HOW EFFECTIVE ARE RESEARCH EXEMPTIONS IN PATENT LAWS?

CSIC/OECD/OEPM Conference

Research Use of Patented Inventions

Madrid 18-19 May 2006

Trevor Cook

trevor.cook@twobirds.com







BIRD & BIRD

Experimental Use and Related Defences

- The problem
  - Recent concerns as to the application of the experimental use defence to "gene patents" and "research tool" patents
- Analysis of the defence in the UK and most of the rest of Europe for "use for experimental purposes relating to the subject matter of the invention"
  - "Use for experimental purposes"
  - "Relating to the subject matter of the invention"
- Developments in the USA
  - Lacking a viable experimental defence
  - Introducing and extending the scope of their regulatory review defence
- Other proposals
  - Canada, Australia
  - Belgium, Switzerland
- Recommendations for the UK

BIRD & BIRD

Recent UK concerns as to the application of experimental use defence to "research tools"

- Nuffield Council – "The Ethics of Patenting DNA" - July 2002
  - "We recommend that the research exemption is given a statutory basis in the USA and clarified in Europe by policymakers as a matter of urgency"
  - "We further recommend that companies work together to extend the concept of the "research exemption" throughout industry for DNA sequences which appear in patents and which have a use in research"
- Royal Society - "Keeping Science Open: the Effects of IP Policy on the Conduct of Science" - 2003
  - "At present, broadly, people are entitled … to do experiments to establish the scope and application of a patented invention, including experiments to discover an improvement to it. They are not entitled to experiment simply to prepare to duplicate and sell what is already on the market."
  - "Between these two extremes there is doubtful ground, and prudent people avoid doubtful ground. It would be conducive to the development of science if the position of scientific work under the exemptions was clearer."
  - "A case in point is the difficulties plant breeders face in breeding a non-patent infringing variety from a patented parent."
  - "We recommend that governments consider clarifying and harmonising the existing exceptions for "private and non-commercial" and "experimental" use."







BIRD & BIRD

Recent UK concerns as to the application of experimental use defence to "research tools"

- Patents for Genetic Sequences, IPI for DTI, UK 2004
  - "In the case of patented genes, particularly with product *per se* patents, there may be significant difficulty in discriminating between research on the subject of the invention and research with or using the subject of the invention"
  - "What constitutes use of a research tool for unconnected (and therefore unexempt) experimentation?"
  - "What in the course of clinical work counts as "experimental purposes"?
- TMPDF Submission to Gowers Review, UK 2006
  - Question 5.5 Are there other issues than those in this paper you feel the Commission should address in relation to the patent system?
  - Some patent related issues, which may or may not give rise to policy concerns but might justify some consideration include:
    - a) abuse of strong patent positions; patent ambushes; patent trolls; and related matters;
    - b) use of patented technology in setting standards and access to the necessary patents;
    - c) uniform rules on acceptable exemption of research (commercial or non-commercial) from patent infringement.

BIRD & BIRD

Case law in Europe on "experimental purposes relating to the subject matter of the invention"

- Most decided cases concern whether or not field or clinical trials are "acts done for experimental purposes"
- As it is assumed that they are "relating to the subject matter of the invention" – ie are on, rather than using, the invention
- Cases
  - *Monsanto v Stauffer* - English Court of Appeal – 1985 …
  - *SKF v Evans* - UK - Aldous J – 1985 …
  - *Clinical Trials I* – DE – BGH - 1995 …
  - *Clinical Trials II* – DE – BGH – 1997 …
  - *Auchinloss v Agricultural & Veterinary Supplies* – UK - Aldous LJ English Court of Appeal – 1998 …

BIRD & BIRD

Case law in Europe on "experimental purposes relating to the subject matter of the invention"

