Government Policy on IPRs and International Treaties

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Layout of the Presentation

- Uruguay Round: How did IPR get connected with Trade
- TRIPS Agreement: A primer
- Government Policy on Patents
  - Report of Justice Ayyangar and the amendments of 1970
  - Parliamentary Debate
  - Contribution of Justice VR Krishna Iyer and others
  - Flexibilities also called TRIPS flexibilities incorporated in the Patent Act
- FTA negotiations and the policy level challenges

How IPR got linked to trade?

- Uruguay Round – first time that IPR got linked to trade
  - Paris and Berne Conventions were considered without teeth
  - Special 301 Action by the US
  - Reduction in trade barriers –tariff and non tariff

TRADE RELATED INTELLECTUAL PROPERTY RIGHTS

A Primer

TRIPS- A Primer

- TRIPS is the only multilateral treaty on protection and enforcement of IPRs
- It is a binding agreement and a part of the WTO Agreement
- sets minimum standards of protection
  - Substantive obligations under Paris and Berne Conventions grandfathered
  - Additional obligations over Paris and Berne Conventions
  - Non derogation clause for existing obligations
- Rules on administration and enforcement of IPRs and provides for the application of the dispute settlement mechanism

TRIPS: Basic Principle and General Provisions

- National treatment and Most Favoured Nation Treatment
  - No discrimination in treatment
  - No carve out for Regional/Plurilateral Agreements
- Exhaustion of Rights
  - free to determine the exhaustion of rights
  - International, regional or national exhaustion
- Objectives & Principles
  - *Protection should promote technological innovation and transfer and dissemination of technology*
  - *Improve social and economic welfare*
  - *balance rights and obligations*
  - *Members could protect public health and nutrition and promote public interest in sectors of vital importance*
  - *Prevent abuse of intellectual property or when practices unreasonably restrain trade or affect international transfer of technology adversely*

