
The Recent Practice of the European Patent Office regarding Life Sciences/Biotechnology

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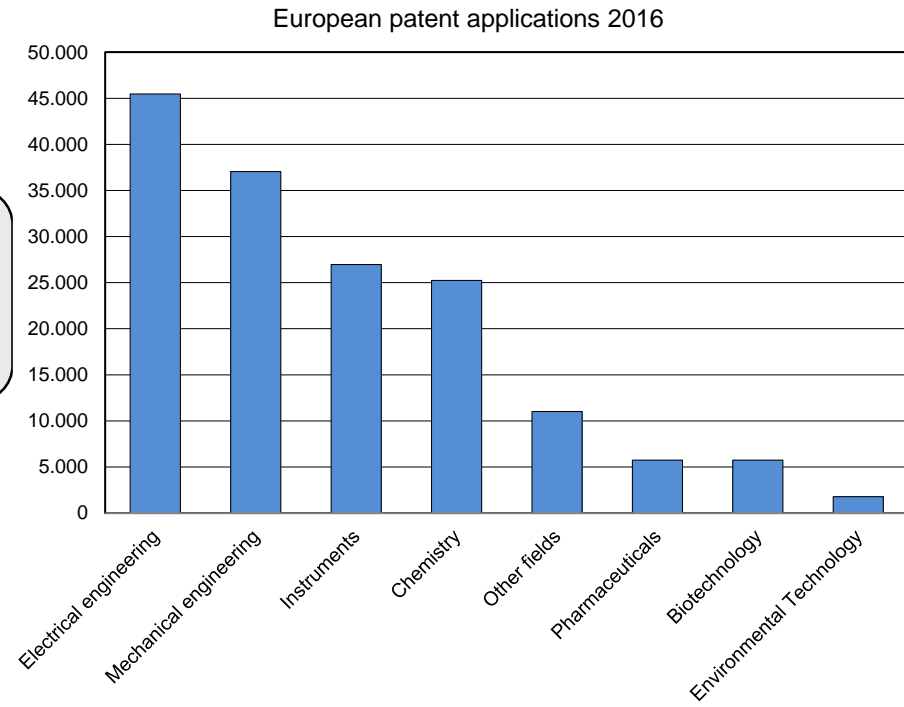
- I. Introduction
- II. Legal Framework
- III. Stem Cells
- IV. Genes
- V. Plants and Animals
- VI. Medical Methods
- VII. Problems Regarding Inventive Step

- Definition life science (Merriam Webster):

A branch of science that deals with living organisms and life processes

- EPO filings in life science field

- still small number compared to other fields, but increasing



Source: EPO statistics

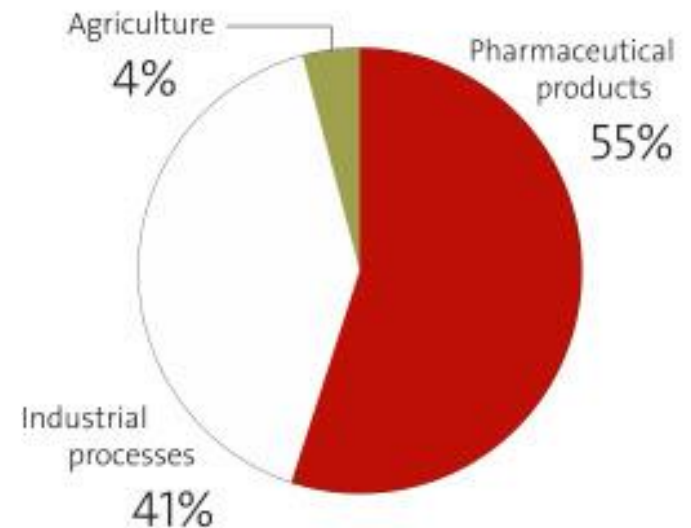
- Biotechnology¹:

Use of biological processes, organisms or systems to manufacture products, intended to improve the quality of human life

- EP patents in biotechnology:

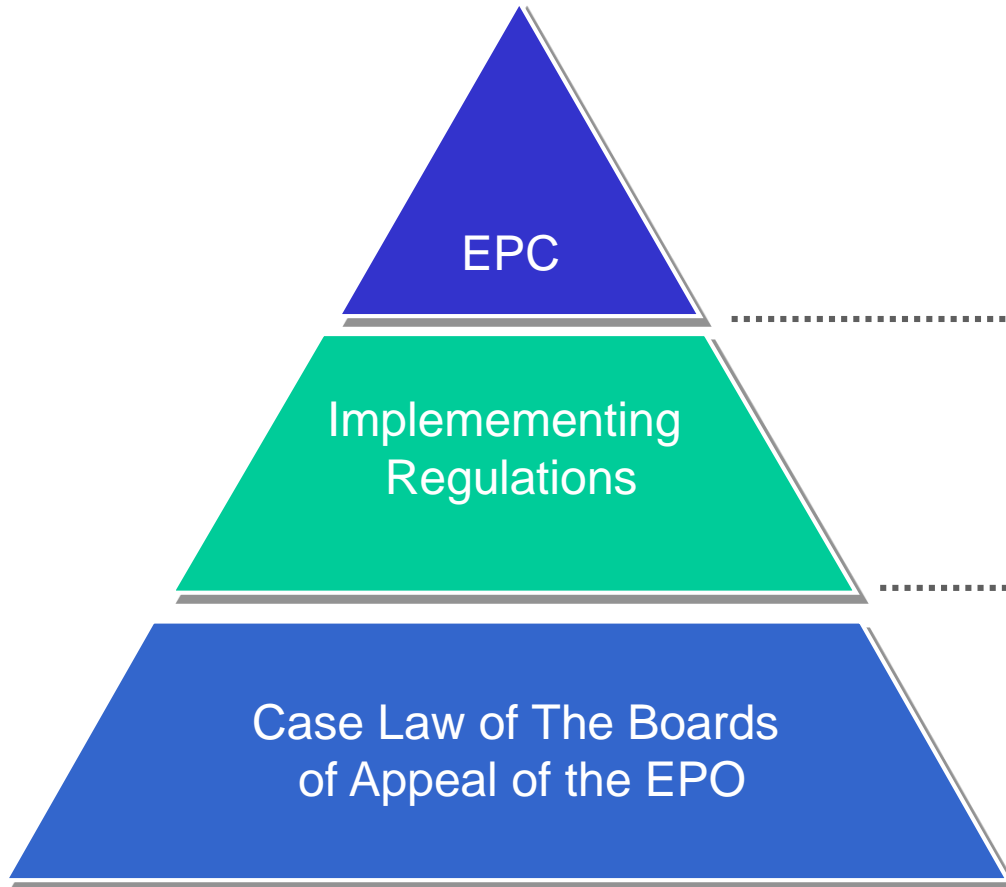
- medical and pharmaceutical products
- industrial processes
- agriculture

