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The Effectiveness of Compulsory Licensing in Accessing Vaccines COVID-19 Case Study”

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Abstract

Countries seek to halt the Corona pandemic by searching for a legal means to access medicines and vaccines considering the owner's refusal to voluntarily waive their patent rights, their scarcity, and the inability of developing countries to access them in sufficient quantities. Countries have different positions on the pandemic and the possibility of implementing compulsory licensing, based on the political and economic obstacles that create reluctance. As such there must be concerted efforts internationally to make vaccines 'public goods' in the near future. Hence, this study is carried out to find implementable solutions to limit ascendancy and achieve justice since lives are being lost and losses incurred in all sectors around the world, including both rich and poor countries.

Key words: Patents, Compulsory Licensing, Vaccines, Coronavirus, TRIPS Agreement, World Trade Organization, World Health Organization.

Introduction

Compulsory licensing is an ideal way to create balance and a way to access the medicines and vaccines to combat any pandemic, especially in developing and poor countries that are unable to pay huge sums to obtain them, as well as considering the intense competition between countries to access these vaccines, as what we faced during coronavirus pandemic. (Sadykova et al., 2022)

This made it important and necessary for all countries in the world to act in order to prioritize the interest of humanity over the profits that global pharmaceutical companies seek to achieve.

As an example, The World Trade Organization had received a petition signed by more than 900,000 people demanding that it ensure access to life-saving vaccines and treatments for Coronavirus for everyone in the world.¹ Such actions emerge from the entrenched beliefs of peoples around the world that all medicines should be 'public goods', based on which intellectual property rights is not considered valid (Li & Noor, 2022).²

In this study there are many problems that require finding legal and realistic solutions which raises the following questions: Do intellectual property rights hinder the delivery of vaccines to all countries of the world? Are international legislations and agreements (Kim et al., 2023)

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sufficient in their texts to lift patent protection to combat pandemic internationally? Why do developed countries stand in the way of any attempt to implement compulsory licensing and oppose any move under the World Trade Organization (WTO) towards halting or waiving protection for patents on medicines and vaccines? Can a voluntary waiver or pooling of patents be made to combat any upcoming pandemics or diseases in the future? Is it possible to assign the World Health Organization and the World Intellectual Property Organization (WIPO) the task of making decisions on compulsory licensing with an international character? (Van Dung & Hoa, 2023)

Compulsory Licensing is A Means for Countries to Access Vaccines

Compulsory licensing is one of the important issues that developing countries defended after the conclusion of the TRIPS Agreement and demanded the initiation of a review of their provisions governing it, because it is considered a tool that may limit the exclusive rights of the patent holder when necessary, contribute to safeguard public health, and ensure the provision of essential medicines and vaccines at reasonable prices (Barnawi, 2022).

There is no doubt that some countries inclination towards compulsory licensing is sometimes an urgent matter when patent owners refuse voluntary licensing or to waive their patent rights to confront an exceptional circumstance such as the Corona pandemic. Furthermore, resorting to compulsory licensing as a last option is an indication of the failure of patent owners in their duty to safeguard public health, which may damage their reputation and increase the pressure on them at the international level.³ (Fakhrou et al., 2022)

Most countries have adopted in their national legislation the compulsory licensing system, which has become with time a common feature of patent laws, both in developed and developing countries alike, and whose provisions have been regulated on the international level. It is no secret that there are many reservations about the compulsory licensing system which limit resorting to it and assume its ineffectiveness (Prataksita et al., 2022).

The Position of Some Countries Regarding Compulsory Licensing of Coronavirus Vaccines

Countries had different positions regarding the Corona pandemic. Some have had a positive role and endeavor since its inception. For example, on the legislative level, there were exceptional and emergency legislation in line with the requirements of compulsory licenses that may be resorted to when needed. Also, there were actions taken at the level of the legislative authority to combat the pandemic represented in the great competition between pharmaceutical companies in developed countries to reach effective vaccines. For example:

First: France

The French legislator regulated the legal provisions related to patents and their licensing in the Intellectual Property Law amended in 2019.⁴ Moreover, it approved a new article in the French Public Health Law⁵ that allows the imposition of compulsory licenses when necessary, to combat Coronavirus, overcoming the general provisions in the intellectual property law. In addition, the government had put in place measures to facilitate the conduct of industrial property procedures during the pandemic period.⁶ However, France has not made any compulsory licenses during Corona pandemic (Al Doghan & Sundram, 2023).

Second: India

The Patents Act 1970 (as amended in 2005)⁷ regulated the provisions regarding compulsory licensing.

