

Socio Economic Impact of Intellectual Property Rights Evidence from Pharmaceutical and Handicraft Sectors of India

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Scheme of presentation

- Globalisation, WTO, TRIPS
- What are our concerns regarding patents in pharmaceuticals
- What purpose does Geographical Indication protection serve for handicrafts

Distinct Features of Patents and GI

Patents

- Associated with specific invention
- Individually held
- It is a monopoly in the traditional sense
- An entry barrier created by invention, R&D,

GIs

- Associated with a specific geographic region
- Collective IP
- It is a 'monopoly' –conditions created on the basis of links with the region and reputation, results in a proprietary right for those who own it as against those who fall outside the demarcated region
- An entry barrier created by the link to the place and geo climatic factors

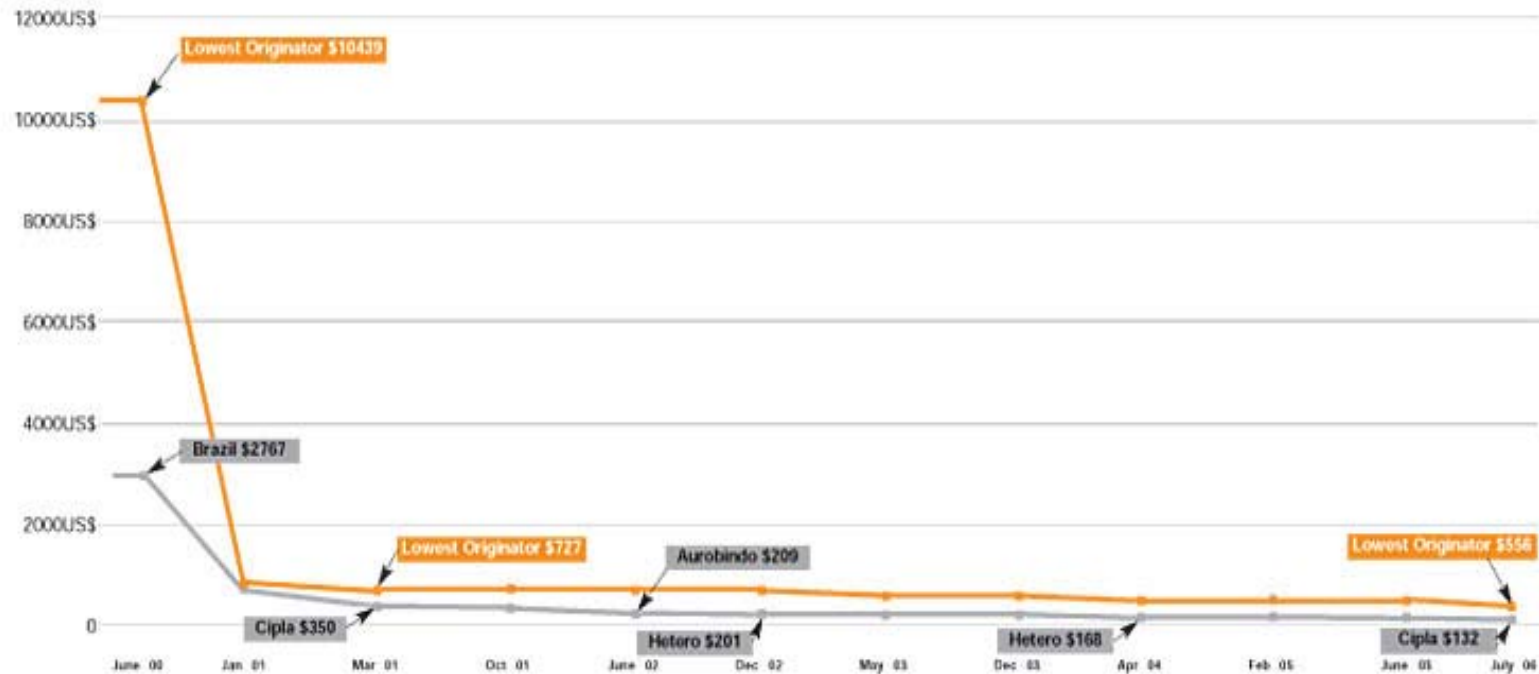
Why India is an important player in pharma

- India is the pharmacy of the third world; India meets nearly 90 per cent of the needs of the AIDS patients in Africa; 60 countries without pharmacy; -87 have only capacity to make finished drugs
- High capacity in generic drugs and reverse engineering
- Heavily export intensive
- New drugs are arrived after intensive and expensive research- mostly coming from the US, UK and Germany

High Prices Linked to Patent Protection

The Effects of Generic Competition

June 2000 - June 2006



Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year. Generic competition has shown to be the most effective means of lowering drug prices. During the last five years, originator companies have often responded to generic competition.

