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Role of Patent Law in Covid-19 Pandemic: An Analysis

AJOY JOSE[1] AND DR. TAPAS BANDYOPADHYAY[2]

ABSTRACT

Equitable access to safe and effective vaccines is critical to ending the Covid 19 pandemic, so it is hugely encouraging to see many vaccines proving and going into development. Equitable access to safe and effective vaccines is critical to ending the Covid 19 pandemic, so it is hugely encouraging to see so many vaccines proving and going into development. Safe and effective vaccines are a game changing tool, but for the foreseeable future we must continue wearing masks, cleaning our hands, ensuring good ventilation indoors, physically distancing and avoiding crowds.

Being vaccinated does not mean that we can throw caution to the wind and put ourselves and others at risk, particularly because research is still ongoing into how much vaccines protect not only against disease but also against infection and transmission. But its not vaccines that will stop the pandemic, its vaccination. We must ensure fair and equitable access to vaccines, and ensure every country receives them and can roll them out to protect their people, starting with the most vulnerable.

I. INTRODUCTION

Patents grant vaccine developers exclusive rights to produce the vaccine they developed. They can also charge a price that covers their research and development expenses, however large profit margins can be contentious in times of crisis, such as the current Covid pandemic. A patent waiver would allow any company with the necessary capacity to begin producing the shot, even though the original creator had not agreed to it. If the Covid 19 pandemic is to be halted, equal access to safe and effective vaccines is critical, so seeing so many vaccines being tested and produced is highly encouraging[3]. Safe and effective vaccines are a game-changing weapon, but for the time being, we must continue to wear masks, wash our hands, maintain good indoor ventilation, and physically distance ourselves from crowds. Being vaccinated does not exempt us from exercising caution and putting ourselves and others at risk, particularly because research into the extent to which vaccines protect not only

[1] Author is a Doctoral Research Scholar at RGSOIPL, IIT Kharagpur, India.
[2] Author is an Associate Professor at Metallurgical and Materials Engineering, IIT Kharagpur, India.
[3] Barrios, L. C., Koonin, L. M., Kohl, K. S., & Cetron, M. (2012). Selecting Nonpharmaceutical Strategies to Minimize Influenza Spread: The 2009 Influenza A (H1N1) Pandemic and Beyond. *Public Health Reports (1974), 127*(6), 565–571. https://www.jstor.org/stable/23646639

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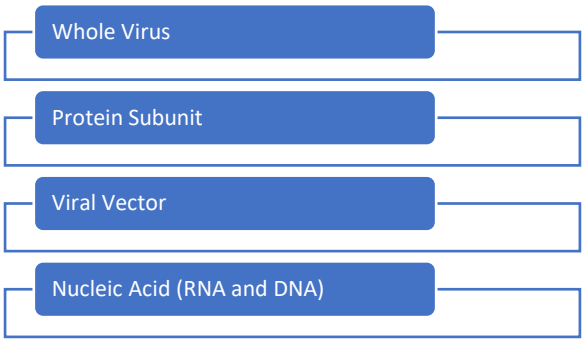
against disease but also against infection and transmission is still ongoing. But it is prevention, not vaccines, that would put an end to the pandemic. We must ensure that vaccines are distributed fairly and equally, and that every nation receives them and is able to use them to protect its citizens, beginning with the most vulnerable[4]. All Covid 19 vaccines in production aim to induce immunity to the SARS CoV 2 virus by eliciting an immune response to an antigen, which is usually the virus's signature spike protein. In clinical trials, there are four types of vaccines[5].



(A) Whole Virus

To elicit an immune response, many traditional vaccines use whole viruses. There are two key approaches to this issue. A weakened version of the virus is used in live attenuated vaccines, which can still reproduce without causing illness. Inactivated vaccines use viruses that have had their genetic material killed, making them unable to reproduce but still capable of eliciting an immune response.

(B) Protein Subunit

To elicit an immune response, subunit vaccines use parts of the pathogen, typically protein fragments. It reduces the risk of side effects, but it can also weaken the immune response.

This is why adjuvants are often used to help improve the immune response.

(C) Viral Vector

Vaccines based on viral vectors function by giving cells genetic instructions to make antigens.

They differ from nucleic acid vaccines in that they transmit these instructions into the cell using a harmless virus that isn't the one the vaccine is targeting. Vaccines based on viral vectors can mimic natural viral infection and, as a result, should elicit a strong immune response.

