This article was published in the Markgraf Ergänzende Schutzzertifikate - Patent Term Extensions on 2015.

Patent Term Extensions in Taiwan

Ruth Fang, Lee and Li Attorneys at Law

I. Introduction

The patent term extension practice was introduced into the ROC (Taiwan) patent system through Patent Act Amendments that took effect on 23 January 1994, which stipulated the requirements for patent term extension, procedures for examination of such applications, and grounds for cancellation against granted extensions. Of the subsequent Patent Act Amendments, only the 2011 Amendments involve the patent term extension practice.

Pursuant to the initial practice, a term extension can be sought for a pharmaceutical-related or an agrochemical-related patent under the condition that the first market approval for practicing said patent is not secured until two years after patent publication ("two-year limitation"). The two-year limitation was lifted as a result of the 2011 Patent Act Amendments, which came into force on 1 January 2013. As of said effective date, a term extension can be sought if the first market approval for practicing a pharmaceutical-related or an agrochemical-related patent is secured after patent publication. This new practice retroactively applies to patent term extension applications pending on the above effective date.

To implement the patent term extension practice, the Intellectual Property Office (IPO), the competent authority on examination and cancellation of patent term extension, jointly promulgated and announced the Regulations Governing Patent Term Extensions (the "Regulations") on 1 January 1997 with the cabinet-level regulatory authorities on pharmaceuticals and agrochemicals, the Department of Health (DOH) and the Council of Agriculture (COA), respectively. The Regulations were amended on 6 October 1999 due to government restructuring involving the competent authority on agrochemicals, and on 3 March 2004 for consistency of article numbers cited therein with those of the Patent Act amended in 2003, and clarification of the term "patent publication" as "patent grant publication." The third amendments, made on 28 December 2012 and effective from 1 January 2013, introduced changes to the substance of the practice.

To guide the examination and cancellation of patent term extension cases, the IPO announced Examination Guidelines on Patent Term Extension ("Guidelines") on 14 December 2004, which were revised first on 15 April 2009 and subsequently on 19 February 2013. The latest revision retroactively entered into force on 1 January 2013.

II. Formal Requirements

1. Critical Filing Date

Patent term extensions are available only for patent cases filed on or after 23 January 1994, the day on which the patent term extension practice first took effect.

2. Applicable Patents

Patent term extensions are available only for published invention patents relating to pharmaceuticals or agrochemicals which are in force, including product patents, manufacturing process patents and use patents. Patent term extensions cannot be sought if no patent is granted before the first market approval is secured.

Term extensions are not available for patents granted for utility models and designs, or those for non-pharmaceutical or non-agrochemical inventions. Veterinary medicines,

medical devices, cosmetics, health foods, intermediates, catalysts, machines or apparatuses for manufacturing pharmaceuticals, and chemicals and their uses other than those as pharmaceuticals or agrochemicals are all excluded. Even compounds that are contained in pharmaceuticals or agrochemicals but do not work as the active substances are ineligible for patent term extension.

3. Entitled Applicants

A patent term extension application must be filed by the patent owner, or the exclusive licensee that has recorded the relevant licensing arrangement with the IPO. If the patent is jointly owned by two or more co-owners, each co-owner can independently file such application unless the contract between the co-owners has appointed a representative.

4. Deadlines for Applying for Patent Term Extension

An application for patent term extension must be filed within three months from the "date on which the first market approval is obtained."

In practice, there will be lag between the date on which a market approval is issued by the competent regulatory authorities and the date on which the approval is actually collected by the market approval applicant. The "date on which the first market approval is obtained" refers to the latter date. Where the patent term extension applicant cannot prove the actual date of collection, the issue date shown on the market approval will be deemed the "date on which the first market approval is obtained."

In the case of an addition of indication (for pharmaceuticals) or expansion of scope of use (for agrochemicals) endorsed for an existing market approval, the "date on which the first market approval is obtained" refers to the date on which the newly endorsed approval is actually collected.

