

Harmonization of the Korea-Japan Systems in Chemical and Pharmaceutical Patents*

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The development of a "blockbuster" was a business model of the pharmaceutical industry in the 1990s. However, sales dramatically decreased as a result of the gradual reduction of the number of new blockbuster medicines and the expiration of patent rights for them. A method called Drug Repositioning (DR) that utilizes medicines for which manufacturing approval has already been obtained and the active components of medicines for which development was discontinued has recently been attracting attention. Matters that could not be assumed in the past have recently become problems in each country due to the operation of various systems for raising national competitiveness through medicines.

This research deals with recent issues regarding medicine-related patent systems, including the extension of the term of a patent right based on permission, etc., construction of claims for a product described as a manufacturing process (PBP), eligibility for a patent of hazardous substances such as poisons, advisability of granting a patent to a medical activity such as a method of medical care or diagnosis, and restrictions on the effect of a patent right for a patent of which the term was extended, and conducts comparison and analysis in relation to the situation where redevelopment of related legal provisions and examination guidelines is necessary due to factors including related judicial precedents and laws and regulations and changes in the examination requirements.

Countries should operate a system that is the most matched to the actual conditions of the medical policy. However, whether such system perfectly fits in with each country's own interest is a difficult issue. Therefore, countries need to harmonize systems by reflecting international trends in reference to other countries' systems.

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Matters that could not be anticipated in the past have become problems in each country due to the operation of various systems for raising national competitiveness through medicines.

The main purpose of this research is to promote harmonization of medicine-related patent systems by dealing with general problems with medicine-related patents in South Korea and Japan, countries where the systems are similar to each other, and by additionally dealing with the operation of systems in individual countries.

Chapter II deals with a theme about the extension of the term of a patent right based on permission, etc.

There are two forms of registration of extension of the term of a patent right in South Korea. One is a system where, when the registration of establishment of a patent right is delayed for four years or more from the filing date of a patent application or three years or more from the date of filing a request for examination of a patent application, the term of the patent right is extended based on either of the aforementioned two periods whichever is later.¹ Another is a system of extension of the term of a patent right based on permission, etc. under other laws or regulations. Such system has been in effect in South Korea, Japan, the EU, and other countries since it first came into force in 1984 in the United States. This research deals only with the medicine-related content regarding the system of extension of the term of a patent right based on permission, etc. as its theme. The systems of extension of the term of a patent right based on permission, etc. under other laws or regulations are operated around the world, and all of those systems are similar in the basic concept of extending the term of a patent right. However, there are a few differences among individual countries' systems. This research is intended to compare differences among countries and promote the international harmonization of systems of extension of the term of a patent right based on permission, etc.

There are the following ideas regarding the direction toward harmonization of the systems.

(1) With regard to the period of extension, it is considered desirable to adopt a system where, when the remaining period of the term of a patent right is 14 years or more, the term is terminated when 14 years pass, like the United States.

(2) With regard to the period during which an application for extension can be filed, it is desirable that South Korea adopts the practice where an application for registration of extension can also be filed even after six months before the expiration of the term of a patent right if a document certifying delay of permission, etc. is submitted, like Japan. In addition, South Korea has not established a system of subsequent completion of procedure in relation to the system of extension of the term of a patent right, but it seems that it needs to amend related provisions.²

¹ Jo Jaeshin, "Consideration of Revised Patent Law according to the Korea-U.S. Free Trade Agreement," *Hogakuronso*, vo 1. 32, no. 3, 49-83, p. 61.

² Article 17 of the Patent Act of South Korea (Subsequent Completion of Procedure).

(3) With regard to the case where multiple patents exist in relation to one permission or registered matter, it is considered desirable in consideration of the purpose of the system of registration of extension of the term of a patent right and the interests, etc. of patentees and the general public that Japan adopts a system in which the term of only a single patent right can be extended in relation to one or many permissions, like the United States, Europe, and other regions.

(4) With regard to inventions subject to an application for registration of extension, Japan enumerates dispositions that serve as a ground for registration of extension in Article 2 of the Order for Enforcement of the Patent Act. However, there is no provision stipulating that the active component of a permitted medicine must fall under a new substance, and Japan's system differs from South Korea's system in that the scope of permission subject to extension is broader in Japan than in South Korea. Therefore, it is considered desirable that Japan considers a system in which term is extended only in relation to new substances.

