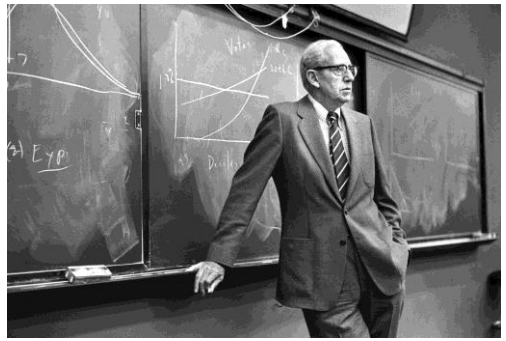
Protection and exploitation of research results through intellectual property rights: an introduction

03/07/2023
Human Technopole

Andrea *Frosini*

"*Any* **new idea** *– a* **new conceptualization** *of an existing* **problem**, *a new methodology, or the investigation of a new area – cannot be fully mastered,* **developed** *into the stage of a tentatively acceptable hypothesis, and possibly exposed to some* **empirical tests** *without a large expenditure of* **time**, **intelligence**, *and research* **resources**"



George J. Stigler – Nobel Lecture, 1983

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Why Intellectual Property? The Value of IP

- ✓ Is an **Essential business asset** in the knowledge economy
- ✓ Producing and **sharing technological information**, **fostering innovation**
- ✓ Increases **funding for innovative projects**: Without IP many innovative projects would not be profitable because anyone who wanted could simply copy the results
- ✓ Protects **small innovative firms**
- ✓ Needed to release IP into the **public domain** under **controlled conditions**

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A little bit of history…

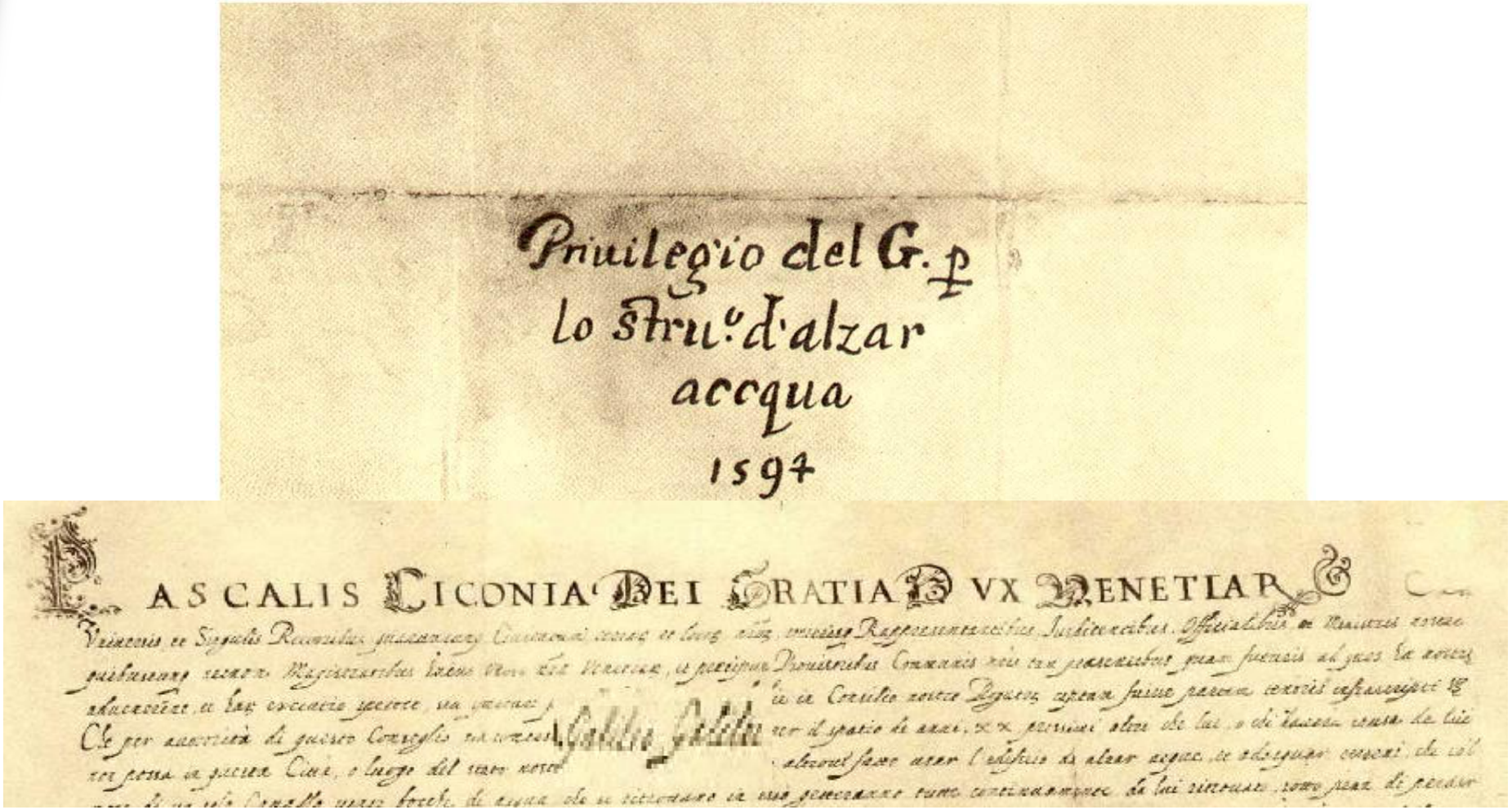
The first account of a "patent system"

In the ancient **Greek city of Sybaris** (destroyed in 510 BC), leaders decreed:

*"If a cook invents a delicious **new** dish, no other cook is to be **permitted to prepare** that dish for **one year**.*

*During this time, only the inventor shall reap the commercial profits from his dish. This will **motivate others** to work hard and compete in such inventions."*

In the Italian Renaissance we made a bright start…

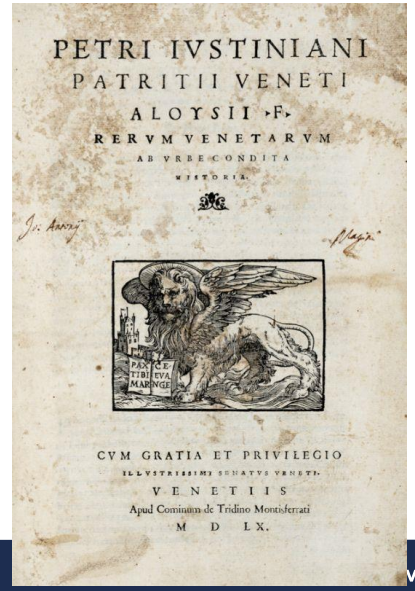


The Italian 15th century: «la Serenissima»

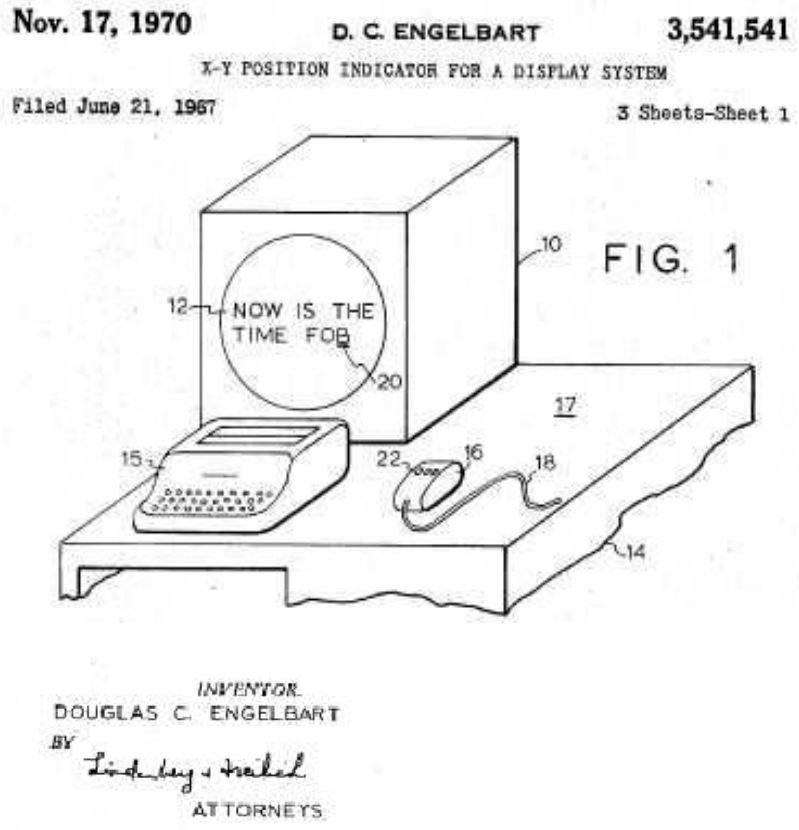
- Venice, by diminishing the power of the guilds, boasts examples of privileges since the early 15th century, in various fields:
  - mining techniques;
  - glass technology (Angelo Barovier, c. 1450);
  - mills for grinding;
  - tools for digging canals or raising water;
  - tools for fulling cloth (an example is the privilege granted in 1416 to a certain Franciscus Petri, a foreigner in Venice).

  The privilege often had value at a maximum distance of 10 miles from the city.

- The first literary privilege was granted to Marcantonio Cocci (the Sabellian) in 1486 for his work rerum venetarum libri: **copyright «cum gratia et privilegio»** was born
- In 1474, a statute was issued in Venice, regulating the matter
- 'New and suitable' are the characteristics required of the found



…up to Engelbart's Mouse (1970)


Nov. 17, 1970 D. C. ENGELBART 3,541,541

X-Y POSITION INDICATOR FOR A DISPLAY SYSTEM

Filed June 21, 1967 3 Sheets-Sheet 1

FIG. 1

INVENTOR.
DOUGLAS C. ENGELBART
BY
Lindenberg & Freibel
ATTORNEYS

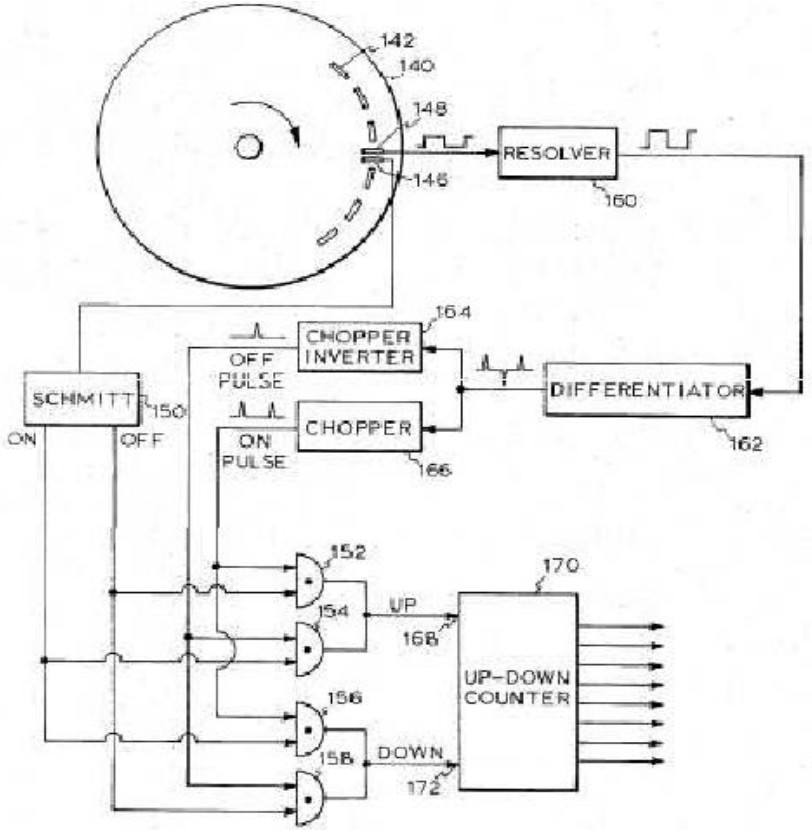


FIG. 7

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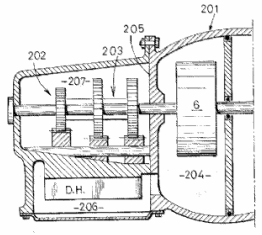
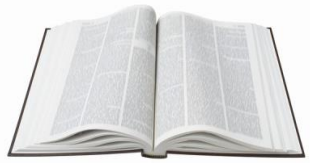
Overview on intellectual property

Legal Right	For what?	How?
Patent	New inventions	Filing and exam
Copyright	Original creations and artistic forms	It exists automatically
Trademark	Distinctive identification of products or services	Use and/or registration
Design	External appearance	Registration
Trade Secret	Valuable information unknown to the public	Keeping the secret





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Intellectual property in a mobile phone

Trademarks :

- ✓ Made by "Nokia"
- ✓ Product "N95"
- ✓ Software "Symbian", "Java"

Patents:

- ✓ Data processing methods
- ✓ Semiconductor circuits
- ✓ Chemical compounds
- ✓ …

Copyrights:

- ✓ Software
- ✓ Manual
- ✓ Ringtone …

Trade secrets:

???

Designs (some registered):

- ✓ Phone shape
- ✓ Key layout
- ✓ Three-dimensional key shape
- ✓ …

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Trademark

- ✓ A trademark is a **distinctive sign of goods/services: words, designs, figures, sounds** (and their combinations and/or colours)
- ✓ It is obtained by **registration** (exception: de facto trademarks, distinctive sign already in use)
- ✓ Has **unlimited duration**, renewable every 10 years (use obligation - lapses after 5 years of non-use)
- ✓ Has recognisable **territorial validity** depending on the competent office in the territory of interest (Italian, European - Community)
- ✓ It has sectoral limitation: **products/services are divided into product classes** (Nice Classification: classes 1 to 34 for products, classes 35 to 45 for services)
- ✓ Requirements: **Novelty, Distinctiveness, Lawfulness**

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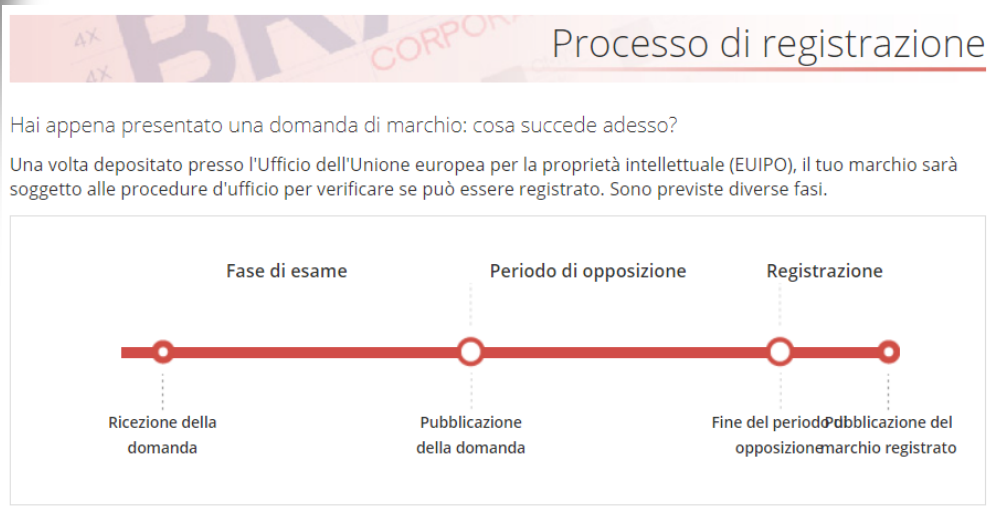
Community (EU) Trade Mark Registration

EUIPO
UFFICIO DELL'UNIONE EUROPEA
PER LA PROPRIETÀ INTELLETTUALE



- **Ownership:** Any natural person or company may own an EU trade mark. The data is made public and must be kept up-to-date so that there can be no doubt as to who is the owner of the trade mark
- **What an EU trade mark can be**: the trade mark must be a clear graphic representation.
- **Goods and services**: must be defined in such a way that others in the sector understand which goods and services your application refers to.

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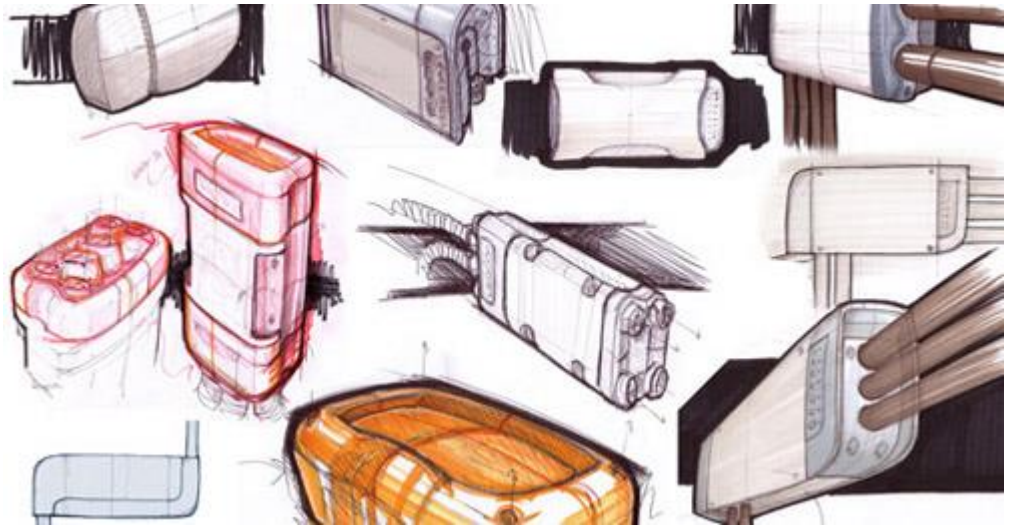
Industrial Design

- ✓ Has as its object the **shape**, **appearance and/or style** of objects (not functions -> patent)
- ✓ Is obtained by **registration**
- ✓ Has a duration of **25 years** (renewable every 5 years)
- ✓ Has a recognisable **territorial validity** depending on the competent office in the territory of interest (Italian, European, international)
- ✓ Design requirements: **novelty and individuality** (impression it creates compared to other registered designs)



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The utility model (Il modello di utilità)

- ✓ It represents an invention that is **effective, comfortable or convenient** in its application or use, and applies to machines, instruments, tools in general.
- ✓ Is protected by **registration**, without examination
- ✓ Has a maximum duration of **10 years**
- ✓ Exists **only in certain countries** (e.g. Italy, Germany)
- ✓ Utility model requirements follow those of a patent (**novelty, inventive step and industrial applicability**), assessed only in invalidity or infringement proceedings.

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Software as copyright

- ✓ Subject is the **software programme (including source codes)**
- ✓ Author is the owner or, in the case of an employee, the employer
- ✓ The **right arises from the moment of creation** and does not require registration
- ✓ Lasts **70 ye**ars after the death of the (last) author
- ✓ Requirements: **originality**
- ✓ Rights are granted to the owner of the software (and in general of artistic works): possibility of giving third parties the right to: translation/adaptation/adaptation, reproduction, distribution (licences)

DECRETO LEGISLATIVO29 dicembre 1992, n. 518 (Attuazione della direttiva 91/250/CEE relativa alla tutela giuridica dei programmi per elaboratore).
Art. 1 - «Sono altresì protetti i programmi per elaboratore come opere letterarie ai sensi della Convenzione di Berna sulla protezione delle opere letterarie ed artistiche…»

Patentable software

- ✓ Art 45 para. 3 CPI: Software (computer program) is not patentable as such (as is).
- ✓ It becomes **patentable if**:

- produces a **technical effect** (e.g. computer control of a machine)

- the patent concerns the **'logical structure'** of the software or system

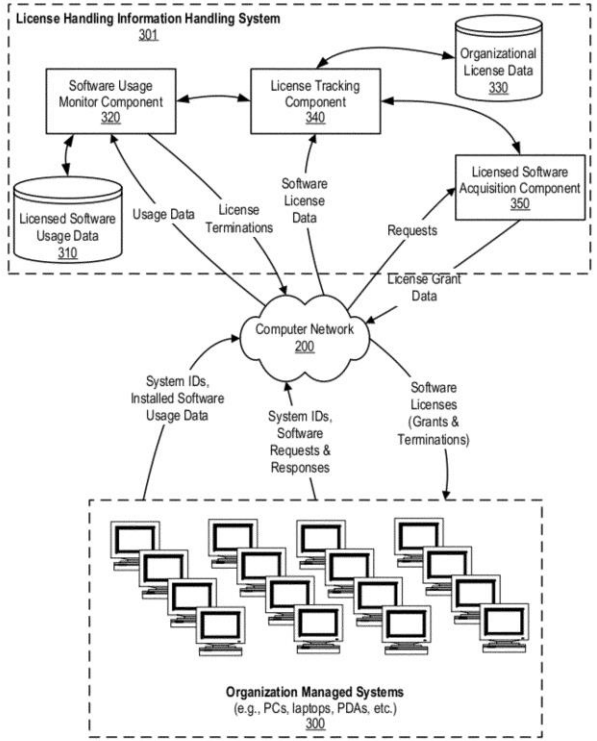

FIG. 3

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The Patent

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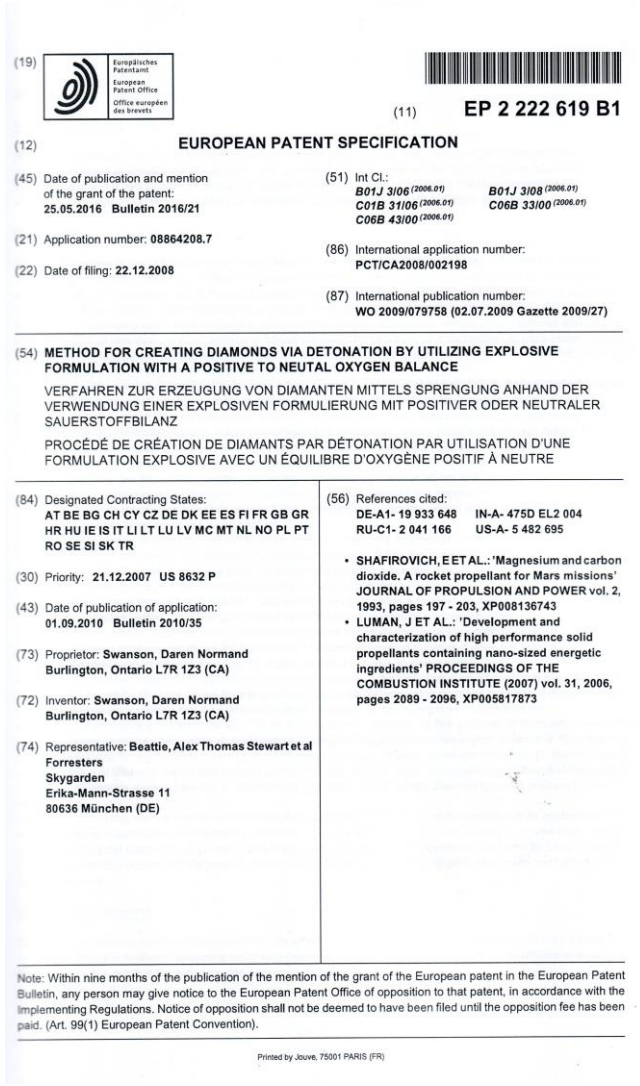
What is a patent?

