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Intellectual Property and Pharmaceuticals: Ethical Battle between India and the United States

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India has always been known for its ancient knowledge of medicinal sciences. All this knowledge was rooted in nature and deriving ingredients from natural sources. Thus, it is no surprise that India has not always had a flair for Western medicine. With globalisation, several MNCs were eager to invest in cheap labour, which was readily available in India. In order to attract foreign investments, India had to ensure that certain protections were granted to the MNCs. Such protections included labour laws, corporate laws, and intellectual property laws. The pharmaceutical industry has always been one that is constantly evolving and developing. In order to ensure that companies are motivated to invest more in R&D, it is important to grant intellectual property rights protection to them. The most common IPR that is sought after by pharmaceuticals is patented. Patents are granted to inventions that have novelty, and are not obvious or currently available in the market. Moreover, there must be a need for the invention. They are of many kinds, predominantly utility and design. In the pharmaceutical industry, however, patents are granted for the different methodology of production of drugs, but not for the substance itself. This is important, as it encourages R&D for manufacturing with better technology, and inventing better tools for production.

In India, the implementation of patent laws tends to be very neglectful towards the international pharmaceutical giants. This has created a certain animosity between India and the international community for IPR. In light of this, the paper shall do a comparative analysis between the IP laws of India and the USA, as the USA has the most competitive pharmaceutical industry in the world. Furthermore, it shall look into the causes of negligence and the suggestions to overcome the same.

Keywords: *intellectual property, pharmaceuticals, India, USA, patents.*

INTRODUCTION

The drug market in the USA is one of the most competitive and successful ones in the world. It is one of the highest grossing industries in the US and is considered a crown jewel of the country. The reason for its booming success is the dedication that the companies put towards the R&D of drugs.¹ These companies spend billions of dollars every year on research alone. Of course, they come up with various techniques of research and manufacturing their drugs.² This gives them a competitive edge as they have an immense amount of advanced technology at their command. According to various estimates, out of thousands of potential drugs, only 4-5 make it for clinical trials, and only one is approved for marketing. This ensures that only the best drugs reach the people.³

These drugs can be patented for obtaining the exclusive rights for selling the drug. The money and energy put into research and development of the drug are finally made from the cost of the medicines paid by the patients, which enables the companies to create more drugs that target certain conditions faced by patients. However, the pricing of drugs is a major issue faced by the Indian people, given the status of the Indian economy. The Indian government is of the opinion that life-saving drugs should not be priced at exorbitant prices, as most people cannot afford them. The market forces should not be an influence on drug pricing, according to the Indian Government.⁴

The international standards for granting patents for drugs are extremely high and rigid. The patents are awarded for 20 years internationally, during which time no other drugs are allowed to compete with the patented one. Once the patent expires, the other companies are

¹ Gerald J Mossinghoff and Thomas Bombelles, 'Intellectual Property Protection and The Pharmaceutical Industry' (*Oblon.com*, 1996) <<https://www.oblon.com/publications/intellectual-property-protection-and-the-pharmaceutical-industry>> accessed 01 August 2021

² *Ibid*

³ Chittaranjan Andrade and others, 'The New Patent Regime: Implications for Patients in India' (2007) 49 *Indian Journal of Psychiatry* <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2900001/>> accessed 01 August 2021

⁴ *Ibid*

given the right to manufacture and produce the drugs, but their versions are known as the generic versions. The General Agreement on Tariffs and Trade (GATT), and the North American Free Trade Agreement (NAFTA), along with the Agreement on Trade-Related Aspects of Intellectual Property Right (TRIPS) have created high standards for granting patents to pharmaceutical companies for their drugs. However, some countries, including India have created much delay in the implementation of these standards, which has adversely affected the international pharmaceutical industry.

US MODEL

Commitment to R&D:

The most important feature of the international pharmaceutical community is the investment into high tech and expensive R&D. Such intense R&D could not be manifested if the resultant products did not have exclusive patent rights in the market that disallowed others from copying the products. Contrary to the interests of the commitment of the US companies towards the best possible R&D and the principle of intellectual property rights and patent protection given under Article 1, Section 8 of the US Constitution, these standards are not reflected universally. This is especially true in developing countries. The laws on intellectual property in these countries tend to be discriminatory towards the international pharmaceuticals, which affects these companies adversely, as it depreciates the revenue collected internationally, and reduces the amount of money that can be dedicated towards R&D. The entire purpose of having intellectual property rights is to give protection to the inventors and creators, which provides them with financial stability and motivates them to invent and create better products that make the previous ones obsolete and redundant. Thus, in order to encourage better medicines and their creation, it is important to provide monetary protection to the pharmaceuticals in terms of patents and trade secrets.

