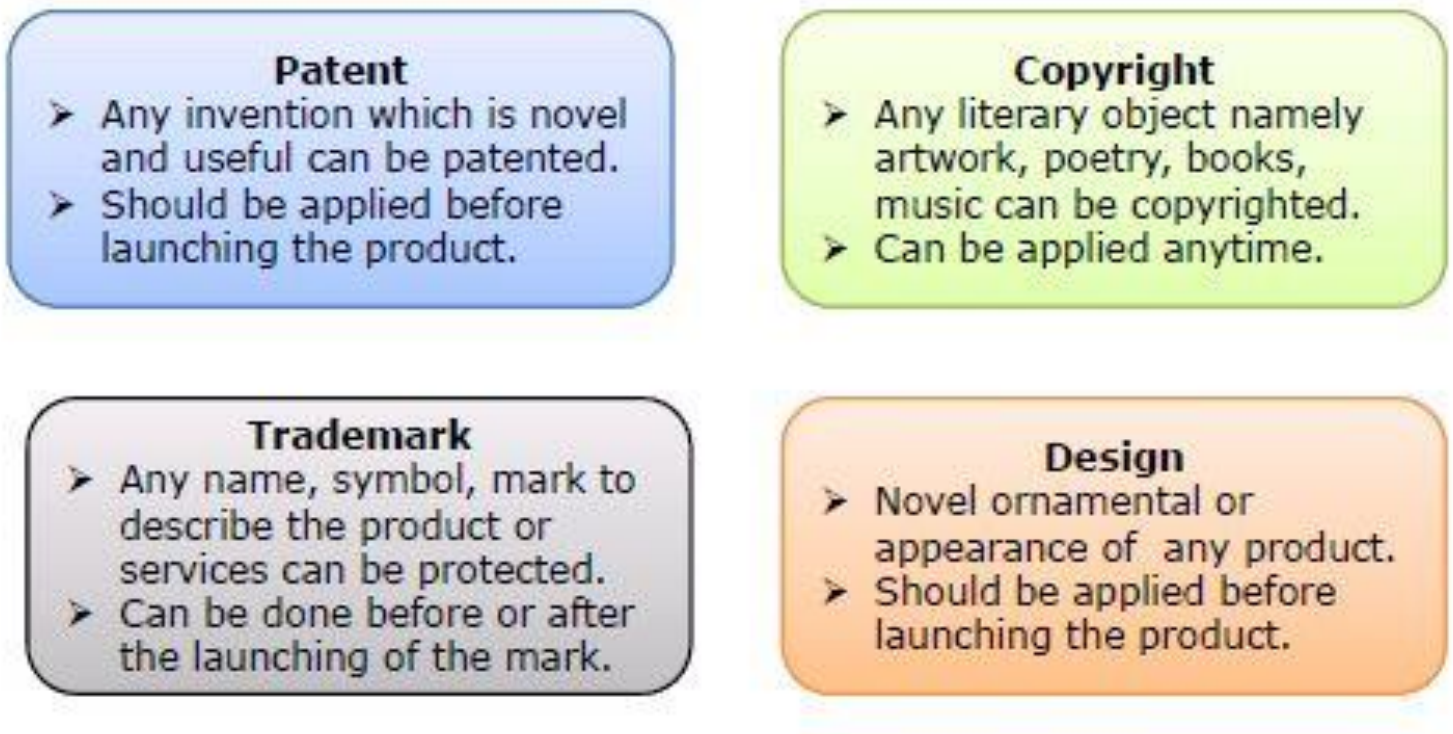
# Patenting Microbial Biotechnology

- **What IPR means?**

Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time.

- There are four main types of intellectual property rights, including **patents, trademarks, copyrights, and trade secrets**. Owners of intellectual property frequently use more than one of these types of intellectual property law to protect the same intangible assets.



# TYPES OF IPR

## Patent

- A Patent is granted for Invention which is a new product or process.
- Law: Patents Act, 1970, amended in 2006
- Ministry: DPIIT, Ministry of Commerce and industry
- Period: 20 Years



## Trademark

TM

- A trademark is typically a name, word, phrase, logo, symbol, design, image, or a combination of these elements.
- Law: Trademark Act 1999
- Ministry: DPIIT, Ministry of Commerce and industry
- Period: 10 Years





## Geographical Indication

- A geographical indication (GI) is a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin.
- Law: Geographical Indications of Goods (Registration and Protection Act), 1999
- Ministry: DPIIT, Ministry of Commerce and industry
- Period: 10 Years




# 4 TYPES OF INTELLECTUAL PROPERTY TO PROTECT YOUR IDEA

## TRADE SECRETS

- Protects secret information
- E.g., New invention, Coke formula

## TRADEMARKS

- Protects brands
- E.g., Apple for cell phones

## COPYRIGHTS

- Protects works of authorship
- E.g., books, movies, drawings

## PATENTS

- Protects functional or ornamental features
- E.g., swipe feature or iPhone design

# Patenting in biotechnology

- Many products of nature (e.g. specific antibiotics, microorganisms, proteins, etc.) have been successfully patented.
- It might be argued that simply to find any substance naturally occurring on the Earth is categorized as a discovery and would be unpatentable because it lacks true novelty or any inventive step.
- However, if you enrich, purify or modify a product of nature such that you make available the substance for the first time in an industrially useful format, that product/process is generally patentable.
- In other words, patenting is possible if the 'hand of man' has played an obvious part in developing the product.

- **Why are patents so important?**

A patent is important because it can help safeguard your invention. It can protect any product, design or process that meets certain specifications according to its originality, practicality, suitability, and utility. In most cases, a patent can protect an invention for up to 20 years.

**How do patents benefit society?**

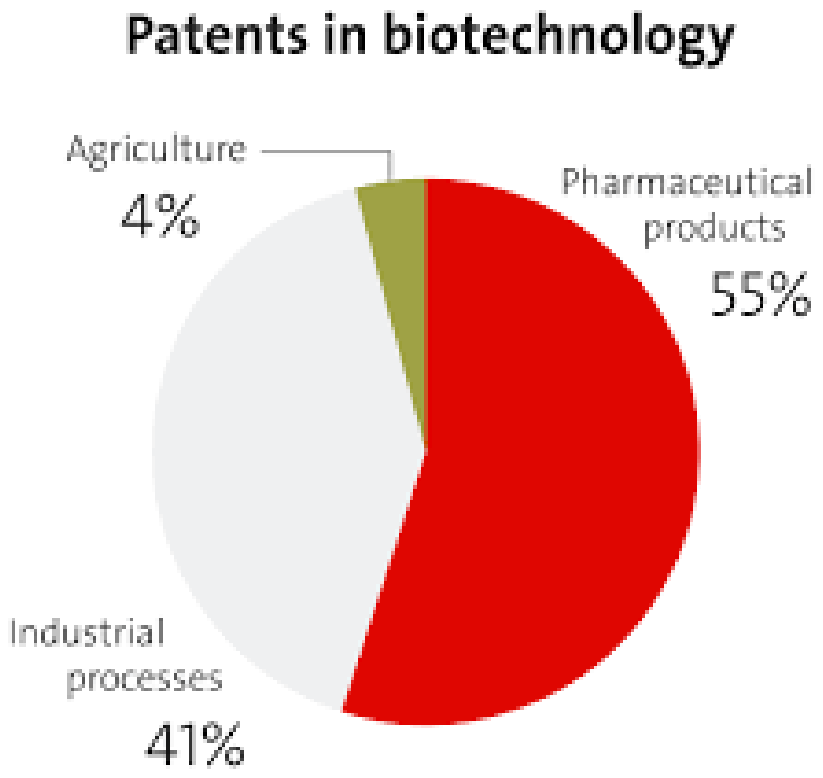
Patents **give owners rights to exclude others from making, using, or selling their inventions**. inventors and adopters can transact more efficiently in the market for inventions. Patents promote disclosure of inventions, which reduces costs of search and bargaining in the market for inventions.

