



Advanced
Accelerator
Applications

BRIDGING
SCIENCE
WITH LIFE



Relevance of intellectual property in the development of the Biotech Industry

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Advanced Accelerator Applications



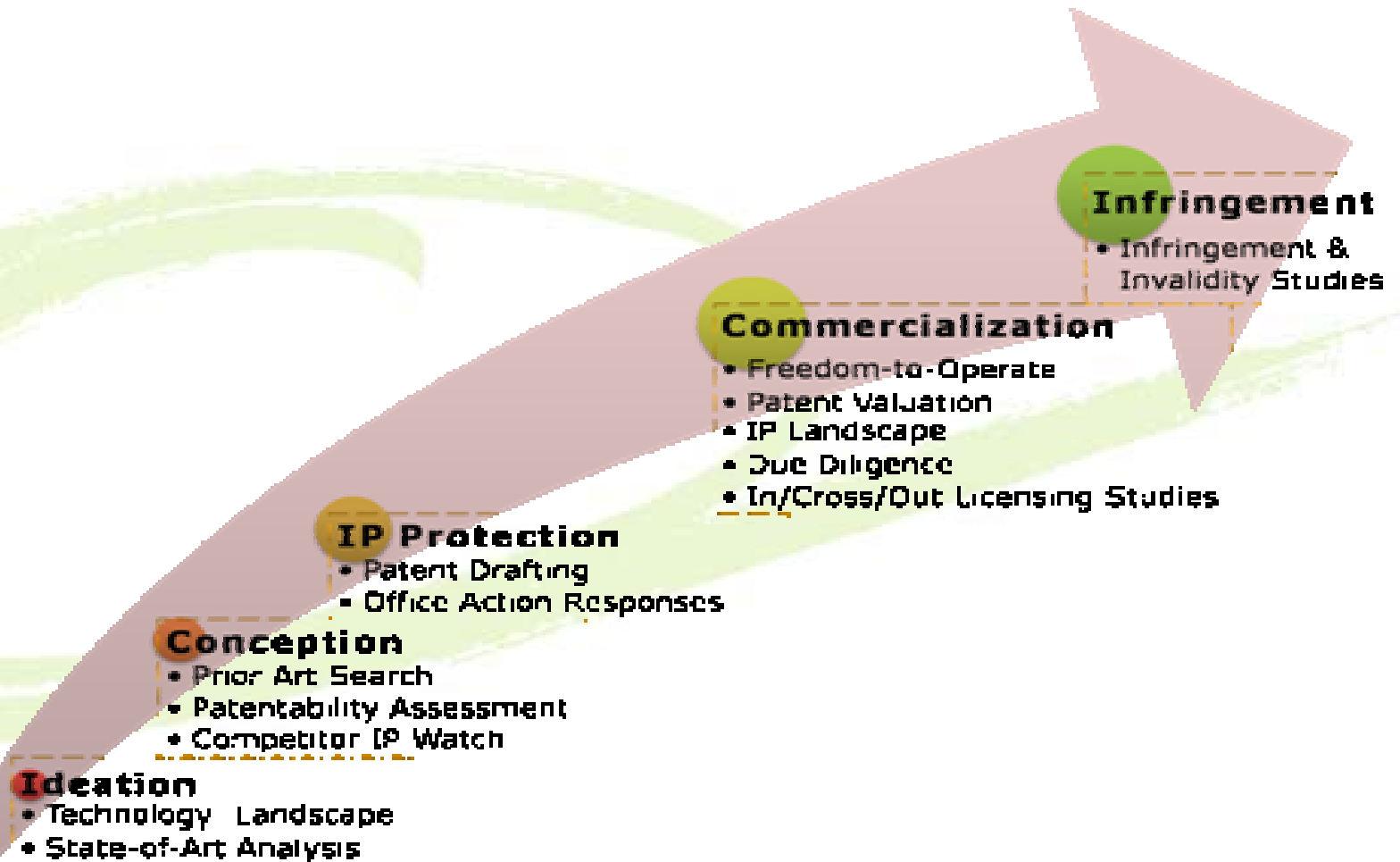
What is a Patent ?

