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GNL37: UK experimental use exemptions

The exemptions to patent infringement applicable in the UK to life sciences products are often a source of confusion. This is not least because of the introduction of a third such exemption on 1 October 2014. The extent of protection offered by each differs, but to some extent overlaps, and there is only slim guidance from the courts. This article attempts to disentangle the issues raised by these exemptions, by explaining what they are, and what we know about their field of application and scope.

Some definitions

When dealing with the Bolar Exemption and related experimental use exemptions in the UK, it is first necessary to explain some issues of terminology. To assist, it is helpful to create some definitions:

- **'Original Experimental Use Exemption'** – the experimental use exemption in Section 60(5)(b) Patents Act 1977. This is still in force and it applies to all patent subject matter, including medicines, medical devices and agrochemicals.
- **'Bolar Exemption'** – the regulatory review defence, which is based on European law but enacted in Section 60(5)(i). Again, this exemption is still in force. It applies only to medicinal products as governed by Directive 2001/83/EC (the "Directive").
- **'New Experimental Use Exemption'** – this was introduced into the **UK only,** on 1 October 2014. As explained below, because this exemption was designed to expand the protection offered by the Bolar Exemption it is often referred to as a new Bolar Exemption. But actually it is not based on European law like the Bolar Exemption, and the Bolar Exemption has not changed as a result of it. Instead, this exemption expands the scope of experimental purposes found in the Original Experimental Use Exemption. It is found in Section 60(6D) and (6E) Patents Act 1977. However, like the Bolar Exemption, it applies only to medicinal products under the Directive.

Why so many exemptions?

The Original Experimental Use Exemption, although based on the Community Patent Convention 1975, was and is provided in the national law of most European countries by national statutes. This has meant that it varies from one European country to another, not so much because of differences in drafting but more because of different judicial interpretations in the national courts.

A further issue was the doubt about the extent to which, if at all, protection is afforded by this exemption for the conduct of clinical trials and other tests necessary to obtain a marketing authorisation. This was a particular issue for generic pharmaceuticals who faced waiting until patent expiry before they could perform equivalence studies for the purpose of obtaining abridged marketing authorisations; effectively extending monopoly protection for branded drug makers after patent expiry until the approval for the generic could be obtained.

As a result, the Bolar Exemption (named after a similar provision in US law, following the *Roche v Bolar* case), was introduced in the EU by Article 10(6) of the Directive. Its purpose was specifically to address uncertainty about the scope of application of the Original Experimental Use Exemption to bioequivalence and stability studies conducted for the purpose of obtaining an abridged marketing authorisation under the Directive.

Although the Directive is intended to harmonise legislation across the Member States of the EU, as a Directive, it must be implemented by the national laws of each country concerned. This means that, much like the Original Experimental Use Exemption, there have been varying – or, quite different – implementations of Bolar in the European Member States.

In the UK, furthermore, it is the apparent limitations on the scope of the Bolar Exemption and the Original Experimental Use Exemption that have led to the need for the New Experimental Use Exemption. This is explained further below, beginning with the Original Experimental Use Exemption in the UK:

The Original Experimental Use Exemption in the UK

What were the limitations of the Original Experimental Use Exemption that provided a need for the Bolar Exemption in the first place?

The Original Exemption has broad application to all subject matter, but the three leading cases are actually about agrochemicals and medical devices. The first is the Court of Appeal decision in *Monsanto v Stauffer*[4] . In this case the defendants sought the modification to an injunction that had been ordered against the manufacture and sale of their Touchdown herbicide for agricultural use.

The Court of Appeal permitted limited modifications to the injunction so that it didn't prevent the defendants from conducting experiments on Touchdown in laboratories or glasshouses in the UK to find out more about it. But the court wouldn't allow field trials for the purpose of full commercial clearance from the Pesticides Safety Precautions Scheme and approval from the Agricultural Chemicals Approval Scheme (that existed under legislation at the time). Explaining where the line is to be drawn between exempted and non-exempted experiments under the Original Experimental Use Exemption, Dillon LJ, the leading judge explained as follows:

> *Trials carried out in order to discover something **unknown**, or to test an hypothesis, or even in order to find out whether something which is known to work in specific conditions, e.g. of soil or weather, will work in different conditions can fairly … be regarded as experiments. But 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 such as the PSPS or ACAS, that the product works as its maker claims are not to be regarded as acts done for 'experimental purposes'.*

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In other words, the court reasons that exempted experiments are those that generate new knowledge, but not those that verifying existing knowledge, for example for getting regulatory clearance. The later decision of the Court of Appeal in *Auchincloss* is consistent with this, when it holds that making and experimenting with a patented invention merely for the purposes of gaining official approval would not fall within the Original Experimental Use Exemption. The facts of the *Auchincloss* case again concern agrochemicals: a sample of a dry water-soluble biocidal composition sent by the defendant to MAFF, the old Ministry of Agriculture, Fisheries and Food. Here, the Court of Appeal held that supplying a sample to MAFF in order to obtain official approval rather than to discover something unknown or to test a hypothesis, was not covered by the exemption.

