HUMAN TECHNOPOLE

4-DAYS FULL IMMERSION TRAINING ON TECHNOLOGY TRANSFER IN LIFE SCIENCES

10-13 October 2022
Human Technopole, Milan (IT)

“PROTECTING RESULTS WITH INTELLECTUAL PROPERTY RIGHTS”

Laura Spinardi, PhD, RTTP

11th October 2022

WHO I AM

- Biologist
- PhD in Neuroscience
- Master in patenting and IP Law

- 1991-1995 – PhD student at NYU Medical Center, USA
- 1996-2001 – Post Doc at EMBL Heidelberg/ Monterotondo (Rome)
- 2002-2006 – Research Fellow at University of Milano Bicocca, Milan
- 2007-present – Head of **TTO at IRCCS Policlinico Hospital**, Milan

- ATTP Registered Technology Transfer Professional (RTTP)
- Founding member of the **IRCCS TTO Group** at Italian Ministry of Health
- Board member of **NETVAL** - Italy
- Member of the **ASTP Professional Development Committee**

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WHO ARE YOU?

- **Your name**
- **Your University/Company/ Institute**
- **Your role(s)**

Any patents, trademarks, copyrights..???

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Agenda

- ✓ **WHEN do we start ?**
- ✓ **What is Intellectual property (IP)?**
- ✓ **What is an invention?**

  New, Inventive, Applicable
- ✓ **What can we protect?**
- ✓ **How is the patenting process?**

  Priority date, PCT, national phases

Let's try it!.....

WHEN do we start?

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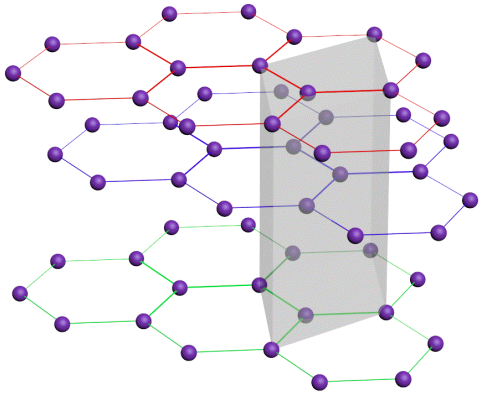
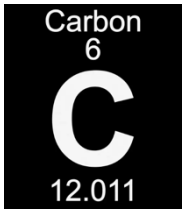
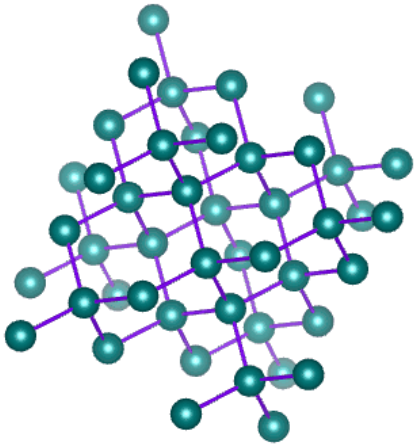
Project management





Allotropes of Carbon



1-2 Mohs scale

10 Mohs scale

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Lab Notebook

- - **Daily** report of **detailed** protocols.
- - Use **unerasable** pen: no pencil!
- - Use bound **notebook** and not flying papers.

1)….COLLECT SAMPLES !!!

2)….COLLECT INFORMED CONSENTS !!!

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What is Intellectual Property?

- **Intellectual Property (IP**) relates to **creations** of the **human mind** (“intangible asset”).

- **Intellectual Property Rights (IPRs**) are **legal rights** granted to creators of IP to give them protection over their intangible assets.

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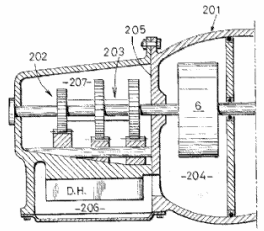
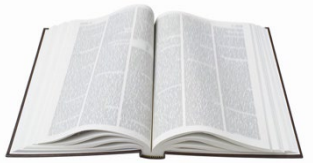
HOW to protect your invention: an overview

Legal right	What for?	How?
Patents	New inventions	Application and examination
Copyright	Original creative or artistic forms	Exists automatically
Trade marks	Distinctive identificati of products or servic	Use and/or registration
Registered designs	External appearanc	Registration*
Trade secrets	Valuable information not known to the public	Reasonable efforts to keep secret





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PATENTS

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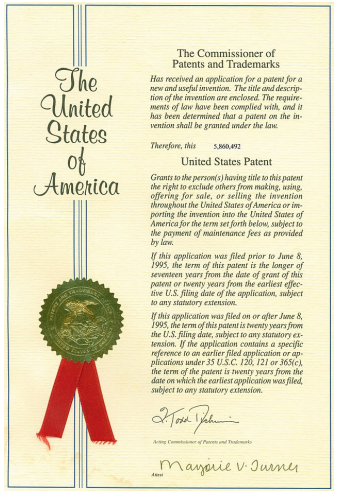
PATENTS

Patent is a type of IPR which relates to **"Technical Inventions".**

Prevent others from making, using, selling or importing infringing products in the country where the patent was granted

Patent is a "contract" between the inventor and the State:
monopoly against the obligation to publish

It is a **territorial right** granted by a State for a **limited time period (20 years).**


The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this 5,860,492

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extension.

- ✓ **It is a negative right!**
- ✓ **A patent does not grant the right to use the invention!**

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What is an invention?

A technical solution to a problem, that can be described and reproduced.

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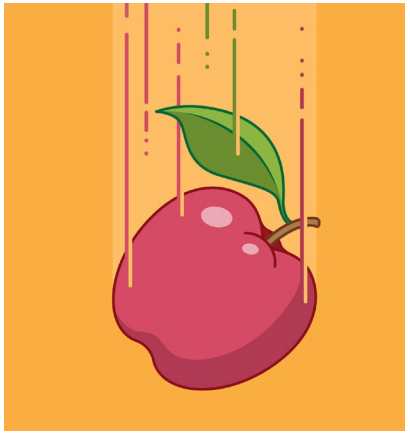
Discovery versus Invention

A discovery is finding something that ***already existed.***

Penicillin

X-rays



Gravity

✓ **You can't patent a discovery!**

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Patentability criteria

Inventions which are:

1) New – not already in "*prior art*"

2) Inventive – not obvious to someone skilled in the art

3) Industrially applicable – solves a technical problem

- **Ethical**
- **No military interest**
- **Full description** (to enable third parties to carry it out)

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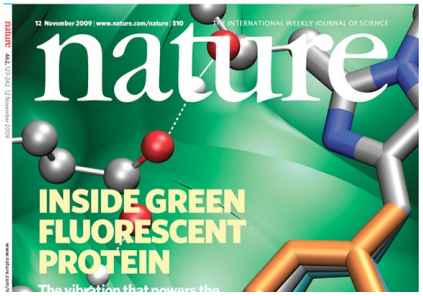
What is “NEW”?



Published in books/journals

Presented at a conference/ Thesis

Discussed at a meeting

Described in emails, web pages

✓ **Never used, described or disclosed anywhere before.**

Objective Criteria!

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Patent searches:

EPO www.epo.org/

Patentscope www.wipo.int/patentscope/en/

UIBM www.uibm.gov.it/

PubMed, Web of Science, SciVal,…

Orbit intelligence www.orbit.com

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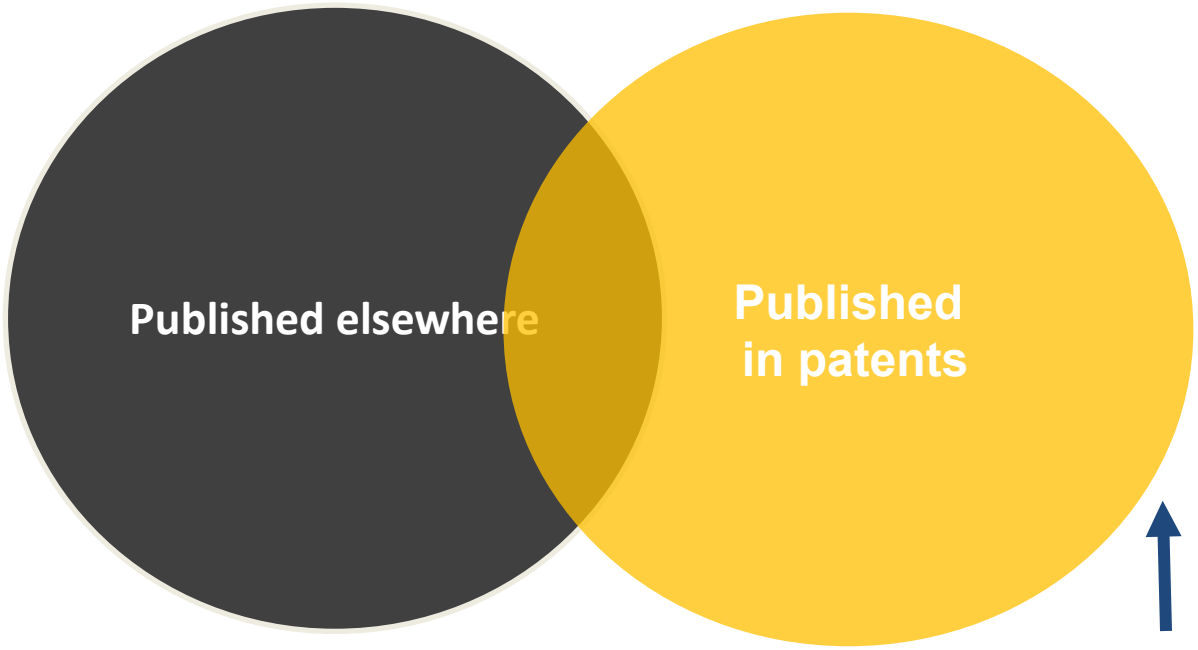
Information only available in patents



80% found only in patents!

