

# 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 reseach 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.