

RESEARCH METHODOLOGY AND INTELLECTUAL PROPERTY RIGHTS

Course Code: AL58

UNIT 4

Unit IV

Intellectual Property Rights

Introduction to IPR: Different forms of IPR, Role of IPR in Research and Development. TRIPS Agreement, Patent Cooperation Treaty (PCT).

Patents: Brief history of Patents-Indian and Global Scenario, Principles Underlying Patent Law, Types of Patent Applications in India, Procedure for Obtaining a Patent. Non Patentable Inventions. Rights Conferred to a Patentee, Basmati Rice Patent Case.

Necessary is the mother of invention

- **Intellectual Property –**
refers to creations of the mind, such as inventions;
literary and artistic works; designs; and symbols,
names and images.
- **Intellectual Property rights provide protection for
creations and inventions, to enable creators and
inventors to earn recognition and financial benefit
from their work.**

Meaning of Intellectual Property

Intellectual Property rights so far identified for the purpose of legal protection are as follows:

- **Rights of artists, painters, musicians, sculptors, photographers and authors** for copyright in their works.
- **Rights of computer programmers** whether in source or object code for a copyright in their programs and compilation data.
- **Right of performers, producers of phonograms (sound recording) and broadcasting organization** in respect of fixation of their programs for a copyright in their work.
- **Right of traders** in their trade mark.
- **Right of the inventor** for patent in his invention.

- **Right of computer technologists for their layout designs of integrated circuits** for patent in the work developed by them.
- **Right of breeders in bio-technology** for a patent in the new plant variety grown by them.
- **Right of designers** for their distinctive industrial design striking to the eye.
- **Right of manufacturers and producers** on geographical indication in relation to such products and produce.
- **Right of businessmen** for protection of their undisclosed information on technology and management i.e., trade secrets.
- **Rights of the creator** in integrated circuits.

Role of IPR in R&D

- IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to reap **commercial benefits** from their **creative efforts** or reputation.
- The term 'ip' refers to **unique value-adding creations** of the human intellect that results from human ingenuity creativity and inventiveness.
- As there are many players involved in **facilitating the market success of an innovation**, the effective use of IP plays an **important role in reducing the risk for the players involved**, who may then be able to reap acceptable returns for their participation in the process.
- IP acts as a key in facilitating the process of taking innovative technology to the market. At the same time, IP helps in **enhancing the competitiveness of technology-based enterprises**, whether such enterprises are commercializing new or improved products or providing service on the basis of new or improved technology.

Role of IPR in R&D

- **Innovation** is a process, which begins from the **conception of an idea** to the launching of a new product/process in the market place.
- Intellectual property rights can be used effectively to facilitate successful innovation. Innovative technologies stand a better chance of **successfully reaching the marketplace** if IP is used strategically.
- Gauging the importance of IP in innovation by merely focusing on patents as input and/or output of innovation, does not do justice to the significant role that can be played by the other tools of IP.
- There are **several types of intellectual property** protection like patent, copyright, trademark, etc

FORMS of Intellectual Property Rights

- Copyrights
- Trademarks
- Service marks
- IC Layout Designs
- Plant Varieties
- Trade Secrets
- Geographic Indicators
- Patents

