Biotech Inventions: Essentials of drafting a Patent Specification

WORKSHOP ON STRATEGIC MANAGEMENT

OF INTELLECTUAL PROPOERTY RIGHTS

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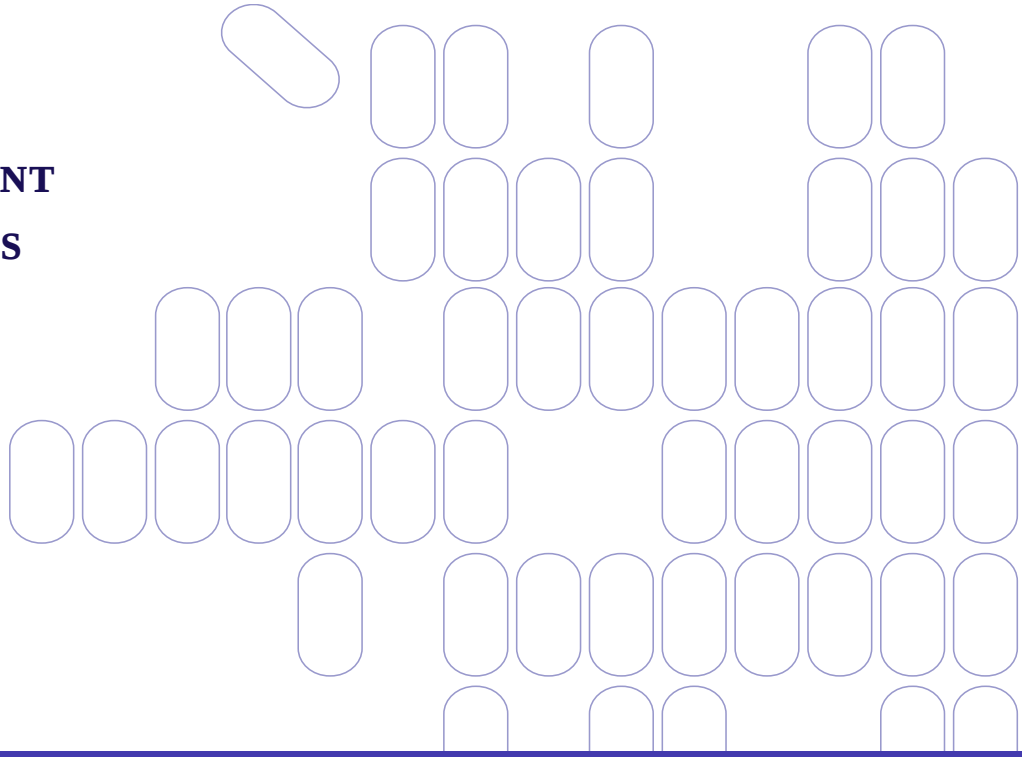


Scope

Description of an Indian Patent specification

- a convenient model similar to the required formats of patents granted in other major jurisdictions including US & Europe

Why should I obtain patents?

- Disseminate research to society's benefit
- Level the playing field and stimulat markets
- Increase the value of an institution
- Generate revenue for the institution
- Generate revenue for the inventor

Patent Document

Techno-legal document

- The technical aspects of inventions are mentioned in the patent application for which the patent protection is sought
- It is a legal document since it provides exclusive right by the government to the inventor/patentee and prevents use by others

Patent Document

- It is important to decide what components are to be protected

- The protection is sought based on claims that defines the boundaries and scope of the invention and provide legal protection to only claimed subject matter

Filing a patent application

Prior art search

- Patent
- Non-patent literatures

Patent has three main sections

(i) a **cover page** which presents bibliographic information,

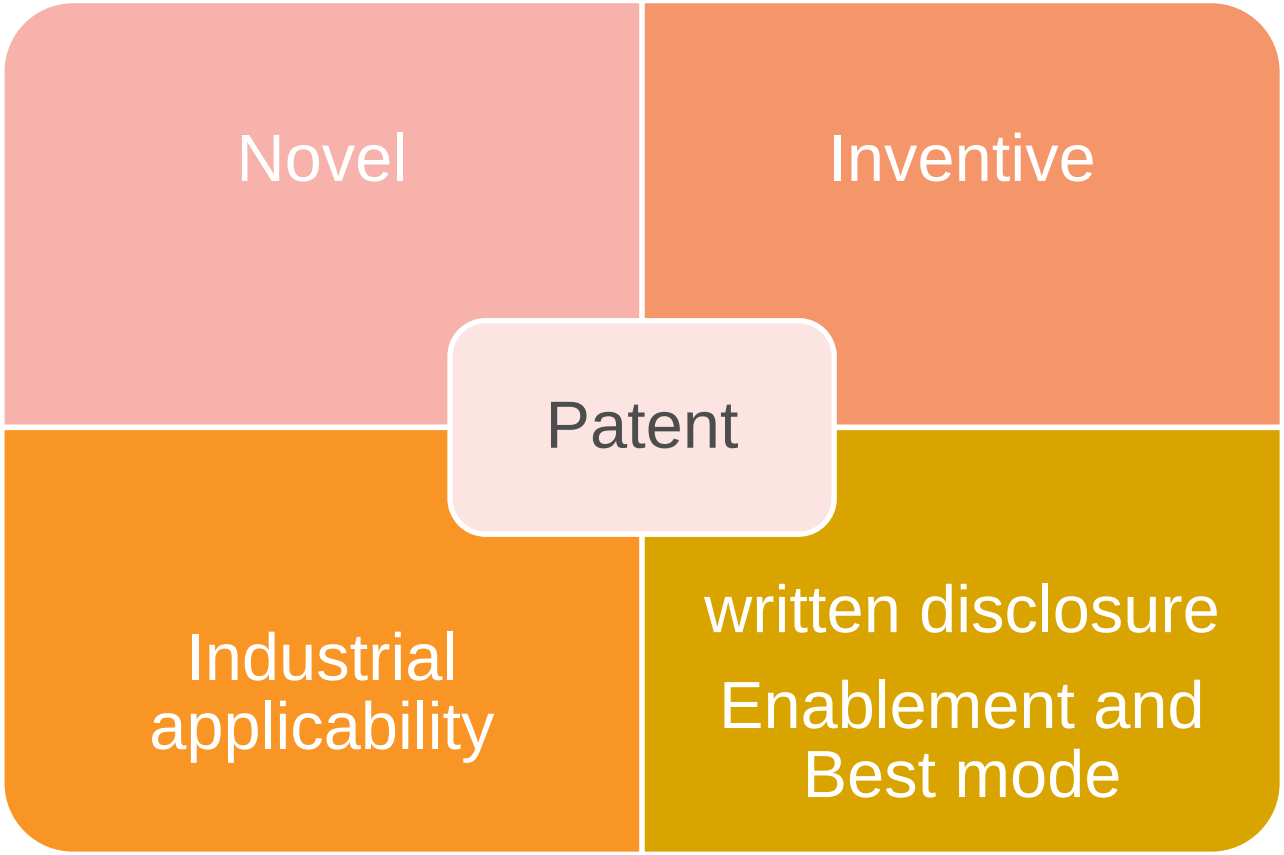
(ii) a **specification**, which describes the invention, and

(iii) **claims**, which define the metes and bounds of the patentee's right.

Text of a Patent

- Also called the disclosure or specification
- According to the TRIPS Agreement, the invention must be disclosed “in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art” (Article 29.1)

Requirement



Written description

- Title
- Technical field/ Field of invention
- Background of the invention
- Objective of the invention
- Summary
- Description of drawings
- Detailed description of the invention
- Sequence Listing of relevant nucleotide and peptide sequences
- Claims
- Drawings
- Abstract

Written description

Background of the invention

- Typically drafted for an Examiner
- Selected Prior art in the field is discussed to emphasize differences with the current invention.
- It compares selected art in the field with the current invention and explains the needs for the current invention
- Discusses problem(s) associated with the prior art

Written description

Summary of the invention

- distinct from the abstract and summarizes the scope of the invention i.e. independent claims
- meant to discuss the invention (i.e., the claims) rather than the disclosure as a whole.
- the advantages of the invention or explains how it solves problems existing in the art.

Written description

Detailed description of the invention

- Purpose: adequately and accurately describe the invention.
  - First section: general explanation of the invention and how to practice it.
  - Second section: specific examples of the invention how to practice the invention i.e. **Enablement and Best Mode Examples.**

Written description

General explanation of the invention

- Invention is described in its broadest sense.
- Shows the inventors have a broad view of the scope of the elements.
- Preferred embodiments of invention described.
- Definitions of key terms- extremely important in interpreting the scope of claims.

Written description

Specific Examples: how to practice invention

- The applicant has to enable his invention in order to allow a person with ordinary skill in the art to make and work the invention. He should not only enable, the applicant should also describe the best mode of carrying out the invention.
- Typically, examples demonstrate practice of one or more specific embodiments of the invention.

Written description

Sequence listing

- If necessary, may be present as third section
- Including every nucleic acid molecule that is at least **10** nucleotides
- And every disclosed protein that is at least **4** amino acids

Written description

- **Deposit (Microorganisms):**
  - If an invention involves microorganisms, which cannot be described by writing, a sample of the microorganism has to be deposited at an internationally recognized depository.
  - There is an internationally recognized depository at **IMTECH** Chandigarh

Written description

Claims

- Claims drafting is one of the most important element of patent application.
- It is an art as well as science: it is important to ensure that the scope of protection is adequately mentioned and scientific knowledge of what is to be protected should be known.