A patent is a **title/document/intangible asset** that gives its owner (**proprietor/assignee**) the (**negative**) right to deny third parties to implement the invention for profit in the **territory** in which the patent is granted for a certain **period of time**.

The patent is an exception to the right to free competition in that it represents a contract between the inventor(s) and the state by virtue of which the exclusive right to use an invention is granted subject to its **clear and comprehensive description**



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

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(45) Date of publication and mention of the grant of the patent: 25.05.2016 Bulletin 2016/21

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(21) Application number: 08864208.7

(22) Date of filing: 22.12.2008

(86) International application number: PCT/CA2008/002198

(87) International publication number: WO 2009/079758 (02.07.2009 Gazette 2009/27)

(54) METHOD FOR CREATING DIAMONDS VIA DETONATION BY UTILIZING EXPLOSIVE FORMULATION WITH A POSITIVE TO NEUTAL OXYGEN BALANCE

VERFAHREN ZUR ERZEUGUNG VON DIAMANTEN MITTELS SPRENGUNG ANHAND DER VERWENDUNG EINER EXPLOSIVEN FORMULIERUNG MIT POSITIVER ODER NEUTRALER SAUERSTOFFBILANZ

PROCÉDÉ DE CRÉATION DE DIAMANTS PAR DÉTONATION PAR UTILISATION D'UNE FORMULATION EXPLOSIVE AVEC UN ÉQUILIBRE D'OXYGÈNE POSITIF À NEUTRE

(84) Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MT NL NO PL PT RO SE SI SK TR

(30) Priority: 21.12.2007 US 8632 P

(43) Date of publication of application: 01.09.2010 Bulletin 2010/35

(73) Proprietor: Swanson, Daren Normand Burlington, Ontario L7R 1Z3 (CA)

(72) Inventor: Swanson, Daren Normand Burlington, Ontario L7R 1Z3 (CA)

(74) Representative: Beattie, Alex Thomas Stewart et al Forresters Skygarden Erika-Mann-Strasse 11 80636 München (DE)

(56) References cited:
DE-A1- 19 933 648 IN-A- 475D EL2 004
RU-C1- 2 041 166 US-A- 5 482 695

- SHAFIROVICH, E ET AL.: 'Magnesium and carbon dioxide. A rocket propellant for Mars missions' JOURNAL OF PROPULSION AND POWER vol. 2, 1993, pages 197 - 203, XP008136743
- LUMAN, J ET AL.: 'Development and characterization of high performance solid propellants containing nano-sized energetic ingredients' PROCEEDINGS OF THE COMBUSTION INSTITUTE (2007) vol. 31, 2006, pages 2089 - 2096, XP005817873

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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Patent as a social contract

Applicants and patent owners are interested in benefiting from their inventions.
Owning a patent gives them the right to prevent others from making, using, offering for sale, selling or importing a product that infringes the patent, for a limited amount of time and the country for which the patent has been granted.
The exceptions to this are use of the patent for non-commercial purposes, including private use and academic research.

Society is interested in:
- Encouraging innovation so that better products can be made and better production methods can be used for the benefit of all;
- Protecting new and innovative companies so that they can compete with larger established companies, in order to maintain a competitive economy;
- Finding out the details of new inventions so that other engineers and scientists can further improve them;
- Promoting technology transfer, that is from universities to industry.

In return for this protection, applicants must reveal their inventions to the public, so others can build on them. This takes the form of publication of the application by the relevant patent office.

Patent system: an incentive for economic growth

- ✓ Enables patent holders to recoup their development costs
- ✓ Makes the latest technological knowledge available to the public
- ✓ Inspires further innovation
- ✓ Prevents duplication of R&D and expenditure
- ✓ Provides the legal basis for licensing and R&D co-operation
- ✓ Attracts venture capital funds and investors

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Why patenting an invention?

To ensure exclusive commercial exploitation of research results in order to recover the investment made for the research and development phases

A patent is a resource to be exploited!

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Some definitions for navigation

Science (abstract and a-facilitated knowledge), **technology** (the finalisation of scientific knowledge to useful ends and specific objectives), **technique** (the materialisation of science and technology into projects, machines and products)

Innovation is the implementation of the invention (new idea) in a new product or production process and the subsequent commercial exploitation

What are we talking about?

The result of research can be a discovery or an invention

Discoveries

If there are no foreseeable practical applications of the observed results (Basic Research)

Inventions

Whether there are foreseeable practical applications of the results obtained (Applied Research)

Examples of discoveries or inventions

DISCOVERY: the cell receptor through which a substance exerts a certain known effect; or the binding site to which a virus binds

INVENTION: the action on that receptor or site to prevent the formation of the complex that will cause the effect

DISCOVERY: the three-dimensional structure of an antigenic protein complex above the surface of a pathogenic micro-organism (molecular model)

INVENTION: On the basis of the molecular model identify and synthesise three-dimensional conformational antigenic sites for use as vaccines or diagnostic agents

What constitutes an invention?

- An invention always has a technical character, resulting from technical skills, and often from the application of a certain discovery to the solution of a technical problem.

"***technical solution to a technical problem***"

- Inventions often result from the application of a given discovery to the practical solution of a technical problem. In fact, an invention can be defined as the proposed 'technical solution to a technical problem'.

Requirements for patentability, Procedures thereof

Benefit the public

by making the detailed description of the invention available to everyone

Technical information available 18 months after filing

Benefit the owner

by preventing third parties from exploiting the invention for commercial purposes without authorisation

Patent valid for max. 20 years

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Patents: overview

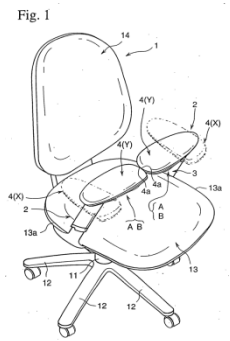
- ✓ Patents protect (technical) inventions
- ✓ Patent: A legal title which grants the holder the *exclusive* right to prevent others from making, using or offering for sale, selling or importing a product that infringes his/her patent without authorisation
- ✓ Principle of territoriality: Valid in countries for which the patent was granted
- ✓ Exist for a limited time (up to 20 years)
- ✓ Exceptions and limitations apply

What can be patented

Patents protect technical inventions which solve technical problems:

- Chemical substances, pharmaceuticals

- Processes, methods, uses



- Products, devices, systems

For an invention to be patentable, it must usually be

- ✓ **new** to the world (i.e. not available to the public anywhere in the world)
- ✓ **inventive** (i.e. not an "obvious" solution), and
- ✓ susceptible of **industrial application**

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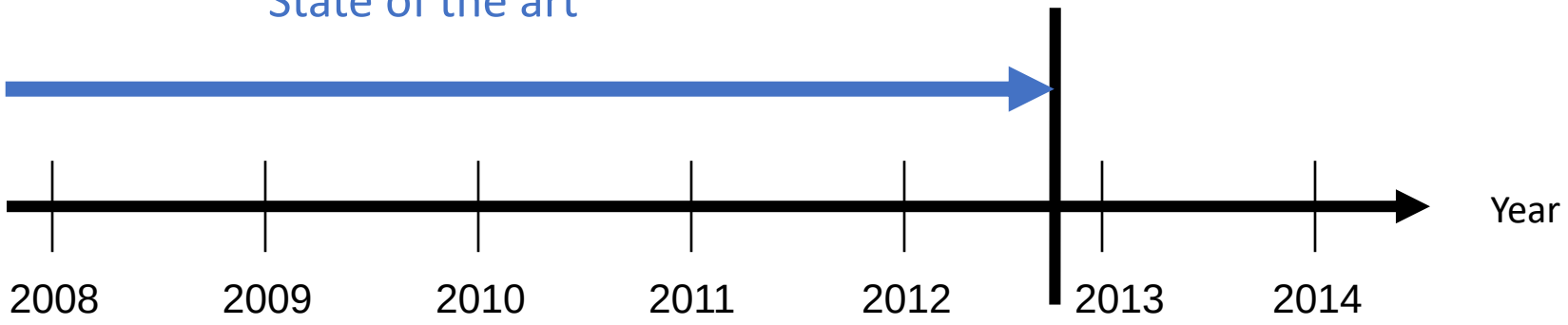
When is an invention "new"?

- When it is not part of the state of the art
- State of the art = everything made available to the public before the date of filing

State of the art

Patent application

Date of filing



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Do’s and don’ts for safeguarding novelty

Don’ts

- Do not publish any articles, press releases, conference presentations/ posters/ proceedings, lectures or blog posts, etc. before you file
- Do not sell any products incorporating the invention before you file

Do’s

- Sign a non-disclosure agreement (NDA)
- Seek professional advice at an early stage
- File before anyone else does!

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When is an invention "inventive"?

- ✓At the EPO, inventive step is assessed using the Problem-solution Approach
- ✓ When it is not obvious to the person skilled in the art in view of the state of the art
- ✓ The person skilled in the art
  - is a skilled practitioner in the relevant technical field
  - has access to the entire state of the art
  - is aware of general technical knowledge
  - is capable of routine work

Problem/solution approach

In the problem-and-solution approach, there are three main stages:

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(i) determining the "closest prior art",
(ii) establishing the "objective technical problem" to be solved, and
(iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

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When is an invention "inventive"?

In order to assess inventive step in an objective and predictable manner, the so-called "**problem-solution approach**" is applied in three main stages:
(i) determining the "closest prior art",
(ii) establishing the "objective technical problem" to be solved, and
(iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person

Inventive step assessment in the field of biotechnology

In the field of biotechnology, obviousness is considered at hand not only when results are clearly predictable, but also when there is a reasonable expectation of success. It is sufficient to establish that the skilled person would have followed the teaching of the prior art with a reasonable expectation of success. Likewise, a mere "try and see" attitude in light of the closest prior art does not necessarily render the solution inventive.
On the other hand, a "reasonable expectation of success" is not to be confused with the "hope to succeed". If researchers are aware when embarking on their research that, in order to reach a technical solution, they will need not only technical skill but also the ability to make the right non-trivial decisions along the way, this cannot be regarded as a "reasonable expectation of success", **experimental results make a difference!**

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Industrial Application

✓Can it be made or used in any kind of industry, including agriculture?

For a European patent to be granted an invention has to satisfy the requirement of being "susceptible of industrial application". This requirement is fulfilled if the invention can be made or used in any kind of industry, including agriculture.

Exceptions to patentability (I)

In most countries, patents are not granted for mere business methods or rules of games, or…

Under Art. 52 EPC
The following in particular shall not be regarded as inventions within the meaning of **paragraph 1**:
(a) **discoveries, scientific theories and mathematical methods**;
(b) **aesthetic creations**;
(c) schemes, rules and **methods for performing mental acts, playing games or doing business**, and **programs for computers**;
(d) **presentations of information**.
Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Exceptions to patentability (II)

… for methods of treatment, diagnostics and surgery of the human or animal body, or for inventions that are contrary to *ordre public* or morality, or for plant and animal varieties.

The human body and its elements

(1) 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.

(2) **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.

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

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 essentially biological processes for the production of plants or animals**; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for 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; hence, patents may be obtained for surgical, therapeutic or diagnostic instruments or apparatuses for use in such methods.

What can be patented according to EPC - the European Patent Office?

Inventions that are…

- ✓ **new** to the world (no previous public notice)
- ✓ **inventive** (i.e. not an "obvious" solution)
- ✓ susceptible of **industrial application**

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NOT Patentable:

- ✓ Mere ideas not reduced to practice
- ✓ Software as such
  (but algorithms that achieve technical results)
- ✓ Business methods
- ✓ Medical therapeutic, diagnostic, surgical methods
- ✓ Plant varieties

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Patent Unity and Divisionals

Article 82 EPC - Unity of invention

The European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

Article 76 EPC - Divisional applications

A European divisional application shall be filed directly with the European Patent Office in accordance with the Implementing Regulations. It may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed; in so far as this requirement is complied with, the divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall enjoy any right of priority.

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Inventor vs Assignee

Art.62 CPI *(Diritto morale): l'inventore*

- Il diritto di essere riconosciuto autore dell'invenzione può essere fatto valere dall'inventore e, dopo la sua morte, dal coniuge, e dai discendenti fino al secondo grado

The right to be credited as the author of the invention may be asserted by the inventor and, after his death, by his spouse, and descendants up to the second degree

…The Italian Exception

Art. 63 CPI *(Diritto patrimoniale): il titolare - Assignee*

1. I diritti nascenti dalle invenzioni industriali, tranne il diritto di essere riconosciuto autore, sono alienabili e trasmissibili.
2. Il diritto al brevetto per invenzione industriale spetta all'autore dell'invenzione e ai suoi aventi causa.

Rights arising from industrial inventions, except the right to be credited as an author, are alienable and transferable.

The right to a patent for an industrial invention belongs to the author of the invention and his successors in title.

The Italian Exception: professor's privilege

Art. 64 CPI *(Invenzioni dei dipendenti) - Employees*

1. Quando l'invenzione industriale è fatta nell'esecuzione o nell'adempimento di un contratto o di un rapporto di lavoro o d'impiego, in cui l'attività inventiva è prevista come oggetto del contratto o del rapporto e a tale scopo retribuita, **i diritti derivanti dall'invenzione stessa appartengono al datore di lavoro**, salvo il diritto spettante all'inventore di esserne riconosciuto autore.

2. Se non è prevista e stabilita una retribuzione, in compenso dell'attività inventiva e l'invenzione è fatta nell'esecuzione o nell'adempimento di un contratto o di un rapporto di lavoro o di impiego, i diritti derivanti dall'invenzione appartengono al datore di lavoro, ma all'inventore, salvo sempre il diritto di essere riconosciuto autore, spetta, qualora il datore di lavoro ottenga il brevetto, un **equo premio** per la determinazione del quale si terrà conto dell'importanza della protezione conferita all'invenzione dal brevetto, delle mansioni svolte e della retribuzione percepita dall'inventore, nonché del contributo che questi ha ricevuto dall'organizzazione del datore di lavoro.

The Italian Exception: professor's privilege

Art. 65 CPI *(Invenzioni dei ricercatori delle università e degli enti pubblici di ricerca) – University Employees*

In deroga all'articolo 64, quando il rapporto di lavoro intercorre con un'università o con una pubblica amministrazione avente tra i suoi scopi istituzionali finalità di ricerca, **il ricercatore è titolare esclusivo dei diritti** (***researchers own the rights***) derivanti dall'invenzione brevettabile di cui è autore.

Obblighi derivanti:

- ✓ Comunicare il deposito;
- ✓ Dare una quota dei proventi al proprio ente (30/50%).

Le disposizioni del presente articolo **non si applicano** nelle ipotesi di **ricerche finanziate**, in tutto o in parte, da soggetti privati, ovvero **realizzate nell'ambito di specifici progetti di ricerca finanziati da soggetti pubblici diversi dall'università**, ente o amministrazione di appartenenza del ricercatore.

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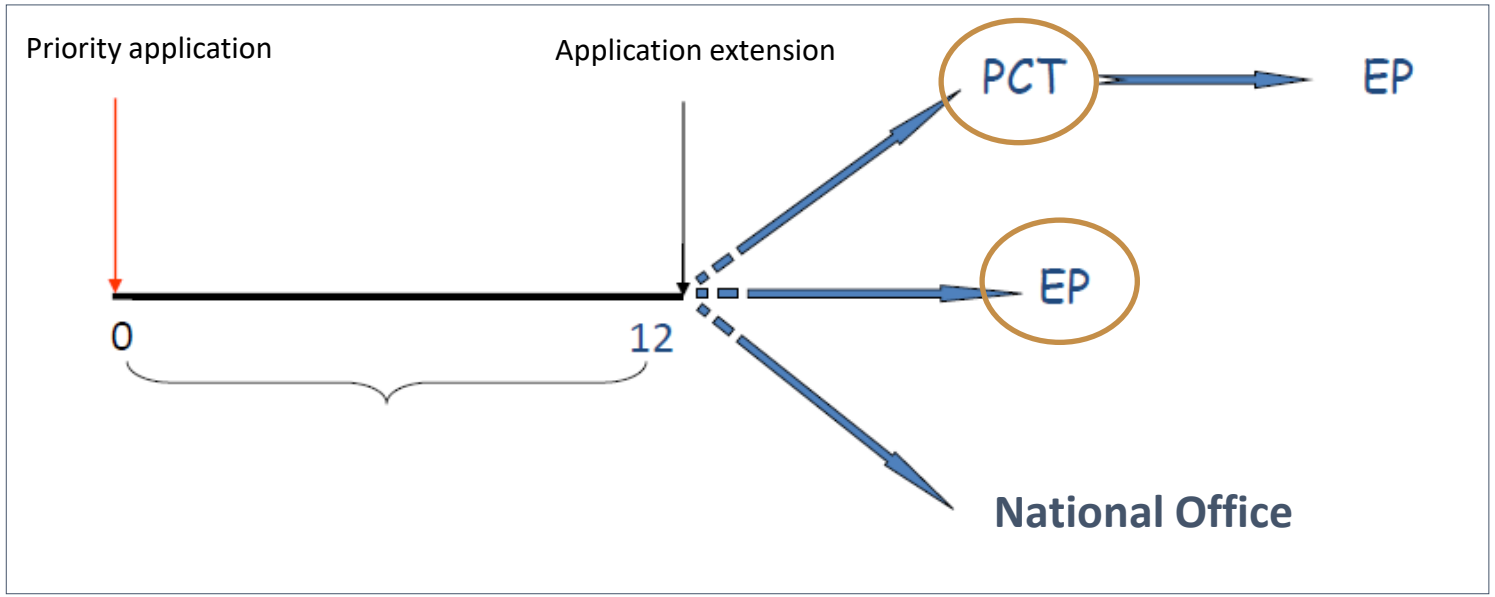
Routes to patenting

Route	National	European	International
Via	National offices	European Patent Office or national offices	International Bureau or European Patent Office or national offices
Valid in	One country	Up to 39 countries + one extension state + four validation states	Up to 156 countries
In brief	Applications are filed with the relevant national office and are valid for that state only	One single application in DE/EN/FR for all EPC contracting states. Same legal effects as national patents	Centralised international patent application procedure. After the international phase, applicants can choose to enter the national/regional phase in various states. No international patent

What's the law effetcs of a patent worldwide?

