

Innovation: the choice between patenting and trade secrets - traps in prior-disclosure and the experimental exception, particularly in the chemical, cosmetic, pharma and biotech sectors



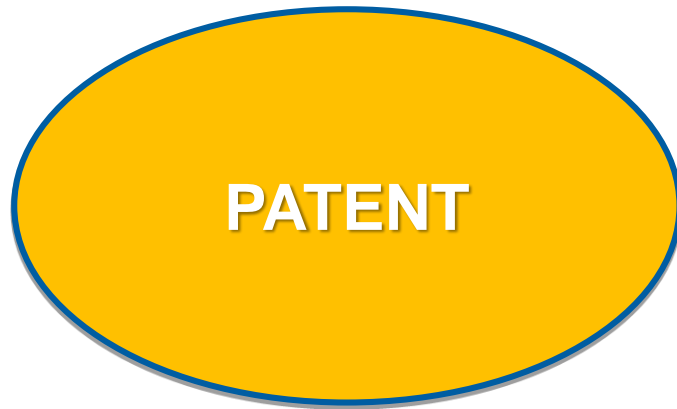
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## Index of the presentation

- 1) The tools for protecting innovation: patents and trade secrets, advantages and disadvantages and the relevant enforcement;
- 2) Prior-disclosure traps and remedies in case of abuse;
- 3) The rights granted to the patent: direct and contributory infringement – limitations to the patent rights: experimental exemption and the Bolar clause.

## Protecting innovation

Tools for protecting innovation apparently antithetic at a first approach but, if correctly exploited, can be combined for a proper better protection



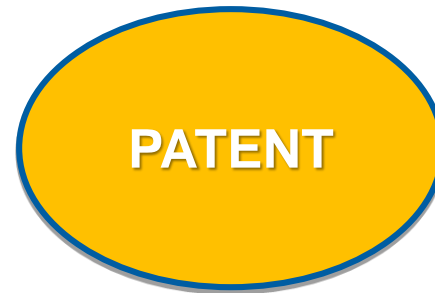
It implies the **publication** of the patent, with a clear and precise description, which enables the **implementation** in all its embodiments, covered by the patent claims



It implies the strict application of **measures apt at safeguarding** it - **total lack** of publication – ineffective protection in case of **disclosure**

## Patent vs Trade Secrets

- Profit for the efforts in R&D activities
- Direct or indirect exploitation, through licence
- Duration: 20 years
- Territoriality
- Typical instrument of industries requiring remarkable investments (e.g. pharmaceutical industry)



- Non patentable innovative ideas may be protected as trade secrets (artt. 98 and 99 of Italian IP Code)
- Duration: potentially unlimited
- Territorial extension potentially unlimited
- Stronger efforts to keep secrecy (e.g. some cosmetic industries – secrecy of the components of flagship products)

## Choosing between patent and trade secrets

Which one is the best protection for innovation?

Is it possible to combine patent and trade secrets?

1) Concrete risks of reverse engineering:

**PATENT**

2) Processes and machines for internal use:

**TRADE SECRETS**

**PATENT**

3) Lack of an adequate organization for keeping secrecy:

**PATENT**

4) Short term competitive advantage:

**TRADE SECRETS**

5) Cooperation with other companies, license agreements:

**PATENT**

6) Lack of funds to invest in patents:

**TRADE SECRETS**

## Patent

Art. 45 of Italian IP Code – solution to a technical problem, having an industrial application: novelty, inventive step and industrial application

❖ **Industrial application** → Profit for patent's owners

❖ **Secrecy**: fundamental before filing patent applications

❖ **Effective protection** against any form of **infringement**

❖ **Staticity** of patent vs **dynamism** and **flexibility** of trade secrets



## Trade secrets

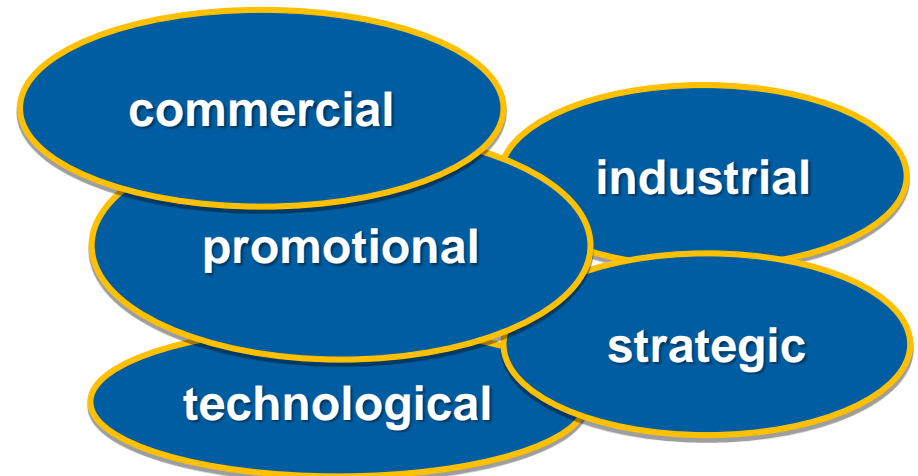
Notion of trade secrets: confidential information and technical expertise (know-how), also under a commercial perspective:

- 1) secrecy;
- 2) economic value (profit);
- 3) protective measures.

### Legal sources

- 1) IP: artt. 98 and 99 of Italian IP Code
- 2) Civil: art. 2105 of Italian Civil Code
- 3) Criminal: artt. 621 and 623 of Italian Criminal Code
- 4) EU: Directive 943/2016

### Different kinds of know-how:



## Trade secrets

How to keep secrecy, essential for the maintenance of the protection?

### technical measures

- 1) Documents labeling: «*confidential*»
- 2) Limited access to documents
- 3) Password to open files

- 1) NDA (Non Disclosure Agreements)
- 2) MTA (Material Transfer Agreements)
- 3) Confidentiality clauses
- 4) Guidelines for employees
- 5) Judge's faculty of protecting confidential information during a proceedings (introduced by the Directive – art. 121 ter of Italian IP Code)

### legal measures

**Essential clauses of a NDA:** 1) clear indication of the **scope** of use of the confidential information 2) clear identification of the **information**, which has to be kept **secret** 3) **duration** of the agreement 4) **non-competing** clauses 5) **penalties** in case of infringement 6) applicable law and jurisdiction



## NDA's and contractual strategies

The subscription of a NDA shall be linked to a precise strategy

With  
whom?

- ❖ R&D Partners
- ❖ Suppliers

What ?

The scope of the project (or know-how / trade secrets) shall always be indicated: clear identification of the confidential information, **a generic definition may impair the legal protection**

When?

Patent: NDAs shall be concluded before the filing of the relevant patent; however an **abusive disclosure** of the NDA (breach of contract) may hinder the patentability in countries **different from Italy**, where the protection against abusive disclosure is not foreseen

## Practical suggestions – the importance of NDAs

Agreements and NDAs shall be adequately drafted and adapted to the concrete case. It is fundamental to carefully read the contractual clauses and to identify the real extent of secrecy obligations


Case study of «*disclosure agreement*», signed by Julio Palmaz, stent's inventor, in 1982

The agreement, in the back page, included the following clauses:

14 05 05 88

**CONDITIONS OF SUBMISSION**

1. The Company shall not be committed to keep secret any idea or material submitted.
2. All material shall be considered as having been submitted without any requirements of confidence on the part of the Company, and no confidential relationship, express or implied, shall be established between the Company and the submitter in respect to such material.



## MTA – Material Transfer Agreement



Object: transfer of materials, **for non commercial purposes** – useful for obtaining material for carrying out **experimental** activities

Parties: Provider and Recipient

It may involve any materials, research prototypes, also in informatics and in the pharmaceutical sector (e.g. compound, intermediate product etc.)

**Secrecy** of the agreement and of the **use of the materials** are key elements of the contract

IP rights regulation – the **material** object of the transfer can be the **component** of the invention and/or an intermediate product: generally, the ownership of IP rights on the developed product is attributed to the Recipient, with a possibility to grant a license to the Provider

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## The prior-disclosure trap

Secrecy before patent's filing

Art. 46 of Italian IP Code:

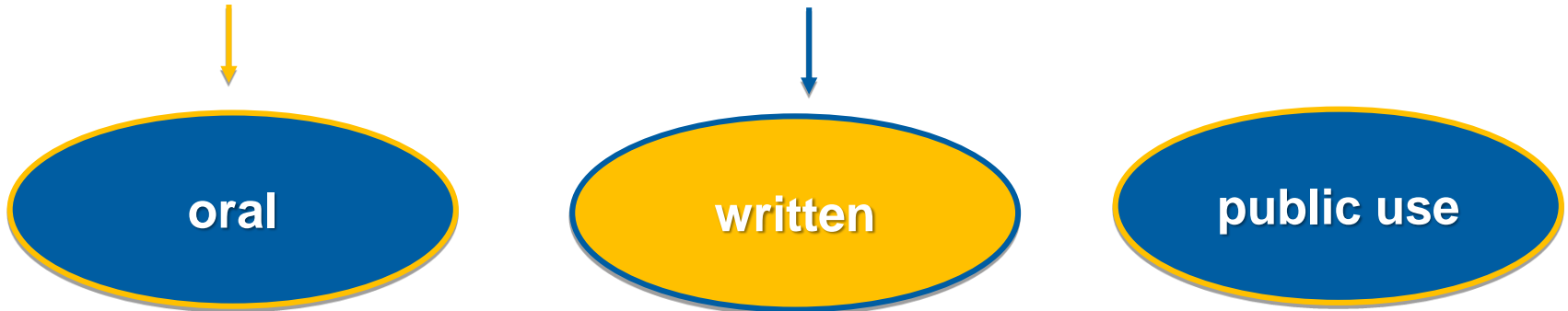


The concept of prior-disclosure involves everything included in the state of the art or, in any case, accessible to the public at the moment of the filing of the patent application

Companies shall know the risks related to prior-disclosure and take all the necessary measures, also of a **contractual nature**, so as to avoid the intervened impossibility to **patent an innovation**, or protect it as a **trade secret**

## Prior-disclosure: means

Art. 46 of Italian IP Code: description



Practical case: EPO decision of July 28, 1992, T-877/90 – an **oral description** of the invention during a conference constitutes a case of prior-disclosure, also in case of a meeting for invited participants only, **unless this latter have signed a confidentiality agreement**

## The relevant public

**Oral** prior-disclosure implies a description to a specialized public, which shall be able to realize and implement the invention

Italian Supreme Court,  
April 19, 2010, n. 9291



**specialized public  
and lack of  
confidentiality  
obligations**

Italian Supreme Court,  
December 27, 2019, n. 34537



**effective knowledge  
of the essential  
elements of the  
invention**

Strict burden of proof for the party requesting the revocation of the patent due to prior-disclosure and lack of novelty (Court of Appeal of Turin, March 27, 2012)

## Internet disclosures

Internet disclosures are included in the prior art. However, in case of the so-called «hidden» disclosures, the requested burden of proof is more restrictive

**Court of Milan, April 8, 2015** (+ EPO decision of March 28, 2007 T-1553/06) – **online prior-disclosure:**

- 1) the document shall be accessible typing key-words on search engines and
- 2) it shall remain available at the same URL for a sufficient period of time, so as to reach the public





## Exceptions – non opposable disclosures

In Italy, as in the EPC, there is no grace period for prior-disclosure **by the same inventor**. Non opposable disclosures are exclusively ruled by art. 47 of Italian IP Code

### 1) Abusive disclosure

- ❖ Occurred **within the 6 months** before the filing
- ❖ Directly or indirectly deriving from an evident abuse against the applicant

More restrictive notion in respect of art. 55 EPC – **no earlier than 6 months** prior to the filing of the patent application (it covers also the abuse relating to the filing of a patent application, which shall be published after 18 months from the filing)

### Art. 47 of Italian IP Code

2) Official exhibitions, or those officially recognized by the Paris Convention of 1928

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## Patent owner's rights – art. 66 c.p.i.


Following the patent grant, the patent's owner shall be aware of the real extent of the rights granted by the patent

Exclusive rights granted by the patent:

If the patent claims a **product**

- 
- Manufacture
  - Use
  - Offer on sale
  - Sale
  - Import

If the patent claims a **process**



Right to prohibit to third parties, except for the case of the owner's consent, to implement the process, to use, offer on sale, sale and import the product directly obtained from that process

**Art 66.2 bis:** patent owner's exclusive rights to prohibit third parties to supply to subjects not entitled to use the invention the means inherent to an essential element of the invention and necessary for its implementation, in the State

## Limitations to patent rights

The exclusive right granted by the patent has some limitations, although **restricted** and **specific**

The owner of the patent shall know the scope and the extent of the activities allowed to third parties, as to promptly react, in case these limitations are overcome – **Action of Infringement**

Art. 68 of Italian IP Code – limitations to patent rights:

- 1) Private and non commercial use 68.1 a)
- 2) **Experimental exemption art. 68.1 a) bis c.p.i.**
- 3) **Bolar clause art. 68.1 b) c.p.i.**
- 4) Galenic exception art. 68.1 c) c.p.i.



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## Experimental exemption - Bolar clause

**Art. 68 of Italian IP Code** – recently amended by Law Decree February 19, 2019, n. 18:

Whatever the object of the invention may be, the exclusive right attributed by the patent does not extend to the following:


[...]

**a-bis)** acts carried out for experimental purposes, related to the subject matter of the patented invention, or the use of biological material for cultivation, or the discovery or development of other plant varieties;

**b)** studies and trials aimed at obtaining a marketing authorization for a drug, including in foreign countries, and the resulting practical requirements including the preparation and use of the pharmacologically active raw materials, strictly necessary for the same.

[...]

## Notion of experimental activity

Research activity  overcome / improvement of the invention

Advance of the technical-scientific knowledge

Research **on** the invention vs research **with** the invention

↓  
**Lawful**

↓  
**Unlawful**

↓  
Aimed at **overcoming  
the invention**

↓  
Simple **implementation  
of the invention**

*Ex ante* assessment of the nature of the experimental activity

**Objective nature** of the experimentation – non extension of the exemption to third parties

Research centers – Universities – Companies



## Notion of experimental activity

Experimentation carried out **on** the invention, to achieve new knowledge and with the aim of improving the invention (**improvement inventions**)



- ✓ **unexpected effects of a substance**
- ✓ **new, previously unknown, uses**
- ✓ **further development of existing technologies**



## Notion of experimental activity

Experimentation aimed at **simply reproducing** the invention

- ✓ carried out to prove the feasibility and efficacy of a patented invention (creations under test)
- ✓ potentially directed to production



constitute an **implementaion** of the patent





## The rationale of the experimental exemption



- ❖ Encourage the scientific and technical progress (same logic of patent system)
- ❖ Balance of interests between the exclusive rights of the patent holder and the public interest in promoting innovation
- ❖ The connecting element between these interests is the non-admissibility, for the researcher, to obtain a direct **profit** from his/her experimental activity

## Limitations in the application of the experimental exemption

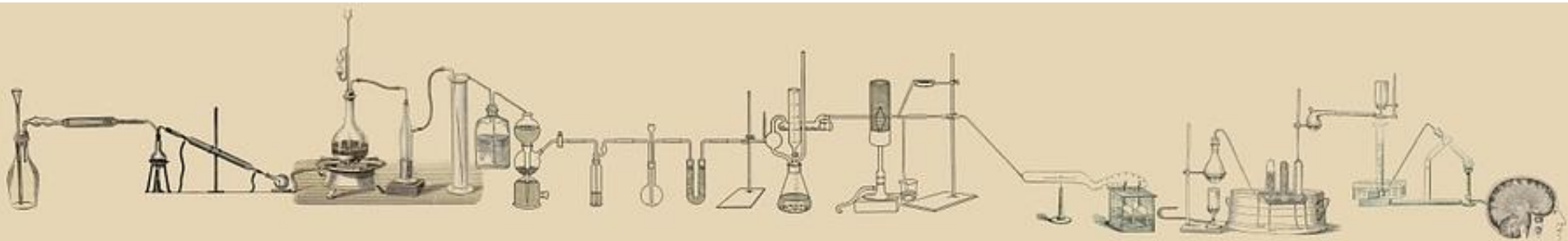
Research aimed at overcoming and/or improving the invention, without **direct profit** and without **prodromic activities** for sale or production on a scale incompatible with experimentation



Advertising promotion incompatible  
with experimentation



- ❖ Court of Turin, July 26, 1984
- ❖ Court of Vicenza, February 7, 1996
- ❖ Court of Bologna, September 12, 2008



## Limitations in the application of the experimental exemption



Direct experimenter vs supplier - **art. 66.2 bis and 2 quater of Italian IP Code (art. 26 UPC – Law Decree 214 / 2016)**  
– no extension of the exemption

