

THE EMERGENCE OF INDIA'S PHARMACEUTICAL PRODUCT LIABILITY LAWS IN INDIA

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Abstract

The Indian pharmaceutical industry's recent modifications to patent regulations provide an opportunity to examine how have institutional and administrative framework conditions changed for innovation and social-state support in low-income markets? Globally competitive Indian companies have embarked on product R&D, generics and clinical trials. Researchers explored how India's new product patent law affects these trends. The authors examine the internal characteristics and international competitiveness of the Indian pharmaceutical industry. They argue that changes in patent law have shifted the focus of Indian pharmaceutical companies from process to product development. In conclusion, they address the strategic implications for the Indian pharmaceutical industry and the need for research and public policy to identify the best social benefits from the product patent system. Product liability is the area of law that offers compensation for bodily harm and property damage brought on by defective and unreasonably harmful items, as well as from the failure of a manufacturer or seller to warn the customer about those hazards.

Keywords: India's, Pharmaceutical, Product Liability, Laws in India, Industry

1. Introduction

The administrative and institutional conditions for innovation in the Indian pharmaceutical business have changed as a result of legal and political concerns for more significant societal rewards. The first beta-blocker to inhibit survival hormones such as adrenaline was propranolol, developed in the 1960s by the British company ICI Pharmaceuticals. However, many Indians considered the drug expensive. Yusuf Hamied, the chief's son and his R&D director at Cipla, has started production of a lower-priced version for the Indian market. The ICI filed a complaint with the Indian government, and Hamid used an earlier legal judgment to convince then-Supreme Leader Indira Gandhi that his actions were in the public's best interest. Hamied endorsed the proposals of Justice Rajagopala Ayyangar contained in the 1959 report to urge India to introduce a half-baked patent system in the public interest. He asked state officials, "Should millions of Indians be denied access to life-saving medicines simply because the Creator wanted to avoid the color of our skin?" I asked. Political and legal considerations seem to have influenced Indira Gandhi. In 1970, she lobbied legislators to change the rules governing pharmaceutical patents so that rights applied to the technology of manufacture rather than the compounds themselves. Despite India's advantages as a low-manufacturing location, the retrograde development of expensive new drugs in India by 2005 related to HIV/AIDS, aging, cardiovascular disease, and malignancies It meant considerable costs for Western companies. Shows possible outcomes for state social assistance.

Prior to December 31, 2004, the pharmaceutical and agrochemical sectors within the administrative and institutional framework of India were obliged to grant patent protection exclusively to the manner in which the goods were supplied and not to the actual goods themselves. Was limited These circumstances have led India's excellent creative and low-cost pharmaceutical industry to manufacture, supply and legally sell affordable Indian versions of expensive western medicines in developing countries without infringing patents. An Indian company has the legal right to offer and sell a drug if the process used to manufacture the drug is sufficiently different from that of the original patent holder.

India introduced a system of product patents on January 1, 2005 to meet the requirements for World Trade Organization (WTO) membership. These administrative and structural changes may provide an early opportunity to test the hypothesis that the product patent system promotes innovation. Unlike many other Asian countries, India's institutional and administrative system should facilitate product patents.

India has long followed both the general rulebook and the rules adopted by the British Controlled Patents. India enacted her first patent law in 1856. Unlike other former British colonies in Asia, India adopted and maintained a secular, people-based political system after her 1947 independence. Poland has a long history of law and order and patent regulation, but it is one of the latest countries to move from a process patent to a product patent system. But unlike India, most of these countries had communist leaders who were unfamiliar with Western patent law. Most of these governments controlled and coordinated the manufacturing, distribution and research of pharmaceuticals, similar to India's. India thus provides a near-perfect legal environment for evaluating claims that the pharmaceutical patent system promotes the speed of innovation.

