

# **Intellectual Property Rights (IPR)**

## **Patent Protection of Biological Materials**

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# What is Intellectual Property?

- **Some thing that arises from human intellect**
- **It is a product of human creation**

**Property Like.....**

- **Movable Property – Car, Furniture, Dress, Pen.....**
- **Immovable Property – Land, House....**

**Similarly.....**

- **Intellectual Property – Literary work, Inventions.....**

# **Intellectual Property includes...**

- **Literary and Artistic works**
- **Performance of performing artists, phonograms and Broadcasts**
- **Inventions in all fields of human effort**
- **Scientific discoveries**
- **Industrial designs**
- **Trademarks, Service marks, commercial names, Designations**
- **Protection against unfair competitions**

# **Intellectual Property Rights (IPR)**

- **Intellectual – Related to intellect**
  - **Property – A thing or things belonging to someone**
  - **Rights – A moral or legal power to have or to do some thing or prevent others from doing something**
- ‘A legal right given to a person for his intellectual activity on Industrial, Scientific, Literary or Artistic products’**

# Forms of IRP

1. Patents
2. Copyrights
3. Trade Secrets
4. Trade Marks

**Idea + Innovation + Invention = Patent**

**Idea + Expression = Copyright**

**Idea + Appearance = Design Trade Secret**

**Idea + quality + Identity = Trademark**

# Classification of Rights

❖ **Automatic rights**

**Ex. Copyright**

❖ **Granted rights**

**Ex. Patent, Trademarks, Trade Secret**

# Patents

- **Patent is a special right to the inventor that has been granted by the Government**
- **A patent is a personal property which can be licensed or sold by the person/organization just like any other property**
- **A Patent is a monopoly right granted to exclude others to exploiting or using a particular invention**

# Copyrights

- **The copyright is protection of expression of ideas**
- **It is given to authors, editors, publishers or both publisher and author**
- **The materials of the book cannot be reprinted or reproduced without written permission from copyright holders**
- **In Biotechnology, materials subject to copyright include database of DNA sequence or any published forms, photomicrographs, etc.**



# Trade Secrets (Knowhow)

- **It is a private exclusive information that benefits the owners**
- **Under this, a company will have no obligation to reveal the trade secrets**
- **If the trade secrets become public before the granted period, the intellectual is paid compensation and unauthorized users are punished by the Court**

## **The Trade Secrets may be .....**

- **Hybridization conditions and cell lines**
- **Survey Methods**
- **Manufacturing Process**
- **Chemical Formula**
- **Experimental Results**
- **Recipe**
- **Client Database**

# Trade marks

- **It is an identification Symbol or Mark which is used to enable the public to separate on trader's goods from the similar goods of the other traders**

**Ex. KODAK for photography goods,**

**IBM for computers**

**Zodiac for readymade cloths**

## **The Trade Marks may be .....**

- **Word**
- **Device**
- **Label**
- **Combination of Letters and Numeral**
- **Combination of Colour**
- **Sound Mark**
- **3D designs**

# Patents

➤ **A Patent describes an invention for which the inventor claims the exclusive rights**

**An invention may be patentable if .....**

- **It is new (Novel)**
- **It is useful (Valuable)**
- **Not obvious (Clear)**
- **Appropriate to patentable subject matter**

# History of Patenting

- **1856 – First provision of nature of Patent Right**
- **1872 – The Patent and Design protection Act**
- **1911 – The Indian Patent and Design Act**
- **1970 – Patent Act**
- **1994 – General Agreement on Tarif and Trade**
- **1999 – First Amendment of patent Act**
- **2002 – Second Amendment of patent Act**
- **2005 – Third Latest Amendment of patent Act**

# Conditions of Patentability

- ✓ **Novelty**
- ✓ **Inventive steps**
- ✓ **Industrial Applications**

# Patentable Subject Matter

## ❖ An Invention

- **Related to a Process or Product or both**
- **Involves an inventive step**
- **Capable of industrial application**
- **A new machine**



