

**Twenty Years of TRIPS Agreement:
What Difference Did Product Patent Protection Make to
the Pharmaceutical Industry in India?**

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International Workshop on the Impact of the TRIPS
Agreement on Key Sectors and its Continuing
Relevance in the Context of Regional and Bilateral
Trading Agreements

**Centre for WTO Studies, IIFT, New Delhi,
26 and 27 October, 2015**

Outline of Presentation

- Present some evidence on what has happened after TRIPS in India in pharmaceuticals
- Analyse how these statistics may change if product patent protection is again abolished in India
- Raise the question of desirability of limiting product patent protection in developing countries

Price of MNC monopoly drugs in India, 2013: Examples

MOLECULE	BRAND	MNC	GROUP	Price per unit in Rs
Jevtana 60 Mg Injection	Cabazitaxel	Sanofi-Aventis	Anti-neoplastics	330000
Herceptin Injection 50 MI	Trastuzumab	Roche	Anti-neoplastics	110700
Erbix 500 Mg Injection 50 MI	Cetuximab	Merck Ltd	Anti-neoplastics	92316
Mabthera 500 Mg Injection 50 MI	Rituximab	Roche	Anti-neoplastics	80000
Novoseven (Eptaccog Alfa) 2.4 Mg Injection 1	Factors Ii, Vii, Ix And X	Novo Nordisk India	Blood Related	79000
Torisel 25 Mg Injection 1 MI	Temsirolimus	Pfizer Ltd	Anti-neoplastics	74520
Alimta 500 Mg Injection 1	Pemetrexed	Eli Lilly and Company (India)	Anti-neoplastics	73660
Sandostatin 0.1 Mg Injection 1	Octreotide	Novartis India	Blood Related	72081
Ixempra 45 Mg Injection 1	Ixabepilone	BMS India	Anti-neoplastics	71175
Sandostatin Lar 20 Mg Injection 1 MI	Octreotide	Novartis India	Blood Related	65499

MOLECULE	BRAND	MNC	GROUP	Price per unit in Rs
Velcade 3.5 Mg Injection 1	Bortezomib	Johnson & Johnson	Anti-neoplastics	60940
Caelyx 20 Mg Infusion 10 ML	Doxorubicin (Liposomal)	Fulford (India)	Anti-neoplastics	48956
Macugen 0.3 Mg Injection 90 ML	Pegaptanib	Pfizer	Ophthal / Otologicals	47164
Remicade 100 Mg Injection 10 ML	Infliximab	Fulford (India)	Pain / Analgesics	41039
Actemra 400 Mg Injection 1	Tocilizunab	Roche	Anti-neoplastics	40799
Avastin (Roche) 100 Mg Injection 1	Bevacizumab	Roche	Anti-neoplastics	37180
Neulastim 6 Mg Injection 1	Pegfilgrastim	Roche	Anti-neoplastics	33800
Eligard Depot 45 Mg Injection 10 ML	Leuprorelin	Ranbaxy Laboratories	Hormones	33600
Orencia 250 Mg Injection 1	Abatacept	BMS India	Pain / Analgesics	30000

