

The Development of Pharmaceutical Company in India
-A case study on Ranbaxy Laboratories-

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Outline

1. Introduction
2. Brief Overview of Indian Pharmaceutical Industry
3. The Development of Ranbaxy Laboratories
4. Conclusions

INTRODUCTION :MOTIVATION

Motivation

- Indian Pharmaceutical Industry succeed import-substitution and has emerged as one of the major drug exporters since the late-1980s.
- Growth Factors
 - Anti-patent policy under the Patent Act, 1970
 - The Drug Policy, 1978
 - Industrial Policies
- The primal aims of the Patent ct, 1970 and the Drug Policy, 1978 is to improve the accessibility of medicines in India thorough achieving self-reliance of pharmaceutical production.
- There is no doubt that these measures the government of India implemented since 1970 contributed to the growth of the industry.
- Even then, without “corporate capability “that companies understand the trends of policies, technologies, and market as information and transform the information to commercial activities, it is impossible to achieve success as mentioned above
- It is important to evaluate the corporate capability in examination of the industrial development .

BRIEF OVERVIEW OF INDIAN PHARMACEUTICAL INDUSTRY

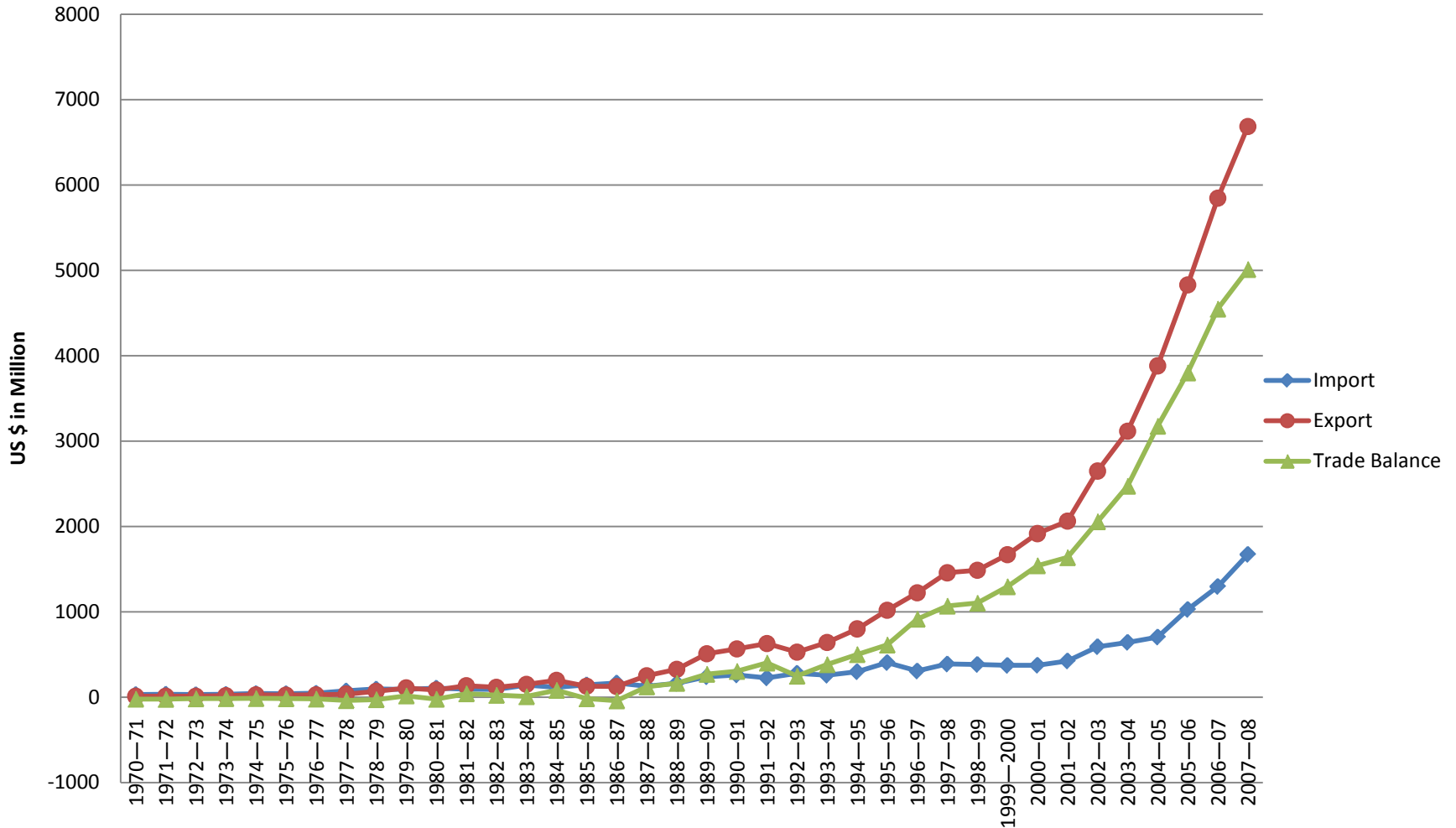
2. Brief Overview

- India is one of the major drugs producing countries in the world being the fourth largest producer by volume and the thirteenth largest by value, with about a 20% share in global generic production.
- The industry has emerged as one of the major drug exporters since the late-1980s, at number seventeen in the world.
- The balance of trade has moved into the black and trade surplus has been increasing since 1987 .

2. Brief Overview

- The development of the industry is a result of its continuous technological innovation.
 - The Patent Act of 1970 and Drug Policy, 1978 paved the way for progress of indigenous R&D.
 - The ability to develop generic drugs was acquired and improved during the mid-1970s to 1990s.

Trends in Trade Balance of pharmaceutical products



DEVELOPMENT OF RANBAXY LAORATORIES