2. Product liability

Product liability is the area of law that offers compensation for bodily harm and property damage resulting from faulty and disproportionately harmful items, as well as from the failure of a manufacturer or seller to adequately warn the public about such risks. It is an injury claim based on a faulty product. It encompasses all legal proceedings initiated owing to faulty and excessively risky items that caused bodily harm and property damage. Losses resulting from a manufacturer or seller failing to alert the customer to a product's risks are also included.

3. The pharmaceutical sector in India has undergone institutional and regulatory reforms

Figure 1 depicts Timetable of institutional and regulatory improvements in the Indian pharmaceutical industry. India he passed the first patent law in 1856. In 1859 the first significant

changes were made. India attempted a major overhaul of its patent rules in 1872 with the Patents and Designs Act.

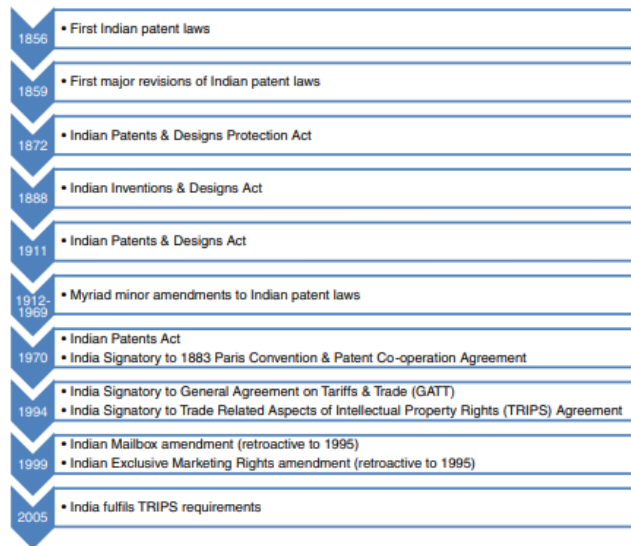


Figure: 1. a timeline of the institutional and regulatory developments in India's pharmaceutical sector

Key components of patent law and treaties in our research include the Indian Patent Act 1970, the signing of India's General Agreement on Tariffs and Trade (GATT) in the Uruguay Round of 1994, and the TRIPS Agreement. . Under the Patents Act, 1970, a process patent system was created in the pharmaceutical and agrochemical sectors of India. Thanks to the 1994 Agreement, from January 2005, India has been able to introduce a complete system of product patents in all economic sectors including pharmaceuticals and agrochemicals.

The Patents Act of 1970 replaced a system of product patents that had previously prevented the Indian pharmaceutical sector from competing in the domestic market. By introducing a process patent system to the Indian pharmaceutical and agrochemical industries, the law addressed intellectual property practices supported by the pharmaceutical industry in developed countries. Process patents were available under the law for seven years from the date of filing or five years from the date of sealing (the date the patent was effectively granted), whichever was earlier. In addition, Indian Patent Office instructs patent holders to license their innovations to individuals or

companies at a fair price if they find that the patent does not bring social benefits and it will benefit the Indian people. can. I am interested in such technology. After 3 years, if the Indian Patent Holder appears to be charging excessive license fees, the Indian Patent Office will, based on its view, set a reasonable royalty fee and provide the Patent Holder with a license. can be requested to provide.

After the passage of the Patent Act in 1970, the Indian pharmaceutical industry experienced rapid development, challenging the notion that the existence of a product patent system was necessary for innovation, economic growth and social benefit. . Shows how companies grew in the late 20th century and the age of process patents. Many Indian pharmaceutical companies. Domestic market share, exports, and bulk pharmaceuticals (used in pharmaceuticals and compounds) produced in India for domestic and foreign markets all experienced similar growth.

