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Patent and Trade Mark Attorneys

The European Bolar exemption from infringement

Under the so-called 'Bolar' exemption, clinical trials for generics and biosimilars are exempt from infringement. In some European countries, including the UK, the exemption even extends to innovative products.

Introduction

In order to market a medicinal product, a manufacturer must first obtain regulatory approval by conducting clinical tests and trials to prove that the product is safe and effective. However, when the medicinal product is a generic (1) or biosimilar (2) product, a company can avoid having to carry out full trials by relying on at least some of the data submitted by the original applicant for marketing authorisation in connection with the original (reference) medicinal product. To use this so-called abridged procedure for obtaining marketing authorisation, however, it is necessary to demonstrate that the generic/ biosimilar version is bioequivalent to the approved reference medicine.

If the medicinal reference product is patent protected, then there is a real risk that acts relating to that product infringe the patent. Historically, this risk of patent infringement potentially deterred generics manufacturers from carrying out the tests required to obtain marketing authorisation until after patent expiry, resulting in a delay of market entry of generics.

In an attempt to harmonise the position in Europe and to speed up the entry of generic products onto the market after patent expiry, the so called "Bolar exemption" was introduced by the European Union (EU) to exempt from patent infringement thetests and trials necessary to use the abridged procedure for obtaining marketing authorisation.

EU Directive

The Bolar exemption is governed by European Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by European Directive 2004/27/EC, particularly Article 10 thereof.

Article 10 (6) excludes from infringement of patent rights or supplementary protection certificates (SPCs): "Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4". Paragraphs 1-4, i.e. Articles 10 (1)-(4) of the Directive, concern the provision of data during the marketing approval process.

Implementation

Although the Directive was aimed at harmonising the position in the EU member states, the implementation of the Directive into national law has not been uniform, resulting in significant differences between the member states.

Thus, whilst some countries, notably the UK, have adopted an exemption that is limited to generic or biosimilar medicinal products, others, including Germany and France, have adopted an exemption that is not so limited, extending also to innovative medicinal products.

Exempt acts

The Directive does not provide any guidance as to which acts are exempt from infringement, referring merely to "conducting the necessary studies and trials". It is widely accepted that actual trials testing the safety or efficacy of the medicinal products would fall within the scope of this exemption, but there has been uncertainty regarding other acts, such as the manufacture, supply or import of the medicinal product.

A particularly contentious issue is whether a third party is free to supply the medicinal product to the party carrying out the trials necessary to obtain marketing authorisation. This question was referred to the Court of Justice of the EU by a German court, but the case was subsequently closed without any guidance being issued, as explained here.

Data exclusivity and market exclusivity

It is recognised that allowing the producer of a generic or biosimilar medicinal product to use an abridged marketing authorisation gives the producer of the generic or biosimilar an advantage. To redress the balance and reward innovators, the Directive sets a period of "data exclusivity", during which the data submitted in connection with an innovative drug may not be used by third parties.

In addition, a further period of "market exclusivity" runs from the end of the data exclusivity period and prevents manufacturers of generic/biosimilar medicinal products from placing their products onto the market. The combined period of data exclusivity and market exclusivity is about 10 years in Europe.

Detailed further information regarding these forms of exclusivity, as well as regarding the requirements for obtaining marketing authorisation for generics and biosimilars may be found on the website of the European Medicines Agency.

Experimental use exemptions

In addition to the Bolar exemption, many EU member states have an "experimental use exemption" which exempts certain experimental activities from patent infringement. Again, the scope of these provisions varies widely among the member states. Thus, whilst in some countries, notably Germany, the experimental use exemption has been interpreted by the courts to exempt all experimental uses aimed at gaining knowledge, in others the exemption has been interpreted much more narrowly.

The scope of the UK's experimental use exemption used to be particularly narrow, but in 2014 the UK adopted a much broader experimental use exemption, as reported here.

Under the new UK law "anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention"(3). A "medicinal product" is defined in this context as "a medicinal product for human use or a veterinary medicinal product". Thus, whilst there is no explicit reference to innovative products, there seems to be no restriction placed on the types of medicinal products covered, so it is widely accepted that this provision exempts from infringement trials relating to innovative drugs.

A "medicinal product assessment" is defined as "any testing, course of testing or other activity" undertaken with a view to providing data for obtaining marketing authorisation. It remains to be seen precisely which acts are exempt under this provision.

Outlook

The Unitary Patent (UP) and the Unified Patent Court (UPC) are expected to come into effect in 2017.

The Agreement on the UPC contains a narrow Bolar exemption, which refers to the European Directives mentioned above and will therefore be limited to generic or biosimilar medicinal products. There have been suggestions, however, that the EU may in due course issue a new Bolar directive that would provide a wider exemption akin to the scope of the German Bolar exemption.

The Agreement on the UPC also contains an experimental use exemption, but no guidance on the scope of this exemption has been issued.

It remains to be seen how any differences between the national exemptions and the exemptions under the Agreement on theUPC will be reconciled.

Further advice

If you would like any further advice please contact us at Dehns using the details below.

(1) The term "generic medicinal product" is defined in Article 10 (2) of Directive 2004/27/EC.

(2) Article 10(4) of Directive 2004/27/EC refers to biological medicinal products that are "similar" to a reference product, but does not provide a definition of "biosimilars".

(3) Section 60(6)(D-F) of the UK Patents Act 1977 as amended.

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