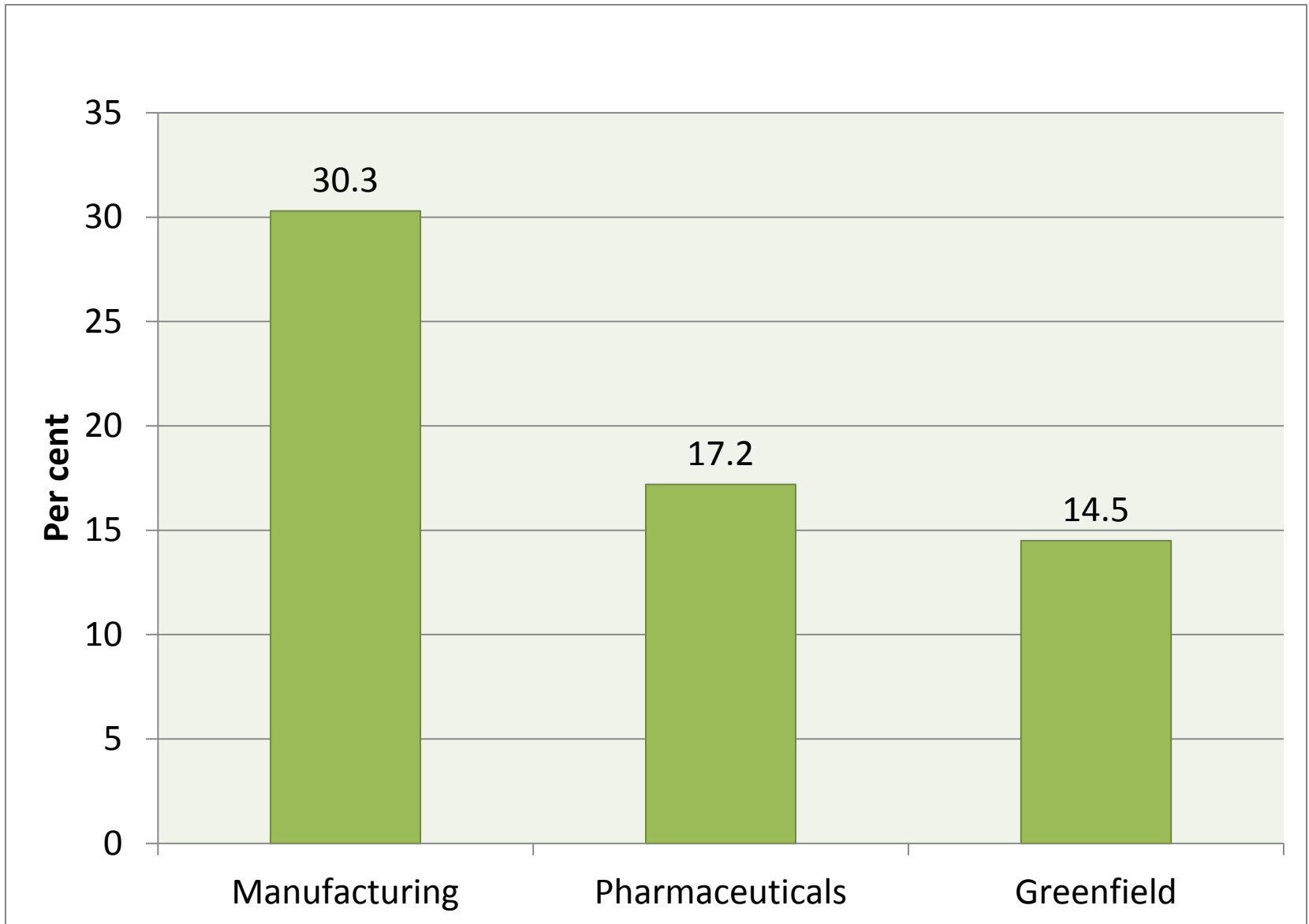
TRIPS Flexibilities

- **Section 3(d):**
 - Specially after the Supreme Court judgment on Novartis' Gleevec patent, secondary patent applications without improved therapeutic efficacy expected to be denied
- **But Compulsory Licensing is potentially much more powerful**
 - Only three applications of which two rejected
 - Unless CL is pursued as an Industrial Policy and a Health Policy matter, outcome unlikely to improve in future

Partnership with MNCs: Examples

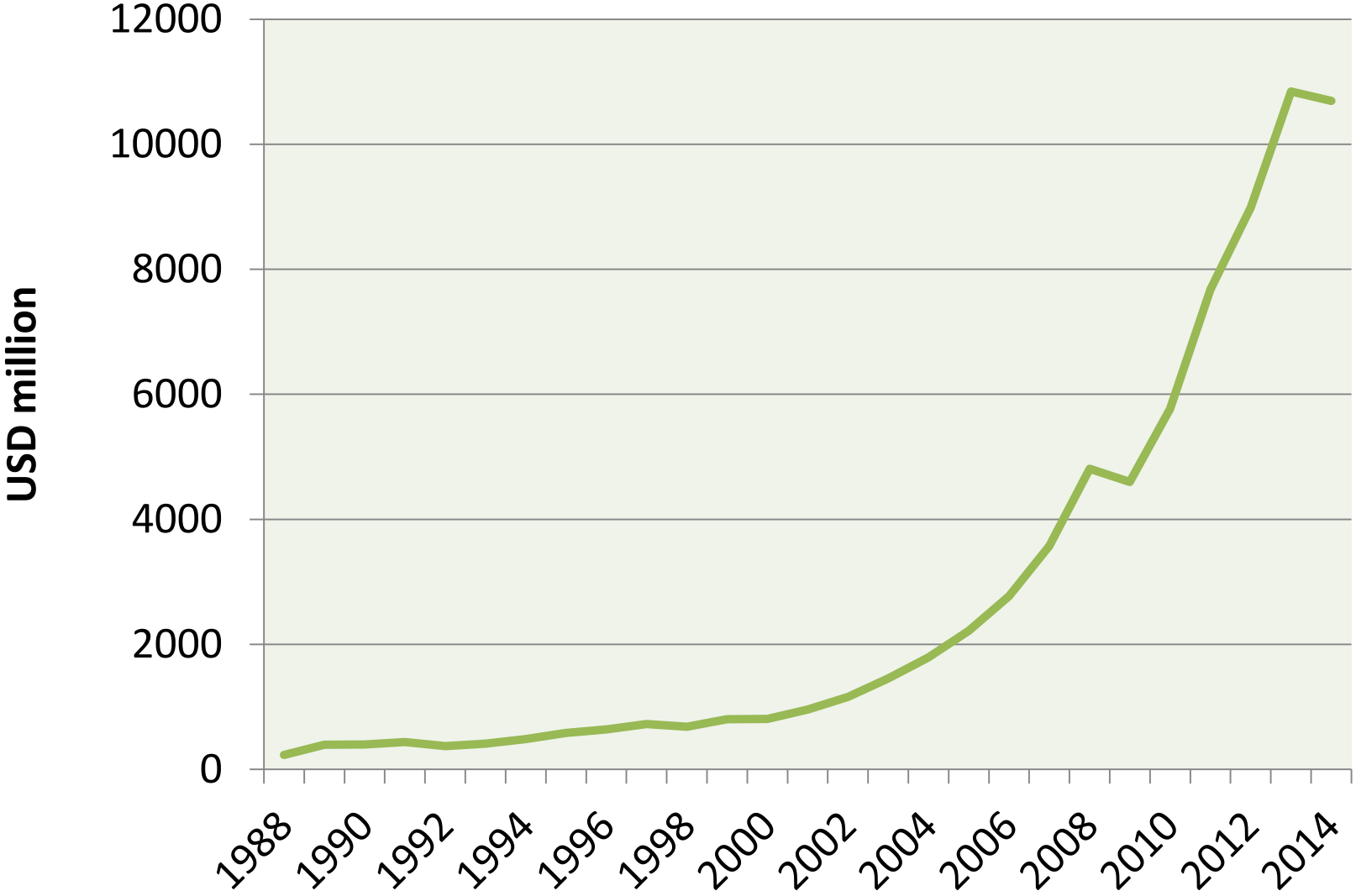
- **Marketing tie ups**
 - Sun Pharma/Merck
 - Zydus Cadila/Bayer
 - Lupin/Eli Lilly
 - Biocon/Bristol Myers Squibb
- **Manufacturing tie ups**
 - Aurobindo Pharma/Pfizer
 - Dr Reddys Labs/GSK
 - Torrent/AstraZeneca
 - Shasun/Eli Lilly