Contents

- Early Years
- Conversion to “Pharmaceutical Manufacturer”
- Conversion from Local Pharmaceutical Company to Multinational Pharmaceutical Company
- Conversion from Copycat to R&D-based Pharmaceutical Company
- Economic Liberalisation and Management Reform

Ranbaxy Laboratories Ltd.

- Ranbaxy Laboratories Ltd.
 - The Largest Pharmaceutical Company in India in terms of sales
 - The first Multinational Pharmaceutical Company in India
 - The 50th largest pharmaceutical company in the world(10th largest Generic pharmaceutical company in the world)
 - On June 11, 2008, Ranbaxy Laboratories Ltd and Daiichi Sankyo Company Ltd announced a binding share purchase agreement between Daiichi Sankyo, Ranbaxy and the Singh Family, the largest and controlling shareholders of Ranbaxy.

Early Years

- The Origin
 - Founder of RL: Bhai Mohan Singh (B.M.Singh)
 - B.M. Singh began his business career in the construction business during the Second World War.
 - His firm bagged a contract to build roads in the North East(Assam) from Military Engineering Services(MES). Contract to build a 550km road connecting Bongaigaon in Assam to the Indian border with Myanmar in Nagaand.
 - This Assam contract made a sizable profit.
 - After Partition, he left Rawalpindi and settled down in New Delhi.
 - He started business as a moneylender.
- Ranbaxy & Co.(RC)
 - In 1938, RC was started by B.M.Singh's cousins, Ranjit Singh and Gurbax Singh in Amritsar Punjab. Ranbaxy's name was a fusion of Ranjit and Gurbax's names.
 - RC was distributors for Shionogi(A. Shionogi), a Japanese pharmaceutical company manufacturing vitamins and anti-TB.
- When RC defaulted on a loan, B.M.Singh bought the company on August 1, 1952, for Rs 2.5 lakh.

Early Years

- Joint Venture with Foreign Company
 - In 1952, RC became the solo Indian franchisee of Italian pharma company Lepetit SpA(LS) .
 - In 1959, RC started a manufacturing joint venture with LS.
 - RC had no experience of running a manufacturing outfit.
 - LS ran the joint venture , exercising total control.
 - LS held a 45% stake in RC,an Indian investor of LS's choice held another 6%, RC held 49%.