(D) Nucleic Acid

RNA or DNA are used in nucleic acid vaccines to give cells the guidance they need to produce the antigen. This is normally the viral spike protein in the case of Covid 19. If this genetic material enters human cells, it uses our cells' protein factories to create the antigen that will activate the immune system.

The current issue is a demand-supply imbalance, which is primarily due to vaccine manufacturing

[4] *An Unnecessary Proposal on JSTOR*. (n.d.). Retrieved May 8, 2021, from https://www.jstor.org/stable/resrep27669?Search=yes&resultItemClick=true&searchText=patent+vaccine+public+good+compulsory&searchUri=%2Faction%2FdoBasicSearch%3FQuery%3Dpatent%2Bvaccine%2Bpublic%2Bgood%2Bcompulsory%26acc%3Doff%26wc%3Don%26fc%3Doff%26group%3Dnone%26refreqid%3Dsearch%253A72ac94efb3f64a3726179ba0f64e63b1&ab_segments=0%2FSYC-5770%2Ftest&refreqid=fastly-default%3Ae7dc22a0bcf9f634f11fa08ca17a19ce&seq=1#metadata_info_tab_contents

[5] *There are four types of COVID-19 vaccines: Here's how they work*. (n.d.). Retrieved May 14, 2021, from https://www.gavi.org/vaccineswork/there-are-four-types-covid-19-vaccines-heres-how-they-work

capacity limitations. To close this void, there is growing pressure to use the Patents Act of 1970's provision of "compulsory licencing," as was done a decade ago for cancer care[6]. The compulsory licence provision allows the Indian government to grant manufacturing rights to other producers without the owner's consent in the case of a proprietary product, particularly during national emergencies. In 2017, the Indian Patent Office granted the Hyderabad-based drug manufacturer Natco India's first compulsory licence under the amended 2005 Act. It helped the company to produce and market a drug that was similar to Bayer's Nexavar for the treatment of kidney cancer. The compulsory licence was issued because the life-saving medication was not available at a fair price and Bayer had not produced the drug in India to a reasonable degree. India and South Africa submitted a proposal to the World Trade Organization (WTO) in October 2020 to loosen provisions in international agreements that control IPR for medicines and vaccines required for the treatment and prevention of Covid-19[7].

In India, medical experts believe that since the vaccine was developed with the help of the ICMR, vaccine technology could be transferred from Bharat Biotech to other manufacturers using the open licence process. However, it is important to note that the ICMR's assistance is comparable to banks providing startup funding. As a result, since Bharat Biotech is a different body from the government, it is not possible to take away the vaccine manufacturer's IPR.

Since they are all separate bodies, legal disputes often arise even within different PSUs or government agencies.

Several developing countries have requested other WTO members to join them in a wide waiver of IPR related to those vaccines, citing the dissatisfaction with global efforts to ensure that Covid 19 vaccines are available to all citizens everywhere. Their request for a waiver reignites a long-running debate within the WTO about how to strike the right balance between protecting IPR and ensuring that developing countries have access to critically needed medicines[8]. In the other hand, the WTO wants to have another discussion about alleged trade barriers to public health. Unless WTO members reach an agreement, a delay in resolving the two-decade-old dispute between developed and developing countries over compulsory licencing and generic distribution of HIV/AIDS drugs may further complicate the multilateral trade process.

India and South Africa asked WTO representatives in early October 2020 to waive patent, copyright, industrial design, and trade secret protections in relation to the "prevention, containment, or treatment of Covid-19" before

[6] Bonadio, E., & Baldini, A. (2020). COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health. *European Journal of Risk Regulation*, *11*(2), 390–395. https://doi.org/10.1017/err.2020.24

[7] Chesbrough, H. (2020). To recover faster from Covid-19, open up: Managerial implications from an open innovation perspective. *Industrial Marketing Management*, *88*, 410–413. https://doi.org/10.1016/j.indmarman.2020.04.010

[8] Bruynseels, K. (2020). Responsible innovation in synthetic biology in response to COVID-19: The role of data positionality. *Ethics and Information Technology*. https://doi.org/10.1007/s10676-020-09565-9

universal vaccination and immunity has been achieved for the majority of the world's population. India and South Africa want to give all WTO members the ability to refuse to grant or enforce patents and other IP rights related to COVID-19 vaccines, drugs, diagnostics, and other innovations for the duration of the pandemic. In their waiver request, India and South Africa argued that "an effective response to the Covid-19 pandemic needs urgent access to accessible medical supplies, such as diagnostic kits, medical masks, other personal protective equipment, and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in critical need." The WTO representatives failed to achieve the necessary consensus to continue with the proposed waiver later in October. The waiver offer was rejected by the European Union, the United States, the United Kingdom, and other developing countries[9].