Separately, patents whose patent life will expire within six months are ineligible for patent term extension.

5. First Market Approval Requirement

A pharmaceutical-related or agrochemical-related patent is eligible for a term extension only under the following conditions:

(i) A market approval for practicing the patent is required under the Law Governing Pharmaceutical Affairs, Article 39, or the Act of Management of Pesticides, Article 9; and

(ii) The patentee or the licensee thereof secures the first market approval after the publication of the patent.

III. Substantive Requirements

1. Determination of First Market Approval

Whether a market approval is the "first market approval" is determined on the basis of both the active ingredient(s) and use identified in the market approval. The "active ingredient" refers to the substance in the formula of the pertinent pharmaceutical or agrochemical that exerts the intended pharmaceutical or agrochemical effect. The "use identified in the market approval" refers to the contents recited in the "INDICATION" section of an approval for pharmaceutical, or the "METHOD OF USE AND SCOPE" section of an approval for agrochemical.

Under DOH practice, new drugs may be classified into (i) new chemical entity, (ii) new

administration route, (iii) new combination use (of two or more active ingredients), (vi) new dosage form, (v) new dosage amount and unity amount, (vi) new formulation, and (vii) new indication. Only the market approval under category (i), (iii) or (vii) will qualify as the first market approval.

Approvals for different uses of the same chemical entity can all serve as a first market approval. In this connection, a salt or enantiomer of a compound is considered the same chemical entity as the compound. Therefore, where a compound was previously approved for a certain use, a subsequent approval for the salt or enantiomer thereof for the same use will not qualify as a "first market approval." However, a prodrug is not considered the same chemical entity. Accordingly, a previously approved market approval of a compound does not disqualify the market approval for a prodrug (such as an ester) of said compound as the first market approval even if both approvals are for the same use.

On the other hand, if a chemical entity previously approved for a certain use (e.g., treating Kaposi's Sarcoma) is subsequently approved for a new indication B (e.g., for treating active chronic hepatitis), such approval is the first approval of the new use of said chemical entity. If the new indication is granted to the same approval holder, instead of issuing a separate market approval, the DOH will endorse the new indication on the existing market approval for said chemical entity. Such endorsement is deemed the first market approval for the new use of said chemical entity. Nevertheless, an endorsement for changing the name of a disease or disorder for consistency with that adopted by the DOH is not recognized as a first market approval. Similarly, where a new indication is correlated with the previously approved indication, a relevant endorsement is not recognized as a first market approval, either.

New agrochemical may be classified into (i) new chemical entity, (ii) new combination, (iii) new dosage form, and (iv) expansion of scope of use (addition of applicable crops or target pests). A market approval for an agrochemical issued under category (i) or (ii) will qualify as the first market approval. Whether an approval under category (iv) qualifies as the first market approval depends on the mode of action of the previously granted use and the added use. If the mode of action is the same (e.g., both act as pesticides), the grant for the added use does not qualify as market approval.

2. One-Patent-One-Extension Requirement

Patent term extensions are only available for patents which have not been granted a term extension. Once a term extension is allowed, the same patent is not eligible for application for another term extension even if said patent covers different pharmaceutical-related or agrochemical-related inventions and more than one market approval is secured. For instance, in the case where a term extension has been granted to a patent covering both a bactericide and a pesticide on the basis of a market approval for the bactericide, it is not possible to apply for a further term extension of the same patent on the basis of a market approval for the pesticide. In the case where two separate applications for patent term extension are filed for the same patent on the basis of an approval for bactericide and an approval for pesticide, respectively, the patent term extension applicant will be asked to elect one of the approvals as the basis for term extension.