Types of IPRs

Intellectual Property



Industrial Property

Copyrights and related rights

Industrial
Designs

Patents

Trademarks
Service marks

Trade Secrets

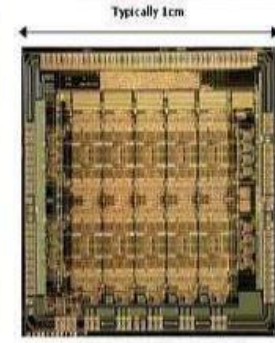
Geographical
Indications

Layout Designs of
Semi Conductor ICs

Plant varieties &
Farmer's rights



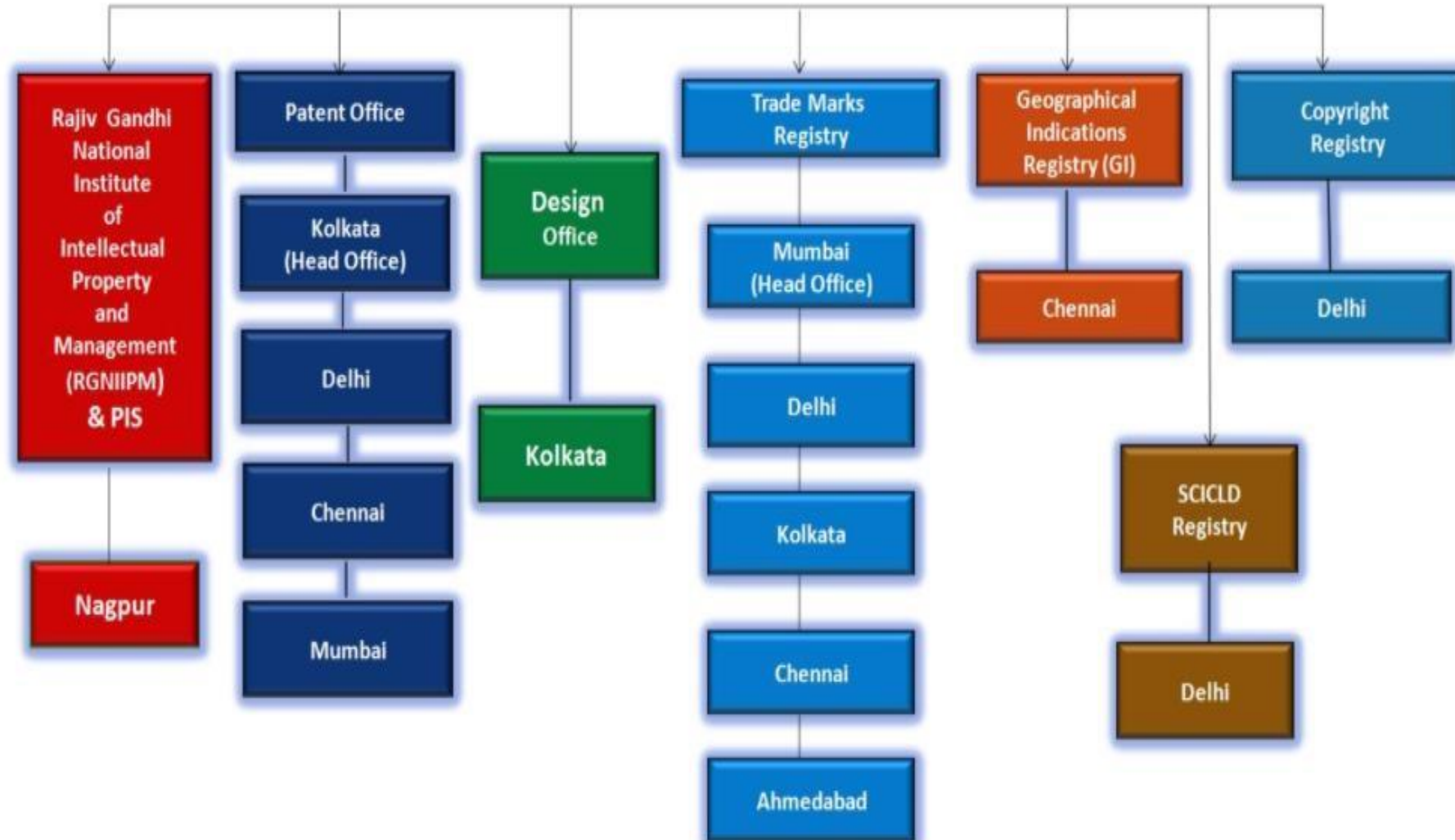
Coca-Cola



Containing up to 1 million components



Office of Controller General of Patents, Designs & Trade Marks
(O/o CGPDTM)



Copyright – Protects creative works like musical compositions, audio recordings, movies, books, articles, diagrams, photos, website content and software applications.

Work must be original or expressed differently to be protected under Copyright.

Copyright exists upon fixation of work in tangible medium; no registration necessary except for evidence or establishing ownership.

An author of a work has the following exclusive rights;

- Reproduction of a work;
- Distribution of copies of the work;
- Public performance of the work;
- Broadcasting of the work;
- Communicating the work to public by wire or wireless means;
- Commercial rental of the work.



Article 2(1) of the Berne Convention

- Copyright protection must be provided to **“every expression and production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression”**
- Copyright protection **does not extend to**
 - ideas
 - procedures
 - methods of operation
 - mathematical concepts
- Copyright holders of a work have the **exclusive right to authorize on agreed terms or prohibit its:**
 - reproduction in various forms
 - public performance
 - recordings
 - broadcasting
 - translation into other languages
 - adaptation

Trademarks

- A trademark is a distinctive sign or mark used in trade to distinguish your goods or services.
- Trademarks identify the source of products to the consumers.
- A trademark can be any distinctive word, symbol, slogan, logo, brand label, name, signature, letter, numeral or any combination of them.
- Distinguish products in market place and helps consumer to identify of source of product or service.



Trade Marks



Name

Logotype

Symbol

Slogan

Shape

Color



i'm lovin' it[®]



TRADE MARKS

- Trade Marks Act, 1999 defines TM as a mark capable of being **represented graphically** and which is capable of **distinguishing the goods or service of one person from those of others** and **may include shape of goods, their packaging and combination of colours.**
- **Mark** includes **“Device, brand, heading, label, ticket, name, signature, word, letter, numeral, shape of goods, packaging, combination of colours, and any combination thereof.”**
- **Brand** refers to a name, term, sign, symbol, or design, or a combination of them, intended to identify the goods or services of one seller or group of sellers and to differentiate them from those of competitors. E.g. McDonald for restaurants, Cycle brand agarbattis, etc.
- **Brand Name** is that part of a brand which can be vocalized-the utterable.
- **Brand Mark** is that part of a brand which can be recognised but is not a utterable, such as symbol, design or distinctive colouring or lettering.
- **Device** refers to pictorial representations – e.g. animals, birds, landscape buildings, etc.
- **Letter** as a mark is the identity created out of letterforms and has its inbuilt strength of distinctiveness and individuality – e.g. IBM, GM,

Industrial designs

Protects the appearance of a product/logo, from the shape of an aeroplane to a design of a cloth. The design may consist of three-dimensional features, such as the shape or surface of an article, or of two-dimensional features, such as patterns, lines or color.

An industrial design must be new or original and aesthetic to be protected.



Industrial design is what makes a product attractive and appealing hence adding commercial value to product and increase its marketability.

Industrial Designs

The laws governing designs are the **Designs Act of 2000** and the **Designs Rules of 2001**. In India designs are defined as follows:

- *'A design refers to the features of shape, configuration, pattern, ornamentation or composition of lines or colors applied to any article, in two or three dimensional (or both) forms'.*

(Design Office, Kolkata: Guidelines for Registration)

- Designs are **valid for a maximum of 10 years**, renewable for a **further five years**.
- The **'right of priority'** for previous filings of designs overseas requires filing in **India within six months** of an overseas filing.



Trade Secrets

- A trade secret consists of
 - a formula, device, idea, process, pattern, or compilation of information that gives the owner a competitive advantage in the marketplace,
 - a novel idea that is not common knowledge and is kept in a confidential state.
- A trade secret is **not protected** by federal law
- Can only be protected through employment contracts and/or maintaining tight security
- Recipes, ingredients, codes, manufacturing costs



GEOGRAPHICAL INDICATIONS



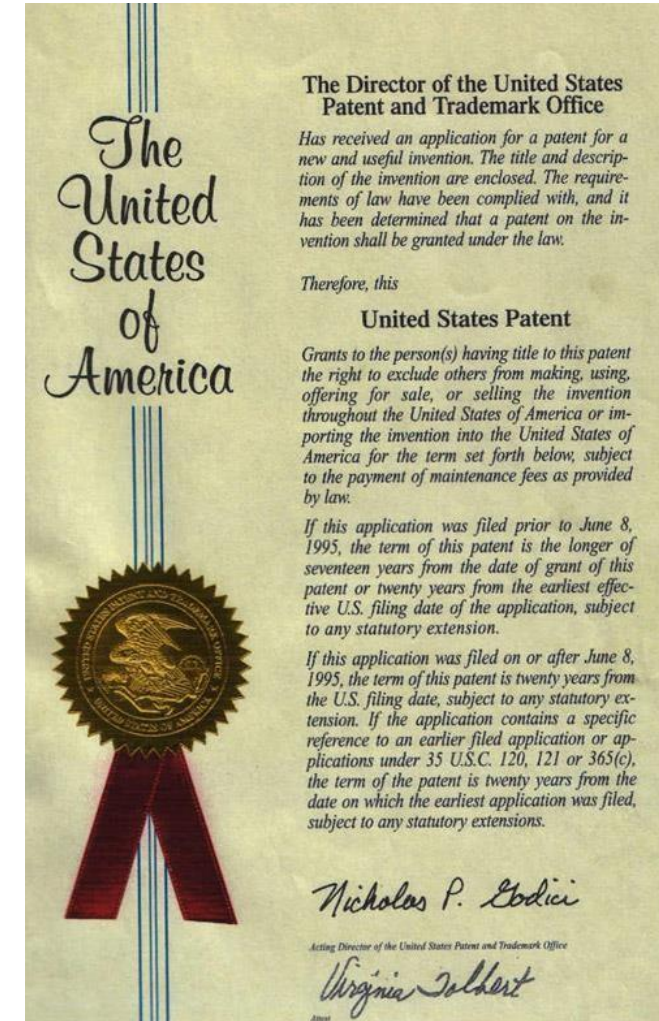
- Geographical indication is an indication originating from a definite geographical territory and used to identify agricultural, natural or manufactured goods. The manufactured goods should be produced or processed or prepared in that territory. It should have a special quality or reputation or other characteristics. (e.g. Gadwal / Pochampalli/ Kanchipuram silk sarees, Nirmal paintings, Banginapalli /Alphonso Mango, Darjeeling Tea, Kolhapuri Chappal, Solapur Chaddar, Tirupati Laddu, Nagpur Orange, Bikaneri bhujia).

