

## **Patent Term Extension (PTE)**

Term of the patent right is extensible for the period (up to 5 years) where the patented invention cannot be carried out due to obtaining a marketing approval which is indispensable for carrying out the patented invention. In this respect, there are no caps like 14 years from the marketing approval in US and 15 years from the marketing approval in EU.

Besides, although in US and EU, only one patent (namely, “Basic patent” in EU) can be extended, all patents pertaining to an approved drug can be extensible, except patents relating to intermediates, in Japan. Therefore it may be a good strategy for innovator companies to obtain many patents covering an approved drug and enjoy PTEs on all such patents.

Contrary to US and EU, scope of protection during extended period only covers/protects the use of the approved drug for the approved indication (Article 68-2). In this regard, after the following two Supreme Court decisions on the PTE, whenever an innovator company obtains additional marketing approvals on the already approved active ingredients, PTE is basically possible on every subsequent approval as far as the additional approvals can be distinguished from that approved already.

# 2009 (Gyo-Hi) 326 (Judged on 2011.04.28)

[http://www.courts.go.jp/app/hanrei\\_en/detail?id=1103](http://www.courts.go.jp/app/hanrei_en/detail?id=1103)

# 2014 (Gyo-Hi) 356 (Judged on 2015.11.17)

[http://www.courts.go.jp/app/hanrei\\_en/detail?id=1427](http://www.courts.go.jp/app/hanrei_en/detail?id=1427)

The every extended patent runs separately and simultaneously.

With regard to the conditions for enjoying PTE on combos, the following is the summary comparison among US, EU and Japan.

	<b>Conditions for enjoying PTE on combos</b>
US	At least one active ingredient of a combo has not been marketing-approved (Based on “Amold” case).
EU	If a combination is novel, a new marketing approval on the combo, all active ingredients of which have been already marketing-approved, may extend one of compound per se patents covering active ingredients of the combo or patents on the combo per se (Based on “MIT” case before ECJ).
JP	If the combination is novel, a new marketing approval on the combo, all active ingredients of which have been already marketing-approved, may extend patents on the combo per se (Based on “Combivir” case).

#### 1. Subject matters to be extended

- \* Human or veterinary medicines;
- \* Human or veterinary diagnosis reagents or kits;
- \* Agrochemicals;
- \* In vitro diagnostics; and
- \* **Regenerative medicine products.**
- \* Not applied to medical devices or apparatus.

# Subsequent approvals on the same active ingredient and indication/effect that

only differ in dosage form, administration route etc. may serve as a basis for additional extensions under the Supreme Court decision mentioned above.

# Subsequent approvals on the same active ingredient differing only in the indication/effect may serve as a basis for additional extensions.

# Subsequent approval on an active ingredient covered by the broad patent which also covers already approved another active ingredient may serve as a basis for an additional extension.

For the details, please see

[https://www.jpo.go.jp/tetuzuki\\_e/t\\_tokkyo\\_e/Guidelines/6.pdf](https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/6.pdf)

## 2. Amount of time that can be extended

\* Maximum of 5 years.

\* The extended term is equal to the “period which a patented invention could not be carried out” because pharmaceuticals need governmental approval before marketing. The period starts on the IND filing date (for human and veterinary medicines, diagnosis reagents and kits and regenerative medicine products) / on the day when the field trial is started (for agrochemicals), or on the patent grant date, whichever is later, and ends on the marketing approval date.

## 3. Procedures to be followed

(1) Applicant

\* Patent holders

Where the recipient of the regulatory approval is not the patent holders, the recipient must be an exclusive or non-exclusive licensee.

## (2) Filing timing

- \* Before the original patent term expires, and
- \* Within 3 months of the receipt of the regulatory approval
- \* When regulatory approval is not expected to be issued by six months prior to the expiration of the original patent term, the applicant must submit a provisional application to notify the Patent Office as such.

## 4. Clinical trials conducted outside Japan

In case the following conditions (1) to (3) are satisfied, the period during which the clinical trials have been conducted outside Japan may be added to the extension term of the patent:

- (1) The IND date in the foreign country is after the JP patent grant date;
- (2) The clinical trials are essentially required to obtain the regulatory approval in Japan; and
- (3) The clinical trial data is closely related to obtaining the regulatory approval.

The 2008 (Gyo-Ke) 10486 and 2008 (Gyo-Ke) 10487 (Judged on 200910.28) before the IP High Court relate to this point and judged that the extended term of the Patents beyond December 25, 2008 which corresponds to the terms for overseas clinical trials was invalid.

**Since the procedures and requirements for the PTE are complicated, please do not hesitate to contact us.**