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The Role of the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) in the Protection of Pharmaceutical Products

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Abstract:
Pharmaceutical products are among the most prominent outcomes of scientific advancement in the fields of medicine and health, as they directly contribute to disease prevention, treatment, and the improvement of quality of life. Due to the importance of innovation in this vital sector, protecting intellectual property rights for pharmaceutical products has become essential to ensure the continuity of research and development and to encourage companies and institutions to invest in the discovery of new drugs. In this context, both the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) play a pivotal role in establishing legal and regulatory frameworks that safeguard the rights of inventors and developers in the pharmaceutical sector, while striving to strike a balance between protecting these rights and ensuring access to medicines for those in need, especially in developing countries. This role is embodied through international mechanisms and treaties such as the Patent Cooperation Treaty (PCT) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which define the relationship between pharmaceutical innovation and global health equity.

Keywords: *Pharmaceutical products, protection, World Trade Organization, pharmaceutical products, World Intellectual Property Organization.*

Le rôle de l'Organisation mondiale de la propriété intellectuelle (OMPI) et de l'Organisation mondiale du commerce (OMC) dans la protection des produits pharmaceutiques

Résumé :
Les produits pharmaceutiques figurent parmi les réalisations les plus marquantes des progrès scientifiques dans les domaines de la médecine et de la santé, car ils contribuent directement à la prévention et au traitement des maladies, ainsi qu'à l'amélioration de la qualité de vie. Compte tenu de l'importance de l'innovation dans ce secteur vital, la protection des droits de propriété intellectuelle sur les produits pharmaceutiques est devenue essentielle pour garantir la continuité de la recherche et du développement et encourager les entreprises et les institutions à investir dans la découverte de nouveaux médicaments. Dans ce contexte, l'Organisation mondiale de la propriété intellectuelle (OMPI) et l'Organisation mondiale du commerce (OMC) jouent un rôle central dans l'établissement de cadres juridiques et réglementaires qui protègent les droits des inventeurs et des développeurs du secteur pharmaceutique, tout en s'efforçant de trouver un équilibre entre la protection de ces droits et l'accès aux médicaments pour les personnes qui en ont besoin, notamment dans les pays en développement. Ce rôle se concrétise par des mécanismes et des traités internationaux tels que le Traité de coopération en matière de brevets (PCT) et l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC), qui définissent le lien entre l'innovation pharmaceutique et l'équité mondiale en matière de santé.

Mots-clés *: Produits pharmaceutiques, protection, Organisation mondiale du commerce, Organisation mondiale de la propriété intellectuelle.*

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Introduction:

The pharmaceutical industry is one of the most important economic sectors, due to the continuous demand for pharmaceutical substances. This has prompted developed countries to encourage investment and provide a suitable environment for innovation in this field.

International intellectual property law seeks to guarantee the inventor of pharmaceutical substances the exclusive legal protection granted to them. The international community has worked to generalize this protection to all countries, including developing ones.

The protection of pharmaceutical substances is among the most prominent issues attracting the attention of the international community, due to its direct impact on public health and human rights. With the significant advancements in research and development in the field of medicine, the need has emerged to regulate intellectual property rights associated with these products. This regulation aims to strike a balance between encouraging innovation and ensuring the availability of affordable medicines for all, especially in low-income countries.

In this context, international organizations play a key role in establishing policies and legal standards governing the protection of pharmaceutical substances. Among the most prominent of these organizations are the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO), which work to regulate patent rights related to medicines and provide mechanisms to protect the interests of inventors without undermining the rights of

states to secure the health needs of their populations. These organizations aim to achieve a delicate balance between protecting pharmaceutical innovation and ensuring fair access to medicine.

The role of international organizations in reinforcing the legal protection of pharmaceutical substances is realized through the protection of patent rights, by overseeing the implementation of the provisions of international agreements and treaties related to intellectual property in general, and pharmaceutical patents in particular.

The most important international organizations concerned with the protection of pharmaceutical substances include the World Intellectual Property Organization, the World Trade Organization, and the World Health Organization. The TRIPS Agreement serves as the legal foundation for this protection, alongside relevant laws and the Patent Cooperation Treaty.

The importance of this study lies in highlighting the efforts made by international organizationsespecially the World Intellectual Property Organization and the World Trade Organization—in providing protection for pharmaceutical substances within the framework of international intellectual property law.

The study also emphasizes the role of these two organizations in implementing the provisions of international agreements related to the protection of pharmaceutical substances, particularly the TRIPS Agreement and the Patent Cooperation Treaty, as well as the contribution of international organizations in resolving disputes related to patent rights.

This study aims to achieve several objectives, most importantly to clarify the specific nature of patent protection

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in the field of pharmaceutical substances, and to highlight the role of international organizations in ensuring adequate protection of pharmaceutical products worldwide.

