WORKSHOP ON EFFECTIVE GRANT WRITING SKILLS & STRATEGIC MANAGEMENT OF IPR

ORGANIZED BY

DEPARTMENT OF BIOTECHNOLOGY MINISTRY OF SCIENVE AND TECHNOLOGY,GOVT.OF INDIA

&

BIOTECHNOLOGY INDUSTRY RESEARCH ASSISTANCE COUNCIL

IN ASSOCIATION WITH

BIOTECH CONSORTIUM INDIA LIMITED(BCIL)

AT KOLKATA

DATE:18TH July,2012

SPEAKER:

DR. SUDIPTA BANERJEE

L. S. DAVAR & CO.

KOLKATA / NEW DELHI

TOPIC FOR DISCUSSION

BIOTECH INVENTIONS:ESSENTIALS OF DRAFTING A PATENT SPECIFICATION

Cont..d

WHAT MAY BE PATENTED

A patent may be awarded in respect of an invention. The invention may relate either to a new product or to a novel process. The Act provides that any invention to be patentable, it requires that:

(A) It involves an inventive steps;

(B) It is capable of industrial application; and

INTRODUCTION

Modern biotechnology counts among the most important technological breakthroughs occurring the last two decades.

The cost structure associated with easy copying, the rapid pace of innovation, the extreme technicality and, most of all, the existence of powerful methods able to systemize product innovation, have all contributed to create patent law problem specific to biotechnology.

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Admittedly, some legal questions were settled early by the courts in foreign countries, such as the patentability of living organisms, and the basic equivalence of recombinant proteins with their purified natural counterpart. However, many other legal issues have arisen concomitantly with the development of new biotechnology techniques. Among the new issues, the determination of non obviousness in biotechnology products is one of the most daunting.

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DRAFTING A DISCLOSURE

One of the reasons why patent drafting is often such a difficult process is that patents are at once technical., commercial, and legal documents. As such, they are written with a number of different purposes in mind. To take one example, patent law stipulates that the patent specification ought to disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

IMPORTANCE OF SCOPE OF PROTECTION FROM AN ECONOMIC POINT OF VIEW

Patent breadth is a crucial issue in the whole patent system which is not doubted by most patent lawyers.

Broad-scope protection has the advantage that provides better protection for the original inventor against (trivial) improvements and second-generation innovations.

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Broad-scope protection, however, makes it more difficult for newcomers or subsequent innovators. It hinders competition.

Narrow scope protection has the advantage that it creates more competition after the original innovation. More competition, however can lead to duplication of entry costs, inefficient production, etc. Due to the fact that the scope of protection is narrow, and that more competitors are thus attracted to enter the market with competing products, there is less profit for the original innovator because of the limited-value monopoly right. This could lead to a reduced incentive to innovate or a tendency to keep innovations secret.

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A narrow patent will not provide the protection as mentioned and will then prove to be of little value.

Thus, the patents must in any event have a certain breadth, and the scope of protection must be broad enough to recompensate the cost of invention.

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THE DISCLOSURE REQUIREMENT: DEFINITION AND RATIONALE

The invention must be disclosed in such a way in the patent application that the man skilled in the art is capable of carrying out the invention without undue burden or inventive skill.

The rationale of the disclosure requirement is the quid pro quo; that is, a monopoly right is granted in exchange for a description of the invention in the patent application which allows the public and others active in the same field to make of the technology disclosed in order to make further technological developments. In other words, technological development is stimulated by disclosure.

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CONNECTION WITH 'SCOPE OF PROTECTION'

Scope of protection is traditionally linked to the post-grant phase and, even more particularly, in the context of a patent infringement claim and the possible application of the doctrine of equivalence. The scope of protection of a patent, however, can only be based on the scope of the invention or the inventive concept.

For example, if one claims a genetically manipulated animal in general in a patent application, but only discloses the invention applied to mice, what is then the scope of the invention? The genetic manipulation

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of animals or of mice or rodents? A strict application of the disclosure requirement could lead to the conclusion that the scope of the invention is mice. The scope of protection of such a patent will be identical to the scope of the invention, and thus it can be concluded that scope of invention and scope of protection are different terms used in different phases of the patent grant for the same phenomenon. Thus, it is only possible to determine the scope of protection once the scope of the invention is identified, this will then be the scope of protection.

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THE DISCLOSURE REQUIREMENT IN INDIA

GENERAL REMARKS

An analysis of the enabling disclosure requirement in India requires that the various elements contained in this requirement be treated separately. The enabling disclosure requirement could be said to consist of the following elements:

- the practicability of the invention;

- the reproducibility of the invention which is actually part of the requirement of practicability; and

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THE DESCRIPTION OF THE INVENTION.

In order to establish whether the disclosure is sufficient, there are basically three possible tiers. First, one can decide to use a strict application of the requirement: what is not expressly disclosed is not protected.

A second approach, is a lenient application according to which the patent applicant is entitled to obtain a broad protection for sharing his invention with the public.

A third possible approach, and the best one, is a kind of middle way.

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If the invention is a general principle, then the applicant can suffice with disclosing only one or some embodiments representing the application of the principle. If the invention does not relate to a general principle, but only to discrete products or methods, then the disclosure requirement is only fulfilled if all products or methods claimed are also described in the application.

The words of Justice Fortas in Brenner v. Manson should perhaps stimulate us in our search for a fair and equitable scope of protection:

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CONTENTS OF A PATENT

Before we proceed further on our discussion, let us first have a quick review on the contents of a disclosure. Patents specification is made up of fourkey parts: (i) an abstract, (ii) a description of the invention, (iii) one or more claims, and (iv) any drawings referred to in the description or claims.

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(a) THE ABSTRACT

The first element of a patent is the abstract. This is a brief summary (usually around 150 words) of the more important technical features of the invention. Normally, an abstract contains the title of the invention, a concise summary of the matter contained in the specification, and an indication of

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the technical field to which this invention belongs. Patents abstracts are used by the Patent Offices as a search tool in the examination of other patent applications.

(b) THE DESCRIPTION

In most cases, a description will begin with an account of the background to the invention. In so doing, it will summarize the prior art, usually referring to existing patents and other published documents. This is usually done by outlining the technical problem that the invention attempts to solve and the solutions that it offers. Following a

Cont..d

brief introduction to any drawings that are used, the description will normally provide a detailed account of how the invention is carried out.

At a general level, the application ought to describe the invention in a manner that is clear and complete enough for it to be performed by a person skilled in the art. The description must also support the claims.

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(c) THE CLAIMS.

While the purpose of the description is to ensure that the invention disclosed in the patent is of some
practical use, the primary function of the claims is to set out the scope of the legal protection conferred by the patent. There are basically two different types of claims, namely a claim to a physical entity(for example,a product, or apparatus) and a claim to a physical activity (for example a method, process, or use).

Typically, a patent will consist of a number of claims that are arranged hierarchically. Such patents will commence with a widely drawn ‘principal’ or ‘generic’ claim that defines the invention by setting out its distinctive technical features. General claims of this

Cont..d

THE SCOPE OF CLAIMS

Each invention should be claimed as broadly as possible, taking into account the limitations imposed by The prior art known at the time of drafting, and by the technical feasibility of the scope which is claimed.

It is always better to start out with claims which are too broad rather than too narrow, so long as the basis

Exists in the specification for the restrictions which may have to be made when new prior art is found, or when inventor finds that part of his invention does not work.

Cont..d

DRAFTING OF CLAIMS

EXAMPLE

✪Subject Matter to be claimed is a ‘Pencil with Eraser’

Claim 1

A writing device comprising :-

☞ An elongated cylindrical lead core;

☞An elongated cylindrical wooden shell with first and second ends substantially surrounding the lead core; and

☞an eraser, the eraser being attached to the first end of the wooden shell, wherein the lead core extends at least partially beyond the second end of the wooden shell.

Alternative set of claims

(1) Claim 1- a writing device comprising :

☞ An elongated core including a solid first material, the first material having a property of exfoliating when frictionally engaged with and moved across a surface; and

☞ an elongated shell comprised of a second material substantially surrounding the elongated core, wherein the elongated core extends at least partially beyond a first end of the elongated shell.

(2) The writing device as claimed in claim 1, comprising an eraser, the eraser being attached to the first end of the wooden shell, wherein the lead core extends at least partially beyond the second end of the wooden shell

CONCLUSION-- ALTERNATIVE

Cont..d

United States Patent [19]

Galer

[11] Patent Number: 4,667,843

[45] Date of Patent: May 26, 1987

[54] **IMPACT-RESISTANT THERMOPLASTIC PAINT CAN AND LID**

[76] Inventor: **Herbert W. Galer**, 24 Woodland Trail, Newnan, Ga. 30263

[21] Appl. No.: **886,613**

[22] Filed: **Jul. 18, 1986**

[51] **Int. Cl.**[4] **B65D 43/06**

[52] **U.S. Cl.** **220/354**; 220/307

[58] **Field of Search** 220/354, 307, 306; 150/55

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,512,494	4/1985	Von Holdt	220/354
4,530,442	7/1985	Vogel, Jr. et al.	220/354
4,619,373	10/1986	Galer	220/354

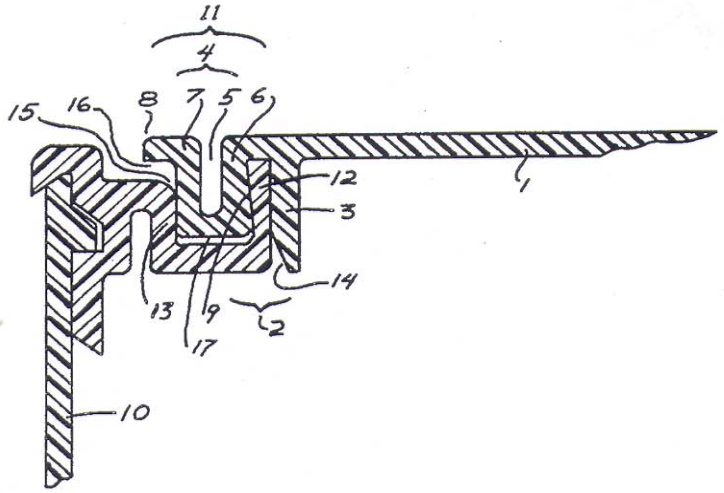
Primary Examiner—George T. Hall

Attorney, Agent, or Firm—William L. Krayer

[57] **ABSTRACT**

A thermoplastic container and lid assembly comprising a vertical circular flange on the container top and a complementarily dimensioned channel on the lid for receiving it, the flange being tapered from relatively narrow base to a wide terminus, and the channel having a relatively narrow opening and a wide terminus.

12 Claims, 3 Drawing Figures



ARTICLE HAVING TWO PERVIOUS SURFACES

Patent number: WO9719803
Publication date: 1997-06-05
Inventor: WEIL FRANCOIS RENE (FR); MARTIN CLAUDE ANDRE RAYMOND (FR)
Applicant: EUREPAK SARL (FR); WEIL FRANCOIS RENE (FR); MARTIN CLAUDE ANDRE RAYMOND (FR)
Classification:
- international: ***B29C51/14; B32B27/12; D04H1/00; D04H13/00;*** *B29C51/10;* **B29C51/14; B32B27/12; D04H1/00; D04H13/00;** B29C51/10; (IPC1-7): B29C51/14; B29C51/28; B32B27/12
- european: B29C51/14B; B32B27/12; D04H1/00B; D04H13/00B4
Application number: WO1996FR01907 19961129
Priority number(s): FR19950014389 19951130

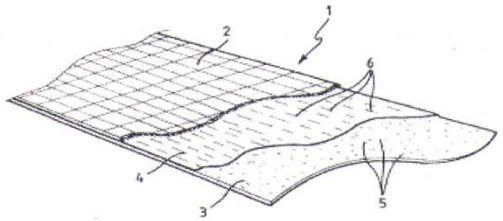
Also published as:
EP0868286 (A1)
EP0868286 (B1)

Cited documents:
EP0568812
DE2706446
GB2184032
DE1635404
WO8707557
more >>

Report a data error here

Abstract of **WO9719803**

An article including two surfaces of which one consists of a pervious web (2) previously made of a non-woven, woven, meshed or complex material on a textile base, whereas the other surface (3) consists of a sheet of pervious synthetic material.



THE PRESENT INVENTION

Describes that the sides of the first upwardly open channel (22) flow from the receptacle (1) such that the second upwardly open channel (16) provides a sealing function of the lid via the complementary shaped wedges (22) formed underside of the second channel (16). A separate retention function of the lid is provided by snap-engagement between the projection (11) and the underside of the second channel (16).

Accordingly, the sealing and the retention function is separated.

Cont..d

Accordingly, the new claim 1 as filed with the response to the office Action is shown on the screen, which
Was allowed by the Patent office:-

NEW CLAIM 1

An improved container comprising a receptacle (1) and lid (6), the receptacle having a rim (2) projecting inwardly form adjacent walling and the lid (6) being a press fit into the rim (2) wherein the rim (2) of the receptacle (1) has an upstanding first flange (21) forming the inner limb of a first upwardly-open channel (22) between whose outer limb (23) and the walling of the receptacle (1) laterally extends a second flange (24), and the periphery of the lid (6) has an inner depending skirt (10) that closely co-operates with the inside of the first flange (21), an undulating portion (16) outward of the skirt (10) forming two open channels, namely a downwardly-open channel (14) which receives the first flange (21) and a second upwardly-open channel (16) which seats sealingly within the first upwardly-open channel (22), and an outer flange (18) that overlies the second flange (24), characterized in that the inner and outer sides of the first upwardly-open channel (22) flow from the base of the channel respectively inwardly and outwardly of the receptacle (1) so that the second upwardly-open channel (16), whose underside is of complementary shape, wedges therein to provide a sealing function, and in that a projection (11) at the base of the skirt (10) has snap engagement under the first upwardly-open channel (22) as sealing is effected to provide a retaining function.

sort are often followed by a series of narrower dependent or subsidiary claims (which may refer back to earlier claims).

(d) DRAWINGS

The final component of a patent is the drawings. These provide a representation of the invention. Along with the description, the drawings may be used to interpret the claims.

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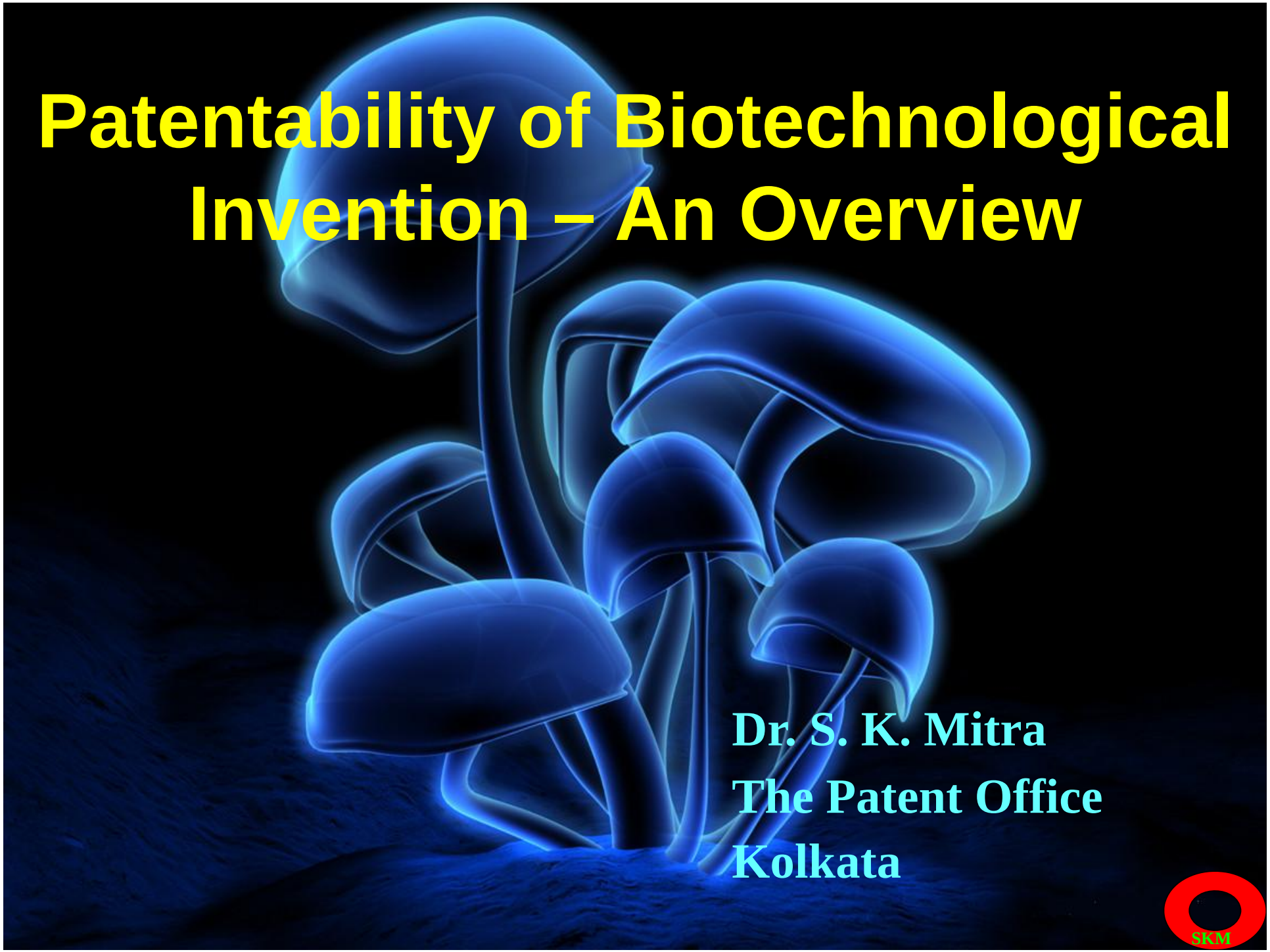
"A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."


Thank You!

Patentability of Biotechnological Invention – An Overview



Dr. S. K. Mitra
The Patent Office
Kolkata

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Provisions for Patenting Biotechnological inventions in India

Sec 2 (1) (j) : **Inventions (novelty, inventive steps & industrial applications)**

Sec 10(4)(d): (A) to (D) **Mandatory deposition of biological Materials in IDA & disclosing date & number of deposit at Institution with proper characterization**

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Exclusions of Patenting Biotechnological inventions in India

Sec 3(b)	**:**	**Morality/ethical issues**
Sec 3(c)	**:**	**Scientific principles, natural livings/ non-livings**
Sec 3(d)	**:**	**Mere discovery of known substance**
Sec 3(e)	**:**	**Mere admixture**
Sec 3(h)	**:**	**Agricultural/horticultural methods**
Sec 3(i)	**:**	**Method of human/animal treatment**
Sec 3(j)	**:**	**Human/animal in whole or parts**
Sec 3(k)	**:**	**Computer program**
Sec 3(p)	**:**	**Traditional knowledge**

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Biotechnological Inventions

Classical

- **Fermentation**

  Wine, Bread, Roqueforte French cheese (*Penicilium roqueforte*), Alcohol,

- **Yeast clones**

  (Louis Pasteur, 1873)

- **Isolation of active compounds from natural resource**

  (*Reserpine, Quinine etc.*)

Modern

- **Recombinant DNA Technology**
- **Vaccines**
- **Mabs**
- **New Drug Diagnostics**
- **Stem cell**
- **Transgenic**

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Modern Biotechnology Innovations

- Polymerase Chain Reaction (PCR) Technology
- Sequencing and analysis
- Micro array/ Functional genomics
- Bioremediation
- Medical applications
  - * Gene therapy
  - * Cure for cancer
- Bioinformatics

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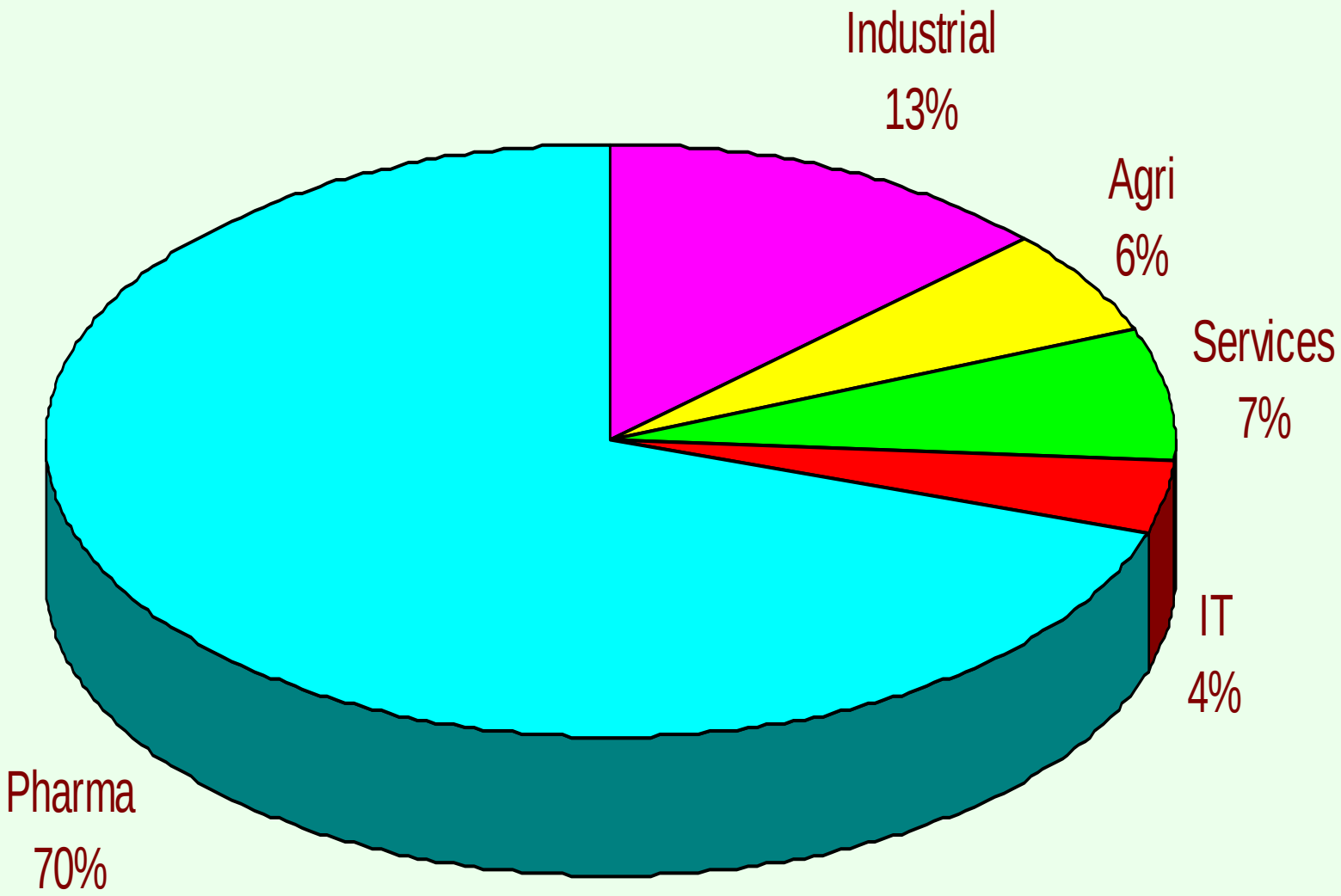
Indian Biotech Sector



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Thrust Areas of Biotech Research in India

- Nanobiotechnology
- GM Crops
- Stem Cell Research
- Bioinformatics

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Classical Biotechnological Patents

Process :

- Inventions on the production of bio-products having novelty & at least one inventive steps

Products :

- Isolated organisms having industrial application
- Plant extract having a specific indication about its utility
- Fermented food and beverages
- Chemical substance derived from extraction or isolation such as Morphine, Quinine, Reserpine, Digitalis etc.