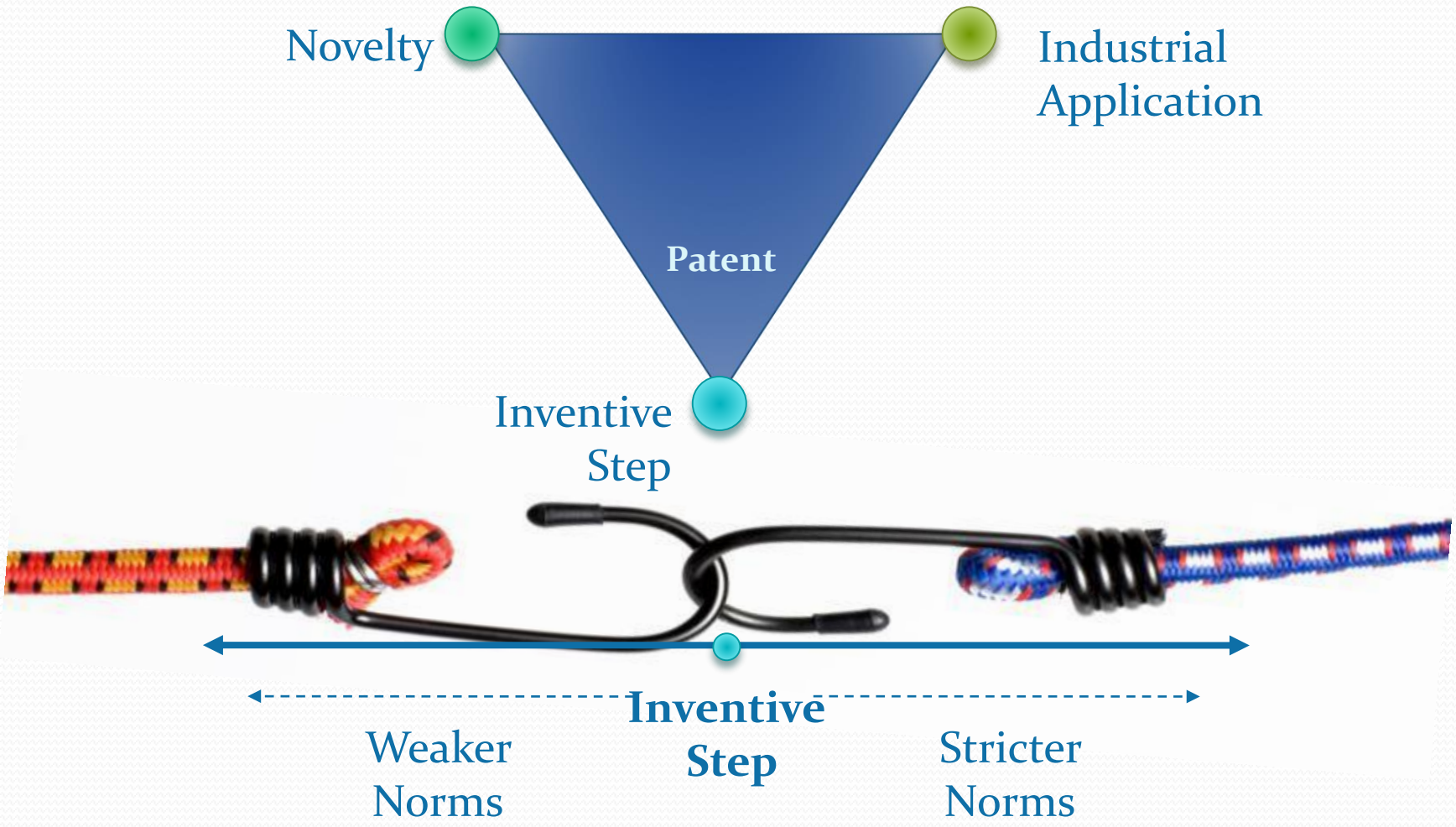
TRIPS Agreement and Patents

- *Patentable Subject Matter(Article 27.1)-"Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. ...Patents shall 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"*

- *Exceptions to the subject matter :-*
  - *Diagnostic, therapeutic and surgical methods.*
  - *On grounds of public order or morality.*
  - *Plants & Animals.*

- Term of Protection -20 years from the date of filing

Debate on Patentability Criteria



Flexibilities in the Definition

TRIPS does not Define:
-Novelty –Global or local novelty?
-Inventive Step
-Industrial Application

<u>Examples of use of these (non patentable) by the Indian Patent Act</u>

- Global Novelty
- Traditional Knowledge (novelty)
- New form of a known substance unless enhanced efficacy (inventive step)
- admixture resulting only in aggregation of properties (inventive step)
- computer programme per se (industrial application)

How has Non discrimination been interpreted?

"Patents shall 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"

Some interpretations

Brazil: Article 68 of the Patent law allows for compulsory license if not locally produced unless economic reason exists

India: Section 84 provides that CL can issue if the patent is not worked in the territory of the country

Exceptions to Rights

- Article 30 – limited exceptions to the exclusive rights without prejudice to the legitimate interest of the patent owner.
  - Experimental Use
  - Research and Development
  - Educational Purposes
  - For Purposes of Regulatory Approvals ('Bolar')
- Article 31 – other use without authorization of the right holder.
  - Compulsory license on individual merits
  - Compulsory license in National Emergency, other circumstances of extreme urgency or public non-commercial use
- Article 31 bis – New amendment to allow Compulsory license for supply of medicines to countries that do not have the capacity to produce

Doha Declaration on TRIPS and Public Health

- ".. the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."

- "... the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

- Flexibilities under TRIPS include the following:
- Each member has the right to grant Compulsory License and to determine the grounds for this
- Each member is free to decide what constitutes national emergency and other circumstances of extreme urgency
- Each member is free to decide the type of Exhaustion of rights-international, regional or national.
- Countries that lack adequate manufacturing capability can source the concerned pharma product from a country that has the requisite facilities

Government of India's Policy on Patents

Patent Regime: Pre and Post Justice Ayyangar's Report and TRIPS

Indian Regime provided for both Product and Process Patents

→ Ayyangar Report, 1959 →

Patent Act, 1970: Patents for drug, food and chemicals restricted to Process only.

