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Investigating and Analysing the Effects of Product Patents on Innovation and Drug Prices on the Pharmaceutical Industry in India

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Abstract*: This research paper aims to thoroughly analyse the effects of product patents on innovation and drug prices in the pharmaceutical industry in India. In compliance with the 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement by the World Trade Organisation (WTO), India switched to using product patents for its pharmaceutical industry [1]. Before that, the government used process patents that allowed drug developers to only patent the drug's manufacturing process rather than the drug itself. This law made them prone to techniques like reverse engineering that could reduce their return on investment on the development of the drug as competitors could sell them for cheaper due to lower development costs [2]. This paper delves deeper into how the introduction of product patents might have impacted the average prices of drugs and innovation in the Indian pharmaceutical industry. Furthermore, it also highlights the potential and actual effects of product patents on the average prices of the drugs. The overall findings conclude that while product patents are impactful to some extent on innovation and drug prices in the pharmaceutical industry, the impact is not as prominent in the case of India. For this research, I initially narrowed its scope to a specific country, industry and the factors influenced by product patents. I started my research by reading more on this topic in general by going through articles and websites of WIPO (World Intellectual Property Organisation), Indian patent office, World Trade Organisation (WTO) and Intellectual property India etc. Then I thoroughly read and gained more knowledge on each section individually. The majority of the specific patent data and trends were gathered from research papers written by credible industry experts to ensure reliability. For this research, I initially narrowed its scope to a specific country, industry and the factors influenced by product patents. I started my research by reading more on this topic in general by going through articles and websites of WIPO (World Intellectual Property Organisation), Indian patent office, World Trade Organisation (WTO) and Intellectual property India etc. Then I thoroughly read and gained more knowledge on each section individually. The majority of the specific patent data and trends were gathered from research papers written by credible industry experts to ensure reliability.

***Keywords*: compulsory license, dual license, inelastic demand, process patent, product patent, reverse engineering.**

1. Introduction

The pharmaceutical industry throughout the world, including India, has experienced rapid growth. The number of pharmaceutical companies in India has increased from 2257 in 1970 to 23000 in 2005[3], severely increasing Dual license competition. Without any methods to protect their inventions from being copied, pharmaceutical companies could start to face fierce competition for their drugs and lose the potentially large amounts of money invested in making them; thus, discouraging them from innovating. To prevent that, the Patents Act was launched in 1970 that allowed pharmaceutical companies to obtain *process patents*, allowing them to gain exclusive rights to the process with which they manufactured their drug. However, this made the drug manufacturers prone to reverse engineering. Other drug manufacturers could simply tweak the process of making the drug and that allowed them to sell the same drug legally. Over time the industry became an expert at reverse engineering and at the time, there was "an average of 23 firms making each of the 15 products with the highest global sales, and an average of 89 firms making each of the top 15 drugs with the highest sales in India," according to research done by experts Mark Duggan, Craig Garthwaite and Aparajita Goyal [2].

For instance, Cipla, an Indian pharmaceutical company, has made drugs such as Erecto, Nuzac, Forcan and Lomac that are knock-offs of drugs patented in the USA. Its managing director Yusuf K Hamied has also boasted that "I make every Pfizer product" [4] (Pfizer is an American pharmaceutical company). Just like Cipla, there were many other Indian pharmaceutical companies that took advantage of process patents and reverse engineered to sell them at 1/20th to 1/15th of the US market price in India [4]. The astonishing part was that it was legal in the Indian markets. This made it next to impossible for American pharmaceutical companies to compete in the Indian markets unless they reduced their prices significantly; thus, discouraging them from entering the Indian markets. After a certain point in time, those firms stopped trying to obtain or enforce a patent in India as they knew that it would be ineffective, rendering the original premise of having a patent useless. Due to this, process patents started to receive criticism. The Pharmaceutical Research and Manufacturers of America (PhRMA) claimed that India's patent law was "designed to punish importers of patented technology into India and to

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coerce local production" and called India's licensing practices "infamous."[4] Therefore, in compliance with the 1995 TRIPS agreement and in order to prevent some of the issues caused by process patents, the government switched to providing *product patents* for unique drugs in the Indian market in 2005, the impact of which will be analysed in the upcoming sections.

