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Is Compulsory Licensing a Panacea for COVID-19 woes

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ABSTRACT

The ongoing COVID-19 pandemic has further highlighted the important role that scientists and pharmaceutical companies play in our everyday lives. Now more than ever, their production capacity, expertise and supply chain are key factors in determining the rate of inoculation and supply of other vital drugs to the general populace. With all the spotlight and pressure on the pharmaceutical companies, it was only natural that the issue of compulsory licensing was raised again in order to bypass Intellectual Property protections and to make the medicines and vaccines more affordable for people and governments alike. The demands do have some merit considering the recent cases of predatory pricing, alleged collusion and instances of controlling production to drive up prices. This short article, however, advocates against the usage of compulsory licensing regime as a tool in order to tackle the pandemic as it can have serious repercussions. It also suggests approaches that should be taken instead to better handle the current public health crisis at hand.

I. INTRODUCTION

Ever since Wuhan reported a cluster of pneumonia cases back in December 2019 which was eventually identified as a novel coronavirus, the coronavirus has spread across the length and breadth of the world terrorizing the population and claiming many lives in the process.² The virus has impacted trade, economies and the general lifestyle of almost every individual on the planet. It is not an exaggeration to state that a pandemic of this magnitude is unprecedented

in both the reach and the death toll in recent times. Countries, governments and international actors around the world have been trying to contain the virus and also explore preventive medicine and vaccines in order to shield its population from the coronavirus.

The World Health Organization on 11th March, 2020 declared COVID-19 as a pandemic.³ Following which governments across the world sprang into action in order to contain the virus and further explore measures which will prevent the spread of the coronavirus. Various groups of

¹ Author is a student at The National University of Advanced Legal Studies, India.

² Archived: WHO Timeline - COVID-19, Who.int (2021), <https://www.who.int/news/item/27-04-2020-who-timeline---covid-19> (last visited Jul 4, 2021).

³ WHO announces COVID-19 outbreak a pandemic, Euro.who.int (2021), <https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic> (last visited Jul 4, 2021).

scientists and researchers started to work on a possible vaccine as a response to the pandemic so that the general populace can be immunized against the virus. The efforts were both governmental and private in nature and various patents rights were given to private entities for their breakthroughs.⁴

II. PATENT RIGHTS AND COMPULSORY LICENSING

The patent rights and allied rights are bestowed by national legislations and hence, the companies gain protection in jurisdictions wherein their patent applications are accepted. However, in multiple countries there are certain rights invariably provided to a patent holder such as an exclusive right to commercially utilize the invention for a limited time, other rights given to them include right to license and assign the patent, right to exploit the invention and the right to bring a suit against entities who infringe the patent.⁵ In other words, it provides limited monopolistic rights to the patent holders, the rationale behind this is to incentivize inventors and researchers to further innovate and they are expected to recoup their cost of research and development and make profits thereafter within that time period. The rights of the patent holders in almost every

country are based on Article 28 of the Trade Related Aspects of Intellectual Property Rights Agreement (hereafter referred to as TRIPS).⁶ TRIPS offers certain flexibilities which can be invoked in a case of national emergency, public health crisis or other circumstances of extreme urgency. One such flexibility is enshrined in Article 31 of the TRIPS agreement, which equips the governments of member nations to issue compulsory licenses regarding a patent provided certain criteria are met. Furthermore, The TRIPS Agreement does not explicitly list the reasons that might be used to justify compulsory licensing. However, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences, and to determine what constitutes a national emergency.⁷

As discussed above, the patent holders are given wide privileges regarding the commercial application of the product. One of the rights is licensing the patent to third parties. Permissible licensing happens when a patent holder allows a third party to make use of the invention often in lieu of a premeditated fee.⁸ In contrast, a compulsory licensing can be defined as the imposition on the patent holder, who would have not otherwise licensed his patent, to permit

⁴ Gaviria, M., Kilic, B. A network analysis of COVID-19 mRNA vaccine patents. *Nat Biotechnol* 39, 546–548 (2021). <https://doi.org/10.1038/s41587-021-00912-9>

⁵ Frequently Asked Questions: Patents, Wipo.int (2021), https://www.wipo.int/patents/en/faq_patents.html (last visited Jul 4, 2021).

⁶ WTO | intellectual property (TRIPS) - agreement text - standards, Wto.org (2021), https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited Jul 4, 2021).

⁷ WTO | intellectual property (TRIPS) - TRIPS and public health: Compulsory licensing of pharmaceuticals and TRIPS, Wto.org (2021), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Jul 4, 2021).