Therefore, the central research question arises: **To what extent have the World Intellectual Property Organization and the World Trade Organization contributed to the protection of pharmaceutical substances?**

To answer this question, the study is divided into two sections:

- The first section addresses the role of the World Intellectual Property Organization in protecting pharmaceutical products.
- The second section examines the role of the World Trade Organization in protecting pharmaceutical products.

1. The Role of the World Intellectual Property Organization (WIPO) in the Protection of Pharmaceutical Products

Pharmaceutical products have recently been included within the scope of intellectual property and patent protection, especially in developing countries. This comes in response to the evolution of intellectual property laws in developed countries, which were pioneers in providing legal and institutional protection for pharmaceutical substances. International organizations represent one of the institutional mechanisms relied upon by the international community to ensure the protection of pharmaceutical product patents. Among the most prominent of these organizations is the World Intellectual Property Organization (WIPO).

Based on the above, this section will examine the protection of pharmaceutical products under the World Intellectual Property Organization by addressing the organization's supervision of the implementation of agreements and treaties in the first subsection, while the second subsection will focus on WIPO's efforts in the field of pharmaceutical patent protection, as follows:

1.1. The Organization's Supervision of the Implementation of Agreements and Treaties

Supervising the implementation of agreements and treaties by the World Intellectual Property Organization is one of the forms of protection it seeks to provide for pharmaceutical products. Other forms of protection are evident in the efforts made by this organization in the field of intellectual property, specifically in the protection of pharmaceutical patents[1]. This subsection will address this through two parts: the first part will discuss the organization's supervision of the implementation of agreements and treaties, while the second part will cover WIPO's efforts in the field of patent protection.

1.1.1. "The organization's direct supervision over the implementation of agreements and treaties.

Paragraph 3 of Article 4 states that WIPO may accept to undertake administrative tasks arising from the implementation of any international agreement aimed at supporting the protection of intellectual property, or to participate in such tasks. This represents an explicit authorization for the organization to supervise the administrative implementation of any international agreement, provided that the agreement falls within the

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scope of WIPO's objectives—namely, the protection of intellectual property[2].

Paragraph 8 of the same article further states that WIPO may take any other appropriate action it deems necessary in order to achieve its objectives, particularly the protection of intellectual property at the international level. This implies that the organization is empowered to take any measures it considers appropriate to contribute to the protection and promotion of intellectual property, including assuming supervision over the implementation of bilateral or multilateral international agreements in this regard[3].

Supervision is considered direct when the World Intellectual Property Organization, through its internal bodies, undertakes the international implementation tasks itself, without the involvement of any external bodies outside its recognized administrative structure.

1.1.2. The organization's indirect supervision over the implementation of agreements and treaties

In contrast, indirect supervision occurs when the implementation of an international agreement is entrusted to WIPO, which in turn delegates the task to a body or entity outside its recognized administrative framework—whether this body or entity already exists on the international scene or is created specifically for this purpose. However, WIPO retains the authority of oversight and supervision over the entity charged with implementing the agreement.

Finally, it should be noted that supervision may be assigned exclusively to WIPO, without the participation of any other international or local organization or authority. Each party may supervise the implementation of the agreement in a

specific part of it, and this is referred to as "joint implementation"[4].

1.2. The Patent Cooperation Treaty as a Legal Basis for Protection

As part of international efforts to protect patents—particularly pharmaceutical patents—the Patent Cooperation Treaty (PCT) was concluded and has been joined by many countries, especially developing ones. This treaty forms the legal foundation upon which the World Intellectual Property Organization (WIPO) relies when engaging in activities related to the protection of pharmaceutical patents. In addressing the PCT as a legal basis for protection, we will examine the treaty's objectives and its operational system in the field of patents.

1.2.1. Objectives of the Treaty

The objectives of this treaty can be summarized as follows:

- To simplify the procedures for requesting patent protection when such protection is sought in multiple countries, while increasing the efficiency of those procedures and reducing costs, thus serving the interests of both the beneficiaries of the patent system and the offices responsible for managing it.
- To avoid the repetition of filing and examination procedures resulting from submitting applications in each country where protection is sought.

In order to achieve these goals, the Patent Cooperation Treaty, concluded in Washington on June 19, 1970, and amended on September 28, 1979, and on February 3, 1984, stipulated the following .Filing Patent Protection

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Applications as International Applications in Any of the Contracting States

Article 03, Paragraph 01, of Chapter One of the Treaty under the Title "International Application and Search":

The international application must be filed with the receiving office as specified, which must examine and search it in accordance with the provisions of this Treaty and its Regulations (Article 10 of the Patent Cooperation Treaty). Subsequently, each international application shall be subject to an international search, the purpose of which is to reveal the relevant prior art in the industrial field (Article 15 of the Treaty), which is taken into account when assessing the patentability of the invention[5].

