Patenting University Inventions: Case study in the field of the Life Sciences.

Crash Course on Research Funding and Intellectual Property at Trento University
Trento May 30th 2018

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OUTLINE OF THE TALK

• Patentability requirements (basic)
• Patentability requirements for biotech/pharma inventions
• A case study in the life sciences from University
• Emerging technology: Crispr
WHAT CONSTITUTES «INTELLECTUAL PROPERTY»?

**Trademarks:**
- company name
- product name
- logo

**Patents:**
- communications technology
- user interface
- operating system

**Models:**
- structure design
- icons on screen

**Secret information:**
- processing techniques
- customer / supplier lists
- business plan
- commercial agreements

**Copyright:**
- software
- brochure
- manuals
- website
- video

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RATIO OF THE PATENT

EXCLUSIVE RIGHT
(20 years)

complete disclosure of the invention (description) 
+ 
legal certainty on the limits of the invention (claims)

The "monopoly" has a limited duration, designed to recover research costs and an economic profit from the invention.

At the end of this period, the invention becomes something available to the community and, as such, commercially exploitable by anyone.

"contract between inventor and State"
How can you make profits from a patent?

A company/spin-off ...

... produce, use for industrial / commercial purposes, offer for sale, market, import/export in an exclusive way the invention subject of the patent.

University or research Institution...

... granting a license or selling the patent.
Patent requirements

• An application contains
  – Bibliographic information
    • Inventor, proprietor, date of filing, technology class, etc.
  – Description
    • Summary of prior art (i.e. the known existing technology)
    • The problem that the invention is supposed to solve
    • An explanation and at least one way of carrying out the invention
  – Claims
    • Define the extent of patent protection
  – Drawings
    • Illustrate the claims and description
  – Abstract
    • Around 150 words as a search aid for other patent applications
Article 52(1) EPC - Patentable Inventions

European patents shall be granted for any *inventions*, in all fields of technology, provided that they are *new*, involve an *inventive step* and are susceptible of *industrial application*. 
Patentability requirements in Europe

**IS THE MATTER PATENTABLE?**

- **NO**
- **YES**

**PATENTABILITY CRITERIA**
- Novelty
- Inventive step
- Industrial applicability
- Sufficient disclosure
- Clarity

**Exclusions - Art. 52(2) EPC**
**Exceptions - Art. 53 EPC**
What is \textit{not} an invention? 

Article 52(2) EPC - Patentable Inventions

(2) The following, in particular, shall \textit{not} be regarded as inventions within the meaning of paragraph 1:

(a) \textit{discoveries}, scientific theories and mathematical methods;
(b) aesthetic creations;
(c) schemes, rules and \textit{methods for} performing mental acts, playing games or \textit{doing business}, and programs for computers;
(d) \textit{presentations of information}.

\textbf{Exclusions} from patentability (only when it is referred to said subject-matter \underline{as such} - Art. 52(3) EPC)
Discovery or Invention?

- A mere finding of something already existing in nature is a **Discovery**: e.g. To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable.

- If a technical character is associated to this finding, then, this finding can be regarded as an **Invention**: e.g. if a substance found in nature can be shown to produce a technical effect, it may be patentable.
Human body and elements isolated therefrom

Rule 29(1) EPC
The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

Dir. 98/44/EC Rec. 16:
dignity and integrity of the person;
a mere discovery cannot be patented
Rule 29(2) EPC
An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Rule 29(3) EPC
The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.
Examples of Patentable biotechnological inventions

- Polypeptides: Enzymes, Hormones etc.
- Isolated DNA and RNA molecules
- Elements isolated from the human / animal body (cells, tissues, organs)
- Plasmids and Vectors
- Monoclonal Antibodies and Hybridomas
- Microorganisms (e.g. bacteria, viruses, phages, etc.)
- Plants and non-human Animals
- As well as *methods* related to these products, and their *use*
Is everything patentable?
Article 53 EPC - Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essential biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.
Medical treatments are not patentable
why such exclusion?

A patent confers a monopoly to the Proprietor; however, in the pharmaceutical/medical field:

• Medical practice must not be hindered by protection rights (need to ensure medical care for the population). The doctors must be free of practising their profession.

• Even though it may be commercial in nature, the medical profession is not a branch of industry.
The biotech-specific exclusions under Rule 28(a)-(d) EPC

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.
EXAMPLES OF DISCLOSURES

POSTER

THESIS

PAPERS
BUT ALSO

INTERNET

ORAL DISCLOSURE
Novelty in pharma
(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Art.53(c), provided that such use is not comprised in the state of the art.
WHAT ARE THE FACTORS THAT IDENTIFY A NEW MEDICAL APPLICATION?

