Recent interpretation of the Bolar provision in Europe

A Bolar provision was introduced into European patent law by Directive 2004/27/EC relating to medicinal products for human use. Implementation of the Directive in the national legislation of the Member States of the European Union has been far from uniform. The Bolar provision has recently been interpreted by the German and Polish courts. In this article we discuss these decisions and how they might impact on the current review of the Bolar provision as implemented in UK patent Legislation.

Background

A Bolar provision was introduced into European patent law by Directive 2004/27/EC relating to medicinal products for human use (The Directive):

"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]"

Implementation of the Directive in the national legislation of the Member States of the European Union (EU) has been far from uniform. The Directive sets the minimum level of protection but there are marked differences in the scope of the Bolar exemption across the EU. Consequently there are uncertainties and financial implications for companies wishing to carry out the studies and trials required for regulatory approval in Europe. We discussed the recent UK consultation on amending the Bolar provision in the UK in our article “Bolar and research exemption consultation — Patent exemptions for clinical trials to be extended in the UK” in the February 2013 issue of Vista.

The Bolar provision has also recently been interpreted by the German and Polish courts. In this article we discuss these decisions and how they might impact on the current review of UK patent legislation.

The German and Polish decisions

The Polish pharmaceutical manufacturer Polpharma placed advertisements for the supply of an active ingredient, protected by a third party’s substance patent, on its website and in pharmaceutical magazines including SCRIP.

SCRIP has worldwide readership of about 100,000 people with 45% of subscribers being registered in Germany.

The patentee sued Polpharma in Poland and Germany.

Polpharma’s defence

Polpharma argued that the activities on which the complaint was based were exempted by the ‘Bolar Provision’, since its customers were going to use the ingredient only for testing purposes. Furthermore, Polpharma argued it was necessary for many generic drug companies to get supplies of the ingredient from third party manufacturers, as they were often not in a position to manufacture it themselves.

Polpharma proposed that the national judge submit the following preliminary question to the CJEU: is manufacturing of patented substances permissible under Article 10 (6) of the Directive 2004/27/EG where the privileged purpose will be conducted by a third party? And if the first question is answered affirmatively, which conditions must be fulfilled by the third party so that the supply falls within the requirements of the Directive.

New legislation in Germany

The Regional Court (Landgericht) of Dusseldorf (at first instance) and the Higher Regional Court (Oberlandesgericht) of Dusseldorf (in the second instance) concluded that a reference to the CJEU was not required. Instead, amongst other things, they determined that while the Directive’s intent and purpose is to increase the competitiveness of pharmaceutical manufacturers it must be understood as an exceptional regulation (so it should not be given too broad an interpretation). Whilst Germany is considered by many to take a
broad approach to acts covered by Bolar, to support Polpharma's arguments would go too far. The Courts held that only a party performing the tests themselves is protected by the 'Bolar Provision'.

In supporting this conclusion, the court observed this was consistent with the proposal of the European Parliament concerning the Directive 2001/83/EC, which was part of the lineage for the 2004 Directive.

Polpharma was similarly enjoined in Poland. The appeal court in Poland concluded that the provision does not include all possible actions aimed at obtaining registration or license. Polpharma's purpose had been to achieve financial benefits.

**What does this mean for the UK?**
Companies importing API for regulatory approval purposes are exempt under the Bolar provision, but what about companies such as Polpharma who provide API for companies who are unable to manufacture their own?

The UKIPO concluded a consultation in December 2012 seeking views on proposed amendment to the UK Bolar exemption. The respondents (including Polpharma) highlighted the need for a more generous and clear exemption.

The UK Government accepts that Solar should include an exemption from infringement, for activities involved in preparing or running clinical or field trials involving innovative drugs for the purpose of gaining regulatory approval in any country. The exemption should also cover activities involved in health technology assessment (HTA).

**How broadly will "activities" be interpreted in the context of the proposed amendment?**
Certain suggestions were made by the respondents, including exempting third parties who manufacture for the purposes of trials or HTA, and CROs, from contributory infringement. It was also suggested that "Activities" should be defined; that the UK provision be more aligned with the Hatch-Waxman Act in the US, namely to exempt activities "reasonably related to the development of a product; and that the exceptions for innovative drugs should be extended to cover the generic industry where they go beyond those currently specified in the Act.

The UKIPO has indicated that it does not currently intend to consult further prior to implementing a revised Bolar provision to address the changes required. We will continue to monitor this. The amendment is expected to be effective from April 2014.