A STUDY ON COMPULSORY LICENSING IN THE TIME OF COVID-19

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ABSTRACT

The outbreak of a global pandemic has brought the entire world to a halt. It has handicapped every sector from businesses to the legal systems. However, one field that has been immune from it is the pharmaceutical sector. The need for a vaccine for the deadliest disease has made pharmaceutical companies work day and night to come up with a cure. The demand for the vaccine is extremely high given the alarming number of deaths every day. If a company comes up with a cure, they are going to ensure they take all the necessary measures in order to protect the drug under a patent. But given the pandemic situation where lives of millions of people are at stake, there is a need for intellectual property rights to be balanced out with public wellbeing. This is when the concept of compulsory licensing comes into play. The present paper aims to discuss the principles and provisions of compulsory licensing, the evolution of patent laws in India, position of the judiciary and the TRIPS agreement. It also highlights how compulsory licensing has been a blessing to some and a curse to some other. The paper then progresses into discussing how the concept of compulsory licensing comes into play during the COVID-19 outbreak, it also discusses what measures were taken during "emergency situations" or "pandemics" in the past.

Keywords: Compulsory License, Patents, TRIPS, Intellectual Property, CL, COVID-19

INTRODUCTION

The whole world has come to a halt due to the spread of COVID-19. However, it has not affected the pharmaceutical sector, instead the pharmaceutical companies around the world have been aggressively involved in the research and development for the treatment of COVID-19. Once a drug or a vaccine is produced and is proved to be effective, the pharmaceutical company which developed the same will definitely take the necessary steps for the grant of patent for such invention. However, there is a need for there to be a balance between the protection of an intellectual property right and public well-being which can be acquired through Compulsory licensing.

"A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem."[i] Exclusive rights shall be given to the patentee over his invention for a period of 20 years, and he can deny others from using his patented product. Although, under certain circumstances, a compulsory license to use a patented product may be given to a third party. The Indian Patents Act, 1970 in its Chapter XV explains the concept of Compulsory licensing. Compulsory licenses provide the owner of a patent or an invention to use his rights by giving authorization to another party (individual or business entity) against some payment or consideration. The intention behind the concept of compulsory licensing is to encourage inventions among the people and so that one may not misuse the monopoly achieved by such invention of the patent. Indian Patents Act, 1970 and the TRIPS Agreement recognized the concept of compulsory licensing and is hence recognized in India as well as other countries. All the patents and inventions cannot be issued to another party in the name of compulsory licensing. For another person to be given a license for a patent or an invention, certain conditions need to be fulfilled which are provided under Sections 84 to 92 of Indian Patents Act, 1970.

Even after the license is granted to a third party, the patentee does not lose absolute rights from the patent and still has a right to be paid for the products made under compulsory license. While considering the grant of a license to another party, certain factors like nature of invention, reasonability and capability of the applicant to use such product for public benefit are

considered but the patentee may still deny the grant of license and the final decision lies with the patentee whether to grant a license to another party or not.[ii]

Article 21 of the Indian Constitution provides the right to health as a right to life. The ultimate duty to sustain public health and safety is that of the government. Therefore, the idea of compulsory licensing is against the exploitation of a patent and may be helpful for the larger public in the times of emergencies like in the case of COVID-19 which shall be discussed in detail later.

EVOLUTION OF COMPULSORY LICENSING LAWS IN INDIA

Patent laws in India have had a very long history. Lord Macaulay Law Commission[iii] recommended the first law relating to patents in 1856, it was introduced majorly to encourage people to create new things. This law was replaced by Act XV of 1859, which made some modifications to the previous law, for instance exclusive rights were only given to inventions that were useful. This was further amended in the years 1872 and 1883 with minor changes in each amendment. In 1911, all the previous acts were replaced by the Indian Patents and Design Act. This Act, for the first time since the inception of patent laws, brought the entire administration of patents under the Controller of Patents. It provided for grant of license if there has been a misuse of the patent rights.[iv] It allowed people to apply for a compulsory license after three years of its registration on certain grounds, such as, if it is not being commercially worked in India to its fullest extent, if the demand for the invention is not being met, etc.