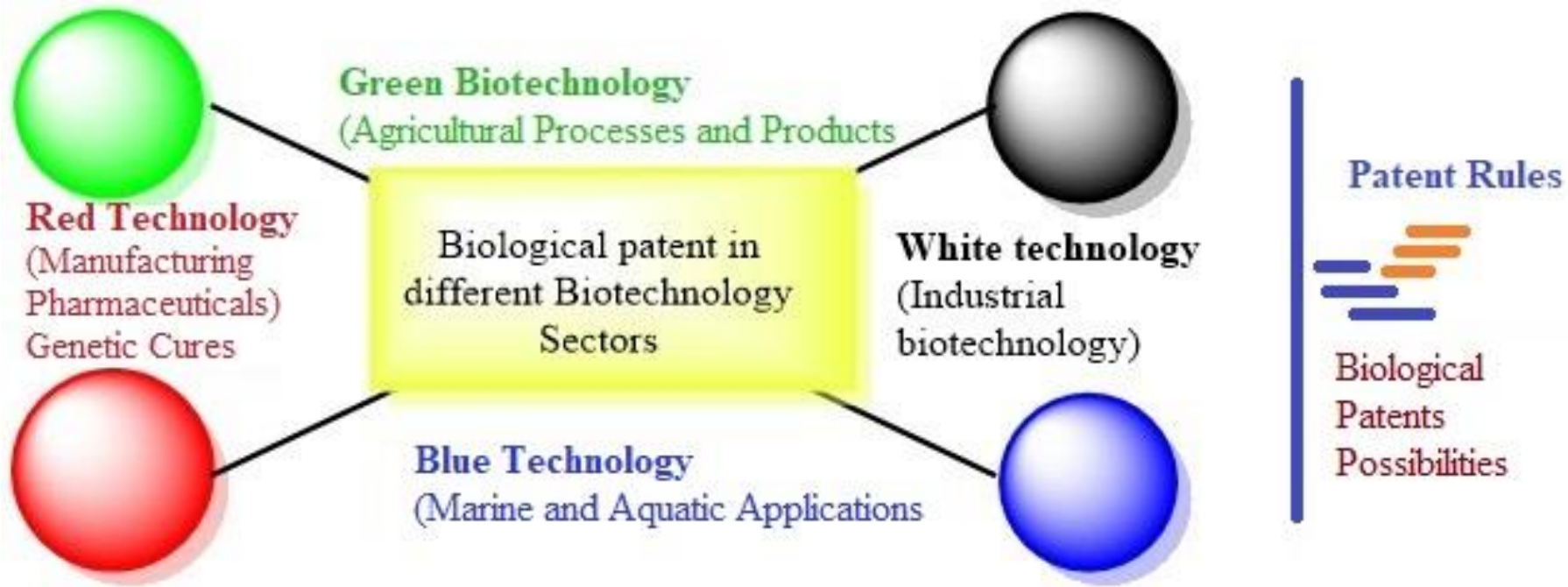
- **What are the pros and cons of patenting?**

•Advantage #1: Exclusive Rights.
•Advantage #2: Sparks Innovation.
•Advantage #3: Easily Commercialized.
•Disadvantage #1: Difficult to Acquire.
•Disadvantage #2: Dealing with Infringers.
•Disadvantage #3: Limited Time.

## Examples of Emerging Life Science Innovations

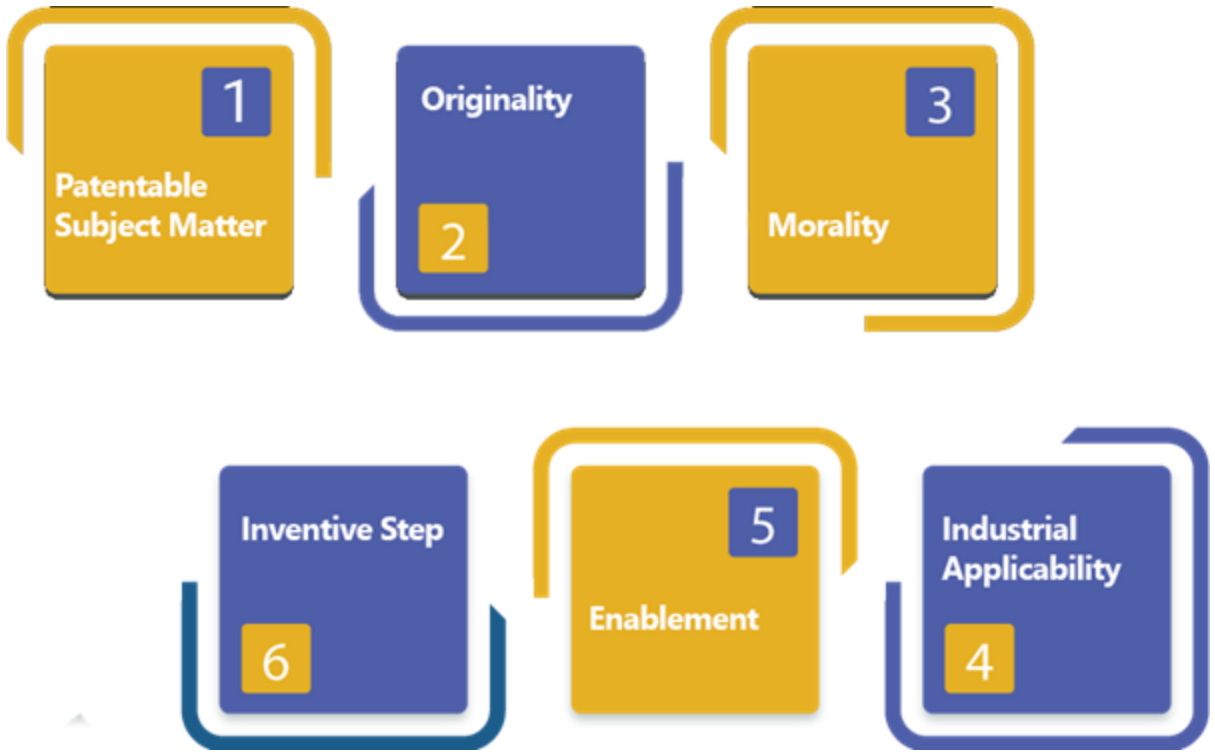
- Pinpointing genetic determination/predisposition to disease and injury.
- Customizing medicines and therapies to the individual's genome.
- Engineering bacteria to attack and kill disease in human cells.
- Melding human tissue and microcomputers to produce diagnostics, treatments, and therapies.
- Developing XNA (man-made DNA) to produce useful new life-forms.
- Increasing the roster of 1,200 single gene disorders curable by gene therapy.
- Expanding our knowledge of 3,500 traits in the human fetus that give rise to maladies.
- Employing prenatal genetics to predict physical outcomes and traits.
- Tweaking genes to make drug therapies more effective.
- Engineering organisms to produce biofuels and eliminate environmental hazards.
- Growing organs in a laboratory.