Due to global pharmaceutical piracy, the cost of R&D has gone up to \$82,000 million.⁵

International Agreements:

The world trading community, upon recognising the damage caused to the international pharmaceutical industry and the lapse in the consensus among countries, came up with two landmark agreements- the North American Free Trade Agreement (NAFTA, 1994), and the Trade Related Aspects of Intellectual Property (TRIPS, 1995). The TRIPS agreement made it explicitly clear that all the signatory countries must abide by the international standards of enforcement of intellectual property for all industries, including the pharmaceutical industry. Unfortunately, the agreement gave a 10 year transition period to all the developing nations. The world trading system has recognized the damage caused to the pharmaceutical industry by an earlier lack of consensus among nations.

Why do US Pharmaceutical Companies Value Intellectual Property Rights:

The reason that US pharmaceutical companies spend so much on R&D is that the process of invention and development of not only new drugs, but new methods of production is expensive, lengthy, and involves a lot of risks. According to a study conducted by Tufts Center for the Study of Drug Development,⁶ pharmaceutical companies spend close to \$2.6 billion in order to obtain approval from FDA and get it to the stage of marketplace access, with the average time from drug discovery to approval by the FDA being around 7 years.⁷ The risk associated with the development of a drug is so high, that out of 5,000 compounds synthesized, only 1 is approved by the FDA. Thus, the money spent on the other 4,000+ drugs

⁵ Pharmaceutical Research and Manufacturers of America, '2020 PhRMA Annual Membership Survey' (*Pharma.org*, 2020) <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Membership_Survey_2020.pdf> accessed 02 August 2021

⁶ Thomas Sullivan, 'A Tough Road: Cost to Develop One New Drug Is \$2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less than 12%' (*Policy & Medicine*, 2019) <<https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html>> accessed 02 August 2021

⁷ Ezekiel Emanuel, 'Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up' (*The Atlantic*, 2019) <<https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/>> accessed 02 August 2021

has been wasted. Despite the risky process of the pharmaceutical industry, the private sector is the main source of bringing new pharmaceuticals into the market.⁸

Thus, without adequate IP protection, the rigorous research performed by the pharmaceutical companies cannot be fulfilled as there would be no monetary surety. The standards for intellectual property protection for Europe, United States, Japan, are mostly adequate and meet the international standards. The duration of patents is extended in order to compensate for the years lost in seeking and receiving approval through the lengthy regulatory approval processes.

History of Pharmaceutical Industry in the US:

Since the intellectual property rights of the pharmaceutical industry worldwide are not respected internationally, the Pharmaceutical Research and Manufacturers of America (PhRMA), and its members made it their mission in the 1980s to make the protection of American Pharmaceutical companies a priority in international trade policies. Ever since US companies have made the shift for production from basic industrial manufacturing to the advanced technology industry, intellectual rights protection has become the most important asset owned by companies.

The pharmaceutical industry in the US is probably the most dependent on patent protection than any other industry. It is an extremely vital industry because it directed has an effect on the economy of the country and public health. Because of this, the government saw the potential in the industry and prioritised its protection for intellectual property on an international level. This resulted in NAFTA and GATT (General Agreement on Tariffs and Trade), which include chapters on intellectual property rights.

INDIAN MODEL

Brief History:

⁸ *Ibid*

Patents as an intellectual property right for inventions with novelty were first introduced in India in 1856, and in 1970 the Patent Act⁹ was passed, which repealed all other preceding legislation on the subject matter. India also became a signatory to the Paris Convention for the Protection of Industrial Property, 1883¹⁰ (or simply, the Paris Convention), and the Patent Cooperation Treaty, 1970.¹¹ Under the Patent Act, 1970 an invention that satisfies all three criteria for novelty, usefulness, and non-obviousness will be granted a patent. The inventions that do not come under the ambit of patentability are the methods of agriculture, horticulture, processes for the medicinal, surgical, curative, prophylactic, or other treatment of human beings. In the case of pharmaceuticals, for substances that are intended to be used for food, medicine, or drugs, the substances are produced using chemical processes. These chemical processes can be given patents, but the substances themselves cannot be patented in India. Thus, pharmaceutical products cannot be granted patents under Indian law.

