

METHODS OF TREATMENT OR DIAGNOSIS

Introduction

1. This Guidance Note explains how changes to UK patent law are made by the Patents Act 2004 which implements provisions of the revised European Patent Convention (“EPC 2000”). The law relating to inventions comprising a method of treatment or diagnosis and inventions comprising use of a substance or composition in such a method is clarified. This ensures continued consistency with the European Patent Convention.

What is the background?

2. EPC 2000 comes into force on 13 December 2007. The Patents Act 2004 includes provisions to implement changes necessary to ensure that UK patent law is consistent with EPC 2000. However, these provisions are not yet in force and it is proposed that they will come into force on 13 December 2007 to coincide with EPC 2000.

3. Currently methods of treatment or diagnosis are excluded from patentability under UK patent law as not having industrial applicability. However, an invention comprising the use of a substance or composition in such a method is not excluded from having industrial applicability and may be patentable. A subsequent, different medical use of a known substance or composition for such a method may currently be patentable in the form “Use of X for the manufacture of a medicament to treat Y” where X is the known substance and Y is the medical condition in question. This is known as the Swiss form of claim.

What legislation is changing?

4. The view taken in EPC 2000 is that it is undesirable to uphold the legal fiction regarding the lack of industrial applicability of methods of treatment or diagnosis as they are, in fact, excluded from patentability in the interests of public policy. UK law is therefore changed to maintain consistency between the approach in the UK and in Europe. The law is also simplified and clarified with respect to the patentability of substances or compositions for use in a method of treatment or diagnosis to be consistent with the EPC 2000.

What is the purpose of the new legislation?

5. New section 4A of the Patents Act 1977 is introduced to define methods of treatment or diagnosis as not being patentable in their own right.

6. Also provided is sub-section (3) which relates to inventions comprising use of a known substance or composition in such a method. Such an invention may be patentable as long as the use of the substance or composition in any such method does not form part of the state of the art.

Such an invention is therefore considered novel where the substance or composition is first used in a method of treatment or diagnosis.

7. Sub-section (4) relates to a subsequent specific medical use of a known substance or composition used in a method of treatment or diagnosis which is different from the method for which it was first used. Such an invention may now be claimed more directly in the form "Substance X for use in treatment of disease Y" as long as the specific use does not form part of the state of the art. Inventions may now be claimed using the simpler, more direct form of claim.

8. While these provisions do not extend the patent protection available, they simplify and clarify the manner in which patent protection may be obtained for these inventions and provide consistency with EPC 2000.

Who will be affected by the changes?

9. Anyone applying for a patent in respect of an invention comprising a substance or composition for use in a method of treatment or diagnosis. An applicant may now claim a subsequent, different use of a known substance or composition in such a method in a more direct form than the Swiss form of the claim.

10. The law relating to such practice is more clearly stated for third parties affected by the patenting of such inventions.

A brief summary

- Methods of treatment or diagnosis are now defined as un-patentable in their own right.
- The law relating to inventions comprising the use of known substances or compositions for use in such methods is more clearly and simply defined.
- A subsequent, different use of a substance or composition in a method of treatment or diagnosis may be claimed in a direct form.

Where can I get more information?

11. Explanatory Notes to the Patents Act 2004 remain available from the OPSI website:

<http://www.opsi.gov.uk/acts/acts2004/20040016.htm> (The Patents Act 2004)

<http://www.opsi.gov.uk/acts/en2004/2004en16.htm> (Explanatory Notes)

12. Furthermore, the UK Intellectual Property Office's comprehensive guide to patent law and practice, the *Manual of Patent Practice*, will be updated to

reflect these changes. The *Manual* is available to download from the UK Intellectual Property Office website at:

<http://www.ipo.gov.uk/patent/p-decisionmaking/p-law/p-law-manual/p-law-manual-practice.htm>

Status of this Guidance Note

13. This Guidance Note has been prepared by the Intellectual Property Office. It gives the Office's view of the changes made by the Patents Act 2004 and as such it has no legal force.

UK Intellectual Property Office

Edition 1
November 2007