- A single patent office — the receiving office — is obliged to conduct the formal examination of the international application.
- Centralized procedures ensure the international publication of international applications and the corresponding international search reports, and the communication of these to the concerned offices.
- The possibility of conducting an international preliminary examination, based on which a report is prepared containing a general opinion on whether the claimed invention meets certain international standards for patentability. This report is submitted to the offices responsible for deciding whether to grant or refuse the patent to the applicant.

1.2.2. Operating System of the Patent Cooperation Treaty (PCT)

To define the operating system of the Patent Cooperation Treaty, it is necessary to address the following: the right to file an international application and the place of filing, international search, international publication, in addition to international preliminary examination.

First: The Right to File an International Application and the Place of Filing

Article 9 of the Patent Cooperation Treaty allows the nationals of contracting states and any person residing in these states to file an international application. Such applications may be filed with the receiving office acting in this capacity based on the Treaty[6].

The Implementing Regulations, in its Article 19, Paragraph 1, specifies the place of filing of the application. It states that the international application may be filed at the choice of the applicant with:

1. The national office of the contracting state in which the applicant resides or the office acting on behalf of that state.
2. The national office of the contracting state of which the applicant is a national or the office acting on behalf of that state.
3. The International Bureau, regardless of the contracting state where the applicant is a national or resides.

Furthermore, the nationals of the states parties to the "Harare" Protocol, the Eurasian Patent Convention, the "Banjul" Agreement, or the European Patent Convention, as well as the residents of those countries in general, may file international applications with the ARIPO Office, the

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Eurasian Patent Office, the European Patent Office, or the African Intellectual Property Organization, depending on the case, should they wish to do so.

For the nationals and residents of certain developing countries, they have the option to file international applications with the International Bureau of the World Intellectual Property Organization, which acts as the receiving office for those countries.

In general, nationals and residents of all contracting states to the Patent Cooperation Treaty may file their applications with the International Bureau, acting as the receiving office.

Requests, if desired, may be made, and the international application shall, from the date of international filing, have the effect resulting from any national application filed in the contracting states under the treaty, which are designated by the applicant in their request for a national patent, and it shall have the effect of a regional patent application, provided that the designated states are specified in the request for a regional patent[7].

The Patent Cooperation Treaty (PCT) sets out certain criteria that must be met in international applications, and all contracting states under the treaty are required to accept the international application prepared in accordance with those criteria, both in form and substance. This eliminates the need for any subsequent amendment due to differences in national or regional conditions and requirements. No national law may require the fulfillment of conditions regarding the international application that conflict with or add to the requirements stipulated by the treaty[8].

Secondly: International Search

Every international application must be subject to an international search according to Article 15, paragraph 1. The international search is characterized by its high accuracy in patent documents and other technical texts available in the languages in which most patent applications are filed[9]. The quality of these international searches is ensured by applying the standards set forth in the treaty regarding the documents used in offices that are experienced patent offices. These offices are specially chosen by the Patent Cooperation Treaty Assembly to carry out international searches, based on an agreement to observe the standards and deadlines stipulated in the treaty. This is the supreme administrative body established under the treaty.

The International Search Authority sends the international search report to the applicant and to the International Bureau. The International Bureau includes the report in the international publication of the international application and sends a copy of it to the designated Offices[10].

The international search allows the applicant, through the citations in the report regarding the prior art, to assess the likelihood of obtaining a patent in the designated countries under the international application. It also helps the applicant decide whether it is worthwhile to continue seeking protection for the invention in those countries in light of the prior art indicated in the documents cited in the search report[11].

Third: The International Publication

The international publication serves two main purposes:

1) Disclosing the invention to the public.

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2) Determining the scope of protection that the inventor may obtain.

The International Bureau publishes a pamphlet that includes the bibliographic data provided by the applicant, along with other data such as the International Patent Classification code determined by the International Search Authority, any necessary diagrams, and the abstract. It also includes the description, the claims, any drawings, and the international search report. If the claims in the international application have been amended, the pamphlet publishes both the claims as originally filed and as amended.

This pamphlet is published in the language of the international application if it is in Spanish, German, English, Russian, Chinese, French, or Japanese. If the application is filed in any other language, it must be translated into one of the aforementioned publication languages. The pamphlet or journal is then distributed free of charge and on a regular basis to all contracting states under the treaty.

Fourth: The International Preliminary Examination

When the applicant receives the International Search Report, they gain the right to request an International Preliminary Examination. The purpose of this examination is to provide a non-binding preliminary opinion on whether the invention for which protection is sought appears to be novel, involves an inventive step, and is industrially applicable[12].

The term *non-binding* means that submitting a request for an international preliminary examination is not automatic. Rather, the applicant must submit a specific request indicating their desire to use the results of the examination

in certain designated countries included in the international application[13].