2. Key Factors Affected by Product Patents in the Indian Pharmaceutical Industry

A. Effect on Innovation

"If people don't get a fair return in innovation, they won't invest in finding new cures for disease this will be disastrous for patients" [1]. This quote perfectly sums up why firms might get demotivated to innovate if they do not have an incentive to do so, which is the intention behind product patents being adopted because they supposedly provide a better return on investment as copying of the drug via *reverse engineering* can be prevented. Whether product patents have created a significant impact on innovation in the Indian pharmaceutical industry is what will be analysed in the proceeding paper.

While it is not easy to necessarily measure innovation since it is a qualitative element, we can illustrate a certain level of innovation by considering quantitative elements such as the number of patents and amount of research and development carried out by pharmaceutical companies [1].

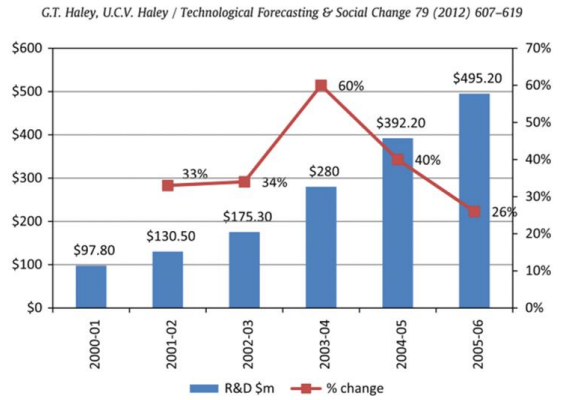

Fig. 1. R&D (millions of dollars) in India's Pharmaceutical industry, 2000-2006.

Figure 1 portrays the amount of money spent on research and development and percentage increase in research and development by the Indian pharmaceutical industry from 2000-2006 [3]. The amount of money spent on R&D increasing every year clearly suggests a growing interest by pharmaceutical companies to spend on creating new drugs. Between 2000 and 2004, the percentage of average research and development expenditure costs of total sales increases from 2% to 5-6% [1]. This may make a favourable case for product patents as it may suggest that they provide better protection on the drugs, which is motivating the pharmaceutical companies to take this step.

The percentage change in the amount of money spent only increases from 33% to 34% and then made a large jump to 60% in 2004-2005, only a year before the introduction of the product patents. However, after peaking at 60% percentage change in 2003-04, it drops heavily to 40% in 2004-05 and 26% in 2005-06, which is even below the percentage change in 2001-02. This gives concerning indications as pharmaceutical companies may have discovered that the product patents in India may not provide enough protection for their innovations. Furthermore, even though process innovation did appear to reduce in India, some companies did not reduce it. One of the largest pharmaceutical companies in India named "Cipla" had one of the lowest percentage sales invested in research and development even after the introduction of product patents showing their reliance on processes like reverse-engineering as an effective tool to make profits without high investment [3]. This could be an indication that such techniques would be effective despite the introduction of product patents, threatening their effectiveness in protecting innovation.

Table 1
Pharmaceutical patents in India's product patent regime, 2005-2008

Company	2005	2006	2007	2008
Alembic	9	12	27	8
Aurobindo	6	20	54	28
Biocon	2	11	21	4
Cadila	41	32	61	35
Dr. Reddy's	107	8	100	51
Hetero Drugs	15	6	4	3
Jubilant Organosys	2	9	16	16
Lupin	18	27	35	16
Matrix Labs	2	15	23	21
Natco	29	18	34	14
Nicholas Piramal	4	5	8	5
Orchid	7	2	31	10
Ranbaxy	57	67	221	133
Reliance Life Sci.	10	12	12	13
Sun Pharma	84	14	25	6
Themis	3	6	2	3
Torrent	20	16	7	11
Wockhardt	8	13	33	87
Total	468	315	750	484

