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# EU Case Reports

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This section summarises and comments on recent interesting judgments. It is not intended to be exhaustive, nor are the papers intended to constitute legal advice. For further information contact:

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# UK high court revokes Escitalopram UK patent; Validity of second medical use claims based on dosage regimes in the UK; Stay of proceedings in the UK courts pending EPO opposition proceedings

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## UK HIGH COURT REVOKES ESCITALOPRAM UK PATENT

Escitalopram is an antidepressant that is an enantiomer of the drug citalopram. It is sold by a Danish pharmaceutical company, Lundbeck, which specialises in diseases of the central nervous system. The patent was revoked at the UK Patents Court, on the grounds that the claims of the invention were broader than the technical teaching of the invention, and thus the invention was insufficiently disclosed across its claimed breadth.

The Decision was handed down on 4 May by Mr Justice Kitchin in relation to European Patent (UK) No. 0347066. Three generic manufacturers attacked the patent on the grounds of lack of novelty, lack of inventive step and insufficiency.

### The claims were novel and inventive

The novelty attack was based on the disclosure of two US patents, 4136193 and 4650884. These patents disclose a racemic mixture of the (+) and (–) enantiomers of citalopram. Claims 1 and 3 of the patent were

directed to the (+) enantiomer and salts thereof, and to pharmaceutical compositions containing the (+) enantiomer, respectively. It was alleged that claim 1 and claim 3 of the patent had a scope that extended to the (+) enantiomer when in the form of the racemate, and therefore such claims were anticipated by the disclosure of the 193 and 884 patents, which disclosed the racemate.

The Judge concluded that, in the context of the specification, the skilled person would consider that the claims were directed to the individual (+) enantiomer of the citalopram racemate, and not the (+) enantiomer when in the form of the racemate. Accordingly, the claims to the individual (+) enantiomer were considered to be novel.

With respect to obviousness, the generic companies used two arguments. First, they considered that the synthetic route to make escitalopram described in the patent was obvious. Secondly, they considered that enantiomers of citalopram would be separated using chiral HPLC, allowing the (+) enantiomer to be used to make a pharmaceutical composition.

The Judge adopted the standard approach to assessment of inventive step in the UK,

namely adopting the four-pronged approach of:

- identifying the inventive concept of the claim;
- assuming the mantle of the person skilled in the art at the priority date;
- identifying the difference between the prior art and the inventive concept of the claim; and
- asking whether the difference would have been obvious or required any further invention.

In respect of the common general knowledge of the skilled person, there was disagreement over:

1. what the skilled person would have known as to the likely activity of enantiomers and whether that person would have had any motive to resolve a racemate of a selective serotonin reuptake inhibitor (SSRI) such as citalopram into its enantiomers; and
2. what the skilled person would have known of the various possible techniques for resolving racemates, and in particular what that person would have known about chiral HPLC and its use on an analytical and preparative scale.

The Judge found that, by 1988, it was well understood that the activity of individual enantiomers of a racemate may well be different and that inactive enantiomers might properly be considered an impurity, and might have pharmacological or toxicological effects. The Judge was satisfied that a medicinal chemist would be well aware of the desirability of resolving racemic drug candidates and testing the individual enantiomers. The generic companies, however, needed to prove that either synthesis or chiral HPLC purification were obvious. They failed to do so.

The Judge held that use of chiral HPLC was not routinely used and at the priority date of the patent application was not within

the common general knowledge of the skilled person. The Judge further concluded that the synthetic reaction schemes would not have been obvious. The Judge considered that the previous unsuccessful attempts by Lundbeck to solve the problem addressed by the patents were further evidence of non-obviousness.

### **The claims were too broad**

The patent finally was revoked for insufficiency. The generic companies argued that citalopram was an obvious target for resolution. If any technical contribution had been made by the invention, then it lay in finding a way to carry out that resolution. Claims 1 and 3, however, claimed the (+) enantiomer however obtained. Therefore it was argued that these claims were too broad. This followed the arguments in *Biogen v Medeva* at the House of Lords.

The Judge agreed that it was obviously desirable to separate and test the enantiomers of active racemates at the priority date. He agreed that the inventive step was not in deciding to separate the enantiomers, but finding a way it could be done. The Judge concluded that the claims were too broad as they covered methods of resolving citalopram that owed nothing to the technical teaching of the patent or any principle it disclosed. In other words, areas of the claim were not taught sufficiently by the patent, those being ways of making (+) citalopram using techniques other than the synthetic route disclosed.

Thus, despite the fact that the invention had been clearly and completely described to allow the skilled person to perform it, as generally required for 'classic' sufficiency of patent disclosure, the claim was invalidated for so-called 'Biogen' type insufficiency in which the excessive breadth of claim leads to a disconnect between the monopoly sought and the technical contribution to the art. The Judge stated:

The first person to find a way of achieving an obviously desirable goal is not permitted to monopolise every other way of doing so.

The turnover of Lundbeck is highly dependent on citalopram, and it seems likely that the case will be appealed.

