16 The Nature and Function of Patentability

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This study analyzes the subject matter of patent rights from three perspectives, which are functions, principles, and morality. Chapter I takes a look at the function each requirement plays in demarcating the patentability. It discusses that the patentability is and should be decided not only from the technology perspective, but also from various viewpoints including policy, economy, and morality, by focusing on the concept of a person skilled in the art, which plays a particularly important role in demarcating the patentability. Chapter II takes a look at theoretical grounds for justification of the patent law. It emphasizes the need to consider a perspective of promoting use of invention in addition to the conventional perspective of promoting invention. The chapter reveals that such an approach will result in opening up a new prospect also for the various arguments on patentability such as the dichotomy between inventions and discoveries. Furthermore, Chapter III takes a look at the morality aspect that the patent law has come to face more radically along with the progress of biotechnology in particular. It examines how the subject matter of patent rights can be defined from the public order and morality point of view.

Introduction

This report sums up three studies on the subject matter of patent rights, which are discussions about objects that are patentable. While all three studies are on the subject matter of patent rights, they approach the theme from different perspectives, which are functions, principles, and morality, as indicated by their titles.

Chapter I takes a look at the function each requirement plays in demarcating the patentability. It discusses that the patentability is and should be decided not only from the technology perspective, but also from various viewpoints including policy, economy, and morality, by focusing on the concept of "a person skilled in the art," which plays a particularly important role in demarcating the patentability.

If considerations from the policy, economic, and morality perspectives were essential for demarcating the patentability, the next necessary step would be to gain a viewpoint on the policy objectives to which the patent law is regarded to contribute in order for patents to be justified. Thus, Chapter II takes a look at theoretical grounds for justification of the patent law. It emphasizes the need to consider a perspective of "promoting use of invention" in addition to the conventional perspective of "promoting invention." The chapter reveals that such an approach will result in opening up a new prospect also for the arguments on patentability.

Furthermore, Chapter III takes a look at the morality aspect that the patent law has come to face more radically along with the progress of biotechnology in particular. It examines how the subject matter of patent rights can be defined from the public order and morality point of view.

Chapter Ⅰ From the Perspective of Functions

1. The Japanese Patent Law often refers to "a person with ordinary skill in the art to which the invention pertains," in other words, "a person skilled in the art" as referred to in studies. For example, this term is used with respect to the inventive step requirement for patent registration, the enablement requirement in disclosing an invention, as well as the obviousness-of-replacement test and the prior-art limitation for the doctrine of equivalents. These indicate that the concept of a person skilled in the art serves as a standard for various determinations in the respective phases from the filing of a patent application to patent infringement, and it is an important fundamental concept that is used throughout the Patent Law. However, in Japanese patent law studies to date, there has been no study that has made cross-sectional research on the significance and functions of the concept of a person skilled in the art across the various application scenes as above. In fact, there is an accumulation of practical precedents with regard to a person skilled in the art in individual application scenes and for the respective technical fields, but conventional research had merely summarized and categorized those precedents.

Therefore, this chapter clarifies the function of the demarcating process of a person skilled in the art under the Patent Law, and derives necessary viewpoints for the demarcation, consequently

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indicating that the patentability should not only be decided from a technical perspective but also from various policy perspectives. To this end, the chapter refers to court decisions and academic theories in U.S. patent law studies. In the United States, discussions have been made on the concept of a person having ordinary skill in the art (PHOSITA), which corresponds to a person skilled in the art in Japan, and interesting developments that are not seen in Japan can be observed. Thus, firstly, how the various concepts of a person skilled in the art in the United States are demarcated with respect to the enabling requirement and the nonobviousness requirement for invention will be confirmed based on court decisions by the Court of Appeals for the Federal Circuit (CAFC) related to DNA inventions, among others. Then, the general functions and the required viewpoints for the demarcating process of a person skilled in the art will be examined by referring to recent academic theories, in particular, articles written by Professor Merges.

