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COVID-19, Patents and Right to Health

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ABSTRACT

The COVID-19 pandemic has created an unprecedented scene and situation across the globe in terms of the health of people at large. Hitherto unknown, unheard and unprecedented health emergency it has created which was never foreseen and anticipated by any wild stretch of the imagination by anyone. It has called for Resolution of the World Health Assembly, which recognizes that the COVID-19 pandemic has an impact on the poor and the most vulnerable, with repercussions on health and development gains, in particular in low-income countries. It further calls on cooperation between multilateral organizations and other stakeholders and the World Health Organization (WHO) to identify and provide options that respect the provisions of relevant international treaties, like the TRIPS Agreement and the flexibilities within TRIPS Agreement for ensuring Public Health. It is indeed required that, as proposed in the Doha declaration, flexibilities within the TRIPS agreement be used in protecting public health at large during the COVID pandemic times. Such flexibilities could include scaling up the development, manufacturing and distribution of medicines, including the vaccines, injunctions, capsules and tablets used in treating COVID at present. It is also required that capacities be built for transparent, equitable and timely access to quality, safe, affordable and efficacious diagnostics, therapeutics, medicines, and vaccines for the treatment of COVID. It can be ensured only by using the flexibilities under international agreements like TRIPS while promoting innovation in pharma for finding better solutions for COVID.

Introduction

It is opined that if we do not keep intellectual property and patents rights for at least 5 years, it is not possible to complete the vaccination process across the globe. The developing and underdeveloped countries are supplied the vaccine by the international society probably free of cost or at nominal prices, keeping health and humanity at higher levels than profit-making. In countries like Israel, the entire population has been vaccinated, and in countries like the USA and UK, more than half of the population has been vaccinated. In India, only around 2% of the population out of 135 crores of population. In most other countries, the situation is not that different. In this regard, counties like India and South Africa demanded before the World Trade Organization to suspend intellectual property and patent conferment temporarily in the light of the COVID-pandemic. Recently, the USA has also joined the league while second the thought of suspending intellectual property and patent conferment temporarily. It is reported that World Trade Organization which also looks after international intellectual property law protection and enforcement, is poised to meet sometime soon to discuss the matter and take a pragmatic view. However, countries

like Germany, Brittanand such other European countries are against such a move. The established pharma companies are arguing that if intellectual property conferment is suspended, their innovations and technology regarding COVID vaccines and related treatment may be misused. Pharmacy companies are not really willing to accept suspension of their rights and conferment of compulsory licenses on innovations regarding the COVID vaccine and related treatments to other potential producers. However, Indian pharma companies are willing to transfer their technology to potential producers to meet the needs of the country. For instance, Bharat Biotech company Hyderabad is willing to transfer the technology related to the production of COVID vaccines to other pharma companies in India to produce the vaccine on a large scale. The government of India convinced Bharat Biotech, Hyderabad, India and Ceeram Institute of Virology, Pune, India, to transfer vaccine technology to other established pharma companies in India. In the USA government convinced Jonson and Jonson Pharma company to transfer the technology to Mork company for ensuring quick and mass production of COVID Vaccine.[1]Similarly, the University of Pennsylvania has also granted a license on their developed technology to potential pharma companies to produce COVID related medicine.

However, it is feared that big pharma companies from the USA and Europe may not be willing to transfer technology to other countries, in particular developing countries, to produce COVID vaccines and related drugs on a mass scale as those companies would not like to forgo their potential patents, which they can fetch for their developed technology and innovation in this regard. Of course, any pharma company, for that matter, would like to get back the investment they have made in the production of vaccines and earn profits on the commercial production of vaccines through patent rights which is understandable in regular and ordinary times. But currently, during COVID-19 times, there is a health emergency across the globe, and it is extraordinary times for mankind and the matters connected with the same, including the production of the vaccine and other medical kits, have a huge public interest which needs to be served keeping in mind the health and well-being of the entire mankind. In this background, it is very much required that big pharma companies that can produce COVID vaccine transfer the technology to other pharma companies for quick and mass production of a vaccine to ensure that the population across the globe is vaccinated at the earliest to gain immunity and resistance power to tackle and withstand with any further waves of COVID-pandemic in the near future.

It is inferred that pharma companies from other countries would also fear using such technology without the permission of these big pharma companies; otherwise, they have to face huge patent infringement litigations. In this regard, keeping in mind the emergency that has been resulted because of the COVID pandemic, it is very required that international society should resolve to either convince big pharma companies to transfer their technology by using the flexibilities under the TRIPS agreement are intellectual property and patent rights should be suspended temporarily until we have successfully controlled the COVID through complete vaccination to the global mass. At this juncture, the exceptions prescribed in the patent regime for patent conferment are of an interesting reading.

