

# Global Pharma in Indian IP Hospital

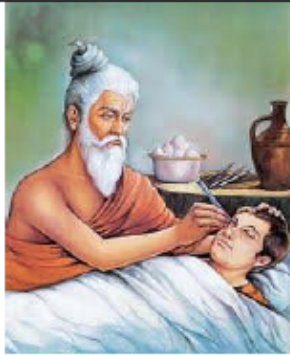
By Dr. Rajeshkumar H. Acharya



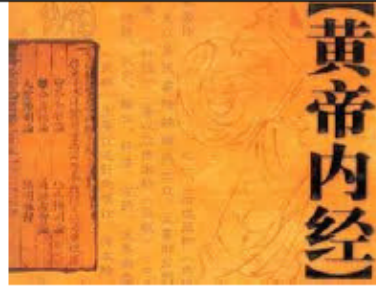
*Homo sapiens*-used medicinal substances



Sumarians- roots of pharmacy



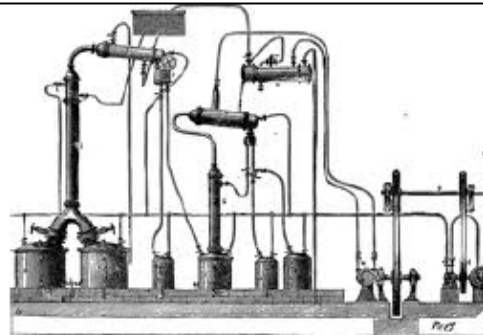
Charak(a) Samhita



Huangdi Neijing or 'Yellow Emperor's Inner Canon'



Galen



Muslim chemists -alcohol distillation

## The origins of pharmacy



Holy Roman Emperor Frederick II  
separate roles of physicians and  
pharmacists



Tsar Peter the Great (1672-1725)  
created an eighteenth century model  
of pharmacy

End of the 18th century in the  
American frontier society role began  
to divide doctors' and 'drug clerk'  
employees

Nineteenth century the  
pharmaceutical sciences -include  
inorganic and organic – carbon  
compound based – chemistry,  
alongside pharmacognosy,  
pharmaceutics and pharmacology



MERCK



SANDOZ



Beechams

ALLEN & HANBURYS

The specialist respiratory division of  
GlaxoSmithKline



Scientific developments : Formation of pharmaceutical companies

## The origins of pharmacy

# Indian Position

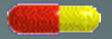
- During the interim period pharmacy in India -pharmaceutical chemistry and pharmaceuticals focused
- Patents (Amendment) Act, 2005 - opened up new avenues for the pharmaceutical sector
- ❖ March 4, 2013: INTELLECTUAL PROPERTY APPELLATE BOARD (IPAB), upheld Indian Patent Office decision to grant Compulsory License of Bayer Corporation invented a drug called 'Sorafenib' in favour of Natco Pharma Limited
- ❖ April 1, 2013: Novartis loses seven-year Glivec battle against the Indian Patent Office
- ❖ April 5, 2013: The Hon'ble High Court of Delhi rejects Merck Sharp and Dohme Corporation (MSD) suit for injunction restraining infringement of Sitagliptin - patent and seeking interim relief restraining the Glenmark Pharmaceuticals Ltd.

# 1<sup>st</sup> Compulsory License in India: NATCO PHARMA LIMITED V/S BAYER CORPORATION

- Compulsory License in favour of Natco Pharma Limited - royalty at the rate of 6% of the net sales of the drug on a quarterly basis - Bayer Corporation (Licensor)
- Bayer Corporation invented a drug called 'Sorafenib' (Carboxy Substituted Diphenyl Ureas)



