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The Balance Between Free Trade and Health Care: Challenges Faced by the World Trade Organization in the Context of Trade in Medicines

Równowaga między wolnym handlem a ochroną zdrowia. Wyzwania systemu Światowej Organizacji Handlu w kontekście handlu lekami

ABSTRACT

The role of the World Trade Organization (WTO) essentially boils down to regulating trade, but in the face of growing cross-border health challenges, such as infectious diseases, we are witnessing an expansion of the WTO's scope of influence into matters in other branches of law. The COVID-19 pandemic exposed the WTO's structural weaknesses in responding to global health crises. The paper addresses the issue of trade in medicines within the WTO, focusing on the legal framework currently in effect, its operation in practice, and the challenges arising out of the need to ensure global access to medicines. It primarily analyses the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including the flexibilities, and the Doha Declaration, which aimed to reconcile the protection of intellectual property rights with the exercise of the right to health. It also assesses recent initiatives aimed at the reform of the WTO system in the context of cross-border threats. The article demonstrates that a more flexible approach to interpreting WTO rules is needed, taking into account the importance of public health. It also concludes with *de lege ferenda* proposals on the need to strengthen synergies between the international trade system and the exercise of the right to health. The article is of a scientific and research character. The issues presented have an international impact. The paper can be of cognitive value for both scientific and practical spheres.

Keywords: World Trade Organization; WTO; TRIPS; public health; intellectual property; compulsory licensing

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INTRODUCTION

The liberalization of international trade has been one of the foundations of the post-WW2 economic order, and its institutional guarantee became the World Trade Organization (WTO), established on 15 April 1994, as the successor to the general principles of the General Agreement on Tariffs and Trade (GATT). In the preamble to the WTO Agreement, the states establishing the WTO recognized that "their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development".[1] Based on this, it can be considered that raising the living standards of the societies of member states is an important task of this organization.[2] Nevertheless, there are increasingly frequent proposals put forward to revise this system in order to ensure adequate regulatory space for actions undertaken by states to protect public health.[3] The recent decades, especially the experience of the COVID-19 pandemic, have exposed the weaknesses of existing solutions and highlighted the importance of flexibility mechanisms, derogation clauses, and exceptions to trade commitments.[4] This entails the question: Whether, and if so, to what extent, the TRIPS Agreement, bringing together most countries in the world, provides states with sufficient freedom to interpret it in a way that supports the implementation of the right to health and access to medicines?

In view of the above, the main thesis boils down to the statement that the current WTO legal framework, in particular the TRIPS Agreement regulations, does not provide sufficient legal instruments for effective protection of public health in crisis situations, which entails the need for their reinterpretation or revision. Thus, the aim of this paper is not only to assess the effectiveness of current solutions but also to point out possible directions for their modification in light of global health challenges.

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[1] Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299, 33 I.L.M. 1197 (1994).

[2] A. Wróbel, *Handel lekami w regulacjach Światowej Organizacji Handlu* [in:] *Ochrona zdrowia w stosunkach międzynarodowych. Zagadnienia wybrane*, eds. W. Lizak, A.M. Solarz, Warszawa 2013, p. 75.

[3] E.U. Petersmann, *Human Rights and the Law of the World Trade Organization*, "Journal of World Trade" 2001, vol. 35(3), pp. 241–281.

[4] C.M. Correa, *Intellectual Property Rights and the Protection of Public Health*, Geneva 2002, p. 17.

LEGAL FRAMEWORK FOR THE TRADE IN MEDICINES IN THE WTO SYSTEM

1. The TRIPS Agreement as a foundation for regulation

The primary legal instrument of the WTO concerning the trade in medicines is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),[5] which constitutes Annex 1C of the Marrakesh Agreement establishing the World Trade Organization (WTO Agreement) of 15 April 1994. The TRIPS Agreement was first to establish universally applicable standards for the protection of intellectual property at a multilateral level. Particularly noteworthy are the provisions regarding patent protection for pharmaceutical products, which may lead to restricted access to medicines in developing countries.[6] The principle of patent protection has been recognised as a manifestation of protecting the interests of the pharmaceutical industry in developed countries, at the expense of health needs of poor countries. In response to the criticism of the TRIPS Agreement, the WTO system provides instruments allowing member states some flexibility in the application of patent protection to safeguard public health.

