



# **PROTECTING INTELLECTUAL PROPERTY: *CHEMICAL & BIOLOGICAL INVENTIONS***

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# WHAT IS INTELLECTUAL PROPERTY ?

- ***creations of the mind***
  - inventions [PATENTS]
  - trademarks [*symbols, names, images, etc.*]
  - industrial designs
  - geographical indications of source
  - Layout-Designs (Topographies) of Integrated Circuits
  - Plant Varieties
  - Copyright - *literary and artistic works*



# WHAT IS A PATENT ?

- A **patent is an agreement** between the government and an inventor whereby, in exchange for the **inventor's complete disclosure** of the invention, the **government gives the inventor the right** to exclude others from using the invention in certain ways.
- The property **right provided in a patent is quite different** from what we typically think of when we own property. What is granted is not the right to make, use, offer for sale, sell or import, but the **right to stop others from making, using, offering for sale, selling or importing the invention.**



contd...

## WHAT IS A PATENT ?

- **A patent is an intellectual property**, which if properly utilized, **is an asset** that reaps monetary **benefits for its assignee** for the next **twenty years from the date of filing the application.**
  - **A MONOPOLY RIGHT**
  - **A NEGATIVE RIGHT**
  - **A TERRITORIAL RIGHT**
  - **GRANTED BY THE GOVT.**
    - **FOR DISCLOSURE OF INVENTION**
    - **TO OWNER OR HIS ASSIGNEE**
    - **FOR LIMITED PERIOD OF TIME**



## WHAT IS THE PURPOSE OF A PATENT ?

- To provide an **advantage to society** as a whole by **rewarding** the **development of new inventions**.
- **Promoting technological advancement** by the **disclosure** of valuable information that can **stimulate research** across the globe.

For instance, **developing innovative drugs** is a risky, time-consuming and expensive process; therefore, companies seek the **protection of a patent** to **ensure that competitors will not immediately copy a product** they have researched and developed.



# WHAT CAN BE PATENTED ?

## An INVENTION :

An invention means a new product or process involving an inventive step and capable of industrial application.



contd...

## WHAT CAN BE PATENTED ?

- **A process** - for example, a process of enzymatic catalysis or a process for the isolation of a new microbe.
- **A composition of matter** - for example, a new pharmaceutical drug or a new enzyme.
- **A machine** - for example, an NMR machine, spectrophotometer.
- **An article of manufacture** - for example, a water clarifier or a specially molded piece of plastic for electrophoresis apparatus.
- Any **new and useful improvement** to an invention that falls under any of these categories.



# WHAT IS REQUIRED GET A PATENT ?

- ☞ NOVELTY
- ☞ INVENTIVENESS ( non-obviousness )
- ☞ INDUSTRIAL APPLICABILITY
- ☞ The application must **describe the invention in sufficient detail** to allow the public to make and use the invention



# WHAT IS NOVEL ?

**"NEW"**  
MEANS  
**SHOULD NOT BE**

- I. **PUBLISHED IN INDIA OR ELSEWHERE**
  - by **communication of Abstract**
  - by **online Publication**
  - by **oral Disclosure**
  
- II. **IN PRIOR PUBLIC KNOWLEDGE OR PRIOR PUBLIC USE**
  
- III. **CLAIMED BEFORE IN ANY SPECIFICATION**



# EXCEPTIONS TO NOVELTY

□ As per **section 31** of the Indian Patents Act, **an invention shall not be deemed to be anticipated, if and only if:**

- the **display of the invention** is done **at an exhibition notified by the Central Govt.** in the Official Gazette
- the **reading of the paper** is done by the true and first inventor before a learned society,
- the **publication of the paper** is done by the true and first inventors **in the transactions of a learned society**

and thereafter, the **application for patent** is made **not later than 12 months** from the **date of** opening of **exhibition or publication of paper.**



# WHAT IS INVENTIVENESS ?

**A FEATURE  
THAT MAKES THE INVENTION  
NOT OBVIOUS  
TO A PERSON  
SKILLED IN THE ART**

For example, the **substitutions of one material for another**, or **changes in size**, are ordinarily not patentable.