Green Biotechnology
(Agricultural Processes and Products
Red Technology
(Manufacturing
Pharmaceuticals)
Genetic Cures
Biological patent in different Biotechnology Sectors
White technology
(Industrial
biotechnology)
Blue Technology
(Marine and Aquatic Applications
Patent Rules
Biological
Patents
Possibilities

# Patent

- It is a part of intellectual property which is a legal way to protect all creations of the human mind.
- It is an exclusive right granted by the state for an invention that is new, involves an inventive step and is capable of industrial application.
- It gives its owner the exclusive right to prevent or stop others from making, using, selling or importing a product or a process, based on the patented invention without the owners prior permission.



## Why Patent?

- Patents were historically developed to insure that inventors could share in the financial returns and benefits deriving from the use of their inventions. With the development of the modern corporation, patent rights were always assigned to the company rather than an individual.
- This gives the patent holder a form of monopoly control for 20 years from the filing of the patent, and creates a legal means of limiting competition. Private investors generally regard such monopolies as favorable to their interests, so in many industries patents aid in the development of new products.



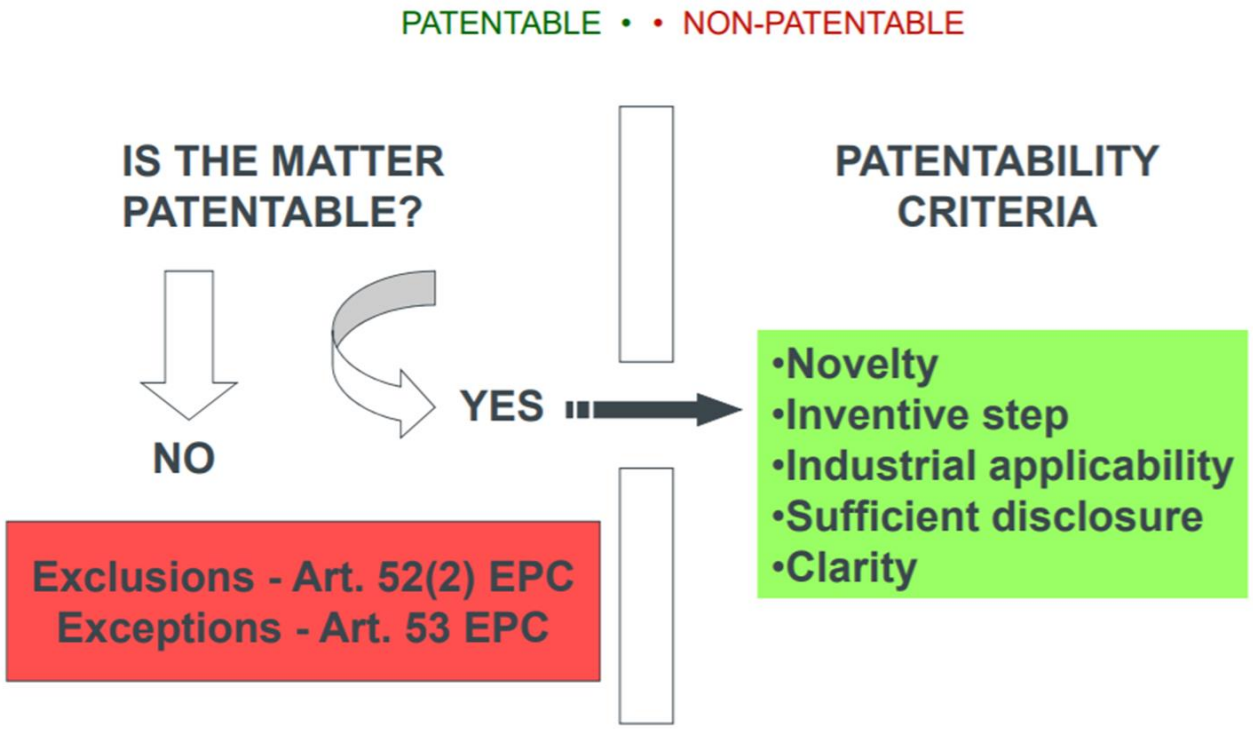
## What can be patented?

- In order to patent an object, the inventor has to prove that
  - it has never been made before,
  - involves a "non-obvious" inventive step,
  - and that it serves some useful purpose
- Patents are to be granted only on human inventions, not on discoveries.
- Existing living organisms, like plants and animals as well as their genes, are of course no-one's invention and should therefore, by definition, never be patented and put under private control.

# Introduction

- Patent is a government authority or license conferring a right or title for a set period, especially the sole right to exclude others from making, using or selling an invention.
- Patent claims to inventions relating to micro-organisms may be directed to the micro-organism itself, its products or processes involving it.
- All over the world, governments set up patent or intellectual property laws, which have two aims.
- First, they are intended to induce an inventor to disclose something of his/her invention.
- Second, patents ensure that an invention is not exploited without some reward to the inventor for his/her innovation; anyone wishing to use a patented invention would have to pay the patentee for its use.
- The prerequisite for the patentability of inventions all over the world are that the claimed invention must be new, useful and unobvious from what is already known in 'the prior art' or in the 'state of the art'.
- For most patent laws an invention is patentable:
    a. if it is new, results from inventive activity and is capable of industrial application, or
    b. if it constitutes an improvement upon a patented invention, and is capable of industrial application.

- Patentability requirements
  - Novelty - Art. 54 EPC
  - Inventive Step - Art. 56 EPC
  - Industrial Applicability - Art. 57 EPC
  - Disclosure and Support - Clarity - Art. 83, 84 EPC
- Biotech-specific issues
  - Exclusions - Art. 52(2)
  - EPC Exceptions - Art. 53 EPC



# Patents: **Frequently asked questions**

## WHAT IS A PATENT?

Patents protect inventions of technical subject matter against unauthorized exploitation by others.