→ TRIPS Compliance →

Product and Process Patents

1999
- Product patent applications through a "mailbox"
- Exclusive Marketing Rights

2002
- Addressed scope of patentable inventions, strengthened compulsory license provisions.

2005
- Product patents in the area of chemicals, pharmaceuticals, and agricultural chemicals and foods

The deadline for complying with TRIPS obligations was January 1, 2005.

Debate in the Parliament over the Patent Amendment Bill

- Concerns expressed by the Members of Parliament
  - Use all TRIPS flexibilities to the advantage of a developing country
  - Strengthen the provisions on Compulsory license
  - Strengthen pre-grant opposition to include appeal
  - Measures to prevent Evergreening
  - Provisions should be TRIPS compliant but not TRIPS plus
  - Need to keep prices of medicines under control
  - Ensure parallel imports
  - Need to build a world class patent system
  - Modernize the patent office

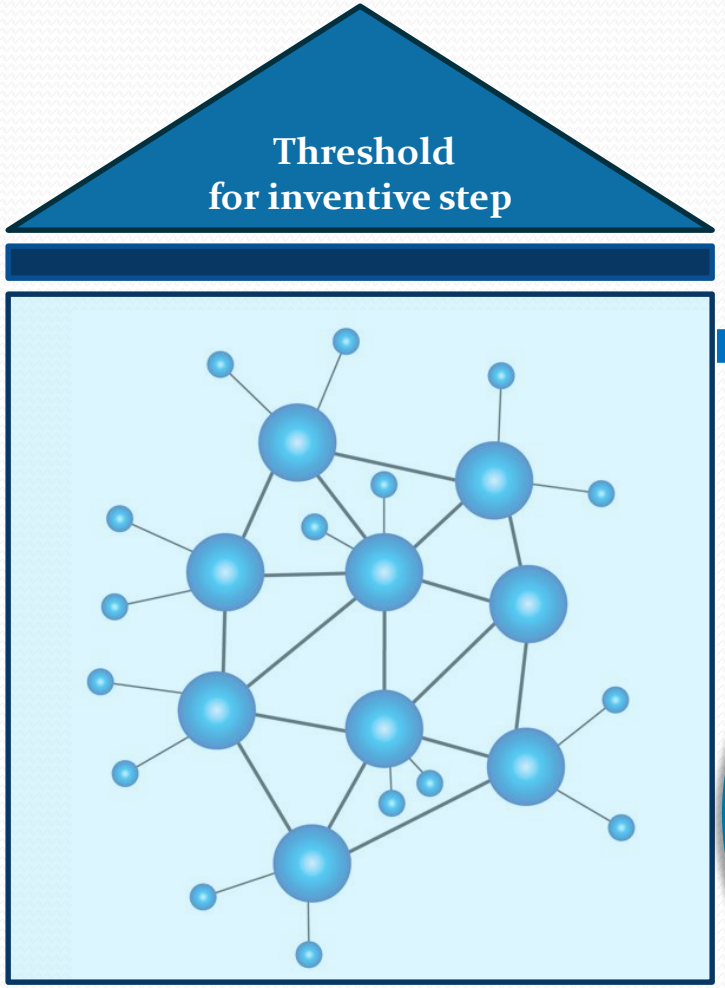
Contribution of Justice VR Krishna Iyer and others to Section 3(d)

- Section-3 of the Patent Act as amended in 2005 while defining the inventions not patentable provides under sub-section (d) the following:-

- **The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance** or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

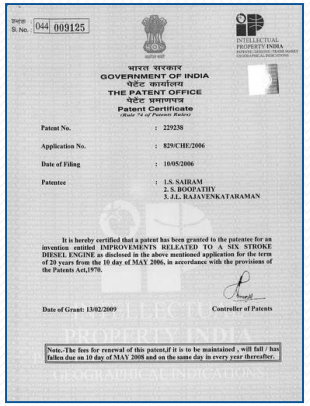
- Explanation.—**For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in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

Patentability Criteria (Section 3(d))



Salt, Ester, Ether, Polymorphs etc

Significant Enhancement in Efficacy



Interpretation of Section 3 (d)- Novartis Judgment

- M/s. Novartis obtained patent for 'Imatinib and its salts' in 1993 in other countries, before the international obligations under TRIPS took effect in India.
- Novartis applied for a patent for 'Beta Crystalline form of Imatinib Mesylate' in India in 1998 claiming that it could be stored better and was easier to process.
- The Indian Patent Office found that there was no significant medicinal benefits and therapeutic efficiency in the Beta Cyrstalline form of Imatinib Mesylate over the Imatinib Mesylate.

