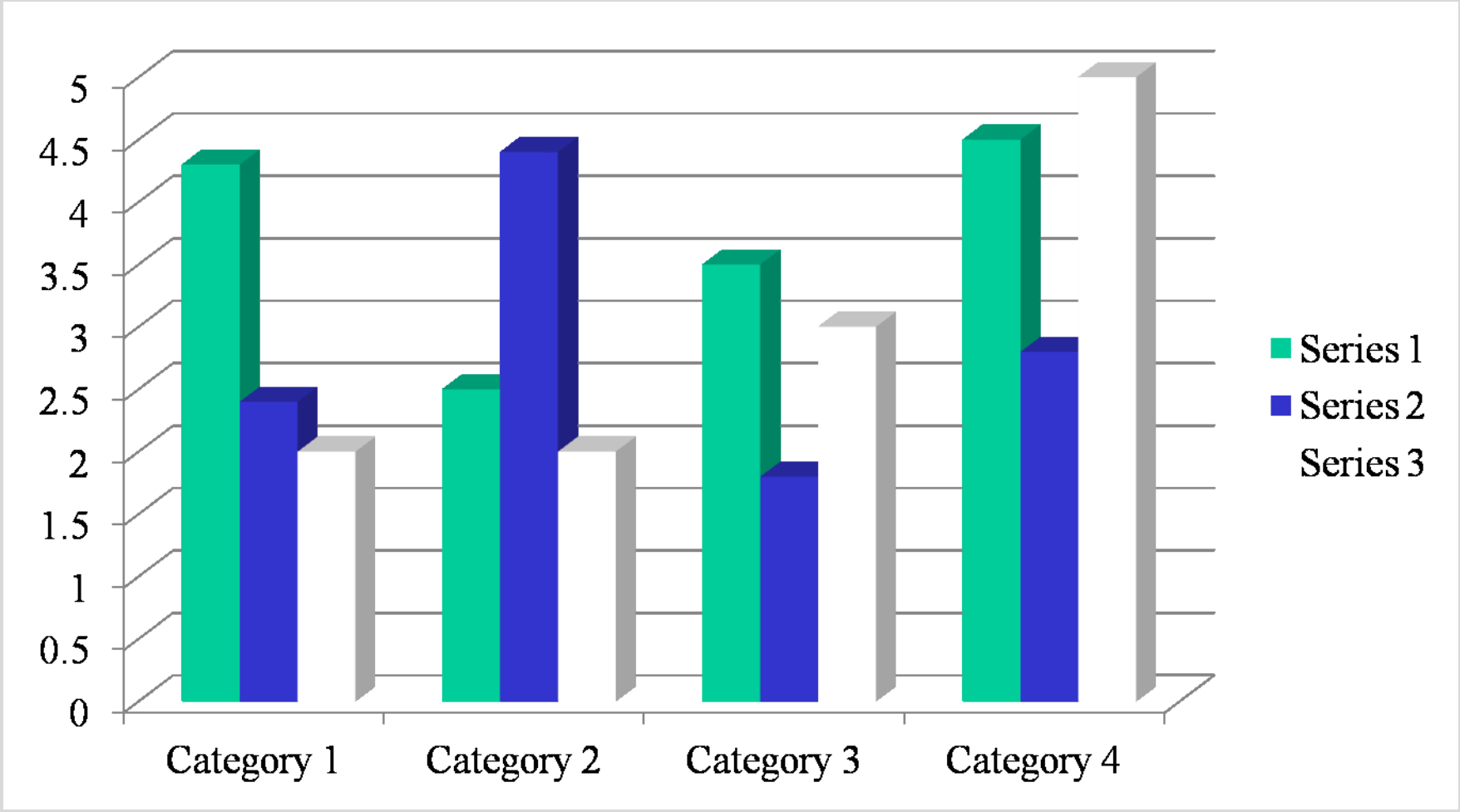
Nature of Indian Economy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Category 1
Category 2
Category 3
Category 4
Series 1
Series 2
Series 3

Theory of Underdevelopment:---

1. Theory of Vicious circle of poverty

2. Theory of Low Income Level Equilibrium

Features of Indian Economy as An Underdeveloped Economy:-----

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Indian Business Environment Has Compulsions* To Change And Indeed Is Changing And Changing Fast.

Indian Industry Now Looks For :

- **Access To The Best Technology**
- **Technology Converted into production in the :**
  - **Shortest Possible Time.**
  - **Most Cost-effective Manner.**
  - **With ability to make incremental improvements through sustained R&D.**
- **Globally Competitive Marketing Strengths.**
- **International Collaborations.**

*** These Compulsions were triggered by the advent of the General Agreement On Tariffs & Trade (GATT).**

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GATT TRADE ROUNDS

Eight Major International Negotiations were held aimed at reducing tariff and non-tariff barriers to trade under the GATT auspices.

