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Pandemic, Patents and Pharmaceuticals: An Analysis

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Abstract

The emergence of a pandemic has put the whole planet at a standstill. Any field, from corporations to legal processes, has been handicapped. A mutual responsibility is global health security; it needs a collaborative collective reaction focused on accountability and trust. One main problem in a collaborated effort is that company wants to gain back its investment by exercising monopoly in the market. In recent years, numerous countries have undergone serious re-examinations of the legal frameworks they use to promote innovation. This is partially attributed to the creation of and implementation of the TRIPS Agreement by the WTO. Analysis of compulsory licensing mechanisms across countries and deciding policy measures based on the amendments is necessary. Covid-19 pandemic has revealed shortcomings in the planning of public health agencies and policymakers. Would the presence of pre-existing guidelines help in bringing larger range of plans? The present paper discusses how the concept of compulsory licensing comes into play during the pandemic; measures were taken during emergency situations or pandemics by different countries. A cross-country analysis of the provisions in relation to compulsory licencing has been done to understandthe need for the adopting such laws. Further, the ways in which Indian pharmaceutical companies are addressing the medicine supply and innovation during pandemic time has been also analysed. The findings indicate need for collective and coordinated preparedness for pandemics and increased need for collaboration in sharing solutions.

Keywords: Pandemic, Covid19, Pharmaceuticals, Patents, Compulsory licensing, TRIPS, WTO

Introduction

Pandemics like COVID-19 need legislative initiatives to secure healthcare system coverage for citizens. Healthcare access includes easy and ready availability of basic vaccines, drugs and medical devices for all. In this practice, the clash of fundamental rights arises as a critical obstacle for decision-making to balance the capitalist rights of industries and health of citizens. Judicial decision-making and public policy-making for better handling of pandemic is imperative for countries to protect public and private health services and health interests of their residents. It is desirable, at both legal and ethical levels, that public health decision-making, that is much more important in the sense of a pandemic, follows the inalienable values of universal human rights, even constitutional rights, and respects legal-guided ethical norms in a manner that enhances the protection of human health rights and also guarantees the safe preservation of healthcare systems. The Declaration of Alma-Ata, 1978 co-sponsored by WHO, is a noteworthy milestone of the twentieth century in the field of public health and established primary health care as the route to accomplishing the goal of Health for Everyone. At an international level, it is WHO, a specialized body of UN that is responsible for public health announcing measures and monitoring the international scenario in this area. TRIPS which entered into force on 1st January 1995, establishes an obligation to lay down the least requirements for the safeguard and compliance of IPR in Member States which are expected to facilitate efficient and sufficient protection of IPR with a view to removing misrepresentations and barriers to foreign trade. Article 31 of the TRIPS (Other usage without the right to be authorised holder) that stipulates, inter alia, person or corporation asking for a licence must have attempted to obtain a voluntary licence with the patent holder on fair business terms within a reasonable period of time. Only if this fails will a compulsory licence be granted and - even if a compulsory licence has been issued, payment has to be obtained by the patent owner. To further facilitate countries who were unable to manufacture their own medicines even with the provision of compulsory licensing, a large number of developing countries submitted a joint proposal to the IP/C/W/296 TRIPS conference, which formed the basis of the Doha Resolution, for a special declaration on the TRIPs Agreement and on access to medicinal goods. The special compulsory licencing scheme in the modified TRIPs Agreement (paragraph 6 of the Doha Declaration) deals only with compulsory licences for the manufacture of medicinal goods specifically for exporting. Compulsory licences issued exclusively for the provision of domestic markets have always been possible. A small amount of production under 'ordinary' compulsory licences could still be exported, provided that it was not the predominant part of production. Similarly, compulsory licences given to address anti-competitive activities have never been limited to a significant portion of the domestic business service. In a landmark move on October 2, 2020 India and South Africa along with the support of MSF requested the World Trade Organisation (WTO) to allow all countries to opt not to award or implement, for the duration of the pandemic, any patents and other IP relating rights to COVID-19 medicines, vaccines and diagnostics. The analysis reveals different approaches that deal with specific molecules to development of nanobased platforms to address the COVID19 disease [1-10].

Developments since a year of pandemic declaration

On January 3, 2020 WHO declared COVID-19 as a "Public Health Emergency of International Concern" or the PHEIC. Soon countries started implementing the WHO call for monitoring, tracing and social distancing to curb coronavirus. Lack of a rapid response to the call resulted in at least 100 million cases (as of February 2021) and more than 2 million people have died worldwide (Reports from the Johns Hopkins Coronavirus Research Centre). The World Bank reports that the world [4]economy has contracted by 4.3 per cent in 2020, with increase in government debt and severe poverty. Increased funding propelled research in relation to COVID-19. Several vaccines have been produced and approved in record time, and many are in the pipeline. There economists started to discuss what the immediate and long-term consequences of the pandemic would be.