Patents in biotechnology¹



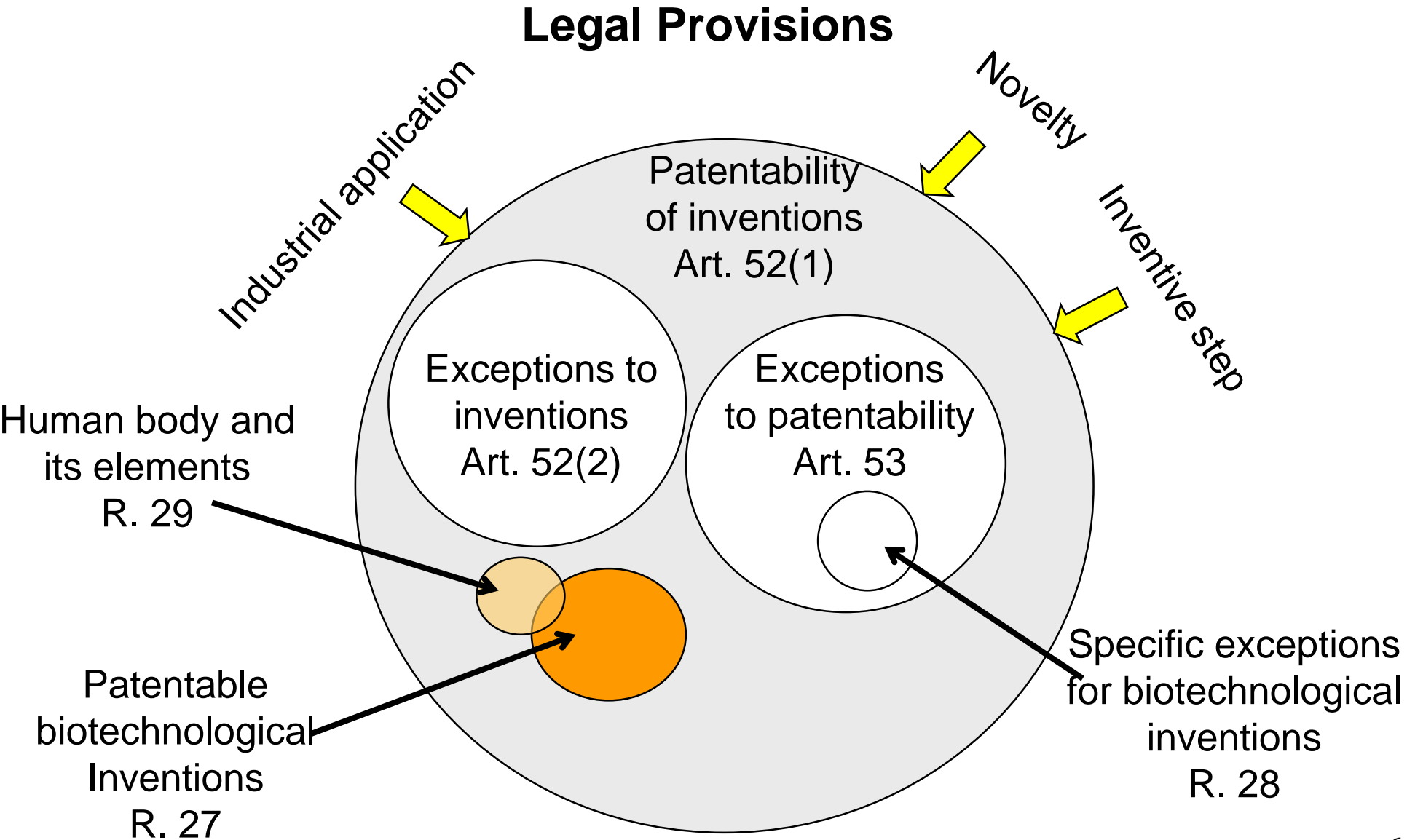
¹ Source: EPO, 5.7.2017

Legal Provisions



- EPC European Patent Convention
- Implementing Regulations, specifically Rules 26 to 34 ; based on Directive 98/44 EC (Biotech Directive of EU)
- Case Law of Enlarged Board of Appeal (G decisions) and of Boards of Appeal (T decisions)

II. Legal Framework



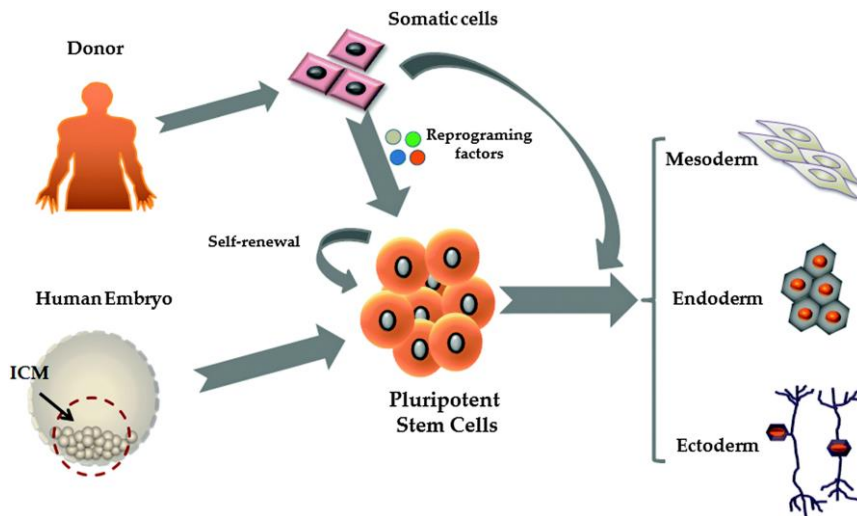
General Provision (Art. 52 (1) EPC)

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

Exceptions of what is regarded as an invention (Art. 52 (2) EPC)

not be regarded as inventions within the meaning of para. 1:
(a) discoveries

(human) Pluripotent Stem Cells



- Can give rise to every other cell type in the body
- Human embryonic stem cells (**hESCs**) are pluripotent stem cells derived from inner cell mass of blastocyst of human embryo; destruction of embryo
- Induced pluripotent stem cells (**iPSCs**) (Yamanaka 2006) can be generated from adult somatic cells by reprogramming; no need of destruction of embryo
- Stem cells generated by stimulating unfertilized eggs (parthenogenesis)

B. Lucendo-Villarin et al. J. Mater. Chem. B, 2016, 4, 3433-3442

Relevant legal provisions

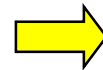
Art. 53a) EPC

Exceptions to patentability

Rule 28 EPC

Exceptions to patentability

(a) inventions the commercial exploitation of which would be **contrary to "ordre public" or morality;**



(c) uses of **human embryos** for industrial or commercial purposes;


Problems underlying stem cell patents

- Obtaining human embryonic stem cells (hESC) e.g. from surplus embryos of in vitro fertilization by destroying the embryo is contrary to morality?