Written description

Claim(s)

most important part of a patent

- At least one claim in a patent
- A claim defines the scope of protection given to the owner of the patent
- It must particularly point out and distinctly claim the subject matter which the applicant regards as his/her invention
- Each claim must be written as a single sentence.
- Each claim is treated separately for purposes of determining validity and infringement.
  - apparatus, methods, products, and compositions of matter and new and useful improvements thereof
- Possible infringers must be able to understand what is and is not protected

Written description

Claims

- A claim is presented in two parts
  - the preamble and
  - the body, with a transitional word or phrase between them.
- The preamble is an introductory statement that names the subject of the claim.

For example,

: "*A process for producing a genetically modified plant,----.*"

- The body of the claim describes the elements or steps that compose the claimed subject.

For example the body of the claim consists of the steps of "*stably transforming …" and "regenerating …"*

- The transition words or phrases between

Written description

transitional words or phrases

Commonly used - very distinct meanings:

- "*Comprising*" open-ended language, means
  - the claim encompasses all the elements listed
  - but does not exclude additional, unnamed elements
- "*Consisting of*" means the device (or method) has the recited elements and no more
- "*consisting essentially of*" : meaning intermediate to *comprising* and *consisting of*

  not often used

Claims

Tips on writing claims:

- Decide which are the essential elements of your invention that you want to claim exclusive rights to.
- Begin with your broadest claims and then progress to narrower claims.
- Start claims on a new page (separate from the description) and number each claim using Arabic numbers starting with 1.

Claims

Tips on writing claims

- Precede your claims with a short statement such as “I/We claim”.
- Check to see that each claim consists of an preamble, a transitional phrase, and a body.
- Identify each feature or combination of a minimum features that is not shown in prior art.
- Write independent claims for each novel feature.
- Write dependant claims to the extent desired claiming more than one novel feature .

Claims

Tips on writing claims

- The first claim is the broadest claim – should differ from each of the closest prior art by just one feature.
- One element not found in prior art will be allowed.
- To establish non-obviousness, three basic criteria must be met,
  - the prior art references (or references when combined) must not teach or suggests **ALL** the limitations/, and/or
  - the difference between the prior art and the claimed invention should not be obvious to a person skilled in the art.

Five principle ways of claiming

- Composition claims
  - Composition
  - Method of treatment (US only)
  - Second use claims (Europe)

  Inventions in metallurgy, pharmacy, pharmacology and biology

  Are most frequently claimed under the Markush formula.
- Process claims
- Apparatus claims
- Product by process claims
- Means plus function claims

Two flavours of claims

Independent claim **:** stands alone

- includes all the necessary limitations
- does not depend on or include limitations from any other claim.

Dependent claim **:** refers back to another claim or claims

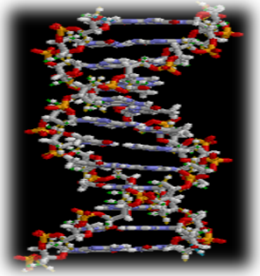
- Further limits another claim or claims
- includes all the limitations of the claim incorporated by reference

Why have dependent claims?

Serve very important purposes :

- defining the scope of elements in an independent claim
- protecting specific embodiments of an invention
- making it easier for a jury to check infringement - activity clearly spelled out not inferred

Biotechnology- Patentable Subject matter



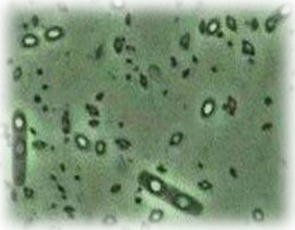
Product Patent

- Microorganism
  - Bacteria, virus, fungi, protozoa
- Nucleic acid-DNA, cDNA, RNA, genes, promotersr, ecombinant vector, siRNA, RNAi
- Protein/Polypeptide, antibodies, monoclonal antibodies, antibody fragments
- A composition comprising DNA and/or protein

Process Patent

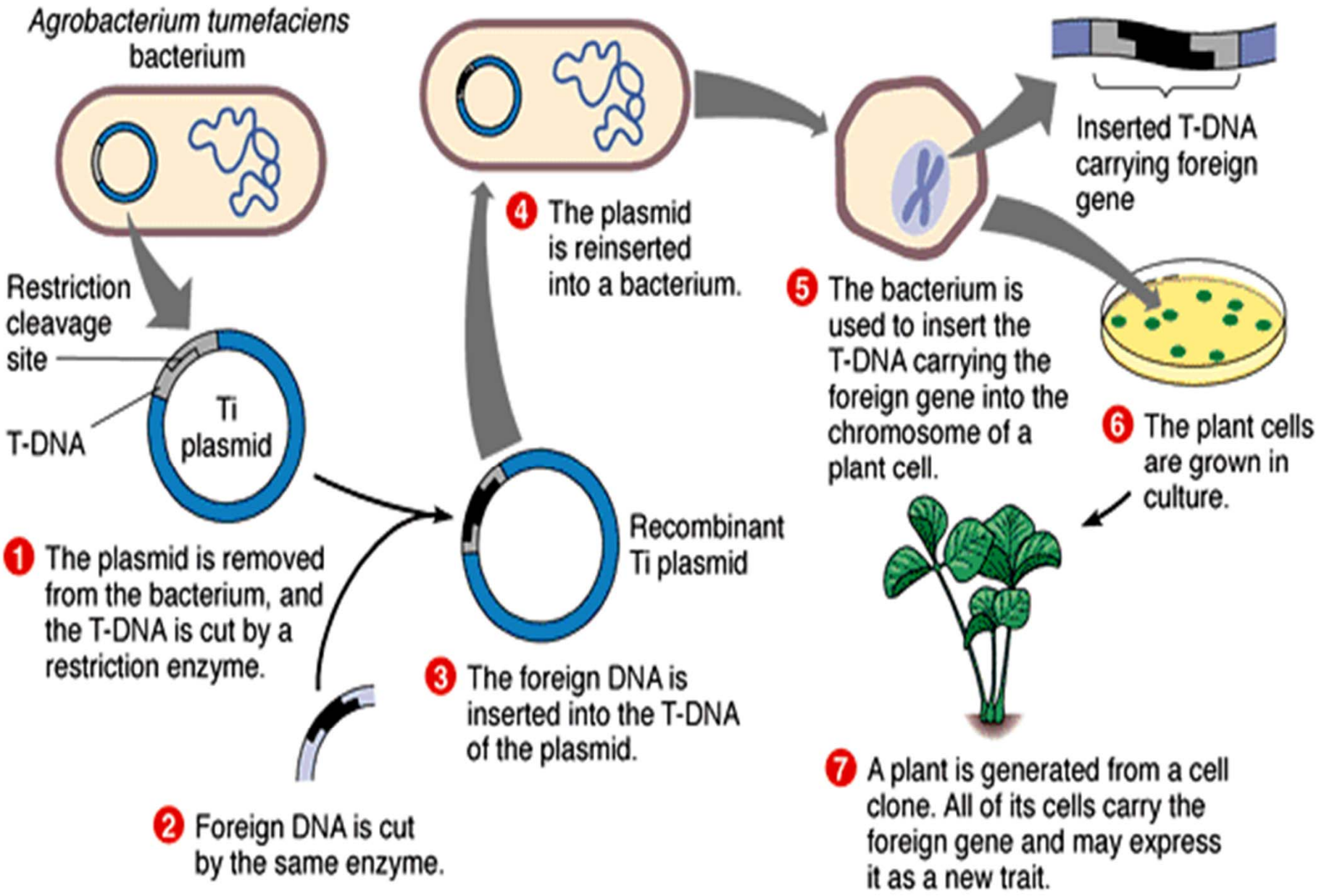
- A process of regeneration of plant
- A process of production of transgenic plant/A process of transformation
- A process of preparation of a vaccine
- A process of production of recombinant protein- Human insulin, Immunoglobulin, vaccine, Blood clotting factor, Bt-toxin

