

Enactment of paediatric extensions of SPCs and of paediatric SPC's in the Swiss Patents Act as from 1 January 2019

Present situation:

Basic patent, covers authorised product (medicinal or plant protecting agent, or combination of such agents), or process of its manufacture or a use thereof



SPC as extension of term of protection for authorised product by maximal 5 years beyond expiry date of basic patent, negative terms of up to 6 months in the negative allowed

As from 1 January 2019:

Basic patent, covers authorised product (medicinal agent or combination of such agents), or process of its manufacture or a use thereof



SPC as extension of term of protection for authorised product by maximal 5 years beyond expiry date of basic patent, **no negative terms allowed anymore**



Paediatric term extension of 6 months of the SPC



mutually exclusive

Paediatric SPC as 6 month extension of term of protection for authorised product beyond expiry date of basic patent

Basic patent, covers authorised product (plant protecting agent, or combination of such agents), or process of its manufacture or a use thereof



SPC as extension of term of protection for authorised product by maximal 5 years beyond expiry date of basic patent

Introduction

This amendment of the Swiss Patents Act is part of an accompanying revision of the Swiss law on medicaments that will enter in force on the same date. It will entail the introduction of both paediatric extensions of 6 months for granted SPC's, analogous to the paediatric extensions in the EU, and the introduction of the new "paediatric SPC", being a title of intellectual property in its own right and unique to Switzerland, with a fixed 6 month term.

The SFIP will simultaneously abolish its current practice of granting SPC's with negative terms up to 6 months in the negative, extendable by a purported paediatric extension of 6 months to a term greater than zero. Any SPC applications filed as from 1 January 2019 will only be granted if the predicted term is positive already without paediatric extension. SPC applications filed before 1 January 2019 with a predicted negative term up to 6 months in the negative will however still be granted and a possible paediatric extension can be added thereto to make the term positive.

Patent owners considering as from 1 January 2019 to apply for a SPC with any predicted negative term will thus instead have to apply for a paediatric SPC, provided they have at their disposition a Swissmedic marketing authorisation order for the product in question containing a confirmation of Swissmedic that the corresponding authorised medicament information contains the results of all studies that were carried out for that product in accordance with a paediatric investigation plan (PIP).

SPC and paediatric SPC are mutually exclusive. That is, one and the same patent owner will get for one and the same product only one SPC (with the option of a paediatric extension thereof) or one paediatric SPC (without the option of extension), but not both.

The following are non-exhaustive summaries of paediatric extensions and paediatric SPC's.

Paediatric extensions of SPC's

A granted paediatric extension of a SPC will extend the term thereof by 6 months. The paediatric extension can be obtained only once per SPC. The owner of record of a basic patent (and thus of the associated SPC) is entitled to the paediatric extension of the SPC.

A very important prerequisite for the obtention of a paediatric extension of an SPC covering a given product is the obtention of a confirmation from Swissmedic that the associated medicament information (in German: "Arzneimittelinformation") contains the results (whether positive or negative) of all studies that were carried out in accordance with an approved paediatric investigation plan (PIP). Swissmedic will normally include such confirmation only into the authorisation order (In German: "Zulassungsverfügung"), and only upon request of the applicant of that marketing authorisation. For already existing Swissmedic marketing authorisations, wherein the associated medicament information already contains all said results obtained with a foreign PIP (a PIP approved by the FDA or the EMA), Swissmedic will issue as from 3 January 2019 upon request such confirmation. This confirmation must be submitted with the application for the paediatric extension. A marketing authorisation wherein the authorisation order contains that confirmation needs not be the first marketing authorisation that formed the basis for the SPC itself. The owner of record may also use any third party's Swissmedic confirmation.

Patent owners considering as from 1 January 2019 to apply for a SPC which have at their disposition a Swissmedic marketing authorisation order for the product in question containing a confirmation of Swissmedic that the corresponding authorised medicament information contains the results of all studies that were carried out for that product in accordance with a PIP, will have the option to simultaneously apply, together with the application for the SPC itself, for the paediatric extension thereof.

