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# **A Decade of TRIPS**

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# TRIPS

- One of the **23 Agreements** at the end of Uruguay Round of GATT Negotiations signed in **1994**
- Inclusion of **IPRs** in Trade; a **tradable commodity**
- Most comprehensive IPR agreement
- Minimum obligations
- National Treatment
- Special Requirements related to **border measures**
- 3 step exemption clause
- **Dispute Settlement Mechanism**

# India and TRIPS

- Amended **Patents Act** in 1999, 2002 and 2005 and **Copyright Act** in 1999
- New legislations for **Trade Marks** and **Designs**
- *Sui generis* legislations for **Plant Varieties and Farmers Rights** and **Semiconductor Integrated Circuits Layout-Design**
- **Competition Act** (Control of anti-competitive practices in contractual licences) in place of MRTPC
- **No** specific legislation for **Trade Secrets** (Undisclosed Information)

# Origin of TRIPS

- Initiative by US and European **Pharma Companies**
- Pharmaceutical Manufacturers Association – PMA- now Pharmaceutical Research and Manufacturers Association – PhRMA lobbied
- USTR and **Special 301**
- Political and economic pressures on developing countries
  - *The Making of TRIPS*, WTO 2015.
  - Robert Weissman, *A Long, Strange TRIPS*, 1996

# India: IPR Status

- Patents
- In 2005 the number of resident patent applications was 4521 and non-resident 15,467
- In 2011-12, the figures were 8921 and 28,965 respectively
- In 2014-15 they were 12,071 and 26,057 respectively

# **PATENTS AND PHARMACEUTICALS**

# Indian Pharmaceutical Industry

- The Indian Pharmaceutical sector is heterogeneous mixture of both organized and unorganized firms. Branded generic dominate the Indian pharmaceutical market.
- The process of drug manufacturing has two interlinked components (a) bulk drugs (b) formulation. The domestic formulation market can be further classified into: (I) retail and (II) institutional drug market.
- India, a global market leader in the export of generic drugs to countries such as the developed countries like United States, Europe and Japan, as well as to developing countries in Africa and Asia.
- Approximately 80 percent of this domestic production consisted of formulations, while the remaining 20 percent comprised bulk drugs. Currently India Increases Bulk Drug production significantly.
- Few things drive the growth of generics in India, Such as- inherent competencies and low-cost manufacturing capabilities, increasing consolidation through cooperative alliances regulatory environment

# Growth Indicators-Indian Pharmaceutical Sector

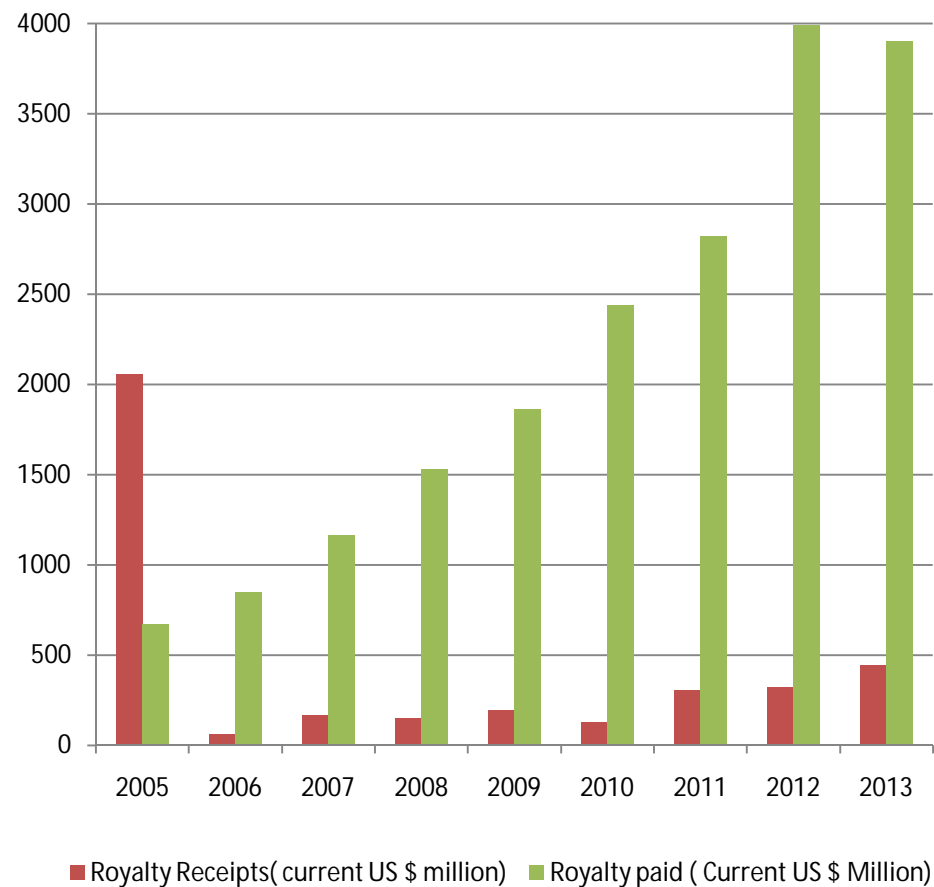
## Major Indicators to reflect growth in Pharmaceutical Sector

