PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Twelfth Delegated Legislation Committee

DRAFT PATENTS (AMENDMENT) (EU EXIT) REGULATIONS 2018

DRAFT TRADE MARKS (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2018

Thursday 17 January 2019

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Monday 21 January 2019

The Committee consisted of the following Members:

Chair: Sir Henry Bellingham

† Duffield, Rosie *(Canterbury)* (Lab)
† Esterson, Bill *(Sefton Central)* (Lab)
† Graham, Richard *(Gloucester)* (Con)
† Harris, Rebecca *(Lord Commissioner of Her Majesty's Treasury)*
† Hill, Mike *(Hartlepool)* (Lab)
† Hollinrake, Kevin *(Thirsk and Malton)* (Con)
† Hughes, Eddie *(Walsall North)* (Con)
† Johnson, Diana *(Kingston upon Hull North)* (Lab)
Jones, Mr Kevan *(North Durham)* (Lab)
† Malhotra, Seema *(Feltham and Heston)* (Lab/Co-op)
† Percy, Andrew *(Brigg and Goole)* (Con)
† Skidmore, Chris *(Minister for Universities, Science, Research and Innovation)*
† Smith, Jeff *(Manchester, Withington)* (Lab)
† Thewliss, Alison *(Glasgow Central)* (SNP)
† Tracey, Craig *(North Warwickshire)* (Con)
† Villiers, Theresa *(Chipping Barnet)* (Con)
† Wragg, Mr William *(Hazel Grove)* (Con)

Anwen Rees, *Committee Clerk*

† attended the Committee

Twelfth Delegated Legislation Committee

Thursday 17 January 2019

[Sir Henry Bellingham *in the Chair*]

Draft Patents (Amendment) (EU Exit) Regulations 2018

11.30 am

The Minister for Universities, Science, Research and Innovation (Chris Skidmore): I beg to move,

That the Committee has considered the draft Patents (Amendment) (EU Exit) Regulations 2018.

The Chair: With this it will be convenient to consider the draft Trade Marks (Amendment etc.) (EU Exit) Regulations 2018.

Chris Skidmore: It is a pleasure to serve under your chairmanship, Sir Henry. Intellectual property is a vital part of the UK's knowledge economy. The Government's ambition, as part of our industrial strategy, is for the UK to be the most innovative country in the world, with a regulatory environment that supports that goal and encourages business to develop new ideas and technologies. The UK is renowned for having one of the best IP regimes in the world, and that will continue to be the case after our departure from the European Union. We will continue to deliver high-quality rights-granting services, lead best practice in enforcing IP rights, and retain our central involvement in international discussions on the development of a global IP system.

The Intellectual Property Office, which I am looking forward to visiting in Newport tomorrow morning, has been preparing for a range of outcomes to our negotiations with the EU. It is working to ensure that the IP system in the UK continues to function effectively once we have left the EU. The regulations, which were laid before the House on 28 November, form part of that preparation. They are necessary to ensure that the patent and trademark systems continue to function properly if no deal is agreed. In doing so, they give as much certainty and clarity for businesses as possible. The draft instruments use the powers granted by the European Union (Withdrawal) Act 2018 to address deficiencies in retained law that would arise upon exit.

On the Patents (Amendment) (EU Exit) Regulations 2018, the majority of UK patent law is domestic in origin or derives from various international agreements. Only a few specific areas are governed by EU legislation, and it is those that this instrument addresses. It focuses on supplementary protection certificates, which are a special type of IP right that applies to patented pharmaceuticals or agro-chemicals, which have to be authorised before they can be sold on the market. Because extensive testing is required to show that those products are safe for use, the authorisation process can prevent the full term of protection given by the patent from being exploited. SPCs are intended to offset that loss of time by giving an authorised product up to five and a half years' additional protection after the expiry of the patent. They are provided by EU regulations that will be retained under the withdrawal Act.

SPCs take effect at a national level, so it will not be necessary to convert or replace existing rights on exit, as UK SPCs will continue to be enforced. However, it is still important to ensure that the current system remains functionally the same, so that users have certainty about the scope of their rights and the conditions in which those rights operate. The instrument therefore makes changes to the retained law, so that the SPC system can continue to operate effectively.