Early Years

- At that time, The Government of India's policy towards foreign capital was realistic.
 - The 1st Five Year Plan: The broad principle is that foreign investment should be permitted in spheres where new lines of production are to be developed or where special types of experience and technical skill are required or where the volume of domestic production is small in relation to demand and there is no reasonable expectation that the indigenous industry can expand at sufficiently rapid pace.
 - This realistic attitude helped in attracting foreign pharmaceutical companies to India. As of 1970, there were 46 foreign pharmaceutical companies in India.
 - The factors that led to the influx of foreign companies in India are the large size of the market and relatively larger demand for drugs, milder drug control measures and the absence of local competition.
 - In addition, the industrial (import substitution) policy provided a seller's market protected by high tariff walls and other import restriction. These factors also helped the expansion of foreign companies operating in India.

Early Years

- LS agreed to ship a chloramphenicol plant to India. LS had shipped a machine to India which was never put to use. Meanwhile, the joint venture company continued to import chloramphenicol in bulk from Italy and package it into capsules, tablets and syrups.
- The joint venture company went into red in 1959.
- The Government of India said LS would put up a plant or would have to leave India. LS agreed to exit the Indian joint venture if B.M.Singh agreed to pick up its share within three months.
- In 1961, B.M.Singh subsequently bought out the shares. RC became Ranbaxy Laboratories Ltd, owned fully B.M.Singh.

Conversion to “Pharmaceutical Manufacturer”

- The Indian pharmaceutical industry was dominated by foreign pharmaceutical companies with 68 % market share in 1970.
 - While foreign companies prevented the Indian companies from manufacturing new drugs, using the then existing patent law(the Patent Act, 1911), they were keen to import bulk drugs.
 - Foreign companies used the monopoly position permitted by the then patent regime to charge very high price. As a result, drug prices in India was among the highest in the world. The access to medicines in India was very poor.
 - To solve this problem , the Government of India decided to change the then patent act and introduce the drug price control order.

Conversion to “Pharmaceutical Manufacturer”

- The Patent Act, 1970
 - The patent law recognised only process patents and not product patents, and reduced the patent period from 16 year to 7 years.
 - The process patent regime allowed Indian companies to produce alternative processes for drugs that were not patented in India. The weak patent regime under the Patent Act of 1970 encouraged reverse engineering and development of alternative processes for the products patented in other countries.
- The Drug Price Control Order, 1970(enact in1972)
 - Under DPCO, 1970, the Government of India regulated the drug prices. The price of the drugs under the price control has been brought down to a very minimum level.
- In addition, drug imports were canalized through the government -owned State Trading Corporation.
- The business model of importing a patented drugs from a country which did recognized patents was unsustainable in the long run. The uncertainty over the drug prices and availability of imported bulk drugs, coupled with the price fixation by the government meant there was only one way a pharmaceutical company could survive . Total control over its raw material by producing bulk drugs.
- The Patent Act paved the way for progress indigenous production and R&D.
- RL changed the business model. RC started pursuing the strategy of in-house R&D and production.

Conversion to “Pharmaceutical Manufacturer”

- In 1971, RL indicated that the company would take up R&D work on its own.
- In 1973, RL set up a new manufacturing facility in Mohali and R&D facility in Okhla.
- RL started manufacturing drugs with CSIR technology.
 - At that time, Indian companies commercialized the process developed by CSIR laboratories and producing the drug.
- In 1973, RL went public to bankroll the project and raised Rs 70 lakh from the market.

Conversion to “Pharmaceutical Manufacturer”

- RL started in-house production of Diazepam(tranquilizer).
- Using indigenous technologies developed by CSIR, B.M.Singh lobbied with the government to get the import of diazepam banned. This import ban gave RL a de facto monopoly in the market.
 - The industrial (import substitution) policy provided a seller’s market protected by high tariff walls and other import restriction. These factors also helped the expansion of RL in India.
- Entry to Antibiotics
 - Diazepam could never be a big business because of its small market scale.
 - RL started in-house production of antibiotics in 1973.

Conversion to “Pharmaceutical Manufacturer”

- In 1978, the Drug Policy, 1978 was announced. The policy was the first comprehensive drug policy in India. The policy loaded in favor of the Indian pharmaceutical companies.
- RL has focused on R&D for development of new process for manufacturing drugs.
- In the trend of economic liberalization in the early 1980s, RL was pursuing the export-oriented strategy .
- In 1979, Drug Price Control Order was tightened. This tightening of DPCO had much incentive for export.