- *Monsanto v Stauffer* - English Court of Appeal - 1985
  - "The distinction between the wording of sub-head (a) and the wording of sub-head (b) in section 60(5) indicates that experimental purposes in sub-head (b) may yet have a commercial end in view....
    - (Article 31(a) – providing a defence for "acts done privately and for non-commercial purposes")
  - "I would regard the sort of experimental activity which was considered by the Supreme Court of Canada in *Microchemicals Ltd v Smith Kline and French* ... , viz, a limited experiment to establish whether the experimenter could manufacture a quality product commercially in accordance with the specification of a patent, as being covered by the words 'for experimental purposes relating to the subject matter of the invention.'"
    - Irony of relying on a common law formulation as an aid to statutory interpretation

Case law in Europe - are clinical and field trials "for experimental purposes"?

- *Monsanto v Stauffer* - English Court of Appeal – 1985
  - "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 a specific conditions ... 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 ... that the product works as its maker claims are not ... to be regarded as acts done "for experimental purposes".
  - "The purpose for which tests or trials are carried out may in some cases be mixed and may in some cases be difficult to discern; indeed, in the present case, if fuller evidence is given at trial, a different result may then be reached."
  - Here however product had already been commercially launched -
    - "… not clear to me what the defendants are still wanting to find out about their product."
  - No analysis of "relating to the subject matter of the invention"







BIRD & BIRD

Case law in Europe - are clinical and field trials “for experimental purposes”?

- *Clinical Trials I* - BGH – 1995
  - "An action for experimental purposes which is related to the subject matter of the invention and therefore legitimate can exist if a patented pharmaceutical active substance is used in clinical tests with the aim of finding whether and, where appropriate, in what form the active substance is suitable for curing or alleviating certain other human diseases"
- Facts
  - Attempts to use Gamma Interferon as a therapeutic
  - Clinical trials pre marketing authorisation (ie Phase II and III)
- Held covered by the defence
- Some comments as to the “relating to the subject matter of the invention” limitation

Case law in Europe - are clinical and field trials "for experimental purposes"?

- *Clinical Trials II* – BGH - 1997
  - "The intention that is associated with an activity begun and carried out for research purposes cannot render such activity infringing merely because the results of the research will not solely serve research purposes but above all will serve commercial purposes as well". An activity is exempted if "oriented towards clearing up insecurities with regards to the patented invention or bringing out new discoveries about said object, provided these activities ... relate to the object of the patented invention".
- Facts
  - Erythropoietin
  - Materials possibly differing in glycosylation but for same indication
  - Clinical trials pre marketing authorisation (ie Phase III)
- Held covered by the defence
- Some analysis of "relating to the subject matter of the invention"
  - And some important general limitations







BIRD & BIRD

Case law in Europe - are clinical and field trials "for experimental purposes"?

- *Clinical Trials I & II* in Germany:
  - Collateral use by filing data with regulators does not prevent true experimentation
    - for example as to possible new indications or because of
    - potential small differences in structure from already authorised product
  - from being covered by the defence
- UK view also apparently consistent with this:
  - No assumed experimentation in *Monsanto v Stauffer*
  - *Auchinloss v Agricultural and Veterinary Supplies 1998*
    - "If the sample sent to the [Regulatory Authority] had been produced during genuine experiments and been used for such experiments, I would have concluded that such experiments were done in relation to the subject matter of the invention ...."
- But does not establish that traditional bioequivalence testing for generic approval excepted – hence new Article 10(6) Regulatory Review Defence introduced by NML …

BIRD & BIRD

Case law in Europe - the "subject matter of the invention" limitation

- *SKF v Evans* - UK - Aldous J - 1985
  - "section 60(5)(b) covers acts done for experimental purposes including experiments with a commercial end in view, but the purposes must relate to the claimed subject matter of the patent in suit in the sense of having a real and direct connection with the subject matter.... '"
  - Thus example of the "master patent" (patent of addition) for cimetidine repeated in order to challenge the "polymorph patent" for cimetidine could provide such a defence as to those two patents, but not as to the "generic patent" for cimetidine.
  - But section 60(5)(a) would provide a defence as these repetitions would not be "done for a commercial purpose."







