International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 1s, 2025
https://www.theaspd.com/ijes.php

The Impact of the TRIPS Agreement and its Amendments on Public Health and Vaccine Access during COVID-19

Mustafa Ibrahim Ahmed Aribi[1*], Emad Ahmed Abousud[2*], Rachid Mohammed Ghazi[3*]
[1,2,3]Business Administration Department, College of Business, Imam Mohamed Ibn Saud Islamic University, (IMSIU), Riyadh, KSA.
[1]miarbi@imamu.edu.sa (M.I.A.A).

ABSTRACT: The TRIPS Agreement introduced new developments by imposing protection on pharmaceutical products, unlike previous agreements that imposed protection on the production process rather than the pharmaceutical product. This measure resulted in negative impacts during the COVID-19 pandemic. The study focuses on the difficulties faced by developing and least-developed countries in obtaining vaccines and the measures taken by the WTO Ministerial Conference to address these challenges, evaluating their effectiveness in combating COVID-19. The focus was on the feasibility of the TRIPS Agreement provisions in ensuring the right to public health and technology transfer to countries in need, as well as the effectiveness of compulsory licenses in providing vaccines. The study highlighted the significant challenges in obtaining vaccines during the pandemic and the complexities in obtaining a compulsory license. We believe that the TRIPS Agreement should be reviewed. Clear and binding legal provisions should be included to balance the guarantee of public health and the protection of patent holders' rights. An effective mechanism should be established to ensure the provision of technical assistance in the pharmaceutical industries to developing countries.

Keywords:
TRIPS Agreement, COVID-19, Compulsory Licensing, Public Health, Patent, Medicine, Doha Declaration, Generic Medicine, Ministerial Decisions, LDCs.

1. INTRODUCTION

A crucial question arises before writing the introduction to this article: why is research and writing about the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement still prevalent in all scientific, research, and academic forums, even though more than thirty years have passed since it entered into force? The answer to this question is that the agreement's provisions remain a subject of debate, discussion, and research across various sectors of society, whether legal, economic, social, or in the fields of human rights and public health or development. The primary reason for this is that the agreement significantly expanded patent protection beyond what was known in previous agreements, making it difficult to balance the rights of patent owners with the protection of public health, human rights, the right of developing countries to development, and access to technology.

The situation was further complicated by the outbreaks of pandemics that swept the world at close intervals after the agreement came into force, such as the HIV/AIDS virus, and the difficulties many countries faced in dealing with it. TRIPS provisions failed to fulfill their commitments in this regard. The major disaster then came in the form of the COVID-19 pandemic, which sparked disputes over vaccines and the rush of major countries to monopolize quantities that exceeded their needs compared to developing countries. These events represented a real test for the TRIPS Agreement, questioning its ability to achieve the goals it outlined.

Given all the above, this article adopts most of what has been previously written about this agreement, with a writing methodology that focuses on highlighting the most important aspects and recent developments of the agreement, clarifying the goals it sought to achieve in safeguarding public health and providing technical assistance to developing countries, then reviewing the amendments and declarations related to the agreement and their effectiveness in achieving its objectives. This is all tied to practical cases that occurred in recent periods and the effectiveness of compulsory licenses in providing solutions to the difficulties encompassed in the agreement. The article will also discuss whether the TRIPS Agreement needs further amendments, the

scope of these amendments, and their impact. The conclusion of the research includes several findings and recommendations that have been reached.

1.1METHODOLOGY:

The research relied on the descriptive and analytical method, addressing the following aspects: defining the TRIPS Agreement, explaining its principles and objectives, presenting the legal provisions related to drug patents, clarifying the relationship between the TRIPS Agreement and public health, and then discussing and analyzing the amendments made to the agreement and their effectiveness in addressing COVID-19.

1.2RrsearchProblem:

a. Did the ministerial decisions and the amendments to the agreement contribute to overcoming the COVID-19 pandemic?

b. Has compulsory licensing become easy and effective during the COVID-19 pandemic?

c. Have developed countries fulfilled their commitment under the TRIPS Agreement to transfer

d. Can the TRIPS Agreement address future health emergencies?

2. Stages of Development in Intellectual Production Protection:

The protection of intellectual property has been of great importance, especially with the flourishing of industry and the opening of global markets during the Industrial Revolution in the 19th century. That era witnessed significant development at the technical, economic, and commercial levels, to the extent that it was called the "Era of Technical or Industrial Revolution." Each passing day highlighted the necessity of such protection, which led to the establishment of a system that ensures legal protection for intellectual property in both its industrial and commercial, literary and artistic branches.

The true beginning was the birth of the Paris Convention for the Protection of Industrial Property in 1883, followed by many agreements working in the field of intellectual property rights, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS is one of the international agreements approved during the Uruguay Round of negotiations around the General Agreement on Tariffs and Trade (GATT). It was signed in Marrakech, Morocco, in mid-April 1994 and entered into force in January 1994 (Zain al-Din, 2000, p. 193 & Muhammad, 2004, p. 29).

TRIPS is considered the most comprehensive tool concerning intellectual property rights and represents a qualitative leap in strengthening the protection granted to these rights and their various methods. However, TRIPS did not come isolated or separate from other international agreements related to various intellectual property rights; rather, it incorporated and developed their provisions and added new types of rights that were not known before, such as new plant varieties and the protection of undisclosed information. It also referred to some provisions of those agreements, such as the Paris Convention for the Protection of Industrial Property in 1883 and the Berne Convention for the Protection of Literary and Artistic Works in 1886, making the referred texts part of the TRIPS Agreement and obliging member countries to apply them even if they were not parties to those agreements (see TRIPS preamble 1994).

The TRIPS Agreement, as declared in its preamble (Fareed, 2006, p. 19), aims to liberalize international trade in goods and services while establishing a sound and sustainable technological base, considering the special needs of the least developed member countries. TRIPS expanded the legal protection granted to innovations compared to previous agreements, allowing for the possibility of obtaining patents for any inventions, whether products or industrial processes, in various fields of technology, provided certain conditions are met (Article 27/1 of the TRIPS Agreement1994).

The text stipulates that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step, and are capable of industrial

application. These conditions, stipulated in the article, represent the substantive requirements for patent granting, in addition to procedural requirements.

Although the TRIPS Agreement imposed patent protection on member states, it left them the freedom to establish procedural legal rules for patent protection within their territorial limits. As for the substantive requirements, the TRIPS Agreement did not define the meaning of these three requirements, novelty, inventive step, industrial applicability, leaving room for flexibility at the national level. The agreement even allowed member states to use synonyms for these terms, such as using "non-obvious" as a synonym for "inventive step" and "useful" as a synonym for "industrial applicability" (M. Carlos, 2007, p. 75).

This led to differences in protection conditions, duration, and scope, which is the natural result of varying legal systems from one country to another. The expansion of patent protection had a significant and evident impact on the fields of food, pharmaceuticals, agricultural chemicals (such as organic fertilizers), and chemicals for combating agricultural pests, creating a monopoly in a vital area affecting human health and nutritional needs (Mousa, 2007, p. 78).

The Italian experience before the conclusion of the TRIPS Agreement is evidence of this; drug prices increased by 200% following the decision of the Italian Constitutional Court on March 9, 1978, declaring Article 14 of the Patent Law unconstitutional for excluding pharmaceuticals from the scope of protection (Mousa, 2006, p. 116).

