DYLEMATY STRATEGICZNE XXI WIEKU

Księga Jubileuszowa
dedykowana Profesorowi
Michałowi Chorośnickiemu
z okazji czterdziestolecia
pracy naukowej

Pod redakcją naukową
Roberta Kłosowicza
Bogdana Szlachty
Janusza Józefa Węca

Dylematy strategiczne XXI wieku

Dylematy strategiczne XXI wieku

Księga Jubileuszowa dedykowana Profesorowi Michałowi Chorośnickiemu z okazji czterdziestolecia pracy naukowej

Pod redakcją naukową
Roberta Kłosowicza
Bogdana Szlachty
Janusza Józefa Węca

Kraków 2013

Recenzent: prof. dr hab. Andrzej Zięba

Opracowanie redakcyjne: Dagmara Małysza, Justyna Wójcik

Korekta: Mateusz Kijewski

Projekt okładki: Igor Stanisławski

Skład i łamanie: Małgorzata Manterys-Rachwał

Publikacja dofinansowana
przez
Wydział Studiów Międzynarodowych i Politycznych Uniwersytetu Jagiellońskiego

ISBN 978-83-7638-375-0

KSIĘGARNIA AKADEMICKA
ul. św. Anny 6, 31-008 Kraków
tel./faks: 012 431-27-43, 012 421-13-87
e-mail: akademicka@akademicka.pl

Księgarnia internetowa:
www.akademicka.pl

Spis treści

Część pierwsza. Historia – państwo – prawo

Część druga. Polityka międzynarodowa

TABULA GRATULATORIA

Piotr Bajor
Piotr Borowiec
Krystyna Chojnicka
Anna Citkowska-Kimla
Zbigniew Czubiński
Krystyna Daniel
Agnieszka Dębska
Andrzej Dudek
Magdalena Geodecka
Irena Głuszyńska
Marcin Grabowski
Łukasz Jakubiak
Małgorzata Jasińska
Agnieszka Kastory
Piotr Kimla
Małgorzata Kiwior-Filo
Beata Kosowska-Gąstoł
Grzegorz Kowalski
Wiesław Kozub-Ciembroniewicz
Renata Król-Mazur
Małgorzata Kułakowska
Roman Kuźniar
Michał Matyasik
Maciej Miżejewski
Tomasz Młynarski
Ewa Myślak
Agnieszka Nowakowska-Swół
Dorota Pietrzyk-Reeves
Agnieszka Podoba
Marta Polaczek-Bigaj
Błażej Sajduk
Dominik Sieklucki
Agnieszka Sikora
Jacek Sokołowski
Irena Stawowy-Kawka
Krzysztof Szczerski
Paweł Ścigaj
Monika Ślufińska
Damien Thiriet
Adrian Tyszkiewicz
Magdalena Ullman-Kulik
Tomasz Wieciech
Rafał Wordliczek
Rafał Woźnica
Andrzej Zięba
Agnieszka Zyza

Sylwia Rasson
Vrije Universiteit Brussels

The Human Right to Health Versus Intellectual Property Rights in the Context of Developing Countries

This paper is focused mainly on the international patent regime as approached from the public health perspective. The primary emphasis has been put on the access to patented medicines in developing countries, which face tremendous difficulties when it comes to paying for drugs manufactured by companies located in developed countries.

Without any doubt, the right to health not only exists, but also is one of the most important human rights. The World Health Organization (WHO) estimates that 50 low- and middle-income countries have insufficient access to generic medicines[1]. The question remains whether the right to health is more important than intellectual property rights. Some people believe that the right to access to pharmaceuticals is implicit to the right to health. Others strongly disagree with such an interpretation. Human rights are implicitly recognized in Art. 8.1 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), but that article is only applicable to the extent that the adopted measures are "consistent with the provisions of this Agreement". The assessment of the relationship between patent rights and human rights has resulted in several findings, such as those by the UN Sub-Commission on the Promotion and Protection of Human Rights. Also, the World Intellectual Property Organization admits that conflicts may exist between the two[2]. The question of importance and priority remains mostly unanswered.

[1] World Health Organization, http://www.who.int/topics/millennium_development_goals/medicines/en/. Generic medicine is a drug which is produced and distributed without patent protection; almost identical to the brand name counterpart; in most cases, generic products are available once the patent protection afforded to the original developer has expired.

[2] H.M. Haugen, *Patent Rights and Human Rights: Exploring their Relationships*, „The Journal of World Intellectual Property" vol. 10, 2007, no. 2, p. 97 (arguing, analyzing the relationship between the right to food and the TRIPs Agreement, that the relationship between the two is based on an established understanding of conflict in international law, namely incompatible obligations).

The right to health is internationally recognized and guaranteed in several international human rights instruments[3]. Art. 25 of the Universal Declaration of Human Rights states that everyone has the right to "a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care". The International Covenant on Economic, Social, and Cultural Rights has a similar provision: art. 12(1) constitutes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"; articles 12(2)(c) and 12(2)(d) let the states take the necessary measures for "the prevention, treatment and control of epidemic, endemic, occupational and other diseases" and "the creation of conditions which would assure to all medical service and medical attention in the event of sickness"[4]. The right to health is also recognized in: the Convention on the Elimination of All Forms of Discrimination against Women, the European Social Charter, the International Labor Organization's Convention 102 Concerning Minimum Standards of Social Security, and in other international agreements. The 1946 Constitution of the WHO affirms that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions"[5].

On the other hand, intellectual property rights are currently not only trade-related rights, but also are considered – at least partially – human rights according to art. 27(2) of the Universal Declaration of Human Rights which states that "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author". Art. 15(1)(c) of the International Covenant on Economic, Social and Cultural Rights has a similar provision. Several human rights instruments recognize a human right to one's own intellectual products[6].

A range of international human rights instruments affirm that good health is a precondition for the enjoyment of all other human rights. Our common sense leads to a conclusion that the right to health is more important than intel-

[3] The right to health has been defined in a number of different ways. Obligations under the right to health require mainly access to medical treatment for serious illnesses and lack of discrimination based on personal wealth or income. See: P.L. Wojahn, *A Conflict of Rights: Intellectual Property Under Trips, the Right to Health, and Aids Drugs*, „The UCLA Journal of International Law and Foreign Affairs" vol. 6, 2001, afl. 2, p. 473.

[4] B. Binkert, *Why the Current Global Intellectual Property Framework under TRIPS Is Not Working*, „The Intellectual Property Law Bulletin" vol. 10, 2006, p. 157.

[5] D.M. Chirwa, *The Right to Health in International Law: Its Implications for the Obligations of State and Non-state Actors in Ensuring Access to Essential Medicine*, „The South African Journal on Human Rights" vol. 19, 2003, p. 553 (arguing that it is clear that although the various international and regional human rights treaties define the right to health differently, access to essential medicine form is a central part of the right to health. The duty to provide essential medicines is a minimum and non-derogable core obligation inherent in the right to health).

[6] P.K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, „The UC Davis Law Review" vol. 4, 2007, p. 1070.

lectual property rights, and that is the reason why the right to health should be given a priority in conflicting situations[7]. Access to medication, treatment and care is indeed an essential element of effective responses to diseases. However, the issue is not so obvious, especially if we take into account that intellectual property rights can encourage development of life-saving medicines. Pharmaceutical companies need business incentives to invest in the expensive research and development. There would not be a generic version of a medicine if an innovative drug company had not first developed a patented version of the product. Those innovative companies are responsible for extraordinary advances in public health[8]. A human rights approach to intellectual property rights emphasizes what is often an implicit balance between the rights of inventors and the interests of the wider society – a broader goal is to improve human welfare. Intellectual property protection is understood more as a social product with a social function[9]. In order for intellectual property to fulfil the conditions necessary to be recognized as a universal human right, intellectual property regime should be consistent with the realization of all other internationally recognized human rights[10]. But it is at the same time difficult to argue that intellectual property should be always subordinated to other fundamental human rights in the event of a conflict between the two[11]. The health of patients, especially in poorer countries, depends upon finding the right balance between access to innovation and innovation, as such[12].

In a global world with a global economy, a debate on intellectual property versus right to health has become intense. With increasing globalization of trade and the rising importance of intellectual property in the 1980s, many developed nations became concerned with the lack of strong protection of intellectual property rights[13]. Global intellectual property rights primarily have been pursued through the TRIPS[14]. The TRIPS Agreement provides a framework for the member states to integrate intellectual property standards into national legislation and it is the most ambitious international intellectual property treaty ever attempted. TRIPS is a minimum standard agreement – the states are free to provide more extensive protection of intellectual property.

---

[7] D.M. Chirwa, *op. cit.*, p. 541; A.L. Taylor, *Making the World Health Organization Work. A Legal Framework for Universal Access to the Conditions for Health*, „American Journal of Law & Medicine" vol. 18, 1992, p. 311.

[8] Ch.B. Rangel, *Moving Forward: A New, Bipartisan Trade Policy that Reflects American Values*, „The Harvard Journal on Legislation" vol. 45, 2008, p. 401.

[9] A.R. Chapman, *The Human Rights Implications of Intellectual Property Protection*, „The Journal of International Economic Law" vol. 5, 2002, no. 4, p. 867.

[10] *Ibidem*, p. 868.

[11] P.K. Yu, *op. cit.*, p. 1042.

[12] Ch.B. Rangel, *op. cit.*, p. 401.

[13] P.L. Wojahn, *op. cit.*, p. 476.

[14] B. Binkert, *op. cit.*, p. 143.

In the area of patent protection, TRIPS represents a compromise between developed countries seeking to increase protection of the intellectual property rights and developing countries seeking to limit their obligations to protect intellectual property. Among others, TRIPS allows for inventions relating to "active ingredients" in medicines to be patented. It also prescribes a minimum patent term of 20 years for all types of inventions. During that patent term, the patentee enjoys a right of sole use over his patent. Although some exceptions have occurred, the patentee is generally able to set the price of the medicine, determining where it is sold and to whom[15]. Developing countries began to voice concerns over many of the proposals in TRIPS, arguing that the tone of the negotiations concentrated only on the owners of intellectual property rights, and that the effects on the consumers of intellectual property should also be equally considered. In practice the TRIPS Agreement established global standards for stringent protection of patents for new pharmaceutical developments. According to some voices, strict protection of intellectual property rights raises the prices of pharmaceuticals, blocking access to these drugs for people in developing countries[16]. The voices argue that TRIPS does not balance the interests properly – after the enactment of TRIPS, many developing countries going through health crises have been faced with a dilemma: provide their population with affordable drugs, or risk violating TRIPS.

However, the TRIPS Agreement acknowledges itself its attempt to balance private and public interests. The Preamble of TRIPS recognizes the "special needs of the least-developed Member States with respect to flexibility in domestic implementation of TRIPS. Art. 8 TRIPS affirms that "members may, in formulating or amending their law and regulations, adopt measures necessary to protect public health". Art. 7 speaks of "a balance of rights and obligations". It affirms that the transfer and dissemination of technology should be to the mutual advantage of both producers and users, should be made in a manner conductive to social and economic welfare, and should be expressed free of conditions. Art. 27 TRIPS allows a country to exclude an invention from patentability if exclusion is necessary to prevent commercial exploitation of that invention within the country's territory "to protect public order or morality, including protecting human, animal or plant life or health". This provision permits countries to refuse a patent for pharmaceuticals, the exploitation of which would be contrary to public order[17]. Art. 30 provides additional flexibilities by way of exceptions to the exclusive rights granted by a patent. It clarifies that such exceptions may be permitted "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".

[15] A.H. Khoury, *The Public Health of the Conventional International Patent Regime & the Ethics of Ethicals: Access to Patented Medicines*, „Cardozo Arts & Entertainment Law Journal" vol. 26, 2008, p. 27.

[16] P.L. Wojahn, *op. cit.*, p. 463, 478.

[17] *Ibidem*, p. 480.

Accordingly, governments can undertake two types of actions in attempts to offset the imbalance. Certain provisions in the Treaty allow countries, in case of national emergency, to permit private manufactures to produce generics, subject to certain conditions, through compulsory licensing. Art. 31 TRIPS authorizes members to adopt limited exceptions to these exclusive rights when necessary "to protect public health and nutrition, to promote the public interest in sectors of vital importance to their socio-economic and technological development and to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology"[18]. That article sets up a regulatory framework for compulsory licensing that allows governments to issue compulsory licenses in order to permit the generic production of essential medicines without the consent of patent holders. This method in practice allows the production of patented medicines. In addition, countries can use parallel importing, or importing of competing generic goods from other countries (so-called 'gray market goods'), to provide cheaper access to necessary drugs. Parallel import means in practice the importation of cheaper generic versions of patented medicines. The goal of those two strategies is to provide greater access to drugs[19]. As a result, the poorest countries, known as the least developed countries, are exempt from the TRIPS intellectual property protection obligations. The exemption will last until July, 2013 and will probably be prolonged[20].

The issue of access to patented medicines brings a theoretical debate regarding values, social priorities, allocation of public and private goods, and the purpose of intellectual property law. From the outset it is important to stress that access to patented medicines constitutes only one component of effective disease treatment, which relies on a long chain of factors. States and individuals have obligations to engage in disease prevention which remains crucial. Without any doubt, the development of new drugs is an expensive, complicated, time-consuming, and very risky process. Fewer than one in one thousand new drugs created by researchers survive clinical trials and make it to the market. It costs in America on average between 800 million and 1.3 billion U.S. dollars of private investment,

[18] M.V. Stout, *Crossing* …, p. 188.

[19] P.L. Wojahn, *op. cit.*, pp. 463-464. A.H. Khoury, *op. cit.*, p. 54. G.E. Evans, *Strategic patent licensing for public research organizations: Deploying restriction and reservation clauses to promote medical R&D in developing countries*, „American Journal of Law & Medicine" vol. 34, 2008, pp. 181-182. Access to medicines depends also on factors unrelated to intellectual property, such as the level of import duties, taxes, and local market approval costs. See: The High Commissioner, Report of the High Commissioner on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, 10-15, 27-58, U.N. Doc. E/CN.4/Sub.2/2001/13, 27 VI 2001, p. 43.

[20] WTO members, meeting on 5-6 March 2013, accepted that the deadline for least developed countries to protect intellectual property generally could be extended beyond the current 1 July 2013 date. But they were still undecided on whether to set a new deadline or leave it until each country "graduates", [on-line] http://www.wto.org/english/news_e/news13_e/trip_05mar13_e.htm, dostęp: 15 VI 2013.

and between 8-12 years to develop a new drug and to bring it on the market. The development costs are increasing, while success rates in developing new drugs remain low. Only 20-30% of drugs in the final stages of testing end up receiving market approval[21]. If intellectual property regimes were abolished today, drug development would cease dramatically, and all of us, either in developed or developing countries, would be left only with drugs that we currently have on market. Nobody would want that, especially as there are still many existing and emerging diseases and conditions for which we would like treatments and cures. In the above mentioned context, intellectual property rights act as an incentive for the innovation of new technology of crucial importance.

On the other hand, a system based on commercial motivation does not always work well in producing medicines appropriate for the needs of the poorest countries. Some commentators believe that strong patent rights, secured by the current intellectual protection regime, have empowered pharmaceutical companies to capitalize on their achievements to the highest extent. Pharmaceutical corporations have been able to obtain global patent protection, enabling them to set the prices of their medicines, to grant patent licenses, and to enforce their patent rights in national courts, paving the way for market dominance. Pharmaceutical industry also prefers directing its research towards rather "profitable" diseases in markets where the return is likely to be great. Diseases that affect people in poorer countries such as tuberculosis or malaria are considered to be risky investments[22]. Patent protection is expansive under TRIPS and benefits the pharmaceutical companies, which are primarily located in developed countries. TRIPS and free trade agreements which establish even stricter standard of intellectual property rights than TRIPS, have given pharmaceutical corporations great powers in their endeavours to protect their drug patents around the globe. Such protection has made it much more difficult for poor countries to secure a sustained supply of medicines at affordable prices for their citizens. Indeed, TRIPS legislative history shows that developing countries have adopted TRIPS standards, including those relating to patents, not by choice but out of a necessity, fearing the risk of not attaining WTO membership, losing foreign investments or bearing economic sanctions that other WTO member states can impose on the non-compliant developing country[23].

Those who remain sceptical of the existing patent regime cite various reasons for their concern over the access to patented medicines. In their view, enforcement of severe international patent regime leads to higher prices for medicines.

[21] *Intellectual Property: Does Ip Harm or Help Developing Countries*?, Convention Proceedings Panel Discussion, 2006 National Lawyers Convention, Panelists: Alex M. Azar, Graeme B. Dinwoodie, Jerome H. Reichman, Robert Sherwood, Bruce A. Lehman, „University of Illinois. Journal of Law, Technology & Policy" vol. 65, 2007, p. 67.

[22] A.R. Chapman, *op. cit*, pp. 877-878. A.H. Khoury, *op. cit.*, p. 34.

[23] A.H. Khoury, *op. cit.*, p. 45.

The high prices may prevent developing countries from purchasing the products for the benefit of their citizens, or might compel such countries to reduce other health-related expenses such as investments in hospitals, labs and machines.[24] The main reason for the price increase is that TRIPS rules disallow (with some exceptions) the use of generic versions of patented medicines. The inability to use generic drugs creates a serious setback for developing countries because the low cost generic drugs have proved to be life-savers in many developing countries such as Brazil, Cameroon, South Africa, Thailand, and Kenya[25]. Generic versions of medicines can lead to improved access in developing countries by dramatically lowering the costs. For example, not long ago a year of antiretroviral treatment for HIV infections cost approximately $10,000 per patient. Once generic alternatives became available, the average cost of treatment dropped to less than $100[26].

Taking into consideration two sets of arguments, one can distinguish two opposite approaches. The first approach states that patent protection should end where saving lives begins. In other words, patent law should be subordinate to certain social interests. The second approach indicates that medicines should be treated in the same manner as any other inventions, and that their prices should be determined by the patentee, in accordance with the rules of supply and demand. While the first approach is driven by pure socio-humanitarian motives, the second is based on the incentive to innovate[27].

The main justification for allowing access to patented medicines is that patent rights benefiting the innovator also carry with them social responsibilities. Patented medicines possess the unique properties of alleviating pain and suffering, and prolonging life. This is so due to the fact that while medicines are undisputedly commercial goods, they also constitute a "common heritage of mankind". Because of these attributes, drug patent owners should be subjected to the dictations of global ethics and responsibility. According to an expert commissioned by the United Nations, "improving access to existing medicines could save 10 million lives a year. Access to medicines is characterized by profound global inequality: 15 percent of the world's population consumes over 90 percent of the world's pharmaceuticals"[28]. A patent regime with a strong mechanism for access to

[24] Research shows that medicines account for over 80% of health expenses in developing countries. However, there are about 300 essential medicines on the WHO list of essential medicines of which only very few are under patent protection. The problem is that still at least 2/3 of the people in the developing world don't get those medicines, which are no longer under patent protection. Besides, high-income countries like India, China, and Brazil are struggling to maximize the benefits and minimize the costs of these intellectual property rights. They have cultural and high-tech industries that are profiting, but they also have problems in their public health sector.

[25] A.H. Khoury, *op. cit.*, p. 42.

[26] CH.B. Rangel, *op. cit.*, p. 401.

[27] A.H. Khoury, *op. cit.*, p. 42.

[28] UN Rights Export Unveils Draft Guidelines for Drug Companies on Vital Medicines, UN News Service, 25 X 2007, [on-line] http://www.un.org/apps/news/story.

patented medicines would generate more support because it would be deemed to contribute to the creation of a more balanced and moral regime[29].

History shows that public health in developing countries takes sometimes precedence over intellectual property protection. Many developing countries are facing health epidemics such as tuberculosis, malaria, and HIV/AIDS but do not have access to effective and often expensive drugs. For instance, there are more than 30 million people across the globe infected by HIV, 70 percent of whom live in Africa. Although the cure for HIV/AIDS remains unknown, antiretroviral medicines had proved to be effective in reducing death rates in high-income countries[30]. In reaction to the health crises, South Africa and several developing countries in Latin America[31] started to change their domestic laws to combat health crises, which in turn angered developed nations because these laws were in violation of TRIPS[32]. In South Africa, of a total population of 39 million people, 5 million have HIV. With HIV/AIDS medications prices ranging from $160 to $1,740 per month per person in 1992, the South African government passed the law which allowed for parallel imports and compulsory licensing. In response to those actions, the US engaged in a court press against South Africa, together with 39 pharmaceutical plaintiffs, challenging the 1998 amendments[33]. Eventually, the Clinton administration reversed some of its more draconian trade threats against South Africa, as a result of intense domestic and international pressure. The private lawsuit was also dropped[34]. A legal standoff occurred between pharmaceutical corporations and the South African government over the latter's authorization to use generic substitutes of patented drugs. This standoff constitutes a classic example of how much is at stake for the both parties. While pharmaceutical corporations were asserting their patent rights, the South African government was citing its obligation towards its citizens to provide them with affordable medicines[35]. Although South Africa later amended its law in response to an outcry by international drug companies, the event is demonstrative of financially-strapped governments disregarding TRIPS, if there is a pressing health crisis. Because the

asp?NewsID=24423&Cr=Health&Crl, dostęp: 15 VI 2013 (discussing the testimony of professor Paul Hunt).

[29] A.H. Khoury, *op. cit.*, pp. 44-46.

[30] AIDS Law Project & The AIDS Legal Network HIV/AIDS and the Law: A resource manual (2ed), 2001, p. 25.

[31] An estimated 1.6 million Latin Americans live with HIV/AIDS, the second leading cause of death in the region. See: M.V. Stouta, *Crossing the TRIPs Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Art. 27.1*, „Boston University Journal of Science & Technology Law" vol. 14, 2008, p. 177.

[32] B. Binkert, *op. cit.*, p. 157.

[33] B.K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and patent/ Registration Linkage*, „American Journal of Law & Medicine" vol. 34, 2008, p. 317.

[34] *Ibidem.* p. 318.

[35] A.H. Khoury, *op. cit.*, p. 43.

HIV/AIDS crisis is so widespread in Africa, the South African scenario is a real possibility for many other African countries. Similar health crises such as flu and famine will likely induce similar disregard for protection of patents, and countries in crisis will produce whatever medication is necessary to effectuate the population's access to drugs at affordable prices[36].

A similar standoff over generic drugs for treating HIV/AIDS patients took place in Thailand. That impasse involved the use of generic versions of Didanosine and Fluconazole, both brand-name drugs sold at high prices. Thailand's actions have prompted trade retaliation by the US, and that, in turn, caused Thailand to challenge the patentability of Didanosine. That patent was a broad formulation patent, granted in 1998. One effect of its issuance was that Thailand had to stop production of the generic version. Doubts about the validity of the patent led to a civil society campaign that included litigation to revoke the patent. The case settled in 2003 and the patent was eventually withdrawn. Fighting involved a large number of government and civil actors in Thailand, and lasted almost six years to produce a result in which the company simply withdrew the patent. These kinds of patent litigation exercises require many civil society activists to coordinate and find resources to fight a case, over a period of years. Thailand has a strong NGO health movement and is one of the few developing countries in which a civil society movement could have mobilized in this way[37].

According to critical voices, too broad guarantee of intellectual property rights proved to be in conflict with the right to health because it prevented many people from having access to much needed drugs[38]. In 2001 the WTO Ministerial Conference in Doha adopted a Declaration on the TRIPS Agreement and Public Health which addressed the heated debate between developed and developing countries with respect to access to patented medicines. The Doha Declaration emphasized the gravity and primacy of developing countries' public health needs, clarified states' right to promote access to medicines for all and reconfirmed countries' broad discretion to issue compulsory licenses and to permit parallel importation. The Doha Declaration can be seen as an important political statement that clarifies certain flexibilities that already existed in TRIPS. It recognizes the importance of intellectual property rights for the development of new medicines; however, at the same time it acknowledges the notion that developing countries may exclude pharmaceutical drugs from patent protection when faced with a public health crisis[39]. In 2003, the WTO General Council decided to effectuate temporary legal changes in TRIPS that would allow a country to produce drugs under a compulsory license in order to export those drugs to an importing

[36] B. Binkert, *op. cit.*, p. 158.

[37] P. Drahos, *„Trust Me": Patent Offices in Developing Countries*, „American Journal of Law & Medicine" vol. 34, 2008, pp. 151-166; A.H. Khoury, *op. cit.*, p. 43.

[38] P.L. Wojahn, *op. cit.*, p. 466; A.H. Khoury, *op. cit.*, p. 37.

[39] B.K. Baker, *op. cit.*, p. 319; B. Binkert, *op. cit.*, p. 158.

country with insufficient manufacturing capabilities. This change aimed to strengthen access to patented medicines by authorizing countries that could not produce the medicines themselves. Two years later, the change was approved as a permanent change to TRIPS. Those actions demonstrate that the WTO is trying to deal with public health crises in developing countries[40].

As a matter of fact, the Doha Declaration does not open up new ways within TRIPS, but reinforced by various instruments of the UN affirming the human right to health, confirms the legitimacy of measures seeking to invoke the norms already existing in the Agreement. In relying on these flexibilities, it should be possible for developing countries to procure medicines either by means of compulsory licensing or parallel import, or by making exceptions to the rules of patent rights in their countries in order to facilitate the manufacture of generic pharmaceuticals[41]. The Doha Declaration provides a procedure by which WTO members can issue a compulsory license for the purpose of exporting pharmaceuticals to countries that otherwise meet the requirements for compulsory license under TRIPS but have insufficient manufacturing capacities to make effective use of the compulsory licensing provisions. However, countries benefiting from the Doha Declaration cannot then permit or support the export of these humanitarian drugs to countries that could otherwise afford to pay for them[42].

Although the Doha Declaration confirms the TRIPS exceptions to patent rights, when it comes to taking actions based on those exceptions, developing countries are reluctant because WTO case law indicates that these exceptions are narrow and because the US and the EU, via bilateral trade agreements, use their economic and political power to dissuade developing countries from restoring to compulsory licensing and parallel import. Mindful of foreign direct investment and access to the markets of the US and the EU, when negotiating bilateral free trade agreements, developing countries have been reluctant to invoke the flexibilities of the TRIPS Agreement as means of providing access to affordable medicines[43]. Furthermore, art. 31bis to the compulsory licensing provisions of the TRIPS Agreement, which is designed to facilitate the manufacture and export of medicines to developing countries, has been distinguished by its lack of acceptance and use. After WTO members adopted the Doha Declaration on TRIPS and Public Health, relatively few developing countries have been able or willing to actually implement its provisions.

[40] The amendment will only take effect after 2/3 of the WTO members ratify it, which has not happened so far. In April 2006, a WHO commission published also a detailed report pertaining to the access to patented medicines issue. In the report, the WHO highlighted the need for ensuring access to medicines and vaccines across developing countries. The WHO revealed that over 50% of the poorest countries in Africa and Asia do not have access to medicines due to prohibitive pricing. See: A.H. Khoury, *op. cit.*, p. 40.

[41] G.E. Evans, *op. cit.*, pp. 182-183.

[42] *Intellectual property: Does IP Harm or Help…*, pp. 69-70.

[43] G.E. Evans, *op. cit.*, p. 184.

It was not until July 2007 that Rwanda became the first country to notify the WTO that it intended to import generic versions of the HIV/AIDS drug, which is manufactured in Canada[44]. Likewise, it was not until 2007 that middle income developing countries found the political will to invoke their compulsory licensing rights under TRIPS[45].

Access to medicine is a fundamental component of the human right to health. As a consequence any state must consider its international obligations when entering into agreements that have an effect on access to medicines. States are bound to raise awareness on right to health, give sufficient recognition of the right in its domestic system, ensure the training of personnel, provide health related facilities and a health insurance system that is affordable to all[46]. On the other hand, the TRIPS Agreement constitutes a great achievement in the battle against free-riders infringing intellectual property rights. However, when affordable access to drugs is achievable through the use of generic drugs, denying access to those drugs may violate the right to health[47]. Due to conflicting nature of many international obligations put on states in different international agreements, what is worded as a right of governments to apply an exception in the TRIPS Agreement, might well be an obligation in human rights law[48]. And that is the case here.

One of the most important reasons why TRIPS allegedly does not work is the conflict between the right to health, which requires access to scientific knowledge in the form of drugs, and intellectual property rights, which seek to protect that scientific knowledge and control access to it by means of patents. This tension is not easily resolved, especially taking into consideration public health crises in developing countries. Indeed, there is a pressing need to counterbalance private- with public goods. The solution begins with committing to a new outlook on the nature of patent rights in the pharmaceutical field and with considering the issue from a wider perspective that takes human rights into account[49]. The WTO holds more TRIPS-related talks and negotiations and a satisfying solution for both developing and developed nations, as well as for pharmaceutical companies and consumers, will hopefully be developed. Perhaps drug companies will more often adjust prices downwards to increase global sales and to avoid their products being

[44] *Ibidem*., p. 183.

[45] In January 2007, Thailand issued a compulsory license to allow generic manufacture of expensive antiretroviral HIV/AIDS drugs patented by US laboratories. Brazil followed Thailand's lead, and issued a compulsory license for a lower-cost version of Merck's antiretroviral HIV/AIDS drug. In 2008 the Philippines introduced the Universally Accessible Cheaper and Quality Medicines Act with the aim of making it easier for the government to issue compulsory licenses and lower costs by allowing parallel imports of pharmaceuticals. See: G.E. Evans, *op. cit.*, p. 184.

[46] D.M. Chirwa, *op. cit.*, p. 565.

[47] P.L. Wojahn, *op. cit.*, p. 467.

[48] E.-U. Petersmann, *Introduction*, „The Journal of International Economic Law" vol. 8, 2005, no. 2, p. 354.

[49] A.H. Khoury, *op. cit.*, p. 50.

subject to a compulsory license or perhaps more governments will introduce price controls[50].

The question remains whether the interest on the part of the human rights community will influence, keeping the necessary balance, the protection of intellectual property rights. In fact in some ways it already has – through both exemptions to TRIPS and the Doha meeting initiated by human rights actors, addressing the needs of the poorest countries and reinterpreting TRIPS in a manner supportive of the protection of public health[51]. There was already a consensus built, confirming that it was morally intolerable that millions would die untreated despite the existence of drugs that could extend life. This consensus was given material form in campaigns that forced the pharmaceutical industry to vary and/or lower their prices[52], in the clear establishment of public health exceptions to TRIPS and also in other initiatives such as the formation in 2001 of a Global Fund to Fight AIDS, Tuberculosis and Malaria which provides aid and funding in order to purchase drugs consistent with the intellectual property regimes and send them to developing countries[53].

The maintenance and improvement of human physical well-being must be considered when allocating intellectual property rights. In order to maximize both benefits derived from the right to health and intellectual property rights, developing and developed countries must continuously work together to find realistic, long-term and large-scale solutions and policies that strike a fine balance between those fundamental values.

[50] B. Binkert, *op. cit.*, p. 159.

[51] A.R. Chapman, *op. cit.*, p. 881.

[52] The reason why pharmaceutical corporations set high prices for patented drugs is also that they do so in an attempt to counterbalance the effects of cheap brand medications that are shipped to developing and poor countries ending up on the shelves of developed countries' pharmacies. The logic is that the higher the price of an imported medicine, the less likely it is that it will be re-exported to the markets of developed countries.

[53] A. Berkman, *The Global AIDS Crisis: Human Rights, International Pharmaceutical Markets and Intellectual Property*, „The Connecticut Journal of International Law" vol. 17, 2002, no. 2, pp. 149-154.

www.akademicka.pl

ISBN 978-83-7638-375-0