

Biotechnological Invention and Ipr: Patent Waiver for Covid-19 Vaccine

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ABSTRACT

For as long as one can remember, Intellectual Property Rights or rather the protection conferred by virtue of Intellectual Property Rights has enabled innovators to come up with exciting new inventions and discoveries which have had a significant impact on the human society in order for it to make strides in innovation and development. For instance, the invention of the Light Bulb by Thomas Edison and securing its patent helped him manufacture the light bulb and market it easily. As a consequence of which, the light bulb can now be found in each house and the patent protection ensures the right of the inventor over its discovery and prevents others from copying it. However, the other viewpoint is that had it not been for patent protection, the light bulb would have been more common in the streets of New York when it was invented and owing to the high market competition, it would even lead to being sold at cheaper prices. From this vantage point, the conscious decision of not patenting the Polio vaccine was taken, for it was a biotechnological invention that eventually helped in the eradication of Polio from the world. Had the makers of the Polio vaccine decided to patent the invention, it would not have been as accessible as it is. This paper attempts to focus on theories of social justice and ascertain the philosophy behind the Intellectual Property Rights in terms of biotechnological inventions tracing their journey from where it started to how far along it is in the process of making human lives simpler in the present times. Furthermore, the paper attempts to bring forth the repercussions of patenting the Covid-19 Vaccine and the implications, both social and legal, of the “Covid-19 vaccine waiver” trend which seems like a promising avenue amidst these times when a global pandemic is wreaking havoc on the entire world.

Keywords: Covid-19, Vaccine, Patent Law, IPR, Philosophy, Patent Waiver.

INTRODUCTION

The protection conferred under Patent Rights is given to the inventors and innovators under Intellectual Property Rights Act, which in turn, encourages them to effectively channelize their minds and resources into creating an invention which has the potential to change the course of human life as we know it. While the relentless zest of the inventors to bring about a change, for the better, has the potential to increase the living standards and even cure diseases that are deemed incurable, when viewed from an economic lens- it problematizes their stance within the larger framework of the IPR network. Even more pertinent is the postulation with respect to the very existence of the Patent Laws. To iterate, it raises questions about the heavy investments people are willing to make in new inventions and innovations. The explanation for this stems from the basic understanding of how the economy works- for instance, the Board of Directors of a certain company, are more likely to invest heavily in the marketing or promotion of a certain product, instead of dedicating huge sums to the Department of Research and Development alone. Therefore, the

need for Patent Protection, in reference to the example cited above, becomes especially clear. To build on that, the Board of Directors may dedicate huge sums to the Department of Research and Development in an attempt to come up with better and effective products to help them gain competitive advantage and Patent Rights prevent their competitors to steal or copy their invention, which gives the company “*First Movers Advantage*” and stay ahead in the competition, making huge profits in the way and balancing the cost incurred on the said invention. This philosophy of securing Intellectual Property Rights in turn fuels the success of Capitalism for centuries by providing the element of “*motive*” to work and invent.

The other perspective to view the same is rooted in socialism, and given the dynamic political nexus, it has to be taken with a pinch of salt. Securing Intellectual Property Rights ensures that the inventors preside over the supply of that particular good, because they invented the said good and thus have autonomy over the production and supply. This leads to the monopoly of the inventors or their company over that particular good in the market. While, this may be harmless if the company deals in something as banal and basic as Staplers, the company, Kangaroo for instance, but can have catastrophic effects if the company manufactures essential pharmaceutical drugs. Hence, the inventors of a lifesaving drug or perhaps, an agricultural company that could feed the entire globe and can prevent people from dying of starvation, choose to sell their product at a price, which not everyone can afford.

Therefore, the cons of bestowing the inventor with Intellectual Property Rights and the kind of power that comes with it, are often neglected in the modern world, which was particularly the case until the late 2019, when the first case of COVID-19 was registered and grossly multiplied, following which the race to develop a vaccine began.

I. EFFECTS OF COVID-19 ON THE IPR NEXUS: PPE KIT PRODUCTION ANALOGY

Without an iota of doubt, Covid-19 has had a significant impact on the human life which, at least in part, can never be reversed even if conscious efforts are made in that direction. The world of Intellectual Property Rights was also greatly affected by the pandemic. For instance, instead of according Patent Rights of the designs or medical equipment’s, etc., on the companies or individuals that came up with it, many companies were forced to share their patent with third parties for public interest at large¹. In fact, they were made to assuage the burden of producing or manufacturing these goods by turning their business into an altruistic profession by parting with their trade and production secrets. While, this was done primarily because a company or manufacturer has an upper limit on the number of supplies that they can provide for instance, the production of PPE kits- it led to an infringement of their Intellectual Property Rights.

