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Impact of IP Exemptions for COVID-19 Vaccines on Vaccinated Populations in Less Developed Countries

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Abstract: Since the outbreak of the COVID-19 in 2020, global economic growth and public health have been greatly impacted. On the one hand, the epidemic has disrupted global supply chains, affecting the economic stability of various countries, and increased the vulnerability of the global economy. On the other hand, the epidemic has exposed the rapid spread of epidemic diseases around the world by globalization, which has become a systemic risk.As one of the best solutions to prevent the spread of large-scale diseases in the greatest public range in the history of human medical development, vaccines have become the key to whether humans can defeat the COVID-19 as soon as possible. This paper shows the changes in the vaccinated population of less developed countries after the implementation of the COVID-19 vaccine exemption by establishing a mathematical model, and proposes that less developed countries should adjust their policies to help the vaccine exemption to vaccinate more people in their own countries according to existing international rules.

Keywords: exemptions, vaccine, resources, maximization

1. Introduction

According to statistics from the World Health Organization, as of November 26 2021, there are 326 COVID-19 vaccines have been developed worldwide, of which 132 have entered the clinical stage. China, the United States, and the European Union have approved and authorized a total of 11 vaccines for marketing. As of November 8, 2022, a total of 12.91 billion doses have been administered globally, or 161.93 doses per 100 people. According to the global vaccination data per 100 people, the per capita vaccination is 1.6 doses, and when broken down to various regions and countries, the problem of insufficient number of vaccines and uneven distribution is highlighted. In general, the number of vaccines per capita in developed countries and regions such as Europe and North America is much higher than that in Africa, and some developing and backward countries in South America have an extra dose per 100 people.

In October 2020, India and South Africa proposed that the WTO grant intellectual property exemptions for COVID-19 vaccines to help accelerate vaccine production and distribution, thereby expanding the volume of vaccines produced and reducing the price at which governments procure vaccines, effectively addressing the shortage and uneven distribution of vaccines [1]. The exemption will mainly involve four aspects, including vaccine copyright, industrial design, research and development patents, and the right to protect undisclosed information, the key of which is patent rights. In the long run, after the intellectual property rights of the COVID-19 vaccine exempted, the

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vaccine can be produced and used more, and the exemption will put manufacturers under pressure, so there will be a balance between long-term and short-term interests [2]. Based on the existing pricing of the COVID-19, this paper establishes a price model, analyzes how much the price of the vaccine will change after obtaining the patent exemption, and correlates the vaccine price with the number of vaccinated populations in each country, and explores how much the current per capita vaccination number of countries can be greatly increased in the number of vaccinated people after the vaccine price is reduced.

2. Literature Review

2.1. Global COVID Vaccine Distribution Process

In consultation with international scientists and public health experts, WHO began research and development of a COVID-19 vaccine in February 2020 to implement COVAX. The Values Framework for COVID-19 Vaccine Distribution and Prioritization provides guidance on the value and ethical considerations for distributing COVID-19 vaccines among countries, broadly divided into two phases in the context of limited supply. The first requirement is to ensure the vaccination of priority groups, which are: 1.Health care workers in health and social care settings; 2.People over 65 years of age;3. People under 65 years of age with underlying diseases with other serious diseases that put them at higher risk of death. In the first phase of the allocation, these priority groups will be immunized at the same time, and these doses will probably cover about 20% of the population of each country, and for the 92 low- and middle-income economies in its organization, reaching 20% will depend on the financing of COVAX AMC, which will determine their participation in COVAX Facility. In the second phase, additional doses will be made available based on funding, and if serious supply constraints remain at this time, the speed at which countries will receive additional vaccine doses will be determined by an assessment of their risk at any given time [4].

As such, it can be seen that financing is a decisive factor for countries to be assured in terms of the number of vaccines. Therefore, reducing the price of vaccines from the supply side is extremely effective in solving the problem of insufficient vaccines.

2.2. COVAX Foundation

The COVAX Fund, a donor-funded mechanism that aims to centralize procurement to increase access to vaccines in low- and middle-income countries, faces serious shortfalls in meeting global demand. WHO predicts that most people in low- and middle-income countries will not be able to complete one dose per capita until the end of 2023.The way it distributes the purchased vaccines is as follows：

COVAX countries will receive enough vaccines to immunize priority groups in their populations. In the first phase of allocation, doses will be provided simultaneously to participating countries until they are able to cover approximately 20% of the population in each country. In most countries, the first priority group will be frontline workers in health and social care.

