

## Clinical trial exemptions from infringement (Bolar Exemptions)



In order to obtain the marketing authorisation needed to market a medicinal product, it is of course necessary to conduct clinical trials to demonstrate the safety and efficacy of the product. A generics competitor will need to do trials, for example, to show bioequivalence, even if they are seeking to rely on the data submitted by the product innovator. If the medicinal product is covered by a patent in a particular country, then performing a clinical trial using the product in that country could infringe that patent. In the past, this meant that a generics company could not perform the necessary clinical trials to obtain marketing authorisation for a medicinal product until the patent, the supplementary protection certificate (SPC) and data exclusivity had all expired. This effectively gave the innovator company an extension to their market exclusivity for the product.

Most countries now have an exemption from infringement for clinical trials performed using patented medicinal products, commonly called “Bolar Exemptions” after the US case which established the exemption in the US. However, the scope of the exemption varies considerably between different countries.

<b>Acts exempt from infringement</b>	<b>UK</b>	<b>EU as a whole</b>
<i>Clinical trials of generics/ biosimilars</i>	Yes	Yes
<i>Clinical trials of innovative medicinal products</i>	Yes	Unclear / depends on country
<i>Manufacturing medicinal products for such trials</i>	Yes	Unclear / depends on the country
<i>Importing medicinal products for such trials</i>	Yes	Unclear / depends on the country

In the UK, the situation has recently been clarified by amendment to the infringement provisions of the UK Patents Act. These provisions now allow:

*“anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent” (s. 60 6(D), UKPA 1977 as amended 2014)*

Medical product assessment in this provision means any testing carried out to provide data for obtaining or varying a marketing authorisation for a medicinal product (whether in the UK or elsewhere). Accordingly, such testing is exempt from infringement. Other acts included in the definition of “medical product assessment”, and therefore exempt from infringement, include testing carried out in order to provide health care on behalf of a government or public authority, or in order to provide advice to, or on behalf of, such a government or public authority about the provision of health care.

The UK IPO has also stated (in a non-binding guidance notice) that manufacturing in the UK or importing into the UK the medicinal product used in such “*medicinal product assessments*” (clinical trials) would also be exempt from infringement.

The situation is not so clear-cut when considering the EU as a whole. In the EU clinical trial exemptions are governed by European Directive 2001/83/EC (as amended by European Directive 2004/27/EC) which exempts from patent infringement the clinical trials of generic medicinal products aimed at demonstrating bioequivalence to an existing authorised medicinal product.

Some EU countries, such as Belgium, have applied the exemption provided by the Directive only to clinical trials involving generic or biosimilar medicinal products.

Others such as Germany and France have applied the Directive in a way which exempts clinical trials for new medicinal products which would otherwise infringe, as well as generic or biosimilar medicinal products.

It is also currently uncertain whether the exemption extends to suppliers of the potentially infringing medicinal product for the purposes of the exempt clinical trials. A referral to the CJEU made in 2013 was hoped to address this issue but the case was otherwise resolved without any guidance being issued.

Looking ahead, it is hoped that the Unitary Patent Court, expected to start early in 2017 and having Europe-wide jurisdiction, will clarify the scope of the exemption from infringement for clinical trials, both in the sense of the purpose of the trials and the manufacture and supply of medicinal products by third parties for such trials.

The legal standing of clinical trials exemptions is complex and fluid. We have explained the general principles in this AL Factsheet but it is only an introduction, and any live situation will need individual assessment. Please contact us if you need more detailed information.