Promoting clinical trials of pharmaceuticals in the UK

It has for a long time been uncertain whether the conduct by the innovative pharmaceutical industry in the United Kingdom falls within the defences to the Patents Act.

Monsanto v *Stauffer* ([1985] RPC 515) casts doubt over the extent to which the research exemption in Section 60(5)(b) of the Act applies to certain types of clinical trials, particularly Phase 3 trials (the larger clinical trials undertaken by the innovative industry).

The so-called "Bolar exemption" introduced into EU law by Art 10 of Directive 2004/27 (amending Directive 2001/83) applies only to activities in support of an abbreviated approval (i.e. one seeking approval of a generic product, not on the basis of clinical trials but essentially on the basis that the generic is bioequivalent to the innovator product).

Many Member States have extended the EU Bolar to cover innovative activity either expressly in statute law or through case law interpreting their research exemption. The UK has not done this, so there is doubt whether clinical trial activity in support of innovative drugs in the UK infringes or not.

The innovative pharmaceutical industry, supported by the IP Federation, has for some time been calling for an amendment to the Patents Act 1977 to permit acts in the United Kingdom done to obtain approval of innovative drugs. The policy rationale is clear. First, the current state of the law means that there is potential for some trials to be carried on outside the UK to avoid the infringement risk, to the detriment of the UK economy and UK clinical trial expertise. Second, it is odd that companies wishing to bring generic products to market have more defences to patent infringement than companies wishing to bring innovative products to market.

Following an informal consultation conducted by the UK Intellectual Property Office (IPO) on the issue, in which nearly all respondents appeared to agree that something should be done and to which the IP Federation responded (PP12/11), the IPO launched a formal consultation on the same issue in October 2012. In February 2013, the Government response to the consultation was published on the IPO website[1].

The Government accepted the need for change and indicated its intent to seek to amend the Patents Act 1977 by way of a Legislative Reform Order to introduce a new exemption from patent infringement. This exemption "would exempt from infringement the activities required to secure regulatory approval to market innovative drugs, and also activities necessary for health technology assessment e.g. data to support assessment by the National Institute for Health and Clinical Excellence (NICE)."

In September 2013, the IPO informally sought comment on proposals for the wording of the new exemption, and the IP Federation was one of a number of organisations to respond.

David Rosenberg, 25 October 2013

[1] http://www.ipo.gov.uk/response-2012-bolar.pdf