WHO has chosen to set an initial priority for health workers (in most countries, this is less than 3% of the population) in the hope of ensuring that numbers meet the needs of well-resourced health systems without disadvantageing countries with a low proportion of health and social care workers. As supply increases, additional shares will gradually be added until 20% of the national population is covered in all participating countries [4]. For the 92 low- and middle-income economies, reaching 20% depends on the financing of COVAX MAX, which will support their participation in COVAX.

Once countries have received enough doses for 20% of the population, additional doses will be made available based on funding availability. In this second phase, if severe supply constraints remain, the pace at which countries receive additional vaccine doses will be determined by an assessment of

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their risk at any given time. Considerations will be based on assessments of threat (potential impact of COVID-19 on a country, assessed using epidemiological data) and vulnerability (a country's vulnerability, based on health systems and demographic factors).

In addition to the first and second phases of vaccine allocation, it is recommended to retain some vaccine doses as part of the "humanitarian buffer". When government-led national processes fail to reach certain populations, a small buffer of up to 5% of the total available doses will be set aside as a back-up mechanism as a last resort. For example, if necessary, populations living outside Government-controlled areas and those working in those environments could be served through humanitarian buffers. Governments and countries are encouraged to include all high-risk individuals and populations, regardless of location and legal status, including internally displaced persons, refugees, migrants and detainees, as recommended by WHO's Strategic Advisory Group of Experts on Immunization.

Through COVAX, the international community obtains funds donated or provided by the governments of the countries concerned or international organizations, purchases or accepts donations of COVID-19 vaccines approved by WHO for emergency use, and then distributes them equitably to countries that do not have the production capacity of COVID vaccines. To date, COVXA has distributed 16 rounds of COVID-19 vaccines, totaling 1.9 billion doses, benefiting 145 countries. In the case of the 16th round of allocations from July to October 2022, a total of 91 countries were "eligible participants", of which 52 countries did not indicate the need for the current allocation, 3 countries said they had abandoned the allocation through COVAX, and 36 countries said they accepted the allocation. As of 9 May 2022, the total country needs receiving this round of allocations are 62.3 million doses, covering seven COVID-19 vaccines currently approved for emergency use by WHO, of which 28% are from procurement and 72% from donations [3]. At present, from the demand side, only about 40% of qualified participants put forward demand, and it seems that demand is less, while the supply side does not have the problem of short supply. In addition to COVAX's multilateral channels, more COVID vaccines are being supplied by producer countries to demand countries through bilateral cooperation. As mentioned earlier, China alone has provided 2.2 billion doses of COVID-19 vaccines to more than 120 countries and international organizations. China also announced in November 2021 that in order to achieve the African Union's goal of vaccinating 60% of Africa's population with the COVID-19 vaccineby 2022, it will provide an additional 1 billion doses of vaccines to Africa, of which 600 million doses will be provided as gratuitous assistance and 400 million doses will be provided in the form of joint production between Chinese enterprises and African countries.

3. Methodology

Because the WHO imposes patent exemptions for vaccines in developing countries, a comparative approach is adopted.

In 2022, on June 17, the World Trade Organization (WTO) ministerial meeting reached an agreement to allow developing countries to be exempted from patents on COVID-19 vaccines. This means that companies in developing countries such as China, India, and South Africa can use COVID-19 vaccinepatents, including mRNA vaccine patents, without the authorization of the patentee [5]. The cause was a proposal submitted by India and South Africa to the World Trade Organization in October 2020. The main content of the proposal is to ask the WTO to discuss abandoning the implementation of some provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the Trips Agreement), so that intellectual property rights related to the diagnosis, treatment, and vaccines of the new crown will be abandoned.

However, the terms of the agreement reached this time are still far from the content of the original proposals of India and South Africa. India and South Africa hope that developed countries will be

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exempted from all intellectual property rights of the new crown prevention and control measures, covering vaccines, drugs and medical facilities, including patents. , technical secrets, etc. In comparison, the scope of this agreement only involves the patent exemption of the new crown vaccine, and the new crown therapeutic drugs are not within the scope, nor will it transfer the technical know-how of the new crown vaccine, which is more important for the production of mRNA vaccines.