3. THE SCOPE OF PATENT PROTECTION:

By reviewing the conditions brought by the agreement, it is clear to us that the patent represents one of the most important sections of intellectual property organized by the TRIPS agreement. Due to the importance of patents in international trade, major countries have sought to extend protection to all patent fields and not exclude any invention from the possibility of obtaining a patent. (John, Agada & Others, 2009, p3) Indeed, the World Trade Organization (WTO) responded to these efforts and expanded the umbrella of protection to include all inventions in all fields of technology, regardless of the subjective considerations of some developing countries or the motivations behind excluding some inventions from the scope of protection. The TRIPS Agreement has been described as reflecting the victory of corporate interests in the United States and Europe over the broader interests of the vast majority of vulnerable people in the developing world. It is believed that the TRIPS Agreement was introduced in the Uruguay Round of trade negotiations through the joint efforts of the United States and some other industrialized countries to force other countries to recognize their patents and copyrights. (Owoeye, 2015, p18). The matter even extended to the equality between product patents and process patents when the protection requirements stipulated in Article (27/1) were met. (Mohamedin, Jalal, 2004, p69) It is clear from this that the negotiators in the agreement, despite strong differences over this issue (patent fields), agreed to extend protection to include all products and methods, thus closing the possibility of leaving some subjects outside the scope of protection, as was common in pre-TRIPS agreements. This flexibility was exploited as an advantage by developing countries and some developed countries. In 1980, 65 countries did not recognize this type of protection, in addition to some countries like France and Canada) had provisions related to compulsory licenses. (M. Correa, Carlos, 2007, p68), especially for pharmaceuticals (medicines). Despite the clarity of the content of Article (27/1) of the TRIPS Agreement, this does not mean that the agreement has unified the rules for obtaining a patent. WTO member countries have the freedom to choose, but within certain limits, depending on the strength and weakness of each country in various fields and the impact that granting patents could have on the ability to acquire and develop technology. Thus, unlike previous agreements, the TRIPS Agreement expanded the umbrella of protection in patents to include process patents in addition to product patents. A product patent means "creating or inventing a new physical entity that did not exist before, with distinguishing characteristics from other similar or identical entities." (Mousa, Mohamed, 2006, p83). Most legislations granted protection to the pharmaceutical production process without the final pharmaceutical product, allowing domestic pharmaceutical companies to import the active ingredient of the drug from global pharmaceutical companies and then manufacture it (Hassan, Nasser, 2006, p3). This had a significant and

clear impact on food and pharmaceutical chemical products (medicines), which have a significant and clear effect on public health in developing and least developed countries by impacting their food and medicine (Mohamedin, Jalal, 2007, p70). No one can overlook the great importance of medicine, which eventually led to the equality between product and process patents. Covering medicine with patents had several considerations: a. Medicine is one of the most popular commodities, which caught the attention of major countries and their companies to extend the umbrella of protection to it. b. The high costs of reaching new and modern pharmaceutical substances, which global pharmaceutical companies have continued to claim, although research conducted in this regard has shown the falsity of these estimates and exaggerations by pharmaceutical companies. In a study published by a consumer group in the United States, it was found that the average real cost of bringing a new drug to market is not as pharmaceutical companies claim (300-500 million dollars), but only 57-71 million dollars. (Dr. Mosa, Mohamed 2007, p. 80). The reasons for this included: i. Achieving effective legislative protection in the field of medicine, which pharmaceutical companies achieved through the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). ii. Creating a psychological barrier for other companies in the field of medicine and chemicals from entering or even approaching the field of new drug research.

Overestimating the costs of research and development (R&D) in the field of medicine has served as the basis for which global pharmaceutical companies demanded strong and long-term intellectual property rights for new and modern drugs. This protection helps them achieve the highest profit margins compared to what industrial companies in other fields achieve. An example of the high profitability rate of the pharmaceutical industries is what happened at Bell University in the United States, where the university was able to invent a drug for AIDS (AIDS), and indeed obtained a patent for it and called it Stavudine. Since the drug was first marketed in 1994, the university has obtained profits estimated at 261 million dollars, which is equivalent to 90% of the books and publications that the university publishes (Dr. Hassan, Nasser 2006, p. 68).

Finally, protecting pharmaceutical companies from the risk of imitation and piracy is one of the reasons for equating the product patent with the industrial process. In the absence of legal regulation and effective protection of industrial property elements, imitation becomes easy and accessible. As a result, there has been effective protection of intellectual property rights, regardless of whether the state is the rightful owner or just licensed to exploit it (Dr. Mosa, Mohamed, 2007, p. 82)."

3.1 The additional provisions brought by the agreement:

Known as (TRIPS PLUS), it means adding more commitments and burdens on developing and least developed countries beyond what the agreement included through bilateral or regional free trade agreements, such as free trade agreements with the United States or the European Union. Some of the conditions contained in (TRIPS PLUS) are: a. Extending the term of drug patent rights to exceed the twenty years stipulated in the agreement as a minimum, to tighten protection, which is the main goal of covering the pharmaceutical product under the patent system to ensure the longest possible protection period. b. Delaying the registration of (generic drugs) that are low-cost in developing countries by granting exclusive marketing rights to high-priced branded drugs for longer periods. c. Limiting the authority of developing countries to exploit mechanisms provided by the (TRIPS) agreement and confirmed by the (Doha Declaration and relevant ministerial decisions), such as restricting these countries' authority to grant compulsory licenses to local producers to manufacture (generic drugs), or preventing them from importing them from other neighboring countries where they are cheaper, thus hindering the process of (parallel importation of drugs) which is one of the most important solutions to counter the negative effects of the (TRIPS) agreement."

3.2 The Protection of Pharmaceutical Products and its Impact on Developing and Least Developed Countries:

"The protection of the final pharmaceutical product had a strong impact on developing and least developed countries, as most of the laws in these countries prohibited patenting the product itself, although they allowed patenting the industrial process, to prevent monopolization by global pharmaceutical companies in a vital and important field, which is human health and nutritional needs (Dr. Mohamedin, Jalal 2007, p. 70). However, the provisions in the agreement were very clear in patenting both the final product and the industrial process together. Thus, the agreement covered all stages and forms related to the patent, manufacturing, and marketing, which constitutes a strict constraint on industrial activity, particularly in the field of drug manufacturing and production. The protection included the raw material of the drug and the technology used in production, regardless of its type, in addition to extending the duration of protection. Before the TRIPS agreement came into force, these countries could manufacture generic drugs, defined as pharmaceutical preparations that are not subject to intellectual property protection and can be produced without a license from the inventor (Article 3 of the Sudanese Pharmacy and Poisons Law 2001) through 'reverse engineering,' based on the protection being for the process, not the final product. Usually, generic drugs are equivalent therapeutically to the modern (commercial) drug and are cheaper due to lower research costs and intense competition among generic drug manufacturers, which reduces costs (Dr. Hassan, Nasser 2006, p. 105). Thus, 'generic drugs' represent a real lifeline for patients with limited financial means to obtain the necessary medicines. An illustrative example of the importance of 'generic drugs' is aspirin, which is the trade name owned by the German company Bayer for its product treating headaches and fever. The generic name for this drug is (Acetyl Salicylic Acid), and any company can package it under this generic name.

Major pharmaceutical companies recognized the threat of 'generic drugs' as an alternative to branded drugs, so they began spreading rumors and false beliefs, questioning their efficacy, safety, and viability within the body. This prompted the U.S. Food and Drug Administration (FDA) to respond and issue a press release refuting these claims. When the companies despaired of questioning the efficacy of generic drugs, they resorted to buying small companies producing generic drugs, thus becoming the monopolist of both the modern and generic product.

