'Experimental Use' and 'Bolar' Exemptions in the EU - How Far Do These Provisions Extend?

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Patent systems were designed to encourage and reward innovation. A system that prevents research into the subject matter covered by a patent would be inconsistent with such goals, and so the patent systems of most countries contain provisions that exempt from infringement experiments performed relating to the subject matter of a patent. More recently the EU has introduced a 'Bolar' provision into its legislation also. But what effect do these combined exemptions have? How far do these exemptions extend to trials performed for the purposes of seeking regulatory approval and what about other clinical trials? Are research tools and their use exempted under these provisions? In this article, the extent of the exclusion for such acts in Europe, particularly the UK, is discussed. I also consider to what extent these provisions may affect scientific development.

The UK 'Experimental Use' Exemption

According to the UK Patents Act of 1977, section 60 (1) a patent is infringed if, for instance, a person 'makes or uses' a product covered by the patent within the UK. However, an exemption is provided such that 'an act which ... would constitute an infringement of a patent for an invention shall not do so if ... it is done for **experimental purposes relating to the subject matter of the invention**'. This is commonly referred to as the 'experimental use' exemption and shall be referred to in that manner herein.

UK Case Law

In interpreting the meaning of the terms 'experimental purposes' and 'subject matter of the invention', certain decisions of the UK courts are relied upon. In particular, the case still used for the interpretation of the scope of these terms is *Monsanto/Stauffer* (RPC [1985] 515), which, although nearly 30 years old, still holds. In the case in question, Stauffer wished to undertake field trials using a herbicide that was known to infringe a patent held by Monsanto, in order to obtain regulatory clearance for this product.

This case established the principle that experiments carried out for the purpose of gaining regulatory approval for a product would not be exempt, under the 'experimental use' exemption, from being regarded as acts of infringement in the UK. However, it seems that 'experiments' performed to find out something new – that is, which advance scientific knowledge – may be exempt from being regarded as acts of infringement, in so far as they relate to the subject matter

of the invention. Further, it is worth noting that according to this case, an exempt act can have 'an ultimate commercial purpose'.

With respect to the meaning of the term the 'subject matter of the invention', the UK courts currently consider that the nature of the subject matter should be assessed by considering the contents of the patent as a whole. Furthermore, it is considered that the experimental purpose must have a 'real and direct' connection with that subject matter. There is an important distinction between research relating to the invention, which is exempted, and a research using the invention, which is not. For example, use of a patented sequencing technology in an experiment to further develop sequencing technologies might be exempted, but it is very unlikely that the use of the same technology in an experiment to determine the sequence of a nucleic acid would be exempted.

Practically, what does the 'experimental use' exemption in the UK permit? It is clear that the scope of the exemption is currently interpreted narrowly: experiments that are performed to further scientific knowledge and discover 'something new' can be exempted from being classed as an infringing act, in so far as the experiments performed have a 'direct' connection with the invention described in the patent. However, experiments performed purely for gaining regulatory approval, such as field trials or clinical trials, are, in general not be considered to be exempt from being classed as an infringing act under this provision.

Importantly, however, with the introduction of the new 'Bolar' provisions, discussed in the following section, acts which were previously been considered according to the 'experimental use' exemption are now being addressed under the new 'Bolar provisions' (section 60, subs (5)(i)).

The 'Experimental Use' Exemption in Other Parts of Europe

In other parts of Europe, decisions indicate that the 'experimental use' exemption is being interpreted more generously. For example, the German Supreme Court has held that an exemption permits the carrying out of clinical trials on a patented drug to ascertain its effect in medicinal indications not indicated in the patent (Klinische Versuche (*Clinical trials I* (Germany) [1997] RPC, 623), and in a subsequent decision (Klinische Versuche (*Clinical trial II* (Germany), [1998] R.P.C, 423, tests carried out to ascertain whether another substance falling within the ambit of the patent claim worked as well as (or better than) the patentee's own commercial product were also held exempt. In these two decisions the Bundesgerichtshof emphasised that the only questioned of relevance are whether the acts concerned were in the nature of an experiment which related to the 'subject-matter of the patent'. It was also noted that it was irrelevant whether or not these acts had commercial value.

Although there is no definition of the word 'experimental' it seems appropriate to say that an act may be deemed to be experimental if it seeks to generate new information and the act is not an experiment if it seeks to do no more than verify existing knowledge.

Moreover, a recent decision in France has deemed that under certain circumstances Phase III clinical trials can be exempted from infringement.

European 'Bolar' Provisions

The Pharmaceutical Regulatory Directive

On 11 March 2004 the EU adopted a new European pharmaceutical regulatory directive (Directive 2001/83/EC [2001] OJ EC L311/67 on the Community code for medicinal products for human use). with the aim of facilitating the movement of generic products to the European market. This exemption applies to generic medicinal products and also to non-generics, but only those that are similar to the reference product and which do not fulfil the generic definition for specified reasons.

The directive was implemented into the UK Patents Act by s60(5)(i). This section provides that *'the conduct of tests and trials for the purposes of art.10(1) to (4) of Directive 2001/83 … and the corresponding practical consequences, shall not be regarded as contrary to patent rights for medicinal products'*.

What Does This Mean, in Practice?

This paragraph, in effect, introduces a form of regulatory review or clinical trials defence into UK patent law (i.e., a 'Bolar' exemption). Noteworthy is the fact that this exemption supplements but does not replace the experimental use defence referred to in the preceding section.

