Summary of IP High Court Grand Panel Decision on Scope of Patent Right with Registered Patent Term Extension

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ABSTRACT

The Intellectual Property High Court (IP High Court) handed down a decision on January 20, 2017, in the 11th Grand Panel case in total, i.e., Appeal Case No. 2016 (ne) 10046, in which injunction against patent infringement was sought. The issue of contention was how to determine the effective scope of a patent right the term of which was extended via patent term extension (PTE) registration based on marketing approval of a pharmaceutical product (administrative deposition). In the decision, the IP High Court ruled that the effective scope of a patent right extended via PTE registration shall not be limited to a product identical to the subject of the deposition on which the PTE registration of the patent is based, but shall extend to a product which is substantially identical to the subject of the deposition. The court also ruled that if there is a difference from the subject of the deposition, the allegedly infringing product shall be deemed to be substantially identical to the deposition subject and thereby fall within the effective scope of the patent right extended via PTE registration, provided that the difference is deemed merely a minor difference or a formal difference as a whole.

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1. PTE System in Japan:

The Patent Term Extension (hereinafter “PTE”) system prescribed in Japan Patent Law is intended to address a situation where there is a period during which a patented invention cannot be worked due to it being necessary to obtain an administrative disposition designated by Cabinet Order. In other words, the PTE system provides compensation for a period lost in order to obtain a disposition by allowing the duration of the patent right (or “patent term”) to be extended for up to five years (Article 67, paragraph 2 of the Patent Law).

The dispositions designated by Cabinet Order prescribed in Article 67, paragraph 2 of the Patent Law[1] include:
(i) registration of agrochemicals under the Agricultural Chemicals Regulation Act; and
(ii) marketing approval and registration of pharmaceuticals, *in-vitro* diagnostics, and regenerative medical products (also referred to as "*pharmaceutical drugs, etc.*" or simply as "*drugs*") under the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (also referred to simply as "*the Pharmaceutical and Medical Device Act*")[2].
Accordingly, PTE registration is allowed in Japan only for patents granted for inventions relating to pharmaceutical drugs or agrochemicals (the following parts of this article focus on pharmaceutical drugs, although they also apply to agrochemicals).

One characteristic of the PTE system in Japan is that patents the terms of which can be extended by PTE registration are not limited to those claiming an active ingredient, but include other related patents such as those claiming a pharmaceutical/agrochemical composition containing such an active ingredient and those claiming a process for producing such an active ingredient. Another characteristic is that the terms of two or more patent rights can be extended by PTE based on a single administrative disposition, and the term of a single patent right can be extended two or more times by PTE registrations based on two or more administrative dispositions. In other words, it is not necessary to choose one of two or more relevant administrative dispositions as a basis for PTE registration or to choose one of two or more relevant patent rights as a subject of PTE registration.

In order to obtain a PTE registration, the patentee has to file an application for which he seeks PTE registration (hereinafter, a PTE application) at the JPO within a designated period of time, together with evidence proving that there was a period during which the patented invention could not be worked due to it being necessary to obtain an administrative disposition (Article 67bis (67-2) of the Patent Law). The JPO Examiner then examines the PCT application and, if any of the registration requirements is not satisfied, issues a reason for rejection (Article 67ter (67-3), paragraph 1 of the Patent Law). Otherwise, the PTE is granted and registered by the JPO (Article 67ter, paragraphs 2 & 3 of the Patent Law), resulting in extension of the term of the patent right.

2. Background:

Two major issues of contention have arisen in relation to the PTE system based on administrative depositions (e.g., marketing approvals of pharmaceutical products): one relates to the JPO's examination guidelines for PTE applications (Article 67ter (67-3), paragraph 1, item 1 of the Patent Law); while the other relates to the effective scope of a patent right extended via PTE registration (Article 68bis (68-2) of the Patent Law).