1. Exceptions in Patent Regime in the context of Right to Health

Perhaps, patent rights are not permanent and have certain exceptions in the context of the right to health and medicine, which are very well established. The Patent system does the Act of balancing private and public interests. On the one hand, it protects the interests of the pharmaceutical companies that invest heavily in the research and development of drugs, and on the other, it intends to promote public health in their respective countries. This balancing act is supported by the exceptions clause under the international patent law as provided under the TRIPS agreement. These exceptions have also been part of the patent regimes across the globe as per the TRIPS mandate. There are three potential and permissible exceptions to the basic rule on patentability and patent conferment under TRIPS agreements which are as follows:

1. Inventions contrary to public order, such as inventions dangerous to animals or humans or

[1] Arya, Selfishness should be avoided to get everybody vaccinated, (Translation from Telugu language) Eenadu Telugu Daily, Monday, My 17th, 2021, available at eenadu.net

seriously prejudicial to the environment or plant life or health, are not allowed for patenting[2].

2. Inventions related to diagnostic, therapeutic and surgical methods for the treatment of humans or animals are exempted from patent conferment.

3. Inventions of plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.[3]

It is also provided that; members may also provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties.[4]

2. Compulsory Licences

Across the globe, patent regimes provide for compulsory licensing of patented inventions in case of need and requirement. At the international level, the TRIPS Agreement allows the use of compulsory licences, which enable a competent state authority to license the use of a patented invention to a third party or government agency with or without the consent of the patent-holder. However, there are certain conditions and limitations to granting compulsory licensing.[5] These conditions include

1) Case-by-case determination of compulsory licence applications.

2) The need to demonstrate prior (unsuccessful) negotiations with the patent owner for a voluntary licence

3) The payment of remuneration to the patent holder accordingly.

Where compulsory licences are granted to address national emergencies or other circumstances of extreme urgencies, such as the current COVID-pandemic prior consultation with the patent owner to get a voluntary license is not required. Mostly, it is left to the nations to determine the established conditions suitable to issue a compulsory licence in the public interest. The Doha Declaration also states that each Member state has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

3. Compulsory licensing under Indian Law

Indian Patent law does talk about compulsory licensing, and it is one of the fundamental provisions of the law. Perhaps, the Act provides for compulsory licensing after the expiration of three years from the date of the grant of a patent[6]. A compulsory licence may be granted if:

- the reasonable requirements of the public have not been met;

- the patented invention is not available at a reasonable price to the public; or

[2] TRIPS agreement under Article: 27 3 (a). The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of order public or morality

[3]TRIPS agreement under Article 27.3(b). However, any country excluding plant varieties from patent protection must provide an effective sui generis system of protection. Moreover, the whole provision is subject to review four years after entry into force of the Agreement.

[4]TRIPS agreement under Article 30

[5] TRIPS agreement under Article 31 sets forth a number of conditions for the granting of compulsory licensees.

[6] Ibid, Section: 84

- the patented invention is not being used in India.

- Further, the Act stipulates that the conditions necessary for granting a compulsory licence will be waived in case of[7]:

- a national emergency;

- other circumstances of extreme urgency;

- public non-commercial use; or

- anti-competitive practices by the patentee.

It is established under the Act[8] that "*the central government, on being satisfied with the existence of conditions of emergency, extreme urgency or public non-commercial use, can waive the three-year requirement mentioned in Section 84, as well as the procedural requirements pertaining to the grant of a compulsory licence under Section 87. Further, the central government is empowered to acquire an invention that is the subject of a patent or a patent application when it is satisfied that it is necessary to do so in the public interest*[9]*. It can do this by publishing a notification to that effect in the Official Gazette. However, the central government must pay any compensation as may be agreed upon between it and the applicant, patentee or related person; in the absence of such an agreement, the amount of compensation is to be decided by the High Court*".

For this reason, it is evident that the Indian Patent Act could be so flexible in dealing with numerous potential challenges, especially relating to public health emergencies. In fact, it succeeds in striking a balance between the rights of the patentee and the rights of the affected public at large. As we observe, the Union government is able to grant a compulsory license to other manufacturers to manufacture a product without the authorization of the patent holder in case of national emergency, extreme urgency, in case of public non-commercial use. Since the pandemic is a situation of public emergency, the government can issue licenses to other manufacturing units to ramp up the production of COVID vaccines overriding the authorization of the patent holder.