ABC company has a patent over PPE kit which is safe against COVID-19, but the ABC company can only make 10,000 PPE kit in a day, whereas the State is in dire need for over a million PPE kit in a month, to be provided to front line workers as well as to export to the global community. Here in this instance, the only option is to forego the Patent of ABC company and share their patent with other factories, manufacturers or companies, so that the demand can be met. Failing which, it can have cataclysmic **Illustration:** effects on the health and well-being of the frontline workers as they would be exposed to the

¹ Mondaq, 2020, available at <https://www.mondaq.com/patent/992968/covid-19-and-its-effects-on-intellectual-property> (Last Modified on 09/10/2020)

virus, which can be proved fatal in some cases. Therefore, the fact that, the aforementioned terrible outcomes can be avoided if the Patent Rights are relinquished, the obvious choice is to waive the Patent Rights for the collective good of the community. Therefore, many governments across the world, suspended patent rights to fight to COVID-19, governments such as that of Germany². It is vital to ensure the availability of medical essential supplies in order to fight the pandemic and save human lives. In the course of achieving that, if Patent Laws become a hindrance, a few countries have managed to suspend them, whereas many developing and leading countries, are still debating over whether to suspend or wait through the process, such as India³.

However, the main issue at hand, arose not with the advent of Covid-19 and the unmet need to ensure adequate production of the PPE kits or medical supplies but, when the Covid-19 vaccine was successfully developed and manufactured by Private companies such as Pfizer or Biotech. According to the report of the *World Health Organization*, the world's Top 10 economies so far have spent over \$2.4 billion on developing Covid-19 vaccines⁴ which is as noble as it is, but according to another report, these economies have the potential for profiting over \$157 billion by 2025, by marketing and selling these vaccines⁵.

While profiting off an invention is acceptable in the modern world's economy which is steeped in capitalism, it is the distribution of goods on the basis of needs as ascertained by a centralized authority, that has caused a Cold war between the countries. At the risk of redundancy, it may be pertinent to say that the capitalist ideology has gained momentum and has in fact, at various levels, superseded the socialist economic model. Recently, the rich countries have invested billions of dollars in the process of vaccination development, seeking to make big money, especially by scrounging from the especially poor and vulnerable nations, that could not afford to invest in their own R&D program. Their dependence on the vaccines saw a fresh a new dawn with the rapidly rising corona cases, and hence used up their limited resources to purchase the vaccines in the desperate attempt to combat their economic and social collapse.

II. THE ETHICAL CONUNDRUM

Ethicality essentially “*involves systematizing, defending, and recommending concepts of right and wrong behavior*”⁶. Hence, an “ethical” act may be taken to mean as that which one ought to view as the right thing to do. In other words, different people or communities might have different perspectives of what is right and what is not. For the wealthy nations, selling off the vaccines at the market price to rest of the world, might be considered as right for they are entitled to earn the profits, given their investment in the

² Hugo Miller , Karin Matussek , Susan Decker , Stephanie Bodoni and Bloomberg, *Coronavirus crisis may bring out old tool in disease fights: suspension of drug patents*, FORTUNE, 02/04/2020, <https://fortune.com/2020/04/02/coronavirus-crisis-suspension-drug-patents/>

³ Rupali Mukherjee, Suspend patents on Covid-19 drugs in India to ensure accessibility & affordability, The Times of India, 27/06/2020, <https://timesofindia.indiatimes.com/india/suspend-patents-on-covid-19-drugs-in-india-to-ensure-accessibility-affordability/articleshow/77188105.cms>

⁴ World Health Organization, <https://www.who.int/news/item/03-12-2020-global-access-to-covid-19-vaccines-estimated-to-generate-economic-benefits-of-at-least-153-billion-in-2020-21>, Last visited on 07/11/2021

⁵ Kevin Dunleavy, Just how much COVID-19 vaccine money is on the table? A whopping \$157B through 2025, report says, Fierce Pharma, last visited on - 07/11/2021, <https://www.fiercepharma.com/pharma/how-much-covid-19-vaccine-money-table-157b-through-2025-analyst>

⁶ Internet Encyclopedia of Philosophy, <https://iep.utm.edu/ethics/> Last visited on 15/01/2022

vaccine research, and the resources employed in the development of vaccine at the times when the world economies were crumbling.

