

Bioindustry Park Silvano Fumero

Exploitation of scientific results in
the biotech field: the crucial role of
intellectual property rights

*Sara Falvo, PhD
BD and TT coordinator*

Who we are

We are an Italian Science Park specialized in
HEALTH



- ✓ We host companies
- ✓ We support the **growth of start-ups and scale-ups**
- ✓ We are a **technology transfer enabler**
- ✓ We **foster innovation** through focused services: technology evaluation & valuation, 'business modelling' and 'go to market' strategies, scientific results exploitation
- ✓ We nurture a **Health Care Innovation Cluster**



- ✓ Headquarter in **Colleretto Giacosa (Turin, Italy)**, with a branch in **Naples**
- ✓ 270.000 sqft
- ✓ 40+ different organizations settled
- ✓ Focused service platform

The innovation process



IPM-4-CITRUS



This project has received funding from the European Union's Horizon 2020 Research and Innovation programme under Grant Agreement No 734921.

The innovation process



Creativity

The use of imagination or original ideas to create something; inventiveness.



Invention

New practical solution for a technical problem



Innovation

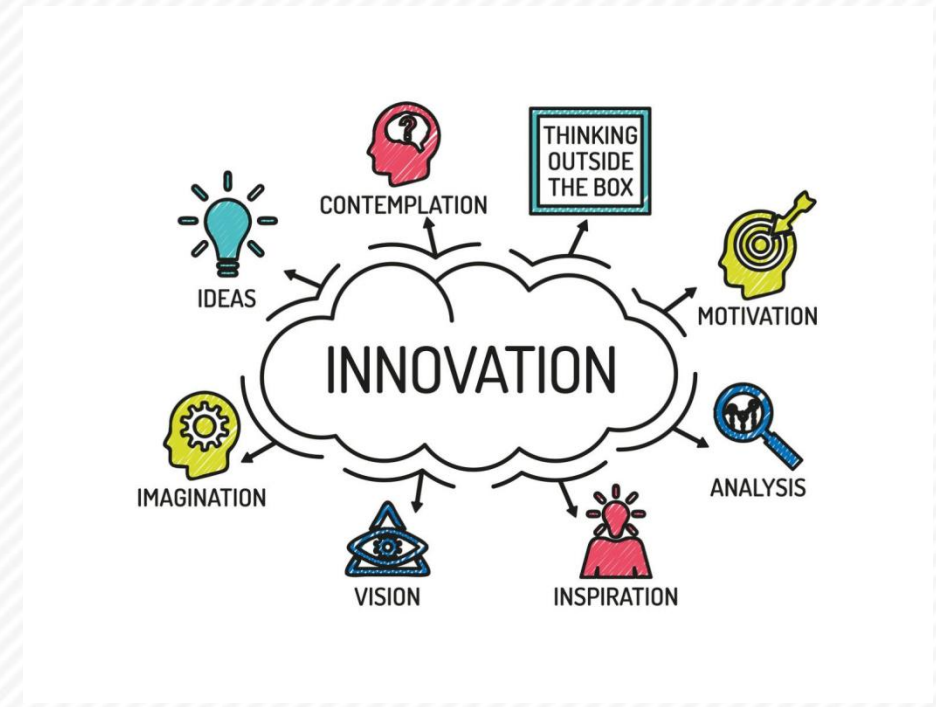
Transformation of the new solution in a profitable business



