THE CONTROVERSIAL PARAMETERS ON PATENT RIGHTS

BY-ROHAN KRISHNA SETH

ABSTRACT

The purpose of this research paper is to focus on the basic rights provided under the Intellectual Property Rights and how they affect other people, as well as companies. The main focus in this paper would be the production of brand drugs and generic drugs, with respect to Patent Law. Patents provide legal protection for inventors in order to prevent other people from making use of their ideas. However, when the ideas that are being protected are medicinal drugs, this can be very controversial. Much of the controversy over pharmaceutical patents relates to the provision of drugs in the developing world, but there are also issues over the ownership of rights to medicines derived from traditional remedies.

In this write-up, a comparison between the pros and cons of generic and brand drugs has been made in countries like United States of America, India and Brazil. These examples seem to be perfect for the current topic as USA seems to promote brand products, while countries like India and Brazil promote generic drugs.

These are several pros and cons for both these types of drugs and the purpose of this paper is to try and find a conclusive point for both the types of countries that produce such drugs, so that both these type of countries (i.e., developed and developing countries) are able to benefit from both the type of drugs.
MANUSCRIPT

There are several ways to explain what Intellectual Property Rights (IPR) actually mean, but the best and the easiest way to understand it is to break it down into three parts, i.e., Intellectual, which means a person possessing a highly developed intelligence/brainpower, Property, which means something which is owned by someone and can be bought or sold, and Rights, which means a moral or legal entitlement to have or obtain something. Now, if we combine all the three definitions, the basic understanding of IPR goes as, a moral or legal entitlement over a certain thing which is owned/produced by a person possessing a highly developed intelligence/brainpower. The basic function of such rights is to protect the interest of the creator and allows them to benefit from their own work in a creation¹.

The origins of globalized IP regimes may be traced to the economic downturn of the 1970s and 1980s which heightened power asymmetries between the industrialized and developing countries. These countries therefore adopted economic reform policies prescribed by international financial institutions such as the World Bank and International Monetary Fund, and western creditor nations such as the U.S.² As of today, Intellectual Property has become a key issue in the global political economy. Over the past two decades, the protection of intellectual property rights (IPRs) globally has become a major issue both for right holders and users, and one that has had profound implications in a number of important areas of public discourse, such as international trade, public health, education and research, national development and the promotion of biodiversity. At stake are decisions about how society can best encourage the creation of ideas, when someone can stake a claim to intellectual property, and how far copyright and patent-holders can go in preventing others from taking their property. The scope of the controversy is vast.

Several trends have made IPR protection a critical³:

¹ United Declaration of Human Rights (UDHR), 1948, Art. 27.
i. The globalization of technology and human resources: With the swift and critical improvement in technology, the need to protect the IPR of the creators has become necessary as these rights are now both valuable, and vulnerable, at the same time.4

ii. The rapid breakthrough in bio-technology and spread of new software has proved that it is not very easy to protect all such rights. Considering the example of generic medicines in bio-technology and softwares like Napster, which have proved to be quite controversial in nature, have rendered the present IPR regimes obsolete.

iii. The ability of a country to protect the IPR: With the markets emerging globally, the interests of a developed and a developing country diverge from each other. Where a developed nation looks forward to try and invent something new, a developing nation’s main focus is to provide products as cheaply as possible.

A great scholar once said, 

“A country would have little or no interest in protecting IPRs in products of which it is solely an imitator and intends to remain so – here the national interest is above all consumer welfare – sourcing the products as cheaply as possible”5

Considering the example of the African government, which has a huge burden on itself as it has to ensure and balance the demands for cheaper drugs and it must also protect the IPR of inventors/creators. Africa is currently leading in efforts to make drugs more affordable for people in the developing world, but the war to ensure such a balance still prevails, as it if extremely difficult to maintain such a balance 6(as pointed out in Point iii.).

The main focus of this paper would be a comparison between the generic drug and the brand name with respect to developed and the developing nations.