A patent provides the right to ***exclude other*** **from making, using, selling, offering for sale, or importing the patented invention for 20 years from the filing date**. Moreover for some patent (es. pharmaceutical product) there is supplementary protection certificate (SPC)

Patent filing Procedure



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European Patent Convention (EPC) and European Patent Office (EPO)

Today ... an area with some 700m inhabitants

39 European member states

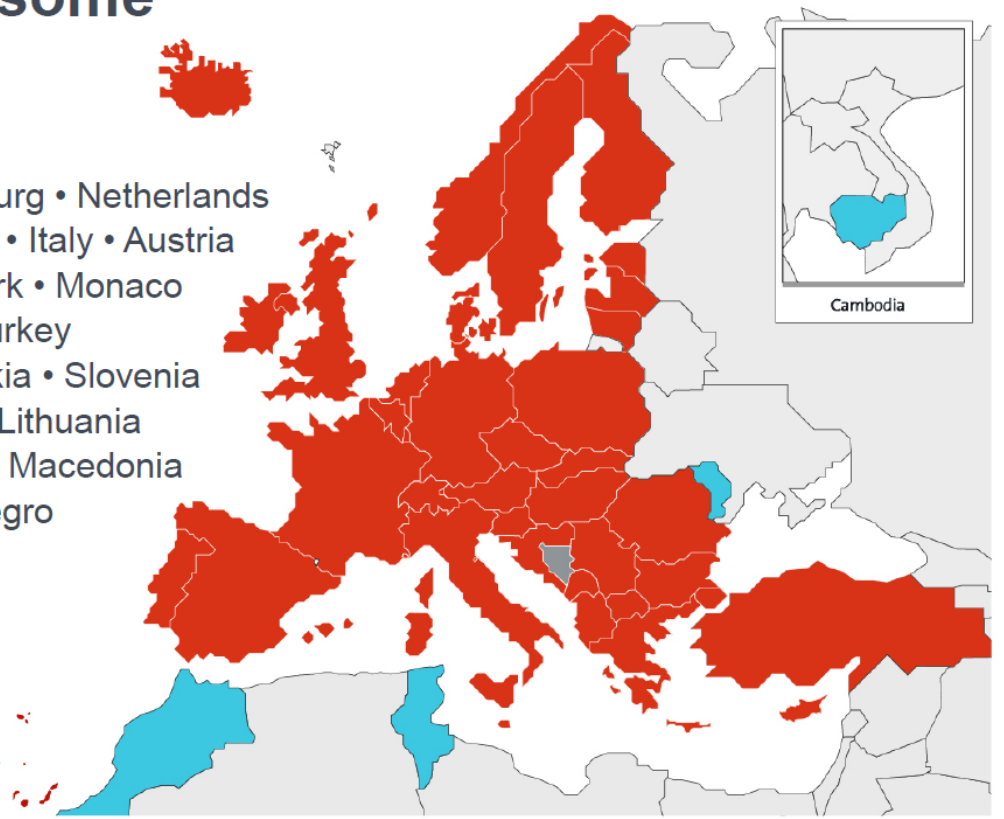
Belgium • Germany • France • Luxembourg • Netherlands
Switzerland • United Kingdom • Sweden • Italy • Austria
Liechtenstein • Greece • Spain • Denmark • Monaco
Portugal • Ireland • Finland • Cyprus • Turkey
Bulgaria • Czech Rep. • Estonia • Slovakia • Slovenia
Hungary • Romania • Poland • Iceland • Lithuania
Latvia • Malta • Croatia • Norway • North Macedonia
San Marino • Albania • Serbia • Montenegro

One European extension state

Bosnia and Herzegovina

Four validation states

Republic of Moldova • Morocco • Tunisia
Cambodia



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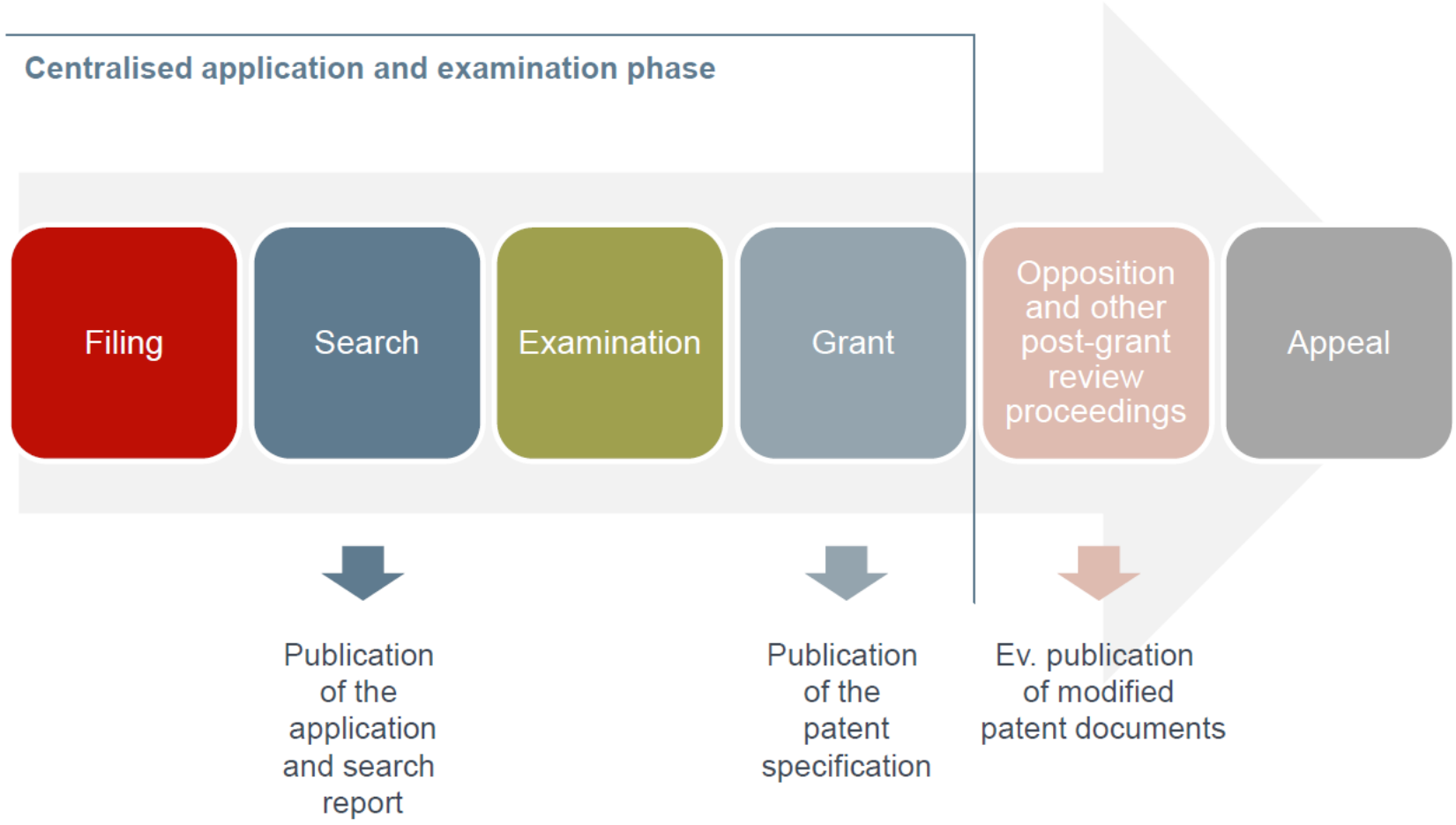
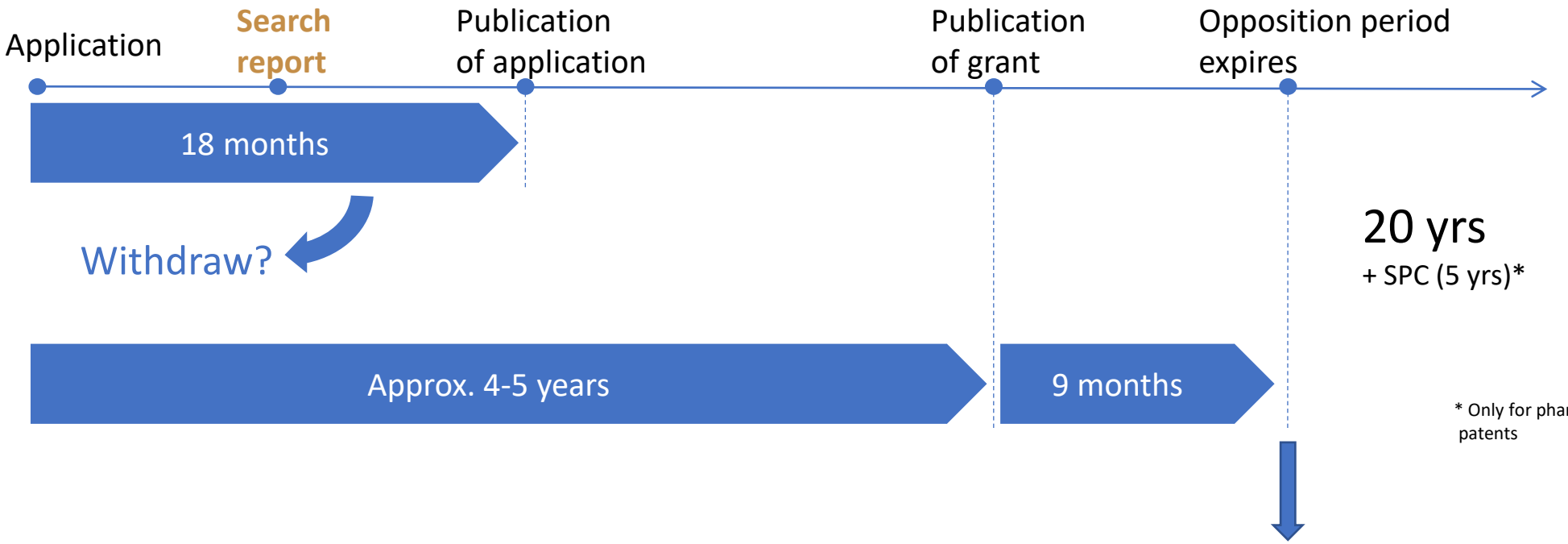
Basic steps in the European grant procedure

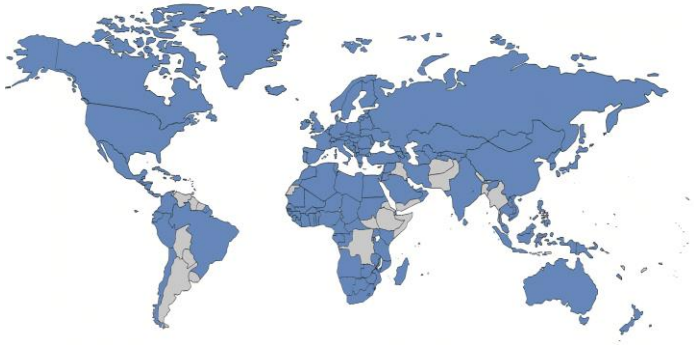


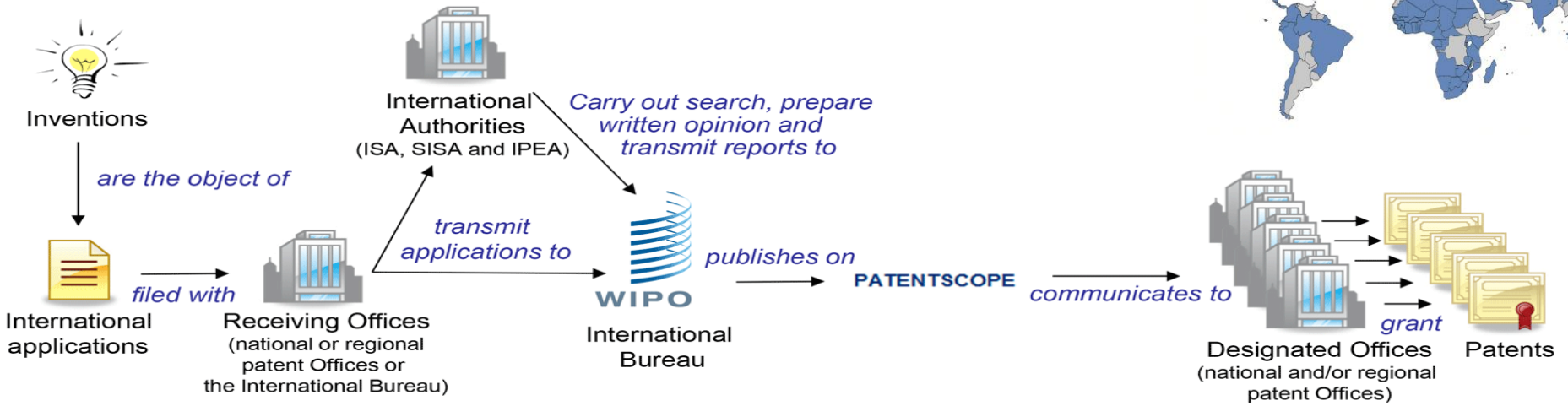

Application
Search report
Publication of application
Publication of grant
Opposition period expires
18 months
Withdraw?
Approx. 4-5 years
9 months
20 yrs
+ SPC (5 yrs)*
* Only for pharmaceutical patents
Legal effect (enforceability) of the patent

The Patent Cooperation Treaty (PCT)

The International Patent System (148 Countries)

To have up to 18 months more than if you had not used the PCT to reflect on the desirability of seeking protection in foreign countries





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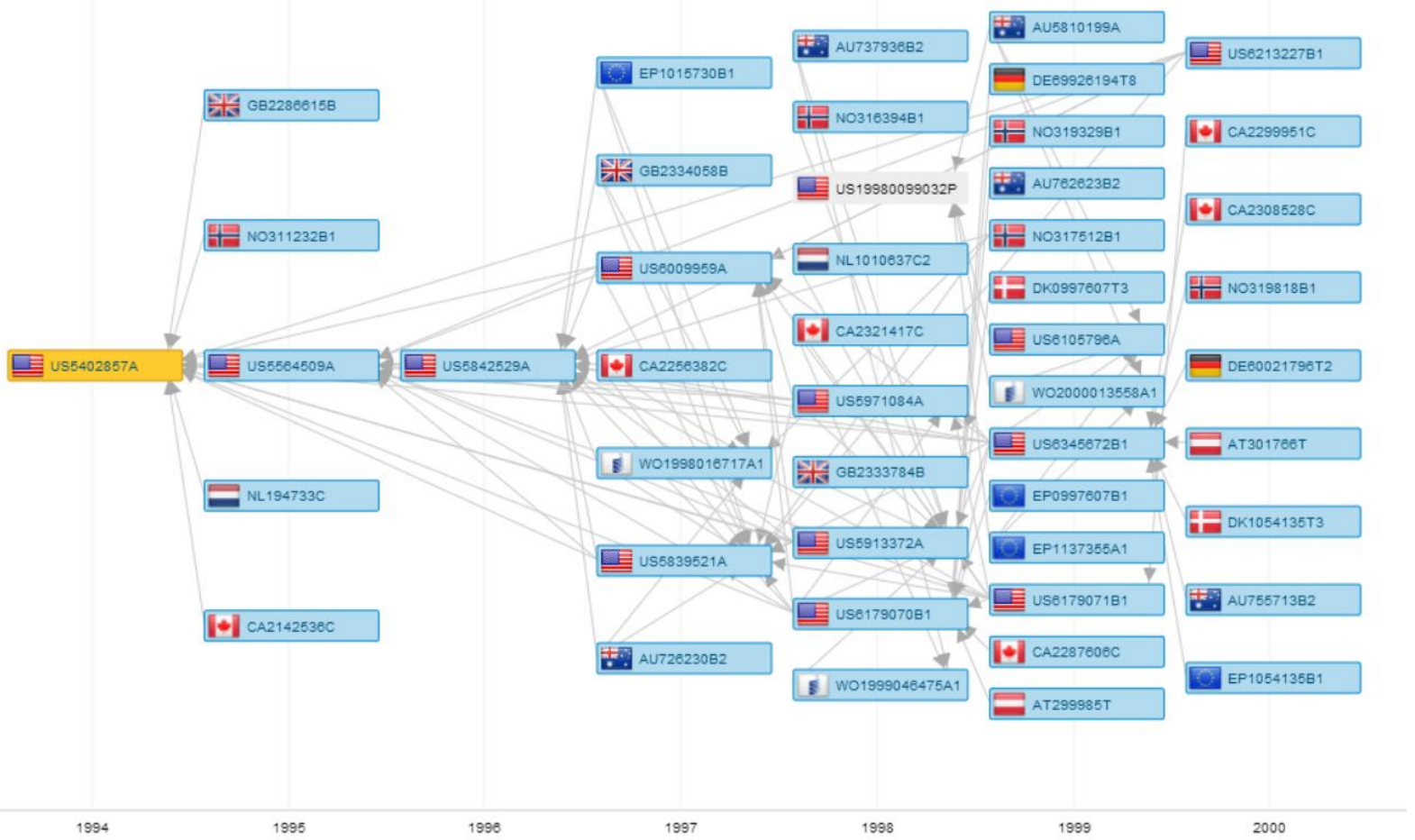
Patent Family

A patent family is a collection of patent applications covering the same or similar technical content.
The applications in a family are **related to each other through priority claims**.



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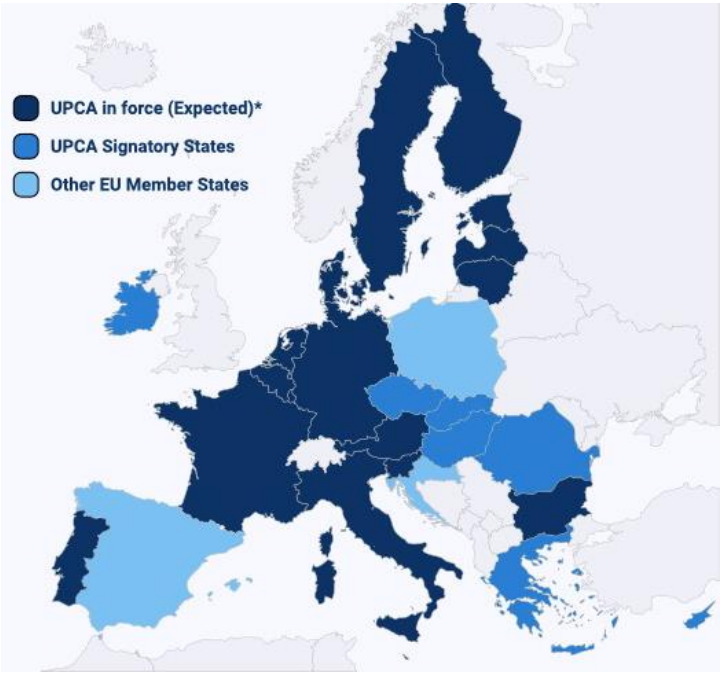
European **Unitary Patent** 'UP' (since June '23)

New: After EP Intention to Grant request of UP
Centralized maintenance @EPO (e.g., taxes and registrer)

Transitional period (1 June '23 - 31 May '30):
- In parallel with traditional EP and national patents
- Possibility of opt-out for EPs;
- Parallel jurisdiction of UPC and national courts on EP not subject to opt-out;
- Translations of claims into the other 2 EPO languages
- Applicable law for the UP is the law of the participating Member State in which (a) the applicant had a residence or principal place of business on the filing date; or (b) the applicant had a place of business on the filing date



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How a patent is structured

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

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

(12) **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**
Postfach 3255
CH-4002 Basel(CH)

(72) Inventor: **Mullis, Kary Banks**
447 Beloit Avenue
Kensington California 94708(US)

title, inventor, owner, filing date etc.

Bibliography

brief overview of the invention

Abstract

Drawings

EGRFvIII one copy (vIII)

```
CTG GAA GAA AAA AAA GGT AAC TAC GTT GTT ACC GAC CAC
L   E   E   K   K   G   N   Y   V   V   T   D   H
```

EGRFvIII three copies (vIII3x)

```
CTG GAA GAA AAA AAA GGT AAC TAC GTT GTT ACC GAC CAC tct ggt
  L   E   E   K   K   G   N   Y   V   V   T   D   H   S   G

CTG GAA GAA AAA AAA GGT AAC TAC GTT GTT ACC GAC CAC ggc tct
  L   E   E   K   K   G   N   Y   V   V   T   D   H   G   S
```

A description of the manner and process of making and using the invention in such **full**, **clear**, **concise** and exact terms as to ***enable any person skilled in the art to which the invention pertains to make and use the same***.

Description

Claims

Define the **legal protection conferred** by the patent for

- Products/Composition
- Processes/methods
- Uses

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Patent Description

The description shall: (a) specify the technical field to which the invention relates; (b) indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, draw up the European search report and examine the European patent application, and, preferably, cite the documents reflecting such art; (c) disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood, and state any advantageous effects of the invention with reference to the background art; (d) describe in detail at least one way of carrying out the invention claimed, using examples where appropriate and referring to the drawings, if any; (e) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable.

The applicant must describe their invention in the patent application so comprehensively and clearly that an expert (e.g. a competitor) could understand and implement it.

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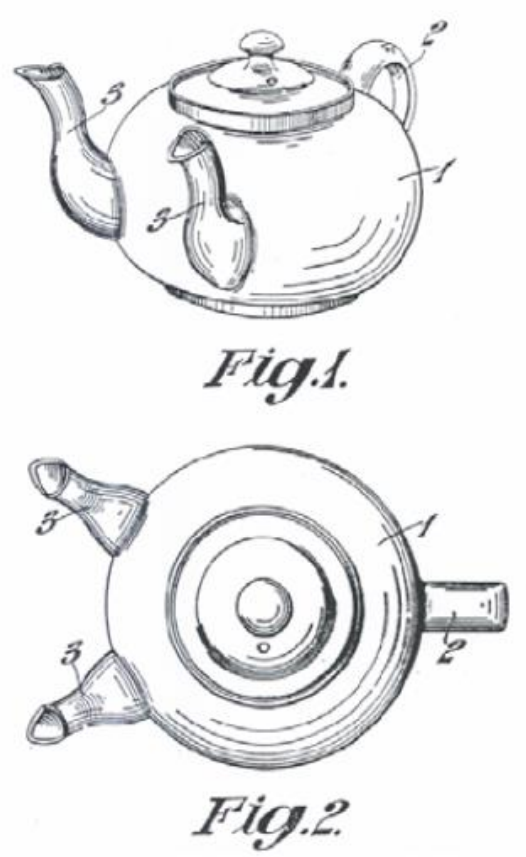
Structure of the description

- Prior art
  - *Teapot with one spout*
- Drawback of prior art
  - *Time-consuming*
- Problem to solve
  - *Reduce filling time*
- Solution
  - *Provide a second spout*
- Advantage of the invention
  - *The time needed to fill multiple cups is reduced*



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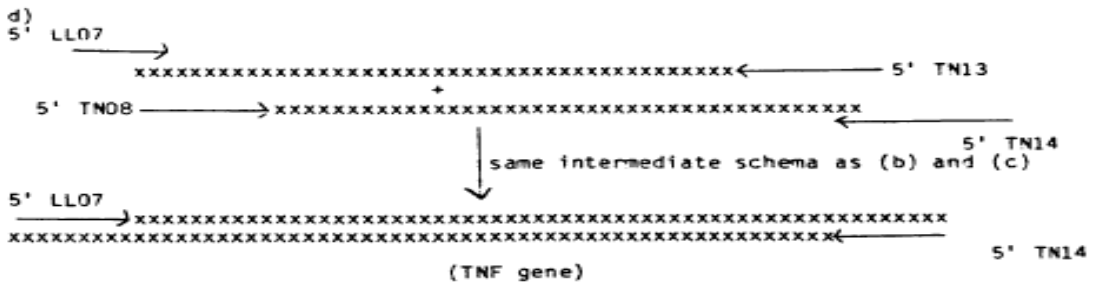


The cell line SC-1 (CTCC #0082) was deposited on March 19, 1985 with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland 20852 USA, with ATCC Accession No. CRL#8756.