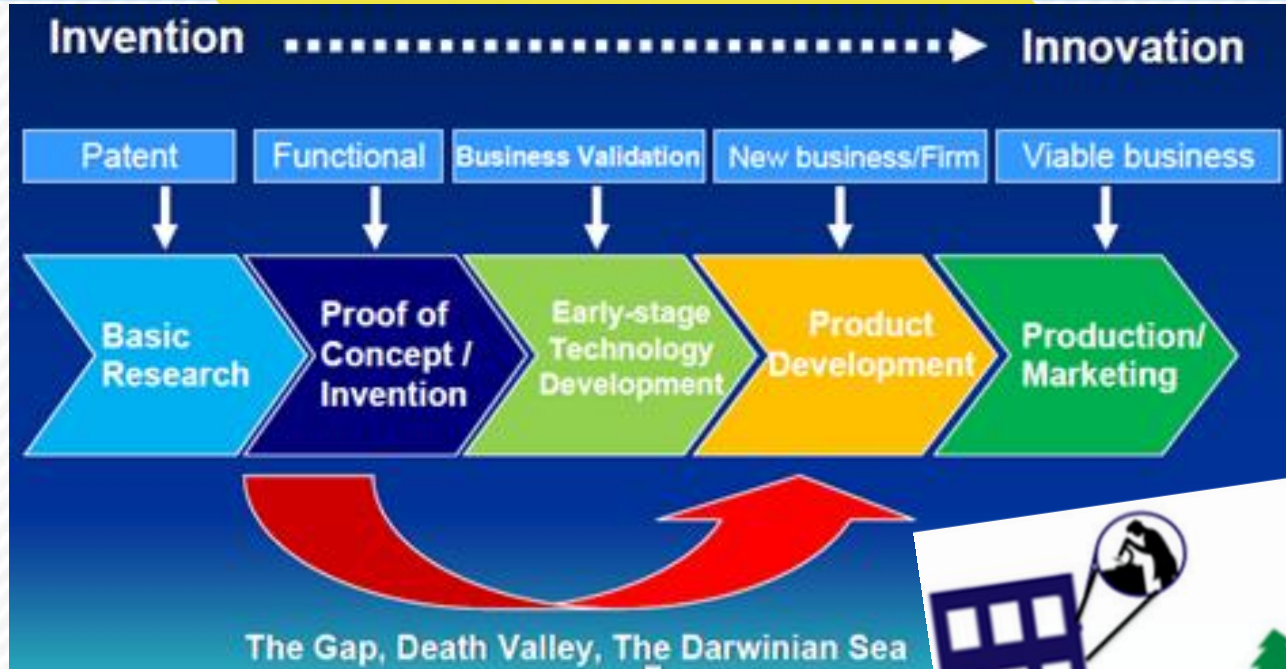
Innovation concept

“Innovation is the successfully exploitation of new ideas”