[1] The dispositions subject to this article are specifically prescribed in Article 2 of the Order for Enforcement of the Patent Law.
[2] Renamed from the previous Pharmaceutical Affairs Law on November 14, 2014.

The issue relating to the examination criteria for PTE applications centered on how to interpret Article 67[ter] (67-3), paragraph 1, item 1 of the Patent Law, which prescribes that a PTE application shall be rejected when "*it is not deemed that obtaining a disposition designated by Cabinet Order recited in Article 67, paragraph 2 of the Patent Law was necessary for working the patented invention*". This issue was recently settled via a series of rulings rendered by the Grand Panel of the IP High Court[3] and accepted by the Supreme Court[4], which led to the JPO revising its examination guidelines on April 1, 2016,[5] in order to clarify how this article should be interpreted.

The issue relating to the effective scope of a patent right extended via PTE registration lies in how to interpret Article 68[bis] (68-2) of the Patent Law, which prescribes that a patent right the term of which is extended via PTE registration "*shall not be effective against any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order recited in Article 67, paragraph 2 of the Patent Law that constituted the reason for the PTE registration (when the specific usage of the product is prescribed in the disposition, the product used specifically for that usage)*". Specifically, there has been controversy over how the terms "*product*" and "*usage*" in this article should be interpreted. However, there are as yet no definitive criteria or court rulings issued as to the interpretation of this article.

Against this backdrop, the Grand Panel of the IP High Court rendered a side opinion as to the effective scope of a patent right extended via PTE registration, in its decisions mentioned above[6]. In this side opinion, the IP High Court ruled that "*in light of the purpose of the PTE registration system and that of a patent infringement action, it is reasonable to understand that in the case of a patented invention relating to an ingredient of a medicine, a patent right whose duration was extended pursuant to Article 68[bis] (68-2) of the Patent Law shall be effective within the scope of working of the patented invention identified by 'ingredients (not limited to API)' as the 'product' and by 'effectiveness/efficacy' and 'dosage/regimen' as the 'usage'.*" This ruling, if interpreted strictly, could mean that the scope of a patent right extended via PTE registration would not be effective against an allegedly infringing medicinal product which is identical to the subject medicine of the deposition in active pharmaceutical ingredient (API), efficacy/effect, and

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[3] The decisions handed down by the grand panel of the IP High Court on May 30, 2014, (Cases Nos. 2013 (Gyo-Ke) 10195, etc.; suits rescinding trial decisions made by the JPO)

[4] The decisions handed down by the third petty bench of the Supreme Court of Japan on November 17, 2015 (Cases Nos. 2014 (Gyo-Hi) 356, etc.; appeal cases against the IP High Court decisions mentioned in footnote 2 above).

[5] The Examination Guidelines for Patent and Utility Model in Japan (last revised on April 1, 2016), "IX: Extension of Patent Term", Section 3.1.1, which prescribes that the Examiner shall deem that a disposition designated by Cabinet Order recited in Article 67, paragraph 2 of the Patent Law has been necessary to obtain for working of the patented invention and issue a reason for rejection under Article 67[ter] (67-3), paragraph 1, item 1 of the Patent Law either:

(i) when an act of manufacturing and distribution of drug products or an act of manufacturing and import of agricultural chemicals subject to the present disposition does not fall under an act of working of the patented invention pertaining to an application for registration of extension; or

(ii) in case an act of manufacturing and distribution of drug products or an act of manufacturing and import of agricultural chemicals subject to both the present disposition and the prior disposition falls under an act of working of the patented invention pertaining to an application for registration of extension, when manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the prior disposition include those subject to the present disposition.

[6] See footnote 2 above.

dosage/regimen, but differs slightly from the subject of the deposition only in an ingredient other than the API (such as an excipient). Thus, this ruling could render the effective scope of an extended patent right unduly restrictive. As a result, many pharmaceutical companies, mainly innovators, have expressed strong concern regarding such restrictive claim construction.

