TRIPS provisions for Pharmaceutical Patents and Access to Essential Medicines

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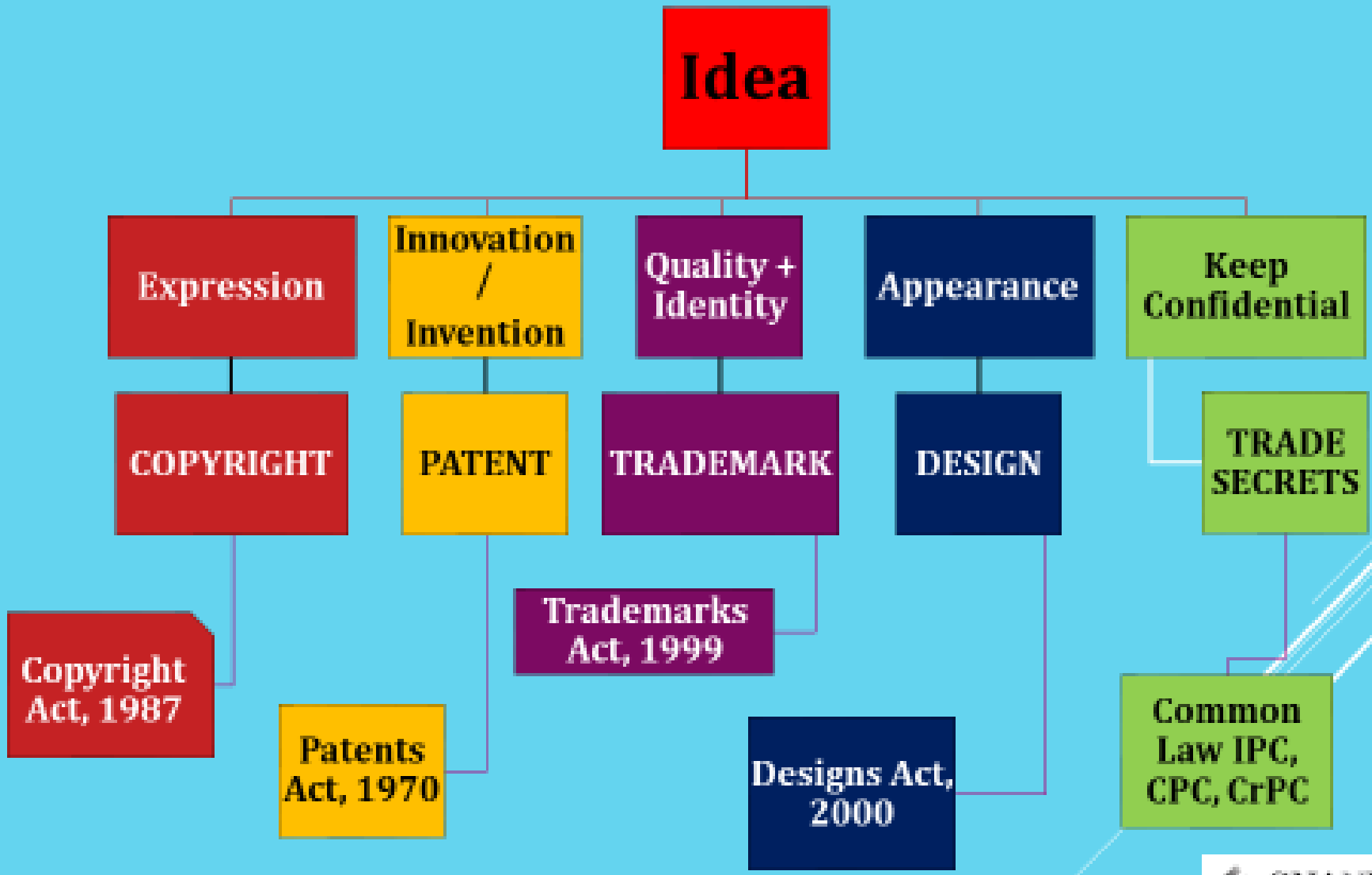
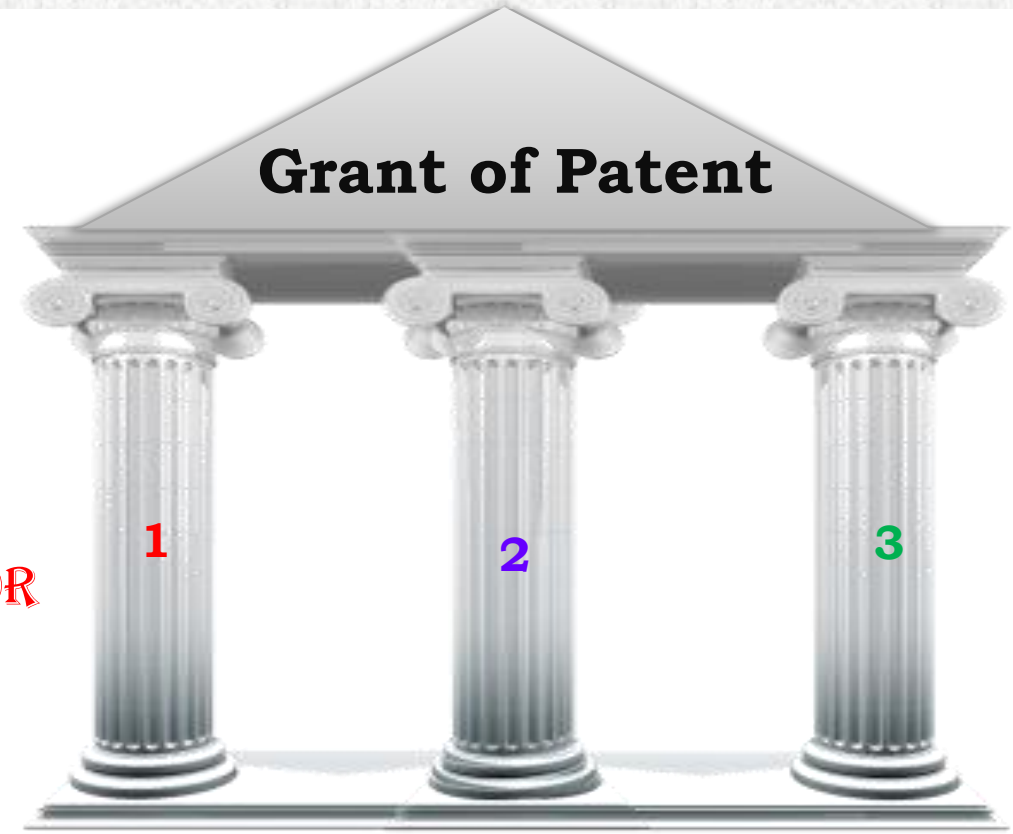
INTELLECT – PROPERTY – RIGHT



