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Novel approaches for utilization of IPRs to enhance access to Medicines

Aishani Pattanaik

INTRODUCTION

Nowadays, the health care system is a topic of concern in both developed and developing nations. With time, it is believed that we will be facing a dramatic shift in health problems resulting from the epidemiological transition. If we see the current situation, the whole world is suffering from the pandemic Coronavirus (Covid-19). This is one of the best examples through which one can realize how important it is to have a stable health care system. Access to medicines is difficult for one-third population worldwide. The cause behind it is the high price of drugs which is beyond the capability of common people to afford especially in the least developed countries. There have been so many global changes in the last few decades which have national consequences. The lives and livelihood of common people are affected due to a change in national policies and practices because of the change in international rules. Changes in Global Trade Systems can disturb domestic policies that also includes health care policies. A report by the World Health Organization clearly stated the about one-third population of the world residing in emerging nations are not able to buy or receive necessary medicines regularly[1]. Access to medicine is one of the challenges faced by the government of different nations. Intellectual Property (IP) has a great role in regards to medicines. The pharmaceutical firms have patents on drugs that they invented. Due to having patented the competition probably gets decreased because no one can use that invented drug but the price in the market of those patented drugs gets higher.

This casual link between IP and health care is increasing and receiving great attention day by day with the great advancement across the universe. The World Trade Organisation (WTO) was established in the year 1995, it then a part of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under it. It was for the first time when policies on intellectual property were a point of concern on the international platform.

TRIPS AGREEMENT ON PHARMACEUTICAL FIRMS:

Agreement on Trade-Related Aspect of intellectual property (TRIPS) is a worldwide lawful agreement between some associated nations of the World Trade Organisation (WTO). This covenant points out the minimum standards so as to preserve and implement the intellectual property rights in representative countries.

[1] Nitsan Chorev, Intellectual Property, access to medicines and health (Apr 2015), http://eprints.lse.ac.uk/61603/1/Shadlen_Intellectual_Property_Access_Medicines.pdf (Last visited May 14, 2020).

Over ten million people die because of infectious diseases in developing countries every year. Nearly about 8000 people die of AIDS in the emergent nations[2]. One of the core basis can be the absence of medicines. High rates of drugs are hurdles for the needed treatment. Strong intellectual property protection can be the reason for the expensive drug crisis. The WTO, TRIPS are there to fix out a minimum standard for the protection of pharmaceutical products. They also came confrontational criticism as they include patents for pharmaceuticals resulting in an increased level of patent protection due to which the price of the drugs is getting higher day by day. However, TRIPS provide a shield to stop the pessimistic effect of patient protection or its misuse. Several medicines are needed but due to its high rate the large part of humans in underdeveloped countries cannot afford it. There are not even 10% of the pharmaceutical market in developing countries[3]. Accessing drug is problematic in developing nations. This is because the medicines are unaffordable or are not acceptable to particular regional conditions or restrictions. Many factors can cause difficulty in access to medicines such as deficiency can be because of less supply or inappropriate storage systems, baseless use, poor manufacture quality, and excess rates. Only 1% of all the 1223 drugs came into the market between 1975 and 1997.[4] In 2006, all the WTO members scheduled the implementation of TRIPS, it was predicted that there may be a chance to acquire new medicines at low prices rates.

The Medicins sans Frontieres (MSF) along with some other NGOs put forward some concerns related to TRIPS: -

- Due to an increase in patent protection, the drugs will be priced higher.
- Developing nations usually depend on the generic drugs but the enforcement of WTO rule will be a slow down the local manufacturing capacity.
- Industrialized countries and pharmaceutical industries make pressure on the economically growing nations to put into effect its patent laws afar TRIPS rules.[5]

BIG PHARMA V. NELSON MANDELA, 1998[6]

In February 1998 the South African Pharmaceutical Manufacturer Association and 39 other multinational pharmaceuticals filed a case against the Medicine and Related Substances Control

[2] Ellen F.M. 't Hoen, Practical Application of the Flexibilities of the Agreement of Trade-Related Aspects of Intellectual Property Right (18 Jul,2016), https://www.who.int/intellectualproperty/topics/ip/tHoen.pdf (Last visited May 12, 2020).
[3] *Ibid.*
[4] Ken Silverstin, Millions for Viagra, Pennies for Diseases of the Poor (July 1, 1999).
[5] *Ibid.*
[6] Big Pharma vs, Nelson Mandela (1998).