3. Original Decision:

The IP High Court's Grand Panel decision on January 20, 2017 for Case No. 2016 (ne) 10046 (hereinafter "the present case") relates to an appeal against the decision by the Tokyo District Court on a patent infringement suit. In the first instance, the Plaintiff, who has a patent right for an invention relating to "*oxaliplatin solution and a production process and uses thereof*" (Japan Patent No. 3547755B)[7], argued that the Defendant's acts of manufacturing and marketing pharmaceutical formulations constituted infringement of the Plaintiff's patent, and sought an injunction against further production and sales of the Defendant's infringing products, and disposal thereof. One of the main issues of contention was whether the scope of the Plaintiff's patent right, the term of which had been extended via PTE registration, effectively covered the Defendant's products.

The Tokyo District Court rendered a decision on March 30, 2016,[8] in which it addressed the above concern resulting from the IP High Court's side opinion regarding the effective scope of an extended patent right. Specifically, the Tokyo District Court ruled that it is reasonable to consider that the scope of a patent right extended via PTE registration shall not be limited to a product which is identical to the product which was the subject of the deposition (or, when the specific usage of the product is prescribed in the disposition, the product used specifically for that usage) on which the PTE registration is based, but shall extend to a product which is deemed to be equivalent, or substantially identical, to the subject product of the deposition (used for the purpose prescribed in the deposition). The court also ruled that whether an allegedly infringing product is equivalent, or substantially identical, to the subject product of the deposition (used for the purpose prescribed in the deposition) shall be evaluated in light of the subject matter and technical features of the patented invention, taking into consideration when the alleged infringer began preparation for marketing, etc., of the allegedly infringing product. The court further ruled that when there is a difference between the allegedly infringing product and the subject product of the deposition (used for the purpose prescribed in the deposition), it is deemed that the allegedly infringing product shall still be equivalent, or substantially identical, to the subject product of the deposition (used for the purpose prescribed in the deposition), provided that the difference corresponds to, e.g., mere

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[7] JP3547755B was granted for JP Application No. H08-507159, which was the Japanese entry of PCT/IB1995/000614 (WO1996/004904A). Claim 1 of JP3547755B reads as follows:
"*A pharmaceutically stable formulation of oxaliplatinum for parenteral administration, consisting of aqueous solution of oxaliplatinum at a concentration of 1 to 5 mg/ml with a pH value of 4.5 to 6, wherein after storage for a pharmaceutically acceptable period, the formulation retains at least 95 % of the initial content of oxaliplatinum, and the aqueous solution remains clear and colorless and yields no precipitate.*"

[8] The decision handed down by the Tokyo District Court on March 30, 2016 (Case No. 2015 (H27) (wa) 12414; suit seeking injunction against patent infringement).

addition, deletion, or substitution of a well-known or commonly-used art, and exhibits no novel effects. Based on these rulings, the court judged that in this case, all of the ingredients of the pharmaceutical product should be considered when defining the scope of the Plaintiff's patent right extended via PTE registration, since the Plaintiff's invention is not characterized by a novel feature of an API, but by a novel formulation containing a known API. The court also judged that each of the Defendant's products differs considerably in ingredients other than API from the Plaintiff's product which was the subject of the deposition on which t the PTE registration of the Plaintiff's patent right is based, and therefore cannot be deemed to be equivalent or substantially identical to the Plaintiff's product used specifically for the purpose prescribed in the deposition. On these grounds, the court found that there was no act of infringement.

However, many considered that the criteria used by the Tokyo District Court for determining the scope of a patent right extended via PTE registration were still unclear, and should be replaced with much clearer criteria.

This case was appealed to the IP High Court, which decided that it should be judged by its Grand Panel[9]. This was presumably because the IP High Court intended to clarify the criteria used by the Tokyo District Court for determining the scope of a patent right extended via PTE registration, and to thereby allay concerns that the scope of an extended patent right may be interpreted very narrowly, as elicited by the opinion in its previous decisions mentioned above.