A drug not subject to intellectual property protection means either its protection period has expired or it is still valid, but the drug was formulated through 'reverse engineering,' which means 'analyzing the components of the original patented drug, understanding them, and then creating another drug called a generic drug with the same efficacy characteristics as the original drug, but with a different scientific name from the commercial name of the original drug, known as a generic drug, and being cheaper than the original drug' due to several considerations, the most important being that it does not require a license from the parent company owning the patent. This was the prevailing situation until the TRIPS agreement came into force in 1996, as previous agreements allowed the manufacture of 'generic drugs' based on the legal protection being for the production process only, not the final product. This allowed countries and pharmaceutical companies to analyze the components of the final product and then produce a generic drug at a lower cost. However, the TRIPS agreement imposed legal protection on both the production process and the final product, leading to complex issues concerning drug manufacturing and access rights in developing countries as a whole.

As it is known, the TRIPS agreement came into force in 1996, while it came into force in developing and least developed countries in 2006 with some exceptions according to agreed regulations. All members countries of the World Trade Organization must provide full legal protection for intellectual property rights, including drug patents. Previously, most countries provided limited protection for the pharmaceutical industry, and a significant number of countries did not provide any protection. This situation was a major concern for pharmaceutical companies, which saw these countries as profitable and thriving markets for drug

trade coming from industrial countries, striving to control it. Before the TRIPS agreement, the prevailing situation was..." In those countries, as previously mentioned, it involves the manufacturing of generic drugs at low prices that are affordable for the citizens of these countries and suitable for their economic conditions. The companies responsible for pharmaceuticals in these countries do not need to obtain licenses from the parent companies that own the patents for the original drug. Some countries even completely ignore the protection granted to drugs and start manufacturing or marketing legally protected drugs without legal justification, or they resort to (parallel import), which means that one country imports patented pharmaceutical products from another country, other than the original country, where those products are cheaper.

4. **The Right to Public Health:** All the mentioned methods and means were used by developing and least developed countries to provide affordable or cheaper drugs for their citizens, in line with their economic conditions, fulfilling their constitutional and ethical obligations imposed by the constitution, law, and international agreements to protect public health as stated in the Universal Declaration of Human Rights1966, which stipulates that everyone has the right to a standard of living adequate for health and medical care (Article 25/1). Additionally, the International Covenant on Economic, Social, and Cultural Rights1948 not only stipulates the right to health but also the right to the highest attainable standard of health (Article 12/1). This obligation is found in all national laws as a constitutional right. Essentially, we can affirm that protecting the health of citizens is one of the state's foremost duties toward its citizens. The TRIPS agreement has confirmed that public health is a goal the agreement seeks to achieve. For instance, it has adopted ensuring access to medicines (the agreement encourages countries to facilitate access to necessary medicines at reasonable prices and facilitate the transfer of medical technology) and has taken the principle of balancing rights and duties as its goal (ensuring the necessary protection of intellectual property rights without harming public health through flexibility in the application of the agreement to serve health interests). Additionally, it allows countries to apply exceptions in some cases to ensure the health of citizens, such as health crises and emergencies. Under Article 27/2 of the TRIPS agreement, member countries have the right not to grant a patent for any invention if it is against public health, and such prohibition can be before or after granting the patent. The agreement considers the protection of public health as a matter of public policy (Exclusions and Exceptions, 2021) (Articles 8, 27, 31, 40 of the TRIPS Agreement 1994). Although the current trend in most countries is to cancel free treatment except in narrow limits and with a contribution that fluctuates between high and low, the sharp rise in drug prices will have a very significant impact on human health in these countries.

Now, we must ask the question that requires an accurate and comprehensive answer, considering the rights of patent-owning companies in the pharmaceutical industry while also contributing to providing drugs for the citizens of developing and least developed countries who suffer from the ravages of disease and poverty. It also urges different countries to bear their legal and ethical responsibilities in protecting public health. The question is: How can the state balance the patent owner's right (drug) to legal protection and the citizen's right to obtain healthcare through medication? This question leads us to discuss the negative impacts of the TRIPS agreement and the available options to address those impacts."

4.1 The Negative Effects of the TRIPS Agreement on Access to Medicine:

"There is no doubt that extending patent protection to the pharmaceutical sector will have many negative and serious impacts on the pharmaceutical industry in developing and least developed countries and on the level of healthcare that governments are obligated to provide to citizens. This impact is evident in:

a. Sharp Increase in Drug Prices**:** This is due to many factors, the first being the expansion of the protection umbrella to include the final pharmaceutical product in addition to the manufacturing process. This represents a new negative development not introduced by any of the previous agreements before TRIPS, as it completely ignores the vast economic, material, administrative, and social disparities between developed, developing, and least developed countries. It deprives the latter of access to low-cost generic drugs, which are one of the essential solutions to overcome high drug prices. The protection extends for more than 20 years, meaning it restricts the manufacturing capabilities in developing and least developed countries and increases the monopoly of patent-owning multinational companies(Aribi,2010.p47).

We should also note that the TRIPS Agreement will significantly increase the technological gap between developing and least developed countries due to the difficulty in technology transfer arising from the failure of developed countries to fulfill their commitments to technical and technological cooperation with developing and least developed countries. As mentioned before, this obligation lacks an enforcement and monitoring mechanism, rendering it empty words. Additionally, the short lifespan of pharmaceutical products is a critical issue, considering the enormous technical and biological developments in drug research, such as genetic engineering, biotechnology, and genetic manipulation. This duration is undoubtedly inadequate for pharmaceutical products, which rely on continuous research, development, and updating.

Keeping up with advancements is crucial in this field to stay abreast of global drug developments. The implementation of the TRIPS Agreement will pose a significant barrier that did not exist before for the pharmaceutical industry in developing and least developed countries. New inventions always represent the latest and most mature fruits with practical and economic value. Conversely, many drugs are withdrawn from the market annually due to strong side effects limiting their use (Dr. Bawazir, Abdullah bin Saleh, 2002, p. 5). Many more will be withdrawn in less time due to scientific advancements, not only due to side effects but also because of the discovery of more effective alternatives. In simpler terms, commonly used drugs will become ineffective in terms of therapeutic value and impact.

Treatment methods will change, especially after the discovery of the genetic map that determines the time and age at which a person can develop a specific disease, whether cancer, AIDS, or others. Thus, new drugs will be used to prevent diseases rather than treat them, as prevention is better than cure. We can conclude that the drugs threatened by price increases are not the commonly used ones, but other drugs necessary for treating more severe and life-threatening diseases like heart diseases, cancer, and antiviral drugs (AIDS and Hepatitis C). Prices will rise, and patients will prefer death over paying the cost of the medication (The Effect of TRIPS on Patents, 2005, p. 3).

b. The Phenomenon of Biopiracy:

"The phenomenon of biopiracy has emerged for various reasons, such as the side effects of (chemical drugs), which pushed major countries and their giant pharmaceutical companies towards using (herbal medicines) and then conducting diligent searches for new plant species. This led these countries and their companies to move towards countries rich in these resources, such as India, Malaysia, and African countries, then attempt to seize ancient knowledge owned by the indigenous local populations over the ages and even obtain patents for them later. A famous case involves the registration of a U.S. patent for Indian herbal heritage. In 1995, an American company registered a patent for the use of turmeric in wound healing, which has been known in India for thousands of years. This caused significant controversy, as many considered it an unfair exploitation of traditional Indian knowledge. India filed an objection to this patent, proving that the use of turmeric in wound healing is part of traditional Indian knowledge. Ultimately, the patent was revoked in 1997 after India provided evidence that this use was already known in India."

