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Terms, Conditions and Challenges for the Protection of Pharmaceutical Patents in Legal Systems in the Event of Accession to the World Trade Organization

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Abstract

Today, various diseases such as AIDS, malaria and others are on the rise in human societies, despite the relative expansion of public health around the world. Therefore, the pharmaceutical industry is among the most important industries that need to be supported so that inventors of new drugs are motivated enough to produce more effective drugs. On the other hand, the undeniable benefits of protecting pharmaceutical patents for developed and least developed countries are considered as a serious threat that may endanger the public health of these societies. Under such circumstances, it must be determined which of the two principles (public health as a basic right of every human or protection of pharmaceutical patents as exclusive rights of its owners) should be preferred and prioritized? One of the most important issues that is directly and indirectly focused in the World Trade Organization is the public health, especially the drug trade and the protection of pharmaceutical patents. The organization has consistently protected the exclusive rights of pharmaceutical patentees to maintain a balance between public health and freedom of access to medicines. Each of the legal systems that seek to access to the WTO may face problems because of these two issues. This study was conducted aimed at examining the conditions and challenges for the protection of pharmaceutical patents in legal systems in the event of accession to the WTO.

Keywords*: protection of pharmaceutical patents, WTO, TRIPS Agreement, Doha Declaration on public health.*

I. Introduction

The advances in modern societies are caused by the science and knowledge that contribute to the growth and development of societies and the enhancement of welfare in various dimensions. One of these sciences is the medical

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sciences, which strives to help increase the health of communities and thus increase the welfare through the invention of various drugs. One of the factors affecting the progress of science is the need to protect pharmaceutical patents in different legal systems. Despite the need for protection, the format and extent of patent protection has always varied in different societies. For some societies, the inventor should be granted the exclusive rights of the commercial exploitation of an invention and so efforts must be made to provide both individual and community benefits. However, others argue that this approach cannot serve the interests of the whole of society, especially developing countries. This objection is especially significant in the field of pharmaceutical patents associated with human life, and the mere protection for these patents creates severe pharmaceutical needs in developing countries.

This study was conducted aimed at examining the conditions and challenges for the protection of pharmaceutical patents in legal systems in the event of accession to the WTO. In addition, the purpose of this study was to investigate the extent to which the TRIPS Agreement has determined the task of the legal systems member of the WTO on the protection of pharmaceutical patents, and the extent to which it has it been able to provide a solution to public health in the event of challenges and obstacles arising from the exclusive rights the patentee. It is assumed that the WTO has stated some minimal terms regarding the patent protection in the TRIPS Agreement and has given the countries freedom of action, and that the TRIPS Agreement, and in particular the Doha Declaration, has been able to find solutions to these challenges.

1. Generalities

The World Trade Organization (WTO) is a relatively newly established international organization that has replaced the General Agreement on Tariffs and Trade (GATT). The WTO was established as a result of governments' efforts after seven and a half years of negotiations in the Uruguay Round in 1994. The difference between the two organizations is that GATT is a world trade organization for goods, but the WTO is also a world trade organization for goods, services and intellectual property. The countries wishing to join the organization must negotiate with current members and align their trade policies with the organization's agreements (WTO agreements and public health, 2002, p. 48).

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is one of the annexes to the WTO that has entered into force on 1 January 1995 and WTO member states are required to comply with (Wipo intellectual property handbook, p 345). The Agreement is considered to be one of the most comprehensive rules on intellectual property rights that have ever existed internationally, encompassing various types of intellectual property rights, and providing relatively complete substantive protections for the protection of them (Molla Ebrahimi; Arfania, 1396, p. 4). By endorsing the substantive provisions of the Paris and Bern Conventions, which are the most important international provisions for the protection of industrial property, the TRIPS Agreement not only has not disrupted the process of international protection of intellectual property but also emphasized the scope of international protections contained in these regulations and added to their quantitative and qualitative scope by explicitly referring to them and requiring WTO member countries to comply with a significant portion of the regulations (Mirshamsi, 2015, p. 70).

