# Amendments to the UK Patents Act to Extend the Bolar Exemption for Clinical Trials

## Background

There is widespread variation across the world in the extent to which conducting clinical trials to assess the safety and efficacy of a patented drug can constitute patent infringement. Many jurisdictions, including the EU, provide that some such clinical trials are exempt from patent infringement. Such exemption provisions are often referred to as the "Bolar exemption".[1]

In the EU, the minimum scope of the Bolar exemption is governed by Article 10(6) of Directive 2001/83/EC as amended. That provision requires EU States to exempt from patent infringement all studies and trials necessary to secure authorisation for a generic medicinal product, by demonstrating bioequivalence to an existing authorised medicinal product. However, the Directive does not require explicitly that clinical trials designed to secure authorisation for an innovative medicinal product be exempt from patent infringement.

EU Member States have taken different approaches when implementing Directive 2001/83/EC. Some States (for example Germany) have sought to exempt from patent infringement all clinical trials, whether for a generic medicinal product or for an innovative medicinal product. Other States (for example Belgium) have followed more closely the provisions of Art 10(6) of Directive 2001/83/EC.

The UK initially took the latter approach. Thus, Section 60(5)(i) of the UK Patents Act was introduced on 30 October 2005 to provide a new exemption from patent infringement. This provision follows closely the language of Art 10(6) of Directive 2001/83/EC, and has been widely understood to provide exemption only for bioequivalence studies designed to secure marketing authorisation for a generic product.

## New amendment to UK Patents Act

Following a period of industry consultation, the UK government determined that the "Bolar exemption" should be extended to cover clinical trials conducted on innovative medicinal products as well as on generic medicinal products. To that end, the UK government laid before Parliament a Legislative Reform (Patents) Order on 6 May 2014. The order was approved by Parliament, and is effective from 1 October 2014.

The Order adds new Sections 60(6D) to 60(6G) to the UK Patents Act in addition to Section 60(5)(i) discussed above. The full text of the new Sections is set out in Annex 1. The new provisions do not provide a new exemption from the infringement provisions of the Patents Act. Rather, they extend (or perhaps clarify) the scope of the existing exemption in Section 60(5)(b) of the Patents Act for acts *"done for experimental purposes relating to the subject matter of the invention."*

More specifically, new Section 60(6D) of the UK Patents Act provides that *"anything done in or for the purposes of a medicinal product assessment which would otherwise constitute infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject matter of the invention."* The language used is designed to extend well beyond bioequivalence studies on generic products. Rather, the intention of the legislator is that it should cover all activities necessary for any clinical trial or field trial necessary to secure authorisation for a medicinal product or for any health technology assessment carried out after a medicinal product is authorised.[2]

## Activities of Contract Manufacturing Organisations (CMOs)

One question that arises when considering the Bolar exemption is the extent to which CMOs benefit from the exemption from patent infringement. Thus, if a CMO manufactures a patented drug and sells that drug to a separate company conducting a clinical trial, is the manufacture and sale of the drug by the CMO exempt from patent infringement?

In the UK, some uncertainty arises here due to the provisions of Section 60(2) of the UK Patents Act. Section 60(2) provides that supply of means for putting an invention into effect can under certain circumstances constitute infringement of a patent for an invention if the supply is not made to somebody *"entitled to work the invention"*. Section 60(6) of the UK Patents Act says explicitly that those who are exempt from patent infringement under the experimental use exemption are not "entitled to work the invention" for the purposes of Section 60(2). It could be argued, therefore, that a CMO which supplies a patented drug to a separate company conducting a clinical trial is liable for patent infringement under Section 60(2) of the UK Act, because although the company conducting the trial is exempt from patent infringements they are not "entitled to work the invention".

Notwithstanding the above discussion, it is likely that the broad reference in new Section 60(6D) to *"anything done in or for the purposes of a medicinal product assessment"* will suffice to extend the exemption to cover the manufacture and supply of a patented drug by a CMO. Nevertheless, some uncertainly will remain until we have some judicial guidance on this issue. In that regard, highly relevant questions were referred to the CJ-EU from the Düsseldorf Court of Appeal in case number C-661/13. The referral was expected to provide welcome clarity. However, the matter at issue before the referring court was settled by the parties before the CJ-EU addressed the questions and, unfortunately, the referral has since been cancelled.

## Situation before the future European Unitary Patent Court (UPC)

Infringement before the future Unitary Patent Court will be governed by Articles 25 to 27 of the Court Agreement. Member States to the UPC agreement will need to amend their national laws for conformity with Articles 25 to 27.

Art 27(d) of the Court Agreement provides an exemption from patent infringement which refers to Art 10(6) of Directive 2001/83/EC, and which is therefore likely to be limited to bioequivalence studies. Art 27(b) of the Court Agreement provides an exemption for *"acts done for experimental purposes relating to the subject matter of the invention"*, but does not make it clear to what extent this covers clinical trials done on innovative products.

It is therefore not yet entirely clear whether and to what extent clinical trials on innovative medicinal products will be exempt from patent infringement proceedings brought before the UPC. Indeed, it has been suggested by some commentators that the determinative factor here may be the identity of the Member State with the governing law.[3] It is to be hoped, though, that this situation will be clarified before the Court Agreement comes into effect.

Please do not hesitate to contact your usual J A Kemp contact if you would any further guidance with reference to any specific situation.

**Footnotes**

1. The term is derived from the US Case Roche Products v Bolar Pharmaceuticals which involved early judicial consideration of the extent to which clinical trials are exempt from patent infringement. The case led to the US Hatch-Waxman Act.
2. The intention of the legislator is described in more detail in the Explanatory Document issued by the UK IPO, which can be found here.
3. Articles 5 and 7 of the relevant Regulation define that member State as the State in which the first named Patentee has its residence or principal place of business.

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