2. The views derived from these analyses can be summarized as below.

Firstly, among the requirements for demarcating the patentability, the nonobviousness of an invention, which is an issue of the requirement for protection, and the enablement of an invention, which is an issue of the scope of protection, are inversely related to each other through the concept of a "PHOSITA" With regard to DNA inventions, CAFC takes a relaxed interpretation of the requirement for protection and a strict interpretation of the scope of protection as a result of estimating the technical level of a PHOSITA lower than the actual technical situation.

Such trend of court decisions is subject to criticisms from technical and policy viewpoints. However, the nonobviousness requirement can also be considered effective for activating R&D investment in highly uncertain technology and achieves more efficient resource allocation (considering the marginal behavioral decision of individual researchers engaged in R&D). Considering the economic uncertainties involved in biotechnology, there is a need for strong inducement to R&D investment in the field. Thus, relaxation of the nonobviousness requirement through a low estimation of the technical level of a PHOSITA is one of the available options. At the same time, considering the nature of biotechnology to rely on basic science and from the public interest viewpoint, it is necessary to limit the scope of protection of the patent rights by requiring particularly detailed disclosure of the inventions.

These analyses derive the conclusion that the court's stance to set the technical level of a PHOSITA low with regard to DNA inventions is reasonable from the normative point of view. In addition, the patentability under the patent law should be demarcated not merely by the actual technical situation, but also from a multi-faceted viewpoint including the economic perspective and the public interest perspective, through the concept of a person skilled in the art.

Chapter Ⅱ From Perspective of Principles

1. This chapter also examines the patentable subject matters by focusing on the relationships of the issue with "discussion on the grounds for justification of the granting of patent rights."

A classical and most general view of the discussion on the grounds for justification of the granting of patent rights in Japan today is the incentive to invent theory, that is, a view that the grant of patent rights by the government is justified as an incentive to create inventions. Accordingly, after intrinsically studying this incentive to invent theory, the chapter presents questions from three perspectives on the frequently observed discussions on patentability based on the incentive to invent theory-for example, a discussion that a specific object should be considered as a patentable subject matter because an incentive should be given to its production.

Specifically, the chapter says that the system of the patent law cannot necessarily be explained solely based on the incentive to invent theory due to the following reasons: (i) the scope of the incentive to invent theory does not fully cover general cumulative technical innovation, though it covers single-shot technical innovation; (ii) the scope of information of which production should be incited is broader than the scope of patentable subject matter under the patent law, and (iii) conversely, the patentable subject matter under the patent law also includes objects that are produced without the special incentive of patent rights.

Based on the fact that strong objections have been made against the incentive to invent theory by empirical studies in economics, the trends of the ongoing research issues concerning the basic theory of the patent law in the United States are reviewed by classifying the issues into the following three: (i) the research issue related to the question of in what conditions patent rights act effectively as an incentive to invest in research and development; (ii) the research issue of why companies that do not attach much importance to the obtainment of patent rights as a means of collecting research and development investment file patent applications; and (iii) the research issue related to grounds for justification of the granting of patent rights-why the granting of patent rights is originally admitted.

2. Based on this, the report introduces the "theory of promoting utilization of inventions" and examines how the patentability will be demarcated by relying not only on the traditional incentive to invent theory, but also on the theory of promoting utilization of inventions. As a result, the following were indicated based on the premise that, as an important starting point, the work of delimiting the patentability is nothing but an activity of sorting out "technology of which transfer, additional research and development, and enjoyment by society should be promoted, by using the patent law as a tool."

Firstly, regarding the distinction between inventions and discoveries, for "inventions" that are technologies close to application to society, efficient resource allocation can be rather achieved by granting patent rights and making them privatized, while for "discoveries," which are principle technologies far from application to society, development competition toward application to society based on discoveries is rather promoted by not granting patent rights and making them public-owned. However, even "discoveries" (spoken as an everyday term), such as a mere substance or gene sequence information, should exceptionally be the subject of a patent right if a means of their application to society (for example, their functions) is obvious.

