

Patenting Plant Material at the EPO

Latest case law of the Boards of Appeal

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Seminar on the interface between
Patents and Plant Variety Rights
Brussels, 24 June 2015

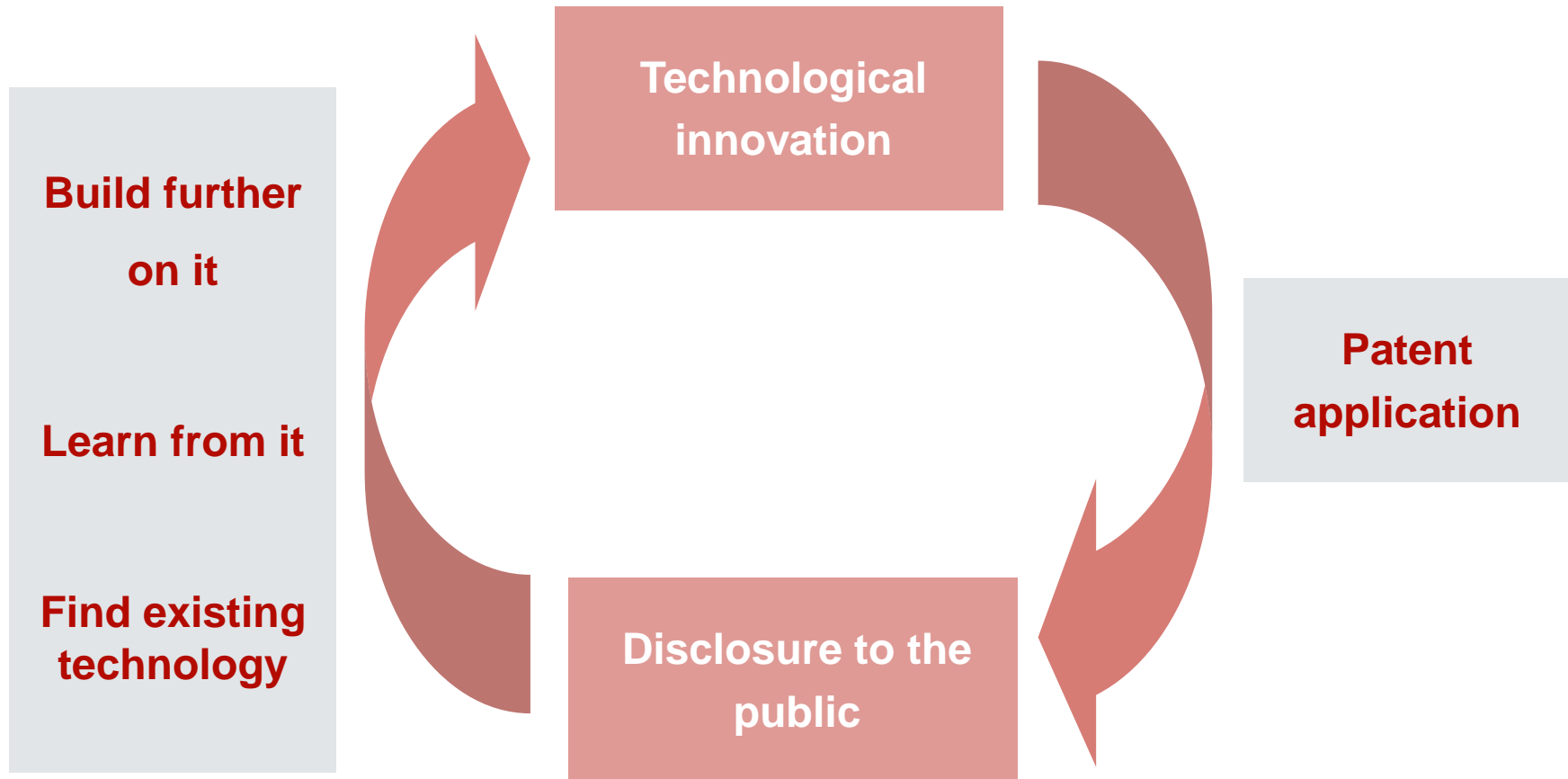


Contents

- Basics of Intellectual Rights and Patenting
- The European Patent Office
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Intellectual Property Rights

A system driving knowledge transfer and innovation



What is a patent?



- A patent is a legal title granting its holder the exclusive right to **prevent** third parties from exploiting an invention (making, using, offering for sale, selling or importing infringing products) without authorisation in a defined country and for a limited period, e.g. 20 years.
 - a passive right
 - a territorial right
 - a right of limited time
- In return for this protection, the holder has to disclose the invention to the public.

**Reveal
invention**



**Get
exclusivity**


The European Patent Office

A Patent office ?



PATENT OFFICE ?

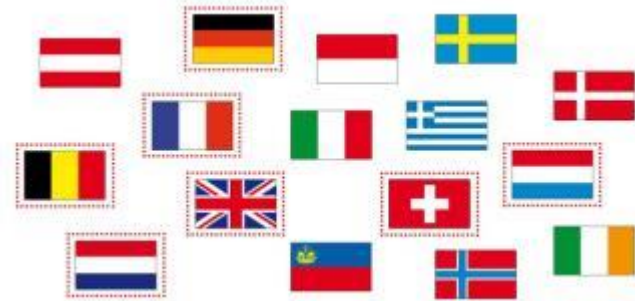
IT HASN'T BEEN

INVENTED

YET !

The European Patent Convention

- **1973– Diplomatic Conference in Munich**
 - ▶ EPC signed by 16 countries on 05.10.1973



- **1977 – EPC enters into force in seven countries**

Belgium • Germany • France • Luxembourg •
Netherlands • Switzerland • United Kingdom

