology patent practices, Theme: Patentability of DNA fragments(http://www.jpo-miti.go.jp/saikine/tws/sr-3-b3b.htm)
(*2) http://www.jpo-miti.go.jp/infoe/dnas.htm

understanding of life and disease. The progress of analytical technologies has made it possible to perform tasks that were previously considered to be impossible or require extensive efforts extremely easily. DNA microarray and DNA chip technologies are analytical technologies that have the potential to bring about revolutionary progress in medical and biological research, leading to significant contributions to health and medical care.

1-3 Bioinformatics

(1) Meaning of Bioinformatics

Roughly speaking, the concept of bioinformatics (biological information science), is composed of the following three components. The first is the construction of databases for containing information such as DNA base sequences, amino acid sequences of proteins, three-dimensional structures of proteins, motifs and functions. The second is the development of various types of search tools and methodologies, including sequence homology searches (e.g., BLAST), for extracting the desired information from these databases. Finally, the third is research for searching for disease-related genes, analyzing information related to evolution and elucidation of the mechanisms of individual life phenomena by conducting detailed investigations of the functions of individual genes and proteins using various function analytical techniques from the resulting large amount of data.

(2) Importance of Bioinformatics

As a result of promotion of large-scale genome projects, the number of sequences that have been identified has increased rapidly, and in looking at these increases in year units, the number of identified sequences is essentially doubling each year. Since it is virtually impossible to analyze such a vast amount of data manually, in order to extract the information that is desired from this huge amount of data, it is necessary to use various types of available analytical tools or create individual simple programs.

In addition to analysis of sequence homology as has been done in the past, bioinformatics is considered to be essential for gathering higher order data relating to proteins coded by genes on a genome scale (including information on three-dimensional structure, functions, expression profiles, individual differences and interaction with other molecules or proteins) as well as for making detailed analyses of that data, and for this reason, is generating an extremely high level of interest.

(3) Gene Structure and Function

Once the protein coding region is predicted from a gene sequence, in order to estimate the function of that gene, the first step of bioinformatics is to refer to the annotation by searching for sequence homology to find those sequences having a high degree of homology. Next, motifs are searched for within the sequence to gather information relating to function. At this stage, with some luck, it may be possible to predict the local site where it is a secretory protein or transcription factor. Moreover, it is also possible to determine if it is possible to predict the three-dimensional structure, or classify to what type of family the protein belongs. Although estimation of the functions of individual proteins is generally performed by taking this approach, since various genomes are analyzed, an approach is probably also effective in which entire genomes are compared to find corresponding gene set Clusters of Orthologous Groups (COGs) (*3) between species. In addition, since genes are also organized relating to metabolic pathways, there are also methods for searching for genes not yet discovered in a particular pathway.

(4) Structural Genomics

Although genome projects involve the comprehensive determination of all gene base sequences by determining the entire genome sequence, structural genomics involves comprehensively determining three-dimensional structure of gene products in the form of proteins (*4). Gaining an understanding of the three-dimensional structure of a protein coded for by a gene provides considerable information with respect to considering the function of that gene. Since it is believed to be necessary to promote structural genomics in order to achieve significant advances in functional genomics, structural genomics projects have been started in Japan (Riken, Prof. Shigeyuki Yokoyama) and in the U.S. (Sung-Hou Kim, U.C. Berkley)(*5). These projects involve classifying into a protein family according to sequence homology, selecting representatives of each family, and determining three-dimensional structure by X-ray crystal analysis or NMR. Once the basic structure of a protein is comprehensively determined, it is possible to predict the three-dimensional structure of the protein with a high rate of success.

(*3) Kooning et al., Science, Vol. 278, pp. 631-637, 1997
(*4) J. Skolnick et al., Nat. Biotech., Vol. 18, pp. 283-287, 2000
(*5) T. Zarembinski et al., Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 15189-15193, 1998

2 Status of Industry (Japan and the U.S.)

2-1 Development Status and Topics of Japanese Pharmaceutical Companies

(1) Technical Aspects (Importance and Difficulty of Selecting Target Molecules)

Importance: The selection of a target molecule is intimately related to developing a drug with a specific mechanism of action. Having action against that target molecule and demonstrating efficacy based on that action is important information not only at the stage of research and development, but also in terms of utilization in treatment and marketing.

Difficulties: In the past when acquiring a gene was a laborious task, genes and proteins were only able to be acquired for proteins evaluated to a certain extent to be able to be used in pharmaceuticals. At present, however, genes and proteins are able to be acquired much easier than in the past before their evaluation as a "pharmaceutical" or "drug development target molecule" is clearly determined.

On the other hand, from the perspective of "evaluating as a drug development target molecule", unless:

* gene and protein function,
* correlation and role in diseases and pathological states, and
* possibility of application to the target disease

are clearly determined, it is not possible to select a gene or protein as a target molecule. Even at present with the progress of technical advances, this step is still the most difficult aspect of target molecule selection. It goes without saying that human body is considered to be a black box in which various factors are intermixed in a complex manner, making it quite difficult to make predictions with any consistent degree of success. For this reason, during the course of pharmaceutical research, answers are only obtained with respect to effects in the human living body at the final stage after extensive research on safety and efficacy.

When it comes to trying to answer questions like what target molecule should be selected and what diseases should be targeted to lead to drug development, the concept of it only being possible to evaluate a target molecule as a target of drug development after a drug useful in human body appears on the market is by no means incorrect.

(2) Technical Aspects (Pharmaceutical Screening)

Even when a gene has been disclosed, this is not sufficiently grounds for immediately starting screening. It is first necessary to establish a measurement system after expressing that gene. If an expression method or activity measurement method is not established, research on such methods becomes necessary. Whether or not this is easy depends on the particular case. In the case of new enzymes or receptors for which the true substrate or ligand is unknown, a considerable degree of difficulty may be involved, including the development of a screening system.

