

COVID-19 VACCINE VIS-À-VIS APPLICATION OF PATENT LAW DURING PANDEMIC

Sai Smrithi Balasubramanian¹, Garima Panwar²

¹Symbiosis Law School, Pune

²Symbiosis International (Deemed University), Pune, India

*Email Id: ²garima.panwar@symlaw.ac.in

Abstract

The SARS CoV – 2 or the novel coronavirus pandemic has wreaked havoc of biblical proportions on the world. Between the index patient (the first human transmission) in late 2019 and mid 2020, the virus brought the entire world to its knees, effectively changing the status quo and establishing a new world order, in terms of economy, normalcy, public health and social interactions. The virus systematically dismantled fiscal systems across the globe, slashed the job market, and sounded a death knell for major economies around the world by inducing a recession. The USA and the UK, earlier rich job markets, saw more than 30 million people applying for unemployment benefits by the end of April itself. The IMF estimates that the global economy will shrink by 3%, (Jones, L., Palumbo, D. and Brown, D., 2020).

Governments scrambled to curb the unrelenting and highly contagious virus through several schemes and rules but the virus thrived on the closely knit social order humans had built for themselves in the many millennia of civilization. In its wake, scientists, researchers, pharmaceutical experts and medical professionals are in the process of aggregating their combined resources to study the virus, in order to invent an antidote or a vaccine that can possibly combat it. While there is rigorous research to end this pandemic, there is also international debate on how one would aim to protect this invention. A patent protects the invention by prohibiting the production, sale, distribution and related processes of the invention by anyone other than the patent holder and his authorized licensees. This is a form of techno-protectionism to ensure that all profits and royalties are funneled to the patent holder and effectively creates a monopoly for the invention in the market. It is no doubt that pharmaceutical researchers and organizations always look to protect their invented product or process legally so as to reap a profit and possess a legally enforceable right to bring a suit against copycat inventions and patent infringements.

This article aims to study the possibility of a vaccine juxtaposed with the law of patents, to see how best the rights of the creator of the treatment kit may be protected while also not jeopardizing public health and safety. The author seeks to discuss the cost benefit analysis between the drug development process and patent protection of the developed drug, the concept of compulsory licensing which acts as a safety valve to block the creation of monopolies in the market during times of emergencies, and also bring to light the relatively modern idea of patent pooling to achieve equitable results across the globe.

Key words: compulsory licensing, patents, drug, vaccine, pricing.

Introduction

Drug development requires a large amount of all kinds of resources like time, human resources, trial resources, etc. The first step in developing a new drug is research and development or R&D. This is a time intensive process, too. The high market price of drugs can be attributed partly to the proportionally high cost of R&D.

The second step is called drug discovery. This is essentially streamlining the R&D. In this step, researchers study the virus or germ or bacteria in detail, try to isolate it, find its Achilles' heel (most vulnerable part) and try to form an attack strategy. This is an extremely expensive step and this may cost anywhere in the billions of dollars. Once this step is successfully completed and the researchers have an attack strategy, a chemical compound is formulated. This may be a vaccine or a therapeutic drug.

Next is the least expensive but time consuming and rigid process of trial. No new drug enters the mainstream market without adequate trial and testing. It goes without saying that these tests are necessary to ensure that no harmful side effects are suffered by humans, as a result of the drug. Tests are first conducted on animals that have largely similar biological structures to that of humans and which are approved for testing (like rats and monkeys), and only if these tests are satisfactory, human trials begin. Human trial is one of the most complex stages of vaccine creation, because of the number of invariables involved. It is mandated that the number of humans in a trial set must be proportionate to the total number of affected people worldwide. To clarify, if a disease affects 10,000 people a year, the number of people employed in the study would be much fewer than in the case of the novel coronavirus, which has affected over 6 million humans in first five months of 2020 alone.

