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# Study of Comparative Advantages of Chinese and Indian Pharmaceutical Industries under Globalization

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**Abstract:** The authors explore the background and major factors that have promoted the growth of Pharmaceutical industry in India. Government policy and globalization strategy have played critical roles in positioning India as a pharmaceutical powerhouse. China, facing similar challenges and opportunities in the global economy, could draw valuable lessons from India's growth story. There are also synergy and strategic fit between the two emerging economy in the pharmaceutical industry

**Key words:** China; India; Intellectual Property Rights (IPR); Pharmaceutical industry; MNE

Since India's independence, its domestic companies have experienced significant growth. After five decades of development, India has become one of the most important sources of active ingredients and bulk drugs. Presently, it's exporting to more than 100 countries in total. Its main export regions are US, Western Europe and Asia (especially China). Although China has a larger domestic market and enjoys phenomenal growth as well, India's expertise on regulatory compliance and process chemistry has given it competitive advantages in the global market. The article will discuss the factors that contributed to India's success and identify some lessons that China could learn from this formidable competitor. The authors believe that four factors have contributed to India's success: Government Policy, internationalization Strategy, Process expertise and regulatory expertise.

## 1. GOVERNMENT POLICY AND LOOSE IP PROTECTION LAW

### 1.1 Beginning of Indian Pharmaceutical Industry

Just after India's independence in 1947, there was no pharmaceuticals industry to speak of. The Indian domestic pharmaceutical companies could not cater to the demands of the Indian population. Because of government price control, there was little incentive to expand production capacity either. In short, there was a crisis in public healthcare and getting access to affordable medicine. The government had two options at

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the time, either to import drugs in large quantities or to develop the local industry by relaxing IP rules. The Indian government opted for the latter solution. From 1970 onwards, instead of granting process and product patents, the new IPR regime began to recognize only process patents.

### **1.2 Indian Patent Act of 1970**

The Indian Patent Act of 1970 increased the incentives for Indian firms as second innovators. The impact of the change in IPR was simply tremendous. Many Indian pharmaceutical firms were able to produce essential drugs like antibiotics with a heavy slashing of prices. Indian consumers revealed themselves to be price sensitive rather than being brand loyal to western brands. Most importantly, the public Indian healthcare system was finally able to stand up on its feet and there was a significant increase in the proportion of the poor who had access to basic drugs. Indian firms even entered into production contracts with the original multinational inventors, permitting them also to enjoy lower costs and a greater mark-up. India became an exporter of bulk drugs and final therapeutics, supplying many parts of the developing and developed world at lower costs. In 1970, the Indian market was clearly dominated by multinational firms and eight of the top ten firms were MNCs. After two decades following the 1970 Patent Act, Indian pharmaceutical industry was dominated by domestic firms and only four of the top ten firms were now multinational. By the mid 1980s most Indian pharmaceutical firms were producing bulk drugs and formulations for the domestic market and the leading domestic firms (e.g. Ranbaxy) had begun to explore markets in Asia and Africa.

The Indian case study shows that in a developing country, with an excess demand and a significant technological retard in a knowledge intensive sector, a narrowing of the IPR regime can serve to create industrial competence and also increase welfare. The case study also shows that a narrowing or a loosening of the IPR might be welfare enhancing, if it leads to a greater quantity being produced and/or a lowering of price in the final market. It might be welfare enhancing even at a global level, if other developing countries are able to thereafter obtain the generic versions of the knowledge intensive commodity more easily or at lower prices.

### **1.3 Government contribution**

In addition to establishing favorable policy and regulations, India government has been instrumental in setting up infrastructure for nascent industry and ensure sufficient industry clustering and knowledge diffusion. Take Hyderabad as an example, India government started India drug and pharmaceutical Limited (“IDPL”) and set up five plants and operations in Hyderabad area. The company has serves as an incubator for many new starts ups for the industry. Statistics shows that one third of the senior management from roughly two hundred biotech and pharmaceutical companies have worked in IDPL at some point of their career. Two of the founders of Dr. Reddy’s, one of the most successful companies, also came from IDPL. In addition to the industry enterprises, Hyderabad has roughly 40 institutions of higher learning. The prestigious India institute of Chemical technology and Center for cellular and Molecular biology are also based in the city. Because of the close proximity to suppliers and peer companies, it’s very easy for knowledge and skills to be diffused from one company to another.