2. Parallel import

One of such mechanisms of flexibility is parallel import, which allows for the legal introducing of patented products in the market, previously introduced in another country with the consent of the right holder. Article 6 of the TRIPS Agreement states that "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 [national treatment clause] and 4 [most-favoured-nation treatment clause], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights". Thus, WTO member states can freely shape their rules regarding the exhaustion of rights, including allowing parallel

[5] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), 15 April 1994; Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299, 33 I.L.M. 1197 (1994).

[6] C.M. Correa, *Access to Medicines and Intellectual Property: The WTO TRIPS Agreement*, Oxford 2021, p. 45. Pursuant to the TRIPS Agreement, the period of protection under Article 33 ends upon the expiry of 20 years from the filing of the invention. It is worth noting that European Union countries, the USA or Japan have provided for the possibility of extending the exclusivity of medicinal products after expiry of their patent protection. M. du Vall (*Uzasadnienie systemu ochrony własności przemysłowej*, [in:] *System Prawa Prywatnego*, vol. 14A: *Prawo własności przemysłowej*, ed. R. Skubisz, Warszawa 2012, pp. 136–137) rightly points out that the process of placing a medicinal product on the market takes 10 years on average, so the effective term of patent protection is considerably shorter than for other inventions.

import, which means the possibility of legally importing a product protected by intellectual property rights after its legal introduction into a foreign market.[7]

The permissibility of parallel imports has also been confirmed in the Doha Declaration on the TRIPS Agreement and Public Health, adopted in 2001.[8] Paragraph 5 (d) of this declaration, as regards exhaustion of intellectual property rights, considers "each member free to establish its own regime for such exhaustion without challenge". This means that states have the freedom to allow parallel imports regardless of the position of exporting countries.

W. Wiśniewska points out that "parallel import is a legal form of distributing a medicinal product, carried out outside the sales network developed by the manufacturer of the medicine and its business partners, and therefore parallel to it and along with it".[9] Proponents of parallel import signal that, as an instrument to counteract the monopolisation of the medicines market, it allows countries to purchase cheaper medicinal products from countries with a more favourable pricing regime, without the need for more controversial measures such as the issuance of a compulsory licence.

3. Permitted use of someone else's inventions

Article 30 of the TRIPS Agreement states that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". C. Correa notes that the very general wording of Article 30 points to difficulties the negotiating parties with agreeing upon the nature and scope of exceptions to patent rights.[10] It should be kept in mind that these conditions apply together, but each of them is a separate prerequisite applied without the authorisation of the patent owner. Exceptions such as the import of a medicinal product placed on the foreign market by the patent holder, with the patent holder's consent or by an authorised person, as well as activities undertaken privately or for non-commercial purposes, can therefore be considered permitted. It is allowed to use the invention in the field of research and experiments and for teaching purposes. There is the possibility to apply for a marketing authorisation before the patent expires. The preparation of medicines for individual use under

[7] C.M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford 2007, p. 78.

[8] Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/1, 14 November 2001.

[9] W. Wiśniewska, *Stosowanie praktyk ograniczających konkurencję w sektorze farmaceutycznym na tle prawa Unii Europejskiej*, Warszawa 2012, p. 33.

[10] C.M. Correa, *Trade Related Aspects…*, p. 303.

a prescription as well as the use of an invention by a third party who has commenced or has undertaken in good faith preparatory activities for this purpose prior to the patent application (or its publication) has been considered legal.[11]

The content of Article 30 of the TRIPS Agreement was subject of dispute in *Canada v. Patent Protection of Pharmaceutical Products*.[12] F.M. Abbott points out that this was "the most important analysis of the TRIPS Agreement to date".[13] The contentious matter in this case were two provisions of the Canadian Patent Act. The first is para. 1 of Section 55.2, the so-called "regulatory review exception", commonly referred to as the Bolar exemption,[14] which allows the use of a patent-protected product by third parties for the purposes of conducting tests necessary to obtain marketing authorisation for a competing medicinal product.[15] In the case of pharmaceuticals, this provision effectively allows generic manufacturers to complete the time-consuming process of placing in the market before the patent expires, in particular allowing the generic manufacturer to produce samples of the patented product for use during the regulatory review process.[16] The second disputed provision was para. 2 of Section 55.2, known as the "stockpiling provision", which allowed generic manufacturers to manufacture medicines and stockpile them for a period of 6 months before the expiry of the patent protection. The European Communities argued that the disputed provisions of the Canadian Patent Act violated Article 28 (1) of the TRIPS Agreement (in conjunction with Article 33 in relation to the stockpiling provision) and Article 27 (1).[17]

