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Pharmaceutical Patents, Public Health and Covid-19 Pandemic

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Abstract

The dichotomy between patent right relating to pharmaceutical products and public health has always been contentious for the policy-makers. Pharmaceutical industry always aims to gain huge profit margins over their investment through patent rights and by monopolizing their product. This has never sat well with the public health proponents who have always been in favour of cheap and affordable medicines in public interest.

The COVID-19 era has reignited this debate. The pandemic has affected over five million people around the world and has claimed many lives. Though there is no claimed medicine or vaccine against Corona virus as of now, there are some medicines that have been shown to be effective against COVID-19 symptoms and mitigate its effect. Governments, pharmaceutical industry, innovators, researchers and academicians around the world are engaged in the struggle against this pandemic.

This article, through a critical and comparative analysis, has explored the contemporary developments in the field of pharmaceutical patents from the lens of COVID-19 pandemic. The author has explored various opportunities, particularly in the domain of patent law, of establishing a synergy in the interest of public health and welfare.

Keywords: Pharmaceutical patents, COVID-19, Corona virus, Compulsory licensing, Patent pooling, Patent pledge

Introduction

The COVID-19 pandemic has taken the entire world by storm. It has claimed many lives across the globe and continues to wreak havoc. Health sectors around the world have been struggling to mitigate its impact. With no cure in any form, vaccine or medicine, this pandemic has again ignited the patent-public health debate. Pharmaceutical companies are heavily engaged in the endeavour of producing effective drugs/vaccines in order to claim an upper-hand in the global market.

Normally, renowned pharmaceutical companies are not inclined towards collaborating with each other in producing essential drugs in order to ensure their monopoly. Huge investment is involved in manufacturing new drugs. Medical resources to tackle COVID-19 and other medical supplies are rapidly depleting and struggle is that patent rights are becoming a hurdle in the way of protection public health. Pharmaceutical companies seek grant of patent to maximize profits on their investment. During the times of this pandemic, these companies may charge exorbitant rates for essential drugs [1-10].

However, during these troubling times, drug companies around the world have been called to discharge their obligation towards humanity by waiving their proprietary rights over their drugs and equipments so that the same can be disseminated for combating COVID-19. There are several companies who have led this initiative. One such company is Abbvie based in United States. It has announced that it would not enforce its patent on a drug called Kaletra, which is primarily a HIV drug, and is being tested for efficacy against COVID-19. But, on the other side, there are companies that are still vying for exclusivity. For instance, Wuhan Institute of Virology (WIV) has filed for a patent on the use of Remdesivir. The patent has successfully been granted as well in China.

Remdesivir is manufactured by Gilead Sciences Inc. and is used for treating infections caused by 'filoviridaevirus'. The drug can used to treat many viruses such as Ebola, Cueva and Marburg. It is claimed that Corona virus belongs to the same genus. Therefore, Remdesivir has been considered as an experimental antiviral drug used to treat novel Corona virus. It's efficacy against COVID-19 has been reflected in a research paper presented by 7 scientists belonging to the Wuhan Institute of Virology and 3 scientists from the Beijing Institute of Pharmacology and Toxicology. The research paper was published on 4th February, 2020. In the research, Chloroquin was another drug that was found to be effective in treating the novel Corona virus. The drug was first developed by a US based company, Gilead. This move was criticized across the word. Jerry Xia, a patent lawyer, went on record stating that this particular patent could leverage WIV's future negotiations. Huang Yanzhong, a global health expert, claimed that WIV has failed to exercise due diligence [11-21].

Gilead also caught heat when it approached the US Regulators for getting Remdesivir "orphan status". Under US law, pharmaceutical companies that come up with drug for treating diseases affecting less than 200,000 people (orphan drug) enjoy market exclusivity for a period of seven years. However, facing such backlash from the people, Gilead wrote to Food and Drugs Administration (FDA) requesting to rescind its exclusive marketing rights over Remdesivir. Most recently, Gilead has issued royalty free license to four Indian pharmaceutical companies to produce Remdesivir. These companies are Cipla, Jubilant Life sciences, Mylan and Hetero Labs. One Pakistan based drug company (Ferozsons Laboratories) has also received such license. These companies would now engage in manufacturing Remdesivir for 127 countries. The license would remain effective till a declaration regarding the end of COVID-19 pandemic comes from the side of WHO or some other COVID-19 medicine or vaccine is approved.

