

Regulator Assessment: Qualifying Regulatory Provisions

Title of proposal	Guidance on invalidity and surrender of Supplementary Protection Certificates
Lead Regulator	Intellectual Property Office (IPO)
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Date of assessment	27/03/2017
Commencement date	12/09/2016
Origin	Domestic/EU
Does this include implementation of a Cutting Red Tape review?	No
Which areas of the UK will be affected?	All

Brief outline of proposed new or amended regulatory activity

Supplementary protection certificates (SPCs) are a sui generis IP right created under EU Regulations. They provide an additional period of protection for patented pharmaceutical and agrochemical products that have been subject to regulatory approval before being allowed to be placed on the market. Because of the delays caused by the regulatory process, such products are not considered to benefit fully from the protection afforded by a patent.

The Intellectual Property Office (IPO) is the UK body responsible for examining applications for SPC protection and granting the resultant IP right. As part of its role, it maintains a register of SPCs which, among other benefits, allows third parties to see what products are protected and determine what they can legally do.

An average of 55 applications for SPC protection are made per year, with 100-160 being in force in any given year. Whilst these numbers are small, the protection itself is considered to be very valuable to the companies involved (although no quantitative data is currently available on the value of SPCs).

SPC protection requires a valid patent to have been in force at the point the protection starts. If the patent is declared to be invalid by the courts, the SPC has no underlying support and is itself invalid as a result. However, because the IPO is not required to be informed when an SPC is made invalid in this way, its register may still identify it as a valid right.

A rightsholder may try to surrender their SPC while proceedings before the court are underway. Rightsholders are required by law to inform the IPO of any active proceedings when requesting surrender of their right, so that the outcome of the proceedings can be awaited before the IPO

goes ahead to action the surrender – this is because surrender and invalidation have different legal effects that can conflict or create uncertainty if the former is allowed to proceed ahead of the latter.

Following situations where these issues arose, this guidance provides information on new IPO processes which will check the status of the underlying patent before an SPC enters into force, to reduce the possibility of an SPC being listed as valid on the IPO register when the underlying patent has been declared invalid. It also reminds businesses of their existing legal obligation to inform the IPO of any proceedings in progress when applying to surrender an SPC.

Which type of business will be affected? How many are estimated to be affected?

Whilst SPCs relate to the life sciences industries, the guidance will be viewed and used by legal professionals – either in-house lawyers or external agents retained by the rightsholder to administer their IP rights, including SPCs. The direct impact of this guidance will therefore be on these areas, rather than the business as a whole.

Summary of costs and benefits						
Price base year	Implementation date	Duration of policy (years)	Net Present Value	Business Net Present Value	Net cost to business (EANDCB)	BIT score
2016	12/09/2016	Indefinite	Zero	Zero	Zero	Zero

Please set out the impact to business clearly with a breakdown of costs and benefits

The cost of reading and understanding the guidance is estimated at £1k. The guidance totals 778 words, with an estimated reading speed of 150 wpm, as it is slightly more complex than standard prose. Legal professionals who view the guidance have a wage rate of £30.15 ASHE incl. uplift, and there have been 169 external views since launch (estimate 313 for a full year).

The new IPO processes have no direct impact on business; however, there may be an indirect cost associated, as any SPC identified as not being valid will be reported to the rightsholder or their agent, who may enter into correspondence with the IPO to resolve the issue. This will require additional legal resource and advice on how to proceed. Because this would depend on the individual case, and data is not available on the average time to resolve this issue, it is not possible to estimate the amount of time that may be involved or the resultant cost to business.

This guidance may provide a saving to third parties, as they would not have to challenge an invalid SPC in order for the IPO to update its register. However, such challenges very rarely happen (as they are more likely to form part of wider litigation), and there is no data on the cost of such actions or the time taken in preparation and participation. As a result, savings stemming for this, if any, are unlikely to be significant.

The more likely saving for third parties will be in having greater assurance as to the status of SPCs in the UK based on the IPO register, and so not needing to undertake

additional work to determine their freedom to operate (for example, searching for court decisions relating to the underlying patent, checking other registers). However, determining what additional work would have been undertaken otherwise and quantifying the cost saving is considered to be disproportionate to the scope of the guidance; it is also likely that businesses will be reluctant to provide details of their legal assurance processes in this area, and we may not get useful data out.

In addition, as these third parties are often other businesses in the same industry, many of which hold SPCs of their own, these two sets of costs and benefits are likely to – in a broad sense – cancel out.

This guidance is considered to be a small and permissive change, as the parts of the guidance that impact business provide no mandatory legal obligation – at most, they remind business of an obligation they should already be meeting.

Despite lacking monetisation evidence, we are reasonably confident that the total cost is less than £50k, and so we consider this guidance to have a zero EANDCB.

Please provide any additional information (if required) that may assist the RPC to validate the BIT Score