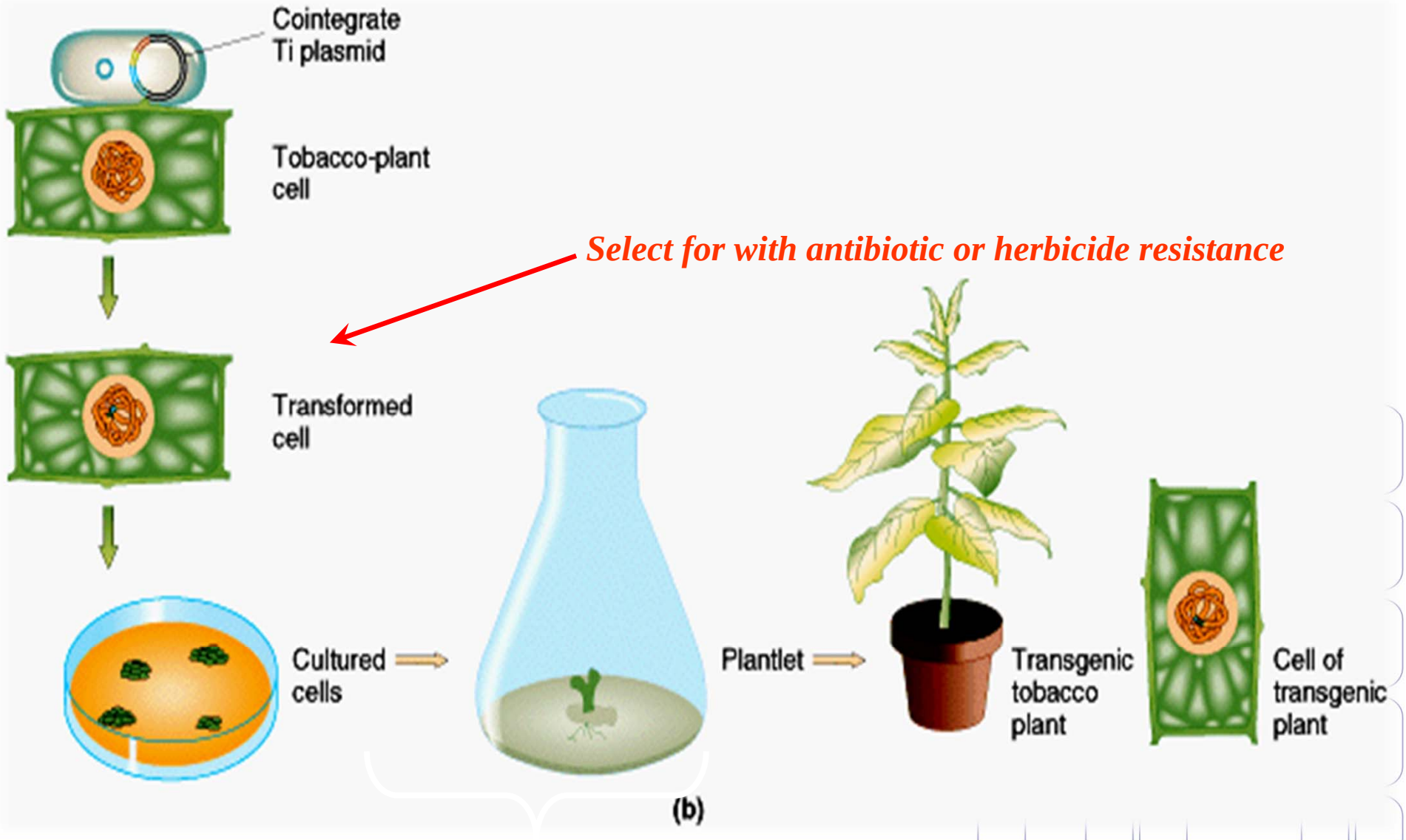
- **Natural products isolated form**



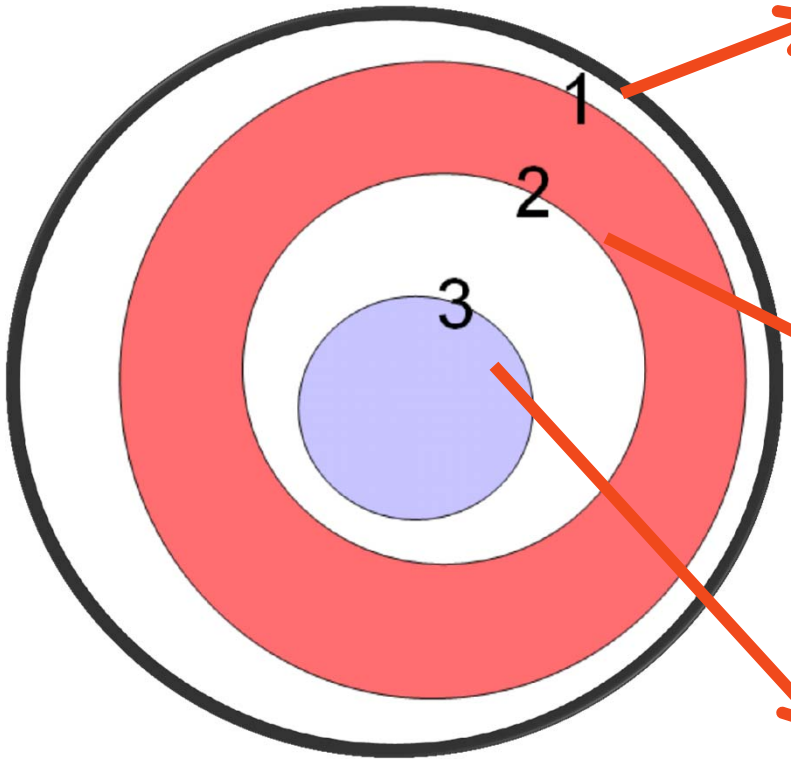
Regeneration Protocols

- Leaves
- Roots
- Hypocotyls
- Cotyledons
- Callus
- Rhizogenic calli
- Somatic embryogenesis





Example of Independent and Dependent claims: Product



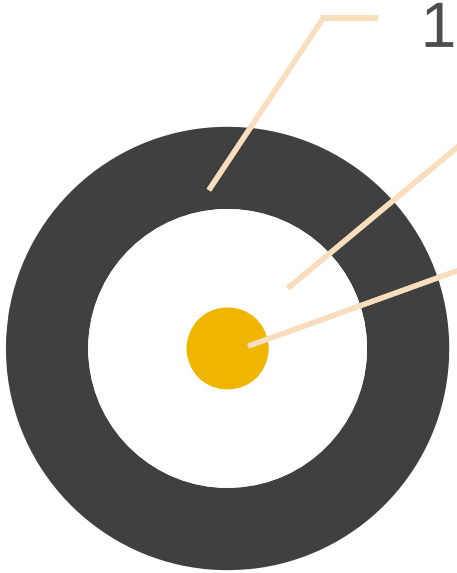
Nested, Dependent Claims

Claim 1: *A DNA molecule conferring abiotic stress tolerance in plant, wherein the DNA molecule has* ***98% identity*** *with the nucleotide sequence as set forth in* ***SEQ ID NO: X.***

Claim 2: *The DNA molecule as claimed in claim 1, wherein the DNA molecule* ***encodes a protein having the amino acid sequence as set forth in SEQ ID NO: Y.***

Claim 3: *The DNA molecule as claimed in claim 1, wherein* ***the nucleotide sequence is as set forth in SEQ ID NO: X.***

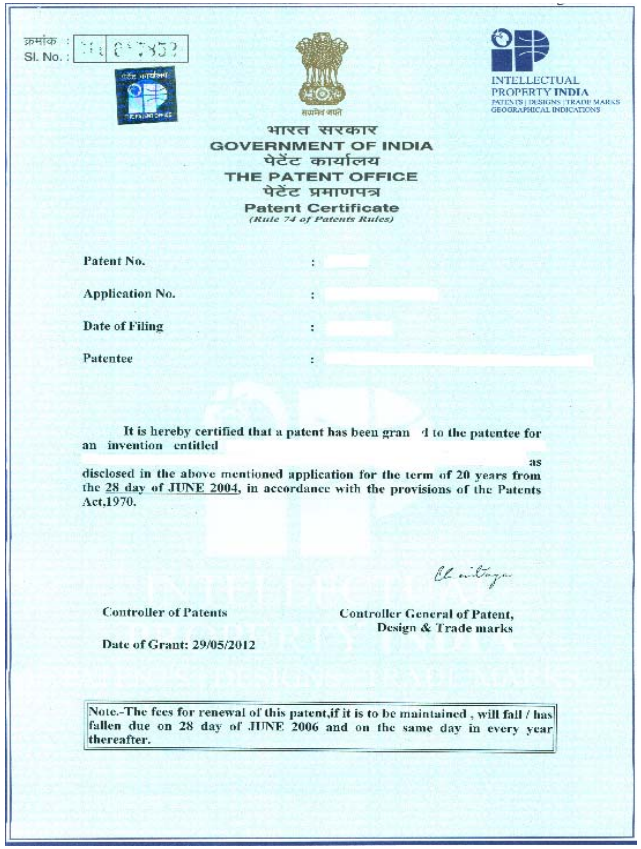
Example of Independent and Dependent claims: Process



Claim 1: A process of conferring *abiotic stress tolerance in plant, wherein the process comprises transforming a plant cell using as DNA molecule having* ***98% identity*** *with the nucleotide sequence as set forth in* ***SEQ ID NO: X*** *, selecting a transformed plant cell and regenerating a transgenic plant from the transformed plant cell.*

Claim 2: *The process as claimed in claim 1, wherein the DNA molecule* ***encodes a protein having the amino acid sequence as set forth in SEQ ID NO: Y.***

Claim 3: *The process as claimed in claim 1, wherein* ***the nucleotide sequence of the DNA molecules is as set forth in SEQ ID NO: X.***



क्रमांक :
Sl. No. :

INTELLECTUAL PROPERTY INDIA
PATENTS | DESIGNS | TRADE MARKS
GEOGRAPHICAL INDICATIONS

भारत सरकार
GOVERNMENT OF INDIA
पेटेंट कार्यालय
THE PATENT OFFICE
पेटेंट प्रमाणपत्र
Patent Certificate
(Rule 74 of Patents Rules)

Patent No. :

Application No. :

Date of Filing :

Patentee :

It is hereby certified that a patent has been gran d to the patentee for an invention entitled

as disclosed in the above mentioned application for the term of 20 years from the 28 day of JUNE 2004, in accordance with the provisions of the Patents Act,1970.

Controller of Patents

Controller General of Patent, Design & Trade marks

Date of Grant: 29/05/2012

Note.-The fees for renewal of this patent,if it is to be maintained , will fall / has fallen due on 28 day of JUNE 2006 and on the same day in every year thereafter.

The United States of America

The Commissioner of Patents and Trademarks

United States Patent

Summary

Patentable subject matter

- Nucleic acid
- Proteins/Polypeptides
- Recombinant vectors
- Micro-organism
- Process for production of transgenic plants using genetic transformation methods
- Process of production of vaccines
- *In-vitro* process of diagnosis

Non patentable subject matter

- Plant, animal or any part thereof including seeds
- Essentially biological methods
- Method of treatment
- Method of horticulture/agriculture
- Use

Key considerations for patenting in Life Sciences

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EXAMINER OF PATENTS & DESIGNS
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Structure of the presentation

- Importance of Patents
- Indian Patent Law
- Patenting in Key Jurisdictions
- Office procedures and examination practice in Biotechnology

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Importance of Patents

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What is a Patent?

