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INTELLECTUAL PROPERTY, PUBLIC HEALTH AND ACCESS TO MEDICINES IN INTERNATIONAL ORGANIZATIONS

Germán Velásquez

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INTRODUCTION[1]

The issue of intellectual property, public health and access to medicines emerged in the World Health Organization (WHO) for the first time in 1996. The timing practically coincided with the end of the Uruguay Round and with the creation of the World Trade Organization (WTO). In 1995, the University of Madrid Carlos Tercero organized a conference together with the WHO Essential Medicines Programme where Professor Carlos Correa[2] presented a paper entitled "The Uruguay Round and Drugs."[3] The paper analyzes the possible implications of the TRIPS agreement on access to medicines and reveals the "margin of manoeuvre" that the Agreement has in order to protect Public Health. "The Uruguay Round and Drugs" is the first document that specifically alerts the health sector on the possible implications of the TRIPS agreement on public health and more specifically on access to medicines.

During the Uruguay Round negotiations (1986-1994) some negotiators from developing countries were already aware that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) would have important implications on the pharmaceutical and health fields. It is well-known that the main lobby group during the Uruguay Round was the pharmaceutical industry, mainly interested in the adoption of the TRIPS agreement. Shortly after its adoption, The United Nations Conference for Trade and Development (UNCTAD) published a study on the TRIPS agreement and developing countries.[4]

Objective of the Paper

The purpose of this research paper is to shed light on and to analyze the mandate, programmes, strategies, and activities that different international organizations have undertaken on the subject of access to medicines, intellectual property, international trade rules and human rights.

Given that the WHO initiated and developed many of the strategies and policies in this area, the analysis presented by this organization is slightly more comprehensive than the others. The analysis includes discussion of what its mandate is, what it does, what it does not do sufficiently, and what are the alliances with the other organizations involved in the subject.

The following international organizations are described and in some cases their role and contributions or the impediments they may represent are analyzed: WTO, WIPO (World Intellectual Property Organization), UNCTAD, UNDP (United Nations Development Programme), UNAIDS (Joint United Nations Programme on HIV/AIDS), the United Nations

[1] See South Centre Research Paper no. 47.
[2] Negotiator of the TRIPS Agreement during the Uruguay Round, in the capacity of Secretary of Industry of the Government of Argentina.
[3] Correa C., "The Uruguay Round and drugs" WHO/TFHE/97.1 Distr: General, 1997, p. 40.
[4] United Nations Conference on Trade and Development (UNCTAD), the TRIPS Agreement and Developing Countries U.N. Pub. 96.II.D.10 (1996) (prepared for the UNCTAD secretariat by Carlos Correa, Keith Maskus, J. H. Reichman, and Hanns Ullrich).

Human Rights Council) and the initiative of the Secretary-General of the United Nations on medicines.

The paper also analyses two cases of existing inter-agency cooperation: the WHO-WTO-WIPO tripartite partnership and the guidance document developed by the WHO, UNDP and UNCTAD: Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective.[5]

Finally, the document analyzes the recent recommendations of the UN High Level Panel (UNHLP) published in September 2016.

[5] WHO – ICTSD – UNCTAD – UNDP "Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective", Working Paper by Correa, C. M., Geneva, 2007. Available from: http://ictsd.org/i/publications/11393.

I. THE WORLD HEALTH ORGANIZATION

I.1 Background: First Mandate of the World Health Assembly

In 1996 the World Health Assembly (WHA) adopted a resolution on medicines[6] which constitutes the first mandate given by member States to the secretariat of the World Health Organization to work on intellectual property in relation to health.

The resolution (WHA49.14) on "Revised Drug Strategy" requested the WHO Director-General to undertake a study on the impact of the WTO, and particularly the TRIPS agreement, on access to health.

I.2 The "Red Book"

Resolution WHA49.14 requested the Director-General to prepare a study on the implications of the TRIPS agreement. This study was entrusted to the Programme of Action on Essential Medicines (PAME). In November 1997, PAME published the study "Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement,"[7] commonly known in the WHO as the "red book" on the TRIPS Agreement.

I.3 TRIPS Flexibilities

The aforementioned UNCTAD document includes the "**room for manoeuvre**" for the creation of national public policies that the TRIPS agreement has. The WHO "red book" speaks about "**margins of freedom.**"(1997)[8] Subsequently, in March 2001, the WHO adopted the term "**safeguards**" in a widely distributed document available in the six WHO official languages.[9]

In June 2001, the European Commission talks about "**a sufficiently wide margin of discretion**" regarding the implementation of the TRIPS Agreement.[10] A few months later, in November 2001, the Doha Declaration on the TRIPS Agreement and Public Health refers to "**the provisions of the TRIPS Agreement that provide flexibility.**"[11] It is only in June 2002 that the WHO referred to TRIPS **"flexibilities"**, in a paper analyzing the implications of the Doha declaration, authored by Carlos Correa.[12]