**NOTE: A patent may be valid for a maximum period of 20 years.**

## WHICH INVENTIONS MAY BE PATENTED?

Any invention that is novel and inventive, subject to some exclusions that include computer programs, business methods, and methods of medical treatment.

**NOTE: Novelty is destroyed by pre-filing non-confidential disclosures! Investigate patenting options first.**

## WHAT IS THE EFFECT OF A PATENT?

The right to exclude others from making, using, exercising, disposing or offering to dispose of, or importing the patented invention.

**NOTE – Patents are territorial. There is no such thing as a "worldwide patent".**

## CAN I FIND OUT IF SOMETHING IS ALREADY PATENTED?

Yes. Investigate patent infringement risk by conducting local patent searches with the assistance of a patent attorney. Investigate patentability by conducting global patent and non-patent searches using online databases such as Google Patents.

## WHAT IS THE VALUE OF A PATENT?

Exclusivity may provide a competitive edge or generate revenue through licensing. As an intangible asset, a patent may also contribute to a company's balance sheet.

## HOW DO YOU APPROACH OBTAINING A PATENT?

Do not disclose the invention • Conduct patentability searching • File a provisional patent application at CIPC, either yourself or through a patent attorney • Develop the invention and assess commercial prospects • 12 months later: File a complete patent application at CIPC through a patent attorney • grant occurs in 12 to 18 months

**NOTE: South Africa sees about 7500 to 9500 new patent applications filed annually**

# What all can be patented

- ❑ Processes Involving Micro-Organisms, Cell Lines, Hybridomas and other Biological Materials:
- When the invention lies in a process, such as fermentation that makes use of a micro-organism, the description of the invention should provide details including the source of the particular organism used for the process as well as its required nutrient and culture condition.
- ❑ New Micro-Organisms, Cell Lines, Hybridomas and other Biological Materials:
- If the invention is a micro-organism, such as a bacterium or fungus or a new cell line, as much as is known of its features should be described. This may include:
  - the taxonomic description
  - morphological characteristics such as shape, size, stain-ability, motility
- ❑ Products of Micro-Organisms, Cell lines, Hybridomas, etc.
- A microbial product, such as a new antibiotic, is best characterized by its chemical structure. As this is not always known, the product may be defined in terms of the organism which produces it and/or by the physical or chemical characteristics that are known and that are sufficient to distinguish it from other known compounds.

Also, patents can be obtained for:

a. an invention is new if it does not form part of the state of the art (i.e., it is not part of the existing body of knowledge);
b. an invention results from inventive activity if it does not obviously follow from the state of the art, either as to the method, the application, the combination of methods, or the product which is concerns, or as to the industrial result it produces, and
c. an invention is capable of industrial application if it can be manufactured or used in any kind of industry, including agriculture.

In the above, ‘the art’ means the art or field of knowledge to which an invention relates and ‘the state of the art’ means everything concerning that art or field of knowledge which has been made available to the public anywhere and at any time, by means of a written or oral description, or in any other way, before the date of the filing of the patent application.

# What all cannot be patented

Patents cannot be validly obtained in respect of:

a. plant or animal varieties, or essentially biological processes for the production of plants or animals (other than microbiological processes and their products),
b. inventions, the publication or exploitation of which would be contrary to public order or morality.

- Principles and discoveries of a scientific nature are not necessarily inventions for the purposes of patent laws.
- It is however not always as easy as it may seem to show that an invention is 'new', 'useful', and 'unobvious'.
- In some cases it has been necessary to go to the law courts to decide whether or not an invention is patentable.

- The most vital and important distinction between the legal practices in India and developed countries is that India do not allow patenting of microorganisms that already exist in nature as the same is considered to be a discovery as per the provisions of the section 3(d) and therefore not patentable.
- But genetically modified versions of the same microorganisms that result in enhancement of its known characteristics are patentable.

## Article 53 EPC - Exceptions to patentability

- European patents shall not be granted in respect of:
  a) inventions the commercial exploitation of which would be contrary to " order 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 essential biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
  c) methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced 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

## Exceptions (Art.53 (a) EPC) - Rule 28 EPC

1. Processes for cloning human beings:
2. Processes for modifying the germ line genetic identity of human beings;
3. Uses of human embryos for industrial or commercial purposes;
4. Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

- Transgenic animals are patentable provided that those are:
  - non-human (Rule 28(b) EPC)
  - their genetic modification does not cause their suffering without any substantial medical benefit to man or animal (Rule 28 (d) EPC)
  - the way to obtain it is sufficiently disclosed (Art. 83 EPC)
  - the animal is not an animal variety (Art. 53(b) EPC)
  - the technical feasibility of the invention is not confined to a particular animal variety (Rule 27(b) EPC)

**Exceptions (Art.53 (a) EPC) - Rule 28 EPC**

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.

- public objections for patenting human genes:
  i. genes cannot be invented
  ii. their patenting is contrary to morality
  iii. life should not be monopolized by companies
  iv. gene claims are too broad
- Can be patented:
  - Sequences whose function is sufficiently characterized by experimental data patentable, provided all other requirements of the EPC are fulfilled.
  - A gene coding for a hormone, its function is experimentally demonstrated, this hormone can be used to treat a certain type of disease (efficacy demonstrated in laboratory).

# What Cannot be Patented

- Mere Idea/Discovery
- Contrary to Natural laws
- Contrary to Public Morality or Order
- Mere Arrangement/Rearrangement
- New use/property of a known material
- Method of Agriculture/Horticulture
- Plants and Animals except Micro-organisms
- Mathematical or Business Method
- Process of treating human beings or animals
- Atomic energy
- Traditional Knowledge

# Patentability of microorganisms

- Patents on micro-organisms are far from new. In the brewing and baking industries, yeast has traditionally played an important part and patents for new types of yeast were granted in Belgium in 1833 and in Finland in 1843.
- The invention must be novel and not obvious, it must have some industrial use, and the description part of the patent application must enable a person skilled in the relevant area of technology to put the invention into practice
- Novelty of a micro-organism in patent terms novel means not previously made available to the public.
- So the first person to find and isolate a new bacterium from a soil sample, for example, might have made a potentially patentable invention.
- If the bacterium have some practical use and is different from other bacteria known for that use, then the use and inventive step hurdles are likely to be overcome.
- If a scientist is familiar with microorganisms, finding microorganism to patent is most likely going to be a hard part.
- Patentable microorganisms can be found in the natural world or they can be genetically engineered.
- The most important part of obtaining a patent is to
    - find a way to isolate and culture the microorganisms and;
    - Find a practical application for it.