4. Theoretical justifications for patents' social rewards

Over 300 years ago, John Locke's economic theory was the basis for patents. In his second treatise on government, Locke argued that humans, like their bodies, have "the fruits of their labor." After Locke, other authors attempted to define "result of effort". When this term refers to the final product created by technology, it has protected product patents. When referring to the technology itself, it protected process patents. Traditionally, countries have granted and defended patents when they are related to economic growth. However, upon its founding in 1776, the United States became the first country in history to make the theft of foreign intellectual property official government policy. The United States is now the leader in IPR. Researchers have long debated whether patents are more effective than other forms of protection, such as confidentiality, in promoting innovation and protecting ideas. The lack of patent protection for technology is made clear by the facts. The usefulness of patent protection was called into question when Mansfield, Shwartz, and Wagner found that 60% of the protected goods were duplicated within his four years. In addition, Mansfield and Co and List and Qui found that industries with high copy counts are those that place the most emphasis on patents. However, even in these areas, the majority of patented products are not protected by patents. Despite the fact that patents are designed to protect technology, research shows that patents often appear ineffective at doing so, and companies typically believe that patents protect innovation. I think it's not enough to do that.

Moreover, Mansfield found that improving patent protection would, at best, have conflicting consequences for foreign direct investment (FDI). Her second study by Lee and Mansfield found that increased patent protection in developing countries increased foreign direct investment (FDI). According to Pfister and Defains' findings, French firms often decrease their investment in nations with stronger patent protection, large GDPs, and low research intensity. Although they appear to be at odds with one another, the investigations of Lee, Mansfield, Pfister, and Defains are logical complements. High GDP nations often have established economies rather than emerging ones. Although there is no discrepancy between the conclusions of the two research, both questioned whether improved product-patent protection boosts FDI.

5. The pharmaceutical business in India is organized, strategic, and innovative

India's pharmaceutical industry comes in at number four globally in terms of volume but at number 12 in terms of sales. Little more than 1% of the global pharmaceutical business is made up of the Indian market, which was valued at US\$5.3 billion in 2005. However, as Fig. 2 shows, India's pharmaceutical industry has grown significantly. In contrast to 1970, when they made up just approximately 20% of the market, Indian pharmaceutical businesses provided 95% of the country's domestic pharmaceutical industry in 2006. In parallel, 75% of the global market for medicines was provided by Indian businesses in 2006. Since 1970, it has evolved into an industry that produces around 45% bulk medicines and 55% formulations, from being predominantly a manufacturer of pharmaceuticals used in formulations.

The pharmaceutical sector in India has also grown to be a major participant internationally. Exports in the Indian pharmaceutical sector have grown at a compound annual growth rate of 22.7% during the last ten years. Roughly 3.7 billion dollars worth of exports, or about 61% of total industrial production, were made in 2005. The largest pharmaceutical business in India, Ranbaxy, exported almost 80% of its output in 2007, and despite being mostly unheard of by US customers, the US was still its biggest market.

With more than 23,000 enterprises, the Indian pharmaceutical sector is still fragmented. Several sizable Indian pharmaceutical businesses compete on a worldwide scale despite industry fragmentation. The top tier of the sector is concentrated; the top 10 Indian pharmaceutical companies control 36% of the market. About 5,000,000 Indians are employed directly by the sector, while 24,000,000 are employed indirectly. The structural traits of the industry are compiled in Fig. 2.



Figure: 2. India's pharmaceutical industry's structural characteristics in 2007. Third World Network, Organization of Pharmaceutical Producers of India, and Intec.net are among sources.

Human resources are also an asset to the R&D efforts of the Indian pharmaceutical industry. One such resource is India's tech-savvy workforce. Fluent in English due to the country's all-English school system. India's workforce has helped create an environment that makes joint venture projects and contract research profitable for multinationals. In addition, it facilitates researchers' access to English-language research reports and articles that encourage free discussion and creativity. Moreover, India's English-speaking environment is more comfortable for foreign academics and businessmen. Given the immense growth potential of the Indian market and the comfort of its executives, foreign companies are more likely to support research in India. India's excellent industrial conditions enhance its desirable research environment. India has 75 facilities approved by the US Food and Drug Administration, more than any country outside the US (FDA). India has a significant advantage in clinical trial research due to its industrial environment that

allows for cost savings in both manufacturing and research, and the ability of companies to manufacture medicines locally.