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What is “INVENTIVE”?

Legal test: “Not **obvious** to a person skilled in the art”

A person skilled in the art :
A person who has a perfect knowledge of all prior art the invention relates to.

A+B=AB

A+B=C Surprisingly!

Subjective Criteria!

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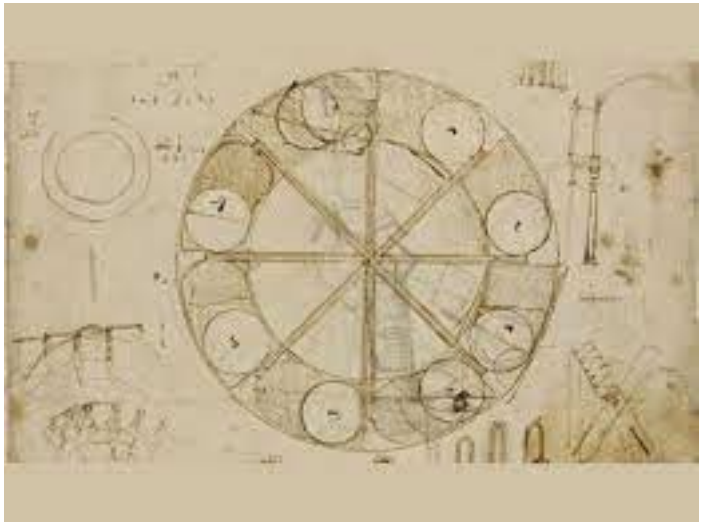
What is “INDUSTRIAL APPLICABLE”?

It does need to have **commercial application** and **be useful**.



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SUFFICIENT DESCRIPTION

✓ When an invention involves a microorganism, completely describing said invention in the description to enable third parties to carry it out is usually impossible.

The Budapest Treaty

- ✓ A deposit of biological material must be made in a recognised institution before filing a patent application.
- ✓ The applicant needs only to deposit the biological material at one recognised institution, and this deposit will be recognised in all countries party to the Budapest Treaty.

The Nagoya Protocol

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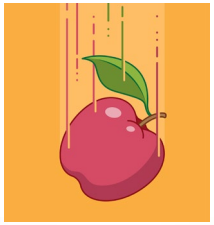
EXCLUDED FROM THE PATENTING PROCEsS

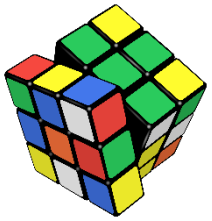
Discoveries, theories or methods and…



Methods of medical treatment or diagnosis

Literary, dramatic, artistic or musical works

Ways of performing mental acts, playing games or doing business



Computer software?

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What to protect

PHARMA

MEDICAL DEVICE

DIAGNOSTICS

RESEARCH TOOLS

✓ **Product** ✓ **Method** ✓ **Use**

"Product By Process"

"re-purposing"

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What to protect

Database

Artificial Intelligence

SOFTWARE/ APP

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An example

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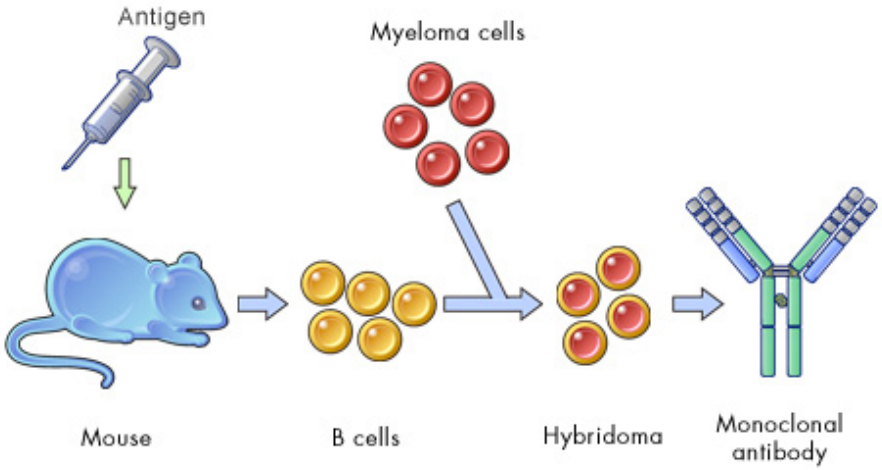
Antibodies

For a given antigen, the production of a monoclonal antibody is considered **nothing unusual**, as techniques for hybridoma production and selection are considered routine.



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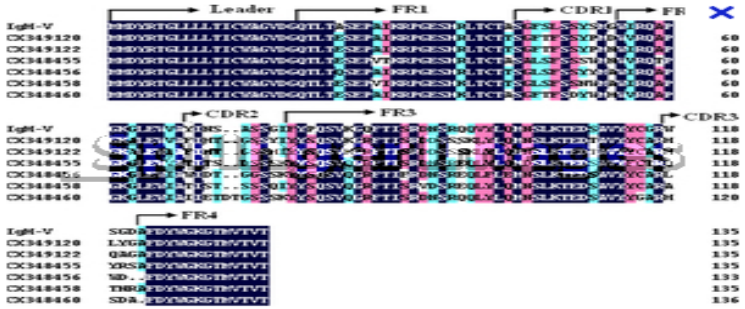
Antibodies

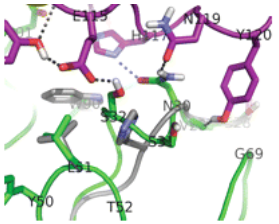
- **MAbs structure(s):**

- **Mabs sequence**: Gln-Ala-Met-His-Tyr-Tyr-Pro-etc.

- **Comparison with other Mabs:**



- **Binding sequence**:



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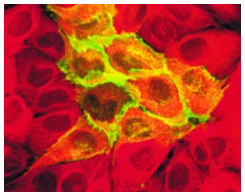
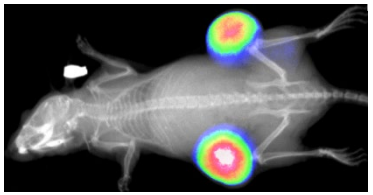
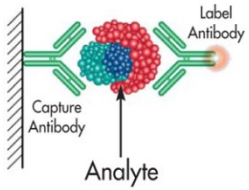
Antibodies

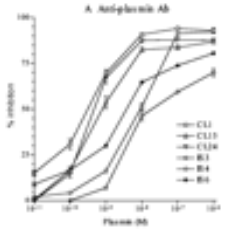
- Efficacy (*in vitro, in vivo*)



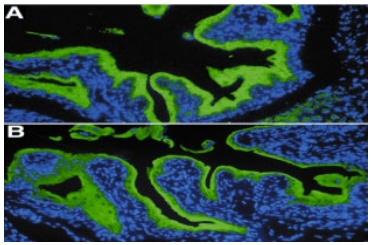




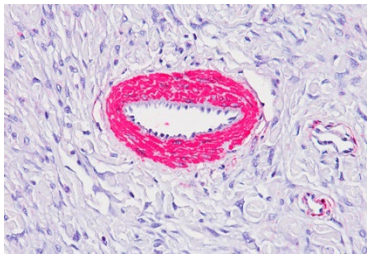
- Differences in Kd, Koff, Kon
- Solubility



- Tissue permeability



- Tissue specificity



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Re-purposing (second use)

- An already known molecule is patentable if it has a different (and non-obvious) application than what is present in the state of the art.

- Freedom-to-operate?

