

Legal Framework Applicable to Supplementary Protection Certificates and Pediatric Extension in the UK following the Northern Ireland Protocol

December 31, 2020

From January 1, 2021, the UK Supplementary Protection Certificates (SPC) system will operate in a way that will be similar as possible to the current regime, while adjusting to reflect the new marketing authorizations that will be valid in the United Kingdom as a result of the Northern Ireland Protocol.

The UK framework for SPCs will largely remain unchanged after the Brexit transition period, as the existing EU SPC regulations will be preserved as retained EU law under the EU (Withdrawal) Act 2018. Some relatively minor amendments were introduced by the Patents (Amendment) (EU Exit) Regulations 2019 to ensure that the retained EU law could operate effectively. To obtain a UK SPC, applicants must have a valid patent and a marketing authorization in the United Kingdom. This will be facilitated after the transition period by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, which ensure that all current centrally approved EU marketing authorizations will automatically become Great Britain Marketing Authorisations on January 1, 2021. Importantly, [guidance](#) issued by the UK Intellectual Property Office titled “Supplementary protection certificates from 1 January 2021” confirms that the duration of the SPC will remain unchanged post-transition and that the SPC calculation will continue to be based on the first authorization to place the product on the market in either the United Kingdom or the European Economic Area. Additionally, the six-month pediatric extension of the SPC for conducting the pediatric studies in accordance with a pediatric plan will still be available.

However, adjustments to how the UK SPC system will operate from January 1, 2021, were necessary to reflect the new types of marketing authorizations that will be valid in the United Kingdom as a result of the Northern Ireland Protocol. These changes have been introduced by the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020, which amend the Patents Rules 2007 (SI 2007/3291), the Patents (Amendment) (EU Exit) Regulations 2019 (SI 2019/801), Regulation (EC) No 469/2009 in relation to SPCs for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council of July 23, 1996. The UK has also retained the “manufacturing waiver” that allows a third party to manufacture a medicine protected by an SPC without the consent of the SPC holder for the purpose of exporting the product outside the UK and the EU as well as stockpiling six months prior to the SPC expiry for sale once the SPC has expired in the UK and the EU.

After the transition period, under the Northern Ireland Protocol, Northern Ireland will continue to be bound by the EU frameworks for medicines, veterinary medicines, and plant protection products, while Great Britain will not be. As a result, new marketing authorizations will be introduced in the UK that are valid for only part of the territory of the UK. This necessitates changes to how the UK SPC system operates from January 1, 2021, because one of the qualifying criteria for a UK SPC is that the applicant must have a valid marketing authorization for the UK. The changes to the legislation will allow SPCs to be granted based on any marketing authorization (UK/GB only/NI only) that allows the patented product to be placed on the market in any part of the United Kingdom after the transition period, provided that the application meets the statutory requirements. The protection provided by the SPC will only extend to the territory covered by the marketing authorization. Protection can be extended to the whole of the UK if a further valid marketing authorization for the same product covering another part of the UK is granted before the SPC comes into force. Note that the pediatric extension will have effect only in the territory where the legal requirements for pediatric extension have been met.

Although the adjustment of the UK SPC system was necessary to ensure that the criteria for a UK SPC are workable in practice when the Northern Ireland Protocol comes into effect, this situation may lead to distinct duration of intellectual property regulatory rights protection (i.e., SPCs and pediatric extensions) among the UK territories.

CONTACTS

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

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