Patents Act, 1970:

The Patents Act, which was enacted in 1970 actively excluded pharmaceuticals and agricultural products from patentability. This was done to detach India from its heavy dependence on imported products and encourage people to manufacture within India. Although the lack of intellectual property rights did increase India's productivity of pharmaceutical products, it has also adversely affected the international community for pharmaceuticals. Furthermore, the compounds produced as by-products of chemical reactions also cannot be patented. Along with this, any admixture resulting in the aggregation of properties that are not synergistic in nature makes it very difficult to patent products in India. The list of patents given to pharmaceutical companies in India is only limited to those which involve new processes for drug invention. Thus, the Indian pharmaceutical market grew because it was able to produce cheaper drugs than the West, which made its demand grow higher not only in India but also internationally. The generic versions of various drugs were available at a cheaper price.

⁹ Patent Act 1970

¹⁰ Paris Convention for the Protection of Industrial Property 1883

¹¹ Patent Cooperation Treaty 1970

The duration of the patent is also extremely short in India. It is either 7 years from the date of filing, or five years from the date of sealing, which is shorter. Thus, the aim of the legislation is to limit the protection in terms of applicability and its term. The Patent Act also has provisions for compulsory licensing, which shall be granted three years after the date of sealing the patent. Under this provision, any person that carries interest in selling the patented product may do so under a licensing agreement, if they are satisfied that the product is reasonably in demand by the public. There is also a provision for “license of right”, wherein the central government, upon the completion of 3 years from the date of sealing the patent, may require the patent be endorsed as a “license of right” if the government is of the opinion that the said patent does not have a reasonable requirement in the public, or the price of the patented product is unreasonable. Products that are not necessarily sold as food, drugs, or medicines, but have the potential to be sold as food, drugs, or medicine will automatically be endorsed as “license of right” upon the expiration of the 3 year duration from the date of sealing.

2005 Amendment:

As mentioned before,¹² the TRIPS Agreement gave all developing countries, including India, 10 years to transition into the phase of granting patents to substances intended for the use of food, drugs, or medicines. Under this amendment, Section 5 was omitted,¹³ which allowed the grant of patents to pharmaceutical products. The amendment also omitted Chapter IV A, which was labelled “Exclusive Marketing Rights”, which allowed patents for processes and products.

The compulsory licensing provisions were only slightly amended. A mailbox application system was introduced, wherein under the 1999 Amendment, the applications for the patent of the substances could be made, but not examined until 2005. The 2005 Amendment stipulated through an insertion that the patent holders could only collect a reasonable royalty, while continuing to market the product, and not facing any infringement.

¹² Patents (Amendment) Act 2005

¹³ Patents (Amendment) Act 2005, s 5

There exists an exception to patent infringement, known as the Bolar exception, under which where there are 3 years for the patent of an invention to expire, then a third party may exploit the patented invention solely for the purposes of research and development, and to obtain the regulatory approvals during the validity of the patent.¹⁴ The Amendment widened the scope of the Bolar exception to apply to imported products as well. This exception mainly focuses on chemical and pharmaceutical products.¹⁵

CASE STUDIES

Novartis vs Union of India¹⁶

This case pertains to the application for the patent for the cancer drug, Glivec (or Gleevec), by Novartis, a Swiss pharmaceutical company. This medicine was an important drug for the treatment of leukemia. The Supreme Court rejected the patent application for the drug stating that it was a life saving drug, and should be readily available to the people. Given that most of India's population would not have been able to afford the drug, the Supreme Court saw it fit to reject the patent application. Now that the drug was introduced into the market, it opened doors for a lot of other drug manufacturers to produce the same drug at a cheaper price.¹⁷ However, a point worth noting is that Glivec is given free of charge to around 16,000 cancer patients, which constitutes about 95% of the patients who need it. These patients avail such benefits through the Glivec International Assistance Program. The remaining 5% are either reimbursed, or have insurance, or can pay through a generous co-pay program.¹⁸