The Panel stated in its report that the provisions of para. 1 of Section 55.2 of the Canadian Patent Act do not violate the TRIPS Agreement, whereas para. 2 of

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[11] M. Barczewski, *Prawa własności intelektualnej w Światowej Organizacji Handlu a dostęp do produktów leczniczych*, Warszawa 2013, pp. 100–101. See also A. Taubman, H. Wager, J. Watal (eds.), *A Handbook of the WTO TRIPS Agreement*, Cambridge 2012, pp. 108–110.

[12] WTO, *Canada v. Patent Protection of Pharmaceutical Products*, Panel Report, WT/DS114/R.

[13] F.M. Abbott, *Bob Hudec as Chair of the Canada – Generic Pharmaceuticals Panel – the WTO Gets Something Right*, "Journal of International Economic Law" 2003, vol. 6, p. 734.

[14] The Bolar exemption was adopted in Europe under Directive 2001/83/EC (amended by Directive 2004/27/EC). Article 10 (6) states that it is not a patent infringement to conduct necessary research and tests in connection with the application of paras 1, 2, 3, and 4, and the resulting practical requirements of patent rights or supplementary protection certificates for medicinal products. In Polish law, the Bolar exemption is included in Article 69 (1) (4) of the Act of 30 June 2000 – Industrial Property Law (consolidated text, Journal of Laws 2020, item 286, as amended), according to which the use of an invention, to the necessary extent, for the performance of activities required by law for obtaining registration without permission, which constitutes a condition for the marketing authorisation of certain products due to their intended use, particularly medicinal products, does not infringe the patent.

[15] M. Barczewski, *op. cit.*, pp. 101–102.

[16] WTO, *Canada v. Patent Protection of Pharmaceutical Products*, Panel Report, WT/DS114/R, p. 2.

[17] *Ibidem*, p. 2.

Section 55.2 of that Act is inconsistent with those provisions. The Panel found that the provision on stockpiling in the Canadian Patent Act does not constitute a "limited exception" under Article 30 of the TRIPS Agreement. As a result, it has concluded that the stockpiling provision constitutes "a substantial curtailment of the exclusionary rights required to be granted to patent owners under Article 28.1 of the TRIPS Agreement", and therefore is inconsistent with it.[18]

The most significant practical result of the report was that many WTO Member States, and the then European Communities, introduced an exception in their legislation to allow third parties to use a product protected by a patent for the purpose of conducting tests necessary to obtain a marketing authorisation for a competing medicinal product.[19] According to H. Hestermeyer, the Panel's reasoning was not convincing, as it focused solely on the interests of the patent holder, which seems to indicate favouring the interests of the right holder.[20] The Panel did not address in any way the problem of balancing the interests of consumers with the interests of patent holders.

The prevailing view in the literature is that the legitimate interests of interested third parties must compete with the legitimate interests of the patent holder to favour the resolution of a public health crisis or the advancement of science and technology.[21] However, as noted by Hestermeyer, the narrow interpretation of the provision by the Panel in *Canada v. Patent* does not allow an exception under Article 30 of the TRIPS Agreement that could significantly improve access to medicines in developing countries.[22]

4. Compulsory licensing

Significantly greater chances for reducing medicine prices are provided by the so-called compulsory licensing set out in Article 31 of the TRIPS Agreement, which lists twelve conditions (a–l) for the admissibility of abandoning patent protection.[23] Licences are granted by the government, or third parties authorised by the government, without the consent of the patent holder, and cover other uses of the

[18] *Ibidem*, §§ 7.36 and 7.38.

[19] M. Barczewski, *op. cit.*, p. 113.

[20] H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicine*, Oxford 2008, pp. 237–238.

[21] C.M. Correa, *Trade Related Aspects…*, p. 311.

[22] H. Hestermeyer, *op. cit*., p. 239.