## case study : inventiveness

A compound may be new and useful but still **not be patentable** because it is so **close to the prior art that there is no inventive step** involved in making it.

In considering how close an invented compound is to a compound of the prior art one must ***consider not merely the structural formulae of the compounds, but the compounds themselves, including their properties.***



contd...

## case study I : inventiveness

### Present invention

Novel brominated aromatic compounds

a) Useful as flame retardants

### Cited Doc

A compound which is Chlorinated instead of brominated

a) No/ different use assigned

In instant case, the invention **should be patentable** in spite of the very close structural similarity, simply because **it would not be obvious** that the bromo-compounds would be useful as flame retardants.

On the other hand, if the prior-art **chloro-compound was known to have flame retardant properties**, then **it would be obvious** that the bromo-analogues would be likely to share these properties and the case would be **non-patentable**.



contd...

## case study I : inventiveness

### Present invention

Novel brominated aromatic compounds

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### Cited Doc

A compound which is Chlorinated instead of brominated

a) No/ different use assigned

### To be patentable:

- it would be necessary for them to be **surprisingly better flame retardants than the chloro-compound**, at least in some respects
- alternatively, **if the bromo-compounds**, although no better than the prior art on most substrates, **could flameproof one substrate for which the chloro-analogue was ineffective.**



## case study II : inventiveness

### Optical isomers

- The **closest** situation to the **prior art** is **when the new compound is an optically active enantiomer of a compound previously known only in racemic form.**
- The **racemate** may be regarded as **not novel**, since the racemate could be considered as an **equimolar mixture of the D- and L- forms**. [*However, in cases both in the UK and the USA it has been decided that optical isomers of known racemates may be considered as novel per se*].
- Usually, the **problem is obviousness rather than lack of novelty**, as the presence of an asymmetric center in the molecule depicts that **optically active forms can exist**, and also obvious that they **can be isolated** by one or other of the **standard methods of resolution**. **The only way in which an optical isomer can be patentable is if it has surprisingly superior properties/ use as compared with the racemate.**



# case study III : inventiveness

## Present invention

A process for reducing the Hg content of a liquid comprising:

- a) engineering *P. aeruginosa* to contain transmissible MER plasmid
- b) bringing the Hg containing liquid in contact with engineered *P. aeruginosa*
- c) keeping the organism in liquid for 5-10 min
- d) recovering the Hg free liquid from the organism

## Cited Doc I

A method of removing Hg from water comprising:

- a) bringing the Hg containing liquid in contact with *P. aeruginosa*
- b) keeping the organism in liquid for 5-10 min
- c) recovering the Hg free liquid from the organism

## Cited Doc II

A method of engineering *P. aeruginosa* to contain transmissible MER plasmid, said MER plasmid having the property of generating Hg-binding protein.

- ☞ Present **invention is novel** compared to cited docs I & II
- ☞ **Lacking inventive step**: as a person of ordinary skill in the art can conceive the idea of using genetically engineered *P. aeruginosa* (for Hg removal) from Doc II <sup>16</sup>



# **WHAT do we mean by INDUSTRIAL APPLICABILITY ?**

**INVENTION IS**

**CAPABLE OF BEING MADE OR**

**CAPABLE OF BEING USED IN**

**AN INDUSTRY**



# NON PATENTABLE INVENTIONS

## FRIVOLOUS INVENTIONS

## INVENTIONS CONTRARY TO WELL ESTABLISHED NATURAL LAWS

- A machine purporting to produce perpetual motion
- A machine alleged to be giving output without any input