The TRIPS Agreement seeks to establish a balance between the rights of the patentees and the interests of consumers and imposes restrictions on the interests of inventors on the basis of social and economic welfare.

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Availability of medicines is one of the social benefits that has established this balance in the TRIPS Agreement (Habiba, 2004, p. 45). Accordingly, one of the most important consequences of the TRIPS accreditation for the drug field is the need to respect the patent and grant the exclusive rights to the drug inventors. However, more than 50 member states of the Paris Convention did not protect the pharmaceutical products, and advanced countries were concerned about the lack of support for inventors in the field due to their economic development until the adoption of the TRIPS Agreement and at least until 1986 (Monfared, 2015, p. 155).

The impact of the TRIPS Agreement on protecting the rights of inventors of new drugs became apparent with poor countries' access to low-cost medicines linked to their public health a few years after the agreement coming into force, and this became a critical issue in the late 1990s.[1] So the WTO member states adopted a special declaration during the WTO Ministerial Conference in Doha called the Doha Declaration in 2001 (Parvin, 2009, p. 18). In the Doha Declaration, the following key issues are reviewed: the worsening public health problems in developing countries, the need to solve these problems in the TRIPS Agreement, and the emphasis on interpreting the agreement in such a way as to give everyone the right to access medicines. In this Declaration, different aspects of the TRIPS Agreement, including the right to grant compulsory license, the grounds needed for exercising this right, the determination of the status and emergency of the subject, etc. are discussed with the accepted principle of public health data and required solutions are specified (S. K. Verma, p. 78). Therefore, the coherence and solidarity of developing countries in cheap access to drugs made the Doha Declaration effective (Banta D, 2001, p. 2659). However, there are various opinions on this statement. Some consider this statement to be nothing more than a repetition of what was stated in the TRIPS Agreement. On the other hand, for some, it is an important but incomplete victory in the struggle for the access to medicine and advocates for public health (Gillespie L, 2016).

2. Terms and Conditions for the Protection of Pharmaceutical Patents

2.1 patent terms of protection

When a drug company first manufactures new drugs for patient use, this drug is placed under the aegis of the patent system and sold under its own brand. Upon patenting the drug, only the manufacturing pharmaceutical company is authorized to manufacture, market, sell, and ultimately benefit from the drug. In most countries, including the United States, pharmaceutical patents have a twenty-year term of protection, but this varies across countries. After the end of the patent term of protection, the drug can be bought and sold by other companies, and at this stage, the drugs enter the generic phase.[2] Article 33 of the TRIPS Agreement has provided a twenty-year term of protection for patents.[3]

However, this twenty-year term is the minimum term of exclusive rights, and it is possible for states to envisage a longer term in their domestic law. It seems that the provisions of the TRIPS Agreement regarding the twenty-year patent protection term for new drugs pose restrictions on access to essential drugs. It is therefore evident that there will be conflicts between the international human rights law on health and the provisions of the TRIPS Agreement on the protection of intellectual property of new pharmaceutical innovations. So efforts should be made to

[1]. https://roshanayee.persianblog.ir/vZgOWw5LbpsEjowDZX5y
[2]. https://www.news-medical.net, health/drug/ patents
[3]. The protection term will not end until the expiration of twenty years from the date of filing.

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establish a balance between these conflicting interests (Niavarani, 2016, p. 38). In this context, a legal relationship must first be established between the obligations derived from the international human rights system and the obligations arising from the TRIPS Agreement, both practically and theoretically, to solve the problem. In the following, this issue will be examined.