⁸ Mitchell, Amanda. “Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government's Options for Accessing Medical Patents.” *California Law Review*, vol. 95, no. 2, 2007, pp. 535–559. *JSTOR*, www.jstor.org/stable/20439101 Accessed 4 July 2021.

a wrongdoer to make use of the invention. However, even when a compulsory license is granted in regard to a patent, the patent holder is compensated by the licensee. The World Trade Organization defines compulsory licensing as when a government allows the usage of a product or process patent by third party or itself without the permission of the patent holder.⁹

TRIPS agreement was brought in to bring about a uniform intellectual property regime across the world which would harmonize the intellectual property protection amongst member nations of the World Trade organization. This was done in order to facilitate smoother world trade and was largely spearheaded by the United States and other developed nations, who were now losing their expertise in manufacturing and shifting more and more to knowledge-based industries which were heavily reliant on intellectual property rights provided by nations.¹⁰ This also explains the continuous trend followed by countries such as United States, United Kingdom etc. in vehemently opposing any concessions, waiver or dilution of the intellectual property regime already set.

III. COMPULSORY LICENSING AND THE COVID-19 PANDEMIC

The recurring call from the general public to grant compulsory license for vaccines in order

to increase accessibility and affordability is not totally misguided. However, the answer to the global demand for vaccines and other medicines is not as simplistic as compulsory licensing. In other words, mere granting of compulsory licenses for patents related to pharmaceutical products and vaccines will not necessarily ensure access to medicines and vaccines for all. The COVID-19 has overwhelmed the medical infrastructure of most of the countries and has exposed the flaws in supply-chain networks, logistics and delivery of medical products and services. Furthermore, in today's world where industries are driven by profit, to even adopt a strategy of price bargaining with the private companies producing pharmaceutical products and vaccines might trigger a negative effect whereby the delivery of the products to citizens might be delayed at the least, this is evidenced by the experience of the European Union who paid less for the vaccines compared to United States and United Kingdom, found itself at the end of the line when production took a hit, countries which paid more per capita prices for the vaccines secured more jabs for its people.¹¹

Although compulsory licensing can be used as an effective tool in bargaining during normal times, it is not necessary and not desired to be used during pandemics as the production and the supply chain networks are facing a lot of pressure and governments around the world

⁹ WTO | intellectual property (TRIPS) - TRIPS and public health: Compulsory licensing of pharmaceuticals and TRIPS, Wto.org (2021), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Jul 4, 2021).

¹⁰ Ganesan, A. (2015), "Negotiating for India", in Watal, J. and A. Taubman (eds.), *The Making of the*

TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations, WTO,

¹¹ Opinion | Europe Failed Miserably with Vaccines. Of Course It Did., Nytimes.com (2021), <https://www.nytimes.com/2021/05/17/opinion/europe-vaccines-commission.html?smid=tw-share> (last visited Jul 4, 2021).

should try and explore other ways to ensure access of medicines and vaccines for all. One such example is the demand raised before the World Trade Organization by around 100 countries led by India and South Africa who are cadging for a waiver of intellectual property protection in order to achieve the aforementioned objective.¹² Initially the United States was relenting against the idea of an IP waiver, however recently the Biden administration in contrast to the previous policy announced that they will be supporting the Intellectual property protection waiver in the WTO. Concerted efforts from countries around the world would better ensure the access of vaccines, medicines and medical equipment in India.

Another way of ensuring availability of vaccines for all can be by providing “direct support” to pharmaceutical companies. In a beautifully articulated blog, Brink Lindsey argues that direct support provided by governments around the world can make patents redundant, the government can either directly channel funds into vaccine development programs, offer tax credits or insulate the pharmaceutical companies from commercial risks.¹³ The government should facilitate public funding in order to help companies pay their hefty R&D costs, they should also extend advance purchase commitments to buy large number of vaccines

at predetermined prices. It is also argued that governments should not be stingy when it comes to payment of vaccines and that they should ensure that sufficient profit is generated from the vaccine sales of the company which would further incentivize vaccine production. To borrow words directly from Brink, “In this regime, the government provides qualitatively *superior* incentives to those offered under patent law. Not only does it offer public funding to cover the up-front costs of drug development, but it also provides advance purchase commitments that guarantee a healthy return.”¹⁴

IV. CONCLUSION

In these trying times, the notion that pharmaceutical companies are to make bank and will obstruct the innovation regarding vaccines and that compulsory licensing is the only way to go, is misplaced. There is no one common solution to the slew of challenges posed by the COVID-19 pandemic and hence merely granting a compulsory license for products and processes or waiving intellectual property protections without bringing in systemic change in approach will not do any good to the general public. It is not the companies and their production capacities which are the only impediment in bringing the vaccines in everyone's reach, what is needed most urgently is a massive drive of technology transfer, capacity expansion, and mending the supply chain and logistics infrastructure to meet

¹² Docs.wto.org (2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> (last visited Jul 4, 2021).

¹³ Brink Lindsey, why intellectual property and pandemics don't mix Brookings (2021), <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/> (last visited Jul 4, 2021).

¹⁴ Ibid

the humongous vaccine demand. The governments have a major role to play in facilitating the process and rather than applying harsh measures such as compulsory licensing which if done prematurely might negatively affect the interests of every stakeholder involved.