4. Present Grand Panel Decision:

The main rulings rendered by the Grand Panel of the IP High Court in the present decision are summarized as follows:

A. The scope of a patent right the term of which was extended via patent term extension (PTE) registration shall not be limited to a product identical to the "product" defined by the "*ingredient, amount, regimen, dosage, efficacy and effect*" prescribed by the administrative deposition on which the PTE registration is based (the subject of the deposition), but shall extend to a product which is substantially identical to the subject of the deposition as a pharmaceutical product.

B. Where there is a difference in any of the elements prescribed in the deposition between the subject of the deposition and an allegedly infringing product, if the difference is merely a minor difference or a formal difference as a whole, then the allegedly infringing product is deemed to be substantially identical to the subject of the deposition as a pharmaceutical product, and thus included in the effective scope of the patent right extended via PTE registration.

[9] The "Grand Panel" of the IP High Court is a special bench consisting of five judges, while normal cases are judged by a bench consisting of three judges.

C. Assuming that the invention protected by a patent right extended via PTE registration is directed to a product characterized by pharmaceutical ingredients, and that an allegedly infringing product is different from the subject of the deposition on which the PTE registration is based only in one or more of the "*ingredients*", "*amounts*", and "*regimen/dosage*" prescribed in the deposition, whether the difference corresponds to a minor difference or a formal difference as a whole shall be determined based on the contents of the patented invention (e.g., whether the patented invention is an invention characterized solely by an API of a pharmaceutical product, whether it is an invention relating to the stability or formulation, etc., of a pharmaceutical product with a known API, or what the technical features and effects of the patented invention are), by comparing the technical features and effects between the subject of the deposition and the allegedly infringing product, and taking technical common knowledge in the art into consideration.

D. In the limited conditions mentioned in item C above, for a case of any one of examples (i) to (iv) below, it is deemed that the difference between the allegedly infringing product and the subject of the deposition corresponds to a minor difference or a formal difference as a whole, and that the allegedly infringing product is substantially identical to the subject of the deposition as a pharmaceutical product.

(i) The extended patent right relates to an invention characterized solely by an API of a pharmaceutical product, while the allegedly infringing product differs from the subject of the deposition only in one or more "*ingredients*" other than the API, but the difference corresponds to , e.g., addition or substitution of one or more "*ingredients*" other than the API based on well-known or commonly-used art at the time a request for the deposition was filed.

(ii) The extended patent right relates to an invention characterized by the stability or formulation of a pharmaceutical product with a known API, while the allegedly infringing product differs from the subject of the deposition in one or more "*ingredients*", but the difference corresponds to, e.g., addition or substitution of one or more "*ingredients*" based on the well-known or commonly-used art at the time the request for the deposition was filed, and the allegedly infringing product and the subject of the deposition share the same technical features and effects, in view of the contents of the patented invention.

(iii) The allegedly infringing product differs from the subject of the deposition in the "*amount*" and/or the "*regimen/dosage*" prescribed the deposition, but the difference corresponds to a mere marginal difference which is quantitatively meaningless.

(iv) The allegedly infringing product differs from the subject of the deposition in the "*amount*" prescribed the deposition, but they are deemed to be substantially identical if the "*regimen/dosage*" prescribed the deposition is taken into consideration.

E. When defining the scope of substantial identity for the extended patent right prescribed in Article 68[bis] (68-2) of the Patent Law, it is not appropriate to employ the requirements of the doctrine of equivalents established by the Supreme Court in the so-called Ball Spline Bearing case[10], except for the fifth requirement, which relates to prosecution history estoppel. Specifically, if there are any exceptional circumstances, e.g., where the allegedly infringing product corresponds to an embodiment excluded from the scope of the patent right by the patentee in the examination of an application for PTE registration, then the allegedly infringing product shall not correspond to an invention substantially identical to the subject of the disposition.

