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Improving Global Public Health: Responsiveness to Public Interest Considerations in Intellectual Property Law

1. Introductory remarks

In 1994, as a result of negotiations taking place within the framework of the General Agreement on Tariffs and Trade, the World Trade Organization (WTO) was established and its members committed, among others, to put in place and harmonize minimum standards of intellectual property protection. One of the annexes to the Agreement establishing the World Trade Organization³ was the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)⁴, imposing upon WTO Members an obligation to provide patent protection for any inventions, in all fields of technology. Given the deep asymmetries between WTO Member States in terms of their development, concerns were raised that it will result in a substantial reduction in availability of medicinal products⁵.

Undoubtedly, the monopoly enjoyed by the pharmaceutical industry based on intellectual property rights is fundamental to the problem of access to medicines, particularly in the developing and least developed countries⁶. On the one hand, patents encourage...

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innovation by securing inventors’ “exclusive rights”, i.e. property rights. This serves public interest in the same way that all property rights serve public interest. The promise of an exclusive right in the fruits of one’s labors incentivizes people to invest and create new valuable assets\(^7\). On the other hand, patents give the exclusive right to grant or refuse permission to manufacture, use, sell or import products with the protected solution. They allow patentees to determine pricing policy and control product distribution, and consequently hinder marketing of competitive goods. For this reason, drug manufacturers have been seeking to strengthen legal protection of their intellectual property, particularly in the field of patent protection.

As noted by Sol Picciotto, the main problem with the TRIPS Agreement is its strong emphasis on intellectual property rights as private rights, subject to only a few limited exceptions to protect the public interest\(^8\). Therefore, over the past few years the WTO Council for Trade-Related Aspects of Intellectual Property Rights recognized that there is a growing concern about an imbalance between intellectual property and public interest. Some of its members pointed out, with regard to health technologies, that without sufficient use of balancing exceptions and limitations to protect the public interest, patents and related monopoly rights in test data permit companies to maintain high prices and aggravate the crisis of access around the world, where many patients cannot afford medicines, and force governments with limited health budgets to ration health care\(^9\). Consequently, more than 20 years after the adoption of the TRIPS Agreement, there is a need for discussion in the TRIPS Council on the relationship between intellectual property rights and the public interest and to broaden the understanding of how the IP system can be more responsive to public interest considerations\(^10\).

2. The theoretical scope of the concept of public interest

The concept of public interest has never been based on a universal legal definition. Being quite an extensive concept, public interest gains meaning in certain conditions and time. Its denotation depends on the social context in the sense of achieving specific values accepted and desired in a given society at a given time. Hence, public interest is being redefined on an ongoing basis and subjected to continuous analysis, re-evaluation and assessment\(^11\).

Early concepts of the public interest were based on the opposition between interests of the individual and public interests. Only the doctrine of the liberal rule of law and the concept of public subjective rights formed the basis for analysing the position of the individual in the state and the nature of its interests\(^12\).


\(^10\) *Intellectual Property and the Public Interest*… (IP/C/W/630), pt. 10.


\(^12\) A. Żurawik, „*Interes publiczny“, „interes społeczny” i „interes społecznie uzasadniony*” [Eng. “Public Interest”, “Social Interest” and “Socially Justified Interest”], “Ruch Prawniczy, Ekonomiczny i Socjologiczny” 2013/2, p. 60.
It was discovered, however, that in practice there are situations of not so much opposing, but rather of combining the individual interest and the public interest. Public interest began to appear as a complex category, consisting of elements previously rejected as its components. The “mathematical” concept, where it was assumed that public interest is the sum total of private interests, has lost its importance. Moreover, it is generally accepted that the broad concept of general good or public interest cannot be formed solo, but that protection of the individual is covered under the general good. There can be no general good that would not include individual freedom as one of its essential elements.

In the approach to the understanding of the public interest, one can also see the dilemma of whether to give the public interest an axiological basis tied to underlying values, or a phraseological basis tied to goals or related to needs. According to Alison Slade, the “public interest” is a phrase often used to rationalize political, governmental, and legal decision making at both the national and international level. Yet, it is a concept that appears devoid of a precise definition. It is broadly understood to convey the message that the action or inaction in question has been undertaken because society as a whole will derive a benefit. National perceptions of common well-being and the philosophical origins of the public interest inevitably vary amongst states and are tied to economic, cultural, political, and historical influences that are as numerous as they are variable.

Regardless of the use of the concept of public interest in a legal text, similar terms are used alongside it, such as the common interest, social interest or socially justified interest. Unfortunately, such legislative measures do not make it easier for lawyers to clearly define the term “public interest”, because they often have to deal with additional interpretation issues. Problems arise already at the stage of linguistic interpretation, when the interpreting party must become involved in important and sometimes extremely complicated considerations regarding the prohibition of synonymous interpretation or the directive of terminological consequence. Without going into the

16 M. Wyrzykowski, Pojęcie interesu... p. 33.
17 A. Żurawik, „Interes publiczny...“ pp. 61–62.
details, for the purposes of our considerations, we will refer to the basic understanding of the public interest. We point out possible theoretical aspects only to the extent that we deem it necessary for the clarity of our text and because of academic reliability.

The definition of public interest can be found in literature on the subject. Accordingly, it is identified as

the normative duty guideline determining the scope and content of values recognized by a given community as worthy of being protected, regardless of individual beliefs of individuals. From the perspective of actions taken by the state, the concept of public interest is the limit of permissible interference of the public authority in social and economic relations and in the freedom of citizens, and from the point of view of citizens – the limit of freedom of individual activity.

The concept of public interest exists both in international and national law. When it comes to the Polish law, it is one of the basic principles of public law, in particular administrative and economic law. In the case of the former, it is even assumed that “when attempting to define the concept of public administration or to determine its features (characteristic, typical, basic), the principle of public interest should be mentioned as the element that typifies its essence.” Moreover, the Polish law makers have already provided for the principle of public interest in the Polish Constitution. For example, in relation to economic freedom, its restriction is permissible only by statute and only on grounds of important public interest. Everyone, however, “has the right to submit petitions, applications and complaints in the public interest,” and certain state bodies, such as the National Broadcasting Council, safeguard “freedom of expression, the right to information and the public interest.” In addition, the Polish lawmaker allows “to create professional self-governments, representing persons exercising the profession of public trust and overseeing the proper performance of these professions within the limits of the public interest and for its protection.”

In an attempt to analyse the nature, understanding, and the use of the concept of public interest, one can begin with the interpretation of each of the words forming this phrase and on this basis strive to decode all its meanings. This approach is theoretically

23 Article 22 of the Constitution.
24 Article 63 of the Constitution.
25 Article 213 of the Constitution.
26 Article 17 of the Constitution.
28 Very interesting considerations of Justyna Michalska deserve attention in this respect. The author first introduces to the readers the Latin source of the word interest, namely interests, which means “to do something”, “to participate”, “to be present”. Then, based on literature, the author describes three basic understandings of the concept of
interesting, however, it will not be of much importance for our considerations. It seems much more valuable in substantive terms to attempt to define public interest by contrasting it against the individual interest. This is the approach adopted in this paper.

Three models are distinguished in legal writings pertaining to this area, namely a model referred to as the theory of superiority, the theory of common interest and the theory of unitary conception. As summarized by Justyna Nawrot, in the first case, it is assumed that it is possible to determine public interest on the basis of individual interests in society, with public interest being the sum of the individual interests mentioned above, which are represented by the majority. The second model, existing in the literature on the subject under the name of “common interest theory” also refers to the interests of individuals. It differs from the theory of the superiority of public interest in that it assumes the sum of all individual interests while taking into account the interests of minorities, while the so-called superiority theory allows the possibility of eliminating minority interests in the process of defining the common good. The last of the mentioned models, the theory of unitary conception, differs significantly from the other two. According to its assumptions, the concept of public interest is based on the rivalry of competing claims based, however, on certain common values functioning in society and constituting the basis for the decisions of public authorities.

The notion of public interest cannot probably be defined once and for all. Despite attempts at constructing a firm definition, it will always remain an open question how to understand it at a particular political, economic and social moment. Public interest is relative in the sense that explaining its essence requires taking into account the current social context, which is susceptible to change over time.

What is more, there is no well-established consensus on the legal nature of public interest. As we have already mentioned, despite the frequent use of this category by the legislator, especially in public law, there are still different views on the qualification of this phrase in the doctrine. Of course, there are voices recognizing it as a strictly normative category, but also those that connect it with sociological or even political categories. Regardless of the above uncertainties, for the purposes of this study “in light of its use by the legislator (including the constitutional legislator), it is impossible to deny that public interest is a category of legal concept”.

From the perspective of the principles of legislative technique, public interest is a general clause. Depending on the desired goal, the legislator will use legislative technique instruments aimed at either making the legal text more precise or more flexible. General clauses serve the latter purpose. The legislator often deliberately avoids unequivocally addressing certain issues at the stage of legislation and leaves it to law-applying bodies.
Thus, the lawmaker also launches overt decision-making play by creating a certain range of decision-making freedom. It reflects the rationality of the legislator, who should also be aware that the legal text quite often becomes “inadequate” given the changing political, social or economic reality. Assuming trust in law enforcement bodies, general clauses offer an excellent instrument for correcting the above-mentioned deficiencies. It can even be more broadly pointed out that, by means of general clauses, “the legislator communicates with the addressees of the norms as to whether non-legal criteria are included in decisions to apply the law or in compliance with the law.”

It is assumed in the German and Polish jurisprudence that a general clause is a phrase contained in a legal provision that refers to a system of opinions or norms, however, other than a system of legal norms. The system to which the general clause refers should be axiologically justified. The provision containing the general clause authorizes and at the same time imposes an obligation upon the given authority applying the law to handle a specific case. In a theoretical approach, the general clause is accepted, not the wording itself, but the entire legal provision containing the authorization.

At this point, general clauses should be distinguished from unclear language phrases. The latter also produces a more flexible legal text and, consequently, offers a decision-making flexibility. However, in their construction, which is easy to see, they do not refer to any extrajudicial system of values or norms.

Summing up these theoretical remarks, we can assume after Leszek Leszczyński that a general referring clause is a norm reconstructed from the given provision (as part of it), authorizing the subject to apply the right to take into account the criterion (which imposes the obligation to take into account the need for such consideration) when qualifying a factual state or determining its normative consequences. The name of the criterion itself, subject to a separate interpretation, referring to the determination of the type of value (moral, political, economic, included in the general social or individual context, etc.) or facts (established habits), being part of the clause, determines the type of non-legal reference and the resulting direction in the course of operational interpretation (as part of the law application process).

The depicted concept of public interest, qualified as a general clause, requires an assessment of individual behaviours or decisions that are possible under certain circumstances from the point of view of the degree of implementation. As noted by T. Pietrzykowski, such concepts are created in order to avoid making decisions in abstracto about what behaviour in particular situations will be appropriate, and to leave the decision in concreto to the entity having in a given situation act in the public interest. There is no doubt that, in a democratic order, a key role in defining what kind of activities are in the public interest is played by the rivalry of individual parties, groups or political forces. The political dispute is at least ex hypothesi a dispute about the understanding and implementation of competing visions of the public interest, including how the concept should be concretized and operationalized.

Accepting the aforementioned guidelines, it can be stated that “the responsibility of supervising the public interest includes the obligation to respect the rule of law and careful observance of the law in all taken actions”.37

3. Human rights as an instrument for balancing the protection of public and private interests

One can argue that in case of the collision between the protection of property interests and the protection of health, and thus life, the former of these values should yield to the latter. In English, the phrase “hard cases” is often used to describe such complicated issues.38 Although originally, mainly due to the legacy of Ronald Dworkin, it occurred primarily in the culture of common law, where it only referred to the application of the law, in the Polish literature it became accepted to discuss hard cases in the broad sense of the term. According to Jerzy Zajadło, it is hard to find a more spectacular area for the formation of “hard cases” than that which applies to the fundamental problems of human life and at the same time creates the need to formulate new ethical and legal standards. In this sense, the collision of law with medicine is a multifaceted issue and affects economics and science.39

From the perspective of the hard cases theory, there is still the problem of maintaining homeostasis between the right to protect interests resulting from intellectual activity and the freedom to use its results or the right to health. It is particularly important to discuss the possible range of restriction of intellectual property rights resulting from the need to protect public interest or ensure the pre-eminence of human rights protection over agreements and economic policies pertaining to intellectual property protection.40

Although both intellectual property rights and human rights are rooted in the philosophical concepts underlying social change of the second half of the 20th century, and the dynamic internationalization of standards relating to these rights took place after the Second World War, both fields of law evolved separately for a long time. This was, largely, due to their differences: human rights are of a public nature, while intellectual property rights are private. It can be noted both in the literature and in the relevant

42 M. Barczewski, Intellectual Property…, pp. 18–19.
43 M. Barczewski, S. Sykuna, ACTA…, pp. 12–14.
UN documents⁴⁵ that there are, and there may be, significant contradictions between universal protection of intellectual property rights and the protection of economic, social and cultural rights⁴⁶.

The Committee on Economic, Social and Cultural Rights noted that “human rights are different from intellectual property rights, because the former derive their existence from the human person, while the latter are instrumental in nature, as they serve to stimulate creativity and inventiveness, used by the general public”. The Committee also believes that “while the human rights focus on ensuring satisfactory standards of human welfare and prosperity, the intellectual property system, although usually provides protection to individual authors, increasingly focuses on the protection of investments and corporate interests”⁴⁷. For this reason, the Committee emphasized that the parties to the International Covenant on Economic, Social and Cultural Rights⁴⁸ have an obligation to ensure at least the basic level of protection of the rights set out therein, and in particular the right to health, food, and education⁴⁹.

Yet, the prospect of recognizing human rights and intellectual property rights as two opposing agendas, although attractive, carries the need to clarify certain ambiguities. It should be noted that certain categories of human rights, such as prohibition of torture and slavery, are widely regarded as dominant over obligations resulting from treaty regulations. Consequently, any system of intellectual property rights that hinders the fulfilment of the obligation to protect the right to health must be regarded as incompatible with the provisions of the Pact⁵⁰. Therefore, due to their fundamental nature, obligations to protect human rights take privilege over agreements of a commercial nature⁵¹, which also includes the TRIPS Agreement⁵². Nonetheless, it should be noted that although we intuitively assume that patent rights limit the availability of medicines, without the protection resulting from intellectual property rights, many drugs which have contributed significantly to improving public health and lengthened the average life span of patients globally would not have been created⁵³.

In this context, the important role of human rights seem to come to the forefront: they are an instrument for the prevention of abuse of intellectual property rights and the restoration of their balance, taking into account the interests of both the beneficiaries of protection and the general public⁵⁴. The need for maintaining balance was noticed by the Committee on Economic, Social and Cultural Rights, which emphasized that:

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⁴⁶ M. Barczewski, Intellectual Property…, p. 171.


Article 15 of the Covenant describes the need to balance the protection of public and private interests in the field of knowledge. On the one hand, Article 15.1 (a) and (b) recognizes the right of everyone to participate in cultural life and enjoy the benefits of scientific progress. On the other hand, Article 15.1 (c) recognizes the right of everyone to enjoy the protection of the moral and material profits resulting from any scientific, literary or artistic production of which he is the author. While adopting and modifying the intellectual property systems, countries should bear in mind the need to maintain a balance between these provisions of the Covenant. In order to encourage creativity and innovation, individual interests should not be unduly favoured and public interests, consisting of broad access to knowledge, should be duly taken into account\(^\text{55}\).

4. Interpretation and implementation of the TRIPS Agreement as a means of strengthening the right to public health

Many of the provisions of the TRIPS Agreement are referred to as “constructively ambiguous”, because, as an effect of compromise between the negotiating countries, the terms and phrases used in the provisions were deliberately not clearly defined, leaving room for interpretation in national law\(^\text{56}\). In Article 3 clause 2 of Understanding on rules and procedures governing the settlement of disputes\(^\text{57}\) it was therefore indicated that the interpretation of agreements shaping the WTO should be made in accordance with the customary principles adopted in public international law. Referring to the standards stemming from Articles 31 and 32 of the Vienna Convention on the Law of Treaties\(^\text{58}\), it should be assumed that the context used for the correct interpretation of the TRIPS Agreement is primarily its entire content, including the preamble, as well as Articles 7 and 8, which define the objectives and principles of the Agreement, respectively\(^\text{59}\).

As Peter K. Yu points out\(^\text{60}\), these two provisions codify the multilateral norms concerning the protection of the public interest in intellectual property law\(^\text{61}\). As such, they “qualify the scope of harmonization of intellectual property standards at the national level”\(^\text{62}\). Article 7 of the TRIPS Agreement sets out the objectives of the agreement, stating that

> the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

\(^{55}\) Substantive Issues… (E/C.12/2001/15), pt. 17. There is a prevailing view that the beneficiaries of the protection provided for in Article 15(1) of the Covenant on Economic, Social and Cultural Rights are creators that are natural persons, and not legal entities, such as pharmaceutical companies – General Comment No. 17 (E/C.12/GC/12), United Nations Committee on Economic, Social and Cultural Right, 12 January 2006, pt. 7; H. Hestermeyer, Human Rights…, p. 155; P. Xiong, An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement. An Interpretation of the TRIPS Agreement in Relation to the Right to Health, Leiden 2012, p. 265.

\(^{56}\) M. Barczewski, Intellectual Property…, p. 73.

\(^{57}\) Annex 2 of the WTO Agreement.


\(^{59}\) M. Barczewski, Intellectual Property…, pp. 73–74.


Furthermore, the principles expressed in Article 8 allow member states of the WTO to adopt, in formulating or amending their laws and regulations, “measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.” In the context of the problem of access to medicines it therefore requires special emphasis on highlighting the importance of that provision in the interpretation and subsequent implementation of the TRIPS Agreement norms need to protect public health.

Use of general and imprecise concepts, such as “public health” or “national emergency” in the TRIPS Agreement, encourages, based on the relevant provisions of the Vienna Convention, references to other treaty regulations in the interpretation process, especially those regarding the protection of human rights. Thus, if we accept a broader conceptual referent of “national emergency” that would include serious public health emergencies arising from infectious disease epidemics, the possibilities to limit or repeal patent protection based on that provision due to the need to ensure protection of health cannot be excluded. As noted by Jerome H. Reichman, in principle, both the public interest exception and measures to prevent abuse, stipulated in Article 8 of the TRIPS Agreement, could justify resort to compulsory licensing. For example, this kind of broad interpretation of the concept of national emergency became the basis for the introduction of a compulsory licensing system in Brazil in the late 1990s, which helped reduce the number of HIV/AIDS cases in that country by more than a half.

The possibility of compulsory licensing was allowed as early as in 1958 by the Paris Convention. In accordance with the current wording of Article 5A thereof, the parties to the Convention may issue compulsory licenses and determine the conditions for their application “to prevent abuses which might result from exercising exclusive rights conferred by a patent, for example, failure to work”. In 1982, the demands from developing countries which pursued to introduce the system of compulsory licenses led to a crash of the negotiations over the adoption of another revision of the convention. Within the framework of the TRIPS Agreement, Articles 30 and 31 lay down a set of conditions for issuing compulsory patent licenses. While Article 30 allows for exceptions of rights conferred by a patent provided they “limited”, “do not unreasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner” and “take into account the legitimate interests of third parties”, Article 31 does not mention the need to meet such conditions to use the subject matter of a patent without the authorization of the right holder. It specifies the possible use of the subject matter of a patent through the introduction of compulsory

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63 According to Gillian Davis, “whether a particular act is “in the public interest” (...) is probably not subject to any objective tests. Inherent in the noble motive of the public good is the notion that, in certain circumstances, the needs of the majority override those of the individual, and that the citizen should relinquish any thoughts of self-interest in favor of the common good of society as a whole”. G. Davies, Copyright and the Public Interest, London 2002, p. 4.
licenses\textsuperscript{69}. It is assumed that they should not be granted just upon the patent holder’s refusal to allow the use of an invention. Against the background of Article 7 and Section 4 of the preamble to the TRIPS Agreement, the rights and obligations must not be balanced by means of weakening the protection of patent holders without consideration for the interest of the society as a whole. Thus, it is assumed that only broadly understood public interest can legitimize the issuance of compulsory licenses\textsuperscript{70}.

Furthermore, the need to interpret and implement the TRIPS Agreement in a way that supports the right to protect public health was expressed directly in the Declaration on the TRIPS Agreement and Public Health of 14 November 2001\textsuperscript{71}. Member states of the WTO agreed in paragraph 4 of the Declaration that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, its signatories affirmed that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all. They also recognized that each provision of the TRIPS Agreement should be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles (set out in Articles 7 and 8).

Furthermore, the Declaration acknowledged that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing. Therefore, it was put into practice in 2003 by the WTO with a decision enabling countries that cannot manufacture medicines themselves, to import pharmaceuticals made under compulsory licences\textsuperscript{72}. In 2005, Members agreed to make this decision permanent through a Protocol Amending the TRIPS Agreement\textsuperscript{73}, which entered into force on 23 January 2017. This amendment provided legal certainty that generic versions of patent-protected medicines can be manufactured under compulsory licences specifically for export to countries with limited or no pharmaceutical manufacturing capacity\textsuperscript{74}.

It can therefore be assumed that, by clarifying interpretative doubts, the Declaration on the TRIPS Agreement and Public Health has contributed to increasing the legal certainty of WTO members with regard to the application of the TRIPS Agreement standards, in particular in the field of protection of medicines. Its persuasiveness in this respect is comparable to the indications resulting from Articles 7 and 8 of the TRIPS Agreement and led to the strengthening of WTO members’ freedom in the field of public health protection.

5. Concluding remarks

Advocates of strong intellectual property protection invoke the prospect of material reward as a key argument to justify the existence and validity of intellectual property rights. Under this approach, strongly rooted in the doctrine of utilitarianism, the

\textsuperscript{69} M. Barczewski, Intellectual Property... p. 109.
\textsuperscript{71} Declaration on the TRIPS Agreement and Public Health (WT/MIN (01)/DEC/2), WTO, 14 November 2001.
\textsuperscript{73} Amendment of the TRIPS Agreement. Decision of 6 December 2005 (WT/L/641), WTO, 8 December 2005.
\textsuperscript{74} Intellectual Property and the Public Interest... (IP/C/W/630), pt. 5.
prospect of receiving remuneration is to motivate intellectual activity\textsuperscript{75}. As a result, all intellectual property law norms reflect the intention to protect the interests of, first and foremost, entities based in industrialized countries, only partly taking into account the conditions of less developed countries related to the need for unrestricted access to cultural heritage or health protection\textsuperscript{76}.

On the other hand, as rightly noted by A. Slade, primary justification for intellectual property protection is the value it holds for the dissemination of knowledge and the transfer of technology both nationally and internationally. The utility of the intellectual property system rests not merely in protecting the interests of the rights holder, but in doing so for the wider public interest. Moreover, the protection of intellectual property is often premised upon social contract theories: society grants the inventor or creator a selection of exclusive rights and in return, the inventor or creator grants full disclosure – the “intellectual property bargain”. Thus, the system is of wider interest to society, which is now free to use that knowledge and information (albeit subject to the requisite licensing arrangements). This use in turn fosters further innovation, creation, and improvement\textsuperscript{77}.

According to the prevailing view, utilitarian approach has been adopted as a standard in international IP norm setting, i.e. creations of the human mind are necessary for the development of society and various forms of a reward are deemed to be the incentive for such creative activity\textsuperscript{78}. This approach influenced most of the international IP related agreements, including the TRIPS Agreement\textsuperscript{79}. Yet, it is difficult to ignore the fact that over-reliance on utility-maximization ignores distributional consequences and equality concerns are second order concerns to efficiency norms\textsuperscript{80}. In such a spectacular plane of collision between the protection of property interests and the protection of health, and therefore life, we are faced with the need to formulate new ethical and legal standards.

Undoubtedly, there is a public interest in defining the boundaries of IP-related components that determine access to medicines. As noted above, the meaning of public interest depends on the current social context in the sense of achieving specific values accepted and desired in a given society at a given time. One of the essential measures that can contribute to accomplishing these goals is the broadest possible use of compulsory licenses, also with respect to the results of preclinical and clinical trials. Another instrument is the process of interpretation of the TRIPS Agreement which aims at not only explaining or clarifying the meaning of the provisions or determining the intentions of the parties to the treaty, but also at reconciling the underlying competing goals and objectives of this Agreement\textsuperscript{81}. The need to interpret and implement its provisions in a way that protects public interest by facilitating universal access to medicines is confirmed by the obligation of acting “in a manner conducive to social and economic welfare” under Article 7 of the TRIPS Agreement. Moreover, Article 8 allows to adopt

\textsuperscript{76} M. Barczewski, \textit{Własność intelektualna…}, p. 78.
\textsuperscript{77} A. Slade, \textit{The Objectives…}, p. 967 (footnotes omitted).
\textsuperscript{80} M. Chon, \textit{Intellectual Property and the Development Divide, “Cardozo Law Review” 2006/6, p. 2824.}
\textsuperscript{81} P. Xiong, \textit{An International Law…}, p. 330.
“measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development”. Therefore, when it comes to access to medicines, human rights are an important instrument for the prevention of abuse of intellectual property rights and the restoration of their balance, taking into account the interests of both the beneficiaries of protection and the general public.

Abstract: Over the past few years the WTO Council for Trade-Related Aspects of Intellectual Property Rights recognized the growing concern over an imbalance between intellectual property and public interest. With regard to health technologies in particular, without sufficient use of balancing exceptions and limitations, patents and related monopoly rights primarily serve to protect corporate interests of the pharmaceutical industry. The broadest possible use of compulsory licenses is one of the essential measures that can contribute to increase in responsiveness to public interest considerations in defining the boundaries of the IP-related components that determine access to medicines. Another instrument is the process of interpretation and implementation of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), which aims not only at clarifying the meaning of the provisions or determining the intentions of the parties to this treaty, but sets sights on reconciling its competing objectives. The need to interpret and implement the TRIPS Agreement in a way that protects public interest is confirmed by the obligation of acting “in a manner conducive to social and economic welfare” under Article 7 of the Agreement. Moreover, Article 8 allows to adopt “measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development”. Therefore, in the context of the problem of access to medicines, the important role of human rights as an instrument for the prevention of abuse of intellectual property rights and the restoration of their balance, taking into account the interests of both the beneficiaries of protection and the general public, should be emphasized.

Keywords: intellectual property, WTO, human rights, public interest, patents, access to medicines, TRIPS