Source: Medico Sans Frontier <http://www.msfaaccess.org/main/hiv-aids/introduction-to-hivaids/pushing-prices-down/>

Number of IP Registrations in India

Comparative Trends of IPRs granted/registered (and disposed off)

Year	2008-09	2009-10	2010-11	2011-12	2012-13
Patents	16061 (17136)	6168 (11339)	7509 (12851)	4381 (8488)	4126 (9027)
Designs	4772 (4897)	6025 (6045)	9206 (9221)	6590 (6705)	7252 (7300)
Trade Marks	102257 (126540)	67490 (76310)	115472 (132507)	51735 (57867)	44361 (69736)
G.I.R.	45	14	29	23	21

Source: Annual Report, CGPTD, 2012-13

Trends in Geographical Indication Applications

Year	2009-10	2010-11	2011-12	2012-13	2013-14
Filed	40	27	148	24	75
Examined	46	32	37	30	42
Registered	14	29	23	21	22

PATENT THEN AND NOW

- 1970
 - Only Process patents in food, medicines and agriculture and biotechnology
 - Working of the patent
 - Patent term and duration
- Since 2005
 - Product patents in all fields of technology including pharmaceuticals and agricultural chemicals
 - Importation of the patent
 - Patent term and duration

ARTICLE 30 OF TRIPS

- Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owners, taking into account of the legitimate interest of the third parties.

FLEXIBILITIES UNDER TRIPS

- Transition periods
- Public non-commercial use of patents
- Section 3d
- Pre-grant oppositions
- CL
- Bolar exception/patent linkage
- Exceptions from patentability
- Limits on Data protection

CONDITIONS FOR CL

- Article 31 Specifies the circumstances when a patent may be used 'without the authorisation of the right holder of patent' is allowed
- TRIPS-refusal to deal by the patentee
- National emergency
- Anti-competitive tendencies

INDIA

- Section 84: 1. reasonable requirements are not met with
- 2. Prices are high
- Patented invention is not produced in the territory of India
- Sec 91 for dependent patents
- Sec 92 for national emergencies
- Sect 92 A for export purposes

USE OF CL

- Zimbabwe, Zambia, Indonesia, South Africa, Cameroon, US, Canada, UK, France, Italy, Germany, Malaysia and Thailand
- Malaysia-higher prices of the patented medicine affecting the government budget

Prices of Glaxo SmithKline

	2001 prices	2004 prices	% reduction
Combivir (60 tablets)	286.28	57.99	80
AZT (100 tablets)	77.58	36.08	53
3TC (60 tablets)	141.75	46.39	67

Prices of Bristol-Myers Squibb

	2001 prices	2004 prices	% reduction
Didanosine (100mg) 60 tablets	63.55	32.68	49
Didanosine (25mg) 60 tablets	44.49	8.17	82

THAILAND

- Stronger patent regime in 1990, GPO production of DDL patented by BMS in 1987 and 1992
- 1997 applied for CL.
- November 2006 CL for Efavirenz, Lopinovir +ritonavir (Kaletra), 0.5 % royalty-250,000 patients
- Anticancer drugs in 2007, drugs for heart diseases in 2008

Prices of Anti-Cancer drugs
(Prices in Baht for one unit of drug)

Name of the drug	Trade name	Used against	Price of the originator	Price of the generic manufacturer
Docetaxel (80mg inj)	Taxotere	Lung/breast cancer	25000	4000
Letrozole (2.5mg)	Femera	Breast cancer	230	6-7
Erlotinib (150mg)	Tarceva	Lung cancer	2750	735
Imatinib (100mg)	Gleevac	Myeloid leukaemia and gastrointestinal Stromal tumor	917	50-70

PATENT LINKAGE

- Bayer's Sorefenib Tosylate patent validity till 2020.
- Bayer files against DCGI and Cipla

NATCO'S CL

- Sorefenib-drug for liver and kidney cancer-brandname Nexavar
- Patented in March 2008
- Cost 2,80,000 a month
- CL under section 84
- Natco cost 8,800Rs.
- CIPLA's price reduction

Patent safeguards most used in India

- Section 3d
- Pregrant opposition
- Remarkable difference to public health
- But there are limits like technology, second line drugs for AIDS



Geographical Indications

Rationale for protection

- By enabling communities to continue producing their traditional products instead of finding alternative means for survival outside their traditional activities, GIs contribute to the preservation of cultural heritage, a factor which strengthens regional identity and reinforces the inter linkages in support of rural development.