5. COMPULSORY LICENSING:

"Compulsory licenses are authorizations by a sovereign state that allow a third party to manufacture, use, sell and/or distribute a product which has been patented, without obtaining consent or explicit permission/license of the patent owner. (Dhruv Nayar, 2020)

Granting compulsory licenses is consistent with the objectives of the TRIPS Agreement outlined in Article 7), which aims to encourage technological innovation and the dissemination of knowledge in a manner that benefits both producers and users. This can only be achieved by exploiting the patent within the territory of the patent-granting state. Compulsory licensing also contributes to the principles of the TRIPS Agreement in protecting public health and nutrition, especially when compulsory licenses are granted for patents related to pharmaceuticals or food, to curb the abuse of patent rights or engage in practices contrary to fair competition. This is especially important in the context of a large segment of the community needing access to medication and food, which has become monopolized by the patent owner.

We conclude from the above that granting compulsory licenses aligns with the objectives of the TRIPS Agreement outlined in Articles (7) and (8) of the agreement. However, if we make a simple comparison between the compulsory licenses under the Paris Convention for the Protection of Industrial Property and the current situation under the TRIPS Agreement, we find that the Paris Convention gave each Union country the right to take legislative measures to prevent any abuse that may result from the absolute right granted by the patent. In contrast, the TRIPS Agreement has moved towards limiting compulsory licenses by setting conditions for their use and introducing measures that may affect any use of the protected patent without the owner's consent (Kothrani, 2011, p. 239). We see that this approach aligns with the goal pursued by industrialized countries and major companies to include intellectual property rights in the World Trade Organization in 1994.

5.1 Compulsory Licensing Conditions:

Normally, the patent owner has the right to exploit the patent under normal circumstances. However, an exception to this rule is the issuance of a compulsory license to exploit the patent by international agreements and various national laws. This license is only granted under certain conditions that must be met, including:

a. Prior Negotiation with the Patent Owner**:** Before seeking a compulsory license to exploit the patent without the patent owner's consent, negotiations must be conducted with the patent owner to grant a voluntary license. This allows a third party to exploit the patent by agreement, considering the interests of all parties involved. This is the basic premise: communication and negotiation with the relevant party should be the first step. The patent owner might agree to grant the license on easier terms. Negotiations should be serious and last for a reasonable period. The third party seeking the license must strive to reach an agreement with the patent owner through serious and continuous negotiations for a suitable period. During negotiations, suitable commercial offers must be presented to the patent owner to help persuade them to grant a voluntary license to exploit the patent. On the other hand, Thailand has a different perspective on prior negotiations, considering it a requirement only when the compulsory license is for commercial use, as stated in Article (51) of the Thai law. This was a response to the objection of the US Trade Representative (USTR) when the USTR objected to Thailand's issuance of a compulsory license (Chaudhry, Faisal I. 2017, P68)

b. The Licensee's Ability to Exploit the Patent**:** The party applying for a compulsory license for a patent owned by others must be capable of exploiting the patent. This capability is demonstrated by having the technical knowledge to exploit the invention, possessing the necessary tools, and having the financial capabilities to exploit the patent. If the ability to exploit the patent is lacking, there is no strong justification for granting a compulsory license to someone who cannot exploit the patent themselves. The result will either be finding

someone capable of exploiting it and granting them a sub-license or leaving the patent unexploited, thus not achieving the intended benefit of granting the compulsory license(Aribi,2010,p43).

c. Absence of Legitimate Excuses**:** The patent owner must strive to exploit the patent in a way that benefits society. This is one of the reasons for granting the patent and protecting the invention by public authorities. In return for the public authorities protecting the invention and limiting its use to the owner, the owner is obligated to benefit humanity by exploiting the invention themselves, especially knowing that one of the protection conditions is that the invention should be beneficial to humanity. Therefore, a compulsory license should not be granted for an invention unless the reasons preventing the patent owner from exploiting the invention themselves and achieving the intended benefit for the public are known and studied. Acceptable excuses preventing the grant of a compulsory license include the patent owner proving that a force majeure prevented them from exploiting the invention. Other reasons include the lack of demand for the invention or low demand, which should be due to technical reasons related to the invention. Additionally, the nature of the invention should be considered, as a technically complex invention may require exploitation requirements that the patent owner may not be able to provide.

d. Primarily Aiming to Meet Local Market Needs**:** The compulsory license is granted primarily to meet local market needs as a basic condition for granting the license. Any exploitation beyond this is considered an infringement on the exclusive right of the patent owner. This condition is stated in Article 31(f) of the TRIPS Agreement of 1994. However, this paragraph was suspended following the Doha Declaration of 2001 due to exceptional health circumstances. The Doha Declaration was supplemented by the WTO General Council Decision of 2003, which represents the operational mechanism of the Doha Declaration, allowing parallel importation of medicines. This permits countries without pharmaceutical manufacturing capabilities to import pharmaceutical products from other countries where the patent is licensed (Moussawi, 2012, p. 55).

5.2 Compulsory Licensing in the TRIPS Agreement:

Article 31 of the TRIPS Agreement, titled "Other Use Without Authorization of the Rightsholder," accurately outlines the provision for granting compulsory licenses for drugs holding patents under exceptional circumstances without the consent of the patent owner. This use must be by the government or a third party authorized by the government. The provision is a narrowly confined exception, restricted to government use or by a third party licensed by the government. This exception comes with additional restrictions that almost render the exception futile. Governments or third parties may find it difficult to benefit from it and achieve the goal of obtaining medication without the patent owner's consent for humanitarian purposes. The path to compulsory licenses is not straightforward for developing and least-developed countries, as statistics show that attempts to obtain compulsory licenses by a developing or least-developed country are rare (Chaudhry, Faisal I. p67, 2017).

This is evident by examining the cases referenced in Article 31, indicating that each case of licensing must be independent. It is worth noting that the use without the patent owner's consent is only permissible if a member country's law allows it. Under such circumstances, Article 31 includes several provisions that must be considered in such cases (sec 31, TRIPS 1994).

Considering the provisions of Article 31 and the conditions under which the use of a patent without the patent owner's consent is permitted, it becomes clear that the conditions make it difficult, if not impossible, to benefit from it. Given the human need for healthcare, especially in times when epidemics spread rapidly and a significant portion of the world's population lives below the poverty line in developing and least-developed countries, the international community was compelled to find a balance that ensures the producing

companies' rights to achieve financial gains from research, manufacturing, and marketing while guaranteeing the right to healthcare and the preservation of human life, as emphasized by religious and ethical teachings.

Preventing access to essential medication is akin to unjustly taking a human life, as international treaties have affirmed the right to healthcare. Given the provisions of the TRIPS Agreement concerning drug patents and the restrictions outlined in Article 31 regarding compulsory licensing, which are of limited utility, and in light of the spread of AIDS, the international community had to act to find a more effective mechanism to balance the rights of drug patent holders with the public health goals of the TRIPS Agreement. This led to the convening of the Fourth WTO Ministerial Conference, resulting in the Doha Declaration on the TRIPS Agreement and Public Health (known as the Doha Declaration) on November 14, 2001. This conference was held amid the escalating spread of HIV/AIDS.

The Doha Declaration is not a legally binding agreement, but it provides guidance on the interpretation and application of the TRIPS Agreement in line with public health objectives. It significantly influences national and international policies and forms the basis for potential amendments to national legislation. The declaration is a political directive showing member states' commitment to balancing intellectual property rights with public health protection, without adding new provisions to the TRIPS Agreement. Instead, it offers guidance on interpreting and applying the TRIPS provisions to align with public health goals. The Doha Declaration emerged in a context where citizens of developing and least-developed countries were suffering and dying due to their inability to access HIV/AIDS medication due to economic constraints. The ministerial conference aimed to balance the conflicting interests of the parties involved by reinterpreting the TRIPS Agreement provisions, which had posed obstacles to the international community's ethical commitment to public health.