The patent exemption of the COVID-19 vaccinates the greatest impact on mRNA vaccines. mRNA is a new technology, and the patents involved are all within the validity period. In comparison, the technologies of inactivated vaccines, vector vaccines, and subprotein vaccines are very mature. Even with a history of hundreds of years, basic patents have expired, and the intellectual property issues involved have little impact. The basic patents of mRNA vaccines, including molecular modification and encapsulating particles, are all within the validity period. Once these patents are exempted, companies can safely and boldly develop applications and produce domestic versions of mRNA vaccines, which is of positive significance. However, the vaccine patent exemption period is only 5 years, which cannot solve long-term problems. In addition, the biggest difficulty in the production of mRNA vaccines is raw materials and manufacturing processes. Only a few suppliers in the world can produce enzymes and lipid-encapsulated particles for RNA molecular modification. Even if developing countries can use patents for free, they must obtain qualified Raw materials are not easy. In addition, there are many steps involved in the production of mRNA vaccines, most of which are protected by technical secrets, which are not reflected in patents. It is difficult to manufacture qualified vaccines only by relying on the information provided by patents.

On vaccine patent exemptions, opponents argued that the exemption would not help generic drug makers because it would not address the lack of manufacturing capacity and weak health care systems in some low- and middle-income countries. In addition, they argue that it cannot alleviate the scarcity of raw materials or mimic the high learning capacity of vaccine development companies in the vaccine manufacturing process. Both of the above-mentioned problems can be solved under the existing international trade system. For example, the vaccines exported by Sinovac to Africa are not simply bought and sold, but established commercial partnerships with local pharmaceutical manufacturers to help them manufacture vaccine.

According to the statistics of the number of vaccinated populations in various countries and the number of vaccines per 100 people shown in Table 1 below, it can be seen that developed countries have great advantages in both the number of vaccinations and the number of vaccinations per capita, while underdeveloped regions, Especially in African countries, not only the number of vaccinations is small, but also because of the large population base, the number of vaccinations per capita cannot even reach one-tenth of that of developed countries.

There are two reasons for the above phenomenon. First, many companies that develop vaccines are located in developed countries. They signed contracts with their governments in the early stage because they required huge capital investment. The price of selling vaccines in their own countries will be relatively cheap, while vaccines exported to other regions will be relatively cheap. The price is on the high side to make up for the huge amount of money invested in research and development. Second, the degree of perfection of the medical construction system in each country is different, and there is a gap in the medical subsidies that can be supported and the ability to purchase vaccines. Developed countries not only purchase vaccines at relatively cheap prices, but also have more funds for the government to purchase vaccines, and the medical security system can support a larger number of vaccine purchases.

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Table 1: Vaccinated population in some countries.

Country	Cumulative vaccination（a hundred million）	Vaccinated per hundred people（doses）
India	22	155.11
Brazil	4.7	219.89
Indonesia	4.4	159，79
Bengal	3.3	190.09
Pakistan	3	127.64
Egypt	0.9842	90.08
Nigeria	0.4399	20.81
South Africa	0.3789	63.26
Ethiopia	0.2937	24.92
Uganda	0.2089	44.35
Kenya	0.1824	33.18
Ghana	0.1612	50.81
Algeria	0.152	34.08
America	6.4	193.04
Japan	3.4	271.01
German	1.9	226.55
France	1.5	223.16
Italy	1.4	241.18
England	1.4	208.42
Netherlands	0.3401	198.09
Belgium	0.2941	252.4

