27 March 2019

PRESS SUMMARY

Actavis Group PTC EHF and others (Respondents) v ICOS Corporation and another (Appellants) [2019] UKSC 15
On appeal from [2017] EWCA Civ 1671

JUSTICES: Lady Hale (President), Lord Kerr, Lord Sumption, Lord Hodge, Lord Briggs

BACKGROUND TO THE APPEAL

Tadalafil is the generic name for a drug which is sold under the brand name CIALIS for the treatment of, among other things, erectile dysfunction ("ED"). Tadalafil is a competitor (second in class) to sildenafil, which was and is sold under the brand name, VIAGRA. The patent which is the subject of this appeal is EP(UK) 1,173,181 ("the 181 patent"). It is owned by ICOS and exclusively licensed to Eli Lilly (collectively "Lilly"). It was filed on 26 April 2000 and granted on 15 October 2003. The 181 patent relates to the use of tadalafil in a dosage form for the treatment of ED.

This case is concerned with section 3 of the Patents Act 1977 ("1977 Act"):

> "An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above)."

Section 2(2) of the 1977 Act provides:

> "The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way."

These statutory provisions mandate the court to assess whether an invention is obvious by having regard to the state of the art at the priority date of the invention. If the invention is not obvious to the skilled person at that date, section 3 deems the invention to involve an inventive step.

Lilly asserts that the essence of the invention is the discovery that tadalafil is effective in treating ED at a low dose and with minimal side effects. This discovery has allowed the drug to be taken daily (for chronic use) rather than on demand, avoiding the need to anticipate when sexual activity might occur. This is, Lilly claims, a significant technical advantage as sildenafil is approved for on-demand use only.

The respondents raised proceedings to revoke the 181 patent. Lilly defended the claim and counterclaimed that the respondents were threatening to infringe its patent. The High Court held that a 5mg daily dose of tadalafil was not obvious as a treatment for ED and therefore concluded that the 181 patent involves an inventive step. The Court of Appeal allowed the appeal on the ground that the 181 patent lacked inventive step. Lilly appealed to the Supreme Court.

JUDGMENT

The Supreme Court unanimously dismisses the appeal. Lord Hodge gives the sole judgment with which the other Justices agree.

REASONS FOR THE JUDGMENT

Since the enactment of the 1623 Statute of Monopolies, the purpose of a grant of a patent has been to encourage innovation. The "patent bargain" is this: the inventor obtains a monopoly in return for disclosing the invention and dedicating it to the public for use after the monopoly has expired **[53]**.

This overarching principle has survived the amendment of UK patent law after accession to the European Patent Convention **[54]**.

In addressing the statutory question of obviousness in section 3 of the 1977 Act it is common for English courts to adopt the so-called *Windsurfing/Pozzoli* structure **[60]**. An alternative approach which the EPO often adopts is the so called "problem-and-solution approach" **[61]**. While both approaches focus on the inventive concept put forward in the claims, neither approach should be applied in a mechanistic way **[62]**. The question of obviousness must be considered on the facts of each case **[63]**.

Factors which are relevant considerations in the present case include the following **[64]**. First, it is relevant to consider whether at the priority date something was "obvious to try", in other words whether it was obvious to undertake a specific piece of research which had a reasonable or fair prospect of success **[65]**. Secondly, it follows that the routine nature of the research and any established practice of following such research through to a particular point may be a relevant consideration **[66]**. Thirdly, the burden and cost of the research programme is relevant **[67]**. Fourthly, the necessity for and the nature of the value judgments which the skilled team would have in the course of a testing programme are relevant considerations **[68]**. Fifthly, the existence of alternative or multiple paths of research will often be an indicator that the invention contained in the claim or claims was not obvious **[69]**. Sixthly, the motive of the skilled person is a relevant consideration. The notional skilled person is not assumed to undertake technical trials for the sake of doing so but rather because he or she has some end in mind **[70]**. Seventhly, the fact that the results of research which the inventor actually carried out are unexpected or surprising is a relevant consideration as it may point to an inventive step **[71]**. Eighthly, the courts have repeatedly emphasised that one must not use hindsight, which includes knowledge of the invention, in addressing the statutory question of obviousness **[72]**. Ninthly, it is necessary to consider whether a feature of a claimed invention is an added benefit in a context in which the claimed innovation is obvious for another purpose **[73]**. A tenth consideration is the nature of the invention. In this case, the Court is concerned with a dosage patent with a Swiss-form claim and an EPC 2000 claim. The possibility that a dosage patent with such claims may be valid has been recognized both by the EPO and in the United Kingdom courts **[74]**.

In the present dispute, the Court considers that the balance or symmetry in patent law and the pre-established or at least readily foreseeable target of the skilled team's tests hold the key to its resolution. The prior art discloses an invention - that is the use of tadalafil in the treatment of ED - in a manner which enables the skilled person to perform it. The task which the notional skilled team would undertake was that of implementing patent EP 0 839 040 ("the Daugan patent"), which was the nearest prior art. The Daugan patent had disclosed that doses of tadalafil for the treatment of ED will generally be in the range of 0.5mg to 800mg daily for the average adult patient. The target of the skilled team would be to ascertain the appropriate dose, which would usually be the lowest effective dose. The skilled team would know of that target from the outset of its research. The pre-clinical and clinical tests involved familiar and routine procedures and normally progressed to the discovery of the dose-response relationship in Phase IIb **[105]**.

In this case the trial judge's findings of what would have been the sequence of the tests, which did not depend upon hindsight, included the finding, which the evidence clearly justified, that the team, having found a therapeutic plateau, would be very likely to test lower doses and so come upon the dosage regime which is the subject matter of the patent **[105]**. The Court considers that the Court of Appeal was entitled to treat the judge's failure to appreciate the logical consequences of the finding - that it was very likely that the skilled team would continue the testing - as an error of principle which allowed an appellate court to carry out its own evaluation **[82]**. As such, the Court is satisfied that the Court of Appeal was entitled to interfere with the trial judge's assessment of obviousness and to hold that the 181 patent was invalid for lacking an inventive step **[105]**.

References in square brackets are to paragraphs in the judgment