# Patentable Subject Matter

- **Patent System varies from country to country**
- **US Patent Law – Any new and useful process or new and useful improvement may be Patented**
- **England Patent Law – Invention against public interest, public policy and morality are not Patentable**

# Patentable Subject Matter

- **Living Beings** – Microorganisms, Plants, Animals produced through biological process are not Patentable
- **Non Natural living beings** – Produced through non biological process (Biotechnological) are Patentable
- **Genetically modified organisms** – Produced through non biological process, thus Patentable

# Patentable Subject Matter

➤ Under the Patent Act 1970, every invention must pass a two-step test in order to be patentable – namely

1. Not fall in any of the categories specifically barred under Section 3 of the Patent Act
2. Pass the well-known three tests



# Patentable Inventions

- **Genetically modified micro-organisms and vaccines**
- **Biochemical, Biotechnological and Microbiological processes Pharmaceuticals and medical devices**
- **Medicinal compounds, drugs, formulations, stents, surgical sutures and staplers**

# **Excluded Inventions (Un-patentable Inventions)**

➤ **Section 3(b) – inventions contrary to public morality**

**Ex. Genetic modification of animals which results in suffering of the modified animal without any substantial medical or other benefit, and inventions causing adverse environmental impact**

➤ **Section 3(c) – discoveries, things isolated from nature, plants and animals**

**Ex. Micro-organisms isolated from nature and DNA, RNA or proteins isolated from living organisms**

**Ex. Plants and animals or their parts including seeds, varieties and species**

**Ex. Essentially biological processes for the production of plants or animals (Ex. conventional methods of plant breeding and tissue culture techniques)**

➤ **Section 3(d) – new forms or uses of known substance**

**Ex. A new form of a known substance, unless it differs significantly in properties with regard to the known efficacy**

**Ex. New use of a known substance is also unpatentable**

**Ex. A second therapeutic effect of a known drug is unpatentable**

➤ **Section 3(e) – simple admixture**

**Ex. The simple admixture of two or more previously known substances, unless such a combination should result in a synergistic effect**

➤ **Section 3 (h) – Agricultural or Horticultural methods**

**Ex. A method of combating harmful insects and/or phytopathogenic fungi is unpatentable**

➤ **Section 3(i) – methods of treatment and diagnosis**

**Ex. Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings and any treatment of animals which renders them free of disease or increases their economic value**



# Unpatentable subject matter

Category	Unpatentable example
<b>Medicinal methods</b>	<b>A process of administering medicines orally, through injection, topically or through a dermal patch</b>
<b>Surgical methods</b>	<b>A stitch-free incision for cataract removal</b>
<b>Curative methods</b>	<b>A method of cleaning plaque from teeth</b>
<b>Prophylactic methods</b>	<b>method of vaccination</b>
<b>Diagnostic methods</b>	<b>Identification of the nature of a medical illness by investigating its history and symptoms and applying tests</b>
<b>Therapeutic methods</b>	<b>Prevention and treatment or cure of diseases</b>

