

RESEARCH EXEMPTION EXPERIMENTAL USE

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DEFINITIONS

- **Research (Experimental Use) Exemption**
 - A provision that certain actions which fall within the claims of a granted patent are not patent infringement if they are done for the purposes of research.
 - May be written into the law, or based on court decisions.

- **« Bolar Exemption »**
 - A provision that clinical trials and other experimental work done to obtain regulatory approval of a generic drug do not infringe the patent for the drug.
 - May be in the law or by court decisions.

GENERAL PRINCIPLES (1)

- National laws
 - Statutory exceptions
 - Europe
 - CPC article 27 (b) : « acts done for experimental purposes relating to the subject matter of the patented invention ».
 - For example
 - UK art 60 (5) (a) & art 60 (5) (b)
 - France art L 613.5
 - Germany par.11
 - Other countries except CH , AT

GENERAL PRINCIPLES (2)

- National laws
 - Statutory exceptions
 - Japan: art 69 (1): « the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research »
 - USA: art 35 USC 271 (e): « it shall not be an act of infringement to make, use, offer to sell, or sell within the US or import into the US 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 ».

COURT DECISIONS (1)

- UK
 - 1985: Monsanto v Stauffer
 - 1985: SKF v Evans
- DE
 - 1995: Gamma Interferon: Clinical Trials I
 - 1997: Erythropoietin: Clinical Trials II
- FR
 - 1998 & 2001: Wellcome v Flamel
 - 2001: Wellcome v Parexel
 - 2001: Science Union v AJC Pharma
 - 2002: Science Union v Biophelia

COURT DECISIONS (2)

- Italy
 - 1995: Squibb v Testaguzza
- NL
 - 1994 & 1995: ARS v Organon
 - 1994: Kirin-Amgen v Boehringer Mannheim
- US
 - 2003: Bayer v Housey
 - 2003/2005: Integra v Merck

TRIPS art 30

- **Exceptions to Rights Conferred:** « Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties »
- **Experimental use exception applies to every technology**

REGULATORY APPROVAL: BOLAR EXEMPTION

- US: Waxman Hatch 1984
- Europe: Directive 2001/83 (EC) amended by the Directive 2004/27
 - Art 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 patent rights or to supplementary protection certificates for medicinal products »

IMPLEMENTATION OF THE E.U. PHARMACEUTICAL LEGISLATION

- Done in certain countries: AT, BE, FI, DE, GR, HU, IE, IT, LV, PL, PT, SK, SI, ES, EE, SE
- To be done: DK, FR, LT, NL, U K, (NO)

RESEARCH TOOLS (1)

A research tool is e.g. a reagent, test, kit, target, screening process, etc. used in the laboratory in the course of research and development of a new commercial product.

The research tool does not check whether the invention works or if it can be improved.

The research should not be covered by any research exemption.

RESEARCH TOOLS (2)

- To make all research activities free of patent infringement would make all research tool patents worthless, and would be contrary to TRIPs.
- It is only the research itself which may be exempted from infringement. Commercial application of the results of the research is not exempted and may infringe.

RESEARCH TOOLS (3)

- OECD Working Party on Biotechnology has published in 2004 a draft best practice Guidelines for the licensing of Genetic Inventions
- The AIPLA special committee on patent legislative strategies has proposed that there should be changes to the legislation about exemption from infringement for experimental use of patented technology

RESEARCH TOOLS (4)

- The JPMA has produced (Jan 2006) a voluntary Guideline to apply to the licensing of research tool patents: « Non-Exclusivity under reasonable Conditions »
- Revisions to the Swiss law include dispositions for research exemption even mandatory licensing of patented research technology.

CONCLUSION(1)

- A research exemption should ensure that a product or process covered by a patent may be freely made or used :
 - to evaluate the validity of the patent by testing:
 - whether the patent description is sufficient.
 - whether the invention performs as stated in the patent
 - To carry out research for the purpose of:
 - improving the invention.
 - making an advance over the invention.
 - finding an alternative to the invention.

CONCLUSION (2)

- There should be no distinction between « academic » and « commercial » research.
- The same rules should apply to both.