After Independence the Indian government felt the need to restructure the patent laws, thus it appointed the Tek Chand Committee to examine and improve the present framework of patent regulations. This committee focused on the inventions related to food and medicine as they involved public interest.[v] The committee submitted that one can apply for the grant of compulsory license after three years of its registration on grounds such as[vi], if the Indian commerce is being substantially affected, if demand from the export market is not being met, if the market of other patent inventions is being affected. It also contained a provision where the government could apply for a compulsory license on behalf of a private property, this was

included keeping in mind the welfare of the public. Thus, scope for applying for a compulsory widened.

However, this report had its own drawbacks as practical applicability of the recommended laws was cumbersome. To further improve the provisions and promote national interest, The Ayyangar Committee was appointed which made some important suggestions.[vii] It reported that 80% to 90% of Indian patents were owned by foreigners and majority of these were not even being worked in India. It further submitted that the foreigners were trying to have a monopolistic control over markets especially in industries relating to food, chemicals and pharmaceuticals. Indians were not being able to afford basic medicines or drugs as their prices were unreasonably high and kept increasing.[viii]

The committee concluded that Indian markets were being exploited and the present framework of patent law is not sufficient to prevent the misuse of patent rights.[ix] For these reasons, the committee made suggestions to change the patent regime which went on to form the foundation for the Indian Patents Act, 1970. This Act proved to be efficient for the then current situation in India and it went on to be in force for twenty-four years without any amendment. In order for it to comply with the TRIPS[x] agreement, which will be dealt later in this paper, it was amended in 1999[xi], 2002 and 2005. The laws relating to compulsory license are enumerated from Section 82 to Section 94 of the Act.

COMPULSORY LICENSING IN INDIA- BOON OR BANE

The Concept of Compulsory licensing is definitely a boon to the larger public but there are some opposing views too. Providing licenses for the patent to another party makes the product reachable and affordable to the consumers nearby. The patentees are also encouraged to form effective products as this process keeps a check on the newly invented product before it can be licensed to other parties. This concept has brought the world together as they can help each other in the time of need or emergencies through the provisions of compulsory licensing.

This also helps in the growth of industries by providing employment opportunities to the local people in the local industries nearby, eventually helping the nation to grow. Most of the

Compulsory licenses are owned by the developed nations and by granting licenses to the underdeveloped countries, the citizens of such countries get access to the patented products.

However, people with opposing views argue that "Compulsory license is an action of a government forcing an exclusive holder of a right to grant the use of that right to other upon the terms decided by the government"[xii] By granting a compulsory license, the exclusive rights of the patent holder are being interfered with. It is not easy to create something new, it requires immense hard work, intellectual abilities, investment of money, time, etc, and in a matter of three years these rights are granted to others, and the government pays a mere royalty fee to the inventor[xiii]. The royalty fee paid is very low compared to the expenditure incurred in inventing and developing the product, and to the benefit the inventor would have enjoyed if given exclusive rights. This leads to discouragement of new talent to invent something, the incentive to create is killed.[xiv] A person who is granted compulsory license reaps the benefits of a product without any contribution to its research, invention and development.[xv] A counterfeit product does not necessarily match with the quality of the original invention which creates a risk for people consuming the counterfeit product.[xvi]

Third world countries suffer from some diseases which are not prevalent anywhere in the world, many multinationals would be ready to investigate, research and come up with a cure if they are ensured that their patent will be protected. Multinationals only take up projects which are financially beneficial and if they are not given exclusive rights to their invention, invention of new drugs curing a certain disease cannot take place. Further the chances of a company with a patent to invest in India and other countries providing for compulsory license regulations are reduced drastically.[xvii] The growth in countries like India which are underdeveloped depends majorly on investments from foreign countries and the fear of compulsory license creates a trade friction with countries which majorly invent patented products and prevents them from investing in India. This has a negative effect on the economic growth of the country.[xviii]

Furthermore, when a country has a weak intellectual property regime, it loses the opportunity to compete with others. As a result, young talent from the respective countries loses interest to create something new and leave the country in search of opportunities.[xix] Critics of compulsory licensing often argue that pharmaceutical companies charge low prices for their products,

sometimes even without a profit margin in countries which are under developed and hence there is no need for compulsory licensing in these countries.[xx]