In summary, the present invention is seen to provide a process for amplifying one or more specific nucleic acid sequences using a chain reaction in which primer extension products are produced which can subsequently act as templates for further primer extension reactions. The process is especially useful in detecting nucleic acid sequences which are initially present in only very small amounts.

It will be appreciated that the process of the present invention may be used for the amplification of any desired nucleic acid sequence. Examples of such sequences include human HLA, DQ, DR or DP-α and -β genes, N-ras oncogenes and TNF genes, or part or modified sequences thereof (e.g. using selected deletions or substitutions).

Claims

1. A process for exponentially amplifyIng at least one specific double-stranded nucleic acid sequence contained in a nucleic acid or a mixture of nucleic acids wherein each nucleic acid consists of two complementary strands, of equal or unequal length, which process comprises:
   (a) treating the strands with a molar excess of two oligonucleotide primers, one for each of the strands, under hybridizing conditions and in the presence of an inducing agent for polymerization and the different nucleotides, such that for each strand an extension product of the respective primer is synthesized which is complementary to the nucleic acid strand, wherein said primers are selected so that each is substantially complementary to one end of the sequence to be amplified on one of the strands such that an extension product can be synthesized from one primer which, when it is separated from its complement, can serve as a template for synthesis of an extension product of the other primer;
   (b) separating the primer extension products from the templates on which they were synthesized to produce single-stranded molecules;
   (c) treating the single-stranded molecules generated from step (b) with the primers of step (a) under hybridizing conditions and in the presence of an inducing agent for polymerisation and the different nucleotides such that a primer extension product is synthesized using each of the single-strands produced in step (b) as a template; and, if desired,
   (d) repeating steps (b) and (c) at least once; whereby the amount of the sequence to be amplified increases exponentially relative to the number of steps in which primer extension products are synthesized.

2. A process according to claim 1 wherein the sequence to be amplified is contained within a larger sequence.

3. A process according to claim 2 wherein (assuming 100% efficiency) after n steps in which primer extension products have been synthesized the amount of the sequence to be amplified which has been synthesized is 2^n-n-1 times greater than the starting amount thereof.

The Claims

Define the scope of the legal monopoly that the applicant is claiming

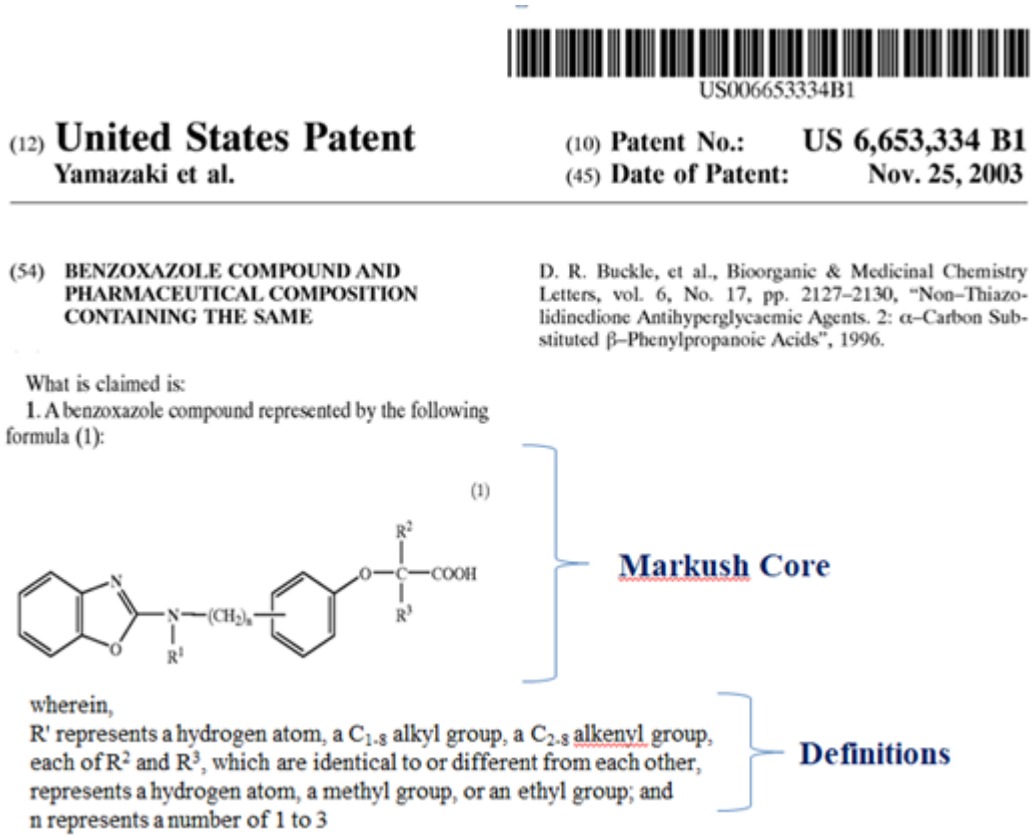
Independent claims, which stand on their own. Independent claims define the broadest protection and are also called main claims

Dependent claims (sub-claims), which depend on one or more claims and generally express particular and more specific embodiments of the invention

Claims of pharmaceutical patents

"Product"
- Molecule or family of molecules (Markush)
- Composition

"Activity"
- Process and Procedure
- 1 st use
- 2 nd use and new use



US006653334B1

(12) **United States Patent**
Yamazaki et al.

(10) **Patent No.: US 6,653,334 B1**
(45) **Date of Patent: Nov. 25, 2003**

(54) **BENZOXAZOLE COMPOUND AND PHARMACEUTICAL COMPOSITION CONTAINING THE SAME**

D. R. Buckle, et al., Bioorganic & Medicinal Chemistry Letters, vol. 6, No. 17, pp. 2127–2130, "Non–Thiazolidinedione Antihyperglycaemic Agents. 2: α–Carbon Substituted β–Phenylpropanoic Acids", 1996.

What is claimed is:

1. A benzoxazole compound represented by the following formula (1):

(1)

Markush Core

wherein,
R' represents a hydrogen atom, a C_{1-8} alkyl group, a C_{2-8} alkenyl group,
each of R^2 and R^3, which are identical to or different from each other,
represents a hydrogen atom, a methyl group, or an ethyl group; and
n represents a number of 1 to 3

Definitions

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Toward a Patent Strategy: a few hints…

Pros and Cons of the Patent System

Disvantages

- Patent Applications Are Published After 18-Months from filing date
- High costs for maintaining and defending patent
- Legal effect only after grant (4-5 years)

Advantages

- Attracting Investors and Funding
- The opportunity to own a market
- economic return on the investment made (es. licensing)
- Promote scientific and technological advance

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Building a Patent Strategy

Patent

- **What ?** — General vs. Specific Claims / Market Product Placement
- **When?** — Soon vs. Late / Publish or perish / Technology Turnover
- **Where?** — Cost vs. Market opportunity

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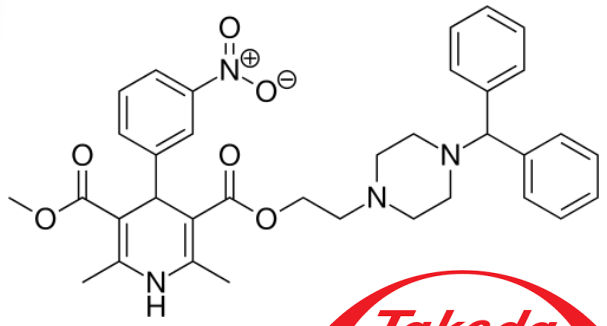
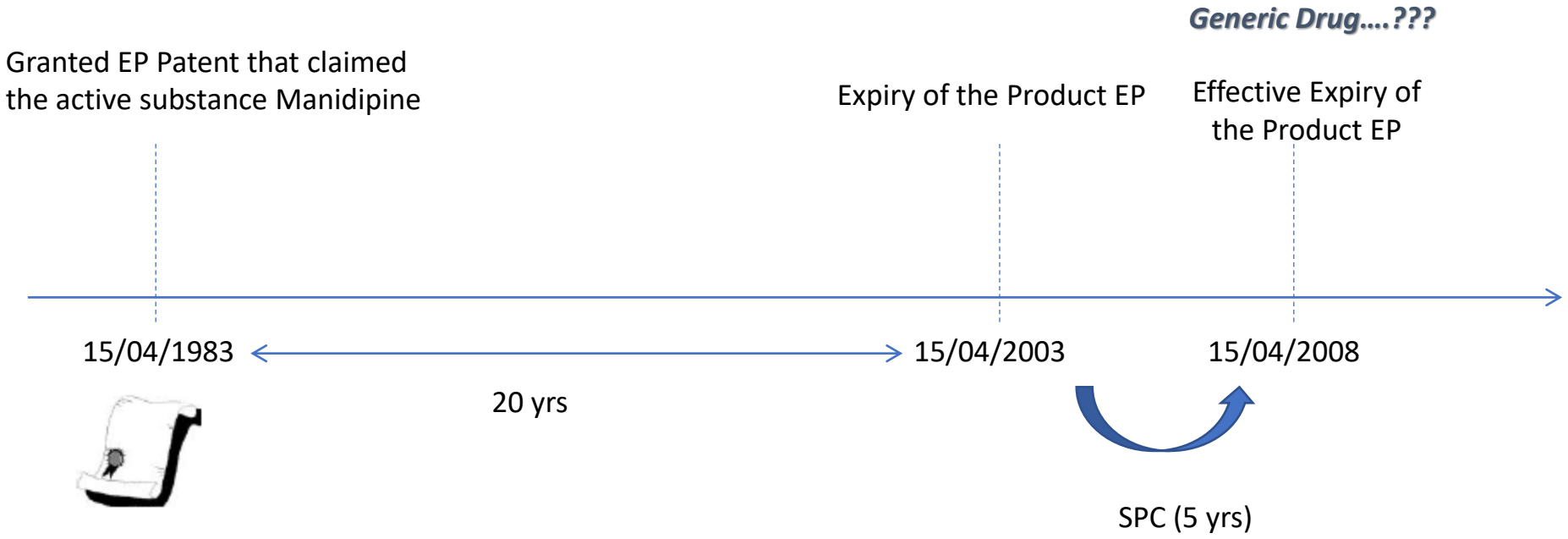
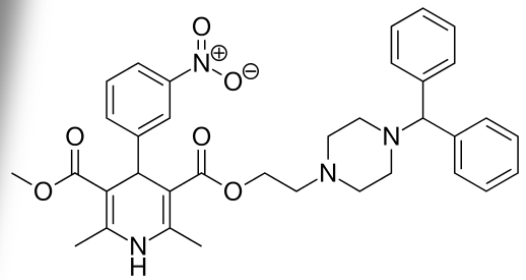


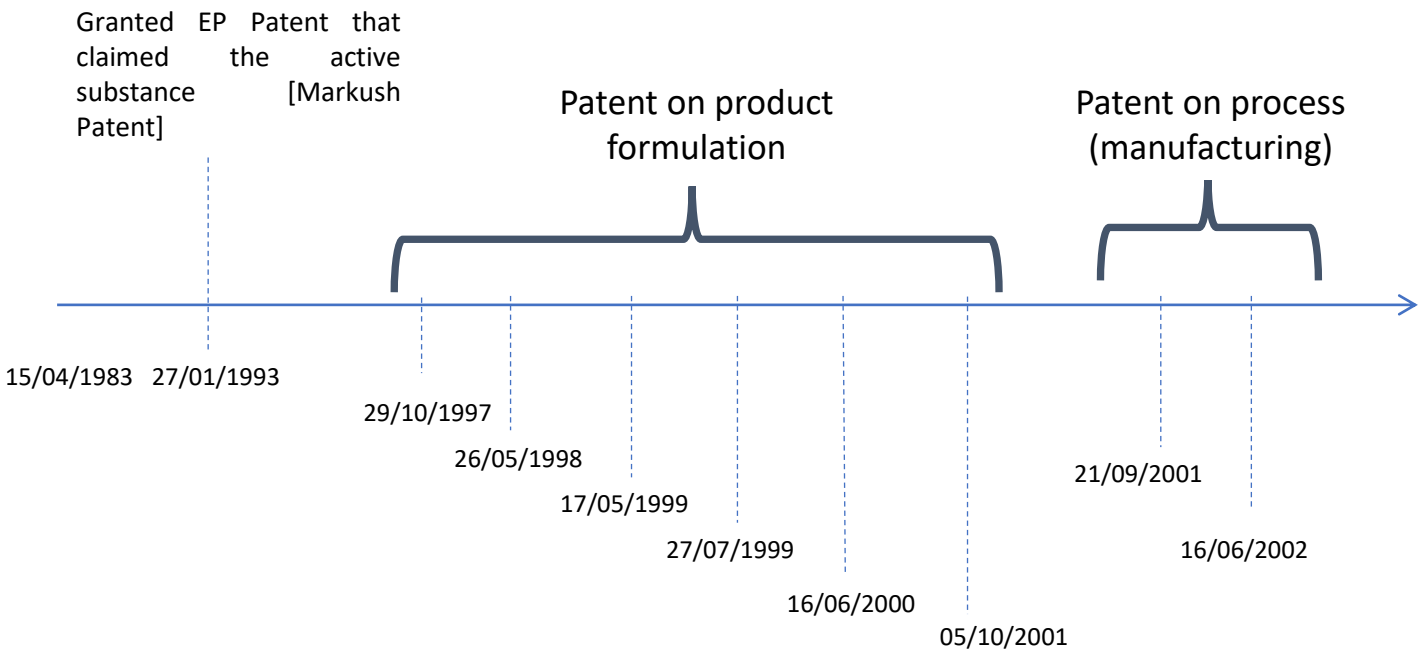
Manidipine is a calcium channel blocker (dihydropyridine type) that is used clinically as an antihypertensive





Manidipine chlorhydrate formulation

Lactose monohydrate
maize starch
Hydroxypropylcellulose HPC-L
Low-Substituted Hydroxypropyl Cellulose LH-31
magnesium stearate
riboflavin



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Trade Secret vs Patent: when to prefer secret

Advantages

is not limited in time;
does not imply any registration costs and has an immediate effect;
does not imply any disclosure of the invention to the public.

Disadvantages

others may be able to legally discover the secret and be thereafter entitled to use it ;
others may obtain patent protection for legally discovered secrets ;
is more difficult to enforce than a patent.

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How to take advantage of a patent?

- ✓ Selling a patent
- ✓ Licensing a patent
  - ***Exclusive licence***
  - ***Non-exclusive licence***
- ✓ Give rise to a joint venture / strategic alliances
- ✓ Rise funds / investments
- ✓ IPR asset as company reputation enhancer

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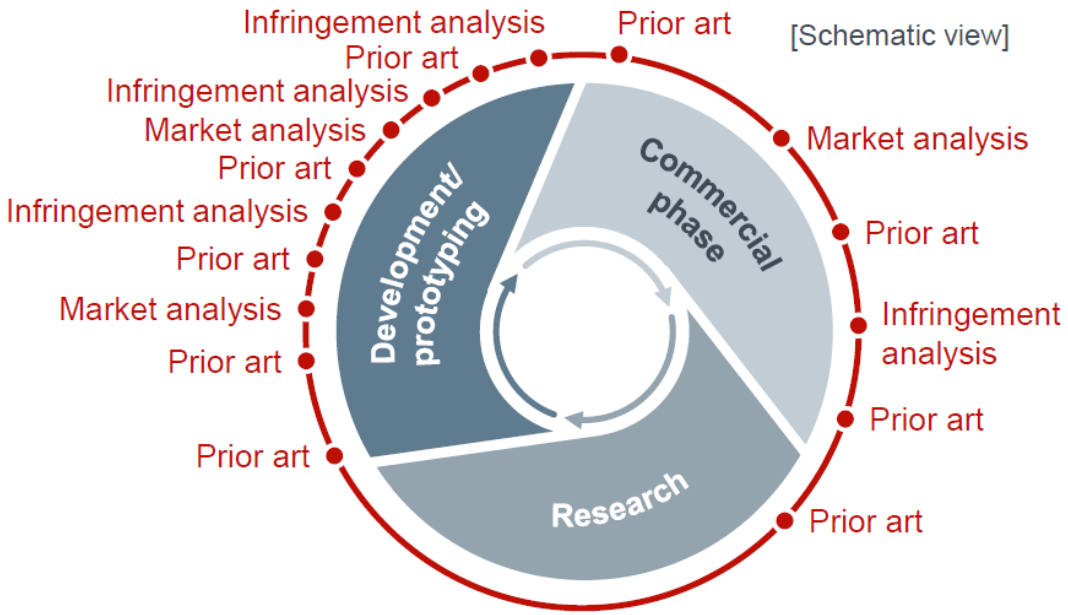
Patent information: a valuable source for innovation

Why patent information is so important



[Schematic view]

Patent information helps to

- find out **what technology already exists** and build on it
- **avoid duplication** of R&D expenditure
- check where an invention is protected
- **avoid infringing** other people's patent rights
- **keep track** of what others are doing
- **identify new partners**, e.g. for licensing
- **spot trends** in technology or the market

… and much more.

☑ Patent information supports informed decision-making at all stages of the innovation process!

☑ With that, patent information makes businesses more successful and supports innovation

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Why Searching: aims of Patent Searching

Landscape Search: to support development of business plan and are not intended for an opinion on patentability

Patentability or Novelty Search: to decide whether a patent application should be filed and to help draft claims that avoid the prior art

Prior Art Search: to draft claims that avoid the prior art and to focus the application on the novel and non-obvious features of the invention

Freedom to OperateFTO Search: to provide reassurance that you will not infringe the valid IP rights of another.

Infringment Search: to determine whether an enforceable patent claims the same subject matter as your concept or unpatented invention

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Source of Patent Information

Online (free) databases

Patent databases

Europäisches Patentamt
European Patent Office
Office européen des brevets
Espacenet
Patent search

ESPACENET (EPO)
https://worldwide.espacenet.com/

LENS.ORG

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National Offices:
US PTO http://patft.uspto.gov/
JPO https://www.jpo.go.jp/
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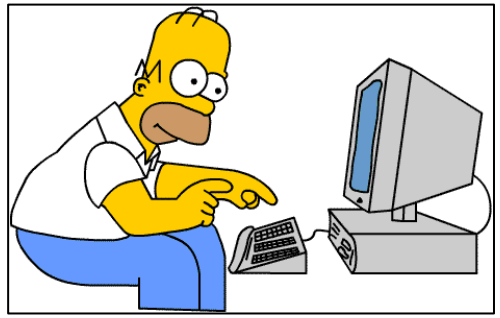

