BIA submission: UK's future exhaustion of intellectual property rights regime

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UK BioIndustry Association

Summary

The BioIndustry Association (BIA) believes that patented medicines should be under a national exhaustion regime. We strongly oppose an international exhaustion regime for medical products and also do not support regional exhaustion with the EEA, which has similar negative impacts to international regimes and is also no longer reciprocated. We understand that different sectors will face different pressures and recognise that a national exhaustion regime may not be in the best interests of every part of the UK economy.

This paper sets out the BIA's rationale for favouring a national exhaustion regime for patented medicines:

- A national exhaustion regime allows patents to function fully to incentivise investment in R&D and business growth
- An international regime would downgrade the UK market for innovative medicines and increase the pull on innovative UK companies to locate activity in the US
- International exhaustion would discourage differential pricing, which supports patient access to medicines in low and middle income countries

Introduction and overview of the UK life sciences sector

The UK's R&D-intensive life sciences sector is universally recognised as world-leading, and it delivers great benefits to the economy, the health of the nation, and is key to the Government's net-zero agenda. From improving patients' lives through new treatments and digital healthcare, to the development of environmentally-sustainable technologies, such as biological fossil fuel substitutes and biodegradable bioplastics, our deep understanding of biology is helping to address humankind's greatest challenges.

It is as a result of having a vibrant UK life science ecosystem that the UK has been able to play a leading role in the global response to the pandemic, putting the UK in a strong position to benefit rapidly from vaccines, diagnostics and therapies. The Oxford/AstraZeneca vaccine encapsulates this: the science came from one of our many world-leading universities, the technology was further developed by Oxford spin-out Vaccitech, the regulatory and global distribution capability was provided by the UK-based multinational giant AZ, and Oxford Biomedica and Cobra Biologics provided their existing UK-based manufacturing capabilities to rapidly scale up domestic production. This has been achieved through a public-private partnership that demonstrates the uniqueness of the UK life sciences ecosystem, which has been rightly recognised in both the recent Life Sciences Vision and the Innovation Strategy.

This is a growing sector of the future that poses a unique opportunity. The UK life sciences industry employs 256,100 people, with two-thirds of these jobs outside London and the South East.[1] There are 6,300 life sciences businesses, 82% of which are SMEs, and combined they generate a turnover of £80.7bn. The average GVA per

[1] UK Government (2019), *Bioscience and health technology sector statistics 2019*: https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2019

employee is over twice the UK average at £104,000[2] and the sector consistently invests more in R&D than any other (£4.8bn in 2019).[3] The sector is attracting record levels of investment and overseas investors.[4] As such, UK life sciences is a key engine of economic growth with the high potential to secure the UK's future prosperity, but it requires coordinated policy across Government to ensure the potential benefits are fully captured. The current consultation is a key part of this and will have a fundamental impact on the Government's ambition to make the UK a global life sciences hub.

National exhaustion of rights will drive investment in and growth of UK life sciences

The biosciences sector is heavily dependent on patents: the significant investment required for the R&D of medicines, including clinical trials, is made possible by the commercial incentive provided by patent protection. The availability of patent protection for innovative products is essential for ensuring investment in such products through the clinical trial process – providing patients with access to medicines during the clinical trial process and subsequently, if and when, successful products are authorised. For smaller companies the ability, in particular, to attract investment at an early stage of R&D is key. (But, even the largest companies need to recoup their investment in R&D and the patent system is central to achieving this.) Patent portfolios are often their most valuable asset and a key consideration of the measure of the company's value, which in turn affects the funding available for R&D from investors.

Pharmaceuticals are more susceptible to being parallel traded than many other products for a number of reasons, including: price differentials between markets caused by price regulation and monopsonist buyers; the mission to promote public health by engaging in differential pricing for poorer markets; and relatively low cost of transportation across borders. At UK exit from the EU, the UK maintained the regime allowing parallel trade into the UK from the EEA. This is no longer reciprocal. Because the UK is now a 3rd country from an EU perspective, IP owners can use IP to prevent product from the UK being imported into EEA countries.

