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Magdalena Krawczyk

Jagiellonian University
Faculty of Law and Administration
The Intellectual Property Law Chair
e-mail: magda.krawczyk@doctoral.uj.edu.pl

# Compulsory Licensing of Pharmaceuticals since the Doha Declaration – a Public Health Triumph or Failure?

## Abstract

The World Health Organization has once declared antiretroviral therapy a state of global emergency. It has initiated a difficult process of change of international policies on export of patent-protected pharmaceutical products to developing countries. Since the World Trade Organization (WTO) adopted the "Declaration on the TRIPS Agreement and Public Health" at its 4th Ministerial Conference in Doha, the public health activists seemed to believe that once it will be implemented, there is hope for third world countries which combat HIV/AIDS epidemic. It was not a long time after when it turned out that such a complex problem consisting of polar opposite interests cannot be handled in the traditional manner of adopting universal provisions of international law. The article focuses on the circumstances which have been a starting point for one of the most controversial policies undertaken by the WTO countries. It shows the consequences of putting into practice the reform of the Agreement on Trade-Related Aspects of Intellectual Property Rights. The aim of the article is to summarize experience of past two decades of tackling the problem and to assess the approach that has been undertaken by the involved countries.

## Keywords

patent law, compulsory license, developing countries, WTO

## Introduction

The state's representatives deliberating at the beginning of the new millennium, sometime around year 2000, during the conferences reflecting on relaxing patent protection on drugs were about to put into practice the ultimate saying "the end justifies the means". They had a strong motivating factor because at the same time, developing countries, especially in Africa, were framing their patent policies and strongly lobbying in the European Union and the United States trying to negotiate their interests with major pharmaceutical companies. The key negotiators acting on behalf of the African NGOs were using all means, fair or foul, iron or poison, for achieving their ends. And they did succeed. The Fourth Ministerial Conference, and strictly speaking the Article 1 of the Doha Declaration seemed to be the turning point in the relaxation of pharmaceutical patents, balancing well the interests of consumers and of the patent holders.

In spite of that, experiences during the last 15 years have taught us that the Doha Conference did not provide a miraculous panaceum for the patenting of AIDS drugs and its rational distribution in the third world countries. Adopted approach for policy-makers and health system managers did not result in the better drugs distribution or better quality of care.[1] I would advocate a thesis we can assess the Doha Declaration's legacy as a backward step.

## Significant health problem

To provide an overview of the subject under consideration it is appropriate to refer the circumstances of the debate launched by the World Trade Organization on the access to the HIV/AIDS medication in the countries which do not have capacity to manufacture the required drugs.

To begin with the African public health problems it has to be outlined that in East Africa the daily number of deaths from AIDS has exceeded 300. Reports say that for instance in Kenya there are 1.2–1.5 million people living with HIV/AIDS. More than 50% population of that country live on 1 USD per day. It reveals the weakness of public health system in such poor countries. Kenya, what is rather exotic in that part of the world, has adopted legislation on intellectual property. What is more, the first Kenyan Industrial Property Act was from 1990, which could imply a strong legal background for a research and development sector. And yet, nothing could be more wrong. However, as Ben Sihanya, a dedicated and inquisitive researcher of the legal obstacles in access to the pharmaceuticals in Africa

[1] D. Ross-Degnan, R. Laing, B. Santoso et al., *Improving pharmaceutical use in primary care in developing countries: a critical review of experience and lack of experience*, Presented at the International Conference on Improving the Use of Medicines, Chiang Mai, Thailand, April 1997.

alleges, the said Act was promulgated in 1989 partly to protect Kenyan scientists and the Kenya Medical Research Institute (KEMRI)[2] over the claim that they had invented a drug for AIDS, Kemron.[3] Even several decades ago, the development of a new drug was a long-term and very expensive process. What is more, the extent and enforcement of intellectual property rights varied widely around the world so the Kenya's Industrial Property Act was pioneering the concept of acquiring benefits from patent protection. The fact that patents have appeared to be a main obstacle to getting antiretroviral drugs, was caused by the failure of the internal research programme and an inefficient politics which had led to lack of funds to pay royalties. Following calls by experts throughout the 1990s, the Industrial Property Act has finally been amended by the Kenyan government to allow for the parallel importation of generics from India, Brazil and other countries.[4]

## Obstacles against providing access to medicines

Until 1995, when the World Trade Organization (WTO) was established, extent and enforcement of intellectual property rights varied widely around the world. Approaches that have been adopted by the contracting states consisted of ground rules for trade and IP protection. The initial standpoint was that trade would be flowing freely around the world with the guarantee of analogous protection of intellectual property rights worldwide.[5] One of the founding documents of the WTO was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[6] which attempted to bring the protection of intellectual property rights under common international rules.

Nearly five years, while the TRIPS provisions were in action, had shown that the third world countries dealing with serious public health problem were depreciated versus the countries of IP rights holders. The problem was aggravated

[2] The Kenya Medical Research Institute is a State Corporation established through the Science and Technology (Amendment) Act of 1979, which has since been amended to Science, Technology and Innovation Act 2013. The 1979 Act established KEMRI as a national body responsible for carrying out health research in Kenya; [online] http://www.kemri.org/index.php/about-kemri/background [access: 20.04.2016].

[3] B. Sihanya, *TRIPS and Access to Drugs, Food and the Relevant Technologies in Kenya: Reforming Intellectual Property and Trade Laws for Sustainable Development*, Research report for EcoNews Africa (Nairobi) preparations for the Cancún WTO meeting, 2003.

[4] K. C. Shadlen, *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies*, Intellectual Property, Pharmaceuticals and Public Health. Access to Drugs in Developing Countries, p 280.

[5] C. M. Correa, *Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options*, Washington 2000, pp. 3–4.

[6] The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994, [online] https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm [access: 2.04.2016].

by two significant factors. Firstly, it has to be stressed that the antiretroviral medication could not be imported due to the lasting patent protection in the wealthy countries where the drugs have been manufactured. Secondly, it was questionable if the Agreement on Trade-Related Aspects of Intellectual Property Rights permitted production for export to the third world countries.

TRIPS Article 31 recognized the right of member states to grant compulsory licenses, but there were several conditions to meet before. Initially, compulsory licensing was limited by requiring a period of negotiation between the member state and the patent holder unless, as noted in subparagraph (b), it is a "case of a national emergency or other circumstances of extreme urgency". That mechanism was expected to accelerate the trade by obtaining voluntary licenses, price reduction or voluntary donation of a IP – protected good. Subparagraph (f) of Article 31 further limited compulsory licensing saying that use of the compulsory license must be made predominantly for the supply of the domestic market.[7] That provision had been actually eliminating the possibility of countries with low manufacturing capacity claiming a compulsory license for drugs imported from another member state.

Article 31 became a subject of a public controversy. The developing and developed countries took opposite stands on the issue of patentability of HIV/AIDS drugs and their export to, so-called, least-developed countries.[8] At height of the HIV/AIDS epidemic in East Africa, World Trade Organization members, especially the forty -one members of the African Group, agreed on the clarification of the problem of international support for poor countries dealing with the serious public health problems accompanied with the economy downturn. The TRIPS Agreement's flexibilities in connection with health were added to the agenda of the WTO's 4th Ministerial Conference in Doha in November 2001.

The restriction of Article 31 (f) of the TRIPS Agreement, was the main recognized problem.[9] Developing country activists claimed that African countries are simply too poor to run specialized pharmaceutical factories and they lack necessary experience and the domestic market is too small to attract sufficient investment in the pharmaceutical sector. For instance, Kenya argued for Article 31(f) of the TRIPS Agreement to be either deleted or amended; it also argued for subsequent interpretations to ensure sufficiency in manufacturing capacity for Kenya to make use of compulsory licensing.[10] Article 1 of the Doha

[7] R. M. Hilty, Kung-Chung Liu, *Compulsory Licensing: Practical Experiences and Ways Forward*, Washington 2015, p. 194.

[8] R. J. Gilbert, W. K. Tom, "Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later", *Antitrust Law Journal* 2001, Vol. 69, p. 45.

[9] A. Eikermann, "The Conditions of Art. 31 lits a-l", [w:] *WTO – Trade Related Aspects of Intellectual Property Rights*, eds. P. T. Stoll, J. Busche, K. Arend, Leiden 2009, p. 574.

[10] B. Sihanya, *Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya*, Managing the Challenges of Wto Participation: Case Study 19,

Declaration[11] recognized the gravity of health problems afflicting developing countries, including AIDS, malaria and tuberculosis. Paragraph 5 reaffirmed the infamous Article 31, recognizing the authority of member states to grant compulsory licenses, to determine the grounds for compulsory licenses to "determine what constitutes a national emergency", and to define its own licensing regime without challenge.[12] Commentators claim that while paragraph 5 did not constitute a policy change, it potentially offered a strong signal of the acceptability of compulsory licensing of medicines. Article 6 empowered the Council to find a "solution" for members with "insufficient or no manufacturing capabilities" to supply their domestic market by the end of 2002.[13]

There have been fundamental misunderstandings. Consequently, many participants of the negotiations during the Ministerial Conference in Doha argued that African firms do not have the capacity to manufacture or distribute specialized drugs, its pharmaceutical economy sector is oligopolistic and processing under a compulsory licenses may lead to misconducts and corruption.

## The way ahead for the developing countries

The first decision was adopted on 24th November 2002, but the African Group argued that it was "unsatisfactory and unworkable". It considered this was "a step back from Doha because it created further restrictions on the current flexibilities in the TRIPS Agreement".

Finally, on 30th August 2003, the TRIPS Council complied with the obligation imposed under the Doha Declaration and issued the decision with a waiver that allowed the states – producers of the medication under patent protection to issue a compulsory licenses for the export of pharmaceutical products to nations with insufficient pharmaceutical production capabilities. The decision finally defined the controversial concept of exporter/importer and left no room for doubts when assessing the criteria of licensed pharmaceutical drug. The negotiator decided that in terms of waived TRIPS pharmaceutical product means

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[online] https://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm#top [access: 20.04.2016].

[11] World Trade Organization (2001 November 20) Declaration on the TRIPS agreement and public health, [online] http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [access: 20.04.2016].

[12] C. M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, South Centre T.R.A.D.E., Working Papers No 5, Buenos Aires 1999, p. 321.

[13] Adopted on 14 November 2001, the "Declaration on the TRIPS Agreement and Public Health" opened with the following words: "We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics".

any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Doha Declaration. It was understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.

According to the Article 2 of the decision, the obligations of an exporting member[14] state under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing member(s)[15] in accordance with the following terms: (a) the eligible importing member(s) has made a notification to the Council for TRIPS, that: (i) specifies the names and expected quantities of the product(s) needed; (ii) confirms that the eligible importing member in question, other than a least developed country member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the annex to the decision of 30 August 2003; and (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the decision of 30 August 2003.

After the Ministerial Conference in Doha the compromise seemed to be satisfactory and lobbying efforts finally began to yield success. Major changes took place also in the internal legislatives. On 27th July 2001 the Kenyan Industrial Property Act of 1989 was replaced by the amended Industrial Property Act. Kenya revised the Industrial Property Act because of the need of compliance with WTO/TRIPS guidelines. The 2001 Act limited a patentee's rights (The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya by the owner of the patent or with his express consent).

The most visible player in the campaign was a business representative Cosmos Industries, which effectively lobbied the government to allow compulsory

[14] „Exporting member" means a member using the system set out in the decision of 30 August 2003 to produce pharmaceutical products for, and export them to, an eligible importing member.

[15] „Eligible importing member" means any least-developed country member, and any other member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some members will not use the system set out in the decision of 30 August 2003 as importing members and that some other members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency.

licensing. This was also the first applicant for a license under the revised provisions. It sought to be allowed to produce a drug, the product of Glaxo SmithKline and Boehringer Ingelheim of Germany.[16]

## Challenges under new regime

Public health advocates were afraid that despite the Doha Declaration and the waiver of Article 31(f) there is fear that compulsory licensing activity would have not be undertaken. The main obstacles were lack of the production capacity, distribution networks, and buying power. In fact, all of their doubts proved to be true.

And, as if all that weren't enough, another identified problem referred to generics and the fact that their influx may lead to an influx of counterfeit drugs. Nowadays, counterfeiting has become a problem to a degree that drastically needs to be addressed.

The main problem is with understanding of what is generic medicine and under what circumstances generic medicine can be manufactured or imported in a country facing fundamental problem with access to medication. Even if countries are adopting anti-counterfeit acts and rules for identifying a fake pharmaceutical product availed to the market or presented to it and intentionally tailored to derive and ride on the reputation or goodwill of another good through labelling or marking. In such community as East Africa to make people aware that the counterfeits are not necessarily substandard, but they are harmful because of causing an infringement of someone's monopoly – is rather challenging. Pointedly, there is widespread ignorance in Africa on the meaning of intellectual property rights. Manufacturing companies are afraid to invest in compulsory licensing or parallel importation for fear generally of taking on the western pharmaceutical concerns. IP law researchers outline that companies often do not actually realize that they have the legal backing to do so.

The Doha Declaration was intended to be a strong political statement that could be an accelerator for developing countries to adopt effective measures necessary to ensure access to health care without the fear of being dragged into a legal battle. However, figures show that because of focusing on laws and politics public health problem became nothing less. The number of patients treated for HIV/AIDS increased more than twelve-fold between 2003 and 2010. In 2003, only 50,000 patients were on anti-retroviral medicines treatment. By 2005, this number had increased to 1.57 million patients in January 2005, a number that increased to 5.2 million patients by December 2009.[17]

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[16] Lastly, Glaxo SmithKline and Cosmos agreed on acceptable terms for a voluntary licence.

[17] A. van Gelder, P. Stevens, *The compulsory license red herring*, London 2010.

Governments procurement of HIV/AIDS medicines, which is not constrained by the WTO, the TRIPS Agreement is largely wasteful. There is particularly no support for research and development economy sector. Generally, the problem of permitted discrimination by sector of the economy seems to be an important unanswered question. The issue of life-and-death importance in many countries which combat epidemics is access to medication. Facing a state of emergency, politicians do not think about framework for adopting a strategy involving universities and cooperation of public and private sector. Policy tailors who promote long-term suppositions and claim that it is also important to invest in the prevention – are rather underrepresented. East Africa is dealing with that kind of "emergency state" for many years.

## Conclusions

It has been nearly two decades since a legal tool of compulsory license was institutionalized in international framework policies. Today we can assess the outcome of that experimental strategy, which has put into practice the standpoint of the negotiators of the 4th Ministerial Conference in Doha.

Unfortunately, that action seems to be a failure of global health governance. Objectively speaking, compulsory license has enabled the rich countries where the HIV/AIDS drugs are manufactured to see how specific legal instruments relevant to international intellectual property law can be misinterpreted and used to the only benefit of local politicians or mafiosos, who have frequently acted in these both roles at a time. By trying to organize a cooperation, it was necessary for the western concerns and their representatives to root in the attitudes and values which have been far from the modern philosophy of free market.[18] Finally, by using the said legal tool by the international pharmaceutical companies and developed countries they were enabled to capture the circumstances which are the significant obstacle to implement the western legal policies in the developing countries.

Overall speaking, experience of last 16 years has shown that the regime on compulsory licensing is in regress and fails to fulfill its function to balance private and public interests.[19] The debate launched two decades ago has not resolved the problem of access to HIV/AIDS medication. Skeptics observe that most of the resources on HIV/AIDS combat are spent on conferences, summits, and awareness campaigns.

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[18] F. M. Abbott, "Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health", *Quaker United Nations Office*, Occasional Paper No 9, Geneva 2008, p. 26.

[19] G. Chaves, M. Oliveira, *A proposal for measuring the degree of public health-sensitivity of patent legislation in the context of the WTO TRIPS Agreement*, Bull World Health Organ 2007, pp. 49–56.

It leads to the conclusion that problem of access to HIV/AIDS drugs in developing countries is more complex and does not only engage the patent holders, the World Trade Organization or activists in social movements and voluntary associations opposing to the patenting of HIV/AIDS drugs. What appear as crucial are political and socio-economic improvements of public health. Undertaking such reforms has to be with finding resources and empowering the significance of the sector of research and development.

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