- GIs when registered confers legal protection in India through the Geographical Indications of Goods (Registration & Protection) Act of 1999, prevents unauthorised use of registered GI, promotes the economic prosperity of the producers of goods produced in a geographical territory which in turn boost exports.



Patents

- The term "patent" originates from the Latin word **patere** which means "to lay open" (i.e., make available for public inspection)
- Patent provides a set of **exclusive rights** granted by a state to a **patentee** for a **fixed period of time** in exchange for a full disclosure of an invention
- **Encompasses any new and useful process, machine, article of manufacture, or composition of matter**
- Also included are any **new and useful improvements** thereof



CONSTITUTIONAL ASPECTS OF IP

- The **Constitution plays** an important part in helping courts and legislature, arrive at and justify a balance between conflicting rights.
- The **US Constitution** specifically **protects the intellectual property**[Article 1(8)] by specifically providing ***“To promote the progress of science and arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries”***.

CONSTITUTIONAL ASPECTS OF IP

- Though the Indian Constitution does not include an intellectual property clause, there are no constitutional restrictions on the power to make laws on intellectual property.
- The Constitution (44th Amendment) Act, 1978, struck off the right to property from the fundamental rights. However, property was made a legal right and was put under Article 300A in the 'Right to Property', which says "***no person shall be deprived of his property save by authority of law***".

Legislations covering IPRs in India

- **Patents:** The Patents Act, 1970 as amended in 1999, 2002 and 2005
- **Design:** The Designs Act, 2000
- **Trade Mark:** The Trade Marks Act, 1999
- **Copyright:** The Copyright Act, 1957 as amended in 1983, 1984 and 1992, 1994, 1999
- **Layout Design of Integrated Circuits:** The Semiconductor Integrated Circuits Layout Design Act, 2000
- **Protection of Undisclosed Information:** No exclusive legislation exists but the matter would be generally covered under the Contract Act, 1872
- **Geographical Indications:** The Geographical Indications of Goods (Registration and Protection) Act, 1999
- **Plant Varieties:** The Protection of Plant Variety and Farmers' Rights Act, 2001

TRIPS agreement; 1994

- TRIPS Agreement, the agreement on **Trade-related Aspects of IP** was signed in Marrakesh, **Morocco** on **15 April 1994**
- In accordance with the TRIPs Agreement, **countries are free to determine the 'appropriate method'** for implementing the Agreement within **'their own legal system and practice'**
- The Agreement reaffirms the well-established principle of **'national treatment'**, which means that the national of any country member of the Agreement are to be treated in the same way as national of the country
- It also extends to IPRs the **'most-favoured-nation clause'**, that is, the obligation to extend, with some **limited exceptions**, to any member the advantages granted to any other member or members.
- These principles are meant to **end discrimination**, both between foreigners and nationals and between nationals of different countries.

- TRIPs Agreement allows member countries to **admit parallel imports** if they so wish. This principle can be crucial for the protection of consumer's interests and for ensuring access to industrial or agricultural inputs at competitive prices.
- TRIPs Agreement embodies an important principle by which the member countries are **empowered to formulate or amend their laws and regulation** and thus to adopt measures to **protect public health and nutrition**, and to promote the public interest in sectors of vital importance to their **socio-economic and technological** development.
- It also empowers the member countries to take appropriate measures that may be needed to prevent the **abuse of IPRs** by right holders or the resort to practices which **unreasonably restrain trade or adversely affect the international transfer of technology** (compulsory licenses in the pharmaceutical field in order to keep prices at a reasonable level to ensure access to particular medicines by the general public)
- TRIPs agreement focuses on **specific areas of IPRs** like copyrights, trademarks, geographical indications, industrial designs, patents, layout designs or topographies of integrated circuits, trade secrets

- TRIPs agreement makes provision for the protection of **software and compilation of data as a literary creation**. It provides rental rights for phonograms, films and computer programs for the first time in an international agreement. (criminal proceedings and to prescribe penalties against copyright piracy)
- Under the TRIPs agreement, **the protection of geographical indications**, which was **granted in a small number of countries**, is now required of all **members of WTO**. Reinforced protection is accorded in respect of wines & spirits.
- The separate section on **industrial designs** makes it mandatory that new or original industrial designs need to be protected for at least **10 years**
- Patents are to be granted **without discrimination** as to the **place of invention**, the **field of technology** or **whether products are locally produced or imported** provided they are new, involve an inventive step and are capable of industrial applications. (Earlier freedom was there for the countries to frame their patent laws)
- The Agreement sets out the rights to be conferred under a patent, including the protection of a **product directly made with a patented process**, and an **exclusive rights to produce, sell and import the protected product**.

- Under TRIPs Agreement, **trade secrets** such as **confidential know-how or commercial information** are **deemed protectable**.
- In addition, **obligation** are recognized in relation to **test results and other data submitted to governments in order to obtain approval** of pharmaceutical and agrochemical products.
- **Non-compliance with the new rules, once adopted**, would give rise to a **dispute settlement procedure** under the WTO rules and possibly, to retaliatory commercial measures in any field by the country whose nationals are affected by such non-compliance. Since **within the WTO, adherence to the new IPRs universal standards will be monitored by the council for TRIPs**

Patents

What are Patents ?