Secondly, regarding the patentability of medical methods, an act of treatment has been considered unfit for technological development competition for profit in the past. However, if whether or not a patent is granted is not related to research and development bodies' choices of actions for the moment, there is no principle reason for denying the patentability of treatment methods as long as they are among the specific technologies of which application to society at the earliest date is rather desired. On that basis, it is necessary to restrict the exercise of patent rights that are actually likely to inhibit application to society, for example, to place working by doctors, etc. outside the subject of injunction and compensation for damage.

Thirdly, the public order and morality clause of which the scope of application is under discussion can be considered as follows. According to the incentive to invent theory, it is possible to argue that: even if technology is undesirable for society, it will be sufficient if its application to society is blocked by imposing administrative/police regulations extrinsic to the patent law with a focus on its utilization. However, if patent rights function to promote the application of inventions to society and thereby the granting of patent rights is admitted, the granting of patents for technology that should not be applied to society should be denied based on the intrinsic principle of the patent law without awaiting regulations extrinsic to the patent law. On the other hand, in the case where an illegal act/act of violating public order and morality lies not in an invention but in the mere process of inventing (for example, an invention completed by using a stolen reagent), the granting of patent rights will be affirmed since grant of patent rights does not foster a relevant illegal act because it only promotes use of the already made inventions according to the theory of promoting utilization of inventions.

Chapter Ⅲ From the Perspective of Morality

1. Chapter III examines how the patentability is demarcated from a public interest viewpoint, particularly in terms of moral limitations. Specially, the chapter analyzes and conducts comparative study on how the countries advanced in biotechnology, specifically, the United States, Europe, and Canada, have handled biological inventions. Fortunately, these three countries and region all have accumulated discussions on the same invention relating to an animal called the Harvard Mouse. (This mouse, which was developed by the medical professor of Harvard University through genetic engineering in the beginning of the 1980s, is "susceptible to cancer" and deemed to be useful for experiments conducted to identify the process of the development of cancer and developing cancer medicine.) There was a clear contrast between the conclusions derived in the respective countries/region as below.

2. In the United States, the requirements that could function as grounds to refuse to grant a patent for an immoral invention are "utility" and "subject matter." However, in current patent registration practice, the utility requirement in effect hardly plays a role as a registration requirement. Meanwhile, the subject matter requirement tends to be operated as being unrelated to morality since the U.S. Supreme Court judgment in the Chakrabarty case in 1980, which held that the scope of patentable subject matters includes anything under the sun that is made by man.

Later in 1988, in connection with the invention relating to the Harvard Mouse, a patent right for "all mammals excluding human beings" with the same gene susceptible to cancer was granted in the United States in 1987. Since then, a number of patents have actually been granted for varieties (or broader categories) of animals reproduced through genetic engineering. Today, in the United States, it is obvious that the scope of patentable subject matters generally include a wide range of life forms including animals.

The question is whether there is any limit to such a permissive attitude toward the patenting of

life forms, and in this respect, a dispute was provoked over the technology of reproducing human/animal chimera through genetic engineering, which is undesirable to human beings and raises a morality problem. Receiving this chimera application, in 1998, the U.S. Patent and Trademark Office (USPTO) issued a media advisory entitled "Facts on Patenting Life Forms Having a Relationship to Humans," expressing that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because they would be contrary to public order and morality and lack utility, which is one of the requirements for patent registration. However, considering that technological development has been advancing at a higher speed than operational difficulties (due to the vagueness of the standard) and theoretical problems are being solved, the USPTO's policy mentioned above should be deemed to be far from effective in reality. The development of human cloning technology is prohibited in the field of embryonic stem cell research and inventions directly relating to human beings cannot be patentable in accordance with the constitutional provisions on slavery, but inventions relating to life forms other than human beings would be very likely to be patented in the Untied States unless legislative measures are taken to prohibit the patenting of such inventions.

