Hogan Lovells

Private use and experimental use

France

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Exceptions to patent rights in France

- Article L.613-5 of the French Intellectual Property Code (IPC):

  "The rights conferred by the patent shall not extend to:

  a) Acts done privately and for non-commercial purposes;

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

  c) The extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

  d) The studies and assays required to obtain a marketing authorisation for a drug, as well as the acts necessary to their completion and for obtaining the marketing authorisation;

  d bis) The acts necessary for obtaining a stamp authorising advertising as provided in Article L 5122-9 of the Public Health Code;

  e) Objects aimed to be launched in the outer space introduced on the French territory."

- Few case law so far.

Research exemption in France

Research exemption

Scope and rationale

- Article L.613-5 b) of the French Intellectual Property Code (IPC):

  "*The rights conferred by the patent shall not extend to:*

  b) Acts performed for experimental purposes relating to the subject matter of the patented invention"

- Research exemption aims at enabling scientific research during patent validity
- Broadly drafted provision:
  - Any and all patents, including pharmaceutical patents
  - Experimental purposes in general, regardless of whether exclusive/immediate purpose?

Research exemption

Scope

- Court of appeal of Paris, 3.07.2002, Peugeot v. Parienti:
  - This provision "*is **to be construed strictly** and can only apply to experimental acts aiming to take part to the verification of the technical interest of the invention or to its improvement in order to expand knowledge, but not […] to acts with a commercial purpose*".
  - Although the urban vehicle developed by Peugeot remained a mere project, its presentation, widely advertised to the public by national media, obviously exceeded the scope of the experimental use.
- French Supreme Court, 14.05.2013, Heidelberg v. Bobst:
  - Delivery and setting up of the machine in the client's premises (invoiced to the client)
  - Supposed to perform tests, i.e. experimentation on the machine
  - The acts have to be **exclusively experimental** in order to be exempted.

Research exemption

Marketing approval before Bolar exemption

- Acts performed for the purpose of obtaining an MA

✘ Prohibited at first

Paris Court of Appeal, 27.11.1984, Science Union & Servier v. Corbiere:

- Samples of the drug subject-matter of the MA application were manufactured within the frame of tests necessary to obtain the MA
- During a *saisie-contrefaçon*, the patentee seized samples bearing the label "tests"
- For the Court, the grant of an MA several months before the infringement seizure was performed showed that the manufacture of the litigious products has a commercial purpose.

Research exemption

Marketing approval before Bolar exemption

✓ Then exempted

- The manufacture of batches within the frame of an MA application is <u>not</u> an act of infringement as the MA itself is not an infringing act (Paris Court of First Instance, 12.10.2001, Sciences Union and Laboratoires Servier v. AJC Pharma and 25.01.2002, Science Union et Laboratoires Servier v. Laboratoires Biophelia)
- Tests to develop of a new process for encapsulating acyclovir in order to reduce the amount of drug administered:
  - *"These tests, assuming they turn out to be positive, do not go beyond, **in their very nature**, whatever the objective pursued, notably the **future marketing**, the experimental nature and **are a prerequisite to an MA**, which does not in itself consists of an infringing act"* (Paris Court of appeal, 27.01.1999)
  - "*Bioequivalence tests consisting in comparing the features of the tested product with the reference product were necessary for the MA to be granted so that they cannot be considered as carried out for industrial and commercial purposes, their **immediate aim** being the grant of the MA.*" (Paris Court Of First Instance, 20.02.2001, Wellcome v. Flamel)
- First applications of the "Bolar exemption" by the Courts in France
- This was only case law → need of a legal framework.

Bolar exemption in France

Introduction of the Bolar exemption

- Introduced by EU directives 2004/28 EC and 2004/27 EC
- Art 10(6) 2001/83 EC (as amended by 2004/27 EC):

  "Conducting the necessary studies, tests 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-related rights or to supplementary-protection certificates for medicinal products."