¹⁴ Adeesh Nargolkar and others, 'Bolar Provision: A Meticulous Exception to Patent Monopoly' (*Lexology*, 2019) <<https://www.lexology.com/library/detail.aspx?g=b9d661d1-c171-4d2c-8c45-4a144c4c3a67>> accessed 03 August 2021

¹⁵ Juan He, 'Indian Patent Law and its Impact on The Pharmaceutical Industry: What Can China Learn from India?' [2019] *Innovation, Economic Development, and Intellectual Property in India and China* <https://link.springer.com/chapter/10.1007%2F978-981-13-8102-7_11> accessed 03 August 2021

¹⁶ *Novartis v Union of India* (2013) 6 SCC 1

¹⁷ *Ibid*

¹⁸ John LaMattina, 'India's Solution to Drug Costs: Ignore Patents and Control Prices - Except for Home Grown Drugs' (*Forbes*, 2013) <<https://www.forbes.com/sites/johnlamattina/2013/04/08/indias-solution-to-drug-costs-ignore-patents-and-control-prices-except-for-home-grown-drugs/?sh=332475902cba>> accessed 03 August 2021

Merck Sharp & Dohme Corporation vs Glenmark Pharmaceuticals Ltd.¹⁹

In 2015, Merck approached the Supreme Court of India to provide an injunction against the Mumbai based pharmaceutical company, Glenmark, which had started manufacturing its anti-diabetic drug, Januvia. The Supreme Court rejected this plea and allowed Glenmark to manufacture the generic version of Januvia. This judgment would be understandable had Januvia been priced at an unreasonable rate for the Indian population. However, it was priced at \$0.86 per unit, which was 5 times less than its price in the United States.

This situation is not unique to Glivec and Januvia. Many other cancer drugs produced by Bayer's Nexavar, Roche's Tarveca, and Pfizer's mutants have been passed over for patents due to the fact that these could save lives. Furthermore, in India, the implementation of the rights of the patent holder is extremely negligent. Until 1995, the foreign pharmaceutical companies invested capital in India with full knowledge that they would not be awarded intellectual property protection and there would be cheaper versions of their drugs in the market, which would heavily compete with them. However, no one could compete with their advanced technology. However, when the TRIPS Agreement mandated change in domestic laws, and India followed through, the implementation of the laws have been unreasonably poor.²⁰

Implementation

While the patent status of the original drug is still valid, and there is a generic drug in the market for which the company applies for an application, then the application will be approved in the favour of the generic drug. However, the generic drug that has been awarded patent protection cannot be introduced to the market if the patent of the original drug is still valid. But this rule is not paid any heed, as there are too many authorities that oversee the process. The Drug Comptroller General of India (DCGI) is in charge of the market approvals of drugs. Sometimes it approves the generic drugs to come into the market without cross-checking with the other authorities on whether the original is still available in the market or not. The DCGI does not maintain any records of the patented pharmaceutical products in the

¹⁹ *Merck Sharp & Dohme Corporation v Glenmark Pharmaceuticals Ltd* 2015 6 SCC 807

²⁰ *Ibid*

market. There is an “orange book” in the United States for the purpose, which makes their cross-checking process even more rigid.²¹ Thus, patent applicants for the generic drug apply without the knowledge of the existence of the patent for the original drug or its current validity.²²

CRITICAL APPRAISAL

Ethical Dilemma:

In the fashion world, when a small clothing manufacturer copies the design of the label, it is known as a knock-off. In the pharmaceutical industry the drugs manufactured with the same chemical composition as the originator, it is known as a generic version. In both cases, the label/originator put in the hard work of designing/researching their products and spend an exorbitant amount of money trying to get even a single product into the market. R&D is given a tremendous amount of impetus in Europe, the United States, and Japan. The fact that a lot of companies produce generic versions of the products without any R&D of their own is an extremely ethically unsound proposition.

The entire purpose of intellectual property rights is to recognise the efforts of the creators, ensure that they have exclusive marketing rights, and ensure that their rights are not infringed by any other party. However, where the laws allow the infringement of these rights, it completely disregards the effort and the capital pumped into inventing a product that requires rigorous research and development. As understood from above, it has come to light that pharmaceuticals spend billions into R&D of 5,000 drugs each year, out of which the only one gets the approval for being introduced to the market. Where another company that has done no research or development and spent absolutely no money on the invention of the product, crosses several boundaries of ethics.