F. The Plaintiff argued that since the marketing approval of a generic drug relies on the clinical data prepared for obtaining marketing approval of the original drug within a period during which the patented invention could not be worked, a generic drug product should naturally correspond to an invention substantially identical to the subject of the disposition. This argument cannot be accepted, since it ignores the gist and interpretation of Article 68[bis] (68-2) of the Patent Law. While it is true that approval of a generic drug relies on the original drug in respect of the quality as a pharmaceutical product, this merely means that the API and the therapeutic effect (including effectiveness and stability) are identical in principle, and has no relation to whether the approval of the generic drug also relies on the original drug from the viewpoint of the patented invention. At the very least, it can be said that Article 68-bis of the Patent Law is not intended to expand the scope of an extended patent right over a generic drug simply because it is a generic drug, i.e., simply because it relies on the original drug as having the same quality.

Based on these rulings, the IP High Court judged the present case as follows. The court first judged that in view of the specification and technical common knowledge, that the "*pharmaceutically stable formulation of oxaliplatinum*", which is the subject of each of the depositions, should be interpreted as meaning a composition which consists of oxaliplatin and water for an injectable

[10] The decision handed down by the third petty bench decision of the Supreme Court on February 24, 1998, which ruled that if there is a different part between the claimed invention and the allegedly infringing product, equivalent infringement shall exist provided that:
1) the different part is not an essential part of the patented invention;
2) the purpose of the patented invention can be achieved if this part is replaced with the part in the allegedly infringing product and also the same function and effect can be obtained;
3) the above replacement was easily conceivable for a person skilled in the art at the time of manufacturing the allegedly infringing product;
4) the allegedly infringing product was not identical to a product in the public domain or not easily conceivable for a person skilled in the art, at the time of filing of the patented invention; and
5) there were no special circumstances such as a case where the allegedly infringing product had been intentionally excluded from the scope of claim in the process of prosecution of the patent.

preparation and does not contain any other ingredient. The court then judged that each of the products of the Defendant of the original instance (Appellee) differs from the subject of the deposition in its "*ingredients*", since it contains, in addition to oxaliplatin and water for an injectable preparation, concentrated glycerin as a stabilizer, in the same amount as oxaliplatin. The court further judged that presence of concentrated glycerin cannot correspond to a minor difference or a formal difference as a whole, since it is one of the technical features of the present invention that the composition of the present invention consists of oxaliplatin and water for an injectable preparation and does not contain any other ingredient. Based on these judgments, the court concluded that each of the products of the Defendant of the original instance (Appellee) does not correspond to a substantially identical product as defined in Article 68bis (68-2) of the Patent Law, and is therefore not included in the effective scope of the present patent right, thereby denying infringement.

5. Summation:

The IP High Court ruled that the scope of an extended patent right can cover a product substantially identical to the subject of the deposition (ruling A above), and that if the difference is merely "*a minor difference or a formal difference as a whole*", an allegedly infringing product is included within the scope of a substantially identical product as the subject of the deposition (ruling B above). Thus, the IP High Court ruled that the effective scope of a patent right should not be limited to the deposition subject, but should cover products substantially identical to the deposition subject. We believe that these rulings are reasonable, since they address the concerns arising from the IP High Court's side opinion in its previous Grand Panel decisions.

On the other hand, the IP High Court established the criteria for judging "*a minor difference or a formal difference as a whole*" (ruling C above), and also indicated four examples (i) to (iv) satisfying the criteria (ruling D above). However, these rulings are so abstract that it is still not clear as to how they may be applied to actual cases. Specifically, these rulings do not explicitly address as to how to deal with various issues concerning "*efficacy/effect*", such as cases where the patented invention relates to a novel "*efficacy/effect*" of a known API, or cases where the subject of the deposition differs from the allegedly infringing product only slightly in the "*efficacy/effect*"[11]. Consequently, it is difficult to predict how these problematic issues will be judged in light of the IP High Court's rulings.