2.2 The need for novelty, inventiveness and industrial application of the invention

In accordance with Article 27[1] of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), a patent may be available for any innovation, whether product or process, in all fields of technology, provided that it is novel, innovative (non-trivial) and of industrial application. Patent is the strongest form of intellectual property protection. The statutory power of this right comes after it has been patented with the patent office. As long as the invention is in the creative mind of the inventor, it is not subject to protection and it is only after being patented at the patent office with the disclosure of the details of the relevant invention that it will be subject to protection and grant the inventor a legal exclusive right for a specified period (Gardiner S, 2001, p.454).

3. Terms of protection of pharmaceutical patents

The TRIPS Agreement aims to establish an international system to protect the exclusive rights of inventors. The agreement provides more effective supportive standards for intellectual property rights for the owners of inventions than the past and fills the gaps in the international system of intellectual property protection. Despite the positive effects of the TRIPS Agreement, it has brought negative consequences for developing countries, because these countries do not have the ability to compete technologically with the developed countries, making their economies more dependent. The exercise of patents on essential products such as medicines, which subsequently lead to higher prices, endangers the lives of millions of people. Consequently, in Articles 30 and 31 of the TRIPS Agreement, there are exceptions to the patentee's exclusive rights that creates a balance between the exclusive rights of the inventor and public health (Pilvar; Hosseini Baluchi, 2018, p. 204). According to Article 30 of the TRIPS Agreement: Members may make limited exceptions on the exclusive rights due to the patent provided that such exceptions do not have an unreasonable contradiction with the conventional use of the patented invention and do not bring unreasonable harm to the legitimate interests of the patentee, taking into account the legitimate interests of the third parties.

Article 31 of the Trips Agreement stipulates: In cases where the law of a member state authorizes other uses, including the use of the subject of invention by the state or third parties authorized by the state without the permission of the patentee, the following rules will be respected:

A. Permission for such use will be reviewed on the basis of the merits of each case.

B. This use is only permitted if the intended user has attempted to obtain permission from the patentee in accordance with reasonable commercial terms and conditions prior to the use, and such efforts

[1]. The patent is available for any innovation, whether product or process, in all fields of technology, provided that it is novel, innovative and of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, registration and enjoyment of a patent shall be available without discrimination, in terms of the place of invention, the field of technology and whether the products are imported or manufactured domestically.

have failed within a reasonable time. A Member may waive this requirement in the event of a national emergency or other emergency, or for non-commercial public use. However, in situations of national emergency or other highly urgent circumstances, the patentee shall be informed of this as soon as possible.

C. The scope and duration of such use will be limited to the permission purpose, and in the case of semiconductor technology, it shall be limited to non-commercial general use or to compensation for an action that has been detected as anticompetitive after judicial or administrative proceedings.

D. Such use shall be non-exclusive.

E. Such use is non-transferable unless it is associated with the section of the firm or business reputation that benefits from this use.

F. Such use will often be permitted in cases where it is intended to provide the internal market for the member that permits it.

G. The permission for such use shall be revoked, with sufficient protection of the legitimate interests of the persons who have obtained it, in the event that the circumstances leading to such use disappear and they are unlikely to be restored. Upon requesting this case, the competent authority shall have the power to verify the continued existence of the circumstances.

H. Sufficient payment will be made to the patentee depending on the circumstances of each case, taking into account the economic value of the permission.

Following the interpretation of the Article 31 of the TRIPS Agreement, it can be concluded that the use of the patentee's exclusive right should be appropriate, restricted, nontransferable, as occasion may arise, in order to secure the domestic market, legitimate and non-gratuitous.

In the following, the most important exceptions to the patentee's exclusive rights will be examined.

3.1 Compulsory License for exploitation

One of the solutions incorporated in most intellectual property laws in cases where the right holder does not exercise his or her rights with no justified reason or non-licensing to third parties on fair terms is to grant a compulsory license for exploitation by the government to use the invention by granting a fair remuneration to the exclusive right holder. In the Doha Declaration, the right to compulsory licensing has been emphasized by WTO member states, and these licenses have been established on several occasions in almost the laws of all countries[1] (Sheikhi, 2016, p. 76).

