

### Experimental use exemption in the pharmaceutical and biotech industries

In the UK, "experimental use" in the pharmaceutical and biotech industries is exempt from infringement where the experimental act concerned falls within either of two provisions:

- (i) the general statutory experimental use exemption for acts done for "experimental purposes relating to the subject matter of the invention";
- (ii) the industry-specific so-called "EU Bolar" provision for acts done for gaining regulatory authorisation.

#### The experimental use exemption

The general experimental use defence applies to acts carried out **on** or **into** the invention rather than **with** or **using** the invention. Thus, experimental acts to test a hypothesis about the invention or to develop and improve the invention would generally fall within the safe harbour of the exemption. However, use of a patented "research tool" in an experiment not related to the subject-matter of the invention would not fall within the exemption. Furthermore, in the UK the exemption has been held not to apply to acts done merely to amass information for regulatory approval of a product.

The scope of the general experimental use exemption differs throughout the EU. For example, in Belgium the research exemption is of wider scope and generally includes research on or with the patented invention.

The desire to remove the uncertainty in the pharmaceutical sector surrounding the experimental use exemption, and its varying scope throughout the EU, led to the adoption of an "EU Bolar" provision in the field of medicinal products.

#### The EU Bolar provision

The EU Directive relating to medicinal products for human use provides that:

"Conducting the **necessary studies and trials** with a view to the application of paragraphs 1, 2, 3 and 4 [of Article 10] and the **consequential practical requirements** shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products [SPCs]"<sup>1</sup>.

The EU Bolar exemption is therefore limited to use only in respect of gaining regulatory approval in the EU for: generic medicinal products under the "abridged" procedure (paragraphs 1 and 2

of Article 10) and for medicinal products that do not fall within the definition of a generic medicinal product (paragraph 2) and so need further pre-clinical test or clinical trial data under the "hybrid-abridged" procedure (paragraphs 3 and 4 of Article 10) (i.e. "bioequivalents" and "biosimilars").

However, implementation of the Directive has been far from uniform. Consequently, although there is a minimum standard for exemption, there are marked differences in the scope of the "EU Bolar" exemption across the EU. Table 2 shows the varying scope from minimum, as in for example the UK, through to broader scope, as in for example Germany, for those countries that have provided guidance on their position.

<sup>1</sup> Directive 2004/27/EC, Article 10(6)

### Exemption applies to:

Use only in respect of gaining regulatory approval in the EU for generic medicinal products, bioequivalents and biosimilars.

Any application submitted for regulatory approval, including innovative as well as generic products, although limited to applications for regulatory approval **within the EEA only**.

Any application submitted for regulatory approval, including the first application for an innovative product, and including for regulatory approval both **inside and outside** the EU.

### Countries applicable in:

UK, Sweden, The Netherlands and Belgium\*  
\*but note broad general exemption.

France

Germany, Italy, Spain, Hungary and Poland; Switzerland\*  
\* not an EU member state, but has a "Bolar-type" exemption of broad scope.

### Comparison with the US position

The US Bolar exemption provides a safe harbour from infringement where an act is carried out in respect of "a **patented invention ... solely** for uses **reasonably related** to the development and submission of information [to the FDA]".

The provision does not limit exemption to a drug product, as it also covers medical devices, nor to a particular type of pharmaceutical, i.e. generic vs innovative. The US provision has been held to provide safe harbour for research where a patented compound is used in research that, if successful, would be appropriate to include in a submission to the FDA.

### Conclusions

The EU Bolar provision provides, as a minimum, exemption for acts for obtaining regulatory approval of a generic medicinal product. However, there is a great deal of variation in scope between individual European countries. For the majority of EU countries, including the UK, the scope of the Bolar provision appears to be narrower than that available in the US.

As in the US, uncertainty around the EU Bolar provision is likely to remain pending clarifying judgements from the national courts and ultimately the European Court of Justice.

The uncertain and differing scope of the safe harbour provided by the general statutory experimental use exemption together with the EU Bolar exemption across the EU member states may impact the choice of location of preclinical tests and clinical trials.

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