From this, it is established that the cost of drug development is astronomical; hence, pharmaceutical companies may naturally look for legally enforceable ways to protect their rights to the drug (and invariably their large investment). Patent law and pharmaceutical industries have a short but colorful history together. Drugs and vaccines are immediately patented to ensure that they are not unlawfully replicated and the copycats made thus are not sold at cheaper prices. But the case of COVID-19 presents a strange, intangible and moral challenge.

In popular culture, the pharmaceutical industry is often compared to a game of high stakes poker. This is so because while successful, these companies are able to put lifesaving drugs on the market while also enjoying a large profit margin. But even a single drug that goes on to give its consumers harmful side-effects which may include paralysis, organ failure, or death, can mark the beginning of the end for the manufacturing organization. This is precisely why producers and distributors seek to make maximum profits on successful drugs.

Another reason for the high cost – high profit equation is the number of players in this industry. Since it requires heavy investment, equally high establishment costs, a significant amount of technical know-how and political discretion for tax breaks and approvals, entry is severely inhibited, thus the startup bubble is almost impenetrable. This invariably results in the high prices of drugs and other treatment kits. This cycle is cited as an argument for not socializing healthcare innovation, as the draining of lucrative profitability pockets will inhibit drug development and further innovation, essentially paralyzing the industry. Without socializing Big Pharma, price ceiling mechanisms can be organically induced by easing some of the entry level processes and fees so more manufacturers are encouraged to enter the arena and level the playing field.

The biggest threat to public welfare and accessibility is monopoly of prescription drug supplies. While patents merely seek to protect the rights of the patent holder, they also end up playing a huge role in creating monopolies and setting steep prices. These companies enjoy profits during the life of the patent and attempt to use methods such as ever-greening (Faunce, T., 2004) to continue enjoying the effects of the monopoly. A relevant illustration for the same would be that of the EpiPen, which is an auto-injectable device with a life-saving medication that is used when someone enters anaphylaxis or severe allergic reaction (Hwang, D., 2019). Even as the patent ends and generic drugs are able to enter the market without risking patent infringement, there exist monopolies within generic drugs itself.

These monopoly structures can be dismantled only through legislative measures easing certain rules and regulations for the establishment of pharmaceutical industries along with tax perks so as to encourage firms with smaller capital and streamlined product ideas to contribute to the industry. The need for this has been felt nationwide. This was seen in debates amongst the peoples' representatives in Lok Sabha. An excerpt from an address from a Member of the 16th Lok Sabha is as follows:

“Pharmaceutical industry holds an important and prime position in the scheme of things as it takes care of the health aspect when it comes to caring and treatment of people. It goes a long way in ensuring the health of the country. But to the utter astonishment of every one, the amount of funds infused for research in the pharmaceutical industry is not only insignificant but also negligible...the National Institute of Pharmaceutical Education and Research (NIPER) sought Rs. 249 crores during the 12th plan, a paltry sum of Rs. 9.39 crores has been received by NIPER... how can the NIPER carry out research and compete with MNCs which take away large slice of medicine manufacturing?”

The situation was largely unchanged even in 2019, when a profile by the Comptroller and Auditor General found that the institutes were sustaining themselves with just 50% of the government approved budget. It was noted that with the present budget, there will be reduction in filing of patents and R&D (Kanwar, S., 2019).

Patenting the COVID-19 vaccine

Pharmaceutical multinational companies and institutes of life sciences and pharmaceuticals have vaccine development in full swing for the SARS CoV 2 strain of the coronavirus. Key players in the development of a drug are Oxford University, Moderna Therapeutics, Sanofi, Novavax and Tel Aviv University overseas, and Pune-based Serum Institute of India, Bharat Biotech, Glenmark Pharmaceuticals in India. In the same pace, the race to patent and monetize the vaccine is also seen around the world. This is not a vaccine by itself, but merely a design, the vaccine could still take anywhere between a year and two to be ready for mass immunization. There are three key concepts one must study to understand how patenting a vaccine works, especially during a lethal pandemic.