- **statutory right for an invention**
- **granted for a limited period of time (20 years) to the patentee by the Government,**
- **in exchange of full disclosure of his invention for**
- **excluding others, from making, using, selling, importing the patented product or process for producing that product for those purposes without his consent.**

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BENEFITS OF PATENTS FOR AN R&D INSTITUTION

- Matter of repute for R&D institution
- Avoid duplication of research
- Can earn revenue by working of patent
- Technology transfer to commercial organisation
- Mortgaging the patent rights
- Transfer of patent rights to interested persons

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Potential of BIOTECH patenting?

- **Researchers are rewarded for their efforts and can use funds gained from patenting to further their research**
- **The investment of resources is encouraged by providing a monopoly to the inventor and prohibiting competitors from making, using, or selling the invention without a license.**
- **Wasteful duplication of effort is prevented.**
- **Research is forced into new, unexplored areas.**
- **Secrecy is reduced and all researchers are ensured access to the new invention.**
- **Creation of a dynamic, knowledge based economy.**

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WHY PATENTING IN BIOTECHNOLOGY

- **Protection of IP is very important in the field of biotechnology since biotech research is expensive, time consuming and results are uncertain.**
- **Patent gives an exclusive territorial right to the patentee to prevent others from making using and selling a patented invention for a fixed period of time (20 years).**
- **Patents in biotech can be for micro-organisms, vaccines, biological materials such as recombinant DNA, plasmids.**
- **Processes of manufacturing such biological materials, provided they are produced by substantive human intervention, processes relating to micro-organisms or producing chemical substances using such micro-organisms.**

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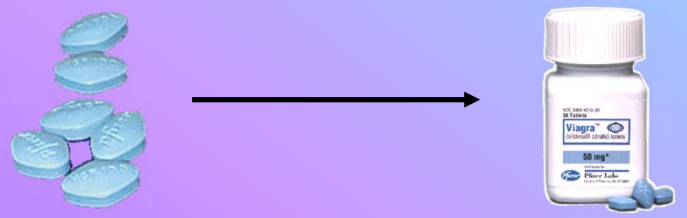
INDIAN PATENT LAW

Basic criteria of patentability

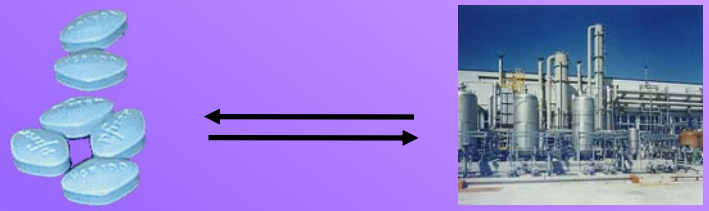
The 3 basic criteria which any invention must meet in order to deserve a patent:

- **Novelty**



Non-obviousness

Industrial application



"NEW"

MEANS

SHOULD NOT BE

I. PUBLISHED IN INDIA OR ELSEWHERE

II. IN PRIOR PUBLIC KNOWLEDGE OR PRIOR PUBLIC USE WITH IN INDIA OR ELSEWHERE IN THE WORLD

II. CLAIMED IN ANY CLAIMS IN ANY PRIOR SPEC. FILED IN INDIA & PUBLISHED LATER

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INVENTIVE STEP

1. **A feature that makes invention not obvious to a person of ordinary skill in the art**
2. **A technological advancement to the existing art or economic significance or both**

Definition of Invention

2 (1) (j) of the Patents Act, 1970:

- **"Invention" means a new product or process involving an inventive step and capable of industrial application.**
- **"inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both that makes the invention not obvious to a person skilled in the art.**
- **"capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry.**

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What are INVENTIONS in Biotechnology

- **Living entities of natural origin: animals, plants, human beings including parts thereof;**
- **Living entities of artificial origin: micro-organisms, vaccines, transgenic animals and plants;**
- **Biological materials: DNA, enzymes, plasmids, genes, vector, tissues, cells, replicons;**
- **Processes related to living entities;**
- **Processes relating to biological material;**
- **Methods of treatment of human or animal body;**
- **Biological processes or essentially biological processes.**
- **Inventions relating to use of living organisms.**

Inventions Not Patentable

Section 3(b): an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment

- **Inventions relating to cloning of human beings, modifications of human germ line, using human embryos for industrial/commercial purpose, genetic modifications of animals, etc. can be excluded.**

- **For example:**
  Claim: A method of cloning of animal……

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Inventions Not Patentable

Section 3(c):the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature

- **Inventions relating to a micro organism occurring freely in nature, isolated polynucleotide, etc. can be excluded.**

- **For example:**

  Claim: *Pseudomonas sp.* RRJ228 as a plant growth promoting agent comprising DNA sequence represented as SEQ ID No. 1 (deposition No. KCTC 10812BP), i.e. non-mutated microorganisms.

  Claim: An isolated polynucleotide according to SEQ ID No. 1 that inhibits a pest biological activity, i.e. merely isolated substances from nature.

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Inventions Not Patentable

- ***Section 3(e):a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substances;***

- **Inventions relating to a mere admixture/formulation without any synergistic effect can be excluded.**

- **For example:**

  Claim: A bio-fertilizer formulation comprising phosphate solubilizing bacteria and nitrogen fixing bacteria.

Inventions Not Patentable

Section 3(a): An invention which is frivolous or which claims anything obviously contrary to well established natural laws

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Inventions Not Patentable

- ***3(h):a method of agriculture or horticulture***

- **For example:**

  Claim: A method for soil administration or plant culture by treating the soil or plant with a fertilizer/bio-fertilizer.

  Claim: A method for improving productivity of plant by spraying a mixture of plant growth regulators.

Inventions Not Patentable

- ***3(i):any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of animals to render them free of disease or to increase their economic value or that of their products.***

- **Since plants do not fall with the ambit of this section, inventions relating to any treatment of plants are patentable provided they do not fall within the scope of Section 3 (h) of the Act.**

Inventions Not Patentable

- ***3(j):plants & animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for the production or propagation of plants and animals;***

- **Inventions relating to plants in whole or in part, animals in whole or in part, seeds, varieties and species of plants and animals and essentially biological processes for production or propagation of plants and animals are excluded from patentability.**

- **However, micro organisms may be patentable provided they are genetically modified otherwise they can be objected under Section 3 (c) of the Act.**

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3(j) Continued..

- **For example:**

  Claim: An eukaryotic plant/animal cell.

  Claim: A genetically modified/transformed plant/animal.

- **Nevertheless, new plant varieties can seek protection in India under the provisions of the 'Protection of Plant Varieties and Farmers' Rights Act, 2002.**

Inventions Not Patentable

- ***3(p):an invention which in effect is traditional knowledge or which is an aggregation or duplication of known properties or traditionally known component or components.***

- **For example:**

  Claim: A method for improving soil fertility comprising growing earthworms

  Claim: A method for ameliorating nitrogen deficient soil comprising growing leguminous plants

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3(p) Continued..

Claim: A method of wound healing by applying a turmeric powder [this claim can also be objected under Section 3 (i)]

Claim: A composition for treating coronary artery disease comprising Arjuna (*Terminalia arjuna*), Ashwagandha (*Withania somnifera*), Garlic (*Allium sativaum*), Guduchi (*Tinospora cardifolia*) and Herde (*Terminalia chebula*) [this claim can also be objected under Section 3 (e),3(p).

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Difference in the practice in key jurisdictions

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US Scenario

- **Most accommodating jurisdiction for biotechnology inventions.**
- **Few if any restrictions on biotechnology and pharmaceutical inventions.**
- **Term "invention" includes discovery. Both patentable.**
- **Plant patents obtainable.**
- **Allows utility (use) patents for human and animal therapeutics and diagnostics.**
- **Utility is an important criteria for grant of a biotech invention which is novel & inventive.**
- **USPTO has time and again rejected applications on the ground of lack of utility.**

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US Scenario contd…

Important criteria:

Whether the specification asserts utility?

Whether the asserted utility is credible?

e.g. In inventions relating to isolated DNA and nucleotide sequences. It is necessary for an invention to:

- **demonstrate utility;**
- **where the utility is asserted for the first time it is also necessary to establish that the utility is "credible".**

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EP **Scenario**

Articles 52 and 53(b) EPC say what can and what cannot be patented.

Biotechnical inventions are basically patentable, but with the following exceptions:

- **methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body**
- **plant and animal varieties**

essentially biological processes for the production of plants and animals.

- **Article 53(a) also prohibits the patenting of any invention whose commercial exploitation would be contrary to public order or morality.**

EDINBURGH PATENT Stem Cells

"isolation, selection and propagation of stem cells of transgenic animals".

- **Patent granted in December 1999**
- **EPO Opposition Proceedings (July 2002)**
- **Amendment to exclude *human embryonic stem cells***

INDIAN **Scenario**

WHAT IS PATENTABLE

- **Microorganisms: microbiological processes, processes for producing new-microorganisms through genetic engineering and the products that result out of this process.**
- **Cell lines: if artificially produced.**
- **R-DNA, RNA, AMINO ACID: if the end result is non-living.**
- **Hybridoma technology (but not on protoplast fusion)**
- **ESTs: if it has a use, such as if it works as a probe.**

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INDIAN **Scenario contd…**

WHAT IS NOT PATENTABLE:

- **Living entities of natural origin: animals, plants, human beings, in whole or any parts thereof; plant varieties, seeds, species, and genes;**
- **Any process of manufacture or production relating to such living entities;**
- **Any method of treatment such as medicinal, surgical, curative, prophylactic, diagnostic and therapeutic, of human beings or animals or other treatments of similar nature;**
- **Essentially biological processes for the production of animals such as method of crossing or breeding etc.,**
- **Biological materials such as organs, tissues, cells, viruses and process of preparing them.**

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INDIAN **Scenario contd…**

Section 3(i) does not include plants.

- **The present invention encompasses:**
  Diagnosis of rice varieties or rather selection of rice varieties susceptible to attack by Gall Midge Biotypes.
- **Claims drawn to:**

Method for screening rice varieties.

Patent Granted

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INDIAN Scenario contd…

TURMERIC PATENT CASE

- Two US-based researchers were awarded a patent in 1995 on turmeric's special wound-healing properties.
- Indian government opposed this patent .
- The patent was eventually revoked after a decade long battle.
- Indian government and private sector spent millions of dollars in legal and research fee to prove that turmeric's qualities were well documented in ancient medical books.

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Office procedures and examination practice in India

Documents required to file a Patent application

- A covering letter in the name of Controller. (Single copy)
- Fees in Cash / Cheque/ DD in the name of the Controller of Patents
- A duly filled application (in Duplicate), Form 1
- F-18
- Complete/provisional specification (in Duplicate), Form 2
- Proof of right to file (If the Inventor is not the applicant)

Documents required to file a Patent application

- **Information regarding foreign filing, Form 3**
- **Form 5- Declaration as to inventorship**
- **Power of authority**
- **Drawings**
- **Abstract of the Invention**

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Who Can Be the Applicant ?

- **The inventor**
- **Assignee of the inventor**
  - ✓ **The natural person**
  - ✓ **The legal entity**
- **The legal representative of the deceased applicant**

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Where to file (jurisdiction)?

- **If the applicant/first mentioned applicant-resides/has domicile/has place of business/has origin of invention/has service address(in case of foreign applicant) IN**

Region	Jurisdiction
Northern	*Patent office of Delhi*
Southern	*Patent office of Chennai*
Western	*Patent office of Mumbai*
Rest of the India	*Patent office of Kolkatta*

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WAYS TO FILE PATENT APPLICATION

1.TRADITIONAL ROUTE

- ***ORDINARY APPLICATIONS***
- ***CONVENTIONAL APPLICATIONS***
- ***DIVISIONAL APPLICATIONS***
- ***PATENT OF ADDITION APPLICATIONS***

2.PCT ROUTE

- ***PCT APPLICATION***
- ***PCT NATIONAL PHASE APPLICATION***

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WHY EXAMINATION ?

- ***Examination essential-***
- ***No examination; No patent***
- ***Different Patent Laws***
- ***Certain exclusions***
- ***Protect prior users of the invention***
- ***Utility for the humanity***

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FORMALITY EXAMINATION

- ***Type of applications***
- ***Application form ?***
- ***Jurisdiction***
- ***All fees ?***
- ***Proof of right to apply from inventors ?***
- ***Foreign filing informations ?***
- ***Declaration as to inventorship ?***
- ***Power of authority ?***
- ***All time limit compliance ?***

Ordinary applications

No priority

- **Provisional application**

a presentable form but not the final shape,
prepare a disclosure of the invention in the form of a written description and submit it to patent office as a *provisional specification* which describes the invention.
helps to establish the priority of the applicant

- **Complete application**
- **Time line:1 year to file from the date of filing of provisional application.**
- **Claims need to be given**
- **Complete in itself.**

INTELLECTUAL PROPERTY INDIA

Convention applications

- Application filed within 12 months from the date of filing the same invention in convention countries
- Helps applicant obtain a priority right from the date of first disclosure of invention
- Only complete specification can be filed as convention application
- Presently 171 countries notified as Convention countries.

INTELLECTUAL PROPERTY INDIA

PCT application

- **Applications filed through PCT Route**
- **Beneficial for seeking protection in multiple countries through a single application**
- **Can be international / National phase application**

INTELLECTUAL PROPERTY INDIA

PCT application cont..

- International Application
  - Filed as basic application for filing in multiple countries at IB/ RO
- National Phase application
  - An application to enter the national phase of the designated country

INTELLECTUAL PROPERTY INDIA

Application Form-1

FORM 1
THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENTS RULES, 2003
APPLICATION FOR GRANT OF PATENT
[*See* sections 7, 54 & 135 and rule 20(1)]

(FOR OFFICE USE ONLY)

Application No:
Filing Date:
Amount of Fee Paid:
CBR No:
Signature:

1. APPLICANT(S)

Name	Nationality	Address

2. INVENTOR(S)

Name	Nationality	Address

3. TITLE OF THE INVENTION

4. ADDRESS FOR CORRESPONDENCE OF APPLICANT/ AUTHORISED PATENT AGENT IN INDIA	Telephone No. Fax No. Mobile No. E-mail:

5. PRIORITY PARTICULARS OF THE APPLICATION (S) FILED IN CONVENTION COUNTRY

Country	Application Number	Filing Date	Name of the Applicant	Title of the Invention

6. PARTICULARS FOR FILING PATENT COOPERATION TREATY (PCT) NATIONAL PHASE APPLICATION

International application number	International filing date as allotted by the receiving office

7. PARTICULARS FOR FILING DIVISIONAL APPLICATION

Original (first) application number	Date of filing of Original (first) application

8. PARTICULARS FOR FILING PATENT OF ADDITION

Main application/Patent Number	Date of filing of main application

9. DECLARATIONS:

(i) Declaration by the inventor(s)

I/We, the above named inventor(s) is/are the true & first inventor(s) for this invention and declare that the applicant(s) herein is/are my/our assignee or legal representative.

INTELLECTUAL PROPERTY INDIA

(a) Date.....

(b) [1][Signature(s) of the inventor(s)]

(c) Name(s)

(ii) Declaration by the applicant(s) in the convention country

I/We, the applicant(s) in the convention country declare that the applicant(s) herein is/are my/our assignee or legal representative.

(a) Date.....

(b) Signature(s)

(c) Name(s) of the signatory

(iii) Declaration by the applicant(s):

I/We, the applicant(s) hereby declare(s) that:—

* I am/We are in possession of the above-mentioned invention.
* The provisional/complete specification relating to the invention is filed with this application.
* The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us.
* There is no lawful ground of objection to the grant of the Patent to me/us.
* I am/We are the assignee or legal representative of true & first inventors.
* The application or each of the applications, particulars of which are given in Para 5 was the first application in convention country/countries in respect of my/our invention.
* I/We claim the priority from the above mentioned application(s) filed in convention country/countries and state that no application for protection in respect of the invention had been made in a convention country before that date by me/us or by any person from which I/We derive the title.
* My/our application in India is based on international application under Patent Cooperation Treaty (PCT) as mentioned in Para – 6.
* The application is divided out of my/our application particulars of which are given in Para – 7 and pray that this application my be treated as deemed to have been filed on .....under section 16 of the Act.
* The said invention is an improvement in or modification of the invention particulars of which are given in Para - 8.

10. FOLLOWING ARE THE ATTACHMENTS WITH THE APPLICATION:

(a) Provisional specification/Complete specification

(b) Complete specification (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies), No. of pages.....No. of claims.....

(c) Drawings (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies), No. of sheets.....

(d) Priority documents

INTELLECTUAL PROPERTY INDIA

(e) Translation of priority document/Specification/International Search Report

(f) Statement and undertaking on Form 3

(g) Power of Authority

(h) Declaration of inventorship on Form 5

(i) Sequence listing in electronic form

(j) ....../.....

Fee Rs.....in Cash./Cheque/Bank Draft bearing no.....

Date.....on.....Bank.

I/We hereby declare that to the best of my/our knowledge, information and belief the fact and matters stated herein are correct and I/We request that a patent may be granted to me/us for the said invention.

Dated this.....day of .....20.....

Signature:

Name:

To, [1][The Controller of Patents]

The Patent Office, at.....

Note.—*Repeat boxes in case of more than one entry.

*To be signed by the applicant(s) or by authorised registered patent agent otherwise where mentioned.

*Tick (√)/Cross (x) whichever is applicable/not applicable in declaration in para 9.

*Name of the inventor and applicant should be given in full, family name in the beginning.

*Complete address of the inventor and applicant should be given stating the postal index no./code, State and country,

*Strike out the column which is/are not applicable *For fee: See First Schedule.

