Comparative Study on Patent-Approval Linkage System [*]

Invited Researcher: SHIN, Hye Eun [**]

Drug inventions require enormous time and cost before their completion, and their development is highly likely to end in failure. In addition, even if development of a drug invention succeeds once, it is also necessary to go through efficacy and safety tests for commercialization. In this manner, drug inventions have different characteristics from inventions in the machinery and electronics fields. Therefore, it is considered that protection of drug inventions by patents is indispensable for new drug developing and manufacturing companies.

On the other hand, as drugs are directly linked to the people's lives and health, there are cases where a patent is not granted or where it is necessary to restrict the patent rights from the aspect of public interest.

The ultimate purpose of the Patent Act is the development of industry. The Patent Act is useful as a means of reasonably achieving such purpose. Therefore, the Patent Act ensures that voluntary disclosure of the content of technical development by those who develop new technology forms the foundation for subsequent studies. In addition, the Patent Act gives a consideration (incentive), which can be considered reasonable, to those who disclose such technology, thereby trying to provide the driving force of technology development.

On the other hand, if the granted incentive is excessively great, it will inhibit the utilization of the relevant invention, which is likely to produce the result of inhibiting development of industry. In contrast, if the granted incentive is excessively small, it is likely to cause the lowering of motivation for technology development. Therefore, it is of the highest importance to ensure a virtuous cycle of development of technology by providing appropriate incentives in accordance with development in technical fields and the situation of the time. In addition to this, in the case of drug inventions, public interest-related elements must also be taken into consideration, and the medical circumstances in the relevant country must also be taken into account.

This study compares the current situation in South Korea and that in Japan regarding drug

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[**] Professor, Chungbuk National University School of Law.

patent linkage, and then suggests a desirable direction for system operation in both countries.

In South Korea, the patent linkage system intended for protection of new drugs came into force in a full-fledged manner on March 15, 2015. On the other hand, in the case of Japan, a full-fledged patent linkage system like the one in South Korea has yet to be introduced. However, Japan is a party to the TPP, and a system for patent linkage is provided in Article 18.53 (Measures Relating to the Marketing of Certain Pharmaceutical Products) of the TPP. Therefore, it is probably necessary for Japan to seek an idea of introduction of a desirable system suited for Japanese law and the actual conditions of the pharmaceutical industry through comparison with the systems of other countries that have introduced patent linkage.

I. Introduction

Drug inventions require enormous time and cost before their completion, and their development is highly likely to end in failure. In addition, even if development of a drug invention succeeds once, it is also necessary to go through efficacy and safety tests for commercialization. In this manner, drug inventions have different characteristics from inventions in the machinery and electronics fields. Therefore, it is considered that protection of drug inventions by patents is indispensable for new drug developing and manufacturing companies. [1]

On the other hand, as drugs are directly linked to the people's lives and health, there are cases where a patent is not granted or where it is necessary to restrict the patent rights from the aspect of public interest.

The ultimate purpose of the Patent Act is the development of industry. The Patent Act is useful as a means of reasonably achieving such purpose. Therefore, the Patent Act ensures that voluntary disclosure of the content of technical development by those who develop new technology forms the foundation for subsequent studies. In addition, the Patent Act gives a consideration (incentive), which can be considered reasonable,

[1] Enormous costs and time are required before creation of a new drug through searching of a new substance, and the success probability is also very low. However, it is considered that once succeeded, the creator can earn a significant profit, specifically, the profit accounts for 20 to 30% of sales. In terms of such characteristic of the pharmaceutical industry, protection by patent right is utilized as an important means of collecting invested research and development funds. Joseph A. DiMasi & Henry G. Grabowski, The Cost of Biopharmaceutical R&D: Is Biotech Different?, 28 Managerial & Decision Econ. 469, 477 (2007); John R. Allison & Mark A. Lemley, “Who’s Patenting What? An Empirical Exploration of Patent Prosecution” 53 Vand. L. Rev. 2099(2000).

to those who disclose such technology, thereby trying to provide the driving force of technology development.