Compulsory Licensing: A Step Forward

We already know that grant of compulsory license and taking of appropriate measures, in case of protection of public health or a health emergency, are well supported by the TRIPS Agreement and

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Doha Declaration on Public Health. However, this is the first global pandemic since the signing of TRIPS and Doha Declaration. Nations across the world have to rise to this new challenge. The hidden patent politics and lack of support from the pharmaceutical companies may operate as a hurdle. Bold moves from the governments are required during these times.

The entire world community is looking directly into the eyes of this horrific pandemic. Governments across the globe have started taking extraordinary measures to mitigate the debilitating impact of COVID-19. Global health crisis coupled with economic slowdown, developments in the area of compulsory licensing of pharmaceutical patents have been taking place. Many countries have started leading the struggle from the front. Most of these are the ones which have been hit badly by the novel Corona virus.

Israel has become the first country to grant COVID-19 related compulsory license. On March 20, 2020, the Minister of Health and Attorney General issued a permit allowing the import of generic version of Kaletra (drug manufactured by Abbvie) from India to treat COVID-19 patients. This license has been issued under Section 104 of the Israeli Patent Statute. The section allows the State to circumvent the law in the interest of national security and other national defence purposes. Furthermore, such circumvention does not require any consultation with the holder of the patent. The patent-holder does not have the right to judicial review in this regard. Israel was concerned that Abbvie would not be able to supply adequate quantity. This was the reason behind the issuance of the permit.

In Canada, the laws have been amended to make the process of issuing compulsory licenses easier. On 25th March, 2020, COVID-19 Emergency Response Act was passed. This law grants wide range of powers to the Federal Minister of Health. If in the opinion of the Minister, a public health emergency has arisen, the Commissioner of Patents may allow the production, sale and usage of a patented product (drug or device). The new law is different from the existing compulsory licensing regime of Canada. It allows the state to issue a license without conducting any prior negotiation with the patent-holder. Patentees have a right to be adequately compensated but the quantum of compensation is subject to the discretion of the Commissioner. In reaching such decision, Commissioner takes the economic value of the permit into account. Licenses granted under this new law are non-transferable and temporary in nature and would expire when the end of the pandemic is declared. The provisions of this law are set to expire in September, 2020.

Germany, on 28th March, 2020, passed the Prevention and Control of Infectious Diseases in Humans Act. It empowers the Federal Ministry of Health with extra powers in case of a national epidemic. It enables the Ministry to issue a compulsory license under Section 13(1) of the existing Patent Act which allows the grant of compulsory license in the interest of public welfare and security. It is also provided that compulsory license granted under the Section can be challenged administratively, however, they will not be suspended during the period of challenge against such grant. As the case in Israel and Canada, patent-related orders issues under the new legislation will cease to operate when the epidemic ends. The law is set to expire in March, 2021.

France has also come up with extraordinary measures amidst the pandemic. On 23rd March, 2020, a new law (No. 2020-290) was passed under which a new article (L.3131-15) was introduced to the public health code. This article authorized the Prime Minister to: (i) issue seizure orders against all goods and services essential to face sanitary challenges; (ii) temporarily calibrate the prices of various products; (iii) to launch generic products in the market; and (iv) to take effective measures to make essential medicines available to patients. It was argued that this step by French Government is much more advanced than any other compulsory license related measure taken around the world.