3. In Europe, the convention on the grant of European Patents (European Patent Convention: EPC) already includes an explicit provision on morality (Article 53). In other words, if inventions that satisfy the patent requirements (Article 52), such as novelty and involvement of an inventive step, fall under (a) inventions the publication or exploitation of which would be contrary to ordre public or morality and (b) plant or animal varieties or essentially biological processes for the production of plants or animals, this fact would be not only an ex ante ground to refuse to grant a patent right for such inventions but also an ex post ground to revoke the patent rights that have been granted.

In Europe, the "Directive on the Legal Protection of Biotechnological Inventions" was adopted in 1998. First, as for patenting life forms, inventions relating to plants and animals per se, which were clearly considered to be unpatentable in the past, shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. Second, as for patenting the human body, while elements of the human body such as an embryo and gene sequences per se shall not be patentable, such elements may be patentable if they are isolated from the human body by means of a technical process, even if the structure of the element is identical to that of a natural element. Third, if inventions of processes, which are deemed to be patentable in accordance with the rules mentioned above, are likely to cause suffering to animals without any substantial medical benefit to human beings and animals, and modify the genetic identity of animals, such inventions must be excluded from patentability. These rules set forth in the Directive on biotechnology were introduced to the EPC in June 1999. Consequently, the provisions set forth in this Directive have become binding on the examination process at the EPO.

At the EPO, the most radical dispute over the relationship between patent rights and morality has been seen, again, in the Harvard Mouse case. In Europe, a patent application was filed not for the Harvard Mouse per se as an invention of a product, but for the invention of the process of producing it. In 1998, the EPO Examining Division once refused the patent application, but in 1992, through a reexamination, a patent was granted for this invention. In the reexamination, the EPO pointed out that the following three types of interests should be taken into consideration: (i) interests achieved by developing technology to cure human diseases; (ii) interests achieved by protecting the environment from uncontrolled proliferation of undesirable genes; and (iii) interests achieved by preventing animal abuse. The EPO listed relevant interests for the three subjects, human beings, environment, and animals, which might be conflicting with one another, and established a framework for drawing a conclusion by comparing these interests. Within such a framework, the EPO determined: the Harvard Mouse is beneficial to the development of cancer medicine and therefore it is considerably beneficial to the treatment of human cancer; the new gene that the Harvard Mouse has will be used exclusively within the laboratory and it will never diffuse in the natural environment; and this invention has the possibility of saving not only the transgenic mouse but also many other animals from cancer, which will result in the salvation of animals as a whole.

Although several oppositions were filed by third parties against the patent granted by the EPO, in November 2001 the EPO finally granted a European patent for this invention, while narrowing the scope of the patent right. In this regard, the EPO offered the following views on "ordre public" set forth in Article 53(a) of the EPC: (i) the existing laws and ordinances allow using animals for experiments, and this means that the working of the claimed invention per se is not prohibited, therefore the invention is not contrary to ordre public; (ii) harm would not be caused to animals at the time when the invention was worked but when a tumor is caused, and therefore the invention per se does not directly cause harm to animals; and (iii)

it cannot be denied that the invention is beneficial to the development of cancer research. Accordingly, the EPO concluded that the patenting of animals to be used for experiments at laboratories would be in conformity with the Directive and Article 53(a) of the EPC but a broad claim covering all nonhuman mammals could not be accepted.

4. Unlike in the United States and Europe, the patentability of the Harvard Mouse was denied by the Supreme Court of Canada. Single-cell organisms such as yeast cell and bacteria, transgenic plants, and genetically-altered human gene sequences are patentable in Canada, but the Supreme Court denied the patentability of the Harvard Mouse by a close vote of five to four (furthermore, by overturning the original judgment of the Court of Appeals).