On the other hand, if the granted incentive is excessively great, it will inhibit the utilization of the relevant invention, which is likely to produce the result of inhibiting development of industry. In contrast, if the granted incentive is excessively small, it is likely to cause the lowering of motivation for technology development. Therefore, it is of the highest importance to ensure a virtuous cycle of development of technology by providing appropriate incentives in accordance with development in technical fields and the situation of the time. In addition to this, in the case of drug inventions, public interest-related elements must also be taken into consideration, and the medical circumstances in the relevant country must also be taken into account.

In South Korea, the patent linkage system [2] intended for protection of new drugs came into force in a full-fledged manner on March 15, 2015. Three years have already passed since full-fledged enforcement of the system, but the South Korean-style patent linkage system can be considered to be still in the process of becoming firmly established.

This study compares the current situation in South Korea and that in Japan regarding drug patent linkage, and then suggests a desirable direction for system operation in both countries.

In the case of Japan, a full-fledged patent linkage system like the one in South Korea has yet to be introduced. However, Japan is a party to the TPP, and a system for patent linkage is provided in Article 18.53 (Measures Relating to the Marketing of Certain Pharmaceutical Products) of the TPP. Therefore, it is probably necessary for Japan to seek an idea of introduction of a desirable system suited for Japanese law and the actual conditions of the pharmaceutical industry through comparison with the systems of other countries that have introduced patent linkage.

II. Legislative Examples and Present State of Other Countries Concerning Patent Linkage System

1. What is Patent Linkage?

The term "patent linkage" literally means the linked operation of the drug approval system and the patent system. In South Korea, before introduction of this

[2] This system is also called approval-patent linkage system, but it is called patent linkage system in what follows.

system, the Ministry of Food and Drug Safety (hereinafter referred to as the "MFDS") had jurisdiction over drug marketing approval while the KIPO had jurisdiction over patent affairs, and these two kinds of affairs were handled by separate government offices, respectively. However, after introduction of patent linkage, where an application for marketing approval is filed for a patented drug, the MFDS must notify the patentee of this fact and must also take a measure in the marketing approval procedure in order to prevent other persons from marketing the relevant product without obtaining the consent or tacit approval of the patentee.

The purpose of said system is to promote development of generic drugs and market entry of generic drugs through challenge to patents while effectively protecting patentees' rights, thereby enabling consumers to purchase drugs at a low price. Therefore, the holders of drug patents are permitted to extend the duration within the range of five years, taking into account the period during which they were substantially prevented from exercising the patents due to efficacy and safety tests. On the other hand, generic drug companies' act of working a patented invention to obtain data relating to drug marketing approval is free from the liability for infringement. Furthermore, for a copy drug, its efficacy and safety have already been proven on the basis of a related new drug, and therefore, an applicant for a generic drug can file an abbreviated new drug application (hereinafter referred to as an "ANDA") only by submitting bioequivalence data showing that said copy drug is bioequivalent to the related new drug.

2. United States

(1) Background to the Enactment of the Hatch-Waxman Act

(2) Specific Content

1) Registration in the Orange Book

2) Notice to a Patentee and Measures for Marketing Prevention

(3) Medicare Act 2003

1) Enforcement of the System and Problems with the Enforcement

2) Major Changes in and after 2003

(i) Clarification of Drugs that can be Listed in the Orange Book

(ii) Limiting the Number of Times of the 30-Month Automatic Stay Procedure to once

(iii) Litigation to Seek Deletion of a Patent from the Patent Registration List Filed by an ANDA Filer

Although Canada is a country in North America in the same manner as the United States, the drug patent linkage system is operated in an extremely different way. In the case of Canada, generic drugs had already been activated to a considerable extent before introduction of the system; therefore, it seems that the patent linkage system was established with a central focus on the protection of patentees' rights and prevention of unjustifiable exercise of rights. On the other hand, unlike other countries, Canada provides for the patent linkage system not under law or regulation concerning drug approval but under the authority granted by the Patent Act. This is the biggest characteristic of Canadian law. This is considered to be a reason that generic exclusivity was not introduced. This is because, although a patent is deemed to have not existed in the first place if it is invalidated, establishing another exclusivity on a specific person in exchange for invalidation of a patent goes against the purpose of the Patent Act.