The compulsory license for exploitation is a license under which the state or other persons are permitted to use a subject matter of an intellectual property right without the permission of the right holder and in exchange for the payment of a fair remuneration. It is issued by a competent government authority for public policy purposes upon eligibility (Sadeghi; Khakpour, 2007, p. 133). So the license for exploitation is part of a public order that strives to establish a balance between the exclusive rights of the patentees on the one hand and the rights of the consumers on the other (Correa, 1999. P3).

[1]. It is acknowledged that WTO members with inadequate capacity or those without capacity in the pharmaceutical sector may face difficulties in using compulsory license effectively under the TRIPS Agreement. The TRIPS Board is ordered to find a solution to this problem and report it to the General Board before the end of 2002.

Compulsory license is also a means for limiting the scope of intellectual property rights and for protecting the public interest and abuse of rights from their origins. The issue of public health is among of the most important examples that is issued to secure social benefits and government benefits. (WIPO intellectual property handbook, 2004, p37).

3.2 Parallel importation[1]

Parallel importation is considered in the framework of doctrine of the rights vindicated in the intellectual property. This was one of the most difficult issues discussed in Uruguay Round that resulted in a compromise between the negotiating parties within the framework of which the Article 6 of the TRIPS Agreement was accepted (Otten Adrian, 1996, p. 24).

Article 6 of the TRIPS Agreement states: With regard to the settlement of disputes under this Agreement, subject to Articles 3 and 4, the Agreement shall give due consideration to the issue of the vindication of intellectual property rights.

So in Article 6 of the TRIPS Agreement, a special attention is given to developing and less developed countries and they are allowed to authorize parallel importation under their own laws. For these countries, especially when drugs are expensive, parallel importation is a useful solution for easier access to medicines and providing public health (Sheikhi, 2016). Goods of this type of importation are those produced by the patentee in one country and imported into another without his / her permission. For example, a country patents a drug and this patent is protected in countries A and B, but the drug is sold cheaper in country B than in country A. This is called parallel importation if a company buys a cheaper drug in country B and exports it to a country at a lower price than the sales price of the country A. When drug prices are high, parallel importation is a very important solution for cheap access to drugs, especially when domestic drug production is not possible and compulsory licensing is not possible for developing and low-income countries (Fathi Zadeh, 2003, p. 43).

3.3 The provisions for the transition period

The TRIPS provisions[2] allow developing countries to delay the recognition of pharmaceutical patents for more than 10 years from the date of entry into force of the TRIPS Agreement. Transition periods are applicable on their own. This means that there is no need for prior notification or declaration by the Member States concerned. However, members who apply the extended 10-year period for medicines or agricultural chemicals are committed to accept new applications made for the patent of medicinal products during that period. They are also committed to apply the exclusive marketing rights for a limited period (Abbasi, Khakpur, Foroughi, 2012, p. 22).

3.4 Manufacture of patented pharmaceutical products without the permission of the patentee

In addition to granting compulsory license or parallel importation, under the other system referred to in Article 8 of the TRIPS Agreement, in some cases, some countries are allowed to manufacture patented medicines

1. A legal principle which is resorted to in parallel importation is the termination of the use of right. The termination doctrine, also known as the doctrine of first sale, means that by selling and supplying patented products, there will be no control over their resupply or resale for the patentee. If the doctrine is accepted internationally, it will lead to a parallel importation license for patented products.
2. In accordance with paragraph 9 of Article 70 of the TRIPS Agreement

without the permission of the patentee before the patent expires. This ensures that the manufactured generic drug enter the market as soon as the patent expires (Sheikhi, 2016, p. 77).

Under Article 8 of the Trips Agreement: In adjusting or amending their national laws and regulations, members may take measures to safeguard the right to health, nutrition and the promotion of public interest in areas critical to socio-economic and technological development, provided that the measures are in line with this Agreement.