## non- patentable inventions : contd...

INVENTIONS, THE COMMERCIAL  
EXPLOITATION OR PRIMARY USE OF WHICH  
IS

➤ **CONTRARY TO PUBLIC ORDER**

➤ **IMMORAL**

➤ **CAUSING PREJUDICE TO**

- HUMAN HEALTH & LIFE
- ANIMAL HEALTH & LIFE
- PLANTS
- ENVIRONMENT



## **non- patentable inventions : EXAMPLE**

The following are not patentable on the **basis that their commercial exploitation would be contrary to the public order or morality:**

- ✓ Processes for **cloning human beings;**
- ✓ 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
- ✓ **Any device or machine or method for committing theft/ burglary**
- ✓ **Any machine or method for counterfeiting of currency notes**



## non- patentable inventions : contd...

### MERELY THE DISCOVERY OF

- SCIENTIFIC PRINCIPLE
- FORMULATION OF ABSTRACT THEORY
- LIVING/NON-LIVING THING OCCURING IN NATURE
- **NEW PROPERTY OF KNOWN SUBSTANCE**
- NEW USE OF KNOWN SUBSTANCES/ PROCESS/  
MACHINE /APPARATUS

For the purposes of this clause, **salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance** shall be considered to be the **same substance**, *unless they differ significantly in properties with regard to efficacy*



## **non- patentable inventions : contd...**

- ☞ **MERE CHEMICAL ADMIXTURES**
- ☞ **PROCESSES RESULTING IN MERE ADMIXTURES**
- ☞ **ARRANGEMENT, REARRANGEMENT OR DUPLICATION OF KNOWN DEVICES**
- ☞ **METHODS OF AGRICULTURE**
- ☞ **METHODS OF HORTICULTURE**



## **non- patentable inventions : contd...**

### **METHODS OF TREATMENT**

- OF HUMAN BEINGS
- OF ANIMALS



## **non- patentable inventions : contd...**

- PLANTS & ANIMALS IN WHOLE**
- PARTS OF PLANTS & ANIMALS**
- SEEDS**
- VARIETIES & SPECIES**
- ESSENTIALLY BIOLOGICAL PROCESSES FOR PROPAGATION OR PRODUCTION OF THE ANIMALS & PLANTS**



## DOCUMENTS REQUIRED TO FILE A PATENT

- **FORM-1** : Application for a patent
- **FORM-2** : Provisional/ Complete Specification
- **FORM-3** : Statement & undertaking regarding corresponding foreign applications
- **FORM-5** : Declaration as to Inventorship
- **FORM-9** : Request for Early Publication
- **FORM-18** : Request for Examination
- **FORM-26** : Power of Attorney [*in case of JOINT patent application*]
- **Sequence Listings** (*if any*) in electronic form



# CONTENTS OF PROVISIONAL SPECIFICATION

- Title of invention
- Field of invention
- Background/ Prior art
- Description of general nature
- Preliminary experiments and results
- Anticipated results
- Drawings [*optional*]



# STRUCTURE OF A COMPLETE SPECIFICATION

- Title of the invention
- Field of the invention
- Background of the invention
- Objectives of the invention
- Summary of the invention
- Detailed description of the invention
- Brief description of the drawings, *if any*
- Examples
- Advantages
- Claims
- Abstract
- Drawings, *if any*



## A COMPLETE SPECIFICATION shall...

- **fully and particularly describe the invention** and its operation or use and the method by which it is to be performed
- disclose the **best method of performing the invention** for which the applicant is claiming protection
- **end with claims** defining the scope of the invention
- be accompanied by an **abstract in not more than 150 words** bearing a title



# CLAIMS

- Claims are the parts of a patent which **define the boundaries of patent protection.**
- Patent claims are the **legal basis** for your **patent protection.**
- They form a **protective boundary line around the patent** that lets others know when they are **infringing on your rights.**
- The **limits** of this line are **defined by the words and phrasing of your claims**



## CLAIMS : contd....

- **should be clear and succinct** [*using words such as "thin", "strong", "a major part", "such as", "when required", depicts that you are probably not being clear enough* ]
- **should be fairly based on the matter disclosed in the specification** [*This means that all the characteristics of the invention that form part of the claims must be fully explained in the description. In addition, any terms used in the claims must be either found in the description or clearly inferred from the description* ]
- **should relate to a single invention or to a group of inventions linked so as to form a single inventive concept**