BIRD & BIRD

Case law in Europe – the "subject matter of the invention" limitation

- *Auchinloss v Agricultural & Veterinary Supplies* – UK - Aldous LJ - 1998
  - "Mr Floyd did not suggest that what I said in *SKF v Evans* was wrong. He submitted that the subject matter of the patent was a biocidal composition involving at the very least a relatively small amount of inorganic halide. That being so the … trial did not relate to the subject matter as the Defendants did not know that [the infringing material] contained such a halide and were not seeking to find anything out about a biocidal composition containing such a halide."
  - "I cannot accept that submission as it relies on too narrow a meaning of the words "the subject matter of the invention". The subject matter of the invention must be ascertained from the patent as a whole and as stated in the aim the invention is a biocidal composition …"







Case law in Europe – what is the "subject matter of the invention" in the experimental use defence?

- "The subject-matter of the invention must be the object of the experimental act for the purpose of gaining information." (CT I)
- " …the subject matter of the invention is the claimed technical teaching, which also includes the use of the inventive substance" (CT I)
- "… not limited to experiments on a narrowly defined subject-matter of the patent but include a range which goes beyond this and covers in any event checking of the utilizability of the subject-matter of the patented invention and checking possibilities of further development of this invention." (CT I)
- "…experimental purposes undertaken with the subject-matter of the invention in order to discover the effects of a substance or possible new uses hitherto unknown." (CT I)
- "The subject matter of the invention must be ascertained from the patent as a whole …" (Auchinloss)

BIRD & BIRD

Case law in Europe – other observations as to what is covered by the experimental use defence

- "… a limited experiment to establish whether the experimenter could manufacture a quality product commercially in accordance with the specification of a patent ..." (M v S)
- "Trials carried out in order to discover something unknown or to test a hypothesis or … in order to find out whether something which is known to work in a specific conditions ... will work in different conditions" (M v S)
- "… all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject matter of the invention, including its use." (CT I)
- "… Since the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests." (CT I)

Case law in Europe – activities NOT covered by the experimental use defence

- " …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 ... (M v S)
- "[use] within the framework of an experiment relating to a different subject-matter." (CT I)
- "… research [having] no relation whatsoever to the technological theory" (CT II)
- "… clarification of commercial facts such as the needs of the market, acceptance of prices, and possibilities of distribution." (CT II)
- " … experiments ... undertaken in such proportions as to no longer allow for justification on research grounds …" (CT II)
- " … experiments …carried out with the purpose of hindering the inventor's distribution of his product." (CT II)

BIRD & BIRD

Applying the experimental use defence in Europe to "gene sequence" patents

- Patents for Genetic Sequences, IPI for DTI, UK 2004
  - "In the case of patented genes, particularly with product *per se* patents, there may be significant difficulty in discriminating between research on the subject of the invention and research with or using the subject of the invention"
  - "What constitutes use of a research tool for unconnected (and therefore unexempt) experimentation?"
- But where is the difficulty for example in predicting that the defence applies to -
  - Finding new functions of a patented gene sequence
  - Verifying asserted functions of patented gene sequence
  - Finding variability associated with a patented gene sequences (eg SNPs)
  - Finding out other information about a patented gene sequence
  - Trying to improve on a diagnostic test based on a patented gene sequence
- And where is the difficulty for example in predicting that the defence does not, and should not, apply to -
  - Using a well established patented diagnostic genetic test in screening patients etc
  - Using a patented gene sequence as a research tool (eg a known promoter) in genetic manipulation experimentation