Amendment Act. They claimed that Act violates the TRIPS and the South African constitution. It established a legal scheme to facilitate the people over there with affordable medicines. The provision amended was to bring the generic version of patented medicines, and to encourage the import of patented medicine. Earlier in the case, the drug company had support from their government. The US pressurized the African government to abrogate the Amendment Act by abstaining trade benefits and threatening further. Later on the group joined by the European Commission as well. The social activists purposely put the spotlight on this strategy and accused the then-presidential candidate AL Gore about his involvement in the dispute. At the end of 1999 the US changed its policies because of increasing public pressure. In May 2000 the drug company lost the support of the home government. Demonstrator demanded the corporations to withdraw the case. In this landmark case the court of South Africa, brought two key issues:

1. There should be a change in the TRIPS and to improve their public health services.
2. No pressure from industrialized nations without repercussions a hand.[7]

In another case of US vs. Brazil[8], the Brazilian AIDS program is an important case regarding the availability of medicines. During mid-1990, Brazil provided full extensive AIDS care and treatment. About 5 lakhs of people were infected by HIV in Brazil. AIDS-related problems were reduced by more than 50% after this initiative. In 2 years this program has reduced hospital costs and treatment of AIDS by 472 million dollars. Over a period of 5 years this program led to the decrement of prices of AIDS medicines by 82%. The Brazilian patent law provides the concept of compulsory license. Brazil AIDS program offered the local drugs to the other developing countries as well. Article 68 of this Act came into controversies when the US took this point at the WTO Dispute Settlement Body (DSB). The US proclaimed that this provision is discriminating against the US owner of Brazilian patent and that it is affecting the right of patent holders. The US also argued that the provision of this Brazil Act violates the Articles of TRIPS. Brazil has always expressed the importance of access to medicine on events like the G-8 and WHO meetings. International NGOs pressurized the US for this action as they feared that this will harm other developing countries. Finally on June 25, 2001 Brazil and the US came to a joint settlement and the US withdraws the dispute against Brazil.

The WTO Ministerial 1999 in Seattle:

The WTO Ministerial Conference was organized in 1999 at the Washington State Convention, USA. Drugs and health was not a topic of discussion in Seattle. Still, it got firm attention for several

[7] *Ibid.*
[8] US v. Brazil The Brazilian AIDS Program (2001).

reasons i.e. a report on TRIPS contains few proposals like to issue compulsory licenses as per the WHO. Patent was provided to only 11 drugs out of 360 essential drugs in certain countries.[9]
At that time US President Clinton, took this platform to declare the change in US policies concerning intellectual property right on access to medicines where he particularly referred to the HIV/AIDS crisis saying that "the US will from now on implement its state policies and health care so that in the poorest countries people won't have to go without medicine they so desperately need"[10]. In 2000 the US changed its policies and promoted the concept of compulsory license.

DOHA NEGOTIATION

It was the conference of WTO for the discussion on the TRIPS and medicines problems that was held at Doha in 2001. A declaration was adopted by the WTO Ministerial that kept human interest before the market interest. In this conference for 'African Group' Zimbabwe stated challenging the access to medicine issues. The TRIPS Council held its first discussion on the intellectual property issues regarding public health. In this meeting, the African Group suggested to issue different rules for the medicines. Zimbabwe stated "We propose that Members issue a special declaration under TRIPS Agreement and access to medicine at the Ministerial Conference in Qatar, affirming that nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health[11]". In September 2001, another discussion was held by the TRIPS Council and this time, the formal Group was united by another 19 nations. The proposal was to ensure that there should not be any restriction on the member countries to codify their schemes in concern with public health. At the same meeting, other developed nations such as the US, Japan, Switzerland, Australia, and Canada passed a different opinion stating the importance of protecting IP. After lots of discussion, the final text draft by the WTO General Council offered two options:-

- The first one is that the TRIPS Agreement shall not avert the member countries to make any law in favour of the general public. This agreement can be interpreted in a way to support their member countries to make laws concerning public health.