3. One-Approval-One-Extension Requirement

A market approval can only serve as the basis for applying for the term extension of one patent. Where multiple patents are eligible for term extension based on the same market approval, the patentee can only use the same approval to seek the term extension of one patent. In the case where more than one patent term extension is filed for different patents based on the same market approval, the IPO will ask the applicant to elect one application for continued examination. If the applicant fails to elect one as required in a specified time, the IPO may elect the patent with the earlier filing date for examination of

term extension, and reject the other application(s) after allowing the term extension of the elected patent.

4. Correlation Between Patent Claims and First Market Approval

To extend the term of a patent based on an approval, the claims of the patent should cover or correspond to the active ingredient(s) and/or use identified in the approval.

Where a compound is concerned, at least one claim of the patent should cover or correspond to the active ingredient identified in the first market approval. While the market approval identifies the active ingredient as a single compound, a compound claim normally covers compounds collectively expressed with a chemical formula. In addition, the chemical name recited in the claim may differ from that shown in the approval due to differences in nomenclature. In such cases, explanations, and sometimes supporting references (e.g., pharmacopeia), should be submitted to show the coverage of the active ingredient in the claim.

It is understood that though a market approval specifies a salt or hydrate of a compound, the active moiety is the free form of the compound. Therefore, when determining the correlation between the patent claim and the market approval, the free form will be compared, instead of the salt or hydrate. For instance, in a case where Claim 1 is directed to a generic scope of compounds which covers compound a, Claim 2 specifically relates to compound a, and a market approval identifies the active ingredient as the HCl salt of compound a, both Claim 1 and Claim 2 correspond to the identified active ingredient even though they do not specify the salt.

In the case of an isomer, the determination will be different. For a market approval that identifies the active ingredient as an isomer of compound a in a specific form, the claim directed to "compound a and the isomer thereof" would correspond to the identified active ingredient, but the claim directed to "compound a" without describing the stereochemistry thereof does not.

Where a composition composed of two or more active ingredients is concerned, a corresponding market approval is the one that identifies the two or more active ingredients. For instance, a composition comprising A+B corresponds to an approval for a combination of A+B, but a claim relating to A alone, B alone, or A+B+C does not.

In the case of a product claim, the use identified in the market approval is not considered if the product claim does not specify a use (e.g., a novel compound claim need not specify a use).

Where a use claim is concerned, the claim should correspond to both the active ingredient(s) and use identified in the approval. For instance, a claim relating to use B of substance A does not correspond to an approval for use C of substance A, use B of substance D, or use B of substances A+D. In the case where the relevant use claim describes a mode of action but the market approval identifies a specific disease or condition, an explanation of the correlation of the mode of action and said disease or condition should be submitted.

Where a manufacturing process claim is concerned, the correlation is determined by the end product of the patented process and the active ingredient(s) identified in the approval. The process actually used for producing the active ingredient(s) is not considered. The use identified in the market approval is not considered, either.

The product, use and manufacture process claims in the same patent corresponding to the first market approval can all be extended based on the same market approval.

5. Recordation Requirement

Where an application for patent term extension is filed by an assignee, the assignment must be recorded with the IPO in accordance with the Patent Act.

The holder of the first market approval serving as the basis for a patent term extension must be the patentee, or a branch office of the patentee in Taiwan. Where the first market approval is held by a licensee, the patent licensing arrangement must be recorded with the IPO in accordance with the Patent Act.

6. Calculation of Extension

The following periods that occur after patent publication are eligible for restoration:

a). The period of foreign and domestic trials conducted for the purpose of securing the first market approval; and

b). The period of applying for and obtaining the domestic market approval (known as "product registration").

For pharmaceuticals, the trials mentioned in (a) above are limited to the clinical trials and bridging studies confirmed by the DOH as ones necessary for securing the market approval. The period during which the DOH reviews the necessity of a bridging study is excluded.

For agrochemicals, the trials mentioned in (a) above are limited to the field trials confirmed by the COA as ones necessary for securing the market approval. Where multiple trials are conducted on the same plant for the same disease or target pest at different times, the period of the longest field trial will be recognized; however, where the multiple trials must be conducted in accordance with a fixed order, the period of the individual trials can be combined.

