

# SPCs cannot be revoked on the grounds of a wrongfully granted reestablishment of rights, confirms Swiss Federal Supreme Court

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Regardless of whether someone intends to enforce their own supplementary protection certificate (SPC) or finds themselves at the receiving end of an SPC infringement action, the question which grounds of invalidity justify the revocation of an SPC may become highly relevant. This question is all the more intriguing in light of the CJEU's corresponding case law, which is often summarized with the catchphrase that the list of grounds of invalidity in Article 15(1) of the SPC Regulation is "not exhaustive".

Indeed, while Article 15(1)(a) of Regulation (EC) 469/2009 on SPCs for medicinal products (and, likewise, Article 15(1)(a) of Regulation (EC) 1610/96 on SPCs for plant protection products) provides that an SPC shall be invalid if "it was granted contrary to the provisions of Article 3", the CJEU ruled in *Hässle (C-127/00)* and *Synthon (C-195/09)* that even if it is not possible to infer from the wording or the origin of Article 15(1) that the list of grounds of invalidity of an SPC set out therein is not exhaustive, the infringement of an Article of the SPC Regulation which is not referred to in Article 15(1), i.e. the infringement of a provision other than Article 3, can still render an SPC invalid "owing to the connection between the provision in question and Article 3 of the Regulation". This same position was also taken by the EFTA Court in *Pharmaq v. Intervet (E-16/14)*.

This rather broad interpretation of the grounds of invalidity of SPCs endorsed by the CJEU and the EFTA Court has given rise to the question whether other requirements of the SPC Regulation which arguably do not have a direct connection to Article 3 could nevertheless lead to the revocation of an SPC. Such cases include, for example, a transgression of the time limit for filing an SPC or a wrongfully granted reestablishment of rights in the course of the SPC grant procedure.

These same questions likewise arise under Swiss SPC law, particularly in relation to the list of grounds of invalidity provided for in [Article 140k\(1\) Swiss Patent Act](#), which closely resembles the corresponding EU legal provisions as set out in Article 15(1) of the SPC Regulation.

Welcome clarification regarding the grounds of invalidity of SPCs has now been provided by the Swiss Federal Supreme Court in its recent [judgment in 4A\\_415/2018 of 7 December 2018](#).

In the case underlying this judgment, Genzyme Corporation as the holder of Swiss SPC no. C00716606/01 (for the active ingredient sevelamer) and their exclusive licensee Sanofi-Aventis (Suisse) SA enforced their SPC against Swiss pharmaceutical company Salmon Pharma GmbH which had started marketing a generic version of Sanofi-Aventis' medicament Renvela® containing the active ingredient sevelamer carbonate. The alleged infringer Salmon Pharma, in turn, tried to defend itself by arguing that the SPC was invalid because the Swiss Patent Office had wrongfully granted Genzyme's request for reestablishment of rights with respect to the time limit for filing their SPC in the course of the SPC grant procedure.

This argument was already dismissed in the [first-instance judgment of the Swiss Federal Patent Court in O2017\\_016 of 12 June 2018](#). Specifically, the Federal Patent Court held that Salmon Pharma had failed to make use of its right as a third party, under the then-applicable Swiss law, to appeal the decision of the Swiss Patent Office to grant Genzyme's request for reestablishment of rights together with the decision to grant the corresponding SPC before the Swiss Appeals Commission for Intellectual Property (which has meanwhile been dissolved and replaced by the Federal Administrative Court) within 30 days from the grant of the SPC, so that the grant decision has become formally final. The Federal Patent Court furthermore found that Article 140k(1) Swiss Patent Act provides an exhaustive enumeration of the grounds of invalidity of an SPC, and that a wrongfully granted reestablishment of rights with respect to the time limit for filing an SPC (even if proven) does not constitute a ground of invalidity according to the Swiss Patent Act.

Salmon Pharma subsequently lodged an appeal against this decision, which gave rise to the [Federal Supreme Court's judgment in 4A\\_415/2018 of 7 December 2018](#). The Federal Supreme Court expressly confirmed the finding of the Federal Patent Court that the list of grounds of invalidity of an SPC recited in Article 140k(1) Swiss Patent Act is exhaustive, just like the list of grounds of invalidity of a patent in Article 26 Swiss Patent Act is exhaustive, and stressed that this is in full accordance with the corresponding case law of the CJEU, including *Hässle (C-127/00)* and *Synthon (C-195/09)*. While the Federal Supreme Court acknowledged that these CJEU decisions did indeed allow invoking a violation of certain provisions other than those of Article 3 of the SPC Regulation as a ground of invalidity, it found that the CJEU thereby never intended to expand the list of grounds of invalidity but merely interpreted the corresponding reference to Article 3. Finally, the Swiss Federal Supreme Court noted that neither a transgression of the time limit for filing an SPC nor a wrongfully granted reestablishment of rights with respect to this time limit can be subsumed under any of the grounds of invalidity listed in Article 140k(1) Swiss Patent Act, and thus cannot justify the revocation of an SPC.

This judgment of the Swiss Federal Supreme Court provides long-awaited clarity (and relief) for holders of Swiss SPCs who had to make use of reestablishment of rights in the course of the prosecution of the SPC. Notwithstanding the Federal Supreme Court's opinion regarding the compliance of its findings with the pertinent CJEU case law, it remains to be seen how similar cases will be decided by the national courts of the EU member states and eventually by the CJEU in the future.

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