II. COMPULSORY LICENSES

The flaws in India's vaccination programme have been highlighted in the last month, as the deadly Covid 19 outbreak swept the region. Vaccination centres across the country are running out of vaccine, and at this pace, India will not achieve herd immunity by the end of the year. In simple terms, when the government issues a compulsory licence, it allows anyone to manufacture or sell an invention or product without first obtaining permission from the patent holder. Compulsory licencing in India is governed by two essential provisions of the Patents Act of 1970. The first is Section 92. In times of national or serious emergency, the government will declare compulsory licencing for any patented invention under this clause. The controller general of patents may award licences to any applicant after a declaration is made. The controller general would set a royalty for the patent holder[10]. On the other hand, Section 100 of the Act requires the Centre or others to use the technology for government purposes if it is considered appropriate. This would allow Indian firms to begin production while the royalty is being worked out. If the negotiations fail, the High Court of Justice has the authority to set a fair royalty.

III. CENTRE'S STAND

The issue was raised by the Supreme Court in a broad case that included everything from oxygen allocations, for which it established a National Task Force, to vaccine policy. In its affidavit to the court, the Centre, on the other hand, claimed that it was opposed to compulsory licencing. In its affidavit, the Centre uses muddled terminology to communicate its stance, making no explicit distinction between vital drugs and vaccines. The Centre has requested that the court refrain from discussing the exercise of regulatory powers in the case of vaccines and critical drugs.

[9] *COVID-19 and Global Inequality from COVID-19 in the Global South: Impacts and Responses on JSTOR*. (n.d.). Retrieved May 8, 2021, from https://www.jstor.org/stable/j.ctv18gfz7c.22?Search=yes&resultItemClick=true&searchText=patent+and+covid+vaccine&searchUri=%2Faction%2FdoBasicSearch%3FQuery%3Dpatent%2Band%2Bcovid%2Bvaccine&ab_segments=0%2FSYC-5770%2Ftest&refreqid=fastly-default%3A9835cd7cd2a508f9d393c212892a3a73&seq=1#metadata_info_tab_contents

[10] Hein, W., & Paschke, A. (2020). *Access to COVID-19 Vaccines and Medicines – a Global Public Good*. German Institute of Global and Area Studies (GIGA). https://www.jstor.org/stable/resrep25695

However, this line appears in a segment on mandatory licences that focuses on medicines. The government's stance, according to experts, should be expected to refer to both vital medicines and vaccines. This includes a statement in the affidavit that the government may consider a manufacturer's application for a compulsory licence under Section 92 of the Patents Act[11].

IV. BALANCING IP RIGHTS AND ACCESS TO MEDICINES

This waiver debate comes nearly two decades after the conclusion of the multilateral trading system's long fight over HIV/AIDS drug access.WTO members "may adopt measures necessary to protect public health in formulating or amending their law and regulations, given that such measures are compatible with the provisions of this Agreement," according to Article 8 of the TRIPS Agreement.In a similar way, Article 7 of the TRIPS Agreement states that "protection and regulation of intellectual property rights" must be done "in a manner conducive to social and economic welfare." The patent holders, who had invested billions of dollars producing the drugs, were adamant about not cutting their costs. An prolonged debate about whether patent rights should take priority over supplying inexpensive drugs for people suffering from a fatal disease tarnished the reputation of the firms, the countries that backed them, and the WTO itself[12].

In the Doha Ministerial Declaration, signed in November 2001, WTO members explained that each WTO member "has the right to grant compulsory licences and the freedom to determine the grounds on which such licences are granted." In August 2003, WTO members approved a waiver that allows developing countries that lack the capacity to produce pharmaceutical products and thus are unable to benefit from compulsory licencing to import cheaper generic drugs from countries where those drugs are patent-protected, as a follow-up to the 2001 declaration[13].