As a precedent for India, compulsory licensing was first granted in 2011 by the Comptroller General of a company called Natco Pharma for a medicinal compound called 'Sorafenib Tosylate'.⁸

During the Corona pandemic, the Health Defense Group in India was urging the government to cancel the patents granted to Gilead Sciences for 'Remdesivir' for the public interest, for it to be distributed more equitably to Corona virus patients around the world, specifically in poor countries,⁹ but it does not happened (Shabbir & Hussain, 2022).

Third: Chile

On 17 March 2020, the Chilean House of Representatives unanimously approved a resolution demanding the government to declare a justification for the use of compulsory licenses to facilitate access to vaccines, drugs, diagnostic supplies and other preventive and treatment technology for the Coronavirus,¹⁰ but no action was taken (Van Tu & Truong, 2022).

Fourth: Brazil

Brazil had submitted a draft legislation to allow the government to suspend any or all patents for medical products that could be used to combat Coronavirus, or in any future public health emergency that would be declared by the Brazilian authorities or the World Health Organization.¹¹

The Position of the (TRIPS) Agreement Towards Compulsory Licensing of Coronavirus Vaccines

The World Trade Organization is the first guarantor of the commitment of all countries to implement the agreements they established, the most important of which is the TRIPS Agreement. This agreement sought to establish a global intellectual property rights system that would harmonize legal standards among the Organization's member states.¹²

TRIPS Agreement and Patent Protection 13

According to the TRIPS-compliant patent system, WTO member states are required to ensure the protection of product patents and the exclusive marketing rights of their owners. This expanded protection for pharmaceutical companies that own patents may contribute to raising the prices of medicines and vaccines, which they see as compensation for the high costs of research and development, thus making them accessible to all except for the poor.¹⁴ This confirms that the TRIPS agreement maintains the high prices of drugs. Today, the TRIPS agreement has become the most prominent challenge facing the national pharmaceutical industry, through its protection of the final product and manufacturing method for twenty years.¹⁵

The TRIPS Agreement and The Compulsory Licensing of Patents

The TRIPS Agreement sets the standards for the use of compulsory licenses in Article 31. In addition, the regulation of national legislation for compulsory licenses was consistent with the provisions contained in the TRIPS Agreement.¹⁶

Except that the question that arises; Can it be said that the compulsory licensing mechanism is effective to access medicines and vaccines under the provisions of the TRIPS Agreement?

The vaccines that have been approved are subject to the legally prescribed protection as patents for a period of twenty years, often they will not be easily accessible to everyone, and even poor countries cannot wait until a general vaccine is available in light of the existing epidemiological situation.¹⁷

Considering the protection of patents that constitute an obstacle to accessing vaccines without the permission of their owner, the TRIPS Agreement however provides a means of access to much-needed Coronavirus vaccines through the compulsory licenses whose provisions are regulated in Article (31) and its amendments.

However, there are controls for the use of compulsory licenses, as if there was a national emergency or other extremely urgent circumstances to safeguard public health.

1. The Doha Ministerial Conference of The World Trade Organization 2001(Doha Wto Ministerial 2001: Trips)

The World Trade Organization Ministerial Conference in Doha adopted a declaration aimed at clarifying the relationship between TRIPS and public health policies. It addressed public health problems and what many developing, and least developed countries were suffering from, the role of intellectual property rights, and the difficulties faced by countries in resorting to compulsory licensing in the pharmaceutical sector under the TRIPS agreement.¹⁸ The declaration also indicated that the TRIPS agreement should be interpreted and implemented in a way that supports the right of WTO members to safeguard public health, and in particular to promote access to medicines for all.¹⁹

Moreover, it called for adjustments to be made to expand the scope of import or export of pharmaceuticals.²⁰

In August of 2003, members of the World Trade Organization issued a decision that if importing countries could not secure access to the required drugs at reasonable prices, they can be produced under compulsory licensing by drug manufacturers in a third country, and that they can be imported from poor countries that are unable to manufacture them themselves. On 6 December 2005, the members of the organization agreed to amend Article 31 in accordance with the previous decision issued on 30 August 2003, based on which Article 31 bis was added to the agreement. The entry into force of the amendment, created flexibility in protecting public health as an integral part of the TRIPS agreement. On the other hand, many countries feared that resorting to this option might be subject to political objection because this amendment makes any member who can export pharmaceutical products under a compulsory license to provide it for countries that face limited difficulty and capabilities in manufacturing.²¹

The Drawbacks of the Compulsory Licensing System in Accessing Vaccines

There are many voices calling for the negative role of compulsory licensing that is undermining all intellectual property rights and eliminating the incentives that inspire innovation, which may contribute to the reluctance in discovery and development which

are necessary in the world.²²

In the midst of these tensions in views towards compulsory licensing, the reservations are summarized as follows:

Compulsory Licensing Under the Provisions of The TRIPS Agreement

Article (31/h) stipulates the payment of an 'appropriate remuneration' to the patent holder in line with the economic value of the compulsory license. However, countries vary in their economic capacity, which may prevent developing and poor countries from paying sums equal to the economic value of the invention in exchange of accessing the vaccines, in addition to

the fact that its procedures are complicated and time-consuming, and some countries may not have the ability to produce it. In the past, it took more than four years for the authorized AIDS drug to reach the population of Rwanda, and the issue of settling the terms of the contract took more than two years. Moreover, the reference in decision-making in compulsory licensing may also be considered an obstacle to implementing it, delay its implementation, or challenge the validity of the decision issued by the competent authority before the judicial bodies.²³

On the other hand, it is stated in Article (31/f) of the TRIPS Agreement that the compulsory license for patents must be used for the purposes of supplying the local market of the country in which it was authorized. Consequently, countries that do not have or have limited manufacturing capacity will not be able to effectively use compulsory licensing measures to produce patented drugs or vaccines. This led to a subsequent amendment of Article 31 bis, which opened the way for countries unable to manufacture to import medicines made abroad under compulsory license in limited circumstances.²⁴

Compulsory Licensing from the National Legislation Perspective

There may be in the national legislation of the exporting and importing countries Additional requirements to complete the compulsory licensing procedures. There is also a deficiency in many of the current laws related to compulsory licenses, and it is possible to challenge the licenses legal validity. This perpetuates the idea of not providing complete solutions to confront the pandemic through compulsory licenses. Although there are voices calling for the possibility of amending legislation, the matter remains confined to the concerned states alone in the domestic sphere.²⁵

Compulsory Licensing from The European Union Perspective

Article (3) of the Commission's regulation on compulsory licensing related to pharmaceuticals²⁶ stipulates that the authorities concerned with granting compulsory licensing are the ones who have the competence to do so in accordance with the national patent law therein.²⁷ That is, this makes the authority of each country within the Union separate with the effect of that license within its territory only. The import of any European Union country of the vaccines subject to compulsory licensing cannot take place in accordance with the provisions of Article (31) bis of the TRIPS Agreement except through resorting to compulsory licensing and exporting the product to an eligible importing country. But the European Union refused to participate as an eligible importing country, and this creates an obstacle as it cannot import the vaccines produced under a compulsory license from a third country or from a member country of the European Union. This narrows the solutions for the European Union countries, and all they can do is to rely on their local production of medicines and vaccines.²⁸

Compulsory Licensing Under the Provision of the Bilateral Investment Agreements

Bilateral investment agreements may include provisions that limit the use of compulsory licenses or place additional restrictions on their use.

This may create problems for countries that want to use compulsory licensing to tackle any pandemic.²⁹ Many developing countries have signed bilateral investment agreements with the home countries of many pharmaceutical companies and when disputes arise between the host country and the patent owner upon compulsory licensing, the state faces the imposition of suspension of its national jurisdiction in compliance with the provisions of the bilateral agreement that refer to international arbitration for the settlement of disputes. Such as: The Washington Center for Investment Disputes Settlement (ICSID).³⁰ This may hinder the

activation of the compulsory license nationally and delay the resolution of the existing objections regarding it, which may exacerbate the problem of not obtaining vaccines and delay the order to access them causing the increases of negative effects and their continuation.

Although we are aware that the ICSID work revolves around the nature of the investment dispute,³¹ some bilateral agreements draft in the text in the definition of investment the intellectual property rights to bring all disputes that violates these rights under the umbrella of arbitration and to suspend the authority of the national judiciary. Example: The Bilateral Investment Agreement between India and Jordan stipulates in Article (1)/ (A) Paragraph (4): '... investment... may include intellectual property rights'.³²

On the other hand, if the vaccine is considered an investment under the bilateral investment agreement, this will severely affect the low-income country, since the high cost of these vaccines will limit the access of most of the public, since they will be viewed from the investment and economic perspective, neglecting the health aspect that should be given precedence within the framework of intellectual property rights.³³

The Obstacles Faced by Countries in Accessing Coronavirus Vaccines

There was interest in the idea of 'compulsory licensing'³⁴ in many countries around the world to combat the monopolistic influence of the patent owner in order to produce and supply vaccines in this difficult health condition through legislation but it has not been resorted to so far.³⁴ At the international level, there was a proposal by some countries within the World Trade Organization to access vaccines against Coronavirus, through waiver and stopping the enforcement of intellectual property rights as a legal mechanism. Moreover, there were moves by the Organization of WIPO in this field, many seminars were held, and recommendations and opinions were issued internationally towards establishing the concept of humanity and not monopolizing treatment for the powerful. It is also necessary for developing countries to take a bold decision towards boycotting any practices that indicate monopoly exaggeration in achieving profits, and to seek to rise rather than wait and remain as consuming markets only.