- Patents are **granted by the government**, for the **commercial exploitation** of an invention for a specific period in consideration of the disclosure of the invention so that on expiry of the terms of the patent the information can benefit the public at large.
- Patent right is the **most important IP right**.
- Inventions are strongly protected by PATENTS
- An exclusive right granted by a nation for an invention that is
 - **New**
 - **Involves an inventive step**
 - **Capable of industrial application**
- An exclusive right because it exclude others from making, using, offering for sale without the permission of the patent holder.

Patent Cooperation Treaty (PCT).

- The **Patent Cooperation Treaty (PCT)** assists applicants in seeking patent protection internationally for their inventions, helps patent offices with their patent granting decisions, and facilitates public access to a wealth of technical information relating to those inventions.
- By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in a **large number of countries**.

Brief history of Patents- Indian and Global Scenario

- *In **1856**, the **first Indian patent** Act granted certain exclusive privileges to the inventors of new inventions for a period of 14 years.*
- This Act was modified and **re-enacted in 1859** which conferred on the inventor *the exclusive privileges to make, use and sell the invention for a period of 14 years.*
- *In 1948, Govt. of India appointed a **Patents Enquiry committee** headed by **Dr. Tek Chand** to review the working of Patent Law in India. The committee submitted its final report in 1953.*
- The report noted that the *Indian Patent System has failed to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in India.*
- Based on the report of the Committee, a *Patents Bill based on the U.K Patents Act, 1949 was introduced in Lok Sabha in 1953. But the bill lapsed due to the dissolution of Lok Sabha.*

- In **1957, the Govt. of India** then appointed a Committee under Justice **Rajagopala Ayyangar** to suggest necessary changes and revise the patent law in India taking into consideration the social needs of the people of India.
- At that period, the **Indian Drug Industry was dominated by the foreign multinationals** who imported drugs into the Indian market.
- Obviously, the prices of even life-saving drugs were the highest in India. In this aspect, the **Ayyangar Committee was guided by the Constitutional guarantee of economic and social justice enshrined in the Preamble of the Constitution of India & Article 21 of constitution.**
- In the above background the Committee recommended for the **process patenting of drugs as against the product patenting** to ensure that the medical needs of the poorer sections of India is met with.
- The **Ayyangar Committee submitted** its comprehensive report in **September 1959.**

- ***In pursuance to the Committee report, the Patents Bill with some additional changes in the field of food, medicine and drugs was introduced in Lok Sabha in 1965.*** A joint committee of the Parliament was entrusted to study this Bill & which made amendments to the Bill after a thorough consideration & ***Bill was passed in 1972.***
- India being a party to the TRIPs Agreement is under an obligation to keep its ***Patent Law in conformity with TRIPS provisions.*** The TRIPs Agreement mandates India to provide Product patents and to provide exclusive rights during the transition period.
- Incorporating these changes, ***the Patents Bill was introduced in Lok Sabha in 1995 & was then amended by the Patents Act, 1999 and then consequently in Patents Act, 2002.***
- The Patent Act 2005 has been adopted thereby meeting the TRIPs deadline.

Principles underlying Patent law in India

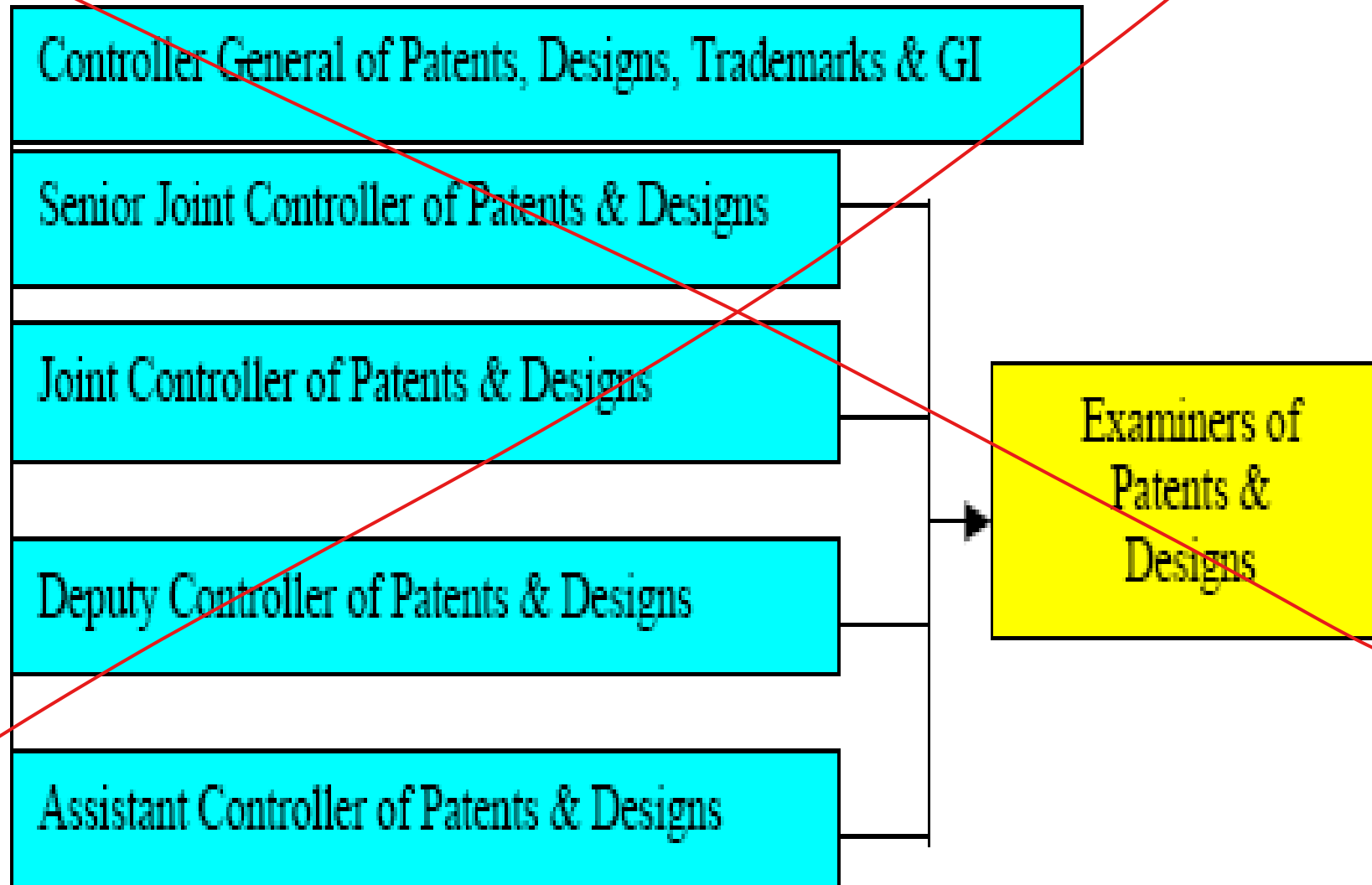
1. **New – novelty** requirement: must have some new characteristic which is not known in the body of the existing knowledge (prior art).
2. **Non-Obvious** – involves an inventive step, which could not be deduced by a person with average knowledge of the technical field.
3. **Usefulness** – capable of industrial application of some economic/commercial value.
4. Should a patentable subject matter – not excluded as not patentable (defined negatively)