1947 – Geneva; 1949 – Annecy, France ; 1951 - Torquay, England

1956 – Geneva; 1961 – Geneva (The Dillon Round).

- All For Tariff Reductions

1964-67 - Geneva (The Kennedy Round) - For Reduction of Industrial Tariff by one third; Anti-dumping Measures.

1973-79 - Geneva (The Tokyo Round) - Non-Tariff & Framework Agreements.

1986-93 - Geneva (The Uruguay Round) - Market Access Concessions; Trade In Services (TAS); Intellectual Property Rights (TRIPS).

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Establishment of GATT & WTO

The Final Act signed on 15th April, 1994 is 550 pages long and contains legal texts which spell out the results of the negotiations since the Round was launched in Punta del Este in September 1986.

The Agreement establishing the World Trade Organisation (WTO) calls for a single Institutional framework. Its structure is headed by the Ministerial Conference held once in two years. A general Council oversees all operations including a Dispute Settlements.

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GATT Establishing WTO (Uruguay Round -1993)

Multi-lateral Agreements on Trade in Goods

General Agreement on Trade in Services

Agreement on TRIPS

Plurilateral Trade Agreements

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WTO's Mandate

- Administering and implementing the multilateral and plurilateral trade Agreements which together make up WTO.
- Acting as a forum for multilateral trade negotiations.
- Seeking to resolve trade disputes.
- Overseeing national trade policies.
- Cooperating with other international institutions involved in global economic policy-making.

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Existing WTO Commitments

TRIPS: Trade related to Intellectual Property

India had to implement TRIPS provisions in two phases, the first by 1st Jan. 1995 by permitting Product Patent Filing, granting EMRs and revoking Section 39 of IPA 1970, the second by 2000, full amendment consistent with TRIPS had to be legislated; however implementation only by 1st Jan. 2005.

India legislated the new Act on March 5th, 2005.

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Protection Of Intellectual and Inherited Assets Have Various Dimensions. They include both Intellectual Assets And Bio-Assets.

Intellectual Property Protection

Patents

Trade Marks

Copy Rights

Designs

Trade Secrets (undisclosed information)

Bio-Assets Protection

Biodiversity

Germ Plasms

Geographical indications

Plant varieties

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Origin Of The term- Patent

The Word “Patent” comes from the Latin “litterae patentes”, meaning an open letter.

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History Of Patents- Patent System Timeline

1200s - 10 year Monopolies granted in Venice, Italy to inventors of Silk making devices.

1449 - First recorded patent granted in England for Glass making process

1624 - Statute of Monopolies issued in England.

1790 - First American Patent Statute passed.

1883 - Paris Convention for IPR Protection.

1970 - PCT signed in Washington D.C.

1993 - Uruguay Round completed.

1994 - GATT signed in Marrakesh.

1995 - WTO established in Geneva

2005 - Indian Patents Act 2005

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The Spirit Behind grant Of Monopolies under Patents.

In North America, in 1788, the U.S. Constitution ratified that :

“ The Congress shall have power ---- to promote the progress of Science and useful Arts by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries”

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What Is A Patent ?

A Patent Is a statutory Instrument of Monopoly granted as a reward :

- **For An Invention**
- **By The Government**
- **To The Inventor**
- **For A limited Period.**

In return for which the inventor has to disclose to the Public, his invention in it's entirety.

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A Patent Provides Legal Rights To You To Exclude Others from Practicing Your Invention; It Does Not Give The Right To Use Your Invention.

That Right Is Granted Only By Authorities Outside The Patent Offices And Is Dependent On Several Other Factors.

Patent Laws Are National Laws. There are No World Patents

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Basic Requirements For Patenting Your Invention

Article 27

Patents shall be available for any invention, whether products or processes, in all fields of technology, provided they are:

- **novel,**
- **involve an inventive step and**
- **are capable of industrial application.**

Patents must be available and patent rights enjoyable without discrimination as to the place of invention, field of technology and whether products are imported or locally produced.

