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SPCS IN FRANCE: AN UNCERTAINTY DISAPPEARS AND A FEW DAYS APPEAR

Patent Law | 02/03/18 | François Pochart



The French National Institute of Industrial Property (INPI) has just dispelled doubts by means of an official statement^[1]: it is now possible for holders of a supplementary protection certificate (SPC), issued in France before October 6, 2015, to require extension of their protection duration.

The conditions are simple: (1) the SPC shall still be in force, (2) the marketing authorization (MA) used as a basis for the SPC shall be a community MA.

Since the Seattle Genetics judgment^[2] of the Court of Justice of the European Union (CJEU), the INPI calculates the duration of the SPCs requested on the basis of a community MA by taking into account the date of notification of grant of the MA, as published in the Official Journal. Its former practice, consisting of taking into account the MA grant date, has been finally waived. As a result of this change of calculation, an extension of up to several days of the duration of protection conferred by the SPC might occur.

The official statement of the INPI for granted SPCs aligns with the actual practice for SPCs under examination. Until now the INPI communicated that it was not able to amend the grant decision, or to correct the term of the SPC indicated in the grant decision. The INPI nevertheless had proposed a compromise: it allowed recordal of the date of notification of grant of the community MA in the National Patents Register, but as it was then indicated "for information purposes only".

The injustice for the holders of SPCs granted before October 6, 2015 and still in force is thus removed by this official statement. The reason of this turnaround is the Incyte^[3] judgement of the CJUE.

In this decision the CJEU affirms that the concerned SPC holders should have the possibility of an appeal in order to obtain correction of the duration indicated in their certificate, as long as the SPC has not expired.

The INPI has decided to respect the terms of this decision by proposing a slight formalism. Correction may be requested by the SPC holder registered on the National Patents Register, in the form of a simple request, accompanied by a copy of the publication in the Official Journal of the date of notification of the concerned community MA. The INPI therefore now applies what was regarded as impossible few months ago... the INPI having rejected requests to correct expiration dates of SPCs on the basis of French administrative law.

One can wonder whether the requests presented according to the previous official statement are sufficient or if it is necessary to proceed via a new request specifically aiming at fulfilling this official statement's conditions and the Incyte judgment. We would advise that carefullness is essential and that the SPC holders should file a new request.

In order to ensure legal certainty of third parties, the request will be recorded in the National Patents Register and a mention will be added to the Official Bulletin of the Industrial Property. The INPI patents database^[4], accessible online, will also indicate the corrected expiration date of the SPCs.

The notification date is available on the European Commission website, in the section dedicated to the Community Register of the drugs^[5].

The possible prolongation of an SPC, even by a few days, is good news for the pharmaceutical industry and the SPC holders, given the daily turnover of some proprietary medical products.

The INPI does not indicate any time in its official statement, except for the expiration date. However as the Incyte judgment refers to an "appeal", it may be that the 5 years limitation period applies. We thus recommend to file the request for correction of the SPC term within a period of 5 years from the date of the Incyte decision, namely before December 20, 2022.

[1] <https://www.inpi.fr/fr/nationales/communique-relat...>

[2] C-471/14 October 6, 2015 which ruled "the 'date of the first authorisation to place the product on the market in the [European Union]' within the meaning of that provision is the date on which notification of the decision granting marketing authorisation was given to the addressee of the decision."

[3] C-492/16, December 20, 2017



[4] <https://bases-brevets.inpi.fr/fr/accueil.html>

[5] <http://ec.europa.eu/health/documents/community-reg...>