- **2015 – 38 member states**

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



European Patent Office - EPO

Our mission

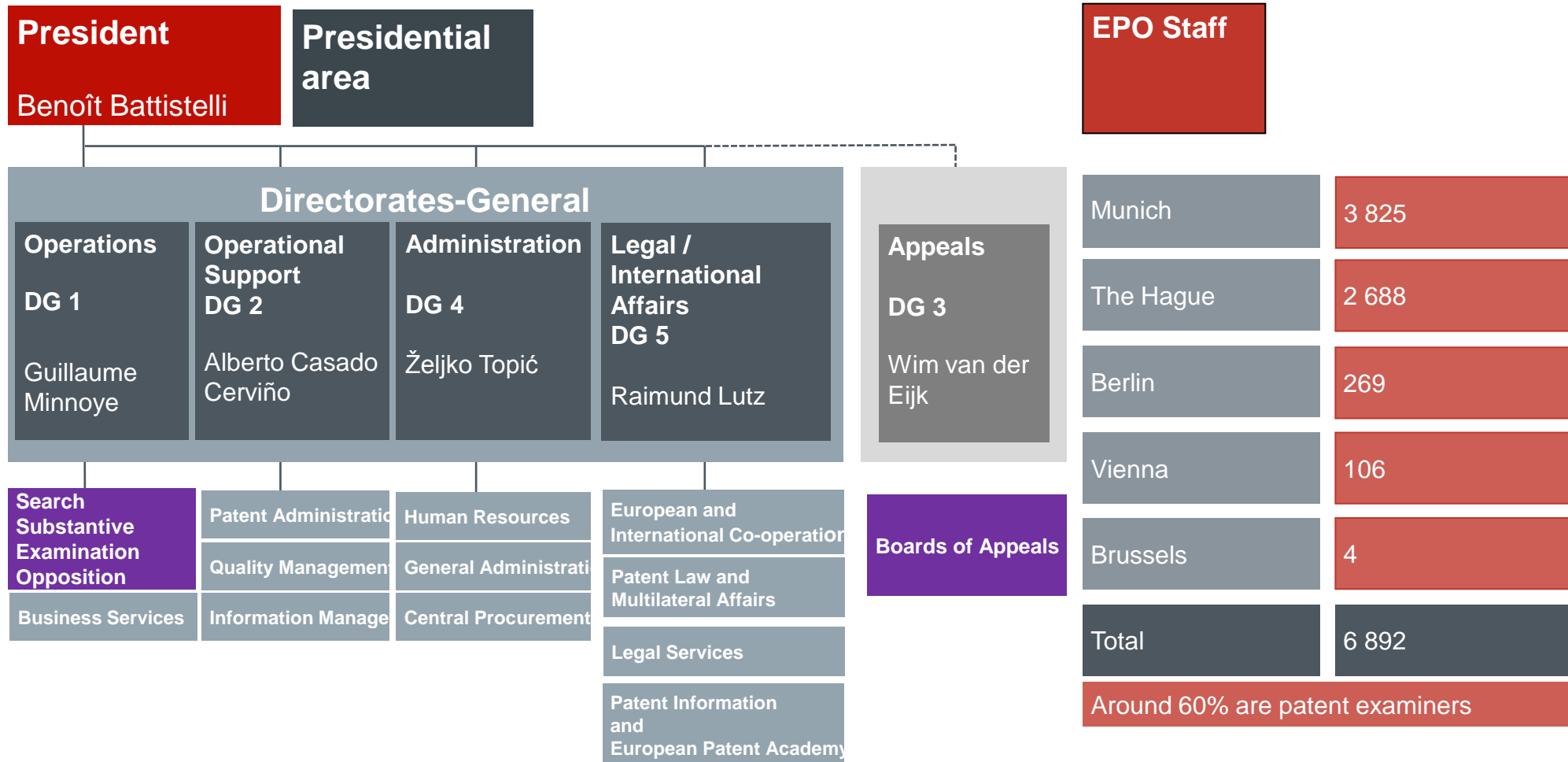


As the patent office for Europe,
we support **innovation**,
competitiveness and **economic
growth** across Europe through a
commitment to **high quality**
and efficient services delivered
under the **European Patent
Convention**.

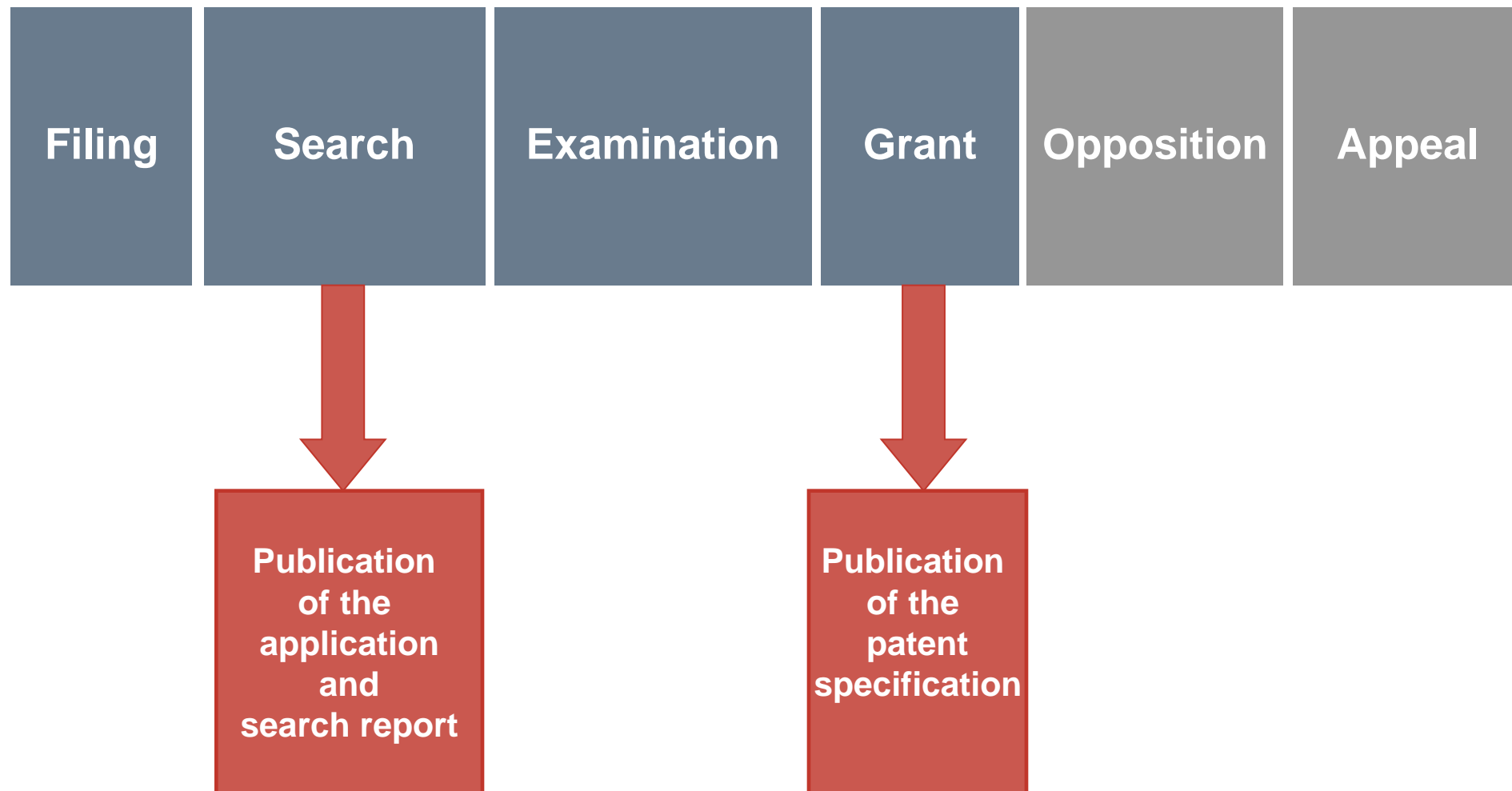
Our five EPO locations in Europe



Structure of the European Patent Office



Basic steps in the European grant procedure



Examination

- Applications are examined by a panel of **three expert examiners**.
- The examiners check that the scope of protection is limited to **what is actually patentable**.
- They take into account the search report and the **requirements for patentability** of the EPC.
- **Oral Proceedings** may be appointed if needed



Outcome

- If the application meets the requirements of the EPC
=> grant



=> possibility to oppose

- If the application does not meet the requirements of the EPC
=> refusal



=> possibility to appeal

All granted European patents are published

For information on the legal status of applications go to www.epo.org/register

Opposition

An **opposition** may be filed by any interested party against the granted patent.