Patent Act 2005

- The Third Amendment of the Patents Act 1970, by way of the Patents (Amendment) Ordinance 2004 came into force on 1st January, 2005 incorporating the provisions for granting product patent in all fields of **Technology including chemicals, food, drugs & agrochemicals**.
- There are **four Schedules** to the Patents (Amendment) Rules 2005;
 - ❖ **The First Schedule prescribes the fees to be paid;**
 - ❖ **The Second Schedule specifies the list of forms and the texts** of various forms required in connection with various activities under the Patents Act are set out in this schedule.

These forms are to be used wherever required and if needed, they can be modified with the consent of the Controller.
 - ❖ **The Third Schedule prescribes** form of Patent to be issued on **Grant of the Patent**.
 - ❖ **The Fourth Schedule prescribes costs to be awarded** in various proceedings before the Controller under the Act.

Hierarchy of Officers in Patent office



Office	Territorial Jurisdiction
1. The Patent Office Branch, Todi estates, IIIrd Floor, Sun Mill Compound, Lower parel (West), Mumbai – 400 013.	The states of Maharashtra, Gujarat and Madhya Pradesh and the Union Territories of Goa, Daman and Diu and Dadra and Nagar Haveli.
2. The Patent Office Branch , Intellectual Property Building, SICCO Area, Guindy, Chennai	The States of Andra Pradesh, Kerala, Tamil Nadu, Karnataka and the Union territories of Pondicherry, Laccadive, Minicoy and Aminidivi islands
3. The Patent Office Branch, Unit No. 401 to 405, 3 rd Floor, Muncipal Market Building, Saraswathi Marg, Karol Bagh, New Delhi – 110005	The states of Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan and Uttar Pradesh and Union Territories of Chandigarh, and Delhi.
4. The Patent Office, 5 th and 7 th Floor, Nizam Palace, Acharya Jagadish Chandra Bose Road, Calcutta – 700 017.	The rest of India
The Address of Patent Information Office:	Patent Information System, 3rd Floor, Block C, C.G.O.Complex, Seminary Hills, Nagpur.

Patentable Inventions



Novelty of Invention:

- There would be no novelty if there has been prior publication and prior use of same or an identical invention.
- For instance, the recent grant of patent in the USA to turmeric products was attacked on this ground. The Indian CSIR **Council of Scientific and Industrial Research** challenged the grant of **patent on turmeric** by the US patent office on the plea that the patent could not be granted since there was no novelty in the invention.
- Also, that what was patented was already published in **Indian texts** and use of turmeric preparation has been made in our country since times immemorial.
- The **CSIR** was successful in getting the grant of patent to an **American company** **revoked**.
- This instance highlights the importance of the element of novelty for an invention to qualify for grant of patent.

Non-obviousness: The invention must be non-obvious to a person skilled in the art to which the invention relates.

Usefulness: The invention, besides being new and non-obvious, must also be useful. If the invention can not be put to any **beneficial use of the mankind**, it can not be patented.

Persons entitled to apply for patent:

- Person claiming to be the true and **first inventor** of the invention.
- Any **person being the assignee** of the true and first inventor of the invention
- By the **legal representative** of any deceased person who immediately before **death** was entitled to make such an application.

Procedure for Obtaining Patent

Steps for Obtaining Patent

- Submission of application,
- filing provisional and complete specification,
- publication and examination of the application,
- communication to the applicant ,
- opposition proceedings to the grant of the patent,
- grant of patent,

Submission of application,

Who can Apply for Patent?

An application for a patent for an invention may be made by a person-

- Who claiming to be the true and first inventor of the invention or his assignee,
- by the legal representative of any deceased person who immediately before his death was entitled to make such an application

TYPES OF PATENT APPLICATIONS IN INDIA

ORDINARY

An ordinary patent application may be filed if the applicant does not have any priority to claim or if the application is not filed in pursuance of any preceding convention.

CONVENTION

Filing a convention application allows the applicant to claim priority in all the convention countries. The applicant can claim priority if the same or substantially similar application has been filed in any of the convention countries in pursuance of any preceding convention.

NATIONAL PCT

In the national phase, the applicant is required to file the national phase patent application in India within 31 months of the international filing date or priority date whichever is earlier.

PATENT OF ADDITION

A patent of addition protects the improvement with respect to the earlier patent. There is no separate renewal fee for a patent of addition and it expires when the main patent expires.

DIVISIONAL

When there is more than one invention in a patent application the applicant may be required to (or of his own accord) divide the application based on the number of inventions the application contains.

Procedure for obtaining Patent

Submission of Application:

- If the application is filed by the assignee, it must be accompanied with the proof of the right to make the application.
- the form of application for grant of an Indian patent asks for
 - (i) full name, address, nationality of the applicant(s) and inventor(s),
 - (ii) patent specifications, and
 - (iii) whether an application has been made or patent granted in a PCT (Patent Corporation Treaty) or
- a convention country, which affords to citizens of India, or applicants for patents in India.
- Every such application (not being a convention application or an application filed under the Patent Cooperation Treaty designating India) shall be accompanied by a provisional or a complete specification.

Procedure for registration of Patents

Filing of Provisional and Complete Specification-

- ❑ A specification is an **accurate description** of the patent stating how the invention can be carried out by the **method best known** to the applicant. The specification **ends with a claim** or claims defining the **scope of the invention** for which protection is claimed.
- ❑ Every application must be accompanied by a provisional or a **complete specification**.
- ❑ It is **possible to file the application** with **provisional specifications**. But it is necessary to file the complete specifications **within one year** of filing the original patent application.
 - ❑ The **twelve months limit** can be **extended to 15 months** if an **application is made** to the Controller with **such request and the prescribed fee** is paid.

PTO/SB/18 (08-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DESIGN PATENT APPLICATION TRANSMITTAL	
(Only for new nonprovisional applications under 37 CFR 1.53(b))	Attorney Docket No.
	First Named Inventor
	Title
	Express Mail Label No.

ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	DESIGN V. UTILITY: A "design patent" protects an article's ornamental appearance (e.g., the way an article looks) (35 U.S.C. 171), while a "utility patent" protects the way an article is used and works (35 U.S.C. 101). The ornamental appearance of an article includes its shape/configuration or surface ornamentation upon the article, or both. Both a design and a utility patent may be obtained on an article if invention resides both in its ornamental appearance and its utility. For more information, see MPEP 1502.01.
APPLICATION ELEMENTS See MPEP 1500 concerning design patent application contents.	
ACCOMPANYING APPLICATION PARTS	
1. <input type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17)	7. <input type="checkbox"/> Assignment Papers (cover sheet & document(s))
2. <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.	8. <input type="checkbox"/> 37 CFR 3.73(b) Statement (when there is an assignee) <input type="checkbox"/> Power of Attorney
3. <input type="checkbox"/> Specification [Total Pages _____] (preferred arrangement set forth below, MPEP 1503.01) - Preamble - Cross References to Related Applications - Statement Regarding Fed sponsored R & D - Description of the figure(s) of the drawings - Feature description - Claim (only one (1) claim permitted, MPEP 1503.03) 4. <input type="checkbox"/> Drawing(s) (37 CFR 1.152) [Total Sheets _____]	9. <input type="checkbox"/> English Translation Document (if applicable)
5. Oath or Declaration [Total Pages _____] a. <input type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> A copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 16 completed) i. <input type="checkbox"/> Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)	10. <input type="checkbox"/> Information Disclosure Statement (IDS) PTO/SB/08 or PTO-1449 <input type="checkbox"/> Copies of foreign patent documents, publications, & other information
6. <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76	11. <input type="checkbox"/> Preliminary Amendment
16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76: <input type="checkbox"/> Continuation <input type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-part (CIP) of prior application No.: _____ Prior application information: Examiner _____ Art Unit: _____	
17. CORRESPONDENCE ADDRESS	
<input type="checkbox"/> The address associated with Customer Number: _____ OR <input type="checkbox"/> Correspondence address below	
Name _____	
Address _____	
City _____	State _____ Zip Code _____
Country _____	Telephone _____ Email _____
Signature _____ Date _____	
Name (Print/Type) _____ Registration No. (Attorney/Agent) _____	

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Date of publication and grant of the patent

Date of filing

Countries where the patent has been filed

Priority date

Publication date

Applicant

Inventors

Representative



(11) EP 3 155 128 B1

Publication number

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
15.05.2019 Bulletin 2019/20

(51) Int Cl.:
C12Q 1/68 (2018.01) A61K 48/00 (2006.01)
C12N 15/11 (2006.01)

Patent classes

(21) Application number: 15732984.8

(86) International application number:
PCT/NL2015/050420

(22) Date of filing: 10.06.2015

(87) International publication number:
WO 2015/190921 (17.12.2015 Gazette 2015/50)

(54) METHODS FOR CHARACTERIZING ALTERNATIVELY OR ABERRANTLY SPLICED MRNA ISOFORMS

VERFAHREN ZUR CHARAKTERISIERUNG ALTERNATIV ODER ANOMAL GESPLEISSTER MRNA-ISOFORMEN

PROCÉDÉS DE CARACTÉRISATION D'ISOFORMES D'ARNM ÉPISÉS DE MANIÈRE DIFFÉRENTE OU ABERRANTE

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

(56) References cited:
WO-A1-2007/135105 WO-A2-01/77380
WO-A2-2013/043878

- OHNUMA S ET AL: "Cancer-associated splicing variants of the CDCA1 and MSMB genes expressed in cancer cell lines and surgically resected gastric cancer tissues", SURGERY, MOSBY, INC, US, vol. 145, no. 1, 1 January 2009 (2009-01-01), pages 57-68, XP025837299, ISSN: 0039-6060, DOI: 10.1016/J.SURG.2008.08.010 [retrieved on 2008-12-27]
- ROB W J COLLIN ET AL: "Mid-frequency DFNA8/12 hearing loss caused by a synonymous TECTA mutation that affects an exonic splice enhancer", EUROPEAN JOURNAL OF HUMAN GENETICS, vol. 16, no. 12, 25 June 2008 (2008-06-25), pages 1430-1436, XP055140967, ISSN: 1018-4813, DOI: 10.1038/ejhg.2008.110
- T. YU ET AL: "Using a minigene approach to characterize a novel splice site mutation in human F7 gene causing inherited factor VII deficiency in a Chinese pedigree", HAEMOPHILIA, vol. 15, no. 6, 1 November 2009 (2009-11-01), pages 1262-1266, XP055140970, ISSN: 1351-8216, DOI: 10.1111/j.1365-2516.2009.02064.x

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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).

Procedure for obtaining Patent

The specification must contain the following:-

- **Title**, sufficiently indicating the subject-matter.
- **Relevant drawings**.
- **Full and particular description** of the invention.
- **Details of its operation** or **use** and the **method by which it is to be performed**.
- **Disclosure of the best method** of performing the invention.
- Claims defining the **scope of the invention** substantiated by the disclosure.
- **Abstract** providing technical information on the invention.
- **Declaration** as to the **inventor ship** of the invention.

FORM 5	
THE PATENTS ACT, 1970	
(39 of 1970)	
&	
The Patents Rules, 2003	
DECLARATION AS TO INVENTORSHIP	
[See Section 10(6) and rule 13(6)]	
1. NAME OF THE APPLICANT(S)	
hereby declare that the true and first inventor(s) of the invention disclosed in the complete specification filed in pursuance of my/our application numbered dated.....is/are.....	
2. INVENTOR(S)	
(a) NAME	
(b) NATIONALITY	
(C) ADDRESS	
Dated this.....day of.....20.....	
Signature:-	
Name of Signatory:-	
3. DECLARATION TO BE GIVEN WHEN THE APPLICATION IN INDIA IS FILED BY THE APPLICANT(S) IN THE CONVENTION COUNTRY:-	
We the applicant(s) in the convention country hereby declare that our right to apply for a patent in India is by way of assignment from the true and first inventor(s).	
Dated this.....day of.....20.....	
Signature:-	
Name of Signatory:-	
4. STATEMENT (to be signed by the additional inventor(s) not mentioned in the application form)	
I/We assent to the invention referred to in the above declaration, being included in the complete specification filed in pursuance of the stated application.	
Dated this.....day of.....20.....	
Signature of additional inventor(s):-	
Name:-	

Procedure for obtaining Patent

Publication of the Application-

- Normally every patent application is published after 18 months of filing the application and objections are invited.
- The patent application shall not be open to the public for eighteen months after the date of filing, or date of priority, whichever is earlier.
- The **Controller** may issue direction to prohibit or restrict such publication.
- In the case of secrecy direction, the application will be published when the secrecy directions cease to operate.
- The publication will include the particulars of the date of application, number of application, name and address of the applicant and an abstract.