INTELLECTUAL PROPERTY INDIA

FEES

Application fees	***Natural person***	***Other than Natural person***
	Rs 1000	***Rs 4000***
Priority claim fees	***Rs 1000 Multiple of Rs 1000 per priority***	***Rs 4000 Multiple of Rs 4000 per priority***
Number of excess pages(30)	***Rs 100***	***Rs 400***
Number of excess claims(10)	***Rs 200***	***Rs 800***
F-18	***Rs 2500***	***Rs 10000***

INTELLECTUAL PROPERTY INDIA

F-18-REQUEST FOR EXAMINATION Section 11B, ules20(4)(ii),24B(1)(i)

- ***Examination: not automatic***
- ***Request to be made on f/18***
- ***By applicant or third parties***
- ***Examintion report to applicant only***
- ***Timelimit: 48 months from date of priority or date of filing of application whichever is earlier***

REQUEST FOR EXAMINATION

For divisional application within 48 months from date of filling of the parent application

Or

from priority date of parent application

Or

6 months from filing of divisional application whichever is later

- No request for examination= application treated as withdrawn
- Form 18 fees= 2500/10000

Publication of Invention

- Promptly after 18 month from priority date
- Early pub. Possible (F/9, Fees 2500/10000)

No publication of applications for which

- C.S. is not filed
- Application withdrawn within 15 months of filing
- Secrecy direction issued

What is published

- Priority details
- Applicants details
- Abstract

INTELLECTUAL PROPERTY INDIA

EARLY PUBLICATION

- FORM – 9
- FEES – RS 2500/10000
- ONE MONTH FROM THE DATE OF REQUEST FOR PUBLICATION

Publication

INTELLECTUAL PROPERTY INDIA

LICATION PUBLICATION

(19) INDIA	(21) Application No.617/DEL/2006
(22) Date of filing of Application3/8/2006 5:52:03 PM	(43) Publication Date : 6/12/2006 3:17:54 PM
(54) Title of the invention : "PUNCHING MACHINE MOLDED DEPTH INDICATOR" (51) International classification : B26D7/00 (31) Priority Document No : NIL (32) Priority Date : NIL (86) International Application No and Filing Date : NIL (87) International Publication No : Nil (61) Patent of Addition to Application Number and Filing Date : NIL (62) Divisional to to Application Number and Filing Date : NIL	(71)Name of Applicant : Chao Min-Hsien. Address of Applicant :No. 24, Jane 160, Chang Ma Road, Changhua City, Taiwan, R.O.C. Taiwan (72)Name of Inventor : Chao Min-Hsien. Address of Applicant :No. 24, Jane 160, Chang Ma Road, Changhua City, Taiwan, R.O.C. Taiwan

(57) Abstract :

A punching machine molded depth indicator to provide precise calibration and setup of the punching stroke by displaying numeric molded depth of a punching cylinder that drives the upper mold is essentially comprised of a base enclosed in a casing and containing multiple numeric gear sets to accumulate the stroke counting; a spiral gear meshed with a another spiral gear of a transmission rod being disposed to one end of a central axial rod of the numeric gear set; the transmission rod being linked to a drive worm gear and gear of the punching cylinder of the punching machine; the transmission rod being linked to the elevation of the punching cylinder thus to synchronously transmit the central axial rod of the numeric gear set; an axial bolt being provided on one side of the numeric gear set; multiple rolling sprockets being arranged in series through the axial bolt; and a dialing plate disposed on one side of each numeric gear dialing the next rolling sprocket in sequence and in decimal pattern for the next numeric gear to turn to carry a number to display the molded depth depending on the elevation stroke of the punching cylinder in the calibration after changed dies; both of the upper and lower limits of the stroke of the punching cylinder being readjusted to protect parts and dies of the console from being improper punching.

INTELLECTUAL PROPERTY INDIA

SUBSTANTIVE (TECHNICAL) EXAMINATION

Examination of

- The description
- The claims

INTELLECTUAL PROPERTY INDIA

FORM 2
THE PATENT ACT 1970
(39 of 1970)
&
The Patents Rules, 2003
PROVISIONAL/COMPLETE SPECIFICATION
(See section 10 and rule13)

1. TITLE OF THE INVENTION

2. APPLICANT (S)
(a) NAME:
(b) NATIONALITY:
(c) ADDRESS:

3. PREAMBLE TO THE DESCRIPTION

PROVISIONAL	COMPLETE
The following specification describes the invention.	The following specification particularly describes the invention and the manner in which it is to be performed.

4. DESCRIPTION (*Description shall start from next page.*)

5. CLAIMS (**not** applicable for provisional specification. Claims should start with the preamble — "**I/we claim**" on separate page)

6. DATE AND SIGNATURE (to be given at the end of last page of specification)

7. ABSTRACT OF THE INVENTION (to be given along with complete specification on separate page)

Note: -
***Repeat boxes in case of more than one entry.**
***To be signed by the applicant(s) or by authorized registered patent agent.**
***Name of the applicant should be given in full , family name in the beginning .**
***Con.plete address of the applicant should be given stating the postal index no./code, state and country.**
***Strike out the column which is/are not applicable.**

TECHNICAL EXAMINATION

Basic criteria of patentability

Prior art search

- *Novelty- anticipation (sec 29-34)*
- *Inventive step*
- *Industrial applicability*

INTELLECTUAL PROPERTY INDIA

JUDGING NOVELTY & INVENTIVE STEP

- For Novelty (Anticipation)
- - All the technical features should be disclosed in a single citation

- For Inventive Step (Obviousness)
- - Mosaic of Citation
- - Motivation factor

INTELLECTUAL PROPERTY INDIA

TECHNICAL EXAMINATION

- *Unity of invention –Section10(5)*
- *Clearness & definitiveness of the claims*
- *Any clerical error*

INTELLECTUAL PROPERTY INDIA

Content of Specification

- **<u>As per Section 10 (4) (d) (ii)</u>: If applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses 10 (4) (a) & (b) and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty.**

- **<u>As per Section 10 (4) (d) (ii) (D)of Patents Act,1970</u>:**
- **the applicant is required to disclose the source and geographical origin of the biological material used in the invention.**

INTELLECTUAL PROPERTY INDIA

NBA permission

- **If invention uses a biological material obtained from India, it is a statutory requirement of the applicant to provide a permission from National Biodiversity Authority (NBA) before the application is filed or if the Patent Office raises an objection regarding the same, required to be submitted before the grant of patent (Section 6 of the Biological Diversity Act, 2002).**
- **As per a notification issued by Ministry of Environment & Forest, GOI dated 26th Oct. 2009, the provisions of the Act (the Biological Diversity Act, 2002) shall not apply to the biological resources specified in column 2 therein provided they are traded as commodities especially for value added extracts.**

INTELLECTUAL PROPERTY INDIA

Consequence of non provision of NBA permission

- No grant of patent
- Pre grant opposition (under section 25(1))
- Post grant opposition (under section 25(2))
- Revocation of patent

INTELLECTUAL PROPERTY INDIA

FIRST EXAMINATION REPORT

- Formal objections
- Technical objections
- Date of FER
- Sent on the address for service
- Normal date for compliance=12 months from date of FER

INTELLECTUAL PROPERTY INDIA

REPLY TO FIRST EXAMINATION REPORT

- As soon as possible
- Study the objections
- If satisfied amend the description & claims to clear the objection
- Otherwise give suitable reply to patent office
- Corrected/amended pages should be submitted retyped

INTELLECTUAL PROPERTY INDIA

SUBSEQUENT EXAMINATION REPORT

- **Reply & amendments are reexamined**
- **If examiner not satisfied with reply of applicant**
- **Or due to amendment new objections**
- **Subsequent examination report by patent office**

INTELLECTUAL PROPERTY INDIA

EFFECT OF NON COMPLIANCE

- **Case abandoned u/s 21**
- **public property**

INTELLECTUAL PROPERTY INDIA

HEARING U/S 14

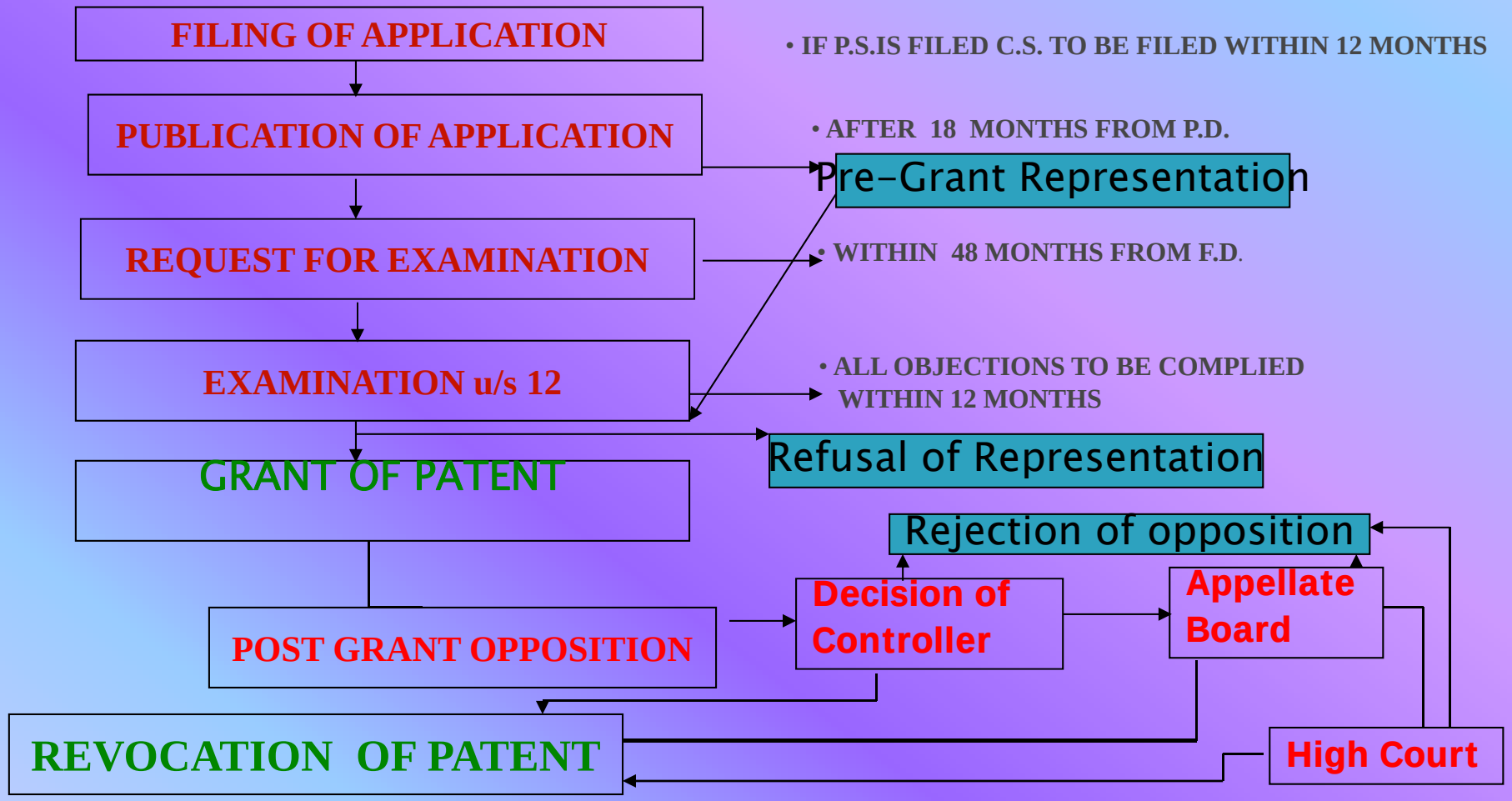
- Patent office not satisfied with compliance
- Applicant not satisfied with objection
- Ask for hearing from controller
- At least 10 days prior to normal Date
- Controller issue decision
- Appealable in IPAB in Patent Office