As pointed out above, it is observed that, it is the developed nations that promote research in the medicinal sector, while the developing nations simply attempt to provide the same drug at a cheaper rate in order to target a larger market (which includes the middle class, the lower-middle class and sometimes, the people below poverty line). As of today, there are more than 1210 genetic drugs available in the market and most of these drugs are produced in developing countries like India7. Whereas, if we focus on the pharmaceutical market of the

6 Reich, supra note 2, at 2.
United States, we observe that the medicines cost fairly expensive, but the inarguable fact is that the country promotes and encourages research and development in the medicinal market. This enables the researchers to come up with new medicines. Such new medicines cost a lot due to the research put into them, whereas, the generic drugs are produced with the reliance on a basic idea of an already existing drug, which reduces the research cost and thus, makes the generic drugs cheaper than the branded ones. Generic competition is one of the most powerful tools that policymakers have to lower drug prices in a sustainable way. Lessons can be learned from Brazil where the price of AIDS drugs fell by 82% over 5 years as a result of generic competition. The prices of drugs that had no generic competitor remained stable, falling only 9% over the same period. Even more dramatic results can be seen in the price of AIDS triple-therapy for developing countries, which fell from US$10,000 per patient per year to as low as US$350 in one year due to generic competition.

So, the question that arises before us is whether the production of generic drugs make a country neglect research to develop a new drug? Does focusing on providing cheap drugs to the consumers ultimately benefit the country in terms of research skills of the pharmaceutical department? Several researchers have said that it ultimately benefits the country while there are still many of them who think that it will not help the country at the end of the day. While this is a conflicting and arguable topic, let’s try to get to a conclusion.

In countries like the United States (developed countries), the pharmaceutical sector produces really expensive medicines which are very difficult to afford. This forces several middle class (and lower ones) to somehow go for a life insurance so that if they fall ill, the insurance company will cover up the expenses for them (at least upto a certain limit). The main reason for such costly sale of medicines is that they are brand medicines and generally not the generic drugs. So, the research and production cost that goes in such medicines is quite high, thus, making them costly for the consumers. Now, let us consider the example of a developing country, like India. As stated before, there are more than 1000 generic drugs sold in India as of the 2013 statistics given Med India. Several experts have pointed out,

---

10 Reich, supra note 7, at 4
“Branded drugs play an important role in medications, but generics are their cost effective alternatives. Generics are similar to branded drugs in terms of purity, efficacy and are perceived to be safer as compared to new drug molecules, as they tend to be older and time tested.”1

The good thing about a generic drug is also that it doesn’t dis-allow other companies to produce and market a similar drug counteracting the same disease. In case of a brand drug, which is always registered as a patent either in every country individually, or through the TRIPS agreement, no other company is permitted to produce the same drug until the patent granted has expired (which is 20 years). So, in other words, generic drugs promote other companies to research (even for the same type of drug) whereas, the brand drugs don’t allow the same.

Now, once a company begins to market their brand drugs, they disable other companies to market a similar product, so basically they are creating a temporary monopoly, which further enables them to price their drugs according to their own profit margins. Therefore, this makes such brand drugs quite expensive. So, should the government ban branding of drugs? No. While such drugs are expensive and disable other companies to market similar drugs, these drugs are created with intensive research and quality ingredients, whereas the generic versions are created with cheap ingredients and do not go through proper testing (which, thus, saves a lot of cost).

There are basically three stages which a company goes through after which it prices its drug for sale,

According to the diagram shown above, the original cost is the one that is required in order to gather resources and invent/create the drug. The price is the amount that is calculated according to the research, testing, etc., for the drug (along with the original cost). Finally, the selling price of the drug is the addition of all sorts of costs that were included in “cost”, “price”, along with the advertisement costs, goodwill, etc. Now, in case of a brand drug, the

Research cost is high due to invention and a lot of time consumption and hard work involved. The companies that market these brand drugs also have a high goodwill, thus, all these factors combine and increase the final price of the drug drastically. Whereas, in the case of generic drugs, the research work involved, the advertisements, goodwill, they are not so high when compared to the brand drug producing companies, therefore, the final price of such drugs is drastically low when compared to those brand drugs.