Firstly, the **time factor** of patents must be considered. Processing of patents usually takes 20 to 22 months but the process has been expedited in the wake of the pandemic. Countries with a capitalistic outlook towards public health and drug development are introducing programs through which a patent can be obtained in a fraction of the original processing time, by radically decreasing the time to reach a final decision down to 6 months. Some countries have also decided to waive any fee involved with this fast paced patent processing, if the applicant is a small or micro entity. While this may be encouraging for such entities to patent their inventions, they hardly have the capital resources to delve into pharmaceutical drug development. These processes are in place to ensure that the company with the patent enjoys the sole rights associated with the vaccine, and thereby the sole flow of revenue from it. In normal scenarios, this would be the status quo. But as the pandemic rages on, a duty is placed to ensure public health and safety.

Compulsory licensing –a pose of balance?

Compulsory Licensing is the second and most important concept in patenting of a vaccine, contextualized to a global pandemic with a considerably high death rate. A compulsory license is essentially the authority vested in the government to allow a party that does not have the patent for the production and distribution of a particular invention to do so, without the consent of the party actually holding the patent. This is not a Hail Mary provision, as much as it tries to ensure fundamental rights to good health. The patent owner may be compensated adequately but they will not have the sole right for production, distribution, and all allied processes.

It is important to note that compulsory licensing is not the same as cancelling the patent. The patent owner retains the right to be paid compensation the number of units produced under the compulsory license. As stated before, this provision is not limited to times of emergency; the TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. The Doha Declaration, which succeeded the TRIPS Agreement to make it more equitable for developing countries, states that countries are free to determine the grounds for granting compulsory licenses and to determine what constitutes a national emergency (WTO, 2020).

While it is true that the basic tenet of IP law is to promote a spirit of competition and protectionism, safety valve provisions like that of compulsory licenses is invaluable to ensure accomplishment of larger goals (like protection of the environment, maintaining of public health and safety, and security). In the case of successful invention of a vaccine or drug to combat the deadly novel coronavirus, nations will aim to wield this compulsory licensing provision (either enshrined in their national laws or adopted from the TRIPS agreement) to ensure equitable distribution of the same.

In India, this provision finds its place in Section 84 of the Indian Patent Act, 1970. The section provides three conditions under any of which the Controller General can grant compulsory license. They are:

1. the reasonable requirements of the public with respect to the patented invention have not been satisfied

2. not giving access to public at an affordable price; and
3. the patented invention is not worked in the territory of India.

Compulsory licensing in India may be requested by any party, irrespective of whether they hold the patent for the invention, and can even be taken up suo moto by the Controller. At this juncture, it is important to study the grant of compulsory licensing for drugs during a health crisis in India. Back in 2012, for the first time compulsory license was granted to Natco Pharma for the generic production of Bayer Corporation's "Nexavar", which is a drug considered a lifesaver for people suffering from kidney and liver cancer. Before the licensing was granted, Bayer Corporation sold this drug at an exorbitant rate of Rs. 2, 80, 000 per dosage per month. Once the licensing was granted to Natco, it offered to sell the drug at a price of Rs. 9000 instead.

Since it satisfied all three conditions set out in the Act, the license was granted. It must be noted that compulsory licenses are a fine balance between the rights of the patent holders and the welfare of the public; hence they are granted after much deliberation (*Franz XaverHuemmer vs. New Yash Engineers MANU/DE/0015/1997*). Some factors that account into the granting of compulsory license are proving of prima facie case, proving of public use of patented invention, and whether the patentee has adopted anti-competitive practices (Shuklaa, N, 2019).

India, albeit having been given the tag of a 'developing nation', has made monumental strides in drug development and nurturing of big pharmaceutical industries. Indian pharmaceutical sector is anticipated to raise at a CAGR of 22.4% and medical devices market might rise upto55 billion dollars by 2020 (Indian Brand Equity Fraction, 2020). Government has also raised their investment marginally i.e. to 1.5% in 2018-19 from 1.2 % in 2014-15 for health (Indian Brand Equity Fraction, 2020). This is also reflective of the strength of the drug developing organizations ranging from the Serum Institute of India to numerous other private players. While the drug development of an anti-COVID-19 vaccine is in various stages of growth, international partnership and agreement is also used to make vaccines affordable. For example, Serum Institute of India (SII) signed a deal with Astra Zeneca to supply one billion doses of vaccine for low and middle-income countries before the end of 2020 to combat coronavirus.