Conversion to “Pharmaceutical Manufacturer”

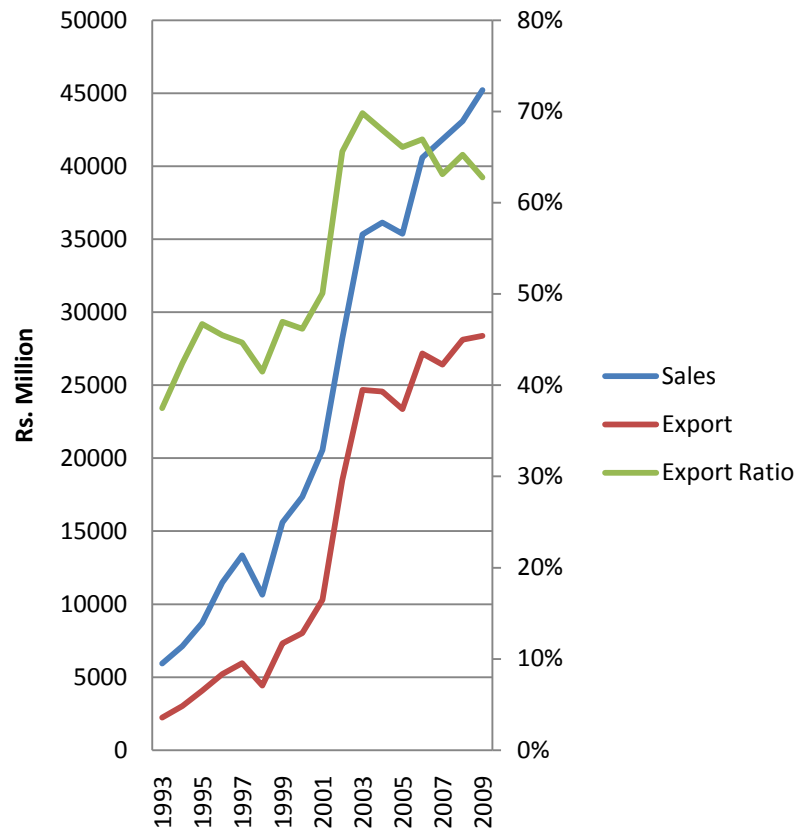
- from the model of importing a patented drugs from a country which did recognized patents to the vertical integration model
 - RL set up own R&D facilities and manufacturing facilities and build a strong sales network.
 - RL has enhanced its operational efficiency through vertical integration.

Local Pharmaceutical Company to Multinational Pharmaceutical Company

- India started the economic liberalization in 1991.
- Multi-nationalization of Indian pharmaceutical companies has been progressed.
- RL has promoted to globalize its operation rapidly
- RL expanded its operations via a joint venture with Eli Lilly(EL)
 - RL entered into an agreement with EL for setting up a joint venture in India to market select EL products.
 - In 1995, the two companies signed two agreements for setting up two more joint ventures, one in India and the other in the US. They would be equal partners in these joint ventures.
 - The Indian venture was for R&D and manufacturing of generic products; and for development of new products of both companies.
 - The joint venture in the US was to focus on marketing of products from RL.
 - In 1995, RL acquires Ohm Laboratories in the United States and builds a new FDA-approved production facility.

Local Pharmaceutical Company to Multinational Pharmaceutical Company

Trends in Sales and Export



- RL crossed a sales turnover of Rs. 10,000 million, with its export reaching an all time high of Rs. 5,000 million.
- In 1998, RL began marketing its own branded drugs in the US.
- Since 1998, Sales and export has been increasing rapidly.

Conversion from Copycat to R&D-based Pharmaceutical Company

- In 2005, The Patent Act, 1970 was amended to comply with the WTO agreement on Trade Related Aspects of Intellectual Property Rights(TRIPS).
- The negative impact of TRIPS that the pharmaceutical industry foresees will be the end of the reverse engineering , incidentally this is the core competence of the industry.

