Actual Conditions and Problems of Protection of Patent Rights for Tissue-Engineered Medical Products, etc., In Vitro Diagnostic Medicines, etc. as Provided in Article 2, Item (ii) of the Order for Enforcement of the Patent Act

I. Purpose of This Research

In this research, we study the actual conditions of protection of patent rights for tissue-engineered medical products, etc., in vitro diagnostic medicines, etc. in Japan and abroad, problems in the relationship with the system of registration of extension of duration, possible disposition (approval for manufacturing and sale), etc., to use the results thereof as basic materials for considering measures to solve problems in the relationship with the system of registration of extension of duration for tissue-engineered medical products, etc., in vitro diagnostic medicines, etc., and consider a desirable structure and operation of the system, etc.

II. Contents of This Research

(1) System of registration of extension of duration in Japan

Article 67, paragraph (2) of the Patent Act provides that "Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of an application to register an extension of the duration, by a period not exceeding 5 years."

The extension of duration can be registered for patents for tissue-engineered medical products, etc. and in vitro diagnostic medicines under this provision. On the other hand, patents for medical devices are not subject to the system of registration of extension of duration in Japan (Article 2, item (ii)(b) to (d) of the Order for Enforcement of the Patent Act).

The "period during which the patented invention is unable to be worked" as referred to in Article 67, paragraph (2) of the Patent Act is defined as follows in "Part IX Extension of Patent Term" in the Examination Guidelines for Patent and Utility Model in Japan: "This period begins on the date on which testing necessary for obtaining the disposition designated by Cabinet Order commences or the date on which establishment of the relevant patent is registered: whichever

comes later; and ends on the day before the date on which the approval or registration reaches the applicant, i.e. the date on which the applicant actually learns of the approval or registration or could have learned of it." The "date on which a testing necessary for obtaining the disposition designated by Cabinet Order commences" is defined as the date of commencement of a clinical trial which is indicated by the date of notification of a clinical trial plan, etc. in the case of a medicine.

Where a tissue-engineered medical product, etc. is subjected to an approval with conditions and limited term, the "date on which the approval or registration reaches the applicant" is a date pertaining to the approval with conditions and limited term, and it is not a date pertaining to a subsequent approval after said approval (Article 2, item (ii)(d) of the Order for Enforcement of the Patent Act).

The scope of effect of a patent right for which extension of duration was registered is provided as the working of the patented invention for which extension of duration was registered for the product which was the subject of a disposition (where the specific usage of the product is prescribed by the disposition, the product used for that usage) in Article 68-2 of the Patent Act.

(2) System of approval for manufacturing and sale in Japan

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Pharmaceuticals and Medical Devices Act") provides relevant regulations. In the Pharmaceuticals and Medical Devices Act, the relevant provisions concerning the manufacturing and sale of tissue-engineered medical products, etc. are mainly in Chapter VI (Articles 23-20 to 23-42), and the relevant provisions of manufacturing and sale of in vitro diagnostic medicines and medical devices are mainly in Chapter V (Articles 23-2 to 23-19).

Review for the approval of manufacturing and sale is conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

Article 23-25 of the Pharmaceuticals and Medical Devices Act provides that it is necessary to obtain approval for manufacturing and sale for tissue-engineered medical products, etc. before selling them. As a long period of time is required for clinical trials for tissue-engineered medical products, etc., the two-stage approval system consisting of "approval with conditions and limited term" and "full-scale approval" is adopted, thereby making it possible to place tissue-engineered medical products, etc. on the market at an early date when a certain number of cases are obtained through clinical trials.

Regarding in vitro diagnostic medicines, it is necessary to obtain approval for manufacturing

and sale for Class III products and Class I and II products which do not conform to the standards before selling them. It is not necessary to obtain approval for manufacturing and selling for Class II products which conform to the certification standards before selling them, but it is necessary to obtain a third party certification from a person who has received accreditation from the Minister of Health, Labour and Welfare ("accredited certification body") for each item in the same manner as for Class II medical devices mentioned later.

Regarding medical devices, it is necessary to obtain approval for manufacturing and sale for Class III and IV products and Class II products for which no certification standards have been set. It is not necessary to obtain approval for manufacturing and sale for Class II products for which certification standards have been set, but it is necessary to obtain a third party certification from an accredited certification body for each item.