[23] The TRIPS Agreement does not use the term "compulsory licensing", but rather "other use without authorisation of the right holder". It is worth noting that the granting of compulsory licences was one of the most controversial topics during the TRIPS Agreement negotiations. The interests of developing countries, which positively responded to the possibility of governments granting such permissions, clashed with those of developed countries, which strongly opposed the introduction of compulsory licences.

patented subject than provided in Article 30 of the TRIPS Agreement. Article 31 (a) of the TRIPS Agreement, authorisation of use without the right holder's consent must be considered on individual merits. The rejection of a "blanket" (framework) approach to case consideration should seemingly lead to preventing the automatic granting of compulsory licenses[24]. The TRIPS Agreement does not specify when and on what grounds such a licence may be granted, and the only requirement in the text is that the requesting party must notify the patent holder of such use as soon as reasonably possible.[25]

Article 31 (b) of the TRIPS Agreement requires that the proposed user first make efforts to obtain authorisation from the right holder on reasonable commercial terms before applying for the licence.[26] However, this requirement is not mandatory in situations of emergency, such as threats to public health or national security. The effect of a compulsory licence is limited only to the territory of the country in which it has been granted, which means that licences must be "predominantly for the supply of the domestic market of the Member authorizing such use" (Article 31 (f) of the TRIPS Agreement). If there is no production capacity in the country granting the licence and the beneficiary does not provide such capacity, the beneficiary can then only work with the licence by importing the patented product from a third country, regardless of whether it was manufactured there by the patent holder or not.[27] It should further be noted that the scope of a compulsory licence issued under Article 31 of the TRIPS Agreement covers only patent protection, which, in many cases, especially where the use of the patented invention depends on knowledge of non-patentable secret information of an organisational or technical nature, may *de facto* significantly reduce the effectiveness of the compulsory licence.[28]

The literature stresses the importance of compulsory licences in the implementation of the right to health. H. Hestermeyer holds that compulsory licences are a valuable tool in promoting access to medicines, especially in situations when the patent holder refuses to supply the market.[29] There is no doubt that the compulsory

[24] Z. Więckowski, *Licencje przymusowe w systemie ochrony patentowej produktów leczniczych*, Warszawa 2020, p. 64. See also M.A. Desai, *Compulsory Licensing: Procedural Requirements under the TRIPS Agreement*, "Pharmaceutical Policy and Law" 2016, vol. 18(1–4), p. 31. The author stresses that compulsory licences should not be regarded as a permanent instrument of state health policy.

[25] P. Xiong, *Pharmaceutical Patents in the TRIPS Agreement and the Right to Health: Can These Rights Be Reconciled?*, "University of Western Australia Law Review" 2012, vol. 36(1), p. 127.

[26] The content of this provision contains a lot of vague phrases, such as "reasonable commercial terms", "reasonable period of time", which, due to the lack of their definitions in the TRIPS Agreement, may lead to interpretative problems. See also D. Halajian, *Inadequacy of TRIPS and the Compulsory License: Why Broad Compulsory Licensing Is Not a Viable Solution to the Access Medicine Problem*, "Brooklyn Journal of International Law" 2013, vol. 38, p. 1224.

[27] H. Hestermeyer, *op. cit*., p. 250.

[28] M. Barczewski, *op. cit*., p. 120.

[29] H. Hestermeyer, *op. cit*., p. 241.

licence, as an instrument that interferes with patent monopoly and a type of sanction, should be used prudently and only in cases where the patent holder does not want or is unable to grant a relevant licence.[30]

Despite this controversy, the construct of Article 31 of the TRIPS Agreement confirms the consistency of compulsory licensing with the right to health. This provision offers a flexible interpretation to member states, allowing this instrument to be adapted to national health policy needs. From the *de lege ferenda* perspective, it would be advisable to put forward changes leading to a shortening of the compulsory licensing procedure, while preserving the exceptional nature of this institution, reserved for use in exceptional cases.[31] Thus, compulsory licences have the potential to become an important tool for promoting competition and increasing the availability of medicines.[32]

ACTIONS TOWARDS THE IMPROVEMENT OF ACCESS TO MEDICINES

1. The Doha Round

Article 1 of the TRIPS Agreement states that the provisions contained therein establish the minimum protection, so members may introduce broader protection in their laws, provided that such protection does not breach the provisions of the Agreement. Members, therefore, have the discretion to determine the appropriate method of implementing the TRIPS provisions within their own legal systems and practice. On the other hand, the TRIPS Agreement allows states to take measures that limit the rights of patent holders. Scholars in the field often argue that the current form of patent protection contradicts the right to health.[33] The WTO itself

[30] J. Wiszniewska, *Licencja przymusowa – panaceum na epidemię?*, "Internetowy Kwartalnik Antymonopolowy i Regulacyjny" 2021, vol. 10(1), p. 79.