India granted its first compulsory licence on pharma patents in 2011 to a company called Natco Pharma over a compound called sorafenib tosylate. In this case, Bayer Corp. was the inventor company, and it marketed sorafenib tosylate under the name 'Nexavar' to help treat liver cancer. Bayer subsequently challenged the compulsory licence before the Intellectual Property Appellate Board, the Bombay high court and finally, the Supreme Court of India. All appeals were dismissed. In *Novartis AG v. Union Of India,*[1] the Supreme Court viewed that; compulsory licensing is required to prevent the ever-greening of patented products and give relief to those who can't afford the lifesaving drug as these pharmaceutical companies sell such lifesaving drugs at a very high price hence unaffordable for the common man. In a developing country like India, it is necessary that the availability of medicines at a cheaper rate is ensured for the lives of 1 billion people and for this reason if the required government should not shy away from using the measure of compulsory licensing. Further, in the case of medicine or drug patents, the government is allowed to import the relevant medicine or drug for merely its own use in the public interest or for

[7]Section 84(6), The Indian Patent Act

[8] Ibid, Section: 92

[9] Ibid, Section: 102

[1] 2013, 6 SCC, 1

public distribution purposes. There is an attempt to balance public health with patents under the Act[1]. Further, it focuses on ensuring that the patents granted do not impede the protection of public health or in any way prohibit the central government from taking measures to protect public health and for ensuring the availability of the patented invention at reasonably affordable prices to the public. The ongoing novel coronavirus pandemic certainly qualifies as a national emergency under *the Patents Act*[1]. Therefore, the government, through compulsory licensing, can authorize leading pharmaceutical companies to produce COVID-related vaccines to ensure India fulfils its national and international obligations.

4. Right to health in the Indian context

The Indian Patents Act, 1970[1] states that *"an invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or the environment, is not patentable."* It is very pertinent to note that gene therapy, biopharma, etc. aid in protecting the right to health, and it can be said that the right to health is being aided through biotech. In the case of *MK Sharma v Bharat Electronics*[1], also right to health was said to be comprised as part of the right to life under article 21. In another case of*ParmanandKatariav UOI*[1], it was stated that the right to health and the right to medical assistance is part of the right to life under article 21. In *Vishakha v State of Rajasthan*[1] Supreme Court gave the International Treaty obligation the status of the rule of law while debating in the context of the Helsinki Declaration, which talks about the right to health and legal assistance. In *MC Mehta v UOI*[1], Supreme Court directed the government to bring regulations with respect to health and read health policy as an obligation of the state under DPSP (Part IV) of the Indian Constitution. The DPSP, in the form of Articles 48 A and 47,[2] cast an obligation on the state to improve the public health of the individuals.

5. Right to Health under International Law

Article 12 of the International Convention on Economic, Social and Cultural Rights mandates the state to recognize the right of every state to guarantee[3] their citizens' right to enjoy the highest attainable standard of life. Article 25 of the UDHR makes every member nation guarantee their citizens the right to health. Various international conventions like UDHR in Article 27(2) and ICESCR in Article 15 (1)(c) link IPR's and human rights and provide the basis for human rights for patent rights or other forms of IPR's. The Doha Declaration[1] on the TRIPS Agreement and Public Health recommends circumventing[4] patent rights for better access to essential medicines. Through the Doha Declaration, governments agreed that The TRIPS Agreement [5] should not prevent Members from taking measures to protect public health and implementation of the agreement be done in support of the right to public health and, in particular, to promote

[1] Ibid, Section: 83 [1]

[1] *section 92 of the Indian Patent Act* [2]

[1] Section 3(b) of the Indian Patent Act [3]

[1] AIR, 1987, SC 1792 [4]

[1] AIR 1989, SC 2039 [5]

[1] 1997, 6 SCC, 241 [6]

[1] AIR 2002, SC 1696 [7]

[1] Doha Declaration was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. [8]

access to medicines for all. The Declaration also specified that Each Member state has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. In 2003, the WTO further allowed developing countries to waive the observance of the patent regime and simply import generic drugs from another developing country. This was further encoded in an amendment to the WTO IP rules in 2017. India, in particular, having manufacturing capacities, has been able to benefit from this provision. By compulsory licensing, it has been able to provide its populations with generic and subsidized drugs at affordable rates, boosting global accessibility. However, not many other countries have been able to benefit from the provision of compulsory licensing apart from Brazil and China, which also have their own manufacturing capacities.