Interpretation of Section 3 (d)- Novartis Judgment

- The Hon'ble Supreme Court of India upheld the finding of the Indian Patent Office that the claimed invention did not satisfy novelty and the higher threshold of inventive step as prescribed in Section 3(d) of our Patents Act.

- The judgement has dealt with the term 'efficacy' in Section 3(d). It mandates that in case of medicine that claims a cure for a disease, the test of efficacy can only be "therapeutic efficacy" and that the therapeutic efficacy of a medicine must be judged strictly and narrowly.

Compulsory License under the Patent Act

- Compulsory licensing is enabled under four sections of the Patents Act
  - Section 84 (general CLs to be issued by the Controller on application) ,
  - Section 91 (issue of CL by the Controller for a related patent on application) ,
  - Section 92 (issue of CL by the Controller based upon a notification by the Central Government) and
  - Section 92 A (issue of CL by the Controller on application for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems).
- In addition, Section 100 provides for use of inventions for the purpose of government and acquisition of inventions by Central Government.

Compulsory License

- Section 84 allows grant on application by an interested person provided
  - Reasonable requirement of Public has not been met
  - Patented invention is not available to the public at reasonable prices
  - Patented invention is not worked in the territory of India

Bayer vs NATCO Pharma : The case on Compulsory Licensing

- The voluntary licence application by M/s Natco Pharma was not accepted by M/s Bayer Ltd.
- The application for Compulsory licence was filed under Section 84(1) of the Patents Act.
- found that the submissions of the applicant was justified and that M/s Bayer Ltd. did not meet the requirements of the public and that the drug was excessively priced. With respect to the issue of "working of the patent in the territory of India", CGPTDM concluded that section 84(1) (c) (regarding working of patents) is also attracted in this particular case.

Bayer Vs NATCO

- M/s Bayer filed an appeal against the said order of CGPDTM dated 9.3.2012 before IPAB.
- IPAB disposed of the appeal while maintaining the compulsory license and increasing the royalty to be paid to M/s Bayer Corporation by 1%.
- M/s Bayer Corporation filed an appeal against the IPAB order in the High Court of Bombay. The Court in its judgment upheld the decision of the IPAB and that of the Controller General.
- It also accepted the view of IPAB on 'working of a patent'
- The Supreme Court did not accept the SLP

TRIPS flexibilities incorporated in the Patent Act

- Policy level carve outs-Public health and nutrition, promote public interest, protect sectors of vital importance (Section 83), prevent abuse (Section 140)
- Substantive-Novelty, Inventive Step or Non-Obvious, Industrial Application or Utility (Section 3, Section 29), Exhaustion of Rights (Section 107 A (b)
- Procedural- Pre and Post grant, Grounds for Pre and Post grant opposition and grounds for revocation (Section 25 (1), Section 25 (2), Section 64); Condition on Applicants (Section 8)
- Limitation and Exception- Bolar provisions, research and educational exceptions (Section 107 A and Section 47)
- Compulsory License-Grounds

Policy Challenges from Free Trade Agreements

Rationale for IPR Chapter

- Promotes creativity and innovation
- Technology Transfer and Diffusion
- Competitiveness and efficiency
- Transparency, “legal certainty”

A. Patentability Criteria: Attempts to Weaken

- Low threshold for inventive step-
  - New uses of a known product- eg. new indication
  - New methods of using a known product- eg. fixed dose combinations,
  - New processes of using a known product- eg. sustained release molecules