Chapter III deals with a theme concerning the scope of claims for a product described as a manufacturing process (PBP; Product-by-Process).

In South Korea, the Supreme Court of South Korea has recently rendered in an en banc decision ruling that where the scope of claims is described as a manufacturing process, novelty or involvement of an inventive step must be determined without regard to parts expressed as a process. That is, a manufacturing process is one means of identifying the structure, nature, etc. of a product that is the end product and merely has a meaning as such. Therefore, it is necessary to understand the invention as a "product" that has a structure, nature, etc. identified by all the statements in the claims and closely study whether the invention is novel and involves an inventive step, etc. by comparing it with prior art that had become publicly known before filing of the application. As there are differences not only in the examination practice of countries but also in the construction, etc. of the scope of claims in trials and infringement lawsuits, international harmonization should be promoted through comparison of practice relating to the scope of claims of a product described as a manufacturing process in each country and differences among countries' practices.

(1) Looking at each country's stance on the construction of PBP claims at the time of making a determination concerning fulfillment of the requirements for patentability, decisions of the United States Court of Appeals for the Federal Circuit³ at the stage of granting a patent and USPTO's examination guidelines adopt the stance of the substance theory to the effect that a decision on the patentability of PBP claims is based on a relevant product per se and unique structural features which a manufacturing process gives to the end product must be taken into consideration.⁴

The Guidelines for Examination in the European Patent Office provide as follows, and the EPO

³ In re Thorpe, 777 F.2d 695 (Fed. Cir. 1985); In re Marosi 710 F.2d 798 (Fed. Cir. 1983).

⁴ USPTO MPEP, "2113 Product-by-Process Claims."

takes the stance of the substance theory:⁵ "Claims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil the requirements for patentability, i.e. inter alia that they are new and inventive ... A product is not rendered novel merely by the fact that it is produced by means of a new process. ... , it is still directed to the product per se."⁶

Countries around the world, in principle, have mostly common examination practice based on the substance theory in relation to the time of making a determination concerning fulfillment of the requirements for patentability. However, in Japan, based on a decision of the Supreme Court of Japan in 2015, unauthentic PBP claims are deemed to have a reason for deficiency in the description, and such description is not permitted and only authentic PBP claims are permitted.

(2) Looking at each country's stance on the construction of PBP claims at the time of infringement, Japan adopted the substance theory, regardless of whether claims are authentic or unauthentic PBP claims, in the Supreme Court decision (decision of the final appellate court in relation to a decision of the Grand Panel of the Intellectual Property High Court on a case to seek an injunction against patent infringement) in 2015. However, the Supreme Court strengthened the description requirements for the scope of claims and deemed that the clarity requirement is not fulfilled if claims are substantially unauthentic PBP claims at the time of filing an application, and did not permit such description. However, there are many criticisms against such clarity requirement for the scope of claims held in the Supreme Court decision.

The United States had adopted the manufacturing process limitation theory. However, it subsequently temporarily adopted the substance theory in the *Scripps* decision but returned to the manufacturing process limitation theory in the *Atlantic Thermoplastics* decision and confirmed adoption of the manufacturing process limitation theory in the *Abbott Labs* decision.⁷

Regarding construction of PBP claims at the time of infringement, Germany and Japan provide absolute protection as an invention of a product through the substance theory. On the other hand, the United States and the United Kingdom set restrictions through the manufacturing process limitation theory.

South Korea, in principle, adopts the substance theory, but there is a room for the possibility of imposing restrictions on the scope of protection by adopting the manufacturing process limitation theory if the scope of rights becomes excessively broad.

In such manner, most countries generally conform to the substance theory at the time of making a determination concerning fulfillment of the requirements for patentability, and countries slightly

⁵ T 205/83 (OJ 1985, 363). 이헌 「심결취소소송 최근 판례 동향」 7면에서 재인용.

⁶ Guidelines for Examination in the European Patent Office, Part F-Chapter IV 15, "4.12 Product-by-process claim."