=> proceedings *intra partes*

An **opposition division** examines the grounds of opposition.

After holding hearings of the parties involved, a **decision** is issued.



In 70% of opposition decisions, the patent is upheld either as granted or in amended form.

What information do patent documents contain?



- **Title** of the invention, name of the inventor
- **Detailed description of the invention**: how it is constructed, how it is used, benefits compared with what already exists
- **Claims** providing a precise definition of what the patent protects
- **Drawings**
- **Abstracts**: summary of the invention - particularly useful for search engines

All patent documents are accessible free of charge on www.epo.org

Espacenet

90 million
patent documents,
easily searchable

Patent Translate

Automatic translation
to and from English
and 31 languages,
including Chinese,
Japanese, Korean
and Russian



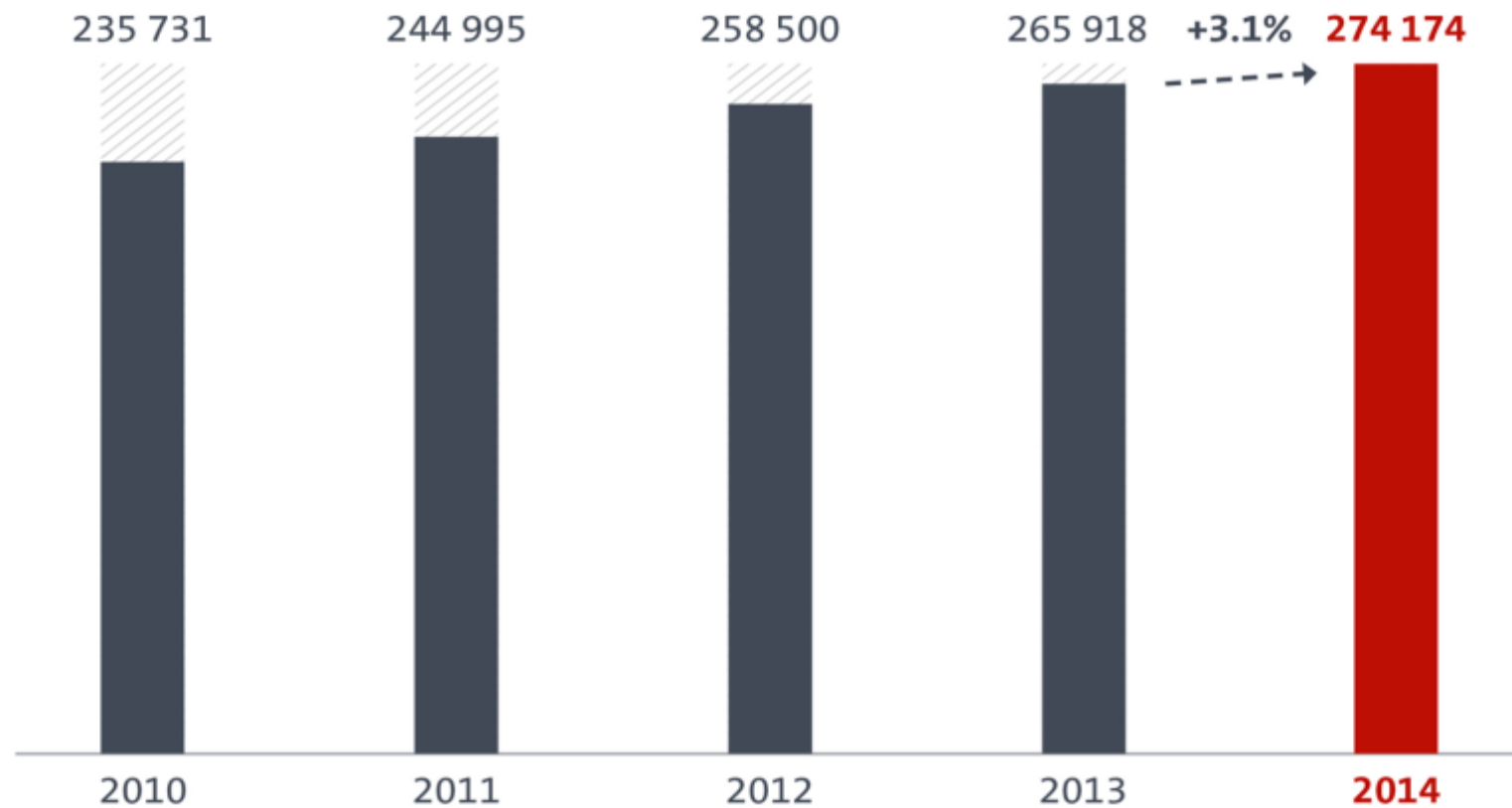
The screenshot shows the EPO website homepage. At the top, there is a header with the EPO logo and name in multiple languages (Europäisches Patentamt, European Patent Office, Office européen des brevets). To the right of the logo is a search bar with 'Site search' and 'Patent search' tabs, an 'Enter search term' input field, and a 'Search' button. Further right are links for 'Deutsch', 'English', 'Français', 'About us', 'Media', 'Service & support', and 'Contact'. Below the header is a navigation bar with links: 'Home', 'Searching for patents', 'Applying for a patent', 'Law & practice', 'News & issues', and 'Learning & events'. The main content area features a large banner on the right with the text 'Access the EPO website anywhere, anytime' and a 'Visit the mobile site' button. On the left, there is a sidebar with a 'Searching for patents' section containing links to 'European patent register', 'European publication server', 'Espacenet - patent search', 'GPI - advanced search', 'Patent Translate', and 'Patent Information tour'. Below this are sections for 'Applying for a patent' and 'Law & practice'. At the bottom, there are four promotional tiles: 'East meets West 2015 - Forum on Asian patent information' with a 'Register now' link; 'The EPO will recruit 150 engineers and scientists in 2015' with a link to 'Apply now for our Spring Selection Events'; 'Business opportunities and validation of European patents in Morocco' with a link to 'Register for Focus Morocco'; and 'Online services and software' with a search bar and a 'Go' button.

