

First and Second Medical Use



Whilst the European Patent Convention (EPC) includes provisions against patenting of medical methods, it is possible to patent medical uses of substances, such as compounds and compositions. However, in order to do this, particular claim formats must be used.

The claim format currently approved for claiming a first medical use takes the form of “Substance X for use as a medicament”. If a substance, even if that substance is known, has not previously been known for use in medicine, a claim of this type (for use as a medicament) may be used.

The claim format currently approved for claiming a second medical use takes the form of “Substance X for use in the treatment of disease Y”. If the substance has previously been used as a medicament but not for treating a particular disease Y, then a claim of this type may be used.

Claims directed to first and second medical uses must fulfil all the other requirements of patentability, including novelty and inventive step, in order for claims to be granted.

The claim formats discussed above can only be used in relation to substances, such as compounds and compositions. If this claim format is used in relation to a device for an intended medical use, this would be construed as claiming a device that is suitable for that use.

Previously, claims known as “Swiss-type” claims were required in order to obtain protection for second medical uses. These claims took the form of “Use of substance X for the manufacture of a medicament for the treatment of disease Y”. This claim format is now only allowable if used in an application having a filing or earliest priority date before 29 January 2011.

When the currently approved format for second medical use claims was introduced, it was generally accepted that this format had an equivalent scope to the Swiss-type claim format. However, a recent EPO Board of Appeal Decision (T1780/12) has questioned this. This case involved a (parent) patent application that included claims in the Swiss-type format and a divisional patent application that included claims in the currently approved format for second medical uses. The claims of both applications related to the treatment of the same disease. The Examining Division of the EPO had refused grant of the divisional application on the basis that it had claims of substantially identical scope to the claims of the parent application (the claims simply being worded differently), such that to grant the divisional application would result in double patenting. The applicant argued that a Swiss-type claim is a purpose limited process claim, whereas a claim in the currently approved second medical use format is a purpose limited product claim.

The Appeal Board found that although the claims of the parent and divisional applications related to the same invention, they did not relate to the same subject matter. The claims were found to be of different scope and to relate to different subject matter. On this basis the Appeal Board concluded that the grant of these two claims would not lead to double patenting and the patents should be granted.

Additionally, a recent High Court decision (*Warner-Lambert Company, LLC v Actavis Group PTC EHF and others* [2015] EWHC 72 (Pat), 21 January 2015) provides a detailed consideration of the scope of protection afforded by claims in the Swiss-type format. In this case, it was concluded that Swiss-type claims cover a process for the production of medicaments that are suitable and intended for treating the defined disease. It was further concluded that Swiss-type claims are directed at the manufacturer of the medicament, not at a doctor or pharmacy. Therefore it followed that the relevant intention to be considered is that of the manufacturer, not of the doctor or pharmacist. Thus, it was held that Swiss-type claims are infringed only when there is subjective intent by the manufacturer for the product to be used for the patented second medical use (it being irrelevant, at least in relation to Swiss-type claims, whether the prescribing doctor or dispensing pharmacist intends such use).

Going forward, second medical uses will be claimed in the currently approved format, as discussed above, making decisions regarding the Swiss-type claim format of less importance. However, it is clear that it is necessary to think carefully about how best to claim medical uses.