Initially, the declaration emphasized the severity of public health problems facing many developing and least-developed countries, particularly those caused by HIV/AIDS, tuberculosis, malaria, and other epidemics. The declaration then stressed. The TRIPS Agreement should be an integral part of both national and international efforts to address these issues. The Doha Declaration reassured pharmaceutical companies in developed countries by emphasizing the importance of protecting intellectual property rights and their role in developing new drugs, while also addressing concerns about the impact on prices (Emmanuel, Combe, Etienne, Pfister, Pluvia, Zuniga, 2011).

The declaration then delved into the core issue by asserting that the TRIPS Agreement should not prevent measures to protect public health. The agreement should be interpreted and implemented in a way that supports the right of WTO members to protect public health and access medicines. The declaration adopted flexibility in understanding and applying the provisions of the TRIPS Agreement through several directives to members, including the importance of reading the TRIPS provisions in light of the objectives it was designed to achieve. It emphasized members' rights to grant compulsory licenses and set appropriate conditions for each case. Members also have the right to determine national emergencies and extreme necessity conditions, including public health crises such as HIV/AIDS, tuberculosis, and malaria, as stated in the TRIPS Agreement. The declaration acknowledged the difficulties faced by WTO members who lack or have insufficient manufacturing capacities in benefiting from compulsory licenses and called for a solution to this problem. These members are the same ones whose citizens suffer from inadequate public health services, which was the focus of the ministerial meeting that issued this declaration. Developed countries were also urged to provide incentives to companies to fulfill their obligations under Article 66.2 of the TRIPS Agreement by transferring technology to developing and least-developed countries. It reaffirmed the commitment of developing and least-developed country members to implement the obligations stipulated in Sections 5 and 7 of Part II of the TRIPS Agreement and to enforce the rights specified in the agreement

(Doha Declaration, 2021). t is noted that the Doha Declaration was held under an urgent and complex health circumstance that affected many countries at that time. Patients in those countries could not access medication due to high prices, despite the availability of treatments for prevailing diseases developed by pharmaceutical companies. These companies refused to offer the drugs at affordable prices to patients, citing the protection of intellectual property rights while ignoring the right to public health. This obstinacy resulted in the death of many AIDS patients.

The Doha Declaration, through its seven paragraphs, sought to balance the interests of pharmaceutical companies, the protection of intellectual property rights, and the guarantee of public health. This balance is evident in the language used in the declaration, which predominantly features pleas and affirmations rather than the legal language that should prevail in such situations. Consequently, it was anticipated that the declaration would face challenges in practical application. The theoretical statements in the declaration were devoid of the mandatory legal language necessary to address critical health conditions.

Therefore, it was expected that the declaration would encounter difficulties in implementation, as it is known that agreeing on principles and showing goodwill is easy, but the details and obstacles in the implementation process would be leveraged by the party solely focused on its interests. Consequently, it became evident that within a short period, there was a need to supplement the Doha Declaration with a decision on August 30, 2003, known as the Decision on the Implementation of Paragraph 6 of the Doha Declaration.

The General Council of the World Trade Organization adopted a crucial decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This decision aimed to quickly address the difficulties faced by member countries that lack sufficient manufacturing capacities in the pharmaceutical sector to effectively utilize compulsory licenses. The decision serves as an operational mechanism for the Doha Declaration, including several essential definitions to facilitate the use of compulsory licensing. These definitions cover pharmaceutical products, eligible importing members, exporting members, compulsory licenses, and preventive measures. The decision also outlines mechanisms for evaluating manufacturing capacities in the pharmaceutical sector across different countries and how to cooperate with them. The decision aims to enhance the ability of developing and least-developed countries to access essential medicines for public health and ensure that intellectual property rights do not hinder global health efforts.

Indeed, the Doha Declaration and the accompanying ministerial decision had a limited positive impact in providing medications despite facing many challenges in its implementation. Here are some examples of compulsory licenses that several countries used to provide medicines to their citizens (WT/L/540, 2, SEP 2003):

In Botswana, the adult HIV/AIDS infection rate was over 37%, severely affecting large segments of society due to the high cost of medication. The issuance of a compulsory license for the medication helped reduce its cost from $15,000 to $150 per person per year (Moussawi, 2012, p. 59).

In Brazil, the price of an AIDS treatment pack dropped to $18 after the price was reduced by 79% when Brazil exercised its authority to issue a compulsory license to provide AIDS medication. This had a positive impact by reducing the mortality rate due to AIDS (Moussawi, 2012, p. 63).

In South Africa, the government applied pressure on pharmaceutical companies for compulsory licensing by filing a lawsuit against Behringer Ingelheim. In the exclusive rights holder to sell antiviral drugs in South Africa. The lawsuit, filed under Article 46 of the Competition Act No. 89 of 1998, held the

company responsible for the deaths of many AIDS patients. South Africa has the highest HIV/AIDS prevalence rate in the world, with about 21.5% of its estimated 43 million population living with HIV/AIDS. In 2002, 1,600 people were said to contract the AIDS virus daily in South Africa, the highest infection rate in the world at that time. The company had refused to grant a voluntary license to a national company to supply the drugs (John, Agada, 2019, p. 5). Before the court issued its ruling, a settlement was reached with the defendant company, under which drug prices for the public sector were reduced, and a voluntary license was granted to Arsine, which supplied the drug to the local market and exported the surplus to other countries (Moussawi, 2012, p. 61).

In another example, the United States and Canada pressured the German company Bayer to sell the drug Cipro, used to treat anthrax, at a reduced price or issue a compulsory license for the drug. The company subsequently reduced the drug's price.

From these cases, it can be said that the reforms to the TRIPS Agreement have somewhat contributed to providing treatment in emergencies, but they have not offered complete solutions to the problem created by the TRIPS Agreement. Given this situation, the need to obtain protected medications to combat diseases affecting impoverished individuals became evident, highlighting the ethical aspect of protecting public health, which is one of the goals of Despite all these efforts, protecting public health under the provisions of the TRIPS Agreement remains below expectations and faces many challenges and complexities in ensuring protection and providing treatment for everyone. The goal is to achieve the objectives of the TRIPS Agreement while balancing the protection of intellectual property rights for companies to encourage them to continue researching and offering therapeutic solutions to health problems.

In light of all the previously mentioned facts and justifications, the World Trade Organization (WTO) amended the TRIPS Agreement through a protocol on December 6, 2005, which came into effect in January 2017. This amendment added Article 31bis along with an annex, providing the legal basis for WTO members to grant special compulsory licenses for the production and export of generic drugs at affordable prices to countries that cannot produce sufficient quantities of needed medicines for their patients. This amendment allows the export of drugs manufactured under compulsory licenses to countries facing difficulties in accessing affordable medicines.

The annex provides detailed guidance on how to implement Article 31bis, including the requirements and procedures that must be followed to ensure compliance with the provisions of the agreement. It also includes practical tools and templates for implementing Article 31bis and the annex, including forms that must be used to submit compulsory license applications and the procedures to be followed.

