COMPULSORY LICENCE

BY

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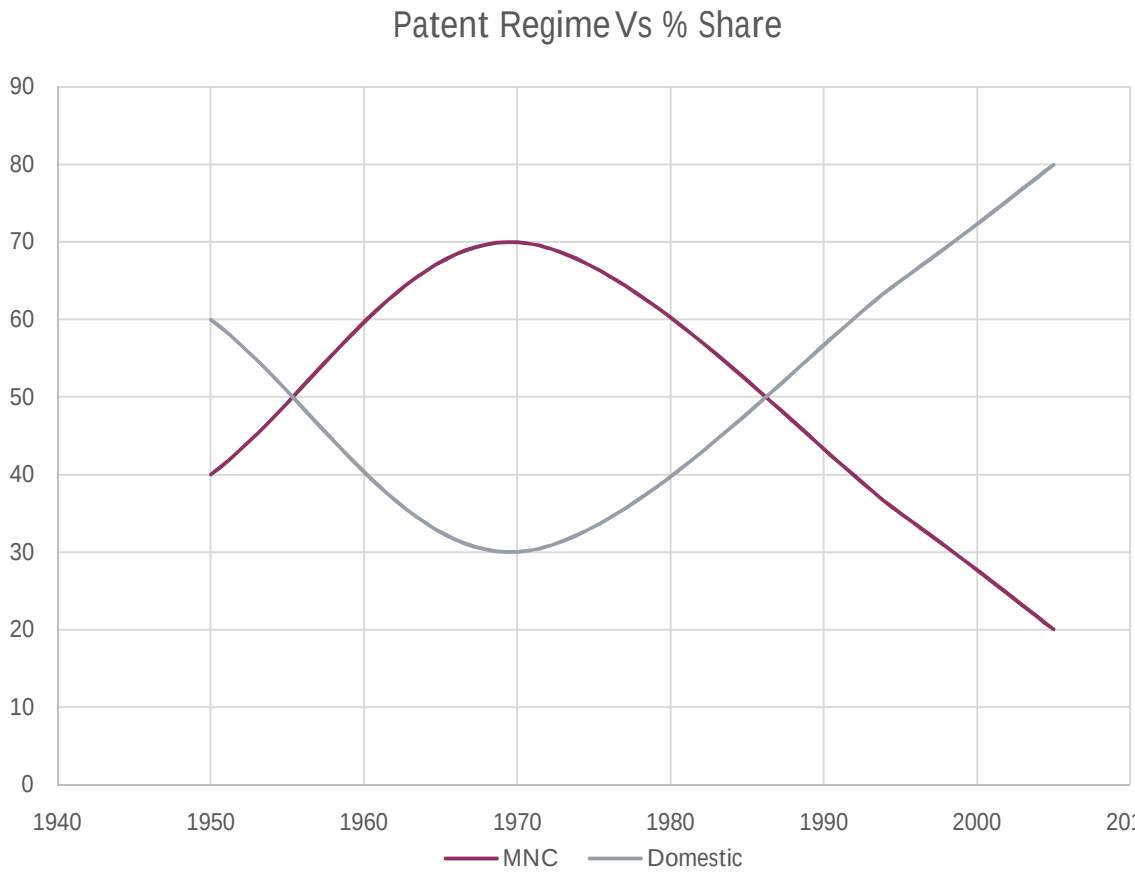
ISSUES

- ccess to patented drugs
- npact of Doha Declaration & TRIPS
- rice of medicines and relative economic condition of the public
- Working of Patents & Availability/access to medicines
- alancing the rights of patients Vs Patent holders
- ncourage Indian companies to protect IP – build IP culture

HISTORY OF INDIAN PATENT LAW

re - 1970	Product Patent Regime
1970	Act amended (Indira Gandhi) - Process Patent Regime
1995	India signs WTO agreement on TRIPS
2005 -	Product Patent regime



INDIAN PATENT ACT - POST – 2005

Law amended - Product patent regime takes effect.

Section 3(d) introduced

- *(d) the mere discovery of a new form of a known substance* ***which does not result in the enhancement of the know*** ***efficacy*** *of that substance or the mere discovery of any new property or new use for a known substance or of the mere use a known process, machine or apparatus unless such known process results in a new product or employs at least one ne reactant.*
- *Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, partic size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to b the same substance, unless they differ significantly in properties with regard to efficacy;*

- Beta crystalline form of Imatinib mesylate – Patent denied. Novartis challenged it till Supreme court and lost. No enhancement of known efficacy.

ACCESS - COMPULSORY LICENSING (CL)

Section 84 - Compulsory licences

At any time after the expiration of three years from the date of the grant of a patent, any person interested e an application to the Controller for grant of compulsory licence on patent on any of the follow unds, namely:—

(a) that the reasonable requirements of the public with respect to the patented invention have not b fied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

ACCESS - COMPULSORY LICENSING (CL)

Sorafenib – Carcinoma.

- Bayer's Nexavar for Rs. 2,84,000 per patient per month.
- Natco's therapy - Rs. 8, 800 per patient per year.
- Question – Return on investment for research vs Access to medicine for life saving drugs.
- Patent office granted CL to Natco.
- Later on decision upheld by IPAB, Bombay high court and Supreme court.