# Patenting Procedure

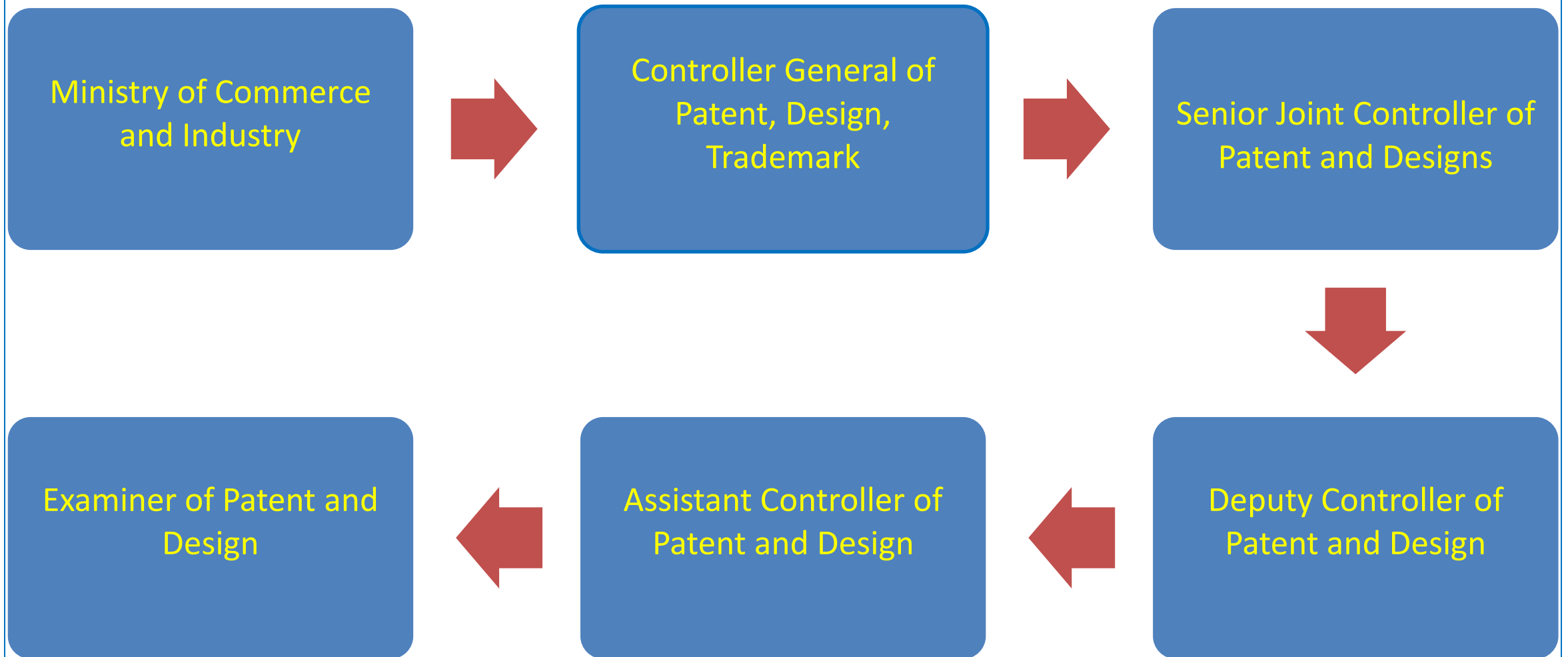
## **A patent consists of three parts**

- 1. The grant – It is filled at the patent office which is not published. It is a signed document which is actually the agreement that grants patent right to the inventor**
- 2. The specification – It is published for public at a minimum charge from the patent office. The specification part is narrative in which the subject matter of invention is described how the invention was carried out**
- 3. The claim – This section specifically defines the scope of the invention to be protected by the patent to which the others may not practice**

# Life and Duration of a Patent

- **The term and date of a Patent is for 20 years from the date of filling**
- **The Patent rights are essentially territorial in nature, the same thing may not be granted Patent by other country**
- **The refusal of Patent in one country does not mean it will be terminated by other counties**

# Patent Administration in India



# Patenting Office in India

Patenting Office	Territorial Jurisdictions
Mumbai	Gujrat, Maharashtra, MP, CG, Daman, Diu, Dadra and Nagar Haveli
Delhi	Haryana, HP, J&K, UP, Punjab, Rajasthan, Uttarakhand
Chennai	AP, Karnataka, Telangana, Tamil Nadu, Kerala, Pondicherry, Lakshadweep
Kolkata (HO)	Rest of India

# Patenting Corporation Treaty (PCT)

- **India become member of PCT in 1998**
- **A single application in a single language in a single office**
- **Priority Documents – Title of Invention, Description and General statement**



# Complete Specifications

- **Techno-Legal Documents**



- **Title**

- **Field of Invention**
- **State of Art in field**

- **Objects of Invention**
- **Detailed Description of Invention**

- **Claims**
- **Abstract**



# Certificate of Grant of Patent

## COPY

Patent Number: GB2399473  
Proprietor(s): Nicholas P Le Feuvre  
Inventor(s): Nicholas P Le Feuvre

*This is to Certify that, in accordance with the Patents Act 1977,*

a Patent has been granted to the proprietor(s) for an invention entitled  
**"Loudspeaker with low distortion precise imaging and deep bass"**  
disclosed in an application filed **8 March 2004**.