However, a question arises; Will the major political and economic powers driving the world and the power of drug companies that manufacture vaccines counteract any moves to keep intellectual property rights unchanged and prevent removing vaccines patents?

The Domination of Developed Countries Over the Countries Granting Licenses for Vaccines Against Coronavirus

Among the major obstacles facing compulsory licensing are the political and economic factors which show in case the state resorts to compulsory licensing resulting in sanctions against them. In addition, it may lead to the emigration of pharmaceutical companies because of these countries' violation of their right, which is guaranteed by national legislation and international agreements. However, considering political and economic power, compulsory licensing is useless, and a scourge of no benefit. This made most developing and low-income countries reluctant to resort to it.

This effect extended within the framework of bilateral relations between countries, such as free trade agreements that contain provisions that explicitly limit the use of compulsory licenses. However, despite this, many countries do not face any legal restrictions on resorting to compulsory licenses, but they avoid doing so, fearing the consequences of commercial retaliation, in addition to the complex nature of imposing compulsory licenses in practice.³⁵

It is no secret that there are movements in developed countries, by their governments, and the lobbying groups of pharmaceutical companies as well as their supporters seeking to reject the idea of compulsory licenses and to distance themselves from it. The great pressure and trade bargaining from the European Union, which is the home of most pharmaceutical companies and medicinal drugs in the world, towards other countries resurfaces in many situations.³⁶

Considering the obstacles created by practices in the past, we find that the compulsory licensing system has not been liberated from the colonial perspective for those who resort to it, and such obstacles deny the rights of states to resort to it.

The history of using Article 31 of the TRIPS Agreement is also laden with pressure from developed countries and patent-holding pharmaceutical companies. This is evident in the states position towards the proposal that was presented at the TRIPS Council, as there was no acknowledgment of the historical oppression towards the countries resorting to licenses, and no commitment to ensuring that developing countries are not subjected to consequences in the future nor any kind of pressure, despite their explicit recognition of the importance of flexibility in TRIPS and compulsory licenses.³⁷

Developed Countries' Thwarting Movements Made for Accessing Coronavirus Vaccines

Many pharmaceutical companies have succeeded in creating vaccines to combat Coronavirus. These companies competed to be the first to provide treatment to the world and ensured that these vaccines are protected nationally and internationally. In this regard, there were movements by some countries within the World Trade Organization.

The proposal of India and South Africa

In anticipation that intellectual property rights would impede the provision of medical products to patients suffering from this pandemic, on 2 October 2020, India and South Africa submitted a proposal to the World Trade Organization (WTO) demanding a temporary waiver of the protection of Intellectual Property Rights, sections (1, 4, 5 and 7) of Part 2 in the TRIPS Agreement which are (copyright, industrial designs, patents, and protection of undisclosed information). This was in order for citizens of all countries to be guaranteed access to vaccines in a timely manner, by producing a generic version.

Through which most of the population is vaccinated and immunized.³⁸ In addition, it pointed out the need to approve a specific period during which the temporary waiver remains in effect starting from the date of its approval, and to be periodically reviewed after application. Also, for the General Council to approve the text of the draft decision that was attached to the proposal considering the TRIPS Board recommendations as soon as possible.³⁹

This proposal sought to give all members of the World Trade Organization the freedom to refuse, grant or enforce patents and other intellectual property rights related to Coronavirus vaccines, medicines, and diagnostics and other technologies throughout the duration of the pandemic to combat it.⁴⁰

Nevertheless, this proposal was viewed with irony from developed countries and the manufacturers of these vaccines affiliated with them, although this is what the world needs today during the pandemic. The calls made by India and South Africa were joined by many member states of the World Trade Organization. Insistence on it resulted from what the world is witnessing of fierce competition between countries over vaccines to access them. Whereas,

developed countries that comprise 14% of the world's population have purchased up to 53% of all Coronavirus vaccines, according to one of the statistics recorded during the pandemic.⁴¹ This confirms that developed countries have the largest share, and that countries with limited resources, developing and poor will struggle to obtain vaccines,⁴² and that the temporary waiver of the protection contained in the TRIPS Agreement of intellectual property rights is the key to access these vaccines as soon as possible. Also, the importance of enabling the countries that have the infrastructure to produce them themselves or to take the necessary measures to import them at reasonable prices.⁴³

The Results of the Proposal

This proposal has not met the desired acceptance. There was clear and frank criticism of it by some countries, as Canada, Australia, Chile and Mexico that raised some disapproving questions in the TRIPS council whether there were actually obstacles that might prevent the use of compulsory licensing in national legislation.⁴⁴