Several nations in South America have also come in front to fight COVID019. On 17th March, 2020, Chamber of Deputies of Chile has passed a resolution demanding the government to declare its support for emitting compulsory license in relation to patented medicines and devices in order to treat COVID-19 patients. The resolution also requests the Minister of Health to issue an instruction to government departments to prepare a report on all the medicines, vaccines and treatment equipments that should be considered for such licenses. Further, the resolution calls the government to approach the WHO and request it to gather information pertaining to R&D costs associated with COVID-19 treatment. However, the resolution, of course, is of a non-binding nature.

Ecuadorian National Assembly, on 20th March, 2020, also passed a resolution requesting the Health Minister to authorize the issuance of compulsory licenses on medicines and other products essential to protect public health against COVID-19.

The Education, Culture, Science and Technology Commission also requested the Health Minister to utilize Article 502 of the Codigo Ingenios, which allows third parties to access and extract patent-holder's data.

Most recently, Brazil, amid intense objection by drug makers, has become the latest country in South America to issue compulsory licence to COVID-19 related medicines and devices. Interfarma, a trade group of drug makers, has criticized Brazilian government's move by contending that compulsory licensing enhances the risk of misallocation of resources. It also acts as a hurdle in the way of efficient use of raw materials for pharmaceuticals. It was further contended that compulsory licenses deplete the incentive to innovate further.

At the other end of the world, Australia has not taken any concrete steps in this regard. However, it is reported that the opposition Labour Party has asked the government to make efficient use of 'Crown Use' provisions to tackle the pandemic. Brendan O'Connor, the shadow Industry Minister, has explained how Crown use of patents can be implemented to combat the COVID-19 pandemic. He laid focus on manufacturing businesses and disrupted supply chains of essential products.

In these efforts, more countries like Argentina, Bahrain, Norway, Iran, South Africa, Spain and Switzerland have affirmed that they would be joining in.

These initiatives have also inspired many innovators across the globe. They have decided to waive their intellectual property right over essential products in relation COVID-19. AbbVie and Gilead are the prime examples of the same.

Patent Pooling and Patent Pledge: Effective Initiatives

In addition to compulsory licensing of COVID-19 related patented products, the world community is moving strong towards patent pools wherein two or more companies associate (by way of a consortium) to cross license their patents in respect to a particular technology. Patent pools can also be defined as an agreement between two or more patent owners to licence one or more of their patents to one another or to third parties. Often, patent pools are connected to complex technologies that

require complimentary patents in order to offer effective technical solutions.

Recently, an idea of voluntary patent pool creation was endorsed by the Director-General of the World Health Organization. The main aim is to assimilate patent rights, regulatory test data and other important information to be disseminated in order to develop medicines, vaccines and diagnostics relating to COVID-19. This came as a challenge to the international pharmaceutical industry. This idea attracted praises from around the globe. However, its effectiveness largely depends on the support of Big Pharma as this pandemic is a wonderful opportunity to grow their business and make exponential profits.

The idea of a global patent pool to fight this pandemic is certainly an ambitious one. It would require a concerted effort of governments, international organizations and innovators across the world. The sheer willingness to implement the idea of a global patent pool is required.

One major reason behind the introduction of this idea of global patent pool is the delay in availability of anti-COVID medicines/ vaccines. A rough estimate shows that it would take at least 6-10 months to come up with an efficacious drug or vaccine. Even after that, dissemination of such drug/medicine across the globe would take even more time because of regulatory procedures in each jurisdiction. This is because commercial production of any product requires prior approval in every country. Measures relating to instant manufacturing and marketing of medicines and vaccines have to be taken. Innovators, manufacturers and supply chain have to come on a single platform to have a dialogue. Intensive efforts have to be made by the world community including governments, international organizations and private players.

There is friction among innovators of different countries because all are engaged in coming up with treatment of COVID-19 by way of a medicine or vaccine. They would all be filing for patents to acquire monopoly and exclusivity. But, there are certain parts of the world where innovators are collaborating with each other to find solutions. Therefore, the contention that patents would create impedance in the way of swift dissemination of COVID-19 drugs/vaccines still prevails. Constructive steps and global consensus have become the need of the hour.