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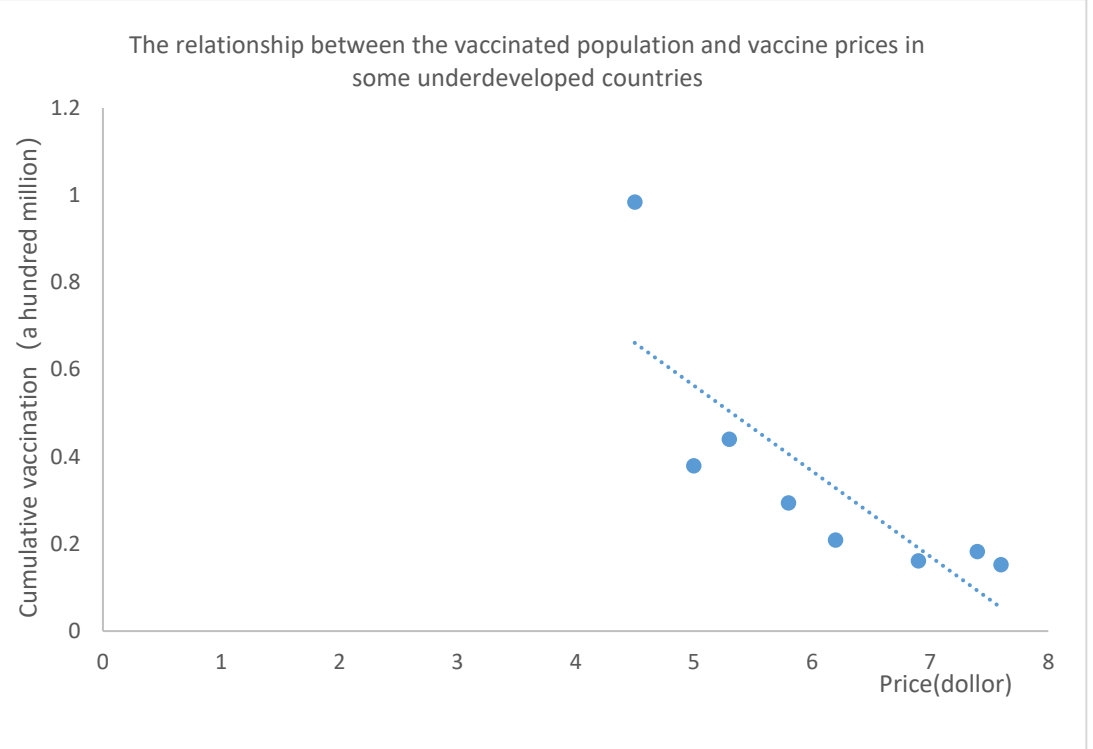

Figure 1: The relationship between the vaccinated and vaccine prices in some underdeveloped countries.

As we can be seen from Figure 1, the horizontal axis indicates that the vaccine purchase price of less developed countries is the independent variable(Name of the vaccine is ChadoX 1-S ,which is popular in low and middle income countries because it is easier to store) and the vertical axis indicates that the cumulative vaccination volume of the country is the dependent variable. Overall, there is a negative correlation between the price and cumulative vaccination volume, with the higher the purchase price of vaccines, the lower the number of vaccinations in the country.

Vaccine immunity has had a positive impact on the vaccinated population in less developed countries. Immunity can help less developed countries reduce the cost of vaccination, thereby improving the vaccination rate and reducing the spread of disease. In addition, immunity can also help less developed countries to obtain more vaccines, thus improving the efficiency of vaccination.

According to the data, the release of vaccine immunity has a great impact on the vaccination population in less developed countries. Countries with strong pharmaceutical vaccine production capacity and mature supply chain will naturally have strong imitation capacity and will benefit from patent exemption in the short and medium term. Among the developed countries, France, Switzerland and Japan are such countries; Among the developing countries, India, South Africa, China and Russia are undoubtedly the countries that meet the above conditions.

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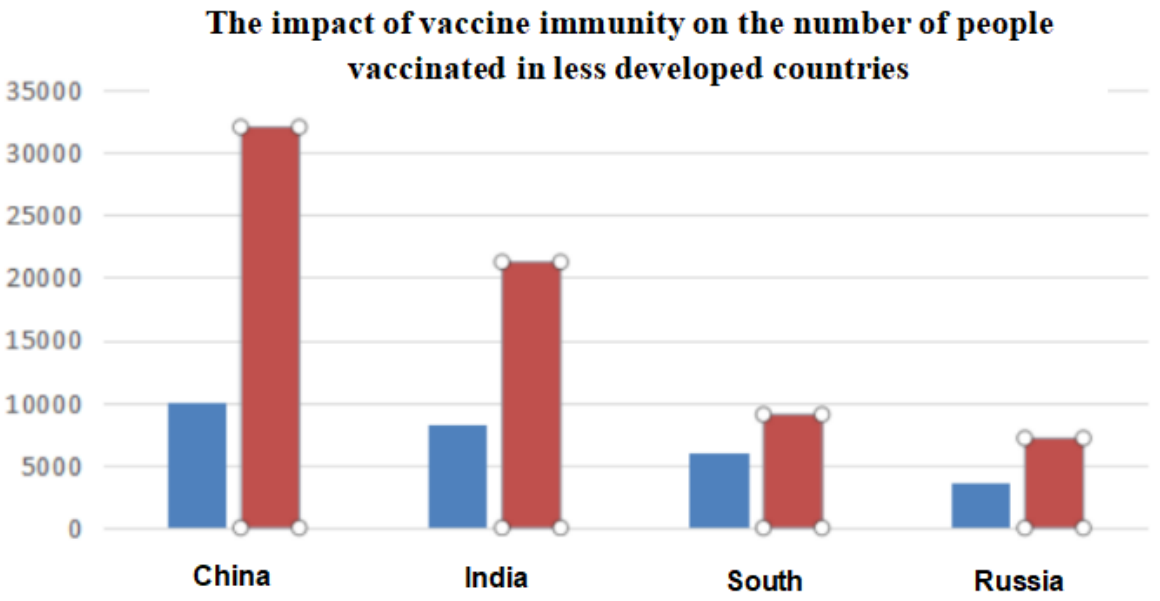

