Received: 25.06.2025. Accepted: 28.06.2025. Available online: 30.06.2025.

МРНТИ 10.87.27
DOI: https://www.doi.org/10.32523/2791-0954-2025-14-2-8-20

The importance of the TRIPS Agreement in regulating access to medicines and pharmaceuticals within the WTO

Azkhodjaeva Roza
DSc, lecture at Tashkent State
University of Law,
Tashkent, Uzbekistan
e-mail: azdroza7@gmail.com
ORCID: 0009-0007-9600-6536

Abstract: Global health issues and its connection with the development of the modern economy are one of the most important problems of our time, which worries every state and the entire world community. Good health for all people is a goal pursued by many international organizations, including both the World Health Organization (WHO) and the World Trade Organization (WTO). This article examines the issues of access to medicines within the framework of the World Trade Organization (WTO), analyzes such important documents as the TRIPS Agreement, the Doha Declaration, the WHO Strategy for Medicines, approved by the 54th session of the World Health Assembly (WHO resolution 54.11), provides factors that ensure wide access to medicines and vaccines. The article presents different points of view on the importance of patents for pharmaceutical discoveries, and examines in detail the tools of the intellectual property system, including parallel import and compulsory licensing, which can be crucial in supporting differentiated pricing and market segmentation. In the final part of the article, conclusions and suggestions are formulated on the issue of access to medicines and vaccines.

Keywords: health protection, public health, World Trade Organization, TRIPS, compulsory licensing, parallel import, Doha Declaration.

ДСҰ шеңберінде дәрі-дәрмектер мен фармацевтикалық препараттарға қол жеткізу мәселелерін реттеудегі ТРИПС келісімінің маңызы

Азходжаева Роза Алтыновна
Заң ғылымдарының докторы,
Халықаралық құқық және адам құқықтары кафедрасының доценті
Ташкент мемлекеттік заң университеті
Ташкент, Өзбекстан
e-mail: azdroza7@gmail.com
ORCID: 0009-0007-9600-6536

Аңдатпа: Денсаулық сақтаудың жалпы әлемдік мәселелері және оның қазіргі экономиканың дамуымен байланысы әрбір мемлекет пен бүкіл әлемдік қауымдастықты алаңдататын қазіргі заманның маңызды проблемаларының бірі болып табылады. Барлық адамдар үшін жақсы денсаулық - бұл Дүниежүзілік денсаулық сақтау ұйымы (ДДСҰ) және Дүниежүзілік сауда ұйымы (ДСҰ) секілді көптеген халықаралық ұйымдардың қызметі бағытталған мақсат. Бұл мақалада Дүниежүзілік сауда ұйымы (ДСҰ) шеңберіндегі дәрілік препараттарға қол жеткізу мәселелері қарастырылады, ТРИПС келісімі, Доха декларациясы, Дүниежүзілік денсаулық сақтау ассамблеясының 54-сессиясында мақұлданған дәрілік заттар саласындағы ДДҰ Стратегиясы (ДДҰ 54.11 қарары) сияқты маңызды құжаттар талданады, дәрілік препараттар мен вакциналарға кең қолжетімділікті қамтамасыз ететін факторлар келтіріледі. Мақала аясында фармацевтикалық жаңалықтарға патенттердің маңыздылығына қатысты әртүрлі көзқарастар келтіріледі, зияткерлік меншік жүйесінің құралдары, соның ішінде параллель импорт және мәжбүрлі лицензиялау егжей-тегжейлі қарастырылады, бұл сараланған баға белгілеу мен нарықты сегментациялауды қолдауда маңызды болуы мүмкін. Мақаланың қорытынды бөлімінде дәрілік препараттар мен вакциналарға қол жеткізу мәселесі бойынша қорытындылар мен ұсыныстар тұжырымдалған.

Түйін сөздер*:* Денсаулықты сақтау, денсаулық сақтау, Дүниежүзілік сауда ұйымы, ТРИПС, мәжбүрлі лицензиялау, параллель импорт, Доха декларациясы.

