



BIA welcomes Minister's Reassurance on the Patents (Amendment) (EU Exit) Regulations 2018

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The Government last night committed to further consultation with the BIA on the UK's future Intellectual Property rights regime in the event of a 'no deal' Brexit following concerns raised in the House of Lords.

The Patents (Amendment) (EU Exit) Regulations 2018, along with other intellectual property related regulations, returned to the House of Lords on 6 February – after previously being “negatived” by the House of Lords Grand Committee. From the dispatch box the Rt Hon Lord Henley, Parliamentary Under-Secretary of State at the Department for Business, Energy and Industrial Strategy, provided reassurance that if they come into law, the “no deal” Statutory Instruments (SIs) are a temporary solution, and that Government is considering options for a future regime and will consult with business. Following debate the SI was agreed by the House of Lords.

Lord Henley stated that if there is a no deal Brexit that Government will immediately start to explore the future landscape with the sector. He stated that this will include discussion on SPC term, and Government had already committed to review this within two years.

Lord Henley stated that: *“I have held further helpful and constructive meetings with the BioIndustry Association and the ABPI. Let me make it clear that I value those regular contacts and the insight that they bring on behalf of this important industry. I will continue to have discussions with representatives from industry and hear their perspectives as we move forward.”*

“The BIA and the other organisations representing pharmaceutical innovators would prefer the legislation to be changed so that the term of an SPC would be calculated based on only a UK market authorisation. They argue that the exit may lead to industry launching new pharmaceutical products later in the UK and that they may receive later market authorisation than in the rest of the EEA.”

BIA had raised concerns that the regulation sends a signal globally that UK Government may not be fully committed to a gold standard intellectual property regime, and that it will in turn impact the attractiveness of the UK as a location for international investment. BIA is also concerned about the lack of formal stakeholder consultation on

the regulation. At the Grand Committee on 14 January, Lord Warner highlighted our concerns to the House and the Minister.

As the number of SIs being laid in preparation for a 'no deal' Brexit increases it is essential that Government considers the impact that they may have on patients, businesses and investors so that the UK continues to be a global leader for the life sciences sector.

Steve Bates OBE, CEO of the BIA said:

“Our members will welcome the Minister’s assurance that this Statutory Instrument (SI) is a temporary solution and that in a ‘no deal’ Brexit they will immediately start to consider the future landscape with stakeholders. It is essential that, if there is a ‘no deal’ Brexit and this regulation comes to be, that there is an immediate formal stakeholder consultation – and BIA stands ready to assist.

“While our sector is currently thriving - it has much to lose. Maintaining a strong intellectual property framework is essential if the UK wishes to have long-term sustained investment in R&D and remain a globally-attractive location for international investment. Any signals that the UK may not offer the same patent protection after Brexit will adversely impact the global reputation of the UK as a location for the life sciences industry.”

In regard to government’s no deal parliamentary programme, Steve said:

“We were concerned at the rushed nature of this and other SIs and in particular the adverse signals that they are sending globally.”