Figure 2: The impact of vaccine immunity on the number of people vaccinated in less developed countries.

The number of vaccinations in China, India, South Africa, Russia and other countries increased rapidly in the short term, and the vaccination rate increased rapidly. Mathematical models can be used to simulate the impact of the implementation of vaccine immunity on the vaccination population in less developed countries, and the impact of the implementation of vaccine immunity on the vaccination rate in less developed countries.

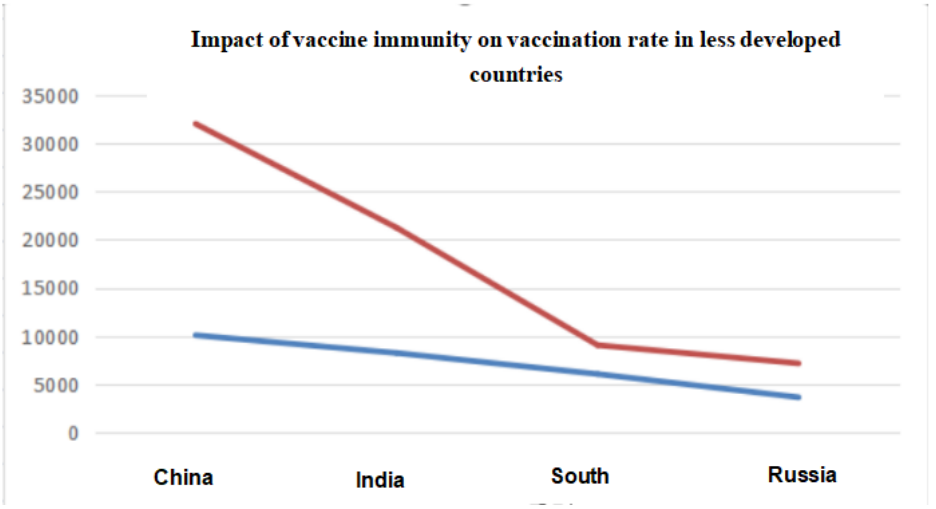

Figure 3: Impact of vaccine immunity on vaccination rate in less developed countries.

From the Figure 3, we can see that the implementation of vaccine immunity has a great impact on the vaccination population in less developed countries. The vaccination population has increased a lot and the vaccination rate has increased.

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4. Result

According to the decision on the exemption of intellectual property rights for COVID-19 , countries such as India and South Africa that have production capacity for COVID-19 but lack relevant independent intellectual property rights can apply for compulsory patent licenses to produce more COVID-19 to supply their domestic markets or export to COVAX international cooperation projects or regional cooperation projects, and pay appropriate licensing fees to patent owners related to COVID-19 on the basis of accessibility and affordability, so as to meet the needs of developing and least developed members as soon as possible. In particular, there is a need for more people in African countries to be vaccinated against the COVID-19.

There is currently no disclosure of patent licensing rates for COVID-19 vaccines, but the usual international technology transfer licensing rate is 5% of net sales or gross production. It can be inferred from this that the patent compulsory license rate should be lower. The appropriate remuneration required to be paid to patent owners in the COVID-19 IPR exemption decision should consider the humanitarian and non-profit purpose of providing equitable access to COVID-19-specific vaccine distribution programs.