Key facts about Espacenet

- Most visited area of our website
 - around **20 million visits every year**
- A **worldwide collection** of patent data
- For beginners and experts
 - **smart search** using key words
 - **advanced search** using combined search information, classification, etc.
- Translation of documents in one click
 - currently covers **translation between English and 31 other languages**, including Chinese , Japanese, Korean and Russian

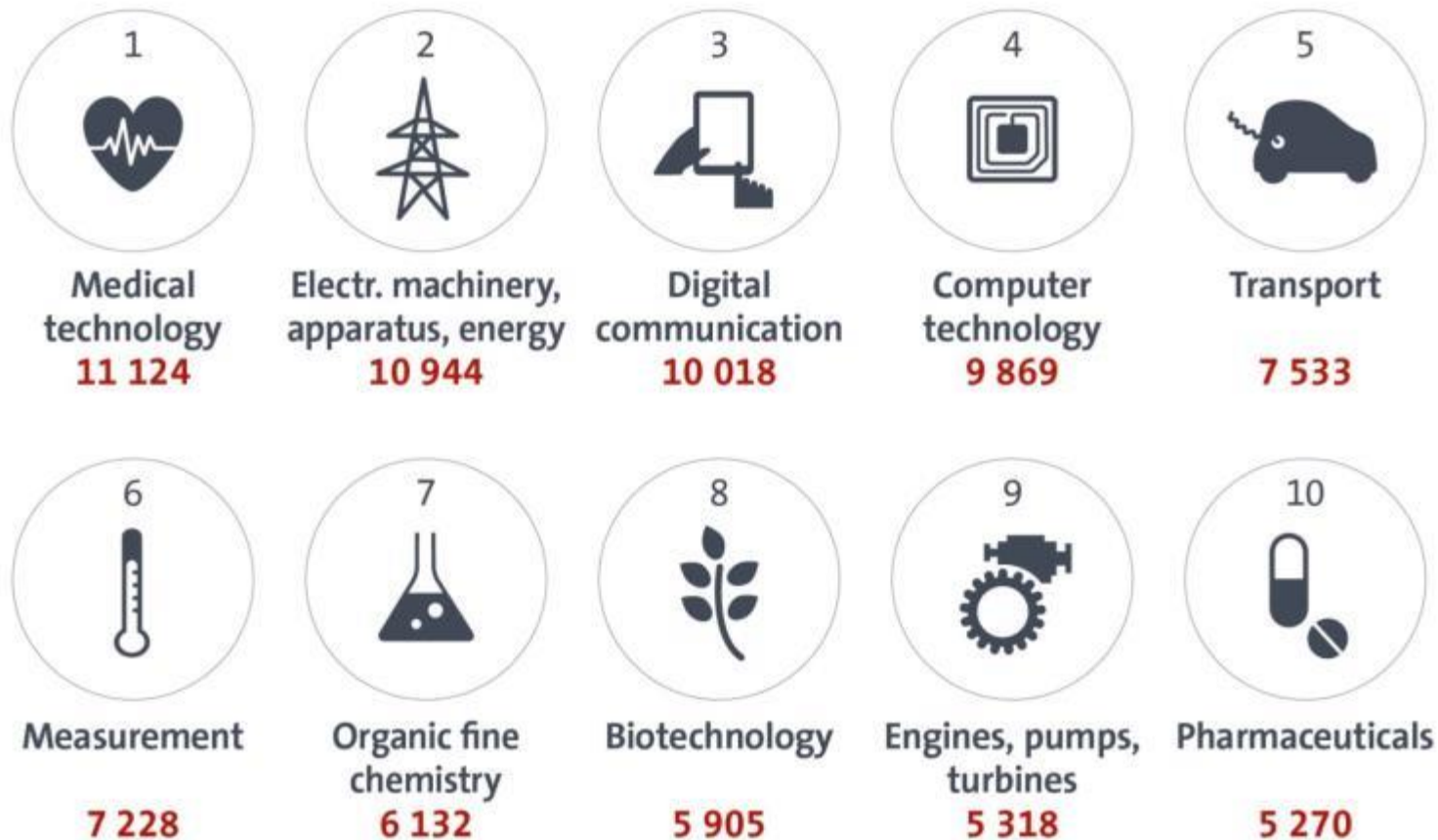


Total European patent filings¹⁾



¹⁾ Direct European filings under the EPC and international filings under the PCT.

Technical fields¹ with the most applications (2014)²

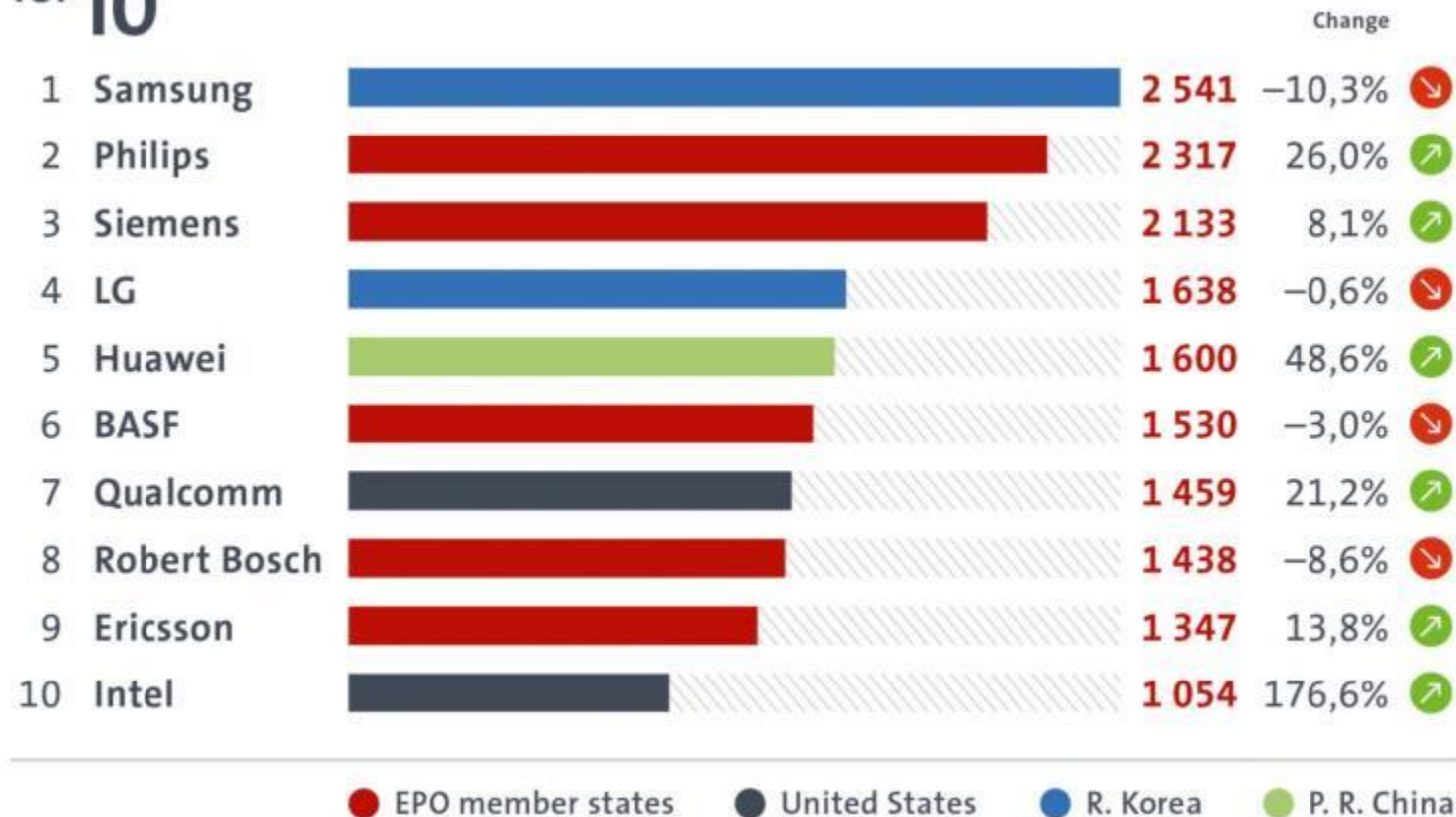


¹ Classified according to the IPC and technology concordance table as revised in January 2013

² Based on European patent applications filed with the EPO.