At this juncture, an important question arises: how will developing countries with no indigenous vaccine or drug of their own acquire the same for their population? The TRIPS Agreement has an amended provision in this regard. Paragraph f of Article 31 used to say that compulsory licenses must be granted mainly to supply the domestic market. But a decision was made in the landmark Doha Declaration in 2001 which recognized that countries unable to manufacture pharmaceuticals should be able to obtain cheaper copies produced under compulsory licenses elsewhere if necessary (WTO, 2020). This is very reflective of the theme of the Doha Declaration, in which the completely different effect of IP laws on developing nations as opposed to their effect on developed nations was vehemently highlighted.

Circling back to the Indian Patents Act, 1970, there are two comprehensive ways to impose compulsory licensing as under Section 84 and also under Section 92, which is more contextualized to the national health crisis. Section 84 is the provision to be used in non-emergency times, with the ensuing wait period of three years, negotiation of voluntary license by the party requesting the license with the patent holder, and hearing of the parties. But, Section 92 expedites this process and places large powers upon the government, as it is their duty to protect public welfare. Section 92 requires that the Indian government should publish a notification in the gazette, any time after sealing of the patent, declaring that compulsory licenses should be granted thereon. This can be done by the central government under the following circumstances:

1. Other circumstances of extreme urgency;
2. Public non-commercial use; and
3. National emergency.

After this notification is published, either a competitor of the patent holder or a generic drug manufacturer may apply to the Controller for compulsory license. The difference between Section 84 and Section 92 lies in the

different grounds required for granting of compulsory license, the procedure which is cut short and expedited in the latter, and also the role of the government. The Act also says that such exceptional circumstances can include “public health crisis” relating to AIDS, tuberculosis, malaria or other epidemics. From this, it is obvious that a pandemic like COVID-19 falls squarely within the purview of this emergency provision. Section 92 has many advantages: it is time efficient in its procedure as well as the prescribed wait time of 3 years is eliminated, it also eliminates the need for negotiation between the party seeking the compulsory licensing and the patent holder.

While studying the emergency provisions of the Patent Act, it is important to discuss the concept of cancellation of patents as well. This is, in fact, the antithesis of the concept of compulsory licensing as the latter seeks to keep the patent alive, come what may. Section 66 deals with the cancellation of patents, based on prejudicial grounds. Hence, this provision is different from Section 64 which cancels patents on grounds of weakness of essential ingredients like novelty, industrial application, etc. In recent history, there has been a strong, rallying call for cancellation of patent for the drug ‘Remdesivir’ (Murugesan N, 2020), which shows strong potential as a treatment drug for COVID-19. Section 66 has been invoked twice before, the only drug related revocation being in 2002 with the cancellation of the patent for the drug ‘Avesthagen’ (Reddy, P., 2012), which was a treatment plan for diabetes. As much as this seems like an equitable option, it is important to note that by invoking Section 66 of the Patent Act, executive powers will be employed, overriding a number of procedural and evidential details. This must be utilized very prudently as it could be a discouraging factor for pharmaceutical industries to invest in drug development during these times. Another significant benefit of cancelling the patent altogether instead of granting compulsory license is the possibility of selling the treatment kit at truly rock bottom prices; as even compulsory licenses attract heavy royalties, and it is not always the cheapest option.

Globally, even before the cure for this lethal virus is set to enter the markets, the marked superiority of compulsory licensing is felt. Even though, it is not a completely socialist measure, it ensures that investors stay motivated to shell out and develop drugs locally and it can also act as a catalyst to induce pharmaceutical investors to themselves price their drugs economically, instead of facing the risk of licensing or patent cancellation (Papadopoulou, F., Tandon, V. and Tandon, A., 2020).

