UKSC 2017/0214

IN THE SUPREME COURT OF THE UNITED KINGDOM
ON APPEAL FROM THE COURT OF APPEAL (CIVIL DIVISION)

BETWEEN:

(1) ICOS CORPORATION
(2) ELI LILLY AND COMPANY

Appellants

-v-

(1) ACTAVIS GROUP PTC EHF
(2) ACTAVIS UK LIMITED
(3) TEVA UK LIMITED
(4) TEVA PHARMACEUTICAL INDUSTRIES LIMITED
(5) GENERICS (UK) LIMITED (T/A MYLAN)

Respondents

STATEMENT OF GROUNDS

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1. The BioIndustry Association ('BIA') applies for permission to intervene and make written submissions under Rule 26 of the Supreme Court Rules 2009 in the appeal in *Actavis Group PTC EHF and others (Respondents) v ICOS Corporation and another (Appellants), UKSC 2017/0214.*

2. The BIA should be granted permission to intervene because the point of law at issue is of vital importance to companies in the biosciences field, many of which make up its membership. One of the Appellants, Eli Lilly, is a member of the BIA. The other Appellant and the Respondents are not members. Members of the BIA include start-ups, small and medium-sized enterprises (SMEs) and established large companies. Our mission is to ensure that innovation can flourish in the life sciences sector, particularly within the UK's vibrant SME community. The BIA seeks to offer an independent view of the way in which the biosciences industry (and especially the clinical trial pathway) operates, the importance of patents to the industry and how the outcome of this appeal will affect its members, and consequently the biosciences industry as a whole.

The BIA

3. The BIA is the national trade association for innovative enterprises in the UK's bioscience sector, representing approximately 200 SMEs and larger life science companies as well as over 100 firms and associations that support and service the sector. The BIA promotes the human health benefits of new bioscience technologies and encourages the commercial success of the bioscience industry by focusing on emerging enterprises and the related interests of companies with which such enterprises trade.

4. An independent analysis by PwC estimated that the UK life sciences sector contributed £30.4 billion to the economy in 2015 and supported 482,000 jobs.[1] Workforce productivity in the

[1] PwC (2017), commissioned by ABPI, BIA, BIVDA and ABHI, *The economic contribution of the UK life sciences industry*:

sector is twice the UK average, with Gross Value Added (GVA) per employee equalling £104,000. The activities of life science companies directly contributed £14.5 billion to the economy in 2015, with an additional £15.9 billion provided through the supply chain and employee spending. Within the sector, as well as large established life science companies, the UK has a vibrant community of bioscience SMEs that are developing innovative new medicines but do not currently have any products on the market. The UK has the strongest research and development (R&D) pipeline among such companies in Europe, with 479 products in development in 2017.[2] Not only does the location of R&D in the UK make a positive contribution to the economy, it also has great social and health benefits. For example, studies have shown that research-intensive NHS trusts have better health outcomes[3] and UK based clinical trials provide patients with early access to medicines they would not otherwise get through routine treatment.

5. 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.

6. The BIA is concerned about the risk of an outcome in this case which would make it harder for UK bioscience companies to attract investment in their R&D programmes. As a result, the BIA is keen to ensure that any outcome in this particular case does not:

   a) have far-reaching implications beyond dosage regime inventions (being the subject of the patent in dispute) which could ultimately disincentivise companies from conducting R&D in the UK;

   b) lead to a lack of clarity as to what types of research could yield patentable inventions; and

   c) lead to an inconsistent approach to patentability across Europe.

7. The issue before the Supreme Court on which the BIA would like to intervene concerns the correct test for obviousness in the context of assessing the validity of a pharmaceutical patent. This will likely include consideration of when and how the assessment as to whether or not something is obvious is made. Importantly, the case concerns the patentability of inventions made in the course of clinical research leading to the development of a medicinal product. This type of research is representative of the endeavours of many BIA members. The BIA, therefore, brings a broader, more rounded perspective to the issue beyond the respective positions of the Appellants and the Respondents and is making submissions in the public interest.

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http://www.abpi.org.uk/media/1371/the_economic_contribution_of_the_uk_life_sciences_industry.pdf

[2] BIA (2018), *Pipeline Progressing: The UK's Global Bioscience Cluster in 2017*: https://bit.ly/2LIPo4J

[3] Ozdemer *et al.* (2015), *Research Activity and the Association with Mortality*: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4342017/ ; and Downing *et al.* (2016), https://gut.bmj.com/content/66/1/89

A. Disincentivising R&D

Clinical Trial Pathway

8. The clinical trial pathway, which underpins medicinal and health R&D programmes worldwide, was summarised by both the judge at first instance and by the Court of Appeal (see paragraphs 76-81 and 23-26 respectively). This pathway and the dose ranging phase IIb studies have been described by the Court of Appeal as 'familiar' and 'routine' (see for example, paragraphs 152 and 160).

9. It is imperative that the Supreme Court appreciates the extent to which the words 'familiar' and 'routine' accurately describe the phases of clinical development. The clinical research pathway is, at one level of generality, well-established. Regulators generally require certain studies to be undertaken to establish that a product is safe and efficacious. However, beyond this, clinical trials are anything but routine. It is important to recognise that there is a considerable amount of skill involved in designing clinical trials and that, as Mr Justice Birss said at first instance, 'value-judgments' will be made about how to proceed based on whatever results are obtained (see paragraph 283 of the first instance decision). These so-called 'value-judgments' are made throughout the process by specialist professionals with clinical trial expertise and are often multi-factorial decisions as opposed to simply binary decisions.