## CLAIMS : contd....

### A few important points to be remembered while drafting claims

- **Decide the essential elements of your invention** [*the ones that distinguish your invention from known technology*] **that** you want to claim exclusive rights to.
- Each **claim should have only one meaning** which can be either **broad or narrow, but not both** at the same time. [*a narrow claim generally specifies more details than a broader claim*]
- **Begin** with the **broadest claims** [*claim1*] followed by **narrower claims.**



# CLAIMS : contd....

## A few important points to be remembered while drafting claims

- **Start claims on a new page** [*after completing the description*] and number them using Arabic numbers starting with 1.
- **Check to see that each claim consists of an introduction** [preamble], **linking word** [*which comprises, including, consisting of, consisting essentially of* ], **and body** [*feature of the invention*]
- **Describe multiple embodiments wherever possible**



## Essentials in case of a biological patent - I

- Disclosure of the **source** and **geographical origin** of the biomaterial i.e., from which source and which place it has been taken
- **Deposition** of the microorganism in an International Depository recognized under the Budapest Treaty like, MTCC, ATCC, DSMZ etc.
- Is the material **commercially available** ?
- in case it is **gifted by somebody** please furnish the certificate from donor that it is gifted
- Is the material **reproducible** ?



## Essentials in case of a biological patent - II

- **Disclose the identification, characteristics and deposition details of the new microbe in the patent specification such as -**
  - **species** identification
  - **morphological details** such as shape, size, stain ability, motility
  - **colony characteristics**, for example, colour, shape, size, swarming and any distinguishing features in appearance, such as, shininess;
  - **metabolic characteristics** including substrate requirements, products or byproducts, isozyme characteristics;
  - **genetic characteristics** such as specific genes or mutations or variants of these (these may be characterized at either the nucleic acid or protein level); and
  - **plasmids and phages** (if any) in the microorganism together with relevant genetic characterization