FDI flows in India, 2000 to 2012



Source Chalapati Rao et al, 2014

Exports of formulations, 1988-2014



Source: UNCOMTRADE

Major Indian Cos: Export/sales (%)

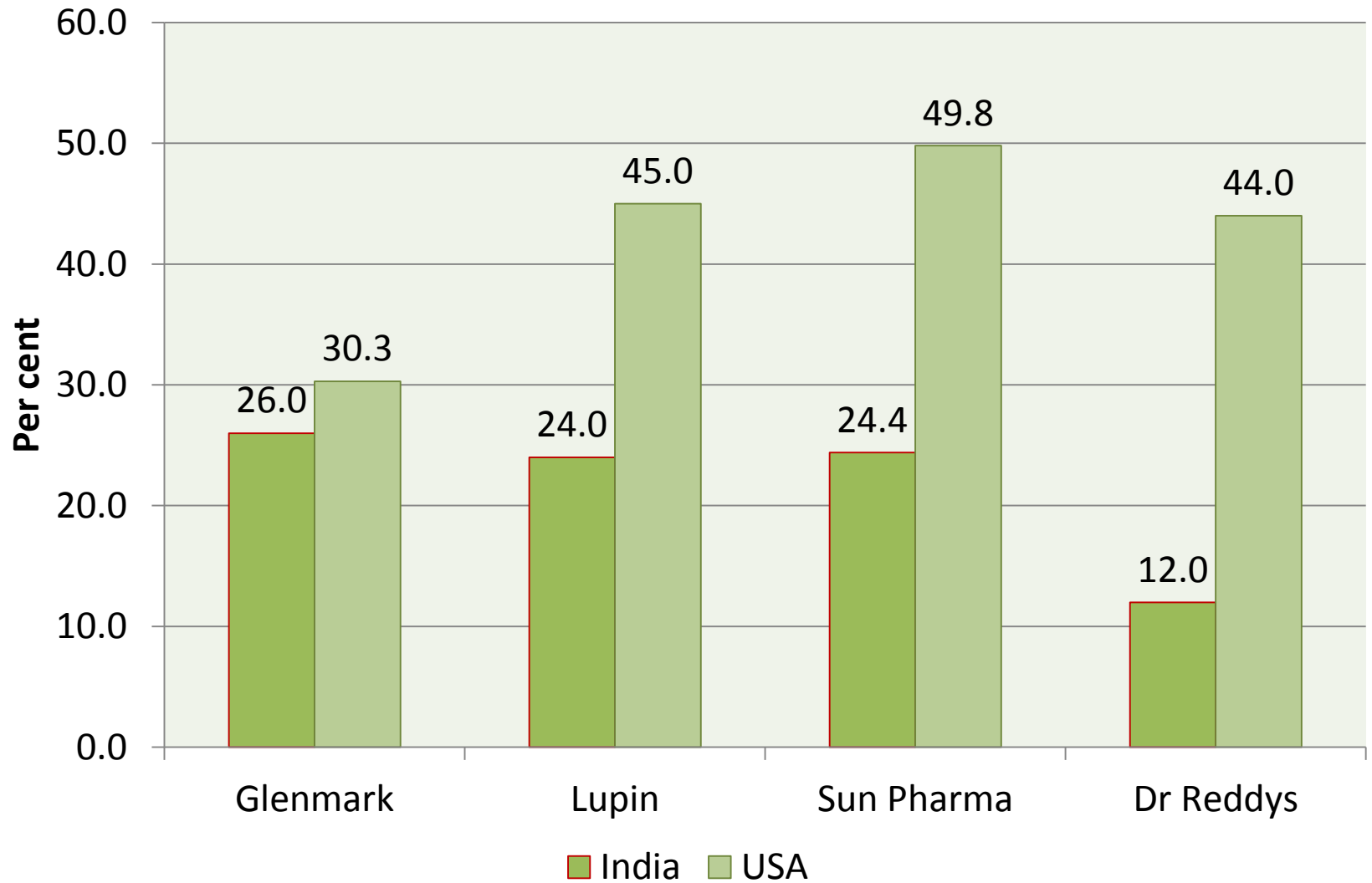
	2000	2005	2014
Dr. Reddy'S Laboratories	30.0	55.8	75.5
Lupin	18.2	44.5	63.7
Aurobindo Pharma	52.8	47.7	73.3
Cipla	20.0	43.9	51.8
Ranbaxy Laboratories	40.7	60.4	53.2
Sun Pharmaceutical Inds	12.8	26.3	75.8
Divi'S Laboratories	87.6	81.9	89.1
Cadila Healthcare	8.5	12.0	54.3
Ipca Laboratories	51.5	53.3	60.2
Intas Pharmaceuticals	2.3	23.6	43.0
Torrent Pharmaceuticals	25.9	15.0	46.6