10. The Court of Appeal has determined that the 'value-judgments' said to have been made to reach the claimed invention provided 'no effective support for the judge's [Birss J at first instance] conclusion' (see paragraph 149). The BIA does not take a position on whether or not this assessment is right in the circumstances of the particular case at issue. The BIA's position is that it would be wrong for the Supreme Court to proceed on the premise that all clinical trials proceed in a way which do not require multi-factorial judgments to be made. These often require skill, intuition and can in some circumstances lead to an invention. In particular, many factors determine the number and nature of dose ranging studies which are undertaken, especially in the context of multiple dosing studies. The BIA would caution against any approach based on an over-simplified suggestion that multiple dosing studies to investigate lower doses is something done without thought. As has been explained above, clinical trials are often complex and involve multi-factorial judgments.

11. It is also critical to recognise, as Mr Justice Birss did at first instance, that the clinical trial process is costly and uncertain (see for example, paragraphs 269, 281 and 282 of the first instance decision). The development pathway for medicines is inherently uncertain, with many novel medicines failing to complete the process and meet endpoints in phase III studies required for regulatory approval. Strong defensible patents are essential to ensure the costs of R&D can be recouped, not only for any medicine which successfully gets through phase III but also for the many failures along the way.

12. The BIA is concerned to ensure that there is no suggestion from the Supreme Court that simply because a product has gone through a clinical trial pathway that a particular development is necessarily determined to be a 'standard', 'uninventive', 'routine' or 'obvious' development. All medicines will have gone through such a process. Many of these will not be inventive, but some will, and innovative medicines (and their processes for manufacture and/or new uses), are deserving of patent protection irrespective of how the invention is made. The assessment of obviousness should be made in respect of the prior art and not in respect of the nature and type of research which led to the claimed invention. In this respect, the BIA would urge the Supreme Court to consider the way in which the obviousness of

pharmaceutical patents is determined at the European Patent Office by reference to the problem-solution approach.

Dosage Patents

13. The BIA would like to highlight that dosage regime patents are a particular type of case and the English Courts and the EPO have considered the principles which should apply when assessing their validity. This case is by no means representative of patents in this sector generally and the BIA cautions against a decision which will have unintended, wider implications.

14. The BIA would, however, endorse the statements of Jacob LJ in paragraph 29 of his judgment in *Actavis* v *Merck*[4] that 'research into new and better dosage regimens is clearly desirable and that there is no policy reason why the discovery of a novel and non-obvious dosing regimen should not be rewarded by a patent.' (see paragraph 131 of the Court of Appeal judgment).

What is 'routine' research?

15. The BIA respectfully asks the Supreme Court to be cautious as to what types of research it might classify as 'routine'. As well as clinical trials, there are many types of empirical pre-clinical research which companies in the biosciences field are involved in (indeed there is likely empirical research conducted in many diverse fields) which should not be characterised as routine. For example, the research involved in identifying novel chemicals or selecting and developing novel antibody candidates against a target might involve the use of established techniques and analyses, but this does not preclude the fact that often considered, multi-factorial decisions are made during such research. Any decision of the Supreme Court in this case which makes it harder to obtain patent protection or defend granted patents for inventions resulting from such research will, in turn, make it harder to attract investment and thus hinder this type of basic research in the UK and the medical innovation that stems from it.

Assessment of Obviousness

16. There is a fundamental question which needs to be answered concerning the timing of the assessment of inventive step. Should the assessment be made at the priority date or in light of data generated downstream at a later time? In answering this question, the BIA considers it important to keep in mind the statutory test which asks if the invention is obvious to a person skilled in the art having regard to any matter which forms part of the state of the art at the priority date.

17. It is also important that due consideration is given to the requirement of a 'reasonable expectation of success' in the assessment of obviousness and, in particular, to the consequences of not requiring this at all. If there is no requirement that for something to be obvious there must be a reasonable expectation of success, the bar to patentability will be set high and this would be particularly concerning if coupled with a determination that a broad range of R&D activities are 'routine'.

[4] Actavis UK Ltd v Merck & Co Inc [2008] EWCA Civ 444, [2008] RPC 26

B. Clarity

18. All three judges in the Court of Appeal judgment comment on the extent to which the requirement of a 'reasonable expectation of success' is a relevant factor in the obviousness assessment. It is important for BIA members that there is some clarity about a) whether or not the requirement is relevant in assessing obviousness, b) if relevant, in what circumstances, c) what factors should be taken into account when determining what is 'success' and d) the time in any project when the assessment should be made.

19. Uncertainty and lack of clarity over whether the fruits of the company's R&D endeavours are ultimately capable of patent protection adversely affects the company's ability to secure funding.

C. Consistency

20. It is important for BIA members, for the bioscience and pharmaceutical industries and for all patentees, that as far as is possible there is a consistency of approach to the assessment of obviousness across Europe, including at the EPO. The BIA would respectfully ask the Supreme Court to consider the approach taken by the EPO and across Europe and, in particular, the approach as to when the assessment should be made, how the assessment is made (and, in particular, the extent to which the method of coming to the invention is relevant) and whether or not there should be a requirement of a 'reasonable expectation of success'.

Conclusion

21. For the reasons set out above, the BIA respectfully requests that it be granted permission to intervene by written submission in this appeal so that the court may consider this statement.

Dated: 4 October 2018