Procedure for obtaining Patent

Examination of the Application-

- Examination is taken up only if the applicant or any other interested person makes a request in the prescribed manner for such examination within 48 months from the date of filing of the patent application.
- If such request is not made within the prescribed time, the patent application is treated as withdrawn.
- When the patent application is in respect of an invention for a chemical substance used as an intermediate in the preparation of a medicine or drug including insecticides etc used for protection or preservation of plants, the request for examination has to be made within a period of 12 months or within 48 months from the date of the application, whichever is later.

Procedure for obtaining Patents

Communication to the applicant

- ❑ This communication between controller and patent applicant is to ensure that all objections raised in the patent application are **resolved**. (if not the patent will not be granted) and the inventor has his fair chance to prove his point and establish **novelty and inventive step** over existing prior arts.
- ❑ Up on finding the patent application in order of grant, it is grant to the patent applicant as early as possible.

PRE-GRANT & POST GRANT OPPOSITION OF PATENT

Pre-grant opposition gives third parties the opportunity to oppose the grant of a patent just after publication of the patent application – a party need not wait until the grant itself.

Post-grant opposition can be filed only after the grant of a patent, but within one year of the date of grant.

Pre-grant and post-grant opposition can be filed only on the following grounds:-

- i. Claimed invention or its part wrongfully obtained;*
- ii. Claimed invention is published in a patent or any other document before the priority date;*
- iii. Claimed invention is published in a patent after the priority date having earlier priority date;*
- iv. Claimed invention was publicly known or publicly used before the priority date;*
- v. Claimed invention is obvious and does not involve clearly any inventive step, as regards to the matter published or used (in India) before the priority date;*

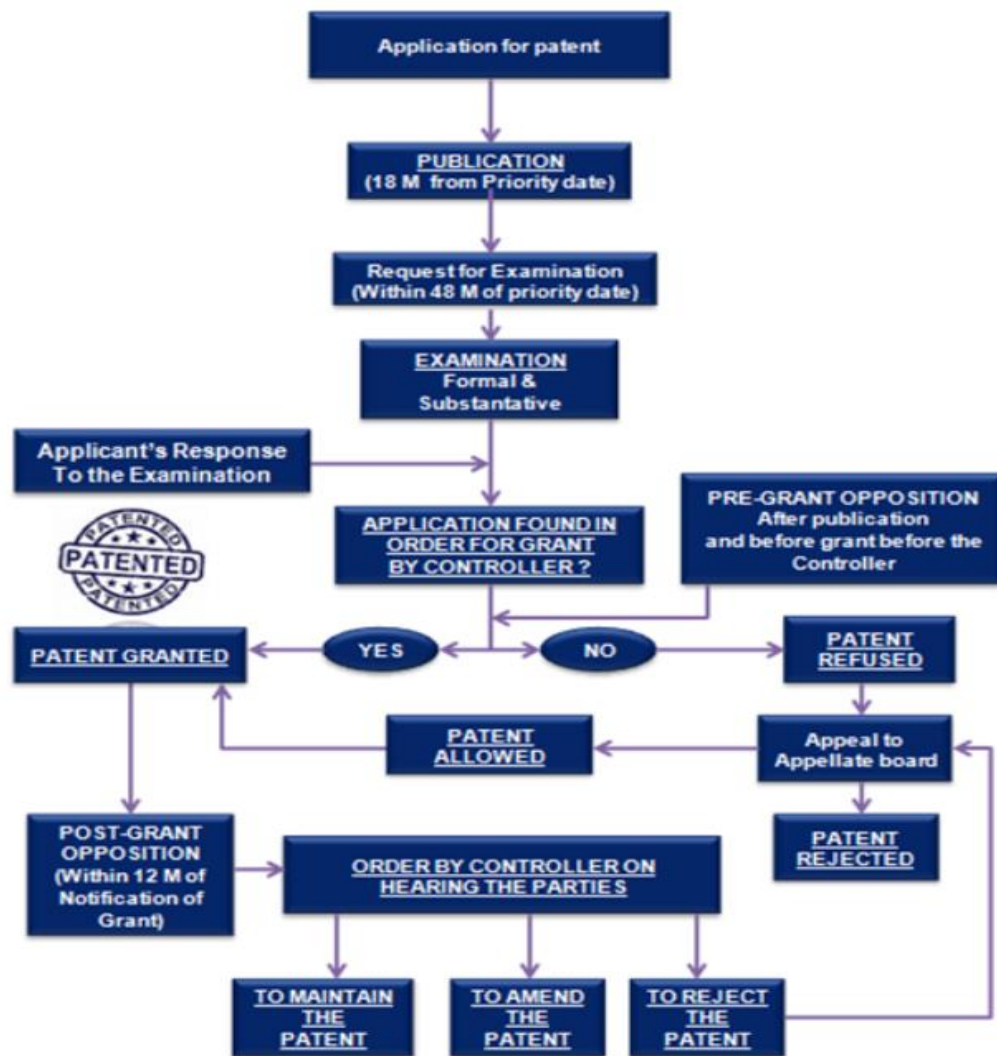
PRE-GRANT & POST GRANT OPPOSITION OF PATENT

- vi. Claimed invention is not an invention within the meaning of the Patents Act or is not patentable under the Patents Act;*
- vii. The complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;*
- viii. The applicant has failed to disclose to the Controller the information regarding foreign applications filed by him for the same invention or has furnished the information which in any material particular was false to his knowledge;*
- ix. In case of convention application if the application is not filed before the expiry of 12 months from the date of first application in convention country;*
- x. The complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used in the invention;*
- xi. Claimed invention was anticipated having regard to the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere.*

GRANT / REFUSAL OF PATENT

When the application for a patent has been found for grant of the patent and:

- 1. The controller has not refused the application by virtue of any power vested in him.**
- 2. The application is not in contravention of any of the provisions of the act,**
 - ✓ Then the patent shall be granted as expeditiously as possible with the **seal of the patent office**, and the date on which the patent is granted shall be **entered in the register**.
 - ✓ On the grant of the patent, the controller shall publish the fact that the patent has been granted and it **shall be open for the public inspection**.
 - ✓ A patent may be granted for one invention only.
 - ✓ **The decision of the controller, if it is against the applicant, can be appealed against in the Appellate Board.**



Note: M – Months ; ENTRIES WITH UNDERLINE ARE INITIATED BY PATENT OFFICE

- A discovery, scientific theory or mathematical method
- Literary, dramatic, musical or artistic work or any other aesthetic creation
- A scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer
- The presentation of information
- An invention, the publication or exploitation of which is offensive, immoral or anti-social
- Any plant or animal variety or any biological process for the production of plants and animals
- An invention which is frivolous or which claims anything obviously contrary to well established natural laws
- An invention the primary or intended use of which could be contrary to public order or morality of which causes serious prejudice to human, animal, or plant life or health or to the environment.