**But if the micro-organism has never been known before?**

- Then a sample of the micro-organism has to be deposited under the Budapest Treaty with an International Depository Authority (IDA).
- Under this Treaty, if a sample of the micro-organism is deposited with one IDA, the enablement requirement is deemed to be satisfied in all of the countries that have signed the treaty.
- A scientist in a country not a part of the Budapest Treaty, need to find out his own country's rules for making deposits.
- Not all countries are a part of the Treaty, e.g. Taiwan

# When to deposit?

- A number of countries and patent offices (notably the European Patent Office) require a sample of the micro-organism to be deposited under the Budapest Treaty before the patent application is filed.
- If the proposed filing date of the patent application (or priority application) is approaching, steps should betaken to ensure that a sample of the micro-organism is deposited in good time.
- Ensure that adequate time is allowed for delays in the mail or customs formalities possibility that the sample is found to be non-viable by the IDA and that a replacement sample be required.

## Classification of Invention on Microorganisms

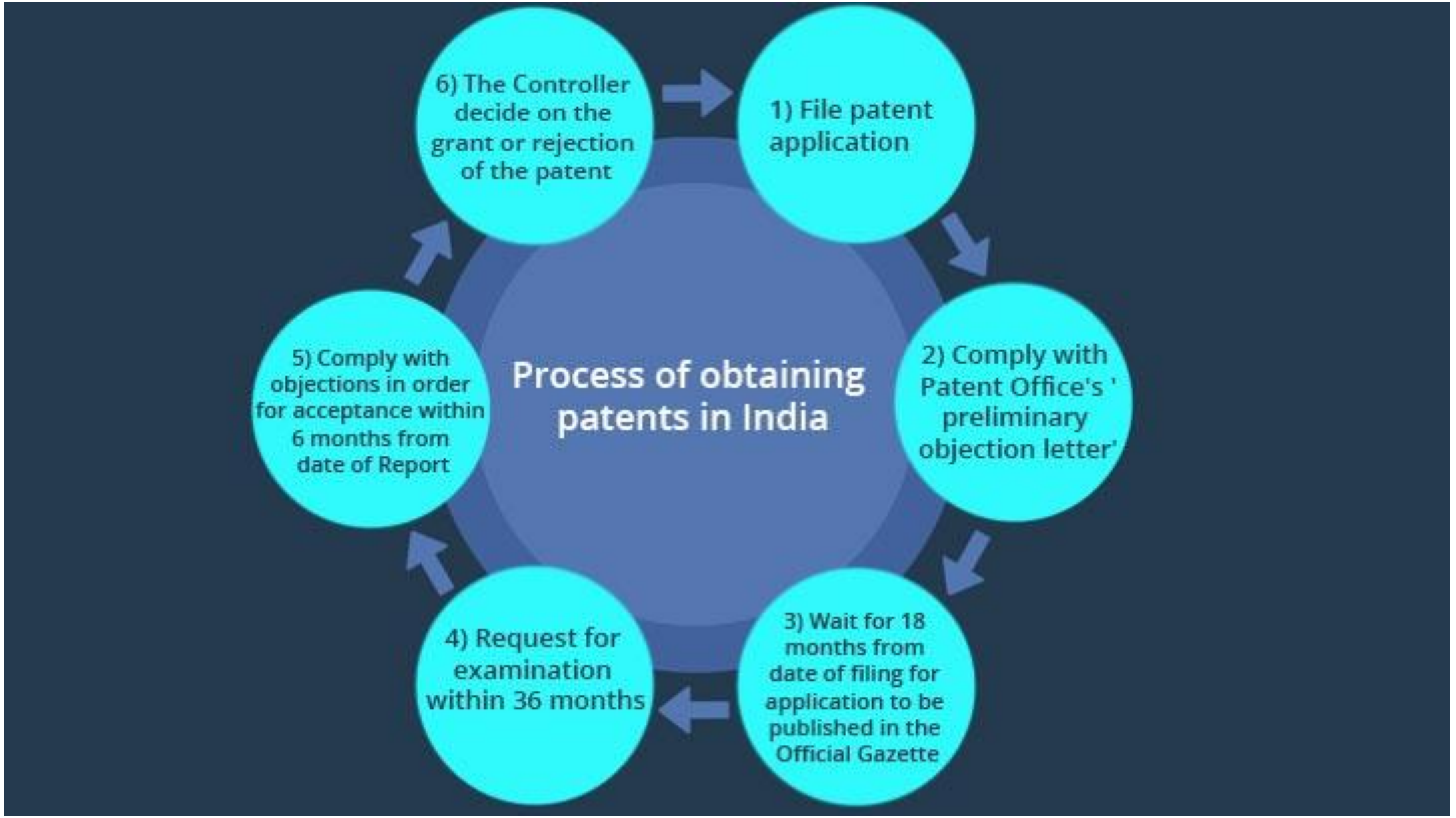
Inventions on microorganisms can be roughly classified into the following two types:

1. Inventions that create novel organisms by using genetic recombination and the like, e.g. Transduce, into bacteria A, a gene for trait b obtained from an organism B, so as to obtain a novel bacteria A' that express the trait b.
2. Inventions of novel systems by using newly found microorganisms obtained from the natural world, e.g. A system that efficiently and safely decomposes waste materials by using novel bacteria C obtained by screening from the soil of a certain location.

- The inventions of type (2) can be further classified into the following two types:
  a) Inventions in which metabolic products of microorganisms play the key role for the work of the system, e.g. A system that efficiently and safely decomposes waste materials in which a special kind of enzymes c produced by bacteria C play the key role for the decomposition of the waste materials.
  b) Inventions in which the microorganisms themselves play the key role for the work of the system. E.g. A genetic transformation system including novel bacteria D and a vector for exclusive use for the bacteria D.