Implications

- Ever-greening of Patents
- Will Impact Competition negatively and affect diffusion of technology
- Keeping a low threshold for grant of patent will disincentivize creativity and innovation
- Delay entry of generics and affect access to medicines

Impact of low patentability standards

- Secondary patents (responsible for evergreening) are common in the industry (Kapczynski, Pak and Sampat (2012)
- They add between 6.3-7.3 years to the patent life
- Secondary patents establish a effective barrier to generic competition….The objective is to secure an optimal competitive position for products in the market by blocking competitors (European commission(2009) pharmaceutical inquiry: final report)

B. Patent Term Extension: Uncertain term

- Patent term of 20 year???-patent term extensions-for delays at the patent office and at the marketing regulator

Implication

- Ratchet Effect
- Uncertain term of patent will impact investment decisions of generic companies
- Access to medicines will be severely restricted

Protection of Undisclosed Information (Art 39.3 of TRIPS): Data Exclusivity Vs Data Protection

- "…… Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

C. Data Exclusivity Vs Data Regulation

Article 39 does not provide for Data Exclusivity

First Applicant

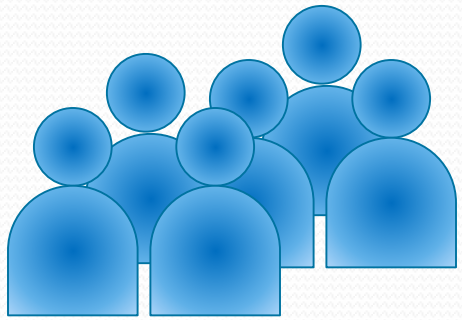
Clinical Trial Data

Marketing Approval

Drug Regulatory Authority

Data on Bio equivalence

Marketing Approval



Second Applicant

Data Exclusivity

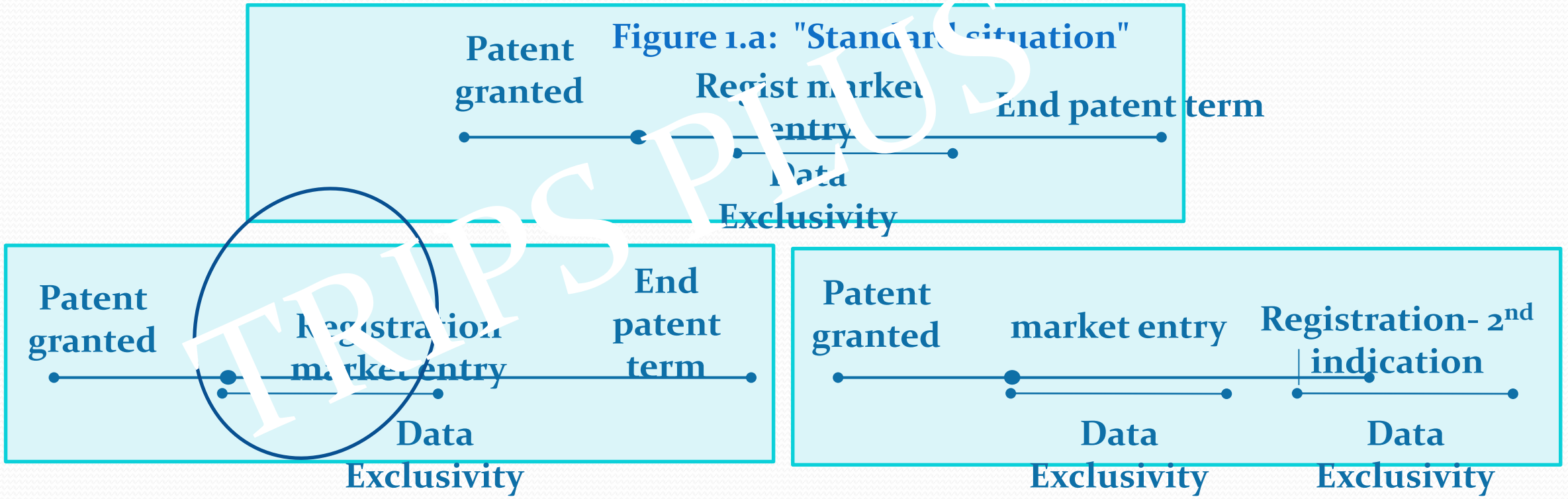


Figure 1.b: CL negated

Figure 2: Patent extension- second indication

Marketing of generics affected when there is no patent
Data Exclusivity is a derogation of circulation of free information and can never be implied unless specifically mentioned.