Значение Соглашения ТРИПС в регулировании вопросов доступа к лекарствам и фармацевтическим препаратам в рамках ВТО

Азходжаева Роза Алтыновна
Доктор юридических наук,
И.о. доцента кафедры международного права и прав человека
Ташкентского государственного юридического университета
Ташкент, Узбекистан
e-mail: azdroza7@gmail.com
ORCID: 0009-0007-9600-6536

Аннотация: Общемировые проблемы охраны здоровья и его связь с развитием современной экономики является одним из самых важных проблем современности, которая беспокоит каждое государство и все мировое сообщество. Хорошее здоровье для всех людей - это цель, на которую ориентируются многие международные организации, в число которых входит как Всемирная организация здравоохранения (ВОЗ), так и Всемирная торговая организация (ВТО). В данной статье рассматриваются вопросы доступа к лекарственным препаратам в рамках Всемирной торговой организации (ВТО), анализируются такие важные документы как Соглашение ТРИПС, Дохинская

Декларация, Стратегия ВОЗ в сфере лекарственных средств, одобренная 54-й сессией Всемирной ассамблеи здравоохранения (резолюция ВОЗ 54.11), приводятся факторы, обеспечивающих широкий доступ к лекарственным препаратам и вакцинам. В рамках статьи приводятся разные точки зрения касательно важности патентов на фармацевтические открытия, детально рассмотрены инструменты системы интеллектуальной собственности, в том числе параллельный импорт и принудительное лицензирование, которые могут иметь важнейшее значение в поддержке дифференцированного ценообразования и сегментации рынка. В заключительной части статьи сформулированы выводы и предложения по вопросу доступа к лекарственным препаратам и вакцинам.

Ключевые слова: охрана здоровья, здравоохранение, Всемирная торговая организация, ТРИПС, принудительное лицензирование, параллельный импорт, Доха Декларация.

Introduction

According to estimates by the World Health Organization (WHO), antimicrobial-resistant microorganisms cause the deaths of 5 million people worldwide each year. “Every day, 1.6 million people fall ill due to the consumption of unsafe food. 340 children under the age of five die daily from preventable foodborne diseases” [15]. Moreover, approximately 2 billion people lack access to essential medicines, and 80% of the global population lives in countries with either no or severely limited access to controlled substances for pain relief [16].

According to WHO estimates, in 2021, there were 247 million cases of malaria reported globally across 84 countries, which is 2 million more than in 2020. In 2022, the number of tuberculosis cases worldwide reached 10.6 million, including 5.8 million men, 3.5 million women, and 1.3 million children[17]. All of this constitutes a public health crisis of unprecedented scale, having a significant impact not only on human health but also on the economy and society as a whole. Therefore, at the present stage, ensuring the right to health protection and maintaining economic stability is among the most pressing challenges.

The global community’s concern regarding the impact of globalization and international trade agreements on access to medicines was first formally expressed at the World Health Assembly in 1996. The Assembly’s resolution entitled "Revised Drug Strategy" included a request for the World Health Organization (WHO) to prepare a report on the effects of the World Trade Organization (WTO)’s activities on national drug policies in Member States and to propose appropriate recommendations for cooperation between the WHO and the WTO.

Pursuant to this resolution, the WHO issued recommendations aimed at encouraging Member States to implement WTO standards in the field of intellectual property protection in a manner that mitigates the negative impact of manufacturers’ patent protection on the cost of medicines. Subsequent resolutions of the World Health Assembly reaffirmed the WHO’s commitment to intensify its efforts to promote

policies that support access to generic medicines and to examine the effects of intellectual property protection agreements on access to essential medicines [18].

The WHO Medicines Strategy, approved by the 54th session of the World Health Assembly (WHO Resolution 54.11), outlines the core actions of the Organization in the field of pharmaceuticals. The Strategy aims to save lives and improve public health by addressing the vast gap between the potential of essential medicines and the reality in which medicines remain unavailable, unsafe, of poor quality, or misused by millions of people.

The aim of this study is to analyze international legal norms and to develop proposals and recommendations for improving access to medicines and pharmaceutical products within the framework of the WTO.

Research objectives:

- To examine the relationship between WTO agreements and the protection of the right to health;
- To analyze the challenges related to access to medicines and pharmaceutical products within the WTO framework;
- To develop proposals for improving international legal norms concerning the protection of the right to health.