Richard Graham (Gloucester) (Con): I have received a letter from the chief patent counsel of Lilly UK, outlining their concerns about the potential erosion of critical intellectual property protection. The life science industry is worried that patients might not be able to continue to access new and innovative medicines. Will the Minister confirm that the UK will remain a hub for world-leading research in the life sciences?

Chris Skidmore: Absolutely. That is why these regulations are so important in the event of a no-deal exit. Obviously, under the EU withdrawal deal and the framework for agreeing a deal with the EU, those rights will automatically be protected. Pharmaceutical companies with significant research and development industries—companies such as GlaxoSmithKline, AstraZeneca and Pfizer—use the SPC regime. In 2016, nearly £4 billion was invested in research and development through the pharmaceutical industry.

I want to mention some of the individual drugs that have benefited from an SPC regime being in place. The blockbuster anti-cancer drug Humira was initially developed by Cambridge Antibody Technology in the UK. Cervarix from GSK, a vaccine that protects against cervical cancer, had global sales of £123 million in GSK's last quarterly statement. My hon. Friend makes an incredibly valid point. We need certainty and stability to ensure that companies are able to continue to develop future products through R&D. Having this stability will ensure that future products can benefit from coming to market, and from the additional five and a half years' protection that the SPC guarantees.

In particular, the draft instrument confirms that authorisations granted in the UK can continue to be used as the basis for an SPC application, and to determine the duration of an SPC. It also ensures that courts and tribunals competent to decide legal challenges to SPCs in the UK retain that jurisdiction. Other technical adjustments ensure that the SPC system is legally sound immediately after exit, and avoid discontinuity.

This approach of maintaining systems that users are familiar with also applies to other areas of patent law dealt with in this instrument, including the interaction of plant variety rights and the granting of compulsory licences for manufacturing a patented medicine for export to a country with a public health need.

The second statutory instrument before the Committee deals with European trademarks and their continued protection after our exit from the EU. It is currently possible to obtain trademark protection in the UK under the Trade Marks Act 1994, and in the European Union under the European trade mark regulation. The two

systems run in parallel, so protection covering the UK may be obtained under either. There is also a great degree of harmonisation between the systems, so the protection provided is essentially the same.

Around 1.3 million EU trademarks are currently enforced, and around 10% are owned by UK businesses. After our exit from the EU, trademarks registered under EU regulation would no longer cover the United Kingdom, as it would cease to be a member state. To avoid any loss of rights, the Government have committed to the continued protection of EU trademark rights in the UK.

This instrument provides those replacement domestic rights on exit day. These created UK rights will be fully independent UK trademarks, which can be challenged, signed, licensed or renewed separately from the original EU trademark. This instrument also provides that these rights retain their original EU filing date and any other relevant dates relating to the original application.

Richard Graham: This is very important for three of the greatest trademarks in the United Kingdom: single Gloucester cheese, double Gloucester cheese and the Gloucestershire Old Spot pig. Could the Minister confirm that these trademarks will be protected regardless of whether we leave the European Union with a deal?

Chris Skidmore: Absolutely. Trademark protections that are currently in force will continue to be in force, as a result of these regulations. The specific brand names that my hon. Friend talked about are actually what are called agricultural geographical indications—GIs. They fall within the remit of the Department for Environment, Food and Rural Affairs, but we recognise the close relationship between trademarks and GIs, and officials continue to work closely to provide a robust framework across all forms of intellectual property.

The policy on non-agricultural GIs is handled by the Intellectual Property Office. They are protected by the trademark system and therefore will continue to be protected in the UK in the same manner as outlined for trademarks. My hon. Friend, as the MP for Gloucester, cares passionately about protecting the origins of his cheese; having been on this Committee, he can go back to his constituents and tell them that he is doing all he can to protect the trademarking system in the UK, and to ensure stability and continuity for the cheese-making industry—and particularly for his constituents, and for employers in the locality.