In addition, Canada limits the subject of listing so as to ensure that a patent can be subject to patent linkage only where it directly contributed to the development and market entry of an individual drug. Therefore, the subject of listing is limited to patents for which an application was filed before filing of an application for marketing approval of a drug, and examination for registration is very strictly conducted. Therefore, a considerable number (about 20%) of patents are refused registration. Moreover, the requirements for marketing prevention are strict, and the probability of citation by the

court is relatively low. A considerable number of cases seem to be withdrawn in the process of court proceedings through settlement, etc.

4. Australia

(1) Background to the Introduction

(2) Main Content

1) Absence of the Patent List

2) Certification Concerning Relationships with a Patent

3) Patent Litigation Filed by a Patentee and Conditions Thereof

4) Compensation by an Applicant for Approval of a New Drug in Association with Marketing Prevention

(3) Point to Keep in Mind

The patent linkage system of Australia is similar to the Canadian system in terms of the basic direction, and it is focused on the preparation of measures for preventing patentees from abusing rights. Therefore, it is provided that it is necessary to make a statement about the existence of a reasonable ground when filing patent litigation and that it is possible to impose a pecuniary penalty if such statement is false. These measures can be considered as systems unique to Australia that are intended to prevent excess protection of patents and blind filing of patent litigations based thereon. As the system is operated based on the defensive principle and direction of preventing abuse of the marketing prevention system under strict conditions, the generic exclusivity system, which is discussed as falling under the granting of another exclusivity, has not been introduced.

5. Taiwan

(1) Background to the Introduction

(2) Main Content

1) Registration in the Patent List

2) Certification Concerning Relationships with a Patent

3) Stay of Approval

4) Marketing Exclusivity

6. China

(1) Operation of the Existing Drug Patent Linkage System

(2) Promotion of Improvement of the System

7. Related Provisions of the TPP

III. South Korea's Patent Linkage System

1. Background to Introduction

The patent linkage system is a system that was introduced in a full-fledged manner by legislation for performance of the South Korea-U.S. FTA that was concluded in 2007 and was put into effect in 2012, but part of the Hatch-Waxman Act that served as the base of the system had already been in South Korean law. South Korea amended the Patent Act in 1987 and thereby introduced a system to extend the duration of a patent up to five years for a person who was unable to work the patent due to efficacy and safety tests on the drug. [3]

On the other hand, there were a district court decision [4] and a decision of the Intellectual Property Trial and Appeal Board [5] to the effect that even before the expiration of the duration of a drug patent, the act of conducting a test for marketing approval of a drug does not constitute infringement of the patent. In order to make this clearer, the Bolar provision of the Hatch-Waxman Act was introduced in the amended Patent Act of 2010. [6]

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[3] Article 89 (Extension of Patent Terms by Permission, etc.) (1) Notwithstanding Article 88 (1), the term of a patent on an invention may be extended only once by up to five years to compensate for the period during which the invention cannot be practiced, if the invention is specified by Presidential Decree and requires permission, registration, etc. under any other statute (hereinafter referred to as "permission, etc.") to practice patented invention but it takes a long time to undergo necessary tests for validity, safety, etc. for such permission, registration, etc.
(2) For the purposes of paragraph (1), the period required due to a cause attributable to the person who has obtained permission, etc. shall not be included in "period during which the invention cannot be practiced" in paragraph (1).

[4] Southern Branch of the Seoul Central District Court, June 15, 2001, 字2001□ □ 1074 decision (case of provisional disposition of prohibition of patent infringement); the court held as follows with regard to a third party's act of manufacturing a pesticide whose effective ingredients, etc. are the same as those of a pesticide that is a patented invention and asking for a test necessary for obtaining a certificate of analysis to be attached to an application for registration for the registration of a manufacturing item as prescribed in Article 8 of the Pesticide Control Act during the duration of the patent: "The act of manufacturing and using a difenoconazole drug that is a patented invention for the purpose of obtaining various certificates of analysis that are requirements for the obtainment of registration of a manufacturing item within the country under the Pesticide Control Act falls under use for the purpose of testing referred to in Article 96, paragraph (1) of the Patent Act and does not constitute infringement of the patent."