Top applicants seeking patent protection from the EPO in 2014¹

TOP 10



¹ Based on European patent applications filed with the EPO.

Technical fields of Biotechnology at the EPO

Diagnostics

- Nucleic acid based analysis
- Protein based analysis

Immunology

- vaccines
- antibodies

Biomedical Virology

- Viral strains
- Gene therapy

Microorganisms

- Medical Microbiology
- Industrial Microbiology

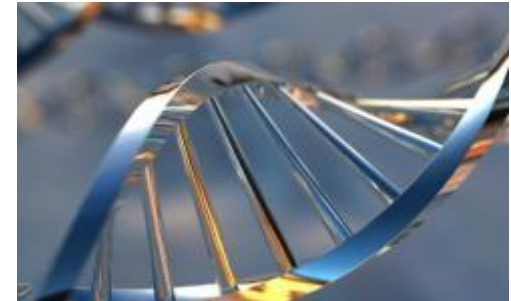
Genetically modified organisms

- plants
- animals

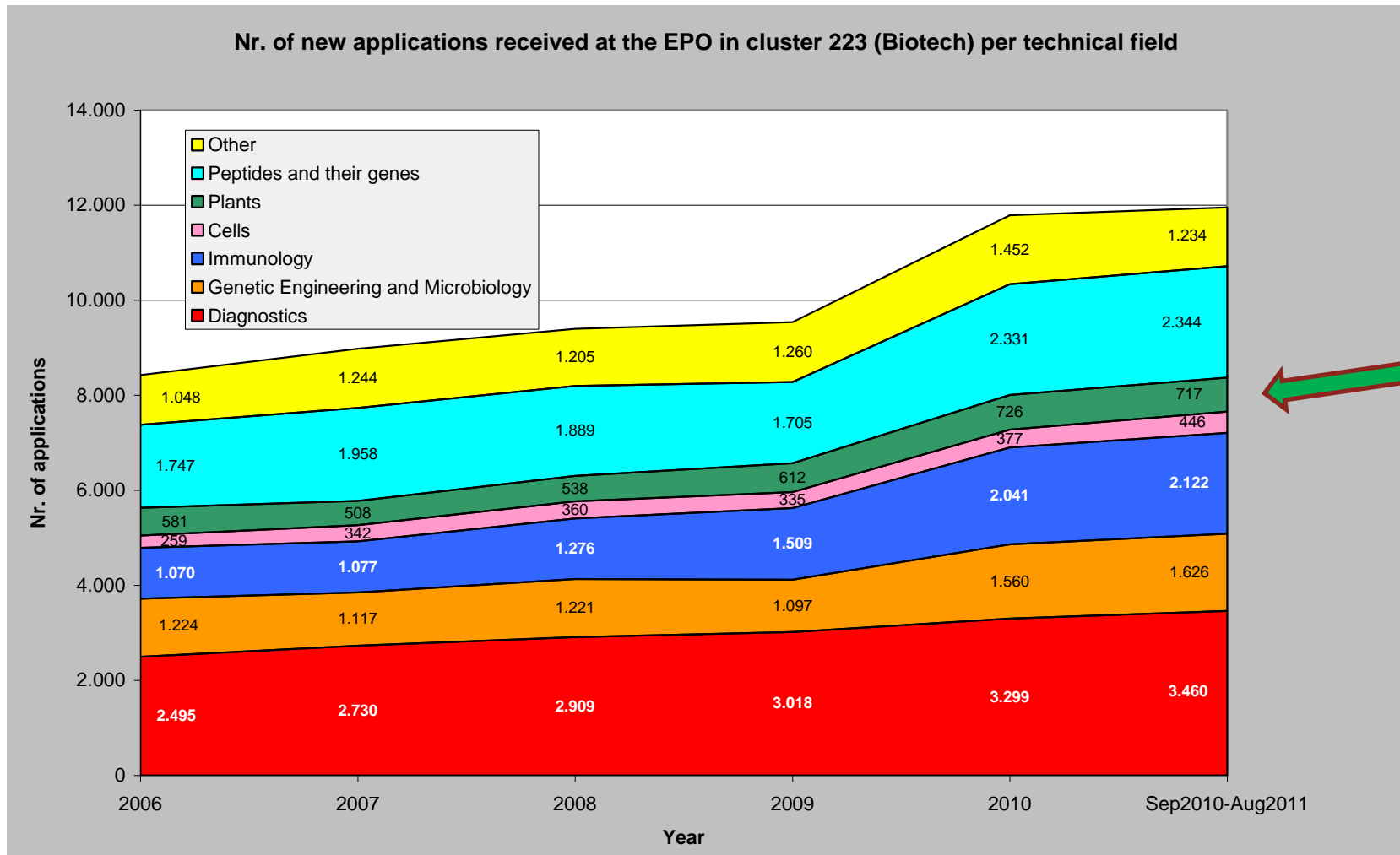
Cells

- cell cultures & lines,
- cell therapy

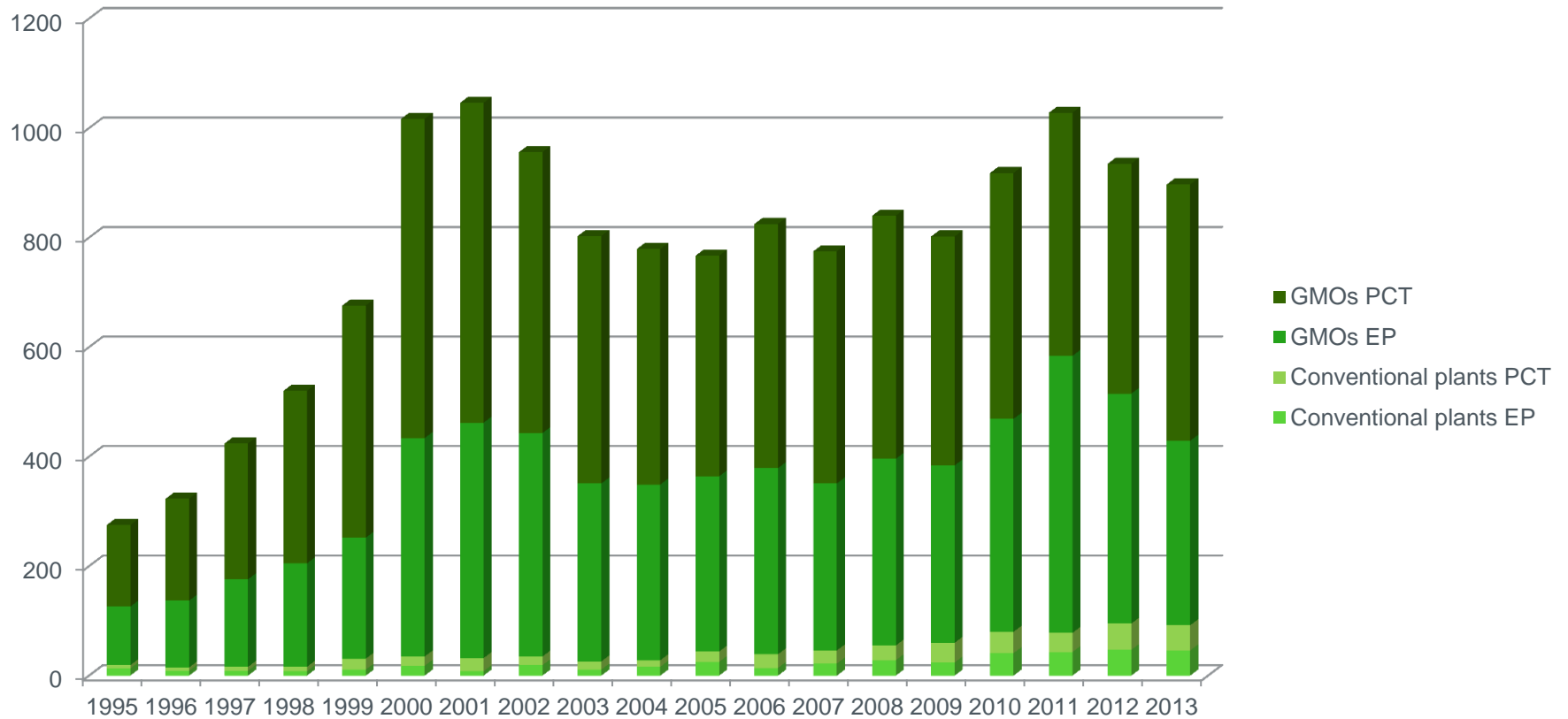
Peptides, enzymes and their genes



Evolution of patent filings in Biotechnology



Plant applications : filed and published per year

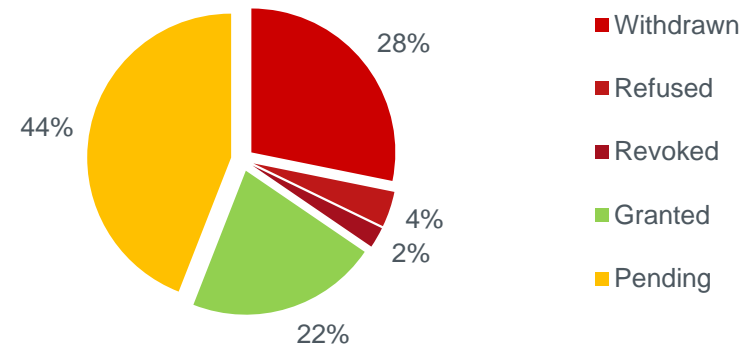
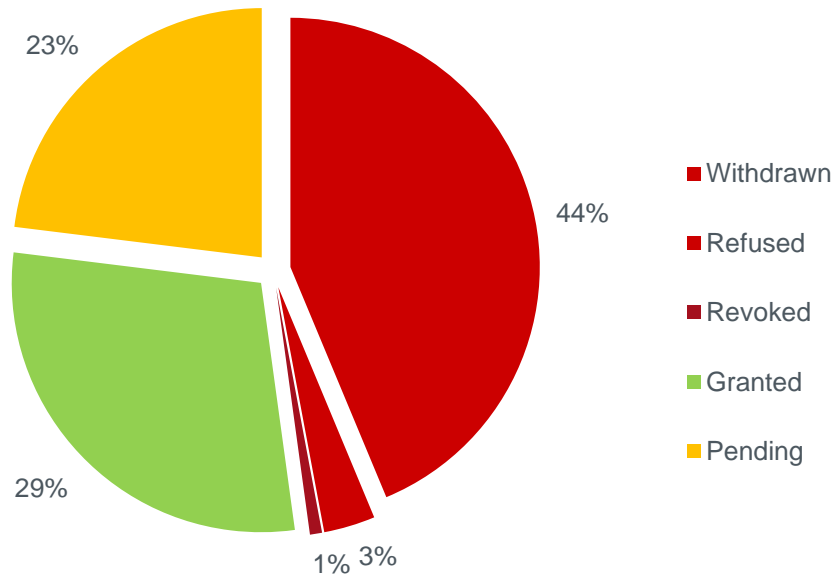


GMO: Introduction of foreign genetic material into plant cells
 Conventional plants : Conventional plants and plant breeding

Plant applications : stage of proceedings on 08.10.2014

6 751 applications on GMO plants

724 application on Conventional plants



GMO: Introduction of foreign genetic material into plant cells
Conventional plants : Conventional plants and plant breeding

Legal basis



Legal basis for patenting biotechnological inventions

- **European Patent Convention – EPC** (1973 and revised 2000)
