Section 3(d) of the Patents Act, 1970 and its Impact

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Historical Background

- Indian pharma industry - timeline
- WTO/TRIPS Agreement – 1995

- India's obligations v India's needs
  - Product patents for pharma
  - Agrarian economy, pharmacy of the world, developing nation

- Patents (Amendment) Act, 2005 – Balancing act
  - Repeal Section 5 – allow product patents for medicines
  - Amend Section 3(d) – set up 'second tier' of qualifying standards for pharmaceutical products/ check **evergreening**

Section 3(d)

- Novartis AG v Union of India

Imatinib (1994) → Imatinib Mesylate → beta crystalline form of Imatinib Mesylate (1998) (therapeutic efficacy)

- Roche v Cipla

Erlotinib → Erlotinib Hydrochloride (polymorph A+B) (1996) →Erlotinib Hydrochloride (polymorph B) (2002) (rejected under 3(d))

Section 3(d)

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…

(d) 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

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Section 3(d)

- Paracetamol → Injection → Tablets → Drops
- New form of paracetamol that may have efficacy in treating diabetes?
- US law v Indian law

Purpose of Section 3(d)

- Pharma patents need to satisfy:
  - Novelty
  - Inventive Step
  - Industrial Applicability
  - Section 3(d) – “second tier” of patentability
- Trend of multiple patenting/evergreening
  - Broad markush claims
- Allow ‘good’ patents, deny ‘bad’ patents
- Efficacy = Therapeutic efficacy

Criticism

- Anti – innovation
- Against TRIPs
- Unique to India
- Tool to deny patents
- Will not reduce price difference between innovator and generic drugs
- Will have adverse impact on industry
- Will result in reduction in foreign investment in pharma
- Badly drafted
- Needs to be struck down

Is Section 3(d) anti-innovation?

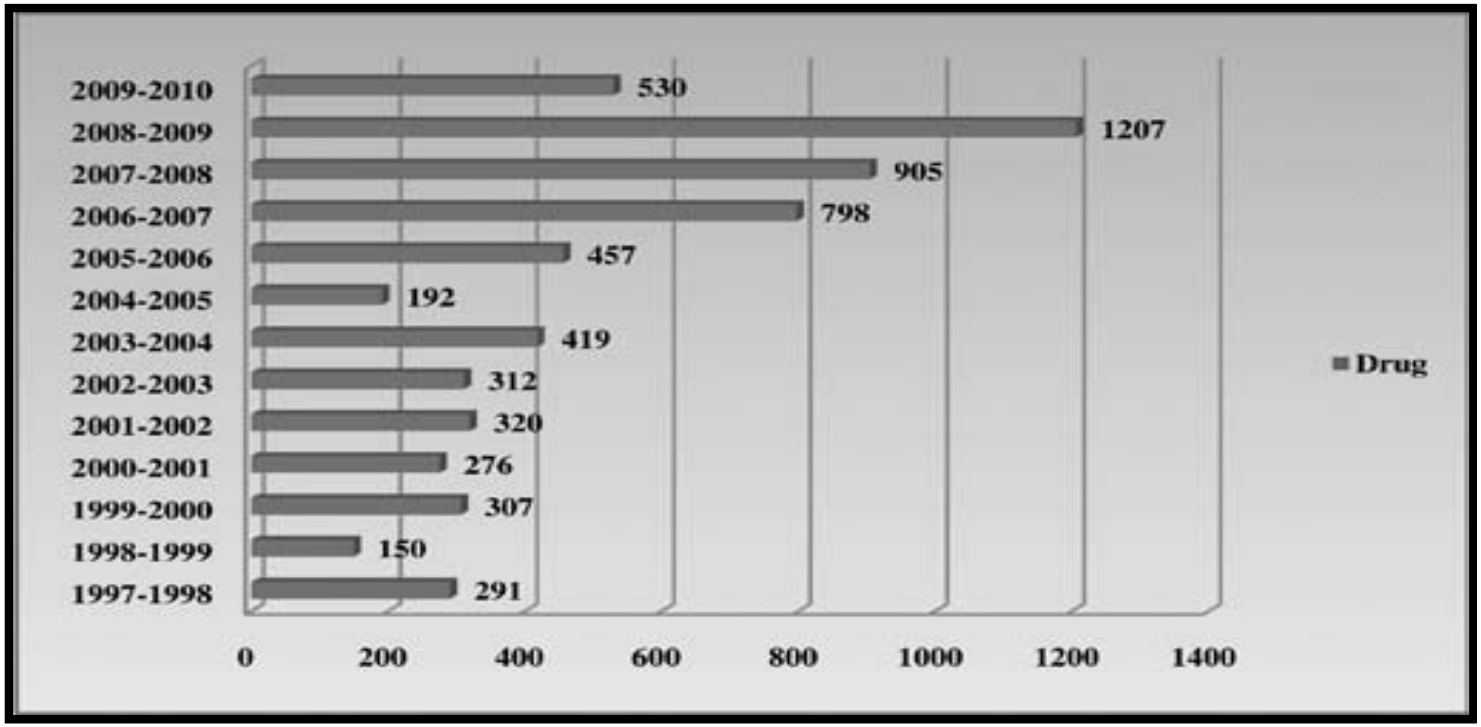
- Most countries have exceptions to invention
- Rewards genuine inventions
  - Evergreening v incremental innovation
- Denying frivolous patents
- MSD v Glenmark
  - Sitagliptin → Sitagliptin HCl → Sitagliptin Phosphate Monohydrate
- Level playing field
- Maintain balance between inventor's rights and requirements of public health