JUDICIAL PRECEDENTS

The Controller in a landmark case has granted a compulsory license which stands to be the first case of compulsory licensing in India. Also, in a majority of cases, the Controller rejected the grant of a compulsory license on a few grounds such as when a prima facie case is not established or when a license of patent is not applied for applying for a compulsory license. The judicial approach to the grant of compulsory license is that this provision is basically for public welfare and it shall not be misused to diminish the rights of the patent holders. There has to be a balance between public welfare and preserving the rights of the patent holders.

- ***Bayer Corporation v. Union of India***[xxi]

The three grounds set out in Section 84 of the Patents Act, 1970 were upheld in this landmark and the first ever case of Compulsory Licensing in India i.e., Natco Pharma Ltd. v. Bayer or popularly known as the Nexavar case. In this case, Natco Pharmaceuticals approached Bayer Corporation for the grant of a voluntary license for manufacturing and selling Nexavar (a drug used in the treatment of kidney cancer) which wasn't manufactured in India at Rs.10,000/- as against the price of Rs. 2,80,428/- charged by the patent holder. The three grounds upheld in this case were that there was an inadequate supply of the drug which was of an extremely high price and no other patented drugs were working at the same pace in India.

- ***Bristol-Myers Squibb Holdings v. Bdr Pharmaceuticals***[xxii]

In this landmark case, Compulsory License was rejected when a pharmaceuticals company filed an application to make an anti-cancer drug named 'Dasatinib'. The company claimed to make a generic version of this drug on which a United States based drug maker Bristol-Myers Squibb held a patent. The main reason for the rejection by Controller was that the India based pharmaceuticals did not complete the process as required under Section 84, subclause (iv) of

clause (6). Also, BDR did not make an application to obtain a license from the patent holder with a reasonable time.

- ***LEE Pharma Ltd. v. AstraZenaca***[xxiii]

In this case, the applicant was rejected a compulsory license for a drug named 'Saxagliptin' and the applicant had failed to provide authentic evidence to satisfy the provisions under Section 84 of the Act.

COMPULSORY LICENSING IN THE TIME OF COVID

In the past few months, many countries including the developing countries have been devastated by COVID- 19. Till now, there is no proven cure, drugs or treatment for COVID-19, also known as Coronavirus. Our government is making a lot of efforts each day to reduce the spread of coronavirus but at the same time we need to ensure that the COVID-19 treatments are affordable and accessible to everyone.

Therefore, there is a need to anticipate the need of the country and use the concept of compulsory licensing once there is any effective COVID-19 treatment which can be used by the people. National governments should definitely consider the option of Compulsory licensing once there is a treatment available for COVID-19 as this tool of Compulsory licensing was proved to be successful when there was a better access to antiretroviral drugs at the time of AIDS epidemic.

We cannot foresee if our country will be in a need to use compulsory licensing or not. The government must have legislations and provisions ready to authorize such compulsory licensing for COVID-19 related use in case we need to get a license for the treatment of Coronavirus. We also at the same time might not require compulsory licensing as the drug used for the treatment may be an existing drug or even if it is a patented discovery, the patentee may offer voluntary licenses at affordable prices, keeping in mind the welfare of the larger public.

WHO (World Health Organization) has declared COVID-19 as a pandemic and therefore, the government has the rights to grant compulsory licensing in cases of national emergency, urgency and for non-commercial public use after the patent has been sealed? When the effective coronavirus treatment will be developed, license can be granted by the government for the same as it will be for the interest of a larger public. Grant of such license will result in the manufacture of the product in bulk and such products will be sold at reasonable rates. However, the government must make use of such rights only if the patentee refuses to grant license for its patent for reasonable prices. Such license is granted for easy access to drugs at affordable prices.