[5] Intellectual Property Trial and Appeal Board, March 24, 2008, 字2007□ 2503 trial ruling (case of a trial to confirm the scope of active rights); Regarding bioequivalence tests conducted for approval of a generic drug during the duration of a patent, the Intellectual Property Trial and Appeal Board rendered the following decision: "The demandee manufactured the invention subject to confirmation for the purpose of conducting the bioequivalence tests, and these tests are recognized as those falling under tests referred to in Article 96, paragraph (1)1 of the Patent Act as tests to confirm whether the generic drug is bioequivalent to the existing new drug to the extent that it can replace the existing new drug. Therefore, it is reasonable to consider production of the invention subject to confirmation, that is, the act of manufacturing it, for that purpose as "practice of a patented invention for the purpose of research or testing" provided in Article 96, paragraph (1)1 of the Patent Act."

[6] Article 96 (Limitations on Effects of Patents (1) The effects of a patent shall not extend to the following:
1. Practice of a patented invention for the purpose of research or testing (including research and testing for

The patent linkage-related provisions that were newly introduced through legislation for performance of the South Korea-U.S. FTA were relating to the system of a notice to a patentee and measures for preventing marketing approval without right holder's consent. The part relating to a notice to a patentee was introduced into the system of South Korea on March 15, 2012 through coming into force of the South Korea-U.S. FTA. The part relating to measures for preventing marketing has been in effect since March 15, 2015 with a three-year grace period granted.

The ultimate purpose sought by the patent linkage system is to promote the market entry of generic drugs by granting legitimate and sufficient compensation for patentees' development of new drugs and by providing incentives to those who have promoted the market entry of generic drugs through challenge to patents. The legislative purpose can be considered ideal, and it is reported that implementation of the system promoted the market entry of generic drugs in the United States.[7] However, even in the United States, implementation of the system caused many problems that were not expected in the initial stage of designing of the system. The United States amended relevant law in 2003 in order to correct problems arising from abuse of the system. In the case of the United States, many problems were improved through legal amendment in 2003, but not all the problems were solved, and even now, various bills are presented in order to solve problems caused by the system.

South Korea designed the South Korean-style patent linkage system based on lessons learned from trials and errors in the United States in conformity to the South Korean legal system and the environment which the pharmaceutical industry is facing. The patent linkage system of South Korea is specifically explained below.

2. Related Procedures

(1) Provisions of the South Korea-U.S. FTA

(2) Provisions of the Pharmaceutical Affairs Act

1) Listing in the Drug Patent List

2) Notice of an Application for Approval

3) Measures for Marketing Prevention

4) Exclusive Marketing Approval

(3) Difference from the U.S. System

obtaining permission for items of medicines or reporting items of medicines by under the "Pharmaceutical Affairs Act" or for registering pesticides under the "Pesticide Control Act") (the rest is omitted)

[7] Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration: An FTC Study," 2002.

IV. Japanese Patent Linkage System

1. Current Japanese System

In the case of broadly defining the patent linkage system, that is, in the case of defining the patent linkage system as a mechanism whereby the regulatory authority considers the existence or absence of patents relating to the original drug in the examination/approval procedure of a generic drug so as to prevent the occurrence of a problem with the stable supply of the generic drug due to patent infringement litigation, etc. after the start of the marketing of the generic drug,[8] Japan can be considered to have already partially introduced the patent linkage system.

Under Article 67 of the Japanese Patent Act, the duration of a patent for a new drug is "20 years" plus five years at most. As a long period of time is required for the development and examination of a new drug, extension of the duration of a patent is permitted for a maximum of five years.[9]

Unlike the South Korean Patent Act, the Japanese Patent Act does not include an explicit Bolar provision that "the effects of a patent shall not extend to research or testing for obtaining marketing approval of a drug." However, the court has determined that a generic drug company's act of conducting a bioequivalence test during the

[8] Survey on Actual Conditions of Intellectual Property Systems, etc. for Biotechnology-Based Drugs in Other Countries, Institute of Intellectual Property (March 2018), page 23 (https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000202523.pdf) [last access date: August 14, 2018]