Members of the WTO failed to create the consensus required to move forward with the proposed waiver because decisions were passed unanimously, even though there were close to 100 countries agreeing to the proposal. There was strong opposition from the European Union and the developed countries.⁴⁵ The European Union also viewed that ‘there is no indication that intellectual property rights issues were a real barrier regarding drugs and technologies related to Coronavirus’.⁴⁶

Usually, the justification of drug and vaccine manufacturers is that the goal of patenting them and setting high prices is to recover costly research and development costs. However, most medicines and vaccines as corona vaccine have been fully funded either by the governments of these countries, taxpayers’ money, or crowd funding.⁴⁷

Financing Vaccines

For example, the company of Moderna vaccine received nearly 2.5 \$ billion in the United States of America from taxpayer money to support research and advance studies on vaccines, which is acknowledged by the company.⁴⁸ Pfizer on the other hand received 455\$ million from the German government to develop its vaccine. While AstraZeneca got some public funding when it was developing the vaccine, and it got a total of more than 2\$ billion from the United States of America and the European Union. This confirms that vaccines were developed by these companies thanks to taxpayers' money in whole or in part.⁴⁹

The President of the European Commission announced at the International Donors' Conference, held in Brussels on 4 May 2020, that an amount of (7.4) billion euros was raised for the development of vaccines, treatments and tests for the emerging corona virus, and on behalf of the European Commission, she pledged \$ 1 billion to develop vaccines.⁵⁰

Based on the above, correspondingly, patent-owning companies should support the right to health for all, and respect human rights as well as to consider them in the near future as a prerequisite for providing financing and support for companies the time of pandemics.⁵¹

Solutions to Accessing Vaccines and Their Distribution Equitably “COVID-19 as an example”

In light of the obstacles facing access to vaccines for Coronavirus, the shortcomings of the regulations for compulsory licensing, the international failure to comply with all the efforts made by some countries under the World Trade Organization, which sought a temporary

waiver and a halt to the enforcement of the protection contained in the TRIPS Agreement for Intellectual Property Rights in order to combat this pandemic, the problem of delivering vaccines to all countries in the world still persists.

The calls of many world leaders faded in declaring that the future Coronavirus vaccine should be a global public good and not restricted by monopoly rights,⁵² the effects of which can be found in the decision of the Seventy-third World Health Assembly entitled 'The COVID-19 response, which was striving to provide a unified global response to combat the pandemic.⁵³ Also, the World Health Assembly failed at the time to declare Coronavirus vaccines as a 'public good', and it was confirmed that the vaccines would remain private property subject to protection as a pharmaceutical product.⁵⁴ This led to searching for a legal system that takes either an approach outside the system and rules of compulsory licensing or through adopting a compulsory licensing system for patents with an international character, as a response to the voices concerned about the general health calling for overcoming the many obstacles facing the traditional legal system on patents and compulsory licensing.⁵⁵

Patents Pooling for Medicines and Vaccines

It appears that pandemics are a critical example of the need for international cooperation to counter transnational threats. Viruses and other pathogens do not recognize borders, and pandemic control requires a participatory commitment and international scientific cooperation because national solutions are not enough considering the development and continuation of the pandemic. The need to exchange public knowledge and its applications in the medical field is crucial to mitigate the impact of the disease and accelerate the discovery of effective treatments and vaccines.⁵⁶

In this sense, there is an urgent necessity to pool patents when many of the basic patented technologies are needed to promote a new innovation as this would reduce infringement claims and licensing procedures costs, in addition to eliminating the need to license patents.⁵⁷

Furthermore, due to the concerns that rich countries and large pharmaceutical companies could prevent or delay the arrival of the vaccine to people at risk, especially those who live in developing countries, the World Health Organization officially launched in May 2020 (during corona pandemic) a voluntary gathering for the purposes of pooling patent rights, all regulatory test data, technical knowledge, plans for manufacturing diagnostic tests, drugs and vaccines, and other information that can be shared for the purposes of developing drugs and vaccines to combat the pandemic.⁵⁸

This was Costa Rica's proposal to the World Health Organization and the purpose of its establishment was to lift restrictions that prevent access to vaccines, medicines and other health products for combating Coronavirus. This proposal has gained the support of many countries⁵⁹ because if it applied on a global scale, it would ensure that all countries could produce or import low-cost versions of any Coronavirus vaccines and treatments.