INTELLECTUAL PROPERTY INDIA

GRANT OF PATENT

- After compliance of all objections
- Or decisions in favour of the applicant
- Case become in order for grant
- No patent shall be granted before the expiry of period of 6 months from the date of publication of the appln. u/s 11A
- Letters patent is granted

PROCEDURE FOR GRANT OF PATENT



INTELLECTUAL PROPERTY INDIA

Statistics

INTELLECTUAL PROPERTY INDIA

STATISTICS

Year	Chemical	Drug	Food	Electrical	Mechanical	Computer/ Electronics	Bio-technology
2004-05	3916	2316	190	1079	3304	2787	**1214**
2005-06	5810	2211	101	1274	4734	5700	**1525**
2006-07	6354	3239	1223	2371	5536	5822	**2774**
2007-08	6375	4267	233	2210	6424	4842	**1950**
2008-09 **2009-10**	**5884** **6014**	**3672** **3070**	**340** **276**				**1844** **1303**

Patents granted

PATENT NUMBER	APPLICATION NUMBER	TITLE OF INVENTION	APPLICANT NAME
236079	370/MUM/2004	METHOD FOR SYNTHESIS OF HUMAN RECOMBINANT INSULIN WITH IMPROVED PROCESS EFFICIENCY	RELIANCE LIFE SCIENCES PVT LTD.
231303	2898/CHENP/2005	VARIANT SUBTILISIN ENZYMES (SUBTILASES)	NOVOZYMES A/S
231288	168/MAS/1999	A METHOD OF TREATING SUNFLOWER PLANTS	INDIAN INSTITUTE OF SCIENCE
228705	1087/DELNP/2005	"PLASMID-FREE CLONE OF E. COLI STRAIN DSM 6601"	PHARMA-ZENTRALE GMBH
228492	1882/DELNP/2004	"POLYNUCLEOTIDE MOLECULE COMPRISING A NUCLEOTIDE SEQUENCE THAT IS THE STREPTOMYCES AVERMETILIS AVEC ALLELE"	PFIZER PRODUCTS INC.
228220	668/MAS/1998	VACCINES AGAINST INFECTIONS CAUSED BY YF VIRUS; YF INFECTIOUS cDNA, METHOD FOR PRODUCING A RECOMBINANT YF VIRUS FROM THE YF INFECTIOUS cDNA AND PLASMIDS TO ASSEMBLE THE YF INFECTIOUS cDNA	FUNDACAO OSWALDO CRUZ - FIOCRUZ
228182	2554/CHENP/2005	DNA CONSTRUCTS AND METHODS TO ENHANCE THE PRODUCTION OF COMMERCIALLY VIABLE TRANSGENIC PLANTS	MONSANTO TECHNOLOGY, LLC
226291	709/DEL/2001	"A PROCESS FOR TRANSFERRING FOREIGN DNA INTO CALLUS CELLS OF TAXUS SP."	DABUR RESEARCH FOUNDATION
225008	IN/PCT/2001/01208/KOL	LIM MINERALIZATION PROTEIN SPLICE VARIANTS TO INDUCE BONE FORMATION	EMORY UNIVERSITY

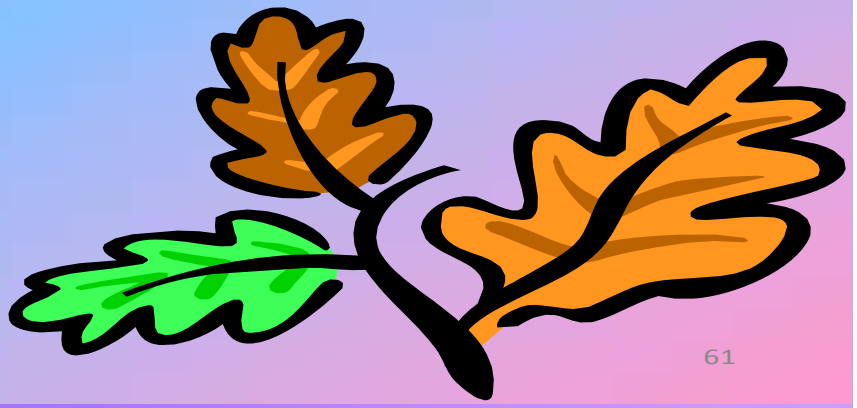
Patents granted

PATENT NUMBER	APPLICATION NUMBER	TITLE OF INVENTION	APPLICANT NAME
224298	490/MAS/1998	A METHOD OF IDENTIFYING A PHARMACOLOGICALLY ACTIVE SUBSTANCE AND A DNA TEMPLATE FOR THE SAME	HOECHST AKTIENGESELLSCHAFT
221076	629/MUMNP/2006	INTACT MINICELLS AS VECTORS FOR DNA TRANSFER AND GENE THERAPY IN VITRO AND IN VIVO	ENGENEIC MOLECULAR DELIVERY PTY LTD
218516	740/CHENP/2004	HEPATITIS C VIRUS VACCINE	ISTITUTO DI RICERCHI DI BIOLOGIA MOLECOLARE P. ANGELETTI SPA
218499	375/MAS/2003	PREPARATION OF OLIGOSACCHARIDE BIONANOPARTICLES FROM MORINGA OLEIFERA LAM	DR. SAMBANDAM SHANMUGASUNDARAM
217619	504/DEL/2004	A PLASMID CONSTRUCT FOR TESTING THE RESISTANCE OF HIV-1 SUBTYPE C VIRUS ISOLATES TO ANTIRETROVIRAL DRUGS IN VITRO.	SETH PRADEEP
217407	763/KOLNP/2004	A METHOD OF EXPRESSING A LIM MINERALIZATION PROTEIN IN A NON-OSSEOUS MAMMALIAN CELL	WARSAW ORTHOPEDIC, INC.
213334	423/MUMNP/2004	METHOD FOR PRODUCTION OF RECOMBINANT PROTEINS IN MICROORGANISMS	N-ZYME BIOTEC GMBH
213289	826/MUM/2002	RECOMBINANT DNA MOLECULE ENCODING A NOVEL HUMAN INTERFERON ALPHA 2B LIKE POLYPEPTIDE METHOD FOR PRODUCING IT IN PICHIA AND ITS USE	CADILA HEALTHCARE LIMITED
212080	1276/DEL/2002	"A PROCESS OF SYNTHESIZING HIGH QUANTITIES OF HUMAN INTERFERON ALPHA 2a PROTEIN"	

Patents granted

PATENT NUMBER	APPLICATION NUMBER	TITLE OF INVENTION	APPLICANT NAME
208414	732/MUM/2000	STREPTOMYCES AVERMITILIS GENE DIRECTING THE RATIO OF B2:B1 AVERMECTINS	PFIZER PRODUCTS INC.
208063	IN/PCT/2001/58/CHE	A METHOD FOR PREPARING A YEAST STRAIN	NOVO NORDISK A/S
199888	569/DEL/2001	"A PROCESS FOR PREPARING A PROTEINS, USED FOR DETECTION OF HIV ANTIBODIES"	UNIVERSITY OF DELHI
199578	566/DEL/2002	"A PROCESS OF OBTAINING RECOMBINANT LAMBDOID BACTERIOPHAGE AND THE RESULTANT NOVEL PHAGE DISPLAY SYSTEM"	UNIVERSITY OF DELHI
189732	616/DEL/1998	"A PROCESS FOR PREPARATION OF AN IMPROVED PLASMID FRAGMENTS"	IDEC PHARMACEUTICALS CORPORATION
210988	IN/PCT/2001/01140/MUM	CHIMERIC EXPRESSION PROMOTERS ORIGINATING FROM COMMELINA YELLOW MOTTEL VIRUS AND CASSAVA VEIN MOSAIC VIRUS	MERISTEM THERAPEUTICS
210988	IN/PCT/2001/01140/MUM	CHIMERIC EXPRESSION PROMOTERS ORIGINATING FROM COMMELINA YELLOW MOTTEL VIRUS AND CASSAVA VEIN MOSAIC VIRUS	MERISTEM THERAPEUTICS
235741	1274/DEL/2002	"A PAIR OF OLIGONUCLEOTIDE PRIMERS FOR SPECIFIC AMPLIFICATION OF THE HUPB GENE OF MYCOBACTERIUM SPECIES"	DEPARTMENT OF BIOTECHNOLOGY
232332	1149/DEL/2000	"HUMAN ORAL CANCER CELL LINE ESTABLISHED AND PROPAGATED IN VITRO FROM ORAL"	THE DIRCTOR, ALL INDIA INSTITUTE OF MEDICAL

THANKS



For more details Visit our Website:

www.ipindia.nic.in or mail your query to delhi-patent@nic.in

STRATEGIC MANAGEMENT OF INTELLECTUAL PROPOERTY RIGHTS (IPR)
BIRAC & BCIL

05 JULY 2012

NEW DELHI

Gautam Bakshi
Head & DGM – Corporate IP
Registered Patent & Trade Marks Attorney
PROMED Research Centre, Gurgaon

IP STRATEGY – DO WE NEED IT???

