# From Lab to Life: The Pharma Product Journey

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# Agenda

**11:00** – **Welcome remarks**
Emilio Hirsch, Fondazione Molinette
Fabrizio Jacobacci, Jacobacci Avvocati

**11:10** – ***Patenting in the pharmaceutical sector: what is patentable and practical insights***
Rebecca Rimini, Jacobacci & Partners

**11:40** - ***From invention to pharmacy: ownership, inventorship and exploitation***
Fabrizio Jacobacci, Jacobacci Avvocati
Barbara La Tella, Jacobacci Avvocati

**12.10** - *Q&A*

# *Patenting in the pharmaceutical sector: what is patentable and practical insights*

**Rebecca Rimini - *Italian and European Patent Attorney*, Jacobacci & Partners**

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# What is a patent?

- A legal right protecting **new inventions**
- Grants the owner (“Patentee”) the **exclusive right** to stop others from using the invention without permission
- Important: Owning a patent does not automatically give you the right to use the invention yourself. You must still **avoid infringing** on others' rights
- Typically lasts for **20 years**
- Special case: The term for a pharmaceutical patent can be extended by a maximum of 5 years (EU) with a **Supplementary Protection Certificate (SPC)** to account for the time taken to obtain Marketing Authorization

# Aims and Limits of a Patent

**Reward for Research:**

A patent compensates the inventor for the costs of research and development. It grants a **limited monopoly** in the market (**Time and Geographical limitations**).

**Incentive for Disclosure:**

The patent system requires the inventor **to publicly disclose the invention** in the application. This ensures that scientific and technical progress is shared with the public.

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# Understanding Patent Rights

## *What is a Patent Right?*

A legal monopoly granting the holder **the exclusive right** to their invention for a limited time. It is a **territorial right**, valid only in the country or region where it was granted.

## *The Power to Exclude:*

The patent holder has the authority to prevent others from:

- **Making** the patented product or using the patented process;
- **Using** the patented product or the product directly obtained by a patented process;
- **Selling** or offering for sale the patented product;
- **Importing** the patented product into the country where the patent is in force.

# Limitations to patent rights

## *Research exemption & Bolar clause*

### Research exemption

Patent rights do not extend to **experiments conducted** on a patented product or process for the **sole purpose of gaining new knowledge** and **improving the invention**, with no commercial intent.

### Bolar clause

Legal provision that **allows generic and biosimilar manufacturers** to perform all activities required for regulatory approval (manufacturing and clinical trials) prior to patent expiration, without fear of infringement.

# Territorial Scope of Patents

**National Patents:** Granted by a single country's patent office. The protection is valid only within the borders of that country.

**Regional Patents:** Granted by a regional patent office (e.g., the European Patent Office - EPO). They offer protection in multiple member states through a single application.

**International Patent Applications:** There is no single global patent. The Patent Cooperation Treaty (PCT) provides a unified procedure for filing a patent application, simplifying the process of seeking protection in numerous countries before entering the national/regional phase.

# Key Patentability Requirements in Europe

**Novelty:** The invention **must not have been publicly** disclosed anywhere in the world before the patent application filing date.

**Inventive Step:** The invention **must not be obvious** to a person skilled in the relevant technical field.

**Industrial Application:** It **must be possible to make or use** the invention in some **form of industry**.

**Sufficiency:** The patent application must **describe the invention clearly and completely** enough for a skilled person to reproduce it.

**Exclusions:** **Certain items**, such as discoveries, scientific theories, aesthetic creations, and methods for medical treatment, diagnosis and surgery, **are not patentable**.

# Prior Disclosure and Patent Novelty

***What is a prior disclosure?***

Any information about an invention made public by anyone (including the inventor) before the patent application is filed.

***The Consequence:***

It destroys the **invention's novelty**, a fundamental requirement for a patent.

***What Counts as Disclosure?***

Any written publication (articles, patent applications, technical brochures, etc.), giving a presentation or displaying a poster at a conference, displaying the invention at a trade fair, selling the product, or even non-confidential discussions.

***The European Rule:***

The "**grace period**" is extremely limited. Disclosures are only exempted if they are a result of an abuse of confidence (e.g., a breach of an NDA).

**Inventors must ensure strict confidentiality before filing.**

# Patents in the Pharmaceutical Field

**Therapeutic** and **surgical methods** are not patentable in Europe.
This exclusion is based on ethical principles to ensure the freedom of medical practice.

***What can be patented?***

- a **pharmaceutical substance**:
  - a new active ingredient (API) or a new combination of APIs;
- specific **drug formulations**:
  - a novel dose, dosage form (such as a new tablet or injectable) or dosage regimen;
- new **therapeutic uses**:
  - using a known drug for a completely new therapeutic indication (called a "second medical use") (e.g a new disease or a new group of patients).

# APIs and Drug Formulations

An Active Pharmaceutical Ingredient (API) can be patented if it is:

- a **new chemical entity** (NCE);
- a **novel form** (e.g. salt, hydrate/solvate or polymorph) of a known compound that offers an unexpected advantage, such as improved stability or bioavailability.

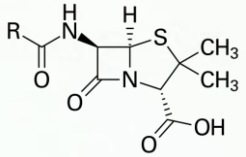
**Drug formulations** can be patented if they demonstrate a new and non-obvious technical effect.

***Examples***

- Formulations using novel excipients that enhance drug delivery;
- New compositions that improve stability or extend shelf life;
- Controlled-release systems that increase patient compliance.

# Pharma patent strategy

Primary compound patent



Initial research → Lead identification → Clinical trials → Further indications, salts, dosages, formulations…..

***Secondary Patents***

- Lead compound
- Second medical indications
- Formulation
- Dosage regime
- Mode of administration

# Biologicals

## *Nucleic acids (DNA, RNA, cDNA)*

Simply disclosing a nucleotide sequence is insufficient for patent protection, a **specific function** for the nucleic acid must be clearly described (*e.g.* coding sequence, amplification primer, hybridization probe, antisense oligonucleotide, regulatory sequence such as transcription promoter or enhancer).

## *Proteins (enzymes, antibodies, ligands, etc), peptides*

## *Bacteria and cells*

The mere discovery of a naturally occurring biological molecule is not patentable. The molecule must be **isolated from its natural environment** or **produced by means of a technical process**.

# Diagnostic assays

In Europe, a method for diagnosis practiced on the human or animal body is not patentable.

***What is Patentable?***

- **In vitro Methods** (lab tests on a biological sample taken from the body, e.g. blood, serum, urine, etc);
- **Imaging methods**;
- **Diagnostic Kits** (containing reagents, probes, etc.);
- **Specific Biomarkers** (e.g., a new protein or gene indicative of a disease state);
- **Methods using Diagnostic Algorithms** to analyze test results.

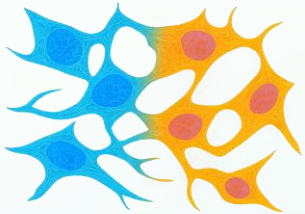
# YOU CAN PATENT:

Drug

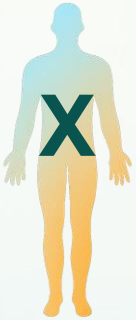
Nucleic acid

Protein

Diagnostic kit



Imaging method




Human body

# *From invention to pharmacy: ownership, inventorship and exploitation*

**Fabrizio Jacobacci – *Partner*, Jacobacci Avvocati**
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# What happens when an employee has a patentable idea?

Article **64** Industial Property Code

The inventor is an **employee of the hospital**

Article **65** Industial Property Code

The inventor is **researcher of a university** or **public entity** of research

Inventions are owned by the employer, except for the inventor's right to be recognized as **the author**.

**P.N. The result is the same even though the relevant path is slightly different**

# More in detail

## Article 64 IPC – Employees' inventions

- Inventions for hire;
- Company inventions;
- Occasional inventions.

The economic rights **belong to the employer** (with a possible fair compensation for the employee in the case of a company invention), while in the third case, the rights **belong entirely to the employee**, except for the employer's right of option.

# More in detail

## Art. 65 IPC - Inventions by researchers at universities, public research institutions, and scientific hospitals.

This article applies to inventions **created after August 23, 2023**, provides specific procedures for communication and filing a patent application, including the inventor's right to a significant share of them.