The following is an explanation and commentary on the provisions of Article (31bis) TRIPS Agreement**:**

In the first paragraph, it suspended the application of Article 31(f), which stipulated that such use should primarily serve the domestic market of the member authorizing such use. This paragraph, titled "Other Use Without Authorization of the Rightsholder," allows use but under many conditions. The direction of Article 31bis was to remove many of the restrictions imposed by Article 31. This is evident in paragraph 2 of Article 31bis, which acknowledged compensation to the patent holder for the compulsory license and clarified that the compensation should be reasonable. It also suspended the application of Article 31(h), which allowed repeated compensation if a compulsory license was issued for the same patent by the importing member (Article 31(h)).

Additionally, to encourage developing and least-developed countries, which make up the majority of WTO members, the amendment under Article 31bis, paragraph 3, allowed countries issuing compulsory licenses for pharmaceutical products not to be limited to local production only, as was required under Article 31(h). Instead, they could benefit from regional trade agreements under Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favorable Treatment, Reciprocity and Fuller Participation of Developing Countries (L/4903). This allowed the export of the pharmaceutical product to countries facing the same health problem, provided this did not harm the regional nature of the relevant patent rights. Notably, the provisions were articulated in clear legal terms aimed at ensuring the right to public health without infringing on the rights of patent holders, which was previously lacking. The amendment also suspended all provisions that could conflict with its terms. The amendment was protected from legal challenges that could be raised under Article 23.1(b)(c) of the TRIPS Agreement 1994 by any affected party against actions taken under Article 31bis and its annexes.

Furthermore, paragraph 5 of Article 31bis confirmed that the amendment does not affect the rights, obligations, and flexibility enjoyed by members under the TRIPS Agreement, except for what was excluded under Articles 31(f) and (h). It also ensured the rights mentioned in the TRIPS Agreement and Public Health Declaration. This means that the amendment aimed to add more facilities to contribute alongside the existing ones. The main objective is to protect public health and support developing and least-developed countries that lack the technology or have weak capabilities to develop their technical capacities in this field (Article 31bis, 2005).

Article 31bis was followed by an annex that laid down its implementing principles, detailing procedures and definitions aimed at applying the amendment. The annex defined pharmaceutical products, importing members, and exporting members. The purpose of these definitions is to specify and limit the individuals eligible to use, request, or issue compulsory licenses and to clarify what falls within or is excluded from the definition of pharmaceutical products. The annex aimed to address the challenges that might hinder the implementation of the amended article, taking into account the difficulties encountered in previous experiences.

The annex then provided detailed procedural conditions for submitting a license application, starting with whether the member is qualified or not, and progressing to the stage of marking the pharmaceutical product produced under a compulsory license and its destination. These procedures are precise and sufficient unless obstructed by bureaucratic measures, either in good faith or otherwise. The exporting member must notify the TRIPS Council of the license and its attached conditions and provide all necessary data for follow-up. Qualified importing members must take the necessary measures to use the imported products under the system for public health purposes and prevent their diversion for other purposes or re-exportation.

The annex placed great emphasis on the technical and technological support that should be provided to developing and least-developed countries that lack capacities in the pharmaceutical industry. For this purpose, qualified importing and exporting members are encouraged to use the system in a way that promotes this goal. Members commit to cooperating and giving special attention to technology transfer and capacity building in the pharmaceutical sector, as stipulated in Article 66.2 of the TRIPS Agreement and paragraph 7 of the TRIPS Agreement and Public Health Declaration. The TRIPS Council must review the system annually to ensure its effective operation and provide an annual report on its operation to the General Council (Annex, 2005).

5.3 Compulsory Licensing and the COVID-19 Pandemic

The COVID-19 pandemic, which has swept across the globe recently, serves as a true test of the effectiveness of the amendments made to the TRIPS Agreement in ensuring public health and providing essential treatments to prevent the disease. The reality is that, despite intensive research efforts leading to the development of a vaccine, major countries rushed to secure large quantities of vaccines far exceeding their citizens' needs. This left the majority of the world's population, particularly in developing and least-developed countries, without access to the vaccine, facing a deadly pandemic.

The leaders of major countries, in their pursuit of monopoly and self-interest, overlooked the necessity of herd immunity, which requires everyone to be vaccinated for the collective recovery. Instead, they left poorer countries to their fate, and any assistance provided was often driven by economic or political considerations. In this situation, developing and least-developed countries began seeking solutions to provide vaccines for their citizens. They considered compulsory licensing, leveraging the amendments made to the TRIPS Agreement under Article 31bis. However, they found the path to be thorny and complicated by bureaucratic procedures.

While the theoretical provisions exist and ostensibly guarantee the right to compulsory licensing, they are not easily attainable. Not all countries in need of compulsory licensing can obtain it promptly, and everyone knows the importance of accessing medication when needed, not afterward. Now, let's explore the experiences of countries that sought compulsory licenses during the COVID-19 pandemic and understand what transpired. In October 2020, India and South Africa proposed a temporary waiver from certain sections (1, 4, 5, 7) of Part II of the TRIPS Agreement for at least three years. After this period, the WTO General Council would determine whether the removal of patents was still justified (Council for Trade-Related Aspects of Intellectual Property Rights, 2020 and 2021). This request was part of their efforts to ensure vaccine availability for developing and economically limited countries. The proposal not only focused on vaccines but also included other patent-protected subjects such as health products and technologies, including diagnostics, treatments, medical devices, personal protective equipment, and their materials or components, as well as manufacturing methods for preventing and treating COVID-19.

The idea behind this proposal was that manufacturing a vaccine requires not just the removal of a single patent but a wide range of intellectual property-protected elements. This proposal, quickly supported by 100 countries, including China and Russia, was also backed by the World Health Organization and the Joint United Nations Programme on HIV/AIDS. Hundreds of Nobel laureates, Doctors Without Borders, and the editorial team of Nature magazine also supported this measure. Importantly, the United States, which had historically resisted this proposal, changed its stance. However, the US government was not prepared to go as far as the Indian and South African proposal requested (Paquin, 2023).

This supports the notion that major countries and their companies do not have enough enthusiasm to prioritize or even balance the right to public health with protecting their interests. The US entered with clear reservations to support the India-South Africa proposal. Let's see what their companies did.

When Joe Biden changed the US position on this issue, pharmaceutical companies quickly mobilized to pressure the US government and elected officials. Many companies, including Pfizer and Johnson & Johnson, supported the public relations campaign initiated by PhRMA. This lobbying group sought to undermine Biden's stance on easing patent restrictions. Among the initiatives taken were strategies targeting members of Congress. The group argued that Biden's policy would destroy jobs in the US and allow China to benefit from American innovations. Many elected officials and figures from both the Republican and Democratic

parties publicly supported pharmaceutical companies. PhRMA presented some arguments, including national security issues, claiming that lifting patents would cause companies to lose their ability to fund research.

A study by the Corporate Europe Observatory (2021) found that pharmaceutical companies spent at least 36 million euros lobbying the European Union. The industry employs 290 lobbyists to defend its interests in Brussels, not counting lobbyists hired by consulting firms. As a result of this lobbying, between March 2020 and May 2021, EU commissioners and their staff met with members of major pharmaceutical companies more than 160 times regarding the production and distribution of COVID-19 vaccines, but held only one meeting with a non-governmental organization in favor of the waiver (Corporate Europe Observatory, Paquin, 2023).