Does Section 3(d) violate TRIPs?

- Uses TRIPs flexibilities
  - Preamble
  - Art 8 (public health)
  - Art 27 (exclusion of inventions for public order, morality, health)
  - Used by most nations, including USA
- Doha Declaration
  - TRIPs allows interpretation according to national requirements to protect public health and access to medicine
- Various other countries have adopted 3(d)-like provisions
  - Thailand, Brazil, Japan, Philippines, Argentina, Mexico
- Novartis AG v Union of India

Is Section 3(d) a tool to deny patents?

- No reduction in grant of patents



Pharma Times - Vol. 44 - No. 07 - July 2012

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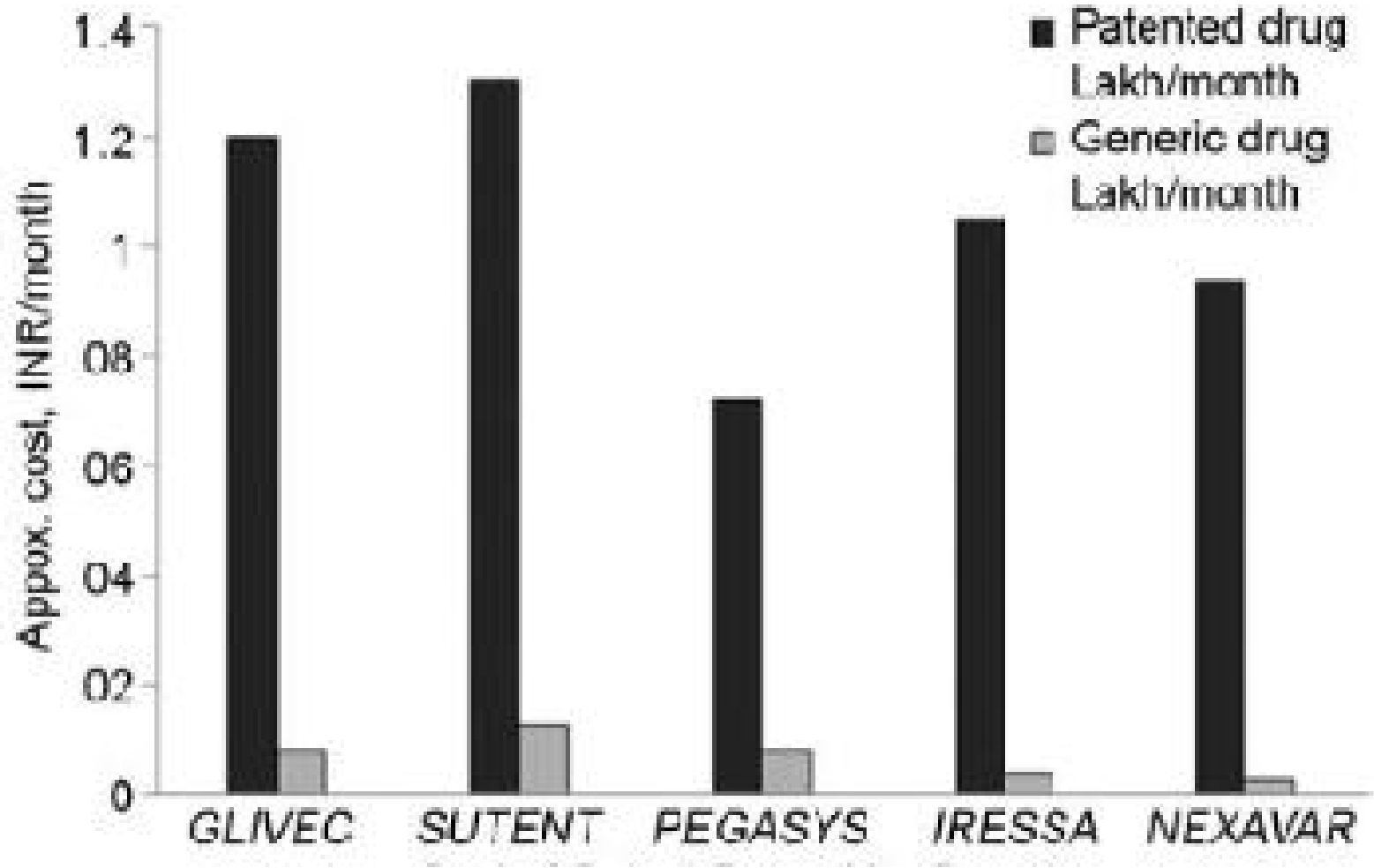
Patent granted in year	Bio-Medical				Bio- chemical			
	Filed		Granted		Filed		Granted	
	Indian	Foreign	Indian	Foreign	Indian	Foreign	Indian	Foreign
2010-11	22	700	60	353	10	117	6	43
2011-12	176	890	0	24	50	129	9	29
2012-13	183	870	0	11	75	291	1	16
2013-14	163	449	0	12	72	118	3	53
2014-15	348	1321	4	66	136	248	6	60
Total	**892**	**4230**	**64**	**466**	**343**	**903**	**25**	**201**

Annual Reports of CGPDTM

Price Difference



JIPR, Vol 21, January 2016, pp 16-26

Novartis AG v UOI: Effect

- Glivec in **South Africa**:
  - Patents upto 2022
  - 10 patents granted for Imatinib and its 'variants'
  - Price: Rs. 1890 per tab = Rs. 56,700 p/m = **Rs. 6,80,400 pa**