## **VALIDITY OF SECOND MEDICAL USE CLAIMS BASED ON DOSAGE REGIMES IN THE UK**

In the UK High Court decision dated 6th May, 2007, Actavis successfully revoked Merck's European patent EP724444 relating to the use of a low dose of Finasteride for the treatment of androgenic alopecia. While the claims were considered inventive, the claim format was not considered to provide novelty, in contrast to the position that apparently would be taken by the European Patent Office following decision T1020/03 of the Technical Board of Appeal.

Finasteride was originally sold by Merck under the name PROSCAR for the treatment of Benign Prosthetic Hyperplasia (BPH). Merck European patent EP285382 disclosed a further use of finasteride in the treatment of male pattern baldness (MPB), a condition of androgenic alopecia, at a dose of 5–2,000 mg.

EP724444, the patent in suit, disclosed that the use of low doses of finasteride were effective in treating androgenic alopecia. Claim 1 was in the second medical use form; 'the use of [finasteride] for the preparation of a medicament for oral administration of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 1.0 mg'.

UK practice was developed in the decision of the Court of Appeal *Bristol-Myers Squibb – v- Baker Norton* (2001) which considered the second medical use of taxol in the treatment of cancer. Claim 1 in the taxol case specified the use of taxol for manufacturing a medicament for administration of defined amounts of taxol over a period of 3h or less, as a means for treating cancer. The use of taxol was already known as a treatment for cancer and the only difference was the dosing protocol. The Court of Appeal considered that the dosing protocol could not provide novelty.

In this present case Mr Justice Warren was clearly bound by the *Bristol-Myers Squibb* decision, and saw no distinction between that case and the Merck claims of EP724444. Accordingly, the patent was invalid for lack of novelty over the prior disclosure of the use of finasteride for the treatment of MPB.

The Judge went on consider obviousness (although he was not required to do so, having disposed of the case on novelty) and found that, on the facts, it would not have been obvious to a skilled team at the priority date to embark upon trials of oral finasteride as a treatment for androgenic alopecia. This finding on inventive step is relevant if the decision on the novelty provided by the second medical use claim is appealed.

Decision T1020/30 was issued by the European Patent Office after the *Bristol-Myers Squibb* decision in the UK courts. Any appeal that is filed will allow the current discrepancy between the UK approach and the European Patent Office approach to second medical use claims to be addressed.

## **STAY OF PROCEEDINGS IN THE UK COURTS PENDING EPO OPPOSITION PROCEEDINGS**

Two recent decisions have looked at different aspects of the interrelation between court actions before the UK Courts in respect of an EP (UK) patent, and opposition proceedings against the same patent before the European Patent Office.

With respect to the general principle of staying UK proceedings, the UK Patents Court Decision of Mr Justice Lewison in *Glaxo Group Limited v Genentech Inc* has reviewed the relevant law in this area. Genentech owned a second medical use patent for the use of an anti-CD20 antibody in the manufacture of a medicament for the treatment of rheumatoid arthritis. GlaxoSmithKline (GSK) sought to revoke Genentech's patent, and filed an opposition at the European Patent Office in August 2006. GSK also launched revocation proceedings in

the UK Courts. Genentech applied to stay the UK proceedings, pending the EPO decision.

Mr Justice Lewison considered that there was a presumption, although not a strong one, in favour of a stay when considering all the relevant law. In this case, however, he decided the balance of justice was in favour of allowing the proceedings to go trial. Of interest is that he also stated:

I would, however, add that the practice now adopted in patent cases does seem to be to some extent out of line with the more usual commercial case which comes before our Courts...It may well be time for the Court of Appeal to examine the current practice to see whether it is justified and if it is, to say so definitively, once and for all.

In an earlier case at the Court of Appeal the question of whether payment of costs and damages following a UK judgment should be stayed pending the outcome of EPO opposition proceedings has been decided.

Unilin owned a European Patent found to be partially valid and infringed in both the Patents County Court and the Appeal Court. Leave to appeal to the House of Lords had been refused.

The defendants, Berry, had orders to pay costs to Unilin. Unilin elected to take

compensation by account of the profits made by Berry, and had applied for directions for this inquiry. Berry applied for a stay of that enquiry and a stay in the assessment of costs because the European Patent was subject to a continuing opposition in the EPO, arguing that if the EPO revoked the patent, that decision would have retrospective effect and nullify the EP(UK) patent.

The Appeal Court concluded that Berry was prevented from challenging Unilin's entitlement to an account of profits and costs, whatever the ultimate result before the EPO. This decision means that if a patent has been found to be valid and infringed before the UK Courts, damages and costs will be payable even if the European patent is then revoked during opposition or appeal proceedings before the EPO at a later date.

The fact that an infringer in the UK will have to pay damages under a European patent (UK) that is later revoked at the EPO (and thus effectively never existed) might well be a factor arguing in favour of a stay of any proceedings pending the outcome of an opposition or appeal, should the UK Court of Appeal take up the issue in due course.

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