Investors in these organizations may try to add in caveats to ensure a significant amount of profit as well as important rights are funneled to them, without any curbs. This may not work but be outweighed by the intangible yet concrete need for public welfare. At this juncture, the powers of another government regulatory agency specific to India must be studied. The National Pharmaceutical Pricing Authority is a government regulatory agency that controls the prices of pharmaceutical drugs in India. This agency concerns itself with not just therapeutic drugs but also supplies related to medical sciences. This was observed when the agency issued an advisory to bring down the price of N-95 masks by 47% in order to combat overpricing and the resulting inaccessibility.

Another important scheme, with respect to price ceilings and combating of monopolies, is the Pradhan Mantri Bharatiya Jan Aushadi Pariyojana under Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, in order to make generic medicine available to all. This scheme was discussed in the Rajya Sabha in early 2019. This programme also called for the establishment of PMBJP Kendras, which were centers for the distribution of unbranded generic drugs. It is mandated that the MRP of the drugs sold through these outlets should be at least 50% lesser than that of the average MRP of the top three brands of that medicine. There have even been cases where the medicine was sold at 90% the reduced price of the average branded price. This ensures that quality medicines reach the needy. Unbranded generic medicines worth Rs. 417 Crores have been sold through these Kendras till the end of 2018. This sale is equivalent to sale of Rs. 2085 crores of branded medicines (Rajya Sabha debates, Written Answers to Unstarred Questions, 04-01-2019). This scheme has been successful in its implementation and distribution. But it must also be noted that, in the context of a widespread pandemic, these Kendras which have the authorization to only sell generic medicines at subsidized prices, will be unable to distribute patented drugs without a policy change.

Is patent pooling the ethical solution?

In the recent COVID-19 crisis, drug development was undertaken at grassroots levels across the globe. At this juncture, the advantages of information sharing certainly outweigh the disadvantages.

As studied earlier, countries with large interests in the intellectual property behind the vaccine and the governments of which are lobbied by large pharmaceutical conglomerates seem unready to adopt this method and are proceeding with traditional IP protection for the vaccines, thereby capitalizing an essential immunization drug and placing it out-of-reach of persons in poverty. This kind of techno-protectionism can also prevent the vaccine from making its way to developing countries, with larger population, higher density, and weaker healthcare systems. As the coronavirus pandemic is bordering on a global humanitarian crisis, it is definitely prudent to consider the concept of patent pooling.

Patent pooling is as an agreement between two or more patent owners to license their patents to one another or to third parties. It is comparable to a partnership to share their patents with either each other or with other parties. It is usually undertaken when a party is unable to proceed further in the invention because of complex technology or drugs because of blockage by complementary patents.

Patent pooling saw its inception in the late 19th century with the pooling of patent rights by several sewing corporations. Patent pooling was adopted as it helped retain their profits, which they would have lost had they sued each other for patent infringement, like they had originally planned. Their patents were pooled for profitable reasons. On the other hand, the case that really brought patent pooling to the spotlight as a viable premise in patent law is that of the Wrights and Curtiss Companies. They were airplane manufacturers who had hit a dead-end which could only be solved by patent pooling (catalyzed by the US government as a wartime measure). This is an example of how patent pooling can be used during times of emergency.

As always, patent pooling has its share of disadvantages. It is widely regarded as a way of flouting competition laws. This is severely looked down upon as it flouts the basic tenets of patent law, which is kindling of competition in the industry. So, there are some standard forms that an ideal patent pool must conform to.

Conclusion

After thorough analysis of provisions of patent law and international norms juxtaposed with the growing health concern, it is the author's opinion that a democratic approach be taken to the distribution of COVID-19 vaccine kits to the masses. It is also important that the rights of the manufacturers are taken into cognizance and they are paid, if not equal, at least fair remuneration for the drug development. With all these criteria in mind, the tool of compulsory licensing brings equilibrium to the equation. The state should opt to become a licensee in order to ensure efficient, impartial distribution through its subsidiary organs. In a modern welfare state, the onus of public health is placed on the state; hence the responsibility of ameliorating a pandemic is also on the state.