Source: CMIE Prowess database

EXPORTS OF PHARMACEUTICALS	1994-95 USD million	1994-95 Percentage of India's total exports	2013-14 USD million	2013-14 Percentage of India's total exports
Regulated markets	351.45	43.9	7147.22	47.5
US	85.78	10.7	4025.8	26.7
Other markets	448.91	56.1	7902.78	52.5
Asia	206.3	25.8	2711.43	18.0
Latin America	20.2	2.5	984.23	6.5
Africa	85.3	10.7	3007.09	20.0

Source: Compiled from DGCI&S

Market Share: US and India, 2014-15

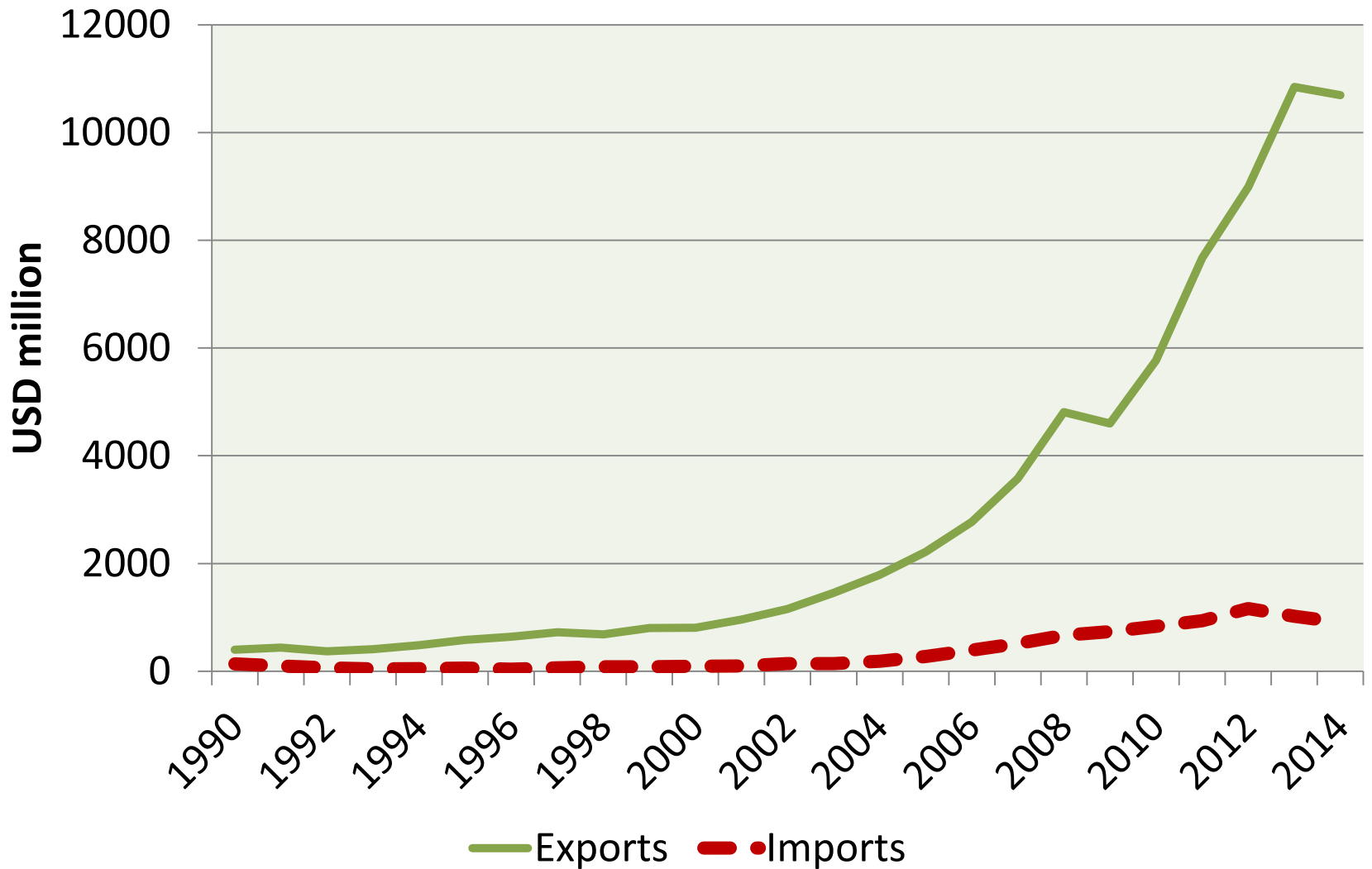


Major MNCs in India: Export/sales (%)

	1995	2000	2005	2014
Sanofi India	13.52	13.26	24.30	22.38
Merck	4.66	4.98	2.99	8.57
Astrazeneca Pharma India	10.00	0.75	0.54	5.58
Abbott India	0.39	0.86	0.58	0.61
Glaxosmithkline Pharmaceuticals	2.79	8.22	1.90	0.36
Novartis India	8.29	6.74	1.83	0.89
Wyeth	1.06	8.65	0.03	0.11
Pfizer	1.77	2.01	0.55	0.04