The sum of the above periods a) and b) will be subtracted by the following periods, if any:

a). Periods of failure to act attributable to the applicant;

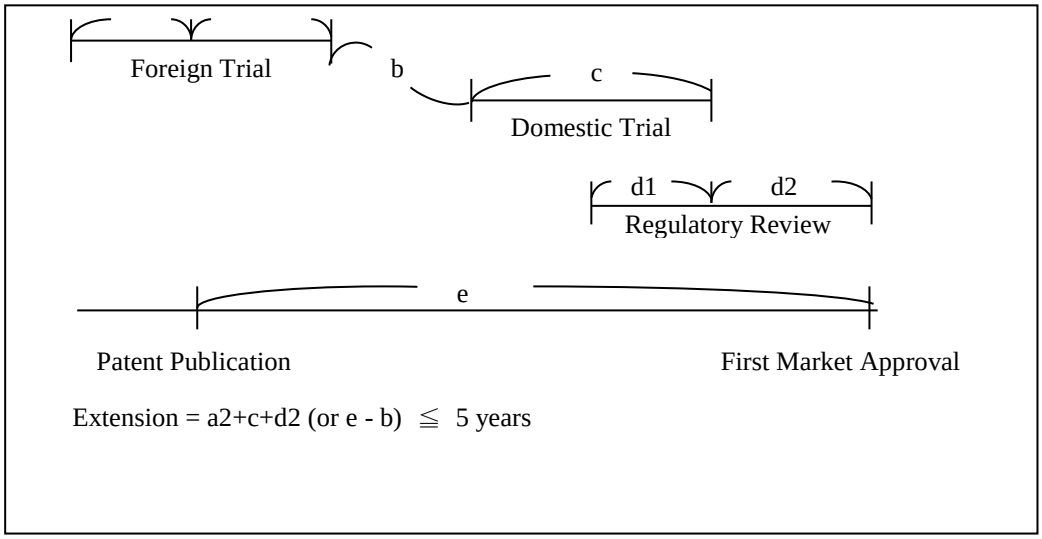
b). The overlap between the period of foreign trials and the period of domestic trials; and

c). The overlap between the period of foreign and domestic trials and the period of product registration.

The "periods of failure to act attributable to the applicant" refers to interruption or delay to the approval-obtaining-process caused by the applicant's failure to act with due attention. For instance, the requirements and application fees for filing product registrations are expressively stipulated in the laws, so a delay due to failure to submit all required documents or pay the full fee are considered attributable to the applicant. Similarly, after a product registration is approved, the competent authority will send a notice to the applicant requiring collection of the approval; the regulatory review by the competent authority ends on the day on which the applicant receives such notice; the days that elapse between the receipt of such notice and the collection of the approval are considered the period of failure to act for which applicant is accountable.

To verify the relevant registration procedure, the IPO may require the applicant to submit evidentiary documents, initiate its own investigation, or request the assistance of the authority concerned.

In any case, an extended patent term shall not exceed the total amount of time required for obtaining the first market approval that occurs after the publication of the patent to be extended, and where the total amount exceeds five years, a maximum extension of five years can be granted. See the following chart:



Note that where the periods during which the patent cannot be practiced due to the securing of the market approval in fact exceed the number of days claimed by the applicant, the extension allowed by the IPO is limited to the number of days as claimed.