To ensure effective aggregation, administration and dissemination of anti-COVID products, patent pools are proposed to be created. The main advantages of a patent pool are:

Managed by a central agency for effective functioning;

Balance of interests of participating innovators; and

Conveniently approachable for licenses

Patent pools have been a popular phenomenon in many areas such as biotechnology, digital innovations and even pharmaceuticals. But, this time, the need is dire and situation is highly demanding.

There are certain research organizations that have made their own pools, But, the most effective idea, as already discussed, is creation of a global patent pool to fight this horrific pandemic.

Innovators and lawyers around the world have also come together to launch a noble initiative to fight COVID-19. A COVID-19 patent pledge has been launched to ensure swift rolling-out of technologies effective against Corona virus. A patent pledge is allowing the royalty-free use of one's technology. There have been various instances of patent pledges in field of environment protection and pharmaceuticals. The primary aim is to streamline these technologies without the hurdles of IP procedures and protection. It is a global sharing of patents to fight COVID-19. The Open Covid Pledge (OCP) clearly mandates to intellectual property available free of charge in order to eradicating COVID-19 and mitigating the impact of this disease. The founding adopters of the OCP include several big names such as Facebook, Amazon, Intel, IBM, Microsoft, Uber, AT&T, etc.

Founding Professors Jennifer Doudna, Mark Lemley and Jorge Contreras have explained the plan of operation of the pledge. Under the OCP, the pledgor grants to every person or organization that is willing to accept it: (i) non-exclusive; (ii) royalty-free; and (iii) fully paid-up license. The said license is meant for use, practise and exploitation of all intellectual and industrial property rights (other than trademarks and trade secrets) for the sole purpose of combating and ending the COVID-19 pandemic. It also includes minimising the impact of the disease, including without any limitations the diagnosis, prevention, containment, and treatment of COVID-19.

It is true that pharmaceutical companies are facing enormous pressure in relation to their patent rights. The introduction of this pledge is made in the backdrop of the argument that pharmaceutical companies should waive their patent rights. The prime focus is on the combat against the novel Corona virus. However, management of the IP rights of these companies after the end of this pandemic is also an issue. Therefore, there has to be a clear position in the arena of public health and patent rights. Academia may find it a viable solution, but the major pharmaceutical companies are standing at the verge of making bold choice. It can fairly be contended that a bold move at this juncture would work in favour of these companies in the longer run. This is, above all, a matter of morality, and afterwards of public relations policy.

Pharmaceutical Patents and Covid-19: Indian Scenario

In India, patent application in respect of Remdesivir was made by Gilead in 2015 which was finally granted on 18th February, 2020. This drug has gathered attention only when the COVID-19 pandemic began. During a global drug trial which was conducted by the WHO for finding a treatment of COVID-19, Remdesivir was given the status of the most promising medicine.

The move of relaxing the patent rights on Gilead's Remdesivir, as discussed earlier, doesn't seem to be enough. Unlike other countries that have taken active steps to ensure swift grant of compulsory license against the drugs relating to COVID-19, the trend in India is witnessed to be on a different frequency altogether.

In latest development, Cancer Patients Aid Association (CPAA) has written a letter dated 9th April, 2020, to the Ministry of Health and Ministry of Chemical & Pharmaceuticals asking to immediately revoke Gilead's patent on Remdesivir under Section 66 of the Patents Act, 1970, so that the medicine could be made available at affordable prices to those who are in need of it. In their eighteen-page long letter, CPAA has raised questions on the novelty and inventive step aspects of the drug. CPAA has strongly contended that patent shouldn't have been granted to Remdesivir the first place. In this regard, CPAA also made reference to AbbVie's Kaletra.

The letter by CPAA contains many cogent arguments and the letter carries a lot of weight especially when the COVID-19 pandemic is at its peak. Right to health and right to life arguments come in strong support of this patent revocation request. This again has ignited the patent rights versus public health debate.