Although the amount of time required for screening depends on the degree of complexity of the activity measurement system and to what extent the scale can be reduced, when various factors are considered, normally from several months to several years are required to perform screening on the several ten thousands of specimens in the compound library. The ability to achieve high throughput and the adequate use of technologies as robotization and equipment makes it possible to make the screening method more efficient, enabling it to be completed in a shorter amount of time.

(3) Patents Relating to Drug Development

(i) General-purpose Technology and Tool-Type Patents(*6)

Although researchers seek materials that are widely available, inexpensive and can be used as research materials, in reality, this is not always the case. In actuality, even though a patent license may be owned for a tool at the upstream stage of research, there are few cases in which royalties are sought on a product basis.

(ii) Drug Development Target Molecule-Oriented Patents(*7)

Since there are many cases in which patents that orient target molecules do not have an alternative method in correlation with the fact that human genes and proteins themselves have no alternatives, effects resulting from exclusive possession are considered to be great. Therefore, the issue has been raised as to whether or not the release of pharmaceuticals onto the market is obstructed by exclusive possession.

(4) From Results of Upstream Research to Results of Downstream Research

The results of upstream research are brought about as output in the form of development into a product following maturation and evolution through the accumulation of downstream

(*6) Revolutionary dominant patents: PCR technology, DNA chip, others/ Improvement patents: general-purpose assay, vector, cell, combinatorial chemistry, others

(*7) Gene patents, protein (receptor, enzyme) patents, screening method patents, functionally expressed pharmaceutical use patents, DNA fragment (EST, SNP) patents, protein high-dimensional structure patents, others

research. On the other hand, the results of downstream research are brought about on the basis of upstream research. Thus, the results of upstream and downstream research are mutually dependent on each other.

Under such circumstances, there is an even greater desire to achieve a form in which the results of upstream research are effectively transferred downstream to achieve the proper balance such that the overall method leads to the promotion of technical innovations. Within this method, although the role played by patents is large, the effects they have, including the risk of hindering technical innovations, are also considered to be large.

In consideration of the characteristics of this technical field, it is important to study patent issues requiring adjustment from the viewpoint of the validity of the scope of patent rights, the scope to which the rights are extended, and the exclusive possession of rights (with respect to the balance with improvement of the public welfare). At that time, it should be taken into consideration that this technical field involves a higher degree of prediction difficulty than other fields. In addition, in this technical field, single occurrences of revolutionary research results are rare based on the above-mentioned characteristics. Instead, this technical field has a background in which its nature is such that the majority of the results of upstream research mature and evolve into the results of downstream research as they increase in reliability while going through the extensive accumulative research that follows. Moreover, another background factor that should not be forgotten is that human genes and proteins themselves do not have alternatives.

2-2 Status of Venture Business Companies in Japan, the U.S. and Europe

(1) Flow of the Establishment of Biotechnology Venture Business Companies in the U.S. and Europe

Universities and research institutes in the U. S. are aggressive in successively transferring various technical seeds and intellectual property rights they have discovered to industry, and numerous venture business companies have been established on the basis of these transfers, enabling these companies to play the role of efficiently and rapidly promoting research and development. A pattern has been established in which, once a venture business company has proceeded with research and development to a certain stage, later acquisition of FDA approval as well as manufacturing and sales are taken over by large companies who then proceed with commercialization. Researchers are employed as scientific advisors of related venture business companies, and during the course of continuing technical guidance, discover basic research themes and search for seeds that contribute to next-generation industries to secure intellectual property rights, enabling this cycle to work effectively. In other words, venture business companies specialize in the incubation of technology until they are succeeded by a larger company that ultimately inherits commercialization and marketing of intellectual property rights created by universities and government research institutes, being responsible for the intermediate method that leads to rapid product development.

(2) Establishment of Genome-Related Venture Business Companies in Japan

The "Human Genome Project" that began to operate in the 1990's provided the impetus for the growing interest in gene analysis. In Japan, the responsibility for structural analysis has been borne primarily by public institutions such as the University of Tokyo, the University of Osaka and the Institute of Physical and Chemical Research. Later, the scope of analysis expanded to include genome structural analysis of living organisms other than human beings, examples of which include analysis of rice genome led by the National Institute of Agrobiological Resources of the Ministry of Agriculture, Forestry and Fisheries, analysis of heat-resistant bacterial genome conducted by the Biotechnology Center of the National Institute of Technology and Evaluation of the Ministry of International Trade and Industry, and analysis of photosynthetic bacterial genomes conducted by the Kazusa DNA Research Institute. However, the primary objective of these gene analysis institutions was not industrialization of analysis results, but rather to basically contribute to the furthering of scientific studies. Later, these analyses entered a second stage starting around 1998 following the appearance of venture business companies in the U.S. and Europe. Namely, efforts began to be concentrated in the areas of gene structure and functional analysis. Once functions are identified, a patent can be acquired together with that structure. A trend in which U.S. and European venture business companies began to attempt to acquire intellectual property rights based on this DNA analysis information began to become apparent.

Although this trend can be said to be a natural outcome in consideration of the tremendous proliferation effects on industry, in Japan, related companies did not have a sufficient understanding of the potential for the DNA industry to grow into a giant industry, and

their accommodation of this proceeded slower in comparison with that in the U.S. and Europe.

However, the birth of large-scale DNA analysis centers around the world, including the start of operation of the Sanger Centre as the institute of gene analysis in the U.K. and Genethon and Geneset, Inc. in France, following those established in the U.S., led to the establishment of the Helix Research Institute, Inc. jointly funded by the Japan Key Technology Center of the Ministry of International Trade and Industry and ten private companies, and the Genox Research, Inc. funded by the Organization for Pharmaceutical Safety and Research of the Ministry of Health and Welfare and seven private companies. In addition, pharmaceutical companies also began to conduct human gene analysis, finally resulting in the start of a trend towards securing intellectual property rights.