The wording of the paragraph is in two sections (i) and (ii). Section (i) exempts *'an act done in conducting a study, test or trial which is necessary for and is conducted with a view to, the application of'* the relevant paragraphs of the appropriate directive; whilst section (ii) in addition exempts *'any other act which is required for the purpose of the application of those paragraphs'*.

The meaning of these terms is rendered clearer by considering the wording of the directive which they implement. Specifically:

'conducting the necessary studies and trials with a view to the application of [the relevant paragraphs] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products'.

Accordingly, in effect a *'consequential practical requirements'* provision has been introduced into the exemption. This seems to relate to the manufacturing, importing and processing of the active material for the necessary studies.

Guidance on how to interpret the provision was issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Patent Office. This guidance is not binding in UK courts, but it is likely that it will be considered and followed in case of doubt.. The MHRA provided a detailed list of exempted activities. These can be summarised as:

- the manufacture or import of active substances and validation of manufacturing process,
- the manufacture or import of finished product and validation of manufacturing process,
- development, testing and use of analytical techniques associated with the manufacture of the active and the finished product,

- conducting pre-clinical tests, clinical and bioavailability trials and stability studies on the medicinal product,
- the compilation and submission of a marketing authorisation and samples of products to regulatory authorities.

The UK approach, like the German version, does not make a distinction with regard to the kind of patents exempted.

Importantly, and in contrast to the US version of the Bolar type exemption, the UK provision has no application to Phase I, Phase II, and Phase III clinical trials on a medicinal product containing a new active substance that has not yet received an authorisation in any medicinal product.

However, as noted above in the clinical trials cases, it appears that in Germany at least, Phase I, II, and III clinical trials may be exempted using the 'use for experimental purposes into the subject-matter of the invention defence'.

It is also worth noting that other member states in Europe have gone further than the UK in their implementation of the 'Bolar' directive. This will be discussed in brief below with respect to Germany.

Germany
In Germany, a new subsection was introduced into the patent code in order to implement the directive. It translates as:

[the following acts do not constitute infringement]

'Studies and trials and the consequential practical requirements necessary to obtain permission to market [a drug] in the Member States or in third countries according to the effective pharmaceutical regulations'.

The new German 'Bolar' provision is often seen as a continuation of the extension of the Experimental Use Exemption in Clinical Trials I and II However, as in the U.S., the German 'Bolar' exemption applies not only to the approval of generics but also to drugs in general, unlike the more restrictive UK provisions.

What About Research Tools?

Do They Fall Within These Exemptions?
It is generally accepted that the term 'research tool' in its broadest sense describes the full range of resources that scientists use in the laboratory. This may include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software.

Was it the intention of the European legislature to include within the exemptions the use of research tool patents? There is no hint in the preamble of Directive 2004/27/EC that the legislature intended to include these patents. It only aims at facilitating the access of 'medicinal products' to the market. A strong argument against an inclusion of patents other than those which will be subject to future approval is that the 'Bolar' provision was enacted as part of the Community code relating to medicinal products for human use and not as part of EC Patent Law. Systematically, it is therefore more likely that the European legislature did not want to address any patent involved in the process of drug discovery but only focused on those patents which are going to be subject to future approval.

What is the Practical Effect of This?

The concern that the value of research tool patents could be diminished by exemptions for market approval studies has led to a vivid debate about the scope of 'Bolar' exemptions, naturally, particularly by research tool companies. It will be interesting to watch the debate unfold and we await decisions to guide us in this respect. I do not consider that the legislation intended the use of research tools patents to be exempted by the 'Bolar' provisions. Such an interpretation would be inconsistent with the intention of the patent system to reward and encourage innovation.

Summary

Experimental acts using a patented product may be exempted, in the UK at least, using either the 'experimental use' exemption and/or the 'Bolar' provisions. Experiments designed to elicit new knowledge – that is, which can be considered to advance scientific knowledge – will generally be exempted under the former, whilst experiments and clinical trials using the patented drug and which are designed to obtain regulatory approval will generally be considered for exemption under the 'Bolar' provisions. In the UK at least, these exemptions do not extend to non-generics. In some other EU countries, Germany for example, these provisions have been interpreted more generously.

The importance of a fair interpretation of scope of these exclusions is clear; too broad an interpretation of the exempted acts may lead to a diminution of the value of patent rights for innovative drugs and also the research tools patents involved their production. Effectively, this would discourage the generation of new drugs, whilst at the same time promoting the value in generics. Surely, this is contrary to the goals of the patent system. Conversely, too narrow an interpretation of the exempted acts would confer upon the patent holders of innovative drugs an unfair monopoly and one which would discourage the generic market. The effect? Fewer low-cost generics for consumers. This is certainly not in line with the aims of the EU directives. It will be interesting to see how this area unfolds.

References:

- *Monsanto/Stauffer, RPC, (1985) 515.*
- *Dr C.J. Soames. Nature Review. Drug discovery 2005); 4(4), 271.*

- *CIPA Guide to the Patents Act, Sweet and Maxwell Trevor Cook, 'A European Perspective as to the Extent to which Experimental Use, and Certain other, Defences to Patent Infringement, Apply to differing types of Research'. C.I.P.A. J (2007) 36(3), 159-160.*
- *Esther Pfaff, International Review of Intellectual Property and Competition Law (2007); 38(3), 258-274: "Bolar" exemptions - a threat to the research tool industry in the US and the EU?*
- *Fiona Bor, European Intellectual Property Review (2006); 28(1) 5-14, 'Exemptions to Patent Infringement applied to biotechnology research tools'.*