References

1. Archer, D., 2017. Does Pfizer Care About Malfunctioning Epipens?. [online] justcareusa.org. Available at: <<https://bit.ly/3hHJZfm>> [Accessed 19 June 2020].
2. Archer, D., 2018. Pharma'S Monopolies Are The Reason For High Drug Prices. [online] justcareusa.org. Available at: <<https://bit.ly/30V47V5>> [Accessed 19 June 2020].
3. Faunce, T., 2004. The Awful Truth About Evergreening. [online] The Age. Available at: <<https://bit.ly/37HNxt9>> [Accessed 19 June 2020].
4. Franz Xaver Huemer vs. New Yash Engineers (08.03.1996 – DELHC) : MANU/DE/0015/1997.
5. Hwang, D., 2019. What Is An Epipen And Who Needs It? | Atlanta Allergy & Asthma. [online] atlantaallergy.com. Available at: <<https://bit.ly/3fFtkHq>> [Accessed 19 June 2020].

6. Jones, L., Palumbo, D. and Brown, D., 2020. Coronavirus: A Visual Guide To The Economic Impact. [online] BBC News. Available at: <<https://www.bbc.com/news/business-51706225>> [Accessed 18 June 2020].
7. Kanwar, S., 2019. NIPER Unable To Sustain For Wants Of Funds From The Ministry - Times Of India. [online] The Times of India. Available at: <<https://bit.ly/2AWS13k>> [Accessed 22 June 2020].
8. Murugesan, N., 2020. Govt Urged To Revoke Patent For Gilead'S Potential Anti-COVID19 Drug Remdesivir. [online] SpicyIP. Available at: <<https://bit.ly/30IxERT>> [Accessed 15 June 2020].
9. Papadopoulou, F., Tandon, V. and Tandon, A., 2020. [Guest Post] Revocations, Special Compulsory Licenses, Patent Strategies & COVID-19: A Note On Indian Patent Law. [online] The IPKat. Available at: <<https://bit.ly/3d238oz>> [Accessed 13 June 2020].
10. Rajya Sabha debates, Written Answers to Unstarred Questions, 04-01-2019.
11. Reddy, P., 2012. DIPP Notifies Revocation Of Avesthagen Patent In Gazette; Patent Office Announces New Policy For TK Related Patent Applications. [online] SpicyIP. Available at: <<https://bit.ly/2BemjhB>> [Accessed 15 June 2020].
12. Shuklaa, N., 2019. Compulsory Licensing In India - Intellectual Property - India. [online] mondaq.com. Available at: <<https://bit.ly/3hrcC01>> [Accessed 13 June 2020].
13. Team, Trefis. "How Big Is Roche's R&D Expense?". Forbes. Retrieved 2020-01-14.
14. The New Indian Express. 2020. Prices Of N-95 Masks Down By Up To 47 Per Cent After NPPA Advisory. [online] Available at: <<https://bit.ly/3hP9fjR>> [Accessed 21 June 2020].
15. wipo.int. 2011. SURVEY ON COMPULSORY LICENSES GRANTED BY WIPO MEMBER STATES TO ADDRESS ANTI-COMPETITIVE USES OF INTELLECTUAL PROPERTY RIGHTS. [online] Available at: <<https://bit.ly/30H8V0g>> [Accessed 13 June 2020].
16. wto.org. WTO | Intellectual Property (TRIPS) - TRIPS And Public Health: Compulsory Licensing Of Pharmaceuticals And TRIPS. [online] Available at: <<https://bit.ly/37v7G5B>> [Accessed 13 June 2020].
17. wto.org. WTO, Intellectual Property (TRIPS) - TRIPS And Public Health: Compulsory Licensing Of Pharmaceuticals And TRIPS. [online] Available at: <<https://bit.ly/37v7G5B>> [Accessed 13 June 2020].