Draft Order laid before Parliament under section 14(1) of the Legislative and Regulatory Reform Act 2006 for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2014 No. XXXX

PATENTS

The Legislative Reform (Patents) Order 2014

Made - - - -	***
Coming into force - -	***

The Secretary of State for Business, Innovation and Skills ("the Secretary of State") makes the following Order, in exercise of the powers conferred by section 1 of the Legislative and Regulatory Reform Act 2006(**1**) ("the 2006 Act").

For the purposes of section 3(1) of the 2006 Act, the Secretary of State considers that the conditions under section 3(2), where relevant, are satisfied.

The Secretary of State has consulted in accordance with section 13(1) of the 2006 Act.

The Secretary of State laid a draft Order and an explanatory document before Parliament in accordance with section 14(1) of the 2006 Act.

Pursuant to section 15 of the 2006 Act, the affirmative resolution procedure (within the meaning of Part 1 of that Act) applies in relation to the making of the Order.

In accordance with section 17(2) of the 2006 Act, the draft has been approved by resolution of each House of Parliament after the expiry of the 40-day period referred to in that provision.

Citation, commencement and extent

1.—(1) This Order may be cited as the Legislative Reform (Patents) Order 2014.

(2) This Order comes into force on 1st October 2014.

(3) This Order extends to the whole of the United Kingdom.

(4) The amendments made by Article 2 extend to the Isle of Man.

(**1**) 2006 c.51; section 13(1) has been amended by the Government of Wales Act 2006 (Consequential Modifications and Transitional Provisions) Order 2007 (S.I. 2007/1388), Schedule 1, paragraph 147; see section 32 for the definition of "Minister of the Crown".

Amendments of the Patents Act 1977

2. In section 60 of the Patents Act 1977(**2**) (meaning of infringement), after subsection (6C) insert—

"(6D) For the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention.

(6E) In subsection (6D), "medicinal product assessment" means any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes—

(a) obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);

(b) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;

(c) enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of—

(i) providing health care on behalf of such a government or public authority, or

(ii) providing advice to, or on behalf of, such a government or public authority about the provision of health care,

to carry out an assessment of suitability of a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care.

(6F) In subsection (6E) and this subsection—

"medicinal product" means a medicinal product for human use or a veterinary medicinal product;

"medicinal product for human use" has the meaning given by article 1 of Directive 2001/83/EC(**3**);

"veterinary medicinal product" has the meaning given by article 1 of Directive 2001/82/EC(**4**).

(6G) Nothing in subsections (6D) to (6F) is to be read as affecting the application of subsection (5)(b) in relation to any act of a kind not falling within subsection (6D).".

Name
Parliamentary Under Secretary of State
Date Department for Business, Innovation and Skills

(**2**) 1977 c.37; relevant amending instruments are S.I. 2000/2037, S.I. 2005/2759, and S.I. 2013/2602.
(**3**) OJ No L 311, 28.11.2001, p 67.
(**4**) OJ No L 311, 28.11.2001, p 1.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order is made under section 1 of the Legislative and Regulatory Reform Act 2006 (c.51) to amend section 60 of the Patents Act 1977 (c.37) on infringement of patents. Section 60(5)(b) of the Patents Act 1977 provides an exemption from infringement in relation to acts done for experimental purposes relating to the subject-matter of the invention.

Article 2 amends section 60 to ensure that the exception to patent infringement in subsection (5)(b) applies to anything done in or for the purposes of a medicinal product assessment. Article 2 inserts new subsections (6D) to (6G) in section 60.

New subsection (6D) provides that anything done in or for the purposes of a medicinal product assessment is to be regarded as done for experimental purposes relating to the subject-matter of the invention.

New subsection (6E) defines what is meant by "medicinal product assessment". A medicinal product assessment includes acts done in the United Kingdom or the Isle of Man in testing or in a course of testing or other activity undertaken with a view to providing data for a specified purpose.

The purposes specified are as follows—

1) obtaining or varying an authorisation for a medicinal product to sell or supply, or offer to sell or supply a medicinal product (whether in the United Kingdom or elsewhere);

2) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;

3) enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of—

   - providing healthcare on behalf of such a government or public authority, or
   - providing advice to, or on behalf of, such a government or public authority about the provision of health care,

   to carry out an assessment of suitability of a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care.

New subsection 6(F) defines the meaning of "medicinal product" by reference to Directives 2001/82/EC and 2001/83/EC defined currently in section 60(7).

New subsection (6G) provides that nothing in subsections (6D) to (6F) is to be read as affecting the application of subsection (5)(b) in relation to any act of a kind not falling within subsection (6D).

A full impact assessment of the effect that this Order will have on the cost of business is available from the Intellectual Property Office, Concept House, Cardiff Road, Newport, South Wales, NP10 8QQ and is annexed to the Explanatory Document which is available alongside the instrument on the Legislation UK website at www.legislation.gov.uk.