Three Statutory Pillars for Patentability as per the Patents Act, 1970



SINGLE PRIOR ART

Must not be covered by Sec. 3 and Sec. 4

UTILITY

Novelty

Inventive Step

Section 2(1)(ja))

Industrial Application

Section 2(1)(ac))

MOSAICKING PRIOR ART

PERSON SKILLED IN THE ART

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Compulsory License (CL)

- *"A compulsory license is an involuntary contract between a willing buyer and an unwilling seller, imposed and enforced by the state."*

- **Mostly applicable when;**
  - **dependent patent is being blocked,**
  - **patent is not being worked,**
  - **relates to medicine (price / access),**
  - **in antitrust or misuse or abuse situations,**
  - **for National Defense,**
  - **use by the State (Govt).**

Definition of CL by WTO

When a government allows someone else to produce the patented product or process without the consent of the patent owner.

It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS Agreement.

VL vs CL

VL	CL
Voluntarily granted by the Patentee Patentee's consent	Granted by the CG of Patents No consent by the Patentee's
Can be non-exclusive	Exclusive Licence granted to CL Applicant
License Terms Mutually Agreed	License Terms approved by CG
Authorised Generic	Generic
Likelihood of Tech Transfer	No Tech Transfer
Royalty maybe or may be not (COVID-19) on mutually agreeable terms	Royalty payable approved by CG
VL rejected. CL can be pursued at the Patent Office 3 years are date of grant	CL rejected appeal before High Courts
Common Law / Contract Law	Under Section 84 Patents Act, 1970
No such criteria	3 grounds under Section 84 have to be satisfied • Reasonable requirements not met • Not available affordable price • Not worked in India
No such criteria	Prior approved Mfg & Marketing
Low costs/time	High Costs/Time (litigation)

Essential Medicines - WHO

Essential medicines are those that satisfy the priority health care needs of a population.

The objectives of WHO's essential medicines and pharmaceutical policies programme are to save lives and improve health by ensuring the quality, efficacy, safety and rational use of medicines, including traditional medicines.

NLEM-2015

- NLEM-2015 notified on 23rd December, 2015
- 376 drugs listed as essential medicine
- Revision of NLEM deferred till mid-2021
- COVID-19 Essential Drugs*
  - **Remdesivir:** NPPA max retail price Rs. 3500
  - **Tociluzumab:** Supply monitored by NPPA and CDSCO
  - **Favipiravir, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine**: production and supply reviewed by NPPA and DCGI

**Hon'ble Supreme Court Of India Suo Motu Writ Petition (Civil) No.3 of 2021 In Re: Distribution Of Essential Supplies And Services During Pandemic*

Paris Convention, 1883

Article 3(a)

Each contracting State that takes legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by a patent may do so only with certain limitations.....

TRIPS

- **Article 2:** *TRIPS article shall not derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.*
- **Article 7**: Objectives (verbatim Sec 83(c) of IPA)

  The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations
- **Article 8**: Principles

  Article 8(1) (inspired Sec 83(d) of IPA)

  Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

  Article 8(2) (inspired Sec 83(f) of IPA)

  Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

TRIPS

- **Article 27:** Patentable Subject Matter
- **Article 30:** Exceptions to Rights Conferred
- **Article 31:** Other Use Without Authorization of the Right Holder
  - 12 (a to l) conditions/caveats listed for CL
  - conditions/caveats **do not apply in case of national emergency, extreme urgency or public non-commercial use**

Para 5 of Doha Declaration

- Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
- Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relation to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstance of extreme urgency.

Contd.....

Para 6 of Doha Declaration (For Exportation)

*We recognize that WTO members with **insufficient or no manufacturing capacities** in the pharmaceutical sector could **face difficulties** in **making effective use of compulsory licensing** under the TRIPS Agreement.....*

IN INDIA

- **Section 83:** General principles applicable to working of patented inventions.
- **Section 84:** Compulsory licenses by 3rd Party

Conditions

(a) reasonable requirements of the public not satisfied, or

(b) not available at reasonably affordable price, or

(c) not worked in the territory of India.

- **Section 85:** Revocation of patents by the Controller for non-working
- **Section 86, Section 87, Section 88:** Procedure & Power of Controller.
- **Section 89:** General purposes for granting CL

Contd…..

IN INDIA

- **Section 92**: Special provision for compulsory licences on notifications by Central Government
- **Section 92A:** CL for export of patented pharmaceutical products in certain exceptional circumstances. (**Doha**)
- **Section 93:** Order for licence to operate as a deed between parties concerned.
- **Section 94:** Termination of CL

Contd.....

INDIA - Government Use

- **Section 99:** Meaning of use of invention for purposes of Govt.
- **Section 100:** Power of Central Govt to use inventions for purposes of Govt.
- **Section 101:** Rights of third parties in respect of use of invention for purposes of Govt.

