

BIA submission: Proposals for Patent Harmonisation

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The BIA

Established over 25 years ago at the infancy of biotechnology, the BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK. The BIA's 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. The BIA promotes an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

The BIA's member companies include UK companies who routinely utilise patents (and the European Patent Office (EPO)) to protect investment in innovation either on their own behalf or on behalf of their global client base. The life sciences sector is heavily dependent on patents: the significant investment required for the research and development of medicines is made possible by the commercial incentive provided by patent protection. Robust patent applications are also essential to persuade investors to finance the research. As a result, a key concern of members of the BIA is that there is clarity and certainty in patent law.

The Consultation

The UK IPO has requested views from stakeholders on the specific areas of the grace period, conflicting applications and, prior user rights in the context of the Common Consultation Document currently live within the B+ group. BIA understands that this document seeks views based on three current live harmonisation proposals drawn from the IT3 industry group, FICPI and AIPPI. The proposals essentially differ in that the IT3 proposal has significantly more detail about it on many of any future system's features but, as a result, descends into increased complexity.

Comments

The BIA notes that its membership is likely to be biased towards SMEs and mid-size companies that have more limited resources as regards legal and patent functions than larger multi-national industries. Therefore, the obvious desirability of having greater global harmonisation on the patent process including rules around grace periods, conflicting applications and prior user rights needs to be measured against those BIA members that currently operate within the EPO and adhere to its procedures which are relatively simple to follow in the areas under consultation by the B+ Group/UK IPO.

For example, as regards the introduction of a grace period, BIA members currently adhere to first to file/strict conflicting applications rules and compliance with these rules negates the value of the existence

of grace periods elsewhere in the world (i.e., if they were in a position where the only patent protection they could obtain depended on the application of a grace period then currently they would not have any protectable rights in their home markets). Hence the compromise position that is proposed by all three proposals would, if adopted, make life more complicated for BIA members in the current global patent system by introducing a globally harmonised grace period. This is because by adhering to the current European system, BIA members have confidence that they necessarily comply with the requirements of other global patent systems due to the relatively strict approach the EPO imposes in numerous fields. In switching to systems such as those proposed, BIA members would find they have to navigate a more complex set of rules around prior disclosures and prior user rights and inevitably this could lead to more mistakes being made in smaller companies. Hence, whilst the introduction of a harmonised grace period could well complicate both daily operation and global freedom to operate projects for SMEs, the benefits of one common global rule set to operate within does hold attractions, and if these rules needed to include a grace period to achieve compromise this would be supported.

BIA therefore requests that the UK IPO represents back to the EPO/B+ Group that whilst global patent harmonisation is a laudable aim in and of itself which is supported by the organisation, the B+ Group is asked to have in mind all users of the patent system when agreeing any compromise package. Smaller companies do not have the same capabilities to navigate complex systems as do larger companies and the BIA does not wish to see the global patent system become the preserve of larger industry. BIA notes that the online survey asks for stakeholders to indicate a preference for the three proposals summarised in the Common Consultation Document. Purely on the basis that the FICPI and AIPPI proposals are easier to understand than the IT3 proposals, then either of the former two would be the BIA's preference as a basis for progressing this global harmonisation project.

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