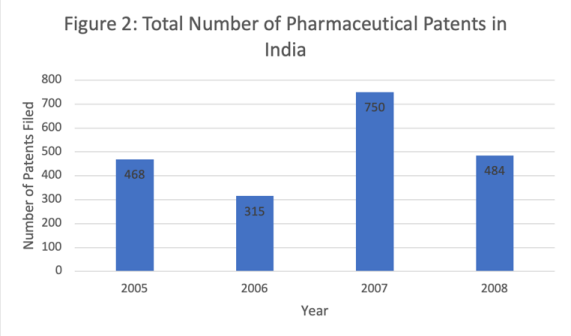

Fig. 2. Total Number of Pharmaceutical Patents in India

When it comes to judging innovation in terms of the number of patents filed, the results are quite compelling. The new regime is supposed to be aimed towards increasing patents and innovation; however, according to table 1 and figure 2, [3]. The number of pharmaceutical patents in India fluctuates quite aggressively in either direction. The number of pharmaceutical patents initially reduces from 468 to 315, which already raises signals for concern, then they sharply escalate to 750 in 2007 and make a large drop to 484 in 2008. These results are were quite reassuring of the effectiveness of the new system as any

concrete trend cannot be derived from the following set of data. Additionally, the company-wise breakup in table 1 does not suggest any strong trends either, with each company having major fluctuations with their total number of patents also.

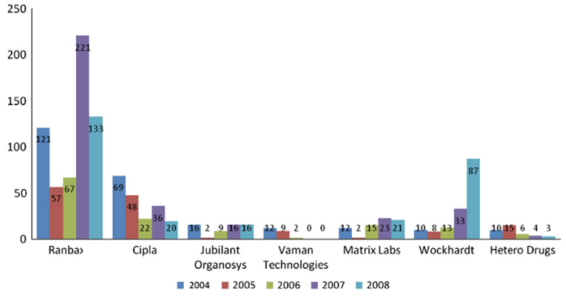

Fig. 3. Total patents for seven Indian Pharmaceutical companies, 2004-2008

The data from figure 3 also confirms the prior results. It shows the number of patents filed each year from 2004 to 2008 by seven pharmaceutical companies [3]. There is no general trend that can be derived from this data. Each company seems to have their own response to the introduction of product patents. Cipla's patents reduce from 69 in 2004 to 20 in 2008 as they increase their reliance on reverse engineering. In contrast, Wockhardt demonstrates a positive trend by moving strongly into bio-genetics and product patents through acquisition and research [3].

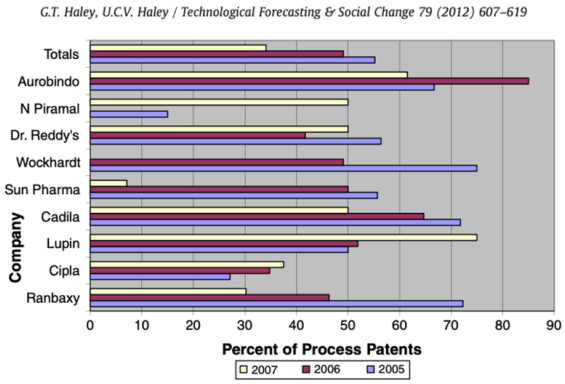

Fig. 4. Percent of process patents in India's Pharmaceutical industry, 2005-2007

While the total number of pharmaceutical patents does seem to fluctuate every year after the launch of product patents, their change in the proportion of product patents compared to process patents does express some promising results [3]. Figure 4 shows the percentage of process patents by nine pharmaceutical companies from 2005 to 2007 [3]. The aggregate data clearly depicts that the percentage of process patents used has decreased from approximately 55% in 2005 to approximately 34% in 2007, implying that majority of the pharmaceutical companies have started to over to product patents. This may suggest that they believe more in the effectiveness of product patents than process patents, thus helping justify their introduction. However, not all companies follow this trend. For example, Cipla, Lupin and N Piramal had an increase in the percentage of process patents and Aurobindo did not have a consistent trend. This further expands on the point that pharmaceutical companies may have different strategies when it comes to patent protection, leading to more unpredictability about the effectiveness of a certain type of patent.

Consequently, the patent data presented suggests that product patents do not necessarily improve innovation in the pharmaceutical industry in India. While the percentage use of product patents compared to process patents increases, its total effect on research and development and the number of patents is minimal. The reason for these results in India ultimately comes down to two reasons: a poorly functioning patent system and lack of sufficient returns [2]. Due to India's weak patent functioning and enforcement system, it is more likely that a firm's innovation would get copied by other companies. This reduces the incentives necessary to induce innovation in the industry as the companies would not get the desirable profits for their expenditure on the development of a particular drug. If other companies can copy it with relative ease due to a weaker system, the R&D costs are unlikely to be recouped because it will increase competition and lead to lower sales and prices for the company creating the drug. If less money or percentage of total sales is being invested back in research and development, the companies and industry are likely to be indulging in less innovation.