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Rights conferred by the patent

- **Prevent others** from making, using, offering for sale, selling or importing infringing products **in the country where the patent was granted.**
- For up to **20 years** from the date of filing of the patent application

A patent does not grant the right to use the invention!

You might need access to other people's intellectual property in order to use your invention commercially (FTO)

- ✓ **But they might not give you permission.**
- ✓ **Or they might demand a considerable access fee (e.g. royalties).**

A **patent search** is indispensable!!!

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Another example

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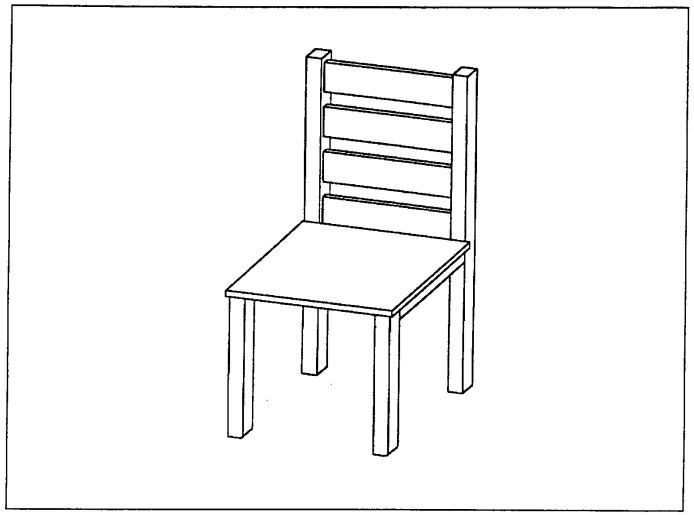
- **Technical problem:**
  - Instable
  - Nothing for the back

ANY SOLUTION?



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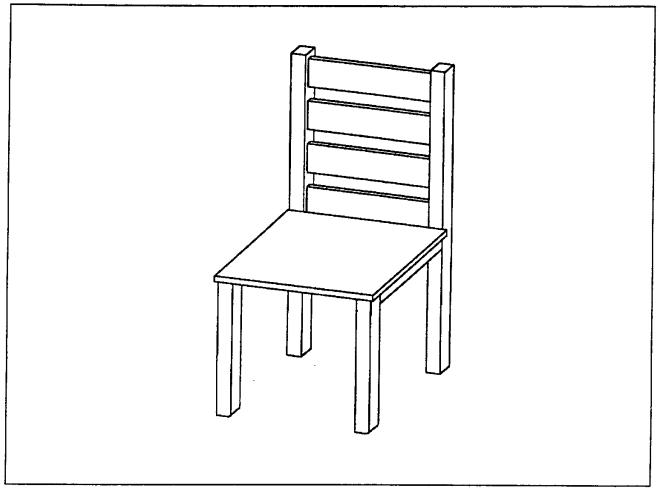
INVENTION (Technical SOLUTION)



A patent to protect:

- a chair with 4 legs,
- a seat with 4 legs,
- a backrest starting from the seat

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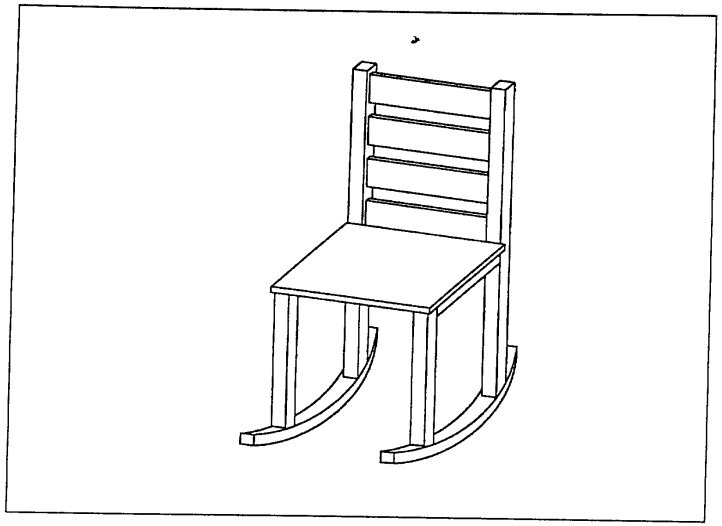
INVENTION 2 (Technical SOLUTION)

How about rocking with a chair?



A patent to protect:

- a chair with 4 legs and a backrest starting from the seat
- a swinging base to connect two legs

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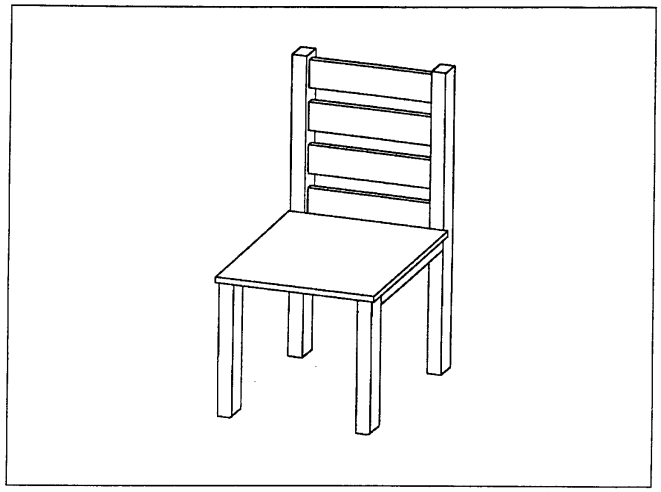
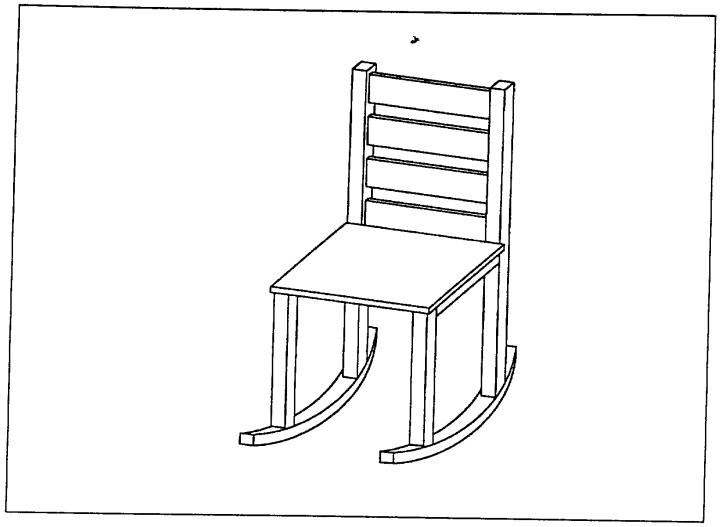
WHO MAKES AND SELLS:



Invention #1



Invention #2

Inventor 1: Invention #1 YES, Invention #2 only with permission (license) of inventor 2

Inventor 2: invention #2 only with permission for invention #1 (included in the #2)

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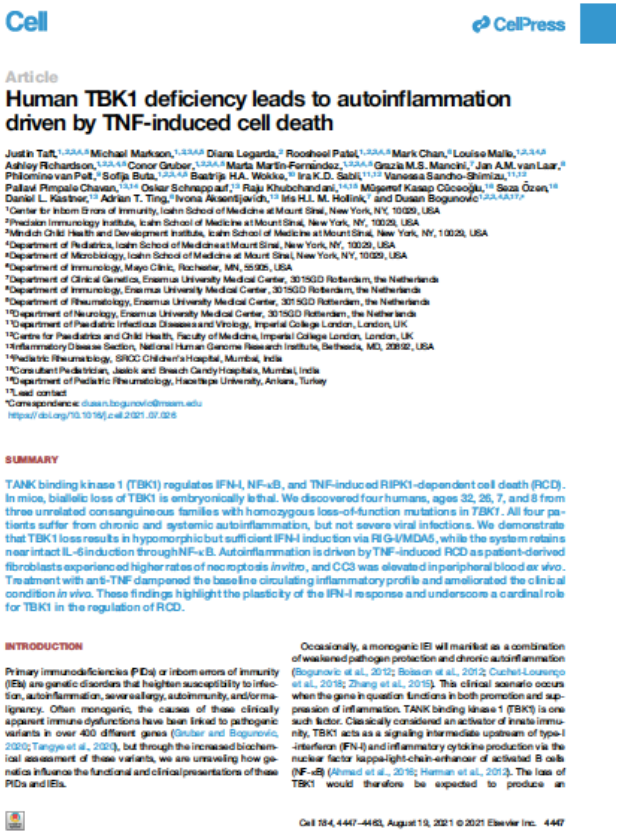
Publish or Perish

