Patent Term Extension (PTE) in Japan

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Overview

1. What is PTE?
2. What kinds of approvals are the basis for PTE?
3. How to calculate the term restored by PTE
4. PTE Applications
5. Examination of PTE Applications
6. Scope of an extended patent right
7. Summary and Tips for PTE in Japan

1. What is PTE?

- PTE aims to compensate patent owners for the term of their patents shortened by a process of regulatory authorizations!

> *"The purpose of the system for registration of extension of the duration of a patent right is to allow the patentee to reclaim a period of time during which the patentee has been unable to work the patented invention because of the necessity to obtain a Cabinet Order disposition."*
>
> **JPO v. Genentech, Supreme Court case ref. 2014(GYO-HI)356, 17 Nov. 2015**
> **English translation provided by the Court**

2. What kinds of approvals are the basis for PTE?

	 *	**
Drug products (e.g., a new drug, antibiotic drug, human biological product, new animal drug, and veterinary biological product)	✓	✓
In vitro diagnostics	✓	✓
Medical devices	✓	***
Food additives	✓	
Color additives	✓	
Agrochemicals		✓

* cf. 35 U.S.C. 156(f)

** cf. Art. 67(4) of the Patent Act and Art. 2 of Order for Enforcement of the Patent Act

*** except for regenerative-relative devices

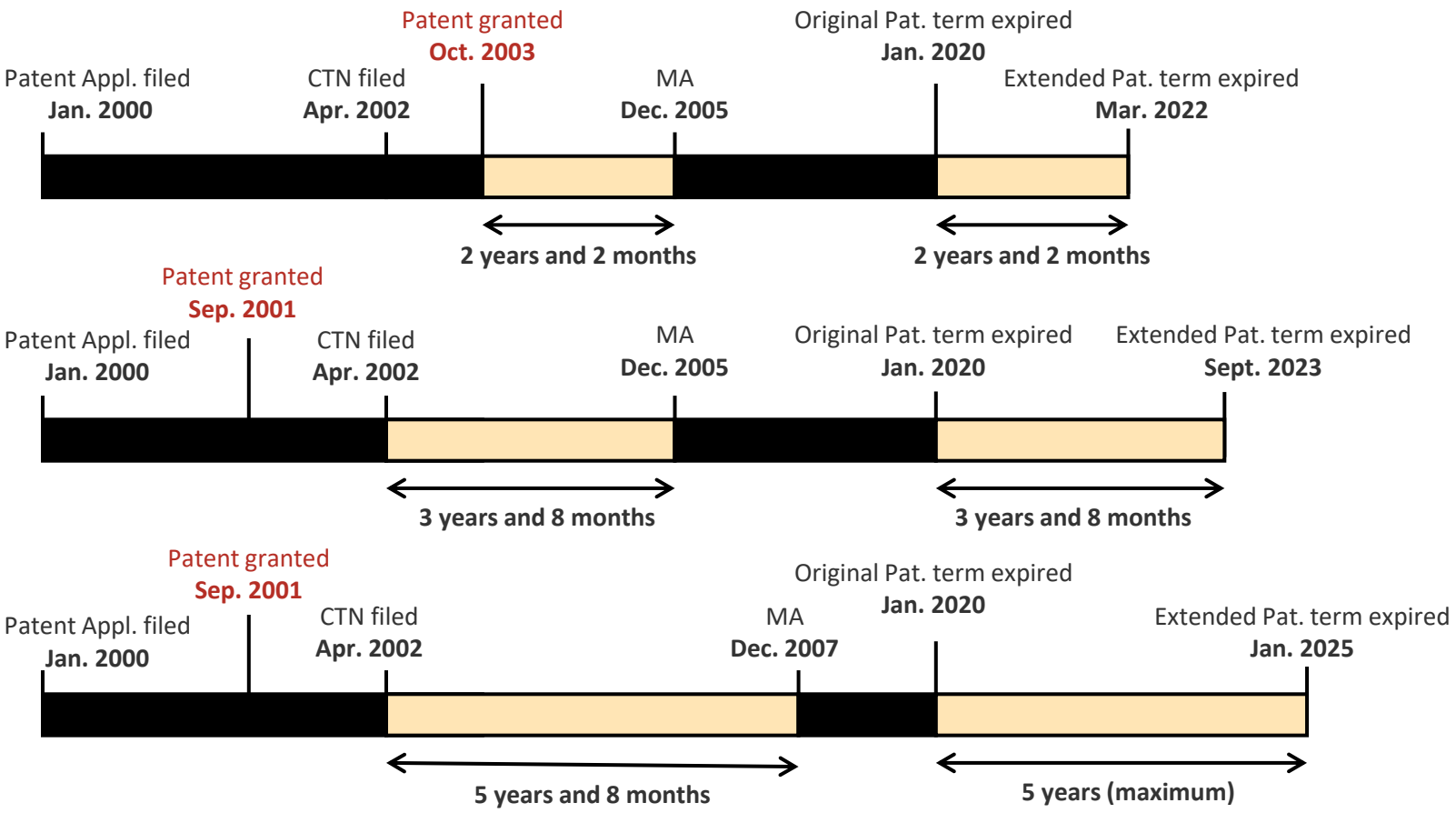
3. How to calculate the term restored by PTE

The extended term shall be calculated:

from the date on which the patent is granted or the date on which Clinical Trial Notification (CTN) is filed, whichever comes later, to one day before the date on which Marketing Approval (MA) is reached to Applicant.

- Maximum term: 5 years
- No pediatric extension
- No 14-year cap on the remaining period after the date of MA

3. How to calculate the term restored by PTE



4. PTE Applications:
4-1. Who can file PTE applications?

PTE applications must be filed by Patentee. [cf. Art. 67-7(1)(iv)]

If the patent right is jointly owned, PTE applications must be filed by all the joint owners. [cf. Art. 67-5(4)]

4. PTE Applications:
4-2. When you can file PTE applications?

In principle: within 3 months of MA

[cf. Art. 67(4) of the Patent Act, and Art. 3 of Order for Enforcement of the Patent Act]

Exceptions: PTE applications …

- may be filed even after the 3 months of MA if there is a reason beyond the control of Applicant (e.g. devastating natural disaster);
- cannot be filed even before the 3 months of MA after expiration of the original patent term (20 years from the filing date); and
- cannot be filed even before the 3 months of MA after six months prior to expiration of the original patent term unless a **preliminary notice** is filed before 6 months prior to expiration of the original patent term [cf. Art.67-6(2)].

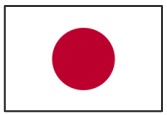
4. PTE Applications:
4-3. Who must receive the MA?

The recipient must be a patentee or a licensee. [Art. 67-7(1)(ii)]

If the recipient is a licensee (e.g., a Japanese subsidiary of the US company, who is a patent owner), a certificate document needs to be filed to prove the fact that the recipient is a licensee.

5. Examination of PTE Applications:
5-1. Introduction: Differences between the US and Japan

- Only one patent can be extended based on an approval.
  [cf. 35 U.S.C. § 156(c)(4)]
- A patent can be extended once based on a first approval
  [cf. 35 U.S.C. § 156(a)(2) and (5)]



- Multiple patents can be extended based on an approval.
- A patent may be extended multiple times based on second or other subsequent approvals (e.g., approvals on 2nd indication).

5. Examination of PTE Applications:
5-2. Statutory Requirements for PTE

Article 67-7(1) Where an application for the registration of extension of the duration defined in Article 67(4) falls under any of the following items, the examiner shall render the examiner's decision to the effect that the application is to be refused:

i. where the disposition designated by Cabinet Order under Article 67(4) is not deemed to have been necessary to obtain for the working of the patented invention;
ii. where the patentee, or the exclusive licensee or non-exclusive licensee of the patent have not obtained the disposition designated by Cabinet Order under Art. 67(4);
iii. where the period for which the extension is requested exceeds the period during which the patented invention was unable to be worked;
iv. where the person filing the application is not the patentee; and
v. where the request does not meet the requirements under Article 67-2(4) as applied mutatis mutandis by Article 67-5(4).

5. Examination of PTE Applications:
5-2. Statutory Requirements for PTE (Summary)

i. **MA is necessary to exploit the patented invention**,
ii. MA must be granted to the patentee or licensee,
iii. the extension period must be correct,
iv. PTE application must be filed by the patentee, and
v. PTE application must be filed by all the patentees if the patent right is jointly owned.

5. Examination of PTE Applications:
5-3. MA is necessary to exploit the patented invention

i. MA is necessary to exploit the patented invention

According to the Examination Guidelines, the requirement (i) is met if items (a) and (b) are met:

(a) The approved drug product must be covered by at least one granted claim of the patent.

5. Examination of PTE Applications:
5-3. MA is necessary to exploit the patented invention

i. MA is necessary to exploit the patented invention

According to the Examination Guidelines, the requirement (i) is met if items (a) and (b) are met:

(b) If there is a relevant prior MA, the manufacturing and distribution of the drug product subject to the present MA must not be included in those of the drug product subject to the prior MA in terms of ingredients (not only AIs but also other ingredients), dose, dosage/administration, indication, and optionally other matters.

