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Intellectual Property Advisory: Patentability of Dosage Regimens at the EPO and in the UK

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It has long been established that second (and further) medical uses of a known medicament may be patented at the European Patent Office (EPO) and in the UK, provided that appropriate claim formats are used, including those now specified under the EPC 2000. What has been more controversial is where no new disease/condition is being treated and the distinguishing feature of the invention lies in a novel and inventive treatment regime (*e.g.*, in the method, timing, frequency, or dosage of administration of the medicament). The UK courts have in the past found against the patentability of such claims whereas the EPO has generally (but not uniformly) adopted a more permissive position to such subject matter.

A recent decision of the English Court of Appeal (the second highest court in England and Wales) has, however, indicated a shift in the UK approach, whilst a referral to the EPO's Enlarged Board of Appeal seeks to obtain clarification and a more uniform approach on the correct position to be taken at the EPO.

The *Actavis v. Merck* Court of Appeal Decision[1]

Actavis had applied to the English High Court to have the UK part of EP(UK) 0,724,44 revoked. The patent had been granted by the EPO and, whilst the relevant statutory provisions of the UK Patents Act 1977 mirror those of the European Patent Convention, the UK courts occasionally adopt a different interpretation of the relevant provisions or have different facts or evidence presented to it, meaning that patents granted by the EPO are not infrequently found to be invalid or only partially valid by the UK courts.

The case turned entirely on the validity of claim 1, which read:

> The use of [finasteride] for the preparation of a medicament for oral administration useful for the treatment of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 1.0 mg.

It had already been suggested in the prior art to use finasteride for treating androgenic alopecia, albeit with a daily dosage of 5 mg or more. Therefore, the case turned on whether patentability for a new and non-obvious manner of using finasteride could be saved by specifying the particular dosage regimen.

The High Court revoked the UK part of the patent, relying on the previous *Bristol Myers Squibb / Taxol*[2] decision, where a claim directed to the use of a known substance to treat a known medical indication but by a particular dosing regimen was found to lack patentability.

Merck appealed the decision to the Court of Appeal. In coming to its decision, the Court of Appeal considered both UK case law (the Court of Appeal's previous *Bristol Myers Squibb / Taxol* decision) and the relevant EPO case law. The usual rules of precedent mean that the Court of Appeal is bound by its previous decisions, but is not bound by decisions of the EPO, although EPO decisions may be of significant persuasive authority.

Perhaps surprisingly, the court decided that it was able to and saw fit to go against its earlier *Bristol Myers Squibb / Taxol* decision and follow what, in its view, was "settled" EPO practice in allowing such claims (this was despite conflicting case law at the EPO on this point and the referral of the matter to the Enlarged Board as discussed below). The court's reasoning was that the facts of the case could be distinguished from those of the *Bristol Myers Squibb / Taxol* decision so that there was no clear precedent and, moreover, even if there was a clear precedent, then a special exception to the usual rules of precedent should apply in view of the settled position at the EPO. Accordingly, the Court of Appeal saw fit to rescind the High Court's decision to revoke the patent, thereby ruling in favour of the validity of the claims.

The Referral to the EPO's Enlarged Board of Appeal (Pending As G 2/08)

The referral to the Enlarged Board came about from an appeal (T 1319/04) from the Examining Division's decision to reject European Patent Application No. 94306847.

The application concerned the use of nicotinic acid in the treatment of hyperlipidaemia in a once-per-day prior-to-sleep regimen. The prior art already disclosed the use of nicotinic acid in treating hyperlipidaemia, but it did not suggest the dosing regimen that resulted in reduced side effects. Notwithstanding this, the Examining Division rejected the application on the basis that the feature "once per day prior to sleep" was incapable of distinguishing the claimed invention from the prior art because this feature reflected a medical activity excluded from patentability under the provisions of the EPC and it did not represent a further medical indication from which patentability could be derived.

In the appeal proceedings, the Board of Appeal reviewed the case law on the patentability of dosage regimens and, to ensure a uniform and authoritative interpretation of the relevant provisions, it saw fit to refer various questions to the Enlarged Board.

The following questions were referred:

1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?
2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?
3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

Decisions from the Enlarged Board generally take at least one year and more usually two to three years. In the meantime, first-instance proceedings (proceedings before the Examining and Opposition Divisions) where the decision depends entirely on the Enlarged Board's decision may be stayed pending the outcome of the Enlarged Board referral. Interestingly, the English Court of Appeal has also decided to give Merck a longer period than usual to seek review of the case by the House of Lords, such period expiring only once the decision of the EPO Enlarged Board of Appeal has been handed down.

Endnotes

[1] *Actavis UK Limited v. Merck & Co Inc.* [2008] EWCA Civ 444

[2] *Bristol-Myers Squibb v. Baker Norton [1999] RPC 253*

If you would like more information or have any specific concerns about any of your European patent applications, please contact:

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