Source : WHO

Implications of Data Exclusivity

- Ever greening of Data Exclusivity
- Stronger right than the patent right
- Will impact the domestic industry-uncertainty, economies of scale will get affected
- Delay in the entry of generic medicines and access to medicines

Impact of Data Exclusivity on Access to Medicines

- Data exclusivity protection brought in Jordan as a consequence of the US Jordan FTA led to an increase in prices by 20%.
- Malpani(2007) identified 81 medicines of the 108, sales of which were $31.49 million (2002-06) where data exclusivity prevented entry of generics
- A similar situation was reported by Health Affairs (2009) in respect of impact on Guatemala of the Central American Free Trade Agreement.

Patent Linkage

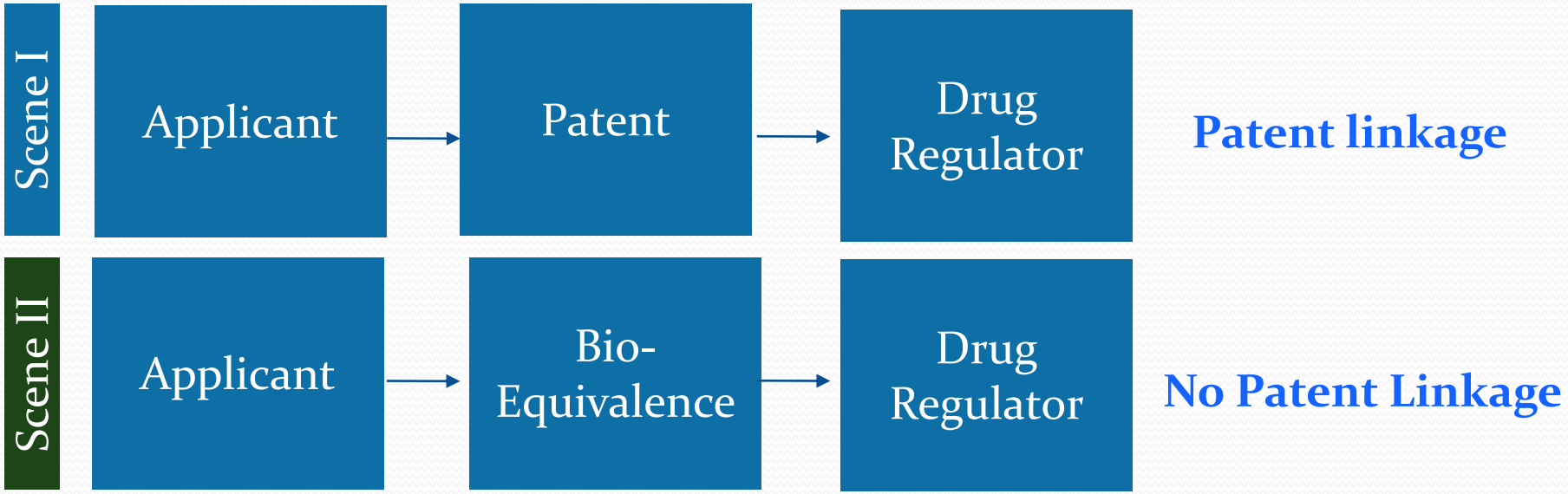
IPO

Drug Controller General of India (DGCI)

Seeks to link two separate legal and regulatory systems which have different objectives, are administered separately and function differently.

Patent Linkage-TRIPS does not mandate

Mechanism by which Regulatory Authority links marketing approvals to the existence of patent granted under the Patents Act



India's stance

Patent linkage is not acceptable as :

- Role of marketing regulator and patent office are different
- Scope and claims of patent are beyond capacity of regulator and cannot be evaluated by him.

Thank You