 - Implementing Regulations (Rules 26-30 EPC)
 - Guidelines for Examination in the EPO

- **Case Law of the Boards of Appeal of the European Patent Office**
 - establish practice
 - rule on how to interpret the law

- **Directive 98/44/EC** of the European Parliament and the Council of the European Union of 6 July 1998 on the legal protection of biotechnological inventions
 - incorporated into the EPC in 1999
 - Directive shall be used as supplementary means of interpretation



National Legislation and National Court decisions

Excluded from patentability under the EPC ¹⁾

- Discoveries
- Scientific theories
- Mathematical methods
- Computer programs
- Aesthetic creations
- Business methods
- Methods for playing games
- Methods for performing mental acts
- Presentations of information

If claimed
"as such"

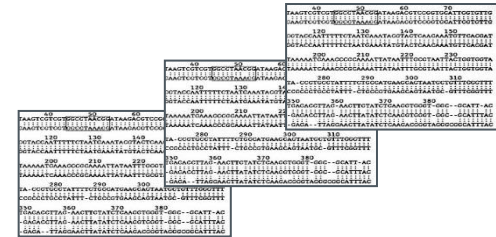


¹⁾ Article 52 EPC and the case law of the boards of appeal.



Exceptions to patentability as defined by the EPC ¹⁾

- Inventions whose commercial exploitation would be **contrary to "ordre public" or morality** (e.g. processes for cloning of human beings)



- **Plant or animal varieties**



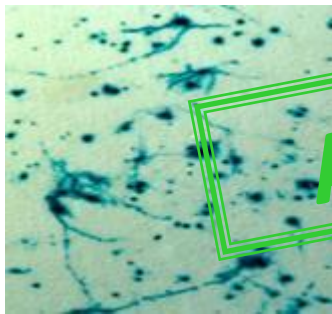
- Methods for **treatment** of the human or animal **body** by **surgery** or **therapy** and **diagnostic** methods



¹⁾ Article 53 EPC and the case law of the boards of appeal.