BIRD & BIRD

Applying the experimental use defence in Europe to "research tool" patents

- Patents for Genetic Sequences, IPI for DTI, UK 2004
  - "What constitutes use of a research tool for unconnected (and therefore unexempt) experimentation?"
- Research tools
  - Widely "defined"
- More useful concept is "research tool use"
  - Which in effect equates to "use other than in relation to the subject matter of the invention"
  - However some inventions have only research tool utility and it is not the legitimate application of an experimental use defence to deprive these of all value
- Reflecting the fact that it is hard to apply the defence to the use of anything as a research tool
  - eg using a patented gene sequence as a research tool (eg a known promoter) in genetic manipulation experimentation
  - eg peptide sequence in *Merck v Integra* could be, but was not being, so used – instead its use as a therapeutic was under investigation

BIRD & BIRD

Meanwhile in the USA - #1

- 1984 *Roche v Bolar* (CAFC)
  - Interpreted as excluding any experimentation as part of commercial activity from the scope of Justice Story's common law experimental use defence
- 1984 Regulatory Review Defence introduced as part of Hatch Waxman Act
- 1987 *Scripps v Genentech*
  - Common law defence not argued
  - Regulatory review defence held not to apply to early stage research
- 2001 *Bristol Myers Squibb v Rhone Poulenc Rorer*
  - Regulatory review defence held to apply to early stage research
- 2002 *Madey v Duke* (CAFC)
  - Common law defence held not apply to use in a University

Meanwhile in the USA - #2

- 2003 *Merck v Integra* (CAFC)
  - Regulatory review defence held not to apply to pre-clinical research
  - Common law defence abandoned
  - Newman dissent as to there being a spectrum from common law defence through to the regulatory review one
- 2005 *Merck v Integra* (Supreme Court)
  - Reversed CAFC and held regulatory review defence to apply to pre-clinical research
  - But left open as to how much further back upstream in drug discovery (First instance court finding that even earlier stage research to fall within the common law defence not apparently challenged)
- Representative claim:
  - "A substantially pure peptide including as the cell-attachment-promoting constituent the amino acid sequence Arg-Gly-Asp-R wherein the R is Ser, Cys, Thr or other amino acid, said peptide having cell-attachment-promoting activity, and said peptide not being naturally occurring peptide
- Not here used as a research tool, although it could be

Proposals in USA for introduction of an experimental use defence

- AIPLA 2005 (post *Merck v Integra* in CAFC but pre Supreme Court) proposal:
  - (c) [EXPERIMENTAL USE] – The rights granted to the patent owner under section 154 and acts of infringement described in section 271, shall not extend to making or using the patented subject matter for purposes related to scientific or philosophical inquiry, including to discern or discover
    - (1) the validity of the patent and the scope of protection afforded under the patent;
    - (2) features, properties, inherent characteristics or advantages of the patented subject matter;
    - (3) methods of making or using the patented subject matter; and
    - (4) alternatives to the patented subject matter, improvements thereto or substitutes therefore.
  - In addition, the exemption under this subsection from the rights granted under section 154 and described in section 271(a) shall extend to making or using the patented subject matter in activities that are incidental to preparations for commercialisation of an alternative to the patented subject matter. Otherwise, subject to section 271(e)(1), making or using the patented subject matter in connection with preparations for its use in commerce is encompassed by the rights granted under section 271(a).

Proposals in Canada for introduction of an experimental use defence

- The Report of the Canadian Biotechnology Advisory Committee (CBAC) to the Canadian Government entitled "Patenting of Higher Life Forms and Related Issues" of June 2002
  - 5. We recommend that the Patent Act be amended to include a research and experimental use exception that includes the following statement:
    - "It is not an infringement of a patent to use a patented process or product either:
      - (a) privately and for non-commercial purposes, or
      - (b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process."
  - "The addition of the words "to investigate its properties, improve upon it, or create a new product or process" is designed to eliminate [an] uncertainty."
  - "We have ... used the more general term "to study" rather than the narrower terms "research" or "experimental.""