However, the United States of America did not agree and tried to delete the reference to pooled patents and to emphasize respect for patents of the pharmaceutical industry.⁶⁰

There have been calls from the People Vaccine's Alliance for all pharmaceutical companies working on coronavirus vaccines to openly share their technology and intellectual property by pooling access to technology affiliated with the World Trade Organization, to enable the safe manufacturing of billions of doses and make them available to everyone who needs them. In addition, there were calls from the Coalition to governments to do everything in their power

to ensure that coronavirus vaccines are made a global public good free of charge for the public, and to be distributed fairly and based on need.⁶¹

This confirms that patent pools achieve a lot of advantages through their role in collecting all data that voluntarily provide clinical trials, technologies, and other information necessary for the purposes of developing treatment. Once a company has given its patented invention an open license, other companies and governments can legally rely on the knowledge provided thereunder. The matter of choosing the companies participating in the pool is up to them, and compulsory license cannot be used to provide the pool with additional data.⁶²

On the other hand, there may be a voluntary means in which the patent owner voluntarily waives patents under certain circumstances for the purpose of confronting an exceptional circumstance. There has been evidence from some past initiatives in this regard. For example, (Jonas Salk), the American scientist who invented the treatment of polio and refused to have his name written on his patent to benefit all of humanity, without monopolizing the treatment or raising its price, which contributed to saving the lives of many children around the world.⁶³

Although there is a trend by pharmaceutical companies that they are not looking to achieve high profits, it may start soon and after a period of time to do just that⁶⁴ without wavering the patents they own. This is what creates the problem we are trying to solve under an international umbrella.

A question was raised in the European Parliament⁶⁵ regarding the patent of PFIZER Coronavirus vaccines. Since the company indicated that it does not intend to waive the patent protection that grants it the exclusive right to produce the vaccine, even though it is only able to produce limited quantities. The question focused on many axes, the most important of which was whether there was a negotiation with the company to purchase vaccines, or at least consider the option of compulsory licensing. Also, regarding the possibility of concluding an agreement on exchanging patents and exchanging technical knowledge in relation to Coronavirus vaccines, and even if this has not been put forward, is there a willingness to consider compulsory licensing for the purpose of negotiating future agreements with pharmaceutical companies? The answer was that the European Commission is calling for voluntary solutions, such as patent pooling, and that a Memorandum of Understanding will be signed with the UN-supported Medicines Patent Group to explore future cooperation in the field of voluntary licensing of intellectual property.

In the event of failure of voluntary solutions, it is possible to resort to compulsory licensing if its conditions are met.⁶⁶

There have also been many calls for adopting policies regarding the internationalization of vaccines and intensifying efforts at the international level to deliver vaccines and medicines to poor countries and distribute them fairly, after that the efforts under the WTO system have failed. Oxfam for example has proposed a global plan to access vaccines as a means to combat Coronavirus:⁶⁷

- 1- The mandatory sharing of all knowledge, data and intellectual property related to Coronavirus. And committing to make public funding conditional upon providing treatments and vaccines without patent protection.
- 2- The commitment to provide all capacities for the global manufacture and distribution of vaccines. And to build factories in countries that want to participate in order to provide prevention and treatment.

- 3- Adopting a fair and globally agreed distribution plan for vaccines, so that the demand is based on need, not ability to pay. And that vaccines and treatments are produced and supplied at the lowest possible cost for governments.

An invitation presented to the General Council of the World Trade Organization from a group of countries, including Colombia and Costa Rica on 1-2 March 2021, indicated the need to prevent export restrictions for Coronavirus vaccines, and to recognize that the Corona pandemic represents the greatest challenges in modern history. Also, it pointed out that the global pandemic can only be resolved in a collective manner and by strengthening multilateral cooperation.⁶⁸

These calls are confirmed by the World Bank through granting 12\$ billion as soft loans to developing countries to finance the purchase and distribution of vaccines, tests and treatments for Coronavirus during the pandemic. The aim of this funding was to promote a globally coordinated approach to ensure broad and equitable access to Coronavirus vaccines as an alternative to a profit-driven market. On 18 August 2020, the WHO Director-General urged member states to join the Global Vaccine Facility (COVAX), as a means aimed at ensuring equitable access to vaccines for all countries.⁶⁹

The Aim to Establish an International System for The Compulsory Licensing of Patents

The Role of The World Health Organization in Combating the Corona Pandemic

Within the framework of the World Health Assembly and its 73rd meeting held on 19 May 2020, there was confirmation from the Director-General of the World Health Organization on the general mandate enjoyed by the organization to work in light of the Corona pandemic, as the authority and competence to direct and coordinate international health work. In addition to the role of The United Nations body in promoting multilateral cooperation in addressing the Coronavirus pandemic and its wide negative effects.⁷⁰

The Constitution of the World Health Organization defines health as a state of complete physical, mental and social well-being and not only the absence of disease or disability, and that the enjoyment of the highest level of health can be achieved, as it is one of the basic rights guaranteed to every human being in constitutions and legislation without distinction of race, religion, political position or economic or social status.⁷¹