With respect to structure analysis of human gene, since U.S. and European venture business companies have all placed emphasis on DNA sequence analysis, the situation was such that they had hardly conducted any analysis on the structure and functions of proteins on the basis of that sequence information. In order for Japanese companies to be successful in competition, the development of efficient DNA sequence analysis technology, the development of technology for rapidly elucidating the structures and functions of proteins originating in this DNA, and the securing of intellectual property rights would be of key importance. Since a well-defined methodology has not been established for technology relating to protein function analysis, in addition to making this the focus of future research, this field will also allow the securing of intellectual property rights unique to Japan.

Under such circumstances, there was a sudden increase in the number of bio-venture business companies in Japan these days, and genome-related venture business companies have been successively established throughout Japan, examples of which include the Institute of Medicinal Molecular Design, Inc., Pharma-Design, Inc., Gencom, Inc., Medogene, Inc., UP Science and the Advanced Medical and the Institute of Bioscience Research, Inc. The steady acquisition of intellectual property rights and continued growth of these venture business companies will have a significant impact on the creation of new bio-related industries in Japan.

III Topics to Be Examined when Protecting Genome Results with Patents

1 Present State of the Bio-Business and Intellectual Property Rights

(1) Pathway to Effective Utilization of Infrastructure Patents

In the past, patents that protected "successful achievements" equivalent to drilling a so-called good quality oil field (oil field-type patents) were valid. However, when considering the manner of excavating oil fields in genome drug development, how elegantly that oil field was reached is important, and simply excavating for the sake of excavating is no longer realistic. On the contrary, the extent to which an expressway is used to reach the oil field, where the fuel supply bases are placed for reaching the oil field and other strategies like this become important. Although the expressway may be in the form of a tool box or genome information, a considerable number of inventions (infrastructure patents) are being filed that provide a tool for efficiently reaching the oil field that is equivalent to an expressway.

Infrastructure patents are considered to be able to be roughly divided into two types.

The first is a so-called breakthrough type of patent that are obtained through research in pursuit of creativity such as the patenting of the tool box itself.

The other type is a so-called portfolio type of patent that is filed comprehensively for results obtained from region-specific research.

Both breakthrough and portfolio patents have the capability of being able to be suitably networked by the patent holder, and optimization of collaboration is important for the development of industry.

(2) Venture Business Companies and Intellectual Property Rights

Patent strategies are extremely important for bio-venture business companies.

Although bio-venture business companies are highly dependent on a core technology, that core technology itself can be made exclusive with a patent. In addition, patents have an exclusion period of 20 years from the time of filing with respect to the long incubation period of biotechnology. Moreover, although the extent to which collaborations can be formed is also important for bio-venture business companies, if it is possible to indicate core competence supported by rights by a patent, there is a greater potential for the formation of collaborations. On the basis of these factors, it is no exaggeration to say that bio-venture business companies are

dependent on patents at the most fundamental level. Namely, patents can be said to be positioned at the core of management of bio-venture business companies.

(3) Patent Acquisition by Bio-Venture Business Companies

There are considered to be various structural obstacles with respect to the acquisition of patents, said to be the lifeline of bio-venture business companies. There are many cases in which filing of patents relating to basic inventions must be performed immediately after establishment of the company. Despite this, capital and manpower are usually lacking at that time. In addition, although it is necessary to be able to have some idea of the future of business deployment in order to file for an effective patent, that outlook is difficult in the initial stages.

Enhancing "intellectual property incubation abilities" is one way to compensate for these structural obstacles as much as possible. The "intellectual property incubation abilities" mentioned here refers to the ability to recognize and deploy valuable inventions. Thus, the value of intellectual properties can be said to be the product of multiplying research results by "intellectual property incubation abilities". Since the "intellectual property incubation abilities" of venture business companies lacking experience in the filing of patents are nearly always low, structural obstacles on the contrary end up being amplified. The health development of blue-chip venture business companies is considered to be the providing of an infrastructure for the biotechnological industry of Japan in the creation of breakthrough patents originating in Japan in particular. However, without support from the outside, even if there is the knowledge to obtain a breakthrough, there is the possibility of not being able to file an effective breakthrough patent.

(4) Summary

The generation of infrastructure patents from Japan as well can basically be expected to lead to the effect of vitalizing Japanese industry. However, the problem is their effective utilization. Even if an infrastructure patent is produced, it can be said to be meaningless unless that technology is effectively utilized by others. What is more, in the case the patent holder attempts to obstruct the research activities of others by mischievously using the rights pertaining to that technology as a shield, this can become a serious obstruction to the development of industry.

Although there is the sense that current discussions are focused only on the acquisition of infrastructure patents, this is thought to be senseless unless discussions are also conducted regarding effective utilization. With respect to venture business companies, sound management is probably the most important factor. Namely, whether or not each venture business company is provided with management capabilities enabling optimization of collaborations in order to acquire maximum profits is important. Thus, it is necessary to provide venture business companies with support for management simultaneous to providing support for acquisition of intellectual properties. At present, since there is an extreme shortage of both support for acquisition of intellectual properties and support for management, it is believed to be imperative to establish an infrastructure for these.

Finally, it should be pointed out that putting patent strategies ahead of research strategies is an inherently incorrect approach. Research strategies should first be established in the form of national policies of company directives followed by the establishment of patent strategies based on those strategies. In order to ensure that this inherently ideal form is maintained, it is essential that protection of patents be granted corresponding to the degree of contribution of research. If the balance between degree of contribution and protection is destroyed, there is merit in filing questionable, incomplete patents, leading to the inherently undesirable result in which those whose patent strategies are completed first end up successfully acquiring patents. Ultimately, the correct implementation of the patent system and the sound development of biotechnology industries are like the wheels on a car in that discussing either one alone is essentially nonsense.