⁷ 김병필, 최근 미국(2009년)과 일본(2012년)의 판례를 통해 살펴본 제법한정 청구항의 해석론에 관한 고찰, 2012. 10., p. 11. 엄인권 「‘제조방법이 기재된 물건발명’의 청구범위 기재 요건 및 신규성·진보성 판단 기준에 대한 제언-대법원 2015. 1. 22. 선고 2011후927 판결」 특허청, 2015. p. 17-20에서 재인용.

differ from each other at the time of infringement.

(3) Regarding harmonization of application of the substance theory and the manufacturing process limitation theory at the time of infringement, there is still disagreement about whether the scope of rights is limited by a manufacturing process described, as closely studied above, when construing PBP claims at the time of infringement although a long period of time has passed.

South Korea has made clear that PBP claims absolutely fall under inventions of products and that manufacturing processes are not at all an element to be considered since the en banc decision of the Supreme Court of South Korea on 2011 Fu 927 in 2015.

Article 42, paragraph (6) of the Patent Act of South Korea provides that "The scope of claims ... shall state such matters regarded necessary to specify an invention as structures, methods, functions and materials or combination thereof to clarify what to be protected." Japan also newly established the following provisions (Article 36, paragraph (5) of the Patent Act) to make it possible to state claims in various ways based on the applicant's choice, irrespective of the structure of the invention: "the patent applicant must state all matters that the applicant finds to be necessary for defining the invention for which the patent is sought, separately for each claim."

Such provisions mean that the mere fact that an invention is described by PBP claims cannot be considered to constitute a failure to fulfill the description requirements because the form of stating PBP claims is a matter to be chosen by a patent applicant.

In consideration of international trends and harmonization, it is considered desirable to permit PBP claims only where a structure can be limited only by a manufacturing process, for example, where the structure of a novel product is unknown or its nature is unknown.

Moreover, in the case of an invention of a product in the field of chemistry and alloy or the field of biology, it is difficult to identify a product without depending on a manufacturing process in many cases. Therefore, it can become one means to handle such inventions as those that differ from general inventions of products.

(4) With regard to the harmonization of the dualistic construction of the scope of claims and application, there are the unitary theory that claims should be construed based on the same standards at the "time of making a determination concerning fulfillment of the requirements for patentability" and the "time of making a determination concerning infringement" and the dualistic theory that claims should be construed based on different standards. Examining each country's stance, Japan and the EPO apply the unitary theory and most of other countries apply the dualistic theory.

It is considered as desirable application to broadly construe PBP claims by deeming the relevant invention as a product according to the substance theory at the "time of making a determination concerning fulfillment of the requirements for patentability," make it possible to limit rights through amendment at the examination stage and through correction at the stage of trial for patent invalidation,

and limit the scope of rights within the scope of the manufacturing process according to the manufacturing process limitation theory at the "time of making a determination concerning infringement."

Chapter IV deals with a theme about the eligibility for a patent of toxic or hazardous substances.

All countries consider toxic or hazardous substances, etc. to be unpatentable, and South Korea and Japan seem to be basically in harmony with each other.

In addition, when making a determination concerning fulfillment of the requirements for patentability in relation to a toxic or hazardous substance, etc., an invention of toxicity per se is considered to be unpatentable and is rejected in most cases, and it was also revealed that such invention is, in practice, rejected for the reason of non-fulfillment of the description requirements of a description or lack of inventive step in some cases.

However, due to cases such as the case where silver nanomaterial that had been known as one that is beneficial to the human body in the past was revealed to be a chemical substance that is harmful to the human body, there has been increasing need for an institutional measure whereby a patent is not granted to a patent application for an invention: to which a chemical substance that is likely to impair human health is applied, by considering whether or not the invention is unpatentable in the patent examination process. Therefore, it is considered desirable that countries share information about toxic substances, restricted substances, prohibited substances, substances that require accident response, hazardous chemical substances, priority management substances, etc. and cooperate with each other.

Chapter V deals with a theme about medical activities, such as methods of medical care or diagnosis.

As methods of surgery, therapy or diagnosis, for which the human body is an essential constituent element are related to human dignity, inventions of medical activities for humans are handled differently from other inventions under patent law. As an example, as there are several hundred kinds of anticancer drugs and it is impossible to administer all anticancer drugs to a patient in order to know what anticancer drug is the most adapted to the patient, it is important to administer the most adapted anticancer drug according to the condition and genes of the patient. Such dosing strategy can be a method of therapy in the end.