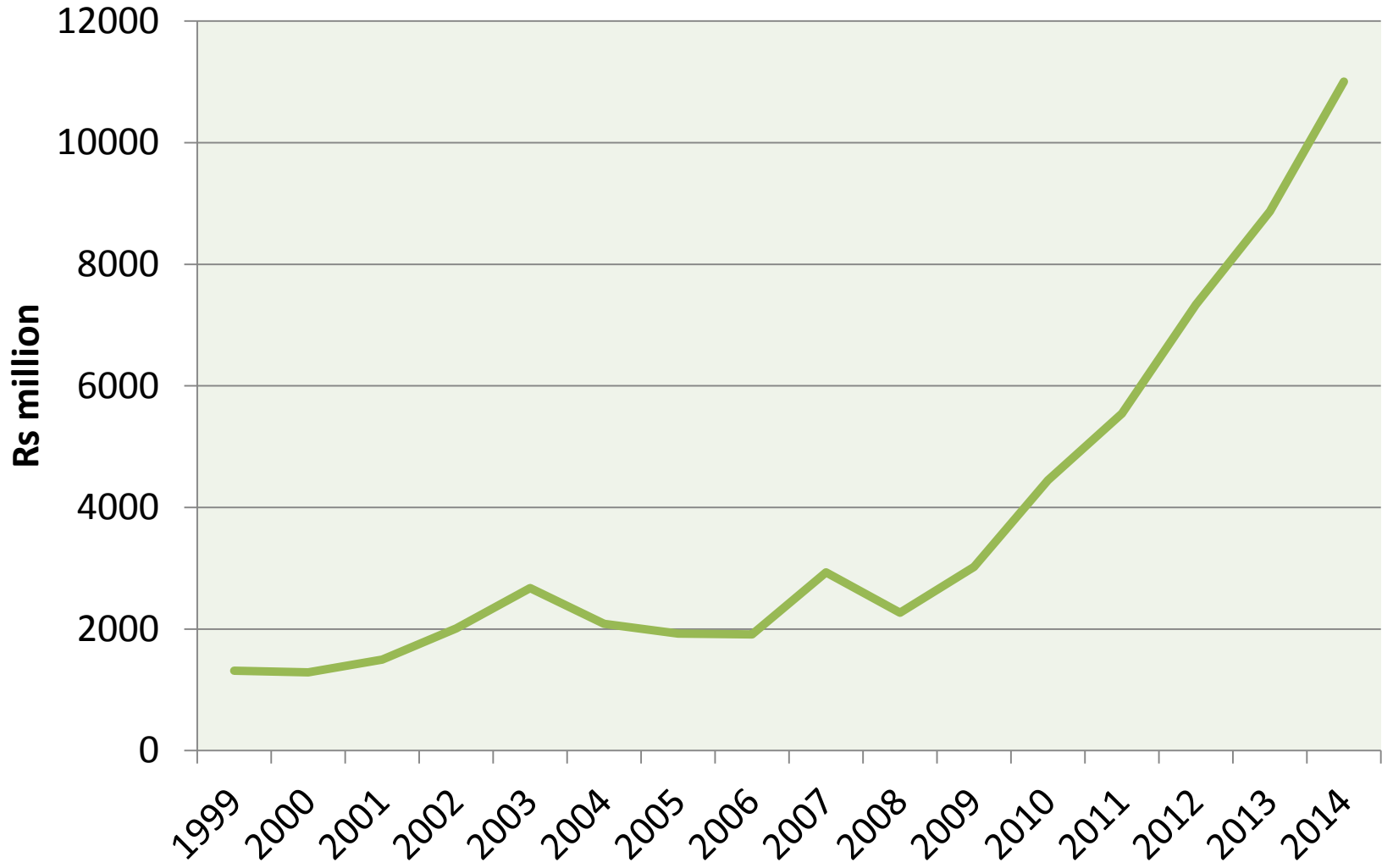
Source: CMIE Prowess database

India: Formulations Trade



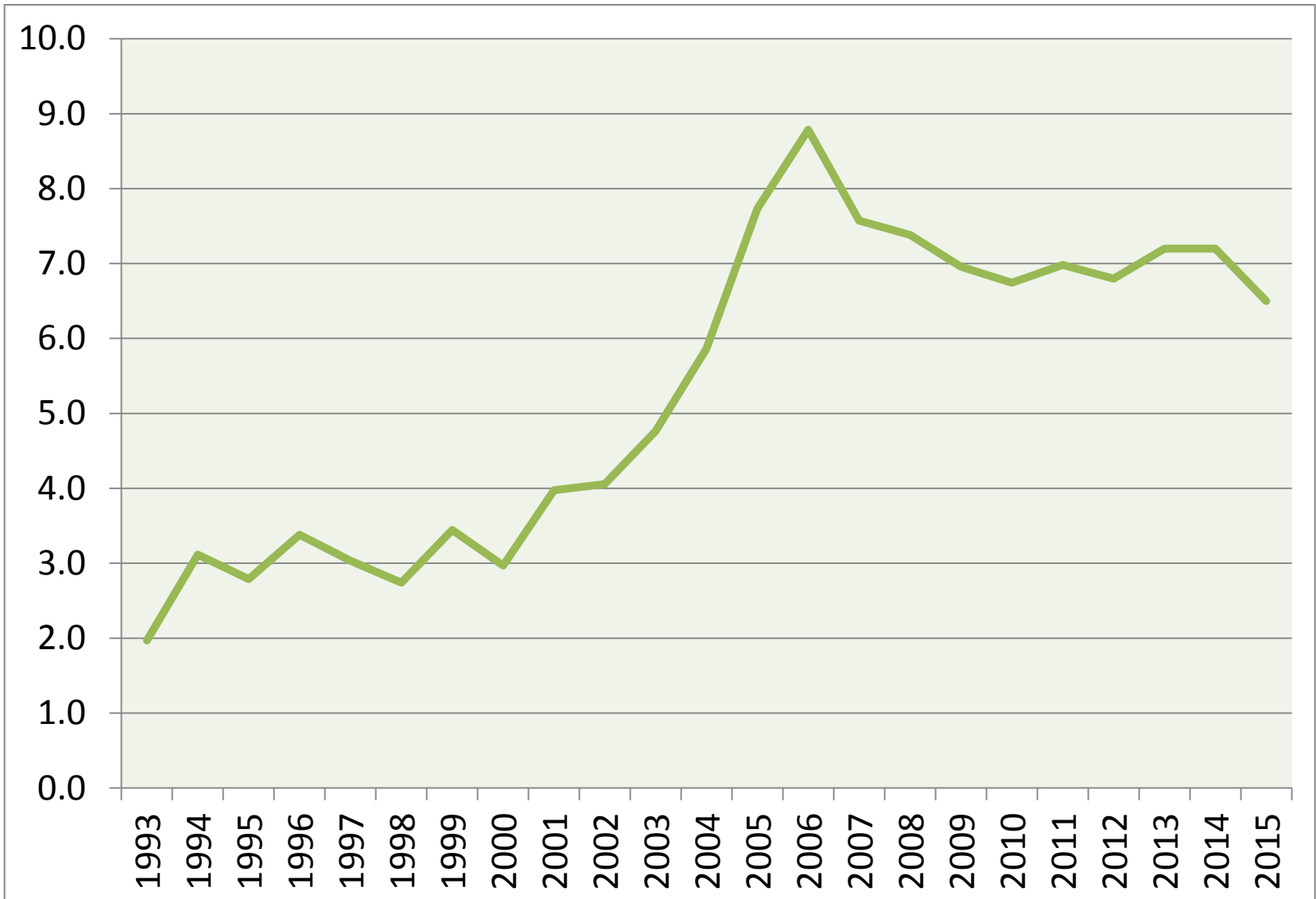
Source: UNCOMTRADE

MNCs: Finished goods imports



Source: CMIE Prowess (Top 7 MNCs)

Major Indian Cos: R&D/sales



Companies with more than Rs 100 million R&D expenditure in 2012

Source: CMIE Prowess database

Major Indian Cos: R&D/sales

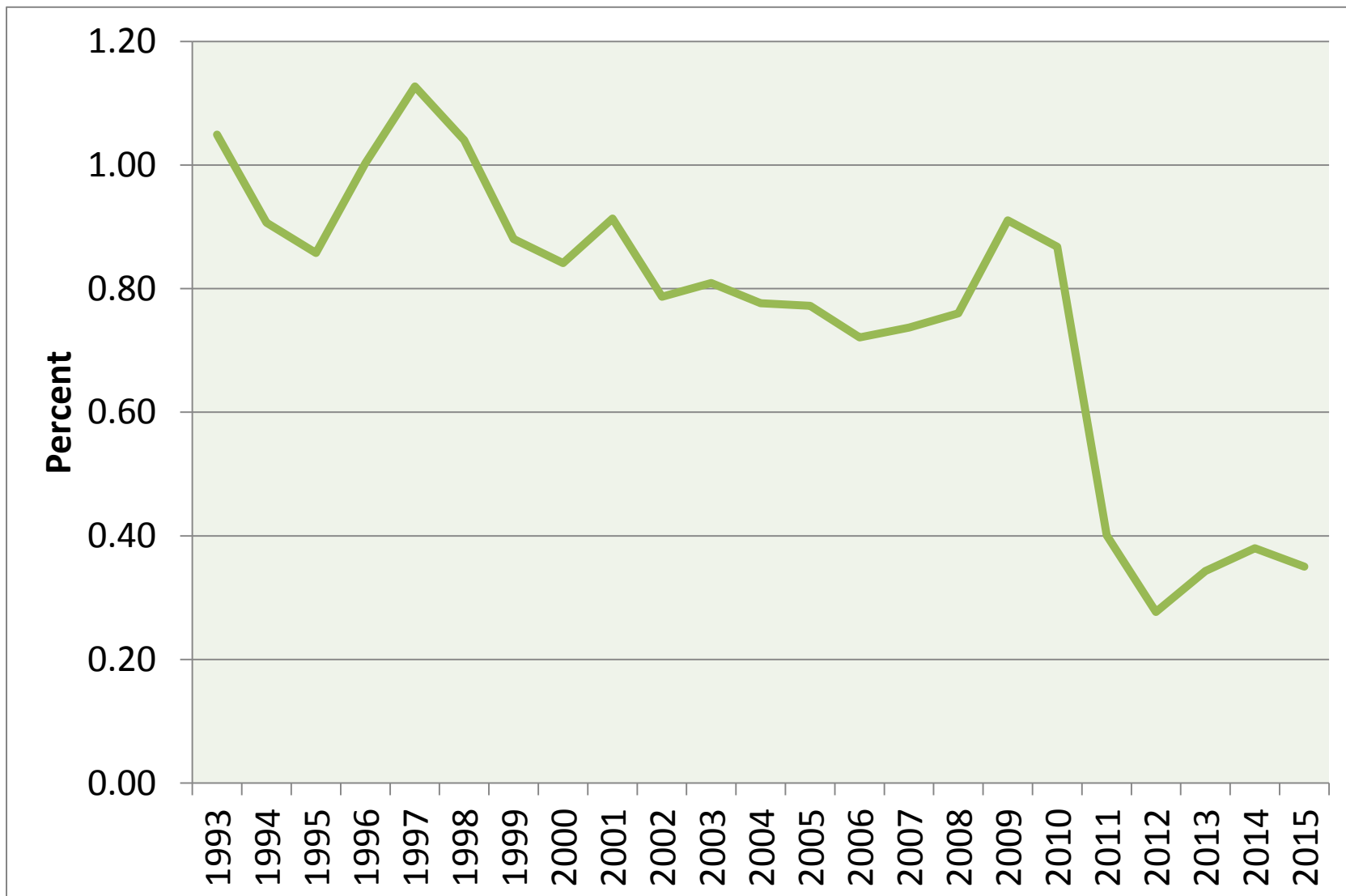
	1995	2000	2005	2014
Dr. Reddy'S Laboratories	2.0	2.7	18.2	10.9
Lupin	NA	0.7	6.9	11.1
Ranbaxy Laboratories	5.1	3.3	10.3	10.3
Cadila Healthcare	NA	4.7	9.0	12.1
Cipla	NA	3.9	4.1	5.4
Sun Pharmaceutical Inds	4.1	3.9	11.1	14.1
Aurobindo Pharma	NA	1.9	4.7	3.7
Wockhardt	NA	4.2	7.9	13.3
Glenmark Pharmaceuticals	NA	3.6	9.0	5.2
Biocon	NA	NA	3.5	4.2
Suven Life Sciences	NA	3.8	2.4	9.8
Natco Pharma	5.2	0.1	3.0	6.5

