

PATENTS ACT 2004

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Section 1 – Methods of treatment or diagnosis

16. This section inserts a new section 4A into the 1977 Act. The new section 4A corresponds to Articles 53(c) and 54(4) and (5) EPC 2000, which deal with the exceptions to patentability and novelty respectively. New section 4A reflects the manner in which inventions of methods of treatment or diagnosis are treated under the provisions of EPC 2000, thus ensuring conformity of practice.
17. New section 4A(1) corresponds to Article 53(c) EPC 2000 and makes clear that an invention which consists of a method of treatment (by surgery or therapy) or a method of diagnosis cannot be patented. The provision replaces existing section 4(2), which corresponds to Article 52(4) EPC. Under existing section 4(2), such inventions are treated as incapable of industrial application, a fiction which EPC 2000 regards as undesirable to uphold since methods of treatment and diagnosis are excluded from patentability in the interests of public health.
18. New section 4A(2) corresponds to Article 53(c) EPC 2000 and replaces existing section 4(3) which corresponds to Article 52(4) EPC. It ensures that the exclusion of methods of treatment or diagnosis from patentability in section 4A(1) does not extend to inventions consisting of substances or compositions for use in such methods.
19. New section 4A(3) and (4) is concerned with the patentability of inventions consisting of a known substance or composition for use in a method of treatment or diagnosis, and corresponds to Article 54(4) and (5) EPC 2000. While these subsections do not extend the availability of patent protection in respect of an invention consisting of a substance or composition for use in a method of treatment or diagnosis, they simplify and clarify the manner in which patent protection may be obtained for such inventions.
20. To be patentable, an invention must be new. Existing section 2(6), which corresponds to Article 54(5) EPC, provides for the patentability of an invention consisting of a known substance or composition for use in a method of treatment or diagnosis when the substance or composition is first used in any such method. The invention is considered to be new if the use of the substance in any such method is unknown. New section 4A(3) has the same effect, so that such an invention is considered novel where the substance or composition is first used in a method of treatment or diagnosis.
21. Where the substance or composition is subsequently used in a method of treatment or diagnosis which is different from the method in which it was first used, the courts have held, on the basis of existing section 2(6), that the subsequent use may be regarded as new but only if the invention is claimed 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, since it was first used in the Swiss Patent Office before becoming embodied in EPO practice.

*These notes refer to the Patents Act 2004 (c.16)
which received Royal Assent on 22nd July 2004*

22. New section 4A(4) enables patent protection to be obtained for the second or subsequent use of a substance or composition in a method of treatment or diagnosis by a direct claim in the form “Substance X for use in treatment of disease Y”. The second or subsequent use, that is, the “specific use” of a known substance or composition in a method of treatment or diagnosis, is treated as new if that specific use was previously unknown. Where patent protection is sought for a substance or composition for specific use in a method of treatment or diagnosis, the Swiss form of claim will still be possible, but inventions may now be claimed in the simpler form.
23. *Paragraph 2 of Schedule 2* amends section 1(1) in order to make clear that the provisions in new section 4A form a part of the definition of patentability. Under section 72(1)(a), a patent may be revoked if the invention is not a patentable one. The change to section 1(1) ensures that it will be possible to revoke a patent on the grounds that it does not meet the requirements of one or more of the provisions in new section 4A. *Paragraphs 3 and 4 of Schedule 2* omit the provisions in sections 2 and 4 that are made redundant by new section 4A.