Patentability of biotechnological inventions (Rule 27 EPC)

- Biotechnological inventions shall be patentable if they concern
 - biological material which is **isolated** from its natural environment or technically produced even if it previously occurred in nature
 - **plants or animals** if not confined to a particular plant or animal variety
 - **microbiological processes** and products



ALLOWED

Legal background of the plant patentability

Article 53 EPC - Exceptions to patentability

European patents shall not be granted in respect of:

(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;

Rule 27 EPC - Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

Rule 26(5) EPC

A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection

Plant varieties

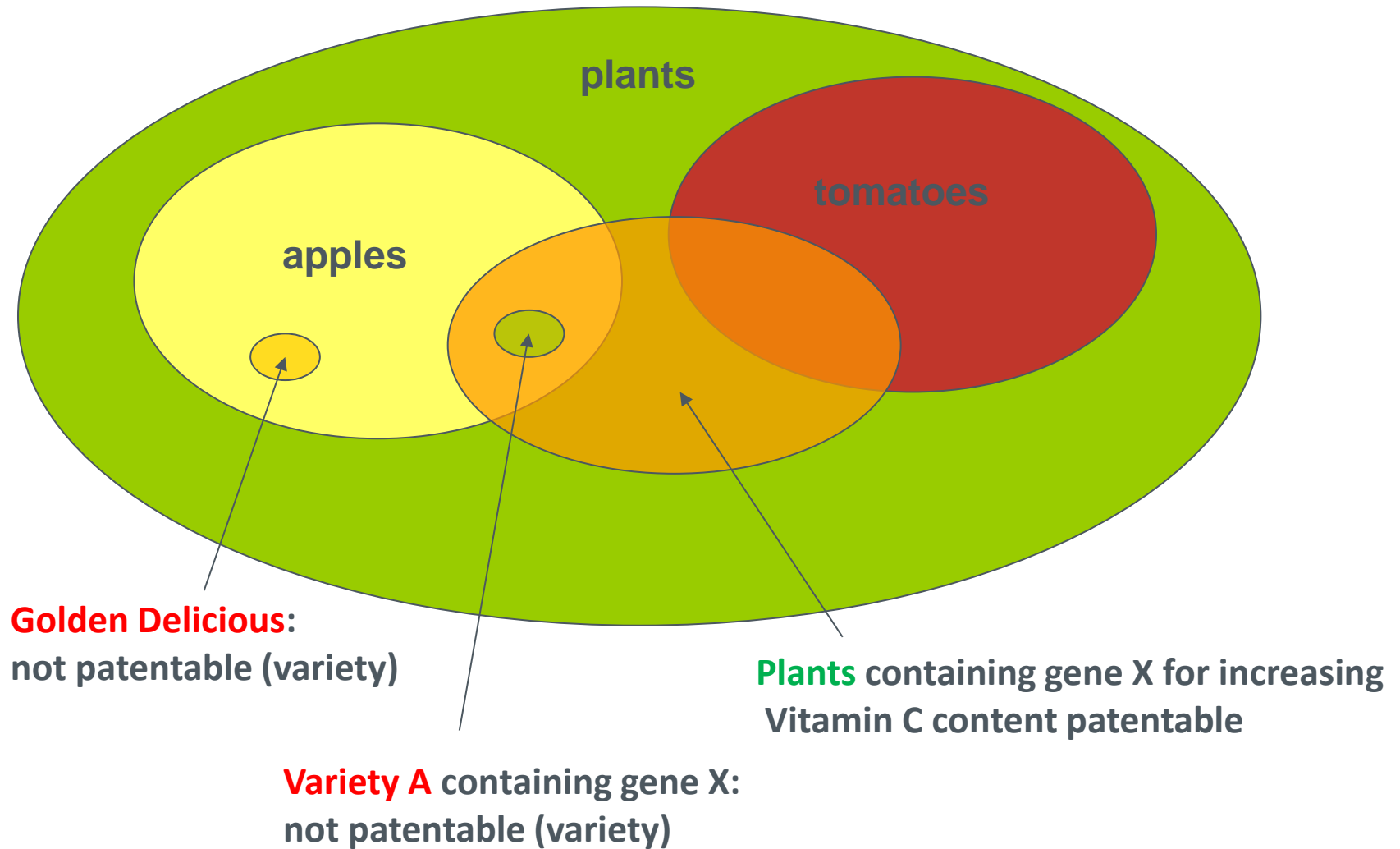


Plant varieties : G 1/98, Headnotes 20.12.1999

- A claim wherein specific plant varieties are **not individually claimed** is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties.
- The exception to patentability in Article 53(b), first half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.



Plants vs Plant varieties



Exclusion from patentability of plant varieties because

- Plant varieties to be protected under UPOV
 - legislator did not want double protection (possible since 1991)
- Classical plant breeding processes relying on sexual crossing and the resulting varieties are not reproducible
 - every variety is a random event defined by its entire genome
 - no general technical teaching
 - biological, not technical processes
- Some indication that legislator wanted to exclude breeding processes used by plant breeders for making new plant varieties from patentability



Definition of plant variety Rule 26(4) EPC & UPOV Convention

Distinct Uniform Stable

Any plant grouping within a single botanical taxon of the lowest known rank, which grouping, *irrespective of whether the conditions for the grant of a plant variety right are fully met*, can be:

- (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes (**distinct**),
- (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics (**uniform**), and
- (c) considered as a unit with regard to its suitability for being propagated unchanged (**stable**).





Patent rights vs Plant variety rights

- | Patent rights | Plant variety rights |
|---|--|
| <ul style="list-style-type: none">■ Plant defined by one or more inventive characteristics, not by whole genome■ All plants with the inventive feature protected, however obtained<ul style="list-style-type: none">– foreign genes, e.g. from related species (broccoli, tomato) or bacteria (glyphosate resistance)– gene mutation (e.g. sunflower)■ Teaching must be novel and inventive■ Plant protected for all uses<ul style="list-style-type: none">– no EU-wide breeders' exemption | <ul style="list-style-type: none">■ Variety defined by whole genome or gene complex (DUS criteria)■ Only single variety and varieties essentially derived from it protected<ul style="list-style-type: none">– phenotype as defined by the genome■ Variety must be distinct (novel)<ul style="list-style-type: none">– no inventive step requirement■ Breeders' exemption<ul style="list-style-type: none">– free use of protected variety for further breeding– free commercialisation of new varieties (except for essentially derived ones) |

Plant patentability if requirements are met

- Plants are patentable
 - if the plant grouping is not a variety
 - if the invention can be used to make more than a particular plant variety
 - no matter how they are prepared
 - as long as no individual plant varieties are mentioned in the claim
- Conventional, non-transgenic plants obtained by breeding are also patentable as long as they are not varieties by DUS criteria



Examples

- **Excepted** from patentability as a plant variety:
 - ✗ A plant obtained from seed deposited as *Brassica napus oleifera* 975N-1650 with the accession number 97838
- **Allowable** (e.g. EP-0 891 130, T0788/07):
 - ✓ A **hybrid plant** comprising an inheritable and stable fertility restorer gene for ogura cytoplasmic male sterility, **produced by a cross** between a plant obtained from seed deposited as *Brassica napus oleifera* 975N-1650 with the accession number 97838 as a male parent, **and a second *Brassica* plant** as a female parent....
(plant is hybrid and not a variety)
- **Hybrid plant may** be variety and hence not patentable!