In light of these organized campaigns, let's look at the official positions of countries on the India-South Africa proposal. Several countries, including the United Kingdom, Japan, Switzerland, and South Korea, opposed the proposal, while Germany, Portugal, and Belgium had reservations, and France and Italy supported it. To counter the India-South Africa proposal, on June 4, 2021, the European Commission submitted another proposal to the WTO regarding compulsory licenses, addressing export restrictions and increasing production instead of lifting patents. Pharmaceutical companies also promoted the idea that lifting patents would slow pharmaceutical innovation in the long term, arguing that scientific research would lose many of its funding sources, even though vaccines, in particular, are largely funded by the public sector as they support public health (Paquin, 2023). In December 2021, quadrilateral discussions began between India, South Africa, the European Union, and the United States, resulting in an agreement during the 12th Ministerial Conference in Geneva in the form of a Ministerial Decision on the TRIPS Agreement, adopted on June 17, 2022.

Examining the Ministerial Decision reveals that it focused on addressing COVID-19 by amending the TRIPS provisions through compulsory licenses, a method previously employed for HIV/AIDS. Members are allowed to use the patent without the patent holder's consent to the extent necessary to produce and supply COVID-19 vaccines through any means available under the member's law, such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, regardless of whether the member has a compulsory licensing system (MC12, 2022).

To achieve this, members are not required to make efforts to obtain a license from the right holder, nor is the authorized use limited to supplying the domestic market. The decision also urged members to take legal measures to prevent the re-exportation of products imported under the decision. Additionally, it balanced appropriate compensation for the patent holder with the humanitarian and non-profit purpose of vaccine distribution programs (MC12, 2022).

From the above, it is evident that the WTO has tackled each situation individually related to the TRIPS Agreement through declarations (e.g., the Doha Declaration for AIDS), amendments (e.g., Article 31bis), or Ministerial Decisions (e.g., in 2022). However, these measures have limited impact as they address only the current emergencies, like COVID-19. The fundamental issue remains unaddressed: the broad scope of protection in the TRIPS Agreement, which is more extensive than previous agreements, necessitates a balance to ensure the rights of patent holders.

The original proposal by India and South Africa was much more ambitious. It involved lifting patents and allowing countries to manufacture generic vaccines, diagnostics, and treatments without complex procedures, facilitating production by granting local manufacturers access to manufacturing data. The agreement does not cover COVID-19 testing and treatment, which are also priorities for low-income countries. Treatments like Molnupiravir or Paxlovid are not part of the agreement.

Other countries have also sought to provide COVID-19 vaccines to their citizens. In 2021, Mexico issued a decision under Article 31 to grant compulsory licenses for producing and exporting COVID-19 vaccines. This decision allowed local companies to produce vaccine copies without the original rights holder's consent, increasing the available doses for the population. In 2021, Canada issued a decision under Article 31 for compulsory licenses to produce and export COVID-19 vaccines, similarly enabling local companies to produce vaccine copies without the original rights holder's consent, thereby increasing the available doses. In 2021, Argentina also issued a decision under Article 31 for compulsory licenses to produce and export vaccines. This decision allowed local companies to produce copies of the vaccines without the need for the original rights holder's consent, increasing the number of doses available to the population. These examples illustrate how Article 31 was used to enhance access to vaccines during the COVID-19 pandemic, contributing to improved healthcare in developing and economically limited countries.

However, we believe the fundamental issue remains: the broad scope of protection established by the TRIPS Agreement. The proposal by India and South Africa should have received more consideration, especially as it was presented after decades of experience with the TRIPS Agreement and was a response to the global challenges posed by its implementation.

6. OPTIONS AVAILABLE FOR DEVELOPING AND LEAST-DEVELOPED COUNTRIES TO MITIGATE THE NEGATIVE EFFECTS OF THE TRIPS AGREEMENT:

a. Avoiding additional commitments beyond TRIPS: Developing and least-developed countries should avoid entering into bilateral agreements with developed countries that seek to achieve what could not be accomplished within the general framework of TRIPS, such as TRIPS-plus provisions. These countries should recognize the dangers of additional commitments during accession negotiations and be cautious about excluding the pharmaceutical sector from any additional TRIPS commitments(Aribi,2010, p. 51).

b. Defining the concept of invention: The agreement does not provide a unified definition of invention due to the lack of standardized concepts. This offers flexibility in a rapidly changing scientific and technological environment. Developing and least-developed countries can use different interpretations to create flexibility, within certain limits.

c. Adopting the minimum standard of protection: To consider public interest, developing and least-developed countries can adopt the minimum standard for protecting pharmaceutical products, which is 20 years. The agreement states, "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date" (Article 33 of the TRIPS Agreement, 1994).

d. Utilizing patent grant criteria: This refers to both substantive and procedural conditions. Article 27.1 of the agreement requires patents to be granted when the three criteria novelty, inventive step, and industrial applicability are met. However, the agreement does not specify the meaning of these terms, allowing members to use synonyms. Regarding procedural conditions, the agreement leaves it to member countries to determine them according to their national legislations.

e. Adopting the principle of international exhaustion: This principle refers to the loss of the patent holder's right to prevent others from importing protected products once they have been sold in any market, either by the holder or with their consent. Article 6 of the agreement addresses this. Applying the principle of international exhaustion is particularly important in the pharmaceutical sector because allowing the importation of medicines sold at lower prices in other countries can benefit a larger number of patients.

f. Benefiting from exceptions to exclusive rights: Article 31 allows member countries to grant limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. National laws can specify necessary exceptions according to the conditions mentioned above. The agreement's Article 30 provides developing and least-developed countries with a significant opportunity to benefit from protected inventions without incurring substantial costs to obtain the granted rights.

g. Utilizing the flexibilities provided by Article 31 of the TRIPS Agreement, which addresses other uses without authorization of the right holder. The literal interpretation of this article focuses on both compulsory licenses and parallel importation of medicines. The article grants the authority to issue a compulsory license in cases of public health emergencies, subject to several restrictions, including limiting the license to local use, providing compensation to the patent holder, and making serious efforts to obtain a voluntary license on commercial terms. Compulsory licenses can have a significant impact on making medicines available to individuals. Holding the authority to issue a compulsory license does not necessarily mean it will be used. Sometimes, the mere threat of issuing one is enough to incentivize companies to lower their prices. For example, this happened with the governments of the United States and Canada when they faced the threat of anthrax bioterrorism.

h. Establishing frameworks to prevent biopiracy of the genetic resources of developing and least-developed countries. This can be achieved by creating a digital database of traditional knowledge in these countries, compiling and disseminating information about the past and current uses of biological resources at national and international levels. This documentation serves as evidence of prior and current knowledge using biological resources, thus preventing the patenting of traditional knowledge. Some organizations have started publishing their community's knowledge to negate the novelty requirement for obtaining a patent. This protects the biological wealth of developing countries and ensures its use in pharmaceutical manufacturing (Al-Haddad, 2016, p. 315). This approach prevents biopiracy based on the relative novelty requirement. India has been a pioneer in this field, with the Indian Council of Scientific and Industrial Research developing a program to analyze around 500 medicinal plants, compiling the information on CD-ROMs, and making it available to patent offices as a reference. Consequently, digital databases enable patent offices worldwide to search and study the prior use of any known knowledge, thereby preventing the granting of patents on existing expertise or use (Hoare, Martin, 2007, p. 6).

i. Creating a monitoring mechanism to hold developed countries and large corporations accountable for fulfilling their obligations under the TRIPS Agreement towards developing countries, specifically regarding providing necessary technical assistance and technology transfer to developing countries.

7. RESULTS:

1. The Impact of the TRIPS Agreement on Public Health and Drug Prices: The TRIPS Agreement extended intellectual property protections to pharmaceutical products, leading to increased drug prices and reduced access to essential medicines, especially in developing and least-developed countries. This highlighted a failure to balance the rights of patent holders with public health needs.
2. The Efficiency and Limitations of Compulsory Licensing: While compulsory licensing is a powerful tool to counter monopolies and ensure medicine accessibility, it faces legal and administrative complexities that hinder its effective implementation. The provided solutions within the Agreement have proven insufficient for future challenges.