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Modern Biotechnological Patents

Composition	**:**	**Vaccine composition**
Process	**:**	**Bioremediation based on Enzymes**
Microorganisms	**:**	**Cultivated bacteria and fermentation**
		Microorganisms to dissolve hydrocarbon

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What is Microorganism ?

Unicellular organisms with dimensions beneath the limits of the visions which can be propagated & manipulated in a laboratory e.g.

- Bacteria
- Yeast
- Fungi
- Algae
- Protozoa
- Human, Animal & Plant Cells
- Plasmids
- Viruses

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MICRO-ORGANISM

- **Legislative framework / Regulator mechanism for protection**
- **Invention relies on a biological material should include reference to a deposit of such material**
- **Deposit patentable living organism with a recognized Institutions (Budapest Treaty)**

Deposits required to support claims if isolation process requires undue experimentation to obtain desired Biological Material

No deposits required where Biological Material obtained publicly available material with routine experimentation & screening tests

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International Depository Authorities in India under Budapest Treaty

MTCC (Microbial Type Culture Collection)

Institute of Microbial Technology (IMTECH)

Chandigarh, India

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Requirements for IDA & IPO

- **Date/number of deposit**
- **Source/geographical origin**

Sec 10 (4) (d) (A) to (D)of The Patents Act, 1970

In case of use of new biological materials in the invention disclosed in the patent application, such materials are required to be deposited in any of the International Depositary Authorities (IDA) recognized under the BUDAPEST Treaty on or before filing of the application in order to supplement the description for sufficiency of disclosure of the invention and reference of such deposit to be made in the patent specification.

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Living Organisms

- Micro organisms - patentable
  - Isolated
  - Mutated
  - Recombinant
- Mandatory deposition of the micro organism in an IDA
- Source and geographical origin to be disclosed

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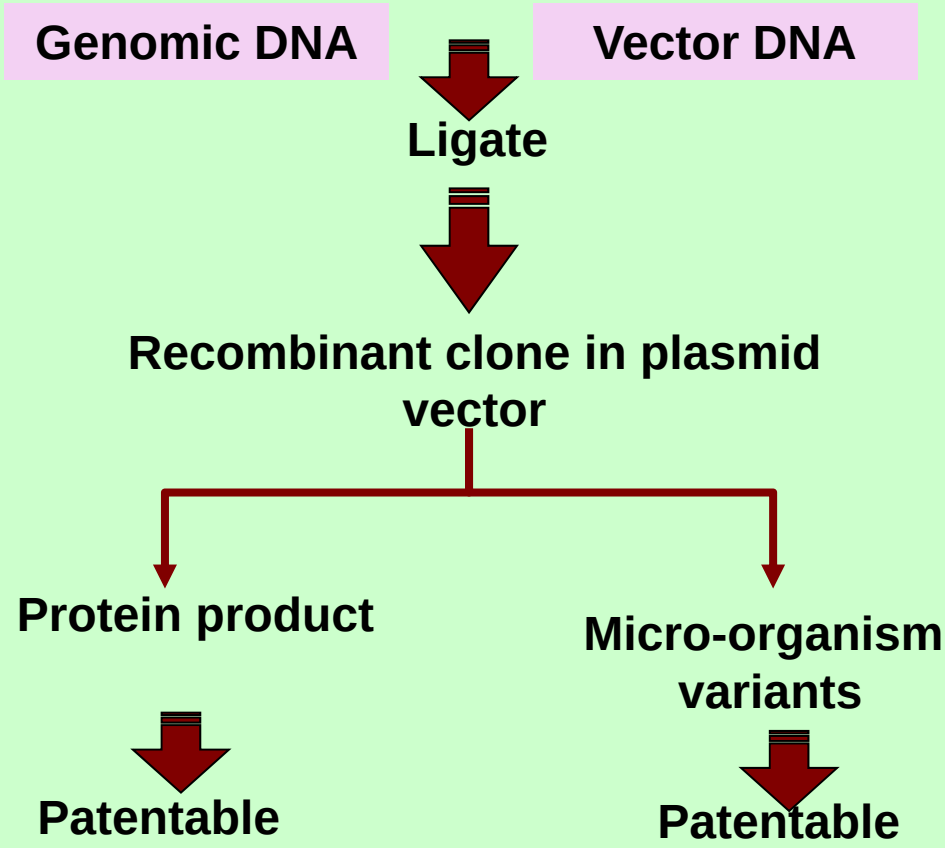
Recombinant Micro-organisms



Process and Product Patentable

Products

- Human insulin
- Immunoglobulin
- Vaccine
- Blood clotting factor
- Bt-toxin

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Examples of Micro-organisms Patentability

1. **An attenuated Salmonella strain, wherein the strain: comprises a first attenuating mutation decreasing the LD.sub.50 of said strain at least 50,000 times when compared to wild-type strain, comprises a mutation that prohibits the strain from making a functional RecA protein, and is a Salmonella gallinarum 9R strain**

2. **A *vaccine* for combating Salmonella infection, comprising: an attenuated Salmonella strain according to claim 1, and a pharmaceutically acceptable carrier**

3. **A method for the preparation of a *vaccine* for combating Salmonella infection, comprising admixing: an attenuated Salmonella strain and a pharmaceutically acceptable carrier**

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Micro-organisms-Bioremediation

Patentability issues

1. **A consortium of ligninolytic bacteria for degradation of lignin, said consortium comprising three bacterial strains having accession numbers MTCC 5094, MTCC 5095 and MTCC 5098, which are respectively Serratia marcescens, Pseuodomonas aeruginosa and Pseuodomonas aeruginosa.**
2. **The bacterial consortium as claimed in claim 1, wherein the bacteria are isolated from a mixture of sawdust and soil from Roorkee, Uttar Pradesh, India.**

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Plant Processes

Patentable Inventions

- Processes involving plants to increase the yield
- Genetic transformation
- Tissue culture methods
- Micro-propagation
- Somatic embryogenesis

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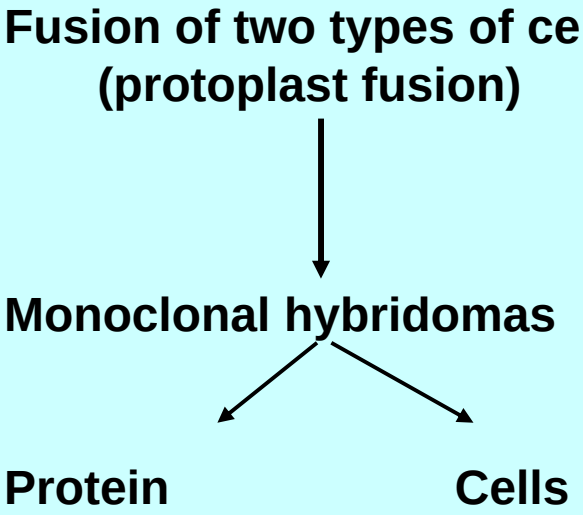
Hybridoma Technology



Process is patentable

- Blood group
- Hepatitis B
- HCG
- HIV
- Polio
- Leprosy
- Malaria

Product patentable

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Gene Patents

- **Useful Products Claims**
- **DNA of specific function/nucleotide sequence**
- **Protein/polypeptide from DNA sequence (if novel)**
- **Recombinant plasmid (vector)**
- **GM Organism containing the plasmid**
- **A process for the production of the product**

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Indian Scenario

- Living entities of Natural Origin

  Plant, Animal, Microbes, Seeds, Plant-variety and their process for production – Not patentable

- Living entity of Artificial Origin (Human Intervention)

  Transgenics – Not Patntable

  Recombinant Microbes – Patentable

- Biological materials

  Tissues, Organs, Genes, Cells – Not Patentable

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Indian Scenario

- Gene sequences, DNA sequences without having disclosed their functions – Not patentable for lack of inventive step and industrial application

- Essentially biological processes for the production of plants and animals such as method of crossing or breeding etc. – Not patentable

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Bioinformatics

- Bioinformatics has been described as – the marriage between information sciences & life sciences

- Involves the application of information technologies to solve the complex problem of biological structures and processes, and the information so generated

- Involves the use of mathematical tools to extract useful information from "noisy" data produced by high-throughput biological techniques such as genomics and screening

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Applications of Bioinformatics

- Gene sequencing
- Search for genes, regulatory sequences,etc.
- Genome annotation
- Analysis of gene expression and regulation
- Analysis of protein expression
- Prediction of protein 3-D structure

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Bioinformatics patenting in USA

- Prior to 1980, it was the practice of the USPTO not to grant patents for computer programs, although there was no prohibition of this in the Patent Law.
- Over the next 15-20 years, most computer programs became regarded as patentable, but computerized business methods were not.
- In 1998, the CAFC ruled in *State Street* that a data - processing system designed for making financial calculations was not an unpatentable abstract idea: it was useful and patentable invention.
- Essentially, the *State Street* case ruled in favour of the patentability of computer algorithms in any situation. Algorithms, whether claimed as a machine or a process, that produce a useful, concrete, and tangible result are patentable subject matter. That means, for now at least, that new and useful bioinformatics algorithms are patentable.

Bioinformatics patenting in EPO

- Unlike the US law, the EPC specifically excludes computer programs from protection (Art. 52(2)).
- However, Art. 52(3) states that this prohibition applies only to computer programs as such, allowing for the possibility that a computer program plus something else may indeed be patentable.
- The courts in member states and the EPO Boards of Appeal have interpreted this exclusion narrowly, so that a computer program which is entirely abstract is unpatentable, whereas one having a technical effect may be patentable.
- It is still unclear whether this will enable patenting of algorithms which "merely" process data.

Bioinformatics patenting in India

- The Indian Patents Act, as amended in 2002, excludes from patentability "A mathematical or business method or a computer program per se, or algorithms."
- Does this mean that there will be no patenting of bioinformatics in India?
- Not necessarily. In the EPC, a similar exclusion has been narrowly interpreted, and some patents on bioinformatics are being granted.
- It all depends on how the Indian patent office and courts decide to interpret the law.
- Indian expertise in biotech and IT potentially put Indian companies in a strong position in bioinformatics, and they may demand IP protection for their work.

- A process of culturing microorganism without using culture medium……
- Section 3 (a)

- A process for producing a superman having 10 times memory & muscle power as compared to a normal human……..
- Section 3 (a)

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✓ **Processes for cloning human beings**;

Sec 3 (b)

✓**Processes for modifying the germ line genetic identity of human beings;**

✓Sec 3 (b)

✓**Uses of human embryos for industrial and commercial purposes**;

✓Sec 3 (b)

✓**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**

✓Sec 3 (b)

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- A process for the pre natal sex determination which comprises……

- Section 3 (b) …

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1. A process for isolation of the gene responsible for baldness from the DNA sequence which comprises……..

SEC 3 (c)

2. A DNA sequence that relates to hair loss identified & isolated from the human genome useful to develop an injectable medicinal for treatment of baldness.

SEC 3 (c)

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1. A method for extraction of saffron pigments and flavor concentrate, comprising steps of

(a) mixing saffron with food grade solvent(s)

(b) macerating and agitating the mixture with continuance protection from light conditions……

(g) obtaining orange color shining saffron pigments and flavor concentrate with recovery of 95%

2. A method as claimed in claim 1 wherein the concentrate is of flavoring and pharmaceutical grade and free from decomposed impurities.

3.A method as claimed in claim 1 wherein the saffron does not undergo enzymatic and thermal hydrolysis and degradation during processing.

4. A method as claimed in claim 1 wherein the concentrate is odor free.

1st claim allowable rest under sec 3 (d)

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- Use of deferiprone for the prevention/stabilization/reduction of the risk of heart disease having an iron overload condition. Deferiprone is known iron chelator and being used as anti-thallesemic drug.

Sec 3 (d)

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•**A process for the preparation of novel vaccine formulation for prevention of multiple diseases along with polio which comprises mixing Sabin strain derived inactivated polio vaccine absorbed on conventional adjuvant with one or more of other antigens such as Hepatitis C,D,E, Meningitis A,B,C,W,Y, Smallpox, Typhoid or TB, absorbed** on conventional adjuvant(s).

Sec 3 (e)

SKM

•A method of dwarfing plants, which comprises the steps of:

(a) introducing a substance that represses the expression of the DNA described in (a), (b), or (c) of claim 1 into the plant cells; and

(b) regenerating said plant cells to obtain transgenic plants.

Sec 3 (h)

•A process for production of Mushrooms in such a way that the production per hector is increased ten-folds, comprising the steps of preparing improved Murashige and Skoog medium with cow dung as herein described, culturing the mushroom inoculums in the above said medium in cool and dark conditions, planting the seedlings in the compost.

Sec 3 (h)

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A method of treating a mammal suffering from a cancer comprising the steps of administering to said mammal a chemical targeted to PKC .alpha. and monitoring said mammal to determine state of said cancer;
wherein said cancer is a cancer sensitive to said chemical targeted to PKC .alpha.,
wherein the amount administered is a quantity sufficient to constitute effective treatment,
wherein said chemical is chosen from a group consisting of:
A) Go6976 (trade name): C.sub.24 H.sub.18 N.sub.40 (formula): 12-(2-Cyanoethyl)-6,7,12,13-tetrahydro-13-methyl-5-oxo-5H-indolo [2,3-a] purrolo[3,4-c] carbazole (chemical name), ……
…….

Sec 3 (i)

SKM

A method for the localized diagnostic detection of diseases in the oral cavity, which method comprises:
(a) placing a semipermeable, polymeric, capillary hollow fiber, which contains a known quantity of a diagnostic-indicator agent within the lumen of the fiber, about or adjacent the tooth in the oral cavity where a dental or oral disease is suspected, the hollow fiber composed of a polymeric material which is permeable to the diagnostic agent therein, the indicator agent providing diagnostic information by chemical reaction with the products elaborated by the localized disease process in the oral cavity; and, thereafter,
(b) analyzing, after a designated period of time, the change in the nature or quantity of the diagnostic agent in the lumen as a measure of the dental disease in the localized area

Sec 3 (i)

SKM

A process of increasing weight and milk production in ruminants, comprising the steps of culturing yeast *Pischia anomala* in a conventional media, mixing the cultured yeast in conventional animal feed in a ratio of 1:10 to 10:1 and feeding the ruminants the same in piece meal basis

Sec 3 (i)

SKM

An effective and economical method of processing clinical samples useful for simple, rapid, safe, sensitive and accurate diagnosis of bacterial infections comprising the steps of-

(a) obtaining the clinical sample,

(b) mixing 1.5 to 2 volumes of Guanidinium hydrochloride (GuHCl) to the sample

(c) homogenizing the mixture while avoiding frothing,

(d) adding Sodium phosphate or sterile water to the homogenate followed by centrifugation to obtain pellet,

(e) washing the pellet with GuHCl and water

(f) resuspending the washed pellet in Tween 80 to obtain processed sample for diagnosis.

Sec 3 (i)

SKM

A method of production of islets of langerhans that can be transplanted to diabetic patients without evoking rejection from patients body, comprising the steps of culturing beta endocrine cells taken from pancreas of healthy subject in media A and B as herein described respectively so that the cells grow into islets and vibrating the islets back and forth to break the fibroblasts from the islets.

Sec 3 (j) Body parts manufacturing/or claiming body part

SKM

1. A seed deposited at ATCC under No. 3456

2. A process for controlling an insect pest comprising the step of contacting said pest by expression of a DNA encoding insecticidal proteins in cells of a plant

Sec 3 (j)

SKM

Living Organisms

Section 3(j) excludes from patentability:

- Plants and animals and parts
  - Whole e.g. transgenic animals
  - Organs
- Seeds
- Varieties and species
- Essentially Biological Processes

SKM

Essentially Biological Processes

- Grey Area - between Essentially Biological Processes and non-biological processes
- Processes exist where biological reproduction is employed
- Steps consisting of direct human intervention could warrant patentability

SKM

Essentially Biological Processes

UK Examination Guidelines suggest the following:

- To be judged on the basis of the invention
- Extent of human intervention to be considered
- But human contribution should not be trivial

Lubrizol / Hybrid plants [1990] OJEPO 71

SKM

Lessons:

- **Inventions in certain fields of Biotechnology Patentable**
- **Genetically Modified Microorganisms Patentable**
- **Natural occuring living / non-living with distinctive industrial application may be Patentable**
- **Patent Amendments a welcome change for Pharmaceutical and Biotech Industries**

SKM


THANK YOU
SKM

S.Majumdar & Co.

RELEVANCE OF INTELLECTUAL PROPERTY RIGHTS FOR LIFE SCIENCES

S. MAJUMDAR
PATENT ATTORNEY
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LIFE SCIENCES AND IP

Life sciences encompass scientific study of living organisms, like plants, animals, and human beings, as well as related considerations like bioethics. While biology remains the centerpiece of the life sciences, technological advances in molecular biology and biotechnology have led to a burgeoning of specializations and new, often interdisciplinary fields.

LIFE SCIENCES AND IP

Types of IP protection pertinent to Lifesciences

Patent
Trademarks
Geographical indications
Copyrights x
Design x

Related protection available for life sciences

Plant variety protection
Biodiversity

TRADEMARKS

- A trademark is a word, symbol, design, or combination of a word and design which serves to identify and distinguish the goods or services of one source from those of another.
- Can be a sound (Windows start up sound)
- Smell (perfumes) – NOT IN INDIA
- Color (Best Buy- yellow and gray)

Functions of a Trademark:

- ✓ identifies the source of the goods or services;
- ✓ guarantees of the quality of the goods or services.
- ✓ advertises the goods or services

- **Basic Concepts of Trademark law:**
  - ➢ distinctiveness;
  - ➢ deceptive similarity of marks; and
  - ➢ similarity of goods

BRANDING

- “a symbolic embodiment of all the information connected to a company, product or service . . . which serves to create associations and expectations among products made by a producer.”
- Branding can be used in a lot of different ways at any sized biotech or life science company
- Invitrogen is regarded to be the first company that brought formalized marketing and branding to the life sciences, with a distinct “look and feel,” which was incorporated into their product packaging, newsletters, catalog, and clever, consistent advertisements.
- All of these evoke an opinion of the company in the mind of the customer. For instance, when a scientist opens a kit from a well-branded company, there is already an expectation as to how the product will work, and normally this is a good association, otherwise it would not have been purchased.

Brand-Finance® Global 500 (2012) lists the top 500 brands by value, including 6 pharmaceutical brands:

#128 Johnson & Johnson
#319 Pfizer
#323 Bayer
#369 Novartis
#455 GlaxoSmithKline
#497 Roche

Branding

Large companies normally have a branding style guide directing

- The colors and fonts to use,
- layouts for Ads and all communications with customers, and
- at times even a “voice” which describes the style of the wording used.
- Consistency is the most important aspect of branding
- When consistency is paired with high quality products, consumers associate the marketing materials and communications with the products, leading to increased loyalty and purchases.

How to be consistent?

- Product packaging and inserts should be consistent in content and with the brand.
- Employing a consistent font in all of your advertisements, and communications if possible
- Employees should include a company-wide, consistent signature in emails, with all contact information.
- A short training for all employees on the importance of company image and consistency of the brand

FREEZE BRANDING - ETHICS

In the process of Freeze Branding, super-chilled irons are applied to the hide of an animal, altering the pigment-producing cells of the hair. As a result, the hair that grows back in the branded area will be white. In light-colored animals, the branding iron can be applied for a longer amount of time to destroy hair growth altogether, producing a mark similar to one made with a hot iron.

Freeze branding of livestock has become popular for several reasons:

- The brand is more legible throughout the year than a hot brand.
- Freeze branding is less painful and does not result in sores and fly problems.
- A properly applied freeze brand causes no permanent damage to the skin that interferes with leather quality.

Geographical Indications (GIs)

- Purpose of GIs
- encourage diverse agricultural production, -protect product names from misuse and
- imitation, -give consumers information about the

  specific character of the products

Example – DARJEELING TEA

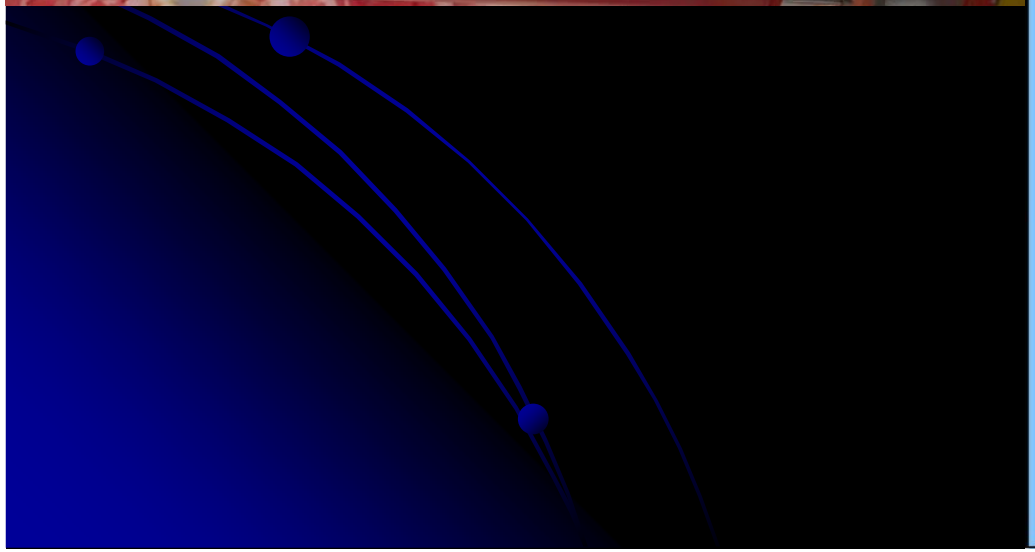
Branded Products

- Identified and differentiated from competitors
- Differentiated products kept separate from regular products
- Products will be sold at much higher prices than commodity products
- Producers have greater ability to set price

Examples of a few agricultural branded products

- Darjeeling Tea
- Vidalia Onions – State of Georgia, USA
- Cinta Senese Hogs – Tuscany, Italy
- Radiccio rosso di Treviso – Treviso, Italy
- Charlevoix Lamb - Charlevoix, Quebec, Canada
- Kagoshima Kurobuta Pork, Kagoshima Prefecture, Japan

Kagoshima Kurobuta Pork, Kagoshima Prefecture, Japan



Cinta Senese Hogs – Tuscany, Italy

Radiccio rosso di Treviso

Vidalia Onions – State of Georgia, USA

Charlevoix Lamb - Charlevoix, Quebec, Canada

WHY PROTECT PLANT VARIETIES

UPOV MISSION STATEMENT

"To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society"

TRIPS Article 27

Patentable subject matter 1. ..., patents shall be available for any invention, ...,

3. Members may also exclude from patentability [...]

(b)plants and animals other than micro-organisms, ... However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof .

The Role of Plant Variety Protection

Development of new varieties of plants encouraged where there is commercial viability

Subject matters beyond the scope of an effective PVP system PVP system does not regulate the marketplace.

Article 18 of UPOV convention

- “The breeder’s right shall be independent of any measure taken by a Contracting Party to regulate within its territory the production, certification and marketing of material of varieties or the importing or exporting of such material. In any case, such measures shall not affect the application of the provisions of this Convention”

The Benefits of Plant Variety Protection

- Incentive to stimulate new breeders and new breeding work and/or providing a basis for more effective breeding work at the domestic level
- Promotes partnerships between the private breeding sector and public breeding sector
- Removes barrier in trade vis-à-vis international market
- Helps in technology transfer and effective utilization of genetic resources
- Economic benefits – varieties with improved yields often leads to reduction in price of the final products
- Improved quality
- Health benefits – varieties having improved nutritional content
- Environmental benefits - through varieties with improved disease resistance or stress tolerance; Aesthetic benefits – ornamental plants

PLANT VARIETY PROTECTION ACT

- Provides developers of new varieties of plants some patent-like rights, that protect the reproduction and distribution of their varieties.
- Varieties that are protected under this act can be sold as seed stocks only with permission of the certificate holder and in some cases, only as a class of Certified seed.
- Varieties that are protected must have labels on the seed containers indicating the type of protection.
- Farmers may save a limited amount of seed for replanting, but cannot sell it to anyone without permission of the owner.

CONDITIONS FOR THE GRANT OF THE BREEDERS RIGHT

A variety *shall* be granted protection if it is

- **New**- It should not have been sold.
- **Distinct**- Clearly distinguishable from any other variety .
- **Uniform**-If subjected to variation that may be expected from the particular features of its propagation, it should be sufficiently uniform in its relevant characteristics.
- **Stable** -A variety is deemed to be stable if its relevant characteristics remain unchanged after repeated propagation.

Protection of Plant Varieties and Farmers' Right Act (PPV&FR Act)

- India enacted PPV&FR Act in the year 2001 and its Rules in 2003.
- The Protection of Plant Varieties and Farmers' Right Authority was established in the year 2005.
- To be protectable – the variety should be distinct, uniform and stable

Non-registrable plant varieties in India

- Varieties and exploitation are harmful to ecosystem (human, animal, plants and environment)
- Genetic use restriction technology and terminator technology
- Genus or species not notified in Official gazette at the time of filing application

Farmer’s rights

- Entitled to save, use, sow, re-sow, exchange or sale his farm produce
- Compensation for failure of expected performance of registered variety
- Protection against innocent infringement
- Exemption from payment od DUS testing fee

Researcher’s rights

- Use of registered variety in conducting research
- Use of variety as an initial source for producing new variety

Breeder’s rights

- To produce, sell, market, distribute, import, export seeds of the protected variety
- Breeder authorization for production or commercial exploitation of protected variety
- Penalties for infringement of Breeder’s right

Plant Varieties Registered till 31.10.2010 in India

Sl.No.	Crop	No. of varieties
1.	Rice	11
2.	Bread Wheat	48
3.	Pearl Millet	29
4.	Sorghum	13
5.	Maize	45
6.	Black Gram	9
7.	Field Pea	15
8.	Green Gram	20
9.	Lentil	9
10.	Kidney Bean	3
11.	Garden Pea	5
12.	French Bean	2
13.	Chick Pea	2
14.	Cotton	7

Biological Diversity

Biodiversity is the vast variety of all the species of plants, animals, insects and micro-orgasm inhabiting on the earth.

The human civilization depends directly or indirectly upon this biodiversity for their very basic needs of survival. This diversity is the need for the long term sustainability of the environment, continuity of life on earth and maintenance of integrity. Now IPR and biodiversity rights are interlinked because IPRS are recognises and provides the rights and economic benefits to the formal innovators and not to the informal innovators.

Convention on Biological Diversity (CBD)

It was adopted in 1992.

This Convention, aims for the conservation of biological diversity.

The sustainable use of its components

The fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate
Transfer of relevant technologies.

TRIPS and CBD as a part of WTO are legally binding on the parties to it.

Objectives

States have sovereign control over the biological resources within their Borders and shall ensure conservation and sustainable use of their same

Although states, Shall have the authority to control access to their biological resources, they shall endeavour to create conditions that facilitate such access

The benefits of commercial or other utilisation of genetic resources shall be shared in a fair and equitable way with the party providing such access

The wider application of the Knowledge, innovations and practices of indigenous and other local communities shall be conducted with the approval and involvement of the holders of such knowledge.

Controversies involving IP and biodiversity

- The patenting of ancient herbal remedies, e.g. the US Patent granted for the healing properties of turmeric, known for centuries to Indians. Patent was granted to 2 US inventors. CSIR filed re-examination proceedings. Patent was rejected for being anticipated and obvious.

- In May 2000, the patent granted to W R Grace Company and the US department of Agriculture on neem by the European patents office was quashed on similar grounds.

- The US Plant Patent) on the 'ayahuasca' plant, considered sacred and used for medicinal purposes by Amazon's indigenous peoples. Thousands of indigenous people of the region use it in sacred religious and healing ceremonies, as part of their traditional religions. Patent was rejected.

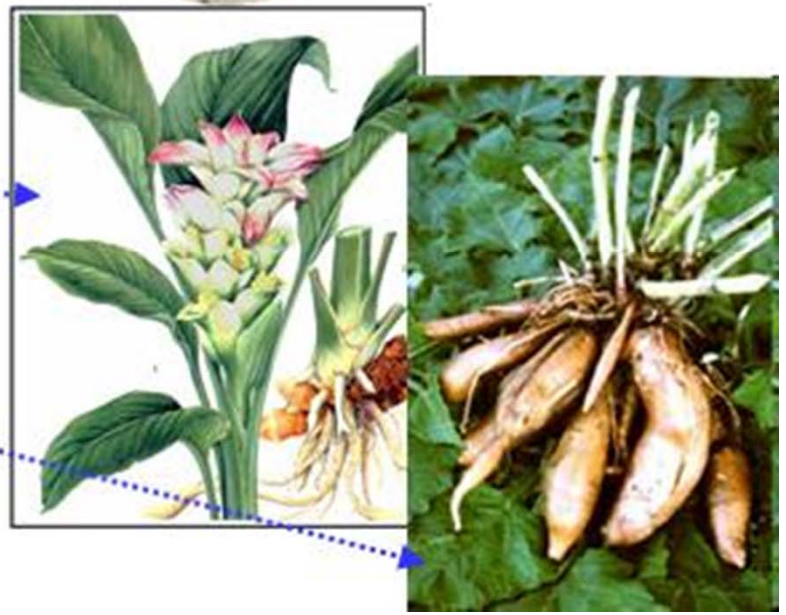
- The US Plant Patent for the use of combination of herbal compositions as hypoglycaemic (anti-diabetic) agents that have been in use and are also well-documented in Indian scientific literature and ancient texts for the same antidiabetic properties. Patent was rejected.

- The patenting of crop varieties that is similar to those grown for centuries in certain Geographical areas, e.g. for varieties of Basmati rice by Rice-Tec Corporation in the US Rice-Tec even uses the term Basmati, long used to refer to aromatic rice grown in northern India and Pakistan, to describe its rice varieties;

- Patents on technologies that threaten farming systems worldwide, such as Granted to Delta and Pine Land Co., nicknamed the Terminator Technology for its capability to stop plant regeneration after the first generation.

Other controversial patents

- popping beans (Ehlers & Sterner, 2000)
- neem tree oil (Roland and Blouin, 1996),
- maca (*Lepidium* sp.; DeLuca et al., 2000; Zheng et al., 2001, 2002)
- basmati rice (Sarreal et al., 1997)
- turmeric (*Curcuma longa*; Das & Cohly, 1995; overturned)
- ayahuasca (*Banisteriopsis caapi*; Miller, 1986)



Types of Biopiracy

Traditional Knowledge Biopiracy

This kind of biopiracy covers the unauthorized use of common traditional knowledge, whether acquired by deception or on the basis of exploitative transactions. Various patents can claim traditional knowledge in the form it was acquired, or cover a refinement or an invention based on it.

Genetic Resource Biopiracy

It is about the unauthorized extraction and use of widespread resources and of those found only in one location. It also covers authorized extraction of resources on the basis of exploitative transactions. Patents claim the resource itself, even derivatives or purified versions of it.

Case Studies

Banaba and other medicinal plants (Philippines)

Japan has been patenting the country's native plants with medicinal properties, such as banaba, saluyot, sambong, lagundi, and takip kuhol. These plants have been the subject of patent claims there. Pharmaceutical firms in Japan have started to process these plants as medicines and claimed the process these plants as medicines and claimed the knowledge as their own, when in fact, the healing properties of these herbs have been known in the Philippines for ages.

Bitter gourd (Thailand)

Since Thailand has a big problem with AIDS, their national scientists have been researching for all sorts of ways to help relieve the suffering the victims experience, and maybe even prevent against the infection of the HIV virus.
One team was focused on bitter gourd (Momordica spp.), and they found certain compounds in it that work against HIV. Later on they found out that American scientists have copied their research and have already patented the active Map-30 protein from a native strain of bitter gourd

Rosy Periwinkle (Madagascar)

The Rosy Periwinkle case dates from the 1950s. The Rosy Periwinkle, while native to Madagascar, had been widely introduced into other tropical countries around the world. This meant that researchers could obtain local knowledge from one country and plant samples from another. The use of the plant as a cure for diabetes was the original stimulus for research, but cures for cancer were the most important results. Consequently, different countries are reported as having acquired different beliefs about the medical properties of the plant.

Hoodia Cactus (South Africa)

The Hoodia Cactus originates from the Kalahari Desert of South Africa. For generations it has been known to the traditionally-living San people as an appetite suppressant. In recent years, from 2004 onward, there has been sensationalist media coverage of the cactus. A wide variety of products have been produced since then.

TRIPS vs. CBD in India

India has enacted two laws to implement TRIPs and the CBD: the Plant Varieties and Farmers' Rights Bill (PVFRB) and the Biological Diversity Act (BDA). The PVFRB is intended to serve as India’s sui generis plant variety protection regime The BDA, on the other hand, would implement the CBD provisions related to access to genetic resources and Art 27.3(b) of TRIPS.

Technology Commercialization

Factors to consider while commercializing:

Overall objectives: is the inventor looking just to fund further research, or to create a new industry particularly for the benefit of your own country, or to build up a capital asset, or simply to disseminate the fruits of your research as broadly as possible?

Financial position: Can the inventor accept the cost and financial risk of investing in patents and other IPRs, and other aspects of commercialization?

Skills and resources available: does the inventor have the capacity to develop and implement a product development and marketing program for a new product? What are the focus and core expertise of your organization?

Regulatory requirements for getting onto the market: does the inventor have access to sufficient expertise and resources to undertake the kind of testing and approval processes that might be required for a new product, such as a new pharmaceutical, a new pesticide or a genetically modified crop?

Factors to consider while commercializing contd.

Options for overseas production or export: does the inventor have the capacity to produce, export and market your invention in major foreign markets?

Nature of the technology: the invention may require access to other IP protected technologies or know-how for it to be produced; and particular manufacturing technologies might be required for it to be made in an economic manner, so that the product is competitively priced.

Strength of the competition: does the inventor's product need to find a place in a crowded market with strong competition, requiring the backing and resources of a major company in the field?

Range of possible uses for your invention: does the inventor have the capacity to put it to work in all the areas it could be used, or do you need partnership with others to make sure your invention achieves its full potential?

TYPES OF TECHNOLOGY TRANSFER

COOPERATIVE RESEARCH AND DEVELOPMENT

Cooperative R&D involves a collaborative effort between a business and one or more research organizations to develop new technology (and, in certain instances, new science as well). Cooperative R&D takes place in four basic arrangements—multi-firm strategic research alliances, university-industry collaborations, nonprofit research institute-industry collaborations, and federal agency or laboratory-industry collaborations.

COOPERATIVE RESEARCH AND DEVELOPMENT

Cooperative R&D at the Houston Advanced Research Center

The Houston Advanced Research Center (HARC) is a nonprofit research institution located outside of Houston, Texas. Examples of cooperative R&D at HARC include:

- The Center for Fuel Cell Research and Applications is carrying out a fuel cell research project with two utility companies, an energy company, and a supplier of engine components and automotive products.
- The DNA Technology Laboratory is working with a biotechnology firm to develop a DNA chip to detect the presence of alterations in genes.
- The Industry Affiliates Program houses small- and medium-size enterprises in an on-site incubator and provides access to HARC researchers for contract R&D.

TYPES OF TECHNOLOGY TRANSFER

STRATEGIC RESEARCH ALLIANCES

The reasons that firms work with corporate research partners include:

- the greater complexity of technology;
- cost of technology development;
- increased competitive pressure for new products;
- more willingness to use technical expertise outside the firm; and
- improvements in communications technology that facilitate collaboration.

In many situations, a strategic alliance may be a prelude, that is, a sort of a trial phase before committing, to a longer-term relationship of a joint venture or an eventual merger or acquisition. In each of these situations, however, both sides to safeguard their respective interests must adequately address the intellectual property issues.

Types of Strategic research alliances

JOINT VENTURES

- It is a form of alliance of two separate companies.
- where the separate companies agree to act together, typically forming a separate legal entity,
- for a particular purpose.

The exact form of the joint venture, in other words the type of legal entity that it is, depends on the wishes of the parties to the joint venture and on national law.

Types of Strategic research alliances

CONTRACT R&D

Purchase of R&D services by one firm from another. The number of contract research organisations (CRO) is in a rise throughout the world, particularly in the biomedical field.

With CRO's one has:

- Innovations being carried out
- Problem solving
- Additional capacity
- Technology diversification
- Business intelligence

CRO

REASONS FOR INCREASE OF CROS

- Efficiency
- Competency
- Technology diversification
- Product life cycle reduced
- Insufficient competence of company purchasing technology in that specific field
- Market competition

WHY CROs PREFERRED IN BIOTECH/PHARMA INDUSTRIES?

- Cost effective
- Source of quality expertise
- If a foreign company is the purchaser: CROs have the local knowledge and skill
- Reduce development time of products

Example of Outsourcing

Outsourcing at Biogen

In 1996, Biogen received permission from the Food and Drug Administration to manufacture Avonex, a drug for treating multiple sclerosis. The firm examined four core tasks of drug production—bulk manufacturing, formulation (freeze-drying and storing the drug), packaging, and warehousing/distribution. Biogen decided it could handle bulk manufacturing at its facility in Cambridge, Massachusetts, but decided to contract out all other services:

- Formulation was handled by a biomedical contract manufacturer in Bedford, Ohio.
- Packaging was given to a small firm in Philadelphia, Pennsylvania.
- Warehousing and distribution was turned over to Amgen, with a distribution facility in Louisville, Kentucky.

MODES OF TECHNOLOGY TRANSFER

ASSIGNMENT

- It is the sale by the owner (assignor) of all his or its exclusive rights in a patented invention and the purchase of those rights by another person or legal entity(assignee).
- When all the exclusive rights to a patented invention are transferred, without any restriction in time or other condition, by the owner of the patented invention to another person or legal entity.
- Concept of assignment is recognized in the laws of many countries.

MODES OF TECHNOLOGY TRANSFER

LICENSING

- the permission by the owner(licensor) of a patented invention to another person or legal entity(licensee) to perform: in the country and for the duration of the patent rights, one or more of the acts(making, using or selling) which are covered by the exclusive rights to the patented invention in that country.
- the legal document prepared usually referred to as a “license contract” or, more simply yet, as a “license.”
- the license is usually granted subject to certain conditions

In biotechnology, invention may be related to

-living entity of natural origin, such as animal, plant, human beings including parts thereof,

-living entity of artificial origin, such as micro-organism, vaccines, transgenic animals and plants etc.,

-biological materials such as DNA, Plasmids, genes, vector, tissues, cells, replicons etc.,

-process relating to living entities, process relating to biological material,

-methods of treatment of human or animal body, biological process or essentially biological process.

NOT ALL BIOTECHNOLOGICAL INVENTIONS ARE PATENTABLE

•The **living entities of natural origin** such as animals, plants, in whole or any parts thereof, plant varieties, seeds, species, **are not patentable**.

•Any **process of manufacture or production** relating to such living entities is also **not patentable**.

•**Essentially biological processes** for the production of plants and animals such as method of crossing or breeding etc. are **not patentable**.

•The living entity of **artificial origin** such as microorganism, vaccines are considered **patentable**.

•The biological material such as **recombinant DNA, Plasmids and processes of manufacturing thereof** are **patentable** provided they are produced by substantive human intervention.

•**Gene sequences, DNA sequences** without having disclosed their functions are **not patentable** for lack of inventive step and industrial application.

•The processes relating to micro-organisms or producing chemical substances using such micro-organisms are **patentable**.

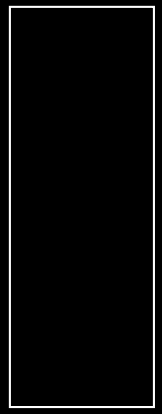
GENENTECH INC. VS. WELLCOME FOUNDATION LTD. 31 USPQ 2d1161 (FED. CIR.) 1994

GENENTECH CLAIM: Covered natural sequences and naturally occurring variants of tissue plasminogen activator (tPA) used as a drug for dissolving blood clots.

WELLCOME : Developed modified tPA named FEIX with 15% lesser amino acids than the natural one and minor variants.

It stayed active in blood for ten times longer than the natural one

GENENTECH

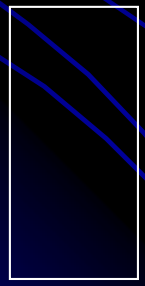


Active for

X hours

Amino acids in tPA is equal to natural

WELLCOME



Active for

10 X hours

Amino acids in tPA is 15% less than natural

DISTRICT COURT: They are equivalent. In other words Wellcome's FEIX was obvious vis-à-vis the Genentech's claim

APPEAL

There was no motivation from Genentech that if amino acids could be reduced by certain percentage it would prolong the effect of the protein and thus give a better result in usage.

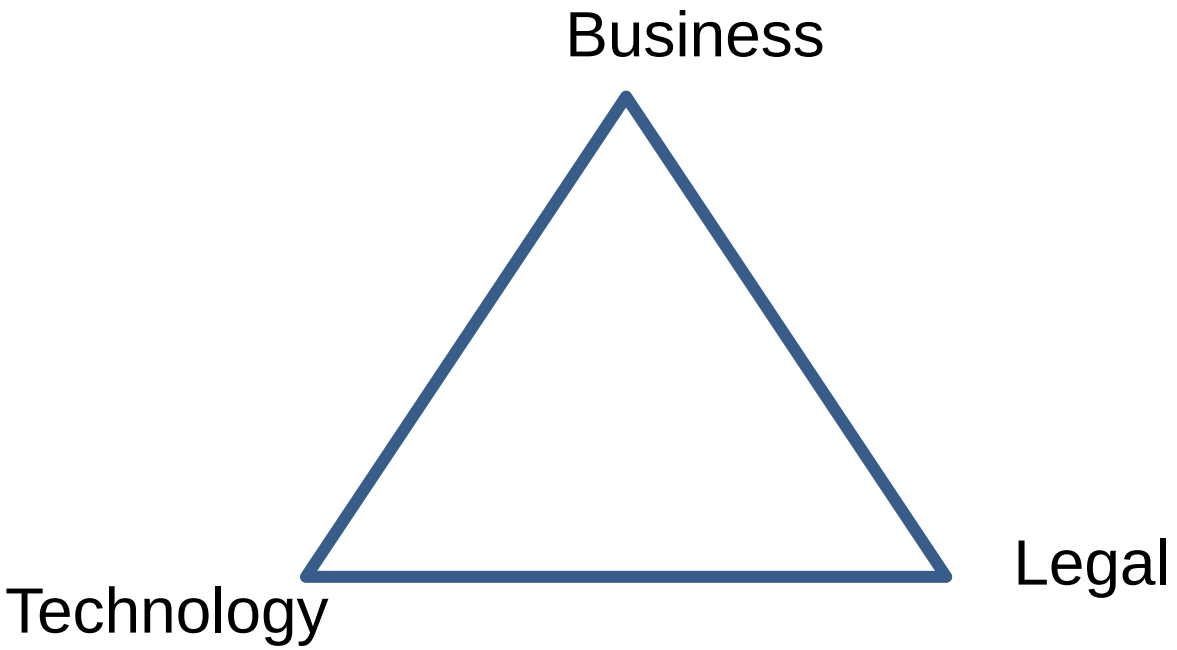
Thus FEIX did not function in the same way as natural Tpa/Genentech's tPA

HELD: FEIX not obvious vis-à-vis Genentech's claim

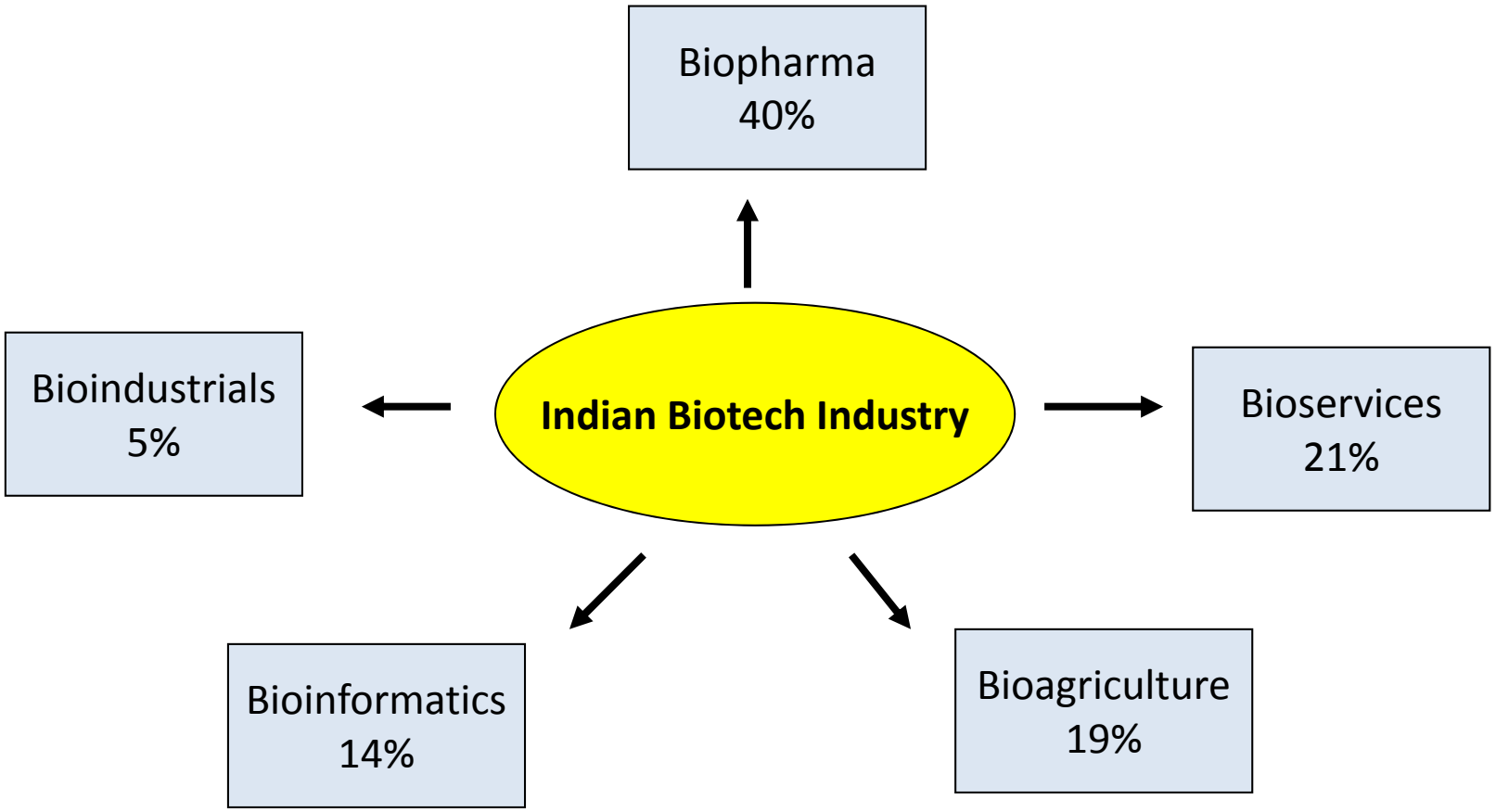
Strategies for Effective IP Management

Dr. M.Padmavati
Associate Professor
Rajiv Gandhi School of
Intellectual Property Law
IIT Kharagpur
INDIA

IP Management



New technology sectors in Biotechnology Industry in India



Biopharma

- Vaccines
  - Largest producer of recombinant Hep B vaccine in the world today
  - Strength in vaccine development and manufacturing
  - *Combination vaccine development*
- Therapeutics
  - 1/4th of the 50 global recombinant therapeutic products now made in India
  - Strength in over 7 recombinant therapeutics
  - *Active lead and presence in global biogenerics*
  - *Contract manufacturing for global biopharma farms*
- Diagnostics
  - Diagnostic kit development
  - National Biotech Strategy Draft – emphasis on strengthening diagnostic capabilities

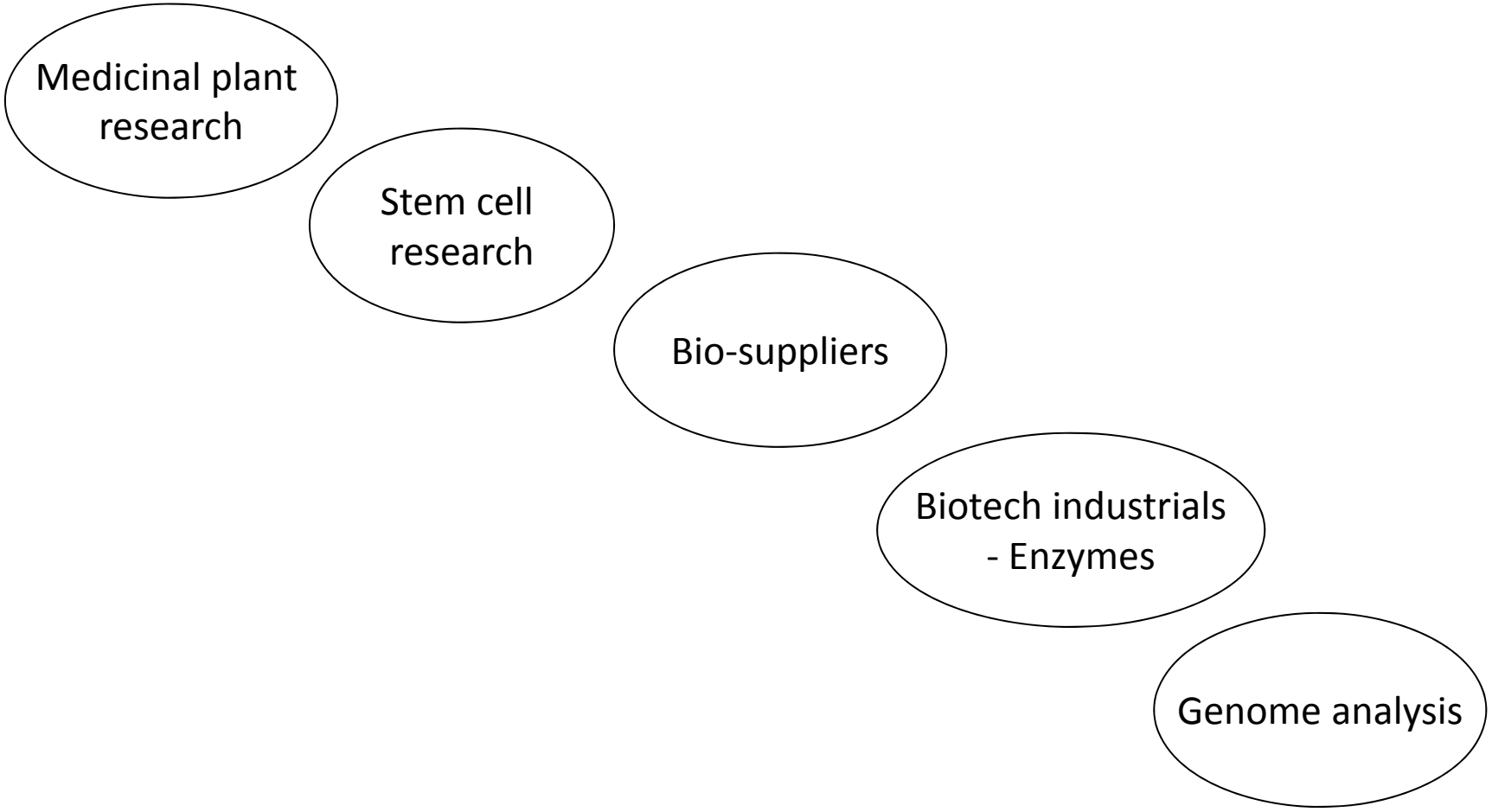
Bioservices

- Clinical Trials
- Contract R & D
- Contract manufacturing

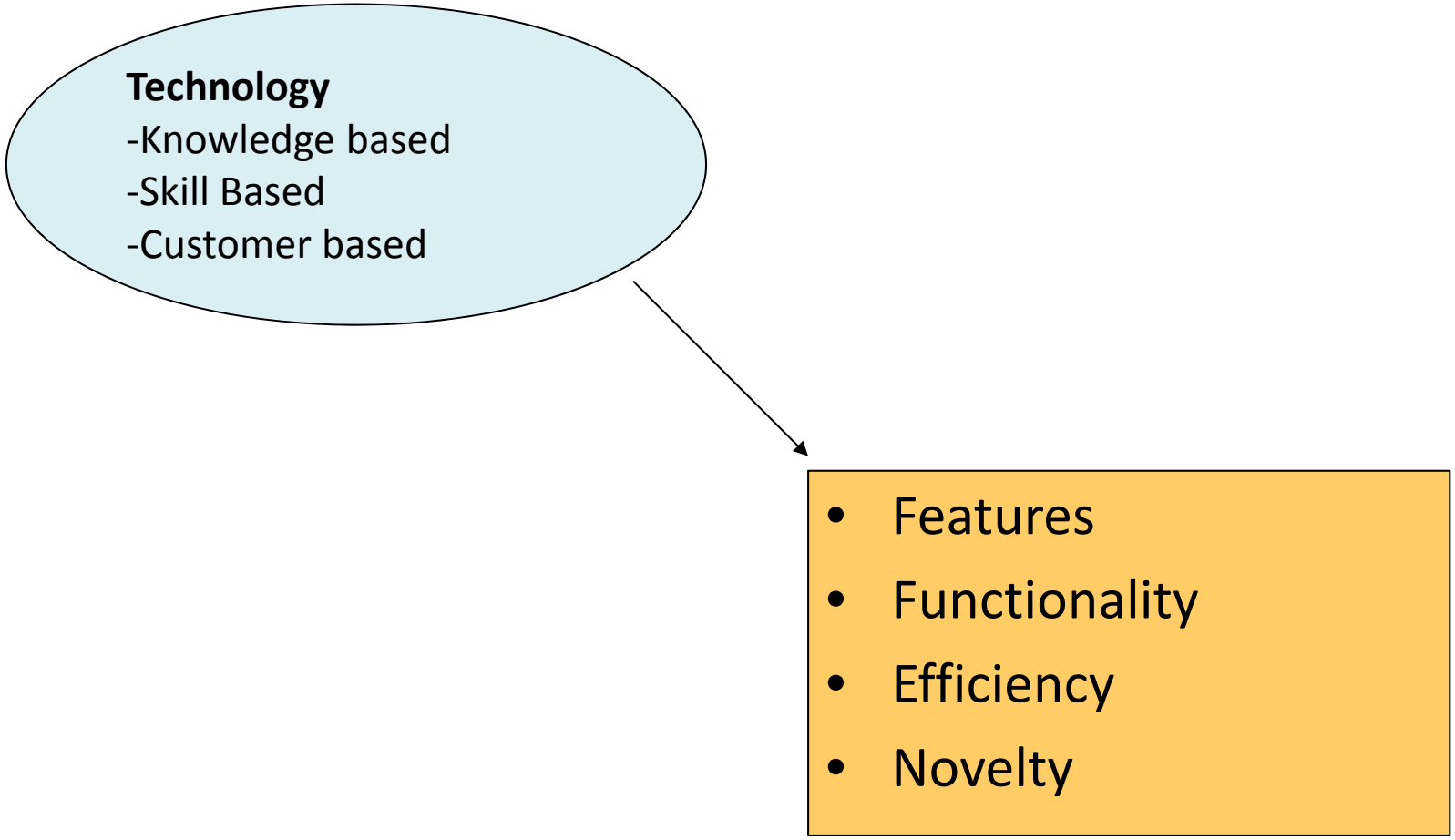
Agri-biotech

- Genetically engineered crops
- Biofertilisers, biopesticides
- Bio-diesel
    - National Mission Biodiesel programme
        - Draft biodiesel policies

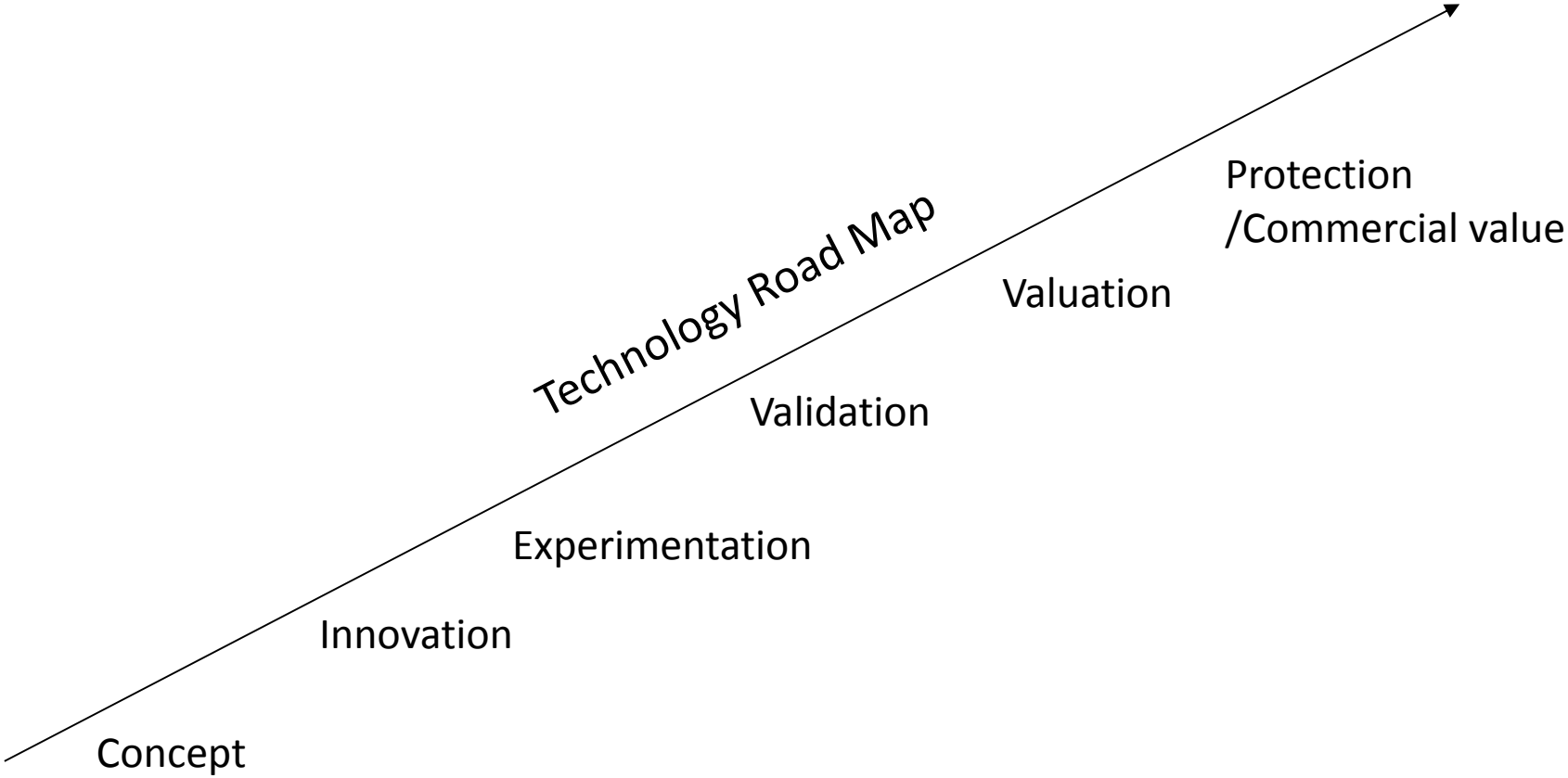
Innovations ahead in biotech - for global commercialisation



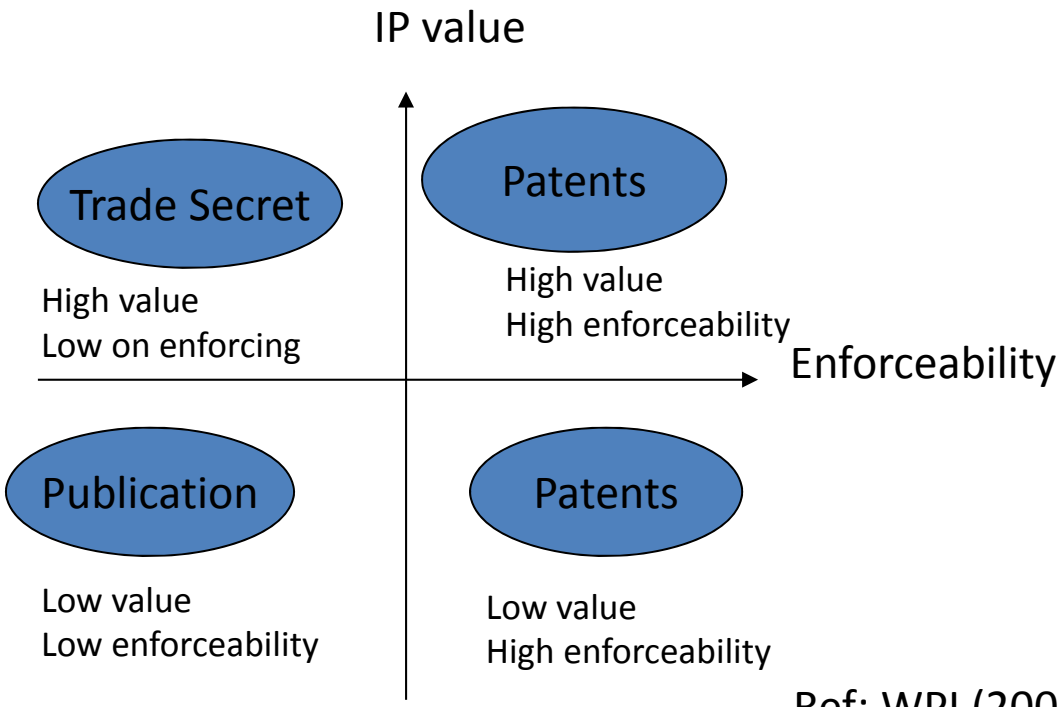
Understanding Technology



Elements of Technology



IP value index:



Ref: WPI (2004) 26: 149-156

Developing a policy- Patents

- ✓ Sector wise
- ✓ Institute wise
- ✓ Invention wise

Valuation of IP
Management of IP
Commercialisation of IP

Identify Issues that predominate
Today and Future

Guidelines and Policies

- ➢ Institutional policies
- ➢ National policy
- ➢ International Policies
- - Procedures
- - Players

The objective of Patent Law is to balance private rewards and public dissemination of knowledge

IP portfolio creation strategy both in global & local context

- Different organisational arrangements are suited to different types of competitive environments and differing type of innovations

- **Organisational archetypes and innovations:**

- Individual Inventor and laboratories alone
  - Inventor specific,
  - Difficulties for individual inventor-entrepreneurs
  - Protection of invention against imitation
  - In a weak IP regime, decreased value of capturing value for inventions
  - Individual inventor options – license, use IP as collateral for raising funds, exchange patent for equity in new venture funded firm, exchanging IP for cash or equity

Understanding the ‘Invention’ process

- Innovation to invention process – Concept mapping, working hypothesis/objectives, design and development and time lines
- Difference between academic and corporate innovations
  - Corporate perspective of generating revenue
  - Academic perspective of advancement of research
- Idea to implementation
  - Experimental design and plan
  - Explanation of results as per the state of technology
  - Substantiation of results as per the state of technology
  - Clear description of the utilities of the improved process/product

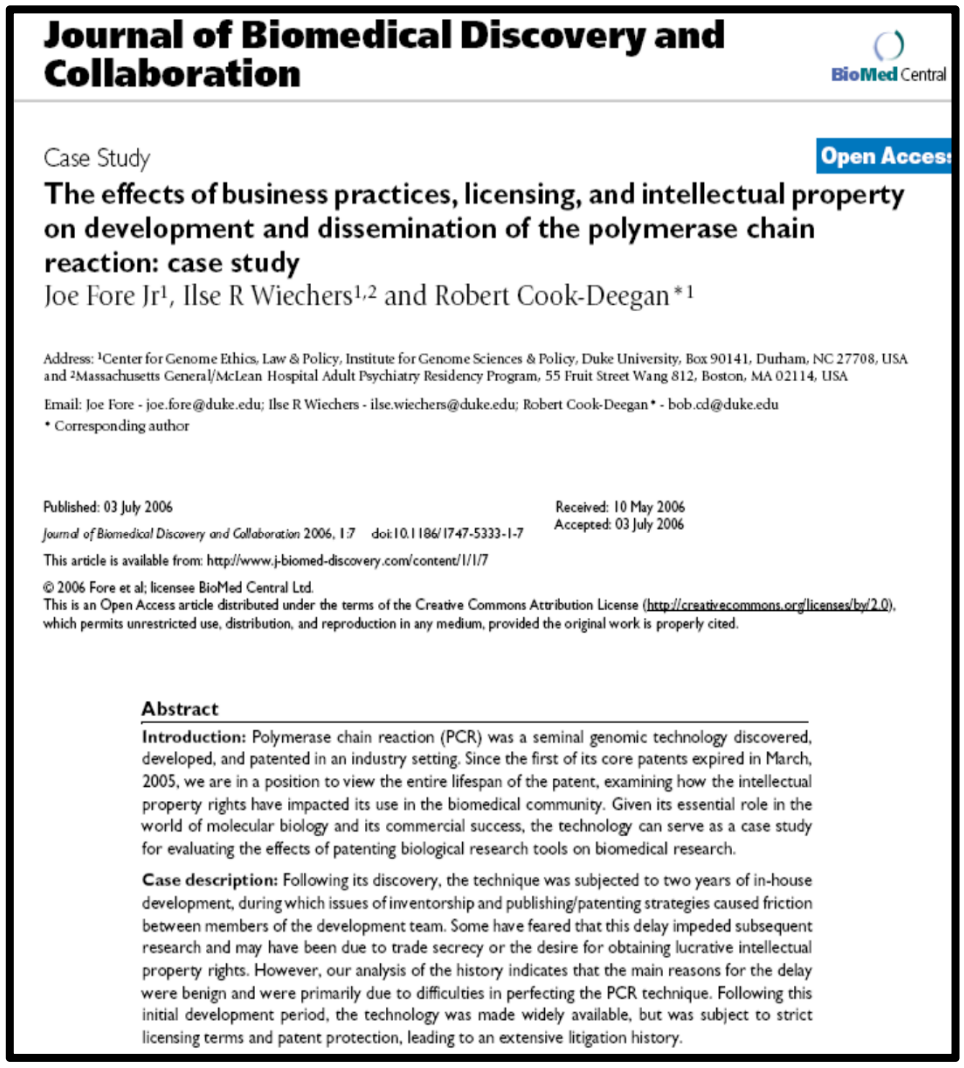
  (cost effective, less time taking, delivery system, ease of use, new product etc.,)

- Validation – substantiation of results, statistical validity, trial data
- Record keeping – Accurate record note book keeping is key to research in academic as well corporate sectors

Invention disclosure management

- Institutional/Corporate guidelines for writing an effective invention disclosure statement
- Necessary to be IP compliant
- Peer review kind of process to screen out inventions that are non-patentable
  - Communication process of rejection of an invention is quite challenging
- Identification of the alternatives to improve the invention

Research ----- technology development– commercialisation and IP



Journal of Biomedical Discovery and Collaboration

BioMed Central

Case Study

Open Access

The effects of business practices, licensing, and intellectual property on development and dissemination of the polymerase chain reaction: case study

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Abstract

Introduction: Polymerase chain reaction (PCR) was a seminal genomic technology discovered, developed, and patented in an industry setting. Since the first of its core patents expired in March, 2005, we are in a position to view the entire lifespan of the patent, examining how the intellectual property rights have impacted its use in the biomedical community. Given its essential role in the world of molecular biology and its commercial success, the technology can serve as a case study for evaluating the effects of patenting biological research tools on biomedical research.

Case description: Following its discovery, the technique was subjected to two years of in-house development, during which issues of inventorship and publishing/patenting strategies caused friction between members of the development team. Some have feared that this delay impeded subsequent research and may have been due to trade secrecy or the desire for obtaining lucrative intellectual property rights. However, our analysis of the history indicates that the main reasons for the delay were benign and were primarily due to difficulties in perfecting the PCR technique. Following this initial development period, the technology was made widely available, but was subject to strict licensing terms and patent protection, leading to an extensive litigation history.

- Discovery and development of R and D in PCR technology
-Development and dissemination of PCR
- Commercialisation and intellectual property challenges
-Improvement in PCR technology
- Business strategies

-Conception of PCR by Karry Mullis - 1983
-First process patents filed in 1985

Journal of Biomedical discovery and collaboration (2006) 1: 1-17

Date	Event description
May 1983	"Eureka" moment, Kary Mullis first conceives of PCR concept.
August 1983	Mullis presents PCR idea at Cetus in house seminar; reaction is unenthusiastic.
8 September 1983	Mullis performs first PCR experiment "PCR01." He sees only a "great smear" on the gel.
16 December 1983	According to Mullis, first successful amplification achieved.
June 1984	Mullis presents poster at annual Cetus scientific retreat.
Summer 1984	"PCR group" is formed and charged with the task of developing PCR as a diagnostic tool.
15 November 1984	First "knock out" experimental data. Lab technician Stephen Scharf writes in his notebook: "IT WORKS."
Spring 1985	PCR group achieves "reliable and quantifiable data". Norman Arnheim, Tom White and others take road trips to Kodak, SmithKline, etc. to present diagnostics potential of PCR
28 March 1985	First PCR process patents filed with USPTO.
September 1985	PCR "applications" paper is submitted to *Science*.
October 1985	Randy Saiki presents PCR's applications in diagnostics at the meeting of the American Society for Human Genetics.
December 1985	Cetus enters joint venture with Perkins-Elmer to develop diagnostics instruments for use with PCR. Mullis' "theory" paper is rejected by *Nature*.
20 December 1985	PCR "applications" paper, with Randy Saiki as first author, appears in *Science*.
4 February 1986	Cetus enters into agreement with Kodak to develop *in vitro* PCR diagnostics.
May 1986	Mullis presents PCR at Cold Spring Harbor Symposium; receives a standing ovation for his talk.
28 July 1987	Patent #4 683 202 "Process for Amplifying Nucleic Acid Sequences" and #4 683 195 "Process for Amplifying, Detecting, and/or Cloning Nucleic Acid Sequences" issued to Cetus.

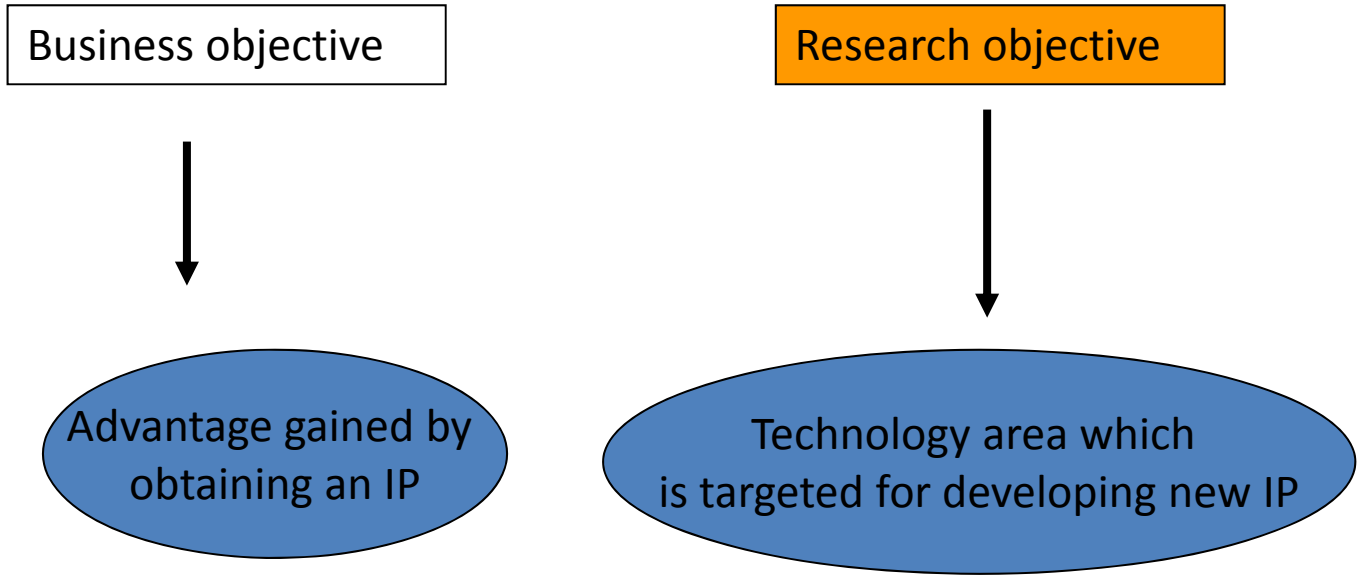
Figure 1
Timeline of key events in the early development of PCR.

Patent strategies

- From the corporate perspective: Patent strategy for a product line is the science and art of employing the business, technical, and legal resources of a company to afford the maximum support to adopted policies with and without competition.
- Patent strategy for a technology area is the science and art of managing research to meet competitors in the marketplace under advantageous conditions

Developing a patent strategy

- **Objective**:



- **Offensive**: Method of acquiring IP
  - Develop IP: control over developed information as well as developer can decide when and how to apply it
  - Develop it jointly with researchers from another group: Expertise to do the technical development not available in house, contracting the work, joint ownership of IP, control of technology reduced
  - Buy IP: Licensing is the most common method of obtaining IP

- **Competitive advantage**: key to a patent strategy
  - Advantage may be a particular method of making a piece of equipment or it may be a technique used in manufacturing process or may be the manufacturing process itself
  - By considering competitive advantage one determines whether or not the objective will be achieved in a manner that will have lasting value

The light bulb is associated with Thomas Edison because he was the first to be commercially successful. He designed not only the bulb, but also the distribution system and the electrical dynamos to produce electricity

- **Unity of command**: How will decisions be made
- Making decision on whether on not to file patent application
- Inventor is too close to his invention to be able to make an independent decision
- Research managers can be decision makers as they understand both the business and technical impact of an invention

- **Generating the mass**
- Focus on the efforts on building resources to accomplish the task
- Requisite amount of money, manpower and equipment needed
- Once a key finding is made, for patent purpose it is best to experiment throughout the entire operating range of the invention and investigate many different embodiments of the invention

Alexander Graham Bell was trying to develop a better telegraph when he came across the technology which became the telephone

- **Economy of force**
- Response to competitive patents
- Technology review to know analyse if any patents might restrict future manufacturing or those patents that may impact a future market area
- **Maneuver**
- Most researchers recognise the need to be up to date in their areas of technology
- Researchers require to review prior art in the area of technology to avoid duplicating others work
- Technology forecasting
- **Coordinating patent filings**
- Where to file and how to file a patent application
- An understanding needed on will business concentrate on the local area or whether it will branch out into other countries

- **Security**
- How to protect proprietary information and rights to intellectual property protection are not compromised.
- Maintaining confidentiality and avoiding unwanted disclosure
- Important to have legal advice available during the development of technology to help prepare written agreements
- **Changing the strategy**
- Current strategies to be reviewed
- Many things can happen for the patent application during both the preparation and prosecution of the application

How to develop a patent strategy for an invention

- What is an invention
- What is to be achieved by filing the patent application
- What additional information is required for the patent application
- How much additional information must be disclosed in the application
- When must the patent application be filed
- Who is going to develop the information for the patent application
- Who is going to help you prepare the application
- How broadly can/should the invention be claimed
- Where is patent protection wanted

Characteristics of researchers who are prolific inventors

- No hard and fast requirements of being a profilic inventor but they are usually the ‘independent tinkerers’
- Synthesising concepts
- Getting ideas; ability to see the problem in prior technology
- Understand the fundamentals behind the invention
- Can do attitude about invention
- Hands-on inventors
- Not highly respected by their peers!

- **Documentation**: Its good research practice!
- Document both successful and unsuccessful results: both have value for a patent application
- Unexpected results or unexplained results also need to be mentioned
- Every researcher should document his work – important for proof that they are the true inventors for the patent application

Patent Strategy

- Technology Space

1. Adhoc blocking and inventing around
   - One or few patents for protection
   - R & D costs and time for inventing are low
   - Inventing around possibilities many

2. Strategic patent searching
   - Single patent with large blocking power
   - Invent around costs are very high

3. Blanketing (or flooding)
   - Given area covered by scores of patents
   - Characteristic of emerging technologies where R & D growth is uncertain with respect to economic scope
   - Includes typically all major and minor inventions

4. Fencing

   - For a similar functional result a range of technology solutions

   - Series of patents block a certain line of R & D (chemical subprocesses, molecular design, operating conditions such as temperature, pressure, medium conditions

5. Surrounding

- central patent followed by individually less important patents (applications of the same inventions)

- effective commercial use of patent even after expiration

6. Combination

– Patents of various kinds and configurations to strengthen overall protection and bargaining power

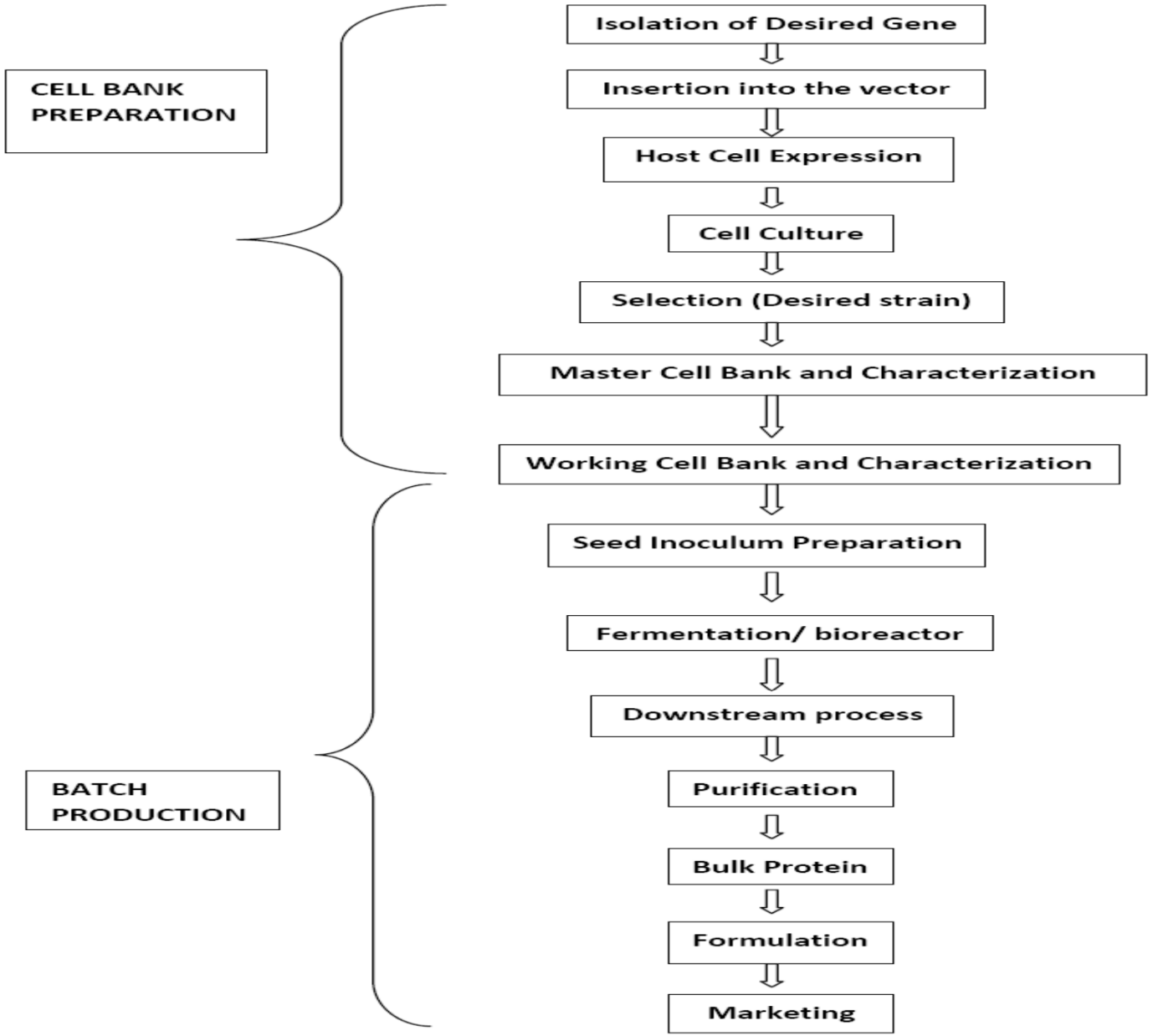
- Product life cycle
  - Sporadic patenting: few patents at key steps in R & D process
  - Part of business development process
  - Continuous or follow up patenting, patent portfolio for business in question
  - Reflects R & D work at different PLC stages
- Technology life cycle
  - 'Old' technology
  - New technology
  - Hybrid type

Recombinant drugs marketed in India

Drug name	Companies (and Brand names of the drug)
Hepatitis B vaccine	Biological E (Bevac) Indian Immunologicals (Elovac- B) Serum Institute of India Ltd (Gene Vac-B) Wockhardt (Biovac-B) Panacea Biotec (Evinac HB) Scigen Biopharma (SciTojet2™) Shantha Biotechnics (Shanvac-B) Bharat Biotech (Revac-B)
Granulocyte Colony Stimulating Factor	Dr Reddy's (Grafeel) Zenotech (Nugraf, Macrogen) Emcure (Emgrast) Intas Pharma (NEUPEG, Pegex™) Reliance Life Sciences (ReliGrast™) Ranbaxy (Xphil) Biocon (NUFIL™)
Erythropoietin	Ranbaxy (Ceriton) Biocon (Erypro) Emcure (Epofer) Wockhardt (Wepox) Intas Pharma (Epofit and Erykine) Reliance Life Sciences (ReliPoietin) Shantha Biotechnics (Shanpoietin)

Contd.

Human growth hormone	Serum Institute of India Ltd. (Saizen) Bharat Biotech (RegenD)
Interferons Interferon beta 1a Interferon alpha 2b Interferon alpha 2b Interferon alpha 2b	 Piramal Healthcare Ltd (Avonex) Glenmark (Markferon) Reliance Life Sciences (ReliFeron) Shantha Biotechnics (Shanferon)
Insulin	Biocon (Insugen) Wockhardt (Wosulin)
Monoclonal antibody Anti-EGFR Anti-CD20	 Biocon (BioMAB-EGFR) (nimotuzumab) Dr Reddy's (Reditux) (rituximab biosimilar)
Streptokinase	Cadila Pharmaceuticals (STPase) Bharat Biotech (Indikinase) Shantha Biotechnics (Shankinase)
Interleukin	Zenotech (Recil)
Follicle Stimulating Hormone (FSH)	Serum Institute of India Ltd (Gonal F) Bharat Serum and Vaccines (Foligraf ™)


CELL BANK PREPARATION
BATCH PRODUCTION
Isolation of Desired Gene
Insertion into the vector
Host Cell Expression
Cell Culture
Selection (Desired strain)
Master Cell Bank and Characterization
Working Cell Bank and Characterization
Seed Inoculum Preparation
Fermentation/ bioreactor
Downstream process
Purification
Bulk Protein
Formulation
Marketing

Identify patenting trends for recombinant drugs in India.

Methodology

- PCT applications
- Indian applications and granted patent
- US and EU applications and granted patents by Indian applicant/assignee

Databases used

- Subscribed Database: QPat version-7.1
- Other sources:
  - www.ipindia.nic.in and gazettes published
  - www.uspto.gov
  - www.ep.espacenet.com
  - http://www.wipo.int/pctdb/en/index.jsp

Duration

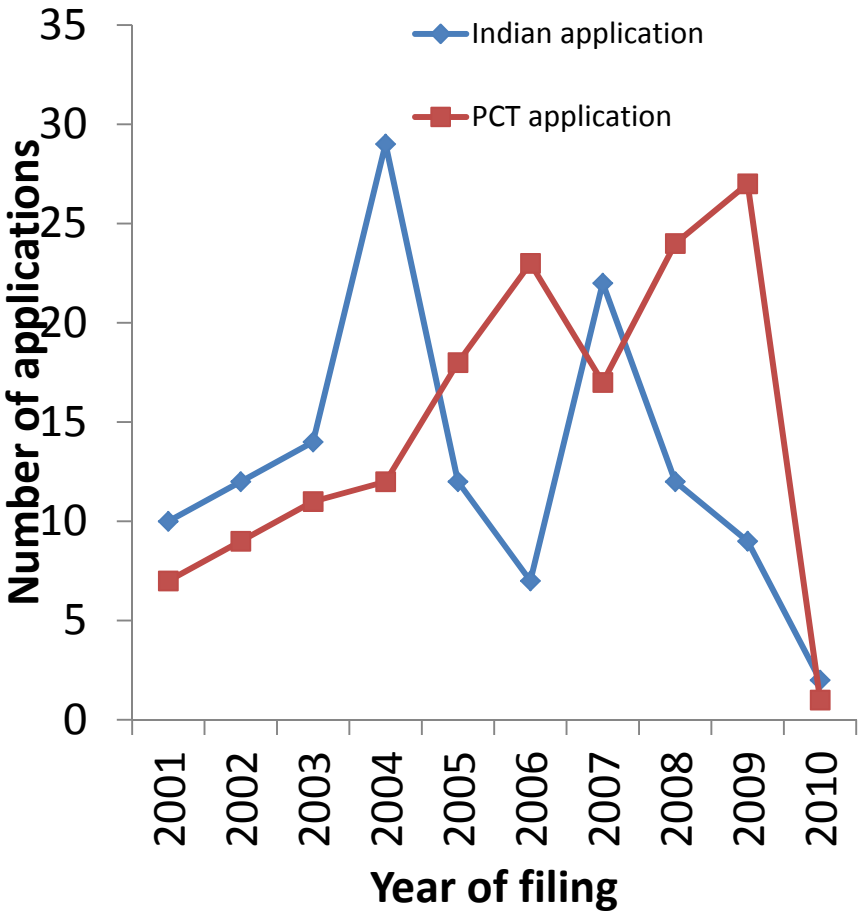
- Applications: For last 10 years
- Granted patents

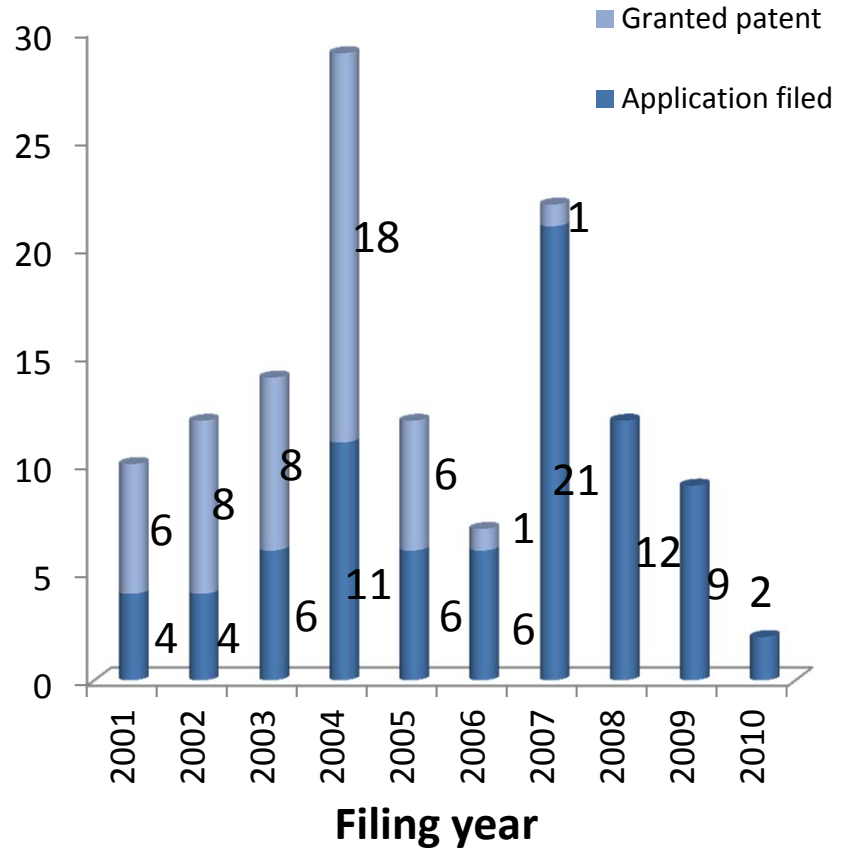
Search Strategy

- Identification of keywords and synthesis of search strings
- Title, abstract, independent claim search
- Patents related to human use in a specific disorder/disease
- Collation of data

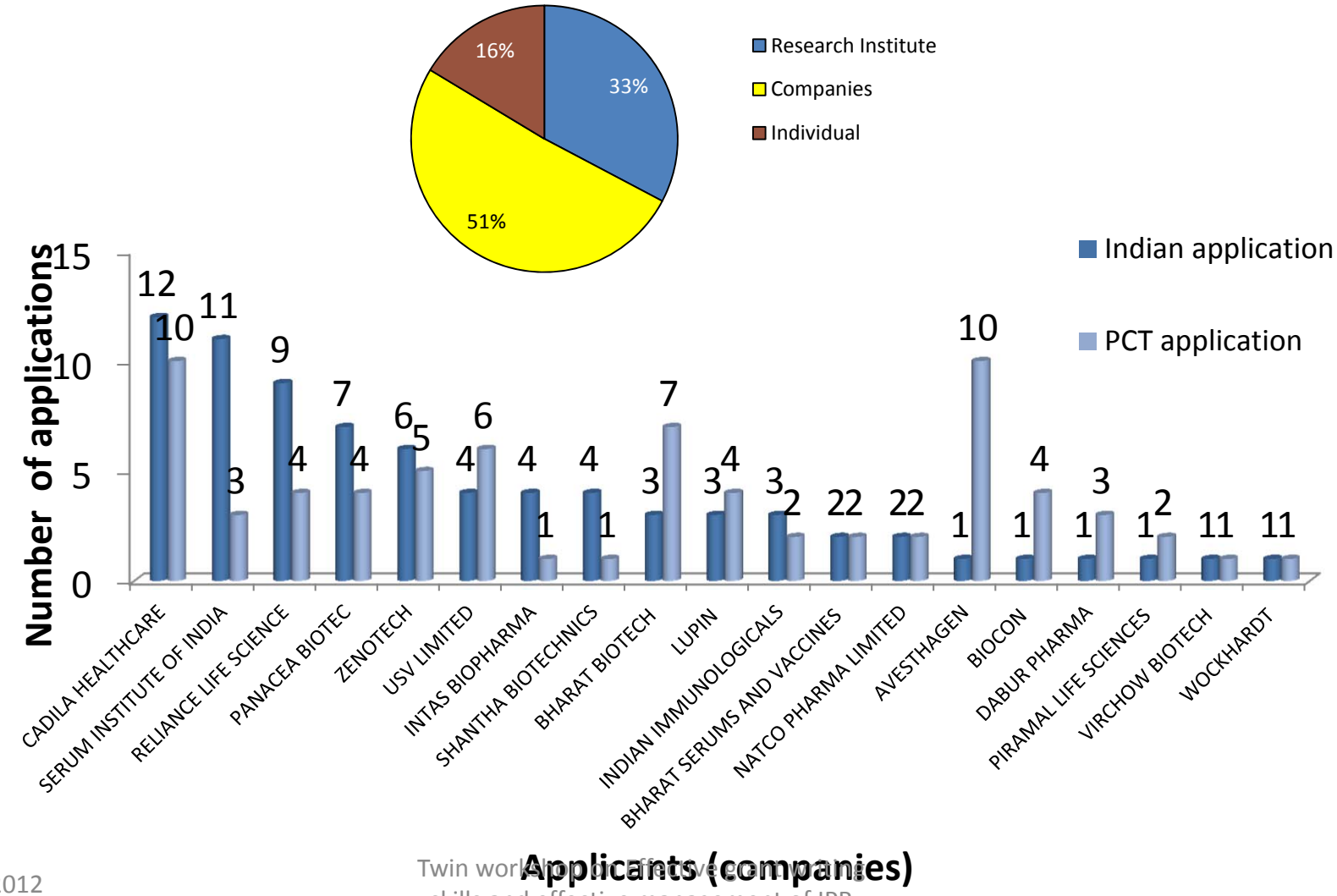
- **Analysis**
  - Year wise
  - Assignee/applicant wise
  - Major areas/molecule wise
- **Landscape study**
  - Identification of current trends in patenting
  - Evolution of technologies
  - Patenting focus of in India
  - Future trends in patenting

Year wise distribution of applications in recombinant drugs

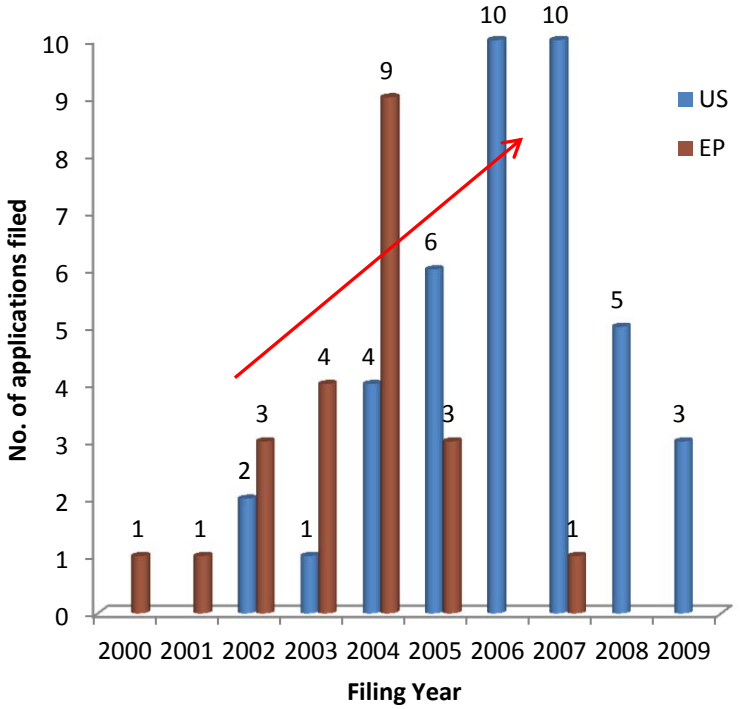


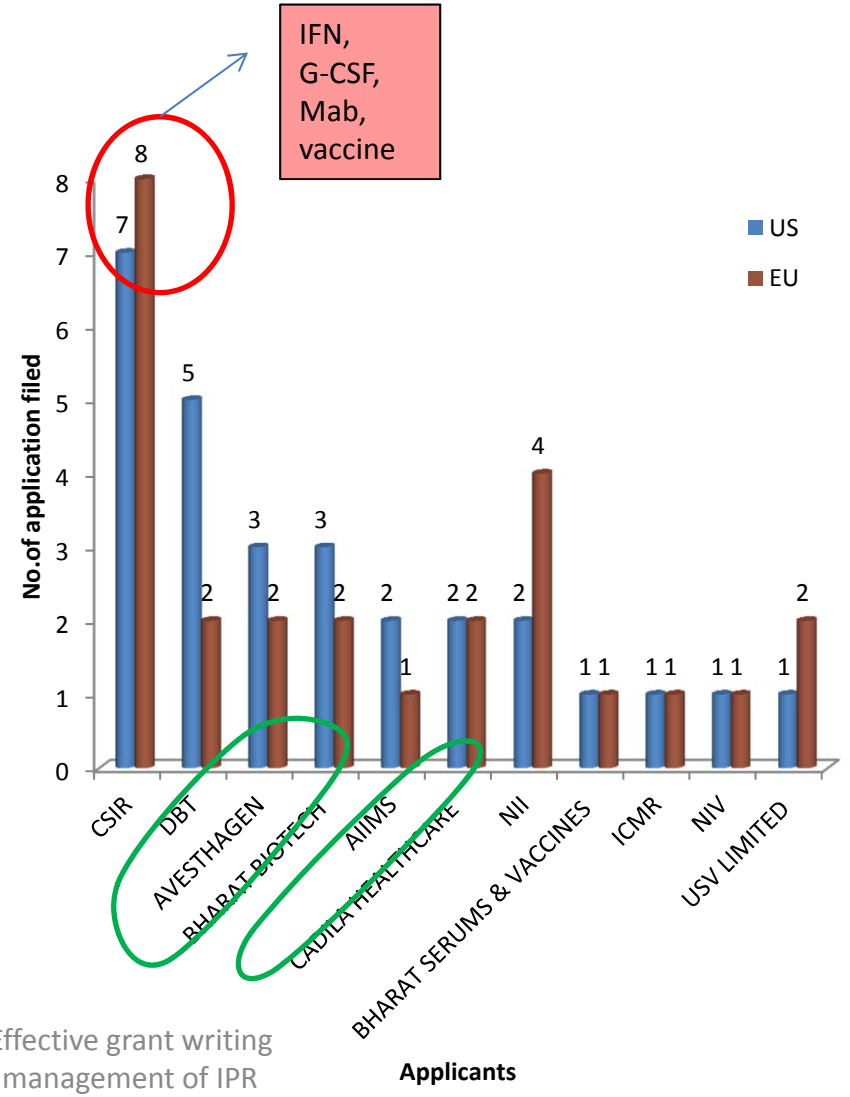


Distribution of Indian and PCT applications among research organization/institute(s)

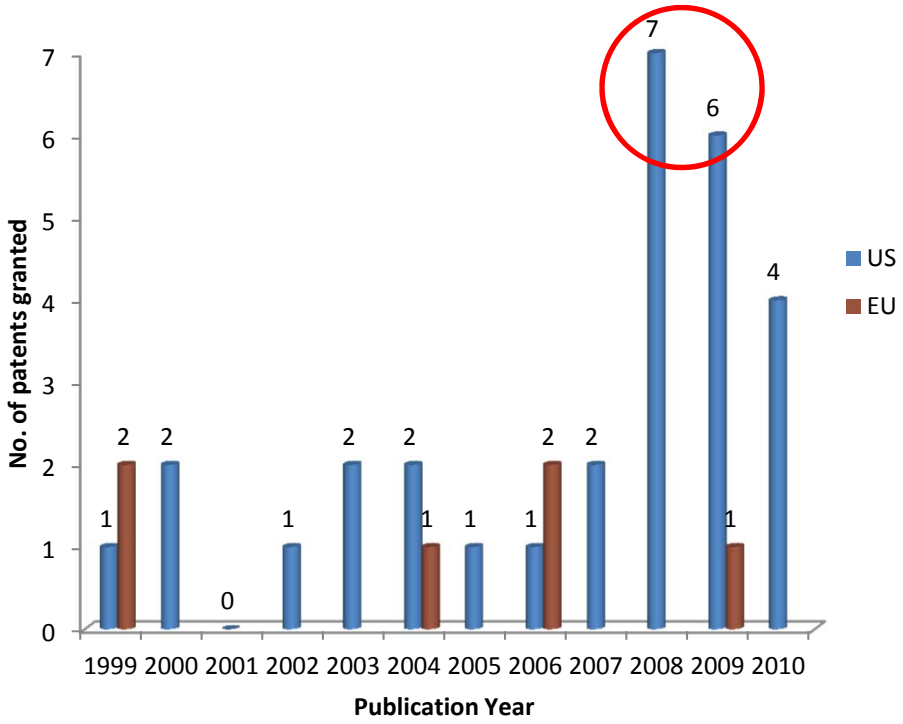


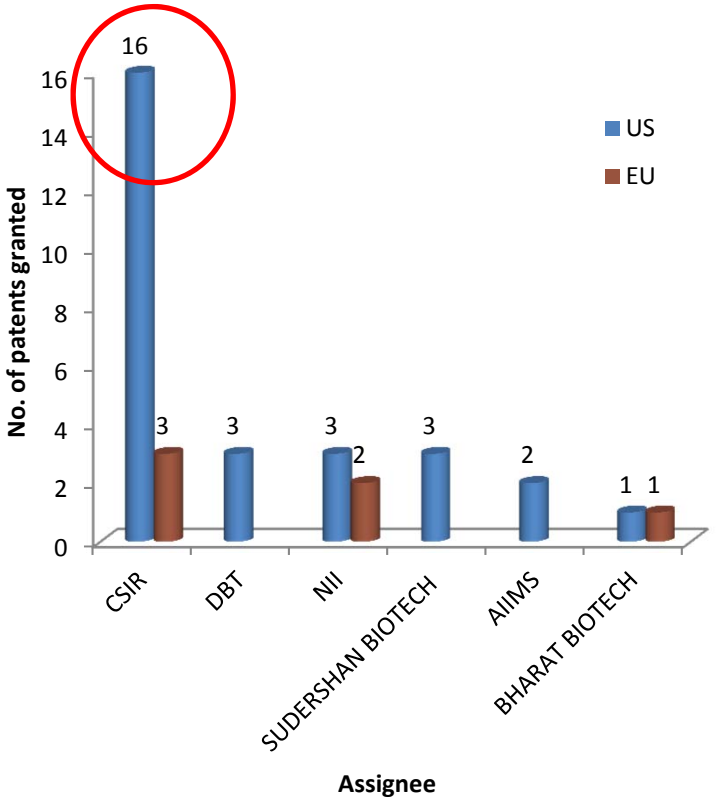
Patent Application Distribution in US and EU



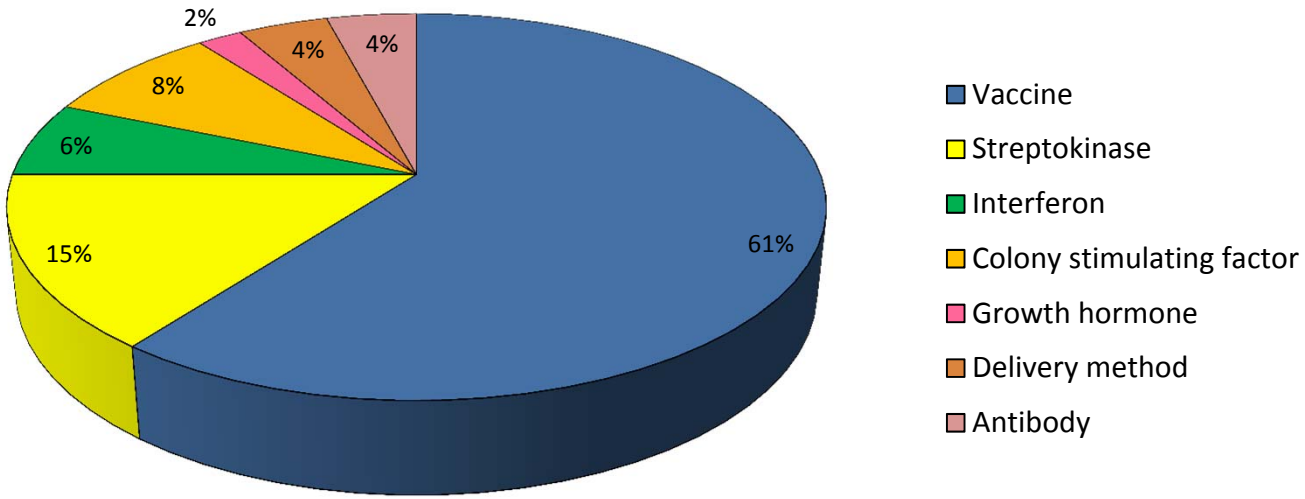


Granted Patent Distribution in US and EU

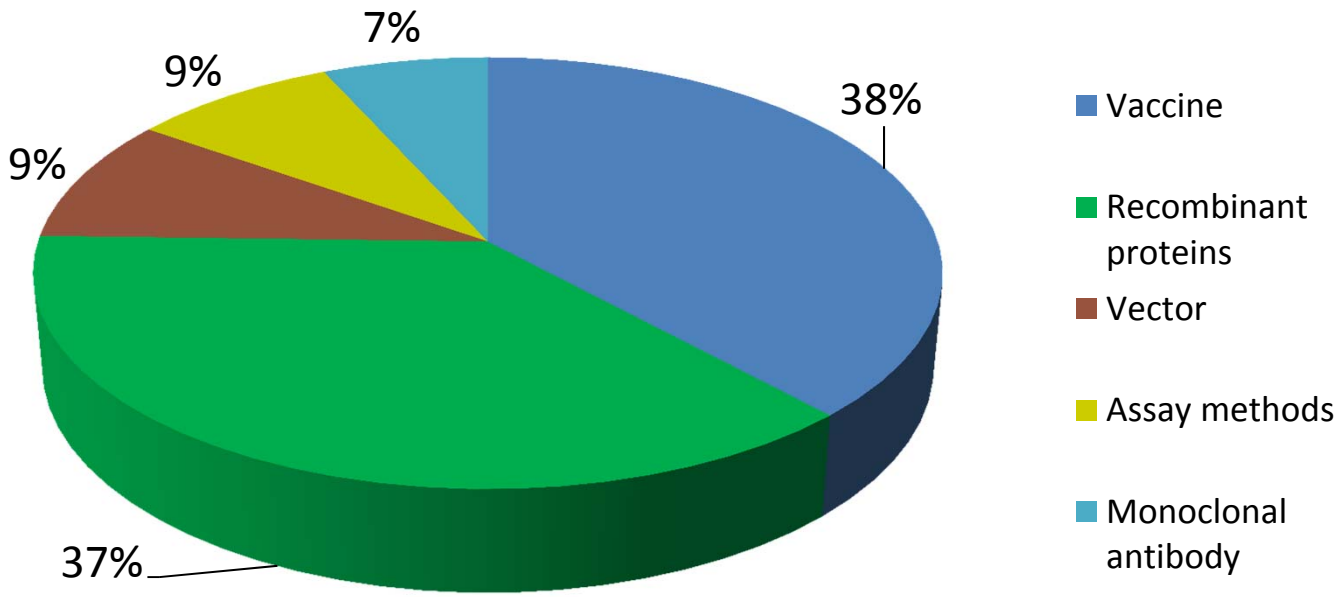




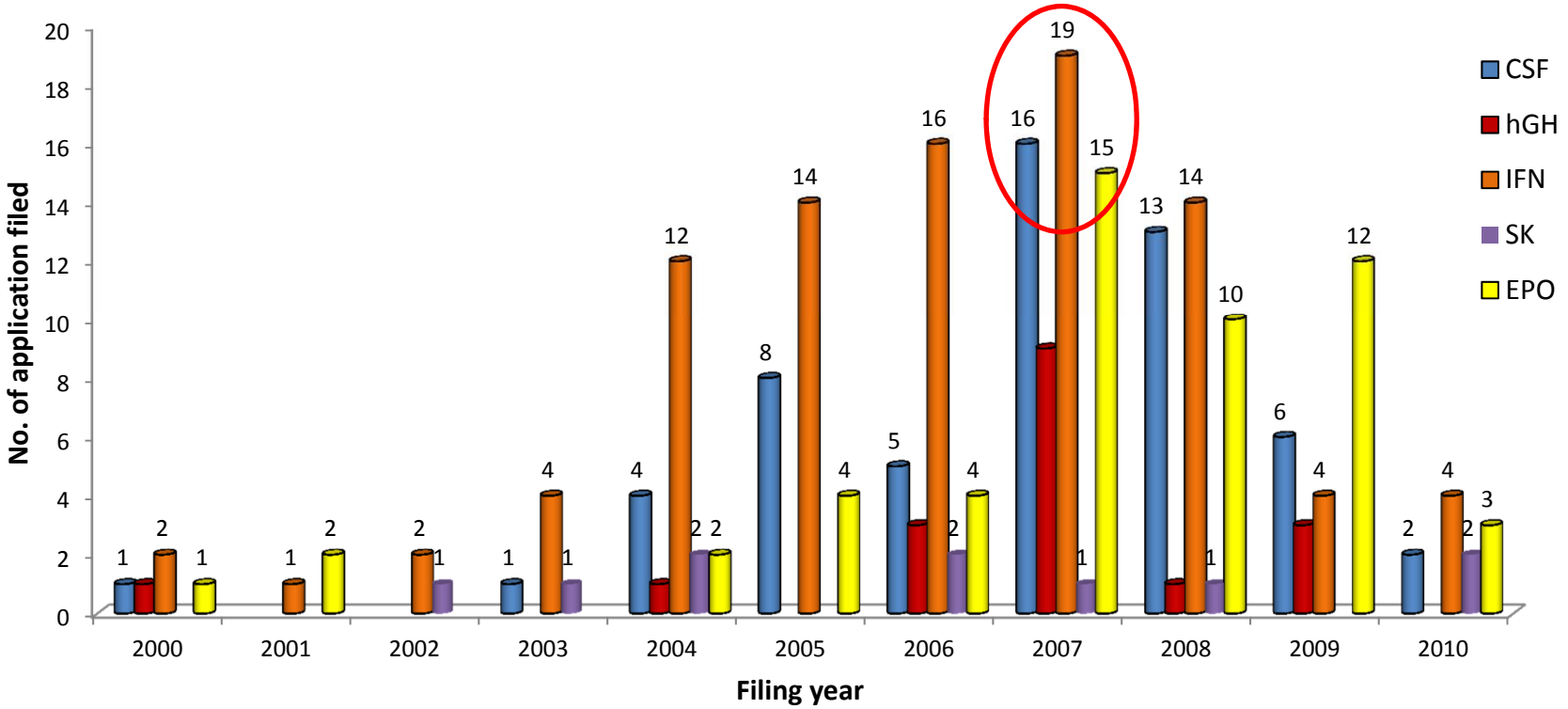
Area wise distribution of Indian granted patents



Major claimed areas in PCT applications



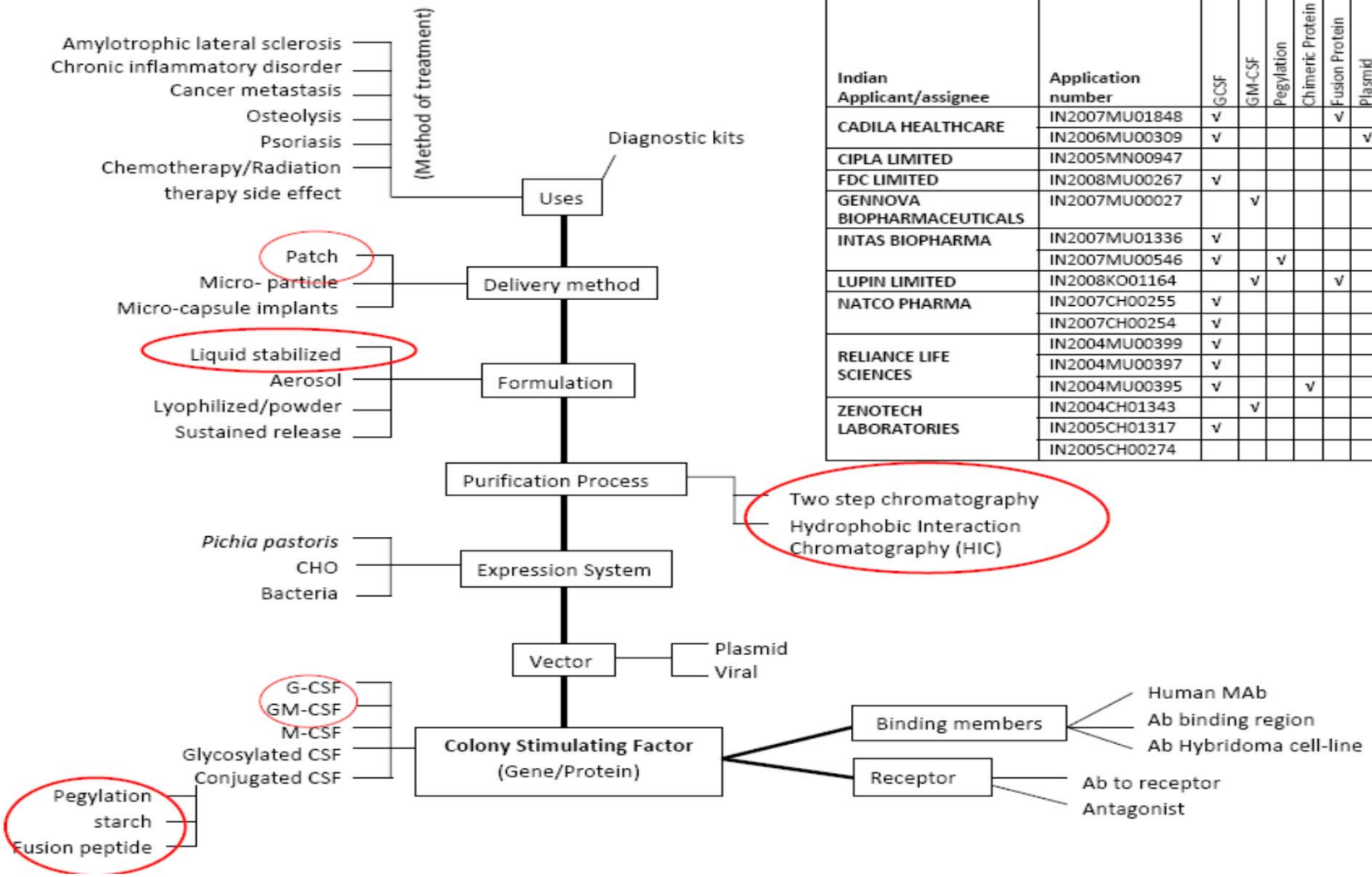
Distribution of IN Applications for Recombinant Drugs



