Actavis Group PTC EHF and others v ICOS Corporation and another (United Kingdom Supreme Court, 2019 UKSC 15)

Prepared by UNCTAD's Intellectual Property Unit

Case summary

This judgment deals with an appeal submitted to the Supreme Court of the United Kingdom (hereinafter "the Supreme Court") that concerns an application of a test of obviousness on a dosage patent under section 3 of the Patents Act 1977. The Court held that the inventiveness of dosage patent claims needs to be determined on a case by case basis and that the routine nature of the research that resulted in the discovery of a lower efficient dose undermines the inventiveness of the claims.

The facts

The patent which is the subject of this appeal is EP(UK) 1,173,181 ("the 181 patent"), owned by ICOS. It relates to the use of a 5mg daily dose of *tadalafil* for the treatment of erectile dysfunction ("ED"). Tadalafil is the generic name for the drug Cialis, which is a second in class (a "me too") medicine used to treat ED as an alternative to sildenafil (more commonly known by its brand name, Viagra). The patent also discloses that (i) tadalafil is effective in treating ED at a lower dose and with minimal side effects as compared to VIAGRA and (ii) could be taken daily (for chronical use) rather than "on demand" due to its increased half-life (i.e. the time it takes for the concentration of the drug in the body to be reduced by 50%).

The respondents challenged the patent on the ground that it is obvious to try. The prior art for the claim is contained in patent EP 0 839 040 ("the Daugan patent"), which 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 first instance court held that a 5mg daily dose of tadalafil was not obvious as a treatment for ED. The Court of Appeal reversed the decision and held that while a skilled team of researchers would find the efficacy of the 5mg dose to be "rather surprising", this was not enough for the patent to be considered inventive, given the routine nature of the research that resulted in the unexpected discovery.

The legal issues

In this case, the Supreme Court emphasized that the statutory question as to whether the inventive step is obvious to a skilled team is critical, and the obviousness must be considered holistically on the facts of each case by taking the particular circumstances into account. In this vein, it is important for a court to consider a stepwise series of tests when the skilled team would undertake pre-clinical and clinical research in the context of a clearly foreseeable research pattern. Addressing the approaches to obviousness, the Supreme Court firstly acknowledged the so-called "patent bargain", noting that the purpose of the grant of a patent is to encourage innovation.[1] So, the general principle is that the extent of the patent monopoly

[1] P17, para. 53 of the Judgment. In English law, this principle was stated by Lord Mansfield in *Liardet v Johnson* (1778), quoted in Hulme, "On the History of Patent Law" (1902) 18 LQR 280, 285 and cited by Lord Sumption in the leading judgment in *Generics (UK) Ltd (trading as Mylan) v Warner-Lambert Co LLC* [2018] UKSC 56; Bus LR 360, para 17.

should correspond to and be justified by the actual technical contribution to the art[2] (*Generics v Warner-Lambert*[3]). This overarching principle was confirmed both by the UK patent law and the European Patent Convention.[4]

The Supreme Court went on to consider whether an invention is obvious by having regard to the state of the art at the priority date of the invention".[5] The Court also defined the scope of prior art for consideration by noting that "the uninventive steps which the skilled team would take after the priority date to implement the closest prior art are not excluded from consideration in the assessment of the alleged invention's obviousness at the priority date".[6]

The Supreme Court pointed out the so-called *Windsurfing/Pozzoli* structure established by domestic jurisprudence and the European Patent Office's (EPO) *problem-and-solution* approach to address the question of obviousness. First, the *Windsurfing/Pozzoli* test requires the following in assessing non-obviousness:[7]

1) (a)Identify the notional 'person skilled in the art';
   (b)Identify the relevant common general knowledge of that person;
2) Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;
3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim as construed;
4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

Second, the EPO's *problem-and-solution* approach contains three main steps:

1) Determining the 'closest prior art';
2) Establishing the 'objective technical problem' to be solved; and
3) Considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

The Court noted that approaches on the evaluation of inventive step should not be applied in a literalist way.[8] For this purpose, the Court recalled the direction provided by *Generics (UK) v Lundbeck*,[9] that:

> "The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible

[2] P19, para. 57 of the Judgment
[3] Decision cited in footnote 1, above.
[4] P17, para. 54 of the Judgment, referring to the EPO Technical Board of Appeal in its decision *Agrevo/Triazoles* (Case T-939/92) [1996] EPOR 171, para 2.4.2.

[5] P19, para. 58 of the Judgment
[6] P19, para. 59 of the Judgment
[7] P20, para. 60 of the Judgment
[8] P21, para. 61and 62 of the Judgment
[9] *Generics (UK) Ltd v H Lundbeck* [2007] RPC 32

avenues of research, the effort involved in pursuing them and the expectation of success."[10]

Based on this, the Court identified the following ten factors as relevant considerations in the present case, although the list is not exhaustive:

(1) Whether something was "obvious to try" at the priority date, in other words, whether it is obvious to undertake a specific piece of research which had a reasonable or fair prospect of success;
(2) The routine nature of the research and whether there is an established practice of following the research through to a particular point;
(3) The burden and cost of the research. The Court noted here that the need to facilitate expensive pharmaceutical research is an important policy consideration. But the effort involved in research is only one of several factors which may be relevant to the question of obviousness;
(4) The necessity for and the nature of value judgements, which act in favor of non-obviousness;
(5) The existence of alternative or multiple paths of research often but not necessarily indicates the non-obviousness of an invention.[11] But it is necessary to bear in mind the possibility that more than one avenue of research may be obvious;
(6) Whether the skilled person undertook the technical trials with some specific technical purpose in mind and not for the sake of doing so.[12] The absence of a motive to take the allegedly inventive step makes an argument of obviousness more difficult;
(7) Whether the results of research are unexpected;
(8) The need to avoid hindsight: where the pattern of the research program which the skilled person would undertake can clearly be foreseen, it may be legitimate to take a step by step analysis, subjecting each step the skilled person is required to take to an obviousness test;
(9) Whether a feature of a claimed invention is an added benefit in a context in which the claimed innovation is obvious for another purpose. The Court referred to other cases where a patent was found invalid on the ground of obviousness because it was obvious to select the features of the claim for the one purpose notwithstanding that it was not obvious for the other purpose;
(10) Whether the nature of the claim is validly recognized. In relation to dosage patents the Court reiterated that there is no blanket prohibition on such patents. On the other hand, there has been no relaxation of the rules in relation to the assessment of inventive step for these patents.

In the present case the Court conceded that the efficacy of the 5mg dose was unexpected and that a value judgement was required to characterize a minimum effective dose. However, the Court considered that the relevance of these factors, in addition to the burden and cost of the research, was undermined by the routine nature of the research that resulted in the discovery. In its analysis, the Court stated that in patent claims for dosage forms, the target of the skilled person's research is in large measure pre-determined. It is common general knowledge that regulators are often interested in and could require evidence of the minimum effective dose. The skilled team would therefore aim for a dose as low as possible but consistent with

[10] P22, para. 63 of the Judgment.
[11] P24, para. 69 of the Judgment, Also stated in *Brugger v. Medic-Aid Ltd* (No 2) [1996] RPC 635, 661, Laddie J stated;
[12] P24, para. 70 of the Judgment

effectiveness. In the Court's view the inventiveness of the dosage regime has to be assessed in that context.

The starting point in the assessment of obviousness in this case was the Daugan patent that 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 Daugan patent has enabled the skilled person to perform the invention of the use of tadalafil for the treatment of ED. The notional skilled person's task is to implement the *ex hypothesi* valid patent. That involves finding the appropriate dosage regime having regard to safety, tolerability and effectiveness. The procedures to achieve that end are familiar and routine. The team, having found a therapeutic plateau, would be very likely to test even lower doses as part of Phase II clinical research and so come upon the dosage regime which is the subject matter of the disputed patent. It is not necessary for the skilled team to identify in advance of the clinical testing the specific dose which is the subject of the claim.

The Court agreed with the Court of Appeal that the logical consequence of this finding is to undermine several of the factors for non-obviousness, such as the lack of an expectation of efficacy at a 5mg dose, the fact that the effectiveness of tadalafil at a dose of 5mg was a surprise; and that there was an important value judgment to be made on how to proceed in the course of the research program. What prevailed in the view of the Court was the routine that drove the completion of the dosage studies (which in turn led to the added - and surprising - advantage of tadalafil at 5mg).

Points of Significance

- The decision diverted from previous judgments. As a result of the present decision, the inventiveness of dosage patent claims in the UK needs to be determined on a case by case basis. The finding that developing the appropriate dosage regime is part of Phase II clinical research and hence, it is obvious to embark on that exercise and carry out tests in a routine way until an appropriate dose is ascertained is likely to impact many dosage patents.
- The Court outlined ten factors for testing obviousness. Although the Court has not provided an overriding importance to any of the factors, it held that a routine character of the steps related to drug testing seems to undermine other factors. An invention is unlikely to be considered inventive, if the dosage regime was discovered using routine experimentation, following the standard procedures used to establish a dose response relationship.
- In assessing the obviousness of a dosage patent, a court should avoid hindsight and consider the facts as a whole. All the general principles for assessing patents also apply to the dosage patent.
- Under the broader context of the TRIPS Agreement, dosage patents, other patents claiming new use and new forms are not expressly mentioned. Developing countries can exclude them on the basis of novelty (i.e. the claim concerns the new dosage of a known product). Alternatively, dosage claims may be excluded from patentability as methods of medical treatment (TRIPS Art. 27.3(a)). This is the approach taken under the Argentinian patent guidelines (2012):

  > "Some patent applications are directed to inventions consisting of dosages of an existing product, such as once a day pediatric dosages or dosage forms. While at times they are filed as product claims, they are equivalent

to claims on medical treatment methods, since dosage is not a product or process, but a dose of the product with which the therapeutic action is obtained for that use. Therefore, they are not patentable."[13]

Key Words: dosage patent, inventiveness, obviousness, pre-clinical and clinical research, obvious to try.

Decision available at: https://www.supremecourt.uk/cases/uksc-2017-0214.html

[13] Argentina, Ministry of Industry, Ministry of Health and National Industrial Property Institute, Joint Resolution, Adoption of Guidelines for Patentability Examination of Patent Applications for Chemical and Pharmaceutical Inventions, Buenos Aires, 5/2/2012.