[31] *Ibidem*.

[32] An example of the use of compulsory licensing is the production of an equivalent of the AIDS drug Efavirens in Brazil, which, since 2007, has had the status of a medicine of public interest there. In March 2020, some countries, including Germany, France and Canada, among others, amended their laws or issued additional regulations to facilitate the possibility of compulsory licensing. For more detail, see X. Wu, B.P. Khazin, *Patent-Related Actions Taken in WTO Members in Response to the COVID-19 Pandemic*, 21.10.2020, https://www.wto.org/english/res_e/reser_e/ersd202012_e.pdf (access: 24.9.2024).

[33] See P. Cullet, *Patents Bill, TRIPS and the Right to Health*, "Economic and Political Weekly" 2001, vol. 36(43); C. Feng-Wu, *Raising the Right Concerns within the Framework of International Intellectual Property Law*, "Asian Journal of WTO and International Health Law and Policy" 2010, vol. 5, pp. 141–205; G. Velasquez, *The Right to Health and Medicines: The Case of Recent Negoti-*

is therefore making attempts to improve this situation by amending existing regulations to better address public health needs.

In view of the exceptions described above, it follows that the TRIPS Agreement provisions provided for a mechanism that allowed member states to supply essential medicines. The issue was when it could be applied. As J. Harrison rightly argues, such ambiguities can lead to political pressure on developing countries that will try to use the relevant regulations.[34] A particularly noteworthy example is South Africa, which, in the face of a serious epidemic, adopted legislation authorising the health minister to take measures such as compulsory licensing. This met with massive opposition, resulting in forty-two applicants, including several large pharmaceutical companies, filing a lawsuit against the South African government on 18 February 1998. The substantiation behind the lawsuit was that the adopted regulations violated Article 27 of the TRIPS Agreement. Eventually, the lawsuit was withdrawn following pressure from the public. Although the dispute was not subject to the dispute settlement procedures within the WTO framework, it pointed to the need to define the adjustment possibilities allowed by the TRIPS Agreement, ensuring that developing countries could use them without yielding to legal or political pressures.[35]

Consequently, in April 2001, as a result of the exacerbating HIV/AIDS pandemic, a group of developing countries, led by representatives of Zimbabwe, requested a special session of the TRIPS Council[36] to address the problem.[37] This initiative was supported by many countries (e.g. Argentina, Brazil, Japan, Poland, Switzerland, and the USA), so it was decided to discuss the issue at the next TRIPS Council meeting.[38] The most important question was how to strike a balance between the protection of intellectual property and access to essential medicines.

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ations on the Global Strategy on Public Health, Innovation on Intellectual Property, "South Centre Research Papers" 2011, vol. 35, pp. 1–45.

[34] J. Harrison, *The Human Rights Impact of the World Trade Organization*, Oxford–Portland 2007, p. 160.

[35] M. Barczewski, *op. cit*., p. 83. See also K. Gamharter, *Access to Affordable Medicines: Developing Responses under the TRIPS Agreement and EC Law*, Wien–New York 2004, p. 114.

[36] The TRIPS Council was established as a forum for cooperation and consultation between WTO members to discuss questionable or contentious issues without the need to initiate dispute resolution procedures. See G.B. Dinwoodie, W. Hennessey, S. Perlmutter, G. Austin, *International Intellectual Property Law and Policy*, Newark 2008, p. 41.

[37] Referring to the devastating AIDS crisis in Africa and the growing public concern, Zimbabwe, as the head of the Africa group, stated: "We propose that Members issue a special declaration on the TRIPS Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health". See E. Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, https://www.who.int/intellectualproperty/topics/ip/tHoen.pdf (access: 12.4.2024).