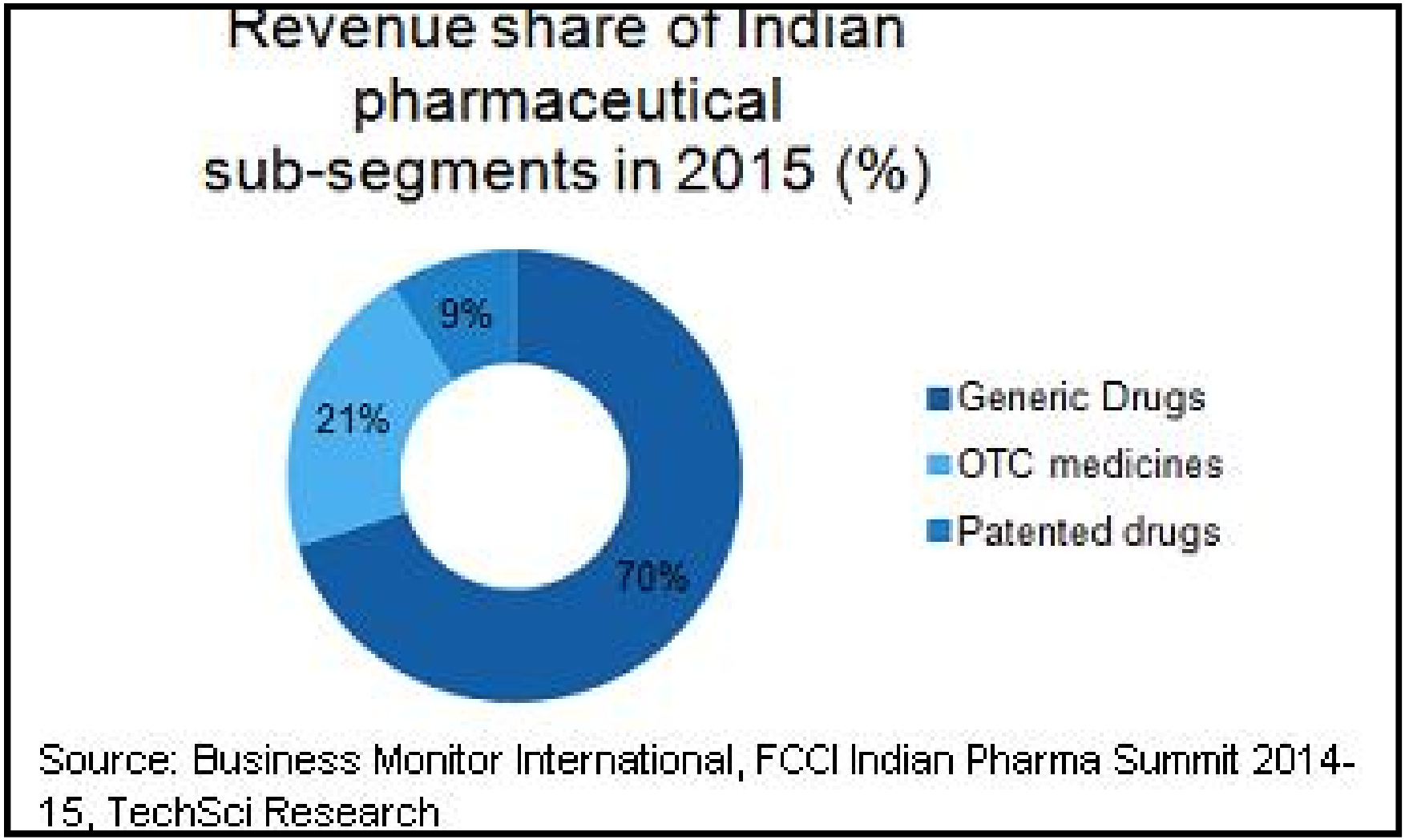
- Glivec in **USA**:
  - Imatinib patent expired in 2015
  - Beta Crystalline form of Imatinib Mesylate: 2019
  - Price: Rs. 8099 per tab = Rs. 2,42,970 p/m = **Rs. 29,15,640 pa**

- Glivec in **India**:
  - No patent
  - Price: Rs. 80-90 per tab =Rs. 2400 p/m = **Rs. 28,000 pa**

Impact on Industry

- Pharma – consistently fifth largest recipient of FDI since 2000
- Mylan acquired Unichem's formulation plant in 2013
- Abbott acquired Piramal Healthcare's core formulations business for $3.8 billion in 2010
- Sanofi invested $722 million in acquiring and upgrading Shantha Biotech (2009-12)
- Daiichi Sankyo – Ranbaxy deal
- Sun Pharma acquired Ranbaxy
- Mylan has invested $3 billion in India in the last six years and operates some 14 facilities with about 12,000 people in the country.

http://www.livemint.com/Industry/PwT7zsLRodSjrKZhf6ga1N/Pharma-still-attractive-for-foreign-investors.html


Revenue share of Indian pharmaceutical sub-segments in 2015 (%)
9%
21%
70%
Generic Drugs
OTC medicines
Patented drugs
Source: Business Monitor International, FCCI Indian Pharma Summit 2014-15, TechSci Research

Conclusion

- Section 3(d) has had no negative impact on industry
- Genuine patents are granted
- Price control is maintained
- Generic industry continues to grow
- Healthy competition among Indian and foreign players

Thank You

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