According to the above article, countries are permitted to produce essential medicines, despite the exclusive rights of drug manufacturers, whenever there is a need for public health that conflicts with the public interest and endangers public health.

4. The challenge of protecting pharmaceutical patents

4.1 WTO and the challenge of protecting public health

In Article 27 of the Universal Declaration of Human Rights, the material and intellectual rights of intellectual property and their protection are emphasized. According to Article 25 of the Universal Declaration of Human Rights of 1948: All human beings have the standard right to adequate protection of health and welfare for themselves and their families, including food, clothing, housing, medical care, necessary social services and the right to security in the event of unemployment, illness, disability etc. in acute conditions.

The most important challenge facing developing countries against the exclusive right of patents is public health. Achieving the goals of public health is the most important aspect of countries' public policy towards patentees (Azizi Moradpour, 2012, p. 137). The use of the benefits of scientific advancement and its applications as a human right requires that every human being enjoy the benefits and facilities of scientific advancement in solving problems, fighting diseases and improving the quality of life (Amir Arjomand; Habibi Mojandeh, 2005). Taken together, the above legal principles consider human rights to be paramount in the unresolved conflict between these two rights, and consider medical patents as a means of ensuring human health that must be secured and preferred in addition to recognizing the inventors' right to their own medical innovations (Borhani, Abouzari, 2017, p. 19).

In the two-way debate between inventors' right to own their own pharmaceutical innovations and everyone's right to access medicines, it should be noted that the right to health and access to essential medicines are preferable to the right to pharmaceutical innovations. It must be borne in mind, however, that excessive emphasis on each of these will exacerbate the gap and neglect of the preferable causes. Moderate approaches should therefore be taken to increase health in developing societies without tracing the intellectual property system and using other ways such as improving health infrastructure, distribution systems in these countries and allocation of dedicated funds by the World Health Organization and other relevant international organizations. Therefore, the attention of countries to protect the interests and health of the international community and taking every step to protect human health are essential health after granting patents to pharmaceutical innovators and creating exclusive rights in production, distribution, sale, import and export of pharmaceutical products in cases where the patentees abuse their granted rights and endanger human health (Moon, Sueri, 2012, p2).

Since legal systems are required to comply with the provisions of the TRIPS Agreement, if they accede to the WTO, they must adhere to the principles and regulations of human rights organizations, including the WHO, regarding the health of the body and access to essential medicines that are among the basic rights of all human beings, regardless of their religion, religion, race, skin color, etc. Since the right to health and the right to intellectual property are both among the basic human rights, neither should be lost in the other's favor, but rather an effort should be made to establish an interaction between the two. It is worth noting that, in addition to the private interests of the innovators, it must also take into account the interests of society and the health and development needs of developing and poor countries due to the special role of medicine in human life. Moreover, developing countries should adopt appropriate strategies for drug distribution and to provide citizens with appropriate access to medicine.

4.2 WTO and development challenge

In recent years, in spite of the need to pay more attention to the link between intellectual property rights and public health, coupled with widespread efforts to reduce poverty and promote public health, developing countries continue to face poverty and disease. The provisions of the TRIPS Agreement have not only made it possible for them to be saved but also made it more difficult for them to access drugs (Habiba, 2007, p. 39). This is because increased protection of intellectual property rights and the prohibition of their production and commercial proliferation in developing countries has led to increased demand and higher prices for these products, in addition to reduced production. This has also adversely affected the cost of research and development in developing countries and has shifted the focus of investment to developed and industrialized countries (Ibid, p. 53).

Article 7 of the TRIPS Agreement states: The protection of intellectual property rights and the enforcement of such rights shall contributes to the development of technological innovations, the transfer and dissemination of technology and the mutual use of producers and users of technical knowledge and it must be done in such a way as to lead to socio-economic prosperity and a balance between rights and obligations.