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The design and development of vaccine candidates has increased. As many as 44 vaccine candidates have been announced worldwide some of which are a result of collaborative effort. Nanodrug research has assisted the development of vaccines. Vaccines formulated of lipid nanoparticles have been progressed into clinical trials. Viral proteins such as the spike protein have been utilised in development of nanodrugs as part of the various solutions to COVID-19. The National Science Foundation (NSF) had predicted one-third of patents and start-up companies in the nanotechnology sector will involve biomedical applications also predicts that nearly half of future pharmaceuticals will have some nanotechnology components.

Several nanobased SARS COV2 formulations have been developed in the time of the pandemic. Utilising the properties of nanomaterials, the use of biobased or synthetics molecules provide a great opportunity for research and development. The use of nanosensors in diagnostics for detection of SARS COV2 antibodies has been found to have potential applications. The paper attempts to analyse the filing of such patents under the special programs announced under some patent offices to identify the type of inventions. The trends reveal developments in relation to specific biomolecules, receptors and nanobased platforms.

Response of countries

Some nations have recently addressed pandemic concerns through patent law. Canada and other EU Member States found that their current compulsory licencing law was insufficient to comply with the pandemic and passed emergency legislation. Israel has used current laws to grant a mandatory pandemic related compulsory license [11-15].

In April 2020, Canada passed the 'COVID-19 Emergency Response Act', which made it faster for the government to award compulsory licences for the prevention and care of COVID-19. Under current § 19.4 of the Canadian Patent Act, if the Minister of Health confirms a national emergency prior to 30 September 2020, the Government can grant compulsory licences to third parties. In fact, it can do so even though the patent holder is capable of creating,using and distributing the patented invention. The Government ofCanada is under no duty to consult with the patent holder prior to issuing a licence to a third party for the manufacture of the drug. This would not amount to patent infringement.

While Israel has not passed any new laws, it has taken the toughest step among developing countries by granting a COVID-19-related compulsory licence. Sections 104 and 105 of Israel's patent law authorise the government to grant compulsory licences if the Minister "finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services." Shortly thereafter, AbbVie announced that it would not pursue Kaletra's patent rights. It is plausible that more countries would follow the example of Israel and grant their own permits, creating precedents that would make it easier to make more extensive use of compulsory licencing in potential health emergencies.

Pursuant to Regulation (EC) 816/2006, the EU ratified the resolution of the WHO concerning the export of pharmaceutical goods to countries which do not have adequate manufacturing capability. Member States are expected to issue a compulsory licence to anyone making a legitimate proposal for the manufacture of export drugs. Beyond this case, the law on compulsory licences is largely dealt with at state level. Overall, the EU is much more relaxed with the use of compulsory licences, possibly because EU Member States already control drug prices and the EU already permits broad parallel imports [16-20].

In March 2020, France announced a state of health emergency related to COVID-19 and also passed Emergency Law 2020-290, which inserted Article L.3131-15 into the Public Health Code. Under the new provision, when France is in a state of health emergency, the Prime Minister can temporarily track and take charge of the prices of goods and services for the fight against the virus and take steps to guarantee supply of medicines.

In March 2020, Germany approved the 'Prevention and Control of Infectious Diseases in Humans Act', which will remain in force for one year. This Act grants the Federal Ministry of Health a number of new rights in the case of a nationwide outbreak proclaimed by Parliament, including the right to require pharmaceutical corporations to make patented vaccines and medications available to the public in return for equal compensation.

The Netherlands has taken steps to ensure that medicine prices remain affordable. Health Minister Bruno Bruins revealed in 2017 a proposal to "extensively explore" the use of compulsory licences to counter "absurd pricing" of medicines. Following the outbreak of COVID-19, the Netherlands promised to help the WHO project to create a pool of intellectual property rights for outbreak technologies [21-30].

Response of International Organizations

International organisations have a crucial role to play in the global response and also carry out essential tasks—where they may. Key agencies are organising international activities, including airlifting supplies and medical professionals, handling transnational pandemic studies, exchanging critical knowledge and launching relief funds. International bureaucracies work in regions where they have the most autonomy. But where the political stakes are higher for their members, and where their members have veto authority, that partnership is stalled.

