This article was published in the *International Law Office IP Newsletter* on April 16, 2017.

Intellectual Property, Taiwan

TIPO amends examination standards for patent term extension

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On December 14 2017 the Taiwan Intellectual Property Office (TIPO) announced amendments to Chapter 11, Part II of the Patent Examination Guidelines, entitled "Examination Guidelines for Patent Term Extension".

Amendments

- If the name of the market approval holder is inconsistent with that of the patentee, the applicant should provide documentation proving that the two are the same legal entity or have an exclusive or non-exclusive authorisation relationship. In addition, the licence must be recorded with TIPO.
- The active ingredients in the first market approval should be determined based on the active ingredient per se rather than the moiety having pharmacological effect (free base). The term 'first market approval' means that it has been obtained for the same active ingredient and the same use. In principle, different licences obtained for different salts, esters or different hydrates of the same chemical moiety should each be identified as a first market approval.
- For determination of correlation between the patent scope and the first market approval, the correspondence relation originally specified in the guidelines has been redefined as 'coverage'. The relevant descriptions and examples in the guidelines have been amended accordingly. For the examination of an application for extension, TIPO requires that the active ingredients and use stated in the first licence should be covered by the scope of the patent application. In the case of an invention patent for a product, the active ingredient contained in the first market approval should be covered by the scope of the product claims. For a use invention patent, the active ingredients and use stated in the first market approval should be covered by the use claims. In the case of a manufacturing process for a product, the active ingredients contained in the first market approval should be covered by the process claims.
- The amendments clarify that the commencement and conclusion dates of the foreign clinical trials are, respectively, the study initiation and the study completion dates defined in the clinical trial report in line with International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. When applying for an extension based on foreign clinical trial periods, the focus of the foreign clinical trial protocol should be stated, and the study initiation and completion dates as stated in the clinical trial report that conform to the ICH should be recorded at the commencement and conclusion dates of foreign clinical trial.
- The conclusion of a regulatory review of an application for an agricultural chemical has been redefined as the issue date recorded on the market approval for the agricultural chemical. Moreover, delay during regulatory review attributable to the applicant includes the period from the issue date of approval of the use methods and scopes of agricultural chemical, to the completion of documents for regulatory review.
- The requirement to submit documents regarding the allowance of patent term extension in foreign countries has been lifted.
- The following stipulations have been added to the guidelines:

- The period during regulatory review in which an interruption or delay in obtaining a market approval occurs due to data inconsistent with the criteria for approving a market approval is now attributable to the applicant.
- In respect of applications for market approval of a drug or agricultural chemical, the documents and regulatory fees required for filing market approval have been defined.
- Any delay during regulatory review in obtaining a market approval due to incomplete data, non-payment of fees or data not in conformity with the requirements for obtaining a market approval during examination by the Department of Health and Welfare is now, in principle, attributable to the applicant.

- For an academic clinical trial converted into a clinical trial, the initiation date of the academic clinical trial should be taken as the commencement date of the domestic clinical trial.

Comment

TIPO announced the implementation of the amended guidelines on April 1 2018. Although the changes to the definition of 'first market approval' relax the criteria on determination of first market approval, they also impose a limitation on the scope of extension to the specific ingredients stated in the market approval according to Article 56 of the Patent Act. In addition, the update to Paragraph 7 may adversely affect patentees by expanding the explanation of the 'periods of delay attributable to the applicant'.

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