[9] (Patent Term) Article 67 (1) The term of a patent right expires after a period of 20 years from the filing date of the patent application.
(2) If there is a period during which it is not possible for a person to work the patent invention due to the need to obtain permission under the provisions of the law that is intended to ensure safety, etc. of working the patent invention or to be issued any other disposition that Cabinet Order specifies as one that it require considerable time to properly reach due to things such as the purpose of the disposition and procedures, etc., involved in it, the term of patent right may be extended, upon the filing of an application to register an extension for a maximum of five years.

duration of a patent for a new drug does not constitute infringement of the patent right. [10]

In addition to this, for a new original drug, the reexamination period of up to 10 years is set after marketing approval. An original drug manufacturer needs to collect efficacy and safety data concerning the actual use of the original drug at medical institutions and undergo reexamination after passage of a certain period of time after approval. Even if the patent term of the original drug has already expired, generic drug manufacturers are prevented from filing an application for a generic drug during this period. [11]

On the other hand, in Japan, as an operation corresponding to "patent linkage," where there is a valid patent for an effective ingredient of an original drug based on patent information on the original drug that was reported by the original drug manufacturer ("drug patent information report sheet"), marketing approval is not to be granted for a generic drug based on guidance under a Ministry of Health, Labour and Welfare's notice addressed to the prefectural heads of hygiene departments and bureaus, etc. [12] so as to prevent the occurrence of a problem with the stable supply of the generic drug product due to patent infringement litigation, etc. after the start of the marketing of the generic drug. [13] However, this provision of information on actual operations is on a voluntary basis and is not made available to the public.

As a whole, in Japan, it is made a principle that "a generic drug is not approved if there is a patent for an effective ingredient of the original drug."

As a means thereof, an applicant for a generic drug is required to "make adjustment for an item involving concerns about a patent among the parties in advance

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[10] Judgement of the Second Petty Bench of the Supreme Court of April 16, 1999 (1998 (Ju) 153) (Minshu, Vol. 53, No. 4, at 627) [pancreatic disease therapeutic agent case].
"Where a person holds a patent for a chemical substance or a drug containing it as an effective ingredient, it is reasonable to understand that a third party's act of producing a chemical substance or a drug that falls within the technical scope of the patented invention and conducting a test necessary to obtain a material to be attached to a written application for approval prescribed in Article 14 of the Pharmaceutical Affairs Act by using the produced chemical substance or drug during the duration of the patent for the purpose of filing the application for approval in relation to the manufacturing of a generic drug with the aim of manufacturing and marketing the generic drug after the expiration of the duration of the patent falls under the 'working of the patented invention for experimental or research purposes' referred to in Article 69, paragraph (1) of the Patent Act and does not constitute infringement of the patent."

[11] Competition and Incentives for Research and Development in the Drug Market – Through Verification of Impact that the Entry of Generic Drugs Had on the Market), Japan Fair Trade Commission, pages 13 to 15.

[12] "Handling of Drug Patent Information in Relation to Application for Approval" (Pharmaceutical Affairs Council's Notice No. 762 of October 4, 1994) and "Handling of Drug Patents in Relation to Application for Approval of Generic Drug for Medical Use under the Pharmaceutical Affairs Act and NHI Price Listing" (Notice of the Director of the Economic Affair Division of the Health Policy Bureau No. 0605001/Notice of the Director of the Safety Division of the Pharmaceutical and Food Safety Bureau No. 0605014 of June 5, 2009).

[13] https://blog.goo.ne.jp/hatatomoko1966826/e/0b21b3ab697d71c3bc1fff7d43108e35

of the (National Health Insurance Drug (NHI) listing of a generic drug and take the listing procedure only if the item can be stably supplied."

That is, in the case of filing an application for a generic drug, a generic drug company is required to file it after the end of the reexamination period, to examine whether there are substance patents or use patents for the effective ingredient of the drug, and to attach material showing that the drug can be promptly manufactured and marketed after approval if there is any substance patent or use patent. In addition, in the case of desiring to list an item that seems likely to cause a patent dispute, a generic drug company is sometimes required to make adjustments with a new drug manufacturer, who is the patentee, in advance (preadjustment procedure) and take the listing procedure only if the item can be stably supplied and to submit materials that can objectively prove that stable supply of the item is possible (a written consent, etc. of the patentee (original drug manufacturer, etc.)) as needed. [14]