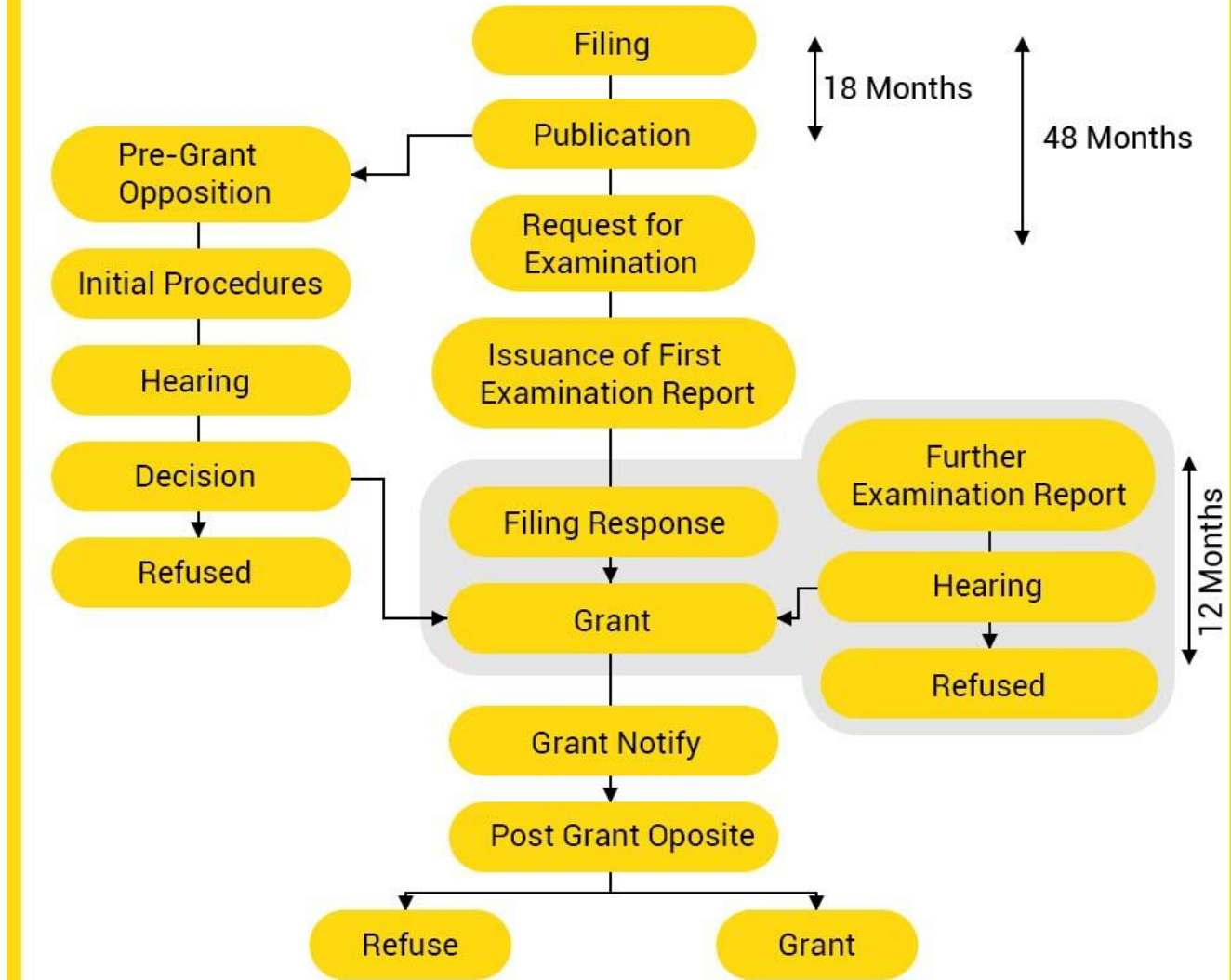
## Patenting of Microorganisms in INDIA

- Inventions pertaining to microorganisms and other Biological material were subjected to product patent in India unlike many developed countries.
- But with effect from 20.05.2003 India has started granting patents in respect to invention related to microorganisms.
- Microorganisms patenting was 5 years from the date of grant or 7 years from the date of filing of application for patent.
- Now grant of patents for microbiological inventions is for a period of 20 years from the date of filing the most vital and important distinction between the legal practices in India and developed countries is that India do not allow patenting of microorganisms that already exist in nature as the same is considered to be a discovery as per the provisions of the section 3(d) and therefore not patentable.
- But genetically modified versions of the same microorganisms that result in enhancement of its known characteristics are patentable.

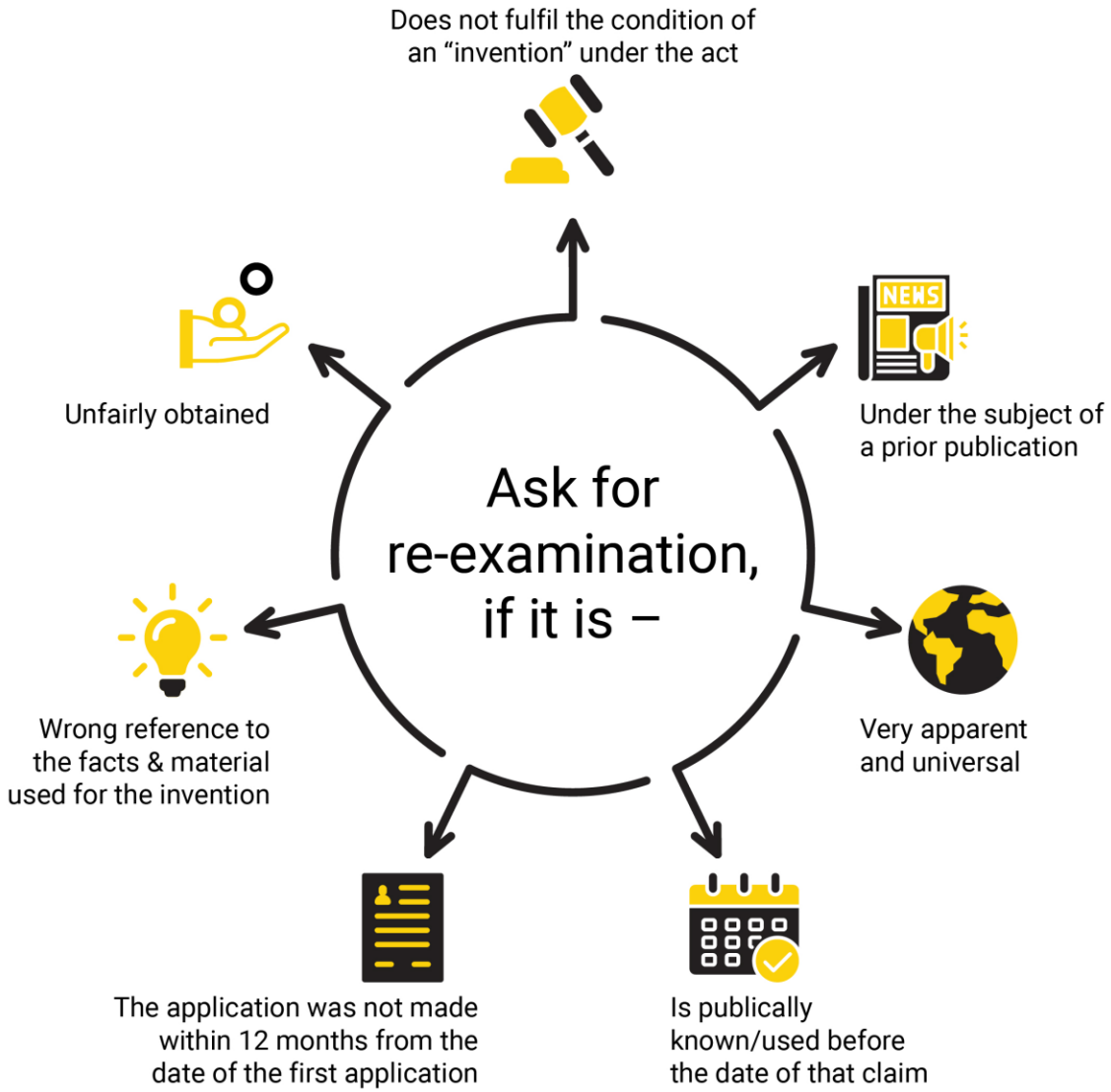

Process of obtaining patents in India
1) File patent application
2) Comply with Patent Office's ' preliminary objection letter'
3) Wait for 18 months from date of filing for application to be published in the Official Gazette
4) Request for examination within 36 months
5) Comply with objections in order for acceptance within 6 months from date of Report
6) The Controller decide on the grant or rejection of the patent