[38] M. Barczewski, *op. cit.*, p. 85.

The importance of creating a positive, mutually reinforcing link between the intellectual property system and access to medicines was made clear at the Fourth WTO Ministerial Conference in Doha, Qatar, held in November 2001.[39] The adoption of a separate declaration on the TRIPS Agreement and public health, initiated unanimously by a group of developing countries, clearly articulating and seeking common interests, is considered one of the most significant achievements of this Ministerial Conference.[40]

2. Doha Declaration on the TRIPS Agreement and Public Health

When drafting the text of the Doha Declaration, WTO members adopted three assumptions: first, the TRIPS Agreement does not allow the problems addressed in the Declaration to be solved; second, the content of the Doha Declaration would allow them to be addressed, or at least would set the direction for actions toward solving them; and third, the remedies it identifies would address the shortcomings of the TRIPS Agreement.[41] It was also emphasised that, while applying customary rules of interpretation of public international law, each provision of the TRIPS Agreement should be interpreted with respect for the right of member states to protect public health and, in particular, to promote access to medicines for all, so as to allow them to take advantage of TRIPS flexibilities (para. 5 letter a). The Doha Declaration thus recognises the principle of interpreting and implementing the TRIPS Agreement in such a way as to ensure the protection of public health in member states, including, in particular, by allowing access to medicines for all.[42] Thus, each state has the right to grant compulsory licences and the freedom to determine the grounds on which such licences are granted (para. 5 letter b), and each state can determine what constitutes "a national emergency or other circumstances of extreme urgency" (para. 5 letter c). The Doha Declaration has further indicated that each WTO member is free to establish its own regime for the exhaustion of intellectual property rights, subject to the MFN and national treatment provisions (para. 5 letter d).

One of the unresolved issues was the question of the use of compulsory licences by states that do not have the infrastructure to manufacture a medicinal product on their territory. Many developing and least developed countries do not have the capacity to produce active ingredients or formulations due to a lack of technology, equipment, human resources, or the economic viability of such production.

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[39] A. Taubman, H. Wager, J. Watal (eds.), *op. cit.*, p. 180.

[40] M. Barczewski, *op. cit*., p. 88.

[41] *Ibidem*, p. 89.

[42] M. du Vall, *Okres globalizacji ochrony (ujednolicanie w skali światowej przepisów prawnych, tworzenie ponadnarodowych systemów ochrony)*, [in:] M. du Vall, E. Traple, P. Kostański, J. Ożegalska-Trybalska, P. Podrecki, *Prawo patentowe*, Warszawa 2017, p. 172.

Article 31 (f) of the TRIPS Agreement clearly indicates that granting a compulsory license is permissible where primarily granted "for the supply of the domestic market of the Member authorizing such use", thus blocking the possibility of exporting medicines from countries that have production capabilities. Paragraph 6 of the Doha Declaration reads: "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002". Therefore, as M. Barczewski points out, while the previous provisions of the declaration clarified and specified certain doubtful regulations, this paragraph left *expressis verbis* unresolved the issue of the use of compulsory licences by states that do not have the infrastructure to manufacture medicinal products.[43]

An agreement to resolve the problem was finally reached on 30 August 2003. On that date, the General Council adopted the decision on the implementation of para. 6 of the Doha Declaration,[44] which provides for temporary derogations concerning the obligations contained in Article 31 (f) of the TRIPS Agreement, in order to ensure: rapid and effective response to public health needs; equal opportunities for countries in need, regardless of the patent status of the medicine in the importing country and regardless of its WTO membership; sustainable supply of high-quality products at affordable prices; facilitation of a wide range of potential suppliers, both developed and developing countries, that can compete to reduce prices; a wide range of offer of pharmaceutical products to address a wide range of health issues.[45]

Under the 2003 Decision, also known as the "waiver decision", least developed countries have been granted the option to waive certain conditions of application of compulsory licenses contained in Article 31 (f) of the TRIPS Agreement. As a rule, it allows countries equipped with production capacity to issue compulsory licences for the export of medicines to countries without such capacity. This solution should be understood in terms of whether it will be able to strengthen the capacity of countries to take steps towards increasing the availability of medicines, especially those which do not have adequate production capacity and thus fulfill their basic obligation to progressively implement the human right to health.[46]

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[43] M. Barczewski, *op. cit.*, p. 93.