A resolution was issued by the United Nations General Assembly on global solidarity to combat Coronavirus, and it referred in its content to the pivotal role of the United Nations system in stimulating and coordinating the global response to control and contain the outbreak of Coronavirus, and also the need for joint action based on a coordinated global response to confront the pandemic and its social, economic and financial consequences that affect all societies.⁷² In addition to another decision on international cooperation to ensure universal access to medicines, vaccines and medical equipment for combating Corona pandemic. It indicated the possibility of establishing inter-agency working groups within the limits of available resources, including WIPO.⁷³

The Aim to Approve a Compulsory Licensing System for Patented Vaccines under an International Umbrella

In light of the United Nations General Assembly resolutions and the efforts that confirm the importance of participatory work as happened during Coronavirus, we find that the World

Health Organization plays a pivotal role as one of the main agencies of the United Nations, which has the authority and competence in the global health sector, and whose works under the confirmation of The General Assembly requires that it be positive in the current and future stage, which involves distributing vaccines in a fair and transparent manner, especially for the developing countries.

However, the question that arises, are the powers granted to the World Health Organization sufficient on their own to access vaccines and distribute them equitably?

By examining the beginning of the provisions of these UN resolutions, we find that they are limited to using terms that do not carry any binding terms, for example ... 'confirms ...requests ... encourages ... calls ...' and this does not carry a legal obligation and thus allows the manufacturers of vaccines and medicines of the manufacturing countries not to conform to the international will. Therefore, it is possible to talk about the need for the United Nations to carry out its international responsibilities as the first guarantor for the maintenance of international peace and security,⁷⁴ by adopting an international approach that establishes an international agreement that gives the World Health Organization absolute powers as the authority and competence to assess the compulsory licensing of patents in such circumstances and to present consultations for WIPO as it is concerned with intellectual property rights. By achieving the aforementioned, it can be said that the World Health Organization is able to fulfill its responsibilities and implement the recommendations it receives in the midst of emergency circumstances that require international solidarity and participation in voluntary work to deliver vaccines and medicines to all countries in a manner that achieves justice. Moreover, the countries affiliated with the manufacturers, voluntarily carry responsibilities imposed by internationally binding provisions that compel them to do so because otherwise they will be subject to penalties. The Corona pandemic that invade the world is a threat to all of humanity since it is the cause of loss of lives, profits, and economy, as well as the suspension of all aspects of life, which represents in the near and distant future a realistic and direct threat to international peace, security and the social and educational systems in all societies.

This call is for the adoption of an international agreement under the United Nations system because the matter does not tolerate discussion of the economic and political aspects at the expense of health, as the protection of lives takes precedence over any other considerations. As it is known that the goals of the World Trade Organization are far from the lofty goals that the World Health Organization seeks to achieve under an exceptional emergency circumstance that is costing humanity heavy losses. Despite the fact that there are those who defend intellectual property rights and claim that compulsory licensing cannot be achieved absolutely in light of the subsequent political and economic constraints and restrictions on the state that may resort to such a solution, the main idea is that there are more important issues to address than talking about exclusive rights of individuals at the expense of human rights in Life. In such matters, limitations and all controls fall in order to protect lives.

Therefore, according to the reality that reflects the difficulty of adopting any amendments to the TRIPS Agreement, and the inability of the World Trade Organization to adopt a compulsory licensing system with an international character, countries assess whether to implement it in cases of pandemics, emergencies and exceptional circumstances in which the peoples of the world are collectively going through. In order to get out of the impasse of political and economic restrictions when states implement their right to activate the compulsory licensing system nationally, the World Health Organization will take the lead in settling this in partnership with the World Intellectual Property Organization (WIPO).

This may contribute to neglecting intellectual property rights, the economic exploitation of patents by their owners, or waiting for a voluntary waiver of a vaccine in this circumstance that may or may not happen. The fate of nations cannot be at the will of individuals who get to decide who lives! Therefore, the adoption of an international policy and effective control by a party whose primary role is to safeguard international public health in the world and protect humanity from the injustice of those with power, influence and money.