Intepat
Mere discovery of a scientific principle
Frivolous invention or against natural laws
Mere re-arrangement of known devices
Non-Patentable
Mathematical or business method, algorithms
Agricultural method or horticulture, copyright work
Plants and animals, therapeutic treatment
Non-Patentable Inventions in India

# PATENT FILING PROCEDURE IN INDIA FLOWCHART

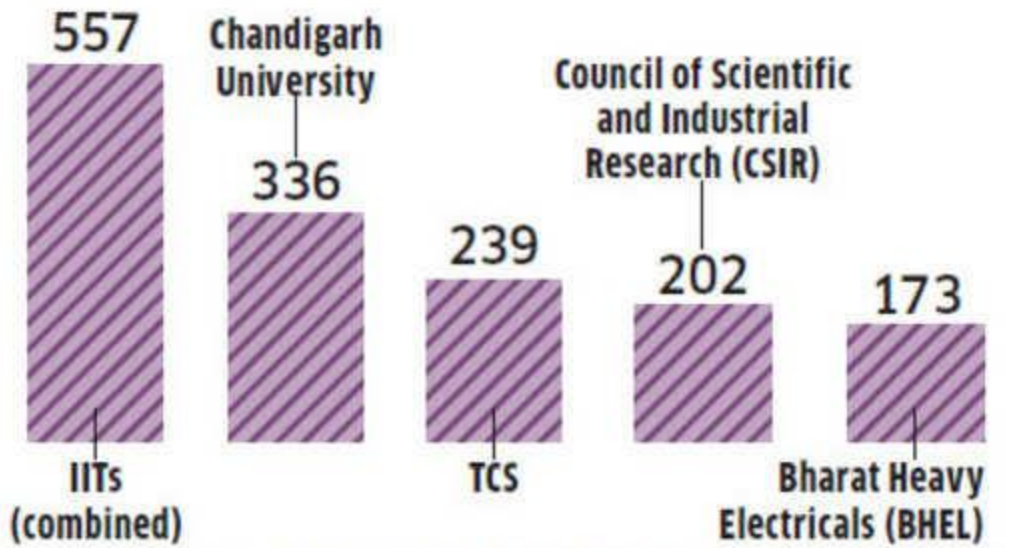


# Patent Opposition Claims



**Indian applicant**

Patents filed in India in 2018-19

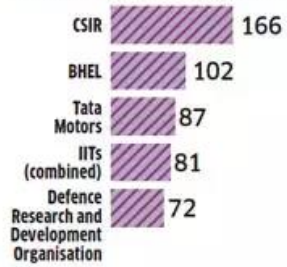



Source: Office of the Controller General of Patents, Designs & Trade Marks

## CSIR is the Top Indian Patent Grantee

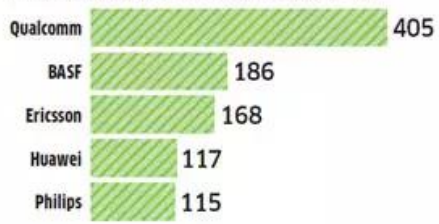
**Indian applicants**

Patents granted in India in 2018-19




**Foreign applicant**

Patents granted in India in 2018-19

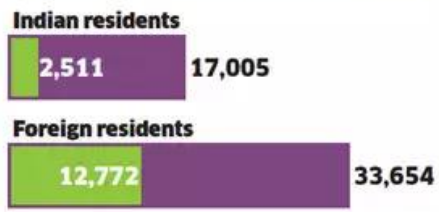



Source: Office of the Controller General of Patents, Designs & Trade Marks

## Domestic Patents in India are One-fifth of Foreign Patents

Patent applications in India in 2018-19

Patent grants in India in 2018-19




Source: Office of the Controller General of Patents, Designs & Trade Marks

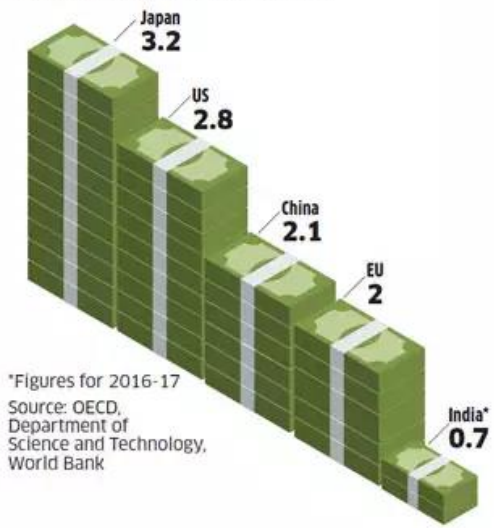
## India Takes Way Longer Than Other Countries to Grant Patents

Time taken to grant a patent as of 2017


*European Patent Office

## India Spends Less than 1% of its GDP on R&D

R&D spend as % of GDP in 2017




*Figures for 2016-17

Source: OECD, Department of Science and Technology, World Bank

## Patenting of Microorganisms in EUROPE

- The European Union has defined 'biological material "instead of "micro-organism", as under [Article 2.1 (a)]
- "Biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system"
- The Board held that a micro-organism would include bacteria, yeast, fungi, algae, protozoa, plasmids and viruses, but also animal or plant cells and generally all unicellular entities with dimensions beneath the limits of human vision.
- Article 53(b) of the European Patent Convention (EPC) provides that European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.
- Rule 23c states patentable biotechnological inventions, including: Material isolated from their environment, even if known in nature. This particularly applies to genes that are isolated from their natural environment by means of technical processes and made available for industrial production.
- Rule 23d sets out what is not patentable. This includes processes for cloning human beings, processes for modifying the genetic identity of human beings, using human embryos for commercial purposes and modifying the genetic identity of animals such as may cause them suffering without substantial medical benefit.
- Rule 23e indicates what is and is not patentable with respect to the human body. The human body and its elements cannot be patented. However, elements of the body, when isolated from the body, may be patented.

