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Which One Should Be Prioritized During Pandemics: Patents or Global Health?

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ABSTRACT

Introduction: Despite the existence of the human health rights at global and national levels, patent laws are singularly in the battle against public health crises due to exclude others from making, using and selling the patented health products. These laws impose costs on health care systems and cause of human death worldwide. **Methods:** A retrospective literature search was conducted using appropriate key words. In addition to international intellectual property rights, published studies were reviewed. **Results:** Experiences from the Medicines Act in 1997 of the South Africa and the current pandemic showed that compulsory licensing and parallel importation do not have the necessary effectiveness and cause economic and political pressure of developed countries on developing countries. In addition, high price of technology transfer, insufficient disclosure of necessary data and commercial impediments by patent holders, make virtually impossible to apply TRIPS waivers in national emergencies and pandemics. Insufficient manufacturing capacity of health products manufacturers and prompt need of people worldwide to essential health products in public health crises, lack of transparency and interpretable Articles of the TRIPS Agreement hamper rapid and sufficient production, adequate and equally supply of the effective and affordable essential health products. **Conclusion:** The South Africa case and the current pandemic clearly showed the ineffectiveness of TRIPS waivers, public health endangerment and loss of human lives in public health crises. Once and for all, through national legislation and international treaties, the lack of access issues to essential health products in public and global health crises must be solved.

INTRODUCTION

From a human health rights perspective, the United Nations Charter (1945), the Universal Declaration of Human Rights (1948) and the Constitution of World Health Organization (1948) stipulate access to medicines and other health products and emphasize on public health promotion [1]. In addition, the General Agreement on Tariffs and Trade (GATT) - that transformed into the world trade organization (WTO) - has been recognized the right of governments to enact trade-restricting measures to access to patented products to protect human life and to support public health. Before TRIPS agreement enters into force, many countries in the world did not grant patents for pharmaceuticals and many others only supported the process patents on pharmaceuticals. After January 1, 1995 that TRIPS came into effect, TRIPS requires nations to protect many health products including pharmaceuticals, diagnostics and medical devices. Otherwise, they will be subject to WTO sanctions [2].

Patent law is properly an important element of an innovation system. However, it is singularly ill-suited to the public health crisis such as pandemics and national emergencies because for a period of time (generally 20 years), no competitors can manufacture or sell the patented product without the permission of the patent holder due to exclusive rights or monopoly privileges of the patent holder and these rights impose costs on health care systems.

Despite the existence of the above-mentioned rights at global and national levels, according to the report of the WHO Director on January 24, 2022, about fifty percent of the world's population lacks still access to essential health services [3]. This issue manifests itself more intensely in situations of emergency such as pandemics. For instance, the March 2022 UN Development Program (UNDP) report showed that despite administration more than 10 billion doses of COVID-19 vaccines, 2.8 billion people worldwide are still waiting to get their first dose of vaccine [4].

Experience has shown that there has always been a fundamental conflict between private profits of manufacturers of essential health products (EHPs) including drugs, vaccines, diagnostics and medical devices and public health interests. In

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other words, there is a basic mismatch between intellectual property rights and effective control of public health crisis. The main objective of the present study is evaluating the issues of intellectual property rights in pandemics.

MATERIALS AND METHODS

Retrospective Literature Search

The search was conducted in PubMed and Google Scholar using appropriate key words such as: patentability, essential health product, drug, pharmaceuticals, vaccine, diagnostic, medical device, effectiveness, intellectual property, exclusive rights, access to medicines, TRIPS Agreement, TRIPS waivers, compulsory licensing, parallel importation, national emergency, pandemic, manufacturing capacity and infrastructure. In addition to international intellectual property documents, published studies were reviewed.

RESULTS

The Past Experience

Big Pharma's response to anti-HIV/AIDS drugs has well demonstrated that patents stymie accessible treatment and cost lives. According to the 2020 UNAIDS Report on the Global AIDS Epidemic, sub-Saharan African countries alone accounted for 25.3 million of the 37.7 million global HIV infections [5]. Poverty, poor health infrastructure, inadequacy and the poor quality of drugs are the factors affecting to the lack of access to safe, effective and inexpensive medicines in the area. However, critical factor in the affordability of newer anti-HIV/AIDS is the impact of patent protection [6].