Section 66 of the Patents Act, 1970 allows the Central Government to revoke a patent in public interest. It is noteworthy that to revoke

a patent, Section 66 has been used only twice in the Indian patent history. In 1994, a patent granted to a US-based company Agracetus, on a process for manufacturing cotton was revoked to safeguard the interests of farmers and to avert a negative impact on the economy. Later, in 2012, a patent on a method treating diabetes was revoked which belonged to Avesthagen. After these two cases, public interest and public health have become important governing factors as far as patents are concerned. The Remdesivir patent is facing the same challenge during this pandemic.

Following CPAA's lead, two more organizations (A Malaysia based non-profit group called Third World Network and Medecins Sans Frontieres) have made similar appeal. It is contended that Gilead's patent over Remdesivir and the related exclusivity is completely imprudent and unacceptable during these trying times. The world community is facing a global health emergency and no exclusive right granted to any individual or organization could ever supersede public health and welfare

Thus, in India, the issues of compulsory licensing and patent revocation are prevailing side by side and the latter is receiving more traction. Given the magnitude of the COVID-19 pandemic and the globally known efficiency of Indian Pharmaceutical Industry to create generic versions of known and efficacious drugs, it is actually for the government to decide on a viable course of action. One more noteworthy fact is that except for Remdesivir, there are no medicines or vaccines that can be used to fight COVID-19. Also, the letter by a renowned organization in the field of Cancer gives an underlines testimony as to the efficacy of Remdesivir. However, the final decision, obviously, is that of the government's.

Pharmacetucial Patents Versus Public Health: The Perennial Conundrum

When it comes to intellectual property right, particularly patent relating to pharmaceuticals, public interest and private monopoly have always been at sixes and sevens. The issue has always been contentious mainly because no pharmaceutical company ever wants to jeopardize its monopoly. Pharmaceutical companies around the world are majorly opposed to the government or any other organization gaining involuntary access to their patented product. These companies have remarkable R&D and financial position. It is always difficult to tackle their monopoly that is statutorily protected. There have been instances in the past which have magnified this very fact.

Back in 1998, in an unfortunate series of events, the South African government was sued by a group of pharmaceutical companies. The aim of this suit was to prevent the government from introducing laws to make some medicines cheap and affordable, particularly HIV-AIDS medicines. It was objected that the laws were aimed at toning down the patent protection in their territory. This suit attracted vehement global criticism. This showed the bitter conflict between patent rights and public health. Ultimately, the legal action was abandoned by the companies.

In India, the very famous Bayer vs. Natcocase has been the prime example of the struggle between the interests of pharmaceutical companies and public health. Indian Patent Law, in consonance with TRIPS, holds a strong stance in favour of public health and Indian courts are always inclined towards making life-saving widely available at affordable prices.

Balancing these two factors has always been a tedious task for the governments around the world. This is precisely the reason why measures like compulsory licensing have been contemplated in the TRIPS Agreement and Doha Declaration was signed. During the COVID-19 pandemic, we are again standing at the same spot. Fortunately, this time around the pharmaceutical industry has started contributing to the struggle.

Conclusion

During the COVID-19 pandemic, there is active mobilization in all domains – governments, pharmaceutical industry, innovator as well as researchers and academicians. Various mechanisms have been activated by governments around the world to make helpful and effective medicines and devices available to fight COVID-19. The landscape pertaining to pharmaceutical patenting has always been extensive and its constant clash with general public interest has always been a contentious issue. However, it is up to the policy-makers to take the most efficient steps according to the need. In India, the law relating to patent provides many options to the government to exercise its rights in relation to a patented pharmaceutical product and make it easily and cheaply available in the larger interest of public health. However, it is extremely necessary to balance government's intervention with the rights of the patentee otherwise litigation entails and the target benefit is unnecessarily deferred which is the last thing to have during these challenging times.

Therefore, it is very important that morality and prudence come to the forefront of this constant debate and both pharmaceutical industry and governments, not only in India but in all those countries that are facing the brunt of COVID-19, reach a viable solution which would also create a benchmark for the future. This pandemic will end but it is equally important that patent rights and public health co-exist peacefully in the larger interest of humanity.

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