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The Bolar Clause, good for competition?

The increasing prominence of generic drug manufacturers in the pharmaceutical market has highlighted a massive market for cheap medicines. The need for cheap alternatives to expensive blockbuster drugs can be seen everywhere; whether it be for AIDS victims in sub-Saharan Africa; or anti-obesity drugs in Europe and the United States.

The price of a medicine is normally directly related to its research and development costs. This means that for a drug to be worthwhile commercially, there must be a lucrative market to compensate for the large amount of money spent before the drug is certified. The use of patents

allows these companies to retain a monopoly over the particular molecule or process for a period of time, in order to recoup the costs of its development. For this reason the prices over the patent period will be set at a higher level than the cost price of the particular drug.

Generic manufacturers in comparison to pharmaceutical companies generally have small R&D departments, instead relying on the production of drugs that are now no longer under the security of patents. This allows them to sell at almost cost price, thereby massively reducing the costs to the consumer.

In many countries the generic market for patent expired drugs is huge. Therefore the speed that the generic drug manufacturers are able to start manufacturing the drugs is vital to that manufacturer becoming competitive. For a medicine to be marketed approval has to be gained from the relevant governmental department for this to occur research and testing data have to be submitted and approved. This process can take many years and therefore cost a generic drug manufacturer money and possible market share.

Current UK law stated in the Patent Act 1977 s60(5) is that:

‘An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if—

- a) ...
- b) It is done for experimental purposes relating to the subject-matter of the invention’.
- c) ...”

At first glance it would seem that this clause would be sufficient to allow the generics to test patented drugs before the patent had expired. The case of *Monsanto v Stauffer* [1985] FSR 55, stated otherwise, comprehensively holding that s60(5)(b) did not protect trials aimed at gaining regulatory approval from patent breach claims. This was the case in many EU countries, resulting in many ge-

neric manufacturers basing themselves in non-EU countries, in order to circumnavigate a possible patent breach.

Due to the increasing market in this sector, many countries are keen to try and encourage generic manufacturers to base themselves in their countries for economic and employment reasons. This has led to the EU Regulatory Pharmaceutical Package (EURPP) containing the 'Bolar clause' being put forward by the European Parliament. This includes a number of Directives, which have 18 months from the 30 April 2004 to be implemented into national legislation.

The Bolar cause originated in the United States after the case *Roche Products Inc v Bolar Pharmaceutical Co* (1984). In this case the American Court of Appeal decided that testing a drug (in this case Flurazepam) for the purpose of gaining FDA (Food and Drug Association) approval contravened the patent and therefore was a breach. In response to this case the Hatch-Waxman Act was approved in 1984. This allowed manufacturers to make, use, or sell a patented invention within the US for the sole purpose of submission to the FDA under federal law.

The new EU Regulation 2004/27/EC (revised) Article 10(6) states that:

'Conducting necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 [to a generic medicinal product] and the consequential practical requirements shall not be regarded as contrary to patent rights or supplementary protection certificates for those medicinal products'

This allows the testing of patent-pending drugs and the registration and approval by the regulatory authority before the patent has expired.

The EURPP also contains a regularisation towards data protection, in the 8+2 formula, allowing:

- A 10 year exclusivity for the pharmaceuticals; and
- generic manufacturers to be able to rely original research and testing data of reference pharmaceutical products and be able to register them after 8 years.

By allowing generic manufacturers to begin testing and registration using current data after 8 years of the 10-year exclusivity period the protection for the pharmaceutical companies has been dramatically reduced. Currently authorisation for a new drug can take up to 18 months in the UK, therefore giving a pharmaceutical company up to 11 years and 6 months exclusivity. This will have a significant effect where data exclusivity rather than a patent is protecting a market by allowing earlier competition and causing a possible drop in profits. It isn't all bad for the pharmaceutical companies, as in some countries where the data exclusivity period is only 6 years, such as in Austria and Denmark, they are gaining an extra 4 years of exclusivity.

The general introduction of the Bolar clause into the UK legislature will allow a greater number of generic manufacturers to compete within the UK. This will hopefully in the long run increase competition in what is sometimes seen as a monopolist sector having the effect of driving down medicine prices and making some drugs more widely available.

Bibliography

The Bolar Clause in the new European pharmaceutical regulatory package, *L'Ecluse P Longeval C*, Global Counsel Life Sciences, Practical Law Company, 2004/05

European Union: 2004 –Annus Horribilis for innovative pharma?, *Dragg N Brook D*, Life Sciences Law and Business , 2005, Vol. 1(6)

Idiots Guide To Intellectual Property, Part 1

Intellectual property is based on one founding theme, the monopoly, the basic idea that the inventor / writer should be allowed a period of time to reap the reward of their idea.