Year wise distribution of Indian published applications

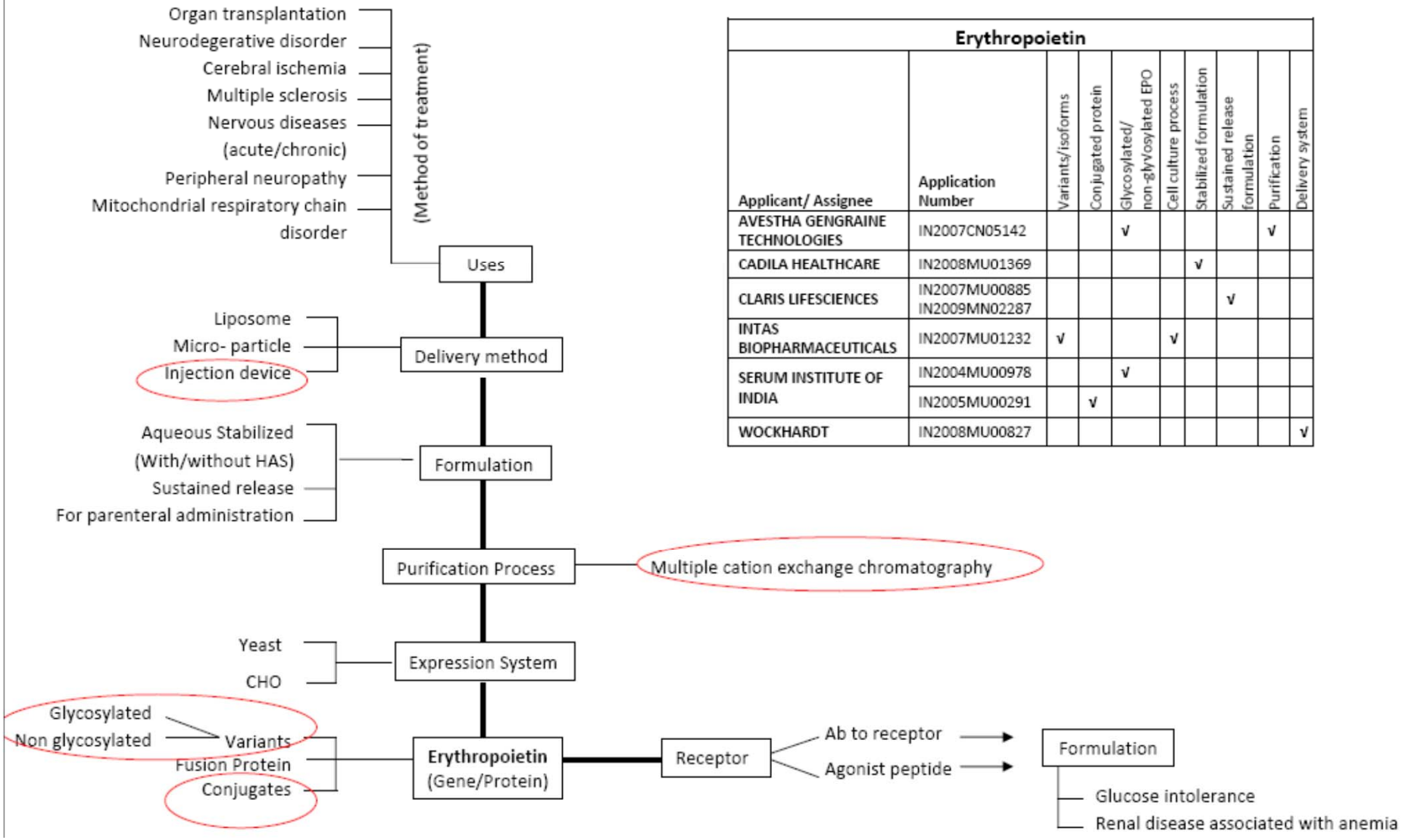
Landscape analysis of IN applications

- Colony Stimulating Factor
- Interferon
- Erythropoietin
- Streptokinase
- Human Growth Hormone



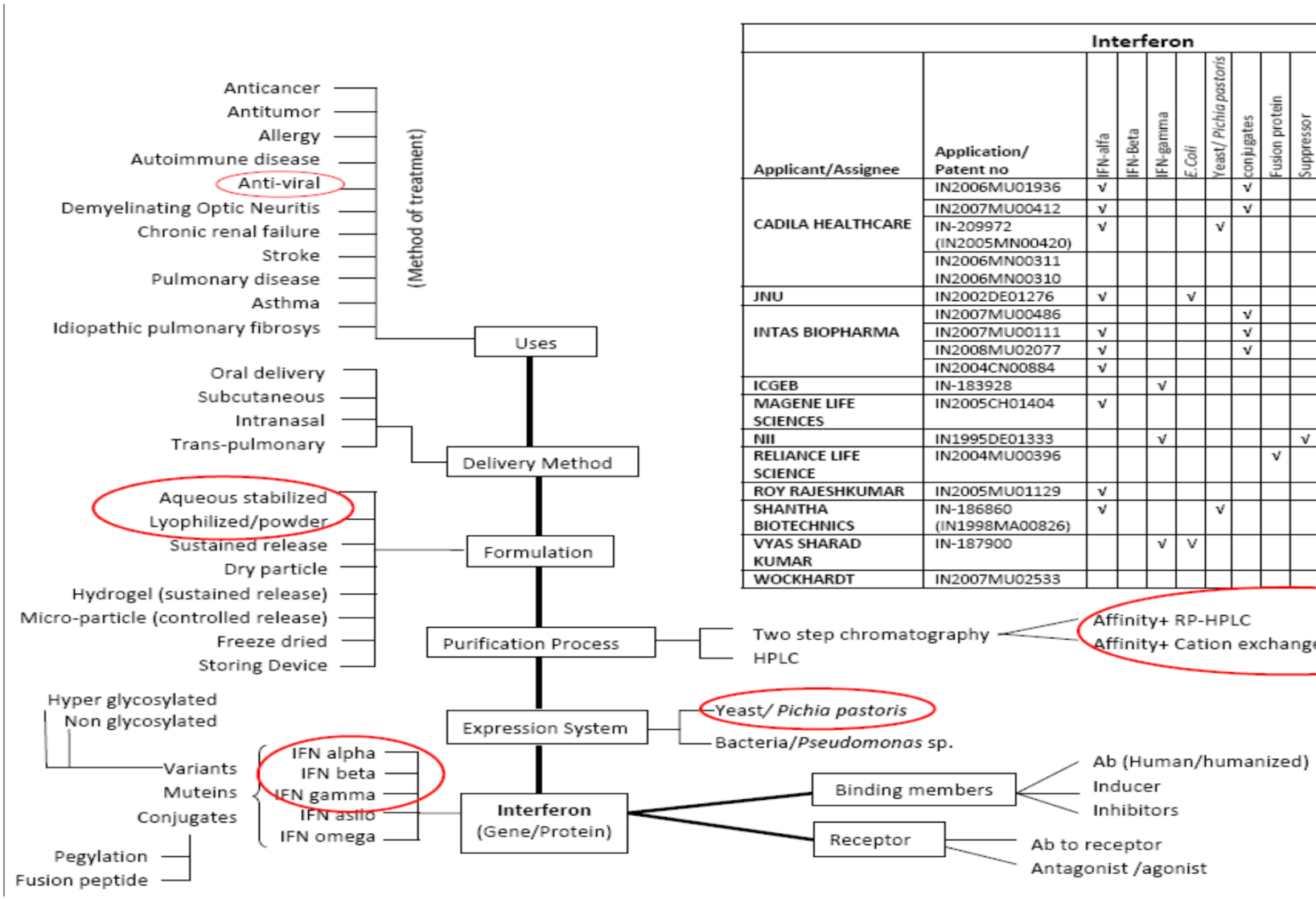
Colony Stimulating Factor

Indian Applicant/assignee	Application number	GCSF	GM-CSF	Pegylation	Chimeric Protein	Fusion Protein	Plasmid	Culture medium	Bioassay method	Purification	Stabilized formulation	Patch delivery
CADILA HEALTHCARE	IN2007MU01848	√				√						
	IN2006MU00309	√					√					
CIPLA LIMITED	IN2005MN00947											√
FDC LIMITED	IN2008MU00267	√							√			
GENNOVA BIOPHARMACEUTICALS	IN2007MU00027		√					√				
INTAS BIOPHARMA	IN2007MU01336	√										
	IN2007MU00546	√		√								
LUPIN LIMITED	IN2008KO01164		√			√						
NATCO PHARMA	IN2007CH00255	√								√		
	IN2007CH00254	√										
RELIANCE LIFE SCIENCES	IN2004MU00399	√										
	IN2004MU00397	√										
	IN2004MU00395	√			√							
ZENOTECH LABORATORIES	IN2004CH01343		√							√		
	IN2005CH01317	√								√		
	IN2005CH00274										√	

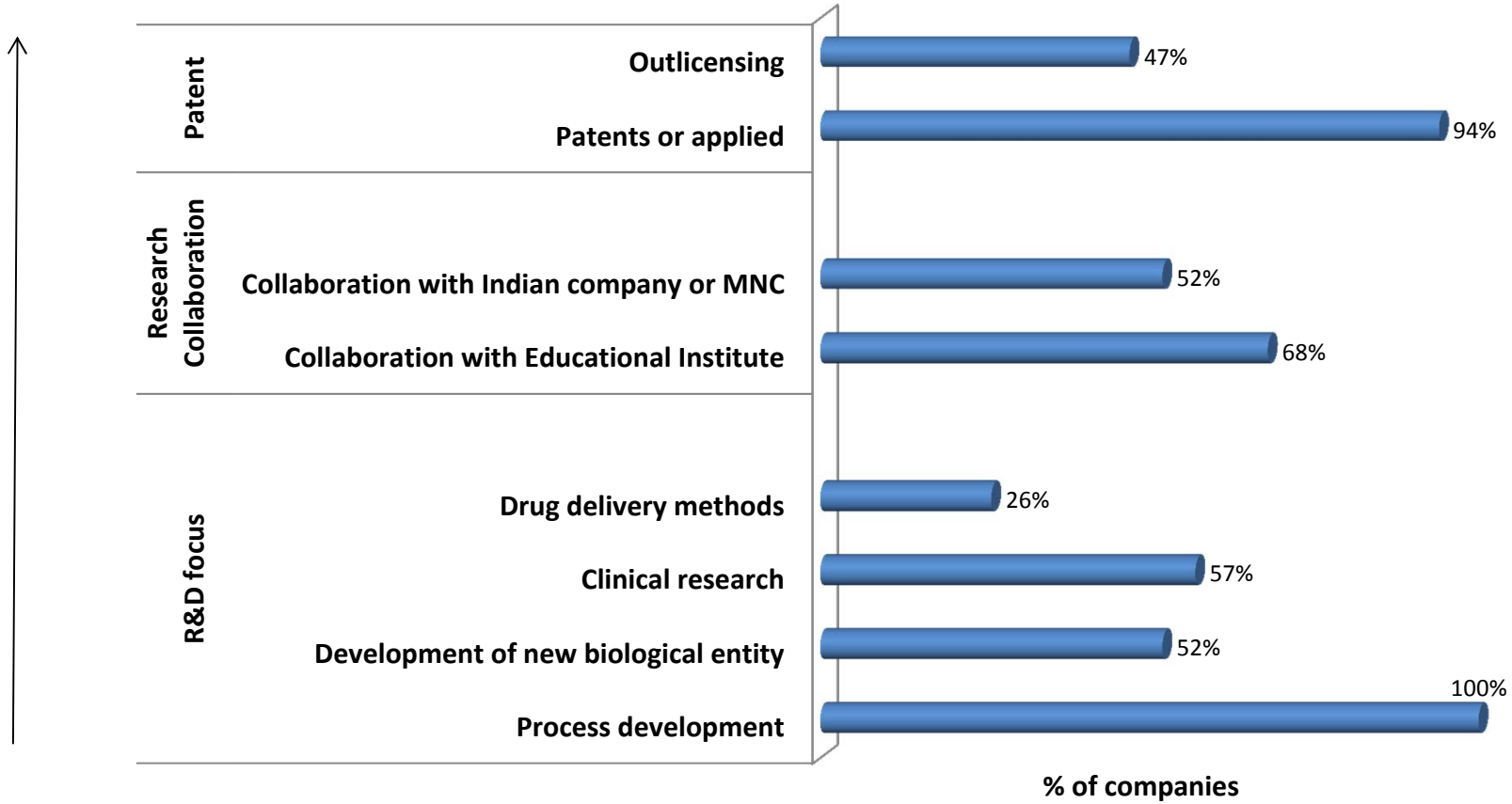


Erythropoietin

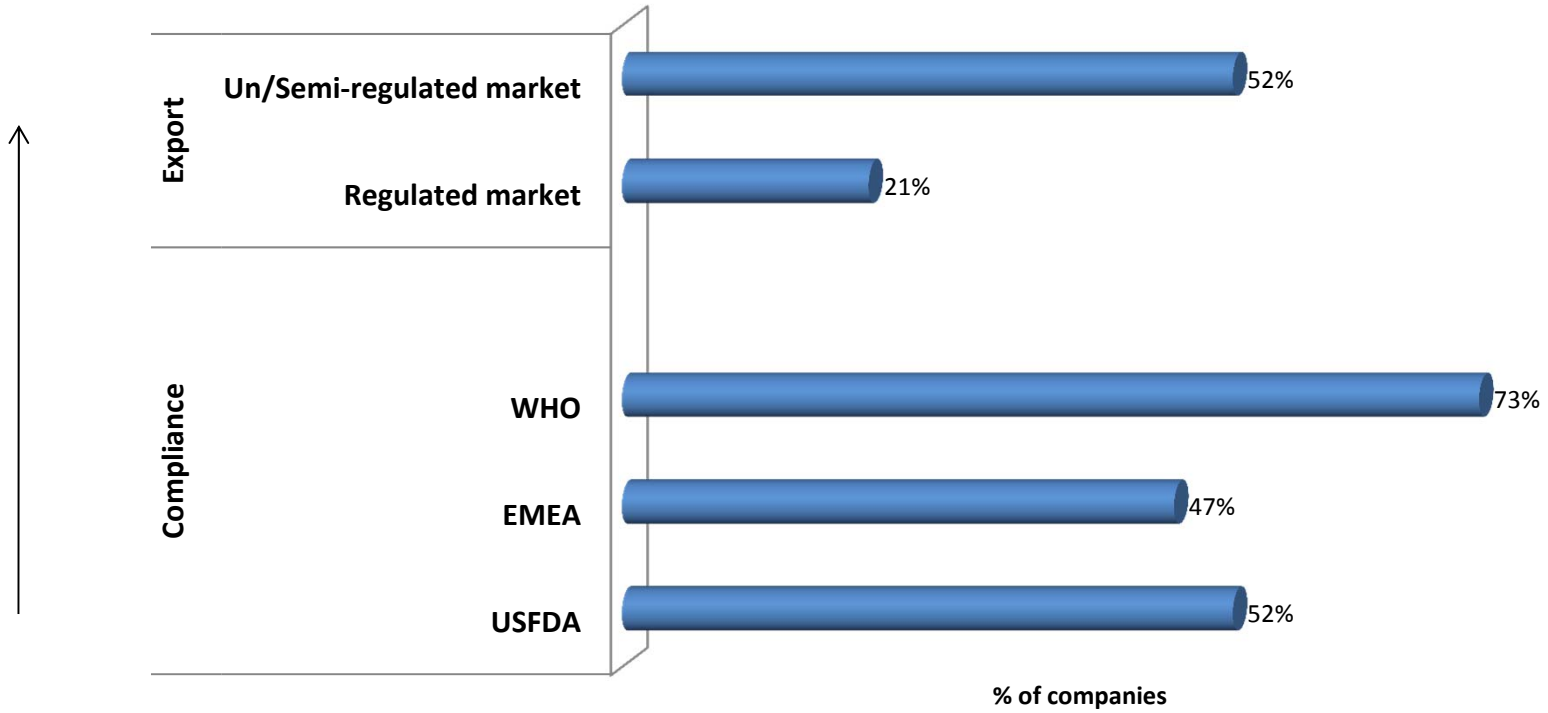
Applicant/ Assignee	Application Number	Variants/isoforms	Conjugated protein	Glycosylated/ non-glyvosylated EPO	Cell culture process	Stabilized formulation	Sustained release formulation	Purification	Delivery system
AVESTHA GENGRAINE TECHNOLOGIES	IN2007CN05142			√				√	
CADILA HEALTHCARE	IN2008MU01369					√			
CLARIS LIFESCIENCES	IN2007MU00885 IN2009MN02287						√		
INTAS BIOPHARMACEUTICALS	IN2007MU01232	√			√				
SERUM INSTITUTE OF INDIA	IN2004MU00978			√					
	IN2005MU00291		√						
WOCKHARDT	IN2008MU00827								√



Interferon																	
Applicant/Assignee	Application/ Patent no	IFN-alfa	IFN-Beta	IFN-gamma	*E.Coli*	Yeast/ *Pichia pastoris*	conjugates	Fusion protein	Suppressor	Purification	Formulation	Stabilized aqueous	Lyophilized powder	HCV Treatment	SARs treatment	Antiviral activity enhancement
CADILA HEALTHCARE	IN2006MU01936	√					√				√		√			
	IN2007MU00412	√					√				√		√			
	IN-209972 (IN2005MN00420)	√				√				√	√					
	IN2006MN00311 IN2006MN00310														√	
JNU	IN2002DE01276	√			√											
INTAS BIOPHARMA	IN2007MU00486						√					√				
	IN2007MU00111	√					√									
	IN2008MU02077	√					√						√			
	IN2004CN00884	√												√		
ICGEB	IN-183928			√						√						
MAGENE LIFE SCIENCES	IN2005CH01404	√														
NII	IN1995DE01333			√					√							
RELIANCE LIFE SCIENCE	IN2004MU00396							√								
ROY RAJESHKUMAR	IN2005MU01129	√														√
SHANTHA BIOTECHNICS	IN-186860 (IN1998MA00826)	√				√					√					
VYAS SHARAD KUMAR	IN-187900			√	√					√						
WOCKHARDT	IN2007MU02533										√	√				

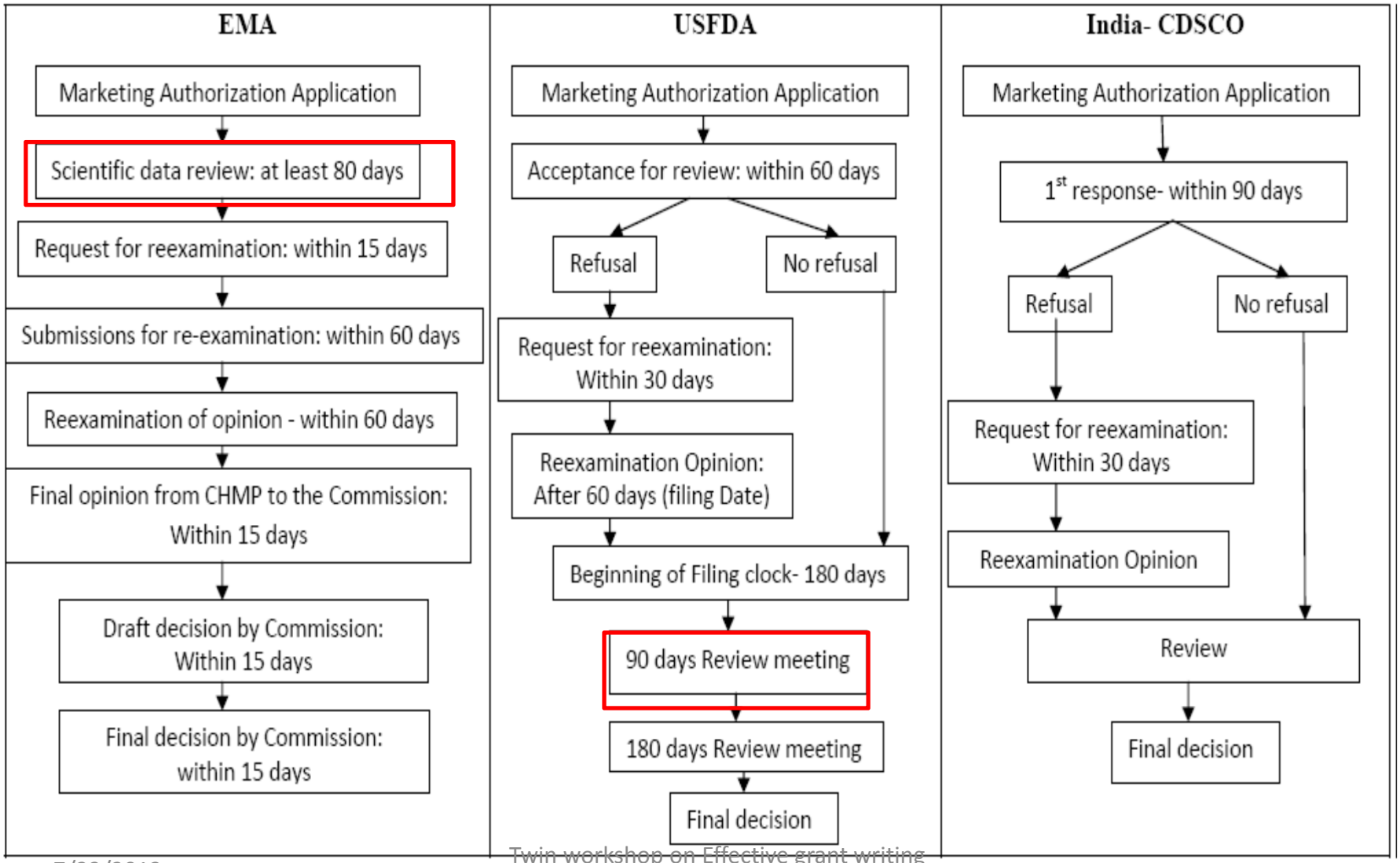


Aspects of research and development in Indian recombinant drug industry



GMP compliance level of Indian recombinant drug industry

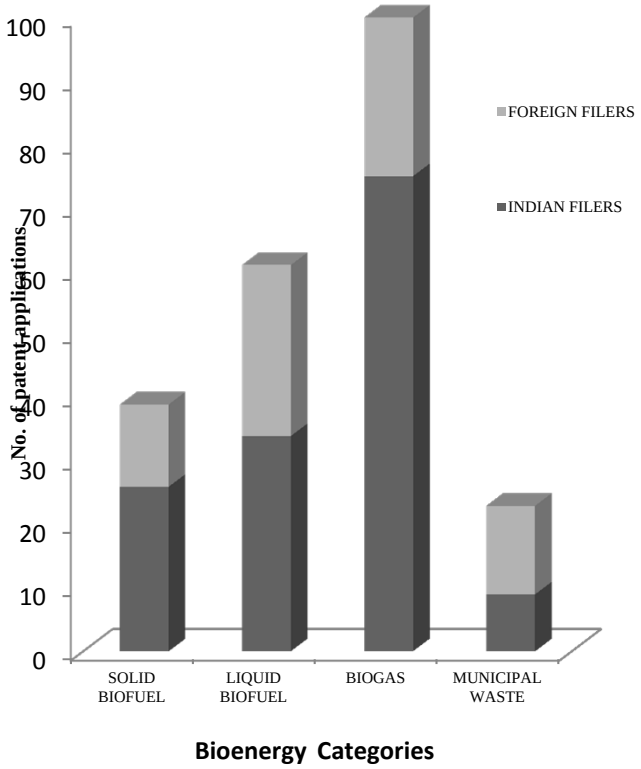
Regulatory issues in Indian recombinant drug industry