BIRD & BIRD

Proposals in Australia for introduction of an experimental use defence

- ACIP October 2005 Recommendation to amend Patents Act to include:
  - "The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent."
  - "Acts done for experimental purposes relating to the subject matter of the invention include:
    - - determining how the invention works;
    - - determining the scope of the invention;
    - - determining the validity of the claims;
    - - seeking an improvement to the invention."
- And that "appropriate guidance be provided in the Explanatory Memorandum to the above amendment, explaining that the purpose of the exemption is to encourage the further development of patented fields of technology without unfairly devaluing patent rights or breaching the TRIPS Agreement, and that the exemption is not intended to derogate from any other exemption from infringement that exists under the Act."

BIRD & BIRD

Belgian amendment of experimental use defence

- Original text
  - 28(1) Les droits conférés par le brevet ne s'étendent pas... b) aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée
- Amended text 2005
  - 28(1) Les droits conférés par le brevet ne s'étendent pas... b) aux actes accomplis à des fins scientfiques sur et/ou avec l'objet de l'invention brevetée
- Replaces one alleged "uncertainty" ["relating to"] with another ["scientific purposes"] which, as "clarified" in Parliament, is to be given a broad meaning and concerns both
  - "Acts performed for pure scientific purposes"
  - "Acts performed for mixed scientific and commercial purposes"
- Deprives patents for inventions having only research tool utility of any value

Swiss introduction of an experimental use defence, and more - #1

- 9) (new) (1) The effects of a patent do not extend:
  - (a) to acts undertaken in the private sphere for non commercial purposes.
  - (b) to acts undertaken for experimental and research purposes in order to obtain knowledge about the object of the invention, including its possible utilities; in particular all scientific research concerning the object of the invention is permitted.
  - (c) to acts necessary to obtain a marketing authorisation for a medicament according to the provisions of the law of 15 December 2000 on therapeutic products.
  - (d) to the use of the invention for the purpose of teaching in teaching establishments
  - (e) to the use of biological material for the purposes of selection or the discovery and development of a plant variety
  - (f) to biological material, obtained in the field of agriculture which was due to chance or which was technically unavoidable.







BIRD & BIRD

Swiss introduction of an experimental use defence, and more - #2

- Defences
  - 9(2) Agreements which limit or exclude the exceptions foreseen under paragraph (1) are void.
- As to compulsory licences
  - 40b) Whoever intends to use a patented biotechnological invention as an instrument or accessory of research, is entitled to a non exclusive licence.
  - 40c) In the case of an invention concerning a diagnostic product or process in the human field, a non-exclusive licence is available to remedy a practice held to be anticompetitive in judicial or administrative proceedings.







BIRD & BIRD

Indentifying the concerns of plant breeders

- Royal Society - “Keeping Science Open: the Effects of IP Policy on the Conduct of Science” - 2003
  - “It would be conducive to the development of science if the position of scientific work under the exemptions was clearer. A case in point is the difficulties plant breeders face in breeding a non-patent infringing variety from a patented parent.”
- Patents for Genetic Sequences, IPI for DTI, UK 2004
  - Sections 3.3.5 – “… they were concerned that the UK law on research exemption does not clearly allow plant breeders to make across with a variety with a patented gene sequence in it and to develop a new variety without that gene in it.
  - “They therefore view a breeders exemption similar to that in plant breeding legislation as essential even though they acknowledge that production of a commercialised variety falling within the claims of a valid patent would require a licence.”
  - ie, an issue of overlap between the PVR and patent regimes, not of the scope of the experimental use defence

Addressing the concerns of plant breeders

- Article 15 CPVR, reflecting Article 15(1) UPOV 1991
  - "The breeder's right shall not extend to;
    - (i) acts done privately and for non-commercial purposes;
    - (ii) acts done for experimental purposes
    - (iii) acts done for the purpose of breeding, or discovering and developing other varieties."
- And by Article 13(5)(a) CPVR unauthorised activities in relation to "varieties which are essentially derived from the variety in respect of which the [CPVR] has been granted" infringe
- German legislation introduces a new defence in Article 11:
  - "The effect of a patent does not extend to .. 2a) use of biological material for the purpose of breeding, discovery and development of a new plant variety"