Gilead, a pharmaceutical company has patented Remdesivir, a broad-spectrum antiviral drug which can be a potential drug for the treatment of COVID-19. They have signed voluntary license agreements with five generic pharmaceutical manufacturers based in India and Pakistan. The licensing agreements grant non-exclusive right to receive the technology needed for the manufacturing of the drug and also does not include any charges for the royalty until WHO declares the end of this pandemic or until some other vaccine or drug has been discovered for the treatment of COVID-19. Voluntary licensing helps both the company and the public during the times of COVID-19 as ihe Government also does not need to be involved to use its rights for compulsory licensing for a national emergency in the face of a pandemic.

COVID-19 AND THE TRIPS AGREEMENT

The TRIPS Agreement was negotiated between the WTO members to harmonize the legal standards of Intellectual Property Rights globally. The main intention behind the agreement was to prevent the exploitation of the Intellectual property and hence it was made mandatory to enact such legislation in their countries. This agreement also provides a proper mechanism to deal with the IPR related disputes among the state members. Not only does it provide a systematic mechanism, it also benefits the society and helps in the growth of industries in the long run.

Before the TRIPS agreement was signed many countries did not allow for patentability of drugs and medicines as it would lead to an increase in the price of drugs. Hence many companies in these countries could reverse engineer and make the same drugs. According to the TRIPS agreement, member states are required to ensure patentability of products. This led to pharmaceutical companies charging heavy prices for their drugs and making them out of reach for the lower class. Hence the agreement was called "a death warrant for thousands for people in the poorest countries of the world"[xxiv]

However, the agreement permits the governments of different countries to manage patents of pharmaceuticals. This is when the concept of Compulsory Licensing came into picture. In November 2001 the Doha Declaration explained and clarified Article 31 of the TRIPS agreement, the right to grant compulsory licenses. It stated that when a compulsory license is issued to a medicine, the government can manufacture the same drug or import versions of that drug without permission of the inventor. India in its legislation provides for compulsory licensing under Section 84 to 92 of Indian Patents Act, 1870. These legislations were enacted in accordance with the TRIPS Agreement. Further Clause 5 of the Doha Declaration states that freedom to determine grounds for granting a compulsory license is given to member states. It also states that during "national emergencies" governments can grant compulsory licenses without following the normal requirements. It also clarifies that public health crises like HIV/AIDS, malaria, etc constitute "national emergencies". Hence as the COVID-19 outbreak has been officially declared by the WHO as a global pandemic, it undoubtedly falls under Clause 5 of the Doha Declaration.

PAST EXPERIENCES: COMPULSORY LICENSES FOR ANTIRETROVIRAL TREATMENTS

In March 1999, in the light of the HIV/AIDS pandemic, delegates from around thirty countries met in Geneva to examine the concept of compulsory licensing to confront the crisis of access to essential medicines in the developing and underdeveloped countries of the nation. It was estimated that around twenty-six million people affected by HIV/ AIDS around the world live in the sub-saharan region of Africa and have no access to antiretrovirals. The price of the

medications and antiretrovirals made it impossible for a few countries to reach out to essential medicines.

It was observed that medication for other fatal diseases such as malaria, tuberculosis and meningitis were equally high prices and out of reach to millions of people staying in the under developed and developing countries who were comparatively more prone to these diseases considering their high population and low resources. For instance, a new standard combination treatment was invented for the treatment of tuberculosis which priced at $15,000 per course making it impossible for patients in countries like India who wouldn't be able to afford such a treatment.

Further to which, around twenty countries have either issued or entertained issuing a compulsory license.[xxv] In a lot of cases, the patent holder himself has offered a discount or a voluntary license in cases of emergencies and in dire need of a certain pharmaceutical product. Further, in the 2000s, developing countries like Malaysia, Mozambique, Thailand, Rwanda, Zambia, Brazil, Zimbabwe, Ghana and Ecuador have issued compulsory licensing to a few medicines in the plight of their HIV/ AIDS- infected citizens. However, as most of the countries issued compulsory licenses to a maximum of one or two drugs, Ghana and Zimbabwe were the only countries to issue licenses to all of the antiretroviral drugs used in the treatment of HIV/AIDS.