(3) Results of the domestic questionnaire and interview surveys

(i) Regarding the system of registration of extension of duration

According to the results of the questionnaire survey, many respondents answered, as the matters on which emphasis should be put in relation to the system of registration of extension of duration, that "the system achieves a balance between promoting innovation by original product producers and not inhibiting the market entry of generic products" and that "the system and its operation are easy to understand." Regarding the scope of effect which is extended through registration of extension of duration of a patent right, many respondents answered that it is necessary to "make clear the scope of effect of extended patent rights" and "to ensure that the scope of effect of extended patent rights for innovative inventions are appropriate so that it matches the innovativeness of the inventions" because there were many unclear points in relation to the scope of effect as of the time when this research was started though there were relevant holdings in the obiter dictum in the judgment of the Grand Panel of the Intellectual Property High Court of May 30, 2014 and the judgment of the Tokyo District Court of March 30, 2016 (2015 (Wa) 12414).

(ii) Regarding the registration of extension of duration for tissue-engineered medical products, etc.

Regarding the registration of extension of duration for tissue-engineered medical products, etc., it was revealed that [i] there are still few cases of registration in Japan because only a few tissue-engineered medical products, etc. have been approved, that [ii] for overseas, there is no case of registration in the United States, and there are only a few cases of registration in Europe and South

Korea, and that [iii] there has been no relevant trial and court decision in Japan and abroad.

However, as a long period of time is required for the development of tissue-engineered medical products, etc., the questionnaire and interview survey results indicated the high need for the registration of extension of duration for tissue-engineered medical products, etc. in the same manner as medicines, etc. among companies and universities, etc.

Moreover, when considering the system of extension of duration, it is important to ensure that the system of registration of extension of duration does not inhibit the development of subsequent products, and it is thus necessary to consider subsequent products that can be developed. However, as a result of the questionnaire and interview surveys, companies and universities, etc. expressed the opinion that it is difficult at present to determine equivalence of cells and the subsequent products of tissue-engineered medical products, etc. are therefore very unlikely to be put on the market. Consequently, it is necessary to keep a close eye on the development of tissue-engineering research in the future.

Regarding patents that protect tissue-engineered medical products, etc., in the interview survey, companies and universities, etc. made the comment that the ratio of process patents is on the increase. However, there were also the following opinions: [i] relationship between process patents and tissue-engineered medical products, etc. is difficult to understand; [ii] the scope of effect of extended patent rights is difficult to understand; and [iii] it is difficult for universities, etc. which are licensors to move licensing activities forward.

(iii) Regarding the registration of extension of duration for in vitro diagnostic medicines

Regarding the registration of extension of duration for in vitro diagnostic medicines, it was revealed that there are not many cases of registration of extension because the period necessary for clinical trials and dispositions for in vitro diagnostic medicines is generally short and no adverse effect has arisen due to a period during which a patented invention is unable to be worked. However, regarding companion diagnostic medicines, many respondents expressed the opinion, in the interview survey, that registration of extension is necessary because a period during which a patented invention is unable to be worked is likely to be longer than that for in vitro diagnostic medicines in general because clinical trials for companion diagnostic medicines are conducted in parallel with ordinary medicines.

(iv) Regarding the need for the registration of extension of duration for medical devices

According to the questionnaire and interview survey results, regarding the registration of

extension of duration for medical devices, only a few companies consider the fact that medical devices are not subject to the system of registration of extension of duration to be inconvenient, and there was the also opinion that there is little need for the registration of extension of duration because the period necessary for obtaining approval and the life cycle of medical device products are short. Therefore, the need for making medical devices in general subject to the system of registration of extension of duration is recognized as low in the present circumstances. However, for medical devices in some fields, the period necessary for obtaining approval has become longer, and there is also the opinion that the system of registration of extension of duration is necessary. Therefore, it is necessary to keep a close eye on the progress of development of medical devices and the trend of the period necessary for obtaining approval, etc. in the future.

(4) Regarding the system of registration of extension of duration in other countries

(i) United States

In the United States, extension of duration can be registered for patents for tissue-engineered medical products, etc., in vitro diagnostic medicines, and medical devices (Section 156 of U.S. patent law). However, for in vitro diagnostic medicines and medical devices, only Class III products that are subject to a premarket approval application (PMA) are subject to the registration of extension of duration. Regarding in vitro diagnostic medicines, there are very few patents for which extensions of duration were registered, in the present circumstances.

Section 156(a) of U.S. patent law provides that duration can be extended only for the product which was first approved. In the case of tissue-engineered medical products, etc., extension of duration is unlikely to be available for a product whose "major ingredient" has already been approved even if the product is subsequently approved after the medium, culture solution, and transportation tube are changed.