A **patent** is a legal title granting its holder the right to prevent others from making, importing, using or selling the invention without his consent.

It only confers these exclusive rights :

- ✓ for a limited period (in Europe, 20 years from filing)
- ✓ for a limited geographic territory.

From discovery to market : IP is key



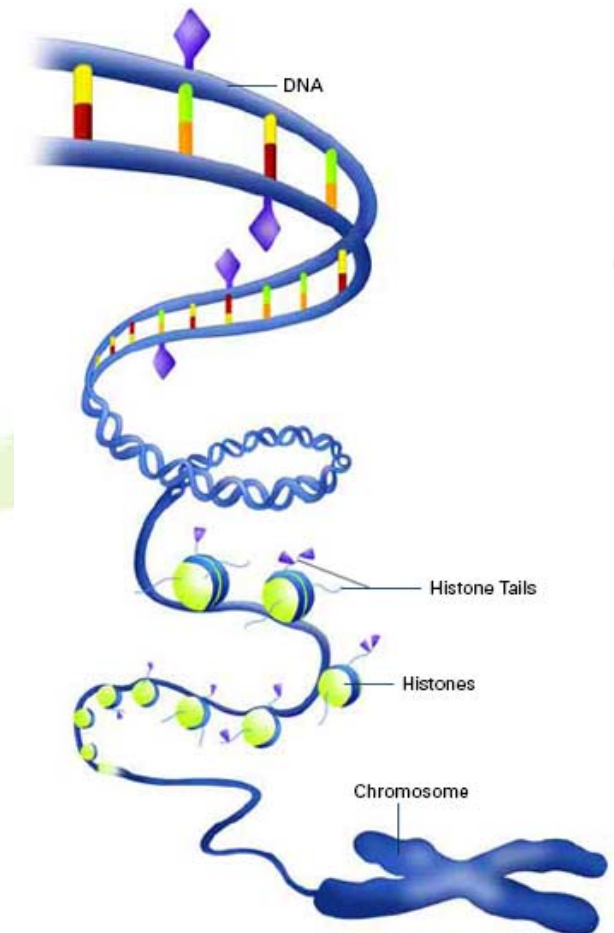
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Biotechnology definition

According to the European Patent Convention (EPC) :

«Biotechnological Inventions» are inventions which concern a product consisting of or containing :

- ✓ a biological material, or
- ✓ a process by means of which biological material is produced, processed or used (rules 26(2) EPC)



Essential for Patentability in biotechnology

In principle, biotechnology inventions have to meet the same criteria as those in any other technical field

✓ **Novelty** – new, **No Disclosures!**

Papers, posters, web-sites, informal discussions, letters, other patents etc...

New "meaning" made available to the public. This means, for example, that a gene, which existed in an organism before, but was « hidden » from the public in the sense of having no recognised existence, can be patented when it is isolated from this organism.

✓ **An Inventive Step** – not obvious from prior art

A technical process or solution to a technical problem

✓ **Industrially Applicable**

Given the nature of biotechnology and its ethical implications, there are specific rules which apply when considering the patentability of an invention in this field.

What the law says

Biotechnological inventions are basically patentable
However, no European patent can be granted for the following reasons:

- ✓ any invention whose commercial exploitation would be contrary to public order or morality
- ✓ plant and animal varieties
- ✓ essentially for treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body

Discoveries (e.g. the discovery of natural substances, such as the sequence or the partial sequence of a gene) are not patentable because they are not regarded as inventions, without :

- ✓ a description of the technical problem they are intended to solve and,
- ✓ a technical teaching,



EU-Directive 98/44/EC

With the aim of clarifying the distinction between what is patentable and what is not, and harmonising EU member states' laws in this area :

the **EU Directive 98/44/EC** on the legal protection of biotechnological invention was adopted on 6th July 1998

So what is patentable?