Innovation Unit (2004) UK Department of Trade and Industry



From invention to innovation



BPDDC, LLC www.bpddc.com



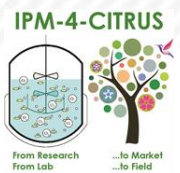
Output from Academia
Incomplete

Early stage IP
Incomplete Validation
Unclear Market Potential

\$\$\$
Competencies

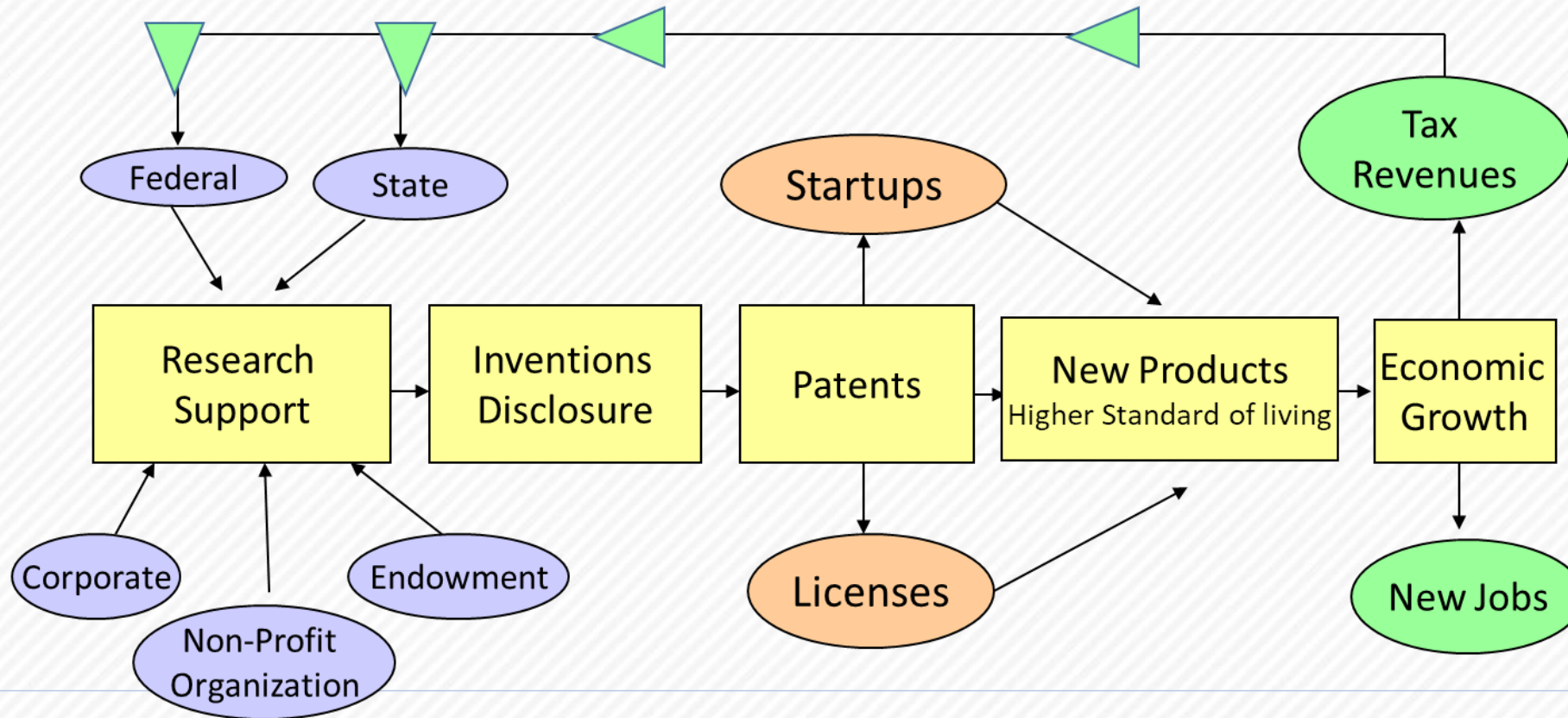
Industry Requirements
Validated

Validated IP
Validated Technology
Clear Market Potential



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TT stages: From Research Support to Economic Growth



The patent: essential tool to exploit a biotech solution

- ✓ **The right to exclude others from commercially** making, using, distributing, or selling the invention **without the patent owner's consent**
- ✓ **Public disclosure** of the invention.
- ✓ **Fee payments**
- ✓ Any **process, machine, manufacture, or composition of matter, or improvement thereof.**

NOT PATENTABLE:

- The **laws of nature, physical phenomena, mathematical methods, and abstract ideas** are not patentable.

Any person who performs any of these exclusive rights in respect of the invention without the patentee's authorization **infringes** the patent



Patents are limited:

- in time
- in territory
- in scope

The patent requirements

INVENTION

- ✓ A **technical solution to a technical (concrete, useful, and functional) problem.**

NOVEL

- ✓ The invention must **not have been used, sold, offered for sale, disclosed, or published**

INVENTIVE STEP

- ✓ Must **not be an obvious extension of what is known**
- ✓ Must be **non-obvious to a person of ordinary skill in the art**

INDUSTRIAL APPLICATION

- ✓ Possibility of **being made or used**

UNITY SUFFICIENT DISCLOSURE CLARITY OF CLAIMS

- ✓ The patent application shall relate to **one invention only or a group of closely related inventions**
- ✓ Sufficiency and **clarity of the description**
- ✓ **Claims** shall be **clear and concise** and be supported by the **description**



BIOTECH

Patent requirements

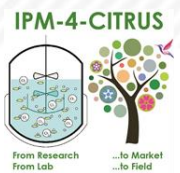
Europe: legal protection of biotechnological inventions – Directive 98/44/EC –

✓ Inventions are patentable even if they concern a product consisting of or containing biological material IF isolated from its natural environment or produced by means of a technical process.