(ii) Europe

In Europe, extension of duration can be registered for patents for tissue-engineered medical products, etc. However, patents for in vitro diagnostic medicines and medical devices are not subject to approval for manufacturing and sale, and therefore, they are not subject to the registration of extension of duration (Article 63, paragraph 2(b) of the Convention on the Grant of European Patents and Article 1 of the Supplementary Protection Certificate (SPC) Regulation). However, there are cases where extension of duration was granted for products for which clinical

trials of the same level as those for medicines are required at the member state's discretion in Germany, the United Kingdom, the Netherlands, France, Italy, etc.

In the case of tissue-engineered medical products, etc., there is little chance of extension of duration being granted in the case where the only difference between a prior product and a subsequent product is a difference in the carrier, such as medium and culture solution, and said subsequent product is designated for the same usage as that of the prior product.

(iii) South Korea

In South Korea, extension of duration can be registered for patents for tissue-engineered medical products, etc. However, patents for in vitro diagnostic medicines and medical devices are not subject to the registration of extension of duration (Article 89 of the South Korean Patent Act and Article 7 of the South Korean Enforcement Decree of the Patent Act) because they are not subject to the regulation under the Pharmaceutical Affairs Act but are subject to the regulation under the Medical Devices Act.

Article 7, paragraph (1) of the South Korean Enforcement Decree of the Patent Act provides that being a new medicine is a condition for being subject to the registration of extension of duration. In the case where a component cell or transgene, which is the major ingredient, is the same, only the structures other than the major ingredient, such as the medium, culture solution, and transportation tube, are changed, and permission is obtained for the major ingredient, the relevant patent cannot be subject to the registration of extension of duration in the same manner as the cases of general medicines even if another permission is subsequently obtained.

(5) Results of discussions at the committee

The committee held discussions on a desirable structure of the system of extension of duration of a patent right, including a desirable structure of the system of registration of extension for tissue-engineered medical products, etc. and in vitro diagnostic medicines, etc.

Various opinions were expressed due to differences in the positions of individual committee members. However, all the committee members, including original product producers and generic producers, agreed that the matters on which emphasis should be placed in relation to the system of extension of duration of a patent right are that [i] the system of extension of duration of a patent right should be one that achieves a balance between promoting innovation by original product producers and not inhibiting the market entry of generic products" and that [ii] the system and its operation should be easy to understand. The committee members, including original product

producers and generic producers, achieved the consensus that a desirable structure of the system of extension of duration of a patent right should be considered based on such recognition.

Moreover, both original product producers and generic producers expressed concerns about the fact that the system of extension of duration of a patent right has become more complex as a result of multiple Supreme Court judgments concerning the requirements for filing an application to register an extension of duration and revisions to the JPO Examination Guidelines associated with those judgments.

(6) Opinions concerning the judgment of the Grand Panel of the Intellectual Property High Court

On January 20, 2017, the appeal court judgment for the aforementioned Tokyo District Court judgment was rendered as the judgment of the Grand Panel of the Intellectual Property High Court in relation to the effect of a patent right for which extension of duration was registered. Therefore, we heard the opinions of the committee members again.

The committee members presented the opinion that they appreciate said judgment in that the court ruled that a patent right whose duration was extended is effective not only against products that are identical with the product subject to a disposition but also against products that are substantially identical with the product subject to a disposition as a medicine and indicated standards for determination of the scope of substantial identity and specific types. In addition, the committee members expressed the opinion that they expect the same idea to be adopted for tissue-engineered medical products, etc.

On the other hand, the committee members expressed the opinions that said judgment differs from the interpretation that has been adopted since the establishment of the system of registration of extension of duration, that interpretation of "substantial identity" in specific cases remains unclear, and that an accumulation of judgments in the future is awaited for the clarification of interpretation of "substantial identity."

III. Summary

This research made clear that the system of registration of extension of duration of a patent right needs to be one that fits with the times, taking into account changes in the research and development environment and emergence of patents in the forms that were not assumed at the time of establishment of the system of extension of duration of a patent right, such as tissue engineering and drug delivery system (DDS), after 30 years have passed since the establishment of the system.

Therefore, we hope that further discussions will be held on the current system of registration of

extension of duration of a patent right that includes matters such as tissue-engineered medical products, etc. and in vitro diagnostic medicines as its subject of protection, in relation to matters such as "patent rights subject to extension," "dispositions subject to extension," the "number of patents whose duration can be extended by one disposition," the "number of times of extension for one patent," and the "effect of extended patent rights," as needed, in light of the coming trends of judicial rulings while listening to the needs of both original product producers and generic producers, in order to make the system one that achieves a balance in its influence on the development of original and generic products.