

This article was published in the *International Law Office IP Newsletter* on October 8, 2018.

Intellectual Property, Taiwan

Supreme Court clarifies foreign clinical trial periods in patent term extension applications

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Article 4 of the Regulations for Governing Patent Term Extensions, the amended version of which took effect on 1 April 2018, stipulates that:

the patent term extension period for a pharmaceutical, or its manufacturing process patent, includes (1) the foreign clinical trials and domestic clinical trial periods needed for issuance of drug market approval by the Central Authority; and (2) the period needed for local regulatory review... [these] foreign clinical trials and domestic clinical trial periods are limited to those necessary for issuance of market approval by the Central Authority.

Regarding the calculation of foreign clinical trial periods, the Patent Examination Guidelines Governing Patent Term Extensions (PTE Guidelines), which were also amended and took effect on 1 April 2018, provide that:

if a foreign clinical trial is used as a basis to file for a patent term extension, the points of the foreign clinical trial should be explained. For example, the clinical trial name, the trial number, the trial drug, the trial stage, etc.; and the study start date and study completion date described in the clinical trial report needs to have met the requirements of the International conference on harmonization for registration of pharmaceuticals for human use, and are considered as the start date and end date of a foreign clinical trial.

According to the PTE Guidelines, the end date of a foreign clinical trial should be the study completion date.

However, in Decision 106-Tai-Shang-Zi-1904 of 31 May 2018, the Supreme Court held that the end date of a foreign clinical trial should be the report date, not the study completion date. The court reasoned that the results of a clinical trial cannot be obtained immediately after the study is completed. Meaningful results can be obtained only after professional analysis and data processing. The results can then be used by the Central Authority to determine eligibility for market approval.

Therefore, the clinical trial period mentioned in the Regulations for Governing Patent Term Extensions should be calculated from the start date of the clinical trial to the date on which the trial results can be presented.

The Supreme Court's opinion clearly differs from that of the Intellectual Property Office (IPO). However, the decision is a civil judgment rather than an administrative judgment, which are binding on government authorities' decisions. Therefore, whether the IPO will change its position on calculating trial periods remains to be seen.

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