[44] Decision of the WTO of 30 August 2003: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 2 September 2003.

[45] World Trade Organization, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (access: 3.8.2024).

[46] P. Ranjan, *Understanding the Conflicts between the TRIPS Agreement and the Human Right to Health*, "Journal of the World Investment and Trade" 2008, vol. 9(6), pp. 568–569.

Due to the temporary nature of the 2003 Decision, the WTO General Affairs Council adopted on 6 December 2005 a Protocol amending the TRIPS Agreement.[47] The amendment was to add, after Article 31, an additional Article 31bis, consisting of five paragraphs concerning: the authorisation of exports of pharmaceutical products manufactured under compulsory licences to countries with no manufacturing capacity in the pharmaceutical sector, the avoidance of double remuneration for the patent owner, regional trade agreements to which developing or least-developed WTO members are parties, appeals and maintenance of the rights, obligations and flexibilities applicable within the WTO.[48] The amendment should be considered as beneficial, as it responds to actual needs of developing countries,[49] but the complex procedure of applying such exceptions poses a serious problem.

The first to implement the mechanism established by the WTO was Rwanda. The Rwandan government notified the TRIPS Council on 17 July 2007 that it intended to import TriAvir from the Canadian company Apotex, the entity responsible for the patents on the production of this generic drug used in the treatment of HIV/AIDS.[50] Regretfully, due to the excessively complicated procedure (the delivery of the medicine to Rwanda took over a year), this collaboration was discontinued.[51]

When assessing the Doha Declaration, S. Sen points to a certain weakness of it, namely its lack of binding mature, which raises serious doubts as to its implementation.[52] In their assessments of the provisions of the Doha Declaration, many authors point out that it is simply a repetition and confirmation of the principles existing within the WTO. On the other hand, J. Harrison writes that even if the declaration is only used to prevent misuse of the TRIPS Agreement, its importance should not be underestimated if it allows WTO member states to apply important measures

[47] Eventually, the Protocol amending the TRIPS Agreement became effective on 23 January 2017.

[48] Z. Więckowski, *op. cit.*, p. 59.

[49] S. Guennif (*Evaluating the Usefulness of Compulsory Licensing in Developing Countries: A Comparative Study of Thai and Brazilian Experiences Regarding Access to AIDS Treatments*, "Developing World Bioethics" 2017, vol. 17(2), pp. 90–99) points out that the decision to grant a compulsory licence has effectively contributed to the improvement of access to medicines, including in Brazil and Thailand.

[50] Rwanda notified the WTO of the intention to apply the procedure of 2003. The purpose of the actions taken was to import 15.6 million doses of medicine produced by Apotex in Canada. Ultimately, on 16 September 2007, the company obtained a compulsory licence. See O. Aginam, *Health or Trade? A Critique of Contemporary Approaches to Global Health Diplomacy*, "Asian Journal of WTO and International Health Law and Policy" 2010, vol. 5(2), pp. 357–358.

[51] The Apotex representative has publicly stated that Apotex "is reluctant to participate in the initiative again unless changes are made to streamline the regime". See L.C. Esmail, J.C. Cohen-Kohler, *The Politics Behind the Implementation of the WTO Paragraph 6 Decision in Canada to Increase Global Drug Access*, "Global Health" 2012, vol. 8.

[52] S. Sen, *The WTO Agreement and the Right to Health. Conflict or Consensus: A Developing Country Perspective*, "National University of Juridical Sciences Law Review" 2008, vol. 1(2), p. 234.

such as compulsory licensing of essential medicines without fear of trade-based retaliation.[53] The use of Doha Declaration provisions by WTO dispute resolution panels and the Appellate Body will be crucial for its assessment. The achievements of the Doha Declaration should therefore be balanced with these ongoing attempts to limit the extent to which many developing countries can make use of the mechanisms provided for in order to meet their public health needs.[54] The challenge for the future is to create such patent regulations that would not violate human rights, and the existing ones would support countries in access to basic medicines.