Source: CMIE Prowess database

New Drug R&D by Indian companies

- Started by Dr Reddys and Ranbaxy in early 1990s followed by several others - Glenmark, Lupin, Zydus Cadila etc
- Several molecules under development including in collaboration with foreign companies, for example Sanofi and Forest labs by Glenmark
- Initial euphoria subsided; setbacks; limited success
- Neglected diseases: Ranbaxy, anti malarial drug an exception
- Main target: developed countries market which in any case had product patent protection

MNCs: R&D/sales



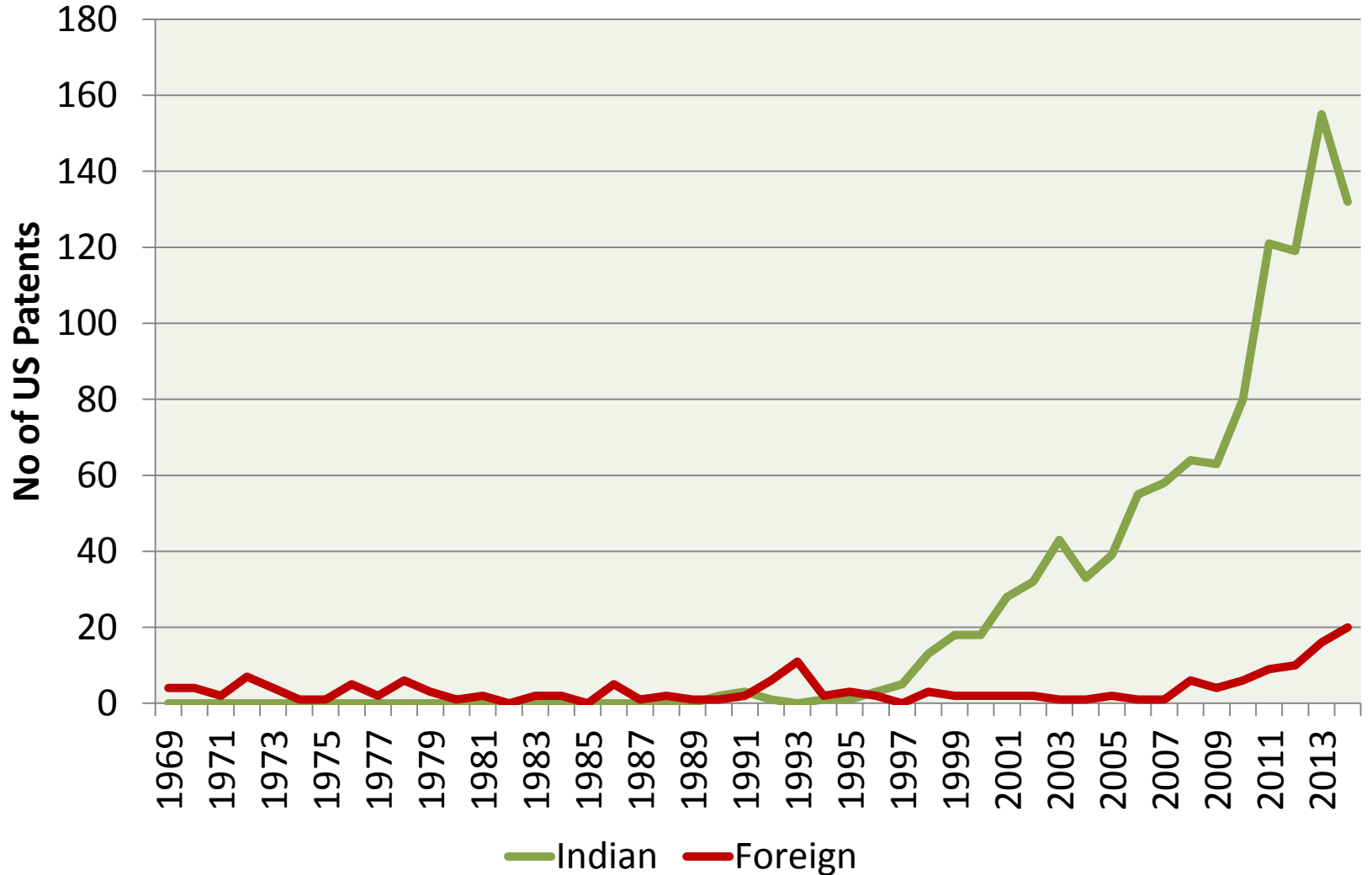
Source: CMIE Prowess database: Top 8 MNCs