Conversion from Copycat to R&D-based Pharmaceutical Company

- By the late 1990s and the first couple of years of the new millennium, three distinct business models had emerged.
 1. The first model is to stick to manufacture of off-patent drugs, sell these in India as well as export some quantities abroad. This is the model opted for by Cipla.
 2. The second model is outsourcing business. There was no point in fighting MNCs and it would make more sense to partner with MNCs. This is the model opted for by Piramal Healthcare (PH). PH started positioning as contract manufacturing of patented drugs for MNCs.
- The third model is the most daring model. While playing on the generic opportunity, some companies began investing in R&D for new drug development in the mid-1990s. This is the model chosen by RL and Dr. Reddy's Laboratories.

Conversion from Copycat to R&D-based Pharmaceutical Company

- NDDS
 - RL developed the NDDS for ciprofloxacin whereby patients are required to take the drug once a day rather than the previous twice-a-day dosage .
 - The NDDS for ciprofloxacin was the most successful example .RL licensed its once-a-day ciprofloxacin formulations to Bayer in 1999.

Conversion from Copycat to R&D-based Pharmaceutical Company

- NDDR

- In 1994, RL set up a new R&D Center at Gurgaon and started R&D for new drug development.
- In 2003, RL and GlaxoSmithKline (GSK) entered into collaborative drug discovery and clinical development. Total milestone payments, excluding royalties, could exceed over US\$ 100 million.
- No success at the clinical trial stages have yet been reported from the much publicized Ranbaxy-GSK R&D collaboration.

Novel Chemical Entities developed by RL

NCE	Indication	Development Stage
RBx7796	Respiratory	Phase II
RBx6198	Urology	Early discovery
RBx9001	Urology	Pre-clinical stage
RBx9841	Urology	Pre-clinical stage
RBx8700	TB	Pre-clinical stage
RBx7644	Bacterial Infection	Phase I
OZ222/RBx1160	Malaria	Phase III

Source: Ranbaxy website

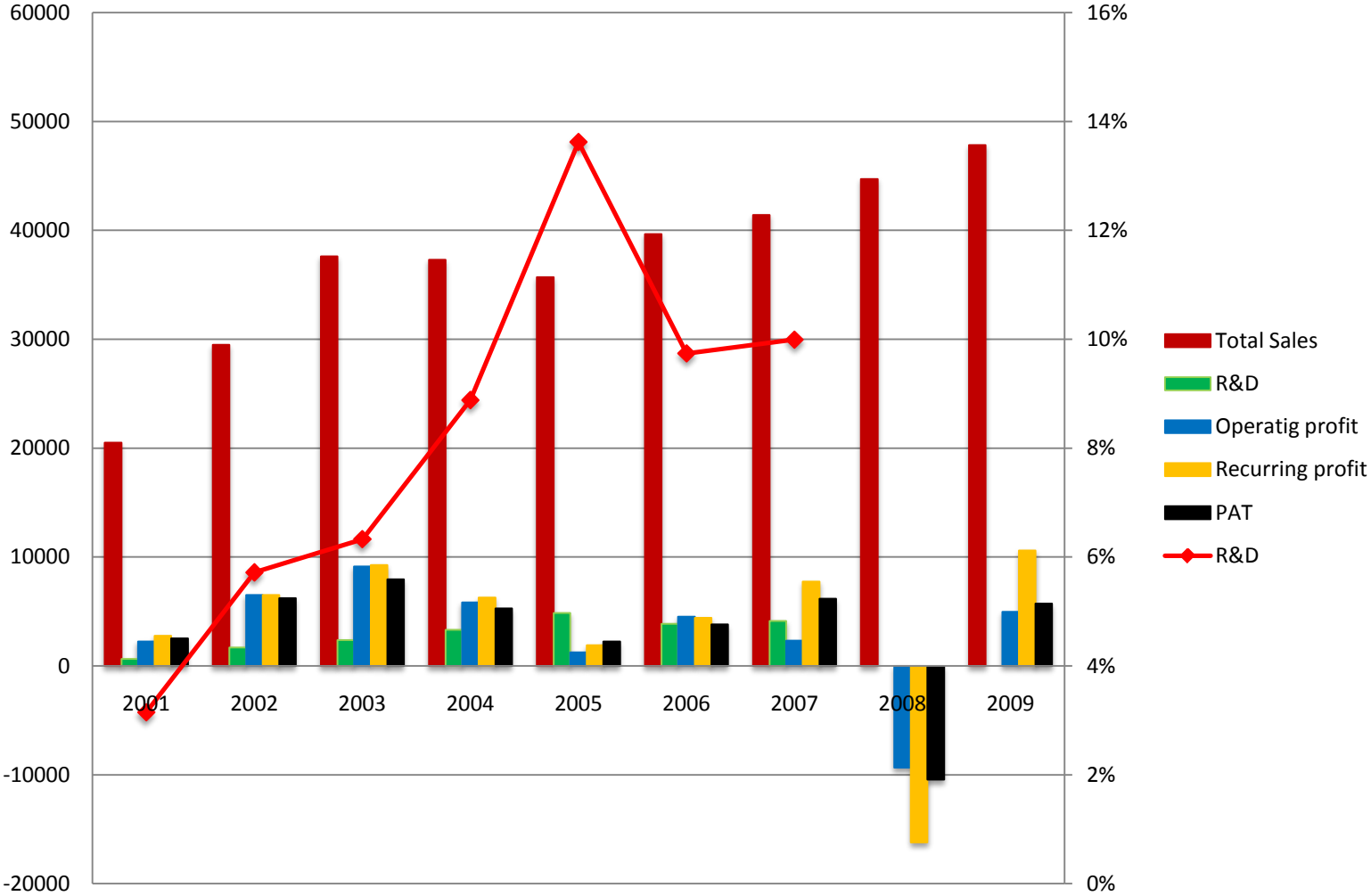
Economic Liberalisation and Management Reform