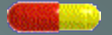
<b>Date</b>	<b>Event of case</b>
<b>Jan. 12, 2000</b>	PCT application date
<b>July 7, 2001</b>	National Phase entry
<b>March 3, 2008</b>	Bayer -patent No. 215758 for 'sorafenib'
<b>July 28, 2011</b>	Natco Pharma ("Natco") -an application U/S 84(1) - grant of CL
<b>August 9, 2011</b>	The Controller - being satisfied that a prima facie case existed, issued an order for publishing the CL application in the official journal.
<b>October 2011</b>	Bayer filed interlocutory petition - stay of proceedings on the ground that infringement suits and contempt petitions against Natco were pending in the Delhi High Court. These petitions were refused by the Controller.
<b>Nov. 2011</b>	Bayer filed its opposition to the compulsory license application and each party filed their respective evidence.
<b>Jan-Feb 2012</b>	The parties were heard extensively
<b>March 9, 2012</b>	Order of the Controller -in favor of "NATCO"
<b>June 2012</b>	Deadline for filling an appeal - before the Intellectual Property Appellate Board ( <b>IPAB</b> )
<b>September 4, 2012</b>	IPAB refused interim stay on controllers decision
<b>March 4, 2013</b>	IPAB dispose application in favor of "NATCO"



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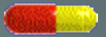
- Natco-proposed to sell the drug at a price of Rs.8800/- for one month therapy as compared to the price of about Rs.2,80,428/-, which was being charged by the Patentee
- reasonable requirements - Patentee had made available the drug only to a little above 2% of the eligible patients

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- Not reasonably affordable price- Rs.2,80,000/- (for a therapy of one month)
- Not 'Worked in the territory of India- failed to achieve this by either manufacturing the product in India or by granting a license to any other person for manufacturing in India.



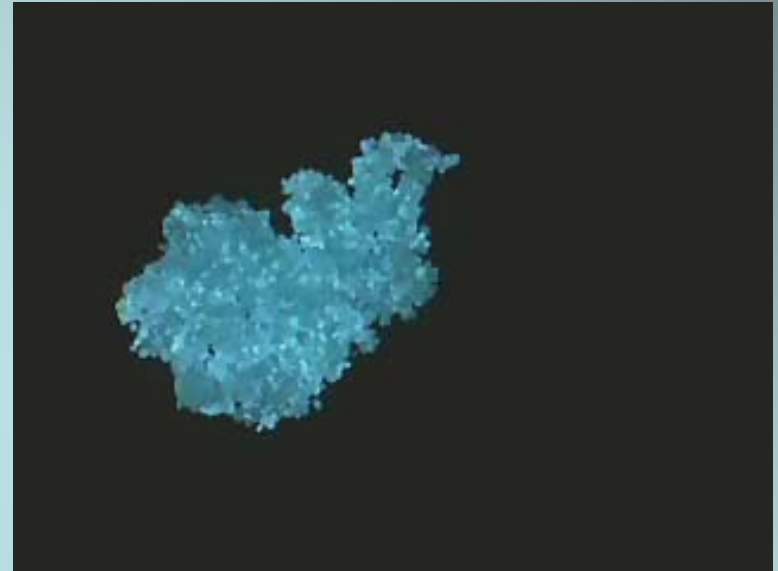


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- Aggrieved by decision Bayer appealed the decision IPAB
- IPAB withheld the decision of the controller but there are differences in following issues
- **1) “Working” can also cover imports:** "working" should be interpreted on a case-by-case basis - patentee must show why the invention could not be manufactured locally
- **2) Royalty rate:** IPAB increased the royalty fixed by the controller by 1% to make it fairer

# Novartis loses seven-year Glivec battle

- The Hon'ble Supreme Court of India denies of Novartis- Glivec patent that fails in the tests of invention and patentability under section 2 (j) (ja) and section 3 (d)



Date	Event of case
1998	Novartis applied for Glivec patent in India
2002	Novartis applied for grant of exclusive marketing rights
2003	The Indian Patent Office granted EMR
January 2006	The Indian Patent Office rejected Novartis's Glivec patent application
May 2006	Novartis filed writ petitions before Madras High court
April 2007	After formation of the Intellectual Property Appellate Board, five writ petitions transferred from the High Court to IPAB. However, the Madras High Court, reserved the right to pronounce its judgment on the issue of the constitutional validity of section 3 (d) of the Act.
August 2007	The Madras High Court held that Section 3(d) does not violate Article 14 (Right to equality) of the Constitution of India
June 2009	IPAB : the subject matter of the invention was barred from patentability U/S 3 (d)
August 2009	Special Leave Petitions (SLPs) under Article 136 of the Indian Constitution
2011	The matter was heard
April 1, 2013	The Supreme Court rejects Novartis's appeal