7. Required Information & Documents

To apply for patent term extension, a written application, a copy of the relevant first market approval, and an official fee (currently NT$9,000) must be submitted, along with the following documents, where applicable.

a) Pharmaceutical-Related Patents

(i) A document issued by the institute or organization that performs the relevant foreign clinical trial which shows the period, commencement date and conclusion date of the foreign clinical trial (e.g., a copy the summary page of a clinical report that depicts the name of clinical trial, the trial proposal no., the medicine under test, the phase number of clinical trial, the name of the trial institution, and commencement and conclusion dates of the trial);

(ii) A copy of the DOH consent letter for the patentee or the licensee thereof to perform a domestic clinical trial or bridging study on the relevant pharmaceutical (the issue date of the letter will be recognized as the commencement date of the domestic clinical trial), and where a bridging study is performed, a copy of the DOH's evaluation and results of such study;

(iii) A copy of the DOH letter confirming the entry of the clinical trial or bridging study results (the issue date of the letter will be recognized as the conclusion date of the domestic clinical trial);

(iv) A copy of an official document showing the date on which the application for market approval is filed (e.g., DOH's correspondence wherein the application date is identified);

(v) A copy of a relevant label, insert or specification stamped with the date on which the market approval is collected from the DOH;

(vi) A list showing the name of relevant trials, the number of clinical proposals, and the commencement and conclusion dates thereof; and

(vii) In the case where a patent term extension was granted for a foreign

counter-patent based on the relevant foreign trial, a document showing the period of extension granted (e.g., a copy of the official gazette publishing such grant).

b) Agrochemical-Related Patents

(i) A document issued by the institute or organization that performs the relevant foreign field trial, which shows the period, commencement date and conclusion date of the foreign field trial (e.g., a copy the summary page of the relevant field trial report that depicts the name of trial, the trial proposal no., the agrochemical under test, the name of the trial institution, and commencement and conclusion dates of the trial);

(ii) A document issued by the institute or organization that performs the relevant domestic field trial, which shows the period, commencement date and conclusion date of the domestic field trial (e.g., a copy of the summary page of the relevant domestic field trial report);

(iii) A list showing the name of the above trials, the number of the clinical proposals, and the commencement and conclusion dates thereof;

(iv) A document that shows the payment of relevant registration fee, which activates the registration procedures (e.g., a copy of the COA's notice to pay the registration fee and a receipt of payment);

(v) A copy of the label stamped with the date on which the approval is collected; and

(vi) Where a patent term extension was granted for a foreign counter-patent based on the relevant foreign field trial, a document showing the period of extension granted (e.g., a copy of the official gazette publishing such grant).

For a market approval obtained under previous registration procedures, the document proving commencement of domestic field trials will be a copy of the consent issued by the COA for proceeding with entrusted field trials, that for proving the conclusion of such trial will be a copy of the acceptance letter issued by the COA approving the registration, and that for proving the commencement of registration can be any official document that shows the date on which the registration application enters the COA, e.g., a copy of a registration application stamped with the entry date by the COA.

Neither notarization nor legalization is required for the above documents.

Since a patent term extension is only available for patents which are still in force, the status of the patent to be extended should be provided in the application, e.g., the patent number, patent publication date, patent expiration date and annuity payment status.

In addition, to support the relevance of the patent claims to the active ingredient(s)/use identified in the market approval, evidentiary documents can be submitted as necessary, e.g., a chemistry review of the active ingredient, including its chemical formula, characteristics, etc.

IV. Examination of Patent Term Extension

The IPO will publish the written application in the Patent Gazette if an application for patent term extension complies with the formal requirements.

The list showing the information of relevant trials provided by the applicant will be forwarded to the competent regulatory authorities for affirming the necessity of the relevant foreign and domestic trials.

The IPO will notify the applicant to make a response and submit supplements if it finds that the holder of the market approval is not the patentee, or a licensee thereof recorded with the IPO, the evidentiary documents are insufficient, the number of days for restoration claimed by the applicant are incorrect, or there are delays in the process of obtaining the market approval attributable to the applicant. To clarify the issues raised in the IPO's notice, the applicant can petition for an interview with the examiner.

According to an announcement by the IPO, an application for patent term extension should be concluded within twelve months from the date of receiving such an application; however, the 12-month period does not include the time involved in the issuance of notification or office action requiring the applicant to effect supplement, explanation or response, or other delays with proper causes.