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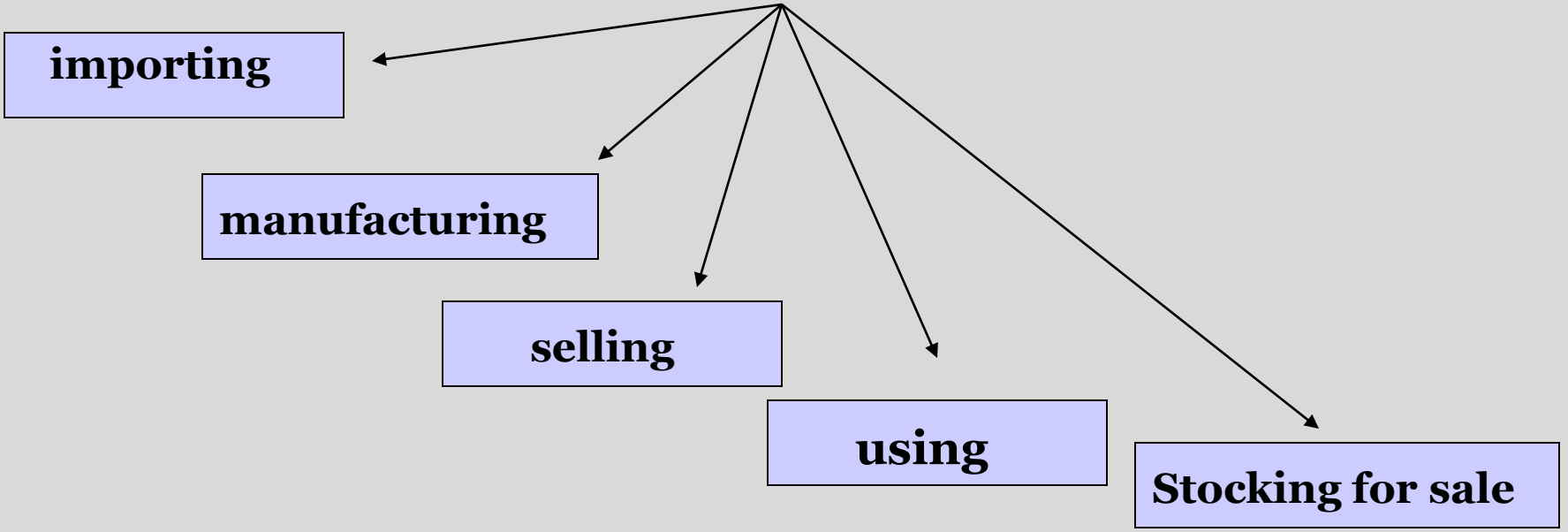
PATENT RIGHTS (Common To All Sectors)

Right to restrain any unauthorised third party

Depends on law, harmonized rights



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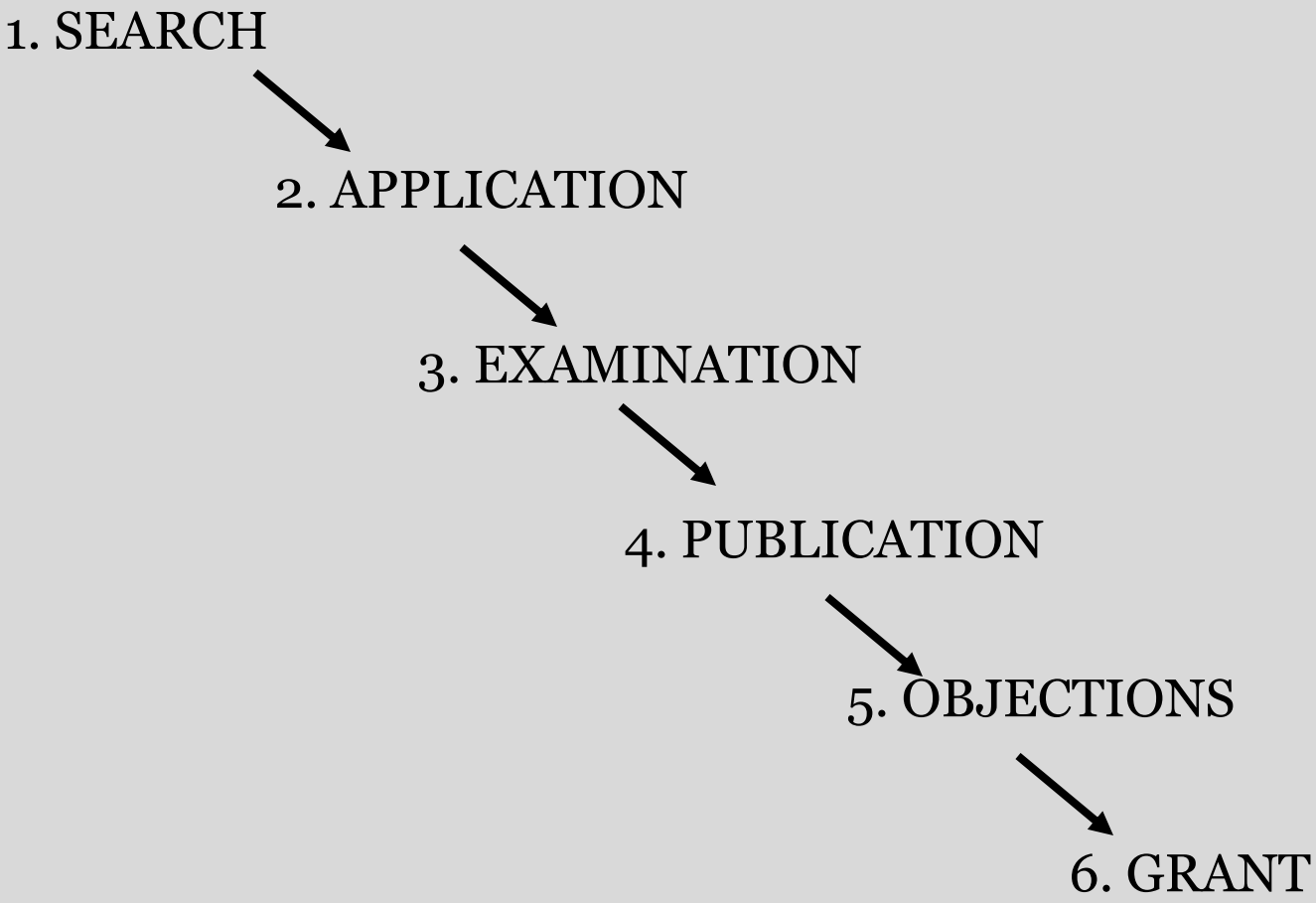
How To Obtain A Patent?
(A Simple Model)



