

SPIPA
Seminar on
Impact of WTO and FTAs on Gujarat

Intellectual Property Rights & International Trade :
The Context and SWOT Analysis

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Patent applications filed with Indian Patent Office

Year	Total Patent applications filed with Indian Patent Office	Patent applications <u>from India</u>
2009-10	34287	7044 (20.30 %)
2008-09	36812	6161 (16.75 %)
2007-08	35218	6040 (17.00 %)

Source : Indian patent office
: Compiled & analysed by GITCO Patent Cell



Foreign Patent Application with Indian Patent Office

(Thru National Phase PCT Route)

Main Countries (2009-10)

Country	Share (%)
USA	34.50
Germany	11.00
Japan	10.20
Switzerland	5.50
Netherlands	5.50
France	5.10
U K	3.90
Others	24.30
Total	100

Source : Indian patent office
: Compiled & analyzed by GITCO Patent Cell



International Patent Applications (PCT route) by India based applicants

Year	Individuals	Legal Entity	Total
2009-10	231	521	752
2008-09	232	655	887
2007-08	169	538	707

Source : Indian patent office

: Compiled & analysed by GITCO Patent Cell

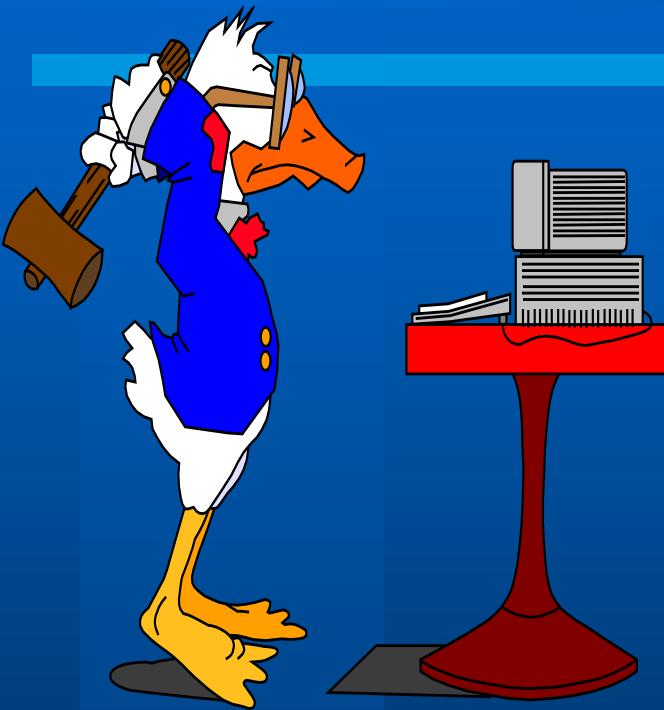
Patent applications filed with Indian Patent Office

Year	Total Patent applications filed with Indian Patent Office	Patent applications <u>from India</u>	Patent applications <u>from Gujarat</u>
2009-10	34287	7044 (20.30 %)	319 (0.93 %)
2008-09	36812	6161 (16.75 %)	295 (0.80 %)
2007-08	35218	6040 (17.00 %)	286 (0.81 %)

Source : Indian patent office

: Compiled & analysed by GITCO Patent Cell





“If you think you are going to be successful running your business in the next ten years the way you did in the last 10 years, you are out of your mind”

“To succeed, you have to disturb the present”

**Robert Goizueta
CEO, CocaCola**

IPR :

THE CONTEXT



Globalisation



“Integration of economies and societies through cross country flows of information, ideas, technologies, goods, services, capital, finance and people”

WTO & TRIPS



- Market access through efficiency is the central theme of WTO
- Reduction/elimination of unfair business practices
- ✓ *Trade Related Intellectual Property Rights (TRIPS)*

