

DOSING REGIMENS MAY BE PATENTABLE IN THE UK

The UK Court of Appeal has decided that a “second medical use” claim can be patentable even if the sole distinguishing feature of the claim over the prior art is a new dosing regimen or new dosage form (*Actavis UK Limited v Merck & Co Inc* [2008] EWCA Civ 444). This decision effectively brings UK practice into line with common practice at the European Patent Office (EPO).

The Court’s decision is a surprise, as an earlier decision of the same court found a lack of patentability for a claim to a different dosing regimen. However, the Court of Appeal found reasons to distinguish the facts of the case at hand from those of the earlier case.

Surprisingly, the Court also commented that, even if the facts could not be distinguished, they were entitled to overturn the earlier decision. Although this goes against the usual rule of the Court of Appeal being bound by its own decisions, the Court decided that a limited exception applied to the facts of the case at hand, which exception allowed it to ignore the reasoning of the earlier decision.

Background

The EPO granted a European patent to Merck, the claims of which patent related to the use of finasteride for the treatment of androgenic alopecia (AA), wherein the finasteride was administered to the subject by way of a previously undisclosed dosing regimen (oral administration of about 0.05 to 1.0 mg of finasteride).

At the time the patent in question was filed:

- (a) finasteride was already known to be useful in the treatment of benign prostatic hyperplasia at a 5 mg oral dose (i.e. a dose much higher than specified in the patent at hand); and
- (b) finasteride had already been proposed to treat AA, using the same 5 mg dose.

Actavis applied to the UK High Court to have the UK part of the European patent revoked, and succeeded in gaining an order for revocation. The High Court ruling relied upon an earlier decision of the UK Court of Appeal in the “BMS” case (*Bristol-Myers Squibb v Baker Norton* [1999] RPC 253). In the BMS case, a lack of patentability was found for a claim directed to the use of a known substance to treat a known indication, but by using a particular dosing regimen.

The Court of Appeal Decision

In the decision of the Court of Appeal ([2008] EWCA Civ 444), the Court pointed out that the facts of the case at hand could be distinguished from those in the BMS case. Essentially, the BMS patent had claims directed to a patient-specific dosing regimen, which regimen was questionable in terms of industrial applicability. In contrast, the claims of Merck’s patent were capable of industrial application because they were directed at the manufacture of a pill and not to a method of medical treatment. Also in contrast to the BMS case, the features of the dosing regimen could not be asserted to have been inherently disclosed in the prior art.

Because the BMS decision was found not apply to the case at hand, and because the claims were additionally found to be inventive, the Court of Appeal rescinded the order for revocation of the patent.

The Court then went on to discuss the hypothetical situation where it was not possible to distinguish over the facts of the BMS case. Even in that situation, the Court found no reason to change their decision. This was on the grounds that an exception applied to the case at hand that allowed the Court of Appeal to ignore the precedent established by the BMS case. As explained in the decision, the exception arose because the Court of Appeal was satisfied that the EPO Boards of Appeal have formed a settled view of European patent law that is inconsistent with the BMS case.

The main EPO decision referred to by the Court of Appeal in reaching this view were *Eisai* (G5/83), as interpreted in *Genentech* (T1020/03). Despite the presence of conflicting EPO case law (and even a pending reference to the Enlarged Board of Appeal on the very point of patentability of dosing regimens), the Court of Appeal held that the EPO had a clearly established policy to allow second medical use claims for new and inventive dosing regimens and dosage forms.

Conclusions

The decision by the Court of Appeal appears to make it possible to gain (or maintain) patent protection in the UK for second medical use claims containing a dosing regimen (or a dosage form) as the sole distinguishing feature over the prior art. This means that examination at the UK Intellectual Property Office (rather than at the EPO) is now a viable alternative route for obtaining a UK patent relating to a new dosing regimen.

However, certain comments in the decision imply that it will not necessarily be easy to enforce such claims. For example, Lord Justice Jacob (who gave the judgment of the Court) commented that:

"... 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 ... could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim".

In other words, while such claims may be found to be novel, it may be difficult to establish non-obviousness.

If you require any further information, please contact your usual adviser at Potter Clarkson.

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N:0131/cld/ms/jk/lc

4 June 2008

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