3. The Widening Technology Gap Due to Ineffective Technology Transfers**:** Developed nations have not fulfilled their commitments to transfer technology to developing and least-developed countries, thereby exacerbating technological disparities and dependence.
4. Vaccine Hoarding During the COVID-19 Pandemic**:** The pandemic revealed the inadequacy of existing mechanisms within the TRIPS framework to guarantee equitable vaccine distribution, as wealthier countries hoarded vaccines, leaving less-resourced nations disadvantaged.

8. RECOMMENDATIONS:

1. Comprehensive Review of the TRIPS Agreement to Ensure Balance: **Amend** provisions related to pharmaceutical patents to better balance intellectual property rights with the right to public health.
2. Simplifying Compulsory Licensing Processes**:** Reduce legal complexities to enable the efficient use of compulsory licensing mechanisms, alongside establishing a permanent framework to assist developing and least-developed nations in accessing medicines.
3. Strengthening Technology Transfer Mechanisms**:** Implement effective monitoring systems to hold developed nations accountable for fulfilling their obligations under the TRIPS Agreement, specifically technology transfers to developing nations.
4. Promoting Transparency Through a Digital Knowledge Database**:** Develop a centralized digital registry for traditional knowledge and biological resources of developing countries to prevent biopiracy.
5. Raising Global Awareness of TRIPS Challenges**:** Conduct international campaigns to increase understanding of the TRIPS Agreement's limitations and promote advocacy for necessary amendments.

9. CONCLUSION:

In the introduction of the research, we clarified that multiple scientific articles have been written on this topic under various titles. The novelty of this article lies in incorporating most of what has been written and then discussing the provisions of the TRIPS Agreement and the ministerial decisions issued regarding it, along with the amendments made to the agreement to address health emergencies. We also examine the effectiveness of the measures taken to address the COVID-19 pandemic.

The TRIPS Agreement, especially the part related to drug patents, has become an obstacle to ensuring the right to public health. It was included in the WTO Agreement to protect major companies and their profits under the pretext of ensuring the continuity of scientific research. We found this claim to be false. During the COVID-19 pandemic, and before that during the spread of the AIDS epidemic, the organization strived to find solutions to address health emergencies without making a fundamental amendment to the agreement. We affirm that the effectiveness of the response was weak and temporary, specifically tailored to the pandemic and cannot be generalized to future health emergencies.

Moreover, the compulsory licenses adopted by the ministerial decisions and the agreed amendments were not accessible to developing and least developed countries. Our research revealed that achieving the agreement's goal of guaranteeing public health remains elusive under the legal constraints imposed by the TRIPS Agreement. Instead, it has become a gift granted by developed countries to developing ones at their discretion. Furthermore, it deliberately ignored its commitment to transfer technology to developing countries.

The research concluded with several recommendations that are considered effective in addressing the negative impacts of the TRIPS Agreement. The most important recommendation is the comprehensive review of the TRIPS Agreement to remove drug patents from absolute protection and ensure that the inventor's right to benefit from their invention aligns with the protection and guarantee of public health.

10. REFERENCES:

1. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement1994). Retrieved from: https://www.wipo.int/wipolex/ar/treaties/details/231
2. Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017). Retrieved from: https://www.wipo.int/wipolex/ar/treaties/details/231
3. Aribi, Mostafa Ibrahim. "Intellectual Property According to International Agreements and Sudanese Law." Mathab Center for Printing Services, 2010.
4. Bauzeer, Abdullah bin Saleh. "The Impact of the Intellectual Property Protection Agreement on the Pharmaceutical Industry in Developing Countries." Islamic Organization for Medical Sciences, Kuwait, 2002.
5. Carlos, M. Correa. "Intellectual Property Rights, the World Trade Organization, and Developing Countries: The TRIPS Agreement and Policy Options." Dar Al-Mareekh for Publishing, Riyadh, 2007.
6. Chaudhry, Faisal I. "Intellectual Property and the Global Crisis of Noncommunicable Disease." North Carolina Journal of Law & Technology, Vol. 19, Issue 2, December 2017.
7. Dhruv Nayar. "Compulsory Licensing during a Pandemic: Patent Law and COVID-19." 13 April 2020.
8. Ezinne Mirian Igbokwe & Andrea Tosato. "Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31BIS." Fordham Law Review, Vol. 91, Forthcoming, 2022.
9. Emmanuel, Combe, Etienne, Pfister, Pluvia, Zuniga. "Pharmaceutical Patents, Developing Countries and HIV/AIDS Research." Journal of the International AIDS Society, 2011. Retrieved from https://jiasociety.biomedcentral.com/articles/10.1186/1758-2652-14-15
10. Exclusions and Exceptions, Asian Regional Course for Judges on Intellectual Property and Public Health, South Centre, 2021.
11. Hassan Nasr, Abou Al-Fotouh Farid. "Protection of Intellectual Property Rights in the Pharmaceutical Industry (Under the TRIPS Agreement and Egyptian Law No. 82 of 2002)." Al-Maghribi Printing House, 2006.

12. Hore, Martin. "Intellectual Property, Biodiversity, and Sustainable Development: Solving Difficult Issues." Dar Al-Mareekh for Publishing, Riyadh.
13. John, Agada, John, Gathegi, Johannes, Briz, Petr, Lor. "Globalization of Intellectual Property Rights: Implications of the TRIPS Agreement for Access to HIV/AIDS Drugs in Africa." ASIS&T Annual Meeting - Association for Information Science and Technology | ASIS&T, 2009.
14. Koutharani, Hanan Mahmoud. "The Legal Protection of Patent According to the provisions of the TRIPS Agreement." Al-Halabi Legal Publications, 2011.
15. Mohmieddin, Jalal Wafa. "The Legal Protection of Industrial Property According to the TRIPS Agreement." New University House for Publishing, Alexandria, 2004.
16. Moussa, Mohammad Ibrahim. "Patents in the Pharmaceutical Field." New University House, 38 Sweeter St., Al-Azareeta, Alexandria, 2006.
17. Owoeye. "Patents for Drugs and the Right to Development in International Law." Law and Development Review, 8(1), 69–97, 2015. Retrieved from https://doi.org/10.1515/ldr-2014-0029
18. Paquin, Stéphane & Other. "The WTO and the Covid-19 "Vaccine Apartheid": Big Pharma and the Minefield of Patents." Politics and Governance, 2023, Volume 11, Issue 1. Retrieved from: https://doi.org/10.17645/pag.v11i1.6177

19. The Effect of TRIPS on Patents & the Protection of the Right to Health in Egypt, 2005. Retrieved from: http://www.eipr.org/reports/Trips
20. The International Covenant of Economic, Social, and Cultural Rights.1966 https://www.ohchr.org/ar/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights
21. The Universal Declaration of Human Rights, 1948.Retrieved from: https://www.un.org/ar/about-us/universal-declaration-of-human-rights
22. Twelfth WTO Ministerial Conference2022. Retrieved from: https://www.wto.org/english/thewto_e/minist_e/mc12_e/mc12_e.htm
23. Zain Al-Din, Salah Asmar. "Industrial and Commercial Property." Dar Al-Thaqafa Library for Publishing and Distribution, Amman, 2000.
24. Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001: TRIPS WT/MIN(01)/DEC/2. Retrieved from: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm