PHARMA & BIOTECH: EPO ENLARGED BOARD OF APPEAL DECISION G2/08

Posted on 23/03/2010 by Harriet Wilson

The decision confirms the patentability of novel and inventive dosage regimes and also clarifies the style of claims allowed in Europe where a known medicament has been found to be useful for a new therapeutic treatment. If you have a pending application directed to a new therapeutic use of a known medicament you may wish to consider amending your application in light of the decision.

Dosage regime claims are allowable

Under European law it is allowable to claim a new specific medical use of a known medicament in the form of a "product for use" claim, i.e. 'Compound X for use in the treatment of disease Y'.

The Enlarged Board of Appeal was asked in this case to consider whether the "new use" is patentable if it is known to treat the disease Y with the compound X, but the treatment is new due to a new dosage regime.

The Board found that claims to novel dosage regimes are allowable under European practice.

The dosage regime will need to be defined in the claim to provide a technical effect (usually an advantageous one) over the prior art, in order to meet the novelty and inventive step requirements.

An example of the appropriate claim structure is:

"Compound X for use in the treatment of disease Y, wherein the compound is administered according to *a particular regime (define amounts and/or frequency of administration of the medicament)*."

Swiss-type claims no longer allowed

Swiss-type claims have previously been allowed in Europe in addition to claims in the format referred to above as a "product for use" claim. Swiss-type claims have the following structure:

"The use of compound X in the manufacture of a medicament for the treatment of disease Y."

The Enlarged Board also decided that since there is no longer a cause for Swiss-type claims (as a result of the EPC 2000 changes which allow the “product for use” claim for a new specific medical use of a known medicament), Swiss-type claims are no longer allowable.

Accordingly, where the novelty resides in a new therapeutic use, claims shall no longer have Swiss-type format and should be in the format: ‘Compound X for use in the treatment of disease Y’.

The Enlarged Board has also stated that its decision “shall…have no retroactive effect”, and will apply only to future applications whose filing date or, if priority is claimed, priority date is at least three months after publication of G 2/08 in the Official Journal of the EPO (publication has not yet occurred).

However, for pending applications, other than exceptional cases where the invention may lie in the manner of preparation, it is likely that the best approach would be to convert the Swiss-type claims to “product for use” claims if possible. It is important that the amendment be made while the application is pending as it is unlikely to be possible to change to the new medical use format after the patent is granted.