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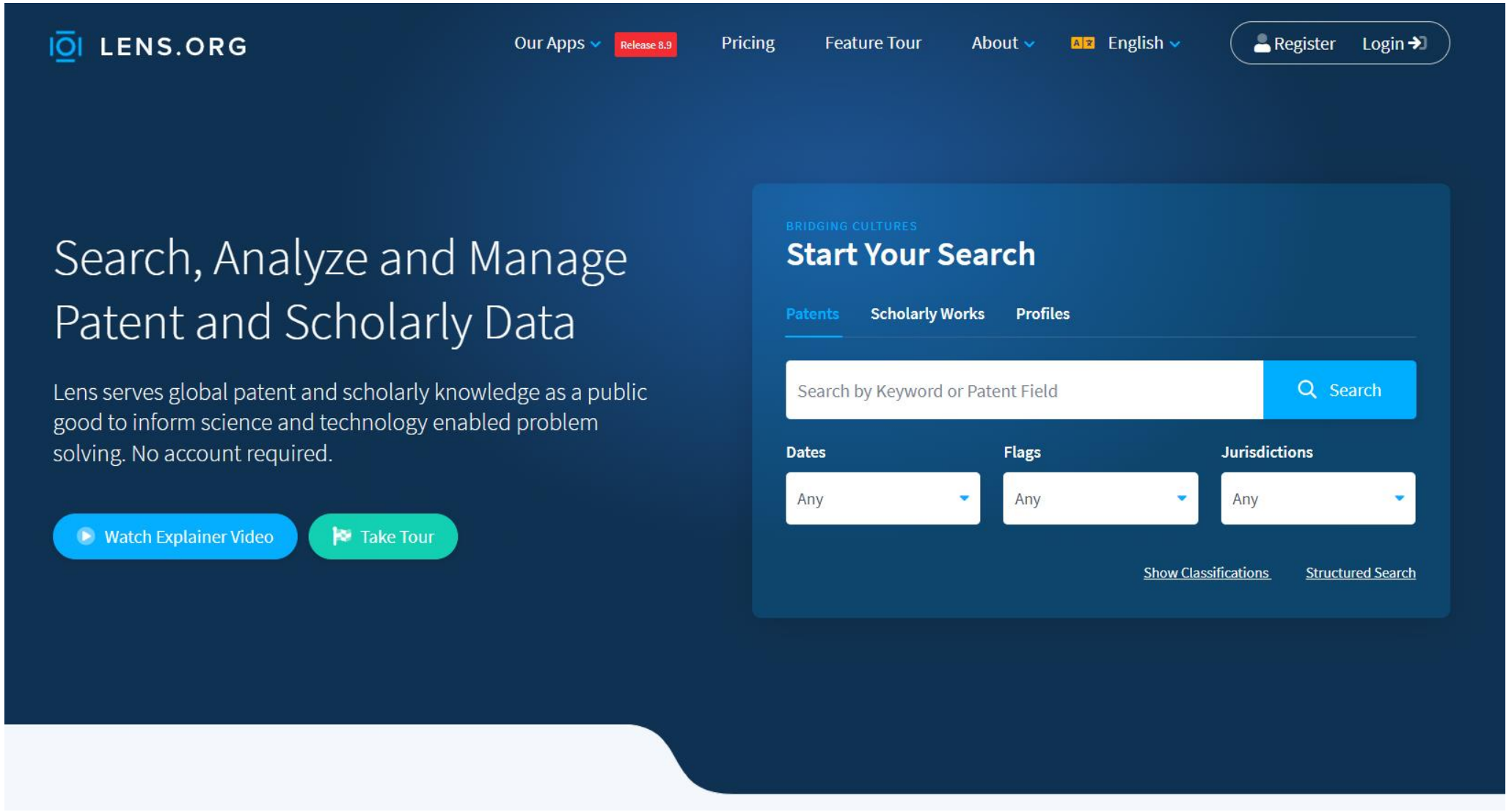
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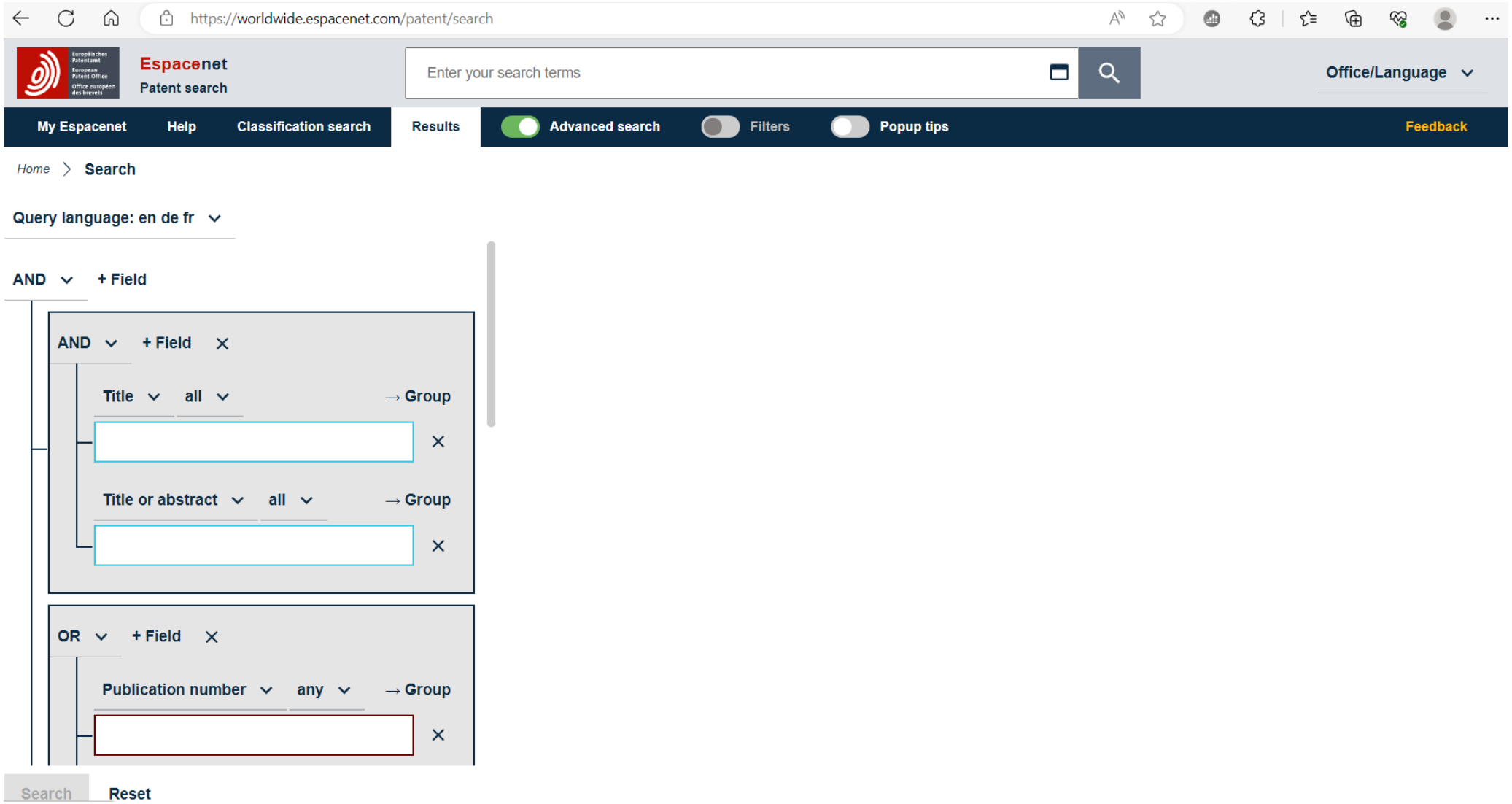
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Patent Classification - Categories: classes and groups

Espacenet

Cooperative Patent Classification

Symbol	Classification and description
A	HUMAN NECESSITIES
B	PERFORMING OPERATIONS; TRANSPORTING
C	CHEMISTRY; METALLURGY
D	TEXTILES; PAPER
E	FIXED CONSTRUCTIONS
F	MECHANICAL ENGINEERING; LIGHTING; HEATING; WEAPONS; BLASTING
G	PHYSICS
H	ELECTRICITY
Y	GENERAL TAGGING OF NEW TECHNOLOGICAL DEVELOPMENTS; GENERAL SPANNING OVER SEVERAL SECTIONS OF THE IPC; TECHNICAL SUBJECTS COLLECTIONS [XRACs] AND DIGESTS

Symbol	Classification and description
A	HUMAN NECESSITIES
	AGRICULTURE
A01	AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FIS
	FOODSTUFFS; TOBACCO
A21	BAKING; EDIBLE DOUGHS
A22	BUTCHERING; MEAT TREATMENT; PROCESSING POULTRY OR FISH
A23	FOODS OR FOODSTUFFS; THEIR TREATMENT, NOT COVERED BY OTHER C
A24	TOBACCO; CIGARS; CIGARETTES; SMOKERS' REQUISITES
	PERSONAL OR DOMESTIC ARTICLES
A41	WEARING APPAREL
A42	HEADWEAR
A43	FOOTWEAR
A44	HABERDASHERY; JEWELLERY
A45	HAND OR TRAVELLING ARTICLES
A46	BRUSHWARE
A47	FURNITURE (arrangements of seats for, or adaptations of seats to, vehicles B60N); SPICE MILLS; SUCTION CLEANERS IN GENERAL (ladders E06C)
	HEALTH; AMUSEMENT
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE
A62	LIFE-SAVING; FIRE-FIGHTING (ladders E06C)
A63	SPORTS; GAMES; AMUSEMENTS

	HEALTH; AMUSEMENT
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE
A61B	DIAGNOSIS; SURGERY; IDENTIFICATION (analysing biological material G01N, e.g. G01N 33/48; obtaining records using waves other than optical waves, in general G03B 42/00)
A61C	DENTISTRY; APPARATUS OR METHODS FOR ORAL OR DENTAL HYGIENE (non-driven toothbrushes A46B; {tongue scrapers A61B 17/24;} preparations for dentistry A61K 6/00; preparations for cleaning the teeth or mouth A61K 8/00, A61Q 11/00)
A61D	VETERINARY INSTRUMENTS, IMPLEMENTS, TOOLS, OR METHODS
A61F	FILTERS IMPLANTABLE INTO BLOOD VESSELS; PROSTHESES; DEVICES PROVIDING PATENCY TO, OR PREVENTING COLLAPSING OF, TUBULAR STRUCTURES OF THE BODY, E.G. STENTS; ORTHOPAEDIC, NURSING OR CONTRACEPTIVE DEVICES; FOMENTATION; TREATMENT OR PROTECTION OF EYES OR EARS; BANDAGES, DRESSINGS OR ABSORBENT PADS; FIRST-AID KITS (dental prosthetics A61C)
A61G	TRANSPORT OR ACCOMODATION FOR PATIENTS; OPERATING TABLES OR CHAIRS; CHAIRS FOR DENTISTRY; FUNERAL DEVICES (embalming corpses A01N 1/00; {chairs or beds in general A47C; walking aids A61H 3/00})
A61H	PHYSICAL THERAPY APPARATUS, e.g. DEVICES FOR LOCATING OR STIMULATING REFLEX POINTS IN THE BODY; ARTIFICIAL RESPIRATION; MASSAGE; BATHING DEVICES FOR SPECIAL THERAPEUTIC OR HYGIENIC PURPOSES OR SPECIFIC PARTS OF THE BODY (methods or devices enabling invalids to operate an apparatus or a device not forming part of the body A61F 4/00; electrotherapy, magnetotherapy, radiation therapy, ultrasound therapy A61N)
A61J	CONTAINERS SPECIALLY ADAPTED FOR MEDICAL OR PHARMACEUTICAL PURPOSES; DEVICES OR METHODS SPECIALLY ADAPTED FOR BRINGING PHARMACEUTICAL PRODUCTS INTO PARTICULAR PHYSICAL OR ADMINISTERING FORMS; DEVICES FOR ADMINISTERING FOOD OR MEDICINES ORALLY; BABY COMFORTERS; DEVICES FOR RECEIVING SPITTLE
A61K	PREPARATIONS FOR MEDICAL, DENTAL, OR TOILET PURPOSES (devices or methods specially adapted for bringing pharmaceutical products into particular physical or administering forms A61J 3/00; chemical aspects of, or use of materials for deodorisation of air, for disinfection or sterilisation, or for bandages, dressings, absorbent pads or surgical articles A61L; {compounds per se C01, C07, C08, C12N} ; soap compositions C11D; {micro-organisms per se C12N})
A61L	METHODS OR APPARATUS FOR STERILISING MATERIALS OR OBJECTS IN GENERAL; DISINFECTION, STERILISATION, OR DEODORISATION OF AIR; CHEMICAL ASPECTS OF BANDAGES, DRESSINGS, ABSORBENT PADS, OR SURGICAL ARTICLES; MATERIALS FOR BANDAGES, DRESSINGS, ABSORBENT PADS, OR SURGICAL ARTICLES (preservation of bodies or disinfecting characterised by the agent employed A01N; preserving, e.g. sterilising, food or foodstuffs A23; preparations for medical, dental or toilet purposes A61K; preparation of ozone C01B 13/10)
A61M	DEVICES FOR INTRODUCING MEDIA INTO, OR ONTO, THE BODY (introducing media into or onto the bodies of animals A61D 7/00; means for inserting tampons A61F 13/26; devices for administering food or medicines orally A61J; containers for collecting, storing or administering blood or medical fluids A61J 1/05); DEVICES FOR TRANSDUCING BODY MEDIA OR FOR TAKING MEDIA FROM THE BODY (surgery A61B; chemical aspects of surgical articles A61L); DEVICES FOR PRODUCING OR ENDING SLEEP OR STUPOR
A61N	ELECTROTHERAPY; MAGNETOTHERAPY; RADIATION THERAPY; ULTRASOUND THERAPY (measurement of bioelectric currents A61B; surgical instruments, devices or methods for transferring non-mechanical forms of energy to or from the body A61B 18/00; anaesthetic apparatus in general A61M; incandescent lamps H01K; infra-red radiators for heating H05B)
A61Q	SPECIFIC USE OF COSMETICS OR SIMILAR TOILET PREPARATIONS

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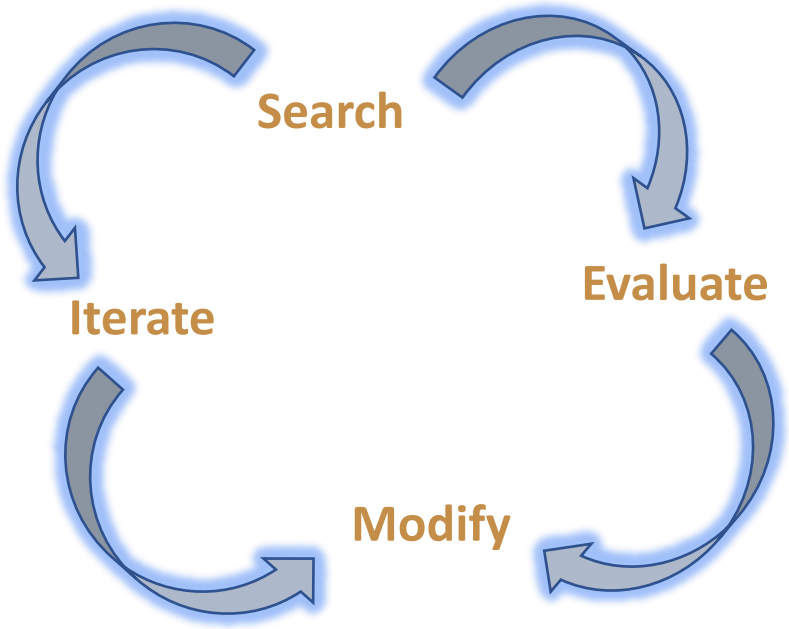
Patent Searching: an iterative process



- Keywords or classes
- Build Keyword and Synonym list
- "Concept search"
- Prepare offline (not in Espacenet document databases)
- Use Boolean Queries
- Use wild cards (* ?)
- Principle:
  - Find most appropriate classifications
  - Copy (into advanced search mask)
  - Refine search with keywords (do not repeat)
  - Other search terms

Patent offices publish the applications (with search report) 18 months after their earliest filing date.

Publication on scientific database es. Pubmed must be included in prior art search

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Example: outer membrane vesicles for cancer therapy

Keyword in Title/abstract: outer membrane vesicles cancer ⇒ 2 results

Keyword in Title/abstract: Out* membran* vesicl* tum* ⇒ 7 results

↓

- Out* membran* vesicl* canc*
- membran* vesicl* canc*
- membran* vesicl* neopl*
- membran* vesicl* tumor*
- bact* vesicl* canc*

Identify CPC class: A61K

Espacenet

HEALTH; AMUSEMENT

A61 MEDICAL OR VETERINARY SCIENCE; HYGIENE

A61K PREPARATIONS FOR MEDICAL, DENTAL, OR TOILET PURPOSES (devices or methods specially adapted for bringing pharmaceutical products into particular physical or administering forms A61J 3/00; chemical aspects of, or use of materials for deodorisation of air, for disinfection or sterilisation, or for bandages, dressings, absorbent pads or surgical articles A61L; {compounds per se C01, C07, C08, C12N} ; soap compositions C11D; {micro-organisms per se C12N})

Approximately **203** results found in the Worldwide database for:
outer membrane vesicles in the title or abstract AND **A61K** as the Cooperative Patent Classification

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Cooperative Patent Classification

Search for polypeptide antibody Search

View section **Index** | A | B | C | D | E | F | G | H | Y

A »

Symbol	Classification and description
A	HUMAN NECESSITIES
B	PERFORMING OPERATIONS; TRANSPORTING
C	CHEMISTRY; METALLURGY
D	TEXTILES; PAPER
E	FIXED CONSTRUCTIONS
F	MECHANICAL ENGINEERING; LIGHTING; HEATING; WEAPONS; BLASTING ENGINES OR PUMPS
G	PHYSICS
H	ELECTRICITY
Y	GENERAL TAGGING OF NEW TECHNOLOGICAL DEVELOPMENTS; GENERAL TAGGING OF CROSS-SECTIONAL TECHNOLOGIES SPANNING OVER SEVERAL SECTIONS OF THE IPC; TECHNICAL SUBJECTS COVERED BY FORMER USPC CROSS-REFERENCE ART COLLECTIONS [XRACs] AND DIGESTS

Cooperative Patent Classification

Search for polypeptide antibody Search

View section **Index** | A | B | C | D | E | F | G | H | Y

A »

Symbol	Classification and description
C07K 16/00	**Immunoglobulins [IGs], e.g. monoclonal or polyclonal antibodies** {(antibodies with enzymatic activity, e.g. abzymes C12N 9/0002)}
C07K 2317/00	**Immunoglobulins specific feautures**
A61K 39/00	**Medicinal preparations containing antigens or antibodies** (materials for immunoassay G01N 33/53)
C07K 14/00	**Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof**
G01N 33/00	**Investigating or analysing materials by specific methods not covered by the preceding groups**
C07K 2319/00	**Fusion polypeptide**
A61K 47/00	**Medicinal preparations characterised by the non-active ingredients used, e.g. carriers, inert additives**
A61K 45/00	**Medicinal preparations containing active ingredients not provided for in groups A61K 31/00 to A61K 41/00**
A61K 38/00	**Medicinal preparations containing peptides** (peptides containing beta-lactam rings A61K 31/00 ; cyclic dipeptides not having in their molecule any other peptide link than those which form their ring, e.g. piperazine-2,5-diones, A61K 31/00 ; ergot alkaloids of the cyclic peptide type A61K 31/48 ; containing macromolecular compounds having statistically distributed amino acid units A61K 31/74 ; medicinal preparations containing antigens or antibodies A61K 39/00 ; medicinal preparations characterised by the non-active ingredients, e.g. peptides as drug carriers, A61K 47/00)

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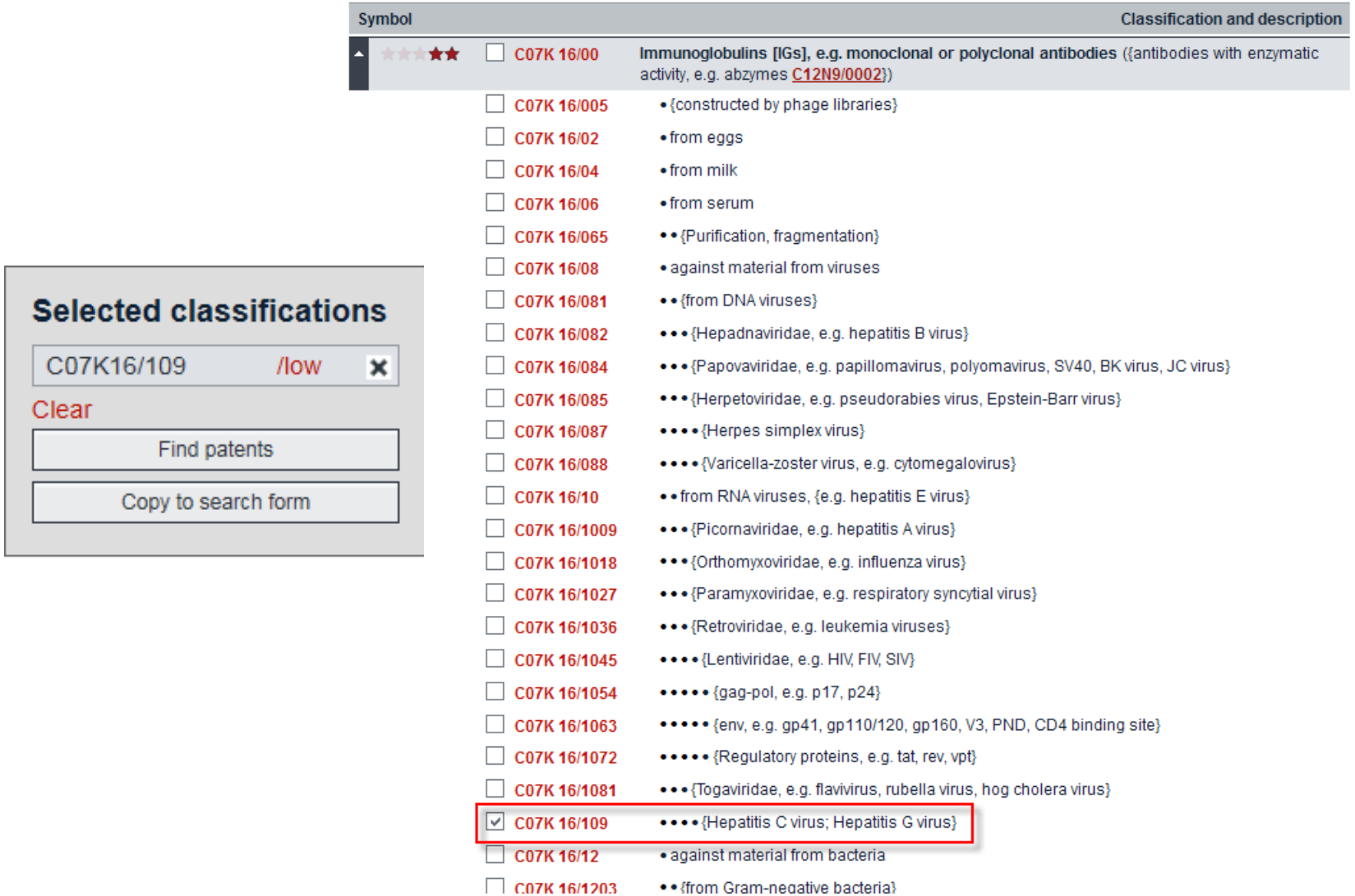
Symbol
Classification and description
C07K 16/00 Immunoglobulins [IGs], e.g. monoclonal or polyclonal antibodies ({antibodies with enzymatic activity, e.g. abzymes C12N9/0002})
C07K 16/005 •{constructed by phage libraries}
C07K 16/02 •from eggs
C07K 16/04 •from milk
C07K 16/06 •from serum
C07K 16/065 ••{Purification, fragmentation}
C07K 16/08 •against material from viruses
C07K 16/081 ••{from DNA viruses}
C07K 16/082 •••{Hepadnaviridae, e.g. hepatitis B virus}
C07K 16/084 •••{Papovaviridae, e.g. papillomavirus, polyomavirus, SV40, BK virus, JC virus}
C07K 16/085 •••{Herpetoviridae, e.g. pseudorabies virus, Epstein-Barr virus}
C07K 16/087 ••••{Herpes simplex virus}
C07K 16/088 ••••{Varicella-zoster virus, e.g. cytomegalovirus}
C07K 16/10 ••from RNA viruses, {e.g. hepatitis E virus}
C07K 16/1009 •••{Picornaviridae, e.g. hepatitis A virus}
C07K 16/1018 •••{Orthomyxoviridae, e.g. influenza virus}
C07K 16/1027 •••{Paramyxoviridae, e.g. respiratory syncytial virus}
C07K 16/1036 •••{Retroviridae, e.g. leukemia viruses}
C07K 16/1045 ••••{Lentiviridae, e.g. HIV, FIV, SIV}
C07K 16/1054 •••••{gag-pol, e.g. p17, p24}
C07K 16/1063 •••••{env, e.g. gp41, gp110/120, gp160, V3, PND, CD4 binding site}
C07K 16/1072 •••••{Regulatory proteins, e.g. tat, rev, vpt}
C07K 16/1081 •••{Togaviridae, e.g. flavivirus, rubella virus, hog cholera virus}
C07K 16/109 ••••{Hepatitis C virus; Hepatitis G virus}
C07K 16/12 •against material from bacteria
C07K 16/1203 ••{from Gram-negative bacteria}
Selected classifications
C07K16/109 /low
Clear
Find patents
Copy to search form

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Patent search

pn=EP3892295A1

Office/Language

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1.

