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The Supreme Court decision in Actavis v ICOS

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The UK Supreme Court today handed down its decision in *Actavis v ICOS*. The decision was unanimous, with Lord Hodge giving the only judgment. The case concerns two principal questions. First, how the test for obviousness applies to a dosage patent; and secondly, whether the Court of Appeal was entitled to reverse the judgment of the first instance court in this case.

The patent

The relevant patent claims relate to the use of a given dosage unit of tadalafil (1-5mg), up to a maximum dose of 5mg per day, for use in sexual dysfunction (the claims are in both EPC 2000 format (a purpose-limited product claim) and in Swiss-form (a purpose-limited process claim)). The patent also discloses that (i) the invention had fewer side effects than the first in class drug sildenafil (VIAGRA) due to increased potency, and (ii) could be administered chronically (i.e. daily) rather than "on demand" due to increased half-life.

The assessment of obviousness of dosage patents

Obviousness was assessed in light of the Daugan patent, which discloses that tadalafil was more potent than sildenafil.

In considering the approach to obviousness, the Court acknowledged the so-called "patent bargain", noting that the purpose of the grant of a patent is to encourage innovation. Lord Hodge went on to consider the statutory provisions, which "*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", noting that "uninventive steps which the skilled team would take after the priority date to implement the Daugan patent are not excluded from consideration in assessing the obviousness of the alleged invention at the priority date*". He then considered both the *Windsurfing/Pozzoli* test and the EPO's problem/solution approach, noting that both are glosses on the statutory provisions and that neither should be applied in a mechanistic way. In endorsing the fact-specific approach in *Generics (UK) v Lundbeck*, he identified that the following factors were relevant considerations in the present case:

(i) Whether something was "obvious to try" which the Court addressed together with whether there was a reasonable or fair prospect of success. The Court agreed that the

results of some experiments can be obvious even if there is no expectation of success;

(ii) Whether the research was routine in nature. The Court noted that this had no primacy and certainly no paramount status as a consideration;

(iii) The burden and cost of the research programme. The Court noted here that the need to facilitate expensive pharmaceutical research is an important policy consideration;

(iv) The need to make and the nature of value judgments during a research programme;

(v) The existence of alternative or multiple paths of research. The Court noted that multiple paths will often, although not necessarily, be an indicator of non-obviousness;

(vi) The motivation of the skilled person to undertake certain technical trials;

(vii) Whether the results of the research were unexpected;

(viii) The need to avoid hindsight. The Court noted that the "obvious danger of a step by step analysis is that the combination of steps by which the inventor arrived at his invention is ascertained by hindsight knowledge of a successful invention", but went on to say that there may be cases in which "the steps which the notional skilled person would take can readily be ascertained without the taint of hindisight";

(ix) Whether the feature of the claimed invention is an added benefit in which the claimed innovation is obvious for another purpose. The Court referred here to the well-known UK authority in Hallen v Brabantia where it was held that a patent to a PTFE coated cork-screw was obvious because it was obvious that the PTFE coating would achieve betting penetration of the corkscrew into the cork, and the fact that it unexpectedly achieved an improvement to the pulling of the cork would not found a valid patent;

(x) In relation to dosage regimen patents, the Court reiterated that there is no blanket prohibition on such patents but that there has been no relaxation of the rules in relevant to the assessment of inventive step for these patents.

In finding the patent obvious, Lord Hodge noted that the starting point was implementing Daugan, which they would do by finding the appropriate dosage regime, having regard to safety, tolerability and effectiveness, via routine and familiar pre-clinical and clinical procedures. There was clearly motive to do so. In conducting such research, they would have identified a surprising therapeutic plateau between 25-100mg. It would then have been "*very likely*" that they would have conducted further testing at lower doses, including 5mg (which the experts suggested would have been a "no brainer"). Little weight should have been attached to the fact that 5mg was a much lower dose than the marketed 50mg of sildenafil, that the expectation of efficacy at 5mg was low, the fact that it was surprising that a 5mg dose had efficacy, and that a significant value judgment had to be made once the therapeutic plateau was identified (because on the facts, not tainted by hindsight, the skilled team would have pursued further dosing tests). Furthermore, the chronic/daily

dosing was obvious because the finding of the half-life of tadalafil would have been an inevitable discovery in routine Phase I tests, and the claims were not limited to daily dosing, but rather a maximum daily dose.

Lord Hodge also noted that it was not necessary for the skilled team to identify the specific dose which is the subject of the claim in advance of Phase IIb tests. He concluded that the requirement was met if the "*step by step approach, without the benefit of hindsight, demonstrates that the skilled team would be very likely to pursue the tests to the point at which they would ascertain the product or process falling within the claims*".

Reversal of the first instance judge by the Court of Appeal

Lord Hodge reconfirmed the limitations on the appellate court's power to overturn a first instance judge. He noted that the assessment of obviousness necessarily involves carrying out an evaluation of many relevant factors which must be balanced to reach a conclusion. He then went on to draw a distinction between reversing the judge's evaluation of the facts where the application of the legal standard involved a question of principle (which is allowable) as opposed to a matter of degree or a finding of fact (which are not): "*the Court of Appeal would be justified in differing from the trial judge's assessment of obviousness if the appellate court were to reach the view that the judge's conclusion was outside the bounds within which reasonable disagreement is possible. It must be satisfied that the trial judge is wrong*".

In this instance, the Court of Appeal did not reverse any findings of primary fact, but was correct to overturn the first instance decision, as the first instance judge had failed to appreciate the logical consequences of his findings of fact. Namely, that the skilled team would have commenced and pursued familiar and routing testing of tadalafil to establish the appropriate dosage regime (in order to implement the teaching of Daugan). In doing so, they would have identified that the 5mg dose remained effective. The unexpected additional benefit of reduced side effects does not prevent the dose from being obvious.

The impact of foreign judgments

Lord Hodge noted that the judgments of foreign jurisdictions were not "*particularly helpful*". Due to differences in evidence and the manner in which that evidence is tested, he noted that "*one may derive support from the approach to the question and methods of reasoning of other national courts but should never rely uncritically on the outcome*".

Interveners

The case attracted inventions from the IP Federation, Medicines for Europe, the British Generic Manufacturers Association and the UK Bioindustry Association, which largely advocated a fact specific analysis on a case by case basis. Of particular note, in response to the interventions, Lord Hodge noted that there is no "*general proposition that the product of well-established or routine enquiries cannot be inventive*", rather, that "*efficacious drugs discovered by research involving standard pre-clinical and clinical tests should be rewarded with a patent if they meet the statutory tests*". He

also noted that "*this judgment does not militate against selection patents or improvements patents*".

A copy of the decision can be found here

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