Obviousness

Consistency in the law and a balanced approach to the approach to inventive step / obviousness are both matters of considerable significance to all IP Federation members. It was therefore a matter of some concern that the judgment of the Court of Appeal in *Actavis* v *ICOS* of 1 November 2017 appeared to open up the possibility of a more restrictive approach to inventive step than had hitherto been generally understood. As a result, and so that the law could be clarified, IP Federation supported an application for permission to appeal to the Supreme Court, and following grant of permission applied to intervene, in writing, in the appeal. This application was successful and, accordingly, written submissions (prepared on IP Federation's behalf by Bristows LLP) were introduced into the appeal, which was heard on 19 and 20 November 2018. Three other organisations also intervened and made written submissions, namely: the UK BioIndustry Association, Medicines for Europe, and the British Generic Manufacturers Association.

Judgment was delivered on 27 March 2019, with Lord Hodge giving the lead judgment (with the President, Lady Hale, and the other Law Lords agreeing). Pleasingly, the Supreme Court clarified that the judgment of the Court of Appeal should not be read as in any way changing the law. Dismissing the appeal, in paragraph 103 of his judgment, Lord Hodge stated as follows:

> "… The IP Federation similarly expressed concern about a perceived risk that people might extrapolate from statements in the Court of Appeal's judgments that the result of routine investigations cannot lead to a valid patent claim. It expressed a particular concern about the breadth of the statement by Lewison LJ (in para 180): "in a case which involves routine pre-clinical and clinical trials, what would be undertaken as part of that routine is unlikely to be innovative". Its concern was that a simplistic adoption of this phrase as a blanket test without regard to the facts of the specific case would be contrary to the fundamental principles of patent law. I do not interpret the Court of Appeal's judgments, including Lewison LJ's statement which I have quoted, as supporting such an extrapolation. Kitchin LJ gave the leading judgment, in which he adopted a fact specific assessment based on the facts of this case and involving the weighing up of several factors, and Floyd and Lewison LJJ agreed with his reasoning and conclusions. I do not construe the judgments of the Court of Appeal as supporting any general proposition that the product of well-established or routine enquiries cannot be inventive. If that had been what the experienced judges had said, I would have respectfully disagreed. But it is not. As Jacob LJ stated in *Actavis v Merck* (above) para 29, there is no policy reason why a novel and inventive dosage regime should not be rewarded by a patent. A fortiori, efficacious drugs discovered by research involving standard pre-clinical and clinical tests should be rewarded with a patent if they meet the statutory tests …"

Alan Johnson, Bristows LLP, 11 September 2019