This indicates that the compulsory license rate for the implementation of COVID-related patents under the decision on the exemption of intellectual property rights for COVID vaccines will be close to the minimum rate for gratuitous use. Pharmaceutical companies that have invested heavily in R&D and clinical trials of COVID vaccines, taking into account the costs and necessary returns, may consider applying for patents in countries with production capacity among eligible members. After all, all WHO-approved vaccines for global use are still limited to emergency use, and their effectiveness and safety need to be improved. At present, drugs for the diagnosis and treatment of new coronary pneumonia are still under development, and once they can be marketed in the future, relevant pharmaceutical companies will also consider their return on investment. Eligible members of COVID-19 vaccine IP exemptions also have to consider these dynamics when deciding to implement compulsory licenses and pay licensing fees for COVID-19-related patents [6]. After all, patent rights are private rights, and their owners have the right to decide whether to apply for a patent in a certain country. If there is no patent for the production technology of the new crown vaccine, there is no object of compulsory patent license.

In short, the development, production and improvement of the COVID-19 are closely related to the relevant intellectual property rights. The exemption of IPRs related to COVID vaccines will help developing members with production capacity in eligible members to produce more COVID vaccines at the lowest compulsory license rates to further meet the needs of their countries, other countries and regions, and even the world, but it remains to be seen which developing members and their manufacturers will implement the compulsory patent licenses stipulated in the IP exemption decision for COVID vaccines, and will effectively improve the global imbalance in access to COVID-19.

Vaccine immunity has had a positive impact on the vaccinated population in less developed countries. Immunity can help less developed countries reduce the cost of vaccination, thereby improving the vaccination rate and reducing the spread of disease. In addition, immunity can also help less developed countries to obtain more vaccines, thus improving the efficiency of vaccination.

5. Conclusion

There are many factors that affect the purchase price of vaccines, and patent exemptions are only the most influential part, so the model cannot be more accurate in deriving changes. The data derived by the model can be made more accurate by introducing more variables, assuming parameters, etc.

Moreover, underdeveloped countries can better align with vaccine exemptions by developing policies.

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Opening up foreign vaccine imports, removing compulsory licenses for the non-free circulation of imported vaccines in domestic markets, and allowing domestically produced vaccines to be exported abroad. It is conducive to encouraging domestic pharmaceutical companies to carry out vaccine research and development and production, cooperate with foreign pharmaceutical companies to produce vaccines in China, and form different levels of vaccine prices in the domestic market to promote their market-oriented development.

According to the principles of the TRIPS Agreement and the decision on intellectual property exemptions for COVID-19 vaccines, explicitly add vaccines as objects of protection. According to the TRIPS Agreement, "eligible members should not be prevented from being able to quickly approve vaccines produced under this decision". In addition, the protection of chemical test data under the TRIPS Agreement can be applied by analogy to the protection of biological drug test data such as vaccines. If the marketing of biological drugs such as vaccines is approved under the compulsory patent licensing rules provided for in the TRIPS Agreement, the marketing of chemicals produced under the rules should also be authorized [7].

References

[1] *How patent rights work in the pharmaceutical industry--Patent Exclusivity&Regulatory exclusivity,https://www.theactuarymagazine.org/pharmaceutical patent regulation in the united-states/.*

[2] *Sekalala, S., Forman, L., Hodgson, T., Mulumba, M., Namyalo-Ganafa, H., & Meier, B. M. (2021). Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccine. BMJ Global Health, 6(7), e006169.*

[3] *Okereke, M. (2021). Towards vaccine equity: Should big pharma waive intellectual property rights for COVID-19 vaccines?. Public health in practice (Oxford, England), 2, 100165.*

[4] *Xu Chunming,Chen Xueni. On the WTO's patent exemption to expand access to COVID-19 vaccines[J]. Technology & Law(Chinese & English), 2022(4):8.*

[5] *Members Welcome Quad Document as Basis for Text-Based Negotiations on Pandemic IP Response, WTO (28 June 2022).*

[6] *Ting-Wei (Alex) Chiang & Xiaoping Wu, Innovation and Patenting Activities of COVID-19 Vaccines in WTO Members: Analytical Review of Medicines Patent Pool (MPP) COVID-19 Vaccines Patent Landscape (VAXPAL), WTO Staffff Working Paper ERSD-2022-01, 10 February 2022, p.5.*

[7] *Zhang Naigen.Analysis of the decision on intellectual property exemption of the new crown vaccine and its importance[J].intellectual property2022(09):53-69.*