The instrument also sets out how applications for EU trademarks that are pending on exit day, of which there are an estimated 85,000, will be handled. Those with pending applications will be able to file a new application with the Intellectual Property Office, claiming the earlier filing date of the EU application, within nine months of exit.

In conclusion, these regulations are a vital part of ensuring the intellectual property system continues to function if the no-deal outcome arises. They are essential for safeguarding rights and to provide maximum certainty and clarity. I commend them to the Committee.

11.39 am

Bill Esterson (Sefton Central) (Lab): It is a pleasure to serve under your chairmanship, Sir Henry. I think this is the first time I have had that pleasure. I look forward to the rest of the deliberations. I think this is the first time that the Minister and I have faced each other as Front Benchers, although we have occasionally crossed swords, if that is not overstating it, on—

Chris Skidmore: The Education Committee.

Bill Esterson: Indeed. The Minister referred to the importance of the intellectual property regime in the United Kingdom. He was absolutely right to state in the terms he used the high regard in which it is held throughout the world. There are key questions for us about maintaining those high standards and that high reputation. In the digital era, that is perhaps more vital for businesses than it has ever been.

The operation of the patent and trademark system after exit day will play a key part in delivering business confidence. I fully welcome the Chancellor's commitment to the business community to ruling out any prospect of no deal; that is most welcome to Opposition Members. I look forward to the Prime Minister's making exactly the same commitment, in order to deliver the certainty for our economy that is so needed and desired by businesses, workers and consumers.

Of course, if we avoid no deal, the regulations before us become less of a challenge, but given that we have to prepare for every eventuality, we need to consider them, as the Minister says. Currently, patent law functions through domestic legislation, while EU law sets out legal provisions on the patenting of biotechnical inventions. That includes exceptions from patenting, the scope of any protection, and a compulsory licensing regime between overlapping patents and plant variety rights.

EU law also provides processes for a compulsory licence to be granted for UK manufacture of a patented medicine for export to a country with a public health need, and sets out an exception under which certain studies, trials and tests can be carried out using a patented pharmaceutical product without infringing the patent. Those provisions are being transposed under these regulations, but in these areas, questions arise to do with patented pharmaceutical products and agro-chemicals, where the EU provides for an additional period of protection after a patent has run out. I ask the Minister to address that.

In the no-deal notice, the Government advised:

> "Supplementary protection certificate holders, applicants for supplementary protection certificates, and third parties may wish to familiarise themselves with any changes to the related regulatory processes (human and veterinary medicines and chemicals)."

What measure have the Government undertaken to promote those among stakeholders, and what progress has been made on certainty regarding the unified patent court? My understanding is that that is an EU-wide agreement, unlike the non-EU European Patent Office, which covers much of what is referred to in this statutory instrument.

As with all the recent SIs relating to no-deal planning, no impact assessment has been carried out of the regulations before us, and only informal consultation has taken place. That is something we have debated a number of times with the Minister's colleague, the Under-Secretary of State for Business, Energy and Industrial Strategy, the hon. Member for Rochester and Strood (Kelly Tolhurst); perhaps the Minister can add this occasion to

[Bill Esterson]

the list. One concern we have raised before, and which I know has been raised in written questions, is the cumulative impact of all these SIs. I draw to the Minister's attention to the fact that there is concern about that within the business community, even if the Government do not see the need for individual impact assessments on specific regulations.

I also ask the Minister to confirm that separate UK and EU registration will be required for applications for intellectual property. Can he confirm what, if anything, is changing in that regard, given that, from my understanding, at present it is a non-EU body that manages EU-wide registration? Perhaps he can clarify exactly what will change in respect of patent applications, given that they are not an EU responsibility.

In relation to EU trademark applications pending on exit day, applicants may file a new UK trademark application within a period of nine months from exit day, maintaining the filing date, priority date, or seniority date. Can the Minister confirm what will happen after that nine-month period, and whether my understanding of the nine-period is indeed right? The draft regulations do not make reference to international trademark registrations or applications. What progress has been made with the World Intellectual Property Organisation to protect existing international registrations? This area is incredibly important, and the protection of IP is of immense value to businesses in the digital era. Getting it right is crucial.