South Africa introduced the Medicines Act in 1997. The Act could allow the South African government to:

• "use 'parallel importing' to obtain patented life-saving medicines from countries where they are sold more cheaply;
• authorize imports of generic versions of patented medicines for non-commercial government use, through compulsory licenses
• adopt measures to ensure that pharmacists dispense cheaper generic copies where doctors have prescribed more expensive brand name drugs;
• establish a pricing committee to introduce a transparent pricing system for all medicines."

After introduction of the Medicines Act and under pressure of the association of the US top pharmaceutical companies, the Pharmaceutical Research and Manufacturers of America (PhRMA), the Office of the US Trade Representatives and the US government have pressured the South African government to abandon its legal attempts to employ compulsory licensing and parallel imports. On April 30, 1998, the US government placed South Africa on the '301 Watch List' and threatened the South African government with trade sanctions if the Act was not repealed. On December 1, 1999, due to the efforts of NGOs, following campaigns by South African AIDS activists and a public outcry in the USA, the US government dropped South Africa from its '301 Watch List'. On March 5, 2001, 39 pharmaceutical companies filed complaints against the South African Medicines Act at the Pretoria high court and argued that the South African legislation infringed their patent rights and contravened WTO patent rules. The companies pursued the case despite the public health crisis of HIV/AIDS in the South Africa [7]. After South Africa promised that the implementation of the Act would comply with the rules of the WTO and under worldwide condemnation and pressure, on April 19, 2001, the pharmaceutical companies completely abandoned their court challenge against the South African government [8]. It should be noted that between introduction of the act in 1997 and February 2001 (after the case was dropped), 400,000 people have died from AIDS related diseases, partly due to the high cost of HIV/AIDS drugs [7].

COVID-19 Pandemic

During the current COVID-19 pandemic, The US President Joe Biden's administration has announced that it supports waiving intellectual property protections for COVID-19 vaccines (not for drugs, diagnostics and medical devices) under the World Trade Organization's Agreement on Trade-Related Intellectual Property Rights (TRIPS) [9]. The decision provoked again the reaction of the PhRMA. According to their statement, this decision debilitates supply chains, fosters the production of counterfeit vaccines, and will not save lives [10]. Thus, it can be seen that health crises have not affected the profit-seeking motives of the big pharmaceutical companies.

Practicality of TRIPS Waivers in National Emergencies

Compulsory licensing and parallel importation ("other use without authorization of the right holder" in the title of Article 31) are the most important flexibilities of TRIPS in national emergencies. However, have countries benefited from TRIPS waivers? In other words, do these waivers provide access to EHPs such as drugs, vaccines, diagnostics and medical devices in developing countries in emergencies?

Compulsory Licensing

According to the Article 31 (a) to (h) of the TRIPS Agreement, the user (person or company) must first make efforts to obtain a voluntary license from the right holder on reasonable commercial terms (b). In addition, compulsory licensing is considered on a case-by-case basis (a), must be non-exclusive (d), non-assignable (e) and to supply of drugs for the domestic market (f). In other respects, the license has limited scope and duration (c) and most importantly, the owner of the patent shall be entitled to "adequate remuneration" (h) [11]. From legal aspects, what level of remuneration is "adequate"? Alternatively, is there any standard for remuneration assessment when the license should be granted case-by-case basis? What is exact and consistent interpretation of general term, "reasonably", in Articles 30 and 31 of the agreement?

As can be seen from the conditions, compulsory licensing is a time-consuming and administratively burdensome process. In addition, implementation of this flexibility is technologically very difficult in national emergencies of the developing countries because these countries realistically do not have suitable and strong infrastructures in pharmaceutical industries [1].

Furthermore, manufacturing of vaccines and drugs require high technologies and it is so expensive to create infrastructures and transfer of these technologies to developing countries. Problems in pharmaceutical infrastructures, high price of technology transfer and low income of developing and least developed nations, make virtually impossible to apply a compulsory licensing in national emergencies [12, 13].

Additionally, Article 31bis was added the option for WTO member states to import or export generic versions of patented drugs and improve access to essential medicines. However, factors such as time-consuming process (the Rwanda-Canada case), the administrative and social burdens, pharmaceutical challenges, refuse of the Article by high-income countries and political pressure from other members to refrain from issuing

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compulsory licensing make Article 31bis system very difficult to implement [14-16].