The BIA supports a national exhaustion regime and opposes maintaining a regional exhaustion or introducing international exhaustion because:

1. Patents, and the ability to enforce them to protect, are a key driver of investment in innovation, and fundamental to UK biotech SMEs' ability to raise finance to support their R&D and business growth. A national exhaustion regime allows patents to function to their full intended effect, including promoting maximum investment.

   International exhaustion fundamentally weakens UK patents and thus disincentives investment in SME biotechs. Moreover, part of the way that these companies finance their growth is to licence some of their IP to larger companies when it has attained some value through the company's R&D. These licence agreements frequently contain a provision restricting the geographic scope of the licence. Clearly, international exhaustion undermines this business model and source of investment. As a consequence, it will run counter to the government's vision of the UK becoming an important hub for life sciences and supporting the growth of innovative companies.

[2] PwC (2017), The economic contribution of the UK life sciences sector: https://www.abpi.org.uk/media/1371/the_economic_contribution_of_the_uk_life_sciences_industry.pdf
[3] ONS (2020), *Business enterprise research and development, UK: 2019:* https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterpriseresearchanddevelopment/2019
[4] Radnor Capital Partners, commissioned by BIA (2021), *UK quoted biotech performance and investor base in 2020:* https://www.bioindustry.org/resource-listing/rcp-bia-2020-review-january-2021-final-pdf.html

2. There is already an encouragement for UK life science companies to relocate to the US when they reach a certain size because of the greater availability of finance there and the primacy of the US healthcare market. The Life Sciences Vision acknowledges this and established the Government's ambition to address the imbalance. A policy, such as international exhaustion, that downgrades the UK as a market for innovative medicines due to the inability of companies to protect their market monopoly, will exacerbate the problems the Government's Life Sciences Vision is seeking to address. Moreover, the attractiveness of the UK for international life sciences investment and clinical trials is strongly impacted by the strength of the UK market for innovative medicines; if an international exhaustion regime discourages medicines launch, there will be knock-on impacts on R&D investment and clinical trials.
3. International exhaustion is contrary to humanitarian goals. Most biotech companies are working on medicines for rare and debilitating diseases and are driven by a social as well as economic purpose to improve global health. Due to the high R&D investment and small patient populations, the medicines produced for these conditions, and rare diseases in particular, are often expensive. Economic efficiency and social welfare are maximized when price differentiation is allowed between various markets. If medicines priced at a low level to increase access in low and middle-income countries (LMICs) are allowed to leak back into the UK, patients in LMICs will be deprived of those medicines and producers will be reluctant to differentially price with a view to increasing access to medicines. For the UK to adopt such a regime could be a precedent for others to follow, exacerbating the impact on LMICs.
4. International exhaustion is not compatible with the functioning and purpose of the SPC manufacturing waiver. Under this legislation UK based manufacturers are able to manufacture pharmaceuticals that are subject to SPC protection in the UK for export to non-UK/EU markets. This stock has to be labelled as being for "UK export". Once sold in the destination market, an international exhaustion regime would make the UK re-import of this stock more likely. These activities would be unwelcome to patentees and generic/biosimilar manufacturers alike given litigation might well have to be initiated by patentees and would target the UK-based generic/biosimilar manufacturer rather than (or in addition to) the parallel importer. This litigation risk would actively dissuade manufacturers from using the UK as a base for early manufacture/export activities which runs counter to the purpose of the legislation.
5. International exhaustion increases the likelihood of products which have not been subject to stringent transport, storage and other conditions entering the UK supply chain. This is particularly important for biological products, which require an intact cold chain or cryo-chain, as the supply of vaccines for the Covid pandemic has demonstrated.
6. There is no logical basis for regional exhaustion now that the UK is separate from the EU.

This list is not intended to be exhaustive; there will be other valid reasons for the UK to have a national regime not listed here.

About the BIA

The BIA is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

Our members include:

- Start-ups, biotechnology and innovative life science companies

- Large pharmaceutical and technology companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors, lawyers, IP consultants, and communications agencies

We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.