A new defence to patent infringement in the UK

The new defence aims to provide certainty regarding the "experimental purposes" exemption from infringement and how this is applied to clinical trials and health technology assessments.

Summary

On 1 October 2014 a new defence to UK patent infringement came into force. The new defence aims to provide certainty regarding the "experimental purposes" exemption from infringement (see section 60(5)(b) of the UK Patents Act) and how this is applied to clinical trials and health technology assessments.

The Law

The following new sections have been inserted in section 60 of the Act:

(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.

What does this mean?

The new sections expand the definition of the "experimental purposes" exemption to cover work carried out by the pharmaceutical industry when seeking to obtain regulatory approval for a new medicinal product for human or veterinary use.

Before these new sections came into force, the UK provided a narrower exemption from infringement to activities covered by the Bolar exemption (as set out in Article 10(6) of Directive 2001/83/EC, as amended) than those available in other EU countries. For example, the

German Patents Act has included an exemption from infringement for work carried out when seeking to obtain a marketing authorisation since 2005.

The UK government hopes that these new sections will encourage the pharmaceutical industry to run clinical trials, field trials and health technology assessments in the UK.

How A.A. Thornton & Co. can help

If you would like more information, please contact one of our **patent attorneys** via our website at **www.aathornton.com**.

At A.A. Thornton & Co. our patent attorneys are qualified to advise on all aspects of UK and European patent law. The services of our patent attorneys are listed below (click on the links for further information):

- **Patent drafting**
- **Patent prosecution**
- **Conducting patent opposition proceedings before the EPO**
- **Advice relating to patent infringement and validity**
- **Advice relating to patent ownership and licensing of technology**
- **Conducting patent due diligence**
- **Patent litigation support**

Contact

For more information please contact Marianne Privett via email at mlp@aathornton.com or your usual A.A Thornton & Co. advisor.

For general information please visit: **www.aathornton.com**

Partners

Vanessa Lawrence
vabl@aathornton.com

Ian Gill
isg@aathornton.com

Martin Hedges
mnh@aathornton.com

Craig Turner
crt@aathornton.com

Rachel Havard
rsh@aathornton.com

Adrian Bennett
arb@aathornton.com

Mike Jennings
mjj@aathornton.com

Emily Cottrill
eehc@aathornton.com

Lawrence King
llk@aathornton.com

Associates

Nick South
ngs@aathornton.com

Heather Donald
hrd@aathornton.com

Sarah Darby
smd@aathornton.com