The offices responsible for conducting the International Preliminary Examination are those designated as International Searching Authorities. At its thirteenth regular session held in Geneva, the Assembly of the Patent Cooperation Treaty (PCT) designated the Spanish Patent and Trademark Office as an authority for the preliminary examination. However, this office has not yet commenced its operations in this regard and therefore cannot be selected by the applicant as an authority for the international preliminary examination[14].

Once the applicant has received the International Search Report and usually also the International Preliminary Examination Report, and has been given the opportunity to amend their application, they are in a strong position to assess their prospects of obtaining patents in the designated countries[15].

1.3. WIPO's Efforts in the Field of Pharmaceutical Patent Protection

WIPO's efforts are focused on its cooperation with regional offices, particularly through collaboration with the Arab Society for Intellectual Property, as well as with the European Patent Office, in the field of intellectual property protection related to pharmaceuticals. WIPO's Cooperation with the Arab Intellectual Property Community and Its Promotion on the International Level.

WIPO (World Intellectual Property Organization) has cooperated with the Arab intellectual property community and worked to enhance its presence on the international level. This cooperation culminated in the establishment of

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the Arab Community for Industrial Property, with Munich, Germany selected as its headquarters, given that Germany is a hub for scientific research in this field.

In 1993, during a meeting held in Jordan, the name of the "Arab Community for Industrial Property" was changed to the new name "Arab Intellectual Property Community." This community has multiple objectives.

WIPO has also cooperated with the European Patent Office (EPO), which acts as the executive body of the European Patent Organization, established under the European Patent Convention. The EPO represents European countries and provides a harmonized approach to protecting inventions. Its model has even influenced many European patent systems.

To support competition and encourage innovation within Europe, WIPO provides technical and professional assistance in various fields to ensure effective intellectual property protection in Europe.

With the aim of significantly developing the international patent system and providing better support for innovation in global economies, an agreement was reached between the EPO and WIPO. This agreement seeks to define and improve the procedural framework of the Patent Cooperation Treaty (PCT) to increase its usage by patent applicants.

Furthermore, the agreement focuses on cooperation to improve the quality and efficiency of the patent granting process, including patent classification and search, and enhancing access to patent information. It also supports innovation programs for companies, universities, public research institutions, and small and medium-sized enterprises.

The organization has not limited itself to traditional concepts of protection but has also kept pace with developments in the technological sphere[16].

2. The Role of the World Trade Organization in Protecting Pharmaceutical Products

The World Trade Organization (WTO) has paid special attention to intellectual property rights in the field of pharmaceuticals, as part of its implementation of the legal protections established in international agreements and treaties related to intellectual property. Among the most important of these agreements is the TRIPS Agreement, which defines the legal framework for trade-related aspects of intellectual property rights. The provisions and laws set out in this agreement serve as the legal foundation upon which the WTO bases its protection of pharmaceutical products. Furthermore, the organization contributes to this protection through its significant role in the resolution of disputes related to pharmaceutical patents.

Based on the above, this chapter will address the protection of pharmaceutical products under the World Trade Organization, by examining the mechanisms for protecting pharmaceuticals under the TRIPS Agreement in Section One, and in Section Two, the efforts of the WTO in protecting pharmaceutical products. This will be discussed as follows:

2.1. Mechanisms for the Protection of Pharmaceutical Products under the TRIPS Agrleement

The World Trade Organization is one of the institutional mechanisms established to implement the GATT Agreement. Among its key objectives is the creation of a

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suitable environment for international trade and investment, as well as the protection of intellectual property in this context. The pharmaceutical industry has become one of the most crucial sectors supporting the global economy. Accordingly, the WTO has sought to protect pharmaceutical products, relying on the provisions set forth in international agreements—most notably, the TRIPS Agreement.

Among the mechanisms for protecting pharmaceutical substances is compulsory licensing, as a means of protection under the TRIPS Agreement, as well as the benefit of intellectual property rights as a protective mechanism for pharmaceuticals according to TRIPS, detailed as follows:

2.1.1. Compulsory Licensing as a Mechanism for Protecting Pharmaceuticals under the TRIPS Agreement

Developing countries have adopted a policy of granting patents for manufacturing processes rather than for the products themselves. This was intended to allow for the production of the same medicines through different manufacturing processes — an option that would be blocked if a patent were granted for the product itself, as this would prohibit all forms of manufacturing that result in the same product, even if those processes are simpler and more cost-effective and not covered by the original patent[17].

It is established that a patent grants its holder an exclusive right, whereby they may prevent others from using or exploiting the invention. To counter the potential abuse of this exclusive right by the patent holder, national laws impose the penalty of compulsory licensing.

Compulsory licensing allows the licensee to exploit the patent without the approval of the patent holder and is

granted by the concerned state in cases defined by its national legislation.

The TRIPS Agreement addresses compulsory licensing in Article 31 under the title "Other Use Without Authorization of the Right Holder." It outlines the situations that justify the granting of compulsory licenses, which include: national emergencies or other circumstances of extreme urgency, remedying anti-competitive practices, non-commercial public use of the invention, and cases where a patent is dependent on another patent. The instances in which compulsory licensing may be granted are exhaustively listed in Article 31 of TRIPS[18].