India's fragmented pharmaceutical industry is largely offset by India's competitive advantage in research and development. This Indian company spends 1.6% on R&D, but most of the smaller micro pharmaceutical companies do not do basic research. Many of India's smaller pharmaceutical companies focus on manufacturing traditional folk and Ayurvedic medicines used in India rather than manufacturing generic or bulk drugs. As shown in Table 1, India's largest organizations still spend about a third less on R&D relative to revenue than their Western counterparts. However, compared to Western firms, Indian firms spend only about one-third as much on comparable research initiatives. Due to their smaller size, Indian pharmaceutical companies have significantly lower overall R&D spending than their Western competitors.

Table: 1. R&D as a share of sales for the pharmaceutical sector in India, 2004–2005. Authors' calculations as a source.

Companies In Pharmaceutical Industry	Percent
Indian Pharmaceutical Industry	2.5
Western Pharmaceutical Industry	24.0
India's Top 10 Pharmaceutical Industry	6.5
Dr. Reddy's	23.6
R&D Growth Of India's Top 5 Pharmaceutical Industry	56.0

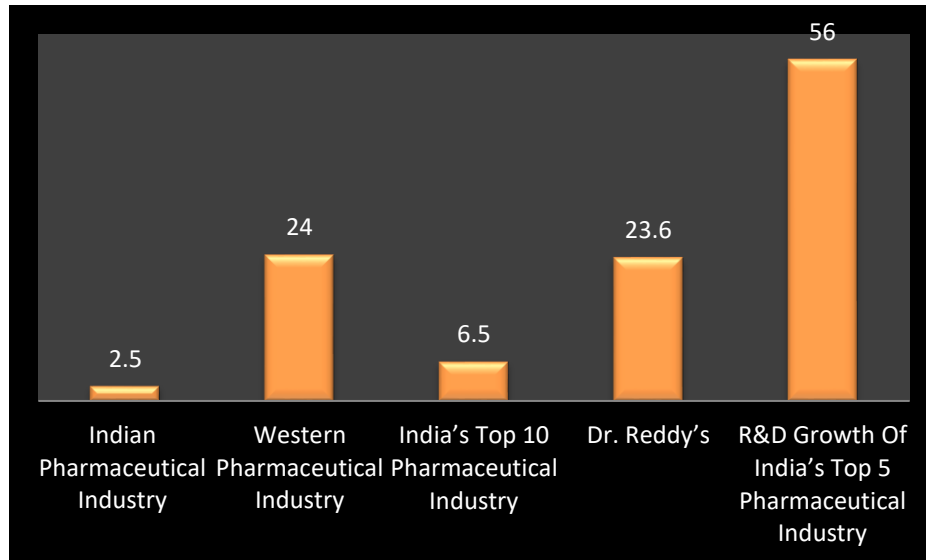


Figure: 3. R&D as a share of sales for the pharmaceutical sector in India, 2004–2005. Authors' calculations as a source

6. Innovation in the Indian pharmaceutical sector is measured

There are several ways to gauge the performance of R&D and innovation more generally. However, a study indicated that just 10% of the businesses employed a single metric of success. In general, patents are the most commonly recognized indicator of innovation, thanks to:

- Offering metrics that are objective
- Making use of both internal and external data
- Clearly stating the value of the research
- Strongly correlated with indicators like research publications and a country's share of technology exports, according to a United Nations organisation.

However, the significance of the improvements that are covered by each patent, as well as whether it applies to a group of items or a single one, vary substantially. Additionally, it can be challenging for businesses and researchers to predict whether or not patented technology will result in significant innovations. For instance, hardly anybody anticipated that simple metal boxes called

shipping containers would completely transform their sector. Some authors contend that the development of container ships and ports, as well as the improved logistical effectiveness of shipping containers, facilitated globalization.

