

## Questions regarding scope of 'Bolar exemption' referred to ECJ

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As reported previously, the UK Patents Act provides for certain exemptions to patent infringement. Among these exemptions is the 'Bolar exemption'.

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

The applicability of the 'Bolar exemption' to parties who are directly involved in conducting studies or trials that are necessary in order to obtain marketing authorisation is generally understood.

However questions remain about the extent to which the 'Bolar exemption' extends to those suppliers who provide patented products to parties who qualify for the 'Bolar exemption'.

### **ECJ Case C-661/13**

In light of this uncertainty it is hoped that the recent decision ( see here) to refer a case to the European Court of Justice will provide some clarification.

The questions referred to the ECJ for a preliminary ruling can be found here.

Essentially the main question seeks to establish whether the 'Bolar exemption' extends to suppliers who supply (or offer to supply) patented products to a party for use in conducting studies or trials for the purposes of obtaining marketing authorisation.

In the event that the 'Bolar exemption' is extendable to cover suppliers, the referral presents secondary questions that seek to qualify the extent to which the 'Bolar exemption' applies to said suppliers.

### **Secondary questions**

1. Does the customer of the supplier actually have to use the patented product in studies or trials in order for the supplier to qualify for the exemption?

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2.
  - Does the exemption apply even when the supplier has no knowledge, or has not satisfied himself in this regard, that their customer is using the patented products in exempted studies or trials; or
  - Is it sufficient that the supplier can legitimately assume that in the circumstances their customer will use the patented products in exempted studies or trials?
3. Does the supplier need to take measures to ensure that their customer's use of the patented product is in exempted studies or trials?

We will report back when the ECJ provides their ruling.