Since Article 8 of the TRIPS Agreement allows member states of the World Trade Organization (WTO) to take necessary measures to protect public health and serve the public interest in sectors of vital importance to economic, social, and technological development, the legislation in some countries has established a special system for licenses granted with the aim of preserving public health or achieving a public interest.

Although Article 31 of the TRIPS Agreement leaves it to WTO member states to determine the cases in which compulsory licenses may be granted—without being restricted to the specific cases mentioned in Article 31—it nonetheless imposes strict conditions that must be met in order to issue a compulsory license. These conditions hinder the use of compulsory licensing and limit its effectiveness as a remedy.

Among these conditions is what is stated in Article 31, paragraph (f) of the TRIPS Agreement, which requires that the use of the compulsory license in a WTO member state

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must primarily be for supplying the domestic market of that state[20].

Given that developing and least-developed countries often lack the technological capacity to manufacture innovative pharmaceutical products, applying this condition means they will face difficulty in effectively benefiting from the compulsory licensing system provided in the TRIPS Agreement. After all, there is no point in granting a compulsory license to a company or companies that lack the technological capability to manufacture the medicine they are compulsorily licensed to produce.

2.1.2. Intellectual Property Rights as a Mechanism for the Protection of Pharmaceutical Substances under the TRIPS Agreement

A patent grants its holder an exclusive right to exploit the invention in every possible way, enabling them to prevent others from manufacturing the invention, offering it for sale, or importing it. This means The owner of a registered patent in a particular country has the right to prevent others from importing products covered by the protection of the patent into that country where the patent is registered.

The application of this rule means granting the patent holder the right to prevent others from importing patented products from abroad into the country where the patent is registered, even if those products were placed on the market abroad by the patent holder himself or with his consent. This results in hindering the free movement of goods across countries and allows patent holders and other intellectual property rights owners to divide markets and practice price

discrimination among countries by offering identical products at varying prices from one country to another.

To address this situation, the legislation of some countries has limited the right of the patent holder to prevent others from importing patented products by adopting the principle of international exhaustion.

According to the principle of international exhaustion, the patent holder's right to prevent others from importing products covered by the patent ends once those products are placed on the market in any country by the patent holder himself, by one of his affiliates, or with his consent.

There is no doubt that the international exhaustion of intellectual property rights is an effective means of preventing the division of global markets and price discrimination among them. It enables countries where intellectual property rights holders sell pharmaceutical products at high prices to import those products from abroad and make them available in local markets at the lowest prevailing global prices. This type of importation is known as parallel importation.

The TRIPS Agreement adopted a neutral stance on the issue of international exhaustion, which is reflected in Article 6 of the Agreement, which states:

"For the purposes of dispute settlement under this agreement, and in accordance with the provisions of Articles 3 and 4, this agreement shall not be interpreted to include any provisions that could be used to address the issue of exhaustion of intellectual property rights"[21].

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2.2. Efforts of the World Trade Organization (WTO) in the Protection of Pharmaceutical Substances

Member states of the World Trade Organization are committed to ensuring the availability of patent protection in all fields, including the field of pharmaceutical substances. This requirement is stipulated in the TRIPS Agreement, which obligates member states to include in their national legislation provisions that ensure patent protection for pharmaceutical inventions. The WTO has been entrusted with the responsibility of overseeing the implementation of the provisions of this agreement in this regard. The Organization also contributes to this protection through its role in the settlement of disputes related to pharmaceutical substances.

In the context of growing competition and the dominance of developed countries in the pharmaceutical industry—while developing countries have tended to grant patents for manufacturing processes rather than for the pharmaceutical products themselves—the WTO has strived to enforce the TRIPS Agreement's provisions on patent protection across all member states. This aims to secure protection for inventors and to guarantee their rights. Moreover, what has come to be known as "tripartite cooperation" has emerged between the WTO and other international organizations to achieve greater protection in this field. This section will address the WTO's efforts in two parts: first, the Organization's efforts in implementing the TRIPS Agreement, and second, its efforts within the framework of tripartite cooperation.

2.2.1. The WTO's Efforts in Implementing the TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) targets the rights of inventors, and this protection is primarily represented by the requirement that inventors be granted authorization to benefit from their inventions, as well as their right to receive financial compensation for these inventions .

In light of the current relationships between developed and developing countries—relationships that are said to be based on equality and justice, but in reality often involve the exploitation of developing countries by developed ones—it is expected that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) will serve as one of the tools that allow developed countries to increase and deepen their exploitation of developing nations.