There are any number of different types of security that can be placed over ideas; these range from a patent over the drug Viagra, a trademark over the MacDonald's sign, the copyright held by a writer, or the design rights of a furniture designer.

The patent.

A patent can be security over any number of different objects as long as it fulfils the criteria set out in the Patents Act 1977.

1. Invention

- Invention is very simply taking the idea beyond a mere discovery. Indeed the Act is very specific that discoveries, scientific theories and mathematical methods cannot be the subject of a patent. To be an invention the applicant must go beyond these and take the extra step to go beyond pure knowledge.

2. Novelty

- This is made up of two facets, firstly previous non-disclosure, and secondly whether the object is state of the art. State of the art is defined as all worldwide knowledge on the subject matter of the invention. There are certain exceptions to this rule in that is an object being used in such a way that it is not part of the previous state of the art. An example of this could be the use of a drug designed for one purpose being found to be useful in treating another.

3. Inventive step

- This is defined as a step that would not be obvious to a person skilled in that art. The test would therefore involve the questions:
 - i. what was the inventive step; and
 - ii. at the priority date what was the state of the art; and
 - iii. how does the step differ from the state of the art; and
 - iv. without hindsight could a person skilled in the art have made that inventive step?

4. Industrial applicability

- This could be made to encompass virtually all inventions (except possibly the theoretical).

If all of these steps are fulfilled a patent will be issued on the invention, thus giving a monopoly to the applicant for an initial 4 years in the first instance then a possibility of further renewal for up to 20 years.

Useful websites:

www.ipit-update.com

www.patent.gov.uk

www.parliament.uk/index.cfm

www.wipo.int

Your guide to the latest news in intellectual property law

Home of the UK patent office

Parliament and the House of Lords

World Intellectual Property Organisation home page

Important Cases in I. P.

Synthon B.V. v Smithkline Beecham plc 20 Oct 2005 HL

This claim centered on an anti-depression drug, Paroxetine. Both Synthon and SKB discovered the chemical's increased stability in a new form almost simultaneously in 1997. Synthon filed a patent in Holland covering a wide area following the discovery that was published in December 1998. SKB filed for a UK patent in April 1999, under priority from an earlier document. In March 2001 Synthon issued proceedings stating that SKB's paroxetine compound was not a new discovery. At first instance Jacob J accepted Synthon's argument that the SKB patent was not a new chemical and was therefore invalid. The Court of Appeal reversed this decision. The House of Lords overturned the decision of the Court of Appeal, stating that they felt the Court had become confused by mixing the areas of disclosure and enablement, two areas that should be kept entirely separate when determining the validity of a patent. In restoring the judgment of Jacob J Lord Hoffman stated

'Nevertheless, in deciding whether there has been anticipation, there is a serious risk of confusion if the two requirements are not kept distinct. For example, I have explained that for the purpose of disclosure, the prior art must disclose an invention which, if performed, would necessarily infringe the patent. It is not enough to say that, given the prior art, the person skilled in the art would without undue burden be able to come up with an invention which infringed the patent. But once the very subject-matter of the invention has been disclosed by the prior art and the question is whether it was enabled, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. If, therefore, one asks whether some degree of experimentation is to be assumed, it is very important to know whether one is talking about disclosure or about enablement.'

This is an important fact that must be understood when dealing with a similar application. Science by its very nature is experimental and in the latter stages a certain degree of trial and error, especially in area such as recrystallisation, to find working or optimum conditions for the experiment. This is however only relevant to the element of enablement. Disclosure requires only that the application describes the compound in question and claims that it can be made. Whether it can actually be made or not is a question of enablement.

Enablement can then move on to deal with whether or not the compound can actually be made in the manner described within the application. In determining this it is necessary to examine the factors laid out in **Mentor Corporation v Hollister Incorporated [1993]** RPC 7 and other similar cases.

Statute and other case law

European Communities Act 1972 (Disapplication) Act

Could this be one of the most important changes to UK law of recent years? Granting the UK Parliament the power to pass legislation that overrides EU law, the potential implications of this legislation stretch far beyond that which could be mentioned in this review. To be heard in Parliament on or around 26 March 2006.

Les Editions Albert Rene v Office for Harmonisation in the Internal Market (Trade Marks and Designs) (OHIM) (Case T-336/03) [2005] All ER (D) 322 (Oct)

A trademark infringement case from the European Court of First Instance. It was held that goods could be found similar if they were complementary or if they could compete with each other. However, if one of the items was a component of the other it was not enough to prove similarity.

Sources: Future Parliamentary Bills website (see useful links)
Lexis Professional