²¹ 'Approved Drug Products with Therapeutic Equivalence Evaluations (U.S. Food and Drug Administration, 2021) <<https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>> accessed 04 August 2021

²² *Ibid*

The cases of Novartis and Merck have highlighted that where the international companies did cater to the Indian market and lowered the prices, the Supreme Court still refused to award exclusive rights to them for marketing their products under the pretense of helping the Indian people access the drugs at a cheaper rate. Novartis was supplying the leukemia patients with Glivec almost free of cost, while Merck supplied Januvia at an extremely low price (approx Rs. 50/unit). Looking at these two cases, the Indian Supreme Court miserably failed to uphold ethics.²³

Economic Perspective:

Where there are several companies that are competing against each other, it is optimal to award intellectual property rights to their inventions, as it would not only help them contribute more money towards R&D, and come up with better technologies for production, but also better drugs. Furthermore, the competition only makes the prices go down, and not up. Each company wants to be more popular than the others and tries to get a competitive advantage over the others by selling at a lower cost, which would only help the people. Basic economic principles dictate that economies are driven by the consumers. Where consumers have the choice between various different versions of a similar product, at different price points, they can choose which they prefer and make their choice. These price points cater to various demographics and give people the choice. Thus, where the product with the most competitive pricing is available in the market, the others follow and try to match that.

The Indian market was once upon a time in extreme poverty and did not have the luxury to afford life saving drugs that were imported. At the time, where Indian companies did not have the financial capability, nor the technical know-how for producing drugs that could compete with the same in the international market. Thus, to help Indian companies blossom and become better in the beginning, it was probably a necessary evil that our laws did not recognise the intellectual property rights of the international pharmaceutical companies. However, after becoming a party to the TRIPS Agreement, and changing domestic laws to

²³ *Ibid*

comply with the same, the Indian pharmaceutical industry still maintains its stance on failing to grant patents for original drugs.

International Obligations:

India is a signatory to various trade agreements. While it has proven difficult to fully comply with all the agreements, and make amendments to the domestic laws for the implementation of the same, India is well on its way to manifesting the same. However, where India has already made such amendments, it is bound by those, as it creates animosity between India and the rest of the international community.

Furthermore, it all boils down to the ethics of the circumstances, where India agrees to fulfill its obligations to the international community, but fails to do so. And when it does the same on paper, it fails to implement the same. India has developed a reputation for being one of the worst infringers of international pharmaceutical patents. While the governments made efforts to improve the intellectual property rights of other industries such as the IT industry, it has miserably failed to do the same with the pharmaceutical industry. This has vastly affected the willingness of foreign pharmaceutical companies to introduce their products into the Indian market. As of 1994, Pfizer had 400+ drugs patented in the United Kingdom. However, it was only able to introduce 45 of those drugs into India. Thus, India was deprived of 300 drugs that could help make millions of lives better.²⁴ It does not make sense to deprive the population of important medicine in order to help the indigenous companies copy products from the originators. If the laws are implemented well, the indigenous companies would stop making the generic versions of the original drugs, and start investing in the R&D and come up with possibly better drugs and techniques of production of drugs. As of now, the indigenous companies rely on the R&D of foreign companies in order to produce cheaper versions of their drugs without consequences. The drugs would obviously be cheaper on the account that absolutely no capital is invested into R&D by the indigenous companies.

Where the Indian lets the implementation of the rights slide, they further encourage the local companies to only copy the original drugs, without any R&D. Furthermore, it creates a bad

²⁴ R Neimeth, *The Economist Roundtable* (New Delhi, India 1994)

image of the Indian market in the international lense.²⁵ Where other countries fulfilled their international obligations and had the most rigorous intellectual property rights implementation in the world, their companies have succeeded and crossed multiple bridges in becoming extremely advanced in technology.

WHY INDIA NEEDS BETTER PATENT LAWS

India needs better patent laws not only to improve international relations but also to push the Indian pharmaceutical industry into becoming better and more advanced. It would not only help the economy of the country but also bring India up to the level of the international pharmaceutical industry and create an even playing field. In order to compete with the big pharma, Indian pharma should be able to justify its technology and quality. This only benefits indigenous pharmaceuticals, rather than protect the foreign brands. India is not far behind at this point in time. It has some of the best private hospitals in the world. It produces the smartest doctors and engineers in the world. Why should it fall behind on having a respectful intellectual property regimen?

SUGGESTIONS

Patent Linkage:

The big gaping hole in the form of the DCGI has caused a lot of problems for the pharmaceutical companies, as their patents have virtually no validity in the eyes of law. Thus, it would be much more conducive to create a record similar to that of the “orange book” in the United States, that can be referred to for cross-checking existing patents. The lack of the same has rendered the provisions of the Patent Act redundant, as they have no meaning without implementation. Temporarily, the DCGI has asked the industry to provide the details of the patents that have validity, with the intention to pass the information of new applications to the Indian Patent Office in order to get an opinion on the approval for generic drugs. However, this solution is tedious and will not sustain for the long term. It is important to have an electronic database where all the information is consolidated and accessible by all the relevant authorities, so they have all the updated information readily available to them.

²⁵ *Ibid*

Duration of Patent:

The validity of patents is very short. While in India it is 5-7 years, it is 20 years in the United States. If the duration of the patents is extended, it would motivate companies to invest more in R&D because they would be able to collect better revenue to dedicate towards quality R&D. Currently, Indian pharmaceutical companies severely lack in R&D. However, if the patent duration is extended then they would be able to collect more capital to invest in more advanced technology for R&D.

Compulsory Licensing:

Compulsory licensing has been extremely detrimental towards the intellectual property rights of the international pharmaceutical companies, as it limits the number of royalties they can collect, and further depreciates the capital they can invest towards R&D. Since R&D is such a risky venture in pharmaceutical companies (each drug has a 1/5,000 approval probability), it is important to ensure that they collect enough revenue for the same.

International Agreements:

For developing countries that lack in resources, capital, and technology, there could be international agreements for life saving drugs, in which all countries mutually agree to waive off intellectual property rights for third world countries, in order to aid them in procuring the medicine and advancing in the field. However, this should not be a long term solution, rather a temporary one, similar to that of the TRIPS Agreement. It is, however, best to not encourage such practises, as it does not have ethically sound backing.

CONCLUSION

Intellectual Property Rights are rooted in the ethics of the recognition of the efforts of a creator, who is entitled to receive the benefits of the fruits of their hard work. Artists and inventors spend a lot of time and money on their works. Thus, in order to help them properly reap the rewards for their works, intellectual property rights are given to them in order to prevent their works from being exploited unfairly.

There is always an objection towards piracy of films, plagiarism of published texts, copying of designs of clothes. Thus, there must also be an objection to the exploitation of inventions, and this objection should extend towards the pharmaceutical industry as well. Where there have been leaps of development in the Indian pharmaceutical industry, it is mainly owed to the intensive R&D conducted by the US pharmaceutical industry. Thus, it is important to assess where the Indian pharmaceutical industry lacks, and try to amend those lapses.

Upon deeper research, it was found that the Indian pharmaceutical industry lacked severely in terms of providing intellectual property law protection for the invention of new drugs (no matter how groundbreaking), and the processes involved in manufacturing the drugs. While the law was amended to recognise the two, it still lacked in the duration of patent protection, and the implementation of the patent rights, as the DCGI has no method of tracking the current patents existing in the market. Thus, it paved way for conflicting patents to be introduced into the market. Furthermore, the Supreme Court took a stance contrary to the interests of foreign patent holders for pharmaceuticals, despite the drugs being almost free, if not extremely cheap for the Indian patients. This not only encouraged unethical infringement of patents but also allowed indigenous pharmaceuticals to become more reliant on the foreign pharmaceuticals for valuable information gather through intensive and highly expensive R&D.

This paper analyses such lapses and tries to provide suggestions in order to rectify them. In order for India to become self-sufficient, it is important for Indian companies to break away from reliance on foreign companies. Furthermore, it would help the economy much more if Indian pharmaceutical companies participate on the same level as the foreign ones, and were able to not only perform their own R&D but also inject better products into the market. In order to protect the interests of the indigenous pharmaceutical industry, we have ended up coddling it, which could be highly detrimental for the industry itself. As most pharmaceutical companies would slowly withdraw from the Indian market, due to violation of internationally and mutually agreed upon intellectual property rights, it would cause a giant void in terms of R&D. thus, in order to prevent such circumstances, the government should focus on creating a more conducive environment for protecting the rights of all pharmaceuticals, without prejudice, and ensuring that the implementation of these rights is absolute and stringent.