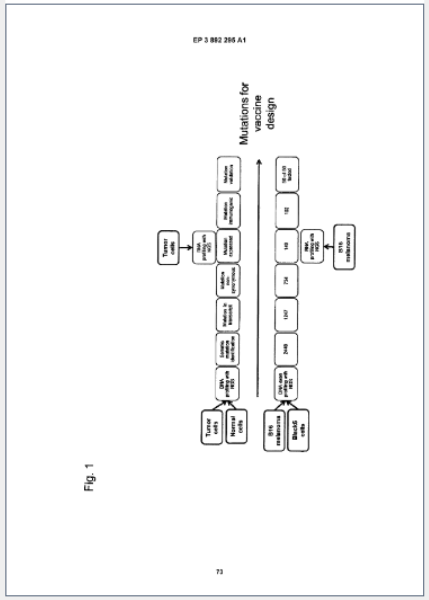
EP3892295A1 INDIVIDUALIZED VACCINES FOR CANCER

Available in | Patent Translate

Bibliographic data | Description | Claims | Drawings | Original document | Citations | Legal events | Patent family

Register ↗ | Global Dossier ↗

Applicants	BIONTECH SE [DE]; TRON TRANSLATIONALE ONKOLOGIE AN DER UNIV DER JOHANNES GUTENBERG UNIV MAINZ GEMEINNUETZIGE GMBH [DE] +
Inventors	SAHIN UGUR [DE]; KREITER SEBASTIAN [DE]; DIKEN MUSTAFA [DE]; DIEKMANN JAN [DE]; KOSLOWSKI MICHAEL [GR]; BRITTEN CEDRIK [DE]; CASTLE JOHN [DE]; LÖWER MARTIN [DE]; RENARD BERNHARD [DE]; OMOKOKO TANA [DE]; DE GRAAF JOHANNES HENDRIKUS [DE] +
Classifications	
IPC	***G16B20/20; G16B20/40; G16B20/50; A61K39/00; A61P35/00; C12Q1/68; G01N33/50;***
CPC	**A61K39/0011 (EP,US); A61P35/00 (EP); C12Q1/6886 (EP); G16B20/00 (EP); G16B20/20 (EP,US); G16B20/40 (EP,US); G16B20/50 (EP,US); G16B40/00 (EP);** C12Q2600/156 (EP);
Priorities	EP12723117A·2012-05-23; EP18199105A·2012-05-23; EP2011002576W·2011-05-24; EP2012000006W·2012-01-02; EP2012002209W·2012-05-23
Application	EP21168360A·2012-05-23
Publication	EP3892295A1·2021-10-13
Published as	**DK3473267T3; EP2714071A2; EP2714071B1; EP3473267A1; EP3473267B1; EP3892295A1; EP3892295B1; HRP20191535T1; ME03498B;**



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European register: a valuable source of useful documents

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EP3473267
European procedure
EP About this file
EP Legal status
EP Federated register
EP Event history
EP Citations
EP Patent family
EP All documents

Quick help

- What is displayed in the "Lapse during opposition" section?
- Why are the Unitary Patent (UP) panel views greyed out?
- Why is there a blue icon in the designated contracting states section?
- What does UPC mean?
- Why do I see the "Opt-out from the exclusive competence of the UPC" section, even if an opt-out has not been sent or received?
- What happens if I click the ST36 button?
- What kind of information can be found if I click on the "Show history" button?
- What kind of information can be found under "Status"?
- What do the digits in square brackets refer to?
- What does N/P stand for?
- What does the letter in square brackets stand for in the "Documents cited" part?

EP About this file: EP3473267

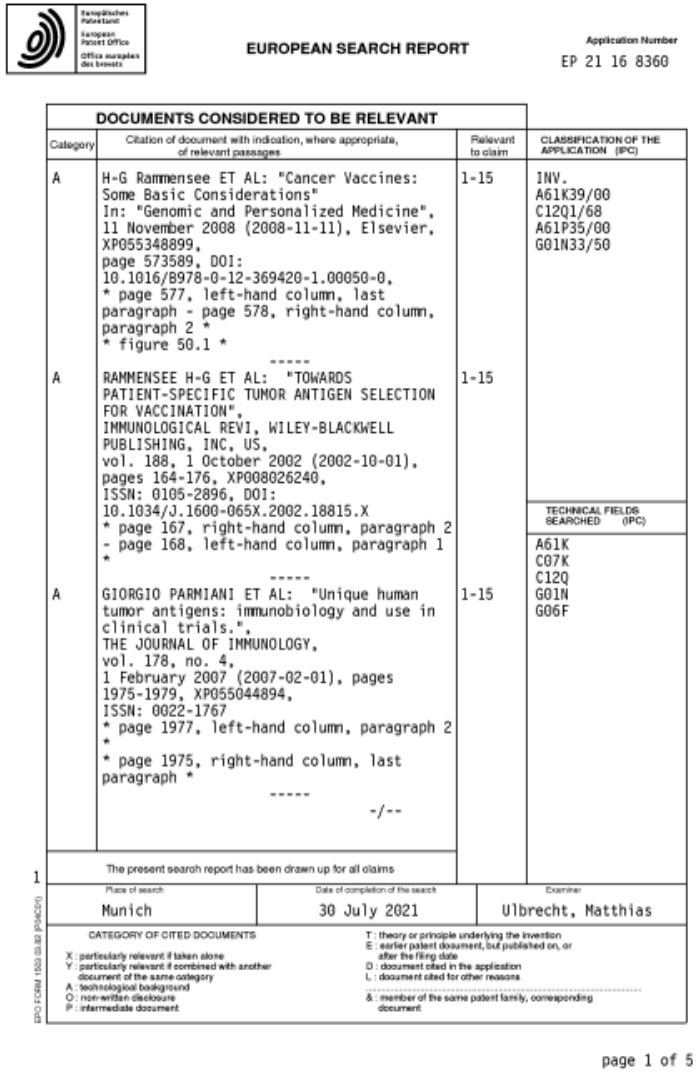
Refine search | ST36 | Show history | Espacenet | Submit observations | Report error | Print

EP3473267 - INDIVIDUALIZED VACCINES FOR CANCER [Right-click to bookmark this link]

Status	The patent has been granted *Status updated on 06.08.2021* *Database last updated on 28.06.2023*	
Most recent event	24.02.2023	New entry: Date of oral proceedings
Applicant(s)	For all designated states BioNTech SE An der Goldgrube 12 55131 Mainz / DE	
	For all designated states TRON - Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg- Universität Mainz gemeinnützige GmbH Freiligrathstrasse 12 55131 Mainz / DE	
	[2021/38]	
Inventor(s)	01 / SAHIN, Ugur Philipp-von-Zabern-Platz 1 55116 Mainz / DE	
	02 / KREITER, Sebastian Niklas-Vogt-Strasse 3 55131 Mainz / DE	
	03 / DIKEN, Mustafa Im Hasenstock 2 55130 Mainz / DE	
	04 / DIEKMANN, Jan Pfannenstiel 27 55270 Ober-Olm / DE	

☐	30.01.2019	Search started	Search / examination	1
☐	24.01.2019	Letter which had not been notified	Search / examination	4
☐	22.01.2019	(Electronic) Receipt	Search / examination	1
☐	22.01.2019	Letter concerning the inventor	Search / examination	2
☐	02.01.2019	Invitation to indicate correct address of inventor	Search / examination	1
☐	02.01.2019	Invitation to indicate correct address of inventor	Search / examination	1
☐	19.12.2018	Priority search results copy provided by EPO	Search / examination	11
☐	18.12.2018	Letter which had not been notified	Search / examination	4
☐	18.12.2018	Letter which had not been notified	Search / examination	4
☐	14.12.2018	(Electronic) Receipt	Search / examination	1
☐	14.12.2018	(Partial) description filed in response to formal objections	Search / examination	5
☐	14.12.2018	Reply to the invitation to remedy deficiencies	Search / examination	2
☐	24.10.2018	Deficiencies in application documents - annex B	Search / examination	3
☐	08.10.2018	Abstract	Search / examination	1
☐	08.10.2018	Acknowledgement of receipt of electronic submission of the request for grant of a European patent	Search / examination	2
☐	08.10.2018	Claims	Search / examination	3
☐	08.10.2018	Sequence listing	Search / examination	-
☐	08.10.2018	Description	Search / examination	122
☐	08.10.2018	Designation of inventor	Search / examination	3
☐	08.10.2018	Drawings	Search / examination	25
☐	08.10.2018	Request for grant of a European patent	Search / examination	5
☐	02.01.2013	Priority document (electronically transmitted)	Search / examination	143
☐	02.01.2013	Priority document (electronically transmitted)	Search / examination	87

European Search Report __&__ European Search Opinion



Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPEAN SEARCH REPORT

Application Number
EP 21 16 8360

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	H-G Rammensee ET AL: "Cancer Vaccines: Some Basic Considerations" In: "Genomic and Personalized Medicine", 11 November 2008 (2008-11-11), Elsevier, XP055348899, page 573589, DOI: 10.1016/B978-0-12-369420-1.00050-0, * page 577, left-hand column, last paragraph - page 578, right-hand column, paragraph 2 * * figure 50.1 *	1-15	INV. A61K39/00 C12Q1/68 A61P35/00 G01N33/50
A	RAMMENSEE H-G ET AL: "TOWARDS PATIENT-SPECIFIC TUMOR ANTIGEN SELECTION FOR VACCINATION", IMMUNOLOGICAL REVI, WILEY-BLACKWELL PUBLISHING, INC, US, vol. 188, 1 October 2002 (2002-10-01), pages 164-176, XP008026240, ISSN: 0105-2896, DOI: 10.1034/J.1600-065X.2002.18815.X * page 167, right-hand column, paragraph 2 - page 168, left-hand column, paragraph 1 *	1-15	TECHNICAL FIELDS SEARCHED (IPC) A61K C07K C12Q G01N G06F
A	GIORGIO PARMIANI ET AL: "Unique human tumor antigens: immunobiology and use in clinical trials.", THE JOURNAL OF IMMUNOLOGY, vol. 178, no. 4, 1 February 2007 (2007-02-01), pages 1975-1979, XP055044894, ISSN: 0022-1767 * page 1977, left-hand column, paragraph 2 * * page 1975, right-hand column, last paragraph *	1-15	

-/--

1 The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	30 July 2021	Ulbrecht, Matthias

CATEGORY OF CITED DOCUMENTS
X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons
& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

page 1 of 5

Datum Date Date: cf Form 1507 | Blatt Sheet Feuille: 1 | Anmelde-Nr: Application No: Demande n°: 21 168 360.2

The examination is being carried out on the **following application documents**

Description, Pages

1-96, 98, 100-122 as originally filed

97, 97a-97c, 99 filed in electronic form on 10-05-2021

Sequence listings, SEQ ID NO

1-39 as originally filed

Claims, Numbers

1-15 as originally filed

Drawings, Sheets

1/25-25/25 as originally filed

1 *Cited documents*

D1 H-G Rammensee ET AL: "Cancer Vaccines: Some Basic Considerations" In: "Genomic and Personalized Medicine", 11 November 2008 (2008-11-11), Elsevier, XP055348899, page 573589, DOI: 10.1016/B978-0-12-369420-1.00050-0,

D11 UGUR SAHIN ET AL: "Personalized RNA mutanome vaccines mobilize poly-specific therapeutic immunity against cancer", NATURE, SPRINGER NATURE PUBLISHING AG, LONDON , vol. 547, no. 7662 13 July 2017 (2017-07-13), pages 222-226, XP002780019, ISSN: 1476-4687, DOI: 10.1038/NATURE23003 Retrieved from the Internet: URL:https://www.nature.com/articles/nature23003.pdf [retrieved on 2017-07-05]

EPO Form 1703 01.91 TRI

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Cited Documents Categories

CATEGORY OF CITED DOCUMENTS

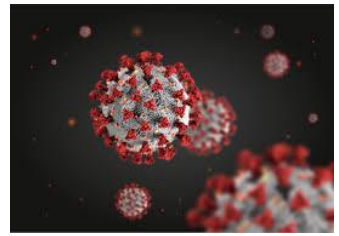
X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

Exploiting research results

BioNTech AG - Pfizer



BioNTech AG is a fully integrated biotech company which combines all building blocks of immunotherapies under one roof. Through its diversified technology platforms and in-house diagnostics and manufacturing units BioNTech is strategically very well positioned to implement its lab-bench-to-market strategy.

BioNTech is pioneering disruptive technologies ranging from individualized mRNA based medicines through innovative Chimeric Antigen Receptors and T-cell Receptor-based products and novel antibody checkpoint immunomodulators.

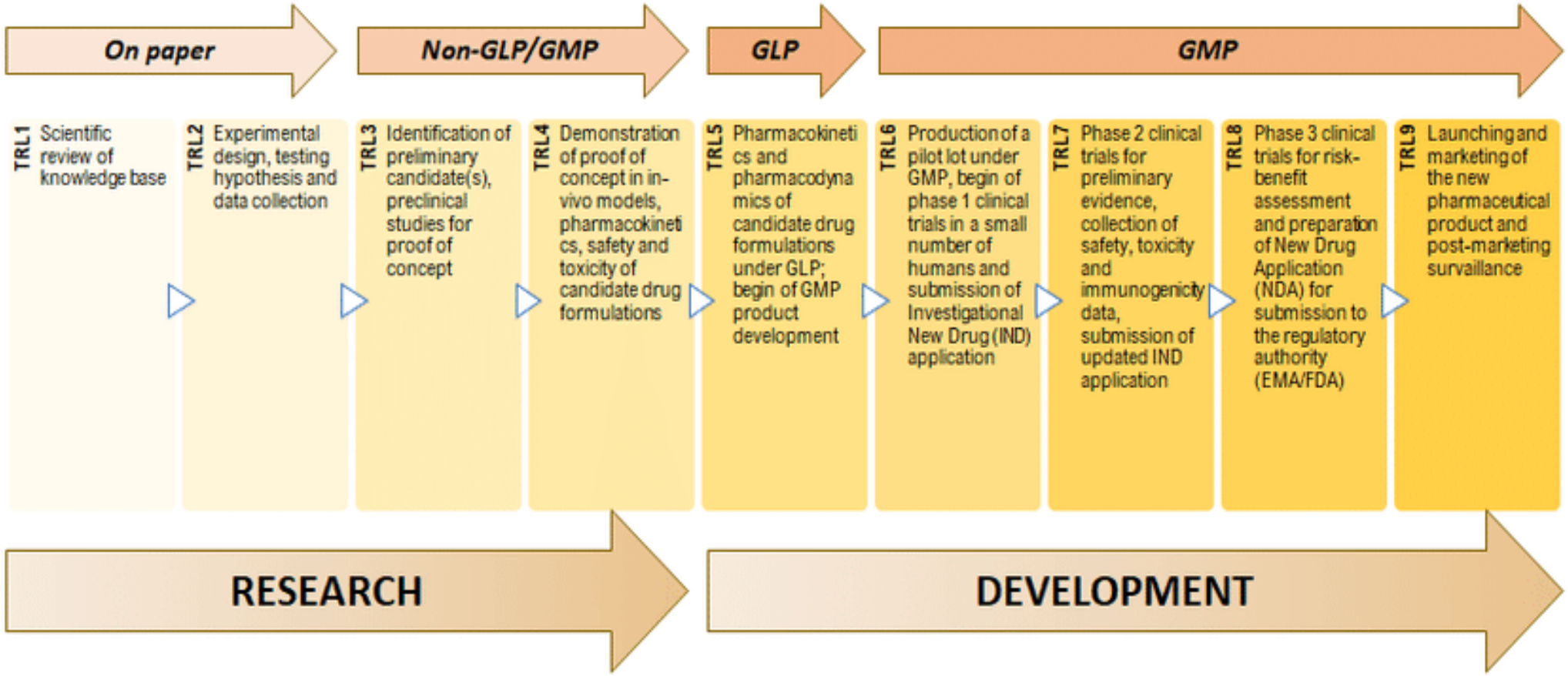
Founded in 2008 as a spin-off of the prestigious Johannes-Gutenberg University in Mainz, BioNTech has grown rapidly to 400 employees with the majority of these engaged in the laboratories. Our research headquarters are based in Mainz, Germany.

BioNTech is privately held and shareholders include the MIG Fonds and the Strüngmann Family Office, with the Strüngmann Family Office as the majority shareholder.

The 'odd couple a traditional American Big Pharma giant and a new German biotech spin-off company.

The decisive move, apart from the innovative technology to make the vaccine, was to ally the marketing and distribution of billions of doses

Technology readiness levels (TRL) in life sciences technologies



Most technologies developed in public research are at a TRL level of 2-3 !

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Technology Transfer Agreements

Technology Transfer agreements

- ✓ Confidentiality Agreement (CDA o **NDA**)
- ✓ Animal/(biological)- Material Transfer Agreement (ATA/**MTA**/BMTA)
- ✓ Collaboration Agreements es. Coresearch, Codevelopment
- ✓ Sponsored research Agreements (prelation/option/company ownership)
- ✓ (Patent) License Agreement (**PLA**)
- ✓ Know-how License Agreement (KHLA)
- ✓ *…(Term Sheets)*

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Key points developing an agreement IP-wise (Disclaim or Define!)

- ✓Subject of the contract
  (Clearly define the technology and the purpose)
- ✓Background IPR
  (brought by the owner, stands on owner)
- ✓Foreground IPR
  (produced during research, reflecting effective inventive contribution)
- ✓Sideground IPR
  (arising during the collaboration, independently of the purpose)
- ✓Implementations
- ✓…
- ✓Money…

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Patent License Agreements (PLA)

- ✓ Licensing can be modulated based on patent characteristics:
  - Field of use
  - Territory
  - Time
  - Exclusivity

- ✓ Product development pathways
  - Milestones (clinical and regulatory)
  - Gateways
  - Collaboration / Sponsorship

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Non-Disclosure Agreements (NDA)

Description of the **PARTIES**

AIM: the Parties have an interest in participating in discussions about…
One Party may disclose **Confidential Information** to the other Party

All Confidential Information disclosed under this Agreement shall be and remain the property of the **Disclosing Party**

the **Receiving Party** shall, since Effective Date and for the indicated period, refrain from disclosing such Confidential Information to any contractor or other third party without prior, written approval from the disclosing Party and shall protect such Confidential Information from inadvertent disclosure to a third party using the same care and diligence that the Receiving Party uses to protect its own proprietary and confidential information,

The Receiving Party shall **ENSURE** that each of its employees, officers who has access to Confidential Information disclosed under this Agreement is informed of its proprietary and confidential nature and is required to abide by the terms of this Agreement.

Authorized Entity Representative signature makes it valid!

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(Biological) Material Transfer Agreements (B-MTA)

Description of the **PARTIES**
AIM: Transfer of **Original Material** (**MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES**)

The PROVIDER retains ownership of the MATERIAL and makes no representations and extends no warranties of any kind, either expressed or implied.

The MATERIAL:
- is to be used **solely for the RESEARCH PROJECT** (for NON COMMERCIAL PURPOSE);
- is not to be transferred to anyone (else within the RECIPIENT organization);

The RECIPIENT:
- agrees to maintain in confidence any Confidential Information received from PROVIDER;
- is prohibited from attempting to analyze or determine the structure and/or the sequence of the MATERIAL by any means, or more generally perform any act of reverse engineering;
- agrees to use the MATERIAL in compliance with all applicable and relevant national and international laws and assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL;

The PARTIES agree that all rights, title, and interests in or arising out of the RESEARCH...

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Assessing the Value of a Patent: Things to Bear in Mind

Strength of the Patent

Amount of Prior Art

Market dimensions

Technology potentials

Investments made so far

Patent Due Diligence

- ✓ **Patent Analysis** (ISR, European Search Report, extension, time span)
- ✓ Maintenance costs
- ✓ NPV – Net Present Value
- ✓ Market Analysis / Competitor Analysis
- ✓ Strenghts Weaknesses Opportunities Threats (SWOT analysis)

Whole agreement Value

- ✓ Cost Approach
- ✓ Market Approach
- ✓ Income Approach

Remuneration Structure

- ✓ Upfront or down payment
- ✓ R&D sponsoring
- ✓ Milestone payment
- ✓ Royalties
- ✓ … !!!

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Cost based

Type of cost associated with developing the technology? Sum of cost associated with developing the technology, e.g.

– R&D: salaries, materials & equipment

– IP protection

– Trials, testing and prototyping

– Marketing & advertising

– Cost of capital

Problems:

– R&D costs are difficult to count (Which costs? Over which period of time? Including failures?)