Similar to 28 USC 1498 of USA

Use or mfg is 'by' or 'for' the Govt

Delhi High Court Order Dated APRIL 20, 2021
Rakesh Malhotra vs Govt Of National Capital Territory Of India & Ors in W.P.(C) 3031/2020

"27. There are a number of other drugs which are being used for treatment Covid-19 patients, such as Tocilizumab, Favipiravir, Ivermectin, Dexamethasone, Methylprednisolone, Dalteparin, Enoxaparin, HCQ and Baricitinib. As per news reports, there are shortages of some, if not all, of the aforesaid drugs. Looking to the emergent situation, we direct the Central Government to immediately reach out to the manufacturers/ patent holders/licensees so as to forthwith ramp up the production capacities of the above, and all such other medications, as are essential for treatment of Covid positive patients. We may take note of the fact that the Patents Act provides for Compulsory Licenses under Section 84, and Special Provision for Compulsory Licenses or Notifications by the Central Government, under Section 92. Section 100 provides the power of the Central Government to use inventions for purposes of the Government.

28. Looking to the present day situation, there can be no doubt that a case is made out for exercise of its power by the Central Government/ Controller under the aforesaid provisions of law. At the same time, the interests of the Patent holders/ licensees should be kept in mind, since it on account of their investments, inventions and hard work that such like medicines are made available to the public at large. The best course would be encourage the existing manufacturers to ramp up their production on a war footing. They should also be encouraged to grant voluntary licenses to other entities to manufacture the requisite drugs. However, if such efforts do not fructify soon enough, the Government/ Controller should not hesitate to invoke their jurisdiction and powers under the aforesaid provisions of the Patents Act, since the lives of thousands of people are being lost each day in the country due to COVID. The lives of the people take priority over everything else. Even if such like powers are exercised, the patent holders/ manufacturers can be adequately compensated by fixation of fair license fee. The Central Government should swing into action in terms of this order in this regard without any delay, and report progress on the next date of hearing."

COVID-19 VLs

Drug	Licensor	Licensee
Remdesivir	Gilead Sciences	Cipla Ltd., Dr. Reddy's Labs Ltd.; Eva Pharma; Ferozsons Labs; Hetero Labs Ltd.; Jubilant Lifesciences; Mylan; Syngene, Biocon company; and Zydus Cadila Healthcare Ltd.
Tocilizumab	Roche	Cipla
Molnupiravir	Merck	Cipla, Dr Reddy's Labs, Emcure Pharma, Hetero Labs and Sun Pharma Inds
Baricitinib	Eli Lilly and Company	Cipla, Lupin, Sun Pharma Inds, Dr Reddy's, MSN Labs, Torrent Pharmas, Natco Pharma Ltd and BDR Pharma
Sputnik V Vaccine	Russian Direct Investment Fund (RDIF)	Dr. Reddy's Laboratories, Gland Pharma, Stelis Biopharma, Virchow Biotech and Panacea Biotec, Hetero
Covishield	AstraZeneca/ University of Oxford	Serum Institute of India
oral, repurposed medication to treat mild, moderate and asymptomatic cases of COVID-19	Ennaid Therapeutics	Strides Pharma Global Pte. Limited, Singapore (Strides Pharma Science)

VL (& CL) APPLICANT

- Need to be a qualified / equipped manufacturer,
- To ensure bioequivalence studies,
- Requisite Permissions from DCGI/CDSCO,
- Offer substantially lower price,
- Preferable (no legal bar)
  - to avoid prior manufacture / infringement.
  - to avoid petition for revocation.

Indian CL Case Law
Natco vs. Bayer

Compulsory License by Natco application	29/07/2011
Published in Patent Office Journal	12/08/2011
Challenged by Bayer in Bombay High Court for not establishing *prima facie* case	
Rejected on jurisdct'n & directed to DHC	11/11/2011
DHC dismisses writ petition & directs to CG Patents, Mumbai	16/11/2011
CL Hearings	Jan-Feb 2012
CL granted by Patent Controller General P H Kurian	09/03/2012
Appeal by Bayer - rejected by IPAB chairman Justice Prabha Sridevan	March 2013

Sorafenib Price Reduction of 97%

INDIA
DRUG - PATENT LINKAGE

The Drugs And Cosmetics Act, 1940

FORM 44 (See rules 122A, 122B, 122D and 122DA)

Application For Permission To Import Or Manufacture New Drugs For Sale Or To Undertake Clinical Trials

FORM 44
The Drugs And Cosmetics Act, 1940

Cont.....