Rationale for protecting through GI

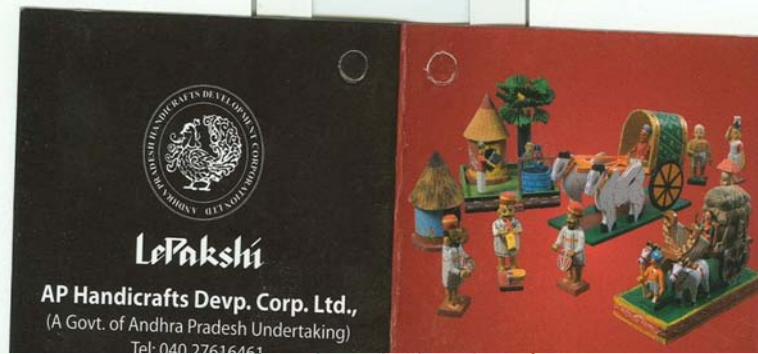
- (1) prevent misappropriation and usurption of products particularly in the export markets which prevents the local actors from benefitting from the traditional products and resources (2) preserve national property of traditional knowledge and cultural heritage, local resources and biodiversity and (3) improve market access, create newer markets and increase the income accrual for the artisans engaged in traditional products.

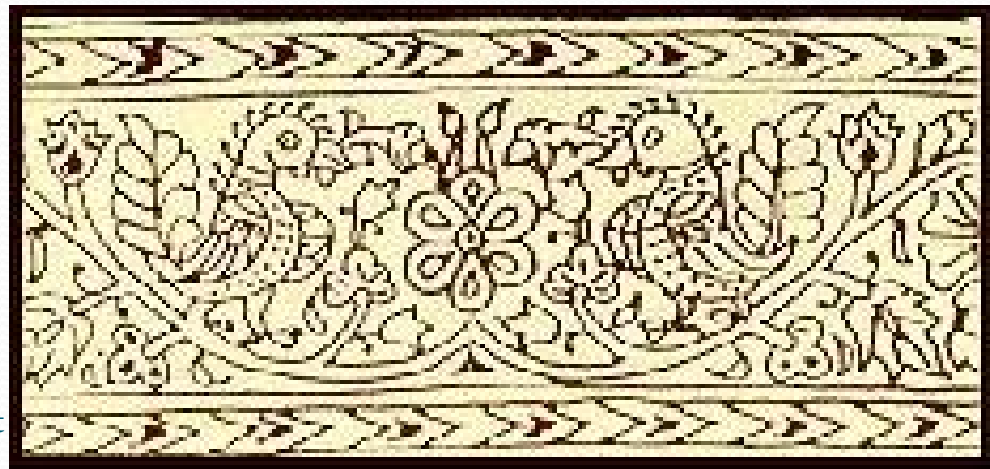
Need for GI

- To access global market through branding
- Correction of a market failure, due to information asymmetries
- Contributes to rural development dynamics
- GI-IP clusters to show case traditional knowledge and craft
- Kretschmer (2003), Sanders (2010)
- Belletti (1999) Deppler,(2011), Cerkia,(2011).
- Sylvander (2004), Warren (1993)
- Kasturi Das











Details/GI Product	Swamimalai icons	Kondapalli toys	Machilipatnam Kalamkari
Socio Economic Factors			
Approximate number of artisans	200-500	200	14/800*
empt potential	high	low	high
Main livelihood	Yes	Yes	Yes
Younger generation	not interested	not interested	not known
Production Related			
Type of enterprise	Informal	Informal	formal and informal
use of machinery	none	none	none
volume of production	low	low	low
Raw materials	available	available	available
Skilled labour	presently yes	presently yes	presently yes
Market Related			
Domestic market	high/seasonal	seasonal	high
export potential	high	medium	high
Promotion of the product	self	self	self
Distri-bution practice	self/state	self/state	self/trader
Price of the product	varies by artisan		varies by design
Economic benefits to the producer	varies	varies	varies
competition	high	low	high
GI Related			
use of GI	no	yes	no
use of logo	no	no	no
GI application by	Devt com	Assn	Assn
GI awareness	limited	limited	limited
Authorised user	not yet	not yet	not being used
GI Factor	High	High	High
Economic benefits due to GI	Not achieved	Not achieved	Not achieved

Pre conditions evident in successful GIs

- The GI product must present an element of identity for all local actors
- The territory should be attractive to attract tourists
- Local resources that have gone to make the product is well recognizable
- Traceability and adherence to code of practice

Code of practice

- Description of the product, physical, scientific
- Ingredients and raw materials
- Definition of the process
- Demonstration of the specific quality linked to GI
- Definition of production area
- Labeling rules
- Verification details

Thai GI strategies

- Code of practice-Internal control system
- Traceability
- Use of logo
- GI Market week



Conclusion

- Intellectual property should be for the betterment of the society and not for individual profits.
- Open source discovery drug projects, creative commons, open access books and articles.



Thank you
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