- With economic liberalisation since 1991, Differences arose between B.M. Singh and Dr. Parvinder Singh(the eldest son of B.M.Singh) over the expansion and professionalisation strategy of Ranbaxy.
- It was clash between two ways of doing business.
 - B.M. Singh was the master of the license- raj
 - Dr. Singh was the votary of professionalisation and internationalization. He focused on R&D and internationliaztion.
- Subsequently, in 1992 in a boardroom coup of sorts Bhai Mohan Singh was forced to bow down and Parvider took over the company.

Conclusion

- The primal aims of the Patent Act, 1970 and the Drug Policy, 1978 is to improve the accessibility of medicines in India through achieving self-reliance of pharmaceutical production.
- There is no doubt that these measures the government of India implemented since 1970 contributed to the growth of the industry.
- In the development of Indian pharmaceutical companies, “corporate capability” that companies understand the trends of policies, technologies, and market as information and transform the information to commercial activities is important.
- RL has successfully changed its business model depending on the changes of the economic environment.

RL-Financial Results 2001-2009



Source: Ranbaxy Laboratories, *Annual Report*, various years.

	RL's milestone	Trends of policies
1938	Ranbaxy&Co. was established.	
1952	RCwas the solo distributor of Lepetit SpA	
1959	RC started a joint venture with Leptit SpA	
1961	A joint venture with Lepetit SpA ended. RL incorporated.	
1970		The Patent Act, 1970 , the Drug Price Control Order, 1970
1973	RL went Public	
1974		Foreign Exchange Regulation Act (FERA)
1977	RL's first joint venture in Nigeria was set up.	
1978		The Drug Policy, 1978
1979		The Drug Price Control Order, 1979
1985	RL Research Foundation was established.	
1986		The Drug Policy, 1986
1987	RL became the largest manufacturer of antibiotics.	The Drug Price Control Order, 1987
1988	RL's Toansa Plant got USFDA approval.	
1990	RL was granted its first US patent for Doxyclyline	
1991		Economic Liberalisation
1992	RL entered into an agreement with Eli Lilly	
1994		The Drug Policy, 1994
1995	RL started R&D for new drug development.	The Drug Price Control Order, 1995
1997	RL crossed a sales turnover of Rs. 10,000 million, with its export reaching an all time high of Rs.5,000 million.	
1999	RL licensed its once-a-day ciprofloxacin formulations to Bayer in 1999.	the Government of India set up the Pharmaceutical Research and Development Committee (PRDC)
2003	RL and GSK entered into a global alliance for drug discovery.	
2005	RL started joint venture with Nihon Chemiphar . RL opened the stat of the art R&D facility .	The Patent Act, 2005
2008	Daiichi Sankyo acquired 34.82% shareholding from the promoters of RL	

Thank You for your attention

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