2 Status of Protection of Biotechnology Patents in the U.S.

(1) Function of the U.S. Patent System from a Scientific Standpoint - Social Impact of Patent Claims

The transition in the manner of perceiving the function of the patent system by U.S. academia is considered to be useful in terms of discussing the positive and negative aspects of the broad meaning of patent claims. The following provides an introduction to recent representative theories while discussing its social impact.

(i)The Prospect Theory(*8)

In 1977, Professor Kitch of the University of

(*8) J. L. & Econ., Vol. 20, pp. 265, 1977

Chicago announced the Prospect Theory that provides a theoretical foundation for allowing broad-scoping patent claims as an alternative to the traditional Reward Theory as a warning to the "anti-patent era" that had previously placed priority on anti-trust law.

The term "prospect" refers to a promising excavation site. Prof. Kitch likened mining rights in the mining law to patent rights, pointing out that wide-scoping patent rights for exclusive possession of research and development towards future commercialization should be granted to inventors of pioneer inventions in the same manner as drilling rights to oil fields and so forth are granted to discoverers of mineral deposits without confirming whether or not the mineral deposit is promising.

It should be noted that another appealing aspect of this theory is that it is able to give compatibility with patent applications and their examinations being performed at a much earlier stage than commercialization of pioneer inventions.

(ii) Innovative Competition Theory(*9)

In 1990, Professor Merges of the Department of Intellectual Property Right Law at the University of California-Berkley and Professor Nelson of the Department of Economics of University of Columbia announced the theory that the patent claims of pioneer inventions should conversely be restricted in order to maintain the incentive for improvement inventions based on the premise of "the faster the rate of innovations the better". It appears that an awareness of problems relating to broad-scoping patent claims in the field of biotechnology, for which patent infringement suits were repeatedly being implemented at CAFC and so forth at the time, was one of the motivations behind the drafting of this paper. As a result, it attempted to solve this problem by limiting patent claims to pioneer inventions.

(2) Safeguards in the Judicature for Excessive Exercising of Rights in the U.S.

Competition among leading U.S. companies in the research and development of biotechnology became extremely intense, and starting in the 1980's, and many of the disputes between litigants ended up going to trial.

U.S. courts restricted the exercising of patent rights using the reverse doctrine of equivalents and so forth with respect to unjustly broad patent claims. Examples of these include the CAFC judgments pertaining to blood coagulation factor Ⅷ:C(*10) and t-PA (thrombus dissolving agent)(*11). More recently, the use of the viewpoint of new disclosure requirements was proposed in the form of "Written Description" requirements(*12) for patent applications that are difficult to be rejected based on workable requirements.

(3) Characteristics of Biotechnology and Antitrust Laws

Current biotechnology has the following two characteristics:

* there is a large number of universal tool patents used in research and development; and,
* it is difficult to develop alternative technologies to avoid cases in which the target is a gene.

There is concern that the exercising of these powerful rights pertaining to basic tool patents may have a significant effect on innovations throughout bio-related fields. In other words, powerful domination with respect to innovations, comparable to the domination resulting from de facto standards and network effects in information technology fields, becomes possible with individual basic tool patents.

Perhaps as a result of U.S. antitrust law authorities having noticed this problem, according to the intellectual property right guidelines published in 1995, the concept of "innovation market" was newly introduced in addition to the conventional product market and technology market. With respect to this point, the Fair Trade Commission of Japan also showed signs of evaluating such that the beginnings of handling from the viewpoint of "private exclusive possession" were clearly indicated in "Guidelines for Patent and Know-How Licensing Agreements under the Anti-monopoly Act" published in July 1999.

In any case, when considering that an era of priority given to antitrust laws consistently continued in the U.S. from the global depression of 1929 though the pro-patent era of the 1980's, the antitrust law has continued to have a significant existence even though it was temporarily paused due to the appearance of the Chicago school.

3 A Discussion for Suitable Protection

(1) Patent Problems Relating to ESTs Inventions in Japan

Numerous papers have been published regarding what form of judgment standards

(*9) Colum. L. Rev., Vol. 90, pp. 839, 1990
(*10)Scripps Clinic and Research Foundation v. Genentech Inc. judgment (18 USPQ2d 1001; Fed. Cir. 1991)
(*11)Recombinant human t-PA derivatives, "FELIX" case (31 USPQ2d 1161; Fed. Cir. 1994)
(*12)University of California v. Eli Lilly and Co. judgment (43 USPQ2d 1398; Fed. Cir. 1997)

should be established with respect to the patentability requirements and scope of protection of ESTs inventions, and it goes without saying that considerable disputes are currently taking place around the world regarding this issue. This is because ESTs inventions have a special nature that is not found in ordinary chemical substance inventions.

In this section, in addition to a discussion focusing especially on the obviousness (inventive step) and enablement of the patentablity requirements of ESTs inventions, a claim form is advocated that can ultimately be recognized with respect to ESTs inventions that supplements these requirements, while also providing a discussion of the scope of protection that can be recognized by claims employing that form.

In reality, the function of ESTs is considered to be limited to functions that allow their use as probes. If this is the case, then it can be inferred that ESTs inventions should unconditionally only be granted patent protection equivalent to inventions of chemical substances that can only be used as reagents. From this viewpoint, the following provides the manner of thinking regarding the obviousness, enablement and scope of protection of ESTs inventions.

(i)Obviousness

Standards have been advocated with respect to judgment of the obviousness of ESTs inventions indicating that criteria for obviousness of the acquisition process, and not criteria for obviousness of the structure, should be used(*13).

Namely, this paper states that, "Although ESTs are chemical substances, at least judging from the current level of technology, there are many cases in which it is difficult to apply typical judgment criteria for obviousness of chemical substances that have been adopted for chemical substances in the past, namely criteria for judging the presence or absence of obviousness according to similarity of dissimilarity of the chemical structure. There are also many cases in which it is more realistic to judge the presence or absence of obviousness based on the ease of the acquisition process." Thus, this paper advocated that the obviousness of ESTs inventions is different from that of conventional chemical substances, and have their own unique judgment criteria.