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Quality Of Patents

Under 35 USC 112 , the model adopted by most Patent Offices, a patent should:

-provide a written description of the claimed invention.

-the written description should define the scope of the claims. Claims cannot be broader than the supporting disclosure.

-has to satisfy the enabling requirement of describing how to make and use the claimed invention.

- disclose the best mode for practicing the invention.

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Patents & Pharmaceuticals

The Industrial Sector most affected in India by the TRIPS Agreement is the Pharmaceutical Sector. That is because the 1970 Indian Patents Act had discriminatory provisions for Drugs , Food and Agricultural Sectors such as :

-Patents for Products not allowed (only processes protectable)

-The term of these patents five years from grant date or seven years from filing date whichever is earlier (other sectors 14 years).

-Provisions for licenses of right in addition to compulsory licenses.

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The New Indian Patents Act - 2005

-Validity for 20 Years from the date of filing of the Patent.

- Product Patents will be granted for all inventions in all areas whether for products or processes provided they satisfy the three basic requirements of novelty, inventiveness and industrial application (under debate).

- Life forms except Microorganisms, not patentable (under debate).

- Import of the product considered equivalent to working of the patent in India.

- Compulsory Licenses to be granted under specified conditions of national emergency or extreme national urgency.

- Under DOHA Declaration, export of patented products to be allowed to LDCs with no capability, provided they have Compulsory License issued to them for the product.

- In case of infringements and litigation on process patents, burden of proof of non-infringement to rest with the defendant.

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The Indian Patents Act 2005 - Concerns

1) Issues on Patentability of so-called trivial inventions as a method of 'ever-greening' patents by the patent holders.

2) Patentability of Microorganisms.

3) Future of products already being manufactured in India which are inventions filed under Mail Box provisions and EMRs. –Gleevac case.

4) Impact on Prices of Patented Products.

5) Terms of Compulsory Licenses both for domestic market as well for exports to LDCs with no manufacturing capabilities even when in possession of Compulsory Licenses.

5) Lack of opportunities for appropriate and timely pre-grant and post-grant opposition procedures.

6) Fear of the procedural problems & lack of infrastructure in the management of the system

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What The Critics Would Have Liked

- Extension Of Transition Period beyond 2005.
- Not only Grant Of Patents, but also priority & validity for product patents to be post-2005 .
- Patents only on the first and Basic Molecule , not on Formulations, New Crystalline Forms, Polymorphs, new Salts, Esters Etc.
- More liberal Compulsory License Norms.
- Conditions For Exports Under DOHA Declaration to be made more practical and less cumbersome.
- Working of the patent to be restricted to local Manufacture (Imports not equivalent).