Research methods. This study employs comparative legal, historical, logical, analytical, comprehensive, and systemic methods of scientific analysis. The article explores the historical development of the Uruguay Round, presents the views of both critics and proponents of the TRIPS Agreement, and provides a logical analysis of the TRIPS Agreement and the Doha Declaration, both of which play a crucial role in the issue of access to medicines.

The application of these scientific methods enables a thorough examination of the subject matter of the article.

Results and Discussion

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), adopted as part of the Final Act of the Uruguay Round in 1994, provides universal international legal protection for the interests of pharmaceutical manufacturers within the WTO framework.

At the Fourth WTO Ministerial Conference (Doha, Qatar) in 2001, the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration on TRIPS") was adopted. It is worth noting that the TRIPS Declaration reflected many of the concerns expressed by developing countries, recognizing the "serious public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" [19].

The Doha Declaration represents an important milestone in the debates surrounding TRIPS and contributes to the interpretation of its provisions in light of public health interests. The Declaration makes it clear that intellectual property rights (IPRs) are subordinate to the objectives of public health protection.

Undoubtedly, the high-tech pharmaceutical industry derives the greatest benefit from the implementation of the TRIPS Agreement. This sector is characterized by high initial research and development costs and the relative ease with which the final product can be replicated. Articles 27 to 34 of the TRIPS Agreement deal with patents and are directly relevant to issues of public health and human development [20].

Patent protection has provided a significant impetus for the development of the pharmaceutical industry in developed countries by creating the necessary incentives for continued research.

It is important to note that access to medicines and vaccines directly depends on four key elements:

• affordable pricing;
• rational selection and use of essential medicines;
• adequate and sustainable financing;
• reliable healthcare and supply systems.

In practice, discussions on health and trade issues tend to focus primarily on the pricing of pharmaceutical products. A number of measures aim to make medicine prices more affordable, including:

• price regulation to cap manufacturers' selling prices;
• discounts through bulk procurement of medicines;
• reduction of import duties and local sales taxes;
• allocation of medicine costs between active ingredients and finished doses;
• utilization of TRIPS safeguards such as parallel importation and compulsory licensing for patented medicines, as well as the application of exceptions to exclusive rights that allow for early testing and official approval.

One of the most important factors in ensuring broad access to medicines and vaccines is the assessment of the impact of patent protection. It is essential to strike a balance between protecting patent rights to promote the invention, development, and marketing of new drugs-which serves as an incentive for further scientific research—and the potential restrictive effect of patent protection on access to existing medicines and vaccines. Under the provisions of the TRIPS Agreement, WTO Member States are required to provide patent protection for the production of a given product, including pharmaceuticals and vaccines, for a minimum of 20 years from the date of registration. This imposes an obligation on Member States to grant patents in the field of public health.

Professor F. M. Scherer argues that the importance of patents for pharmaceutical inventions is confirmed by the following factors:

– Patents provide effective protection for new pharmaceutical products. This is due to the fact that patent protection can be more precisely defined at the molecular level, making it easier to prove infringement;

– The financial costs of developing and producing new drugs are steadily increasing, and the legal protection offered by patents safeguards commercial interests;

– In the absence of protection, other countries may use the research results obtained by pharmaceutical companies regarding the therapeutic value, safety, and efficacy of a new drug with minimal financial investment.

Nevertheless, Langeau noted that the extension of patent protection resulting from the TRIPS Agreements may contribute to a price increase of up to 25% for high-demand goods, relative to global spending on patented medicines [21]. Another factor that distinguishes the pharmaceutical industry from many others is the lengthy period required to invent and develop pharmaceutical products, contrasted with the relatively short timeframe for obtaining returns on them. A reliable and effective patent protection regime can serve as an incentive (as noted by the World Bank) [22] for pharmaceutical companies to develop new medicines for the treatment of diseases such as malaria, tuberculosis, and AIDS (HIV). However, at the same time, there is a growing need to explore methods for ensuring broader public access to medicines.

In 2003, Jean-Pierre Garnier strongly urged drug inventors to use their discoveries to help those most in need [23]. He called on pharmaceutical and biotechnology companies to provide low-cost medicines to developing countries.

From the perspective of WTO experts, the TRIPS Agreement grants countries a significant degree of flexibility in determining how to apply their own patent laws, provided that they meet the minimum standards, including the criteria for patentability set out in the TRIPS Agreement.