[1][FORM 44

(*See* rules 122A, 122B, 122D and 122 DA)

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

I/We*..... of M/s. .... (address) hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information / data is given below :

1. *Particulars of new drug :*

(1) Name of the drug.

(2) Dosage form.

(3) Composition of the formulation :

(4) Test specification.
(i) active ingredients.
(ii) inactive ingredients.

(5) Pharmacological classification of the drug.

(6) Indications for which proposed to be used.

(7) Manufacturer of the raw material (bulk drug substances).

(8) Patent status of the drug.

INDIA: DRUG - PATENT LINKAGE

Bayer Corp v UOI (Sorafenib) dtd 09/02/2010 in DHC

"the attempt at bringing in patent linkage on the basis of the existing provisions of the Patents Act and the DCA cannot be countenanced".

Special Leave Petition filed by Bayer seeking introduction of patent linkage system in India dismissed by Supreme Court in December 2010

Patent Regulatory Linkage is identified as a 'TRIPs-Plus' provision

US ORANGE BOOK

Orange Book lists drug products approved by the US FDA under the Federal Food, Drug, and Cosmetic Act and related Patent and Exclusivity Information

Purple Book – Biologicals / Biosimilars

US: DRUG - PATENT LINKAGE

ARIPIPRAZOLE (ABILIFY MYCITE KIT) TABLET 2MG

Patent No	Patent Expiration	Patent Use Code
7053092	01/28/2022	U-1529
7978064	09/14/2026	
8017615	06/16/2024	
8114021	06/21/2030	
8258962	11/25/2030	
8545402	04/27/2030	
8547248	12/18/2030	U-2167
8580796	09/25/2022	
8642760	09/25/2022	
8674825	04/09/2029	U-2170
8718193	12/05/2029	
8759350	03/02/2027	U-1529
8847766	03/29/2030	U-2167
8945005	08/19/2029	U-2167
8956288	07/06/2029	U-2167
8961412	11/17/2030	
9060708	03/05/2029	
9089567	01/28/2022	U-543
9119554	12/16/2028	
9125939	07/28/2026	U-1749
9149577	12/15/2029	
9258035	03/05/2029	
9268909	10/15/2033	U-2168
9320455	12/15/2031	
9359302	09/25/2022	U-543 U-1529 U-1749
9387182	12/25/2023	U-1529
9433371	09/15/2029	
9444503	11/19/2027	U-2169
9941931	11/04/2030	
10441194	07/26/2029	
10517507	06/13/2032	

Paragraph I Certification: patent information has not been filed

Paragraph II Certification: the patent has expired

Paragraph III Certification: The date the patent will expire

Paragraph IV Certification: the patent is invalid or not infringed by the drug product proposed in the ANDA

COVID-19

- India and Africa initiated proposal at the WTO for the relaxation in the norms of the agreement on TRIPS: Patent waiver for drugs and vaccines
- Support at recently held G7 summit in Britain
- Agreed text by July-end
  - Focus on "health products and technologies "as the prevention, treatment or containment of COVID-19 involves a range of products and technologies and intellectual property issues may arise with respect to the products and technologies, their materials or components, as well as their methods and means of manufacture.
  - Waiver in force for at least 3 years

IN USA

- 28 USC § 1498: Patent and Copyright Cases
  - Outside 35 USC (US Patent Law)
  - Use or mfg is ‘by’ or ‘for’ the Govt
  - Patentee is entitled to reasonable & entire compensation

- Anthrax Drug case: Ciprofloxacin
- Zoltek Corp. vs. United States: F-22 fighter jets.
- Sandoz / CG Merger: Threat to competition.

No Third Party Compulsory Licensing

28 USC 1498 OF USA

(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.....

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.....

IN EUROPE

Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on the Compulsory Licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

COVID-19 CL PROVISIONS

Emergency legislation implemented in response to the public health emergency caused due COVID-19 pandemic

- Canada
- Chile
- Colombia
- France
- Germany
- Hungary
- Israel
- Russian Federation