Grand Committee – 9 January 2018
The Patents (Amendment) (EU Exit) Regulations 2018
Impact on UK life sciences industry and access to medicines for UK patients

Briefing from BioIndustry Association

On Wednesday 9 January the House of Lords Grand Committee will consider a number of Statutory Instruments.

The BioIndustry Association (BIA) has concerns about both the impact and process of the **Patents (Amendment) (EU Exit) Regulations 2018**, specifically Article 3 "*Conditions for obtaining a certificate* 55", which states that "(2) (v) ***the number and date of the earliest of any EEA authorisation, the granting of which predates the granting of the UK authorisation***.[1]"

Article 3 refers to Supplementary Patent Certificates (SPCs), which are extensions for patents of medicines that provide additional patent life to compensate for the period of market exclusivity lost during the essential regulatory approval process. SPCs are an important and powerful incentive to support investment in the development of new medicines.

SPCs can provide up to five years extra protection and the precise period of additional protection is determined using the first regulatory Marketing Authorisation date (currently) within the EEA. The above quoted amendment would maintain this EEA-wide stipulation for UK SPCs despite the medicine covered by the SPC being subject only to a UK Market Authorisation (i.e. it couldn't be marketed in the UK until approval by the UK-based MHRA). This would have the SPC's duration aligned with those granted elsewhere in Europe on the basis of first authorisation in the UK/EEA (i.e. even if the UK authorisation was later).

It appears that Government is seeking to encourage life sciences companies to launch medicines in the UK at the same time that they launch in the EU/EEA. We understand the intention, however in reality, many of our member companies tells us that the regulation will likely delay further the launch of a medicine in the UK and is adversely impacting global reputation of the UK as a location for the life sciences industry. Moreover, we are concerned about the lack of process and consultation for a regulation that will have a huge impact on our sector and UK patients.

A strong intellectual property framework is essential if the UK wishes to have long-term sustained investment in R&D, remain a globally-attractive location for international investment and grow UK companies in the UK. Due to other regulatory requirements in the event of "no deal", the exclusivity term for a medicine in the UK would be reduced as a result of the Article 3 amendment, compared to the rest of the EU.

The threat of a shortened data exclusivity period has adversely impacted global companies' views of the UK, companies have told us that:

- A product will never be launched in the UK before the EU/EEA.
- The UK has moved further down priority launch market – one company has told us that the UK has moved from first tier to third tier launch market for an upcoming new product.
- The international reputation of the UK as a place for global pharmaceutical companies to undertake business has been dented – at the same time as Brexit is already having an impact on the UK global reputation.

[1] http://www.legislation.gov.uk/ukdsi/2018/9780111175347

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

We are also concerned that the proposal has not been consulted on. The suggestion that the government might take this approach first appeared in a Technical Notice [2]at the end of August. BIA raised concerns with Ministers and the MHRA. The MHRA stated that concerns should be included in responses to their "no deal" consultation[3] which concluded on 1 November (the consultation did not ask specifically about exclusivity). The SI was tabled on 1 December, when follow-up discussions from the consultation were still ongoing. There has been no formal consultation.

In our response[4] to the MHRA no deal consultation, BIA, together with ABPI, stated that:

"We are also concerned that the proposal for data and market exclusivity for marketing authorisations is not being consulted on. Data exclusivity is a critical incentive for innovation and therefore highly important to the life sciences industry. For this protection to fulfil its intended function in recognising the enormous investment lying behind clinical trials for new medicines, it is vital that the term should be connected to the actual date of grant of a marketing authorisation in the UK which enables its holder to place the medicine on the UK market. The terms of data exclusivity and other protection (SPCs and orphan exclusivity) may influence the choices made by companies and therefore the activities of the regulatory authority."

In its response[5] to the consultation, on 3 January MHRA stated that there will be a review within 2 years. However, by that time some UK patients will not be able to receive the medicines that they would have if UK was a member of the EU and there will have been a significant impact on the UK industry, as well as the global industry's perception of the UK.

"As communicated in the August 2018 Technical Notice, on how medicines, medical devices and clinical trials will be regulated if there is a no Brexit deal, data and market exclusivity in the UK will start on the date of authorisation in the UK or EU, whichever comes first. This will also apply in relation to marketing exclusivity for orphan products. The Government will review this within 2 years of an EU Exit in order to make sure we remain competitive."

[2] https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal

[3] https://consultations.dh.gov.uk/mhra/mhra-no-deal-contingency-legislation-for-the-regul/

[4] https://www.bioindustry.org/resource-listing/abpi-bia-responses-mhra-consultation-eu-exit-no-deal-contingency-legislation.html

[5] https://www.gov.uk/government/consultations/mhra-consultation-on-eu-exit-no-deal-legislative-proposals