Intellectual Property Office

Changes to patents legislation made by the Legislative Reform (Patents) Order 2014 from 1 October 2014

Background

The Legislative Reform (Patents) Order 2014 ("the Order") makes changes to section 60 of the Patents Act 1977, which will come into force on 1 October 2014.

These changes will mainly affect companies and individuals involved in clinical trial work, or carrying out work to provide information for health technology assessments of medicines.

This document summarises the changes to the Patents Act.

The full text of the Order, and associated documents, can be viewed at http://www.legislation.gov.uk/uksi/2014/1997/contents/made

What's changing?

The Order makes changes to the experimental use exception (also known as the research exception) in section 60(5)(b) of the Patents Act. These changes will allow companies to use a patented product, when carrying out testing or other activity to provide information to the regulatory authorities who decide whether a drug should be given a marketing authorisation. Companies will also be allowed to use a patented product in testing or other activity carried out to supply information for health technology assessments.

These changes will not apply retrospectively. Only activities carried out from 1 October 2014 will be exempt.

What is meant by "medicinal product assessment"?

Paragraph 6E of the Order defines what is meant by "medicinal product assessment".

The definition covers testing or other activity carried out to provide information required by regulatory authorities e.g. clinical trials. The definition also covers testing or other activity carried out to enable a government or public body to assess if a medicine should be used in the provision of healthcare e.g. health technology assessments.

Examples of regulatory bodies include the Medicines and Healthcare Products Regulatory Authority (MHRA) and European Medicines Agency (EMA). An example of a body which assesses if a new drug should be used in the provision of healthcare is the National Institute for Health and Care Excellence (NICE).

Is work done to obtain approval for a drug abroad covered by the change?

Yes. If the purpose of the work is medicinal product assessment, as defined in the Order, it is within scope of the amendment.

Which activities are covered by the new exception?

Although the exact scope of the new exception to infringement will be a decision for the Courts, the following activities are considered to be in its scope:

- Activities carried out to provide data on new medicines to UK or non-UK regulatory authorities.
- Activities carried out to provide data on new medicines to UK or non-UK bodies carrying out health technology assessments.
- Post approval studies to comply with UK or non-UK regulatory requirements.
- Activities carried out to amend a UK or non-UK authorisation for a medicine.
- Activities done to obtain a UK or non-UK authorisation for a new indication of an existing drug.
- Any tests or studies required by UK or non-UK regulatory bodies.
- Activities carried out for the purposes of obtaining full authorisation in the EU of a generic drug or biosimilar i.e. where the abridged procedure exempted by section 60(5)(i) of the Patents Act (the "Bolar exception" is not used).
- Activities related to health technology assessment of a generic or biosimilar product.
- Activities carried out to provide data for obtaining regulatory approval outside of the EU for a generic or biosimilar product.

Does the amendment cover commercial use of a patented drug in a product?

The new provisions **do not** extend to commercial activities, such as sale, commercial supply, or manufacture in preparation for sale or supply. A licence, or other agreement, will be required from the patent holder before a product can be sold or supplied commercially.

Does the amendment cover the use of a patented medicine as a comparator?

Yes. The use of a patented medicine as a comparator in a medicinal product assessment, as defined in the Order, is covered by the amendment.

Are combination products covered by the amendment?

Medicinal product assessments on a combination are within the scope of the new provision. This includes instances where a patented drug is part of the combination.

Frequently asked questions

Are medical device assessments covered by the amendment?

The amendment applies only to activities involved in medicinal product assessment. Medicinal products for human use are defined in Directive 2001/83/EC, and veterinary medicinal products are defined in Directive 2001/82/EC.

Unless a medical device falls within the scope of either of these definitions and requires authorisation under the respective Directive, it would fall outside the scope of the amendment to the Act.

Are assessments of methods of delivering a new medicinal product covered?

The amendment applies only to medicinal products for human use as defined in Directive 2001/83/EC or veterinary medicinal products as defined in Directive 2001/82/EC.

Unless a method of drug delivery falls within the scope of either of these definitions and requires authorisation under the respective Directive, it would fall outside the scope of the amendment to the Act.

Are plant protection products covered by the amendment?

The amendment applies only to assessment of medicinal products for human use as defined in Directive 2001/83/EC or to assessment of veterinary medicinal products as defined in Directive 2001/82/EC. Consequently activities involved in plant protection product assessments are not covered by the amendment.

Would the use of a research tool in a medicinal product assessment be exempt from infringement?

Research tools may be an integral part of a drug therapy and when they are used in, or for, the purposes of a medicinal product assessment, they are within the scope of the amendment. However, their use is only exempt for the specific activities defined in the Order, and a licence agreement would be needed to use a research tool once the product is commercialised. See also "*Does the amendment cover commercial use of a patented drug in a product?"* above.

Is early stage research included?

Early stage research is already likely to be exempt from patent infringement under the existing research exception. However, if the early stage work falls within the definitions in the Order, it will be covered by it.

Will I need a licence to use a patented product in a medicinal product assessment?

If the activities you are carrying out fall within the definition of "medicinal product assessment" in the Order, you do not need a licence to use a patented product.