B. Effect on Drug Prices

1) Possible effects on drug prices

If a drug gets a product patent with strong protection and enforcement, it can have a major effect on its price. According to economic theory, giving a producer sole rights to produce a drug may give them excess power because only they can sell the drug, leading to a formation of a monopoly for the drug.

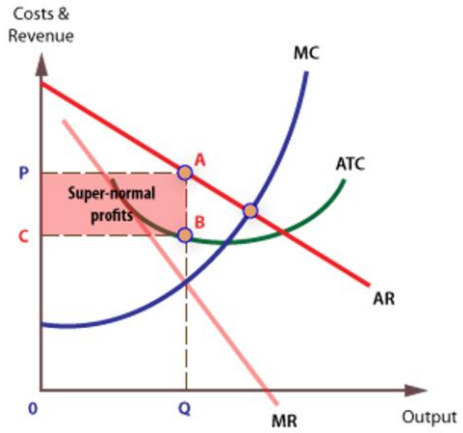

Fig. 5. Economic diagram portraying super-normal profits in a monopoly

Economic theory suggests that patents act as a barrier of entry for other competitors in a monopoly because they cannot create the same drug if the patent is strong. As portrayed in figure 5, [5]. This can enable the producer to earn super-normal profits in the short-run and long-run because the drug's average total cost (ATC) is likely to be lower than its average revenue (AR). ATC is likely to be lower than AR because a monopoly gives the producer the power to charge high prices from the

consumers without reducing unit sales extensively because medical treatment has *inelastic demand*. High inelastic demand for drugs ensures high sales for the drug despite exorbitant prices because the patients may not have another choice but by the drug. Unfortunately for the consumers, abuse of this monopoly power granted by the product patent may increase the price of the drug from C to P, which can be economically damaging for the consumers.

It is predicted that a strong patent system and implementation of product patents in India could lead to an increase in drug prices by 100-400%, which is extremely large for the common population [2]. This case was seen when a drug called 'Glivec was introduced by the company 'Novartis.' The drug helps cure Chronic Myeloid Leukaemia. When introduced in India, its initial price was INR 150,000 (Approximately $2000) for one month's treatment because they had the sole power to produce the drug. It took a supreme court case to bring the price of the drug down to INR 6000 (Approximately $80) in the market. The drug at a heavily reduced price helped save around 500,000 lives in 5 years, which improved the overall welfare of the general population [6].

2) How are they prevented

For a less-developed country like India, experts have strongly argued against a strong product patent protection system for economic reasons. Consumers in countries like India, where the income inequality is high, would suffer unfairly from the price increase of a drug protected by a strong product patent.

To prevent the "possible effects" of product patents on drug prices, which can be detrimental to the consumers, the following methods can be used: Dual Licence, Compulsory Licence and Price Controls.

- *Dual Licence:* Dual License is a type of patent where the product patent would turn into a process patent after a stipulated period, allowing competing manufacturers to then manufacture it using alternate processes [1]. This will ensure that the patent holder is able to make a reasonable amount of profit before any competition kicks in, thus motivating them to invent to some extent. It will also prevent excessive price hikes by the patent holder because they may look to garner maximum market share before any competition enters [1]. Additionally, excessively high prices may harm their long-term standing in the market because they could get driven out by competitors selling possibly cheaper versions of the drug.
- *Compulsory License:* It is a type of regulatory measure by the government which gives them the ability to force patent holders to license their invention to domestic companies under certain conditions.[2] This gave the government the power to force the patent-holder to give its competitors the right to produce the patent protected drug for a royalty if the price of the drug in the market was too unaffordable.[2] The compulsory license was first exercised by the Indian government when "Bayer" had to sell "Natco" its rights to manufacture and sell the drug "Nexavar," which was used to treat advanced liver and kidney cancer. In exchange, Natco had to pay Bayer a 6% royalty and they sold the drug for just $176 a month compared to Bayer's $5,600 a month.[2] This sharp price drop could have helped save thousands of lives as more consumers would have been able to afford it.
- *Price Controls:* Price controls simply allowed the Indian government to place a cap on the prices of certain drugs if their prices got very high, allowing more patients to afford them. By 2013, India had 74 drugs under price controls. They increased that number to 350 in the same year, with approximately 6% of total sales being affected by price controls then [2].