The TRIPS Agreement obliges member states of the World Trade Organization (WTO) to include in their national legislation the possibility for all inventions to be granted patent protection, as long as the conditions for obtaining a patent are met—whether the inventions are products or industrial processes, and across all fields of technology. This provision requires all member states to protect all categories of inventions through patents, regardless of the technological field to which the invention belongs.

This provision also obliges those member states whose laws currently exclude pharmaceutical, chemical, or food-related inventions from patent protection—or whose laws only grant patents for industrial processes but not for the related products—to amend their legislation to comply with the provisions of the agreement. This requires them to modify their laws to allow for both product and process

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patents for all pharmaceutical, chemical, and food-related inventions, just like other inventions from different technological fields, as long as the conditions for granting a patent are fulfilled[22].

Furthermore, Article 27.1 of the agreement requires member states not to discriminate between inventions in terms of granting patents or enjoying ownership rights based on the place of invention, the field of technology, or whether the products are imported or locally produced[23].

Accordingly, the agreement obliges member states that discriminate between inventions from different technological fields to amend this practice and ensure equal treatment among all categories of inventions.

the agreement therefore obligated member states that differentiate between inventions belonging to different technological fields to amend this provision in order to ensure equal treatment of different categories of inventions, both in terms of the conditions for granting patents and the enjoyment of ownership rights[24].

2.2.2. The Organization's Efforts within the Framework of Trilateral Cooperation

Since 2001, the principles established in the Doha Declaration have shaped the framework for multilateral cooperation in the field of pharmaceutical protection. They have guided the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO) in providing the technical and political support requested by member states, issuing joint publications, and participating in shared training programs.

In 2007, WIPO's Development Agenda specifically required, under Recommendation 40, that WIPO's Secretariat intensify its cooperation on intellectual property-related issues with relevant international organizations — particularly the WHO and WTO — in order to enhance coordination and achieve the highest possible efficiency in implementing development programs.

Within the WHO, the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, approved by the organization, called for coordination with other relevant intergovernmental organizations — including WIPO, WTO, and UNCTAD — to effectively implement the global strategy and plan of action.

Given that partnership is essential for effectively responding at the international level to the evolving challenges facing public health, the secretariats of WHO, WIPO, and WTO have focused inter-agency cooperation on matters related to public health, intellectual property, and trade. These joint activities are planned and carried out within the mandates and budgets of each organization, through collaborative efforts to ensure the exchange of... (Note: The sentence seems to be cut off at this point in the original Data, experiences, and other information are essential to ensure optimal use of available resources[25].

This collaboration relies on working with international and regional organizations as well as with civil society and the private sector. Accordingly, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO) have expanded their networks of cooperation and investment dealing with public health issues. The three organizations regularly involve speakers from relevant

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international organizations, industry, and civil society in their capacity-building activities.

Since 2010, WHO, WIPO, and WTO have held a series of joint technical symposia. These symposia were designed to improve the flow of practical information to guide and support future technical cooperation. Similarly, the launch of the initial version of this trilateral study marked another milestone in the path toward strengthening collaboration. The study also laid the groundwork for distance learning and enhancing access to medical technologies and innovation in areas where public health, intellectual property, and trade intersect, a process which began in 2016[26].

2.3. The Organization's Role in Dispute Settlement

The economic significance of the pharmaceutical industry has inevitably led to disputes related to intellectual property rights, especially with the TRIPS Agreement emphasizing the granting of patents and the ability of patent holders to assert their rights. In this context, the World Trade Organization must play an active role in dispute resolution. The contribution of consultations and mediation in resolving disputes is discussed in *Subsection One*, while the role of arbitration and special settlement panels is addressed in *Subsection Two*.

2.3.1. The Contribution of Consultations and Mediation in Dispute Settlement

Consultations and mediation are among the flexible methods relied upon by the World Trade Organization

(WTO) for settling disputes related to pharmaceutical products.

First: Consultations

The consultation mechanism represents the first stage in resolving trade disputes between member states of the organization. This is done through dialogue and continuous communication between the parties to reach an agreement that guarantees the interests of all sides. The Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) addresses consultations as a preliminary phase, emphasizing that the requests of the other party must be taken into consideration and that the request for consultation must be submitted in writing by the requesting country[27]. This is outlined in Paragraphs 2 and 4 of Article 4 of the DSU.

The DSU also pays special attention to the time limits for submitting a consultation request. It states that the consultation process between the parties must not exceed 60 days, and in urgent cases, Paragraph 7 of Article 4 stipulates a limit of 20 days, as mentioned in Paragraph 8 of the same article.

Consultations may end either in the resolution of the dispute or in the resort to a panel, which occurs in several cases, including when the consultations fail to yield any result within 60 days from the date of the request submission.

Regarding the special situation of developing countries in the context of consultations, Paragraph 10 of Article 4 of the DSU affirms that special attention must be given to the issues and interests of developing country members.

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Second: Mediation

Mediation refers to attempts made by a third party to find a middle-ground solution that preserves the interests of the disputing parties. The DSU refers to these methods as optional for dispute settlement.