US Pharma Patents from India: 1969-2014

	Foreign Companies	Indian Companies	Total
1969-1994	77	7	84
1995-2014	93	1080	1173
Total	170	1087	1257

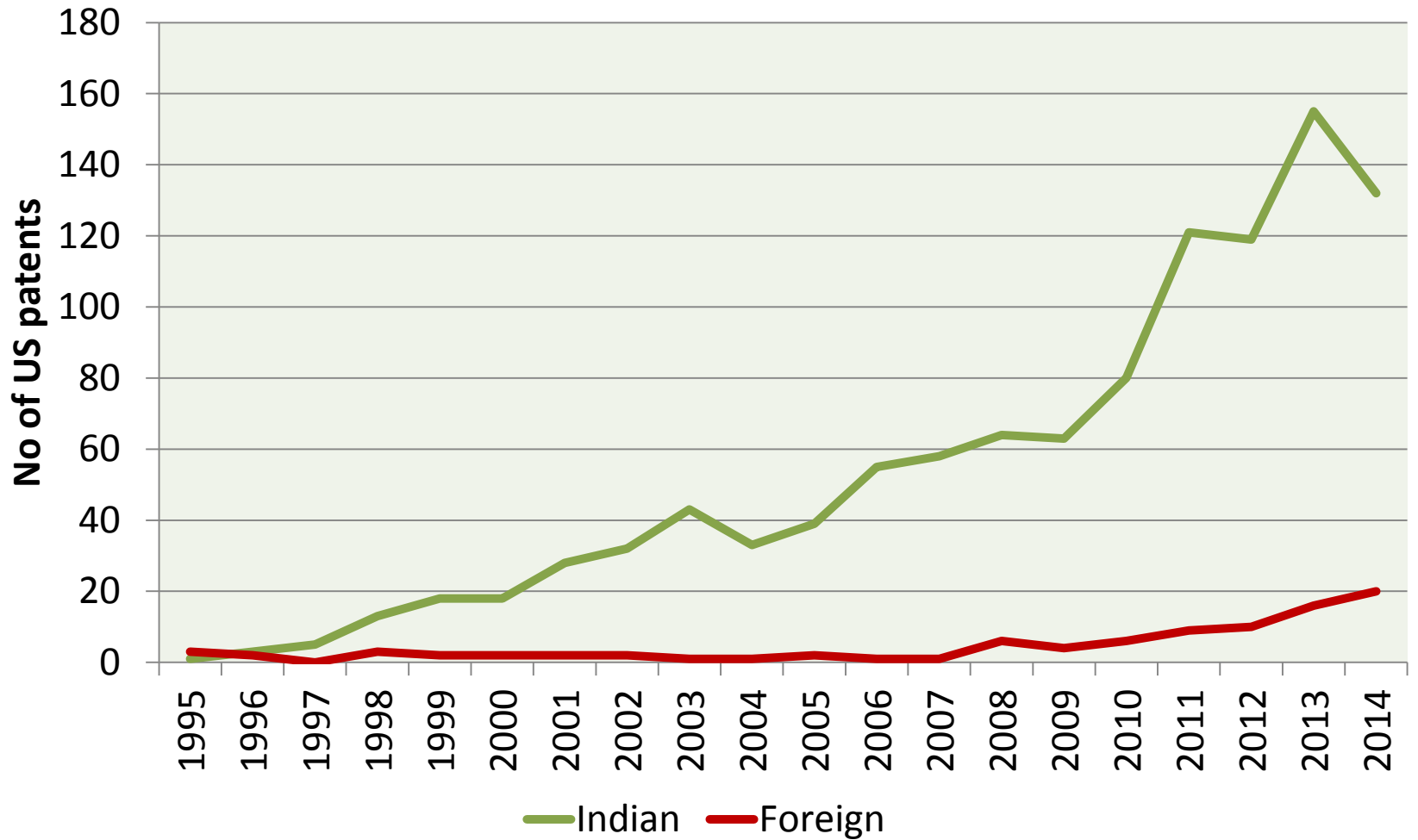
Source: USPTO

US Patents from India, 1969-2014



Source: USPTO

US Patents from India, 1995-2014



India based patenting in USA by foreign cos

- **Before TRIPS**
 - Ciba-Geigy: 42
 - Hoechst: 35
- **After TRIPS**
 - Mylan (including Generics UK): 30
 - Teva: 19
 - Fresenius Kabi Oncology: 8
 - Hoechst: 11
 - Novartis 7
 - Astrazeneca: 8
 - Aventis: 5

Simulation: If product patent protection in pharmaceuticals is again abolished

Prices of new drugs	Will fall
Imports of finished products	Will fall
Export by Indian cos	Expected to continue; in fact situation may improve
R&D by Indian cos: generics	Expected to continue
R&D by Indian cos: new drugs	Expected to continue
Patenting by Indian cos	Expected to continue
R&D by MNCs	Unlikely to worsen further
Patenting by MNCs	Unlikely to be worse

Simulation: Continued

M&As by MNCs	May fall; but not negative
M&As by Indian cos abroad	Likely to continue
Marketing tie ups for patented products	Expected to fall; but not negative
Manufacturing tie ups	Expected to continue
Exports by MNCs	Unlikely to be worse

OVERALL EFFECT

POSITIVE

Conclusion

*If Public Policy is based on Evidence,
TRIPS Agreement needs to be reviewed*

Thank You

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