Compulsory licencing of drugs is unpopular among private drug producers because it deviates from market-based capitalism's usual workings. Compulsory licencing, however, is not a

[11] *Immunity for the People: The Challenge of Achieving High Vaccine Coverage in American History on JSTOR*. (n.d.). Retrieved May 8, 2021, from https://www.jstor.org/stable/20057121?Search=yes&resultItemClick=true&searchText=patent%20vaccine%20public%20good%20compulsory&searchUri=%2Faction%2FdoBasicSearch%3FQuery%3Dpatent%2Bvaccine%2Bpublic%2Bgood%2Bcompulsory%26acc%3Doff%26wc%3Don%26fc%3Doff%26group%3Dnone%26refreqid%3Dsearch%253A72ac94efb3f64a3726179ba0f64e63b1&ab_segments=0%2FSYC-5770%2Ftest&refreqid=fastly-default%3Ae7dc22a0bcf9f634f11fa08ca17a19ce&seq=1

[12] *Intellectual Property Rights and Access in Crisis | SpringerLink*. (n.d.). Retrieved May 21, 2021, from https://link.springer.com/article/10.1007/s40319-021-01041-1

[13] *The Experiences of TRIPS-compliant Patent Law Reform in Brazil, China, India and South Africa—Lessons for Bangladesh from Intellectual Property and Public Health in the Developing World on JSTOR*. (n.d.). Retrieved May 8, 2021, from https://www.jstor.org/stable/j.ctt1d41dm1.10?Search=yes&resultItemClick=true&searchText=patent+vaccine+public+good+compulsory&searchUri=%2Faction%2FdoBasicSearch%3FQuery%3Dpatent%2Bvaccine%2Bpublic%2Bgood%2Bcompulsory%26acc%3Doff%26wc%3Don%26fc%3Doff%26group%3Dnone%26refreqid%3Dsearch%253A72ac94efb3f64a3726179ba0f64e63b1&ab_segments=0%2FSYC-5770%2Ftest&refreqid=fastly-default%3Ae7dc22a0bcf9f634f11fa08ca17a19ce&seq=1#metadata_info_tab_contents

derogation from the WTO members' balance struck between securing IP rights and maintaining access to essential medicines, as these acts by WTO members in 2001, 2003, and 2017 demonstrate. The WTO treaty strikes a balance by allowing compulsory licencing during health emergencies[14].

V. IP ISSUES INVOLVED IN COVID 19

Pharmaceutical companies participating in the global vaccine race have spoken out against the pandemic's proposed waiver of IP privileges. They also warned that compulsory licencing, which would allow their Covid-19 vaccines to be replicated without their permission, would stifle innovation and put people at risk of contracting dangerous viruses. During a pandemic or other global health emergency, it's one thing to temporarily delegate IP privileges to urgent public needs. It's quite another to rule out "profitability" from all policymaking including "access to vaccines, required tests and treatments, and all other medical goods, services, and supplies."

VI. WHETHER MEDICINES SHOULD BE "PUBLIC GOODS"?

Any protection of intellectual property rights of such products is regarded as a breach of human rights and the public interest. However, this viewpoint ignores the reality that many drugs would be unavailable if intellectual property rights and the security they provide were not in place. Intellectual property rights are technically an exception to free trade. The ongoing global controversy over the production and delivery of COVID-19 vaccines is just the latest example.

The primary reason for granting and securing intellectual property rights is that they act as incentives for innovation, which is the primary source of long-term economic development and improvements in human life quality. IP rights encourage creativity by allowing innovators to benefit enough from their own creative work to justify taking significant risks[15]. The experience gained from IP-enabled inventions is passed on to inspire new ideas. The defence of intellectual property rights encourages the spread of emerging technology and new know-how both domestically and globally. The defence of intellectual property rights encourages the spread of new technology and know-how both domestically and internationally.

Land, labour, and capital have traditionally been the primary factors of development. Perhaps an even more important element in the modern pandemic world is the creation of awareness, which adds enormously to "national resources." In the twenty-first century, digital and other forms of economic development are becoming increasingly idea-driven and knowledge-intensive. There would be less new knowledge and therefore less creativity if IP rights were not

[14] *The race for the COVID-19 vaccine: A story of innovation and collaboration | CF - Carnall Farrar*. (n.d.). Retrieved May 21, 2021, from https://www.carnallfarrar.com/articles/the-race-for-the-covid-19-vaccine-a-story-of-innovation-and-collaboration/