1. Royalty receipt and payment on Indian pharmaceutical sector.
2. PCT ( Patent Cooperation Treaty) International Applications filled By the Indian Applicants.
3. Number of Patent Applications Filed Under Pharmaceutical Sector.
4. Number of Patents Granted Under Pharmaceutical Sector.
5. Export-Import of Pharmaceutical products.
6. Foreign Direct Investment on Indian Pharmaceutical sector.
7. Dependency of various developing countries on Indian pharmaceutical sector.



# 1. Royalty Receipt & Payment

Year	Royalty Receipts( current US \$ million)	Royalty paid ( Current US \$ Million)
2005	2059.746	671.8294
2006	60.91326	845.9494
2007	163.1265	1159.824
2008	147.8154	1528.827
2009	191.9395	1860.07
2010	127.3782	2438.303
2011	302.616	2819.291
2012	321.4452	3990.056
2013	445.5683	3903.909
<b>Total</b>	<b>1966.777</b>	<b>19218.06</b>



Source: World Development Indicators

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## 2. PCT International Applications Filled

Year	Individual	Legal Entity	Total
2005- 06	130	352	<b>482</b>
2006- 07	144	390	534
2007- 08	169	538	707
2008- 09	232	655	887
2009- 10	231	521	752
2010- 11	243	628	871
2011- 12	254	519	873
2012- 13	252	790	1042
2013- 14	248	568	<b>816</b>

Source: Controller General of Patents Designs ,Trade marks and Geographical Indications various years( 2009-10-2013-14) Annual Report.  
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# 3. Patent Applications Filed

Year	Chemical	Drug	Total Pharmaceutical Sector
2005-06	5810	2211	<b>8021</b>
2006-07	6354	3239	9593
2007-08	6375	4267	10642
2008-09	5884	3672	9556
2009-10	6014	3070	9084
2010-11	6911	3526	10437
2011-12	6698	2762	9460
2012-13	6812	2954	9766
2013-14	6769	2507	<b>9276</b>

Source: Controller General of Patents Designs ,Trade marks and Geographical Indications various years( 2009-10-2013-14) Annual Report

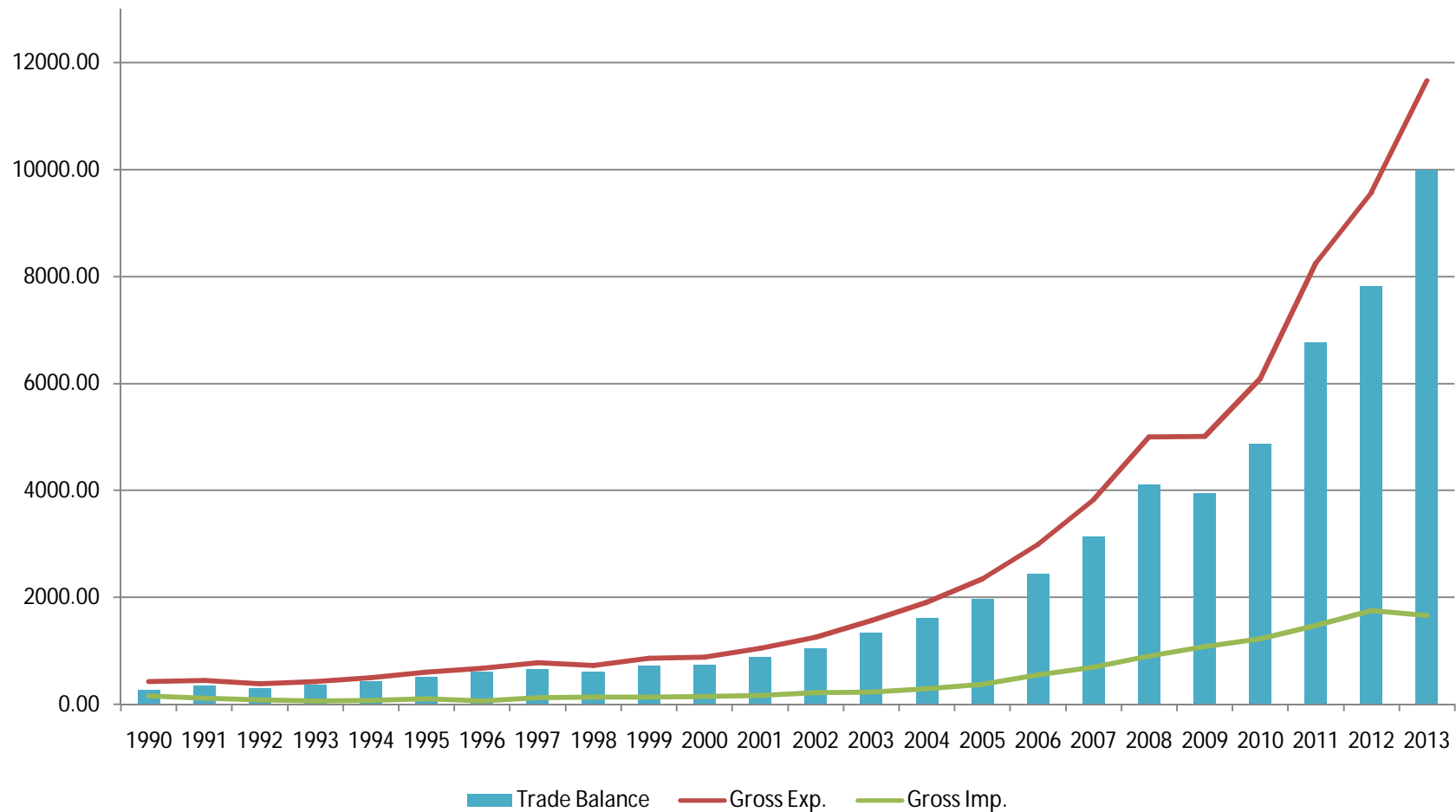
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## 4. Patents Granted