3) Actual effects on drug prices

The actual effects of product patents on the prices of drugs in India are very different from its possible effects, which can be extremely expensive because of the methods used to prevent them. Even though a product patent did help increase the price of the drug, the increase was minimal. Their implementation neither caused a large surge in prices, and neither did it lead to a massive monopolisation of the market [2]. The estimated average increase in drug prices was only by 3% after the patent was granted. This increase was in addition to the 5.3% increase in average prices in general. For some context, product patent-protected drugs are approximately three times more expensive than generic drugs in the USA [2]. This massive difference in prices between US and Indian drugs clearly shows the power of US product patents compared to the Indian ones.

Besides the methods to prevent the prices from rising exorbitantly, the actual drug prices may be different from the possible drug prices due to a few other reasons. In a large developing country like India with a weak patent enforcement system, it is relatively easy to create copycats of a patented drug without facing major consequences. Thus, the presence of such drugs may act as a means of competition for the pharmaceutical company, forcing them to keep reasonable prices for their drugs to prevent themselves from getting driven out of the market by possibly cheaper knock-offs [2]. In addition, it could just be possible that the Indian pharmaceutical market is structured as such that the profit maximising output for the product patent-holding company is marginally higher than the general market price [2].

3. Conclusion

Upon 'Investigating and Analysing the effects of product patents on innovation and drug prices on the pharmaceutical industry in India,' I conclude that the implementation of product patents in 2005 did not cause a large effect on innovation and drug prices on the pharmaceutical industry in India. The level of innovation was highly unpredictable and the increase in drug prices was minimal.

Looking forward, I believe that India should try and make its patent protection and enforcement system more powerful so that it prevents the creation and sale of knock-offs, possibly encouraging more innovation as the patent holders would be confident that they would be able to sell their patented drug without high competition. However, it is vital that they still

control their prices and prevent them from sky-rocketing for the welfare of its primarily low and middle-class population. This will help induce reasonable innovation in the industry while maintaining the prices of the patented drugs.

References

[1] Jena, Saswati & Katual, Manoj & Jena, Shubhashree & S, Harikumar, (2017). Innovation in Pharma Sector: The Impact of IPR (Product Patent) In Indian Scenario: An Overview.

[2] Mark Duggan & Craig Garthwaite & Aparajita Goyal, "The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India," American Economic Review, American Economic Association, vol. 106(1), pp. 99-135, January 2016.

[3] Haley, George & Haley, Usha. (2012). The Effects of Patent-Law Changes on Innovation: The Case of India's Pharmaceutical Industry. Technological Forecasting and Social Change. 79. 607-619.

[4] Mcneil, Donald G. "Selling Cheap 'Generic' Drugs, India's Copycats Irk Industry." The New York Times, The New York Times, 1 Dec. 2000. www.nytimes.com/2000/12/01/world/selling-cheap-generic-drugs-india-s-copycats-irk-industry.html.

[5] "Monopoly: Economics Online: Economics Online." Economics Online, Economics Online, Economics Online, 25 Jan. 2020. www.economicsonline.co.uk/Business_economics/Monopoly.html.

[6] Chatterjee, Patralekha. "Five Years After the Indian Supreme Court's Novartis Verdict." Intellectual Property Watch, Intellectual Property Watch, 14 Aug. 2018. www.ip-watch.org/2018/05/20/five-years-indian-supreme-courts-novartis-verdict/.

[7] "Can You Patent a Process: Everything You Need to Know. Up Counsel, 24 June 2020. http://www.upcounsel.com

[8] Bhatia, Archi. "Product vs Process Patent Regimes: Key Differences." QuickCompany.in, 19 Jan. 2021. www.quickcompany.in/articles/difference-between-the-product-and-process-patent-regimes.