– How to take into account inflation

– Cost / potential value

Market Based

Use Market Approach when sufficient transaction information can be found for

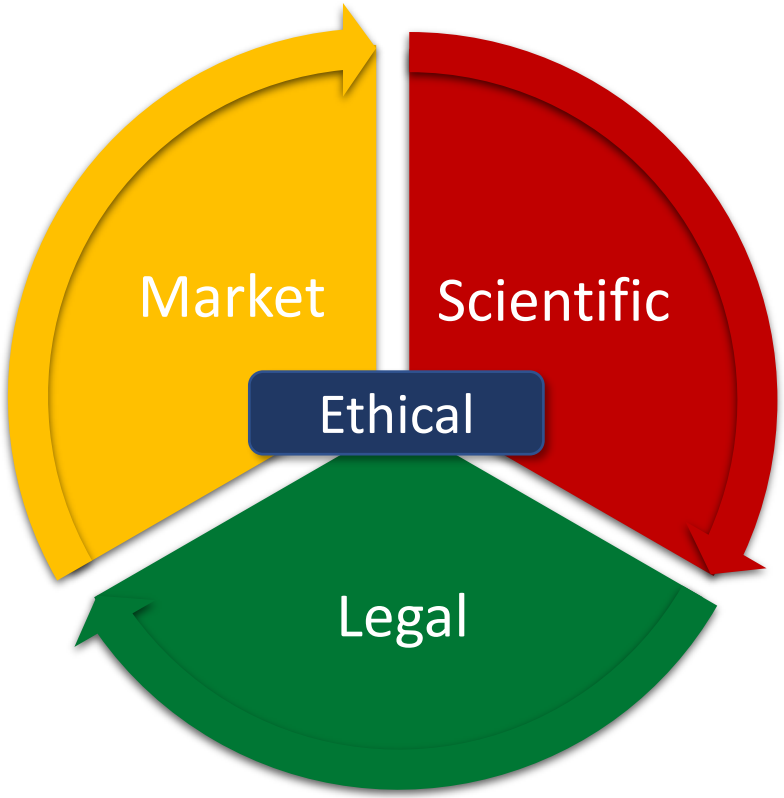
- ✓ Similar transactions: IPR type, industry, market size
- ✓ Technology: technical features, stage of development
- ✓ Specific clauses, financial terms
- ✓ Background: economic conditions, position of the parties

Income Based

- ✓ What do you prefer revenues, Now or xyz Years? Royalties!
  - ✓ share of real market value
- ✓ Value associated with RISK (e.g. development failure or technology turn-over)
- ✓ Discounted Cash Flow (DCF)
- ✓ Two main principles: Time vs. Risk
- ✓ Three key parameters:
  - ✓Amount of the income stream
  - ✓Duration of the income stream
  - ✓Risk sharing (associated with the realization of the income)

The Value of Research

Value



- ✓ *Setting the search track*
- ✓ *Attention to IP protection*
- ✓ *Interdisciplinarity – network*
- ✓ *Public-private Partnership*
- ✓ *Seek for righteous help!*

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Technology Transfer Office duties

- ✓ **Disclosure evaluation** (Theses, publications, papers, presentations and posters)
  - Novelty and Search Closest Prior Art
  - Due diligence (Patents and Technologies)
  - Market scenario analysis

- ✓ **Agreement drafting and negotiating**
  - Non-Disclosure Agreements
  - MTA
  - Grant Agreements / Consortium Agreements
  - Collaborative Research Agreement
  - License and Sale Agreements

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Cultural characteristics affecting technology hand-off

Sponsors	Developers
Many projects compete for resources	Fewer projects at any given time
Business goals are primary	Advancement of science is often a priority
Seek comprehensive data validation	Less intense or different structure for data validation
Highly structured research facilities and expertises	Less structured research environment
Access to cutting edge technology	More limited access to advanced research tools
Project responsibility diffused	Project responsibility consolidated among few

Further learning opportunities:

1. European IP Helpdesk Ambassadors and EEN
2. EUIPO learning portal
3. EUIPO – Ideas Powered for business website
4. WIPO Academy / Diagnostics
5. The Ideas Powered for business SME Fund
6. IPA4SME
7. Horizon IP Scan
8. (IP Booster)
9. Horizon Results Booster
10. LeadershIP4SMEs
11. EPO Academy
12. 4IPCouncil

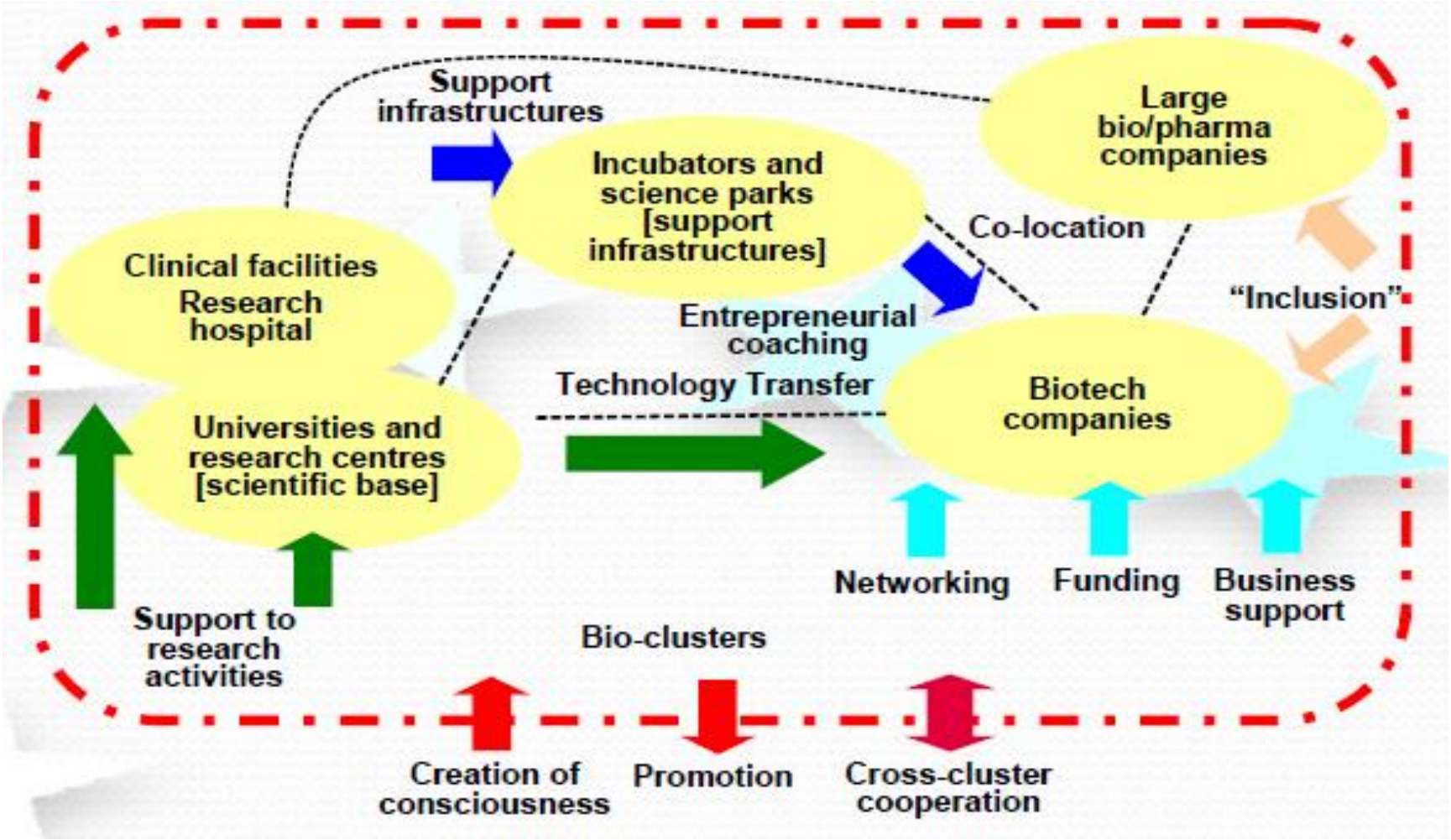
Thank you!

a.frosini@toscanalifesciences.org

Protection and exploitation of research results through intellectual property rights in the life sciences

03/07/2023
Human Technopole

Andrea *Frosini*


Support infrastructures
Incubators and science parks [support infrastructures]
Large bio/pharma companies
Co-location
Clinical facilities
Research hospital
Entrepreneurial coaching
"Inclusion"
Technology Transfer
Universities and research centres [scientific base]
Biotech companies
Networking
Funding
Business support
Support to research activities
Bio-clusters
Creation of consciousness
Promotion
Cross-cluster cooperation

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MAbCo19 project: specific anti-SARS-CoV-2 antibody

INTERNATIONAL

- Imperial College, London (UK)
- University of Kent (UK)
- University of Georgia (USA),
- The Scripps Research Institute (CA, USA)

INTERNATIONAL

- EU Malaria Fund
- Excellgene (Switzerland)

Model based on public-private partnerships in the research, industrial and clinical development and technology transfer to the market phase

ITALIA

Univ. e Enti di Ricerca

- Università di Siena
- Università di Torino

Aziende

VisMederi

ITALIA

SSN

- INMI Spallanzani
- AOU Senese
- AOU Pisana

ITALIA

Aziende e altro

- Achilles Vaccines
- Menarini Biotech
- IBI Lorenzini
- Diesse Diagnostica
- Fondazione MPS

ITALIA

SSN

- INMI Spallanzani
- CRC Verona
- 14 public clinical sites

INVITALIA

ITALIA

- Invitalia
- Partners for industrial and commercial product development (pharma and new focus companies)

June 2020

Patent covers 20 mAbs

Scientific International Publications

CELL Press, "Extremely potent human monoclonal antibodies from convalescent COVID-19 patients" Andreano, Rappuoli et al., February 23, 2021

PNAS, "SARS-CoV-2 escape from a highly neutralizing COVID-19 convalescent plasma" Andreano, Rappuoli et al., September 07, 2021

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Patentability of Biotechnological inventions according to EPC

What are Biotechnological inventions?

Biotechnology (biotech) is the use of biological processes, organisms or systems to manufacture products intended to improve the quality of human life or modernize industry.

Red biotech – healthcare and pharmaceuticals
White biotech – industrial production systems
Green biotech – applications in agriculture

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Biotechnological inventions @EPC

- Biotechnological inventions can be defined as those inventions related to **the industrial use of biologically active material derived from living organisms**, including the use of the organisms themselves.
- Biologically Active Material
  - "**inanimate material**" such as structural proteins, antigens and enzymes, "inanimate material" such as DNA, RNA and gene portions
  - "**animate**" matter such as micro-organisms and cell lines and "animate" matter such as plants and animals

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Rules 23(b)-(e) EPC: biotechnological inventions

The full text of the EU Biotech directive 98/44/EC of July 1998 is explicitly mentioned as source for further guidance. There are a few more details to be said about Rule 23 (c), (e) and (d).

- Rule 23(b) defines the term "biotechnological inventions" and its scope.
- Rule 23(c) provides a non-exhaustive list of patentable inventions.
- Rule 23(d) gives non-exhaustive examples for non-patentable inventions.
- Rule 23(e) is specifically addressed to inventions concerning the human body and its elements.

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Rule 23(c)

non-exhaustive list of patentable inventions

- Biological material which is **isolated from its natural environment or technically produced** even if it previously occurred in nature.
  - Examples for this are nucleic acid molecules, proteins or cells.
- **Plants or animals** if not confined to a particular plant or animal variety.
  - Transgenic plants or animals fall under this definition, as long as the invention can be put into practice in a grouping of plants or animals that is broader than just a particular plant or animal variety. The rationale is that in a variety, the plant or animal is characterized by the ensemble of all of its genes. In an invention under R23(c), the characterizing feature of whole group of transgenic plants or animals is a particular gene.
- **Microbiological processes and their products** – provided they are not essentially biological.
  - Fermentation methods and products fulfill this claim.

Rule 23(e)

inventions concerning the human body and its elements

- An **element isolated from the human body or produced by technical means** including the sequence or partial sequence of a gene, even if its structure is identical to that of a natural element is an in principle patentable invention.
  - However, the human body, at the various stages of its development, and the simple discovery of one of its elements are clearly excluded from patentability. Also a mere nucleic acid sequence without ***indication of a function*** is excluded.

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All subject-matter relating to human **embryonic stem cells** and all further products that are obtainable only by the destruction of human embryos have to be **excluded from patentability**. Non-human embryonic stem cells, foetal stem cells and adult somatic stem cells are patentable as long as they fulfill the normal patentability requirements. Examples for foetal stem cells are haematopoietic stem cells from umbilical cord blood. Adult somatic stem cells include pluri- or multipotent stem cells.

A DNA sequence (or part) which is isolated by means of a technical process is considered to be a chemical product and is as such potentially patentable.

Thus, **there is no a priori bar to patentability of genes and proteins**. As any other product, also DNA sequences or partial DNA sequences have to satisfy the patentability criteria of Novelty, Inventive Step and Industrial Applicability, they have to be sufficiently disclosed and be claimed in a clear manner. DNA sequences or chemical products are not patentable, if their use or function is not defined. In particular, the question of the **"function"** is normally decided in the framework of the examination as to the requirement that a claimed product must be susceptible of industrial applicability.

Microbiological processes and products thereof are patentable

- According to Article 53(b) European patents shall not be granted in respect of *plant or animal varieties or essential biological processes for the production of plants or animals*. However, this exception to patentability does not apply to microbiological processes or the products thereof.

What is patentable: some examples

- ✓ **Genes and nucleotide acid molecules** (e.g. disease related genes for diagnosis, siRNA for therapy)
- ✓ **Proteins** (e.g. Insulin, erythropoietin for therapy, cellular receptors for drug screening)
  - **Enzymes** (e.g. proteases for washing powder, cellulose degrading enzyme for the production of bio-fuels)
  - **Antibodies** (e.g. for cancer treatment, pregnancy tests or diagnostics)
- ✓ **Viruses and virus sequences** (e.g. hepatitis C virus for blood testing, vaccine or therapy development)
- ✓ **Cells** (e.g. haematopoietic steam for the treatment of leukaemia)
- ✓ **Micro-organisms** (e.g. bacteria for bioremediation, yeast for food production)
- ✓ **Plants** (e.g. herbicide resistant soybean, “golden rice” which accumulates pro-vitamin A)
- ✓ **Animals** (e.g. disease models for research such as the genetically modified “oncomouse”, donor animals for xenotransplantations, dairy animals which produce medicaments in milk)

What is not patentable: some examples

- ✓ **Sequences without a known function** (e.g. Expressed sequence tags, ESTs, from automated sequencing)
- ✓ **Genetically modified animals not associated with substantial medical benefit**. (e.g. cosmetics)
- ✓ **Plant varieties** (protected under the Convention of the International Union for the Protection of New Varieties of Plants, UPOV) (e.g. Golden Delicious apples)
- ✓ **Animal varieties** (e.g Holstein cattle)
- ✓ **Human embryos and processes involving their use and destruction**
- ✓ **Human germ cells** (sperm, oocytes)
- ✓ **Human-animal chimera**

Biotechnological inventions @CPI - Italy

express consent, free and informed, to collection and use!

Art. 170-bis

Adempimenti in materia di **invenzioni biotecnologiche**

1. L'Ufficio italiano brevetti e marchi, in sede di valutazione della brevettabilità di invenzioni biotecnologiche, al fine di garantire quanto previsto dall'articolo 81-quinquies, comma 1, lettera b), può richiedere il **parere del Comitato nazionale per la biosicurezza e le biotecnologie**.

2. La provenienza del materiale biologico di origine animale o vegetale, che sta alla base dell'invenzione, è dichiarata all'atto della richiesta di brevetto sia in riferimento al Paese di origine, consentendo di accertare il rispetto della legislazione in materia di importazione e di esportazione, sia in relazione all'organismo biologico dal quale è stato isolato.

3. La domanda di brevetto relativa ad una invenzione che ha per oggetto o utilizza materiale biologico di origine umana deve essere corredata **dell'espresso consenso, libero e informato, a tale prelievo e utilizzazione**, della persona da cui è stato prelevato tale materiale, in base alla normativa vigente.

4. La domanda di brevetto relativa ad una invenzione, che ha per oggetto o utilizza materiale biologico contenente microrganismi o organismi geneticamente modificati, deve essere corredata da una dichiarazione che garantisca l'avvenuto rispetto degli obblighi riguardanti tali modificazioni, derivanti dalle normative nazionali o comunitarie, ed in particolare dalle disposizioni di cui al comma 6 e di cui ai decreti legislativi 12 aprile 2001, n. 206, e 8 luglio 2003, n. 224.

...

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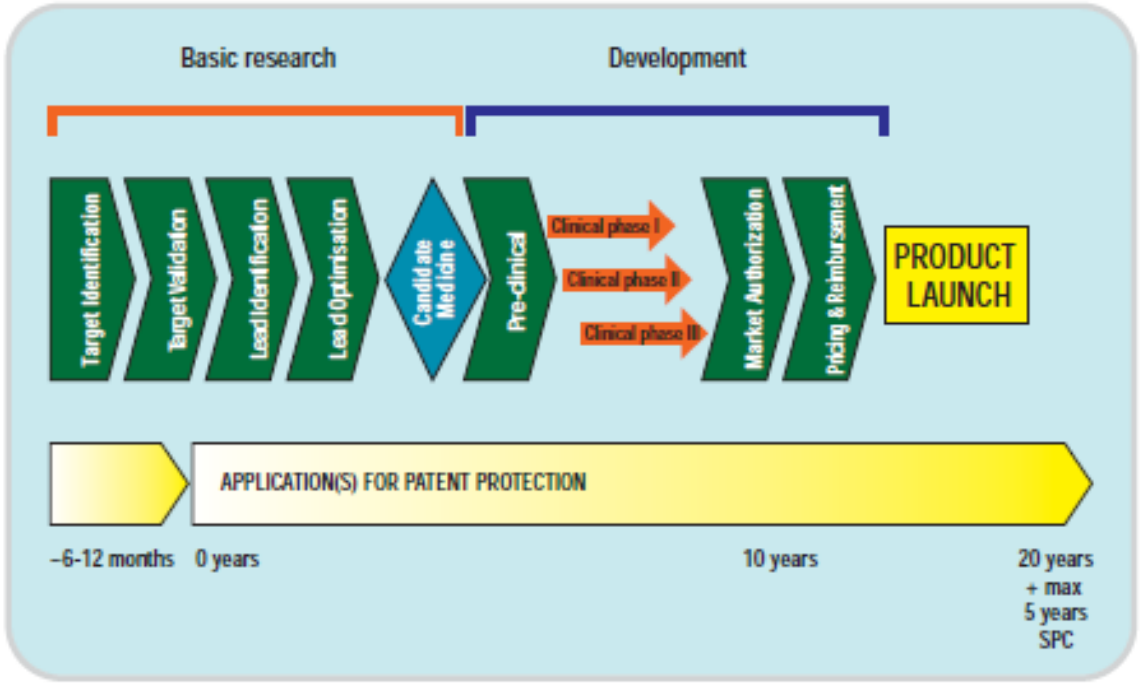
Supplementary protection Certificate (SPC)

In order to **recover at least the years used to obtain the MA (Marketing Authorisation)**, if not all those necessary for the development of the drug, SPCs (Supplementary Protection Certificates) were established, which extend, according to EU Regulation 1768/92 in force since 1/1/93, the duration of the patent monopoly up to a maximum of 5 years.

An SPC can be granted either on a patent corresponding to a product, a process or a therapeutic indication (or use), but only with respect to the active ingredient that is the subject of the MA.



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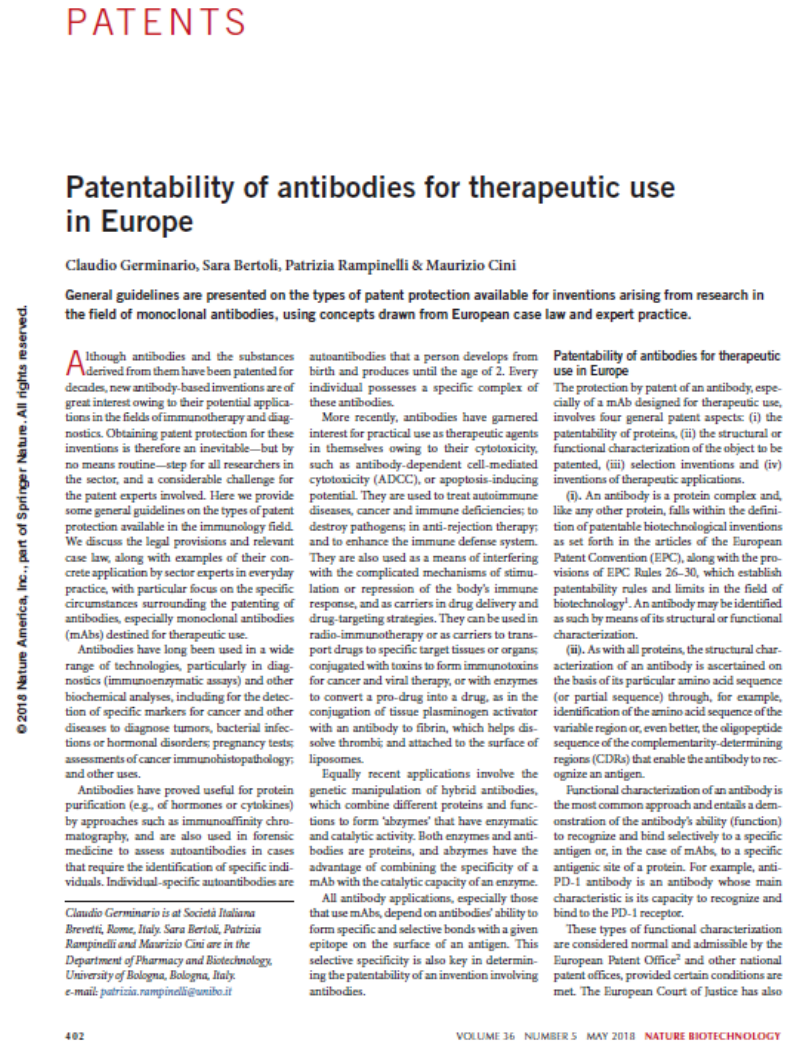
Patenting monoclonal Antibodies

Patentability of therapeutic antibodies in Europe

The protection by patent of an antibody, especially of a mAb designed for therapeutic use, involves four general patent aspects:

(i) the patentability of proteins,
(ii) the structural or functional characterization of the object to be patented,
(iii) selection inventions
(iv) inventions of therapeutic applications.



PATENTS

Patentability of antibodies for therapeutic use in Europe

Claudio Germinario, Sara Bertoli, Patrizia Rampinelli & Maurizio Cini

General guidelines are presented on the types of patent protection available for inventions arising from research in the field of monoclonal antibodies, using concepts drawn from European case law and expert practice.