- What is an embryo?

- What is use of human embryos for industrial or commercial purposes?

Relevant Decisions - 1/4

- **G-2/06**, EPO, 25.11.2008, Wisconsin Alumni Research Foundation's "Use of embryos/WARF"
 - **Making** the claimed product involves **destruction of human embryos**,
 -  **"use of an embryo for industrial or commercial purposes"**
 - hESC which **on the filing date** can be exclusively prepared by methods **necessarily involving the destruction of human embryos** are **not patentable**
 - Applies even if the destructive method is not explicitly part of the claims.

Relevant Decisions - 2/4


- European Court of Justice (ECJ)
 - EPO is not bound by ECJ
 - However, ECJ provides supplementary means for interpretation
- C-34/10, ECJ, 18.10.2011 (Greenpeace vs. Brüstle)
 - **Patentability excluded if destruction of human embryos or their use as base material is required, in whatever stage that takes place** and even if the technical teaching does not refer to the use of human embryos.
 - **"embryo" covers all stages of human development after fertilisation of a human egg, as well as cells capable of commencing the process of development of a human being, e.g. an egg subjected to parthenogenesis.**

Relevant Decisions - 3/4

- Later concretizing meaning of "embryo"
- C-364/13 ECJ, 18.12.2014 (Int. Stem Cell Corp. Vs. Comptroller General of Patents, Designs and Trade Marks)
 - An **unfertilised human egg** whose division and further development has been stimulated by **parthenogenesis does not constitute a human embryo**
 - **embryo** covers only cells having the **inherent capacity to develop into a human being**.

Relevant Decisions - 4/4

- T 2221/10, EPO, Point in time at which destruction of embryo takes place is irrelevant


- T 1441/13, EPO, First disclosure of a method of establishing hESC lines without destroying a human embryo on **February 7, 2008** (Chung et al.)
 - applications relating to hESC which were **filed before February 7, 2008** are excluded from patentability
 - However: obtaining hESC by parthenogenesis described already in WO03046141, published on 5 June 2003
 - Acknowledged by EPO?
- **iPSC**: 2011 Grant of Yamanaka Patent EP 1 970 446 "A nuclear reprogramming factor; use for reprogramming a somatic cell; maintained 2014 after opposition

Conclusion: Patentability of Stem Cells

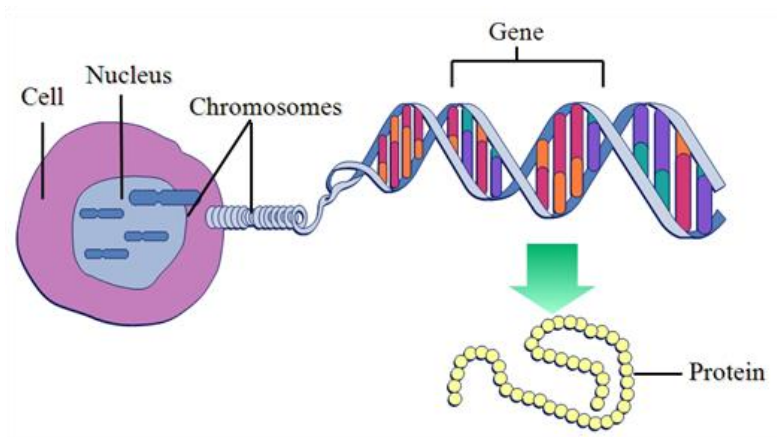
- Human embryonic stem cells that **necessarily** result from destruction of an embryo are **not patentable**

- Essential is whether at **the time of filing** a method was known to generate hESC **without destruction of an embryo**
 - This is generally accepted for the time from **February 7, 2008**

- iPSC and stem cells originating from parthenogenesis seem to be patentable

Strategy:

- claim **pluripotent stem** cells and describe different methods of obtaining them without need of destruction of embryo
- Mention at least possibility of production by parthenogenesis



- A Gene is a region of **DNA** (**D**eoxyribo**n**ucleic **a**cid, large biomolecule) that stores a specific information by comprising a **specific sequence** of its components, the nucleotides
- Forms molecular unit of heredity
- Patents for human genes (or gene sequences) can be basis for life saving drugs, e.g.