If during the examination, the relevant patent right is revoked or becomes extinguished (except for the situation that the patent term has expired), or the claims corresponding to the active ingredient/use identified in the market approval have been deleted or invalidated, the extension application will be rejected.

Where a patent term extension is granted, the IPO will publish the information in the Patent Gazette, and require the patentee to return the patent certificate for an endorsement for the granted extension of patent term.

If dissatisfied with the decision rendered by the IPO, the applicant for a patent term extension may institute administrative remedial proceedings to contest the decision, including administrative appeal with the Ministry of Economic Affairs, administrative suit with the Intellectual Property Court, and appeal with the Supreme Administrative Court.

V. Effect of Extension and Scope of Protection

In the case where the patent under a term extension application expires before the IPO renders a decision on the extension application, the patent term is deemed having been extended since the day following the expiration date of the patent; however, if the term extension applied for is ultimately not allowed, the life of said patent expires on the original expiration date.

A granted patent term extension covers only the product (a compound or composition), use or manufacturing process described in the claims that corresponds to the active ingredient(s) and use identified in the relevant market approval, and does not cover other products, uses or processes which are described in the claims but not in the market approval.

Where a product claim is concerned, an extended patent term covers only the specific product described in the claim that corresponds to the active ingredient identified in the first market approval as well as the use indentified in the approval.

Where a use claim is concerned, an extended patent term covers only the specific use described in the claim that corresponds to the use of the active ingredient(s) identified in the first market approval.

Where a manufacturing process claim is concerned, an extended patent term covers only the process described in the claim that corresponds to the active ingredient with the specific use identified in the first market approval. For instance, a term extension granted for a patent relating to the process for preparing aspirin on the basis of a market approval for the use of aspirin in treating hypertension is limited to the process for preparing aspirin for use in hypertension therapy.

As required during the original patent term, annuities should be paid during an extended patent term in accordance with the annuity year, the first year of which starts from the patent publication date. Currently, the annuity for the 10^{th} and subsequent annuity years is NT$18,000 per year.

VI. Cancellation Against Granted Patent Term Extension

A grant of patent term extension is subject to cancellation based on any one of the following grounds:

1. Obtaining a market approval is not required for practicing the patent;

2. The patentee or the licensee thereof never obtained the market approval;

3. The granted period of extension exceeds the period during which the patent could not be practiced;

4. The application for patent term extension was not filed by the patentee;

5. The market approval based on which the patent term extension was applied for is not the first market approval, or the market approval was used for another patent term extension;

6. Where a patent term extension was applied for on the basis of the period of the trial or test in a foreign country based on which the market approval was obtained, the allowed period exceeds the period recognized by the patent authority in said foreign country; and

7. The drug granted with the patent term extension is a veterinary medicine.

Note that the subject matter under cancellation against an approved patent term extension is the period of extension granted, not the patent claims; therefore, a cancellation should claim for revoking the extension of patent term from "… day, …month, …year" to "… day, …month, …year." The period under revocation cannot be altered unless such alteration is to reduce the period under revocation, and no additional claim for revocation can be made once the brief is filed.

While any third party can initiate a cancellation against an extended patent term prior to expiration of the extended term, an interested party who has recoverable legal interests due to revocation of the patent may file a cancellation action after expiration of the extended patent life.

To initiate a cancellation action, the cancellation petitioner must file with the IPO a cancellation brief together with supporting evidence. If the grant of patent term extension is irrevocably revoked through a cancellation based on any of the grounds listed in Items 1, 2, 4, 5 & 7 above, the originally granted extension period shall be deemed non-existing ab initio; if a cancellation based on either one of the grounds listed in Items 3 & 6 above is irrevocably sustained, the excess extension period shall be deemed non-extended. The IPO shall publish such revocation in the Patent Gazette.