PARLIAMENTARY DEBATES

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OFFICIAL REPORT

Eleventh Delegated Legislation Committee

DRAFT SUPPLEMENTARY PROTECTION CERTIFICATES (AMENDMENT) (EU EXIT) REGULATIONS 2020

Thursday 19 November 2020

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The Committee consisted of the following Members:

Chair: Ms Nusrat Ghani

† Aiken, Nickie *(Cities of London and Westminster)* (Con)
† Bacon, Gareth *(Orpington)* (Con)
Barker, Paula *(Liverpool, Wavertree)* (Lab)
† Charalambous, Bambos *(Enfield, Southgate)* (Lab)
† Fletcher, Mark *(Bolsover)* (Con)
† Henry, Darren *(Broxtowe)* (Con)
† Hunt, Tom *(Ipswich)* (Con)
† Kawczynski, Daniel *(Shrewsbury and Atcham)* (Con)
† Onwurah, Chi *(Newcastle upon Tyne Central)* (Lab)
Osborne, Kate *(Jarrow)* (Lab)
† Sambrook, Gary *(Birmingham, Northfield)* (Con)
† Solloway, Amanda *(Parliamentary Under-Secretary of State for Business, Energy and Industrial Strategy)*
Tarry, Sam *(Ilford South)* (Lab)
Thompson, Owen *(Midlothian)* (SNP)
† Tomlinson, Michael *(Lord Commissioner of Her Majesty's Treasury)*
† Webb, Suzanne *(Stourbridge)* (Con)
Whitley, Mick *(Birkenhead)* (Lab)

Seb Newman, *Committee Clerk*

† attended the Committee

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Thursday 19 November 2020

[Ms Nusrat Ghani *in the Chair*]

Draft Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020

11.30 am

The Parliamentary Under-Secretary of State for Business, Energy and Industrial Strategy (Amanda Solloway): I beg to move,

That the Committee has considered the draft Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020.

It is a pleasure to serve under your chairmanship, Ms Ghani. Intellectual property forms a vital part of the UK economy. A well-balanced IP system supports our citizens in their creativity and ingenuity, provides incentives for companies to innovate through research and development, and ensures that great research and ideas can be turned into great businesses.

Supplementary protection certificates are an important part of the framework supporting our life sciences industry. The sector is one of the UK's most valuable industries and is crucial to our success as a science superpower. It has consistently been the largest investor in research and development in the UK, investing more than £4.5 billion in 2018.

Developing new drugs is expensive. The Association of the British Pharmaceutical Industry estimates that the cost of doing so may exceed £1 billion. It also takes time to reach the point where the drug has been tested and proven to be safe and can be placed on the market. Where a product is protected by a patent, that means that the time during which the holder can benefit from its exclusive rights is reduced. SPCs therefore provide an additional period of protection for patented medicines and pesticides to address that. They give the innovator more time to recoup the costs using those exclusive rights, and they protect some of our most innovative drugs.

The SPC system is also designed to strike a balance between supporting the development of novel drugs and ensuring that those drugs become available more cheaply through competition from generics in good time. It enables the NHS to benefit from innovative new medicines and the wide availability of existing treatments. It is therefore important that any changes to the system recognise and take account of that balance. The SPC system is based on EU legislation, although the right itself is examined and granted on an individual national basis.

The Government have already made a number of changes to the SPC regulations in advance of their being retained in UK law at the end of the transition period. Members of the Committee may recall that we debated some of those changes a few weeks ago. The fixed efficiencies would have existed in the retained EU law when it was brought across.

Why is further legislation necessary? This instrument comes about as an indirect effect of the Northern Ireland protocol. The additional protection provided by an SPC is granted as a result of the patented medicine or agrochemical receiving approval to be sold in the UK market and market authorisation. The connection with the regulatory system is therefore crucial to how the SPC legislation works.

As the Committee knows, the protocol is intended to ensure that there is no hard border between Northern Ireland and the Republic of Ireland. To accomplish that, the protocol sets out that certain EU laws, including those relating to the movement of goods, continue to apply in Northern Ireland for as long as the protocol has effect. For medicines and pesticides, that means that marketing authorisations in Northern Ireland must be granted accordance with EU law, whereas Great Britain will follow separate legislation. That will not, however, prevent a product from being marketed on a UK-wide basis.

Given the relationship between SPCs and the regulatory system, further changes are needed to the SPC legislation to ensure that the arrangements arising from the protocol are properly reflected. The Intellectual Property Office has been working with regulatory agencies to understand those arrangements and integrate them into the SPC system. This instrument is the result.