- ✓ Genes and Nucleic acid molecules (e.g. SiRNA molecules for therapy)
- ✓ Proteins (e.g. insulin...)
- ✓ Antibodies (e.g. for cancer treatment)
- ✓ Viruses and virus sequences (e.g. hepatitis C virus and HIV for blood testing)
- ✓ Cells (e.g. haematopoietic stem cells for the treatment of leukaemia)
- ✓ Micro-organisms (e.g. yeast for food production)
- ✓ Plants (e.g. herbicide resistant soybean)
- ✓ Animals (e.g. disease models for research such as the genetically modified 'oncomouse')

What is not patentable?

- ✓ Sequences without a known function (e.g. expressed sequence tag (ESTs) resulting from automated sequencing)
- ✓ Genetically modified animals which suffer but are not associated with a substantial medical benefit (e.g. genetically modified animal which is solely used to test cosmetics).
- ✓ Plant varieties (already protected under the convention of the International Union for the Protection of New Varieties of Plants, UPOV)
- ✓ Animal varieties (e.g. Hostein cattle)
- ✓ Process which necessarily involve the use and destruction of human embryos
- ✓ Human embryos
- ✓ Human germ cells



The biotechnology paradigm

“The biotech industry is establishing itself as the discovery arm of the pharma industry”