Dated 19 October 2005



**Ron Marchant**  
Comptroller General of Patents,  
Designs and Trade Marks  
UNITED KINGDOM PATENT OFFICE

**The attention of the proprietor(s) is drawn to the important notes overleaf.**



# **The advantages of patents and other forms of IPR are:**

- **Encouraging and safeguarding intellectual and artistic creations**
- **Disseminating new ideas and technologies quickly and widely**
- **Promoting the investment**
- **Providing consumers with the result of creation and invention**
- **Providing increased opportunities for the distribution of the above effects across the countries**

# Patenting of Biological Materials

## Life Forms

### 1. Lower Life Forms –

- Single cell organisms
- Certain Multicellular organisms

### 2. Higher Life Forms –

- Tissues, Cells and Organs of Multicellular organisms like Animals and Human being, Plants and Plant Products

# Patenting of Biological Materials

- ❖ **Till 1980, Life was not considered as Patentable**
- ❖ **Germany Patented Microorganisms**
- ❖ **Australia not allow to Patent microorganisms but allow the use of microbial products**
- ❖ **US Supreme Court permitted to Patent genetically modified Bacteria eating oil spills**
- ❖ **US Patent allowed to Patent of Mutant Maize, Oncomouse, transgenic pig, rabbit and sheep**

# Patenting of Biological Materials

- ❖ **Human cell lines producing cancer fighting protein isolated from patient body name Moore (1984) was Patented**
- ❖ **Methods to isolated human genetic materials was allowed**
- ❖ **Production of foreign protein from transformed bacteria was permitted**
- ❖ **Patent granted on DNA sequencing**
- ❖ **Patent on Chimeric gene**
- ❖ **Cloned sheep (Dolly)**
- ❖ **Patent on DNA and RNA for human insulin**

# Patenting of Biological Materials

- ❖ **Patents for invention involving microorganisms in India (2002)**
- ❖ **Genetic modification of mouse to make it susceptible to breast cancer, particularly suitable for testing cancer drugs**
- ❖ **Tracy sheep with a human gene promoter for production of human insulin protein through milk**
- ❖ **Control of plant gene expression covering genetically modified plants like cereals, fruits and vegetables**

# Patenting in Biotechnology

- **Biotechnology comprises use of living organisms for welfare of Mankind together with Technology**

**Biotechnological inventions can be divided in to two broad categories:**

## **A. Biotechnological processes**

- **Process to invent new genetically engineered Plant , Animal or Microorganism**
- **Process to isolate and incorporate DNA fragments and cells from one organism to another organism**
- **Process of deriving proteins through expressing foreign genes in a host organism**
- **Process of treating diseases through Gene therapy**
- **Process of industrial fermentation**
- **Process of cleaning environmental pollution**

## **B. Biotechnological Products**

- **Genetically engineered microorganisms, plants and animals**
- **Isolated and purified DNA fragments and cells**
- **Purified proteins**
- **Genetically modified plant products like BT Cotton, Golden Rice and fermented products**
- **Chemical substance derived from extraction or isolation such as digitalis, morphine, quinine, and reserpine etc.**

# References

- **Handbook on Intellectual Property Rights In India by Rajkumar S. Adukia**
- **[www.ipindia.nic.in](http://www.ipindia.nic.in) - Intellectual Property Office, India**
- **[www.patentoffice.nic.in](http://www.patentoffice.nic.in) – Patent office, India**
- **[www.ipab.tn.nic.in](http://www.ipab.tn.nic.in) - Intellectual Property Appellate Board, India**
- **National Biodiversity Authority**
- **[www.nipo.in](http://www.nipo.in) – The Indian IPR Foundation**
- **[www.wipo.int](http://www.wipo.int) – World Intellectual Property Organization**



Thank You.....