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Proposals to broaden the UK bolar defence

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On 26 February 2013, the UK IPO announced a proposed change to the UK Patents Act to exempt the experimentation necessary to achieve regulatory approval, including clinical and field trials, and for 'health technology assessments' for new drugs from a claim of patent infringement. If the language of the amendment is sufficiently clear, it can only enhance the UK's position as an attractive location for R&D of innovative medicines and, in particular, as a location for clinical trials that must attract investment and jobs to the UK while providing early access to new treatments for patients.

In the UK it is an infringement to make, dispose of, offer to dispose of, use, import or keep the product of the invention. Where the invention is a process, it is an infringement to operate the process or to make, dispose of, offer to dispose of, use, import or keep the direct product of the process without the consent of the patent proprietor.

When the Patents Act 1977 was introduced, it included, at Section 60(5)(b), a provision specifically excluded from being an infringement, acts carried out for experimental purposes relating to the subject matter of the invention. This exemption is not limited to noncommercial purposes and it was confirmed in *Monsanto v. Stauffer* [1] that an act exempt under the provision of Section (5)(b) can have an ultimate commercial purpose. However, it was held that while "Trials carried out in order to discover something unknown, or to test a hypothesis, or even in order to find out whether something which is known to work in specific conditions ... will work in different conditions", could be regarded as experiments and, hence, be excluded, "Trials carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party, whether a customer or a [regulatory] body ... that the product works as its maker claims are not to be regarded as acts done for 'experimental purposes'".

Thus, this case made it clear that tests necessary to achieve regulatory approval were not excluded under this provision and so were infringing acts. This narrow construction of the experimental exclusion has been maintained by the UK court in subsequent cases and, thus, a third party cannot work the subject of the patented invention to prepare data for seeking regulatory approval without the consent of the patentee.

The *Gowers Review of Intellectual Property* recommended amendment of the Patents Act to clarify this section so that experimentation, innovation and education in the UK could be facilitated [2]. Following this recommendation, in 2008 the

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UK IPO undertook some informal consultation, the findings of which supported the recommendation. However no amendment was made at that time.

Separately, following the adoption of various EU Directives [3] Section 60 was amended to introduce Section 60(5)(i), which excludes from being an infringing act: *“An act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC”, or “Any other act which is required for the purpose of the application of those paragraphs.”*

With this amendment, which introduced the so-called ‘bolar exemption’, it became possible for generic companies to carry out the research necessary to obtain their marketing authorization in the EU prior to the expiry of the patent, such that launch could occur immediately on expiry. However, it did not allow experimentation to obtain regulatory authority for innovative products that might fall within the scope of a pre-existing patent, nor did it allow the generic companies to carry out trials to obtain data for authorizations outside the EU. It further left the position of third parties facilitating the experimentation by generic companies unclear.

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Despite this amendment being occasioned by an EU Directive, it is of narrower scope than the exemption as introduced following the Directive in some other EU territories. For example, in Germany, France, Spain and Italy, the exemption extends not only to preparing data for applications for regulatory approval for innovative products in addition to generic products, but it is also not restricted to the approval being required for the EU and, thus, the exempted experimental use includes obtaining data for regulatory approval outside the EU.

We therefore have a situation where research establishments located in the UK are disadvantaged when compared with those located in some other EU territories. The different application of the exemptions must be one of the factors taken into account by companies when deciding where to carry out preclinical tests and, importantly, clinical trials.

This was identified in a further informal consultation carried out by the UK IPO in 2011, which specifically noted that the UK share of clinical trials had fallen from 6 to 2% in the preceding decade. While it was acknowledged that there may be many factors causing

this decline, it was noted that the risk of patent infringement was one factor.

Despite this, there have been few court cases dealing with infringement by clinical trials. The reasons for this are not clear but may include patentees choosing not to bring actions as they do not want the bad press associated with stopping clinical trials and being aware that they can still assert their patents to prevent commercial launch, or it may simply be that companies are choosing not to have their trials conducted in the UK in situations where there is a troublesome patent, preferring instead to look to a more favorable jurisdiction as the location for their trials.

In 2012 the UK IPO carried out formal consultation and in February 2013 the Government response was published [101]. In this response, it is acknowledged that amendment of Section 60(5) of the Patents Act 1977 is required and that it should be changed: *“to 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. This exemption should also cover activities involved in health technology assessment.”*

The ‘activities involved in health technology assessment’ include data required to support assessment by NICE.

Although the respondents to the consultation provided little in the way of quantitative data, the government was persuaded by the anecdotal evidence that the current position is a significant factor in stakeholders deciding to run trials in other jurisdictions, which in turn results in a loss to the UK economy in monetary terms, and a loss of skills and knowledge to other jurisdictions. It was also acknowledged that the location of the trials can influence the decision on where to commence manufacturing and, thus, there may be a knock-on detrimental effect on the UK economy.

Some respondents also pointed out that the current position is disadvantageous to patient groups that are not eligible for trials abroad, and therefore would be excluded from access to experimental treatments in situations where there is currently no effective medication available.

Some respondents to the consultation requested that the exemption should be sufficiently broad to allow suppliers such as clinical research organisations and ingredient manufacturers to be able to assist in the trials without risk to themselves. It may therefore be desirable for the exclusion to cover patents to reagents, assays, test methods and the like that may be used in such trials. In addition, the question of how patents to combination therapies should be treated, may need to be carefully considered.

We will have to wait to see the language proposed for the amendment to see whether these desires will be achieved.

Assuming that the language of the amendment is sufficiently clear, it will put innovative companies in the same position as generic companies and should also simplify the position when considering the legal impact of third-party rights and conducting freedom to operate opinions. It may also reduce the to-market time for new drugs since testing can be commenced before expiry of third-party patents. It should also facilitate research within the UK and benefit not only the innovative companies *per se*, but also those that supply them.

It is understood that it is intended to introduce the amendment before the end of 2013. It is certainly

desirable that it is in force before the Unitary Patent agreement comes into force as the current Unitary Patent proposals are narrower than the proposed changes.

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