However, in the case of adopting such judgment criteria, the possibility of an ESTs invention being judged as having obviousness becomes extremely great unless the applicant is unable to show difficulty with respect to the acquisition process unique to each EST or an unexpected effect unique to each EST.

Other examples of chemical substances for which the presence or absence of obviousness is typically judged according to the criterion of obviousness of the acquisition process are inventions relating to monoclonal antibodies. Self-evident criteria of inventions relating to monoclonal antibodies are commonly known to be greatly dependent on the degree to which that target antigen protein is publicly known.

There is nothing with respect to ESTs inventions that is equivalent to the target antigen protein in inventions of monoclonal antibodies. However, they are in common with respect to the method for determining their base sequences having become nearly standardized, and at least with respect to judgment of obviousness, it can probably be considered that ESTs inventions are constantly in a technical state that resembles inventions of monoclonal antibodies in a state in which the target antigen is known. This being the case, by applying the implementation described above, as long as ESTs inventions are found to have unique functions that cannot be predicted by persons with ordinary skill in the art, the use of implementation in the manner of claims in the form of "DNA having the function of such and such comprising ESTs sequence S", or by means of using that is demonstrated by said function, "DNA used for such and such comprising ESTs sequence S" is probably in line with the actual situation.

(ii)Enablement

Since chemical substances such as ESTs can usually only be used as probes, in various senses, they cannot be treated in the same manner as other chemical substances that can be expected to potentially demonstrate diversified use. If the discussion is focused on enablement, with respect to other typical chemical compounds, the providing of a compound having a certain fixed function simultaneously becomes the providing of other functions potentially possessed by said compound. From this viewpoint, it is reasonable to think that, as soon as the production process of a specific compound and at least one function possessed by that compound are disclosed, the requirement of enablement with respect to the invention of that compound is fulfilled. In addition, there is also considered to be a fixed rationality in granting strong protective rights such as absolute substance claims to such inventions. In comparison with such inventions, what is the technical contribution provided by ESTs inventions? Even if the specific function of each ESTs is disclosed in the patent applications of ESTs inventions, that function is normally limited to a function that allows it to be used as

(*13)Hiraki et al., AIPPI of Japanese National Group, Vol. 44, No. 11, pp. 669-677, 1999

a probe in a specific application. A person with ordinary skill in the art who has read that specification cannot even anticipate other potential functions possessed by that ESTs, and there is ultimately no other use for that ESTs other than using as a probe. (Ordinary types of substance claims for which there are no limitations on function include enablement that is equal to or greater than that promised in the specification to persons with ordinary skill in the art, and ultimately such claims can be worked throughout.) In this manner, even when considering from the viewpoint of enablement, the use of implementation for ESTs inventions such that claims in the form of "DNA having the function of such and such comprising ESTs sequence S", or "DNA used for such and such comprising ESTs sequence S" as described in (i) above are patented is most likely reasonable.

(iii) Scope of Protection

As was stated in (i) and (ii) above, first from the viewpoint of patentability requirements, patent protection according to typical absolute substance claims is not suitable for ESTs inventions. As was previously mentioned, although claims that are ultimately recognized are those relating to DNA in a form in which the sequence is identified while functions and usage methods are limited, the scope of protection of such DNA can naturally be considered to be limited to working within the scope of said functions and usage methods. Although patent protection in this form is recognized for ESTs, this leads precisely to the achievement of patent protection that is in balance with the technical contribution of the ESTs invention as previously mentioned. At least with respect to DNA claims in the above-mentioned form in which functions and usage methods are limited, and as long as a function is demonstrated that allows the use as a specific probe disclosed in the specification, the scope of protection probably extends not only to DNA comprising the claimed base sequence, but also to DNA comprising sequences that include said base sequence.

IV Effect of Patent Rights

1 Recent Precedents in Japan

1-1 Supreme Court Judgment of Measurement Method (Case of the Physiologically Active Substance Measurement Act)(*14)

(1) Case Summary

X is a person holding the patent right (present patent right) of an invention (present invention) entitled "Physiologically Active Substance Measurement Method". The present invention is an invention of a process relating to a measurement method for the ability to inhibit formation of kallikrein, a type of enzyme protein.

Y received manufacturing approval (Article 14 of the Drugs, Cosmetics and Medical Instruments Act) and received listing in the drug price standards for an extract (Y extract) and preparation (Y preparation, collectively referred to as "Y Pharmaceuticals") obtained by inoculating vaccinia virus (virus used to immunize humans against smallpox) into domestic rabbits and harvesting their skin tissue, and is engaged in the manufacturing and sales of said Y Pharmaceuticals.

Since Y Pharmaceuticals are natural substances having unknown components extracted from living skin tissue, it is necessary to conduct a confirmation test of the ability to inhibit formation of kallikrein-like substances in order to verify the quality standards of the extract. It is also mandatory to describe the method of the confirmation test during application for manufacturing approval.

(2) Gist of the Judgment

1) Injunction of manufacturing and sales of a substance for which quality standards have been verified using a method based on the patent rights as claimed by an invention of that method cannot be demanded.
2) "Acts required to prevent infringement" as stated in Article 100, paragraph 2 of the JPL are required to be those that allow execution of exercising the right to demand injunction and within a scope required to realize the right to demand injunction with reference to the contents of the patented invention, the mode of acts of infringement actually committed or having the risk of being committed in the future, and the specific contents of the right to demand injunction

(*14) Supreme Court Judgment of July 16, 1999, No. 1686, pp. 104, Hanrei Times Vol. 1010, pp. 245, Intellectual Property Right Judgment Update No. 292, Case No. 8861 / Original decision (appeal decision) Osaka High Court Judgment of November 18, 1997, Intellectual Property Right Judgment Update No. 272 Case No. 7856 / 1st Judgment, Osaka District Court Judgment of June 29, 1995, Intellectual Property Right Judgment Update No. 242, Case No. 6894.

exercised by the patentee.