- To keep up-to-date with the dynamic and rapidly changing pharmaceutical field
- To maintain your competitive advantage
- To take advantage of legal trends and emerging opportunities
- To develop a deeper understanding of pharmaceutical patents will help you make a more significant contribution to your research or legal team and your company

Intellectual Property Strategy

- An integral part of the overall business strategy of any pharmaceutical industry
- Influenced by its creative/innovative capacity, financial resources, field of technology, competitive environment……
- IP adds value at every stage of the product development …new, better, and cheaper, product/service on the market

Patent Strategy

- **Patent Strategy:**

……..is a skeleton of decision-making processes and procedures which must ensure that the patent activities support the business in all departments such as:

- *Business area/domain*
- *Platform technology area*
- *Specific individual technology*

Developing a Patent Strategy

- **Why seeking patent protection:**

- Exclusivity

- Licensing

- Freedom of action or design

- **Additional reasons:**

- Sense of achievement / prestige for employees

- Use as a sales aid or marketing tool ("Patent Pending")

- Reputation of being an innovative company

Patent Strategy

- Patent strategy may be:
  - **OFFENSIVE - Small portfolio of pioneering patents**
  - **DEFENSIVE - no intention of developing the invention, main interest: preventing others from doing so**
  - DOMINATING - plan to use the technology, the processes described in the patents and to sue the infringing parties
  - LICENSING PURPOSES (IN/OUT/CROSS)- individuals/institutions that do not intend to manufacture the invention themselves, transfer the rights for development and production to a third party
  - MISC ..profit centers, aggregators, “trolls”…

Offensive patent strategy

- Small portfolio of pioneering patents
  - Niche Market leadership & advantage
  - Licensing
  - Deal & merger leverage
- Small to medium size companies
- Reasonable cost spent on such strategy
- Market monitoring is must

Defensive patent strategy

- Large portfolio of patents of various scope
  - Protect products from copying
  - Reduces risk of patent infringement suit by competitors – Multi protected IP
  - Cross licensing avenues - market entry
- Medium to large size companies
- High cost to follow this strategy
- Leads to competitor/generics designing around due to large IP portfolio

International patent strategy

- Cost Intensive: PCT/CONVENTION
- Cost / benefit analysis
- Strategically select countries and patents to maximize value – business led approach

Infringement

- Patents grant their owners the right to exclude others from practicing the claimed invention.
- Unauthorized practice without the consent of patent owner is infringement.

Infringement

- How is infringement determined?
- Determining Infringement is a Three-Step Process
  - Determine the scope of the claim(s) (Claim Construction)
  - Compare the elements of the claim to the composition or method accused of infringement using the “all elements” rule: every element required by the claim must be present in the accused composition or method either literally or under Doctrine of Equivalents
  - Claim by claim – element by element analysis

Rules of Claim Construction/Markman

- Intrinsic Evidence
  - Claim language
  - Written Description
  - Accompanying Drawings
  - Prosecution History
- Extrinsic Evidence
  - Inventor/Expert Testimony
  - Treatises/Technical Articles

Research Exception

- Narrow exception
  - ***"For amusement, to satisfy idle curiosity, or for strictly philosophical inquiry"***

IP INFRINGEMENT STRATEGY

OFFENSIVE ACTION BY INNOVATORS

- **Preliminary Injunction**
- **Anton Piller order - *Anton Piller KG v Manufacturing Processes Limited [1976] Ch 55 [1] 1976; Templeman J in EMI Limited v Pandit [1975] 1 All ER 418 in 1975***

Preliminary Injunction

Preliminary injunction jurisprudence has its own four-factor test that is similar to that of permanent injunctions. The plaintiff must show:

- *Reasonable likelihood of success on the merits of the case*
- *Irreparable harm if an injunction is not issued*
- *Balance of hardships tipped in favor of the plaintiff*
- *Public interest that is not negatively impacted*

Anton Piller order *(search & seize)*

- In British and British-derived legal systems
- An Anton Piller order (frequently misspelt Anton Pillar order) is a court order that provides the right to search premises and seize evidence **without prior warning**
- They are now known as search orders in England and Wales
- Prevents destruction of incriminating evidence, particularly in cases of alleged trademark, copyright or patent infringements
- Order is named for the case of Anton Piller KG v Manufacturing Processes Limited [1976] Ch 55 [1] in 1976
- First reported such order was granted by Templeman J in EMI Limited v Pandit [1975] 1 All ER 418 in 1975

Anton Piller order

- Essentially unfair to the accused party,
- Issued exceptionally
- **3-step test set out by Ormrod LJ *In re Anton Piller case***:
- There is an extremely strong prima facie case against the respondent,
- The damage, potential or actual, must be very serious for the applicant, and
- There must be clear evidence that the respondents have in their possession incriminating documents

IP INFRINGEMENT STRATEGY

DEFENSIVE ACTION BY GENERICS

- **Invalidity attack**
- **Patent reexamination**
- **Issue Preclusion**
- **License Negotiation/AG**
- **Interlocutory Appeal – *In re Lauro Lines s.r.l. v. Chasser et al., 490 U.S. 495 (1989)***
- **Walker Process antitrust claim**

Invalidity attack

- **Patentability grounds – Novelty, anticipation, Obviousness, OT-DP……**
- **Maintenance fee check**

Patent reexamination

- To reexamine the validity of the accuser's original patent
- When patent reexaminations are sought in the context of pending litigation, patent litigators must have an effective strategy in place to confront the unique issues associated with them

Interlocutory Appeal

- An interlocutory appeal, in the law of civil procedure is an appeal of a ruling by a trial court that is made before the trial itself has concluded
- Most jurisdictions generally prohibit such appeals, requiring parties to wait until the trial has concluded before they challenge any of the decisions
- For example, if a party is asserting some form of immunity from suit, or is claiming that the court completely lacks personal jurisdiction over them, then it is recognized that being forced to wait for the conclusion of the trial would violate their right not to be subjected to a trial at all

Interlocutory Appeal

- The Supreme Court of the United States delineated the test for the availability of interlocutory appeals, called the ***collateral order doctrine***, for United States federal courts in the case of Lauro Lines s.r.l. v. Chasser et al., 490 U.S. 495 (1989), holding that under the relevant statute (28 U.S.C. § 1291) such an appeal would be permitted only if:
- *the outcome of the case would be conclusively determined by the issue;*
- *the matter appealed was collateral to the merits; and,*
- *the matter was effectively unreviewable if immediate appeal were not allowed*

Issue Preclusion – *In re Blonder-Tongue*

- In Blonder-Tongue, the Supreme Court permitted accused infringers to plead collateral estoppel, also known as ***ISSUE PRECLUSION,*** when facing an infringement claim on a patent already declared invalid in a proceeding against another defendant, i.e., after the above CAFC case finding that Apotex has proven invalidity or unenforceability of Pfizer's patents based on obviousness, Pfizer is not permitted to continue to assert the patents in proceedings against Mylan. *Blonder-Tongue* permitted the use of ***DEFENSIVE COLLATERAL ESTOPPEL*** when the accused infringer shows:

Issue Preclusion – *In re Blonder-Tongue*

- 1) that a patent was found invalid in a prior case that had proceeded through final judgment and in which all procedural opportunities were available to the patentee;
- 2) that the issues litigated were identical; and
- 3) that the party against whom estoppel is applied had a full and fair opportunity to litigate.

LICENSE NEGOTIATION/AG - *FDAAA § 920*

- FDAAA § 920 amended the FDC Act to create new § 505(t) – "Database for Authorized Generic Drugs" – that requires FDA to compile and publish a complete list of all authorized generic drugs identified in annual reports submitted to the Agency since January 1, 1999. FDC Act § 505(t) defines an "authorized generic" as a drug listed in FDA's Orange Book that was approved under FDC Act § 505(c) (i.e., a "full" 505(b)(1) NDA or 505(b)(2) application)

***Walker Process* antitrust claim**

- *Walker Process* claims stem from the 1965 Supreme Court case (of the same name) and allow Section 2 Sherman Act antitrust claims for monopolization or attempted monopolization based on enforcement of a **fraudulently procured patent.**
- Here, alleged fraud is that "patent obtained by knowingly and deliberately concealing from the Patent Office prior art that it knew would have resulted in a denial of its application."

DAMAGES - German Law

- No subjective element in damage calculation: **A willful infringer does not pay more damages**
- Damages as difference calculation, includes lost profit (§ 252 BGB)
- "Simple" Equation:
- **Damages = Hypothetical wealth without infringement - Actual Wealth with infringement**
- Problem: Hypothesis is complicated and burdensome
- -Hypothetical damage where patent holder was never willing to license?
  -Non-financial or unquantifiable damage (e.g. to business/goods reputation)?
  -No damage because patent could have been circumvented?
  -Burden of proof upon patentee (need to disclose own profit)
- Not an attractive option for patentee in practice

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Thank you