The IP High Court further ruled that the five requirements of the doctrine of equivalents should not be applied, except for the fifth requirement (prosecution history estoppel) (ruling E above), and

[11] In this regard, taking into consideration the original decision by the Tokyo District Court, the "*invention characterized solely by an API of a pharmaceutical product*" recited in ruling D, example (i) of the present decision can be interpreted as including not only an invention relating to a novel compound/substance for use as an API, but also an invention relating to usage of a known compound/substance as API for a novel "*efficacy/effect*". However, it is not clear as to whether such an interpretation is actually correct. In addition, even if this understanding is correct, it is still difficult to understand as to how specific cases involving issues concerning "*efficacy/effect*" should be treated in light of the present decision.

that a generic drug should not be considered substantially identical to the subject of the deposition only because of the fact that it is a generic drug (ruling F above). While these rulings also appear to be reasonable in principle, they rulings are likely to be used for restricting the scope of an extended patent right rather than to broaden it, and therefore may possibly be disadvantageous to the patentee.

In addition, the specific case which is the subject of the present decision appears to be a somewhat exceptional case since, judging from the description of the specification and the prosecution history, we believe it is natural to interpret the scope of the claimed invention as being limited to a formulation which consists only of oxaliplatin and water for an injectable preparation, and contains no other ingredients (such as concentrated glycerin, which is contained in the Defendant's products). In this respect, this case appears to lacks sufficient universality to be judged by the Grand Panel of the IP High Court, whose primary objective is to render normative rulings on controversial IP issues. Of course, the court's judgment on the specific case subject to the present decision should be considered independently of the general rulings in the present decision. Nevertheless, the fact that the specific case was judged based on very limitative interpretation of the scope of the extended patent right may have a negative impact on the district courts' future decisions.

Overall, we believe that the present decision may ameliorate, but not completely resolve, the concern resulting from the IP High Court's previous opinion, i.e., that the scope of an extended patent right may be interpreted too narrowly.

In any event, we should monitor the results of future infringement litigation cases based on extended patent rights.

END

Appendix: Relevant Provisions in The Japan Patent Law

(Excerpts from "JAPANESE LAWS RELATING TO INDUSTRIAL PROPERTY", Published by AIPPI JAPAN, 2015)

Article 67 (Term of patent right)

(1) The term of the patent right shall be 20 years from the filing date of the patent application.

(2) The term of the patent right may be extended, upon application for registration of an extension, by a period not exceeding five years if, because of the necessity of obtaining an approval or other disposition which is governed by provisions in laws intended to ensure safety, etc. in the working of the patented invention, and which is provided for in Cabinet Order as be ng such that, in view of the object of the relevant disposition, proceedings, etc., a considerable period of time is required for the proper action for the disposition, there was a period in which it was not possible to work the patented invention.

Article 67bis (67-2) (Registration of extension of term of patent right)

(1) A person desiring to apply for registration of an extension of the term of a patent right shall submit to the Commissioner of the Patent Office an. application stating the following matters:

(i) the name and the domicile or residence of the applicant;

(ii) the patent number;

(iii) the term of the extension applied for (limited to a period not exceeding five years);

(iv) particulars of the disposition as provided for in Cabinet Order referred to in Article 67(2).

(2) The application under the preceding paragraph shall be accompanied by materials which give reasons for the extension, as provided for in an ordinance of the Ministry of Economy, Trade and Industry.

(3) The application for registration of an extension of the term of a patent right shall be made within the time limit prescribed by Cabinet Order counting from the date of obtaining the disposition provided for in Cabinet Order referred to in Article 67(2). However, the application shall not be made after the expiration of the term of a patent right provided for in Article 67(1).

(4) Where a patent is owned jointly, each of the joint owners may not, except jointly with the other owners, apply for registration of an extension of the term of a patent right.