→ Bans human cloning and any modifications to germ line genetic identity.

What is patentable?	What is not patentable?
Genes and nucleic acid molecules e.g.: - disease related genes for diagnosis - antisense, - siRNA molecules for therapy	Sequences without a known function e.g.: - Expressed Sequence Tags (ESTs) resulting from automated sequencing
Proteins e.g.: - insulin - erythropoietin for therapy - cellular receptors for drug screening	Genetically modified animals which is suffering without any substantial medical benefit e.g.: - a genetically modified animal which is solely used to test cosmetics
Enzymes e.g.: - protease for washing powder - cellulose-degrading enzymes for the production of bio-fuels	Plant varieties as such e.g.: - Golden delicious apples
Antibodies e.g.: - for cancer treatment - pregnancy tests - diagnostics	Animal varieties e.g.: - Holstein cattle
Virus and virus sequences e.g.: - hepatitis C virus - HIV for blood testing - development of vaccines and therapies	Human embryos
Cells e.g.: - haematopoietic stem cells for the treatment of leukaemia	Processes which necessarily involve the use and destruction of human embryos
Micro-organisms e.g.: - bacteria for bioremediation - yeast for food production	Human germ cells (sperm, oocytes)
Transgenic Plants e.g.: - herbicide resistant soybean - golden rice which accumulate pro-vitamin A - drought-resistant plants - algae and genetically modified yeast for capturing CO2 from the atmosphere	Human-animal chimera
Transgenic Animals e.g.: - disease models for research such as the genetically modified "oncomouse" - donor animals for xenotransplantation - dairy animals which produce medicaments in milk	

Table 2



Freedom to operate analysis

- ✓ The **ability** to perform a particular **commercial activity of your technology/product/service** without infringing third party's valid IPR.
- ✓ Patents: **right to exclude others NOT the right to practice** the patented invention.
- ✓ To **not infringe a patent**
- ✓ Search of **granted** patents:
 - ✓ limited in time: can be limited to 20 years old patents or less
 - ✓ limited in territory: countries of interest for commercialization
 - ✓ **Each part of the invention**

Freedom to operate

The Claim: an apparatus for sitting comprised of...



- A back
- A seat
- Four legs
- U.S. patent



- A back
- A seat
- Four legs
- **Armrests**

- New
- Useful
- Not obvious



Patents are a prevention tool.

Patents do not grant you the right to make, use, and sell.

Patents grant you the right to prevent *others* from making, using, and selling.

Licensing opportunities

License agreement

- ✓ Contract between a licensor and a licensee
- ✓ The licensor grants to licensee the right to practice the technology claimed in the licensed patent
- ✓ A license is a right to use but with some limits



Do NOT forget to sign a NDA agreement before start disclosing and describing your invention!

Out- license	University to Company → IP transfer
Cross- licence	Company to Company → Usually Joint Venture or strategic partnership
Sub- license	Company to Company → Usually product development, marketing

- ✓ Innovation is crucial for our society, even more for the biotech sector.
- ✓ Innovation needs to be managed and fostered (skills & resources).
- ✓ Patents play an essential role in the innovation process, conferring a competitive advantage to the patent owner.
- ✓ It allows to **create value** around the invention but has to be **managed**.
- ✓ Patent information analysis allows to do **competitive intelligence**, to **analyse** a specific **technical field** and helps to make **strategic decisions** and help for **patent exploitation**.
- ✓ **PROPER PATENTS EXPLOITATION CAN FOSTER BIOTECH INNOVATIONS**

The team wins, not the single player



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