It was not defined in Article 05 of the Memorandum of Understanding on the rules and procedures governing dispute settlement.

Therefore, it can be defined in accordance with what is commonly recognized in international law. It is known that these optional or diplomatic methods of dispute resolution are not binding unless approved by all parties. Otherwise, recourse is made either to the judiciary or to an arbitration body[28].

Negotiation is carried out through a person or entity that mediates to find a solution to the dispute in both good offices and mediation. However, there is a difference between the two: good offices are limited to bringing viewpoints closer without proposing solutions, and the process is confidential. Mediation, on the other hand, involves a mediator who intervenes and offers opinions and solutions, like a lawyer or expert[29].

As for conciliation, it involves presenting the dispute to a committee agreed upon by the disputing parties, which attempts to provide solutions. If the two parties do not agree on the committee's formation, a conciliation committee is formed of five members, where each party appoints two members, and the four members collectively choose a chairperson. If there are more than two disputing parties, those with common interests appoint their members by mutual agreement.

Optional methods are characterized by confidentiality and flexibility, and they are not limited by a specific timeframe. They can be initiated at any stage, provided that the parties begin with the consultation phase, as it is mandatory, as confirmed by paragraph 04 of Article 05 of the Memorandum of Understanding on the rules and procedures governing dispute settlement[30]. It is also mentioned in paragraph 02 of Article 24 that in the case of disputes involving a member from the least developed countries, and in situations where settlement can be reached.

In order to facilitate consultations, the Director-General or the Chairperson of the Dispute Settlement Body may, at the request of a least-developed country Member, offer their good offices, arbitration[31], or mediation to assist the parties in settling the dispute before the formation of a panel. The Director-General or the Chairperson of the Dispute Settlement Body may, when providing such assistance, consult any source they deem appropriate.

2.3.2. The Role of Arbitration and Special Settlement Panels in Dispute Resolution

Arbitration within the framework of the World Trade Organization (WTO), or referring the dispute to settlement panels, is used in disputes related to pharmaceutical matters when previous dispute resolution methods have failed.

First: Arbitration

Arbitration within the WTO may either take the form of expedited arbitration or arbitration conducted by special settlement panels or arbitration panels. Expedited arbitration requires that the disputing parties be WTO

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Members and that all WTO Member countries be notified, especially if any of them has a substantial interest in the dispute. The subject of the dispute must also be clearly defined, in accordance with Article 25 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU)[32].

As for the procedures followed in arbitration, the DSU does not obligate the parties to any specific procedures. This has led to a certain ambiguity surrounding this type of dispute resolution method within the organization. Expedited arbitration could have been an e ffective means of resolving disputes in a semi-amicable manner between WTO Members if the DSU had clarified its procedures and timelines. This lack of clarity has led disputing parties to prefer the regular method of arbitration in most cases[33].

Second: Special Settlement Panels

The establishment of arbitration panels is initiated by a written request from the complaining state to the Dispute Settlement Body (DSB) of the organization, in cases where consultations have failed to resolve the dispute. The request to establish an arbitration panel must be in writing, stating whether prior consultations have taken place or not. It must precisely define the subject of the dispute and include a brief summary of the legal basis of the complaint. In cases where the complaining party requests that the panel be given mandates different from the usual ones, the request must also include the proposed wording of those mandates[34].

The request may be submitted by more than one party, and a third party may also intervene if it meets the conditions outlined in Article 9 of the Understanding on

Rules and Procedures Governing the Settlement of Disputes (DSU). These conditions include the requirement that the intervening party be a member of the organization and have a substantial interest in the complaint. This interest is to be determined by agreement between the parties, and the request for intervention must be notified to the DSB either during the meeting in which the panel is formed or within a maximum of 10 days from the date of that meeting.

The DSU sets a time limit of 15 days from the date the request is submitted to establish the panel, provided that the DSB is notified at least 10 days before the date of submission. It also requires that the DSB decision to form the panel be made before the meeting following the one in which the request was first presented[35].

Panels are usually composed of three members, but the parties to the dispute may request within 10 days from the panel's establishment to increase the number to five members. If no agreement is reached on the composition of the panel within 20 days of the acceptance of the panel request, the Director-General of the organization appoints the members who meet the required qualifications. If the DSB refuses to establish the panel, this must be achieved by negative consensus — also known as the negative consensus rule.

A new method that had not previously appeared except within the framework of the WTO Dispute Settlement Understanding (DSU), which differs from the method followed under the GATT 1947 agreement, where a negative consensus decision is required, including the objection of the complainant — something that is unlikely to occur[36].

The dispute settlement panels examine and study the case presented to the Dispute Settlement Body (DSB) through an

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objective assessment of the facts of the case and their consistency with the covered agreements. The panel's jurisdiction is determined with the consent of the disputing parties[37].