To Rectify the Shortcomings by Adopting A Policy of International Compulsory Licensing

If there is a tendency towards activating national compulsory licenses by developing countries through benefiting from the experience of other countries that have resorted to compulsory licenses in previous periods, without having any other considerations as concerns and the consequences of resorting to licenses to confront an exceptional circumstance, so all efforts must be concerted at the international level, and this matter should be kept away from any political or economic

sanctions that the country resorting compulsory licenses may be subjected to, because this is a right enshrined in national legislation and agreements and is not abusively used. However, this matter is difficult to implement on the ground in light of the policy of the strong and the weak, and that the one in power manages the scene, which makes developing and poor countries unable to confront them, even if the matter is in the framework of activating and using their legally established powers. Nonetheless, there can be international efforts that contribute to educating developing countries about the legislative means available to them to access the required vaccines in such circumstances, for example, the role of World Health Organization, the World Trade Organization and legal organizations such as the Consultative Center for World Trade Organization Law (ACWL) in facilitating knowledge exchange between public health officials and government lawyers in developing countries. This is an important time to help developing countries build the legal and logistical capacity to use compulsory licensing in combating any diseases that may appear in the future.⁷⁵ Even though this option is available under the rules of the World Trade Organization (WTO), the reality is proving to be an ineffective system mired in political dispute.⁷⁶

In light of the proven ineffectiveness of the national compulsory licensing system and the absence of an international means to obtain the compulsory license applied in more than one country,⁷⁷ it is possible to overcome all these obstacles and the arguments that were made about the ineffectiveness of the compulsory licensing of patents, and the major drawbacks that it brings. All these arguments can be addressed through logical solutions and in a way that creates balance and does not violate the rights of patent holders through following the international licensing approach that is far from the internal national framework which is ineffective in most of its cases. It includes compensating them and motivating them that what they have developed will not be confiscated for the benefit of a group, but rather it is a human legacy for which they deserve reward, as well as being a public property like the wealth in the bottoms of the high seas with no power or control imposed on it. Then, the international compulsory license that may be resorted to under the umbrella of the World Health Organization (WHO) is achieved in the event of non-voluntary waiver without economic sanctions and political pressures that may be imposed from the rich developed countries to which the patent-holding pharmaceutical companies are affiliated against those seeking the vaccine by resorting to compulsory licensing and enforcing their national and international legislative powers. As a result, this license may achieve its goals in light of emergency

conditions affecting public health internationally. Also, we may go beyond the problems facing compulsory licensing in the national domain, including the resort to international arbitration to settle disputes arising from the national compulsory license.

There may be some considerations that may be considered when approving this agreement, such as referring to the possibility of adopting international programs in

support of pharmaceutical and medicinal inventions and vaccines, and the possibility of declaring a global emergency, so that the World Health Organization has the absolute authority to assess such a matter in light of a global health condition as the case of the Corona pandemic, also, giving a consultative role to WIPO to be the reference in intellectual property rights, in order to avoid losses, while creating some controls to make the license exceptional and for a specific period of time until the end of the pandemic.

This is a step that must be enshrined in light of the evidence from the past, and what the world began to sense of a looming crisis in the absence of any pooling of patents or a voluntary waiver of vaccines patents during corona pandemic.⁷⁸

Conclusion

The world has become aware due to the corona pandemic that there is an urgent need to achieve a balance in the existing relationship between the human right to health and the individual's monopoly on intellectual property rights. This can be done through compulsory licensing, which provides solutions for each country, and each case separately. However, developed countries and pharmaceutical companies have always sought to undermine its use, by creating political and economic obstacles.

In spite of all the efforts of some countries at the international level to confront intellectual property rights and patents specifically to waive them or suspend their enforcement, power and authority prevailed!

The study showed that the world needs in times of pandemics, to maximize the sharing of knowledge and technology and to exploit the manufacturing capacity available to access medicines and vaccines. This goal cannot be achieved simply by relying on Article 31 of the TRIPS Agreement, or the national legislation that may enact additional requirements for compulsory licenses, which may place additional obstacles on granting them. The solutions may be pooling and voluntary waiver of patents.

In light of what the world is witnessing during corona pandemic, the provision of any support to major pharmaceutical companies that have been explicitly proven to be motivated by profits must be reconsidered. In addition to that efforts must be united at the international level, and that all countries must support the proposal regarding the waiver of protection for intellectual property rights during the exceptional global circumstances as public health issues, at least until the end of the pandemic.

The WTO should also weigh all of the viable options, such as compulsory licensing and temporary waiver. This requires a change in the approach taken in the World Trade Organization.

All medicines and vaccines should be global public goods. This is the aspiration of people around the world. Access to and availability of the vaccine cannot be left in the hands of traditional market forces.

The best option is to seek to legalize compulsory licenses with an international character, and under international supervision to combat pandemics and diseases. Also, The World Trade Organization must do its duty fully by working on stopping the enforcement of intellectual property rights or to legalize compulsory licensing with an international character. If it does not make urgent moves in this direction, The United Nations should take the lead by approving an international agreement concerned with the compulsory licensing system of patents for medicines, vaccines and medical supplies in the event of pandemics, emergencies and exceptional transnational conditions, under the umbrella of the World Health Organization in cooperation with the World Intellectual Property Organization (WIPO).

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