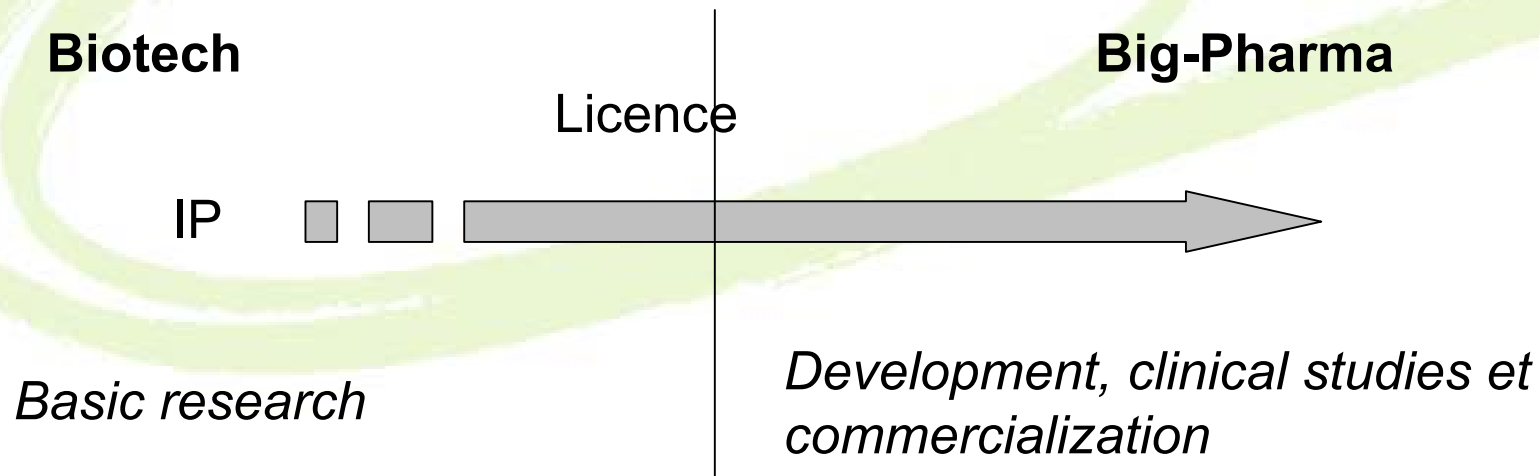
Jurgen Drews

Intellectual Property and research subdivision

The IP allows to define the domain of research and its specialization

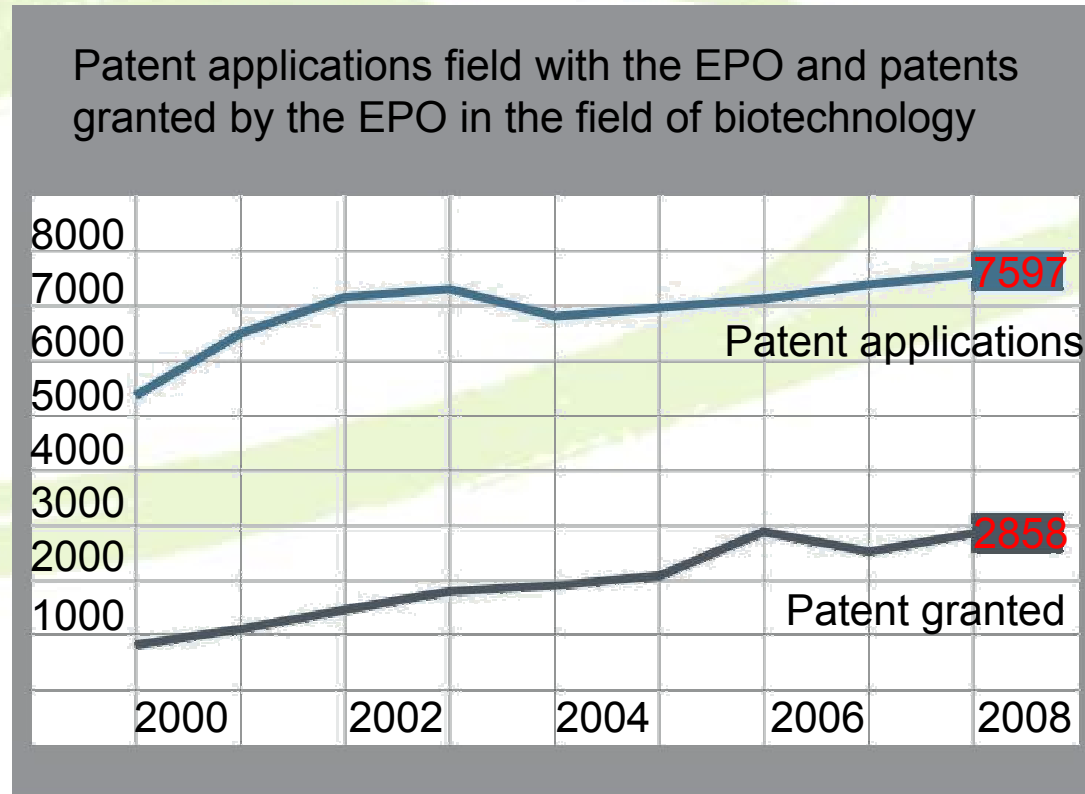
For example: pharmaceuticals and the paradigm of biotechnologies

✓ Random vs. rational drug screening



Patents in the field of biotechnology

Over the past few years, biotechnological inventions have consistently ranked among the 10 largest technical fields in terms of number of patent applications field



Patent and evaluation

Biotech companies have no revenues from the market in first years

They survive thanks risk capital (Vc) running R&D activities, exploiting scientific results in order to maximise future value of the company