The key question in this regard is: what will happen for countries of the world in situations of global emergency (such as the current pandemic)? The answer is clear. The U.S. 2021 Special 301 submission emphasizes trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement [17]. In addition, submission of the Biotechnology Innovation Organization (BIO) that includes Pfizer, Moderna, Johnson & Johnson, and Merck and the PhRMA submission attack explicitly on compulsory licensing in the context of the COVID-19 pandemic despite the legal position of this TRIPS waiver [18]. International medical humanitarian organization, Médecins Sans Frontières/Doctors Without Borders (MSF) criticized and challenged these submissions due to impact of the submissions on access to essential medicines, vaccines and diagnostics [19].

Parallel Importation

In parallel importation, third parties enter the market of health products at a lower price without patent owner's authorization and consequently, a highly controversial issue is arisen due to limitation of brand manufacturers' profits [20]. The lower price is beneficial for governments and consumers; however, it conflicts with exclusive rights and interests of the IP holders. For these reasons, patent holders may use tactics and pose commercial impediments to parallel importation to make it difficult to execute as a TRIPS waiver option. For example, patent owners may use different brand names for the same drug in different jurisdictions or they maybe change packaging, labeling, instructions for use, presentation and strengths of a drug launched in different countries. In these cases, the parallel importer has the burden of proof to show that different brand names are identical to the already exist drugs licensed on the market. These tactics makes it difficult for the parallel importer to obtain import and sales permits [21]. Increased potential risk of counterfeit pharmaceuticals distribution due to shortages of medicines in low-price countries, lack of transparency in drug pricing and discounts because of unpublished and undisclosed negotiations between countries' health insurers and drug manufacturers in different countries are the other negative consequences of parallel importation. These negative outcomes are not subjective and taken place in different European Union Member States [22]. Economic and political pressures of developed countries on developing countries are the results of using TRIPS waivers and trading partners' fury cannot be disregarded [1].

Manufacturing in Pandemic

Ever-present intellectual property and the nontransparent agreements act always as an obstacle in the timely, equitable and inexpensive delivery of health products to the world's people. COVID-19 escalates the conventional straggle between human rights and patent rights, leading to the global race to develop new EHPs.

It is obviously that development of health products needs new programs and investments on research and development. Pharmaceutical companies, on the one hand, emphasize on patent protection to secure their investments and from the other hand patent protection gives rise to the high drug price and monopolism. Therefore, pharmaceutical companies have formed a proprietary research platform, which has several negative outcomes in pandemics.

First, in pandemic situations, billions of people worldwide need prompt vaccination and treatment. However, pharmaceutical companies do not have sufficient capacity for the requested size of vaccines and drugs at national and global level.

Consequently, developed and wealthier countries will be the first to access these medicines and vaccines, as it took place during the 2009 H1N1 influenza and the COVID-19 pandemics. We have not forgotten the H1N1 influenza vaccine case but there are no lessons to be learned from the past. Second, each pharmaceutical company follows its own research and development programs and accordingly, a waste of time, resources (crucial factors for pandemic control) and the fragmentation of knowledge will happen. Finally, pharmaceutical companies argue that strong patent protection is essential in order to recoup investments, to encourage further innovation and to achieve market exclusivity. These exclusive rights result in high drug price and lack of access to EHPs [23]. In the beginning of January 2023, the U.S. Senator Bernie Sanders urges Moderna® not to quadruple the price of its COVID-19 vaccine because millions of Americans will not have access to the affordable vaccine. Moderna® was considering a price between $110 and $130 per COVID-19 vaccine dose while the price of the vaccine at that time was nearly $27 per dose [24]. Exclusive rights are very important for pharmaceutical companies, not only for new drugs and vaccines, but also for old drugs. For instance, when planning and implementation of clinical trials of low-cost anti-inflammatory steroid, dexamethasone, and other old drugs for the treatment of COVID-19 patients in the current pandemic were raised, pharmaceutical companies have been mentioned a number of IP-related issues and questions about drugs repurposing and new use of drugs [25].

Pandemic and Innovation

Innovators concern that removing intellectual property protection through COVID-19 pandemic prevents companies from innovating and a lack of innovation can cause failure during future pandemics. It is obvious that the main and noble purpose of intellectual property protection is economic profit from innovation. In pandemics, billions of people worldwide need a prompt to access vaccines, drugs, diagnostics and personal protective equipment. Therefore, due to the shortage, all health products will be sold and the profit will be made. Howbeit, pharmaceutical companies and health products manufacturers do not have such capacity in pandemics.

