Patent Term Extensions
Trends in South East Asia and Europe

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Topics

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I. Introduction

Reasons for Patent Term Extension:

• Long duration of the marketing authorisation (MA) proceedings (quality – safety – effectiveness)
• Patent protection required from the beginning
• Effective lifetime of the patent: 8 years (12 years for MA proceedings)

Without possibility for patent term extension:

• Decrease in research activities in Countries not granting Extensions
• Falling number of new active pharmaceutical ingredients (API)
• Reduced competitiveness of the pharmaceutical industry compared with the EC, USA and Japan
• Movement of the industry to countries offering better protection of development of new APIs
• Lowering the standards in the safety tests unacceptable
Extensions are known as:

- Supplementary Protection Certificates (SPC)
- Patent Term Extensions (PTE)
- Complementary Protection Certificates (CPC)

II. Where are Extensions available?

SPC/PTE/CPC are available in South-East Asia:

- Australia
- Brunei
- Japan
- Macau
- Singapore
- South Korea
- Taiwan
SPC/PTE/CPC are not available in:

- China
- Hong Kong
- India
- Indonesia
- Malaysia
- New Zealand
- Pakistan,
- Philippines
- Thailand
- Vietnam

Special Case Macau:

Section III, Articles 125 to 128 of Decree-Law Nº 97/99/M of 13 December 1999 provides for Complementary Protection Certificates (CPCs) in Macao.

The Macao CPC law is a vestige of Macao having been a Portuguese colony, since Portugal had provided for CPCs even before other European countries enacted their Supplementary Protection Certificate (SPC) laws.
**Special Case Macau:**

Patents pertaining to medicines and “phyto-pharmaceutical products” (i.e. plant extracts) are eligible for a CPC.

Veterinary drugs may be included within the scope of “medicines” - but the statute does not expressly mention them.

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**Special Case Macau:**

The CPC application cannot be filed until six months from the original (unextended) expiration date. It is recommended that the application be filed on the first possible day, since the legal effect of a patent’s expiration during the pendency of a CPC application is not known.

There is no specific provision in the law for interim extensions comparable to that under the U.S. law.
Special Case Macau:

The statute does not describe any limitation on the scope of the CPC.

The maximum duration of a CPC is 7 years. However, the statute does not provide any formula for calculating the duration in individual cases.

III. Patent Term Extension in Singapore

Legal Basis: Singapore Patents Act – Sections 1, 36

Subject of the Patent Term Extension:

- Extensions are only granted to patents where the subject of the patent includes “any substance which is an active ingredient of any pharmaceutical product”.
- Another condition is that there was an unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval for a pharmaceutical product, being the first pharmaceutical product to obtain marketing approval which uses the substance as an active ingredient (36 (1) c) (i).
- Moreover the term of the patent must not have previously been extended on this ground (36 (1) c) (ii).
Delay in Marketing Approval (36 (5) a) - b):

A curtailment of the opportunity to exploit a patent, the subject of which includes a substance which is an active ingredient of any pharmaceutical product, caused by the process of obtaining marketing approval for a pharmaceutical product, being the first pharmaceutical product to obtain marketing approval which uses the substance as an active ingredient, shall not be treated as an unreasonable curtailment under subsection (1) (c) unless —

(a) the marketing approval was obtained after the date of issue of the certificate of grant; and

(b) the interval between the date the application for marketing approval was filed and the date marketing approval was obtained, excluding any period attributable to an act or omission of the applicant for marketing approval, exceeds 2 years.

There must be an “unreasonable” curtailment of the opportunity to exploit the patent.

The Act defines as unreasonable is understood in the sense that marketing approval was obtained after grant of the patent, and that it has taken more than 2 years to obtain the grant of marketing approval.

This period excludes any period attributable to an act or omission of the applicant.

Similar to many other countries, the pharmaceutical product must be the first pharmaceutical product which uses the substance as an active ingredient to obtain marketing approval.

Finally, the term of the relevant patent must not previously have been extended.
**Extension Period (36 (6) a) - c):**

- (6) Subject to subsections (7), (8) and (9), where the proprietor of a patent has made an application under subsection (1) (c) and has satisfied the Registrar that there was in fact an unreasonable curtailment of the opportunity to exploit the patent under subsection (1) (c), the Registrar shall extend the term of the patent by —
  
  - (a) a period equivalent to the interval between the date of issue of the certificate of grant and the date marketing approval was obtained;
  
  - (b) the period by which the interval referred to in subsection (5) (b) exceeds 2 years; or
  
  - (c) a period of 5 years,

- whichever is the shortest period

**Duration of Extension Period:**

- The term of extension is the shortest of:
  
  - a period equivalent to the interval between the date of issue of the certificate of grant and the date marketing approval was obtained
  
  - the period by which the time taken to obtain marketing approval, less any delays by the applicant, exceeds 2 years; and
  
  - a period of 5 years

- Thus, the maximum period of patent term extension possible for a Singapore patent is 5 years.
Formal Precondition (36 (7) a - c):

(7) The Registrar shall not extend the term of the patent under subsection (6) unless the applicant has procured and submitted to the Registrar a certificate from the relevant authority stating —

(a) the date the application for marketing approval was filed;

(b) the date marketing approval was obtained; and

(c) for each period attributable to an act or omission of the applicant for marketing approval, the dates on which the period started and ended.

“Pharmaceutical Product” as defined in the Act is:

• a substance

• used wholly or mainly by being administered

• to a human

• being for the purpose of treating or preventing disease.
“Pharmaceutical Products” as defined in the Act are not:

- substances used solely for diagnosis or testing or as a device or mechanism;
- an instrument, apparatus or appliance;
- any substance which is a type of food, a food additive or a food supplement;
- any substance which occurs naturally in any plant, animal or mineral;
- any raw material which is used as an ingredient in the preparation or manufacture of any medicinal product any medicated oil or balm;
- any traditional medicine;
- any homoeopathic medicine; or
- any quasi-medicinal product.

Naturally Occurring Products:

- The Act apparently does not consider a substance “which occurs naturally in any plant, animal or mineral” as a “pharmaceutical product”.

- Thus it is questionable whether a patent for a drug originally isolated from natural sources (whether or not now synthesized artificially) or a biologic such as an un-engineered antibody is susceptible to patent term extension. The Act does not define what “occurs naturally” means - no case law is available to date.

- Not being able to obtain a patent term extension for such products, however, would appear to defeat the purpose of the legislation.
Naturally Occurring Products:

- Further, the definition of “traditional medicine” in the Schedule is such that a substance derived from a natural source, which is administered by injection into a human body or used as a vaccine by a human being, is considered not a “traditional medicine”. According to this definition, a “pharmaceutical product” might indeed include a natural substance, provided the use requirements are fulfilled.

Determination of Period (36 (8)):

- (8) In determining the period by which to extend the term of the patent under subsection (6), the Registrar shall rely on, and shall not be concerned to inquire into the truth of, the statements contained in the certificate from the relevant authority under subsection (7).

Scope of Protection (36 (9)):

- (9) Where the term of a patent has been extended under subsection (6), the protection conferred by the patent during the term of the extension shall apply only to the substance referred to in subsection (1) (c).
IV. SPCs in Europe

• Grant of SPCs possible for human and veterinary pharmaceuticals;

• Application is possible within 6 months after grant of basic patent or MA – whichever is the later one.

• Application of an SPC only possible for the owner of the basic patent;

• Applicant of an SPC does not have to be the owner of the MA – third party’s MA can be used.

• The term of extension is calculated by:

• a period equivalent to the interval between the date of application of the basic patent and the date of grant of the MA

• minus 5 years.

• However, the maximum period of patent term extension possible for a European Patent is 5 years.
An SPC is granted for a Product

The subject matter of two patents is directed to the same product, if the two subject matter only differ in (one or more of):

- The indication,
- Human instead of veterinary pharmaceutical,
- Different pharmaceutical additives,
- Different ratio impurity to active compound,
- Different ratio of active compounds.

When a first SPC has been granted for a product, based on a MA for this product, an SPC for a combination of this product with another active ingredient is only possible, if a MA for the combination is available.

If the MA is directed to combinations, an SPC can be granted for parts of the combination, if the subject matter of the SPC is specified in the patent.
An SPC also can be granted, if the active ingredient or the combination of active ingredients is comprised by the MA.

In that case, an SPC can only be granted for parts of the combination, if these parts per se are specified in the patent.

If a first SPC has been granted for a product, based on a MA for this product, an SPC for a combination of this product with another active ingredient is only possible, if an MA for the combination is available.

Example:

Basic patent (claims):  A + B, A + B + C

MA: A + B + C

• SPC possible for:
  A + B + C
  A + B (since A + B is comprised by the MA)

• SPC not possible for:
  A (since A is not specified in the claims)
The scope of an SPC is not restricted to the product. If the subject matter of an SPC is used, the respective SPC is infringed, even if the subject matter is used in combination with other active pharmaceutical ingredients or additives.

Important Novel SPC Case Law from the Court of Justice of the European Union (CJEU)

Medeva and Neurim
Medeva C-322/10 - Conditions for obtaining a SPC

**Art. 3**

A protection certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

a) the product is protected by a basic patent in force;

b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

c) the product has not already been the subject of a protection certificate;

d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

Subject matter of the Medeva decision

**Article 3a**

- Basic patent: A
- Marketing authorisation (MA): A + B
- SPC possible for: A + B?
**Infringement theory vs. disclosure theory**

- **Infringement theory:**

  The infringement theory states that where a product would infringe a basic patent, this product is protected by the said patent within the meaning of Art. 3 a.

  This theory is almost exclusively determined by patent law.

- **Disclosure theory**

  The disclosure theory states that only what is disclosed in the patent is protected by the basic patent within the meaning of Art. 3 a. The decisive factor is what the person skilled in the art derives from reading the claims and the description in the overall context.

  This theory is more strongly determined by marketing authorisation law.

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**ECJ prefers disclosure theory:**

Article 3(a) of Regulation (EC) No 469/2009 ... must be interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate.
Consequence 1 of the Medeva decision

Article 3a

• Basic patent: A
• MA: A + B
• SPC **NOT possible** for: A + B

To be cleared by further referrals:

• Only one SPC per patent?
• Definition of “cited” - Markush formula sufficient?

Subject matter of the Medeva decision

Article 3b

• Basic patent: A
• MA: A + B
• SPC possible for: A ?
Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent Industrial Property Office of a Member State from granting a Supplementary Protection Certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a Supplementary Protection Certificate contains not only that combination of the two active ingredients but also other active ingredients.

Consequence 2 of the Medeva decision

Article 3a

• Basic patent: A
• MA: A + B
• SPC possible for: A

To be cleared by further referrals:

• Is an MA directed to A + B the first MA for the product A?
Neurim C 130/11 – Relevance of an earlier MA

Subject matter of the Neurim decision

- First MA: Compound X - Animals – Indication A
- Second MA: Compound X - Humans – Indication B
- Basic Patent: Compound X - Humans – Indication B

- Is the first MA relevant for an application directed to an SPC for Compound X - Humans – Indication B?

In a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.
Article 13(1) of Regulation (EC) No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.

**Consequence of the Neurim decision**

• An earlier MA for the same compound is only relevant, if the subject matter of the earlier MA is within the scope of the basic patent of the SPC.

• Compound and product of an SPC are only identical if the basic patent is directed to the compound as such.

Otherwise the compound of an SPC is restricted to the scope of the basic patent.