(5) Where an application for registration of an extension of the term of a patent right is filed, the term of the patent right shall be deemed to have been extended. However, this provision shall not apply when the examiner's decision that the application is to be refused has become final and conclusive or when an extension of the term of the patent right has been registered.

(6) When an application for registration of an extension of the term of a patent right is filed, the matters as set forth under each of the items in paragraph (1) and the number and the filing date of the application shall be published in the Patent Gazette.

Article 67$^{bis\text{-}bis}$ (67-2-2)

(1) When it is anticipated impossible to obtain the disposition as pro- vided for in Cabinet Order referred to in Article 67(2) by the day before six months prior to the date of expiration of the term

of a patent right as provided for in Article 67(1), a person desiring to apply for registration of an extension of the term of a patent right shall submit by that day to the Commissioner of the Patent Office a document stating the following matters:
(i) the name and the domicile or residence of the person desiring the application;
(ii) the patent number;
(iii) the disposition as provided for in Cabinet Order referred to in Article 67(2).
(2) Where the document required to be submitted under the preceding paragraph is not submitted, application for the registration of an extension of the term of a patent right may not be made for after six months prior to the date of expiration of the term of a patent right as provided for in Article 67(1).
(3) When the document referred to in paragraph (1) is submitted, the matters set forth under each of the items in paragraph (1) shall be published in the Patent Gazette.
(4) Where, due to reasons outside his control, a person is unable to submit the document under paragraph (1) in accordance with said paragraph by the day prescribed by said paragraph, he may, notwithstanding said paragraph, submit said document to the Commissioner of the Patent Office within 14 days (where he is a resident abroad, within one month) from the date when the reasons ceased to be applicable but not later than two months.

Article 67ter (67-3)
(1) The examiner shall make a decision that an application for registration of an extension of a patent right is to be refused where it falls under any of the following items:
(i) where it is not deemed that the obtaining of the disposition as provided for in Cabinet Order referred to in Article 67(2) was necessary for the working of the patented invention;
(ii) where the disposition as provided for in Cabinet Order referred to in Article 67(2) was not obtained by the patentee, or a person who has an exclusive license or a non-exclusive license on the patent right;
(iii) where the term for which an extension is applied exceeds the period of time during which the patented invention could not be worked;
(iv) where the person applying for an extension is not the patentee concerned;
(v) where the application does not comply with Article 67bis(67-2)(4).
(2) When the examiner finds no reasons for refusing an application for registration of an extension of the term of a patent right, he shall render a decision that the registration of the extension is to be made.
(3) When the examiner's decision or the trial decision is rendered to the effect that the registration of an extension of the term of the patent right is to be made, the registration is made to the effect that the term of the patent right has been extended.
(4) When the registration under the preceding item is made, the following particulars shall be published in the Patent Gazette:
(i) the name and the domicile or residence of the patentee;
(ii) the patent number;
(iii) the number and the filing date of the application for registration of the extension of the patent right;

(iv) the date of the registration of the extension;
(v) the term of the extension;
(vi) particulars of the disposition as provided for in Cabinet Order referred to in Article 67(2).

Article 67^{quater} (67-4)
Articles 47(1), 48, 50 and 52 shall apply mutatis mutandis to the examination of an application for registration of an extension of the term of a patent right.

Article 68 (Effects of patent right)
A patentee shall have an exclusive right to work the patented invention in the course of business. However, where the patent right is the subject of an exclusive license, this provision shall not apply to the extent that the exclusive licensee exclusively possesses the right to work the patented invention.

Article 68bis (Effects of the term extended patent right)
The effects of the patent right of which the term has been extended (including cases in which the term is deemed to be extended under Article 67bis (67-2) (5)) shall not extend to acts other than the working of the patented invention concerned in respect of the product (where, in the disposition concerned, any specific use of such product to be used was specified, the product used for such specific use) which was the subject of the disposition as provided for in Cabinet Order referred to in Article 67(2) and as being the ground for the registration of the extension.

END