[9] Valbona Muzaka, The Politics of Intellectual Property Rights and Access to Medicines(2011) https://books.google.co.in/books?id=NUeEDAAAQBAJ&pg=PA78&lpg=PA78&dq=wto+seattle+ministerial+1999+in+concern+with+pharmaceutical&source=bl&ots=2BwqAzkBES&sig=ACfU3U3AT-bhesDxswPGb-QNO_5UZnKfNQ&hl=en&sa=X&ved=2ahUKEwju4YOfpb3pAhV2wzgGHRSMD_YQ6AEwA3oECAIQAQ#v=onepage&q=wto%20seattle%20ministerial%201999%20in%20concern%20with%20pharmaceutical&f=false, (Last Visited May 14, 2020).
[10] Ellen F.M. 't Hoen, Practical Application of the Flexibilities of the Agreement of Trade-Related Aspects of Intellectual Property Right (18 Jul,2016), https://www.who.int/intellectualproperty/topics/ip/tHoen.pdf (Last visited May 12, 2020).
[11] *Ibid.*

- Another choice was to allow the member countries to get involved with the provisions of the TRIPS which provides security at the time of public health crises. Also this agreement does not enlarge or diminish the right and obligation of the member countries[12].

In these three days of discussion, it was clear that the majority of the member countries preferred the first option. Few countries like the US, Japan, Australia, Switzerland, Canada, and Korea were the supporter of the later one. Finally, after three days of negotiation between the member countries, they reached a compromise. The negotiation was primarily between Brazil and the US in which they stated that they support the interpretation and implementation of the TRIPS Agreement. Also, the TRIPS Agreement should not prevent any member from taking any important steps to preserve the public health[13].

REVOLUTION IN GLOBAL PUBLIC HEALTH

The main and primary concern of the WTO is to work for the international health within the United Nations system. In the year 1997, for the first time, the WHO published a list of medicines and called it as Essential Medicines List (EML). EML gave an idea that which medicine is more necessary. After 25 years, another important decision was taken up by the WHO to prequalify medicines. This Pre-Qualification of Medicine Program (PQP's) was the greatest achievement to improve the standard of medication consumed by a large population. The issue was too strict the national policies for intellectual property (IP) and to introduce new rules on international ground. These restrictions avoid the manufacturing of generic version. At Doha Declaration it was declared that the government of the member countries can make rules and policies concerning the health care system. Also, the use of compulsory licenses was supported along with parallel importation. The declaration also takes away a patent barrier in importing generic medicines from India. These measures called the 'TRIPS Flexibilities'. WHO PQP was set up in the year 2001, and it does screening to more than 350 pharmaceutical products. Earlier its main focus was to prequalify medicines used for the treatment of the HIV-AIDS, TB, and Malaria but now its range has been extended, and now it covers medicines for reproductive health as well.

[12] *Ibid.*
[13] *Ibid.*

PATENTING OF PHARMACEUTICALS- AN INDIAN PERSPECTIVE

Patent is a very important and major form of IPR that is used in the medical industry. Grants of patents in India are covered under the Patent Act 1970. After India signed the TRIPS Agreement in 1995 many changes occurred like the product patent and increase in terms of the patent to 20 years. The pharma industries are one of the most advanced knowledge sector. Whatever research happened there, that are very costly and incalculable. The result of the research can be a new, inventive or useful product or process. These are the three main aspects on which patent right is granted. So as a result patent right is granted on the pharmaceutical research. In this competitive market, the pharmaceutical industry needs to safeguard their new invention for any unlicensed commercial use. There is a list provided by the Indian patent office's which classify the category of pharmaceutical patents. These are –

A. Drug Compound Patent: -

Due to its commercial structure per se, these patents are claimed as drug compounds. This kind provides the highest shielding to the products. Any other company is not authorized to create the same drug by any other compound before the expiry of said patent.

B. Formulation Patent: -

These are prepared by a particular method to make the composition or quality of its key ingredients.

C. Synergistic Combination Patent: -

Synergistic combination patent claims that two or more drugs interact with each other. When it interacts, it increases one or more effects of that drug.

D. Technology Patent: -

These are basically on the technique involved to cure technology concerned issues.

E. Polymorph Patent: -

Polymorphs are the different crystal form structure of an already known compound. Section 3(d) of The Indian Patent Act, 1970 deals with the grant of polymorph patent in India. The main focus of this section was to prevent the "Evergreening of patents" by issuing patents to only those derivatives which remarkably increased efficiency.

F. Biotechnology Patent: -

In this living organism biological materials are used for the preparation of pharmaceutical products.

G. Process Patent: -

In this, the patent is not claimed for any product. It is for the new inventive process[14]. The patentee possesses some rights which can be hand over from holder to any other third party. There are two ways to transfer the right, through the assignment, and by granting a license.

Section 68[15] states that the assignment or grant of a license should be in writing with all the terms and conditions.

1. Patent Assignment: Through the process of assignment, the rights are transferred to another person. The person to whom the right is transferred is called the assignee.
2. Patent licenses: In this type of patent transfer a patentee allows any other third party to use his invention by granting a license. A license may be voluntarily license or compulsory license.

