Bolar exemptions in the UK

Background

The UK Patents Act lists several exemptions to patent infringement. Among these exemptions are the "research exemption" and the "Bolar exemption".

Under the research exemption, experimental acts, using a patented invention, do not infringe the patent.

Under the Bolar exemption, studies or trials, necessary to obtain marketing authorisation for generic or biosimilar products equivalent to a patented drug, also do not infringe the patent.

The Consultation

The UK Patents Act is intended implement the relevant EU Directives on Bolar exemptions.

National legislations across Europe are intended to implement these Directives. However, they vary from country to country.

This pan-European variance led to concerns at the UK Intellectual Property Off ice (UKIPO) that the UK law was adversely affecting companies considering whether to conduct clinical and field trials in the UK.

The UKIPO recently held a consultation to investigate the impact, if any, of the UK Bolar exemption law on UK pharmaceutical trials.

The Results

All respondents agreed that the UK law does not strike the right balance between the patentee's rights and the need to carry out trials for new products.

The respondents identified a number of areas of uncertainty and concern, including:

- New combination products where one or more of the components is patented (e.g. anti-virals and oncological therapy)

- Testing and trials, over and above those required to obtain marketing authorisation, required by certain regulatory bodies;
- Unauthorised use of a patented product in trials to obtain marketing authorisation for a new drug;
- Trials to obtain marketing authorisation for biosimilars using the full market authorisation route, rather than the shortened biosimilar authorisation route;
- Comparative studies for marketing reasons.

The respondents confirmed that infringement risk is one of several factors a company considers when deciding where to run a clinical trail.

All respondents stated that the UK would be a more desirable location for carrying out clinical trials if the infringement risk, associated with the trials were removed.

The majority were of the opinion that there should be a change in legislation, either unilaterally in the UK or at the EU level.

What Next?

In light of the responses, the UK Government has acknowledged the need to amend UK patent law, to ensure that clinical or field trials avoid the risk of patent infringement.

The Government decided that a national law change was preferable one at EU level. It believed that action at the EU level would be too slow, and might be opposed by some member states.

The UKIPO is preparing a proposal to amend the UK law, to clarify the exemption, from infringement, of clinical or field trials.