Essentially biological process



What is an “essentially biological process” for producing plants?

- In 1973, only traditional plant breeding processes possible
 - crossing and selection
 - no controlled genetic engineering
- Modern gene technology made generic plant inventions possible and revolutionised breeding
 - mapping of plant genes and native traits by markers
 - moving genes between plants in a controlled way
- **Where is the line to be drawn between patentable and non-patentable processes?**
 - is marker-assisted breeding patentable?
 - is a breeding process patentable if it includes further steps as well as crossing and selection?

Essentially biological process

EP 1 069 819 (G 2/07- broccoli):

Method for production of *Brassica oleracea*, comprising steps of crossing and selection, wherein **molecular markers** are used to identify desired hybrids



EP 1 211 926 (G 1/08 - wrinkled tomato)

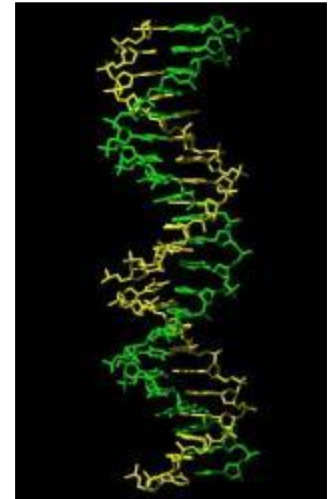
Method for breeding tomato plants that produce tomatoes with reduced fruit water content, comprising crossing and selection steps, **followed by** allowing fruit to remain on the vine until it is partially dried, and screening the fruit for reduced water content



Conclusions of G 2/07 and G 1/08

09.12.2010

- Processes for production of plants based on **sexual crossing of whole genomes** and the **subsequent selection** of plants are not patentable
- Additional technical steps performed **before or after** the process of sexual crossing and selection, e.g. to process the plant or to assist selection, **do not make the process patentable**
 - these steps (markers, processing steps) may be patented *per se*
 - sexual crossing must not be included in claim explicitly or implicitly
- If a trait is introduced into the genome by a technical step, such as by **genetic engineering**, so that the presence of the trait is not the result of sexual crossing, then the process is patentable



Application:

Classical breeding of new plants having a particular starch composition. The plants may be used to isolate starch.

Claim:

Method of making starch comprising **crossing** plant A with plant B and **selecting** desired plant.

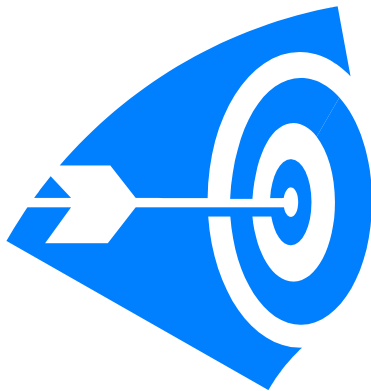


Claim

Method of producing a herbicide-resistant potato plant, comprising the steps of crossing a resistant with a susceptible plant **and identifying resistant plants by using molecular markers.**

Not allowable under Article 53(b) EPC

Not allowable under Article 53(b) EPC



Claim

Method for producing a herbicide-resistant potato plant, comprising

- crossing parental plants A and B;*
- treating the plants with X such that herbicide sensitivity genes are removed from the genome; and*
- selecting herbicide resistant plants*


Allowable under Article 53(b) EPC

Plants products of essentially biological processes



Re-thinking of the outcome of an essential biological process

T 1242/06 (Tomatoes II, Decision of 31.05.2012)

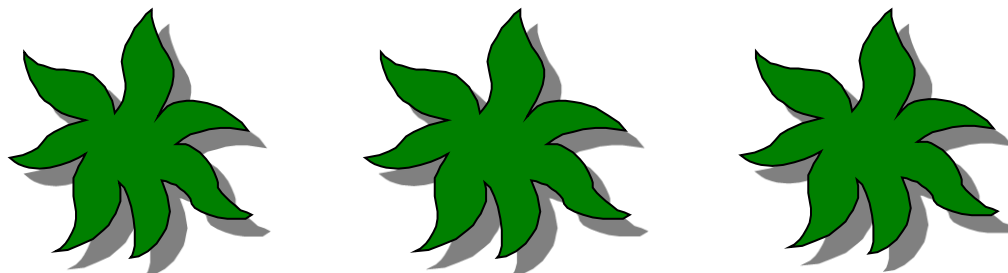
- Board finds that the claimed invention was neither limited nor directed to a plant variety
 - G 1/08 excluded plant breeding processes from patentability
 - Product claims give the proprietor the right to exclude others from making or using the patented product
 - ☑ Do the product claims negate the legislator's intention to exclude breeding processes from patentability?
- 
- Does it make sense if it is prohibited to patent an essentially biological method, that the product (exclusively) obtained thereby may be patented?
 - Does the method fall into the scope of protection of the product claim?

Further questions referred to Enlarged Board of Appeals

G 2/12 & G2/13

1. Can the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit?
2. In particular, is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?
3. Is it of relevance in the context of questions 1 and 2 that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC?

T 1242/06 (Tomatoes II, 31.05.2012)



Conclusion of G 2/12 and G 2/13 (25.03.2015)

The exclusion of essential biological processes for the production of plants in Article 53(b) EPC **does not have a negative effect** on the allowability of a product claim directed to plants or plant material such as plant parts.

This applies even if the only method available for generating the claimed plants or plant material is an essentially biological process . And also if the claimed product , that is the plant or plant material is defined in terms of such a process (product-by-process claim).

For a product-by-process claim to be allowable it needs to be established that

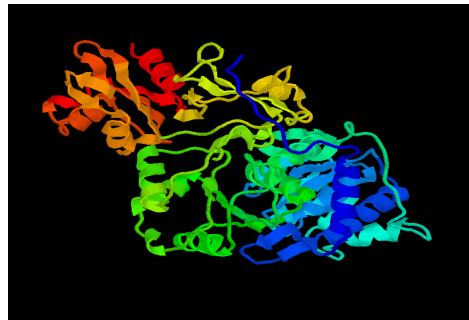
- (a) it is impossible to define the claimed product other than in terms of a process of manufacture and
- (b) the claimed product itself meets the patentability requirements .

Patentable plants and plant material

Plants defined by

- transgene
- biochemical profile (oil, sugar)
- markers (e.g. stacking of desirable traits)
- Elite event

A method of generating a plant having a modified fatty acid profile comprising transforming plant cells with a recombinant vector comprising a nucleic acid encoding fatty acid dehydratase having the sequence as shown in figure X



Nucleic acid sequences & proteins from plants

e.g. markers, promoters, genes, ...

Methods using these materials

“Use of molecular marker X having the sequence ... for the identification of Brassica plants having increased glucosinolate levels.”

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