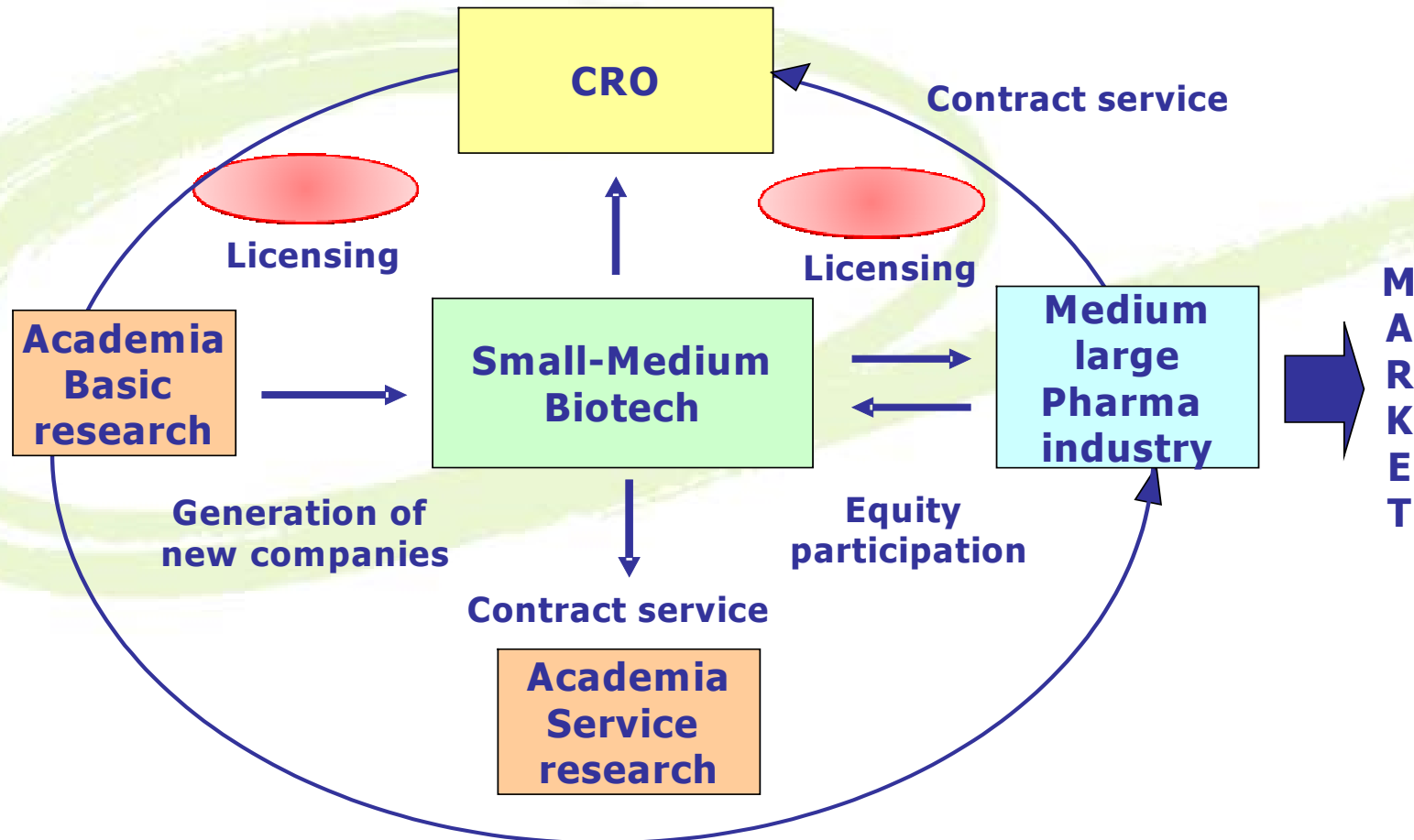
VC evaluate such companies through an analysis of science but also through an evaluation of patent portfolio

Different methods are applicable e.g.:

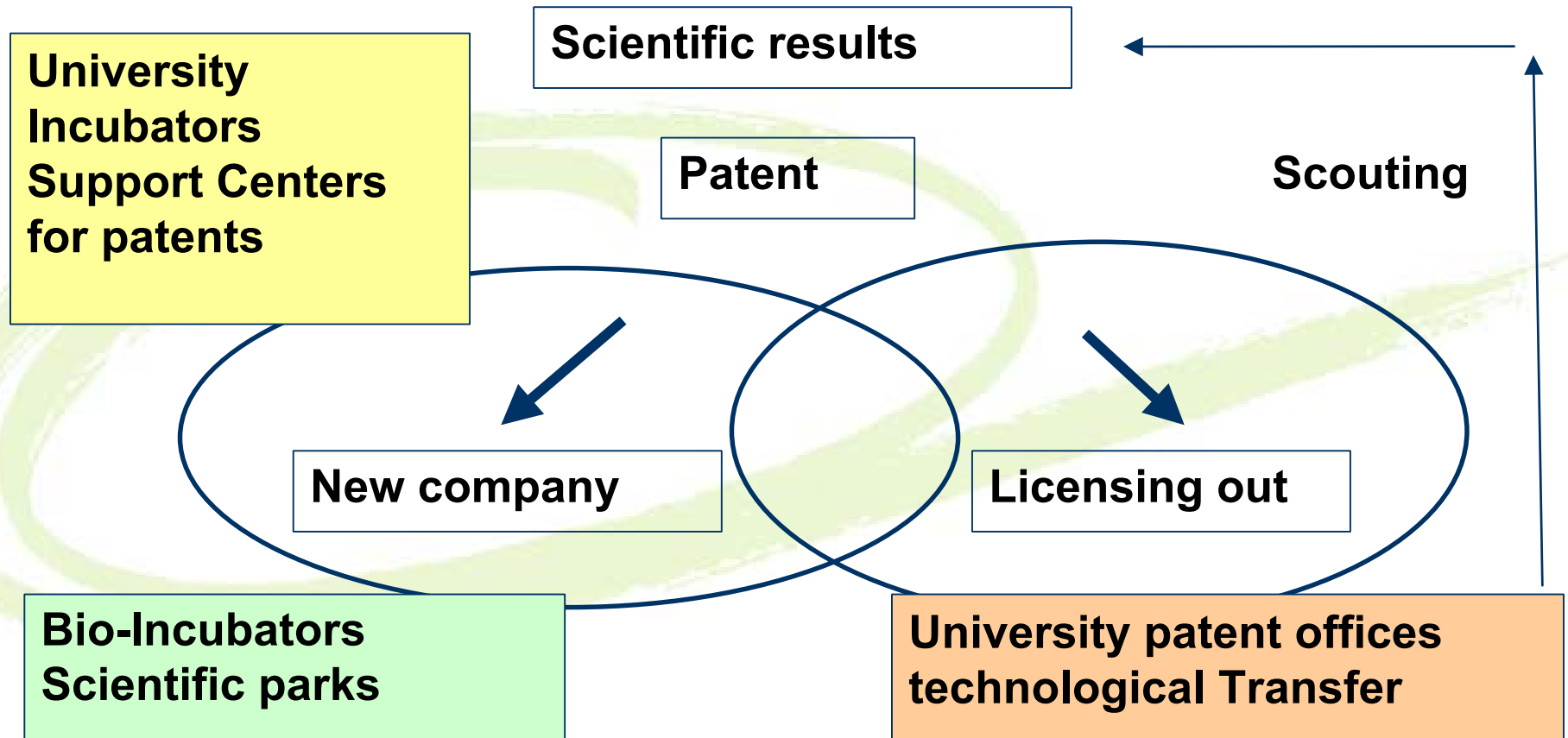
- ✓ Discounted cash flow analysis
- ✓ Market bench
- ✓ Real Options

The partnership in the Biotech sector

Keys are the relationships and collaborations with public research and clinical laboratories



From universities to industry



Universities, IP and commercial exploitation

- ✓ IP is the first step to add economic value to scientific results
- ✓ IP is a basic tool : it must be “packaged” in order to become appealing for an external companies or to be at the core of a start-up
- ✓ Managing IP in a really early stage requires skills and expertises with a focus on qualitative and not quantitative results
- ✓ In some countries, legislation and university policies are strategically focused on the creation of a positive environment to transform scientific results in innovation exploitable in industrial settings.