The case concerning a medical device is the Patents Court decision in *CoreValve v Edwards Lifesciences*[6] . This case supports the view that, in principle, the experimental use exemption permits trials to be conducted on a patented drug to ascertain its effect in *non-patented* medical indications. *But,* it was still held in this case that the trials at issue did not benefit from the exemption. The reason was that the activity in question was the supply of the defendant's valve device to selected hospitals as part of a clinical programme to train cardiologists in the use of the device, for which Corevalve invoiced a "very substantial" amount. The judge thought that this illustrated an outer limit on the principle that a commercial motivation for the work is permissible as long as the "preponderant" purpose of the work is to find out something new. Finding out something new, here, was not the preponderant purpose.

In summary, the English authorities draw a distinction between the application of the experimental use exemption to activity conducted for the purpose of discovering something new about the subject matter of the invention, and merely verifying what is already known. So, to the extent – and this is a matter of fact in each case - that trials and tests on a substance for regulatory approval of that substance are not discovering something new, the exemption will not apply. In particular, it is generally accepted that this is the case as regards bioequivalence studies for an abridged application – they won't be protected – and it is uncertain that full clinical trials would be protected either.

The Bolar Exemption in the UK

The UK implementation of Bolar is linked by explicit reference to the abridged application procedures for marketing authorisations in the Directive. And, although there is no case law on the precise scope of the exemption, it is the view of the UK Intellectual Property Office (UKIPO) and the Medicines and Healthcare Products Regulatory Agency (MHRA) that UK Bolar Exemption exempts from patent infringement activities conducted only for the purpose of obtaining an abridged marketing authorisation application by a generic and no more. The exempted tests must also be for authorisations covering the European Union market and no wider. This is also the view of practitioners.

So the Bolar Exemption, although it assists generic companies to overcome the restrictions of the Original Experimental Use Exemption, is narrow.

The New Experimental Use Exemption in the UK

The New Exemption came into being because of concerns that the UK was losing out on opportunities to conduct work in support of getting marketing authorisations, such as trials, because of the limited UK Bolar Exemption. It is therefore concerned specifically with medicinal products.

The New Exemption came into force on 1 October 2014, by way of addition to the Original Exemption. However, as stated above, the Original Experimental Use Exemption and the Bolar Exemption, remain intact, although because of the breadth of the New Experimental Use Exemption the latter may now be effectively otiose. This can be seen from the scope of the New Experimental Use Exemption, which covers activity that is conducted "for the purpose of a medicinal product assessment"[7] . A medicinal product assessment is defined as "any testing, course of testing or other activity undertaken with a view to providing data for purposes which include the following:"

- *obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);*
- *complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;*
- *enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of—*
    - *providing health care on behalf of such a government or public authority,…*

This means that in addition to the activities covered by the Bolar Exemption, the preparation and running of clinical trials on innovative drugs for marketing authorisation are also exempt. Furthermore, work undertaken in the UK in support of a regulatory filing in any country is also now covered.

The result is that, as far as medicinal products are concerned, the distinction drawn in *Monsanto v Stauffer* and *Auchinloss* between experiments designed to test for new properties, rather than verify known properties for a regulatory body, is swept away by the New Exemption.

GNL37: UK experimental use exemptions

Subject to testing in the courts, the New Experimental Use Exemption may also have other applications that go beyond the previous Exemptions. For example, the New Exemption covers activities conducted "for the purpose of a medicinal product assessment", which would seem to suggest that the provision covers third party supply of patented active ingredient, provided that supply is for the exempted purposes.

The UKIPO has also issued guidance on the New Exemption, which states that:

> *"Research tools may be an integral part of a drug therapy and when they are used in, or for, the purposes of a medicinal product assessment, they are within the scope of the amendment*".

While this guidance is not precise and it is not binding law, it is the view of the UKIPO that research tools are covered. There is ambiguity in the UKIPO guidance though: the New Experimental Use Exemption is intended to apply to post-authorisation studies in general, but the guidance also goes on to state that once the product in question is commercialised the New Experimental Use Exemption is no longer applicable to research tools. The application of the New Exemption to the use of research tools for post-authorisation studies is therefore unclear.

In summary

Although there are three exemptions potentially applicable to patent infringements concerning life sciences products in the UK, the application and development of the Original Experimental Use Exemption and then the Bolar Exemption in UK law has been fairly limited in scope. There is particular doubt about their application to clinical trials on innovative drugs for the purpose of obtaining a marketing authorisation.

The UK responded to these limitations by amending its Patent Act to provide a New Experimental Use Exemption applicable to clinical studies and related work conducted for the purpose of a wide-ranging class of medicinal product assessments. However, although guidance on the New Exemption is available from the UKIPO, the courts are yet to decide a case about its application.

For further guidance please contact Paul England (Tel: 020 7300 7020) or Matthew Royle (Tel: 020 7300 4608)

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