Herceptin against breast cancer
Humira against arthritis

Problems underlying patents for genes

- Genes may be a "product of nature"= "discoveries"?
- Industrial application?
- Medical method?

Relevant legal provisions

Article 57 EPC

Requirement of industrial applicability

Rule 29 EPC

The human body and its elements

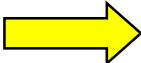
➔ **No patents** on human body and **discovery** of gene or gene sequence

➔ Patents on genes or gene sequences if **isolated** from human body or otherwise **produced by means of a technical process**

➔ **Industrial application** of a sequence or a partial sequence of a gene **must be disclosed in the patent application.**

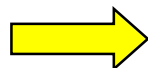
Selected European Patent Office (EPO) Decisions

- **T 1213/05** (*Breast and ovarian cancer/UNIVERSITY OF UTAH, September 2007*)
 - patent claiming a nucleic acid probe comprising a sequence encoding a (mutated) human BRCA1 polypeptide **useful** for diagnosis and prognosis of **human breast** and **ovarian cancer**.

 - The Board held:
 - claimed probes were **isolated** from the human body by **technical means**, (now R. 29 (2) EPC, fulfilled)
 - useful in diagnosis and thus could be used commercially (Art. 57 EPC) fulfilled
-  invention basically patentable and industrially applicable

Selected European Patent Office (EPO) Decisions

- T 1452/06 (*Serine protease/BAYER, May 2007*)
 - Claims directed to a specific sequence SEQ ID NO:24 and a method of screening for agents which regulate the activity of a serine protease polypeptide of this sequence
 - application refused based on lack of industrial applicability (Art. 57 EPC)
- The Board:
 - "*the **only use** of a polypeptide of sequence SEQ ID NO: 24 is to **find out more** about the polypeptide itself and its natural function(s)*". No "*immediate concrete benefit*" can be acknowledged for this use."

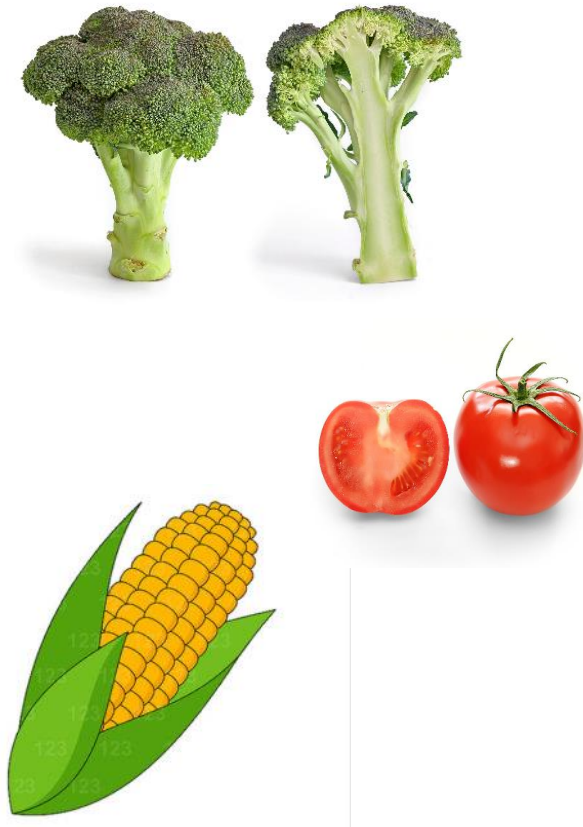


invention does not meet industrial application

Conclusion: Patentability of Genes

- Patenting of human genes and gene sequences generally possible
- **Industrial application** (Art. 57 EPC) may be often a problem
Strategy
 - explain industrial application explicitly in the specification (Rule 29(3) EPC), i.e. describe which **specific function** (e.g. with therapeutic concept) or **specific beneficial use** is associated with the claimed sequence

Plants and Plant Varieties



- Since year 2000 rapid development of gene technology improving classical plant breeding
- herbicide resistance; high yield
- Functional food: e.g. seedless watermelons; Ornamental plants (e.g. new colours)
- Plants as biofactory
- Making new plants
- Plant varieties are protected under classical breeders rights; double protection by patents critically seen in EU

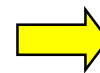
Relevant Legal Provisions

Art. 53b)

Exception to patentability

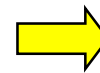
Rule 28(2) EPC, new since
July 1, 2017

No patents for **plant or animal varieties** or **essentially biological processes** for the production of **plants or animals**;.....



