



## LATEST IP UPDATE FROM POTTER CLARKSON

### Decision G 2/08: a dose of the right medicine

In Decision G 2/08, issued 19 February 2010, the Enlarged Board of Appeal of the European Patent Office has confirmed that, even if it is already known in the prior art to use a medicament to treat a particular illness, Article 54(5) EPC 2000 does not preclude this *same* medicament from being patented for use in a different (novel and inventive) treatment, by therapy, of the *same* illness. Thus, a new dosing regimen for using a known medicament to treat a known illness can give rise to patentable subject matter, protectable by a second medical use claim, even when the dosing regimen is the only feature of the claim which is not comprised in the state of the art.

#### Background

The referral to the Enlarged Board arose from Decision T 1319/04, which concerned a claim directed to the use of nicotinic acid in the manufacture of a medicament for treating hyperlipidaemia (elevated lipid levels in the blood). The only novel feature of the claim was a specified dosing regimen, the medicament being for use "by oral administration once per day prior to sleep". The Examining Division initially refused the application on the basis that this novel claim feature reflected a medical activity excluded from patentability under Article 52(4) EPC (1973). The applicant subsequently lodged an appeal against this refusal. During the pendency of the appeal, the patent law revisions of EPC 2000 came into force and so the application fell to be considered under these new provisions. The Technical Board of Appeal referred the case to the Enlarged Board to consider the interpretation of Article 53c and Articles 54(4) and 54(5) EPC 2000 in relation to new dosing regimens.

Specifically, the following questions were referred to the Enlarged Board:

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?

#### The Enlarged Board's decision

In its decision, the Enlarged Board answered the three referred questions as follows:

*Answer to Question 1:* Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.

*Answer to Question 2:* Such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.

*Answer to Question 3:* Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83.

Thus, in its answers to the first and second questions, the Enlarged Board acknowledges that a new dosing regimen for using a known medicament to treat a known illness can give rise to patentable subject matter. This aspect of the Enlarged Board's decision is consistent with the approach taken by the UK Court of Appeal in *Actavis UK Limited v Merck & Co Inc* [2008] EWCA Civ 444 ([see our IP Update No. 131](#)).

However, the Enlarged Board is careful in its decision to emphasise that the new dosing regimen must not only be verbally different from what is described in the prior art but also must reflect a different technical teaching. Where the new dosing regimen amounts to a mere selection from within the broader disclosure in the prior art, the Board states that existing EPO jurisprudence on the novelty of selections shall still apply (presumably including the widely-applied Decision T 279/89). In short, a new technical effect provided by the dosing regimen must be recognised in order for novelty to be acknowledged.

The Enlarged Board's answer to the third question appears to sound the death knell for Swiss-type claims (*i.e.* 'Use of compound X in the preparation of a medicament for the treatment of indication Y'), not only in relation to new dosage regimen inventions but, more generally, for all second medical use inventions. According to the reasoning of the Enlarged Board, this exception to the general novelty requirement, as previously

instituted by Decision G 5/83, is no longer required in light of the introduction under Article 54(5) EPC 2000 of purpose-related product protection for any new use of a known medicament (*i.e.* 'Compound X for use in the treatment of indication Y').

However, the Enlarged Board acknowledged that many granted patents and pending applications exist which contain Swiss-type claims and decided that its decision shall have no retroactive effect on these cases. Instead, this aspect of the decision shall apply only to future patent applications having effective filing dates at least three months after the date of publication of Decision G 2/08 in the Official Journal (which has not taken place as yet). Until such time, there may still be value in including Swiss-type claims (as well as new EPC2000-style medical use claims) when drafting new patent applications, even though they may add to the amount of excess claims fees payable.

The full text of Decision G 2/08 is available from the EPO [website](#).

**This important decision provides some much needed clarity on the extent to which European patent protection may be obtained for new dosing regimens. Your usual contact at Potter Clarkson will be able to provide you with more detailed advice on the impact of this decision on your patenting activities and any new patenting opportunities that it may present.**

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The information in this Newsletter was correct at the date of release. More up to date information is available by contacting Potter Clarkson LLP. All comments contained here are of a general nature and full professional advice should be sought on any specific problem. Please note that all our Newsletters can be found on our website: [www.potterclarkson.com](http://www.potterclarkson.com).

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