



FICPI SWEDEN

FICPI Sweden's comments on the European Commission report on the SPC Regulations (SWD(2020) 292 final).

In November 2020, the European Commission published a report on its evaluation of the SPC Regulations (SWD(2020) 292 final). The relevant documents are available at

<https://ec.europa.eu/docsroom/documents/43847>

https://ec.europa.eu/commission/presscorner/detail/en/IP_20_2187

In its conclusions, the Commission says that the main shortcoming of the existing SPC systems is the fact that SPCs are administered and managed at national level which undermines their effectiveness and efficiency. Further, the Commission points specifically to a lack of transparency within the SPC system.

FICPI Sweden has studied the evaluation report and is concerned that the European Commission highlights three objectives of the SPC system which not quite correspond to the objectives set out in the preamble of the Regulation 469/2009. According to the EU Commission, the objective of the SPC Regulation is to (i) promote innovation for new active ingredients; (ii) attract R&D centres to the EU, thereby preventing delocalisation; and (iii) build a uniform SPC framework at EU level, whereas the objectives set out in recitals 4 and 9 of the Regulation 469/2009 focus on compensating the patentee for the loss of effective patent term due to the long period of time between the filing of a patent application and the authorisation to place the medicinal product on the market.

It is the opinion of FICPI Sweden that, overall, the European Commission's evaluation does not appear to take into consideration the basic purposes of the patent protection. Neither does the report discuss what challenges lie in using of the patent system for other objectives than those for which patent protection was created. Further, it appears that the Commission does not consider that SPCs are available also for national patents and that EU wide patents are not available. A centralized authority to handle SPC applications would therefore be challenged with patents in all languages in the EU, and it would mean that the national competences regarding SPC protection would be affected.

FICPI Sweden hopes for an open and transparent process, and a stronger focus on the patent protection offered by an SPC, if the EU Commission considers such radical changes to the SPC system.

FICPI Sweden is the Swedish national association of FICPI (the Fédération Internationale des Conseils en Propriété Intellectuelle), which is an international organization with members from more than 80 countries. FICPI represents patent and trademark attorneys in private practice and handles issues related to their work, both the practical day-to-day work and legislative issues worldwide, including both traditional trademark protection as well as name and origin protection in general, both for the sake of the interest of owners of the specified rights as well as for the safe of customers.