The instrument will ensure that the SPC remains a UK-wide intellectual property right. There will be no separate SPCs for Great Britain and Northern Ireland. If a patented product has been authorised for sale somewhere in the UK, whether in Great Britain, Northern Ireland or the UK as a whole, an SPC may be granted. However, the protection provided by the SPC will extend only to the territory in which the product has been authorised. That preserves the link between the SPC and the approval for the product. Otherwise, the additional protection of the SPC would be provided in the UK where no protection had been given, which would go against the principle of the SPC system.

If another authorisation is granted for the product in a different part of the UK, the protection provided by the SPC can be extended to cover that territory, but the legislation makes it clear that that would be allowed only up to the point that the patent expires and the granted SPC takes effect. That gives certainty for all. It would not be fair for a third party to find that legitimate action, which had been taken in a territory where protection did not extend, suddenly became an infringement at a later date. That is why the scope of protection is fixed in place when the SPC comes into force.

The process of getting an SPC will remain largely unchanged. Applicants will use the same forms and pay the same fees, and have their applications examined by the IPO using the same principles. Applicants will need to notify the IPO of other authorisations if they want to extend their SPC protection. Although the information required will be essentially the same as that for the initial application, we recognise that that is an additional administrative task.

The IPO will ensure that clear guidance is in place to explain the changes and the actions that business needs to take. That work is already in progress. The guidance will be published in the next few weeks, should Parliament approve the legislation. Any changes to the statutory forms will be in place for 1 January.

Giving business the clear guidance and support it needs is important. That relates to another IP issue that some hon. Members and many IP professionals are interested in, namely the IPO's address for service rules. I am pleased to announce that today, the Government are publishing the response to a recent call for views and will shortly lay legislation to require a UK address for service for new applications and new proceedings before the IPO. That will level the playing field for UK patent and trademark attorney professionals as we leave the EU IP systems.

My officials have collaborated with the major representative bodies on ways to communicate all the changes, such as by taking part in industry webinars. Those bodies have been engaged in the development of the legislation and are in a strong position to help to disseminate our guidance and provide advice to their members.

In conclusion, the instrument will ensure that the SPC system works alongside the regulatory system when the transition period comes to an end, which will give certainty to our innovative businesses in the important field of technology and maintain the fine balance that is critical to the success of the complex area of IP law. I commend the regulations to the Committee.

11.37 am

Chi Onwurah (Newcastle upon Tyne Central) (Lab): It is a great pleasure to serve under your chairmanship for the first time, Ms Ghani, and to follow the Minister—not for the first time. I welcome her opening remarks and I share her support for the United Kingdom's world-beating life sciences sector and the fantastic innovation that it shows, for which we are particularly grateful as we face the pandemic. I agree that patents must recognise the balance between rewarding innovation and ensuring the diffusion of the often life-saving treatments, medicines and products that they protect. I also welcome the levelling of the playing field for IP attorneys, about which we have corresponded.

The UK's relationship with its closest neighbours following the end of the transition period is yet to be decided. The Government's ongoing negotiations are causing confusion and uncertainty for businesses across the United Kingdom. The shadow Northern Ireland Secretary, my hon. Friend the Member for Sheffield, Heeley (Louise Haigh), set out yesterday the immense frustration in Northern Ireland at the Government squandering vital time to prepare for the biggest changes that it has ever known in its trading relationship.

The Opposition wish to do everything we can to ensure effective preparation, certainty and readiness, so we will not oppose the statutory instrument and we welcome the measure of certainty that it provides. I have some brief questions, however.

As the Minister set out, following the end of the transition period and the introduction of the Northern Ireland protocol, the way in which some patent medicines and agrochemicals are regulated will change. New marketing authorisation procedures will therefore be required for those products in certain parts of the United Kingdom. The European Union's SPCs apply to specific pharmaceutical and plant-protection products. They are designed, as the Minister said, to offset the loss of patent protection by products that occur due to the compulsory and, rightly, often lengthy testing in clinical trial phases, and are valuable intellectual property rights, taking effect when a patent expires.

The draft statutory instrument will change the existing legislation on SPCs and the authority of marketing authorisations across the whole UK. At present, two marketing authorisations are valid in the UK: the European Medicines Agency and the Medicines and Healthcare Products Regulatory Agency. Post-Brexit, marketing authorisations from the EMA will need to be converted into the UK equivalent. However, under the Northern Ireland protocol, Northern Ireland will remain bound by the EU law for the authorisation of medicines and agrochemicals, meaning that there will be separate marketing authorities for Northern Ireland and Great Britain.