However, when viewed from the perspective of the poorer nations, the same it may be perceived as wrong and socially problematic because the poor nations are neither advanced enough to build their own vaccines nor can they afford to invest in the process of Research & Development. For instance, countries like Afghanistan or Syria would be likely to view the aforesaid situation as problematic from their perspective. Afghanistan has the population of around 40 million and GDP amounting to 75% of foreign aid, hence, it would not be reasonable to assume that the new regime of Afghanistan would be able to buy off the vaccine from the market to vaccinate its people. Same conclusions can be drawn about the war-torn country of Syria. Therefore, it can effectively be inferred from the aforementioned examples that there are a number of countries in the world, that are either too poor or too isolated to purchase the vaccine off of the global market.

This dilemma further propels another compelling debate around the dilemma that considering the notion that vaccinated people are safe from COVID-19 and that if the rich and powerful countries vaccinate their citizens, then that necessarily mean the end of COVID-19 such countries. In which case, these countries should just focus on getting their own citizens vaccinated. That, however, is not the case.

III. OBLITERATION OF COVID-19

In the present day's modern world, the concept of "Vaccine Nationalism"⁷ or the more generic term "Each for their own" gives rise to a behavioral approach in the western world⁸ - to hoard and vaccinate their own citizens first, and donating or selling excess vaccines to the poor or remote areas of the world. This behavioral approach is causing more harm than good, as buying and storing vaccine with the intention that if not used, will be donated to the poor countries, does not work, for the vaccines come with an expiry date and shelf life, after which the vaccines will not be any good and for all intent and purposes, be wasted⁹.

As mentioned above, the approach would work for wealthy or developed nations for a short term but not long term, because just as all other viruses, the Covid-19 is also prone to mutation and can possibly compromise and escape the immunity provided by the vaccination program¹⁰.

If the countries, continue to vaccinate their own citizens, by avoiding all the other nations that do not have the resources to combat Covid-19, it will culminate in the virus being unstoppable from infecting billions of people living in those countries. This will, therefore, provide an opportunity to the virus, to mutate enough times or to that extent that the virus will eventually become more deadly and may even alter its

⁷ Abhishek De, Explained: Vaccine nationalism, and how it impacts the Covid-19 fight, The Indian Express, 23/08/2020, <https://indianexpress.com/article/explained/what-is-vaccine-nationalism-how-does-it-impact-the-fight-against-covid-19-6561236/>

⁸ Daphne Psaledakis, Developing nations' plea to world's wealthy at U.N.: stop vaccine hoarding, Reuters, 23/09/2021, <https://www.reuters.com/world/developing-nations-plea-worlds-wealthy-un-stop-vaccine-hoarding-2021-09-22/>

⁹ World Health Organization, <https://www.afro.who.int/news/expiry-date-and-shelf-life-astrazeneca-covishield-vaccine-produced-serum-institute-india>, Last visited on 15/01/2022

¹⁰ Ewen Callaway, Could new COVID variants undermine vaccines? Labs scramble to find out, Nature, 07/01/2021, <https://www.nature.com/articles/d41586-021-00031-0>

structure so as to escape the immunization barrier created by the vaccine and still infect a person, and become more lethal than ever.

Hence, it can effectively be concluded from the aforesaid that, even if the wealthy and developed nations get all of their citizens vaccinated against Covid-19, they still would not be cent percent safe from the rather deadly pandemic as long as the Covid-19 virus is not eradicated from the face of the Earth. It is absolutely necessary for the world's leading powers to come together and face this pandemic, presenting a united front for nobody can be safe until even a single person with Covid-19 virus stays infected.

IV. SUSPENSION OF PATENT PROTECTION

“There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple”

- Norman Baylor¹¹

The conjecture around whether the suspension of patent rights of Vaccine of COVID-19 would help eradicate the Covid-19 and restore a sense of normalcy in the world is dependent on various factors, not limited to the scope of Patent Waiver proposal by India and South Africa in the WTO¹². The joint proposal by the governments of India and South Africa hopes to achieve the permission of World Trade Organization to get a Waiver on Patent Rights of Covid-19 vaccine under Trade Related Intellectual Property Rights¹³.