# The Clinical Entrepreneur: Strategies for Valuing Patents

The hospital owning the invention can decide **what to do** with its drug for the economic exploitation.

Keep it and creating a spin-off

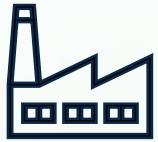
License it

Transfer it

# The Clinical Entrepreneur: Strategies for Valuing Patents

Exploiting a patented drug involves **substantial** financial **investments**.

It is **unlikely** that the hospital has millions of euros to invest in clinical trials and manufacturing infrastructure.



**Pharmaceutical companies** involved in investments and the various stages of the patented drug come into play.

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# The Clinical Entrepreneur: Strategies for Valuing Patents

Exploiting a patented drug involves **substantial** financial **investments**. Sometimes the situation is the **reversed**.

The pharmaceutical company **holds** a patent.

The hospital is **entrusted** with a research project or the clinical trials phase.

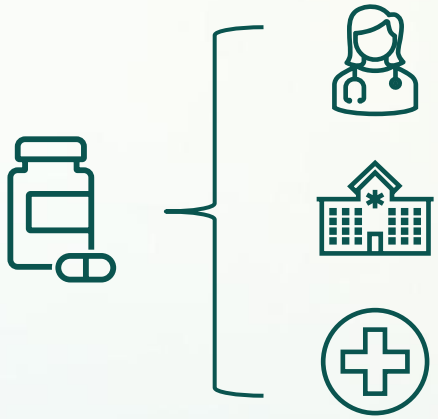
# From Discovery to Distribution: The Final Stage

In order to introduce the patented drug onto the market, a **regulatory process** must be followed:

# From Discovery to Distribution: The Final Stage

Once marketing authorization has been obtained, the patented drug is allowed to enter the market as an **originator drug**.

**BUT**: other regulatory steps are needed: Which class for the medicine? Which price? When is it reimbursable by NHS (National Health Service)?



# The medicine and the market

The drugs are distributed in the market on the basis of various **contracts** signed with the patentee:

| | | |
|---|---|---|
| **Distribution** | *consists of* → | authorization to market the drug, produced by others, in a specific territory. |
| **Licensing** | *consists of* → | authorization to manufacture and market the drug in exchange for royalties. |
| **Supply** | *consists of* → | uninterrupted provision of finished medicines for a fixed or indefinite period of time. |

# Public tenders

- Some medicines are exclusively destined to hospitals (class H)
- How they reach hospitals? public tenders (but not only)
- What price? the most convenient

# The Competition: Patented Drugs and Their Generic

The originator's owner has the **exclusive right** to produce and market the product until the patent expires.

Once patent protection has expired, equivalent drugs —known as generic —can be **freely** produced, marketed, and sold in the same way as the originator drug.

# The Competition: Patented Drugs and Their Generic Counterparts

When a generic drug is produced and marketed **before** the expiry of the originator's patent, the patent is **infringed**.

The patent holder is entitled **to protect** its right before the competent courts pursuant to art. **66** Italian Industrial Property Code and art **24** and **25** of the UPCA.

# The Competition: Patented Drugs and Their Generic Counterparts

Pharmacies play a **key role** in tackling the lawsuits of counterfeiting.

Their location is **sometimes relevant** in determining which court has jurisdiction over the case.

This is a **strategic choice** based on selecting the court that is considered most competent in terms of patent expertise.

# The Competition: Patented Drugs and Their Generic Counterparts

- Two pharmacies sell a counterfeit drug produced by the company A, which is based in Catania. One pharmacy is based in Milan, the other in Rome.
- Since Catania is a less experienced Court in IP matters, the patentee may decide to sue A in Milan or Rome by making a purchase on site. The selected pharmacy will be sued with A.
- The choice hinges on which court is considered most competent for the matter: *Rome or Milan?*

# What happens to the doctor who prescribed the generic drug?

The purposes of pharmacies differ from those of prescribing physicians.

Pharmacies operate **for profit**.

→ **Liable**

Doctors operate **for therapeutic purposes** aimed at protecting the patient's health.

→ **Not liable**

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# Speakers

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