I thank the Minister for his opening remarks, but there are significant questions still to answer about what he seems to think are relatively minor changes. Even minor changes need to be addressed to make sure we get this right. I hope that we will not need these regulations, and I hope that he hopes the same, but we need to get them right in case we do.

11.47 am

Alison Thewliss (Glasgow Central) (SNP): It is a pleasure to serve under your chairmanship, Sir Henry. Having been on lots of financial services SI Committees, I am glad to have a change of scene.

I want to pick up where the Opposition Front Bencher left off. None of us wants these regulations. It seems bizarre that we spend so much time and money debating statutory instruments that we hope we will never have to use; we are in a quite antediluvian situation. I hope very much that in the coming days the Prime Minister will take the threat of no deal completely off the table, given the damage that it would do.

We do not know what damage the statutory instruments before us might do, because there is no impact assessment. The same was true in another delegated legislation Committee I was in last week, where I raised the same issue. As a Member of this House, I am very uncomfortable passing legislation in Committee, away from much scrutiny, without an impact assessment from the Government. For larger pieces of legislation, we would have an impact assessment. For other pieces of legislation, we might also get evidence. I am pleased that Lilly has sent us all a letter, because mostly, when we look at these measures, we have no evidence—only the Government's word. I am not saying the Government's word cannot be trusted, but that is all we have to go on, and that is not good enough for this or any other piece of delegated legislation that we consider. It feels as though these DLs are being rushed through, and the lack of evidence and an impact assessment is deeply worrying.

Turning to the trademark regulations, I understand that when this SI was debated in the Lords, they were not satisfied that it was explicit enough about what would happen if an international trademark were to be challenged in the courts: would it have to be challenged in the UK courts and in the European Court of Justice? Two sets of court actions would certainly mean that there was a greater effect on businesses. The Lords also sought clarity on the consultation process. Paragraph 10.1 of the explanatory memorandum states:

> "In order to ensure that the changes being made would work in practice for users of the system, and would not result in any unintended consequences, the Intellectual Property Office held informal discussions with a small group of selected individuals with expertise in the relevant areas, or in patent law generally, to get feedback on the legal drafting of the instrument. Participants were provided with a draft of the instrument in advance."

Businesses, not just lawyers, should have been consulted on the changes, given the scale of the differences. It is quite worrying.

The draft Patents (Amendment) (EU Exit) Regulations 2018 were also considered in the Lords, where there was similar feedback on the consulting process and the lack of widescale engagement with the legislation. Again, the Government seem to have engaged with people they already know, rather than having consulted more widely on the impact on businesses across these islands. The explanatory memorandum also notes:

> "An Impact Assessment has not been prepared for this instrument because...it is designed to maintain the status quo".

Preparation for a no-deal Brexit is not really the status quo; it is actually something quite different.

IP laws are important for innovation and for subsequent growth within the economy. Industry professionals are concerned that the exclusivity terms for medicine patents would be reduced in the UK. Anecdotally, my hon. Friend the Member for Central Ayrshire (Dr Whitford) has raised this time and again on the Floor of the House and in other places. She is concerned that companies have said that a product would never be launched in the UK before the EU. That could have a serious impact on the competitive advantage to Scotland's life sciences industry, which is an important growth industry in Scotland's economy. She is also concerned about the impact on research and universities if products were no longer produced or trialled here.

My hon. Friend the Member for Livingston (Hannah Bardell) has also raised the issue recently in the House. She has a medicines testing facility in her constituency. She is concerned about where it sits within these measures, because if fewer medicines are trialled and produced here, there will be fewer things to be tested, and that will have an impact on specialist jobs in her constituency.

I understand that Lord Warner raised concerns expressed by the BioIndustry Association, which said:

> "Eroding intellectual property protection whilst also seeking global free trade deals sends a signal to industry that the UK Government may…erode protection as it seeks to quickly conclude deals. This would further impact the industry in the UK and further inward foreign investment."