Obtaining profit from the supply, to the **experimenter**, of the means for the implementation of the invention may constitute direct or contributory infringement by the **supplier**. Contributory infringement by the supplier is not excluded if the experimenter is exempted under art. 68.1 of Italian IP Code (the subjects carrying out the acts exempted according to art. 68.1 **are not considered subjects entitled for the purpose of the contributory infringement provision**)



Direct profit is not compatible with the exemption ruled by art. 68 of Italian IP Code, since it is an exclusive privilege of the patent owner

Burden of proof on the subject, claiming the experimental use

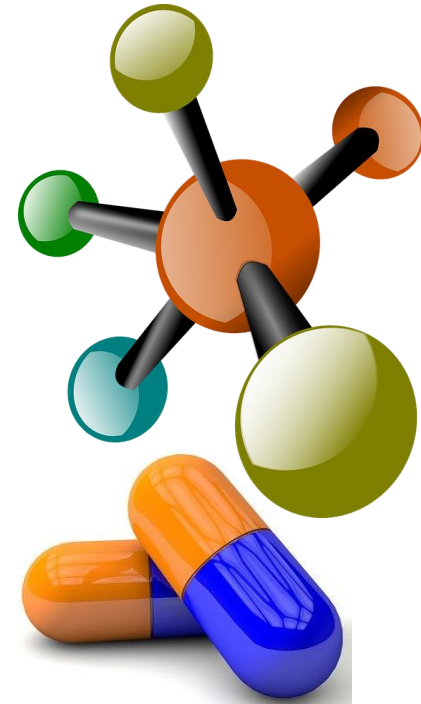
## Case-law – experimental exemption

The experimental exemption in the pharmaceutical field –  
Italian Criminal Supreme Court, April 30, 2003

*«The experimental exemption in the pharmaceutical field concerns the identification of new molecules, or new compounds within the general formula covered by the patent, or further and different production processes, but not the introduction of the patented substance, normally administered in tablets, into gelatine capsules suitable for containing any pharmacological active agent»*



Production trials and not chemical – scientific experiments – **non admissible**

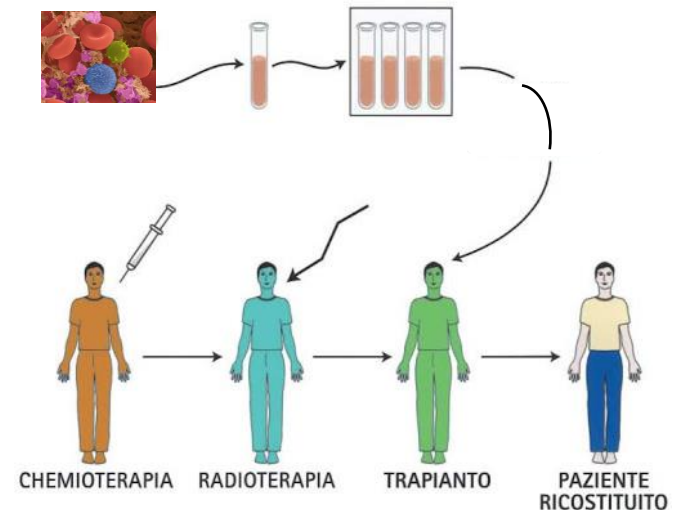


## Case-law – experimental exemption

The experimental exemption in the pharmaceutical field – **Court of Milan, October 21, 2009**

❖ Université Pierre et Marie Curie – Paris VI and LTK Pharma SAS, respectively owner and exclusive licensee of the European patent EP0564646, sued the biotech company MolMed S.p.A for alleged infringement of the Italian portion of said patent (June 7, 2007)

❖ EP 0564646 claims haematopoietic cells, made immunetolerant to an antigen by genetic modification



## Case-law – experimental exemption

- ❖ MolMed was developing the «TK» product for the treatment of high-risk acute leukaemia, based on the use of genetically modified T cells which enable bone marrow transplantation in patients also from partially compatible healthy donors



- ❖ The Plaintiffs requested the prohibition of any form of sale of the «TK» product and damages award, alleging that the experimental activity on «TK» infringed patent EP0564646