No patents for plants or animals exclusively obtained by means of an **essentially biological process**.

Rule 26(5)



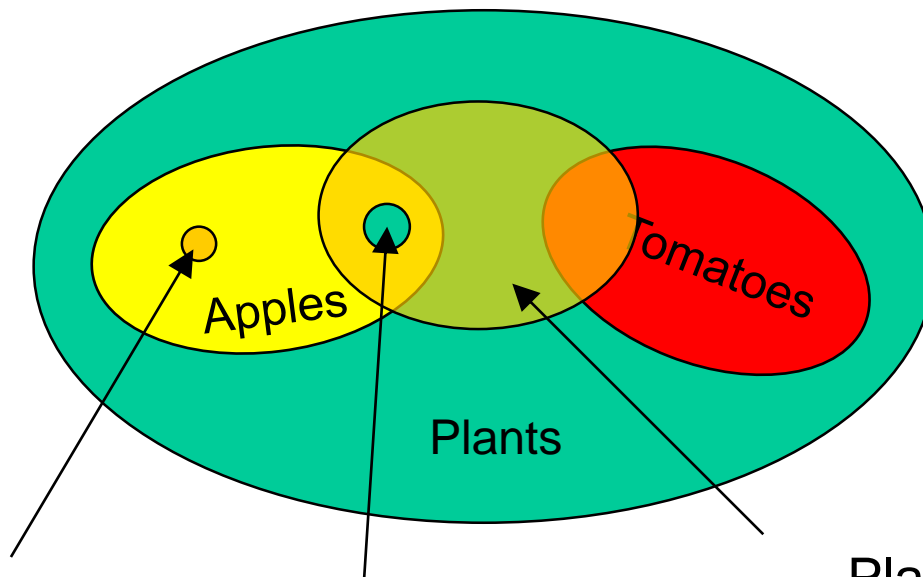
Essentially biological: consisting **entirely of natural phenomena** (crossing, selection)

European Patent Office (EPO) Decisions -1/3

- G 1/98, 20.12.1999 (Transgenic plant/NOVARTIS)
 - Examining division rejected application claiming transgenic plants based on Art. 53b).

- The Enlarged Board:
 - Only **specific plant varieties** are excluded from patentability, but a claim **may encompass plant varieties**
 - Claim to a **process for the production of a plant variety** is in general **not** excluded;
 - protection is extended to products directly obtained by this process (Art 64(2) EPC)

Plants versus varieties¹



Golden Delicious
not patentable (variety)
 Variety A containing gene X
not patentable (variety)

Plants containing gene X
 for increasing vitamin C
 content; **patentable**

¹ Source: EPO, https://ec.europa.eu/food/sites/food/files/plant/plant_property_rights/conference/docs/conf_11102011_11_00_epo_en.pdf

European Patent Office (EPO) Decisions – 2/3

- G 2/07 (Broccoli I/PLANT BIOSCIENCE) and G 1/08 (Tomatoes I/ISRAEL) 9.12.2010

Method claims

- production of broccoli plants that produced a higher level of anti-carcinogenic substances;
 - production of tomatoes with a reduced content of water
- The Enlarged Board:
 - **Sexual crossing** of whole plant genomes and **subsequent selection** of plants with particular traits is excluded from patentability (also if plant genome is genetically engineered).



No patents on essentially biological processes

European Patent Office (EPO) Decisions -3/3

- G 2/12 (Broccoli II) and G 2/13 (Tomatoes), 25.3.2015
 - **Product Claims** :
broccoli **plant** characterized by method of production (product by process claims)
 - tomato **plant**

- The Enlarged Board:
 - **product claim patentable**, although protection of method of production excluded under Art. 53b)
 - **Product by process claim patentable**, although protection of method of production excluded under Art. 53b)



Liberal attitude of Enlarged Board

Recent New Situation

- November 2016, Notice of European Commission
 - Intention of Biotech-Directive 98/44 EC was to exclude biological processes and **products obtained by such processes** from patentability.