3) Under circumstances in which acts infringing on patent rights pertaining to the invention of a method are acts that use said method in confirmation testing for verifying quality standards of a pharmaceutical and only allow demanding of injunction of the use of said method as a demand for injunction of infringement, they exceed the scope required to realize the right to demand injunction, and do not fall under "acts required to prevent infringement" as stated in Article 100, paragraph 2 of the JPL.

(3) Examination

The present judgment was handed down for the basic matters of patent infringement right litigation.

To begin with, even in the case the use of a method of confirmation testing to be performed for verification of quality standards infringes on patent rights, it was ruled that injunction of manufacturing and sales of articles for which quality standards were verified using said method cannot be demanded based on patent rights relating to a simple method invention. This is because the patent rights do not relate to the invention of the production method of a product.

Moreover, the judgment also indicated standards for interpreting Article 100, paragraph 2 of the JPL along with an example. This is highly evaluated with the statement that, "Attention is called to the practices of lower courts that recognized acts required for prevention of infringement beyond the scope that is necessary as a result of being swayed by the demand of the plaintiff in the case a decision of infringement was rendered as a result of emphasis hitherto being placed on trial examinations and judgments for judging infringement or non-infringement, . . . and considerable reference should be given to actual practice." However, there is also the view that a more flexible judgment is required corresponding to the case, and the future trends of lower courts warrants attention. Separate considerations will probably be required in cases of prominent viciousness of the infringing party, such as repeatedly violating injunction judgments of confirmation testing methods for verification of quality standards.

It should be noted that since the judgment in this case was rendered on the basis of specific factual relationships, whether or not the patent for a screening methods can become the patent of the production methods of a product is understood to be left as an issue for the future.

1-2 Patents of Screening Methods and the Relationship with Article 69, Paragraph 1 of the JPL Relating to Testing and Research

(1) Location of Problems

Screening methods using newly discovered enzymes are one mode of recent genome drug development. In the case a patent is established for such methods, would the act of research and development of a new pharmaceutical by a third party using that screening method constitute infringement of patent rights? In what way should the relationship be considered with respect to provisions of the JPL (Article 69, paragraph 1) which state that the effect of patent rights do not extend to working of patented invention for testing or research?

For example, when a patent has been established in the form of "a screening method for enzyme Y inhibitor that uses enzyme Y", there is a problem in the case a third party has discovered an inhibitor of enzyme Y in the form of compound A by performing screening using enzyme Y.

(2) Precedents and Theories Relating to Testing and Research

An explanation is provided by Yoshifuji and Kumagai(*15) respect to the purport of the limiting of the effect of patent rights with respect to working for testing or research by Article 69, paragraph 1 of the JPL. There are many cases in which allowed testing and research is divided into three categories consisting of (a) testing for examining patentability, (b) testing for examining function, and (c) testing for the purpose of improvement and development(*16).

As an example of a judicial precedent relating to Article 69, paragraph 1 of the JPL, numerous lower court rulings and the Supreme Court ruling of April 16, 1999 regarding recent testing for application for approval of generic drugs have attracted attention. In this case, the dispute focused on the interpretation of Article 69, paragraph 1 of the JPL with respect to points such as whether testing and research is limited to that for the purpose of technical progress, and whether testing for application for approval of generic drugs is for the purpose of technical progress.

In response, the above Supreme Court decision cited the grounds indicated below.

(*15)Yoshifuji and Kumagai, Outline of the Patent Law, Vol. 13, pp. 441.

(*16)Someno, K.: "Working of Patented Inventions in Testing and Research (I), (II)", AIPPI of Japanese National Group, Vol. 33, No. 3, pp. 2, No. 4, pp. 2.

1) Being able to use an invention freely by any number of people following the expiration of the term of its patent rights, and general society being widely benefited by that use is one of the bases of the patent system.
2) Since the Drugs, Cosmetics and Medical Instruments Act should allow the obtaining of approval for the manufacturing of pharmaceuticals, and prescribed testing over a fixed period of time is required in advance to apply for approval, if that testing is not considered to fall under Article 69, paragraph 1 of the JPL, then this would result in a third party being unable to freely use said invention for a considerable time even after expiration of the term of patent rights.
3) Since a third party is not allowed to work a patented invention beyond the scope necessary for testing to apply for approval for manufacturing based on the Drugs, Cosmetics and Medical Instruments Act during the term of patent rights, benefits resulting from exclusive working of the patented invention during the term of patent rights is ensured for the patentee. If acts for testing necessary for applying for approval for manufacturing are attempted to be eliminated by a patentee, this would have the same result as extending the term of patent rights for a considerable period of time.

Based on these grounds, the Supreme Court then ruled as follows: "The performing of testing by a third party by taking an act corresponding to working of a patented invention during the term of patent rights in order to apply for approval for manufacturing as defined in Article 14 of the Drugs, Cosmetics and Medical Instruments Act for the purpose of manufacturing and sales of a generic drug following expiration of the term of patent rights is equivalent to "working of a patented invention for testing or research" as stipulated in Article 169, paragraph 1 of the JPL, and does not constitute infringement of patent rights." Thus, this ruling adopted a negative interpretation of Article 69, paragraph 1 of the JPL.

As is clear from its purport, the above Supreme Court judgment emphasizes the point that an interpretation of Article 69, paragraph 1 of the JPL that substantially extends the patent term should not be adopted, and does not respond directly to the present issue.

On the other hand, the referring decision of this case(*17) indicated the following: "Various knowledge and information is obtained that can serve as the foundation of advances in pharmaceutical technology in the future by the conducting and accumulation of a wide scope of technical and basic studies relating to pharmaceutical standards and pharmacology such as drug development technology, and with respect to this point, should be considered to contribute to the broad development of science and technology." Thus, caution is required in relation to the present issue.

