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Clinical trials in the UK are given immunity to patent infringement

New legislation introduced by the UK government should shield clinical trials in the UK from the risk of patent infringement from 1st October 2014.

Background

The UK Patents Act previously included two provisions aimed at exempting certain experiments from infringement. These two statutory devices were:

- an exemption in the Act for any act "done for experimental purposes relating to the subject matter of the invention"; and
- the "Bolar exemption", which specifically exempts acts relating to clinical trials.

Previously, a company wishing to carry out a clinical trial within the UK had to rely on one of these two exemptions. However, the first provision (relief for acts for experimental purposes) has been interpreted too narrowly by the UK courts to provide relief for clinical trials. The second provision (the Bolar exemption) also provides limited relief because it is limited to clinical trials for authorisation of generic or biosimilar products, and only for trials aimed at obtaining authorisation within the EEA.

As a result of these limitations, many clinical trials in the UK would not have been sheltered from patent infringement by the statutory exemptions. For example, companies wishing to carry out clinical trials on innovative drugs could not operate under the safe harbour of an exemption, as opposed to trials for generic approvals.

Although the Bolar exemption came as a result of the UK implementing an EU directive in 2005, the same directive was implemented differently in other EU states. Notably, the Bolar exemption was implemented in Germany, Italy and France using text providing a far broader exemption, whereby clinical trials on innovative drugs and for ex-EEA authorisation are exempt.

The UK Government has been determined to make the UK an equally attractive destination for clinical trials, by broadening the circumstances in which companies can rely on the exceptions to infringement (as we reported here).

The amendment

The new legislation was introduced on 25th July 2014 and will come into force on 1st October 2014 (specifically, the legislation results from The Legislative Reform (Patents) Order 2014).

The legislation does not modify the existing Bolar exemption. Instead, the legislation lists specific acts that will be covered under the "experimental purposes" exemption (the first exemption above), including "anything for the purposes of a medicinal product assessment". A further definition for the term "medicinal product assessment" clearly covers acts for obtaining a marketing authorisation for both generic and innovative products, and for authorisation anywhere in the world.

The primary effect

The amendment to the legislation should have the desired effect and will therefore be welcomed by companies in the pharmaceutical industry wishing to carry out clinical trials in the UK without risk of patent infringement.

The complications

Although the new legislation appears to achieve the UK Government's primary aim, the wording may have side effects and may give rise to complications. Two examples are below.

A negative effect on research tool patents

One possible consequence of the amendment is that some research tool patents may effectively become unenforceable because any would-be infringements would be exempted under the new legislation. Research tool patents may, for example, claim an assay or a kit for determining the effect of a drug on a target. Under the new legislation, these claims might arguably not be enforceable against use of the invention during the process of obtaining a marketing authorisation.

Consistency with the UPC Agreement

The EU unitary patent is on the horizon and so is the UPC (Unified Patent Court) Agreement. In order to ratify the UPC Agreement, an EU member state must amend its national law to define infringement consistently with the UPC Agreement. There are two areas of possible inconsistency between the UPC Agreement and the new legislation.

Firstly, the UPC Agreement mirrors the current UK legislation (i.e. it includes the two exemptions set out above). The term "experimental purposes" is not defined in the UPC Agreement, so does not necessarily exempt clinical trials from infringement in the same way that the new legislation does.

It has therefore been suggested that the UK would need to reverse the change when ratifying the UPC Agreement.

Secondly, there is an ongoing debate on whether infringement of European patents that have been opted out of the UPC will still be governed by the UPC Agreement or, alternatively, national law. It is therefore possible that opting a European patent out of the UPC would result in a (different) national law being applicable, meaning that the exemptions for opted out patents would potentially be more generous than for patents governed by the UPC Agreement. If this situation develops then patentees would be well advised to consider the possibility of avoiding the broad new UK exemption when deciding whether or not to opt European patents out of the UPC.

Conclusion

We expect the new legislation to be welcomed by the UK pharmaceutical industry, and to encourage more companies to conduct clinical trials within the UK. There are nevertheless downsides for proprietors of research tool patents and potential complications, particularly concerning consistency with the UPC.

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This briefing note was first published in the IAM IP Newsletter.