Scientific manuscript



Cell

CellPress

Article

Human TBK1 deficiency leads to autoinflammation driven by TNF-induced cell death

Justin Taft,[1,2,3,4,5] Michael Markson,[1,2,3,4,5] Diana Legarda,[2] Roosheel Patel,[1,2,3,4,5] Mark Chan,[6] Louise Malle,[1,2,3,4,5] Ashley Richardson,[1,2,3,4,5] Conor Gruber,[1,2,3,4,5] Marta Martin-Fernandez,[1,2,3,4,5] Grazia M.S. Mancini,[7] Jan A.M. van Laar,[8] Philomina van Pelt,[9] Sofija Buta,[1,2,3,4,5] Beatrijs H.A. Wokke,[10] Ina K.D. Sabli,[11,12] Vanessa Sancho-Shimizu,[11,12] Pallavi Pimpale Chavan,[13,14] Oskar Schnappauf,[13] Raju Khubchandani,[14,15] Müşerref Kasap Cöceoğlu,[16] Seza Özen,[16] Daniel L. Kastner,[13] Adrian T. Ting,[6] Ivona Aksentijevich,[13] Iris H.J. M. Hollink,[7] and Dusan Bogunovic[1,2,3,4,5,17,*]

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[2]Precision Immunology Institute, Icahn School of Medicine at Mount Sinai, New York, NY, 10029, USA
[3]Mindich Child Health and Development Institute, Icahn School of Medicine at Mount Sinai, New York, NY, 10029, USA
[4]Department of Pediatrics, Icahn School of Medicine at Mount Sinai, New York, NY, 10029, USA
[5]Department of Microbiology, Icahn School of Medicine at Mount Sinai, New York, NY, 10029, USA
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[7]Department of Clinical Genetics, Erasmus University Medical Center, 3015GD Rotterdam, the Netherlands
[8]Department of Immunology, Erasmus University Medical Center, 3015GD Rotterdam, the Netherlands
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[12]Centre for Paediatrics and Child Health, Faculty of Medicine, Imperial College London, London, UK
[13]Inflammatory Disease Section, National Human Genome Research Institute, Bethesda, MD, 20892, USA
[14]Pediatric Rheumatology, SRCC Children's Hospital, Mumbai, India
[15]Consultant Pediatrician, Jaslok and Breach Candy Hospitals, Mumbai, India
[16]Department of Pediatric Rheumatology, Hacettepe University, Ankara, Turkey
[17]Lead contact
*Correspondence: dusan.bogunovic@mssm.edu
https://doi.org/10.1016/j.cell.2021.07.026

SUMMARY

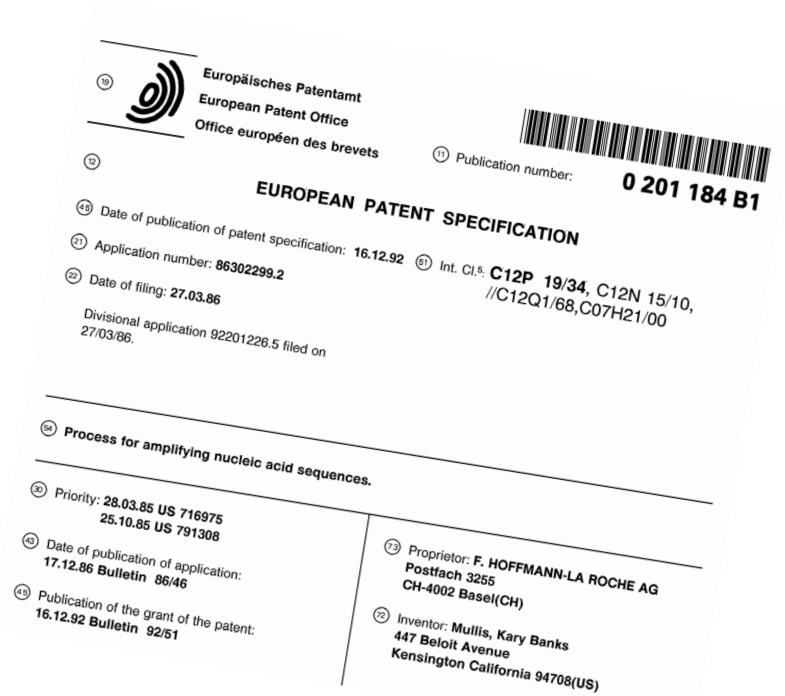
TANK binding kinase 1 (TBK1) regulates IFN-I, NF-κB, and TNF-induced RIPK1-dependent cell death (RCD). In mice, biallelic loss of TBK1 is embryonically lethal. We discovered four humans, ages 32, 26, 7, and 8 from three unrelated consanguineous families with homozygous loss-of-function mutations in *TBK1*. All four patients suffer from chronic and systemic autoinflammation, but not severe viral infections. We demonstrate that TBK1 loss results in hypomorphic but sufficient IFN-I induction via RIG-I/MDA5, while the system retains near intact IL-6 induction through NF-κB. Autoinflammation is driven by TNF-induced RCD as patient-derived fibroblasts experienced higher rates of necroptosis *in vitro*, and CC3 was elevated in peripheral blood *ex vivo*. Treatment with anti-TNF dampened the baseline circulating inflammatory profile and ameliorated the clinical condition *in vivo*. These findings highlight the plasticity of the IFN-I response and underscore a cardinal role for TBK1 in the regulation of RCD.

INTRODUCTION

Primary immunodeficiencies (PIDs) or inborn errors of immunity (IEIs) are genetic disorders that heighten susceptibility to infection, autoinflammation, severe allergy, autoimmunity, and/or malignancy. Often monogenic, the causes of these clinically apparent immune dysfunctions have been linked to pathogenic variants in over 400 different genes (Gruber and Bogunovic, 2020; Tangye et al., 2020), but through the increased biochemical assessment of these variants, we are unraveling how genetics influence the functional and clinical presentations of these PIDs and IEIs.

Occasionally, a monogenic IEI will manifest as a combination of weakened pathogen protection and chronic autoinflammation (Bogunovic et al., 2012; Boisson et al., 2012; Cuchet-Lourenço et al., 2018; Zhang et al., 2015). This clinical scenario occurs when the gene in question functions in both promotion and suppression of inflammation. TANK binding kinase 1 (TBK1) is one such factor. Classically considered an activator of innate immunity, TBK1 acts as a signaling intermediate upstream of type-I -interferon (IFN-I) and inflammatory cytokine production via the nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) (Ahmad et al., 2018; Herman et al., 2012). The loss of TBK1 would therefore be expected to produce an

Patent



(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(12)

(11) Publication number: **0 201 184 B1**

EUROPEAN PATENT SPECIFICATION

(45) Date of publication of patent specification: **16.12.92**

(51) Int. Cl.5: **C12P 19/34**, C12N 15/10, //C12Q1/68,C07H21/00

(21) Application number: **86302299.2**

(22) Date of filing: **27.03.86**

Divisional application 92201226.5 filed on 27/03/86.

(54) **Process for amplifying nucleic acid sequences.**

(30) Priority: **28.03.85 US 716975**
25.10.85 US 791308

(43) Date of publication of application:
17.12.86 Bulletin 86/46

(45) Publication of the grant of the patent:
16.12.92 Bulletin 92/51

(73) Proprietor: **F. HOFFMANN-LA ROCHE AG**
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Publish or Perish

Scientific manuscript	Patent
• Abstract	✓ Abstract
• INTRODUCTION	✓ STATE OF THE ART
• RESULTS • (Figures)	✓ DESCRIPTION ✓ (Figures)
• MATERIAL & METHODS	✓ EXAMPLES
• DISCUSSION	• CLAIMS

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Publish or perish

SEND THE MANISCRIPT, PRESENT AN ABSTRACT DISCUSS A THESIS…

+ 1day

0m

Application filed

SEND THE MANISCRIPT, PRESENT AN ABSTRACT DISCUSS A THESIS…

18 months

Secret time

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Actors

INVENTOR:

Owns the moral rights of the patent

ASSIGNEE (Applicant):

Owns the patrimonial rights of the patent

In Italy: "Professor privilege"

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PATENTING PROCESS

Patent application:

Document as submitted to the patent office.

Patent:

Document as granted (i.e. approved) by the patent office

How can you distinguish between the two ?

