



RESEARCH USE OF PATENTED INVENTIONS*

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FRENCH SITUATION

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* Please note that these slides were not formally presented at the conference, but the substance of some of them was included the remarks made by the author at the closing roundtable.

LEGAL PROVISION

- **Article L. 613-5 CPI (Code of Intellectual Property):**

« The rights afforded by the patent shall not extend to:

a) ...

b) Acts done for experimental purposes relating to the subject matter of the patented invention;

c) ... »



WHICH EXPERIMENTS?

- **Improvements**
- **Filing of an application for getting an administrative approval**
- **Clinical trials**



IMPROVEMENTS

- **No problem concerning the research exemption aimed to improve the patented invention: new process, new application, new formulation**
- **Improvements are patentable**
- **No impact on the research as such**

FILING OF AN APPLICATION FOR AN ADMINISTRATIVE APPROVAL

- **The filing of such an application is not an infringement *per se* (Supreme Court – 1998 – Promedica/Allen)**
- **Concerning a generic, the AMM can be granted before the expiration of the patent protecting the original medicine (Article L. 5121 – 10 of the Public Health Code – Law of December 2003)**

CLINICAL TRIALS

- **Clinical trials executed for getting the administrative approval of a generic:**
 - **Not clear as referred to Court decisions (infringement according to the Supreme Court, non infringement according to later decisions – 2001/2002 – from lower Courts)**
 - **Draft law for transposing the EU Directive 2004-27 (Article 8: clinical trials are not an act of infringement)**



I THANK YOU...

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