- Effective July 1 2017, **new R 28 (2) EPC**:
 - **No patents on plants or animals** exclusively obtained by means of an **essentially biological process** (no product claims).
 - **Contrary** to Broccoli II and Tomatoes II decisions
 - ➔ Liberal Position of EPO abandoned upon political pressure

Animals



- Genetically altered animals used in agricultural, pharmaceutical and biomedical research
 - Food production, e.g. cows producing more milk
 - Production of animal proteins as vaccines
 - Biomedical research, e.g. how cells operate, cancer research etc.

European Patent Office (EPO) Practice

- Same principles as for plant **varietes** applied to animal **varieties**.
- T 19/90 and T 315/03 (Harvard Oncomouse)
 - Protection for genetical modifications of animals which are **likely to cause suffering without any substantial medical benefit** are excluded from patentability under Art 53(a), R 28(d) EPC.

Conclusion: Protection of Plants and Animals

- Plants:
 - Claims to plants obtained by essentially biological processes **appear no longer possible**
 - Still **worth to try to claim**, as it is questionable whether Rule change can overrule Enlarged Boards decisions

- Animals:
 - claim to animal (e.g. mammal [except humans], rodents, mice or the like) possible if a genetic variation can be applied across various animal/animal species/animal varieties (which should be shown in the application)

VI. Medical Methods



- Methods for the treatment of the human or animal body
 - by surgery or
 - by therapy

- Diagnostic methods

- Use of substances for treating diseases
 - Medical practitioners should not be hindered by patents from giving best medical treatment



Relevant legal provisions

Art. 53c) EPC

Exceptions to patentability

No patents for

methods for treatment of the human or animal body

- by **surgery**

- or **therapy**

diagnostic methods **practised on the human or animal body;**

Problems in view of methods

- Does the method require involving a medical practitioner to be excluded from patentability?
- What means: surgery, therapy, diagnostic?
- What means practiced **on** the human or animal body?
- Therapeutic and non therapeutic applications (e.g. cosmetic)

EPO Decisions Surgical Methods

- G 1/07, 15.2.2010 (treatment by surgery/ MEDI-PHYSICS)
 - method comprising **step** of delivering polarized ^{129}Xe to the subject, in particular via inhalation; **injection** of polarized ^{129}Xe **into the heart** encompassed by claims

- The Enlarged Board:
 - method claim **not patentable** if it comprises or encompasses at **least one feature** that constitutes a method step for treatment of a human or animal body by surgery or therapy.
 - Fulfilled if substantial health risk
 - Disclaimer of "surgical embodiment" possible


European Patent Office (EPO) Practice

- Method claim not allowable, if it includes **at least one method step** involving **treatment** of the human or animal body by **surgery** or **therapy**

- Inventions having **therapeutic and non therapeutic** indications: claim **not allowable** as long as **therapeutic indication is included**; claim must be **limited to non therapeutic application**

- **Apparatus** or **product** comprising structural features **for use** in a medical method
 - Not excluded under Art. 53c) EPC

EPO Decision Diagnostic Methods

- G 1/04, 16.12.2005 (Diagnostic Methods):
 - "practised on the human or animal body" fulfilled if **any interaction with the human or animal body** is implied, necessitating the presence of the body (direct physical interaction not required)
 - Patent excluded if **all technical steps** of the method are "practiced on the human or animal body"
 - Patent not excluded, if as a result of the method no clear diagnostic decision can be made by medical practitioner
-  Only limited exclusion of patentability in rare specific case, in favor of applicants

Legal Provisions Medical Use of Substances

Art. 53c) **allows** patents for **substances** and **compositions** for use in therapeutic and diagnostic methods

Art. 54(4) acknowledges **novelty** of such substances for use in medicine (if substance was known in non medical fields)

Compound X for use in medicine

- first medical use
- Broad scope, claim limited by general medical purpose

Legal Provisions Medical Use of Substances

Art. 54(5) acknowledges **novelty** of such substances for use in a new therapeutic application (if substance was already known for use in medicine)