Scotland does fairly well when it comes to foreign direct investment—it enjoys the highest amount in the UK outside London—so this is a cause for deep concern. We want to be able to be part of that global industry, but not at the price of standards.

It is difficult to accept the Government's assertion that these regulations would have a minimal effect on business; for companies conducting business outside the UK, it simply cannot be the case. It is very clear from Lilly's letter how it will be affected. It says:

"We strongly believe that this statutory instrument must be amended or withdrawn."

How does the Minister intend to deal with its serious concerns? It says:

"IP protection in the UK would be significantly diminished"

under a no-deal Brexit. The letter also laid out other concerns, and they need to be addressed because of the impact on companies, jobs and investment in wider society.

This is in the wider context of rising tensions over intellectual property, especially between the US and China. Scottish firms and consumers need the economic weight of the EU and the protection of the world's largest trading bloc more than ever. Brexit will only reduce the protection of Scottish intellectual property on the world stage. This is a huge concern for universities, which have spin-offs and want to develop new products. I have that in my constituency, at Strathclyde University. It is keen to be innovative, but it needs reassurance on the issue.

To pick up on the concerns of the hon. Member for Gloucester, Scotland has many protected GIs, the most notable being Scotch whisky. It is an iconic industry for Scotland, and we need to make sure that it is not put at risk at any point. Our other GIs include Scottish salmon, Scottish lamb, Scottish beef, Arbroath smokies, Shetland lamb, Orkney beef, Orkney lamb, Bonchester cheese, Stornaway black pudding, Scottish wild salmon, native Shetland wool and traditional Ayrshire dunlop. We have lots of wonderful products in Scotland that we wish very much to protect.

The political declaration says:

"Noting the protection afforded to existing geographical indications in the Withdrawal Agreement, the Parties should seek to put in place arrangements to provide appropriate protection for their geographical indications."

We do not have very long to go; there are 71 days until exit day, if I am correct. Still waiting to see and seeking to put things in place is not really good enough for me, and it is not good enough for the protection of these industries. With under three months to go, it is a disgrace that the Government are only now getting round to the details. Businesses, along with voters, have lost belief in the Government's ability to navigate Brexit.

I reiterate my strong concerns about the lack of an impact assessment. I am not comfortable passing this piece of delegated legislation without it. The Government need to get that put in place. It is a huge concern that we are doing this blindfolded, without an impact assessment to give us an idea of the costs to which the measures would give rise.

11.54 am

Chris Skidmore: Let me address the points made in response to my opening speech. I welcome the continuing support from the hon. Member for Sefton Central for the compulsory licensing regime. He made points about what will change, and about whether the UK's departure from the EU means leaving the European Patent Office and the European patent convention. Obviously, that international agreement is open to both EU and non-EU countries, and the UK is a founding member in its own right. Similarly, the European Patent Office was established by the convention and is not an EU institution. The UK will continue to participate in the EPO as at present, including as a member of the organisation's administrative council. European patents granted by the EPO that have effect in the UK will continue to be granted following our exit from the EU.

The hon. Member for Glasgow Central made a point about trade deals. The UK's intellectual property regime is consistently rated as one of the best in the world. One of our priorities will be to ensure that future trade agreement negotiations do not have a negative impact on the standards and balance of the UK's regime, or on its ability to promote trade in intellectual property. As we leave the European Union, the Government will continue to maintain our high level of protection of intellectual property, in line with our World Trade Organisation commitments. Any future trade deal negotiated by the UK will seek to be consistent with the UK's membership of the international property conventions to which we are party.

The hon. Lady also mentioned the erosion of IP rights. We understand that innovators are concerned that the SI could mean a shorter effective period of protection in future, were they to bring their product to the UK market later than to the European economic area. The goal, however, is to minimise disruption; introducing a new way of calculating SPC would not provide the certainty and continuity that businesses tell us that they need, and could have unforeseen consequences. It would not be appropriate to make such a change without a full analysis of possible options and their effects. Above all, businesses tell us how important the current SP regime is to them.