Some argued that without intellectual property protection, innovators do not have the enough incentives for extensive researches and investments on innovations. Consequently, public access to knowledge and technology will diminish. In response to the argument, firstly, patent owners disclose a certain amount of information (not fully disclosed) because some level of protection is required to encourage patenting. Second, it should be stressed that the Article 39 of the TRIPS agreement protects undisclosed information such as trade secrets, 'know-how' knowledge and data disclosed to governments (such as clinical data results) for approval processes. Interestingly, drugs and vaccines manufacturing technologies have much such information that should not be disclosed [26, 27]. In the case of unauthorized use or distribution of such data, a violation of the patent owner's rights has been occurred and results in a lawsuit against the offender.

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DISCUSSION

The current pandemic of COVID-19 has posed an unprecedented global health challenge. It has highlighted a lack of widespread, equitable and affordable distribution of innovative EHPs for the pandemic control. When efficacy, safety and quality of any of these innovative candidates are demonstrated, multiple barriers may hamper rapid and sufficient production, adequate supply of the effective and affordable health products. At the center is the use of intellectual property, especially patent and its exclusive rights, to restrict manufacturing, supply and distribution of the health products. These exclusivities enable patent holders to charge high prices and consequently profiteer from the pandemic, prioritize wealthier countries over ones with less financial capacity, bring up drugs repurposing and new use of drugs and not to share their technologies with other manufacturers who can rapidly scale up the production of these health products.

In October 2020, India and South Africa initially proposed a broad waiver to suspend certain TRIPS agreement obligations including copyrights, patents, industrial designs and undisclosed information (trade secrets) in relation to "prevention, containment or treatment of COVID-19" in low- and middle-income countries until widespread vaccination. The broadness of the proposal was related to its three objectives: preventing, containing and treating Covid-19. The proposal would not only cover vaccination as a preventive measure, but also any means to fight COVID-19, including diagnostics, medicines, medical devices, personal protective equipment, their materials or components, their methods and technologies of manufacturing as containment or treatment of COVID-19 measures. However, it prompted skepticism, largely from a number of high-income countries like the US, UK, EU countries, Norway, Switzerland, Australia, South Korea, and Japan due to concerns about its scope, duration and possible adverse effects on innovation. The India-South Africa proposal was later revised on 21 May 2021 and was supported by more than 100 countries and territories, including China and Russia. In March 2022, after over 18 months from the initial submission of the proposal, the final WTO decision significantly diminished the original proposal and limited it only to patents on vaccines and the use of protected clinical trial data for regulatory approval. Public health advocates, civil society organizations and academics, for too narrow and insufficient support of public health, criticized the WTO decision [28, 29]. In addition, the World Health Organization (WHO) pushed pharmaceutical companies to support the COVID-19 Technology Access Pool (C-TAP), the voluntary platform for sharing scientific knowledge, data and intellectual property. Nevertheless, none of the companies has shared voluntarily and practically their expertise [30]. As can be observed, big pharmaceutical companies show no sign of changing in intellectual property rights policies in the current pandemic compared to the past to prioritize public health over profit (just like it was in the late '90s for anti-HIV/AIDS drugs). TRIPS waivers are legal tools to override patent-protection and the key conditions for governments in order to supply and access of medicines and medical technologies, which are essential to emergency control at national or global levels. In theory, TRIPS waivers are good idea, but in practice, governments are having issues.

An obstacle that has been cited repeatedly is that existing TRIPS waivers mechanisms are too time-consuming, narrow, restrictive, bureaucratic, and cause economic and political pressure of developed countries on developing countries. The Bolivian government struck a deal with Canadian Biolyse Pharma to seek a compulsory license to produce and export 15 million doses COVID-19 vaccine without the permission of the patent holder, but it failed [31]. On the African continent, the use of TRIPS flexibilities has been controversial and suspension of TRIPS flexibilities for at least three years to meet the primary objectives of preventing and treating the COVID-19 pandemic is recommended [32]. On 5 May 2021, the US announced that it would support a waiver for COVID-19 vaccines (only vaccines) but it does not mean that the US supported the waiver as proposed by India and South Africa [33].

As explained, ineffectiveness of articles 31, 31bis and TRIPS waivers to provide equal and affordable access to vaccines, medicines and diagnostics is completely clear. However, some people surprisingly believe that compulsory licensing, articles 31 and 31bis have been abused by governments and they cause damage to the United States healthcare industries! [34]. Article 39 is in the battle against pandemics because generic manufacturers require know-how, clinical data and expertise due to the complexity of the vaccines and pharmaceutical manufacturing processes which all protected by Article 39 of the TRIPS agreement. In addition, even in national or global emergencies, patent owners are not required to include disclosure obligations at all and this is extremely harmful for low-income countries seeking timely, affordable and equitable access to medicines and vaccines [26]. Article 39.3 covers the protection of all data necessary to obtain marketing approval for the governments. However, governments are not obliged to protect any data in national emergencies and may disclose all the relevant data for imposing a compulsory license to protect public health.