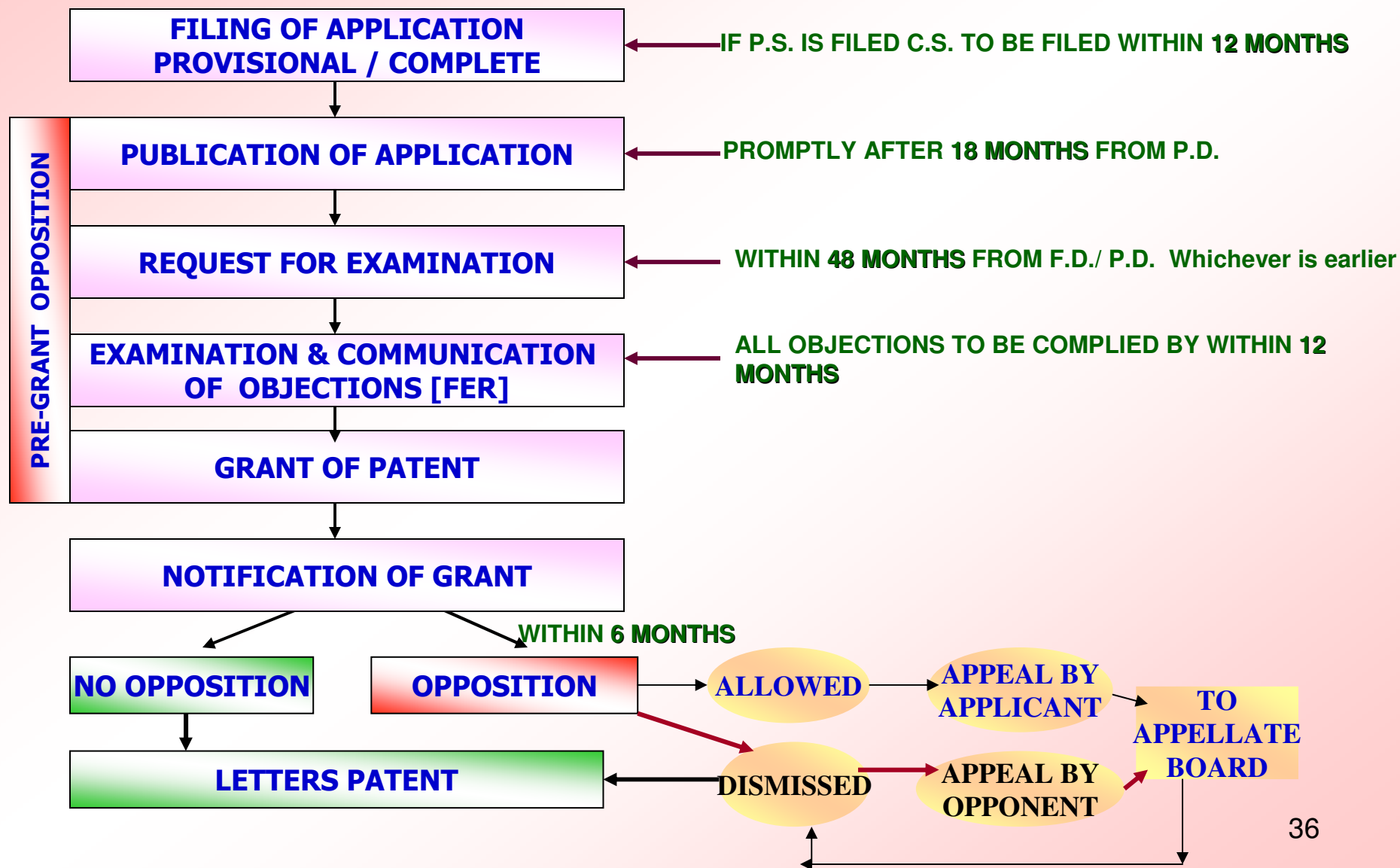


## Essentials in case of a biological patent - III

- Any person desirous of applying for a patent or any other intellectual property based on **research on biological material and knowledge obtained from India** shall make an application to the *National Biodiversity Authority* at **Chennai**.
- **The Biodiversity Act - 2002** primarily addresses **access to genetic resources and associated knowledge** by foreign individuals, institutions or companies, to ensure equitable sharing of benefits arising out of the use of these resources and knowledge to the country and the people.