Natco Pharma wins cancer drug case

Bayer's plea dismissed by the Intellectual Property Appellate Board

The Intellectual Property Appellate Board (IPAB) on Monday u grant of compulsory licence (CL) to the Hyderabad-based Natc Limited, a generic drug maker, to produce and market Nexavar, a cancer drug of multinational pharma major Bayer Corporation. **T will pave the way for reduction in the prices of costly li drugs.**

Disposing an appeal filed by Bayer Corporation, the Board held th international conventions and Indian laws allowed the member co **grant such compulsory licence in order to make medicine available to the public.**

Declining to interfere with the order of compulsory licence, said, "We are not inclined to interfere with the order of Controlle in the interest of the public. **The invention must be availab public at reasonable and affordable price if not compulsor is given."**

"We must bear in the mind of public interest but neither the inv the compulsory licence applicant. Patents are granted to be inventions to the public."

OMPULSORY LICENCE – MIXED BAG

BDR's CL for Dasatinib and Lee Pharm a's – Saxagliptin denied

No other application for compulsory licence filed nor granted

Take aways:

- CL is an effective tool for enabling access to medicines – but depends on merits of a compound
- Every application for CL - need not be successful

TRODUCING OFF-PATENT PRODUCTS

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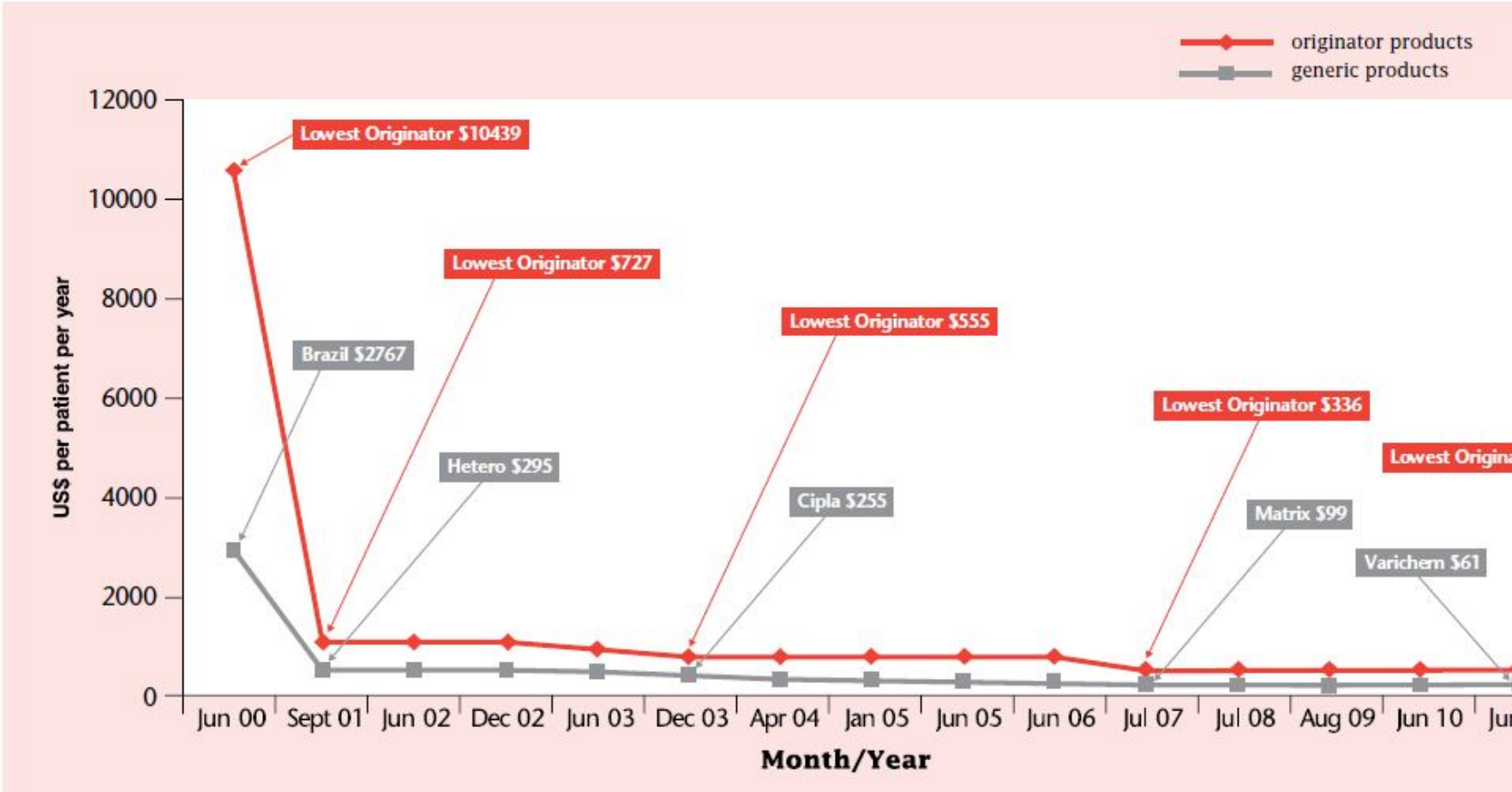

ACCESS AND INNOVATION – WAY FORWARD

- Strategy
  - New Chemical Entity
  - Innovative formulations
  - New Dosage form of existing drugs
  - New processes and intermediates
  - New strength
  - Changes in release pattern
  - Drug repurposing, (new Indication)

ACCESS AND INNOVATION – WAY FORWARD

nnovation

- India pharmaceutical Industry – Mainly generic
- To manage economics well innovation is inevitable. Many Indian companies are already onto this path.
- Blockbuster drugs are going off patent in coming years.
- Generic Competition across the globe within Indian players and from companies in other countries
- Positives – High Quality
  - (Sofosbuvir, Gilead signed agreement with 7 Indian generic manufacturers to sell the product in 91 countries)

Access – Possible options

- CL applications in appropriate case for life saving drugs.
  - By third party under Section 84.
  - By government under Section 92.

Let’s INNOVATE

Thank you