- The mere discovery of scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature.
- A substance obtained by mere admixture resulting only in aggregation of the properties of the components thereof or process for producing such substance.
- The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way.
- A method of agriculture or horticulture.
- Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products

- Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.
- A mathematical or business method or computer program per se or algorithms.
- Topography of integrated circuits.
- An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.
- Inventions relating to atomic energy are not patentable

- **Term of a Patent in the Indian System**
- Section 53 of the Act lays down that the term of the patent after the commencement of the Patents Act, 2002 or the term of every patent which has not expired and has not ceased to have effect, shall be **20 years** from the date of filing of the application for the patent.
- Similarly, the term of patent in case of international applications filed under the Patent Co-operation Treaty designating India, shall be **20 years from the international filing date accorded under Patent co-operation Treaty.**

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Rights conferred by a patentee

- The right to exploit the patent
- Right to licence
- Right to assign
- The right to surrender the patent
- Right to sue for infringement

Basmati Rice Patent Case

- It is known world-wide that the long-grain aromatic rice known as 'basmati' has been produced widely in the Sub-himalayan region. Basmati rice is one of the best-known varieties of rice originally cultivated in India, Pakistan and certain regions of South Asia.^[5]

- *India is a diverse country with traditional knowledge ranging from Yoga to Ayurveda.*

Dr. Vandana Shiva, an Indian environmental activist once quoted that, "Bio-piracy (is) biological theft; illegal collection of indigenous plants by corporations who patent them or their own use and benefit".

The importance of analyzing the issue of Basmati Rice is since India has a bundle of traditional knowledge and rich heritage which if patented by other nations can put restrictions on use of such resources by the indigenous communities. India is a signatory country which complies with the provisions stated in the Trade related aspects of Intellectual Property Rights (TRIPs) for intellectual property, wherein, most countries have been committed to provide minimum standards of protection to intellectual property.

Intellectual properties like plant variety, patents, geographical indications etc. are served extremely crucial for growth of agriculture in a developing country like India. The geographical Indications can be elucidated as particular goods originating from a country, region or a locality due to several special circumstances, quality and reputation of the product.

They are gaining a rapid popularity in the field of trade and commerce and recognize the true heritage of a country in terms of specified goods. This is due to the special quality of such products being rendered because of their goodwill.

Facts:

In late 1997, the United States Patent and Trademark Office granted a patent to Ricetec Inc., the United States based multinational company headquartered in Alvin, Texas for a novel 'grain' also known as 'basmati'.

The company claimed the protection of new varieties of 'basmati' crops with better qualities than the original crop. It has been using several versions of the crop by selling it with the name 'Jasmati' or 'Kasmati' in the international rice market. Moreover, it was also professed to have developed a novel strain of the aromatic rice by inter-breeding of basmati rice with another crop known as American basmati or 'Texmati'. The patent was granted to the company for basmati rice grains and variety by USPTO.

Later, the patent was opposed by the Indian NGOs like Research Foundation for Science, Centre for Food Safety and ultimately, Centre for Scientific and Industrial Research too, objected to it. The Indian sub-continent protected its traditional crop basmati while Thailand contested for the safeguarding of its claim for jasmine rice. In 2000, after examining evidence, the Indian Government challenged the patent claims by the company.

Issues raised

- Whether the name 'basmati' is a 'generic' term or specifically originates from the aromatic rice grown in India and various South-Asian countries?
- Whether the grain developed by Ricetec Inc. is a novel variety and strain?
- Is Ricetec Inc. guilty of bio-piracy and violation of traditional knowledge belonging to indigenous communities of Southern-Asian countries?
- Whether the patent granted to Ricetec must be revoked due to protests by various NGOs and Indigenous Communities?
- Whether USPTO's [United States Patent and Trademark Office](#) decision to grant patent to Basmati Rice violates TRIPs [Trade-Related Aspects of Intellectual Property Rights](#) Agreement?

Critical analysis and emergence of new geographical indication laws in India

Dr. Shiva realized that patenting of basmati rice is not only perceived as an infringement of intellectual property but a cultural theft which threatens the rights of developing countries, their traditional knowledge and practice of such knowledge by farmers.

The theft so involved in Basmati's case is threefold: theft of heritage and biodiversity of Indian farmers; Indian traders and exporters and finally, a deceiving of its consumers.

the importance for emergence of a statute to protect the geographical indicators pertaining to Indian heritage and sub-continent was realized.

in 1999, India enacted a legislation called Geographical Indication of Goods (Registration and Protection) Act, 1999.

It is administered as the first specific law to register and protect the geographical indications.

The crop basmati has been registered as a geographical indication under the Act for states including Haryana, Uttar Pradesh, Punjab, Jammu & Kashmir, Uttarakhand, Delhi and Himachal Pradesh. Prior to 1999, there was no specific legislation to regulate and protect the geographical indications.

It was, however, in 1999 that India adopted the act after complying with Article 22 of the TRIPs Agreement.

The Article stated with regard to the 'protection of geographical indicators' with the help of 3 essential clauses.

Article 22 clause (1) stated the definition of the term and clause (2) explained how the member states shall provide the legal means for interested parties to prevent any sale of misleading products to consumers and unfair competition in the market. Clause (3) suggested that member states shall implement a legislation for registration or invalidation of a trademark which might consist of geographical indications.

Other than basmati crops, indigenous crops like *Karela, Jamun, Neem leaves, Imli, Adrak, Ashwagandha* etc. have also faced similar patent claims by developed nations.

To restrict the further conduct of bio-piracy by other developed nations, India prepared a database called 'Traditional Knowledge Digital Library'.

The idea behind TKDL is to help patent offices across the globe reject patent applications based on Indian Traditional Knowledge.