BIRD & BIRD

A new statutory defence for regulatory review in Europe

- Europe - Article 1(8) of Directive 2004/27/EC ("New Medicines Legislation")
  - Replacing, as from November 2005, Article 10 of Directive 2001/83/EC on the Community Code relating to medicinal products for human use, including:
    - "10(6) Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patents rights or to supplementary protection certificates for medicinal products."
  - "Paragraphs 1, 2, 3 and 4" relate to abridged applications for generic medicinal products
  - Thus apparently of no application to innovative research, which may for example involve comparative trials
- cf USA - "Bolar" or "Safe Harbor" Provision of 1984 Hatch Waxman Act
  - "It shall not be an act of infringement to make, use, or sell … a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products"

BIRD & BIRD

A new statutory defence for regulatory review in Europe – national implementations - #1

- Italy – Amend Article 68(1)(a) of Patent Act to read
  - (a) … acts performed for private or non-commercial purposes, or on a purely experimental basis even if aimed at obtaining a marketing authorisation for a medicinal product, also in foreign countries, and the consequent related practices, including the preparation and utilisation of pharmacologically active raw materials strictly necessary for such purpose
- Spain – Amend Article 52(1)(b) of Patent Act to read
  - (b) Actions carried out for experimental purposes, which concern the subject matter of the patented invention, in particular studies and trials performed for the authorisation of medicinal products and the resulting practical requirements, including preparing, obtaining and using the active substance for such purpose
- ie by describing regulatory review as an instance of the experimental use defence
  - What effect does that have on the scope of the experimental use defence other than in relation to medicinal products?

A new statutory defence for regulatory review in Europe – national implementations - #2

- Germany – Add new Article 11(2b), leaving Article 11(2) on the experimental use defence unchanged (Article 11(2a) addressing patent - PVR overlap)
  - (2b) Studies and trials and the consequential practical requirements, which are necessary to obtain an authorization according to Drug Law for the marketing in the European Union or an authorization according to Drug Law for the marketing in the Member States of the European Union or in third countries.
  - ie also beyond Article 10(6), but in another different way and leaving experimental use and private and non-commercial use defences unchanged
- UK – SI 2005 No 2079 adds new Subsection (i) to Section 60(5)
  - (5) An act which, part from this subsection, would constitute an infringement of a patent for an invention shall not do so if …
    - (i) it consists of
      - (i) 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
      - (ii) any other act which is required for the purpose of the application of those paragraphs.
  - ie copy out of Article 10(6) leaving experimental use and private and non-commercial use defences unchanged

BIRD & BIRD

Recommendations as to UK - #1

- Clear away other pressures on proper analysis of experimental use defence
  - Introduce separate defence aimed at addressing the problems of plant breeders caused by patent – PVR overlap
    - As in France Germany and Switzerland
    - And preventing its exclusion by contract, as in Switzerland
  - Extend regulatory review defence to cover tests and trials conducted with a view to securing a marketing authorisation for medicinal products other than those just required to secure a generic approval
    - To address, inter alia, comparative trials by originators
    - As in France Germany and Switzerland (Germany has broadest version)
    - Known to be TRIPs Compliant (*EC v Canada*)
    - Not as in Italy and Spain, as that risks distorting the experimental use defence

Recommendations as to UK - #2

- Leave defence for use of experimental purposes relating to the subject matter of the invention unchanged
  - Recognising scope for flexibility as to “relating to” and “subject matter of the invention”
  - Consider developing guidelines to clarify accepted scope
  - Consider further possible consequences of amending to at the end to add “or another invention of similar utility” in order to address any uncertainties as to as use of comparators
- Make no special provision for “research tool” or “gene sequence” patents but recognise that should evidence become available that special provision is appropriate for these this be effected -
  - Not by modifying the experimental use defence,
  - But by targeted automatic compulsory licensing, as in Switzerland
  - Limited in the case of research tools to certain types of research tool and to use only,
  - which at least does not deprive patents for inventions having only research tool utility of all value