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## European Court of Justice introduces new opportunity for SPCs

On December 8, 2011 the European Court of Justice (ECJ) has finally issued a long-awaited ruling (case C-125-10) answering a very important question which will likely open the door to the possibility of obtaining prolonged patent protection in situations where such prolongation was excluded until now.

In fact, according to the current European legislation, the owner of a pharmaceutical patent can prolong the duration of its patent by filing a supplementary protection certificate (SPC). This SPC prolongs the duration of the patent by a period corresponding to the period that elapsed between the patent filing date and the date on which the patented product was authorized as a medicinal product, reduced by five years. This means that, in a first scenario, if the elapsed period is of 6 years, the SPC extends the patent duration by 1 year. If however, in a second second, the elapsed period is of 4 years and 8 months, the SPC does not extend the patent duration as in this example, in mathematical terms, the SPC has a negative duration of 4 months.

Until now, anyone finding himself in the second scenario would not have applied for an SPC, as the SPC would not have brought any advantage in terms of prolonging the duration of the patent.

However, with the ruling of December 8, 2011 the ECJ has established that "*medicinal products can be the object of the grant of a supplementary protection certificate where the period that has elapsed between the date of lodging the basic patent application and the first marketing authorisation in the European Union is less than five years*", thereby opening the door to the possibility of obtaining SPCs with a negative duration.

The relevance of this decision lies in the paediatric extension to SPCs, recently introduced by way of a European legislation providing rules and incentives for carrying out clinical studies in paediatric populations. According to this legislation, if a company conducts such clinical studies, and owns an SPC, it is rewarded by means of an additional 6-month extension to the duration of the SPC.

The ECJ decision of December 8, 2011 thus enables pharmaceutical companies which conduct clinical studies in pediatric populations to possibly obtain a (small) prolongation of their patent even in those cases where the elapsed period is less than 5 years. Going back to the second scenario above, in that scenario the original SPC will still have a negative duration of 4 months in the future, but if the SPC owner then receives the paediatric extension upon completion of clinical studies in pediatric populations, he will end up with an SPC conferring a 2-month prolongation of the patent. The ECJ ruling is therefore important because it appears to clarify that PTOs may grant "negative term" SPCs despite their term being negative indeed, with a view to allowing SPC owners to obtain the paediatric extension, and thus obtain some prolongation of their patent, if they conduct the relevant clinical trials.

It thus appears likely that this ECJ ruling will have a significant impact on the number of SPC applications filed and granted, which number will likely increase as a result of the new filing of many negative term SPCs whose negative duration is less than 6 months.