However, the said proposal seeks waiver on the mere patent of the vaccine, in other words, it will let the Member State forego their obligation, in which the government has to protect the “secret components of vaccines” that lend it its efficacy and hold those accountable who try to steal it. The waiver so sought, if approved would free the government of its obligation and in turn, allowing the domestic manufacturers to manufacture the vaccine. Since the vaccine would then be made domestically, significantly reducing the costs incurred in imports, etc., thereby making it available in the market very cheaply and expanding its distribution to wider and more remote areas.

So far, the idea of waiving the Patent rights seems rather utopic and the perfect solution for the Vaccine crisis but the truth is far from that. Waiving the patent rights of Covid-19, if achieved, would be symbolic at best. In reality, it is less likely to affect any practical aspect of our life. An analogy may be drawn with the possibility that, say, NASA releases its Rocket design to a car company and gives them permission to build their own rockets, it will not work, because despite having permission to copy, the car company would still not possess the experience, resources, skill set or even technology to build the rocket. These exact conclusions can be drawn in the case of Patent Waiver, because as farfetched as it may be, even if the wealthy nations allow the poorer nations to copy their patent and build their vaccines using that

¹¹ Formerly headed the Food and Drug Administration's Office of Vaccines Research and Review, and who is now president of Biologics Consulting.

¹² The Hindu, <https://www.thehindu.com/news/national/india-south-africas-patent-waiver-proposal-in-wto-achieved-tremendous-mileage-progression-commerce-secretary/article34778668.ece>, Last Visited on 08/11/2021

¹³ World Trade Organization, IP/C/W/669/Rev.1, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>, Last Visited on 15/01/2022

knowledge, the poorer nations would still lack the requisite skill set and technology to manufacture the said vaccine, let alone face hurdles post the manufacturing process that would entail packaging and transporting.

Patent Waiver of the said Covid-19 vaccine will not provide an adequate solution, as can be observed from the case of *Moderna*. Back in October 2020, *Moderna* vowed that when they launch their vaccine, they would not sue anyone over their patent rights, hence making their patent widely available for anyone to copy and manufacture the vaccine deploying that same knowledge. However, to this day, there have been no reports of that happening, because nobody else has the technology and the requisite knows-how to manufacture the vaccine.¹⁴

One of main criticisms of the proposal is that, the proposal is near sighted, as it seems to waive off the patent “temporarily” for a few months, whereas the pandemic can last longer and can linger on long enough for the waiver to collapse. Further, it is yet again, a “temporary” solution, in place of a permanent solution because Covid-19 is not the first pandemic and it is not going to be the last. Thereby, highlighting the urgent need to be focused on a single time waiver and instead build a medical institute or technology transfer in all the corners of the world.

Furthermore, Patent Rights Waiver is not a guarantee that the country will become COVID-19 free, as besides the technology to manufacture the vaccine, the other vital factors for the same include the availability of raw material and whether the same is available scarcely¹⁵ and if so, the poor countries, compete with larger economies to secure raw material in the free market. Many nations such as United States¹⁶, are also making conscious efforts in the direction to block exports of necessary raw material required for the Vaccine Manufacturing process.

V. PATENT WAIVER ALTERNATIVE

Since it has been contemplated that the Patent Waiver for Covid-19 vaccines is not the answer to eradicate the pandemic, other possibilities are being explored. The most prominent of which being, the technology transfer from the wealthy nations or developed nations to the poorer nations or developing nations coupled with external aid in the capacity expansion as well as helping the less developed nations establish a supply line for an efficient manufacturing plant¹⁷.

The problem with Covid-19 vaccine does not necessarily indwell in the Patent Protection under the Trade Related Intellectual Property Rights (TRIPs) but in the manufacturing process of the vaccines, most of the poor or developing nations are not well equipped with the technology to establish manufacturing plants of the vaccine.