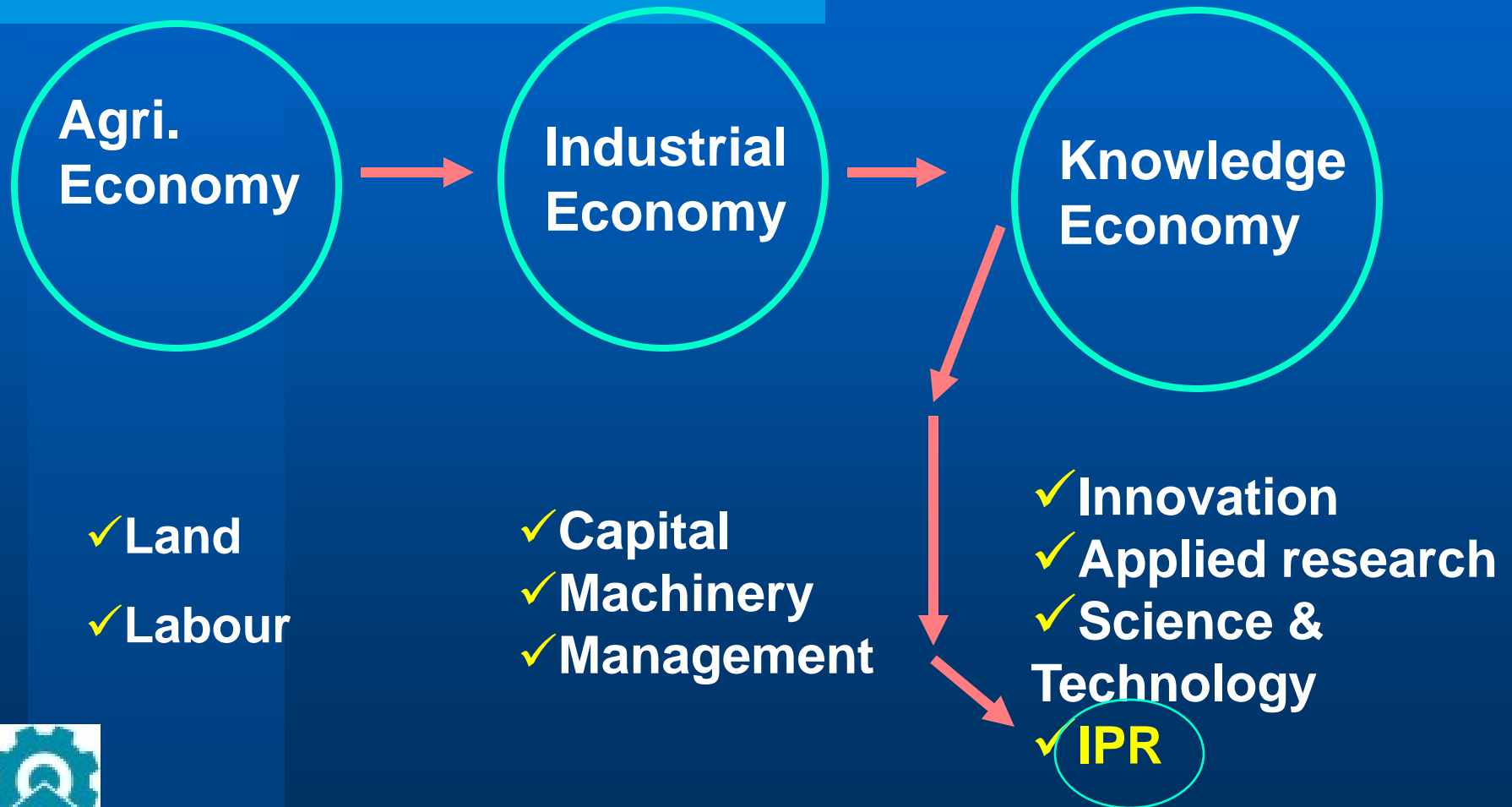
IPR

- Intellectual Property Rights (**IPR**) confers the right of ownership through several ways

- 
- ❖ Patents
 - ❖ Designs
 - ❖ Trademarks &
 - ❖ Copyrights
 - ❖ GI

- Patents in focus mainly because of its direct impact on Industry & Economy
- Affected sector : **Knowledge industries**

World Economy : The Paradigm Shift



- We have moved in to the era of ideas, creativity, inventions and intellectual properties- intensively and aggressively
- It is the intangible, knowledge based, non-replicable proprietary resources that give the competitive edge in the international business

India : The IPR Compliance

- India's IPR policy almost fully WTO compliant
- A few differences remain
- Indian Patent (amendment) Act also has a few provisions (WTO complaint) to safeguard interest of its industry & business
- Adopted Product Patent w.e.f January 2005

Product Patents : The Perspective

- **Product Patent : Reverse Engineering not possible**
- **Introduction of new products curtailed**
- **Increased competition in off patent products**
- **Likely-hood of monopoly/oligopoly**
- **Has greatly influenced India & Gujarat's International Business**

IPR & International Business

- World over IPR is directly under the control of the Government of respective country
- Hence, IPR entails not only legal and techno-economic dimensions
- Also political overtones
- IPR accordingly influences the International Relations & consequently International Trade
- Developed states like Gujarat in turn are also affected

IPR &

International Trade of Gujarat

- Gujarat has significant presence in knowledge based industries
- IPR therefore, has direct & indirect impact on several industries & issues of concern to Gujarat
- **Industries**
 - Drugs & Pharmaceuticals
 - Specialty Chemicals
 - Food & Agro processing
 - Engineering : components
 - Traditional knowledge based industry

IPR & International Trade of Gujarat

- **Issues**

- **Economic : availability, pricing,**
- **Exports**
- **Overseas ventures by Gujarat based companies**
- **Investment from abroad**
- **Outsourcing opportunities**
- **Technology transfer**
- **Litigations**