## **2. REGULATORY COMPLIANCE AND CHEMISTRY EXPERTISE**

### **2.1 Familiarity with regulated market**

When it comes to US FDA approved plants, India easily surpassed China and other competitors. The total number of plants inspected and approved by FDA exceeds one hundred and is more than the total of combined plants in China and Italy. The larger number of approved plants is helping propel long-term growth for Indian drug makers. The approved sites would help the sector widen its presence in the global market by producing high-quality products within the country and in other regulated markets.

## **2.2 Superior Process Expertise**

In addition to regulatory compliance, India has developed very strong process chemistry expertise through many years of “reverse engineering” activities. India’s chemistry capabilities which have formed the foundation for its world class generics pharmaceutical industry are well applied in providing high end chemistry research services to support drug discovery. Medicinal chemistry services provided by Indian companies include the synthesis of building blocks, scaffolds and intermediates for generating analogues; compounds for assays and animal models and custom designed small molecules for Lead Generation and Lead Optimization. The sector’s leading players have been awarded multi-million contracts from the world’s leading pharmaceutical companies and set up facilities with many hundreds of chemists to deliver these projects over 3-5 year time periods. More recently Indian vendors are making deals with international companies whereby the undertake to perform lead generation and optimization for a raft of molecules not for a service fee but for milestone payments and royalties on the successful delivery of lead molecules to pre-clinical or even late stage clinical development.

## **3. INTERNATIONALIZATION STRATEGY**

### **3.1 Synergy creation**

In the last decade Indian pharmaceutical firms have emerged as most aggressive overseas investors of all Indian industries. Analysis of Indian firms’ internationalization strategies suggests that acquisition is preferred route of Indian firms’ international expansion compared with organic routes in advanced countries. The benefits are created through synergies formed by the product pipeline of Indian firms and assets provided by overseas firms. Indian firms have a large pipeline of products, cheap manufacturing facilities and an ambition to enter the advanced market of Europe and the US. However Indian firms lack distribution setup and high-end technological capabilities. Thus through acquisition Indian firms are generating synergies with their competitively priced products.

### **3.2 Market Share Increase**

In addition to synergy creation, Indian firms are seeking to increase their market share by acquiring generic firms in advanced markets and creating business links with MNE pharmaceutical firms. This is clearly evident in NPILS’s acquisition of production facility of Pfizer in Scotland. NPIL has a contract for process development and scale up deal for Pfizer’s animal healthcare products. But with acquisition of Pfizer’s production facility in Scotland NPIL has emerged as the largest supplier in dollar terms as Pfizer has agreed to source from this facility for the next five years. Acquisition of big name Pharma facility gives Indian firms instant credibility and also access to advanced management concepts and process controls.

### **3.3 Access to regulated market**

Although India is a low-cost location for drug manufacturing and process R&D, analysis suggests that Indian firms are acquiring assets in advanced countries to augment their current capabilities and set up business closer to customers. For example in the case of bulk drugs MNC firms are currently outsourcing work on intermediates to Indian firms but really reluctant in the case of outsourcing other work such as finding efficient processes for new or patent expired drugs even though Indian firms have excellent capabilities. Indian firms are responding to these challenges by setting up operations close to customers through acquisition of western firms in highly regulated advance market. Acquisition of UK based Avecia helps the company to fill a knowledge gap in early stage R&D works and bid for contracts from firms operating in advance countries. Customers in the advanced countries often have concerns with the intellectual IP protection status in India. By setting up shops in advanced countries not only fill the knowledge gap, it also helps alleviate concerns on IP protection. These acquisitions are providing access to customers who may not have done business with Indian firms.

### **3.4 Moving up the value chain**

By acquiring specific skills and technologies in advance markets, Indian firms are moving up the value chain. In high volume-low cost API market Indian firms are now facing competition from Chinese firms which can manufacture bulk drugs at a cheaper rate than Indian firms. Indian firms are using access to technology as a differentiating factor where competition on the basis of cost has limitation. Nicholas Piramal's acquisition of Avecia or DRL's acquisition of Trigenesis shows Indian firms efforts to move up the value chain by augmenting existing capabilities through acquisition. Avecia, Nicholas's acquisition is able to make toxic products and other high value drugs such as hormones and owns a fermentation equipment to make drugs more efficiently. These drugs require a high quality of safety and containment and therefore they are highly-priced making them more profitable to innovators. DRL's acquisition of Trigenesis gives company access to certain products and proprietary drug delivery technology platforms to develop a pipeline of drugs in the dermatology segment. One of Trigenesis's proprietary technologies takes care of major challenges faced in the formulation and delivery of drugs in the areas of oral, injectables, inhaled and topical delivery.