Regarding the dispute resolution procedures carried out by the panels, the panel members, after consulting with the parties to the dispute, shall establish — as soon as possible and preferably within one week after its formation and agreement on its jurisdiction — a timetable for the case proceedings[38].

The panel meets in closed sessions, and deliberations are confidential. The disputing parties may not attend the meetings unless invited by the panel members. The panel meets at least twice so that the disputing parties can submit their written memoranda. If a mutually satisfactory solution is not reached, the panel submits its findings in the form of a written report to the Dispute Settlement Body. If a settlement is reached between the parties, the report is limited to a brief description of the case and an announcement of the settlement. In general, the panel's proceedings — from the date of agreement on its formation and jurisdiction until the issuance of its final report — must not exceed six months, or three months in urgent cases. If the panel is unable to issue its report within this timeframe, it must notify the DSB in writing, stating the reasons for the delay[39].

The Appellate Body considers appeals from panel reports and is composed of seven individuals, three of whom are assigned to each case. These individuals are recognized for their standing and expertise.

The method followed in the 1947 GATT agreement requires the meeting of a negative consensus, including the objection of the complaining party — a situation considered unlikely. Dispute settlement panels examine and study the case presented to the Dispute Settlement Body (DSB) through an objective assessment of the facts of the case and their consistency with the covered agreements. The jurisdiction of the panel is determined by the consent of the disputing parties[40].

As for the procedures of dispute resolution by the panels, the panel members, after consulting the disputing parties, set a timetable for handling the case as quickly as possible — preferably within one week after its formation and the agreement on its jurisdiction[41].

Panel meetings are held in closed sessions, and deliberations are conducted in secrecy. The disputing parties may not attend the meetings unless summoned by the panel members. The panel meets at least twice to allow the disputing parties to submit their written statements. If a mutually satisfactory solution is not reached, the panel submits its findings in a written report to the Dispute Settlement Body. If the matter is settled between the parties, the report is limited to a brief description of the case and an announcement that a solution has been reached.

In general, the period from the agreement on the formation of the panel and its jurisdiction until the final report should not exceed six months, and in urgent cases, three months. If the panel cannot issue its report within those timeframes, it must notify the DSB in writing, stating the reasons for the delay.

The permanent Appellate Body considers appeals from panel reports. It is composed of seven members, three of

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whom are assigned to each case. These members are recognized for their high standing and proven expertise in the fields of international trade, law, and the relevant agreements.

Conclusion:

The pharmaceutical industry is one of the most fertile fields for innovation and, consequently, for supporting national economies by encouraging investment in this sector. Therefore, pharmaceutical substances hold significant importance both domestically and internationally, which necessitates the establishment of a legal framework that ensures legal and institutional protection for pharmaceutical products.

The topic of pharmaceutical patents is among the most crucial issues that have received international attention. The international community has sought to apply the rules and regulations outlined in intellectual property agreements to pharmaceutical substances, most notably the TRIPS Agreement and the Patent Cooperation Treaty (PCT).

This has highlighted the role of international organizations—especially the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO)—in implementing legal protection rules for pharmaceuticals globally, particularly in developing countries.

Based on the above, we have reached the following conclusions:

- Pharmaceutical substances are of great importance as they significantly contribute to supporting national economies. Therefore, it is necessary to provide the required legal and institutional protection, with drug patents forming the legal foundation for this protection.
- Based on the legal framework for pharmaceutical patents, international organizations can intervene to contribute to this protection by overseeing the implementation of international agreements, whether directly or indirectly.
- Among the most prominent organizations concerned with the protection of pharmaceutical substances are the WTO and WIPO, which have played a major role in establishing protection standards—either through their own efforts or through tripartite cooperation with the World Health Organization (WHO).
- Granting pharmaceutical patents often leads to legal disputes, and in such cases, the WTO plays a role in settling these disputes through available means such as mediation, arbitration, and consultations.
- The legal foundation for this protection is found in international agreements and treaties, most notably the TRIPS Agreement and the Patent Cooperation Treaty.

Recommendations:

- It is essential to pay greater attention to the pharmaceutical manufacturing sector by developing its legal framework, particularly concerning patents in the domestic legislation of developing countries.

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- Emphasis should be placed on scientific research in this field in Algeria and on leveraging its membership in international organizations that offer protection for pharmaceutical substances through material and strategic support.
- The patent law should be aligned with the provisions of the TRIPS Agreement to increase the likelihood of benefiting from the advantages offered by the WTO, which oversees the agreement.
- WIPO and the WTO must provide technical and legal support to developing countries to help modernize their national legislation in line with global intellectual property standards, without compromising public health.
- Efforts should be made to promote alternative models of pharmaceutical innovation by supporting research on innovative financing mechanisms such as open pharmaceutical models, incentive prizes, and the sharing of knowledge and open data. REFERENCES LIST.

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Footnoot :

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