PATENT PRIMER

Medical treatment inventions

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Although methods of medical treatment *per se* are not patentable in Europe, the use of agents or products in the preparation of medicaments for such treatments are. The drawbacks of such limited protection is clear. The European Patent Office is becoming ever more stringent in their requirements for the presence of experimental data in support of the medical use to be present in the application on filing. Whether Europe will ever harmonize with the US in allowing the protection of medical methods is not clear. Until then the burden on inventors to obtain patent protection for medical-use-type inventions is significant and the return is far from adequate.

Unlike patent law in the US, the European Patent Convention does not permit the protection of inventions relating to methods for medical treatment. However, such methods are often of considerable commercial importance. In this article I discuss the various options for the protection of inventions based on medical treatments in Europe. Further, I discuss the limitations of these approaches and what this means for inventors.

Protecting medical methods in Europe

According to the European Patent Convention "methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions…". The reasoning behind this provision is based on ethical and public health provisions: that is, European Patent law is not intended to inhibit the normal daily practices of physicians. Such a philosophy is, of course, inconsistent with permitting patent protection for methods of medical treatment, surgery or diagnosis.

However, there is a caveat that patent protection can be accorded to products, in particular substances or compositions for use in any such methods. In practice this means that in Europe medical inventions can be formatted into 'Swiss style' or 'second medical claims' which follow the form 'the use of an product/composition/compound in the preparation of a medicament X for the treatment of disease Y'.

Second medical use claims: limitations

It will be apparent that a major problem in protecting medical treatments using such an approach is that only the protection of a compound or composition for the treatment of a disease, rather than the treatment regime *per se*, is permitted. Further, the Examining divisions of the EPO consider that the protection of medical inventions is only permitted in the case of a defined disease. Practically, this means that it is difficult to obtain patent protection for the use of a known agent for the treatment of a known disease in which the inventive contribution lies in the elucidation of the mechanism of action of that agent.

A further point to consider is that often the essence of inventions relating to medical treatments lies in the identification of a new dosage regime. Traditionally, under European Law, such new dosage regimes cannot confer novelty on a claim. That is, the dosage regime is not enough in itself to allow the patentability of a claim describing the use of a known agent for a known disease. A recent case has, however, indicated that this may not be the case. That is, the discovery of a new dosage regime may provide the basis for protecting the use of a known agent for treating a known disease. In some respects then it seems that the scope of protection obtained using Swiss-style medical use claims in Europe is expanding.

Medical use: experimental support

European case law indicates that experimental support for the medical use must be present in the application as filed and that it is no longer possible to file this support during the prosecution of the application in order to remedy an insufficiency on filing (BOX). In addition, case law suggests that the common practice of 'creating' hypothetical examples (paper examples) is becoming increasingly less strategic because the examples in question must be technically correct and reproducible otherwise the application may be deemed insufficient. Of course, in practice it is difficult to know whether such examples are technically correct without performing the experiments, and therefore the value of paper examples must be questioned.

On a brighter note it seems that experimental support in the application on filing does not need to be in the form of *in vivo* and/or clinical trial data. *In vitro* data which show a direct correlation with the medical treatment of the condition in question is sufficient. In this respect the European and US requirements for protecting inventions based on medical treatments are harmonized.

In practice, the effect of these increasingly stringent requirements for experimental support for medical uses in an application on filing means that there is a significant experimental burden of patentability required before filing an application. It seems that it may often not be a wise approach to file speculative applications based on medical treatments with little or no experimental support with the aim of filing the support later during the prosecution.

METHODS MEDIATED BY THE PROTO-ONCOGENIC PROTEIN COMPLEX AP-1

The patent in question related to the use of a steroid hormone or analogue thereof which fails to promote transcriptional activation of glucocorticoid- or retinoic-acid-receptor-responsive genes for the preparation of a pharmaceutical for the treatment of AP-1-stimulated tumour formation, arthritis, asthma, allergies and rashes … The patent was opposed on the basis that it did not teach one skilled in the art how to reproduce the invention without undue experimental burden, That is, it was argued that the patent was insufficient. This objection was raised because of the lack of any experimental evidence in the application describing the identification of a steroid hormone which binds a hormone receptor in such a way that the complex disrupts AP-1-stimulated transcription. The applicant, however, provided post-published documents in support of the claimed invention. The opposition division decided that in the case in hand, in which the description of a patent specification provides no more than a vague indication of a medical use for a chemical compound yet to be identified, then more detailed evidence cannot be used later to remedy the fundamental insufficiency of the disclosure at the filing date of the application. The patent was therefore found invalid.

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