- A new disease
- A new class of patient
- A new regime of treatment
- A new route of administration
- A new dosage regimen
NEW DISEASE

ASPIRIN

ANALGESIC

CARDIOVASCULAR DISORDERS
NEW DISEASE

FINASTERIDE

5 mg Benign prostate hyperplasia

1 mg male baldness
DOSAGE REGIMEN

Alendronato

70 mg osteoporosis

for a dosage regimen of 70 mg once a week
According to the established case law of the boards of appeal, the use of the same compound in the treatment of the same disease for a particular group of subjects, can nevertheless constitute a novel therapeutic application, provided that it is carried out on a new group of subjects which is distinguished from the former by its physiological or pathological status.
An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

What is the Test for Obviousness?
European Patent Office applies the problem solution approach
Disclosure of the invention

Art.83 EPC

The application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Enabling disclosure

A detailed description of at least one way of carrying out the invention must be given
A team of researchers from two Italian universities has co-developed a new system for the delivery of specific anti-inflammatory peptides within the cell using nanoparticles with metal core.
A case study in the life sciences (2)

State of the art
- Nanoparticles with metal core and their use as delivery system were known
- The Vivit peptides and their use as anti-inflammatory drugs were known

Novelty
- The nanoconstruct comprising the Nanoparticle and the active peptide is novel, i.e. the combination of the two elements

Inventive step
- Unexpected efficiency to deliver the active peptide in the cytosol (comparative experiments with other delivery system)
HENCE WHAT CAN WE PROTECT WITH A PATENT?

Patent claims determine the scope of the invention

**Claims:** delineate the **limits** (dimensions and borders) of the invention

**INDEPENDENT CLAIMS:**
- The nanoconstruct comprising the Nanoparticle with metal core and the specific active peptide vivit;
- The pharmaceutical composition comprising the nanoconstruct;
- The nanoconstruct for use in a method of treatment of inflammatory diseases;
- The process for manufacturing the nanoconstruct.
The patent procedure (briefly)

**International patent application (PCT)**
Filed on 19-July-2013

**Italian patent application**
Filed on 19-July-2012

In the mean time:
- Published several scientific papers
- Further experiments/developments
- Licencing out the International patent application to a spin off

**European patent**
Granted on Jul-2017

Filed:
- EUROPE
- USA
- JAPAN
- CANADA
- CHINA
- KOREA
- MEXICO
The patent landscape in an emerging technology

**CRISPR**: Clustered Regularly Interspaced Short Palindromic Repeats”
A very powerful gene editing technique

**Market Opportunities:**
- Cell therapy (cancer, HIV, etc..)
- R&D tool (e.g. CRISPR can produce cells/organisms useful for drug discovery
- Genetic modification of any species

**Already on the markets:** Mushrooms resist browning obtained using CRISPR
Jennifer Doudna (UC/Berkeley) e Emmanuelle Charpentier (University of Vienna)

Feng Zhang et al. (The Broad Institute, Harvard University, e MIT)
CRISPR Application by year

[Bar chart showing the number of CRISPR applications by year from 2005 to 2017. The number of applications increases significantly from 2010 onwards, peaking in 2016 with 566 applications and decreasing slightly in 2017 with 520 applications.]
CRISPR top applicants

CRISPR: Top ten applicants

- MIT - Massachusetts Institute of Technology: 136
- Broad Institute: 114
- Harvard College: 70
- University of California: 46
- Shanghai Jiaotong University: 19
- Regeneron Pharmaceuticals: 18
- Temple University: 17
- Dow AgroSciences: 17
- Institute of Genetics & Developmental Biology: 15
Why filing a patent?

- because the patent provides innovation with an **economic value**
- because the patent is a **sign** of ongoing advanced research activity
- because the **gains** from the patent allow to fund further research
- because someone else could do it before you do...!
The «Key Figures» of the patent

The inventor

Art. 62 CPI

1. The right to be recognized as the author of the invention can be invoked by the inventor [...].

The inventor has at least the "moral" right to be recognized as the inventor and this right is inalienable and non-transferable.

The applicant

Art. 66 CPI

2. The applicant has the exclusive rights to exploit the invention [...]

The right of economic exploitation deriving from the patent lies with the owner. This right is alienable and transmissible.
Thank you for your attention

QUESTIONS?

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