



Status of Pharmaceutical Patents during COVID-19 Pandemic

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Abstract

Authors focused on the complex scenario of Covid-19 and necessity of vaccines around the globe. They have emphasized the urge for patent waiver/out-licensing to combat pandemics like covid-19 efficiently and also discussed a way forward for making available vaccines to the end user effectively, quickly until herd immunity is attained.

Keywords: COVID-19; Patent; Intellectual property rights; Vaccine; Pharma industry.

Introduction

The Coronavirus is a highly contagious and life-threatening disease that has spread into 208 countries (458 million confirmed cases and over 6 million deaths as of 15th March 2022) and had been initially traced in Wuhan City of China, and it has started spreading into several countries by January 2020¹⁻⁵. The novel Coronavirus disease (SARS n-Cov/ COVID-19) is declared as a pandemic by the World Health Organization (WHO) on 11th March 2020. The new COVID-19 variants are surpassing existing vaccine shields with modified genetic structure affecting human cells having different intensities. Many research studies revealed that the COVID-19 waves would continue to hit the countries until herd immunity is attained, or the population is fully immunized with effective vaccines. It was an extraordinary task for the pharmaceutical companies to develop a corona vaccine while battling with multiplying COVID-19 cases⁶.

Ever since the corona was declared as pandemic, the international pharma giants Astra Zeneca-Oxford University (based on a weakened version of the common cold (adenovirus), Covishield), Gamaleya Research Institute (Sputnik-V), Pfizer (BioNTech, m-RNA virus), Johnson & Johnson (J&J adenovirus vector vaccine), Moderna (Moderna m-RNA vaccine), Bharth Biotech (Covaxin-Inactivated virus) and Sinovac biotechnology (Sinovac) had invested in vaccine development with their associates across the world. Economically strong countries are placing bulk order for immunization of their population on a priority basis whereas Third World countries majorly depend on funds from WHO (COVAX) initiatives. Eleven billion different available vaccine doses were administered across the globe as on 12th March 2022.

The WHO data reveals that until now, the Third World countries, more specifically the countries in Africa, the East Mediterranean and Western Pacific regions are far from vaccine availability. Nearly 90 countries have not even immunized their population with a single dose; this issue needs to be addressed immediately. The length of immunity protection offered by certain vaccines is questionable. In such cases, booster doses will be made mandatory and this will further increase the pressure on vaccine production. As the arrival of vaccines would signal a higher level of achievement in battling COVID-19, now the issues of intellectual property rights (IPRs) are arising from biomedical and technological innovations, which are significantly wrapping up the COVID-19 era⁷. The relaxing patent for COVID-19 inventions was echoed by India and South Africa in various international forums, and could get the sympathy of more than 100 countries but failed to obtain the support of developed nations (**Figure 1**). The idea of a patent waiver for the COVID vaccine is not sweet for developed nations and pharma companies. It is an obvious notion of the pharma industry that why expensive technology could be made available to competitors for a cheaper price⁸.



Figure 1. Waiving of IPRs-Data as on 3rd March 2021

It's high time to consider a patent reprieve for COVID-19 vaccines. The pandemic is not a competition between companies and it will not come to an end without equal vaccine distribution. The concept of Patents was never assumed to be used in global emergency conditions such as wars between nations and pandemic conditions. If patented resources are vested in the hands of a few economically and technologically superior countries, which will lead to the widening of accessibility of vaccines and medical supplies among poor and rich countries. A few numbers of companies established in rich countries who are capable of heavy investments in the invention of technology will

exploit the rest of the world. Thus, the intellectual property rights (IPRs) are the determining factors for global access to COVID-19 medical supplies. Mere commercial interests should not defeat humanity before the economic and technological divide of the world. Due to these reasons, in various contexts, the moral justification of patent rights is often questioned and turns into controversial when public health is in jeopardy⁹. Despite the availability of medicine, the loss of life due to poverty is a disgrace to humanity. The ultimate objective of science is the welfare of mankind. It is used as a weapon for upholding peace and humanity, while patents are promising indicators of technological knowledge and production which are widely used in innovation research; these are often under used in biological sciences.

Benefits

1. Declaring the patent waiver for the COVID-19 vaccine for a short period of time (People's vaccine for Covid-19) will have a greater significance in eradicating the pandemic from the globe. This action will send a powerful message from the developed countries and pharmaceutical companies to the population that they can compromise on profits for a greater noble cause of humanity. Once the pandemic is over, IPR protection will be restored as usual.
2. There is a need for increasing licenses of product designs at affordable prices. This will enable many companies to make vaccines. In addition, the World Health Organization is setting up a facility for companies to share their vaccine technology, skills and other know-how (COVAX and WHO in May 2020: the COVID-19 Technology Access Pool (C-TAP), modeled after the Medicines Patent Pool).
3. The governments can use two approaches, such as voluntary licensing and compulsory licensing, to intensify competition in the pharmaceutical market while a patent is still valid, but within a short span, medical supply will be available across the markets.

Defects

1. The pharmaceutical companies, developed nations and renowned researchers argue that the temporary relief from the patent framework would not necessarily speed up COVID-19 related manufacturing and supply. They believe that the world has not

enough manufacturing capacity to meet demand. In case, if patents are relaxed, procuring all vaccine ingredients, establishing factories, hiring skilled people and clearing obstacles of relevant laws.

2. One of the biggest concerns for the pharma industry about IP waivers is, it is injustice to by-pass the R&D process and its consequential investments for competitors who are enthusiastic about obtaining expensive technology at a cheaper price.
3. The vaccine making process involves the manipulation of viral strains in large volumes which is undoubtedly a potential threat to human life. Henceforth, qualitative bio-safety, GMP and sufficient technical domain knowledge are must for effective production of vaccines.

Way forward

1. Based on suggestions from eminent personalities from IP management, few security relaxations are ought to be given with regard to medical devices and usage of vaccines/drugs wherein compulsory licencing will not resolve the above issue.
2. Patent pledges (out-licensing) obviously should be for shorter period of time to combat unexpected global pandemics such as covid and is based on social well-being and legal policies.
3. The WHO needs to set up a common pool of funds to invest in research and development for pandemic vaccines and medicine supplies to meet global needs. If the medicines are invented by developed nations or top companies, the patents are conferred on those who can exploit them commercially, and if it is developed by a common pool of funds of WHO, they can engage in R&D on its own or venture with private companies for the protection of common man's interest.

Conclusion

In this turbulent time, balancing the interests of patent owners, corporates and public health is of the utmost importance. The Doha round (WTO in 2001) declares that public health takes preference over IP rights. This resolution applies not only to pharmaceuticals but also to vaccines, diagnostics, and other medical devices as essential for public health. The policy of patents for commercial benefits should be set aside until the global pandemic subsides. Till then, business will not return to normacy in some or

other corner of the world, and human life will be at a greater risk of life. In these conditions, there should not be a place for patents or corporate profiteering as long as the world is out of danger from the COVID-19 pandemic.

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Conflict of interest

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