Year	Chemical	Drug	Total Pharmaceutical Sector
2005- 06	1140	457	<b>1597</b>
2006- 07	1989	798	2787
2007 - 08	2662	905	3567
2008- 09	2376	1207	3583
2009- 10	1420	530	1950
2010- 11	1899	596	2495
2011- 12	1168	282	1450
2012- 13	1289	344	1633
2013- 14	1111	256	<b>1367</b>

Source: Controller General of Patents Designs, Trade marks and Geographical Indications various years( 2009-10-2013-14) Annual Report

# 5. Direction of India's Trade in pharmaceutical with World (US\$ Million)

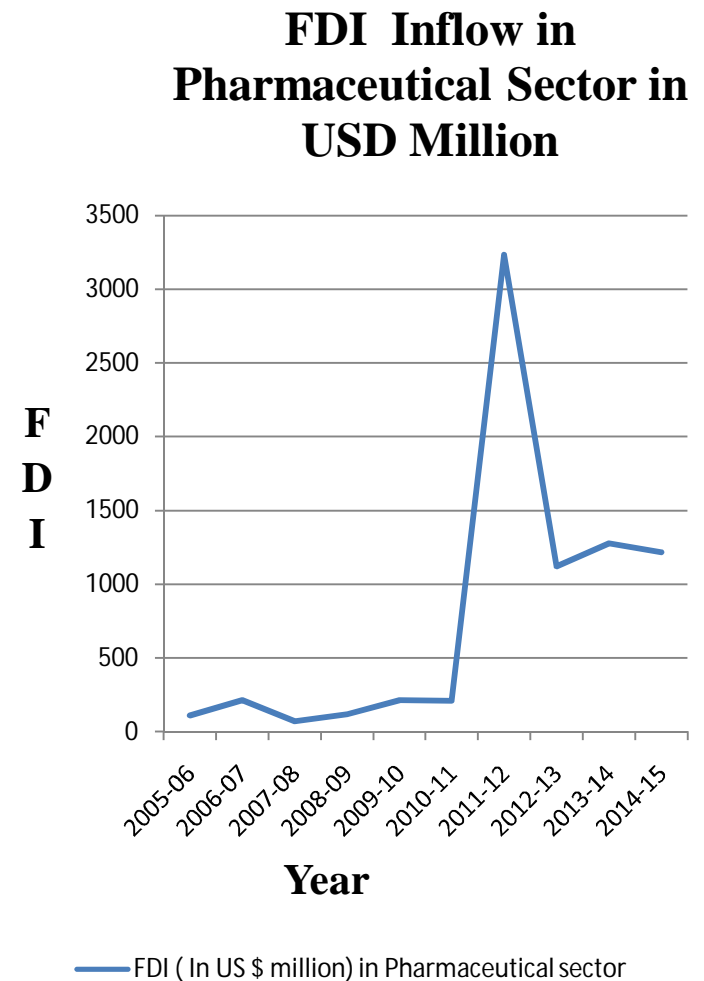


Source: WITS Online Database

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## 6. Inward FDI Inflow (in US\$ Million)

Year	FDI In Pharmaceutical sector	Total FDI	% of FDI in Pharmaceutical Sector
2005-06	111	5540	2.00
2006-07	216.1	12492	1.73
2007-08	72	24575	0.29
2008-09	119.95	31396	0.38
2009-10	213	25834	0.82
2010-11	209	21383	0.98
2011-12	3232	35121	9.20
2012-13	1123	22423	5.01
2013-14	1279	24299	5.26
2014-15	1216	21045	5.78



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Data Source: DIPP

# 7. Major Import from India Dependent Countries

Country Name	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Nepal	-	-	-	-	-	66.27	67.15	81.21	84.02	81.93
Srilanka	50.83	51.77	52.40	53.97	55.18	58.26	53.66	52.13	53.11	50.12
Nigeria	-	22.25	41.42	39.78	31.50	29.98	29.74	37.86	44.44	-
Mayanmar	-	-	-	-	-	39.25	-	-	-	-
Tanzania	17.80	32.32	16.27	26.41	31.41	39.48	32.24	36.76	37.70	-
Ghana	-	37.05	40.20	37.50	36.00	41.86	37.38	37.71	28.21	27.05
South Africa	10.58	13.45	13.57	17.93	17.01	18.13	18.17	21.06	25.58	20.40

Contd.

Data Source: WITS online data base

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Country	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Cambodia	15.45	17.72	16.43	19.01	20.02	18.85	17.38	18.47	18.24	-
Vietnam	10.00	11.11	11.59	11.92	12.74	12.59	13.64	12.46	12.47	-
Thailand	2.40	2.72	3.05	3.89	4.07	4.49	5.94	5.12	4.94	6.38
Malaysia	2.67	2.67	2.55	2.95	4.54	3.21	3.77	3.34	3.54	4.25
Brazil	2.78	3.01	3.07	3.76	2.09	1.99	1.99	2.39	2.44	3.04
South America	2.27	2.51	2.48	2.68	2.21	2.32	2.35	2.49	2.78	2.67
Argentina	0.83	1.07	0.98	0.89	1.03	1.07	0.65	0.65	0.73	1.19
China	0.18	0.20	0.18	0.31	0.21	0.30	0.17	0.09	0.11	0.11

Data Source: WITS online data base



# Outcome

- After approval of both ( Product & Process) Patent regime India still has great Royalty deficit in Pharmaceutical sector.
- PCT International Applications filled by Indian applicants have increased during the years 2005-2014.
- Number of Patent application filed under pharmaceutical sector shows an incremental trend from the year 2005, but more by non-residents.
- Like other sectors food, electrical, Mechanical, computer, number of patents application granted under pharmaceutical sector shows a mixed picture, initially it has risen during the time period 2005-06 to 2008-09, then it declines slightly up to the time period 2013- 2014.
- Export of Indian pharmaceutical product has increased significantly from US\$ 423 million to US\$1.9 billion during the time period 1990 to 2004. From 2005-2013 it has further increased from US\$ 2.3 billion to US\$ 11.6 billion.
- Indian FDI inflows has increased significantly from US\$ 111 million in 2005-06 to 1216 million in 2014-15.
- Few Developing Countries like Nepal, Srilanka, Nigeria Ghana, south Africa are mostly dependent on Indian pharmaceutical industries.

# Post TRIPS: WTO

- TRIPS and Public Health
  - Doha Declaration on Public Health
- Giving short shrift to **Basic Principles**: Articles 7 & 8 of TRIPS
- No positive initiatives from governments on **technology transfer**. Article 67

# Post TRIPS: Current Issues in WTO

- TRIPS Issues in WTO
  - Geographical Indications International Registry
  - Extension of higher level of protection to all goods
  - Patent Law Harmonization
  - Relationship between Convention on Biodiversity and Patent
  - Protection of Traditional Knowledge
- **No real movement** in TRIPS Council

# New Developments

- From WTO to multilateral, Regional and Bilateral agreements
  - TPPI, TPPA, RCEP, BIPAs
- **TRIPS Plus Provisions** in these Agreements
  - Data Exclusivity
  - Patent and drug approval linkage
  - Extension of patent period by other means
  - Software patenting

# Concerns

- Increasing stress on **private rights over human rights**
- **Access to medicine**
  - Countries are being pressurised not to use TRIPS flexibilities
  - One CL by India (March 2012 to Natco Pharma on Bayer's cancer drug "Sorafenib tosylate" (Nexaver)
  - Novartis vs. Uol on the rejection of patent application for Glivec
- **Access to Knowledge**

# Thank You