DISCUSSION AND CONCLUSIONS

Analysing the functioning of the WTO system in the area of trade in medicines, it was important to identify certain potentially contentious areas where WTO rules may pose a real threat to the implementation of public health policies. Although the TRIPS Agreement, forming an integral part of the WTO system, takes into account the need to balance the interests of rights holders with the public interest and provides for flexibilities, the practice of its application demonstrates numerous limitations, especially in emergency situations such as the COVID-19 pandemic.[55] In many cases, procedural barriers, political pressure from developed countries and, last but not least, limited technological capabilities of developing countries, have paralysed efforts to introduce potentially available legal solutions. Therefore, the legislative changes initiated by the Doha Declaration, aimed at recognising the primacy of public health over commercial interests, should be positively assessed, but their effectiveness in practical dimension proved to be insufficient. Current legal instruments are too much formalised, complex and susceptible to political-economic pressure, particularly towards developing countries.[56] In this context, it is advisable to strengthen derogation mechanisms from patent protection in case of public health threats.[57] The analysis leads to the conclusion that current flexibility mechanisms within the WTO do not provide countries with full freedom to implement the right to health and access to medicines in crisis situations. The analysis has also demonstrated that the experience

[53] J. Harrison, *op. cit.*, p. 165.

[54] *Ibidem*, p. 169.

[55] World Trade Organization, World Health Organization, World Intellectual Property Organization, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2020, https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf (access: 12.12.2025), pp. 172–183.

[56] J. Watal, *Intellectual Property Rights in the WTO and Developing Countries*, The Hague 2001, pp. 201–211.

[57] K. Shadlen, *Coalitions and Compliance: The Political Economy of Pharmaceutical Patents in Latin America*, Oxford 2017, pp. 119–142.

of the COVID-19 pandemic manifested the need to redefine the proportions between trade commitments and protection of public health.[58]

As a proposal for the law as it should stand, it would also be worth considering the establishment within the WTO of a permanent advisory body tasked with monitoring the impact of trade policy on access to medicines, initiating inter-institutional dialogue with WHO or WIPO, and putting forward legislative recommendations aimed at realizing the right to health and access to medicines. Undoubtedly, a new value that should be noted in the light of currently valid analyses is the growing importance of health protection as an element of global security, which should result in a reinterpretation of existing trade commitments in the spirit of the principle of proportionality. Only then will it be possible to implement an international order based on solidarity and justice.

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[58] C.M. Correa, *Trade Related Aspects…*, pp. 92–103.

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ABSTRAKT

Zasadniczo rola Światowej Organizacji Handlu (WTO – World Trade Organization) ogranicza się do regulowania handlu, ale w obliczu rosnących wyzwań zdrowotnych o charakterze transgranicznym, takich jak choroby zakaźne, jesteśmy świadkami rozszerzania zakresu oddziaływania WTO na sprawy z innych dziedzin prawa. Pandemia COVID-19 ujawniła strukturalne słabości WTO w reagowaniu na globalne kryzysy zdrowotne. W artykule omówiono problematykę handlu lekami w ramach WTO, koncentrując się na obowiązujących ramach prawnych, ich praktycznym funkcjonowaniu oraz wyzwaniach wynikających z potrzeby zapewnienia globalnego dostępu do leków. Analizie poddano przede wszystkim Porozumienie w sprawie handlowych aspektów praw własności intelektualnej (TRIPS), w tym klauzule elastyczności oraz Deklarację z Doha, które miały na celu pogodzenie ochrony praw własności intelektualnej z realizacją prawa do zdrowia. Ocenie poddano również najnowsze inicjatywy mające na celu reformę systemu WTO w kontekście zagrożeń transgranicznych. Rozważania prowadzą do wniosku, że konieczne jest bardziej elastyczne podejście do interpretacji zasad WTO, uwzględniające znaczenie zdrowia publicznego. W konkluzji sformułowano także postulaty *de lege ferenda* dotyczące konieczności wzmocnienia synergii między systemem handlu międzynarodowego a realizacją prawa do zdrowia. Artykuł ma charakter naukowo-badawczy. Przedstawiona problematyka ma zasięg międzynarodowy. Artykuł może mieć wartość poznawczą zarówno dla nauki, jak i dla praktyki.

Słowa kluczowe: Światowa Organizacja Handlu; WTO; TRIPS; zdrowie publiczne; własność intelektualna; licencje przymusowe