## **4. COMPARISON BETWEEN INDIA AND CHINA**

The global pharmaceutical industry is facing a number of challenges. Companies today need to pursue more efficient, cost-effective and productive ways to conduct their operations, whether in R&D or manufacturing. The key to a quick turnaround is to have drugs discovered quicker, developed faster, manufactured cheaper and marketed more widely. Among the emerging countries, China and India have risen rapidly in the global pharmaceutical outsourcing arena, as both countries possess the unique combination of low cost and quality service. The current global financial crisis has also enhanced the importance of these two countries to many drug companies around the world that are seeking cost reductions.

### **4.1 Environment for patent protection**

As part of concession to WTO admission, both India and China has agreed to product patent protection and tougher enforcement of IP infringement. The improved IP protection environment has promoted R&D investment, both from domestic and direct foreign investments. Empirical evidence suggests that leading India pharmaceutical companies have increased their R&D investment significantly post-TRIPS. Companies, such as Dr. Reddy's, Ranbaxy are moving aggressively into high-margin and high-risk disease areas. In comparison, the R&D funding in China is primarily driven by the central government and very small percentages are from private enterprise. To promote innovation by the private enterprise, China needs to develop a handful leading companies to effectively compete with their western and India counterparts. In China, top ten firms contribute to roughly 20% of total revenue compared with 50% in India. Although China has embarked on a industry consolidation through government guidance and GMP certification, the process is quite slow and premier pharmaceutical company with the statue of Dr. Reddy's and Ranbaxy has yet to emerge.

### **4.2 Interaction between Indian and Chinese Pharmaceutical industries**

Over the past few years, there has been a growing engagement between India and China in the economic sphere, and this has extended to the pharmaceuticals and biotechnology sectors as well. While several major Indian pharmaceutical firms have set up joint ventures and production facilities in China, China has emerged as a very important supplier of APIs and bulk drugs for pharmaceuticals industry in India. As a source of India's imports of medicinal and pharmaceutical products, China's share is the highest, at 34.6 percent in 2005-06, having risen from 6.2 percent in 1993-94. Correspondingly, as a destination for India's exports of drugs, pharmaceuticals and fine chemicals, China's share increased from 0.4 percent in 1993-94 to 3.5 percent in 2005-06.

Because of the mutual economic dependency, India and China can enhance their levels of engagement and learn from each other. Currently China only has 55 plants approved by FDA, compared with 100 approved plants in India. The low approval rate is due to Chinese company's unfamiliarity with rules. India pharmaceutical industry can provide valuable service by providing technical and regulatory support. Many Chinese companies are currently taking steps to implement GMP regulations and in the process of filing Drug Master Files (DMF). However, it will take time to be well-versed in European and US rules and regulations. India has extensive experience in supplying API and formulation products to the regulated market, China can benefit from their Indian counterparts in understanding and implementing GMP regulations. By setting up strategic partnerships with Chinese firms, India firms can benefit from China's better infrastructure and access to vast majority of intermediates and APIs.

### **4.3 Lesson learned from Indian's international expansion**

India's experience in international expansion can provide a lot of valuable lessons for Chinese firms in penetrating into western regulated market. Current high growth rate in Chinese domestic market is not sustainable. Once domestic market is saturated, China will have to look outside for market growth. India companies have set up a lot of good precedence in strategic alliance, joint venture, or asset acquisition in the industry. By setting up joint ventures or acquire assets in regulated market, India has increased its understanding in local regulatory affairs and alleviated concerns of intellectual property protection. Most importantly, India has successfully moved up value chain and is positioning itself in high-margin areas. Obviously, Challenges and opportunities faced by India firms during the international expansion may very well be repeated by Chinese firms tomorrow. It is recommended that China pharmaceutical industry study India's experiences and lessons carefully and transforms itself into a leading player in the global pharmaceutical industry.

## **5. CONCLUSIONS**

The authors think that loose government patent policy has given birth to a very competitive Indian Pharmaceutical industry. Armed with extensive experience and expertise in process chemistry and regulatory compliance, India is moving aggressively into the international and regulatory market. By collaborating with Indian firms, domestic Chinese firms can benefit and strength it's competitive positioning in the global market.

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