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Key Concerns For Big Pharma

The key concerns of Big Pharma may include:

- ***Compulsory Licensing***
- ***Data Protection & Data Exclusivity***
- ***Implementation and Enforcement Problems***
- ***Pre Grant Opposition Provisions***

Another key concern of Big Pharma was the EMR issue. Several of the innovation based companies have faced litigation issues in implementation of EMRs. However this is a self expunging provision and has little relevance for the future.

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Post 2005 - Threats

- Higher drug prices - The impact will be on the new patented drugs which will bear a higher price tag and will be out of the reach of the common patient.
- Many local players assume that most gains from patent protection are likely to benefit MNCs and foreign companies, whereas price increases & local firm's reduced competitive position, will cost India dearly.
- Reverse-engineering of patented molecules will be prohibited.
- The high R&D costs will stifle the growth of the Indian pharmaceutical industry because the smaller firms may not be able to adjust to the transition.

On the other hand, the new regime is expected to encourage research to discover drugs needed for poor man's diseases as well as for those for global markets by the top Indian Companies.

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Post 2005 - Opportunities

- By providing monopoly profits to inventors, the law will give innovator companies incentives to develop new drugs and India can be the destination for new investments.
- The law's disclosure requirement will fuel continuing R&D by disclosing details on all patented products.
- As Indian market primarily consists of drugs which are off-patent, there would be no major impact on the drug prices currently available on the shelves.
- Product patents may improve industry productivity by inducing firms to contract and ally with one another including MNCsbased on complementary strengths.

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Post 2005 – Opportunities (contd..)

- Indian companies can become leading outsourcing destination for the global pharma Industry.
- They are foraying into new segments like NCE, NDDS and several contract based services like clinical trials, contract research, contract manufacturing etc.
- .Several new innovator MNCs will set up their marketing and research collaborations and introduce several new products from their global current & pipeline product portfolio.

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There Are Still Many Unsolved Issues In India On IPR Protection

- Patents On Life Forms & Agriculture.
- Ever-greening Strategies including patentability issues on Drugs. Microorganisms.
- Compulsory Licenses.
- Protection Of Traditional Knowledge, Natural Products & Traditional Medicines.
- Data Exclusivity, Trade Secrets, Petty Inventions & New Utility.
- Anti-Competition Legislation

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Report Of The Mashelkar Committee on Art. 27 of TRIPS

- The Committee consisting of leading Scientists and Legal luminaries was given the mandate of determining whether Amendments to Art. 27 in Indian Patents Act 2005 are TRIPS compliant or not.
- The two contentious issues were:
  - The provision in IPA 2005 that only new NCEs or NMEs would be patentable, not their derivatives such as new salts, new esters, polymorphs, new crystalline forms etc.
  - Patenting of Microorgnisms

The Committee submitted its report on Dec. 28th 2005 that the Amendments would not be TRIPS compliant.

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How To Handle The Concerns Of The Indian Industry And The Public Regarding The Indian Patent Act - 2005

Concerns	Actions
1) Non-accessibility to Patented Drugs	Invoking CL for refusing to deal .
2) Non–affordability of patented drugs	CLs And / Or Price Controls.
3) Frivolous Patents	Due Diligence & Pre-Grant Opposition.
4) Ever-Greening Of Patents	Stringent Examination.
5) Disputes & Jurisdictional Problems	Negotiations & DSB of WTO
6) Impact On Indian Industry	Entry Into R&D, Major Entry Into Generics & More Collaborations

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What Do We Need To Do Now?

- Make maximum use of provisions under TRIPS to the Country's benefit by appropriate interpretations.

- Remove as many ambiguities as possible from the new legislation.

- Rework the Rules to make them effective and implementeble.

- Create adequate awareness among Scientists, Industry, Trade and the Judicial System about IPRs.

- Build up adequate infrastructure and professionalise the Patent Offices.

- Have strict and impartial examination and patent grant systems.

- Continue to negotiate with the TRIPS Council to endorse the amendments made to IPA 1970 and further improve on them.

- Review the impact of the new Act on the Industry, Drug Prices, the Consumers and Society. Take appropriate action under DPCO, Anti-Competition Law , Compulsory Licenses etc when needed.

- Enlist the support of other like-minded Member Countries to make further beneficial changes through the TRIPS Council & IMC of WTO

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All In all, We are in for a major change in the way the patent system will be utilised in India. To succeed you need a change in mindset, new approaches & motivation .

" To Get Something, You Need To Combine Both Method And Motivation.

- Motivation Without Method Is Ineffective.

-Method Without Motivation Usually Sits On The Library Shelf "

Edward De Bono