

# Exhaustive list of SPC nullity grounds according to Swiss Federal Patent Court

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In a decision issued this summer, the Swiss Federal Patent Court had the opportunity to comment on the **catalogue of grounds for invalidity which can be brought against a Swiss SPC**. The Federal Patent Court issued a PI based on Genzyme Corporation's Swiss SPC for sevelamer, although it was unclear whether the Swiss Institute of Intellectual Property (IPI) had approved an application for re-establishment of rights correctly when Genzyme Corporation applied for its SPC.

The Federal Patent Court confirmed in the ordinary proceedings following the PI proceedings that it was irrelevant whether the application for re-establishment of rights was lawful or not. In any case, an unlawful re-establishment is not a ground for invalidity that can be brought against a Swiss SPC under the Swiss Patent Act (PatA). According to the Federal Patent Court, the list of nullity grounds that can be brought against a Swiss SPC is exhaustive.

The decision of the Federal Patent Court has been appealed by the Defendant (Salmon Pharma GmbH) to the Federal Supreme Court. A final ruling may be expected within 3-4 months.

The background to the case is as follows. The Defendant received a Swiss marketing authorization for its pharmaceutical product "Sevelamercarbonate Salmon Pharma". The only active ingredient in this product is sevelamer carbonate, a salt of sevelamer.

Salmon Pharma GmbH does not dispute that its product "Sevelamercarbonate Salmon Pharma" contains the same active ingredient as Genzyme Corporation's SPC and therefore falls within the scope of protection of the Swiss SPC.

Neither does Salmon Pharma GmbH deny that it started at the end of 2016 to market the generic drug "Sevelamercarbonate Salmon Pharma" in Switzerland. However, Defendant asserts that Plaintiff's Swiss SPC is null and void because the IPI wrongfully granted re-establishment of rights (Art. 47 PatA) with respect to the time limit for filing the SPC application.

However, in its ruling the Federal Patent Court comes to the conclusion that it does not matter whether the re-establishment of rights was correctly granted by the IPI or not. The Federal Patent Court issued a PI against Salmon Pharma GmbH and confirmed in ordinary proceedings on the merits that Plaintiff's SPC is valid because a wrongful grant of an application for re-establishment of rights for the filing of an SPC application is not a nullity ground that is accepted by the exhaustive list of nullity grounds for Swiss SPCs.

The Swiss decision is interesting because it also takes the situation in the EU into account. It confirms that Swiss SPC law is interpreted in light of the EU SPC Regulation No 1610/96.

However, there does not seem to be a clear practice or ruling of the CJEU that deals with the question whether the nullity grounds mentioned in Art. 15 SPC Regulation are exhaustive or not.

At least a part of the legal doctrine in the EU advocates that the list of nullity grounds in Art. 15 SPC Regulation is not exhaustive and an SPC should be declared invalid if it was granted by violating any provision of patent law or procedural law (see for example Brückner, ESZ/SPC, 2<sup>nd</sup> edition, Art. 15 para. 45 et seqq.). Brückner discusses the question whether Art. 15 SPC Regulation provides an exhaustive list or not in great detail and comes to the conclusion that this is rather an open list.

However, the Swiss Federal Patent Court disagrees. In its decision it briefly refers to Brückner's opinion and then discusses several rulings of the CJEU, in particular the decisions C-195/09 of 28 July 2011 and C-127/00 of 11 December 2003.

According to the Federal Patent Court, the CJEU did not introduce additional SPC nullity grounds in those decisions but discussed the interpretation of the nullity grounds according to Art. 15 SPC Regulation in combination with Art. 3 SPC Regulation.

According to the Federal Patent Court the CJEU confirms in its decisions that neither the wording nor the history of Art. 15 SPC Regulation lead to the conclusion that the catalogue of nullity grounds of Art. 15 SPC Regulation is a non-exhaustive list.

A decision of the German Federal Patent Court of 11 December 2007 and a ruling of the UK High Court of 2 April 2009 also confirmed the Federal Patent Court's view that no other nullity grounds should be accepted than those explicitly mentioned in Art. 15 EU Patent Regulation and Art. 140k Swiss PatA.

In summary, the Federal Patent Court confirmed Plaintiffs' injunction and rejected Defendant's defense arguments that the Swiss SPC should be held null and void because of an allegedly wrongful grant of re-establishment of rights when applying for the concerned Swiss SPC. The matter is now pending before the Federal Supreme Court.

There was also an **interesting sideshow concerning the calculation of the amount in dispute**. The parties did not agree on the amount in dispute for the remaining time period prior to the expiry of the SPC in 2019 (roughly 2 years). The amount in dispute is relevant for calculating the court costs and the compensation of the winning party's attorneys' fees. Plaintiffs assumed the amount in dispute to be CHF 5 million, while the Defendant only estimated it to be CHF 500,000. When calculating the amount in dispute, the Court applied the following rules of thumb:

- As a general rule, one third of the turnover of the originator's product is replaced by the generic product within 2 years.
- According to the Court, the (generic company's) profit margin is roughly 50%.

In light of this background and Plaintiffs' allegation that the annual turnover with the concerned product is approximately CHF 2.25 million, the Court fixed the amount in dispute at CHF 750,000.