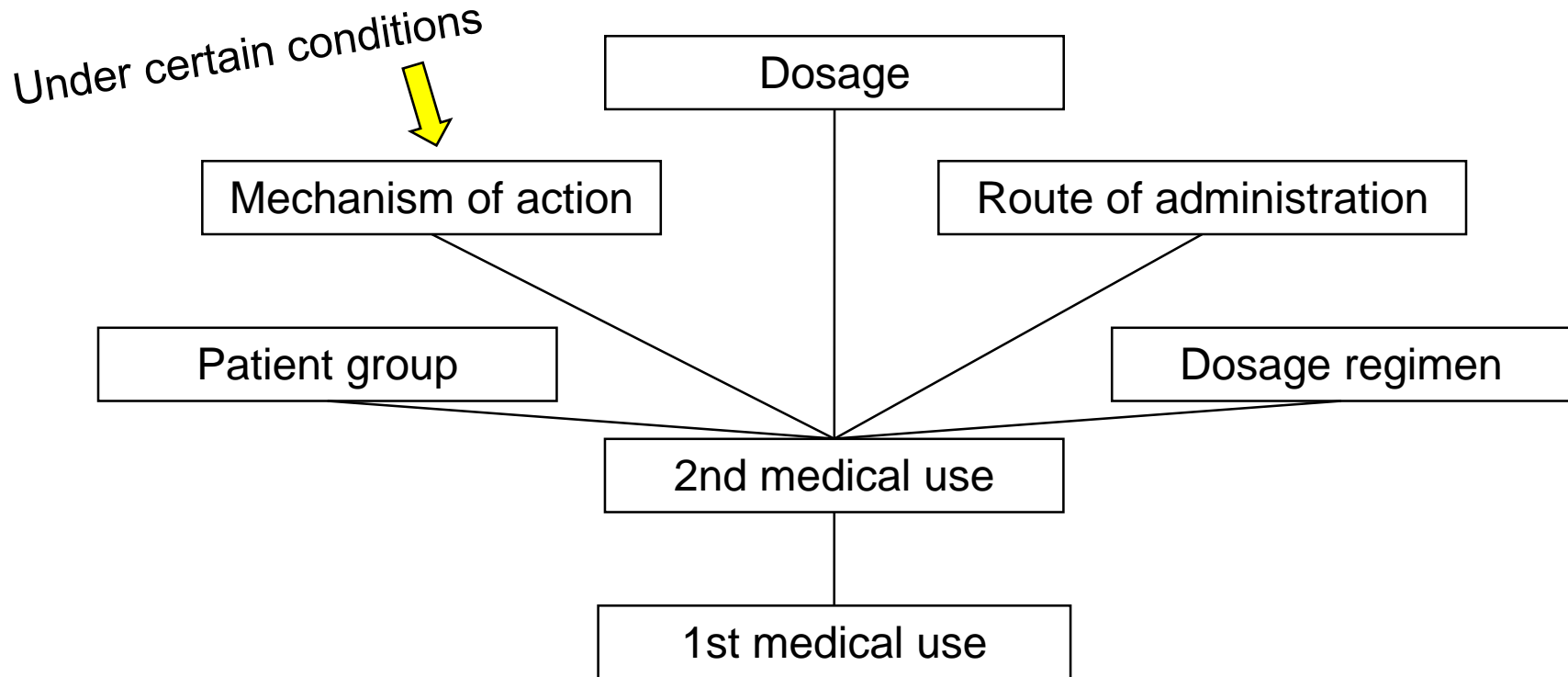
Compound X for use in the treatment of disease Y

- Second and further medical use
- Narrower scope, claim limited by therapeutic indication
- G 2/08 Swiss type of claims **no longer allowed** 'compound X for the manufacture of a medicament for therapy Y'

EPO Decision Dosage Instructions

- G 2/08 19.2.2010 (Dosage regime/ABBOTT RESPIRATORY)
 - dosage instructions are patentable
 - Where it is already known to use a medicament to treat an illness, patent for use in a **different treatment** of the **same illness** possible
 - Patent possible where a **dosage regime** is the **only feature** claimed which is not comprised in the state of the art.

Practice EPO Second Medical Use



VII. Problems Regarding Inventive Step

Inventive step: Plausibility requirement

- Practice EPO in Biotech/Life Science Invention
 - Application shall make it **plausible** that a claimed invention has a technical effect, appropriate explanations required
 - Prevention of speculations about effect
 - Post-filed data can be used for further support, provided plausibility test is positive

- T 0488/16 (1.2.2017) dasatinib/Bristol-Myers Squibb
 - Patent finally revoked as specification did not make it plausible that dasatinib was a PTK inhibitor



Decision raising the bar?

Summary

- Patenting of Life Science applications at EPO is governed by complex legal provisions and case law
- Having this in mind and drafting claims in appropriate manner, useful patents can be obtained for improving human life

Thank you for your attention!



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