Paragraph 1 of Article 8 states: In adjusting or amending their national laws and regulations, members may take measures to safeguard the right to health, nutrition and the promotion of public interest in areas critical to socio-economic and technological development, provided that the measures are in line with this Agreement.

Although Articles 7 and 8 of the TRIPS Agreement emphasize the need for developing countries and facilitating technology transfer, in addition to the need for intellectual property rights, several years after the adoption of this document, developing countries have realized that not only this agreement has not played a role in expanding their development, but also that technology transfer from developed countries has been hampered. Thus, protecting the exclusive rights of developed countries rights leads to a widening economic gap between developing and developed countries and a very small share of developing countries in producing and supplying world markets rather than helping them.

One of the solutions to overcome the challenge is that, in addition to observing the important principles of national behavior and minimum standards set out in the TRIPS Agreement for equality and fairness among WTO member countries, intellectual property rights and the exclusive rights of the patentees must enable developing countries to produce and use technology. This is because basic human needs, including public health and,

consequently, access to medicine, are a prerequisite for all other goals. It is worth noting that, in addition to the private interests of the innovators, it must also take into account the interests of society and the health and development needs of developing and poor countries due to the special role of medicine in human life. Moreover, developing countries should adopt appropriate strategies for drug distribution and to provide citizens with appropriate access to medicine ((Habiba, Moein Eslam, 2018, p. 181).

II. Conclusion

Prior to the signing of the TRIPS Agreement in 1994, the process of granting pharmaceutical patents between developing or less developed countries was slower and many disagreed to grant patents to pharmaceutical products under national laws. The TRIPS Agreement, however, stressed the need to establish an international protection for pharmaceutical patents. The agreement requires all WTO members to recognize the protection for all patents, and in particular pharmaceutical patents, since most of the patents granted in the world are related to pharmaceutical products and processes. So the legal systems that are members of the WTO and those seeking accession to this organization must bring their laws and regulations in line with this agreement.

Compared to other WTO agreements and conventions, one of the features of this agreement is the expression of the requirements and powers of the states in the regulation of their domestic laws, taking into account the necessary standards appropriate to the political and social conditions of each society. Therefore, like other WTO fundamental agreements, this agreement specially focuses on public health in particular access to medicines and seeks to establish a balance between the intellectual property right holder (the patentee) and the public health (as a basic human right) so that the countries are enabled to protect to protect human life and health while protecting the rights of the patentee. The same conclusion is expressed in the 2001 Doha Declaration on intellectual property and public health, and emphasized that the TRIPS Agreement should not impede the measures taken by member states to protect public health.

However, due to the great role of pharmaceutical patents in the field of public health, they have a prominent place among other patents. This place has created a challenge among developing and developed countries. As a result, the contrast between public health and intellectual property rights of patentees is one of the most challenging issues, especially for developing countries. This is because with exclusive rights granted to patentees, developing countries' access to medicines can be very difficult, and even the health of these communities may be compromised by rising drug prices.

III. Recommendations

1. Developing countries are recommended to limit the protection of pharmaceutical patents to the extent that they do not conflict with public health, as some rights are independent and are considered goals and others are means of achieving the goal and are of an instrumentality. The right to health seems to be a goal so that human beings seek to invent and supply the drugs to achieve it. Therefore, it can be said that

the right to invent medicines is a right to instrument, not a genuine right, and it is a right to achieve an inherent goal, that is, the right to health. So it cannot be considered to be unconditional and absolute, but freedom in the exercise of this right is limited to secure the health.

2. As noted earlier, the TRIPS Agreement is satisfied with the expressing the minimal cases, and has given states the freedom of action to adjust their domestic laws according to the circumstances of their communities. On the other hand, developments in the Doha Declaration on public health (such as modifying compulsory licensing requirements, giving developing countries time to reach the minimum level of development, etc.) have led developing countries to exercise their legal powers in cases where they find exclusive powers an obstacle to public health, and to seek solutions to the problems arising from the exclusive rights of patentees.

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