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The Post-Brexit IP Landscape: SPCs

Supplementary protection certificates (SPCs) allow for up to five and half years of additional patent protection for a medicinal product that has been authorised to be placed on the market in a particular territory.

On 1st January 2021, the transition period that ran for the 11 months following the UK's exit from the European Union (Brexit) came to an end. This brought with it some important procedural changes to how SPC applications are processed in the UK.

As background, Brexit involved some complicated negotiations around Northern Ireland and resulted in the "Protocol on Ireland and Northern Ireland", which was put in place to prevent a hard border being introduced between Ireland (part of the EU) and Northern Ireland (part of the UK), as that would be in contravention of the 1998 Good Friday agreement.

The Protocol means that Northern Ireland is subject to a limited number of EU rules, despite being part of the United Kingdom, such as rules applying to goods entering and exiting Northern Ireland, including medicines.

Before the end of the transition period SPCs, although applied for and enforced on a national basis, were part of EU legislation and any court proceedings were appealable to the CJEU.

The UK's SPC processes and laws will remain largely unchanged following Brexit. As under the EU SPC provision SPC applications still require a granted UK or EP(UK) patent and a marketing authorisation (MA) that is valid in the UK (or part thereof – see below).

If a product has a European MA issued (by the European Medicines Agency (EMA)) before 2021, the MA will have been grandfathered into UK law such that the product remains authorised for use in the UK as a whole. Any MA issued after 31 December 2020 will NOT cover the whole of the UK, and this is where SPC applicants need to be aware.

An SPC based on a UK patent can now be applied for on the basis of one of three types of marketing authorisations: an EMA issued MA that covers NI; a UK issued (by the Medicines and Healthcare products Regulatory Agency; MRHA) MA that covers Great Britain (England, Scotland and Wales) or a European MA issued before 2021.

Extra attention is needed when we look at the territories of the UK that these different MAs cover. A European MA issued after 31 December 2020 will only cover Northern Ireland and not Great Britain. An MA issued by the MHRA will only cover Great Britain and not Northern Ireland. An EMA MA issued prior to the end of the transition period will cover the whole of the UK.

The law governing SPCs requires that an application for an SPC is made within 6 months of the grant of the patent, or the issuance of the MA for that territory, whichever is latest. The latter point is important; any SPC for *any part* of the UK is now considered to be the earliest MA for *everywhere* in the UK, i.e. the deadline for applying for an SPC at

the UKIPO may be triggered by an MA issued by the EMA if this is earlier than an MA issued by the MHRA. So an SPC based on a UK patent must be applied for within 6 months of the European MA if this is issued first.

Important to note also is the scope of the granted SPC will only cover the same territory of the UK as the MA covers (i.e. GB or NI). However, the SPC applicant may apply to have the scope extended within 6 months of the grant of the MA for the remainder of the UK.

Similarly, paediatric extensions will only cover part of the UK, depending on which territory the Peadiatric Investigation Plan covers.

In short, this means an SPC based on either of the MAs that cover part of the UK will not give full UK SPC coverage. Therefore, SPC applicants should be aware of two deadlines if they wish any SPC to cover the whole of the UK; six months from the date of the European issued MA *and* six months from the date of the UK issued MA.

For any further information or assistance with your SPC applications, please contact Alison Care, who leads the European Life Sciences practice at Haley Guiliano.

By Alison Care