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- The Hon'ble Madras High Court: “going by the meaning for the word “efficacy” and “therapeutic” ... .., what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/ having a good effect on the body?
- The Hon'ble Supreme Court: decision to prevent "evergreening“
- More beneficial flow properties, better thermodynamic stability, lower hygroscopicity of the product related to improving processability and storage not to pass the test of Section 3(d)
- Increase in bioavailability: No supporting data

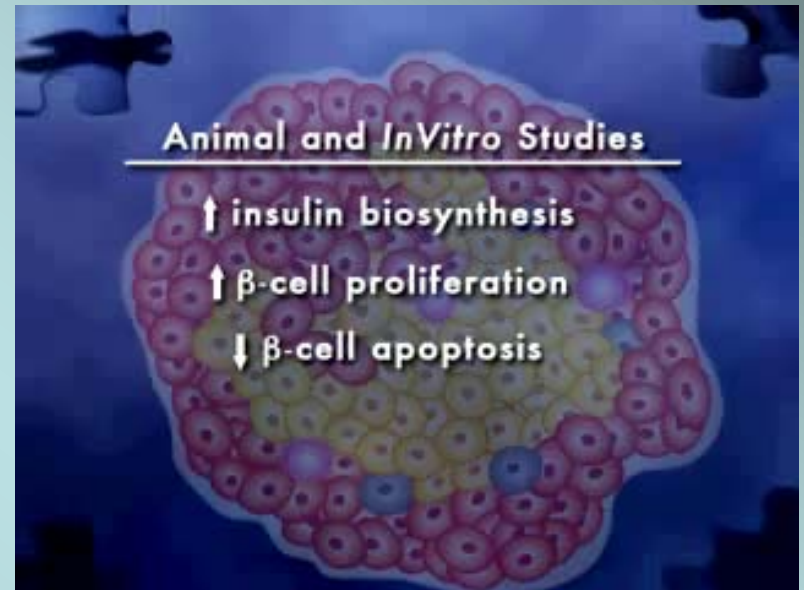


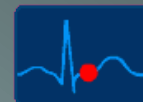
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- “It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment.”

# No injunction to Merck against Glenmark

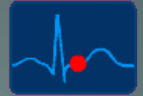
- The Hon'ble High Court of Delhi rejects MSD suit for injunction restraining infringement of patent and seeking interim relief against the Glenmark Pharmaceuticals Ltd.
- MSD -patent on Sitagliptin, sold product under the brand name "JANUVIA" and "JANUMET"





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- License - Sun Pharmaceutical Industries Limited  
- ISTAVEL & ISTAMET
- MSD: process patent obtained by the Glenmark in US -admitted the Merck's US patent in Sitagliptin
- Glenmark: injunction is claimed comprises of three parts namely "S", "PD" and "DC" and Merck in USA has separate patents, for each of the three parts- for India "S" i.e. Sitagliptin only



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- The Hon'ble High Court: Merck in its own application for grant of Sitagliptin Phosphate and which was abandoned
- “.....the plaintiff certainly cannot be granted interim relief on a case not pleaded and in the face of its admission of Sitagliptin Phosphate being a new invention worthy of patent.”



# Rejection of Compulsory License Application by IPO

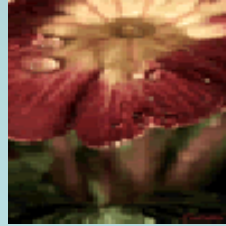
- IPO-rejected -CL application made by BDR Pharmaceuticals -Dasatinib, an anti-cancer drug- patented by US drug maker Bristol-Myers Squibb
- Held : “BDR deliberately refrained from entering into any dialogue with Bristol-Myers for getting a voluntary license and selected only the CL option without taking the steps outlined in the law
- Act of filing of infringement suits cannot be classified as “anti-competitive”

# Opportunities

- US\$ 8 billion market for MNCs selling expensive drugs by 2015
- Domestic pharma market is likely to reach US\$ 20 billion
- Public spending on healthcare - 13 per cent of GDP by 2015
- Low cost of production of bulk drugs
- Low R&D costs
- Strong scientific, technical manpower
- Excellent national laboratories specializing
- Centre for clinical trials in view of the diversity in population.



# Thank You



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