WTO

South Africa and India want the WTO to transitorily revoke intellectual property rights so that developing countries can access the COVID-19 vaccines and other emerging innovations. They called for the abolition of IP privileges pertaining to COVID-19 by the WTO to make sure that not only the richest countries would access and manage the drugs, medications and other emerging technology required to contain the pandemic. The pharmaceutical industry and several high-income countries (HICs) firmly condemn the change, which they argue would, when it is most needed, stifle creativity. Without special steps, advocates claim, emerging technology would help wealthy countries when they reach the market, while the pandemic threatens to devastate poor nations. The resolution notes that inexpensive COVID-19 medicinal devices are obstructed by IP rights such as patents. Instead of keeping production focussed in the control of a limited number of patent holders, a brief ban would encourage other states to start production earlier. The plan from India and South Africa would also make it possible for non-patent holders to manufacture required medical devices such as ventilators, masks and protective equipment.

WHO

WHO has been criticised quite a lot recently by one of its members for improperly handling the pandemic situation and for not holding another member responsible for its actions. This critique illustrates the underlying challenge of being a multilateral body having to interact with its member states. Evidence- based recommendations are strategically risky because the issue about how to get evidence—and what would be accounted as evidence— has political ramifications for influential representatives. Countries areless likely to comply than to protest when the WHO issues guidelines with problematic domestic consequences—for instance, travel bans or widespread testing. All being said, WHO has not only issued recommendations, it has supported those transnational research which are involved in producing a vaccine. It has used its expert web of connections to provide relevant intelligence, provided more than50 bits of technical advice, distributed medical supplies and test kits, set up a Supply Chain Task Force in partnership with the World Food Programme, and supported countries' potential for preparedness and reaction by raising over $800 million through its Solidarity Response Fund. Since May 2020, the WHO COVID-19 Technology Access Pool (C-TAP), initiated by the WHO in cooperation with the Government of Costa Rica and 40 co-sponsors of the Solidarity Call toAction, has called on the global community to take action to exchange information, intellectual property and data required for COVID-19 on a voluntary basis. The aim of C-TAP is to provide a way to facilitate thecreation of the goods needed to combat COVID-19, as well as to speed up the scale-up of production and the elimination of access barriers in order to make products globally available [31-35].

UN

Like WHO, United Nations too faces limitations from fellow powerful countries. At the beginning of April, the UN General Assembly adopted a resolution calling for "intensified international cooperation" and named Secretary General António Guterres to lead the initiative. But the UN Security Council is still left to implement the same. Though the Security Council has taken measures against previous HIV/AIDS or Ebola epidemics, it is now facing diplomatic pressures from its two influential members, China and the United States. China attempts to drive Security Council back to its emphasis on conventional security risks. In spite of Chinese concerns, the Unites States maintains that every resolution should mention the source of the virus. Without a coordinated appeal for universal unity between the world's majorpowers, Guterres concentrated on the need for "science and solidarity" with the U.N. launching a new outreach campaign has been initiated to address the disinformation about the pandemic. U.N. also launched a $2 billion global humanitarian response plan together with UNICEFand the WHO.

EU

It is difficult for the European Union to launch organised solutions that go beyond the expertise of its bureaucrats and require the approval of each Member State, especially with regard to economic and fiscal policies. There is German and Dutch resistance to "coronabonds," which could distribute the burden of supportingthe hardest-hit nations, such as Spain and Italy, across the EU. It contributed to the EU to settle between less optimistic plans and high-profile commitments for economic growth boosting after the recession. The European Commission, the governing body of the EU, has been willing to impose solutions in less politicallycontentious areas. Initially, the EU had 27 members to negotiate a general travel ban outside the EU. SURE, a temporary €100 billion unemployment support programme, has just been launched and €37 billion of its budget has been diverted to help its participants cope with the Covid-19 crisis. A structured escape plan from lockout has also been suggested by the board.

African Union

The African Union, which promotes cooperation among its 55 members and depends heavily on foreign financing for its activities, has various problems. The virus has spread across the continent, where there is already very little and limited scope for research. The AU chair Commissioner Moussa Faki Mahamat called the US decision "deeply regrettable" to cancel WHO funding. Nevertheless, with the assistance of the WHO African Office andthe World Bank, the AU has become the largest standard-setting body on the continent, establishing a shared Coronavirus Fund and sharing expertise among its members through its Centres for Disease Control and Prevention, as well as lessons learned from the Ebola crisis.

Others

Other International Organizations who have risen to the occasion, perhaps unexpectedly, are not necessarily interested with public health. Only two instances are NATO and the World Food Programme. They also transferred their airlifting capability to transport and exchange knowledge with essential medical supplies and employees (Humanitarian Aid, 2020). The secretary general of NATO has already been fighting disinformation,while the Executive Director of the WFP warned of a pandemic of hunger.

Covid-19 has not been stopped from spreading by foreign organisations. No one has. Yet their bureaucracies perform their delegated tasks. And organisations have stepped up and provided their services whose business is usually not international health policy.