¹⁴ Damian Garde , Helen Branswell and Matthew Herper, Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive, Stat News, 06/05/2021, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>

¹⁵ Nature, A patent waiver on COVID vaccines is right and fair, <https://www.nature.com/articles/d41586-021-01242-1> 25/05/2021

¹⁶ Ibid 16

¹⁷ Brink Lindsey, Why intellectual property and pandemics don't mix, Brookings, 03/07/2021, <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>

To establish manufacturing plants of the vaccine, these countries would need rather well-equipped technology which still would be accorded protection under the Trade Related Intellectual Property Rights (TRIPs) Agreement and outside the scope of Patent Waiver, the same that India and South Africa are striving for. One of the reasons behind this is that, India and South Africa do have the economic and technological capabilities to manufacture the vaccines at a vast scale and even export the vaccine to the other underdeveloped nations, but as far as the manufacturing process of domestic vaccines in poorer countries is concerned, the patent waiver for vaccine is not the answer.

VI. TECHNOLOGY TRANSFER

The suitability of technology transfer is contingent on a wide array of external factors and raises a few major concerns about the manufacturing processes of the Covid-19 vaccines. While it does give the country a certain competitive edge against the other countries, and even to those who supplied the technology in the first place, the transfer of technology can sometime cause harm to the country giving the resources, causing resistance in doing so.

The competitive edge can be attained in various other processes and technologies, especially the more developed, such as the IVF programs or DNA slicing, which are invented and innovated after years if not decades' worth of hard work and a huge number of investments. If the transfer, were to happen, it would transfer the technology to a nation, that did not work hard enough to make it for themselves, in which case the technology could go waste, without the proper team of people, specially equipped to handle or operate that kind of technology.

The Political concerns around the handling of technology transfer are further aggravated amidst the rising tensions between United States and China, for the two countries are on the edge of World War III. In order to produce massive number of vaccines, the United States could be asked to send its technology to China as China has a huge labor force whereas the United States has superior technology. In this case, United States would be hesitant to hand over the technology as China, given their rivalry, and the fear of the same technology being used against them in any unfortunate event of war could act as a deterrent. Furthermore, handing over technology would be equivalent of harming their own economy as then the vaccine available in the home country's market would be expensive, whereas the one available from China, that did not even invent it would be available at only a fraction of that price. Hence, transfer of technology would be viewed as against the national interest of the United States, in the context of the aforesaid example.

The question of prioritizing of *National Interest* over *Human Rights* in general, arose as to which way to look in the moral dilemma or whether to choose one's own citizens or the human race at large. While, there is no precedent available to conclude this dilemma, one can make a deduction from how international community is dealing with climate change. The global leaders are promising to attain *Economical Sustainability* which though focuses on curbing climate change, also helps nations attain economic growth. This does, to a great extent help put things in perspective on how a state would handle the aforementioned dilemma, by choosing its *National Interest*, which is exactly what seems to be transpiring in this day and age.

VII. CONCLUSION

It has been around 2 years since the Covid-19's first case was detected in Wuhan, China, changing the course of life as we know it, possibly forever. From lockdowns being imposed in various parts of the world to thousands of deaths, daily, the humanity sure has suffered a great deal in this pandemic. The only solution in the initial phase of pandemic was to maintain the social distancing and proper hygiene, but as the vaccines were developed by the late 2020, the world saw light at the end of the tunnel.

However, that tunnel is placed at different locations for different countries, based on their economical standings. For instance, the United States' 66% population is vaccinated, and while 97% population of United Arab Emirates is vaccinated, countries like Ethiopia, Nigeria and Tunisia's vaccination rates are less than 4% respectively. This is not the first time that the poor countries have faced such discrimination, and it probably will not be the last time either. However, to reiterate, it is pertinent to note that, the eradication of Covid-19 is of utmost importance, if not eradicated, it would continue to mutate and could escape the immunization barrier of Covid-19.

To conclude, in order to fight the pandemic being caused by Covid-19, neither waiving of Patent Law is enough nor providing highly advanced technologies. The main solution lies in global cooperation and unity, in which the advanced countries can provide patents, technological countries can provide their technologies, poor countries can provide their land and labor and resources rich countries can provide their resources for raw materials. A common goal, being met by all the countries in unity. This is why United Nation's ambitious COVAX program is proving to be the much-needed hope for eradicating Covid-19, as the wealthy nations can directly donate the excess vaccines and support the poor nations in the vaccination drive. Further, COVAX aims at accelerating the manufacturing of the vaccine and guaranteeing fair and equitable supply across the world.