2. Problems with the Current System

In Japan, a patent linkage system in a full-fledged sense has not been introduced. However, as mentioned above, where there is a patent for an effective ingredient of an original drug based on patent information reported by the original drug manufacturer (drug patent information report sheet), marketing approval is not granted for a generic drug. Therefore, in a broad sense, Japan can be considered to have already been operating the Japanese-style patent linkage system. The Japanese-style patent linkage system was first introduced in 1994. At first, the system had been operated only in relation to substance patents. It is considered that the Ministry of Health, Labour and Welfare started operating the system in relation to substance patents on which it is easy to make a determination because it is not an expert in patents. However, in 2009, the scope of subject patents was expanded, and use patents became subject to the system in addition to substance patents.

Although the Japanese-style patent linkage system has a relatively long history, it is said that only about three years have passed since the system started to be discussed in a full-fledged manner in Japan. It is a fact that there are still not many experts and persons who have an interest in the system. However, the system is expected to attract increasing interest in the future.

[14] Same as above.

The following are problems with the current Japanese system that the author came to know through interviews with persons involved in the Japanese academic circles and industry and related seminars.

(1) Uncertainness of the System

(2) Expertness

(3) Transparency

3. Possibility of Introduction of a Full-Fledged Patent Linkage System

Japan is a party to the TPP, but it is questioned whether Japan must introduce a full-fledged patent linkage system.

At the time of TPP negotiations, the entire Japanese industry stood in opposition to the introduction of a patent linkage system. In particular, the generic drug industry was fiercely opposed to the introduction, and there were concerns about the frequent occurrence of litigations like in the United States. There was a worry that the introduction would rather require unnecessary costs and time for litigations than promote the market entry of generic drugs. Furthermore, there were many opinions showing adverse reaction to the introduction of a new system, the result of which is hard to predict, in the situation where Japan had already operated the current Japanese-style patent linkage system and the system had been operated without any big problem.

The patent linkage system was suggested based on the assertion of the United States, but the patent linkage system under the TPP is a very relaxed one unlike the system under the South Korea-U.S. FTA. The industry was persuaded to accept the provision of the patent linkage system for TPP based on the idea that the current Japanese practice would hardly be changed even if the patent linkage system is introduced in Japan under the TPP.

In general, from the perspective of the Japanese industry, it is the prevailing view that it is undesirable to introduce the U.S.-style patent linkage system, the impact on the industry of which cannot be confirmed, because Japan has already been operating its own patent linkage system through there are a few problems, such as lack of transparency.

The aforementioned conclusion was probably drawn due to integration of Japan's unique method of operating the system, national character that does not like adventures and changes, and above all, social atmosphere that does not like litigation.

4. Future Direction

In Japan, the reexamination period can be extended up to 10 years, and it is impossible to file an application for a generic drug during the reexamination period. Therefore, it can be considered that original drugs have already been sufficiently protected. Consequently, oppositions to the necessity of introduction of the U.S.-style patent linkage system are also sufficiently convincing in a certain sense.

From the perspective of original drug manufacturers, they oppose the introduction of the system on the grounds that the U.S. system involves significant costs and that litigations will be blindly filed. From the perspective of generic drug companies, many of them consider that the current system is also sufficient because it is possible to enter the market by invalidating patents through the system of trial for invalidation. At present, the Japanese patent linkage system does not require the settlement of a trial for invalidation, and if a trial decision to the effect that the patent is invalid is rendered, an application for approval of a generic drug is accepted. Although around one year is required before the rendering of a trial decision to the effect that the patent is invalid, a generic drug company can obtain approval of the generic drug with no problem in terms of time by filing a request for a trial for invalidation six months before the end of the reexamination period.

In addition, although Japan has no explicit Bolar provision that is like the one in South Korea, the Supreme Court of Japan has determined that the act of conducting a test for filing an application for approval of a drug by producing and using a chemical substance or drug that falls within the technical scope of a patented invention during the duration of the patent falls under the "working of the patented invention for experimental or research purposes" and does not constitute infringement of the patent. [15] In this manner, it is widely thought that the Bolar provision is not necessary in Japan because there is said Supreme Court decision.

