UK Patents Act updated to clarify research exemptions

As previously reported, following a public consultation a decision was made to amend the UK Patents Act to give clarification for companies and individuals involved in clinical trial work, or carrying out work to provide information for health technology assessments of medicines.

As of 1 October 2014 the planned changes to the UK Patents Act came in to force. The changes (see here) affect Section 60 of the Act, which deals with the meaning of infringement.

The principal change to Section 60 brings 'medicinal product assessment' within the experimental use exception (also known as the research exemption).

Amended Section 60 goes on to define that 'medicinal product assessment' consists of testing or any other activity undertaken with a view to providing data for use in:

- Obtaining an authorisation to sell or supply (or offer to sell or supply) a 'medicinal product';
- Complying with any regulatory requirement imposed in relation to an authorisation for a 'medicinal product';
- Enabling a government, public authority, or person functioning on their behalf to carry out an assessment of suitability of a 'medicinal product' for use in the provision of health care (e.g. a health technology assessment).

It is perhaps worth noting that these activities qualify for the experimental use exception regardless of whether they relate to UK or non-UK authorisations.

The term 'medicinal product' used in amended Section 60 is defined by way of reference to European Directives 2001/83/EC(a) (medicinal product for human use) and 2001/82/EC(b) (veterinary medicinal product).

As a final point it is important to bear in mind that although the above law changes came into force on 1 October 2014 they will not apply retrospectively.