- ❖ Molmed, appearing in Court, objected, inter alia, to the absence of infringement, maintaining that the activity carried out was exclusively experimental and therefore covered by the exemption under art. 68 of Italian IP Code

## Case-law – experimental exemption



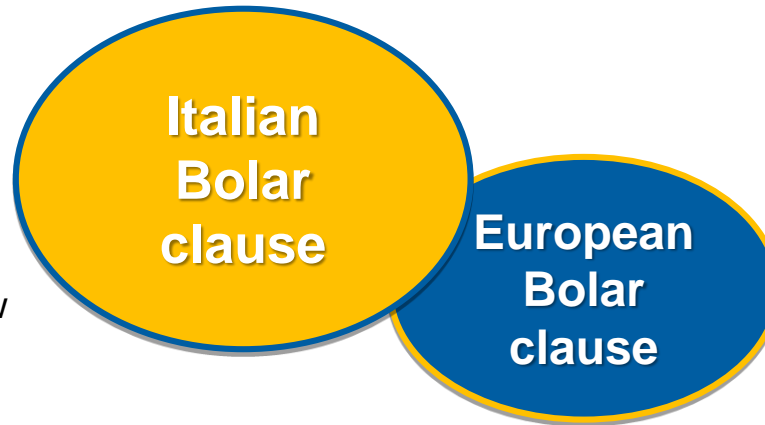
Decision of the Court of Milan, October 21, 2009:

- I. the presentation made by MolMed at a Haematology Conference in the US (2005),
- II. the publication by MolMed on a website of the launch in Italy of a clinical trial for «TK»( cell therapy 2008),
- III. agreements made by MolMed for the development of «TK» therapy in some Asian countries,
- IV. fund-raising initiatives,

do not constitute commercial exploitation of the therapy but legitimate activities with the aim of informing about the study and research activities, obtaining funding for these activities and taking part in the scientific debate

## Experimental exemption - Bolar clause - MA

Implemented in Italy by Law  
Decree April 24, 2006, n. 219, to  
comply with EU Directive 2001/83



IP Code was further amended by Law  
Decree August 13, 2010, n. 131  
accordingly:

- Bioequivalence studies
- Manufacturing and importation of samples

Art. 68.1 b) of Italian IP Code

Art. 10.6 EU Directive 2001/83, as  
amended by EU Directive 2004/27

Lawfulness of studies and experiments directed to a MA

Also for **innovative** drugs

Only for **generic** drugs

Larger scope



## Italian case-law on MA

Before the Italian IP Code's amendments by Law Decree August 13, 2010, n. 131

Court of Milan, June 12, 1995: admitted by case-law the experimental activity for obtaining a MA, also in presence of a valid patent: administrative activity ≠ preparatory commercial activity (e.g. purchase and manufacture of active principles)



The aim is to hinder a de facto extension of the duration of protection of the patent, also after its expiration

The possibility to request a MA, for a generic drug, **even earlier than a year before the expiration** of the patent protecting the originator, was expressly recognized – Court of Milan, June 11, 2009



A request for a MA before the year preceding the expiration of the patent **constituted infringement** – Court of Turin, February 11, 2011: **more restrictive approach of the Court**

**Art. 68.1 bis of  
Italian IP Code  
until 2012**

## Case law– Bolar clause

Aim of the **conduct functional** to the MA

The experimental exemption in the pharmaceutical sector – Court of Milan, July 24, 2018

Offer on sale of active ingredients and Bolar clause

- ❖ Remarkable quantities produced and sold by the supplier (not by the experimenter);
- ❖ A disclaimer on the supplier's website is not sufficient;
- ❖ The exemption does not cover the producers of active ingredients, who pursue a commercial profit;
- ❖ The aim of the registration 1) shall be previously declared at the moment of the production of the active ingredient and 2) expressly indicated to the supplier as limit of use.



Infringement – Bolar clause as weak defense for supplier of raw materias at industrial scale

## Conclusions

- ❖ Patent and trade secrets are not antithetical, but constitute the **negative of each other**



- ❖ Protection strategies of innovation based on the combination of patents and trade secrets



- ❖ It is important to know the limitations of patent rights, as well as the limitations of the relevant exemptions, as to act against any form of **abuse** or **infringement**

- ❖ Patent as the main mechanism to encourage scientific progress and for the largest protection of the companies involved in innovation

# Thank you!

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