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UK SUPREME COURT EXPLAINS THE LAW OF OBVIOUSNESS

02 April 2019

Several generic pharmaceutical companies have prevailed in the UK Supreme Court in a patent dispute testing the practical bounds of patent protection for dosing regimens: Actavis Group PTC EHF & Ors v ICOS Corporation & Anr [2019] UKSC 15 (27 March 2019).

Background

Actavis, Teva and Generics challenged the validity of ICOS Corporation's European patent (EP(UK)1173181) (the patent). The patent claims protection for a low level dosing regimen for tadalafil (the active ingredient in ICOS' licensee's Eli Lilly's CIALIS medicine) for use in treating erectile dysfunction (ED).

The first instance judge found that, in light of prior published information, at the priority date of the patent it would have been obvious to investigate tadalafil as a treatment for ED. However, the judge concluded that the claimed "up to" 5mg daily dose as a treatment for ED was not obvious. This was because although the skilled team would "very likely" test a 5mg daily dose in the course of clinical trials, they would not do so with a reasonable expectation that 5mg would produce a clinically relevant effect at all nor one with minimal side effects.

The Court of Appeal disagreed with the judge, concluding that he had erred and the patent was invalid, albeit for slightly different reasons expressed in three separate judgments of the sitting Lord Justices.

The UK Supreme Court review of the law of

obviousness

The case proceeded to the Supreme Court, where Lord Hodge took the opportunity to address the law regarding obviousness generally. His judgment is therefore likely to be the starting point in all assessments of obviousness undertaken by the courts for the foreseeable future.

Lord Hodge's view was that the focus of an obviousness assessment should be the inventive concept of the relevant claim, whether adopting the approach to assessment conventionally employed by the English Courts (Windsurfing/Pozzoli) or the "problem-and-solution" approach conventionally employed by the European Patent Office (EPO). However, neither formula should distract the court from the statutory question, this being whether 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".

Lord Hodge confirmed that a question of obviousness must be considered on the facts of each case, the court weighing the balance of factors in light of all the relevant circumstances.

While the Enlarged Board of Appeal of the EPO has held (Abbott, G0002/08) that it is possible to obtain a patent for a new and inventive dosage regime for a known medicament to treat a particular illness (i.e. the same illness as the medicament was previously known for treating), Lord Hodge noted that the EPO has not sanctioned any relaxation of the tests of obviousness in relation to dosage patents.

Assessment of the obviousness challenge to ICOS' patent

In the present case, in which the asserted invention of ICOS' patent was a dosing regimen for tadalafil for the treatment of ED, these factors relevant to the assessment of obviousness included the familiarity of the skilled person with the multiple dose ranging studies necessary as a generality, it being the standard practice to investigate appropriate dosing regimens.

The obvious course from the prior art for the skilled person was to embark on routine testing to establish the appropriate dosage regime for tadalafil. Those tests included the completion of the dose-ranging studies which were the purpose of Phase IIb and would lead to the claimed regime. Thus, the patent was obvious. The fact that the Phase IIb

studies revealed that tadalafil at 5mg remained effective for ED, and unexpectedly had reduced side effects, was an added benefit which did not confer an inventive step on the otherwise routine research pathway and obvious dosage.

The judge's failure to appreciate the logical consequences of his own finding - that it was very likely that the skilled team would continue the testing at a 5mg dose - was an error of principle which allowed an appellate court to carry out its own evaluation.

What does this mean for dosing regimen inventions more widely?

Lord Hodge stressed that this did not mean that the product of well-established or routine enquiries cannot be inventive. Nor is there any policy reason why a novel and inventive dosing regimen should not be rewarded by a patent. He expressed agreement with a notable judgment for dosing regimen patents, given by the Court of Appeal in Actavis UK Ltd v Merck & Co Ltd [2008] EWCA Civ 444. In that case, Jacob LJ held that following the decision of the EPO's Enlarged Board of Appeal in Eisai, G5/83 [1985] OJ EPO 64, Swiss form claims are allowable where the novelty is conferred by a new dosage regime or other form of administration of a substance.

However, Jacob LJ continued:

> "So holding is far from saying that in general just specifying a new dosage regime in a Swiss form claim can give rise to a valid patent. On the contrary nearly always such dosage regimes will be obvious - it is standard practice to investigate appropriate dosage regimes. Only in an unusual case such as the present (where… treatment for the condition with the substance had ceased to be worth investigating with any dosage regime) could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim."

This caution was prophetic. On the unusual facts in Actavis v Merck, the skilled person's expectation of success had fallen so low by the priority date that it was not obvious to try finasteride for the treatment of male pattern baldness. Accordingly, Merck's inventive step lay not in the dosing regimen alone. This was

not the case for tadalafil for the treatment of ED at the priority date of ICOS' patent in light of the prior art. In a similar way, technical advances confined, in light of the prior art, to the specific dosing regimen claimed failed to confer inventive step in Generics v Yeda [2017] EWHC 2629 (Pat), FKB v AbbVie [2017] EWHC 395 (Pat), Novartis v Focus [2016]

EWCA Civ 1295, Hospira v Cubist [2016] EWHC 1285 (Pat), Richter v Generics [2016] EWCA Civ 410, Accord v medac [2016] EWHC 24 (Pat) and Hospira v Genentech [2015] EWCA Civ 57. (Of course the obviousness challenge considered by the English court may differ to the prior art considered by the EPO in the assessment of inventive step).

Accordingly, in light of the Supreme Court's judgment in Actavis v ICOS and consistently with the jurisprudence more broadly, it would appear that a dosing regimen that would be reached at the priority date by following standard clinical trial procedures to completion will not, alone, contribute a technical advance that meets the statutory test for inventive step in the UK, however surprising the dosing regimen settled upon.

Lord Hodge noted that while the need to facilitate expensive pharmaceutical research is an important policy consideration for legislators and others involved in intellectual property law, it was also a factor behind the creation of regulatory data protection; the implication being perhaps that patent law should not be stretched to cover the results of obvious research and routine enquiries.

The relevance of judgments in other jurisdictions

Lord Hodge noted that courts in several other jurisdictions had given judgments in parallel patent disputes, including in respect of different designations of the same European patent. In some of these, ICOS had succeeded (so far), in others it had not. Lord Hodge said that he did not find these judgments particularly helpful:

> "Because of the differences in the evidence led, the manner by which it is tested, and the differing findings to which that evidence gives rise, 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."

On the other hand, Lord Hodge considered it well established that although not bound to do so, the courts in the UK "should normally follow the settled jurisprudence for the EPO (especially decisions of its Enlarged Board of Appeal) on the interpretation of the European Patent Convention in the interests of uniformity, especially when the question is one of principle".

The Supreme Court's judgment in Actavis Group PTC EHF & Ors v ICOS Corporation & Anr [2019] UKSC 15 (27 March 2019) is available here.

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