



Changes to Medical Use Claims in Europe

The European Patent Convention (EPC) is the legislation governing the grant of European patent applications. By 13 December 2007 at the latest, the current version of the EPC will be replaced by a revised version known as “EPC 2000”.

When EPC 2000 is adopted, it will be possible to include in European patent applications a new claim format for covering second (and further) medical uses of a known compound.

Background

Currently, in order to protect the use of a known pharmaceutical compound in the treatment of a new indication, claims of the following format (also known as a “Swiss type claim”) must be used in European patent applications:

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

The scope of such a claim is not entirely clear. However, the generally adopted view is that a Swiss type claim enables a patent proprietor to prevent a third party from *manufacturing* a medicament or pharmaceutical that includes the active ingredient X and is intended for the treatment of disease condition Y. Such claims do not appear to cover subsequent commercial dealings in the medicament. Hence, Swiss type claims provide relatively limited protection.

Forthcoming Change

EPC 2000 will allow broader patent protection for new medical uses of known pharmaceutical compounds in Europe by allowing a new format of second medical use claim. That new claim format is:

“Compound X for use in treating disease condition Y”

The new claim format covers not only manufacture of the pharmaceutical product, but also all subsequent commercial dealings in the product. Thus, the new form of claim provides protection for the product *per se*, albeit limited to products that are for use in the treatment of the specified disease. This will provide the proprietors of patents with such claims with more effective protection, and a greater degree of certainty in the future.

Action

We recommend that any pending European patent applications with claims directed to pharmaceutical uses be reviewed now, and that consideration be given to the introduction of claims in the new second medical use format. In particular, if the broadest form of patent protection that may be secured is by a Swiss type claim, the opportunity to obtain broader protection using the new claim format should be taken.

For European patent applications that might be accepted by the EPO *before* December 2007 (ie before EPC 2000 is adopted), we recommend that steps be taken to delay grant of such applications until after December 2007, to enable claims in the new use-limited product protection format to be included.

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