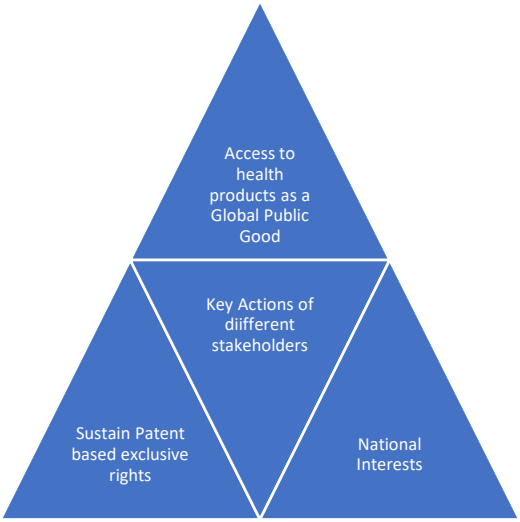
[15] Rahman, M., Bhuiyan, N. A., Kuhn, I., Ramamurthy, T., Rahman, M., Mollby, R., & Nair, G. B. (2006). Biochemical Fingerprinting of Vibrio parahaemolyticus by the PhenePlate System: Comparison between Pandemic and Non-Pandemic Serotypes. *Epidemiology and Infection*, *134*(5), 985–989. https://www.jstor.org/stable/3865901

used as rewards.

VII. VACCINES: GLOBAL PUBLIC GOOD

The idea of a global public good implies that potential vaccinations must be both non-excludable (i.e., widely available to all) and non-rival, since any person's immunisation benefits everyone else. Since public goods are not created by market forces, they must be provided by collective action. This raises the issue of why funding provisions are made, as well as the processes for allocating globally available capital. Collective action seems impossible at first due to a lack of resources to combat other global humanitarian crises[16].

On second thought, there could be a real opportunity to pool financial resources and actions on a global scale at this stage. Indeed, world leaders have pledged to work together in unprecedented ways to ensure that everyone has access to COVID-19-related health products and tests. The economic consequences of fighting Covid-19 are expected to cause significant instability in the global economy, not just for many countries on a national level. There have been many international donor-pledging conferences since the beginning of the pandemic, each raising billions of euros for vaccines and medicines. These commitments are in response to the pandemic's devastating effects around the world[17].



Because of the scale and all-encompassing nature of the Covid-19 crisis, many people believe it should be seen as an opportunity for a fresh start in global collective growth. However, the starting point is a paradox: on the one hand, it is seen as proof of globalization's limits, pointing to the effects of disruption of global value chains and an inward orientation among societies in the fight against the disease; on the other hand, never before has there been a situation in which political discourses all over the world have focused on nearly the same political stance[18].

[16] *Thinking Slow About IP in Times of Pandemic | SpringerLink*. (n.d.). Retrieved May 21, 2021, from https://link.springer.com/article/10.1007/s40319-020-00942-x

[17] *Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development on JSTOR*. (n.d.). Retrieved May 8, 2021, from https://www.jstor.org/stable/4498904?Search=yes&resultItemClick=true&searchText=patent+vaccine+public+good+compulsory&searchUri=%2Faction%2FdoBasicSearch%3FQuery%3Dpatent%2Bvaccine%2Bpublic%2Bgood%2Bcompulsory%26acc%3Doff%26wc%3Don%26fc%3Doff%26group%3Dnone%26refreqid%3Dsearch%253A72ac94efb3f64a3726179ba0f64e63b1&ab_segments=0%2FSYC-5770%2Ftest&refreqid=fastly-default%3Ae7dc22a0bcf9f634f11fa08ca17a19ce&seq=1#metadata_info_tab_contents

[18] Niankara, I., Muqattash, R., Niankara, A., & Traoret, R. I. (2020). COVID-19 Vaccine Development in a Quadruple Helix Innovation System: Uncovering the Preferences of the Fourth Helix in the UAE. *Journal of Open Innovation:*

VIII. CONCLUSION

The growth and availability of Covid-19 vaccines and drugs, as well as policies to resolve the economic crisis, are all highly reliant on global cooperation. Despite the urgent need for COVID-19 medicines and vaccines, experts caution against circumventing current regulatory protections in favour of faster access to immature and potentially dangerous items. They also advocate for entrusting accountability to a supranational body capable of establishing a framework for fair selection, procurement, access, and distribution across all countries. The current pandemic could be a game changer for access to medicines if the global community succeeds in resolving national protectionism impulses and focuses more on defending people's rights to equal access rather than industry's rights to patents.

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Technology, Market, and Complexity, *6*(4), 132. https://doi.org/10.3390/joitmc6040132