(3) Research Tools, Testing and Research

Although testing for economic investigations is frequently listed as one example of testing that typically does not fall under research and testing of Article 69, paragraph 1 of the JPL, in addition to this, in the case the subject matter of an invention relates to a research tool, the use of that research tool in research is frequently explained as not falling under testing and research of Article 69, paragraph 1 of the JPL.

In logical terms, this is believed to be able to be divided into that in which research by said third party relates to the subject matter of an invention of a research tool, and that in which it is merely a means for research. It appears that European countries considered this to be infringement unless it is research relating to the subject matter of an invention.

(4) Study of the Present Issue

The screening method of the present issue are a research tool or type of research method. Thus, in accordance with the above standards, it should be examined as to whether said screening method is research relating to the subject matter of a invention or merely a means for other research.

However, the screening for compound A using a patented invention in the form of "a screening method for an inhibitor of enzyme Y that uses enzyme Y" should also take into consideration examination of the manner in which that patented invention functions. In this case, however, it is most likely clear that the objective of a third party is not to examine a patent, but actually to obtain a useful compound. In addition, a third party is also not attempting to improve said screening method. Thus, research by a third party in this case is not considered to be related to the subject matter of an invention, and there is a strong possibility that application of Article 69, paragraph 1 of the JPL would be denied. In addition, if the conclusion is reached that such an act does not constitute infringement, there is essencially no

(*17)Osaka High Court Judgment of May 13, 1998.
(*18)Dr. Hans-Rainer Jaenichen, "The Patenting and Enforcement of Inventions Relating to Research Tools: Chances and Problems", (November 17, 1998) (http://www.jaenichen.com).

sense in aquisition of patent rights of the screening method, and the potential for eliminating the incentive for new inventions in this field may also be another reason for denying application of Article 69, paragraph 1 of the JPL.

On the other hand, the judgment of the Osaka Supreme Court relating to the generic drugs referred above stated that testing required for application for approval of generic drugs "by the conducting and accumulation of a wide scope of technical and basic studies relating to pharmaceutical standards and pharmacology such as drug development technology, . . . , should be considered to contribute to the broad development of science and technology." It thus appears that this judgment is taking into consideration testing and research with respect to that which is different from the subject matter of the plaintiff's patented invention. Based on an extension of this way of thinking, it is possible to consider the application of Article 69, paragraph 1 of JPL in the present case. However, since the case of generic drugs was somewhat of a special case, it cannot be given much weight.

In the case of understanding in the manner described above, patents relating to research tools simply have the risk of obstructing an invention. On the other hand, inventions of research tools themselves are also commonly known to successively yield new inventions through research activities using those tools. In the case the balance between these becomes excessively biased, there is the possibility that the patent system may hinder technical progress. Therefore, interpretations and legislation should be considered while carefully monitoring technical trends.

2 Status in the U.S.

2-1 Study Relating to Exercising of Rights

(1) EST and Exercising of Rights

In the case of manufacturing and selling pharmaceuticals containing patented EST, does this constitute infringement of the EST patent? It is possible to consider this question in the ways indicated below.

1) Standpoint of recognizing complete effect

In other words, this way of thinking states that EST is used as long as a portion of a full-length DNA sequence contains EST.

2) Standpoint of adding limitations to the effect

This way of thinking states that the scope of rights of an EST patent does not extend to that which contains a full-length DNA sequence (referred to as "full-length products").

This is inherently the relative problem of whether the scope of the effect of patent rights extends to an infringing product in the case an infringing product exists. In other words, this involves judgment of the presence or absence of infringement by focusing only on the relationship between the EST patent and the infringing product.

When following the normal procedure of judgment of infringement, the first problem is the presence or absence of literature infringement. Is the full-length product really infringing on the EST patent in terms of the literature? If the infringing product has a completely identical base sequence, that it naturally is infringing in terms of the literature. For example, if an EST patent has 300 bases and the infringing product also has the same 300 bases, then it is infringing in terms of the literature.

This being the case, what about the case when the infringing product has 301 bases? This type of infringing product is not infringing in terms of the literature, and should rather be treated as an problem relating to the doctrine of equivalents. What then happens in the case of 302, 310 or even 400 bases? Can this still be said to warrant treatment in terms of the doctrine of equivalents.

If the relationship between an EST patent of 300 bases and a full-length product of 500 bases is judged according to the doctrine of equivalents, the problem focuses exclusively on whether or not there has been a non-substantial change. In the case the addition of 200 bases results in a contribution to society that is new worth evaluating and was obtained at considerable cost and time, it would mean that the full-length product does not fall within the scope of equivalency. Namely, in the case a newly added full-length DNA sequence portion not found in the EST is examined based on the patented EST, and it is determined that said added portion is sufficiently and newly disclosed, it is possible to draw the conclusion that said full-length DNA sequence is outside the scope of the patent rights of the EST.

When considering in this manner, it can be said that the scope of rights of EST patents does not always extend to "full-length products".

(2) SNP and Exercising of Rights

(i)EST and SNP

What are the similarities and differences between EST and SNP from the viewpoint of the Patent Law?

As indicated by their name, EST are tags or "fragments" of fixed information. Thus, the relationship between EST in the form of such "fragments" and the full, as well as the usefulness possessed by such "fragments", are important issues. After the existence of an EST is discovered, it is necessary to determine its

function.

SNP refer to specific information on a gene, and when a change in a certain base is found to exist at a frequency of 1% or more in a population, a certain SNP is discovered. Although SNP are not "fragments", since they are information on a gene, after its existence has been discovered, it is also necessary to determine its function. Namely, the relationship between that SNP and certain types of illnesses or protein information must be elucidated. In this sense, EST and SNP are extremely similar and consequently, a discussion similar to the above discussion relating to EST is considered to apply to SNP as well.

