

## Clinical Trials & Patent Infringement for Generic Pharmaceutical Products

In order to secure marketing approval for the launch of a generic pharmaceutical product, a company must normally provide data demonstrating the quality, safety and efficacy of their product. A company can, however, avoid having to supply all the necessary data for approval if they can rely on at least some of the data submitted by the original applicant for marketing authorisation. To use this abridged procedure however, the second applicant has to wait until the original product has been on the market for a specified number of years.

If the pharmaceutical product has been patented, the question arises as to whether or not the conducting of clinical trials required to satisfy regulatory authorities constitutes an infringement of the patent. At present, this matter is largely at the discretion of individual EU member states. Most EU national laws contain an exemption from infringement for actions carried out for "experimental use". It has, however, been left to the courts of each EU member state to decide how this exemption should be interpreted and this has led to different situations existing across the EU.

For example, in the UK, the experimental use provision has been interpreted strictly and in *Monsanto v. Stauffer* it was held that trials aimed at securing regulatory approval were not exempt from infringement. In contrast, the German courts have taken a more permissive approach and exempted from infringement all experimental uses directed towards gaining knowledge. In addition, several of the newer EU member states have clear provisions in their national laws to exempt from infringement clinical trial activities. For example, Hungary exempts from infringement "... experiments and tests necessary for the registration of medicines", a so-called "Bolar Provision".

There exists therefore, considerable disparity in Europe as to the permissibility of such trials and it was recognised that the position in Europe needed to be harmonised to attract generics business into Europe. The EU therefore issued a Directive (2004/27/EC) which includes a "Bolar-type" provision which exempts from infringement activities conducted with a view to obtaining marketing authorisation.

### EU Directive

Article 10 of the Directive concerns the abridged procedure for obtaining marketing approval and includes a "Bolar-type" provision. 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), concern the provision of data during the marketing approval process.

Article 10(1) states that a second applicant for approval cannot rely on data previously submitted until the reference medicinal product has been on the market for a minimum of 8 years. Furthermore, a second applicant cannot place their product on the market (i.e. even if it has been approved) until 10 years have elapsed from the date of grant of the original authorisation. This 10 year period is extendable to 11 years in the event that the original applicant obtains approval for use of their product in a new therapeutic indication. Thus, under the Directive, a generics manufacturer will, after 8 years, be able to commence the approval process without the risk of patent infringement and would typically be in a position to market on the 10 year anniversary of the first marketing authorisation. The exemption does not, however, exempt from infringement the sale, importation etc. of the product so long as the patent or SPC is in force but the Directive may allow the generics manufacturer to be in a position to launch on the day the patent or SPC on the product expires.



Article 10(1) applies to "generic medicinal products" and this term is defined in Article 10 (2). To be a "generic", the product must have: (i) the same qualitative and quantitative composition in active substances as the original product, (ii) the same pharmaceutical form as the original product and (iii) a demonstrated bioequivalence with the original product. Article 10(2) also indicates that salts, esters, ethers, mixtures of isomers, complexes and derivatives will generally be considered to be the same active substance.

Articles 10(3) and 10(4) seem to extend the scope of the Directive outside the realm of pure "generics". Article 10(4) appears to extend the right to undertake trials and studies on "biological medicinal products" which are merely "similar" to the original product (i.e. they do not fall within the definition of generic given in Article 10(2)).

The scope of Article 10(3) is also unclear and has been the topic of considerable debate. Article 10(3) exempts from infringement tests carried out on "medicinal products which do not fall within the definition of a generic medicinal product ... or where the bioequivalence cannot be demonstrated ...". Taken literally, the wording of this Article could be interpreted to mean that pre-clinical and clinical trials are permitted under the exemption when the product is non-generic. If this broad interpretation is taken then the scope of the exemption is extremely wide since there would then not appear to be any limitation on the nature of the products which can be studied and tested.

Current feeling is, however, that this broad interpretation is unlikely to be adopted by the member states. Of note is the fact that none of the stated objectives of the Directive refer to easing access of non-generic products and the fact that there would be little point in defining what is meant by a "generic" if non-generics were also to be exempt. It is therefore thought that the purpose of Articles 10(3) and (4) is to permit studies and trials for products which do not quite meet the requirements to be generic for one of the reasons set out in these Articles.

### Implementation of the Directive

The directive came into force on 30 October 2005. However, the regime will only apply when a second company is seeking to rely on data of a reference product authorised after the directive comes into force. Thus it will be at least 2015 before complete harmonisation within the EU will begin to be seen.

### Summary

The Directive exempts from infringement of patent and SPC rights carrying out the experiments and trials which are necessary to obtain marketing approval for products which are generics or similar biological products. The exact scope of the Directive will, however, remain unclear until it is interpreted in court.

### Further advice

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