Although antibodies and the substances derived from them have been patented for decades, new antibody-based inventions are of great interest owing to their potential applications in the fields of immunotherapy and diagnostics. Obtaining patent protection for these inventions is therefore an inevitable—but by no means routine—step for all researchers in the sector, and a considerable challenge for the patent experts involved. Here we provide some general guidelines on the types of patent protection available in the immunology field. We discuss the legal provisions and relevant case law, along with examples of their concrete application by sector experts in everyday practice, with particular focus on the specific circumstances surrounding the patenting of antibodies, especially monoclonal antibodies (mAbs) destined for therapeutic use.

Antibodies have long been used in a wide range of technologies, particularly in diagnostics (immunoenzymatic assays) and other biochemical analyses, including for the detection of specific markers for cancer and other diseases to diagnose tumors, bacterial infections or hormonal disorders; pregnancy tests; assessments of cancer immunohistopathology; and other uses.

Antibodies have proved useful for protein purification (e.g., of hormones or cytokines) by approaches such as immunoaffinity chromatography, and are also used in forensic medicine to assess autoantibodies in cases that require the identification of specific individuals. Individual-specific autoantibodies are autoantibodies that a person develops from birth and produces until the age of 2. Every individual possesses a specific complex of these antibodies.

More recently, antibodies have garnered interest for practical use as therapeutic agents in themselves owing to their cytotoxicity, such as antibody-dependent cell-mediated cytotoxicity (ADCC), or apoptosis-inducing potential. They are used to treat autoimmune diseases, cancer and immune deficiencies; to destroy pathogens; in anti-rejection therapy; and to enhance the immune defense system. They are also used as a means of interfering with the complicated mechanisms of stimulation or repression of the body's immune response, and as carriers in drug delivery and drug-targeting strategies. They can be used in radio-immunotherapy or as carriers to transport drugs to specific target tissues or organs; conjugated with toxins to form immunotoxins for cancer and viral therapy, or with enzymes to convert a pro-drug into a drug, as in the conjugation of tissue plasminogen activator with an antibody to fibrin, which helps dissolve thrombi; and attached to the surface of liposomes.

Equally recent applications involve the genetic manipulation of hybrid antibodies, which combine different proteins and functions to form 'abzymes' that have enzymatic and catalytic activity. Both enzymes and antibodies are proteins, and abzymes have the advantage of combining the specificity of a mAb with the catalytic capacity of an enzyme.

All antibody applications, especially those that use mAbs, depend on antibodies' ability to form specific and selective bonds with a given epitope on the surface of an antigen. This selective specificity is also key in determining the patentability of an invention involving antibodies.

Claudio Germinario is at Società Italiana Brevetti, Rome, Italy. Sara Bertoli, Patrizia Rampinelli and Maurizio Cini are in the Department of Pharmacy and Biotechnology, University of Bologna, Bologna, Italy.
e-mail: patrizia.rampinelli@unibo.it

Patentability of antibodies for therapeutic use in Europe

The protection by patent of an antibody, especially of a mAb designed for therapeutic use, involves four general patent aspects: (i) the patentability of proteins, (ii) the structural or functional characterization of the object to be patented, (iii) selection inventions and (iv) inventions of therapeutic applications.

(i). An antibody is a protein complex and, like any other protein, falls within the definition of patentable biotechnological inventions as set forth in the articles of the European Patent Convention (EPC), along with the provisions of EPC Rules 26–30, which establish patentability rules and limits in the field of biotechnology[1]. An antibody may be identified as such by means of its structural or functional characterization.

(ii). As with all proteins, the structural characterization of an antibody is ascertained on the basis of its particular amino acid sequence (or partial sequence) through, for example, identification of the amino acid sequence of the variable region or, even better, the oligopeptide sequence of the complementarity-determining regions (CDRs) that enable the antibody to recognize an antigen.

Functional characterization of an antibody is the most common approach and entails a demonstration of the antibody's ability (function) to recognize and bind selectively to a specific antigen or, in the case of mAbs, to a specific antigenic site of a protein. For example, anti-PD-1 antibody is an antibody whose main characteristic is its capacity to recognize and bind to the PD-1 receptor.

These types of functional characterization are considered normal and admissible by the European Patent Office[2] and other national patent offices, provided certain conditions are met. The European Court of Justice has also

Germinario et al., *Nature Biotechnology*, May 2018

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Patentability of therapeutic antibodies in Europe

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Functional characterization of an antibody is the most common approach and entails a **demonstration of the antibody's ability (function)** to recognize and bind selectively to a specific antigen or, in the case of mAbs, to a specific antigenic site of a protein.

(iii). Very often, a patent application is filed for a specific antibody that has been selected from a larger family of known antibodies. In this case, the protection sought from a patent will be for a 'selection invention'. This selection of a subgroup of elements or a specific element from a larger known group of material may be subject to patent protection if the subgroup or selected element in question causes a technical effect that had not been previously recognized and described. In the case of antibodies, this would be when the selected antibodies are found to possess a new characteristic, such as the capacity to induce apoptosis or depress the body's immune response, or simply a highly selective specificity.

(iv). Finally, the distinguishing feature of an antibody is its **capacity to bind to an antigen**, with the resultant bond possibly giving rise to a pharmacological action that may be of therapeutic utility. For example, antibodies specific for cancer antigens may have a cytotoxic effect (ADCC) on tumor cells or may interfere with the body's immune-response mechanisms via either up- or downregulation.

Patentability of therapeutic antibodies in Europe

#	Antigen	Antibody	Invention Is a second antibody patentable if it is…
1	Not known	Not known	(Newly discovered antigen) Novel: yes, even in the generic form An inventive step: yes (usually)
2	**Known**	**Not known**	**Novel: yes** **An inventive step: yes, if it has particular features (binding specificity, non-obvious function, etc.)**
3	Known	Known in the generic form	Novel: yes, if selected by functional or structural characterization An inventive step: yes, if it exhibits a new, non-obvious function
4	Known	Known for use in technical analyses	Novel: yes, if for a first (or subsequent) therapeutic application An inventive step: yes, if the therapeutic application is non-obvious
5	Known	Known in the generic or polyclonal form	Novel: yes, if in the monoclonal form An inventive step: no if it just has the properties of all monoclonal antibodies; yes if it has a novel and non-obvious function (e.g., cytotoxicity, apoptosis)
6	Known	Known in the monoclonal form	Novel: yes, if it is a monoclonal antibody with different specificity An inventive step: depends on functionality
7	Known	Known in the generic monoclonal form	Novel: yes, if characterized very precisely (e.g., giving the CDR sequences) An inventive step: depends on functionality
8	Known	Known	Novel: yes, if an antibody fragment An inventive step: depends on functionality

Inventive step of antibodies: case law

The subject-matter of a claim defining a novel, further antibody binding to a known antigen does not involve an inventive step unless a **surprising technical effect** is shown by the application or unless there was no reasonable expectation of success of obtaining antibodies having the required properties (see also **G-VII, 13**). Examples of surprising technical effects when compared to known and enabled antibodies are, for example, an improved affinity, an improved therapeutic activity, a reduced toxicity or immunogenicity, an unexpected species cross-reactivity or a new type of antibody format with proven binding activity.

If inventive step of a functionally defined antibody relies on an improved property versus the enabled antibodies of the prior art, the main characteristics of the method for determining the property must also be indicated in the claim or indicated by reference to the description (**F-IV, 4.11.1**).

If the surprising technical effect involves the **binding affinity**, the structural requirements for conventional antibodies inherently reflecting this affinity **must comprise the required CDRs and the framework regions** because the framework regions also can influence the affinity (**T 1628/16**).

If a novel antibody binds to the same antigen as known antibodies, inventive step is not acknowledged solely on the basis that the novel antibody is structurally different from the known antibodies. Arriving at alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person. The fact that the structure of the thus obtained alternative antibodies, i.e. their amino acid sequences, is not predictable is not a reason for considering these antibodies as non-obvious (see **T 605/14**, section 24; **T 187/04**, section 11).

Nevertheless, antibodies can be inventive if the application overcomes technical difficulties in generating or manufacturing the claimed antibodies.

http://www.epo.org/law-practice/case-law-appeals/

Patent claims

- 1. A human monoclonal antibody or antigen-binding portion thereof that specifically binds to a region of human severe acute respiratory syndrome (SARS) Corona Virus 2 (SARSCoV-2) Spike (S) protein.
- 2. The human monoclonal antibody or antigen-binding portion thereof according to claim 1, wherein said region is i) in the S1 domain of SARS-CoV-2 S-protein; or (ii) in the S2 domain of SARS-CoV-2 S-protein; or (iii) in the SARS-CoV-2 S-protein trimer in its pre-fusion conformation; or (iv) in the SARS-CoV-2 S-protein trimer in its post-fusion conformation or in a combination thereof.
- 3. The human monoclonal antibody or antigen-binding portion thereof according to claim 1 or 2, wherein said antibody or antigen-binding portion thereof providing equal or more than 25% inhibition of the binding between the human ACE2 receptor and the viral Spike (S) protein as measured by the NOB assay.
- 4. The human monoclonal antibody or an antigen-binding portion thereof according to any one of the claims from 1 to 3, wherein said antibody or antigen-binding portion thereof showing 100% inhibitory concentration (IC100) of less than 100 ng/ml when tested in an in vitro neutralization assay against the SARS-CoV-2 virus.
- 5. The human monoclonal antibody or antigen-binding portion thereof according to any one of the claims from 1 to 4, comprising a heavy chain variable domain (VH) and a light chain variable domain (VL), wherein said VH and VL comprise the following complementarity-determining regions (CDRs):
  - CDR1 of VH having SED ID NO:1,
  - CDR2 of VH having SED ID NO:2,
  - CDR3 of VH having SED ID NO:3,
  - CDR1 of VL having SED ID NO:4,
  - CDR2 of VL having the sequence DAS (Asp-Ala-Ser) and
  - CDR3 of VL having SED ID NO:6;
- …

- 8. A human monoclonal antibody or an antigen-binding portion thereof that compete for the binding to Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Spike (S) protein with any one of the antibody or antigen-binding portion according to any one of the claims 1 to 7.

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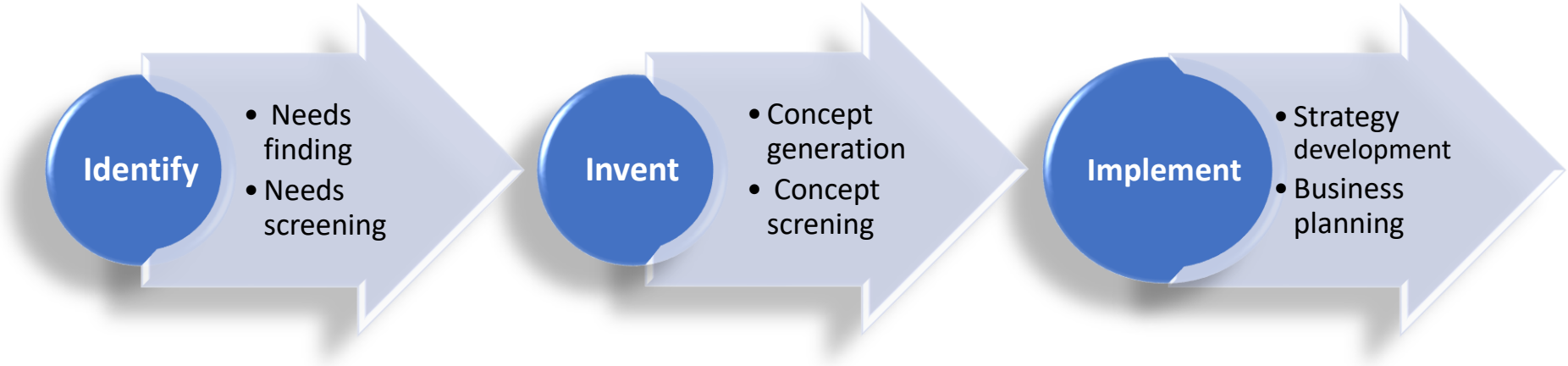
Introduction to clinical innovation

Unmet medical need

- The starting point of any innovation in the medical field is an important Unmet Medical Need, to be answered with an innovative technology.

- A well-characterised Medical Need is the DNA of a good invention.



Source: Stanford Biodesign®

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Clinical Innovation

✓ ***IPR - Patents*** – specific rights (es. ODD)

✓ ***Regulatory*** (FDA, EMA, AIFA)

✓ ***Clinical Trials*** (etica, attrition rate, costi, tempi)

✓ ***Stakeholder analysis***

✓ Reimbursement (HTA, DRG - procurement)

✓ Financing

- ✓ Technical feasibility
- ✓ Team Dynamics
- ✓ Business model
- ✓ Competition
- ✓ Market Dynamics
- ✓ …
- ✓ …

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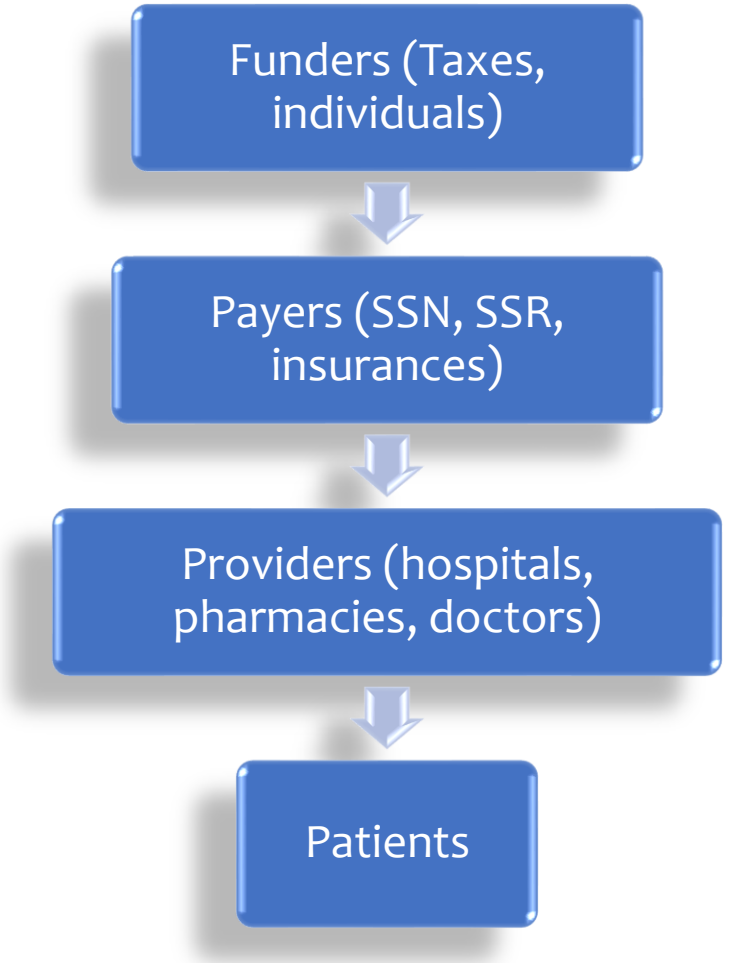
Stakeholders

Unmet Medical Need Stakeholders

- ✓ Patients
- ✓ Families
- ✓ Patient associations
- ✓ Doctors
- ✓ Professional societies
- ✓ Nurses
- ✓ Facilities (hospitals, pharmacies, laboratories)
- ✓ Hospital administrators
- ✓ Public payers (governments)

Stakeholders' analysis

- **Payers** (decision makers): clinical outcome (associated with GCP processes in randomised, peer-reviewed clinical trials - HTA)
- **Doctors** (influencer, Key Opinion Leaders): clinical outcome, safety, economic impact, convenience, ease of use, reputation
- **Facilities** (influencer): economic impact, risk, spending opportunity, reputation
- **Patients** (influencer): clinical outcome, safety, economic impact, perceived risk



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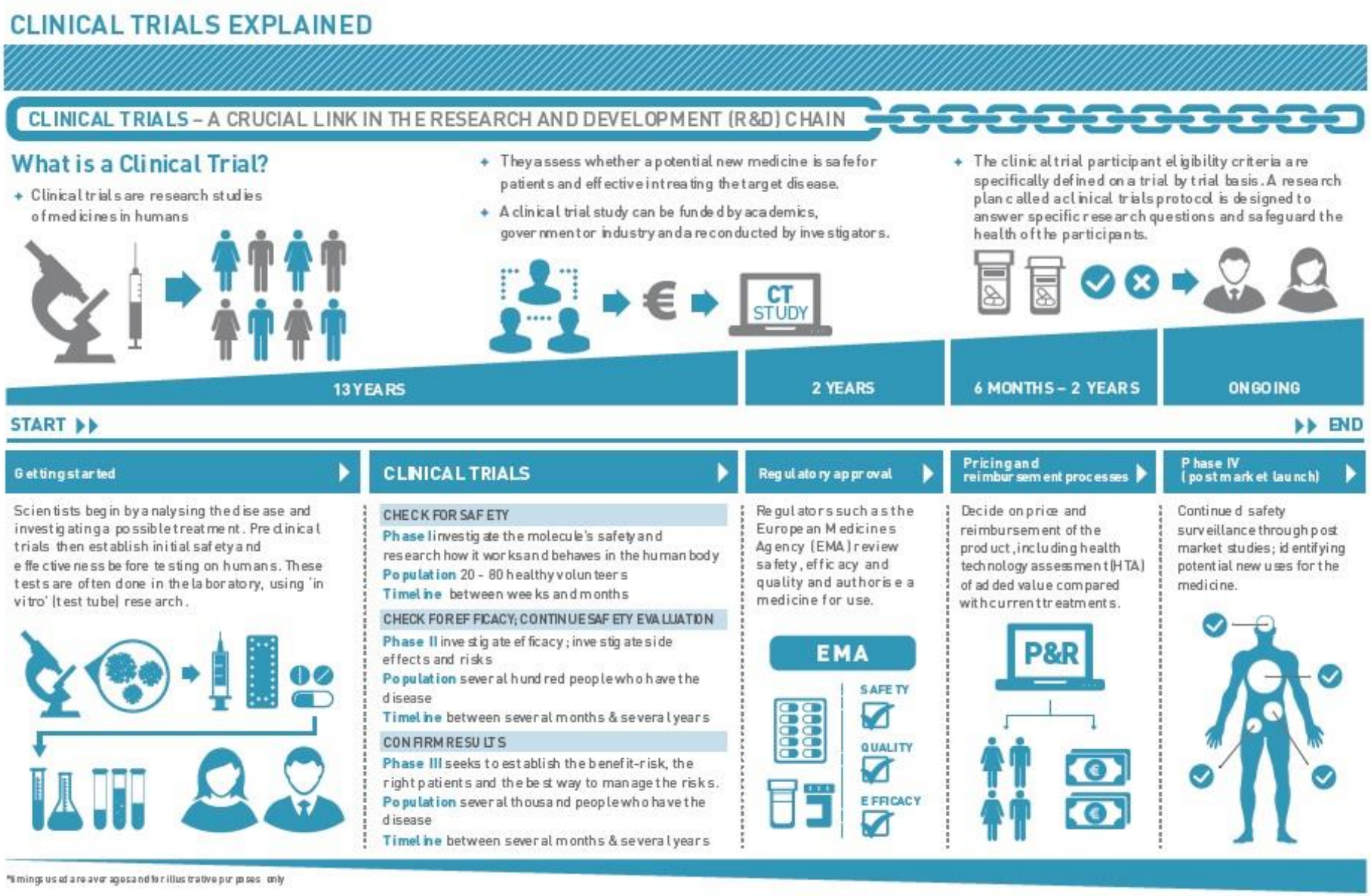
The cycle of healthcare

Once an 'unmet medical need' has been defined, a stakeholder analysis must be conducted in the care cycle: an assessment of how the patient moves through the clinical pathway for certain diseases or treatments, with a focus on money flows (reimbursement mechanisms), in order to understand:

- ✓ Who diagnoses a certain condition
- ✓ Who provides assistance in the first instance
- ✓ Who takes over
- ✓ Which medical specialities are involved
- ✓ Which parties are involved in disease management
- ✓ The role played by patients up to follow-up

Clinical Trials



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Clinical Trials

- The profile of a clinical innovation must be supported by a clinical investigation (clinical trials) to determine it:

✓ Safety

✓ Mechanism of action

✓ Endpoints Indications

✓ Efficacy

✓ ... and Ethics! - Ethics Committees

Limiting and specific step impacting on TT models!

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Clinical Trials

- Providing clinical evidence for your product through clinical trials
- Clinical trials are the most complex, time-consuming and expensive development step for medical technologies
- There are clear and well regulated ethical implications, which are scrutinised by Ethics Committees
- The most appropriate experimental and statistical schemes to provide the expected outcomes (primary and secondary) are evaluated

Quality of the data and organization in Clinical Trials

- Given the complexity of the data that can potentially be aggregated, in order to develop individualized research there is a need for the **creation of a precision research ecosystem that binds clinicians, researchers, companies and the systems charged with the aggregation of clinical information**.
- **Standardizing the way in which the enormous amounts of personal data of patients is evaluated** in diagnostic and prognostic terms is fundamental.
- **The robustness of clinical and research databases is a key point** to guarantee the efficacy and quality of the interpretation of the data.
- For this reason the organization of the information within dedicated databases is the resolving step for the foundation of an individualized research.

Clinical Innovation: Final remarks

1. High time-to-market, attrition rate, investments
2. Ad hoc **regulations** and **procedures** for health sector
3. Strong R&D regulation - compliance AIFA, EMA, FDA, ... (**certification, GxP, SOP, accredited testing**...)
4. Indispensable research **ethics component**
5. Care/research **dyad**
6. Relationship with doctors and clinicians: entry point the **key opinion leader**
7. Experimentation framework **profit - non-profit** (public non-profit by definition...)
8. Developer coincides with public procurer (PCP - PPI would partially resolve): **potential conflicts of interest**

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Thank you!

a.frosini@toscanalifesciences.org