Despite the above theoretical contributions, there are practically at least three reasons that affect usefulness of 39.3 exception in compulsory licensing. From a legal point of view, governments should be successfully implemented the public protection-exemption of the Article first. Otherwise, compulsory licensing will be issued without access to necessary data. Second, when a previous marketing approval has been granted in another Member State, it is not necessary to submit data in connection with the second marketing application. Article 39 does not impose any obligation on a Member State to share the disclosed data with the other Member States wishing to grant a compulsory licensing, resulting in the lack of access to necessary data and how-know information. Third, even with the implement of the Article and necessary data disclosure, due to the significant differences in technical sophistication and expertise, building manufacturing capacity up and set up a functional manufacturing facility without the assistance of the patent holder or another supplier is impossible. Consequently, Article 39 does not seem to support the TRIPS compulsory licensing system. The combination of the Article 31, Article 31bis and Article 39 makes it very difficult for a Member State to overcome the all mentioned challenges [26].

In brief, the use of interpretable words in the Articles which are related to implementation of the TRIPS waivers, time-consuming and administratively burdensome process of the TRIPS waivers, refuse of implementation of the TRIPS waivers by high-income countries despite their legal position, make the TRIPS waivers very difficult to implement. In addition, economic and political pressure of developed countries, using commercial impediments, low capacity of EHPs manufacturing, the exclusive rights, lack of transparency in EHPs pricing and limited necessary data and how-know information are the other important challenges. These challenges along with the

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impracticality of TRIPS waivers implementation complicate the timely and equitable access of the world's people to affordable EHPs in pandemics and leading to global health endangerment [26, 27].

From both legal and human rights perspectives, in order to overcome these obstacles, folarlowing solutions are suggested to support global health in pandemics.

• Unambiguity and clarifying of the Articles related to the TRIPS flexibilities implementation

• Governments legislate unambiguous circumstances and non-bureaucratic process in order to apply TRIPS exceptions by considering legal position of the TRIPS flexibilities

• Prohibition of patents and all kinds of intellectual property rights for EHPs and their materials, components, know-how knowledge, methods and technologies of manufacturing during pandemics and national emergencies by national legislation and international treaties

• Prohibition of commercial impediments through national legislation and international treaties during pandemics and national emergencies

• Governments provide financial support to research, development and manufacturing of EHPs as incentives for EHPs manufacturers and in order to stop wasting time, resources and the knowledge fragmentation

Governments should assess the price of drugs to ensure a reasonable profit for the manufacturers of EHPs

• Governments should assess EHPs prices so that, while providing a reasonable profit for the EHPs manufacturers, rising drug prices are not passed on directly to people and health care systems

In conclusion, while we discuss in favor of and against TRIPS waivers in articles the pandemic frustratingly goes on and at the time of writing (March 24, 2024), more than 7,000,000 people have lost their lives according to the WHO report. We have practically seen the systemic failure of the TRIPS waivers to respond to perhaps the greatest public health crisis of our time. The waivers fail overall to offer an effective solution to help increase people's access to needed health products not only in pandemics but also in national emergencies. Despite the presence of many international rights about access to health and healthcare as fundamental human rights, these rights have achieved recognition mostly in theory rather than in practice. There is a lot of talk and writing about human rights and the importance of human life in the media, however, intellectual property rights trump the right to health and a fundamental question remains unanswered, the patent or the patient? As we have seen with COVID-19, no one is safe until everyone is safe and this pandemic will not be over anywhere until it is over everywhere. A global problem such as the COVID-19 pandemic requires necessarily a global solution. With an eye to this aim, due to the ineffectiveness of TRIPS waivers and public health endangerment, all world countries must have enacted special legislation so that EHPs could not be patented in national emergencies and pandemics. With the two experiences (the South Africa case and the current pandemic), the legislation is now not a choice, but a necessity. In other words, it is necessary once and for all through national legislation and international treaties to solve the lack of access issues to essential health products and the ineffectiveness of TRIPS waivers in national or international emergency situations. We should stop writing in articles and do something in practice, because maintaining the global health requires intention, and will of all the people and governments of the world.

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CONFLICT OF INTEREST

The author declares he has no conflict of interest.

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