# A JOURNEY FROM FILING TO GRANT OF PATENT in INDIA



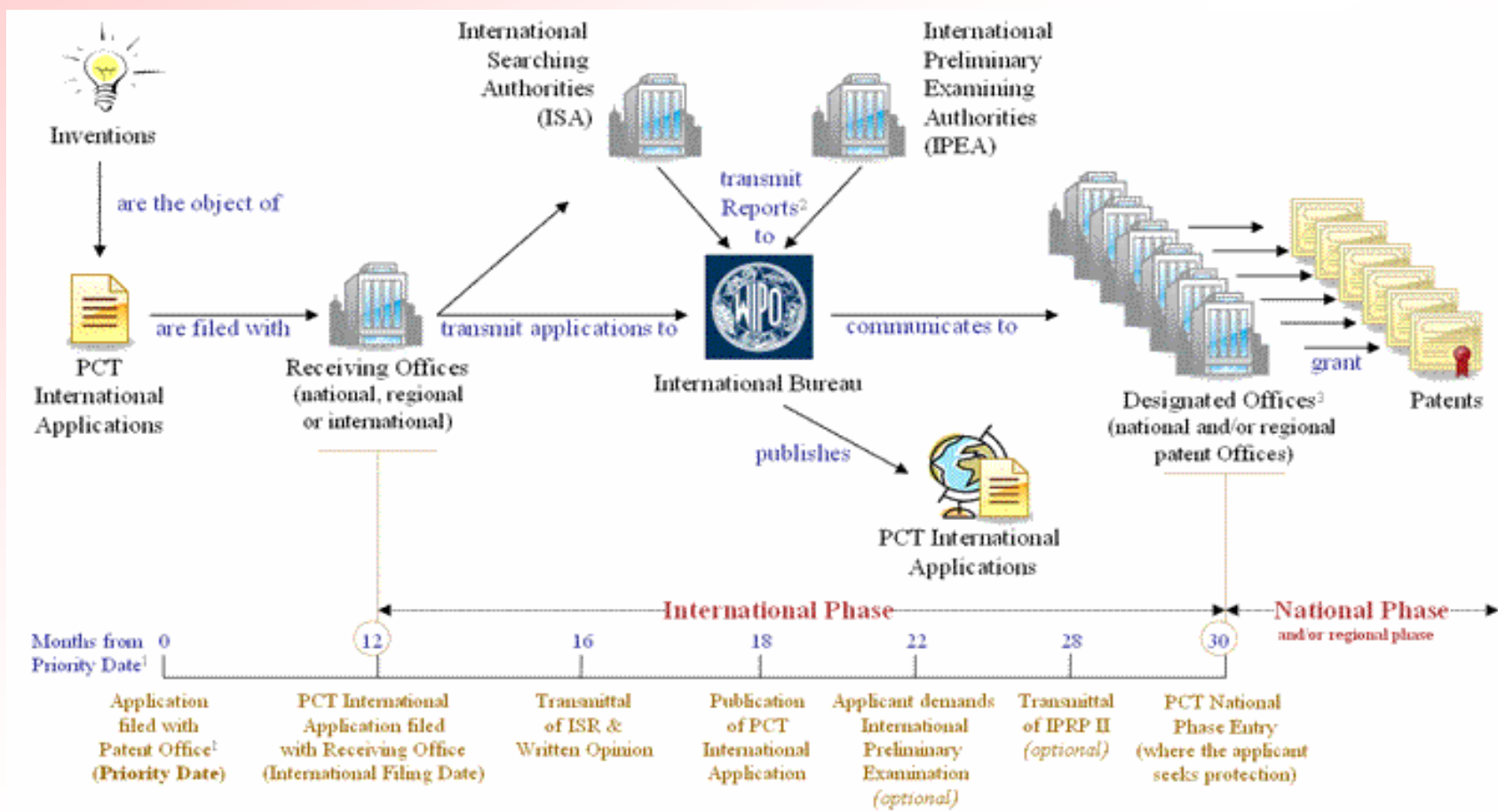


# PATENT APPLICATIONS UNDER THE PCT

- The PCT system originated in 1970 & became operational on 01/6/78 with 18 members
- H.Q. In Geneva, Switzerland known as WIPO
- Joined by India on 7/12/98 as 98<sup>th</sup> member
- Currently the system has 139 members
- Treaty for rationalization & international cooperation in the field of patents particularly for
  - *Filing, Searching, Examining and*
  - *Dissemination of technical information contained in the patent documents*



# THE PCT TIMELINE



<sup>1</sup> Generally, applicants first file a national or regional patent application with their patent Office and within the 12 months from priority date, file a PCT international application

<sup>2</sup> ISAs transmit International Search Reports (ISRs) & Written Opinions / IPEAs transmit International Preliminary Reports on Patentability II (IPRP II).

<sup>3</sup> Called Elected Offices for Applicants having filed a demand for IPRP II.

Source: World Intellectual Property Organization (WIPO)



# **BENEFITS OF PCT FILING**

- **Filing of a single patent application with WIPO, the filing date of which is effective in all designated national phases**
- **Evaluation of the invention in one step by the ISA/IPEA**
- **Saving of time & money**
- **Time period of 30 months to exploit/ explore the commercial viability of the invention**

***THANKS FOR YOUR  
KIND ATTENTION  
AND  
PATIENCE***