IPR & International Trade in Gujarat: SWOT Analysis



Strengths

- Significant presence of knowledge based industries
- More Large private sector units getting IPR ready for international leverage
- Pharma sector in Gujarat has started utilizing the NDDS route & create 'IP' thru patent protection
- Proactive State Government
- Gujarat based academic institutions have taken up IPR sensitization
- WTO compliant & industry friendly IPR policy
- Traditional Knowledge Digital Library (TKDL)

Weakness

- Gujarat based SMEs in General : IPR ignorant & apparently not well prepared
- Lack of Innovation culture
- Lack of documentation by manufacturers of Traditional knowledge based products
- Lop sided agreements in international deals
- Dearth of qualified & experienced professionals in the specific segment of IPR & International trade
- Unavailability of IPR database of Global level in organised & user friendly form

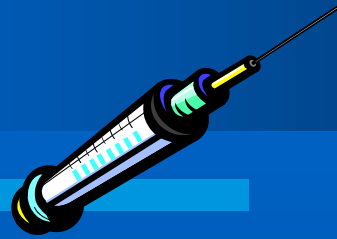
Opportunities

- Value added exports
- Generic & Bio similar drugs exports
- In-Licensing deals with International companies with IP Rights
- Access to latest & appropriate Technology :
 - Agro , Food processing & Dairy
 - Urban transport
 - Environment management
 - Water resources management
- Contract manufacturing & Contract research

Threats

- Losing market to IPR compliant competitors
- Non - tariff trade barriers
- Litigations
- Unresolved IPR policy issues
- Uncertainty in international trade partners & investors
- Bio-piracy
- Monopolistic situations

Case : Small Scale Pharma Unit in A' bad



- Diclofenec: a popular drug for pain therapy
- Products by large/MNCs dominate the market
- Open market : fight of unequal
- *SSI pharmaceuticals, Ahmedabad* has introduced Diclofenec injection using different base
- It uses water as base instead of oil
- This is less painful
- Its medicinal property remains the same

Case : SSI Pharma Unit

- The game plan :
 - Position as research product
 - Supported by clinical trials
 - Secured by IPR protection in India & Abroad
- The outcome : significant increase in international market share
- Spin off effect in international market
 - ✓ On its own other products
 - ✓ Also a few other companies of Gujarat

In conclusion . . .

- IPR is now recognised as significant factor in the International trade
- IPR provides an arena where both conflicts & agreements related to International Trade have to be managed
- Requires high level of co-operation & Governance
- Govt. of India , State Govt. and Industries to work together on this
- A comprehensive study of Gujarat based Industries focusing on IPR readiness in the context of International trade desired

THANK YOU....

....Padmin Buch

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IPR's Legal Implications : Case of Anti-Cancer Drug

- April 2012 : Indian Patent office allowed Indian company Natco pharma to produce & sell **Nexavar** (Sorafenib Tosylate) the **Anti-Cancer drug**
- The drug is patented (up to 2020) by the German pharma company Bayer.
- The Indian Generic version is expected to cost Rs. 8800/- as against Bayer price of Rs.2.80 lakhs (120 capsule pack therapy for a month)
- More such cases expected

Expected cases :

Drug indication	Innovator company	Estimated cost (Rs.)	Indian company	Estimated cost (Rs.)
Blood & Stomach Cancer	Novartis	100000/-	Natco Pharma	7500/-
Kidney & Liver Cancer	Bayer	2.80 lakhs	CIPLA	30000/-
Non-Hodgkin's Lymphoma	Roche	60000/- (Per 500mg injection)	Dr. Reddy's Lab	30,700/- (Per 500mg injection)
Neutropenia	Roche	22,000/-	Dr. Reddy's Lab	7500/-
Breast Cancer	Roche	1,00000/-	NA	NA

Source : Business Today, April 15, 2012

IPR's Legal Implications : Case of Anti-Cancer Drug

- Decision taken under provision of Compulsory Licensing (Sec 84) of Indian Patent Act
- Compulsory License to produce a generic version of a life saving drug can be issued three years after the patent was granted to innovator company
.....If the price is still seen as too high
- The ruling comes after the relevant wording in the Act was changed from “ **reasonably priced** “ to “ **reasonably affordable priced**”.

Number of Patent application filed in India

(Selected Sectors)

Year	Chemicals	Pharma	Bio-tech	Total
2007-08	6375 (18%)	4267 (12.1%)	1950 (5.5%)	35218
2008-09	5884 (16%)	3672 (9.97%)	1844 (5.00%)	36812
2009-10	6014 (17.50%)	3070 (8.9%)	1303 (3.8%)	34287

Source : Indian patent office

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