An invention of a method of diagnosis has recently been rejected in the final appellate instance in the United States. Each country operates a system that slightly differs from other countries' systems. Therefore, it is desirable to closely study examples of lawmaking in each country and promote international harmonization.

The United States has taken a stance of active patent protection for medical activities, but recent judicial precedents take a considerably backward stance. In the United States, patents were granted

for inventions that optimize the dosage of a drug according to individual patients, but many such inventions have not been patented on the grounds of lack of the eligibility for a patent since the Mayo decision in 2012.

In this manner, inventions of medical activities have been rejected on the grounds that they lack the eligibility for a patent because they go against the laws of nature in recent decisions in the United States, a country that had actively protected medical activities.

On the other hand, regarding medical activities, the TRIPS Agreement provides that medical activities are "unpatentable," and based on this, Europe has changed its rule: medical activities, which were denied patents on the grounds of lack of industrial applicability, are now treated as "unpatentable" subject matters.

In Japan, methods of surgery, therapy or diagnosis are not considered to fall under the "industry," category, but patents are not granted for medical activities on the grounds that medical activities are not industrially applicable. In South Korea, patents are also not granted for medical activities on the grounds that medical activities are not "industrially applicable."

In conclusion, all countries are similar to each other in that patents are not granted for fundamental medical activities, and patents are not granted for them on the grounds that they are not "eligible for a patent" in the United States, on the grounds of existence of a ground for unpatentability in Europe, and on the grounds of lack of industrial applicability in South Korea and Japan.

However, the Japanese Examination Guidelines define medical activities as methods of surgery, therapy or diagnosis of humans "practiced by medical doctors (including those who are directed by medical doctors; the same applies hereinafter)." In South Korea, medical activities refer to the activities of surgery, therapy or diagnosis of humans practiced by medical personnel or those who are directed by medical personnel based on knowledge of medicine. Medical activities practiced by those other than medical personnel are widely handled as those lacking industrial applicability if they are considered to be inventions of methods of treatment for therapy or prevention of a human disease or those for enhancement or maintenance of health conditions in light of the purpose, structure, and effect, etc. of the inventions. Under the Japanese Examination Guidelines, medical activities other than those practiced mainly by medical doctors fall under the "gray zone"⁸ in some cases. Therefore, harmonization seems to be necessary.

Moreover, patents are granted for medical activities, but institutional measures in consideration of human dignity are necessary. It is also considered desirable to make a special case: in which a medical activity practiced by a medical doctor is not subject to an injunction against infringement or compensation for damages, like the United States.

⁸ 최재식, 심미랑 외3 「바이오헬스산업의 특허 환경 분석 및 보호 방안에 관한 연구」 p. 35 (KIIP, 2018).

Chapter VI deals with a theme about restrictions on the effect of a patent right.

Out of the matters concerning restrictions on the effect of a patent right, the South Korean system and the Japanese systems are compared in relation to "medical inventions in which two or more medicines are mixed together and inventions of manufacturing processes in which two or more medicines are mixed together" and restrictions on the "effect of a patent right where the term is extended," and differences between them are closely studied. After that, harmonization of the systems is promoted.

In both South Korea and Japan, when a specific usage of a product is prescribed in a permission, etc., the extended patent right is only effective against the act of working the patented invention for the product as it is used for that usage, and when another permission is obtained for usage that differs from the usage prescribed in the permission, etc. that served as the basis for registration of extension, the extended patent right is not effective against the act of working for that usage. This is because, in the case of South Korea, the Patent Act merely provided that the extended patent right is effective against the "working of the patented invention in relation to the product subject to the permission due to which the extension of the duration has been registered," which means that the Patent Act did not limit the scope of working covered by the extended patent right to the working of the "product item" subject to the permission, etc., but provided for a broader scope that included the working of the "product."⁹

The provisions on the effect of a patent right of which term is extended concern a system to extend the term of a patent right to relieve a patentee who cannot substantially exercise the patent right, and do not concern a system to enlarge the technical scope of a patented invention. Therefore, it is considered unfavorable to apply the doctrine of equivalents from such perspective.

⁹ 대법원 2017. 11. 29. 선고 2017후882, 899 판결.