These brand drugs, or patented drugs are often referred to as “nostrum remedium”. Patenting these drugs goes back to 1900, when the first drug of “S. Grover Graham Co.” was patented. For the purpose of discussing about these Brand drugs, let us consider the example of United States of America (hereinafter referred to as “USA”). So, what is the basic purpose of providing patent to a medicinal drug? Patents provide legal protection for inventors in order to prevent other people from making use of their ideas. Pharmaceutical companies often maintain that patent protection for drugs ensures that they are able to invest billions of dollars into the development of new products, by making sure that they will be able to take advantage of the sales. Creating a new medicine can take a lot of time and money. It can involve many years of research and clinical testing, which can be very expensive. If pharmaceutical companies are going to make this kind of investment into a new product, then they want to know that they will be able to protect their intellectual rights and ensure that they will be able to profit from the new drug. While poor countries maintain the only way they can afford medicines to combat epidemics is through domestic production of generic drugs, the pharmaceutical industry argues that developing new drugs depends on the defense

---

of patent rights. It also asserts that rather than being unable to afford medicines, some countries are just opting to spend the money elsewhere.

In the United States, the cost of a medicinal drug is very high. A direct conversion from $ to ₹ of a single medicinal drug comes around ₹ 1,000, which is quite high. Due to such high rates, the middle class (and lower) can barely purchase these medicinal drugs. Most of the middle class people are forced to get their medical insurance in order to save their money on such expensive drugs. The main reason for this is that the pharmaceutical sector of the United States promotes brand drugs over generic drugs. Every medicine sold there must be on prescription and it is compulsory upon the doctor to prescribe a brand drug to the patient. The sole purpose of this is to increase the sales of patented drugs, which would in turn motivate invention of drugs in the USA. This has been favourable for USA in the past as it can clearly be seen that all major patented drugs like Lipitor, Plavix and Viagra were invented in the USA. This step of the US government has motivated companies to invest into research and come up with new drugs, instead of investing a smaller amount and marketing a drug similar to another drug as that would increase the market competition and companies would then attempt to market cheaper drugs from their competitors. This would further result in decline in the drug quality, which may, someday, result in marketing of drugs with grievous side effects. In order to prevent such competition which could gravely affect the consumers and to protect the interest of the inventors, the USA promotes brand drugs and demotes generic drugs.

But, along with all the positives, there are always some negatives. While the patented drugs promote research and invention and provide protection to the inventors, they also disable other pharmaceutical companies to produce the same drug. Due to this, the inventing company can price the good keeping a big profit margin. So, basically the inventing company is creating a temporary monopoly (for 20 years) by dis-allowing other companies to create the same drug. Due to this, consumers are forced to purchase from those companies at their rates, which are quite high. This has made the pharmaceutical sector of the USA very expensive and almost all the middle class families (and lower) have medical insurance.

Now, while promoting brand drugs is viable, the US government must not completely demote the production of generic drugs. A lot of people who are not financially strong also deserve to be treated and their inability to purchase such brand drugs hamper their right to live a peaceful and proper life. Allowance of production of generic drug would enable doctors to
prescribe such drugs to the patients and these drugs would not be so heavy on their pockets as well. Generic drugs are basically a cheaper substitute to the more expensive patented drugs. These drugs would be extremely helpful for the not-so-rich group of people in USA.

Now, let us consider the production and marketing of generic drugs and how effective they are to people in the developing nations like India and Brazil. So, when can a generic drug be produced and marketed? Generic drugs can be legally produced for drugs where:

1. The patent has expired,
2. The generic company certifies the brand company’s patents are either invalid, unenforceable or will not be infringed,
3. For drugs which have never held patents, or
4. In countries where a patent(s) is/are not in force.¹³

A generic drug is a drug defined as "a drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use."¹⁴ Branded drugs play an important role in medications, but generics are their cost effective alternatives. Generics are similar to branded drugs in terms of purity, efficacy and are perceived to be safer as compared to new drug molecules, as they tend to be older and time tested. Indian pharmaceutical market of generic drugs is increasing day by day. In countries like Brazil and India, more than 20% of drug sales are generic. It is a prevalent practice in India (and enforced by law) that a medical practitioner/doctor is under an obligation to issue his/her patients a generic drug. A brand drug may, or may not be issued to the patient, but he is under an compulsion to issue a generic drug¹⁵. Thus, the government itself promotes the marketing of generic drugs. The sole purpose of doing so is to provide every needy person with the medicinal drug at a low price so that a normal person is able to afford it. This has helped India in many ways. For eg., several Australian citizens come to India for a basic dental check-up. Why? Because it’s quite expensive in their own country. If

¹³ Reich, supra note 7, at 3.
¹⁵ Reich, supra note 2, at 2.
we combine the travel cost along with the whole check-up, it would still be cheaper than the dental check-up in Australia.

Production of generics in India can be traced back to a long time ago. Before the TRIPS agreement was introduced, process patenting was permitted in India under the Patent Act. But when the WTO introduced this agreement, India was given a total of 5 years (from 2000 to 2005) to amend its Patent Act in accordance to the TRIPS agreement. Now, before this agreement was introduced, Indian Laws permitted process patent. According to this type of patent, a company could produce the same drug, using a different way, and get a patent of that drug. This caused a production of a plethora of generics and a lot of them counteracting basically the same disease. In order to get rid of a few of such drugs, the Patent Act was amended according to the regulations of the TRIPS agreement. But even after the introduction of TRIPS, the generics still prevail in the country.

The basic aim of a developing country is to provide medicinal drugs to all the patients at a reasonable rate. But, is it reasonable for the inventing company? The same was discussed in *Bayer Corporation V. Natco Pharma Ltd.*\(^\text{16}\), where it was observed by the court that in developed countries, including those of the European Union cautioning against patent linkage. It was believed that the entry of generic drugs resulted in saving of expenditure and health costs. It was further pointed out that patent linkage transforms patents rights which are private property rights that depend on the owner’s promptitude and desire to enforce them, into public rights, whose enforcement is dependent on statutory authorities, who are publicly funded. Such linkage would undermine the “Early Working” of the patent and deny space for generic medicines. Further, the court, in it’s ratio opined that,

> “In the case of pharmaceuticals, access to patented technology can literally become an issue of life or death. Indeed, the recent showdown in the World Trade Organization (WTO) over compulsory licensing of AIDS medication served as a wake-up call for many who had previously dismissed patents as a technical domain of interest only to specialists. Patent protection suddenly became the ugly face of globalization, seemingly a hazard to public health and travesty of social justice.”

In the Bayer Corporation case, the patenting company was selling a drug at ₹ 27,960, while the same (or similar) drug, which was a generic, was being sold in India at ₹ 8,880. Such a

---

\(^{16}\) Bayer Corporation V. Natco Pharma Ltd., LPA 443/2009.
huge price difference clearly shows how a brand drug affects the pockets of the patients when compared to the generics. The generics have helped the Indian population provide medicinal drugs at a much cheaper rate which is easily affordable by the middle, as well as the lower-middle class.

In today’s era, the scope of generic drugs is increasing day by day specially in several ill health conditions such as diabetes, cardiovascular and in microbial diseases etc. When any patent expires, new generics are introduced into the market. But the expiration of the patented drugs takes place after 20 years, which is a very long time. For those 20 years, no other company can either market or even produce the same drug (even though the method of research is different). This has caused a lot of controversy in the past, and this controversy still prevails in the present era. In the third world countries, a large number of people are living below poverty line. They are not able to afford branded drugs because many a times these drugs are too much expensive. Therefore, generic drugs become the preferred alternatives. Indian pharmaceutical companies are primarily generic based; they spend time and money on generic research. Generic market has now also increased due to expiry and shortcoming of patents.\(^\text{17}\)

Now, even though the generic market plays an important role in the developing nations, there are still some problems with it. With so much focus on generic drug production, the very purpose of the existence of IPR is defeated. If every manufactured drug is generic, what is the purpose of the existence of IPR in the pharmaceutical sector? One of the greatest cons of generic drugs is that it does not motivate companies to put more time and effort into research and invent a new drug. Invention plays a very important role in the pharmaceutical industry. All the types of drugs that we use today were once invented by someone. If companies stop inventing new drugs, we might never find a cure for the currently incurable diseases. Most of the greatest medicinal drug inventions have been made in USA, and the main reason for that is because the country promotes research and invention.

But, in developing nations like India, the government only promotes research into generic drug production. If these nations keep marketing with such an aim, they will never be able to invent a new drug and contribute to science. As stated before in an example, in India, the doctors are under an obligation to prescribe a generic drug, prescribing a brand drug is

optional and dis-allowed in certain cases (when no generic drug is prescribed). Even though the international companies have decided to sell their patented drugs in India at a low rate, the Indian government still relies heavily upon the generics. Such an act clearly proves that the developing nations do not encourage invention and are only focused upon marketing medicinal drugs at a cheap rate. Such countries must attempt to strike a balance between these two types of medicinal drugs.

Now, this prevailing issue cannot be easily solved. While both the types of medicinal drugs have their own pros and cons, they are both important for every country. While USA focuses only on brand drugs, the government must not completely ignore the production and sale of generic drugs as they are the sole basis of treatment for several citizens. Due to high rates of brand drugs, an average earning citizen is unable to afford such drugs and thus he must be given an option to be able to get a prescription generic medicinal drug and not only be prescribed a brand drug. On the other hand, developing nations like India and Brazil solely rely upon the generic research and medicinal drugs. They must also focus upon research and invention of new drugs as such researches and invention plays an important role for the whole world, and not just the respective countries. The problems faced by developing nations are very genuine and it is understood that an average earning citizen of such nations cannot afford expensive brand drugs. But then again, these drugs can be exported to other countries which are a member of WTO and WIPO (ensured by WTO). The developing nations must not stop marketing the generic medicinal drugs but must also promote research into invention of new drugs. This would be beneficial for the whole world, as well as the company inventing it. Creating a new medicine can take a lot of time and money. It can involve many years of research and clinical testing, which can be very expensive. If pharmaceutical companies are going to make this kind of investment into a new product, then they want to know that they will be able to protect their intellectual rights and ensure that they will be able to profit from the new drug. However, this could result in many important drugs being unavailable to poorer countries and people. It could also make pharmaceutical companies less likely to invest in medicines that are mainly needed in the developing world by encouraging them to focus on the most profitable investments and ignoring less profitable diseases. Thus, it is necessary to strike a balance between the generics and the brand drugs. This can be done so by promoting research for invention (should be government aided) and also supporting generics for the financially weaker class.
So, I would like to conclude my paper by saying that the Global war for the Intellectual Property Rights is never-ending; these problems are not independent and unrelated but are a result of the fundamental nature of the pharmaceutical market and the way it is regulated. The only thing that can be done is to compress it by striking a balance between the rights of one party, with the rights of the other party. This can be done so by promoting research for invention (should be government aided) and also supporting generics for the financially weaker class. Instead of focusing on the interest of a single company and the profit it will gain out of it, the benefit of the society as a whole must also be considered. By promoting the production of generics, the concept of invention will not be diminished as the company inventing a drug will be awarded for its invention, and at the same time, other companies will not be stopped from creating generic drugs in order to target the poorer section of the society. It must be noted that with the help of this, we are not only protecting the interest of the companies, but serving the interest of the society (whose protection is a lot more important than the un-necessary profit that the inventing company gains). This is for the best interest of both the parties, along with the society at large. Thus, while the conceptual framework for international drug control has changed for the better, it is still far from complete. The pharmaceutical industry is not the only one to be affected by patent regulations, although it is one of the most controversial. Despite of all the dilemmas posed by intellectual property protection, the rights must still be protected. The devil is in the details, however, of how that balance is struck.\footnote{David S. Evans, \textit{Who Owns Ideas? The War Over Global Intellectual Property} (2002), available at http://www.foreignaffairs.com/articles/58450/david-s-evans/who-owns-ideas-the-war-over-global-intellectual-property}