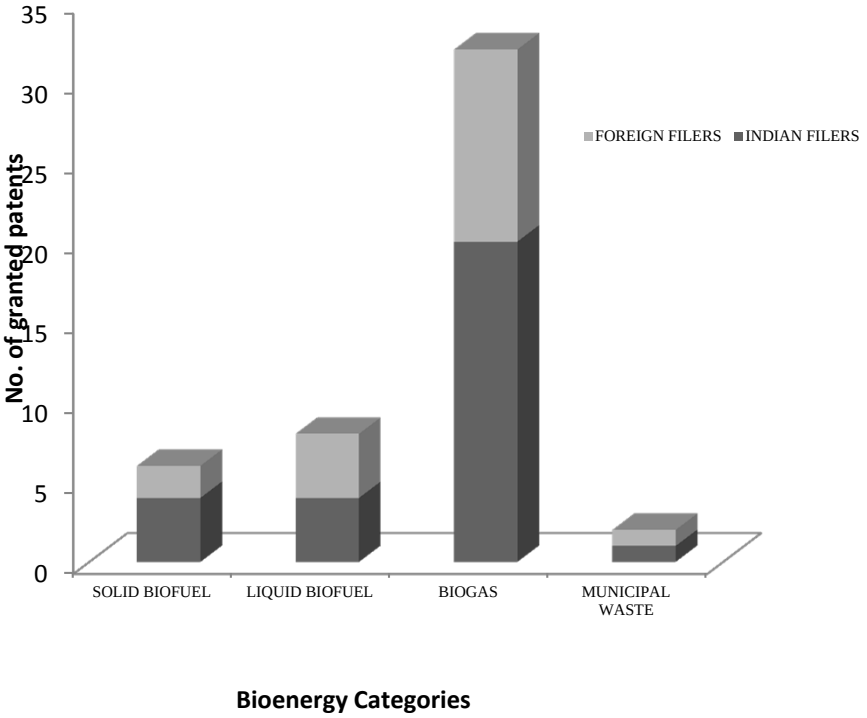

EMA
Marketing Authorization Application
Scientific data review: at least 80 days
Request for reexamination: within 15 days
Submissions for re-examination: within 60 days
Reexamination of opinion - within 60 days
Final opinion from CHMP to the Commission: Within 15 days
Draft decision by Commission: Within 15 days
Final decision by Commission: within 15 days
USFDA
Marketing Authorization Application
Acceptance for review: within 60 days
Refusal
No refusal
Request for reexamination: Within 30 days
Reexamination Opinion: After 60 days (filing Date)
Beginning of Filing clock- 180 days
90 days Review meeting
180 days Review meeting
Final decision
India- CDSCO
Marketing Authorization Application
1st response- within 90 days
Refusal
No refusal
Request for reexamination: Within 30 days
Reexamination Opinion
Review
Final decision

Major changes suggested for recombinant drug regulation

- Separate regulation for recombinant drugs
- Elaborate guidelines on different GMP aspects with more details
- Need for clear submission requirements, development of defined review timelines for drug application
- Faster clearance and building transparency in the approval process, Single window clearance system for recombinant drugs
- Implementation of e-application process
- Unify Indian guidelines with that across countries for recombinant drugs

Distribution of bioenergy related patent applications and grants





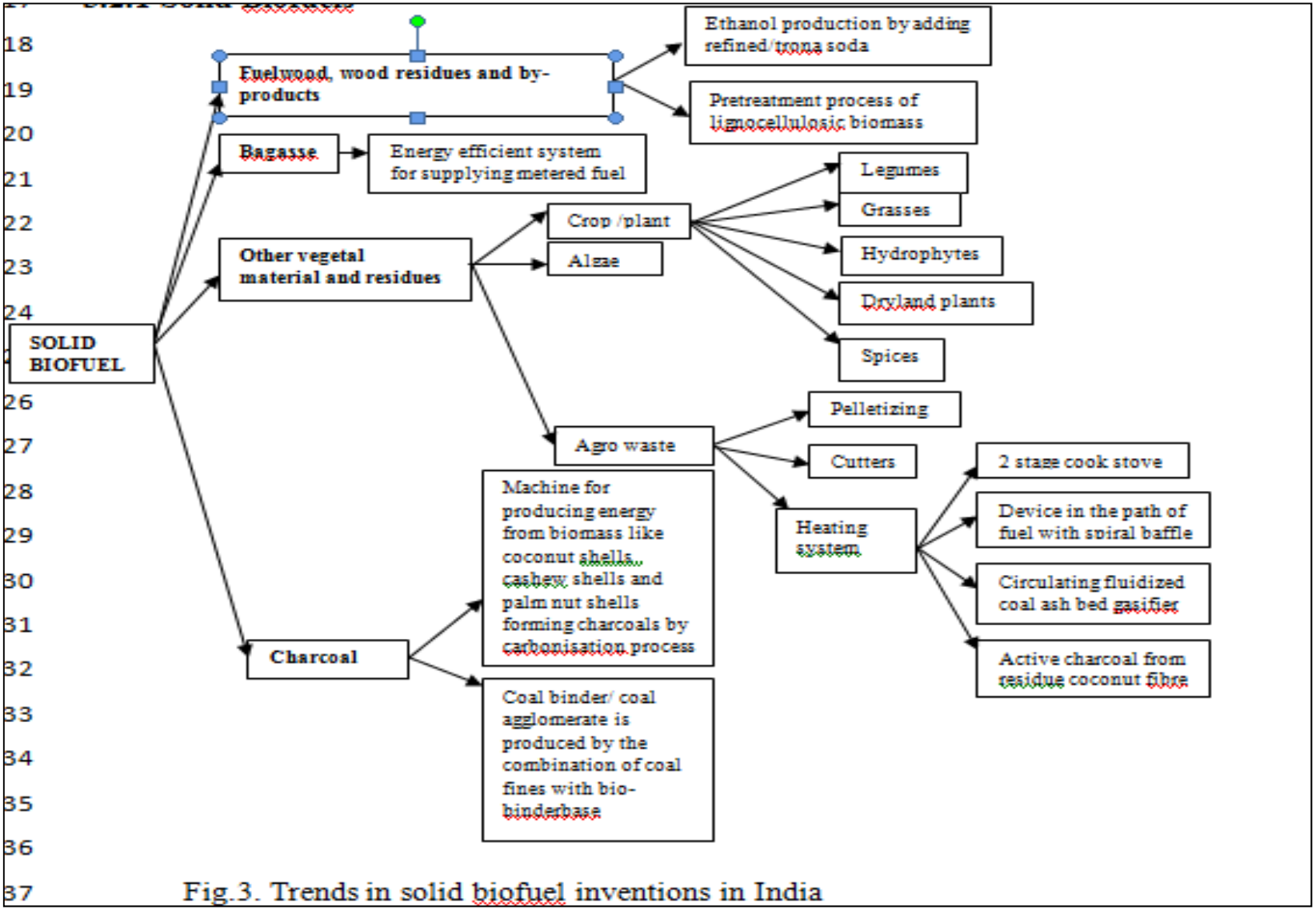
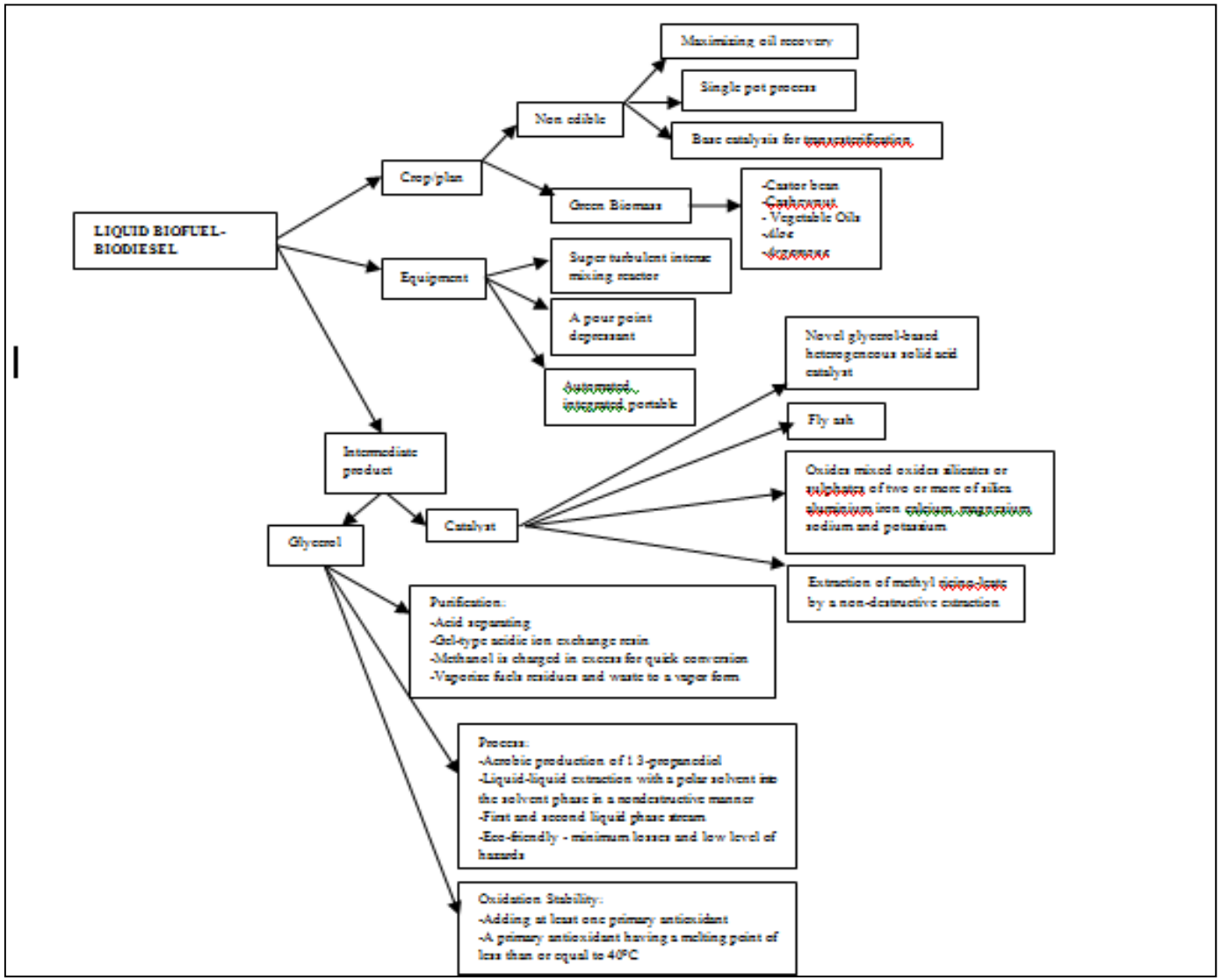
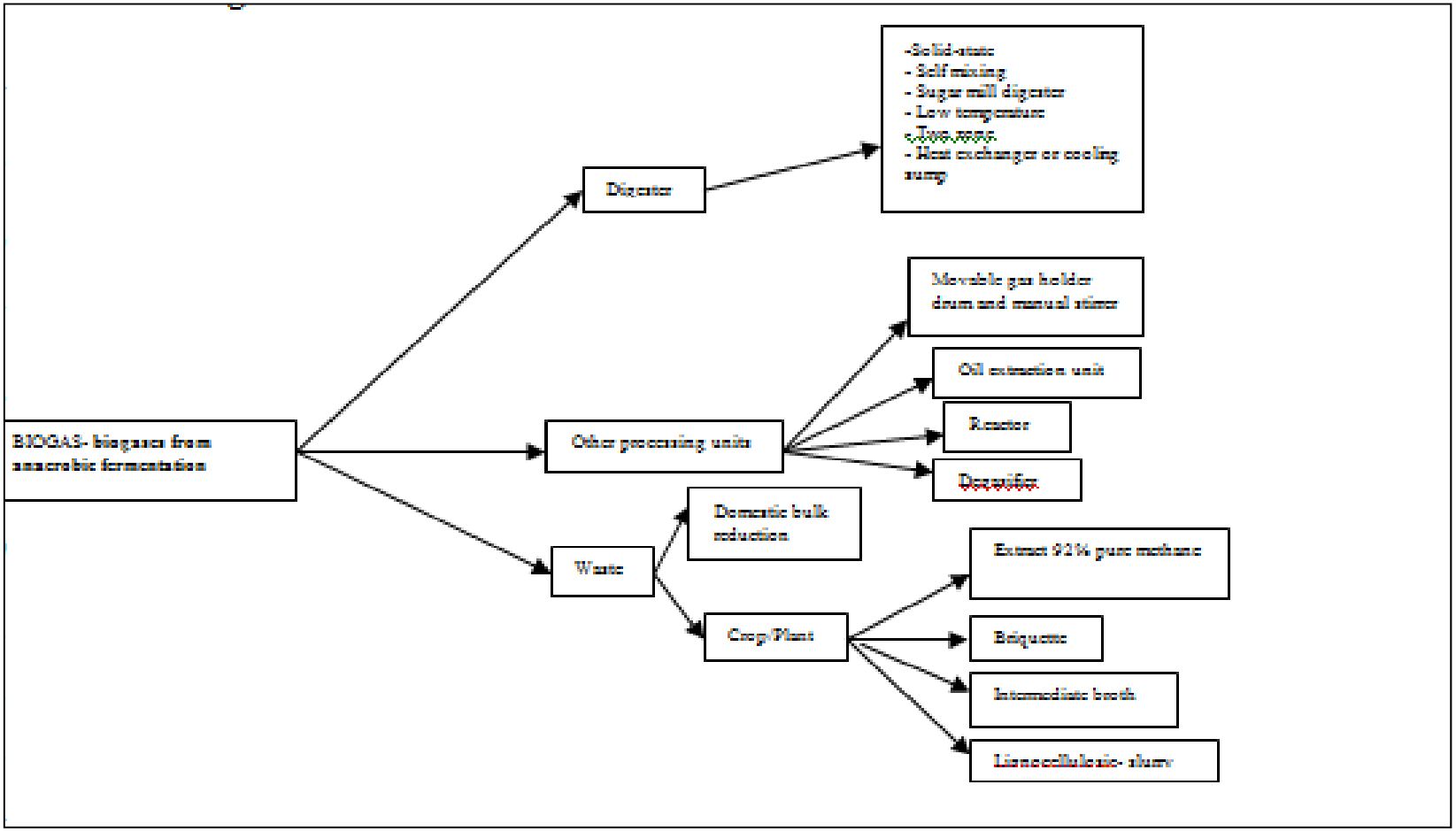


Fig.3. Trends in solid biofuel inventions in India

Trends in Liquid biofuels area



Trends in biogas inventions in India



Trends in Municipal waste derived inventions

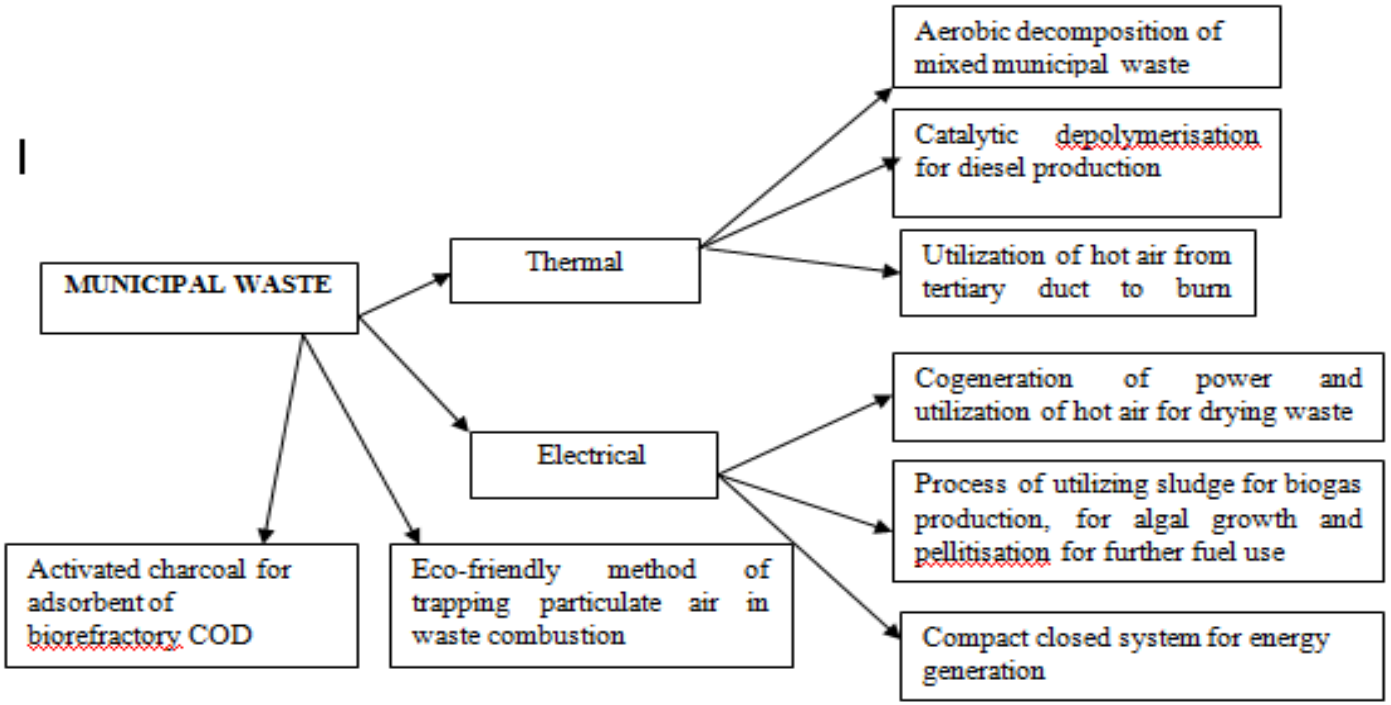
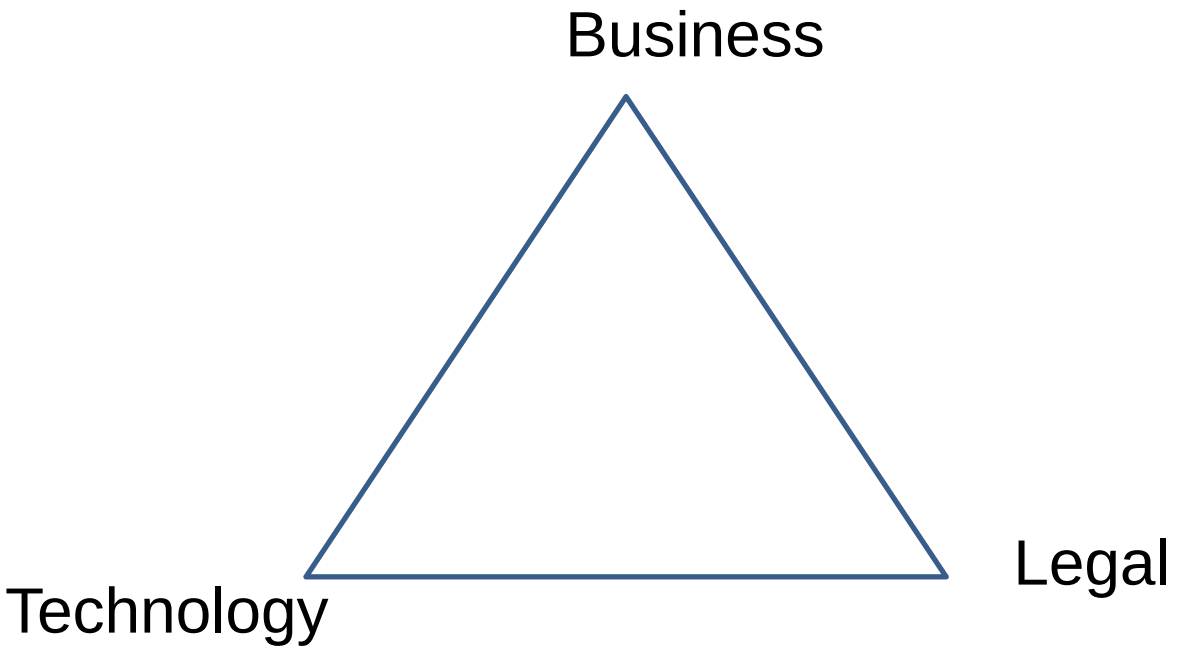


Fig.6. Trends in municipal waste inventions in India

Outcome of the research

- Identification of emerging technologies
- Identification of commercialisation aspects
- Technological feasibility in terms of adoption
- Need to improve on the economics in relation to specific technologies

IP Management



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