Piercing these together, it was concluded that it is more desirable to alleviate problems with the current Japanese system and restructure the Japanese-style patent linkage system than to introduce the U.S.-style patent linkage system.

However, the largest problem is that the Ministry of Health, Labour and Welfare's patent list, which forms the basis of the patent linkage system, exists in Japan but is not publicly available. Furthermore, another problem is that despite great difficulty in determining the scope of rights of a use patent, the Ministry of Health, Labour and Welfare determines whether a drug falls within the scope of rights and does

[15] Judicial precedent cited above (note 67).

not grant marketing approval if the drug is likely to infringe the patent. Responsible persons at the Ministry of Health, Labour and Welfare are experts in drugs, but are not experts in patents. If, despite that fact, approval of a drug is not granted for a generic drug that is likely to infringe a patent based on the Ministry of Health, Labour and Welfare's determination, it is likely to further delay the market entry of the generic drug. [16]

It is necessary to go through the following two stages in order to market a drug.

Marketing approval of a drug – NHI price listing – Marketing

That is, even after obtaining marketing approval of a drug, it is impossible to sell the drug if the NHI price is not listed. In such sense, generic drug companies can be considered to be double-checked in terms of a generic drug's relationships with a patent. Therefore, the market entry of generic drugs is forced to be even later. It is considered possible to further promote the market entry of generic drugs if marketing approval is granted for an application for marketing approval of a generic drug where the generic drug fulfills requirements necessary for marketing approval, such as efficacy and safety information, and the issue concerning relationships with a patent is evaluated at the time of NHI listing.

V. Conclusion

The South Korean patent linkage system was rather introduced through legislation for performance of the South Korea-U.S. FTA than was voluntarily introduced as needed for the environment of the domestic pharmaceutical industry. However, the South Korean government is continuously making efforts to design the legal system as the South Korean-style patent linkage that suits the environment of its own pharmaceutical industry, and the system is evaluated as having been actively established to a certain extent at the present time after three years have passed since the full-fledged enforcement of the system.

The United States has continuously increased the level of protection of intellectual property rights, but in its own legislation, consideration has been given so that the rights

[16] From the perspective of practitioners, it was also pointed out that "For cases that are likely to cause a dispute, responsible persons at the Ministry of Health, Labour and Welfare tend to draw a conclusion in the direction of not easily granting marketing approval."

of creators of intellectual property rights and the right to access of users who intend to use intellectual property can maintain balance, by considering measures for activating exploitation as well as strengthening of the level of protection. This is also very clear from the purpose and content of the Hatch-Waxman Act, which is the representative provision on drug-related intellectual property rights. On the other hand, if the United States requires a third country to protect intellectual property rights at a high level that is equivalent to the level in the United States in FTA negotiations with the third country and the third country, which differs from the United States in the legal system, increases the level of protection to the same level as the United States, a problem of disharmony between the rights of right holders and the right to access of users can arise. Therefore, it is necessary to develop the legal system so that the right to access of users is guaranteed at the same level as the level of strengthened protection of right holders, and it is also necessary to exercise ingenuity in terms of operation so as to ensure that those rights are also appropriately harmonized in terms of legal interpretation.

Japan has already been enforcing its own patent linkage system. However, it has yet to implement a patent linkage system in a full-fledged sense that includes a notice to a patentee and measures for marketing prevention. Moreover, the United States has drastically changed the patent linkage system through the legal amendment in 2003 in order to alleviate various problems that appeared in the implementation of the system. In the case of introducing the patent linkage system that started in the United States into a country that differs from the United States in law, systems, and industrial environment, it is probably impossible to design a perfect system from the beginning. However, it is necessary to design the system so that the interests of both parties can be balanced by using trials and errors in countries that have already implemented the system as teaching materials by negative example and by keeping in mind that the purpose of the system is to promote the market entry of generic drugs by ensuring that patentees are granted legitimate and sufficient compensation for the development of new drugs and by providing those who have promoted the market entry of generic drugs with incentives therefor. By designing the system in such manner, it is probably possible to make a success of designing of the Japanese-style patent linkage system.

It would be appreciated if this research report is of help to understand each country's patent linkage system and to build the Japanese-style patent linkage system and have it be well-established.