- The scope of the exemption within the Directive is **narrow**, as it requires both:
  - Acts to gain regulatory approval for GENERIC medicinal products are exempt from patent infringement
  - Acts must be for marketing authorisation WITHIN EUROPE (excludes countries outside the EU)

Bolar exemption - Inconsistent implementation

- Some countries **strictly** implemented the directive, i.e. adopted an exemption covering acts performed with a view to obtaining an MA within the **European Union** and for a **generic drug,**
- Some countries implemented the directive **broadly, i.e.** adopted an exemption covering:
  - Acts performed to obtain an MA for ANY medicinal products,
  - MA granted ANYWHERE (including countries outside the EU)

- FRANCE: Article L.613-5 of the French Intellectual Property Code (Act of 26 February 2007):

  "The rights conferred by the patent shall not extend to:

  d) The studies and assays required to obtain a marketing authorisation for a drug, as well as the acts necessary to their completion and fro obtaining the marketing authorisation"

  - **Broad implementation of the Directive**
  - Incentive to perform research in France

Bolar exemption - Does it apply to biosimilars? *Sanofi / Lilly France*

Paris Court of first instance, "Lantus" preliminary injunction, 15 December 2014

- Lilly France was manufacturing and holding a **biogeneric version** of the *Lantus* product
- Lilly France had not yet obtained Marketing authorization for its product and was conducting several tests and clinical trials
- The Presiding judge decided that these acts fall within the frame of the French "Bolar-exemption" found at Article L.613-5 d) of the French Code of Intellectual Property.

Does it apply to early access? *Ono Pharma & BMS / Merck*

Paris Court of first instance, "Keytruda" preliminary injunction, 15 March 2016

- Early access refers to the exceptional use for patients with **serious or rare diseases** of a new drug which has no MA and which is outside of a clinical trial
- Allowed by the French Drug Safety Agency for either one specific individual or for a group of persons
- The Presiding judge decided that:
  - The acts as permitted in the Bolar exemption concern not only studies and clinical trial necessary for the obtention of a MA but also the acts which are necessary for the making and obtention of said MA; **the list is not limitative.**
  - The provision of a drug before MA and in the course of **early access** shall be considered as falling within the scope of the Bolar exemption.

Bolar exemption – Third party supplier

- Does the Bolar exemption apply to a third party who supplies the material to the manufacturer for permitted Bolar purposes?
  - C-661/13 Astellas Pharma
  - Case settled before the CJUE issued its interpretation!
  - Still an open question

UPC

Provision of UPC

- *Article 27 - Limitations of the effects of a patent*

  "The rights conferred by a patent shall not extend to any of the following: …

  (b) acts done for experimental purposes relating to the subject matter of the patented invention; (…)

  *(d) the acts allowed pursuant to **Article 13(6) of Directive 2001/82/EC or Article 10(6) of Directive 2001/83/EC** in respect of any patent covering the product within the meaning of either of those Directives; (…)"*

- Narrow version of the Bolar exemption:
  - Mere reference to the provisions of Directives 2001/82/EC and 2001/83/EC
  - But the Directives were just a minimum for Member States!
  - Only for **generic drug** and for MA within the **EU market.**

Scope of the exemption

- Article 27 UPC is applicable to:
  - Unitary patents;
  - European patents litigated before UPC.
- Not applicable to national patents;
- What about:
  - European patents which have been **opted-out** (i.e. excluded from the exclusive competence of the UPC);
  - European patents during the **transitional period** (without opt-out) litigated before national courts.

  ➢ According to the Interpretative note of the UPC preparatory committee dated 29 January 2014, national courts shall apply their **national law** and not UPC provisions in both cases.

  ➢ What would national Courts do?

Risk of inconsistencies?

- Unpredictibility of the patent's scope for patent owners and third parties:
  - Narrow or broad Bolar exemption could be applicable depending on whether the action is brought before the UPC or a national court.
- Alignment of national laws and return to narrow Bolar exemption?
- Research exemption?

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Thank you!

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