Will the Minister provide the Committee with examples of the companies and products that she envisages will take advantage of this situation? Having spoken to the IPO, I know that a limited number of SPCs are granted generally—there are only 70—but the Committee would benefit from some examples so that we can know how the legislation will be used. I note that an impact assessment has not been undertaken, because of the limited impact, but we would benefit from understanding how the Government envisage the SI being used.

The SI will allow an SPC to be granted based on whichever authorisation the applicant has at the point of application. If the SPC enters into force with a marketing authorisation covering only one of either Great Britain or Northern Ireland, the protection provided by the SPC extends only to that territory, as the Minister set out. An applicant may submit an additional marketing authorisation allowing protection to be extended to the whole of the UK.

Ensuring minimum friction between Northern Ireland and Great Britain is of the utmost importance. The Prime Minister promised exactly that just over 12 months ago. My understanding—this follows on from my first question, and I discussed it briefly with the Intellectual Property Office as well—is that the draft statutory instrument could lead to drugs and agricultural products being available in Northern Ireland under different conditions and circumstances from Great Britain, in terms of whether they can be reproduced or generic equivalents can be sold.

A general impact assessment has not been performed, so I would like to know whether the Government have looked at the implications. If drugs are available under different rules, in different circumstances or with the different extent of a patent in Northern Ireland and in Great Britain, is there a possibility of that causing issues, advantages or incentives for trade or movement between Great Britain and Northern Ireland? Will the Minister reassure us that that has been considered?

Finally, will the Minister, representing the Government, provide a commitment to firms that trade in medicines and agrochemicals between Great Britain, Northern Ireland and the Republic of Ireland that the rules and regulations will not change in how they evolve, in order to provide long-term security to British and Irish businesses? The Labour party will not oppose the draft SI, and we are happy to work with the Government in future to ensure the safety of agricultural and medicine products, as well as frictionless trade between all the nations in the United Kingdom.

11.44 am

Amanda Solloway: I thank the Committee for consideration of the draft regulations. I also thank the hon. Member for Newcastle upon Tyne Central for her useful comments, as always.

As I have said in earlier debates, intellectual property matters. The IP system exists to encourage innovation and the sharing of information and knowledge. It provides individuals and businesses with the confidence to invest their time, money and energy in developing something new, whether it be a new business, book or piece of technology. The UK IP system is consistently rated as one of the best in the world.

As the hon. Lady will recall from only a few weeks ago, the World Intellectual Property Organisation recently ranked the UK the fourth most innovative country in the world. The Government are committed to ensuring that we maintain and improve our world-leading position. Innovation will be crucial in the years ahead to support our recovery from the impacts of covid-19, especially in life sciences, where treatments and vaccines will be key to bringing us closer to normal.

The hon. Lady asked several important questions about SPCs and the Government's approach with the draft instrument. I am happy to give some further explanation. On the duration of the rights and whether that will change, the calculation remains the same. SPCs last for up to five years, depending on how long has been taken to approve the product. Between the remaining life of the patent and the SPC, the result is a maximum of 15 years of effective IP protection. That is part of the balance of the system and will not be affected by the amendments in the SI.

On who benefits from the rights, SPCs are granted to the patent holder, which is usually the developer of the original product. SPCs are often held by companies—such as, given that the hon. Lady asked for examples, AstraZeneca and GlaxoSmithKline—but smaller enterprises such as research universities and their spin-off companies also benefit from the protection given by SPCs.

On whether an SPC that provides protection only in Northern Ireland might allow a company to sell a generic product in Great Britain, in most cases we expect pharmaceutical companies to file for authorisations across the UK so that their SPC protection is UK-wide. However, where an SPC provides protection not only in part of the UK—say, Northern Ireland—it could not be used to prevent manufacture or sale of the drug in GB. Other forms of IP protection such as data and market exclusivity might still apply in GB, and any generic medicine would need to be authorised in its own right before it could be sold.

This summer, the Government set out their long-term objectives for research and development through the new R&D road map. We are committed to further strengthening science, research and innovation across the UK, making them central to tackling the major challenges that we face. IP and the Intellectual Property Office have important roles in support of those objectives. The IPO will continue to deliver high-quality rights, grant services, lead best practice in enforcement of IP rights, and retain its central involvement in international discussions on the development of the global IP system. The draft regulations form part of that work, ensuring that the IP system is in a good place to support the Government's goals for innovation, so that the UK is the best place to develop and grow innovative businesses. I hope that the Committee will support the instrument.

Question put and agreed to.

The Chair: Please will Committee members leave the room promptly by the exit door while observing social distancing?

11.48 am

Committee rose.