

Patentability of Dosage Regimes – Decision Issued by EBA

Decision G2/08 of the Enlarged Board of Appeal (EBA) at the European Patent Office, issued on 19 February 2010, addresses patentability under EPC2000 of medical use claims where the only distinguishing feature over prior art is a dosage regime and also addresses allowability of Swiss-type medical use claims under EPC 2000.

In G2/08 the EBA has ruled that medical use claims directed to new and inventive dosage regimes are allowable. This confirms that patent coverage can be extended to new and inventive drug administration regimes. At the same time, the EBA has ruled that the Swiss-type medical use claims are not allowable under EPC 2000, completing the move away from this format of claims started by the introduction of EPC2000.

Background

Methods of medical treatment are regarded in Europe as not being capable of industrial application and are therefore not patentable. Under EPC1973 Swiss-type claims of the following format were developed to allow a means to obtain protection for a new medical uses of a known substance:

“Use of a compound X in the manufacture of a medicament for the treatment of disease Y”.

Art. 53(c) EPC 2000 states that European patents may not be granted for methods of treatment by therapy or surgery of the human or animal body, but they may be granted for medicinal products for use in such methods. Article 54(5) EPC 2000 expressly permits purpose-related product claims for a specific medical use not comprised in the state of the art. Accordingly, EPC2000 allows the following format of use-limited claim to be pursued for a new medical use of a known substance:

“Compound X for use in the treatment of disease Y”

Decision G 2/08

The case at issue concerned a Swiss-type claim where the only distinguishing feature over the prior art was a specific dosage regime for a drug already known to treat a certain disease (hyperlipidaemia).

Prior to G2/08 there had been conflicting Technical Boards of Appeal decisions as to whether a dosage regime could be considered a new medical use capable of imparting novelty to a medical use claim, or whether it would simply be considered a method of medical treatment unable to impart novelty.

The Technical Board of Appeal considered the issue of whether a medicament for use in a therapeutic method could be patentable under Articles 53(c) and 54(5) EPC 2000, where the only feature likely to confer novelty on a claim is a dosage regime, to be an important point of law and consequently referred the issue to the EBA. The referred questions and the answers provided by the EBA are as follows:

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?

***YES** – Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament can be patented for use in a different 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?

***YES** – 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.*

3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

***YES** – Where the subject matter of a claim is rendered novel only by new therapeutic use of a medicament, such a claim may no longer have the format of a so-called Swiss-type claim as instituted by Decision G5/83.*

A time limit of three months after publication of the present Decision in the Official Journal of the European Patent Office is set in order that future applicants comply with the new situation.

Implications

In many ways the EBA's decision can be viewed as a welcome provision of certainty that claims under EPC2000 to a substance for use in a new and inventive medical use are allowable and that the medical use does not necessarily need to be a new disease, but could be a new and inventive dosage regime. This gives the prospect of extending patent coverage to new and inventive drug administration regimes, potentially increasing the time a drug may be under patent protection.

This decision will, in due course, signal the end to use of Swiss-type claims in Europe because the EBA has explicitly stated that such claims are not allowable under EPC2000. The EBA acknowledges that many patents have been granted and many applications are still pending with Swiss-type claims. In view of this, G2/08 will have no retroactive effect. Instead, a time limit of three months after publication of G2/08 in the Official Journal of the EPO has been set for future applications to comply with this new situation.

Therefore, for future applications where the date of filing or, if priority has been claimed, the priority date falls later than three months after publication of G2/08 it will not be possible to pursue Swiss-type claims.

The full Decision is available from the EPO's website at:

[http://documents.epo.org/projects/babylon/eponet.nsf/0/1c9976e4866080a2c12576cf00417e3e/\\$FILE/G2_08_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/1c9976e4866080a2c12576cf00417e3e/$FILE/G2_08_en.pdf)

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