5. Examination of PTE Applications:
5-3. MA is necessary to exploit the patented invention

Case 1

Claim 1. A compound X.

	1st MA	2nd MA
Active ingredient	X	X
Other ingredients	Y + Z	Y + Z
Dose	5 mg	5 mg
Dosage/administration	5 mg/dose	5 mg/dose
indication	pain relief	liver cancer

2nd MA is not included in 1st MA → PTE is given!

5. Examination of PTE Applications:
5-3. MA is necessary to exploit the patented invention

Case 2

Claim 1. A compound X.

	1st MA	2nd MA
Active ingredient	X	X
Other ingredients	Y + Z	Y + Z
Dose	5 mg	5 mg
Dosage/administration	5 mg/dose	10 mg/dose
indication	pain relief	pain relief

2nd MA is not included in 1st MA → PTE is given!

5. Examination of PTE Applications:
5-3. MA is necessary to exploit the patented invention

Case 3

Claim 1. A compound X.

	1st MA	2nd MA
Active ingredient	X	X
Other ingredients	Y + Z	Y + Z
Dose	5 mg	5 mg
Dosage/administration	5 mg/dose	5 mg/dose
indication	stomach cancer	α-gene positive stomach cancer

2nd MA is included in 1st MA → PTE is not given!

6. Scope of an extended patent right:
6-1. Article 68-2 of the Patent Act

The scope of an extended patent right is defined in Art. 68-2.

Article 68-2. Where the duration of a patent right is extended (…), such patent right 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 under Article 67(4) which constituted the reason for the registration of extension (where the specific usage of the product is prescribed by the disposition, the product used for that usage).

In short, the extended patent right shall be effective against only products (typically, generic drugs or biosimilars) comprising the same product for the same usage as the innovator's approved drug.

6. Scope of an extended patent right:
6-2. Standard provided by IP High Court

There was a first IP High court decision (“Debiopharm v. Towa”, 2016(Ne)10046 handed down on January 20, 2017) discussing the scope of an extended patent right, which provided a standard on how to interpret the scope of an extended patent right.

6. Scope of an extended patent right:
6-2. Standard provided by IP High Court

IP High Court ruled that:

"the product" is specified with

- ingredients (not only AIs but also excipients), and
- dose; and

"the usage" is specified with

- Indication, and
- dosage/administration.

6. Scope of an extended patent right:
6-2. Standard provided by IP High Court

IP High Court further ruled that:

the scope of an extended patent right is effective not only against

i. infringer's products identical with the product subject to the MA, but also against

ii. infringer's products substantially identical with the product subject to the MA.

6. Scope of an extended patent right:
6-2. Standard provided by IP High Court

IP High Court provided four typical examples where an alleged infringer's product is deemed to be "substantially identical" with the product subject to the MA.

6. Scope of an extended patent right:
6-3. Four typical examples for "substantially identical"

i. When a patented invention is characterized only by an active ingredient, an ingredient other than the active ingredient is partially added or converted in an alleged infringer's product based on well-known or commonly used art as of the time of the filing of an application for the MA.

6. Scope of an extended patent right:
6-3. Four typical examples for "substantially identical"

ii. When a patented invention relates to the stability or dosage form of a medicine pertaining to a publicly known active ingredient, a different ingredient is partially added or converted in an alleged infringer's product based on well-known or commonly used art as of the time of the filing of an application for the MA, where the alleged infringer's product and the product subject to the MA are recognized as being identical with each other in the technical features and function/effect in light of the content of the patented invention.

6. Scope of an extended patent right:
6-3. Four typical examples for “substantially identical”

iii. There is only a quantitatively meaningless difference between an alleged infringer’s product and the product subject to the MA in terms of the "dose" or "dosage/administration" prescribed by the MA.

6. Scope of an extended patent right:
6-3. Four typical examples for “substantially identical”

iv. An alleged infringer’s product and the product subject to the MA differ in terms of the "dose" but are recognized as identical in consideration of the "dosage/administration."

7. Summary and Tips for PTE in Japan

- To obtain a longer extension, you should get a patent as early as possible!
- Under the current practice, you should consider filing PTE applications whenever you get every kind of MA in Japan!
- You should never give up to bring a infringement lawsuit even an alleged infringer's drug is not completely identical with your drug; there is room for the interpretation that the alleged infringer's drug is substantially identical with your drug.