Lessons learnt

Importance of early response: History always repeats itself and imparts us wisdom along the way. Around 100 years earlier, the international economy was hit by influenza in 1918 on a similar scale. The world has to make similar decisions choosing between the economy and public health. While the pandemic dramatically diminished industrial jobs and production, cities that intervened sooner and more vigorously not only ended up with lower mortality but also quicker economic growth. In US, pair of twin cities Minneapolis and Saint Paul, with identical geographical location, population and industry have taken somewhat different steps in reaction to 1918. Minneapolis made early interventions by closing down the city, while Saint Paul closed very late. As a result, the Saint Paul death rate was much higher than Minneapolis and, later on, the Saint Paul employment rate was much lower. Studies that rigorously contrasted these two cities as well as Los Angeles versus San Francisco before and after the 1918 influenza season came to similar conclusions that earlier measures paid off and made the economy faster. Late public health interventions have resulted in more deaths and stronger global recessions. One interesting contrast is between the United States and South Korea, each of which reported their first case of COVID-19 on the same day. South Korea began major tests soon afterwards, while the US took 45 daysto start scaling up the test and 100 days to catch up with South Korea. Even by July 2020, the US also lagged behind South Korea and several other countries in the number of tests per reported case recorded, a significant measure of whether the test frequency is associated with the

seriousness of infections. Cost-benefit research also leads to early approaches during the crisis, as data indicates that later responses appear to lead to prolonged shutdowns and more economic casualties. In the other hand, investment on public health programs just takes a small portion of the amount of saved lives and eliminates long-term negative consequences. Obedience with prevention steps may make a big difference. Encouraging wearing masks in public alone speeds down the transmission of the virus andis expected to save thousands of lives and a large amount of GDP. Delayed timing of stay-at-home orders has caused a significant number of preventable illnesses and deaths. For example, Germany began its regional lockdown with less than 60 deaths, while the United Kingdom imposed a national lockdown with more than 300 deaths. While 60 deaths and 300 deaths do not seem to be very different, at the endof the day this initial disparity may result in significant performance differences, such as far more reported cases of COVID-19 or deaths per million people in the UK than in Germany.

Policy making: Future policy design could use the history of economic activities and human migration evidence to model which city pairs need to be limited and how much restriction needs to be enforced. Build theoretical models to classify the kinds of cities to prioritise bans, including those in the epicentre of this pandemic, and cities that are large transit centres with close links to the epicentre. Another important aspect is coordination. There has been a lack of coordination in the United States. As America is on the third wave of coronavirus spikes, patterns are very distinct around regional areas. Variations were still large during the second wave of surges, when the epidemic was already under control in the North and East areas, but the spread of viruses in the South and West regions was growing. As no state would like to be the first to implement limits on public health that could affect its own economy and society, cooperation is required to enact concerted action and create constructive spillovers for the good of everyone. Holtz and chen demonstrates that, in a scenario where there is no cooperation at national level, each city would double the restrictions on its outbound traffic relative to thescenario where other cities are subject to optimum restrictions.

Conclusion

Human rights shortcomings have intensified the COVID-19 pandemic, but the right to health should provide a basis for ensuring that the COVID-19 solution helps to realise the right for everyone to the fullest attainable level of physical and mental health. Because of the COVID-19 pandemic, countries have been prompted reassess their views towards compulsory licences and government action to deter drug shortages. High-income nations, long perceived as a tool for protecting public health in the developed world, have come to recognise that compulsory licencing may become necessary in order to ensure a sufficient supply of the medicines required. A number of International Organizations too have come together to help everyone those in need. To best manage pandemics effectively in future we must have a global collaboration to prioritize public health. Collective coordinated effort for vaccines and drug development, enhancing availability and accessibility, sharing information are necessary. No longer sharing 'response to pandemic' is an option. It is imperative and urgent. The consequences of non-compliance will be far reaching in the serious effects of the pandemic on health of nations. Countries must learn to balance the scale of economics and global healthcare by agreeing to pool technologies together. With India's and South Africa's initiative, WTO could be further pressurised to waive off IP rights during pandemic. Studies have found that pre-existing guidelines and early response to a global emergency such as pandemic resulted in cutting back huge economic losses. To date, pharmaceutical companies and other suppliers of drugs required to fight COVID-19 have not demonstrated any desire to take a different path during the pandemic, even in countries where MSF operates, to ensure the requisite comprehensive access to the products needed. They insist on selling to the highest bidder instead. The IP rights exclusion is not a magic bullet. But COVID showed that it doesn't operate with the IP system. It is not crafted to be operated alongside pandemics. Hopefully, this puts us on a path of thinking about ways to reform the IP system to respond to the needs of the members. And this isn't the only pandemic we're going to come across.

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