- Voluntary license: When the right holder voluntarily grants a license to any other party to make use of the patented invention is called voluntary license.
- Compulsory license:

  This is a statutory license that is granted by the controller to any interested person without the accord of the patentee. It is defined under section 84 of the IPA. This section sets out the conditions on the satisfaction of which compulsory licenses can be permitted:-

1. If the practicable requirement of the public did not fulfilled.
2. If the patented invention is unaffordable.
3. If the patented invention did not manufactured in any area of India[16].

All these conditions have to be satisfied for the compulsory license after the expiry of three years from the date on which patent is granted. In the case of Natco Pharma Ltd. v Bayer Corporation[17], the first compulsory license was issued in India was granted to the Natco Pharma Ltd. The Bayer Corporation got patented on the medical element called Nexava in 2008 to treat liver and kidney cancer in India. The Bayer company failed to reach the requirement of the public. The reasons for the failure were-

I. The drug was extraordinarily high in rate and was difficult to buy by common people.

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[14] Vipin Mathur, Patenting of Pharmaceuticals: An Indian Perspective(Jul 11, 2012). https://books.google.co.in/books?id=NUeEDAAAQBAJ&pg=PA78&lpg=PA78&dq=wto+seattle+ministerial+1999+in+concern+with+pharmaceutical&source=bl&ots=2BwqAzkBES&sig=ACfU3U3AT-bhesDxswPGb-QNO_5UZnKfNQ&hl=en&sa=X&ved=2ahUKEwju4YOfpb3pAhV2wzgGHRSMD_YQ6AEwA3oECAIQAQ#v=onepage&q=wto%20seattle%20ministerial%201999%20in%20concern%20with%20pharmaceutical&f=false (Last visited May 16, 2020).

[15] Indian Patent Act, 1870 (India).

[16] The Patent Act, 1970(India).

[17] Natco Pharma v. Bayer Corporation Ltd. WT.No.1323-2013(India).

II. The drug usually faces the problem of shortage in the cities.
III. The Bayer Company failed to manufacture the drug in India. Also they did not grant a license to any third party for manufacturing.

As these failures satisfied the condition of Section 84. So the Indian controller passed the order of compulsory license to Natco Pharma on Nexava on March 9, 2012.[18]

DR PHARMACEUTICALS PVT. LTD. V. BRISTOL MYER SQUIBB, 2013[19]

In this case, the controller rejected BDR pharmaceuticals application for compulsory license made for BMS cancer drug. The BDR company requested the patentee for a voluntary license to manufacture the DASATINIS on which patent was granted to the patentee on 2nd February 2012. The patentee replied to the application of the applicant on 13th March 2012 and raise some queries. On March 4th, 2013 the applicant applied for the compulsory license under section 84 of the Patent Act 1970. The application made by BDR got rejected by the controller stating that the company has not tried to make a prima facie case to get an order under section 87 of the Act. The Controller observed that the BDR company has not made any reasonable attempt to gain a voluntary license from the patent holder and the applicant also does not have the ability to work for the social benefit. The Controller stated that the queries raised by the patentee is valid. At last it was held that it is intentional on the side of the applicant to get into communication with the patentee and exercise the choice in order to avoid the provisions of compulsory licenses.
Section 92A of the Patent Act is a provision about pharmaceutical industries. According to this provision, the compulsory license is in hand for:-

- The medicament products which are patented.
- To produce and sell to countries that doesn't have manufacturing capacity.
- The product is important to solve the problem related to public health in such countries.[20]
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[18] *Ibid.*
[19] M/S BRD Pharmaceuticals International Pvt. Ltd. v. M/S Bristol Myers Squibb Co.-CLA No of 2013(India).
[20] The Patent Act, 1970(India).

CONCLUSION

In this increasingly globalized economy, it is important to have uniform pharmaceutical laws. The fact is that the public health and access to medicines have gained a lot of attention because of its unavailability and increasing requirements. The flexibility in the TRIPS Agreement is to indicate that healthcare and healthcare products should be conducted individually for any other elements. Also in the Doha declaration it was stated that intellectual property protection works for the public interest in a broader sense then commercial sector. Patent laws of every nation are there to protect the rights of the inventors so as to encourage their efforts but it is also important to have a provision to protect the interest of people. The concept of compulsory licensing is on that only. It can protect the interest of the common people and it should work to promote access to medicine which is not available to common people because of its high price or is unavailable because of less production.