Conclusion

In the times of pandemic since the very early days of the pandemic, several concerns have been raised about the implications of strict enforcement of patents held over potential COVID-19 vaccines or treatment alternatives. India and South Africa proposed that members of the World Trade Organisation waive intellectual-property IP protections for COVID-fighting technologies, including vaccines. In October last year, India and South Africa proposed before the WTO to allow the suspension of patents linked to COVID-19 treatment till global immunity is reached. This proposal was widely supported by other lower and middle-income countries, WHO and leading UN experts but could not see the light of day. However, the drug makers warn that it would deal a crippling blow to innovation. Even though patent protections are not a big constraint on vaccine production today, the experience of COVID-19 suggests that a re-examination of patent rights in the context of health emergencies is overdue. It is argued that a pandemic is clearly an extreme event that warrants an exemption from patent laws. The rapid creation and production of numerous COVID-19 vaccines is a testament to the so many years of private investment and research in the associated technologies and the urgency with which experts at biotech firms moved when the beginning of the pandemic. New variants of the virus are appearing that show signs of being more transmissible, more deadly and less susceptible to vaccines. The threat is clear because as long as the virus is spreading anywhere, it has more opportunities to mutate and potentially undermine the efficacy of vaccines everywhere.[1] In this context, some pharmaceutical companies, including AstraZeneca, have signed sub-licence agreements with several producers, including the Serum Institute of India, to increase the supply of future vaccines. AstraZeneca is also said to have agreed to provide vaccines at 'non-profit' prices for as long as the pandemic lasts. Further, Gilead has licensed its Remdesivir patents to generic manufacturers in India, Pakistan and Egypt for supply in 127 countries. Others like Pfizer and Sanofi have made agreements to transfer technology, such as the finishing of vaccine vials. Canada has also made deals with individual companies and is setting up entirely new manufacturing units, which will produce new doses in a matter of months. Germany and Israel have even issued orders for compulsory licensing for any patent-protected drugs which could be

[1] Abbas Poorhashemi, Reforming the United Nations: United of Nations or United of States?, LAWINTER REVIEW - Volume XII– nº 02 – 2021, For the text of the article see: http://www.lawinter.com/98_101lawinterreview.pdf#page=7

used for the treatment of the deadly disease. The trend of globalization is slowing down, reverse globalization has been happening since COVID:19, and anti-globalization is growing in the current scenario.[2] Global organizations like WHO and WIPO suggested that the WTO countries should invoke security exception mentioned under the TRIPS Agreement[2], necessary for security interests in such a threatening time to secure necessary medical products and technologies to face such an emergency and should support the developing countries to suspend their patent rights which may create hindrance for manufacturing of products to protect their population and public welfare.

In times of pandemic such as COVID, public health should be given priority over any economic issues, including patent rights. In an attempt to prioritize public health, the World Health Organisation (WHO) established the COVID-19 Technology Access Pool (C-TAP) in June 2020, which aims to gather patents and all other forms of intellectual property to expand the development and production of new technologies. These technologies are needed for this purpose. However, this is a voluntary mechanism and does not force those who own the rights and knowledge to collaborate. These are significant steps, but we cannot rest until everyone has access, and we need to ensure sustainable vaccine supply chains for the long term that is vastly bigger than what we have now.

6. It is argued that the environmental problems in the contemporary world necessitated the greater emergence of international environmental law[2]. In similar lines, the contemporary problem that is COVID:19 necessitated the international society to debate on the globally acceptable international health care law. It is observed that certain developed countries have gone for stocking doses of vaccines and also placed huge orders in advance for vaccines with big pharma companies, whereas developing countries are relying on international support to vaccinate their population. Even during the crises of HIV/AIDS, the same situation was in the place where developed countries were able to face the problem adequately, and the developing countries suffered a lot. It gives rise to the issue of access to medicine and vaccine, for which not only local governments initiatives are important but as well international cooperation for ensuring public health is on priority in the current pandemic times of COVID.

[2] Agata zwolankiewicz, The Brave New World of Foreign Investment in the Wake of COVID-19 Pandemic: Current Situation and Potential Disputes, CIFILE Journal of International Law, CIFILE, Toronto, Canada, Volume: 2, Issue: 4, 2021 available at http://www.cifilejournal.com/article_130844.html

[2] Article 73 of the TRIPS Agreement

[2] Abbas Poorhashemi, Emergence of international environmental law as a new branch of international public law, CIFILE journal of International Law, CIFILE, Volume:1, Issue:2, Summer, 2020, available at http://www.cifilejournal.com/article_106534.html

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