The hon. Member for Sefton Central mentioned the pharmaceutical industry. It is important to reflect that the BioIndustry Association and the Association of the British Pharmaceutical Industry have both said that SPC protection as it stands is

"key to incentivising the lengthy, risky and expensive process of pharmaceutical and biotech innovation. European benefits from a high standard of IP incentives in the form of SPCs."

I gave examples earlier of some of the drugs for which SPC protection has been critical.

On the points made about consultation, the IPO conducted a confidential technical review of the draft legislation in the summer, to which it invited individual experts who had previously interacted with the IPO as part of their roles with relevant representative organisations or bodies. The IPO received useful feedback on the drafting, and on wider matters that were raised and fully discussed. That process helped to make the draft legislation better, and we appreciate the time and effort that those individuals put into it.

That is consistent with the approach being taken with respect to no-deal legislation across Government. The Government's consultation principles are clear: consultations must have a clear purpose. The statutory instruments only make corrections to retained EU law, and are necessary to give the UK a functional statute

[Chris Skidmore]

book in the event of a no-deal exit. Consultation on wider policy changes would not have been meaningful or appropriate at this point in time, as that is not what the instruments do. As I have said, life sciences stakeholders, including the BioIndustry Association, have taken a number of opportunities to present their position to Government, and we are certainly aware of their views.

The SIs' impact on businesses, which the hon. Member for Sefton Central mentioned, was assessed using the Better Regulation framework and in line with Her Majesty's Treasury's Green Book guidance. The impact was assessed against the static acquis baseline—existing EU regulations and directives—and the instruments simply fix deficiencies in law that will be retained under the European Union (Withdrawal) Act 2018. They will allow current systems on regular provisions to continue to operate in a no-deal scenario. The impact analysis therefore focused on the direct impact of the relevant SI alone. Analysis of the wider impacts of the UK's exit from the EU has been published in the form of the long-term economic analysis in November 2018.

With respect to the guidance that the Government intend to publish to let businesses know about the changes, technical notices were published in September. They gave an overview of how the patents and trademark system will operate in the event of no deal, and the instruments provide the legal detail behind that overview. We expect to publish guidance for businesses on the changes the instruments make that affect them, once Parliament has approved the instruments. In addition, on trademarks, the IPO will publish a notice in every language of the EU, so that right-holders in every member state will be able to access all the necessary information on how to administer their rights.

The hon. Member for Sefton Central mentioned trademarks and international trademarks, and the draft instrument does not include provisions on designs or international systems for trademark design protection. It focuses specifically on EU trademarks and domestic trademark law derived from EU legislation. An instrument setting out our intention to continue the protection of registered community designs, unregistered community designs and international trademark and design rights will be laid before Parliament and debated in due course. This draft instrument will ensure that registered rights are not lost. It will convert current EU trademark legislation into UK-equivalent rights, ensuring that rights protected before exit will continue to have protection in the UK after we leave the EU.

The hon. Gentleman mentioned business certainty. The relevant draft instrument provides for an additional nine months for those who need to register for a UK application. He also mentioned what will happen after those nine months. Failure to file a UK application within nine months from exit day will result in the applicant's losing the right to claim an earlier EU date. This is an additional provision and protection that has been put in place.

Above all, the draft regulations are about ensuring certainty and control as we go forward. It is important to ensure that we have a workable system in place in the event of no deal. Of course, I do not wish to be in a no-deal scenario. If Members had voted differently a few days ago, we may have been in a place where we could begin to introduce and implement the provisions of the European Union (Withdrawal) Act 2018. However, I am confident that, by passing the draft regulations to ensure that we have that insurance mechanism in place, we can have the maximum possible stability in the event of no deal. I commend the draft regulations to the Committee.

Question put and agreed to.

Resolved,

That the Committee has considered the draft Patents (Amendment) (EU Exit) Regulations 2018.

DRAFT TRADE MARKS (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2018

Resolved,

That the Committee has considered the draft Trade Marks (Amendment Etc.) (EU Exit) Regulations 2018.—*(Chris Skidmore.)*

12.3 pm

Committee rose.