The grounds for the Supreme Court's decision were as follows: (i) the fact that the Patent Act in its current state is ill-equipped to deal appropriately with higher life forms as patentable subject matter is an indication that Parliament never intended the definition of invention to extend to this type of subject matter (In this respect, the Harvard Mouse is different from the invention of a new variety of plant for which a legislative solution was achieved.); (ii) although the definition of invention in the Patent Act is broad, the court cannot however agree with the suggestion that the definition is unlimited in the sense that it includes *anything under the sun that is made by man*, as expressed by the U.S. Supreme Court in the Chacrabarty case; and (iii) under the Patent Act, the word "manufacture" denotes a non-living mechanistic product or process whereas injecting the oncogene into a fertilized egg is the but-for cause of a mouse predisposed to cancer, but the process by which a fertilized egg becomes an adult mouse is a complex process, elements of which require no human intervention, thus, the court is not satisfied that the phrase composition of matter includes a higher life form whose genetic code has been altered.

5. The following suggestions can be derived from the above practical handling of biotechnological inventions in the United States, Europe, and Canada.

First, when considering the relationship between the granting of patent rights and morality, the subject matter whose compliance with morality is challenged should be clarified. More specifically, information on natural phenomena (e.g. discoveries and scientific views) should be clearly distinguished from natural phenomena per se that exists as information (e.g. gene information and business methods): the former is originally unpatentable (it could be construed that the former does not fall under the definition of "invention" set forth in Section 2(1) of the Patent Law because of lack of the "use" of laws of nature) whereas the latter is affirmed to be patentable, and then challenged with respect to compliance with morality. If this process is applied to an invention of a living thing, which is, by nature, an intangible invention rather than a tangible living thing per se, the invention is not information on the living thing but a natural phenomenon that exists as information. Therefore, it seems to be inappropriate to deny a priori the patentability of all inventions relating to life forms as construed in the United States.

Second, what kinds of inventions are deemed to be unpatentable on the ground of noncompliance with public order or morality? As shown above, this issue is handled differently depending on the country. As for the patenting of life forms, only inventions directed to human beings per se are unpatentable in the United States (therefore, life forms except for human beings are generally patentable) whereas in Europe, interests to be achieved by the development and use of the invention are individually examined and compared with one another according to the entity entitled to such interests (therefore, some life forms except for human beings are unpatentable). In Canada, on the other hand, higher life forms in general are unpatentable. However, as clearly shown in the case of human/non-human chimera, the scope of exceptions from patentability would be too narrow if it is limited to human beings (it would not be neutral in terms of value to grant a patent right for the development and use of a chimera, a new life form that clearly does not fall under the category of human beings). On the other hand, it would be hardly justifiable for the Patent Law to treat technologies the development and use of which are not prohibited under the laws and ordinances or excluded generally by social norms, such as a new variety of mouse used for experiment, discriminatorily from other technologies (just because they relate to higher life forms). Despite the disadvantage of requiring a case-by-case judgment, the balancing approach employed in Europe would still be appropriate.

Third, what would be a standard or framework for such balancing? It is difficult to answer this question, but at least the following can be pointed out. It would be appropriate that, as seen in Europe, the entities entitled to interests to be balanced may include not only human beings but also animals and more abstract entities, the environment. In this case, however, as is also seen in the practical handling in Europe, the interests to be enjoyed by entities except for human beings would be considered only abstractly or comprehensively. For example, in the case of an animal used for experiments, the interests to be enjoyed by the animal would not be considered in light of the

suffering of the individual animal but only considered from the viewpoint of preserving the species of the animal as a whole. As argued in the United States, such handling could be justified (passively) only by the fact that animals are not entitled to human rights under the Constitution. The evaluation criteria for balancing interests would inevitably include, as pointed out in some court decisions in Europe, not only laws and ordinances but also norms based on the culture and tradition of the society concerned. Where the development and use of the invention is regulated by laws or ordinances for a police or administrative purpose beyond the Patent Law, it is natural that the Patent Law refrains from providing incentives of the development and use, and it is also assumable that the Patent Law does not intend for the state to willingly provide such incentives even if the development and use is allowable under laws or ordinance.