The available patent records of the Indian pharmaceutical industry prior to 2005 and the overall process patent regime are shown in Table 2. In 2004, patents increased significantly from 2001 to 2004. The same his two-year Ranbaxy patent output largely offset the decline in CSIR. As one of the top 5 Indian pharmaceutical companies, Cipla has the lowest investment in R&D, highlighting its reliance on patents for its reverse engineering process. The missing data in Table 2 reflects the missing information on Indian patents filed before 2005.

Table: 2. Pharmaceutical patents under the process-patent system in India from 2001 to 2004.
Source: Independent study; Indian Patent Office.

Organization	Number of Patient			
	2001	2002	2003	2004
All Pharma	384			673
Ranbaxy		55	212	
CSIR	213	58		
Cipla				23
Jubilant Organosys				18
Vaman Technologis				13
Matrix Labs				13
Hetero				20
Wockhardt				20

A signal test was conducted on annual changes in patents of well-known Indian pharmaceutical companies, and changes in patents from 2005 to 2008 were examined. To detect large changes in value over time, the sign test looks for significantly more or less minus or plus signs than expected by the null hypothesis. The null hypothesis for the sign test is that half of the samples produce positives and half produce negatives. If patent innovation rates were to increase in this scenario, the number of negative points in each column would increase significantly. However, the comparison shows only significant progress in the desired direction from 2006 to 2007. Also, the

previous year's patent growth reversed from 2007 to 2008, with the number of patents dropping dramatically. Looking at the total number of patents from 2005 to 2008, we see no apparent change in either direction. Therefore, the Indian pharmaceutical industry patent data does not support the idea that the product patent system encourages innovation. A comparison of the total number of Indian patents in 2004 is not possible due to the lack of data prior to 2005. (Table 2)

The 4 represents 7 companies, allowing you to assess how the process and product patent regimes differ. The number of annual patents granted by 5 of the 7 companies decreased, and the total number of patents granted by all 7 companies also decreased. Ranbaxy's patents declined sharply from 2004 to 2005, stabilized in 2006, peaked in 2007, and declined sharply in 2008. India's second largest pharmaceutical company Cipla's patent portfolio has shrunk over the past five years. Contrary to this downward trend, Matrix Labs and Wockhardt have found many avenues of success. Through both acquisition and development, Wockhardt has made significant breakthroughs in product and biogenetic patents, significantly increasing the number of patents. While prioritizing generics and process research, Matrix reached a higher plateau in his 2008 than his 2004. According to these results, neither process patents nor product patents inherently promote higher innovation rates.

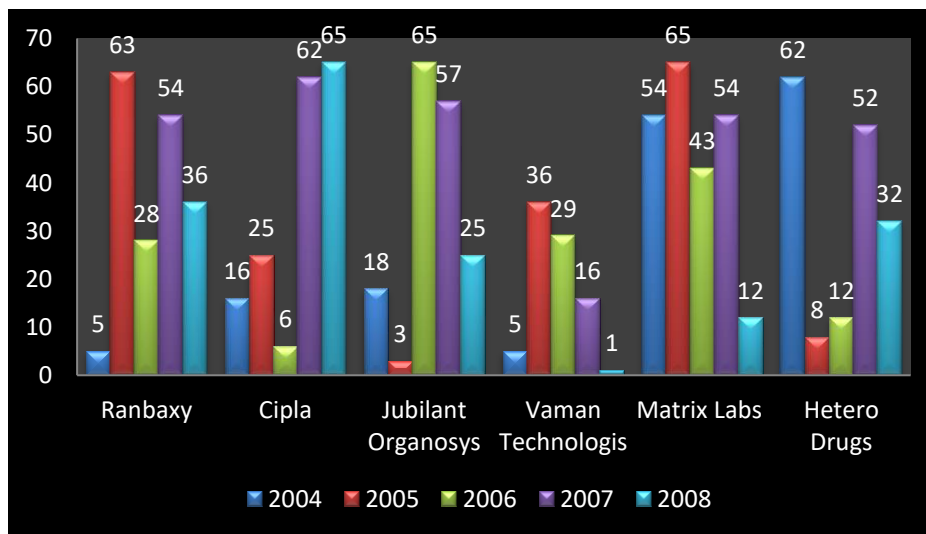


Figure: 4. Seven Indian pharmaceutical businesses in total held patents between 2004 and 2008.