# PATENTING IN

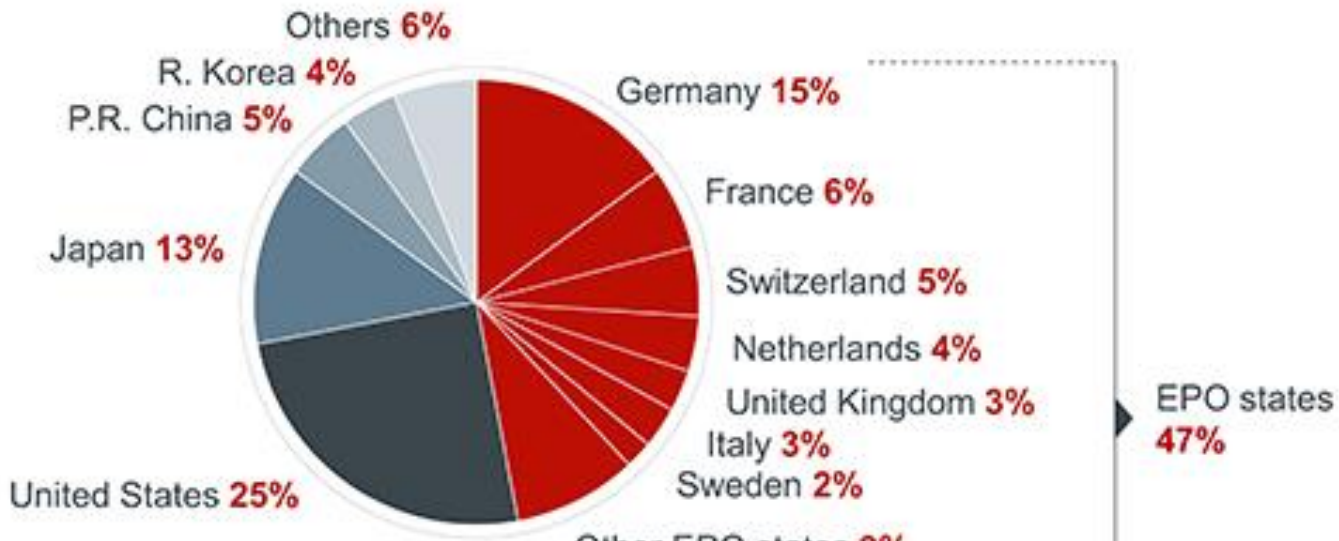
| EUROPE | vs. | THE US |
| --- | --- | --- |
| The European Patent Office (EPO) | **Institution** | The United States Patent and Trademark Office (USPTO) |
| You can choose to protect your innovation in just one country or all the countries that are part of the European Patent Convention (EPC) | **Protection** | The United States |
| - An indication that a European patent is sought<br>- Particulars identifying the applicant<br>- Filing fee<br>- A description of the invention or a reference to a previously filed application | **Requirements** | - A written description of the invention<br>- Cover sheet with the title of the application, name(s) and city/country or state of the inventor(s)<br>- Filing fee |
| From 2 to 4 years | **How long is the process** | An average of 2 years |

## What do both have in common?

- Patents are valid for 20 years in Europe and the US
- You can only file for a patent if your idea is novel and "non-obvious"
- They can increase your startup's valuation!
- They protect you from copycats and idea theft

KISS Patent

# Origin of patent applications in 2018




European Patent Office 2019

## Patenting of Microorganisms in JAPAN

- In 1997, the Japanese Patent Office (JPO) **published** the "Implementing Guidelines for Inventions **in Specific** Fields"
- Inventions in the biotechnology field in the Guidelines are divided into four types:
  - genetic engineering,
  - micro-organisms,
  - plants and;
  - Animals
- Inventions relating to micro-organisms include micro-organisms per se as well as those relating to the use of micro-organisms.
- In Japan, micro-organism means yeast, moulds, mushrooms, bacteria, actinomycetes, unicellular algae, viruses, protozoa, etc. and further includes undifferentiated animal or plant cells as well as animal or plant tissue cultures.

## Patenting of Microorganisms in USA

- In USA, utility requirement in respect of biotech inventions are very strict. A discovery that is not a creation does not meet the requirement of utility.
- A newly discovered micro-organism existing in nature, a newly discovered plant per se are discoveries because they do not involve creativity.
- If an isolated DNA fragment has a specific, substantial, and credible utility, the DNA fragment invention satisfies the requirement of utility and a patent can be granted for the DNA fragment.

## Patenting of Microorganisms in AUSTRALIA

- The Australian patent law defines invention as "any new manner of manufacture."
- The question of patents for living organisms was considered at length in Ranks Hovis McDougall Ltd.'s Application [1976 A OJP 3915] and the Court held that:
    a) No objection can be taken to a claim to a new organism on the ground that it is something living;
    b) Any new variants claimed must have improved or altered useful properties and not merely have changed morphological characteristics which have no effect on the work in of the organism
- Naturally occurring micro-organisms per se are not patentable as they represent a discovery and not an invention, but a claim to a pure culture in the presence of some specified ingredients would satisfy the requirement of a technical intervention.
- The guidelines for a micro-organism in Australian Patent Law states, "what is discovered in nature without any practical application, is a mere chemical curiosity" and is not patentable.

# The International laws

- International laws have helped to bridge some of the differences among the patent practices of various countries.
- The Paris Convention for the protection of Industrial Property has been signed by several countries. This convention provides that each country guarantees to the citizens of other countries the same rights in patent matters as their own citizens. The treaty also provides for the right of priority in case of dispute.
- Following from this, once an applicant has filed a patent in one of the member countries on a particular invention, he may within a certain time period apply for protection in all the other member countries. The latter application will then be regarded as having been filed on the same day as in the country of the first application.
- Another international treaty signed in Washington, DC came into effect on 1 June, 1968. The Patent Cooperation Treaty, facilitates the filing of patent applications in different countries by providing standard formats among other things. A wide range of microbiological inventions are generally recognized as patentable. Such items include vaccines, bacterial insecticides, and mycoherbicides.

# The controversy

- On 16 June, 1980 a case of immense importance to the course of industrial microbiology was decided in the United States Court of Customs and Patent Appeals.
- In brief, the court ruled that "a live human-made micro-organism is patentable". Dr. Ananda Chakrabarty then an employee of General Electric Company had introduced into a bacterium of the genus Pseudomonas two plasmids which enabled the new bacterium to degrade multiple components of crude oil.
- This single bacterium rather than a mixture of several would then be used for cleaning up oil spills. Claims to the invention were on three grounds.
    1. Process claims for the method of producing the bacteria
    2. Claims for an inoculum comprising an inert carrier and the bacterium
    3. Claims to the bacteria themselves.
- The first two were easily accepted by the lower court but the third was not accepted on the grounds that (i) the organisms are products of nature and (ii) that as living things they are not patentable.
- But was granted the patent as it is the organism-inert material complex which is patented, not the organism itself. An example is a US patent dealing with a bacterium which kills mosquito larva granted to Dr L J Goldberg in 1979 for an effective larva-killing concentration of spores of the pure biological strain of *Bacillus thuringiensis.*

## Discovery or Invention ?

- A mere finding of something already existing in nature is a Discovery: contamination with mold kills bacteria
- If a technical character is associated to this finding, then, this finding can be regarded as an Invention: isolated fungus, means for its culturing, isolated antibiotic agent.
- A discovery is cognitive in nature, e.g. finding a plant, finding a mineral.
- An invention is always technical in nature, consisting of a reproducible technical teaching (isolation, purification, characterization, technical effect suggesting a use)
- An invention has to solve a meaningful technical problem (Article 56 EPC) and it has to be industrially applicable (Article 57 EPC)