“CORRECTION” OF EXPIRY DATES FOR GRANTED SPCS NOW FINALLY POSSIBLE IN ITALY - SOMETIMES!

The Italian PTO Board of Appeal has just rendered a milestone decision making it possible, in practice, to “correct” the expiry date of a granted Italian SPC when the “correction” entails the shortening of the duration of the SPC. This decision is evidently relevant e.g. for all those cases, where at the time of SPC grant, the expiry date was calculated on the basis of an EMA or EU marketing authorization but where the 1st marketing authorization in the EEA was actually a Swiss marketing authorization also applicable in Liechtenstein.

Prior to the Board of Appeal decision, the Italian PTO had regularly taken the position that it was not authorized to correct the expiry date of a granted SPC, explaining that neither the relevant SPC regulations nor the Italian IP Code contain any provisions relating to the correction of granted SPCs or IP rights, respectively.

Thus, the practice of the Italian PTO had been to reject all requests for correction of the expiry date for granted SPCs, regardless of whether such correction would result in an SPC with a shorter duration (e.g. following the CJEU judgment in the C-207/03 and C-252/03 Novartis and others cases and the order in the C-617/12 AstraZeneca case) or a longer duration (e.g. following the CJEU judgment in the C-471/14 Seattle Genetics case).

Contrary to this, in its decision dated April 10, 2017 and published this week, the Board of Appeal has held that it is possible to request a limitation of the duration of a granted SPC [which will thus translate, in practice, into a correction of the SPC expiry date], by applying the Italian IP Code provisions relating to the limitation of granted patents, by analogy.

Specifically, the Board of Appeal held that SPCs are rights that are strictly connected to the basic patent in that they are aimed at extending its duration. As a result, when it comes to SPCs, a limitation of the patent protection (which is per se allowed by the IP Code) can only be directed at its duration, which represents the subject-matter of the exclusive right conferred by the SPC. The Board of Appeal also considered that the Italian IP Code provision relating to limitations must be read in such a way as to not hinder anything that might result in the elimination or reduction of the patent monopoly to the benefit of free competition.

The Board of Appeal thus concluded that the renewed determination of the duration of an SPC to reduce such duration cannot be excluded on formal grounds, such as the absence of a specific provision in the SPC regulation on SPCs for medicinal products.

In its decision, the Board of Appeal has also explicitly emphasized that the above finding will make it possible to align the duration of Italian SPCs with the principles established in the CJEU case law, specifically in the Novartis and others judgment and the AstraZeneca order.

With this decision, it appears that Italy is now part of the bloc of EU countries that allow for the administrative “correction” of the expiry date of granted SPCs, even if only when such “correction” entails a reduction in the SPC duration.