Source: Independent study and India Big Patent Database.

Different categories of inventions that are given different priority under the process patent and product patent schemes. In contrast, a product patent system should encourage investment and effort to create new products. For example, the process patent system typically encourages additional investment and effort in reverse engineering current products. As we have already discussed, certain patents show greater innovation than others. A value metric is the use of citation analysis to identify patents that are valuable because they are frequently cited. In our analysis, however, India's exposure to the new product patent regime is very recent, and no authoritative citations can be compared. Research shows that process innovation outweighs product innovation. Also often yield higher returns on a company's investment.

Figure 5 shows that, although not applicable to any particular company, the Indian pharmaceutical industry appears to be less innovative in terms of process innovation under existing systems. India's largest pharmaceutical companies, especially Ranbaxy and Wockhardt, his two leading institutions of pharmaceutical research in India, recently reduced the number of process-oriented patents they registered. The total % as well as the process patents held by Sun Pharma and Cadila have decreased. Innovation in the Indian pharmaceutical sector seems to be shifting from a process to a product emphasis. The consequences of our study for management practise, policy, and research are covered in the next section.

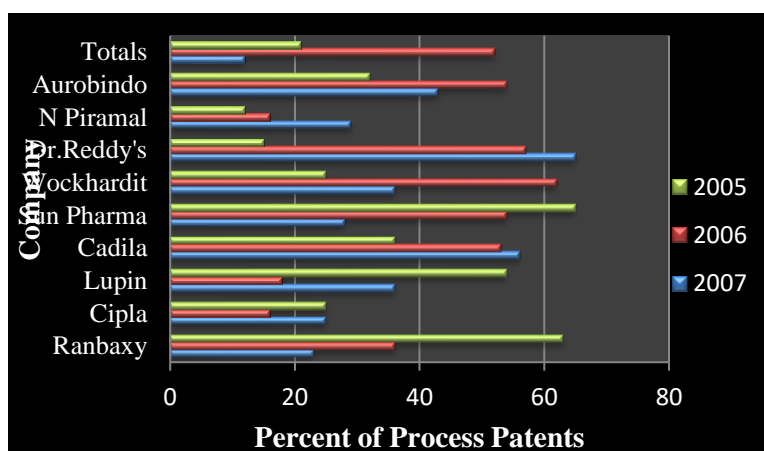


Figure: 5. percentage of process patents in the pharmaceutical sector in India between 2005 and 2007 India Big Patents Database; Unbiased investigation.

7. Conclusion

Although early, our analysis shows that India's product patent regime has slowed the rate of innovation growth, as shown by R&D investment. Therefore, methods that boost social welfare at home and provide larger profits for Indian pharmaceutical companies may not always promote global social returns through effective resource coordination and efficient production. India and other low-income markets need policy tools to deliver more Pareto-optimal solutions. 5 The Pareto principle ensures that gains for one party (e.g. a global company that can take advantage of India's cost advantages to achieve more success) do not lead to losses for the other party. For example, Indian society will not abandon the potential social benefits arising from Indian companies developing and manufacturing pharmaceuticals on their own rather than as subcontractors. Costs for small and medium-sized Indian pharmaceutical companies that cannot establish themselves as contract manufacturers of generic drugs for large companies can also be reduced by using the Pareto Optimal Rule. The results of this study have relevance for other nations, including China that balance social welfare issues with international pressures on IPR.

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