In the case of SNP, however, different from the case of EST, there is no concept of a "part" and the "full". Thus, it becomes extremely difficult to deploy logic using the doctrine of equivalents. In the case of SNP, the concept only involves SNP and other SNP along with the functions that are elucidated, and the question becomes the extent to which the based SNP is disclosed and makes a contribution. In this case, although varying depending how the SNP is carried out by using the function elucidated for that SNP, basically, it is likely that a philosophy can be applied that resembles the discussion of screening methods. In other words, in the case of elucidating the function of an SNP based on SNP information and then using that function to manufacture a pharmaceutical, it is similar to the case of using a certain screening method to discover a certain substance, and then manufacturing a pharmaceutical based on that substance. If this is the case, the scope of rights of claims relating to this SNP information can be said to not extend to the use of that information to search for a specific function, and then use that specific function to manufacture a pharmaceutical (excluding cases in which the performing of such is fully disclosed from SNP information).

V Summary

In this research and study, subjects encountered when protecting patents of genome results and problems regarding the effect of patent rights were examined by the committee and by conducting overseas research after clarifying the present state of genome research.

It is undeniable fact that genome research in Japan is generally lagging behind that in the U.S. and Europe. Although this situation was clearly shown in this research as well, the reasons for this lag were indicated as being not only problems in establishing a research system among Japanese companies, but also problems with research systems at Japanese universities as well as inherent problems with the research environment of Japan. Thus, various problems were found to be encountered in terms of promoting genome research in Japan.

In addition, in research and development relating to biotechnology that includes gene-related technologies, although it has been repeatedly pointed out in the past that the contribution of venture business companies is by no means small, in Japan, although the development of venture business companies is encouraged, considerable unresolved issues remain both in terms of government policies and industry structure, thus resulting in the need to establish a more effective infrastructure in the future.

An examination of patent protection was also made from various viewpoints.

To begin with, it has been pointed out that, with respect to patents in the field of biotechnology, that includes gene-related inventions, there are a fair number of cases in which wide-scoping claims are allowed as compared with the disclosed contents. Numerous opinions have been voiced that seek the granting of patent rights corresponding to the technical contribution as well as the granting of patent rights in a form that matches the disclosed contents. This issue is not only an issue for the procedure for establishing rights at the JPO, but is also an issue relating to interpretation of the scope of rights by courts in cases of infringement. Although it is therefore necessary to examine this issue in the future from various viewpoints, there were no objections to the granting of patents corresponding to the degree of contribution of the technology in the committee as well.

In addition, with respect to EST and gene fragments for which there has been discussion regarding the pros and cons of granting patents, although there is general agreement regarding the opinion that patents should not be granted for those for which function has not been clearly determined, with respect to the degree of disclosure relating to function in actual applications, since there are still very few actual examples and definite interpretations have yet to be made by the trilateral patent offices of Japan, the U.S. and Europe, more detailed studies are expected to be conducted in the future while accumulating case studies.

Moreover, although agreement in discussions has been observed among the trilateral patent offices of Japan, the U.S. and Europe that patents are not granted with respect to inventions that only disclose ESTs or gene fragments for which

function is not clearly indicated, since it is clear that tremendous costs and manpower are required for their research and development, the problem remains as to how to protect those development results. In March 2000, President Clinton of the U.S. and Prime Minister Blair of the U.K. released a joint statement to the effect that the results of the Human Genome Project should be completely disclosed. Although this statement also sought disclosure of not only research results of national projects but also the results of research and development by private companies, in consideration of the costs and manpower invested by private companies in research and development, it is considered to be difficult for private companies to provide research results free of charge. Consequently, it is essential to also examine the granting of intellectual property protection other than patent protection by treating ESTs and gene fragments as information having asset value.

Although it is necessary to use various research (analysis) tools when conducting genome research, if patents are granted for those research tools and they are given excessive protection at that time, it has been pointed out that it may become possible to conduct genome research itself, and there is concern over having an effect on research and development itself.

Inventions relating to screening methods have been focused on in particular. In this committee, although agreement was reached that there is basically no problem with the granting of patents for novel and effective screening methods per se, various opinions were expressed regarding the relationship between claim description and disclosure requirements, and the effect of patent rights relating to screening methods.

With respect to claim description and disclosure requirements, as determined in the results of overseas research as well, although there are no large differences in the way of thinking in each country, it is believed that further examination is required in the future to achieve harmony in specific application examination practices.

In addition, an examination of screening methods was also made while analyzing the Supreme Court judgments in Japan relating to the measurement methods. In applying the way of thinking of the above Supreme Court rulings, the effect of patents of screening methods does not extend to compounds using screening methods. In the results of overseas research as well, there is basic agreement that the effect of patents of screening methods does not extend to compounds using screening methods.

However, when examining this from the viewpoint of the practicality of protection of patents of screening methods, it has also been pointed out that there is a problem with effects not extending to products obtained by screening methods. Since it is only natural that the effect of patents of screening methods extend to the use of screening methods, when licensing the patent of a screening method, opinions have also been indicated which evaluating the value of screening methods should also be considered by making contrivances based on, for example, determining the license fee in terms of sales of compounds using screening methods (although the fee rate is set lower than usual). This opinion was also expressed by several persons in overseas research as well, and problems in determining the license fee of patents should be examined.

In this manner, in the field of biotechnology, there are a significant number of cases in which there are problems with the scope of patent rights, and although there are no problems posed by the granting of patents to outstanding inventions per se, it is expected that studies will be conducted from various viewpoints, including the relationship with disclosed embodiments and the manner of thinking regarding equivalence of action and effect, and the number of issues to be resolved will probably not be small.

It is therefore hoped that research and studies in this field will be continued to be conducted in the future and that additional findings will be obtained.

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