However an integrated legal and regulatory framework, aimed at generating and transferring innovation is not common everywhere

An example with the development of radiopharmaceuticals

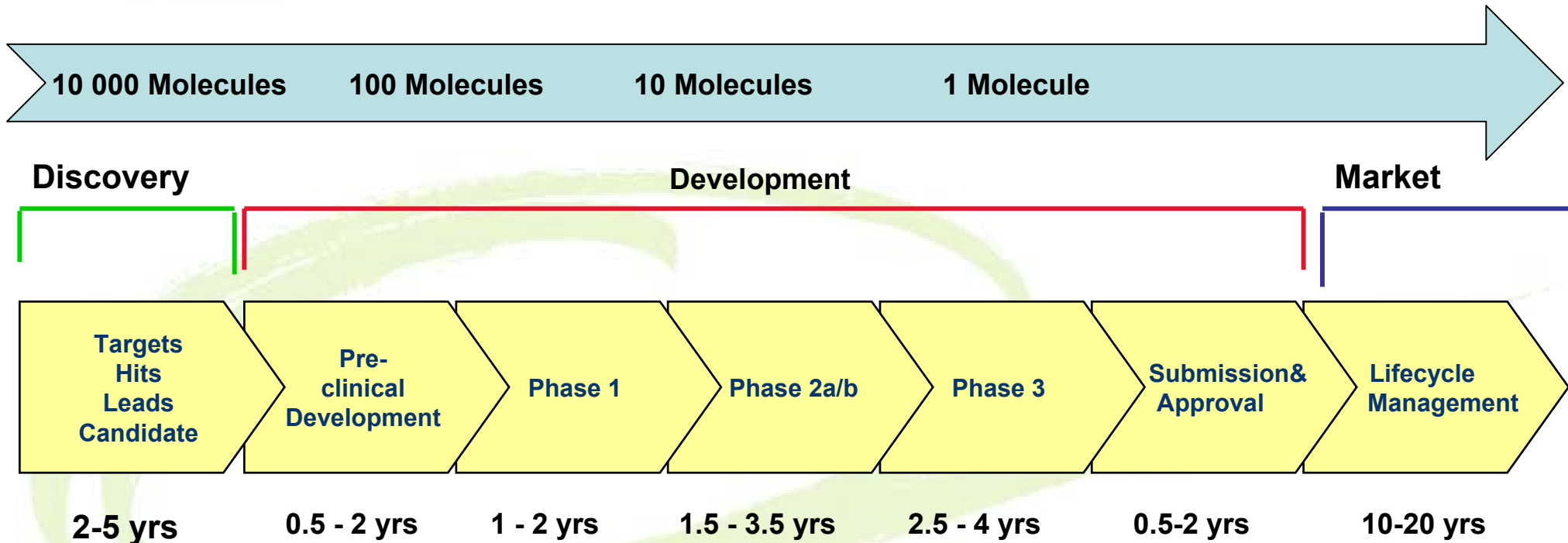
A **radiopharmaceutical** is a radioactive compound used for the diagnosis and therapeutic treatment of human diseases

Has two components :

- ✓ radionuclide
- ✓ pharmaceutical (proteins, Mab, inorganic, organic compounds)



Development of radiopharmaceuticals



The development process of a diagnostic or a therapeutic radiopharmaceutical does not really differ from the development of a classical drug. Some specific properties of these nuclear medicine tools mainly linked to the ease to follow their distribution in the human body, allow to save 2 to 4 years out of the dozen of years required to bring a drug on the market. Overall, development costs can be significantly reduced for the same reason



A public-private partnership patent oriented

An industrial who wants to invest in such a business will base its analysis on the possibility to have a monopoly on the product.

No company will take the risk to invest in a product which is not protected. A published molecular structure makes it non patentable. It is of fundamental importance for scientists involved in research to realize that publication of sensible data will prevent future patentability of the product. The molecule will at the best used as laboratory tool, independently from its potential clinical interest.

Practical example

Amongst hundreds of Fluor 18-labelled molecules, only FDG has a real commercial interest. All other molecules remain only available locally and at a very high cost. The possibility to commercialize new radiopharmaceutical agents will depend on the possibility to protect the molecule and finally from a **well defined private and public partnership**



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Thanks for your attention