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[6] WHA 49.14 «Revised Drug Strategy», WHO, Geneva 1996.
[7] Velásquez, G. Boulet P., "Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement", WHO/DAP/98.9, Geneva, November 1997, p. 58.
[8] Velásquez, G. Boulet P., "Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement", WHO/DAP/98.9, Geneva, November 1997, p. 34. Emphasis added.
[9] WHO Policy Perspectives on Medicines, "Globalization, TRIPS and access to pharmaceuticals", no. 3 WHO, Geneva March 2001, p. 5. Emphasis added.
[10] European Commission's submission on the 12th of June: "a sufficiently wide margin of discretion", (IP/C/W/280), June 12th, 2001. Emphasis added.
[11] WTO "Doha declaration on the TRIPS Agreement and Public health, WT/MIN(01)/DEC/W/2, p. 1. Emphasis added.
[12] C. Correa "Implications of the Doha Declaration on the TRIPS Agreement and Public Health", WHO/EDM/PAR/2002.3, Geneva, 20012, see chapter titles "TRIPS flexibilities", p. 13. Emphasis added.

Currently, there is broad consensus on the use of the term "flexibilities" to refer to the mechanisms and provisions of the TRIPS agreement to protect public health.

I.4 The Commission on Intellectual Property, Innovation and Public Health

The Commission on Intellectual Property, Innovation and Public Health (CIPIH) was created in 2003 by a resolution of the World Health Assembly.[13] WHO member States requested the WHO Secretariat to produce a report by independent experts.

In 2006, the group of experts published a report entitled "Public Health, Innovation and Intellectual Property Rights."[14] It contains 60 recommendations, which have unfortunately not been fully adopted to date (ten years later).

I.5 "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property" (GSPOA) Resolution WHA 61.21

This negotiation, which was two years long, can be considered the most relevant and important in the almost 70 years of existence of the WHO, second only to the negotiation and adoption of the convention against tobacco, FCTC.[15]

The Global Strategy and Plan of Action (GSPOA) sought a substantial reform of the pharmaceutical research and development system in view of this system's failure to produce medicines for diseases affecting the majority of the world's population living in developing countries. The intellectual property rights required by the TRIPS Agreement and recent trade agreements could become one of the main obstacles to access to medicines. The GSPOA made a critical analysis of this reality and opened the door to the quest for new solutions to this problem.[16]

The Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property (Resolution WHA 61.21), adopted by WHO member States in 2008, became entangled in "UN-like" discussions and procedures, and what was eventually achieved in this process was rather limited.

Analyzing the progress[17] made in implementing the "global strategy" and its action plan, the "progress" made so far is reduced to three points:

1) The Patent Pool,[18] a particular initiative, this is one of the many elements of the mandate given to the WHO by resolution 61.21. Patent pools can facilitate equitable access and make new HIV treatments more affordable. They can also facilitate the development of new fixed-dose combinations suitable to address developing

[13] WHA Resolution, WHA56.26 Intellectual Property Rights, Innovation and Public Health.
[14] "Public Health, Innovation and Intellectual Property Rights", Report by the Commission on Intellectual Property, Innovation and Public Health, ISBN 92 4 356323 8, Geneva 2006, 204 pg.
[15] FCTC: Framework Convention on Tobacco Control.
[16] G. Velasquez, "The Right to Health and Medicines: The Case of Recent Negotiations on the Global Strategy on Public Health, Innovation and Intellectual Property" Research Paper 35, South Centre, Geneva, 2011.
[17] Currently a Canadian private firm contracted by WHO is conducting an evaluation of the global strategy. The results will say very little, since the terms of reference were poorly drafted.
[18] http://www.medicinespatentpool.org/.

countries' treatment needs. Patent pools may consist of compulsory licenses or licenses voluntarily granted by the patent holder, as is the case of the current Medicines Patent Pool (MPP) created with funds from the French initiative UNITAID. These patent pools are voluntary, and therefore they do not constitute a structural solution to the access to medicines problem. Unfortunately, in the case of the MPP, its existence has practically meant that the WHO has given up its work on advocacy and assistance to countries to implement the flexibilities of the TRIPS agreement.

2) The second activity that has been developed in the Americas region is the so-called "Platform on Innovation" promoted by the Pan American Health Organization (PAHO). It is a sort of "Facebook of medicines", a virtual network reporting on various activities in the pharmaceutical field.

3) The "Demonstration projects", an idea launched and promoted by the EU at the WHO. These demonstration projects, which were not part of the existing mandate in the various resolutions of the World Health Assembly, were used to delay the start of negotiations on a binding Convention. During 2012 and 2013, project selection took place in a process that involved the six WHO Regional Offices. This selection process was heavily criticized by non-governmental organizations and some observers. It confirmed the initial concern of developing countries that these demonstration projects were only a distraction by industrialized countries to delay the start of negotiations on a binding Convention.

More than 4 years after the approval of the "demonstration" projects, the funding is not there, at the end of 2016, to start this exercise. The start of negotiations for a Convention was not formally contingent on the results of the demonstration projects, but in practice the debate on the demonstration projects took so much space that the start of negotiations was set aside. If the demonstration projects were only a pretext for delaying the subject of a treaty, as many suspected, they were certainly "successful" as the treaty was not only delayed but virtually removed from the WHO agenda.

Given the impasse to approve intellectual property issues within the global strategy the "Consultative Expert Working Group" was created.

I.6 WHO Consultative Expert Working Group (CEWG)

At the beginning of 2011, the WHO Director-General established a WHO Consultative Expert Working Group (CEWG) to address the intellectual property issues that remained unaddressed in the "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property". In July 2011, the CEWG coordinator announced that "the CEWG will recommend to the 2012 World Health Assembly the initiation of formal intergovernmental negotiations for the adoption of a comprehensive and binding instrument for health R&D, on the basis of Article 19 of the WHO Constitution." This recommendation has not yet been ratified by the Governing Bodies of the WHO.

1.7 The Collaboration of WHO with other International Organizations

Interestingly, the United Nations agencies invited to participate in the debates on intellectual property and health, which took place in WHO between 2010 and 2015, were WIPO and WTO. This is despite the fact that there are other United Nations agencies that are much closer to the work of the WHO, such as UNDP, UNAIDS, UNCTAD, or the Commission on Human Rights. These were not invited by the WHO to participate in the discussions on the subject of access to medicines. In the case of UNDP, its presence at the country level has been much more relevant in recent years than the rest of agencies mentioned above.

One of the main collaborative activities between WHO, WTO and WIPO has been the so-called tripartite report, entitled "Promoting Access to Medical Technologies and Innovation". Whereas the study could represent progress for WTO and WIPO given that it talks about the TRIPS flexibilities with no "taboos", it does not reflect the fact that the WHO was the International Organization that had until then led this issue. There are 17 World Health Assembly resolutions referring to intellectual property and public health, adopted between 1996 and 2012, and these are cited by the report in a table on page 44. These resolutions clearly have a prescriptive character for the WHO Secretariat and for countries on how to preserve public health from the potential negative impact of new international trade rules on public health. Numerous WHO publications[19] on this topic published over the past 15 years also point on this direction.

The disclaimer of the report states that "(...) the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the WHO, WIPO and the WTO be liable for any consequences whatsoever arising from its use." This type of "disclaimer" may give the reader the misleading impression that the WHO has no opinion as to whether a compulsory license may, in particular circumstances, promote access to medicines, or whether an international exhaustion regime that allows parallel imports from any country can reduce medicines costs and, therefore, contribute to access. The 17 resolutions mandate the WHO to engage, promote and defend mechanisms and policies in favour of access. This tripartite report has led the WHO to share the "neutral" and totally disengaged view of safeguarding health.

The trilateral report is weak, unambitious and does not reflect the work that WHO has carried out under its mandate. It is curious that the 251 page document has no single recommendation, not even a conclusion.

The dialogues or cooperation between the WHO, WIPO and the WTO from 2010 to 2015 have placed the international debate on access to medicines in a kind of "limbo". This was undoubtedly one of the reasons why UNDP sought to rescue the issue by suggesting to the UN Secretary-General to convene a High Level Panel on access to medicines by the end of 2015. The high level panel of the Secretary released its report on 14 September 2016, to which we will refer at the end of this paper.

[19] See bibliography in Annex II.

II. THE WORLD TRADE ORGANIZATION

II.1 Paragraph 6 of the Doha Declaration, or the Decision of 30th August 2003

In June 2001, the African Group requested the WTO TRIPS council to include in its agenda an item on "access to medicines", which eventually resulted in the Doha Declaration on TRIPS and Public Health. In the last 15 years, this has been the only contribution of the WTO to the access to medicines issue.

The so-called "Paragraph 6" mechanism of the Doha declaration, or the Decision of 30th August 2003, was a mandate of the WTO ministerial conference in Doha (2001) to solve, in an "ad hoc" manner, a problem that affected the poorest countries. The problem still lacks a solution 15 years later.

What was (is) the problem? In section f) of article 31 of the TRIPS Agreement, it is stated that any product manufactured under a compulsory license "shall be authorized predominantly to meet the supply of the domestic market". This can be applied to countries with the capacity to manufacture medicines and limits the volume of medicines that can be exported when their production has been enabled by a compulsory license. Such disposition affects mainly those countries that lack the manufacturing capacity to produce medicines, i.e. the least developed countries. This is the reason why Paragraph 6 of the Doha Declaration gives a mandate to find an expeditious solution to this problem.

After two years of negotiations, on 30th August 2003, WTO Member States reached an agreement on the regulatory modification that would allow countries to import generic medicines at a lower price and manufactured under compulsory licenses, in case they lack local manufacturing capacity. After reaching this Decision, the President of the General Council read a declaration to clarify the way in which this Decision should be interpreted and implemented by WTO members. The purpose of this statement was to ensure to industrialized countries that the Decision would not be abused, it was never clear whether the statement by the President of the Council was part of the decision or not.

The decision on Paragraph 6 contains a number of conditions, requested by industrialized countries, to ensure that beneficiary countries can import generic medicines without undermining the patent system. These include measures to prevent drugs from being diverted to inappropriate markets, and provisions requiring governments using this system to keep all other Members informed.

All WTO Member countries are allowed to import under this decision, but the decision lists 23 developed countries that voluntarily announced that they would not use the system as importing Members: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Iceland, Italy, Japan, Luxembourg, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

After joining the EU in 2004, 10 more countries have been added to the list: Cyprus, Slovenia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Czech Republic and the Slovak Republic.

Subsequently, several potential exporting countries amended their laws and regulations with the aim of applying the exceptions and allow production exclusively for export: countries such as Norway, Canada, India and the EU among others.

The 2003 exceptions are provisional in nature; the ultimate goal is to modify the TRIPS Agreement itself, which would enter into force when two-thirds of Members accept it. Thirteen years after the "expedited solution" agreed by WTO Member States, the mechanism has not been ratified, and only one country, Rwanda, has used it once, with an import of antiretroviral medicines from Canada. The manager of the Canadian generic firm stated, after export, that the system was so complicated that his firm had no intention of using it again.[20]

On 8 November 2016, the CIPLA representative at a "lunch seminar" organized by the South Centre at the WTO in Geneva stated that CIPLA would never use the paragraph 6 mechanism, and that this decision should be completely revised.

At the end of the aforementioned seminar, organized by the South Centre at the WTO, Suerie Moon, Research Director at the Global Health Centre of the Graduate Institute in Geneva, concluded by citing the recommendations of the UN High Level Panel: "WTO member States should review the decision in Paragraph 6 to find a solution that would allow for a quick and convenient export of pharmaceutical products produced under a compulsory license. WTO member States should, as appropriate, adopt an exception and a permanent reform of the TRIPS Agreement."

II.2 The WHO Proposal to Solve the Problem exposed in Paragraph 6[21]

In 2002, WHO published a document on the implications of the Doha Declaration on TRIPS and Public Health, WHO/EDM/PAR/2002.3. This document describes possible solutions to the so-called "paragraph 6 problem" from a public health perspective. These characteristics include: a stable international legal framework; transparency and predictability of the rules to be applied in countries engaged in exportations and importations; simplicity and speed of legal proceedings in exporting and importing countries; equal opportunities for countries in need of medicines, including for products patented in the importing country; multiplication of potential providers of needed medicine; and a wide coverage in terms of health issues and different drug types.

Thus, the basic public health principle is clear: people in a country that does not have the capacity for domestic production of a needed drug should not be less protected by the provisions of compulsory licenses (or other safeguards of the agreement on TRIPS), nor should they have more procedural obstacles compared to people living in countries with the capacity to produce the drug.

Among the solutions that have been proposed, the limited exception under **article 30** is the most consistent with these public health principles.[22] Under the mandate of the Doha

[20] South Centre Policy Brief No. 7, "The Doha Declaration on TRIPS and Public Health: Ten years later – the state of implementation", Nov. 2011.
[21] G. Velasquez, "EL acceso a medicamentos y la propiedad intelectual: contribución de la OMS" in Revista jurídica de Buenos Aires, "Tendencias actuales en propiedad intelectual", coordinada por Sandra Negro, ed. Abeledoperrot, Buenos Aires 2013.
[22] Emphasis added by the author.

Declaration, this solution would give WTO member States expeditious authorization to enable third parties to manufacture, sell and export patented medicines and other health technologies to address public health needs.[23]

[23]Extract from WHO intervention at the WTO TRIPS Council, 1 September 2003.

III THE WORLD INTELLECTUAL PROPERTY ORGANIZATION

According to Carolyn Deere,[24] WIPO is the largest donor providing training on intellectual property issues to developing countries. Between 1996 and 2006, WIPO spent more than US $400 million on technical support. The problem is that this technical advice, according Carolyn Deere, was used to introduce stronger intellectual property management in developing countries, with the philosophy that "the more patents, the better". All of this is done through the provision of computers, computer equipment, salaries, invitations to conferences and consulting contracts, as a means of influencing decision-makers to strengthen the use of intellectual property.

When reviewing the agendas of the different WIPO training programs, published on their website, including online training courses, none of those programmes include contents referring to the flexibilities of the TRIPS agreement. For those who have been following this debate for the last 15 years, it is clear that WIPO is more a part of the problem than the solution in terms of public health. WIPO is certainly responsible for the proliferation of patents on trivial innovations that result in expensive pharmaceutical products.

In the WIPO website, WIPO identifies its main activity, in the field of medicines, to be the fostering of a trilateral cooperation between the WHO, the WTO and WIPO. This point has been already mentioned and analyzed in the section referring to WHO.

The webpage concludes by saying: "The three organizations meet regularly, exchange information on their respective work programmes, discuss and plan, within the possibilities of their respective mandates and budgets, common activities. The trilateral cooperation is intended to contribute to enhancing the empirical and factual information basis for policy makers and supporting them in addressing public health in relation to intellectual property and trade."[25] There is no reference to what part of the work of the tripartite collaboration is devoted to supporting countries in the use of TRIPS flexibilities.

[24] C. Deere, « The implementation Game: The TRIPS agreement and the global politics of IP reform in developing countries » Oxford University Press, 2009, p. 180.
[25] WIPO, http://www.wipo.int/policy/en/global_health/trilateral_cooperation.html.

IV. THE UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

The United Nations Conference on Trade and Development (UNCTAD) has focused its access to medicines work on strengthening production capacity in developing countries.

In 2005, UNCTAD was mandated by the Commission on Investment, Technology and Financial Issues to carry out work related to the manufacture and supply of pharmaceuticals in the context of the Millennium Development Goal No. 8.

The Commission recommended that: "UNCTAD should, within its work programme on investment, technology transfer and intellectual property, assess ways in which developing countries can develop their domestic productive capability in the supply of essential drugs in cooperation with pharmaceutical companies."[26]

Within the framework of this mandate, UNCTAD established in 2006 a pilot programme on local pharmaceutical production and access to medicines, with the financial support of Germany and the United Kingdom.

The aim of the programme: "The overall objective of the programme … is to assist developing countries – and least-developed countries (LDCs) in particular – to establish domestic intellectual property regimes that facilitate increased access to affordable medicines..."[27]

Within the activities foreseen by this programme, there are training courses on TRIPS flexibilities applied to local pharmaceutical production. Among the studies published by UNCTAD there are: "Role of competition in the pharmaceutical sector and its benefits for consumers" or "Enhancing productive capacities: the role of health".

[26] http://unctad.org/en/Pages/DIAE/Intellectual%20Property/Building-local-pharmaceutical-production--supply-capacity.aspx.
[27] Ibid.

V. THE JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS

The 2016-2021 Strategy of the UNAIDS Programme:

- To reaffirm the work of promoting innovation and continuous improvement of HIV-related medicines and technologies while ensuring their availability, quality and affordability.

- To support countries in the adoption and use of TRIPS-related flexibilities and in defending their ability to denounce the provisions of trade agreements that impede access to affordable medicines that go beyond international obligations under the TRIPS Agreement.

- Joins efforts to explore new systems of incentives for research and development where research and development costs are de-linked from product prices.

V.1 Some Examples of the Current Work of UNAIDS on IP-related Issues

- Information papers on IP-related issues have been developed by the UNAIDS / UNDP secretariats: the impact of IPRs on access to medicines, the challenges of IP chapters in free trade agreements,

- In 2013, UNAIDS, UNITAID, WHO and the Brazilian Government organized a consultation on access to HIV medicines in middle-income countries. There were four blocks of recommendations: pricing; regulatory framework; IP and collaboration on local production; and R&D.

- In May 2014, UNAIDS co-sponsored a BRICS side event during the World Health Assembly to discuss access to medicines in the context of members of this group of countries. IP was an important item on the agenda.

- In May 2015, UNAIDS organized a reflection group on IP and access to medicines to inform the secretariat on possible areas and actions that UNAIDS could undertake to improve access to medicines and address barriers to Intellectual property.

- In October 2015, UNAIDS, in collaboration with MSF, the Third World Network and the People's Health Movement, organized a session on TRIPS and access to medicines at the WTO Public Forum in Geneva.

Finally, it is worth mentioning that UNAIDS was part of the Secretariat of the UN SG High-Level Panel that issued their report in September 2016.

VI. THE HUMAN RIGHTS COUNCIL[28]

In 2016 the United Nations Human Rights Council approved a resolution reaffirming that access to medicines is a fundamental element to the full exercise of the right to health. Members also agreed to hold round tables on the issue of access to medicines during the next sessions, in 2017.[29]

Resolution 32/L.23 titled: "Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" was submitted by Brazil, China, Egypt, Haiti, India, Indonesia, Paraguay, Peru, Senegal, Sri Lanka, South Africa and Thailand. The resolution was supported by 72 co-sponsors.

Many resolutions have been adopted in the last 15 years in the context of the WHO. There, the debate has fundamentally been between health and trade. What primes: health or trade? What were the possible contradictions and what were the mechanisms to protect health from the possible negative effects of the new rules governing international trade? On a number of occasions, developing countries attempted to introduce a reference to human rights as an argument for ensuring access to medicines. Unfortunately, all attempts failed because of opposition from the United States of America.

The great value of the Human Rights Council resolution 32/L.23 is to place the debate on access to medicines at another level, at the level of human rights. It may not be just by chance that in December 2015 the UN Secretary-General called for the High-Level Panel with the following terms of reference: to study the incoherence between inventors' rights, international human rights law, trade rules and public health.

The Human Rights Council confirms the primacy of human rights, such as the right to health over trade, intellectual property rights and other bilateral investment or trade agreements. "It is equally important that the resolution reaffirms the ability of countries to take advantage of the flexibilities envisaged by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to promote access to medicines, recognizing that patents can be used to set high prices for medicines."[30]

The resolution reaffirms the importance of access to medicines for all human beings as one of the fundamental human rights and stresses that improved access could save millions of lives every year.

The resolution also refers to the Doha Declaration on intellectual property and public health which confirms that TRIPS does not prevent and should not prevent WTO members from taking measures to protect public health.

The adoption by consensus of the resolution coincided with the celebrations of the 30th anniversary of the Declaration on the Right to Development, which recognized both the

[28] Human Rights Council, resolution (23/14 en 2013) Geneva, 2016.
[29] Viviana Muñoz Tellez and Adriano José Timossi, "Human Rights Council adopts historic resolutions on access to medicines", South Bulletin, Issue 92, 4 August 2016.
[30] Ibid.

right to health and access to medicines and public health as essential elements for the exercise of the right to development.[31]

[31] Ibid.

VII. THE UNITED NATIONS PROGRAMME FOR DEVELOPMENT (UNDP)

The strategy of UNDP on intellectual property and access to medicines has been to frame all its work in the context of the fight against HIV. In other words, access to medicines for people living with HIV is a priority for UNDP. This is a very successful strategy since the drugs used to treat HIV are excellent examples of drugs marketed under conditions such as monopolies, high prices, unethical behaviour, and human rights violations. These issues are common to many other medicines to which many people lack regular access worldwide.

VII.1 HIV and Health

The UNDP website states that "Globally, 35 million people are living with HIV. While new HIV infections have declined by 38 per cent since 2001, the HIV epidemic continues to outpace the response."[32] However, UNDP continues to state that: "There is a growing threat from non-communicable diseases (NCDs) such as cardiovascular diseases, cancers, chronic respiratory diseases and diabetes – accounting for 60 per cent of premature deaths. Over the next twenty years, NCDs and mental health will cause a cumulative economic output loss of US$ 47 trillion globally."[33]

The UNDP Strategic Plan 2014-2017 "Recognizes the broad range of social and economic impacts of HIV and the synergies between health and sustainable development. This plan addresses HIV as a cross-cutting issue and emphasizes the rights of people living with HIV; reducing associated discrimination and violence against women; empowering local governance and national capacities to achieve greater equity in access to services for those affected, and strengthening the rule of law and reform of legal systems."[34]

VII.2 HIV and the Law: Risks, Rights, and Health[35]

This report is undoubtedly one of the most robust works produced by a UN agency in the field of health, access to medicines and in particular intellectual property. The legal environment – laws, repressive and judicial systems – has immense potential to improve the lives of people who do not have access to medicines and can save their lives. International laws and treaties can protect and improve access to healthcare and forbid discrimination stimulating the power of national laws to protect health and to ensure access to medicines as a right.

This 162-page report presents compelling evidence and recommendations that can save lives, reduce costs, help eradicate the AIDS epidemic, and improve access to medicines in general.

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[32] http://www.undp.org/content/undp/en/home/ourwork/democratic-governance-and-peacebuilding/hiv-and-health/.
[33] Ibid.
[34] http://www.undp.org/content/undp/en/home/librarypage/corporate/Changing_with_the_World_UNDP_Strategic_Plan_2014_17/.
[35] http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/hiv-and-the-law--risks--rights---health/.

Laws can prohibit or permit specific behaviours, and in doing so they shape policies economies, and society. Laws can be an excellent tool to protect and guarantee the health of citizens.

VIII. AN EXAMPLE OF COLLABORATION BETWEEN WHO, UNDP AND UNCTAD[36]

Under the TRIPS Agreement, for a product or a manufacturing process to be patentable it has to meet the patentability criteria. These criteria are required by national intellectual property offices and they are: novelty, inventiveness and industrial application (usefulness). However, these three elements are not defined in the TRIPS agreement; therefore WTO member States are free to define these three elements in a manner that is coherent with the public health objectives defined by each country.

According to the report of the United Nations High Commissioner on Health:

> "The requirements under the TRIPS Agreement for the grant of patents – novelty, inventive step and industrial applicability – are open to interpretation under national legislation and each country can decide according to local conditions. Consequently, the High Commissioner encourages interpretations of these requirements that do not lose sight of the public interest in the wide dissemination of knowledge (...).[37]
>
> The world has never had at its disposal such a wide arsenal of treatments to fight the diseases that afflict humanity. At the same time, many people die owing to a lack of certain medicines and/or vaccines. This applies to illnesses such as AIDS, malaria, tuberculosis, cancer, diabetes, hepatitis C, bacterial meningitis and pneumonia, among many others."[38]

It is widely believed that patents are usually granted to protect new drugs, but the number of patents obtained annually to protect new compounds is actually very small and has been declining. Each year, thousands of pharmaceutical patents are awarded, although only a few are for new molecular entities (NMEs).

The cumulative nature of innovations, due to low patentability requirements and deficiencies in patent granting procedures, has important consequences on the patent system, which limits the dissemination of the innovations that the system seeks to promote: access to life-saving drugs. "Patents that are based on broad scientific principles are generally bad, because according to the United States Supreme Court, they may confer power to block off whole areas of scientific development, without a compensating benefit to the public."[39]

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[36] G. Velasquez, **"**Guidelines on Patentability and Access to Medicines**"** South Centre, Research Paper 61, 2015, p. 8.

[37] The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner, E/CN.4/Sub.2/2001/13, 27 June 2001, para 62.

[38] G. Velasquez, **"**Guidelines on Patentability and Access to Medicines**"** South Centre, Research Paper 61, 2015, p. 8.

[39] John H. Barton, WHO Bulletin, October 2004, vol. 82, No. 10.

All of this led WHO, in collaboration with UNCTAD, UNDP and ICTSD, to develop, in 2007, a series of guidelines for the examination of pharmaceutical patents from a public health perspective.[40]

These guidelines were conceived as a contribution to improve the transparency and effectiveness of the patent system for pharmaceutical products. This would help countries to pay more attention to patent examination and grant procedures, in order to avoid the negative effects of patents on non-inventive developments on access to medicines.

"The exercise to draft guidelines for patent examination sought a way to manage the pharmaceutical product patent system and, more specifically, the 'strengthened patent system' arising from the TRIPS Agreement and current regional and bilateral trade and investment agreements. Patents are a social contract between the patent holder and society; therefore it is necessary to explore, identify and implement mechanisms to improve the functioning and transparency of the patent system in the interest of public health."[41]

The report of UN SG's high-level panel, to which we will refer next, recommends to "make use of the space available in Article 27 of TRIPS to adapt and apply rigorous definitions of invention and patentability."[42] The guidelines for the examination of pharmaceutical patents published by the three agencies WHO, UNDP and UNCTAD[43] are precisely the means to put into practice that recommendation.

[40] WHO – ICTSD – UNCTAD – UNDP "Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective", Working Paper by Correa, C. M., Geneva, 2007. Available at: http://ictsd.org/i/publications/11393/.
[41] G. Velasquez, "Guidelines on Patentability and Access to Medicines" South Centre, Research Paper 61, 2015, p. 9.
[42] Report of the United Nations Secretary-General's High-level Panel on Access to Medicines, September 2016, page 9.
[43] In collaboration with the nongovernmental organization, ICTSD, Geneva.

IX. THE SECRETARY-GENERAL OF THE UNITED NATIONS

IX.1 The Report of the Secretary-General's High-Level Panel on Access to Medicines

Towards the end of 2015, at the initiative of UNDP, the Secretary General of the United Nations convened a High Level Panel on Access to Medicines. This high level panel published a report of their work on 14 September 2016.

The terms of reference of the UN Secretary General's call for the High-level panel (HLP) on access to medicines (December 2015) admitted a structural problem in the current medical R&D model. Members of the panel were asked to study the "Incoherence between the rights of inventors, international human rights law, trade rules and public health."[44]

In only 4 months, 180 proposals were received by the High Level Panel from countries, institutions, UN agencies, NGOs, universities, the pharmaceutical industry, and individuals. They can be classified into five categories:

1. Comments on the current R&D model (40)
2. Proposals to strengthen health systems (27)
3. Proposals to modify the R&D model progressively (46)
4. Contributions proposing a major reform of the model (46)
5. Other

Proposals were also received from the Governments of the Netherlands, Lesotho, Japan, and Jordan.

The main recommendations of the UNHLP report released in September 2016 can be summarized as follows:

- Make use of the available space in TRIPS Article 27 to adapt and apply stringent definitions of invention and patentability.
- Governments should adopt and implement legislation facilitating compulsory licenses.
- WTO members should review the paragraph 6 decision.
- Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right to use TRIPS flexibilities.
- No to TRIPS-plus provisions.
- Universities and research institutions receiving public funding should prioritize public health objectives over financial profitability in their patent and licensing practices.
- All interested parties should test and implement new and additional models of research funding (R&D).
- The UN SG should initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies, including negotiations for a binding R&D Convention to delink the cost of R&D from the final price of medicines, thus promoting access to good

[44] Ibid., page 12.

health for all. Governments should establish a working group to initiate the negotiation of a Code of Principles for Biomedical R&D.

- Governments should review the status of access to health technologies in their country through the lens of human rights principles.
- Governments should require manufacturers and distributors to disclose to drug regulatory and procurement authorities information regarding the cost of R&D, production, marketing and distribution of health technologies.
- Governments should make all clinical trial data publicly available.

Although discussions leading to the production of the report were not public, dissenting comments by some members of the panel at the end of the report clearly show that consensus was not reached on some of the recommendations, which would have otherwise significantly advanced the debate and achieved making substantive changes to the current R&D model to improve access to medicines.

The most significant progress made in the debate on access to medicines, through the UN Secretary-General's report, is undoubtedly the assertion that this is a global problem that affects both developing and developed countries. All documents produced in the WHO context stated that the problem encompassed some diseases that disproportionately affected developing countries. A report produced after the appearance of Sofosbuvir for Hepatitis C at a price of $ 84,000 per 12-week treatment could not continue to claim that the problem was only limited to poor countries.

The second most important contribution of the report is the recommendation to "make use of the space available in TRIPS Article 27 to adapt and apply rigorous definitions of invention and patentability."[45] This is undoubtedly the most important flexibility of the TRIPS agreement, i.e. the freedom of each country to interpret and define the three requirements of the TRIPS agreement to grant patents: novelty, inventiveness and industrial application.

The third important point of the report is not new, but it is critical in that it rescues a recommendation that already exists in the WHO, that countries and the WHO secretariat were unable to put into practice: "to begin negotiations on an binding R&D Convention that delinks research costs from final medicine prices to promote access to good health for all."[46] In the 180 contributions from countries, institutions, UN agencies, NGOs, universities, pharmaceutical industry, and individuals from around the world; one-third alluded to some form of treaty or binding convention as an alternative or complementary model for R&D.

The fourth important point concerns the almost "symbolic" contribution that the WTO has made to the problem of access to medicines until now with the so-called "paragraph 6" a mandate given by the Doha Declaration, which has given no results yet after 13 years of existence. The report of the Secretary-General recommends that WTO members should review the paragraph 6 decision.

[45] Ibid., page 9.
[46] Ibid., page 10.

X. CONCLUSIONS

In the last 15 years, a lot of material has been published in the area of public health and intellectual property. There have been World Health Assembly resolutions, 17 of them; and numerous WHO publications;[47] and publications from academia and NGOs, that have analyzed and provided guidance on how to protect access to health vis a vis the new international trade rules required under the WTO. Also, important recently are the free trade agreements and bilateral investment agreements that contain clauses and conditions that are more stringent than the standards of the TRIPS agreement.

In terms of technical assistance to countries for their use of TRIPS flexibilities, the position of WHO seems to have had a turnaround in the last 3 years, due apparently to its alliance with WTO and WIPO. The collaboration between WHO, WTO and WIPO is a good thing, as long as the mandate given by WHA resolutions is respected and implemented. In terms of international trade and investment agreements, WHO cannot have a "neutral position": its mandate is already biased by the perspective of public health and the mandate given by the different resolutions of the World Health Assembly in recent years. International trade rules and public health matters are two different regimes that should not be equated. In the first case, we are talking about norms and rules of the economy and in the second case; we are dealing with the right to health as a fundamental human right.

In this regard, the pronouncements of the Commission on Human Rights and the UN SG High-level panel are fundamental and can relaunch the debate that has been "dormant" in the WHO for the last 5 years.

In the future we will see whether the WHO Secretariat and Member States arrive to an understanding that working and supporting countries in the field of public health and intellectual property is an opportunity rather than a problem to be avoided. It is an opportunity, such as in the case of a possible international treaty to finance pharmaceutical R&D, which could help this United Nations specialized agency to rediscover its identity and a reason to be in the twenty-first century.

Finally, it is important to note that the international organizations are at the service of the member states, which means that countries can always request an additional specific mandate, or demand that in the areas where there is a mandate, this mandate is actually executed.

[47] See list in Annex II.

ANNEX I

WHO resolutions of the World Health Assembly referring to Intellectual Property

1996 WHA49.14: Revised drug strategy

1999 WHA52.19: Revised drug strategy

2000 WHA53.14: HIV/AIDS: confronting the epidemic

2001 WHA54.10: Scaling up the response to HIV/AIDS

2001 WHA54.11: WHO medicines strategy

2002 WHA55.14: Ensuring accessibility of essential medicines

2003 WHA56.27: Intellectual property rights, innovation and public health

2003 WHA56.30: Global health sector strategy for HIV/AIDS

2004 WHA57.14: Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS

2006 WHA59.24: Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action

2006 WHA59.26: International trade and health

2007 WHA60.30: Public health, innovation and intellectual property

2008 WHA61.21: Global strategy and plan of action on public health, innovation and intellectual property

2009 WHA62.16: Global strategy and plan of action on public health, innovation and intellectual property

2011 WHA64.5: Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits

2011 WHA64.14: Global health sector strategy on HIV/AIDS, 2011-2015

2012 WHA65.22: Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

ANNEX II

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