The application for a Swissmedic marketing authorisation wherein the authorisation order contains said confirmation must have been filed at the latest 6 months after the application of a corresponding marketing authorisation in the European Economic Area (EEA), wherein the associated medicament information contains the results of all studies that were carried out in accordance with a PIP. Under the transitional provisions this deadline does not apply if the said Swissmedic authorisation wherein the authorisation order contains said confirmation is applied for at the latest until 30 June 2019. This deadline can thus be expressed as

- a) 30 June 2019; or
 - b) six months after the filing of the said EEA marketing authorisation;
- whichever of a) and b) expires later.

Evidence for both the application for the said Swissmedic authorisation and for the earlier application in the EEA (or a declaration that no such earlier application in the EEA has been filed) needs to be submitted together with the application for the paediatric extension.

The deadline for filing the application for paediatric extension is 6 months before the expiry of the associated unextended SPC, if the application for paediatric extension is filed in the period of 1 January 2019 to 31 December 2023. Otherwise the deadline is 2 years before the expiry of the associated unextended SPC. That is, for any SPC expiring on or before 30 June 2024 the application for paediatric extension must be filed at the latest 6 months before its regular expiry, and for any SPC with expiry on or after 1 July 2024 the application for paediatric extension must be filed at the latest 2 years before its regular expiry. For granted SPC's expiring on or before 30 June 2019 no paediatric extension can be applied for at all because the SFIIP accepts applications for paediatric extensions only as from 1 January 2019.

The SFIIP charges CHF 1500.- official fee for the application for the paediatric extension.

If the application for paediatric extension is filed at the latest 2 months before the start of the term of the corresponding SPC, then the annuity fee for the paediatric extension becomes due together with the annuity lump sum for the SPC itself. That is, the annuity fee for the paediatric extension becomes due on:

- a) the last day of the month in which the basic patent expires,
 - b) the last day of the month in which the SPC is granted;
- whichever of a) and b) is later.

If the application for paediatric extension is filed less than 2 months before the start of the term of the corresponding SPC the annuity fee for the paediatric extension becomes due two months after the filing of the application of the paediatric extension.

Paediatric SPC

A paediatric SPC extends the term of a basic patent by strictly 6 months. The term of the paediatric

SPC itself cannot be further extended. The owner of record of a basic patent is entitled to the paediatric SPC. A paediatric SPC confers the same rights and is subject to the same limitations as the basic patent, that is, it confers the same rights and is subject to the same limitations as a SPC.

As for the paediatric extension a confirmation from Swissmedic that the associated medicament information (in German: "Arzneimittelinformation") contains the results (whether positive or negative) of all studies that were carried out in accordance with a PIP is necessary. This confirmation must be submitted with the application for the paediatric SPC. If the confirmation has been issued on behalf of a third party then furthermore the explicit consent of the addressee of this confirmation must also be submitted.

As for the paediatric extension the application for said Swissmedic marketing authorisation wherein the authorisation order contains said confirmation must have been filed at the latest 6 months after the application of a corresponding marketing authorisation in the European Economic Area (EEA), wherein the associated medicament information contains the results of all studies that were carried out in accordance with a PIP. Also as for the paediatric extension, under the transitional provisions this deadline does not apply if the said Swissmedic authorisation wherein the authorisation order contains said confirmation is applied for at the latest until 30 June 2019. Evidence for both the application for the said Swissmedic authorisation and for the earlier application in the EEA (or a declaration that no such earlier application in the EEA has been filed) needs to be submitted together with the application for the paediatric SPC.

The deadline for filing the application for paediatric SPC is 6 months before the expiry of the associated basic patent, if the application for paediatric extension is filed in the period of 1 January 2019 to 31 December 2023. Otherwise the deadline is 2 years before the expiry of the associated basic patent. That is, for any basic patent expiring on or before 30 June 2024 the application for the paediatric SPC must be filed at the latest 6 months before the regular expiry of the basic patent, and for any basic patent with expiry on or after 1 July 2024 the application for the paediatric SPC must be filed at the latest 2 years before the regular expiry of the basic patent.

The SFIP charges CHF 3000.- official fee for the application for the paediatric SPC, which includes the filing fee and the accumulated annuities for the entire 6 month term.