Thus, the pricing of medicines depends on a wide range of factors: supply and demand, prescribing systems and methods of use, production costs, competitive market conditions, taxes, exchange rates, royalty payments to patent holders from the sale of patented medicines, wholesale and retail distribution processes, the degree of price flexibility for different drugs, and so forth.

The TRIPS Declaration affirms the right of countries, in accordance with the TRIPS Agreement, to fully utilize the flexibilities provided therein to protect public health and promote universal access to medicines. Intellectual property tools—such as parallel importation and compulsory licensing—can play a critical role in supporting differential pricing and market segmentation.

It should be emphasized that “the effect of the TRIPS provisions relating to the exhaustion of intellectual property rights—namely Article 6—is to allow each Member State the freedom to establish its own regime for such exhaustion, without violating the national treatment and most-favoured-nation obligations under Articles 3 and 4” [24].

Parallel importation contributes to reducing the prices of pharmaceutical products when there is a significant price differential between countries [25].

The mechanism of parallel importation involves purchasing medicines in countries where prices are more affordable and importing them into a country where access to such medicines is limited due to high costs. The TRIPS Agreement explicitly recognizes the right of countries to allow parallel importation based on the principle of international exhaustion of intellectual property rights.

As for parallel trade between developed and developing countries more broadly, there is little doubt that restrictions on parallel importation found in the legislation of

most developed countries provide certain advantages. These restrictions help maintain price differences through market segmentation, which can offer potential benefits to developing countries and contribute to keeping prices lower in those countries [25].

Article 31 of the TRIPS Agreement permits the granting of authorization for the use of a patent without the consent of the patent holder. Compulsory licenses may be issued in specific cases, based on the merits of individual applicants. Such licensing should be considered only after all reasonable efforts to obtain a voluntary license have failed, except in situations of national emergency or other circumstances of extreme urgency. Licenses must be granted primarily for domestic use, for a limited duration, and on a non-exclusive basis. TRIPS allows for the use of compulsory licensing in cases of national emergencies, anti-competitive practices, governmental non-commercial use, and in situations involving dependent patents [26].

Compulsory licensing is one of the mechanisms through which the TRIPS Agreement seeks to strike a balance between access to essential medicines and the promotion of scientific research for the development of new drugs. However, in practice, developing countries face significant challenges in implementing Article 31 of the TRIPS Agreement. Although Article 31 grants countries the right to issue compulsory licenses to protect public health, developing nations often struggle to effectively use this mechanism due to economic and technical barriers. The realization of this right requires not only appropriate national legislation but also adequate technical infrastructure.

Thus, compulsory licensing is a mechanism through which a government or a third party may obtain authorization to use a patented pharmaceutical product without the consent of the patent holder, while ensuring that the patent holder receives appropriate compensation. Compulsory licensing has proven to be effective in reducing medicine prices by encouraging competition from generic alternatives [27].

Undoubtedly, the threat of issuing a compulsory license can serve as a tool to "strengthen a country's bargaining position" [28]; however, it is by no means a panacea capable of ensuring adequate access to patented medicines in developing countries. In practice, compulsory licenses are rarely used, and under the TRIPS Agreement, "the circumstances under which compulsory licensing may be considered are even more restricted" [29].

Other alternative approaches to addressing this issue—such as charity—may, according to some researchers and experts, serve as a last resort "in cases of death or utter helplessness" [30]. In this regard, it may be particularly useful for certain countries (or patent holders) to consider the possibility of issuing a "voluntary or negotiated" license under appropriate circumstances, as part of responsible corporate and social conduct [31].

Conclusion

In summary, it is important to emphasize that the TRIPS Agreement is one of the most controversial agreements of the Uruguay Round in terms of its objectives and consequences. A number of researchers and experts who support the TRIPS

Agreement—such as Professor F. M. Scherer, John H. Barton, and others—argue that patent protection for pharmaceutical products should lead to the following outcomes:

• an increase in technology transfer and foreign direct investment (FDI) in favor of developing countries, which would enhance the global dissemination of know-how;

• a rise in the resources allocated to research and development (R&D) by local pharmaceutical companies in developing countries, resulting in the development of new medicines more closely tailored to their needs (patents are viewed as a driver of innovation, encouraging inventors to commercialize their inventions);

• improved public welfare due to the availability of a wider range of higher-quality medicines;

• a reduction in the "brain drain" from developing countries to industrialized nations, as a result of stronger protection for inventions in countries of origin [32].