Further, it is noted that Brazil and Thailand were the only two countries who provided free HIV/AIDS treatments to their citizens and were again the only two countries which successfully reduced the prices of the drugs in the mid-2000s. These countries were keen on procuring two important drugs namely, efavirenz which was produced by Mereck and lopinavir/ritonavir which was primarily produced by AbbVie and then by Abott Laboratories and wanted to further provide them to their patients. With reference to the price negotiations, Mereck and Abott Laboratories have offered to sell their drugs at the price of $500 and $2200 USD respectively per patient per year. Outraged by the high prices, the Thai government rejected these offers and chose to issue compulsory licenses instead where they could import generic versions of these drugs from India at a cost of $224 and $676 USD PPPY. [xxvi]

Similarly, Brazil issued a compulsory license for efavirenz as Mereck offered the drug to Brazil at $760 USD. Brazil, however, after the issuing of the license could import it at $170 USD

PPPY. Brazil, unlike Thailand, did not issue a compulsory license for lopinavir/ ritonavir as Abott Labs lowered the price significantly in Brazil. However, the amount for which Abott Labs sold the drug in Brazil was twice as much as the amount incurred by Thailand by importing. One notable aspect of the past experiences and evolution of issuance of compulsory licensing in the world was in 1996 when the USA initiated a WTO dispute settlement proceeding against Brazil claiming that the amendment made by it in their IP law to grant compulsory licenses for treating the patients of HIV/AIDS was not consistent with the terms of the TRIPS Agreement.[xxvii]

In the same fashion, in 1997, the South African government amended Article 15(c) of their Medicines and Related Substances Act, hence allowing their government to grant compulsory licenses to import cheaper and generic drugs in the plight of immense HIV prevalence in its countries. In response to which, the United States of America and a few European nations threatened them with sanctions and other WTO proceedings. Eventually, with immense pressure from NGOs, AIDS activists, and the Treatment Action Campaign, the US government agreed not to impose sanctions on both the Brazil and South African Governments.

CONCLUSION

The COVID-19 outbreak has been officially declared as a global “pandemic” by the World Health Organisation. Therefore, the present situation falls under the ambit of “national emergency” where governments can grant compulsory licensing. Once a company invents a vaccine for the disease, the government will be well within its rights to grant compulsory licenses to tackle the health crisis. This would ensure that drugs for COVID-19 are priced reasonably and can be afforded by everyone. However, the research work and efforts of the inventor should be kept in mind as granting a compulsory license would severely affect its exclusive rights and monopoly in the market. Innovation is of paramount importance in today's day and age as it leads to growth and development of countries. Issuance of compulsory license weakens the motivation to invent and invest in R&D, invention must be encouraged for the long-term benefit of the public. Compulsory licenses should not act as a barrier to growth and should be granted judiciously. Hence licenses should only be granted if the inventor is not ready to enter into reasonable licensing agreements to supply the given drug at affordable

prices. The judiciary is of the view that while granting a license the rights of the inventors and public welfare should be balanced out and no one should face major damages.

The COVID-19 is undoubtedly a huge public health crisis where lives of millions are at stake and it is the duty of the government to ensure affordability of the drugs. But it also has to keep in mind the effort, hard work, costs incurred by the inventor for research and development and therefore reasonable compensation has to be given to the inventor. This will ensure inventors are not discouraged or demotivated.

THE WAY FORWARD

The COVID-19 pandemic is an unprecedented health crisis with no certainty whatsoever causing great difficulty to the developing and underdeveloped nations in providing affordable medications and treatments to their citizens. In a grave situation like this, granting compulsory licensing is the most feasible option considering the demand for certain drugs and their unaffordable prices. The past experiences which were learned from situations like the HIV/AIDS pandemic where several countries issued compulsory licenses to procure affordable antiretroviral drugs should be put to use in the current situation as well. Countries which have not previously used CL should leverage the experiences of the countries that have. International Organizations such as WHO, WTO and other organisations like ACWL can spread awareness through virtual workshops or any other collaborative forums about the same. Further, the researcher suggests that the governments issue compulsory licenses in medications used for treating other symptoms of COVID-19 such as medicines for fever, cold, cough and even immunity building multivitamins for them to be available at an affordable price and accessible to even the citizens below the poverty line.

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