

The President and Justices of the Supreme Court

The Supreme Court of the United Kingdom
Parliament Square
London
SW1P 3BD

15 December 2017

Dear Sir or Madam

Actavis Group PTC EHF and others (Respondents) v ICOS Corporation and another (Appellants) UKSC 2017/0214

The mission of the BioIndustry Association is to promote the human health benefits of new bioscience technologies and to encourage the commercial success of the bioscience industry by focusing on emerging enterprise and the related interests of companies with whom such enterprise trade. The BIA membership includes start-up companies, biotechnology and innovative life science companies, pharmaceutical and technological companies, universities, research centres, tech transfer offices, incubators and accelerators. The BIA represents the interests of its members to a broad section of stakeholders, from government and regulators, to patient groups and the media.

The BIA brings a broader, more rounded perspective to the issues beyond the respective positions of the Appellant and the Respondents. It is therefore eminently capable of making submissions in the public interest.

The BIA would like to place before the Supreme Court its brief submissions supporting the application for permission to appeal to the Supreme Court from the judgment of the Court of Appeal in this case because we believe clarity and certainty regarding the point of law at issue is of significant importance to the bioscience sector.

This case concerns the patentability of inventions made in the course of the type of empirical research leading to the development of a medicinal product which is representative of the endeavours of many BIA members. As we understand the position following the judgment in the Court of Appeal in this case, extensive work carried out by a BIA member which lead to the discovery of a new improved dosage regime for a medicine which brought unexpected benefits to a population of patients may not be capable of protection by a patent on the grounds that each step in the course of that development could be considered 'routine' on the basis of the results obtained in the step before.

A significant proportion of medicines in development now comprise biologics products (almost 40% of pipeline drugs could be described as biologics in 2017).¹ These include products such as

¹ Lloyd, I. 2017. "Pharma R&D Annual Review 2017". Pharmaprojects: p16.

antibodies, vaccines and interleukins. Such biologics products are often developed following iterative, empirical research. For example, a company can screen its own novel antibody libraries for activity against a known target and in a stepwise fashion progress promising candidates through further established techniques of analyses such as determination of protein target selectivity and affinity assessments and, following such development steps, arrive at a novel antibody with unexpected improved characteristics. We believe that the expectation of the BIA's members in such a case would be that the results of such development should be capable of patent protection. Following the Court of Appeal's judgment in this case this is in doubt. Without certainty around the availability of patent protection in such circumstances the incentive for companies to invest in such research could be significantly diminished, to the detriment of patients.

Furthermore, for smaller biosciences companies, the ability to attract investment funding from an early stage of research and development is key. Patent portfolios are their most valuable asset and a key consideration of the measure of the company's value, which in turn affects the funding available for research and development from investors. Uncertainty and lack of clarity over whether the fruits of the company's research and development endeavours are ultimately capable of patent protection adversely affects the company's ability to secure funding.

Whilst as a trade association we do not seek to support the case for one side or another in this instance, it is because of the significant public importance of the issues raised by this appeal that we respectfully ask the Supreme Court to grant permission for the appeal so that our industry and its investors may have the clarity they require to continue making investments in such research with the potential to lead to the discovery of new ways of treating patients in the future.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Steve Bates', with a stylized flourish extending to the right.

Steve Bates OBE

CEO, BioIndustry Association