Their opponents—who view the TRIPS Agreement with considerably less optimism and, in some cases, openly oppose it (such as Carlos Correa, Thomas F. Murphy, and others)—argue the following:

• the prices of patented medicines and the corresponding royalty payments will continue to rise as the monopoly rights of patent holders are strengthened and extended;

• a situation may arise in which production is concentrated in industrialized countries, as multinational corporations may prefer to export finished products or semi-finished goods rather than transfer technology or make direct foreign investments in developing countries;

• the introduction and expansion of patent protection for pharmaceutical products will not, in practice, lead to increased R&D investment by firms in developing countries, which lack the necessary technical infrastructure as well as financial and human resources. Likewise, the non-patentability of pharmaceutical products prior to the entry into force of the TRIPS Agreement allowed developing countries to advance by acquiring core technologies through reverse engineering, even before they had the capacity to invest in R&D;

• the replacement or adaptation of existing infrastructure—originally designed to produce generic versions of patented products—will entail significant costs;

• the implementation of TRIPS provisions will result in substantial administrative expenses.

The WTO Doha Declaration helped shape the health policy context within the intellectual property system. It emphasized that the TRIPS Agreement should be part of broader national and international efforts to address public health challenges affecting developing and least-developed countries. The Declaration identified specific options available to governments to meet public health needs—commonly referred to as "flexibilities." The importance of such flexibilities was later reaffirmed through their inclusion in the Sustainable Development Goals (SDGs).

In this regard, it is worth considering the advantages and disadvantages of compulsory licensing. Undoubtedly, in the case of epidemic outbreaks—such as during the COVID-19 pandemic—coordinated action by states is essential to combat diseases in emergency situations. One such measure is the issuance of compulsory licenses

aimed at protecting public health and reducing or eliminating outbreaks. However, on the other hand, it is also necessary to assess the risks associated with the use of compulsory licensing. One such risk is the potential for excessive or unjustified use by governments without sufficient legal or factual grounds.

It is also important to emphasize the issue of the quality of medicines produced by local manufacturers under compulsory licensing. In practice, local producers are often not provided with access to the key active ingredient of the drug, which can result in the production of low-quality medicines. This, in turn, raises concerns about public health and safety. In Thailand, for instance, a generic HIV medication led to the development of drug resistance, forcing patients to purchase more expensive first-generation treatments.

Another significant factor is the issue of compensation to patent holders. In many cases, the compensation paid is minimal, which discourages patent holders and manufacturers from supporting or participating in compulsory licensing schemes.

According to experts in the pharmaceutical sector, compulsory licensing also has an impact on a country's investment climate.

Having examined the issue of access to medicines under the TRIPS framework, it can be concluded that the primary significance of the Doha Declaration lies, first, in its affirmation that fundamental human rights-particularly the right to health-take precedence over the commercial interests of states; and second, in its recognition of the importance of public health in the context of international trade cooperation. The endorsement of the Doha Declaration by the international community represents "…a very significant expression of governments' commitment to ensuring the compatibility of a rules-based trading system with public health interests" [33].

At present, it is difficult to fully assess the impact of TRIPS implementation on developing countries. It is essential to strive for the creation of optimal mechanisms and to make full use of the flexibilities provided by the Agreement in order to ensure access to medicines and promote fair competition.

It appears that each country's strategy toward globalization in the production and distribution of medicines should be an integral part of its national pharmaceutical policy, which, in turn, must be regarded as a core component of its national health policy. WTO Member States are advised to incorporate into their domestic legislation the right to apply compulsory licensing, in accordance with the TRIPS Agreement, in cases where such a right can serve as a tool to promote, in particular, research directly related to the specific public health challenges faced by developing countries.

Developed countries and the WTO must take measures to ensure the enforcement of TRIPS provisions in practice, including the transfer of pharmaceutical manufacturing technologies, in accordance with paragraph 7 of the TRIPS Declaration. [34] It would also be beneficial for countries to adopt national legal measures that encourage the introduction of quality generic products to the domestic market after patent expiry—for example, by supporting competition among generics as an effective means to enhance public access to medicines and pharmaceutical products.

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