It is written on the document

A = Application

B = Patent

1 invention= 1 patent

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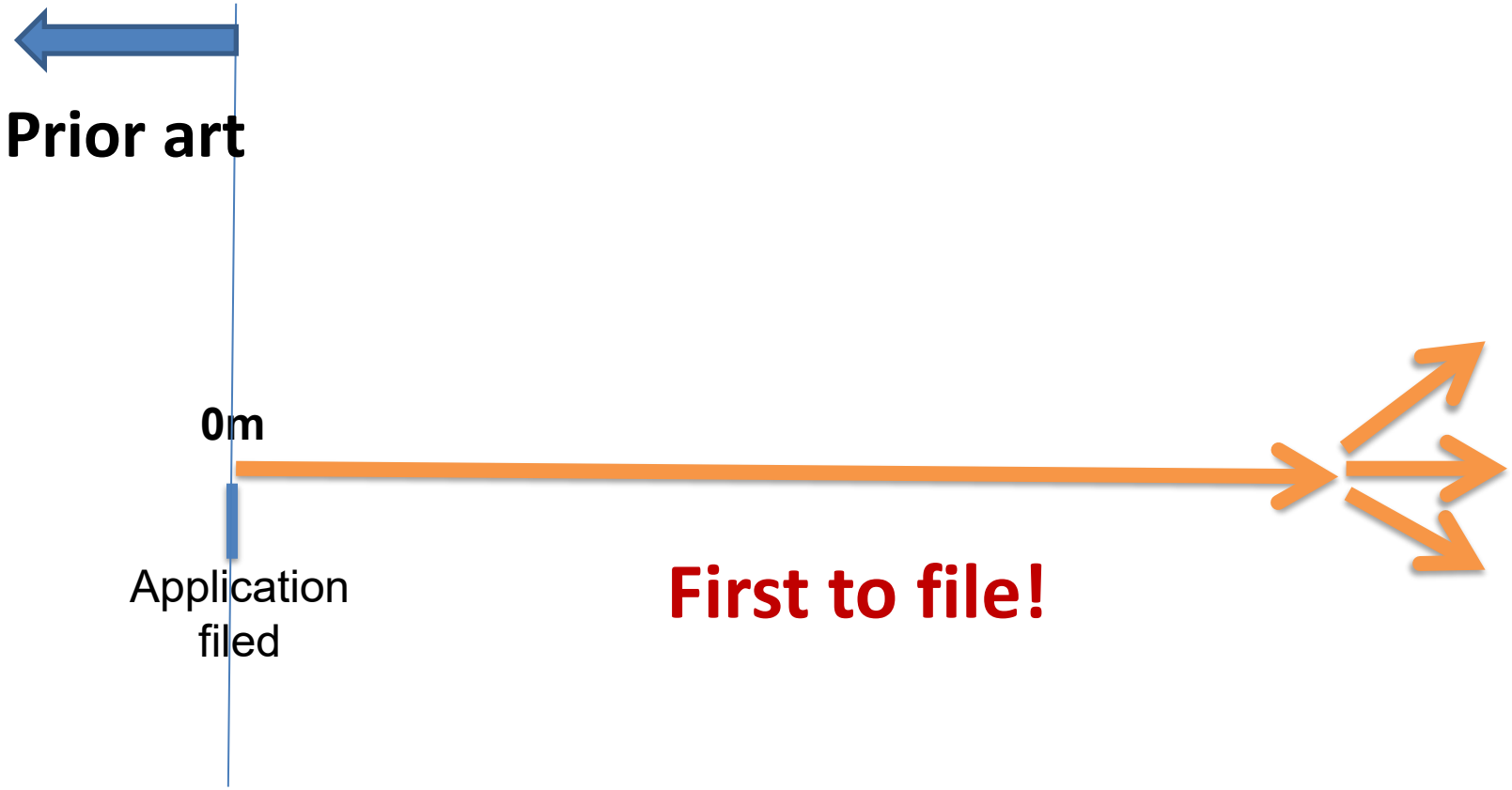
PATENTING PROCESS



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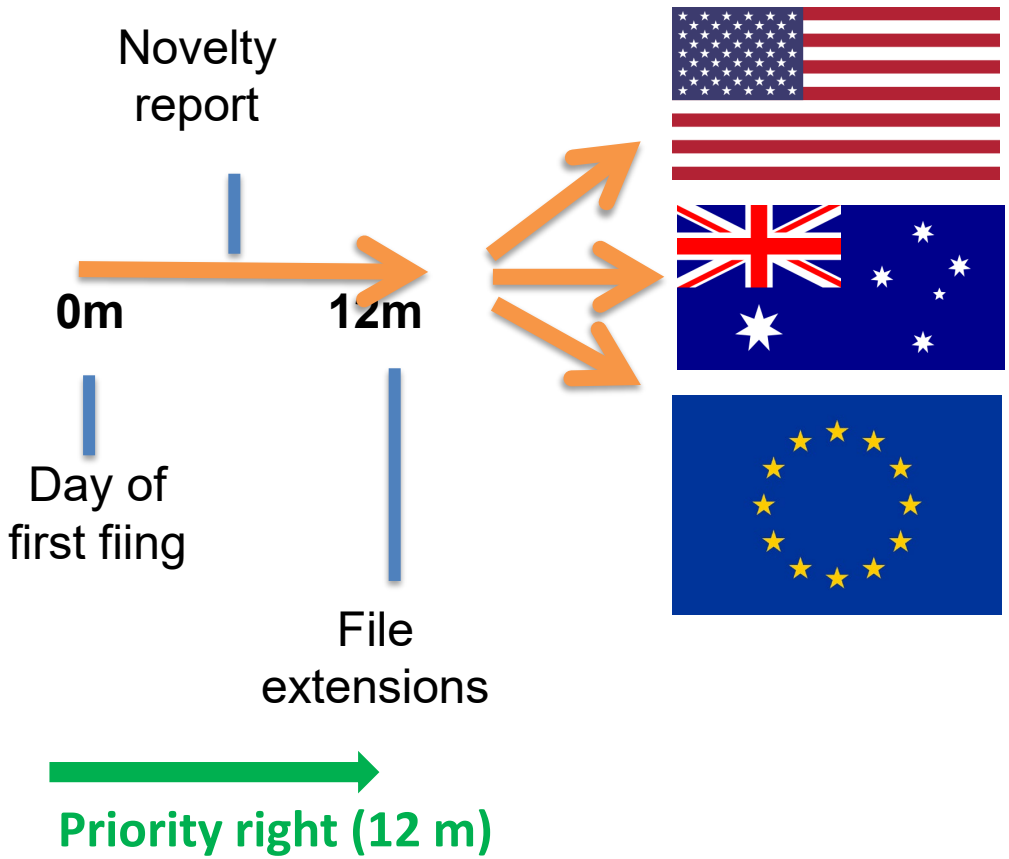
PATENTING PROCESS



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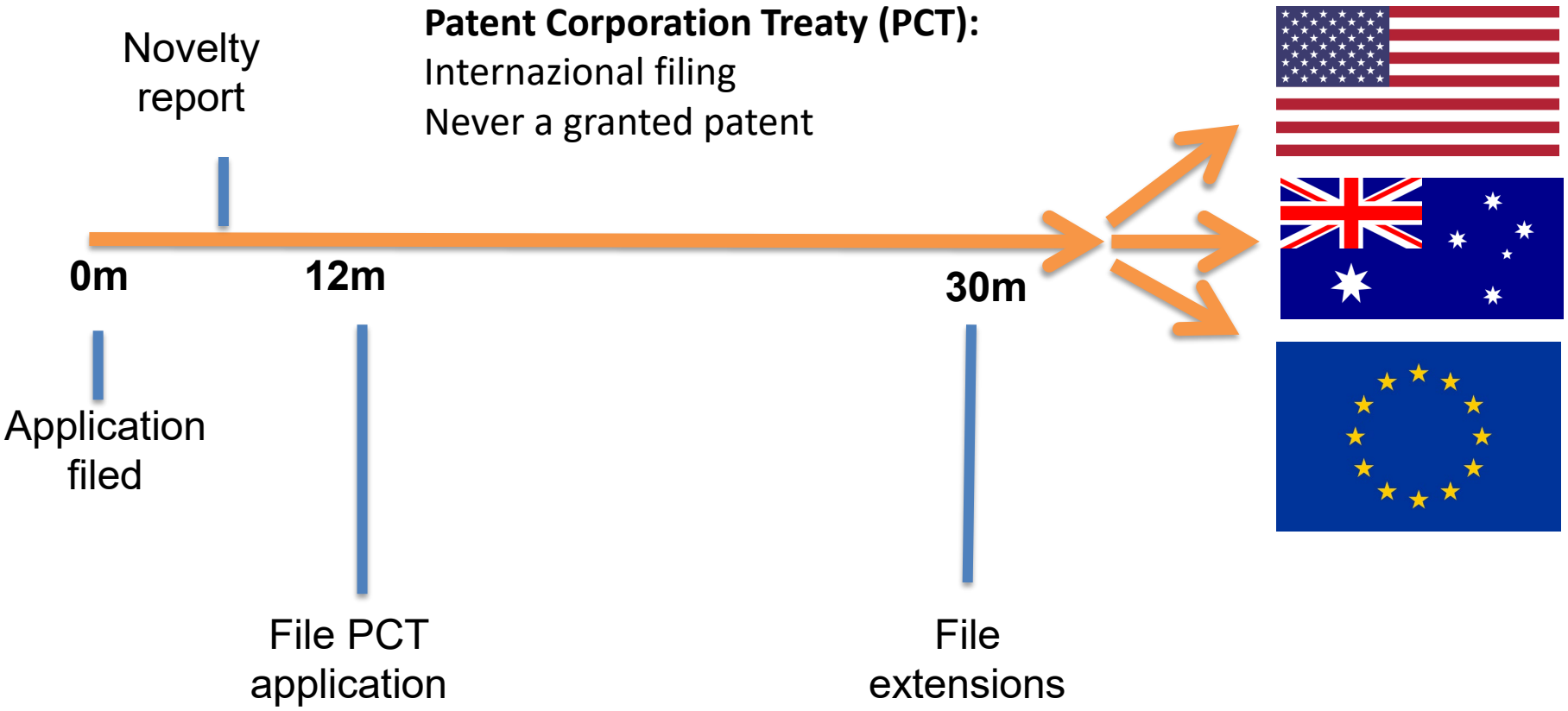
PATENTING PROCESS



PCT: keeps **many options open** up to 30 months (31 in EU) after first filing

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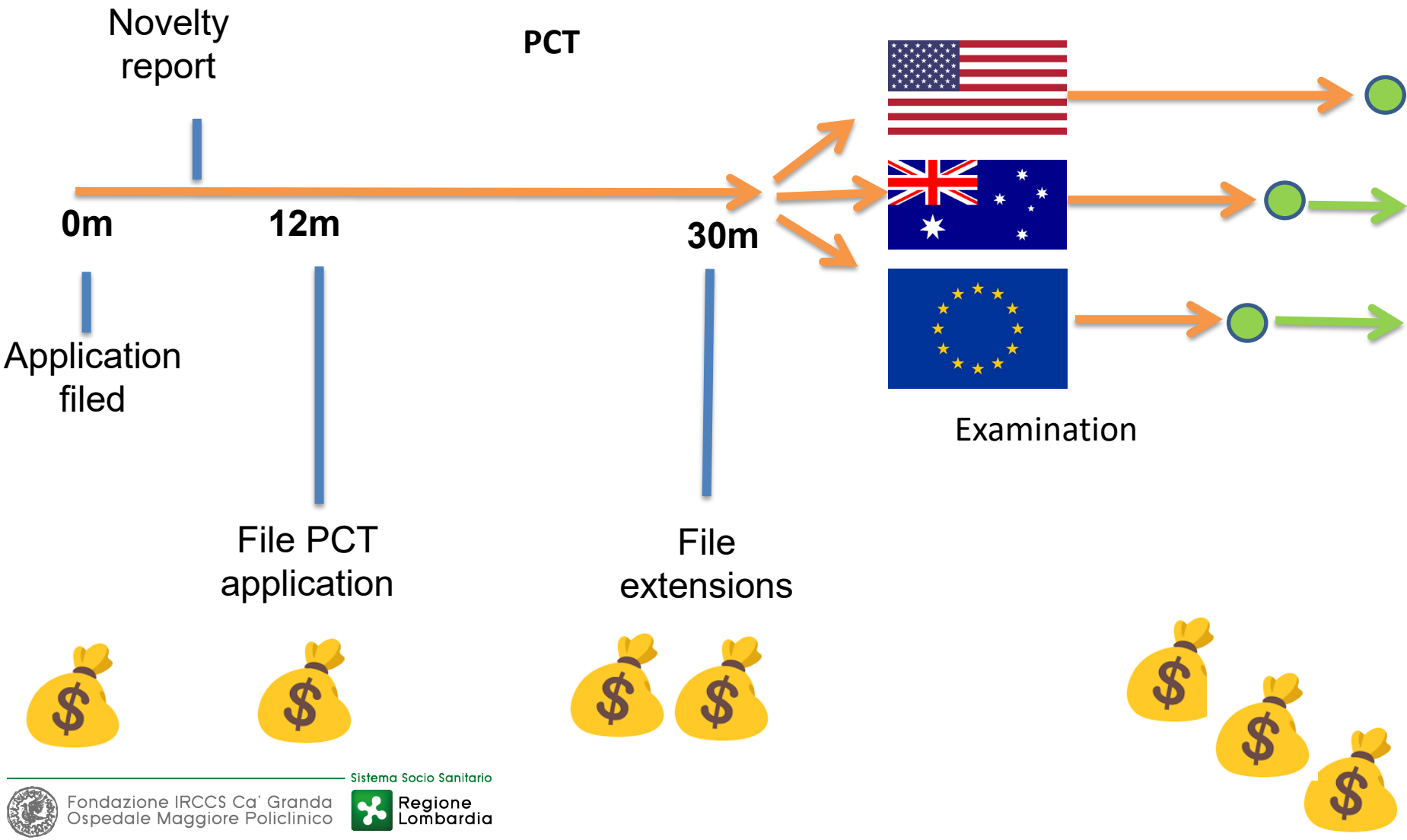
PATENTING PROCESS



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A patent family

It's a family of patents

PCT

Nationalizations

First filing (priority date)

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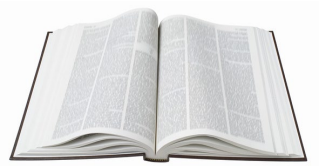
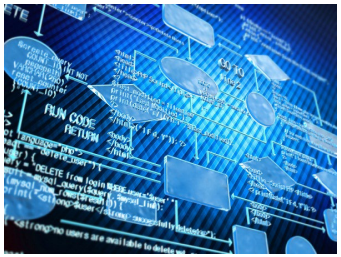


LITERARY WORKS

MUSIC WORKS



SOFTWARE

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COPYRIGHTS

- A copyright exists the moment a **work is "fixed**", NO REGISTRTION REQUIRED
- **" AS SUCH"**
- **It lasts 70 years.**

The **Berne Convention for the Protection of Literary and Artistic Works**, usually known as the **Berne Convention**, is an international agreement, which was first accepted in Berne (CH) in 1886.
The Berne Convention has 181 contracting parties.

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TRADEMARKS

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TRADEMARKS

eppendorf

PerkinElmer®

GILSON®

QIAGEN

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TRADEMARKS

- Trademarks are **distinctive signs, not obvious**, which distinguish them from products or services provided by competitors.
- **It must not be confused with similar marks (novelty);**
- **It's a territorial right (**national, international or European trademark)
- **It lasts 10 years, renewable.**
- It's limited to the goods and/or services indicated in the **NICE Classification**
- **LOGO + DRAWING**

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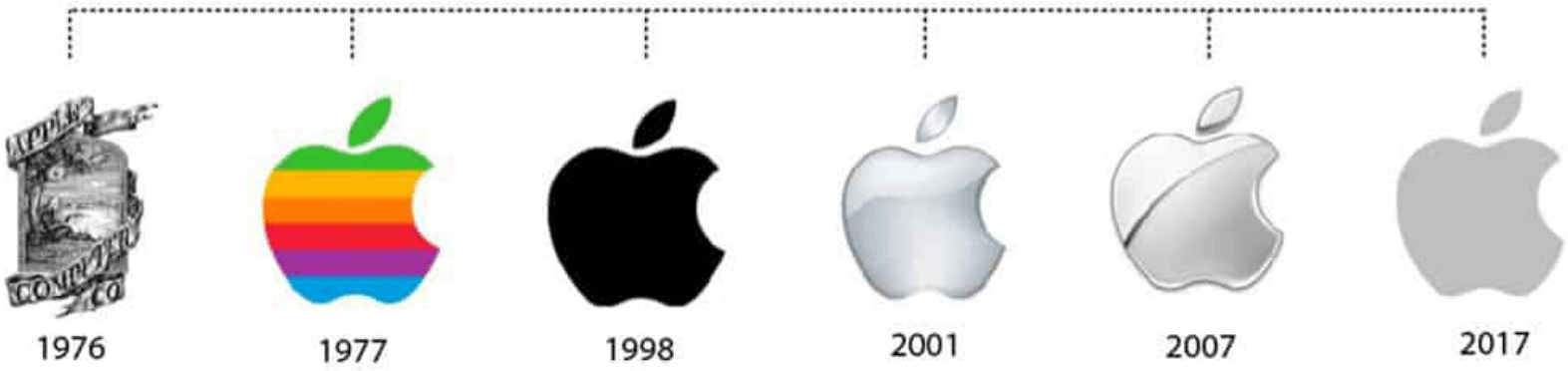
TRADEMARKS



Macintosh computer got its name from the McIntosh apple.
The bite mark was included so people wouldn't confuse it with a cherry. And, it's also a geeky play on words ("byte" is a computer term).

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TRADE SECRETS

TRADE SECRETS

It is secret, meaning that it is not commonly known

It has **commercial value** just because it is secret;

There are **no registration costs;**

The relevant protection is **not limited in time**;

Once it is (illegally) disclosed, a trade secret can be used by **anyone**;

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A case study

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A case study (Credits to: Malcolm Bain2020)

“A custom-designing sport shoes”

Innovative technology with:

- Rapid moulding and colouring
- Adapting to the shape of customer’s feet
- A lot of research, prototyping, validation (TRL5)

What to PROTECT and HOW?

Credits: Josiah Mackenzie, CC BY 2.0 Licence
hiips://creativecommons.org/licenses/by/2.0/

(Credits to: Malcolm Bain @2020)

Design of shoes → Design rights

Custom designing Shoes invention → Patent; Know How

AI model And code → Copyrights Database

Brand & logo → Trademark

Website → Domain name

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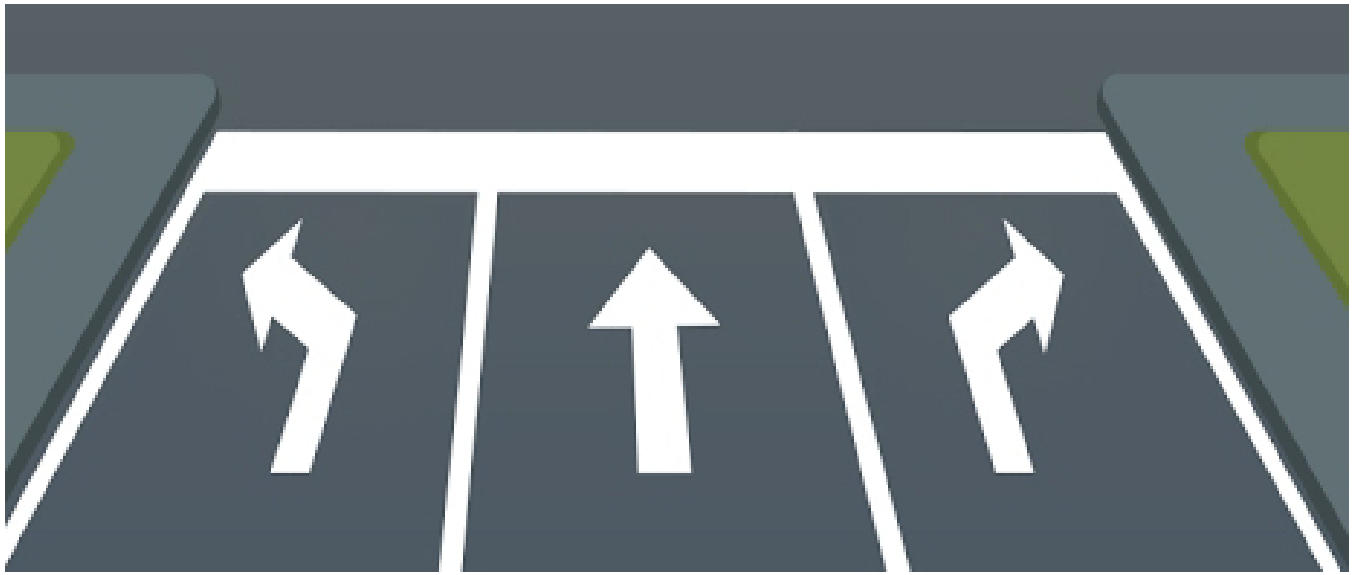
TECH TRANSFER: the three pillars

1. LICENSING OUT

2. COLLABORATIVE RESEARCH

3. SPIN-OFF



WHEN and WHERE protecting IP?

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RESEARCH COLLABORATIONS

- **Background IPRs**

- Are there any existing rights required for the project?
- Who is free to grant them?

- **Foreground IPRs**

  - who will own them?
  - who will pay for them?
  - who will exploit them?
  - any educational purpuse?

- **Sideground IPRs**

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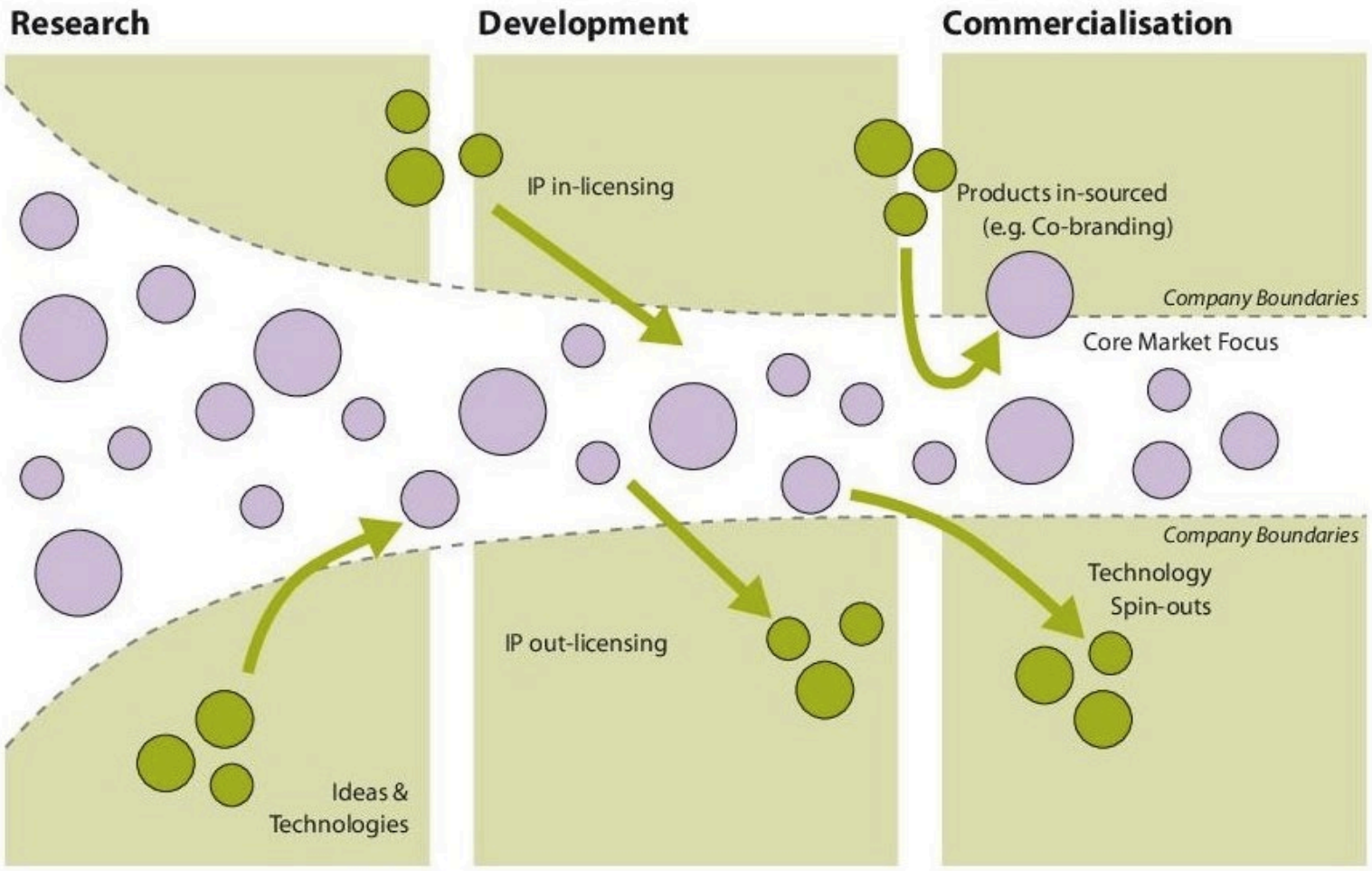
”Tech transfer” funnel



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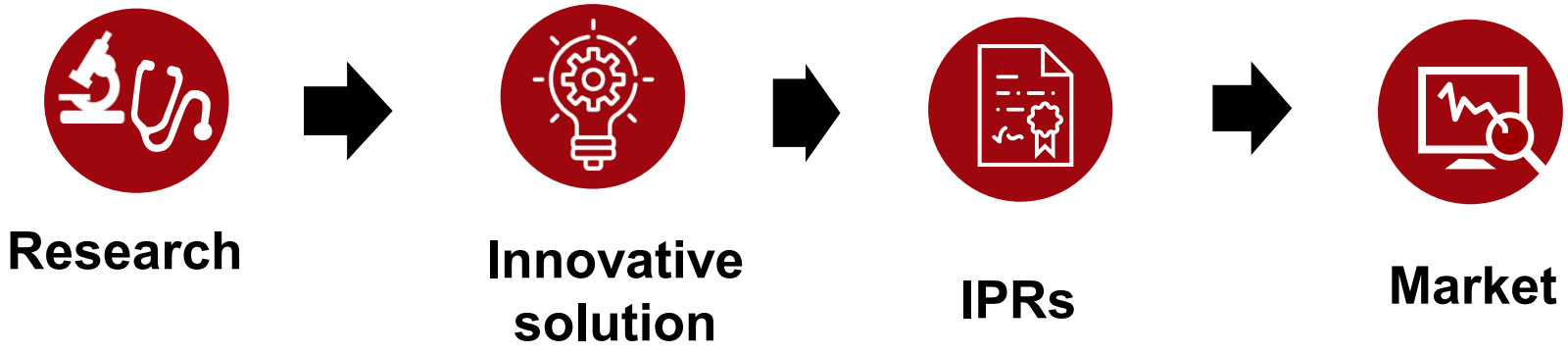
Technology transfer and Innovation



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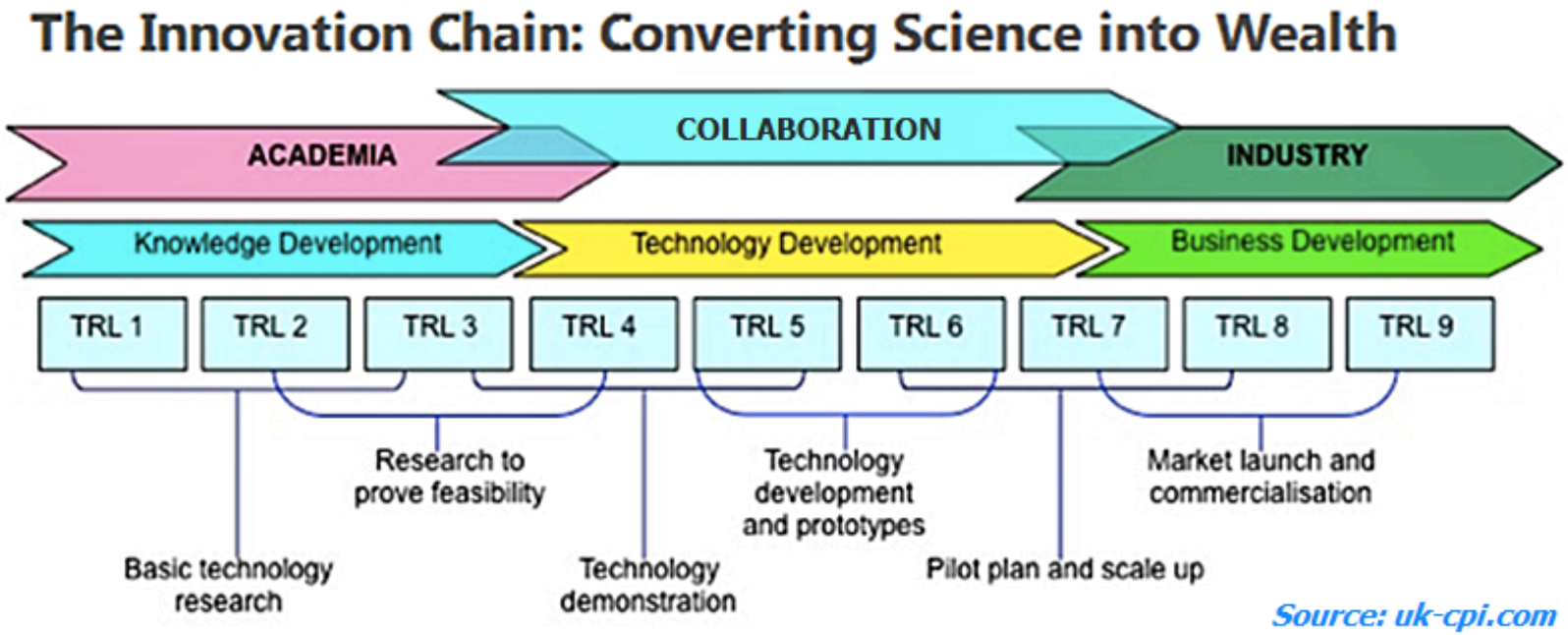
Technology readness levels



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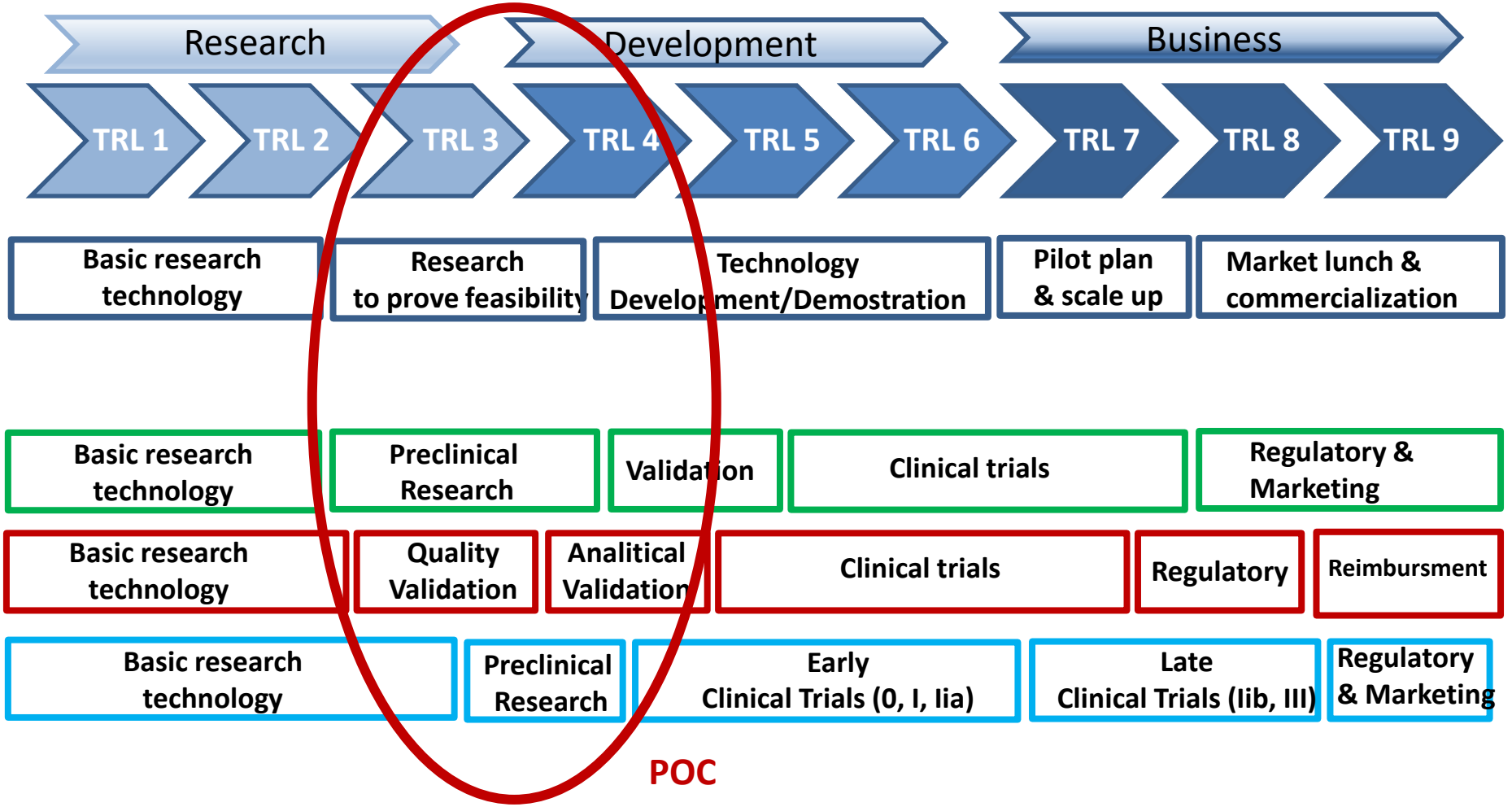
Technology readness levels



Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

Sistema Socio Sanitario Regione Lombardia

Medical device | **Diagnostic kit** | **Pharma**

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….best of luck!

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Grazie per l'attenzione.

Laura.spinardi@policlinico.mi.it

- www.policlinico.mi.it/technology-transfer-office

  www.policlinico.mi.it/tto4irccs